

What does it take to successfully retain organisational cluster sites? A mixed methods, collective case study examining retention processes in the Reducing Smoking Initiation in Young Adults RCT

Ruth Elizabeth Simms-Ellis

Submitted in accordance with the requirements for the degree of
Doctor of Philosophy

The University of Leeds
School of Psychology

April 2020

The candidate confirms that the work submitted is her own, except where work which has formed part of jointly authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

The protocol for the Reducing Smoking Initiation in Young Adults pragmatic cluster trial outlined in Chapter 3 has been published:

Conner, M., Grogan, S., Lawton, R., Armitage, C., West, R., Siddiqi, K., Gannon, B., Torgerson, C., Flett, K. and Simms-Ellis, R. (2013). Study protocol: A cluster randomised controlled trial of implementation intentions to reduce smoking initiation in adolescents. *BMC Public Health*, 13(1), p.54.

MC, SG, RL, CA, RW, KS, BG, CT conceptualised the study. MC led the drafting of the protocol with input from all authors, including RSE, who also read and approved the final protocol in conjunction with her co-authors.

The smoking outcome data used in Chapter 8 has been published:

Conner, M., Grogan, S., West, R., Simms-Ellis, R., Scholtens, K., Sykes-Muskett, B., Cowap, L., Lawton, R., Armitage, C.J., Meads, D. and Schmitt, L. (2019). Effectiveness and cost-effectiveness of repeated implementation intention formation on adolescent smoking initiation: A cluster randomized controlled trial. *Journal of Consulting and Clinical Psychology*, 87(5), p.422.

MC, SG, RW, RL, CA conceptualised the study. MC led the drafting of the paper with input from all authors. RSE and KS managed the trial and all data collection. RSE prepared the data for analysis, conducted the fidelity analyses, contributed to the economic analyses, provided input to the draft paper and read and approved the paper in conjunction with her co-authors.

This copy has been supplied on the understanding that it is copyright material and that no quotation from the thesis may be published without proper acknowledgement.

The right of Ruth Simms-Ellis to be identified as Author of this work has been asserted by her in accordance with the Copyright, Designs and Patents Act 1988.

© 2020 The University of Leeds and Ruth Simms-Ellis.

Acknowledgements

My sincere thanks go to my supervisors Mark Conner and Anna Madill. Mark, thank you for encouraging me to undertake this PhD and for the freedom and flexibility you gave me whilst working for you. Thank you Anna for agreeing to become my primary supervisor as the PhD evolved into a largely qualitative investigation. I am grateful to both of you for your guidance, support and reassurance during the past 6½ years of this part time PhD. I would also like to thank the School of Psychology and Mark who made this research possible through their funding.

The research presented in this thesis would not have been possible without the amazing commitment of the schools, teachers and students who helped me. At a time when teachers are enduring so much stress and pressure, I was grateful that so many gave me their precious time to share their experiences with me. They welcomed me into their workplaces, taught me so much about school life and helped me appreciate the challenges they work under. I am also grateful to all those students who took part in the focus groups and, once again, the highly committed, organised teachers who made these happen. To Keira Scholtens (née Flett), my wonderful colleague throughout the Reducing Smoking Initiation in Young Adults trial: thank you for sharing the highs and lows! I learned so much from you. Many thanks to Cristina Harney who helped me facilitate the student focus groups and Kinga Bugajska and Megan Skelton who so diligently entered all the student and teacher feedback data. It was a joy working with you all. I also would like to thank Siobhan Hugh-Jones for her insightful comments during my annual PhD progress reviews, and David Torgerson for his kind advice when I was investigating the reporting of cluster drop out in the literature.

Thank you to all my cherished friends, colleagues and family members who gave their wonderful support across the 6½ years I took to produce this thesis part-time. Most importantly, I want to thank my darling daughter Eve and loving, patient husband Ian who lived and breathed the PhD with me daily. My gorgeous girl: I obviously have to quote Kate Bush, 'you bring me so much joy, then you bring me more joy'. My dearest Ian: thank you for keeping all our important life things moving forward for us when I couldn't give them ANY attention. Please both hold me to my "when I finish this PhD I'm training as a barista...." promise and the countless others I made! Finally, I dedicate this work to my loving, gentle and inspirational parents, Jim and Barbara Simms, who are very much missed.

Abstract

Achieving high retention rates in cluster trials is challenging. Evidence in the literature predominantly addresses participant-level retention and theoretical insight into the dynamics of effective retention is missing. This thesis aimed to investigate *how* successful cluster retention happens, and offer theoretical explanations for retention.

A systematic review was conducted which identified strategies to promote cluster-level retention. Whilst some participant-level strategies were generalisable to clusters, five uniquely cluster-related, additional strategies were found. Cluster retention was found to be under-researched, particularly researchers' experiences of managing clusters. Participants' voices and relational aspects of retention also appeared to be under-represented.

A collective case study design was used to scrutinise processes operating within a school-based, pragmatic cluster RCT with successful retention outcomes. Key stakeholders' trial experiences were investigated through interviews, focus groups and documentation analysis. **Study 1** identified that personal qualities of in-site teacher-coordinators and the researchers' extensive investment in these relationships appeared to support retention, even in 'unhealthy' organisational contexts. In **study 2** trial staff reported perceiving an ever-present risk of disengagement, with retention demanding complex, hidden intrapersonal and relational work. Interviews with teachers delivering the intervention/control in **Study 3** highlighted their significant personal responsibility for student engagement. Student focus group findings (**Study 4**) suggested that school engagement builds classroom-by-classroom: student engagement was contingent on teachers' ability/willingness to create a supportive climate and 'make the lesson work'. **Study 5** reported a positive impact on school engagement of a £39,000 Engagement Promotion Programme. Schools valued highly complex skills exchanges and services, beyond transactional objects.

Evidence from the thesis suggests that multiple inter-relational complexities influence site retention, beyond traditional transactional strategies. Cluster trials are re-interpreted as inter-organisational collaborations and the task of retention more accurately defined as risk management. Retention is theorised as resulting from extensive relational work, meaningful social exchange and social influence.

Table of Contents

Chapter 1 Introduction: Overview of the literature and thesis aims	14
1.1 Introduction.....	14
1.2 What are complex health interventions?.....	16
1.3 Cluster randomised controlled trials testing complex health interventions.....	17
1.4 The challenges of working with schools as cluster sites	19
1.5 Understanding the processes involved in the retention of clusters in trials	21
1.6 Thesis aims	22
1.7 Thesis overview	22
Chapter 2 Retaining research sites in studies: What evidence exists? A review of the literature	25
2.1 Chapter summary	25
2.2 Reviews of retention strategies: what ‘works’?	25
2.2.1 Findings from systematic reviews	25
2.2.2 Additional findings from non-systematic reviews	32
2.2.3 Overall synthesis of the retention literature	38
2.3 Systematic review of studies exploring strategies for effective site-level retention.....	41
2.3.1 Method	41
2.3.2 Results	43
2.3.3 Summary and conclusion.....	59
2.3.4 Review limitations	60
2.4 Discussion	60
2.4.1 What is lacking in the retention literature?	61
2.4.2 How this PhD addresses gaps in the literature.....	62
Chapter 3 Background and Method	64
3.1 Chapter summary	64
3.2 Background to the PhD: The Reducing Smoking Initiation in Young Adults (RSIIYA) cluster RCT	64
3.2.1 Site-level engagement and retention programme.....	70
3.2.2 Trial cluster retention outcomes	73
3.3 PhD Method	74
3.3.1 Design	74
3.3.2 Epistemological standpoint	77
3.3.3 Analysis	79
3.3.4 Sampling process	80

3.3.5 Participants.....	81
Chapter 4 What are teachers' experiences of coordinating the RSIIYA trial in school? ...	83
4.1 Chapter summary.....	83
4.2 Background.....	83
4.3 Method.....	87
4.3.1 Design	87
4.3.2 Participants.....	87
4.3.3 Research Tools.....	90
4.3.4 Procedure	90
4.3.5 Analysis.....	91
4.3.6 Ethical Considerations	92
4.4 Results	92
4.5 Discussion.....	102
4.5.1 Strengths and limitations	106
4.5.2 Implications	106
4.5.3 Conclusion	107
Chapter 5 How do researchers contribute to cluster retention in the RSIIYA trial and what are their experiences of managing multiple sites?	108
5.1 Chapter summary.....	108
5.2 Background.....	108
5.3 Method.....	112
5.3.1 Design	112
5.3.2 Participants.....	113
5.3.3 Procedure	114
5.3.4 Analysis.....	114
5.3.5 Ethical considerations.....	115
5.4 Results	116
5.5 Discussion.....	131
5.5.1 Strengths and limitations.....	138
5.5.2 Implications	140
5.5.3 Conclusion	141
Chapter 6 What are teachers' experiences of belonging to the RSIIYA trial and delivering the intervention and control lessons?	142
6.1 Chapter summary.....	142
6.2 Background.....	142

6.3	Method	149
6.3.1	Design	149
6.3.2	Participants	151
6.3.3	Research Tools	156
6.3.4	Procedure	156
6.3.5	Analysis	158
6.3.6	Ethical Considerations	160
6.4	Results	160
6.4.1	Teachers' responses to delivering the lessons: <i>Cover Sheet analysis</i> ...	160
6.4.2	Teachers' perceptions and experiences of the trial: <i>interview analysis</i>	169
6.5	Discussion	189
6.5.1	Implications	195
6.5.2	Strengths and limitations	196
6.5.3	Conclusion	197
Chapter 7 How do students experience their participation in the RSIIYA trial?		198
7.1	Chapter summary	198
7.2	Introduction	198
7.3	Method	204
7.3.1	Design	204
7.3.2	Participants	207
7.3.3	Research Tools	210
7.3.4	Procedure	211
7.3.5	Analysis	213
7.3.6	Ethical considerations	215
7.4	Results	216
7.4.1	Students' responses to the lessons: <i>student feedback sheet analysis</i> ..	216
7.4.2	Students' understanding and experience of the trial: <i>focus group analysis</i>	222
7.4.3	Integrating feedback sheet and focus group findings	235
7.5	Discussion	238
7.5.1	Implications	243
7.5.2	Strengths and limitations	244
7.5.3	Conclusion	245

Chapter 8 Does introducing a complex Engagement Promotion Programme impact on engagement and RSIIYA trial outcomes?	247
8.1 Chapter summary	247
8.2 Background.....	247
8.3 Method.....	254
8.3.1 Measures	255
8.3.2 Sample	258
8.3.3 Data Analysis.....	258
8.4 Results	260
8.5 Discussion	265
8.5.1 Strengths and limitations.....	269
8.5.2 Implications and conclusions.....	270
Chapter 9 General discussion.....	271
9.1 Chapter summary	271
9.2 Original thesis aims	271
9.3 Summary of key findings	272
9.4 Strengths and limitations	281
9.5 Implications	286
9.6 Concluding comments.....	294
References.....	296
Appendices	319

List of Tables

Table 2.1 Attempts by systematic reviews to date to ‘thematise’ retention strategies	28
Table 2.2 Attempts by non-systematic reviews and expert consensus papers to ‘thematise’ retention strategies	34
Table 2.3 Synthesis of retention strategy themes highlighted in the general literature.....	39
Table 2.4 Eligibility criteria for inclusion of articles in the systematic review	42
Table 2.5 Cluster retention strategies extracted from the seven articles identified through the systematic review	47
Table 3.1 RSIIYA cluster RCT retention strategy	70
Table 3.2 Summary of component cases/studies within the collective case study	76
Table 3.3 Total participants across the thesis by sampling group, study and role	81
Table 4.1 Key contact responsibilities within schools participating in the RSIIYA trial	86
Table 4.2 Participant background information for semi-structured interviews.....	89
Table 4.3 Factors facilitating and impeding coordinators’ engagement in the study: Framework Analysis results	93
Table 5.1 Researcher background information	113
Table 6.1 Cover Sheets included in the analysis by lesson and condition	152
Table 6.2 Composition of semi-structured interviews.....	155
Table 6.3 Lesson pack utilisation and adherence to Cover Sheet protocol by school and condition, lessons 4 (May 2013) to 8 (July 2016).....	161
Table 6.4 Lesson pack use and return and protocol adherence by condition, community served and Ofsted rating.....	162
Table 6.5 Mean scores by condition for Individual Cover Sheet feedback items	164
Table 6.6 Mean total lesson scores by condition, community served and Ofsted rating ..	164
Table 6.7 Summary of themes resulting from Thematic Analysis of semi-structured interviews with teacher-deliverers	170
Table 7.1 Student feedback sheets subjected to analysis (by lesson, condition).....	207
Table 7.2 Composition of Focus Groups	210
Table 7.3 Mean scores for each feedback sheet item by condition, community served and Ofsted rating	218
Table 7.4 Summary of themes extracted from the four focus groups	223
Table 7.5 Integrated view of students’ experiences from the analyses of focus group transcripts and student feedback sheets.....	236
Table 7.6 Comparison of students’ experiences by condition	237
Table 8.1 Scoring system used by Wyatt et al. (2018) to assess multi-level engagement within the HeLP trial.....	249

Table 8.2 Inter-Scale Correlations between ‘Peripheral school’, ‘Staff’ and ‘Student’ sub-scales in the Measure of Engagement (N=45)	258
Table 8.3 School cluster sample characteristics for the RSIIYA trial	258
Table 8.4 Assumptions used to calculate design and implementation costs for individual benefits	259
Table 8.5 Costs associated with Level 1 ‘Core Benefits’ (N=45 schools)	260
Table 8.6 Costs associated with Level 2 ‘Standard Extra Services’ (N=26 schools)	261
Table 8.7 Costs associated with Level 3 ‘Tailored Consultancy Services’ (N=8 schools)	262
Table 8.8 Schools’ ‘Engagement Promotion Programme’ incentive use by category	263
Table 8.9 Mean scores for Measure of Engagement scale and sub-scales	264
Table 9.1 Thesis aims and research studies undertaken to address these	272
Table 9.2 Total participants across the thesis by sampling group and study (studies 1-4)	283
Table 9.3 ‘Reasons for staying with your current employer’ survey results (N=24,829)...	288

List of Figures

Figure 2.1 PRISMA flow diagram of the article review process in the systematic review....	44
Figure 3.1 RSIIYA cluster RCT procedures for participating schools	65
Figure 3.2 CONSORT diagram showing progress through the cluster RCT	69
Figure 3.3 Four dimensions characterising different forms of qualitative analysis.....	77
Figure 3.4 Sampling groups for component cases/studies one, three and four	80
Figure 4.1 School key coordinators participating in the semi-structured interviews.....	88
Figure 4.2 Flowchart of potential differential recruitment and retention strategies for school based research.....	107
Figure 5.1 Representation of the relationship between categories and themes arising from the researcher review meeting analysis	117
Figure 6.1 Cover Sheet	151
Figure 6.2 Schools participating in the semi-structured interviews	154
Figure 6.3 Frequencies for teachers' ratings of six Cover Sheet items.....	163
Figure 6.4 Themes identified from teacher feedback comments (N=264) by condition....	166
Figure 7.1 Student Feedback Sheets.....	205
Figure 7.2 Recruitment outcomes for the student focus groups.....	208
Figure 7.3 Frequencies for students' ratings of the two feedback items	217
Figure 7.4 Themes from content analysis of student comments by condition	220
Figure 7.5 Themes from content analysis of student comments by ratings for 'This lesson helped me think differently about smoking/homework'	220
Figure 8.1 The Engagement Promotion Programme developed for the RSIIYA trial.....	252
Figure 8.2 Smoking questionnaire item used to determine the trial final outcomes (i.e. percentage of students smoking)	255
Figure 8.3 Final Measure of Engagement	257
Figure 8.4 Mean engagement scores for low, medium and high users of the Engagement Promotion Programme	264
Figure 9.1 Mechanisms underpinning successful retention	278
Figure 9.2 Comparison of exchanges associated with transactional and relational contracts	287
Figure 9.3 The retention wheel: Categorising cluster retention strategies/interventions by their function and form.....	291
Figure 9.4 Positioning retention strategies on a transactional-relational dimension	292

List of Abbreviations

AM	Anna Madill
CC	Children's Centre
CH	Cristina Harney
DNA	Did not attend
FAQs	Frequently asked questions
MC	Mark Conner
OFSTED	Office for Standards in Education, Children's Services and Skills
Para	Paragraph
PSHE	Personal, Social, Health and Economic (education)
RCT	Randomised Controlled Trial
RoI	Republic of Ireland
RSE	Ruth Simms-Ellis
RSIIYA	Reducing Smoking Initiation in Young Adults
SLT	Senior Leadership Team
UK	United Kingdom

Peer Reviewed Publications

- Conner, M., Grogan, S., Simms-Ellis, R., Scholtens, K., Sykes-Muskett, B., Cowap, L., Lawton, R., Armitage, C.J., Meads, D., Schmitt, L. & Torgerson, C. (2019). Patterns and predictors of e-cigarette, cigarette and dual use uptake in UK adolescents: evidence from a 24-month prospective study. *Addiction*, 114(11), 2048-2055.
- Conner, M., Grogan, S., Simms-Ellis, R., Flett, K., Sykes-Muskett, B., Cowap, L., Lawton, R., Armitage, C., Meads, D., Schmitt, L. & Torgerson, C. (2019). Evidence that an intervention weakens the relationship between adolescent electronic cigarette use and tobacco smoking: a 24-month prospective study. *Tobacco Control*. doi:10.1136/tobaccocontrol-2018-054905.
- Conner, M., Grogan, S., West, R., Simms-Ellis, R., Scholtens, K., Sykes-Muskett, B., Cowap, L., Lawton, R., Armitage, C.J., Meads, D. & Schmitt, L. (2019). Effectiveness and cost-effectiveness of repeated implementation intention formation on adolescent smoking initiation: A cluster randomized controlled trial. *Journal of Consulting and Clinical Psychology*, 87(5), 422-432.
- Conner, M., Grogan, S., Simms-Ellis, R., Flett, K., Sykes-Muskett, B., Cowap, L., Lawton, R., Armitage, C.J., Meads, D., Torgerson, C. & West, R. (2018). Do electronic cigarettes increase cigarette smoking in UK adolescents? Evidence from a 12-month prospective study. *Tobacco Control*, 27(4), 365-372.
- Conner, M., Grogan, S., Lawton, R., Armitage, C., West, R., Siddiqi, K., Gannon, B., Torgerson, C., Flett, K., & Simms-Ellis, R. (2013). Study protocol: A cluster randomised controlled trial of implementation intentions to reduce smoking initiation in adolescents. *BMC Public Health* 13: 54.

Chapter 1 Introduction: Overview of the literature and thesis aims

1.1 Introduction

In cluster randomised controlled trials, pre-existing groups of individuals, rather than individuals themselves, are randomised to the different conditions (Donner & Klar, 2004; Puffer, Torgerson & Watson, 2005). These types of trials are multi-level in nature and “most often (...) involve two levels – the cluster and their individual members” (Campbell, Piaggio, Elbourne & Altman, 2012, p.1). A cluster can take many forms, such as a ward, a school year group or a worksite (Donner & Klar, 2004) and its individual members (e.g. patients, students or employees) are defined as the trial participants (Campbell et al., 2012). Clusters may be located within a single organisational site (e.g. a hospital), across multiple, similar organisational sites (e.g. schools), or across multiple, different organisational sites (e.g. heterogeneous worksites).

The success of cluster randomised controlled trials depends upon adequate retention of both clusters and participants to be confident of representative, non-biased final samples when interpreting outcomes and for sufficient statistical power to detect differences between conditions (Puffer, Torgerson & Watson, 2003). Failure to retain sufficient clusters and/or participants may limit the generalisability of findings and differential dropout (differing dropout rates between conditions) can bias results and impact on validity (Bell, Kenward, Fairclough & Horton, 2013; Giraudeau & Ravaud, 2009). In trials with high attrition at cluster or individual level, anticipated effect sizes may fail to emerge (Donner & Klar, 2004) and there are also financial implications: costly extensions may be needed to try and address the issue and, in the worst cases, funders may terminate the trial early (Zweben, Fucito & O'Malley, 2009). The retention of clusters is often more important than the retention of individuals because there are usually many more individuals in a trial than there are clusters.

Ensuring retention within cluster trials is a complex and demanding task because researchers must manage two levels of participation: that of each cluster (i.e. cluster site-level participation) and that of cluster group members (i.e. individual-level participation) (Eldridge, Ashby, Bennett, Wakelin & Feder, 2008). The complexity and demands increase when clusters are located across multiple organisational sites. This is because, for every site, the researcher must usually go through a process of identifying, contacting and persuading heterogeneous organisational ‘gatekeepers’ and ‘stakeholders’ to give their support to the research (Murphy, Spiegel & Kinmonth, 1992). Gatekeepers are defined as those with “power

to negotiate access to individuals within the organisation or to grant formal permission for the organisation to be involved”, whereas stakeholders are “individuals who might be affected by the proposed research, have some kind of investment in it or may be able to promote or obstruct the project” (Walker, Campbell & Grimshaw, 2000, p.187). Given that they are cluster members and directly affected by the research, participants within cluster trials may also be defined as stakeholders (Murphy et al., 1992).

Undoubtedly the highest priority for the cluster trial researcher is engaging and retaining cluster sites in the research, i.e. site-level participation (Befort et al., 2008; Harrell, Bradley, Dennis, Frauman & Criswell, 2000; Petosa & Goodman, 1991), since individual participants are inaccessible without them. However there is considerable evidence that engaging and retaining site-level support within trials is difficult. Trials involving multiple sites consistently report higher rates of recruitment issues than single-site trials (Chapman et al., 2014; McDonald et al., 2006; Puffer & Torgerson, 2003): for example, 51% of multi-centre trials experienced recruitment difficulties compared to just 23% of single centre trials in Puffer and Torgerson’s (2003) review of 79 randomised controlled trials. Once a trial is underway, high levels of commitment to following the protocol across multiple sites are also hard to achieve (Hasson, 2010; Lawton et al., 2011). The retention of cluster sites remains an ongoing concern, particularly those which are ‘hard-won’, right until the last of the data are collected (Flynn, Whitley & Peters, 2002) and withdrawal is not uncommon. For example, in one review of 36 cluster trials, eleven (31%) lost at least one cluster, six (17%) lost more than two clusters and three (8%) lost ten or more clusters during their life cycles (Puffer et al., 2003). These data suggest there is a need to understand more clearly (1) what barriers and levers are involved in engaging and retaining cluster sites in trials, at the site-level and (2) what strategies facilitate site-level engagement and retention.

In recent years there has been an increase in research to identify effective retention strategies (e.g. Abshire et al., 2017; Robinson et al., 2015). However, the current retention literature has two important limitations. The first limitation is that it remains dominated by individual-level strategies to retain participants in studies (e.g. Booker, Harding & Benzeval, 2011; Brueton, Tierney, et al., 2014; Robinson et al., 2015). It remains unclear whether these individual-level retention strategies generalise to site-level retention, i.e. are they appropriate for use with organisational gatekeepers and stakeholders, or whether different strategies are more effective. A second limitation with the current retention literature is that the guidance which has emerged to date for researchers remains unsophisticated. Despite 985 different individual-level retention strategies being identified in one recent systematic review

(Robinson et al., 2015), there is currently no unifying theoretical framework to inform and guide researchers trying to sustain participant engagement. Researchers in the field concur (Booker et al., 2011; Brueton, Tierney, et al., 2014; Robinson, Dennison, Wayman, Pronovost & Needham, 2007) that “we cannot determine which particular strategies are most effective” and the best advice is “to improve participant retention, studies should use many different strategies” (Robinson et al., 2015, p.1487).

The work presented within this thesis adds to the retention literature in two ways. Firstly, it augments the information available to support site-level engagement and retention within cluster RCTs. Secondly, it shifts the analytical gaze from ‘*what* retention strategies work best?’ to ‘*how* does successful retention happen?’ and presents a theory-driven framework to conceptualise retention as a social-psychological process. The research within this thesis investigates the barriers and levers involved in site-level engagement and retention within the ‘Reducing Smoking Initiation in Young Adults’ (RSIIYA) study (Conner et al., 2013). This longitudinal, pragmatic cluster RCT tested a complex health intervention designed to reduce smoking take up in adolescents and involved secondary schools in the North of England. Forty-eight schools originally signed up to the trial and despite three early withdrawals post-randomisation (before data collection commenced), 100% of the 45 remaining schools were successfully retained across the trial’s four year duration. The research within this thesis examines the strategies and mechanisms which appeared to underpin successful engagement and retention. The research draws upon data from focus groups and interviews with cluster site stakeholders, a trial progress meeting with the RSIIYA research team and routinely collected feedback forms. A suite of engagement activities was created to sustain site-level retention and this thesis contains an economic analysis of implementing such an approach, an evaluation of its impact on stakeholder engagement, and an investigation into whether different levels of site-level engagement are related to trial outcomes (i.e. changes in rates of smoking from baseline to the end of the trial).

This chapter now introduces the specific challenges associated with site-level engagement and retention in cluster trials testing complex health interventions, with a particular focus on schools. A detailed review of the literature surrounding individual-level and site-level retention follows in chapter two.

1.2 What are complex health interventions?

Many interventions designed to address health problems, improve wellbeing and health care are defined as complex (Clark, 2013; Grant, Treweek, Dreischulte, Foy & Guthrie, 2013).

Unlike surgical or pharmacological interventions, complex health interventions tend to be behaviourally and/or socially focused (Linnan & Steckler, 2002), targeting health issues and/or behaviours with complex causes and mechanisms (Craig et al., 2008; Moore et al., 2015), such as obesity and smoking. The Medical Research Council stresses that there is no unitary definition of a complex intervention, rather an intervention may be classed as complex due to (Craig et al., 2008, p.2):

- The number of interacting components within the experimental and control interventions;
- The number and difficulty of behaviours required by those delivering or receiving the intervention;
- The number of groups or organisational levels targeted by the intervention;
- The number and variability of outcomes;
- The degree of flexibility or tailoring of the intervention permitted.

By their very nature, the delivery and receipt of these interventions place significant demands on people's time and attention (Petticrew, 2011). Trials testing new complex interventions can increase demands still further because they often involve multiple follow-ups/observations to measure changes over time (Peterson, Pirraglia, Wells & Charlson, 2012). These longitudinal designs (Gul & Ali, 2010; Peterson et al., 2012) and high participant demands (Davis, Broome & Cox, 2002) are features independently associated with higher rates of participant attrition, therefore together they pose a significant retention challenge for researchers trialling complex health interventions (Davis et al., 2002). When the trial is a cluster design, these two features also have major implications at the site-level, with regard to engaging and retaining organisational stakeholders. These implications will now be discussed, after a brief outline of the use of cluster RCTs to test complex health interventions.

1.3 Cluster randomised controlled trials testing complex health interventions

The cluster randomised controlled trial is a popular design choice when testing a new complex health intervention (Grant et al., 2013) and its use has increased significantly in the last 20 years (Giraudeau & Ravaud, 2009). One of the main reasons for using a cluster design is to minimise the risk of bleeding or contamination between participants in different groups (usually intervention and control) (Donner & Klar, 2004). This can happen more readily when

participants in the intervention and control groups share the same facilities (Campbell, 2014), such as a workplace, a diabetes clinic, or a school.

Cluster trials testing complex health interventions frequently involve multiple organisational sites (Craig et al., 2008; Grant et al., 2013) and the importance of securing at each site the ongoing support of key organisational stakeholders for the success of such trials has been well documented (e.g. Evans, Murphy & Scourfield, 2015; Johnson et al., 2018; McMahon, Holland, Miller, Patel & Connell, 2015). Strong stakeholder commitment is particularly important for ‘pragmatic’ cluster trials, where routine employees within the participating organisational sites/clusters are responsible for delivering the intervention being tested (Johnson et al., 2018; McMahon et al., 2015). This is because researchers have to rely heavily on stakeholders at each site to fulfil important tasks, such as planning training sessions for those delivering the intervention/control, arranging and facilitating the delivery of the intervention/control to participants, corresponding with the research team and collecting measurement data. A large degree of control is lost in pragmatic trials when an intervention is handed over to research sites, to be tested in real-world conditions (Lawton et al., 2011). With typically minimal knowledge of the people, processes and systems within an organisational site, researchers are entirely dependent on internal gatekeepers and stakeholders for the informational, material and human resources they hold to run the trial.

It is widely acknowledged that people are not simply “passive recipients of assigned conditions” (Skingley, Bungay, Clift & Warden, 2014, p.752) and inevitably, the level to which an organisation’s stakeholders engage with and commit to a research study significantly affects the outcomes (Durlak & DuPre, 2008). Such factors are likely to be particularly significant within pragmatic trials. In contrast to explanatory trials, which tend to measure the *efficacy* of an intervention (i.e. if and how it works) under ideal, controlled research-clinic conditions, pragmatic trials involve testing an intervention’s *effectiveness* in routine clinical practice (i.e. does it actually work in real life?) (Patsopoulos, 2011; Roland & Torgerson, 1998). Within pragmatic trials, numerous contextual, interpersonal and intrapersonal barriers have been found to moderate stakeholders’ engagement. These include insufficient time or poor senior leadership support to implement trial tasks (contextual barriers), finding that cluster members receiving the intervention/control dislike it (interpersonal barrier) or having little faith in the research or little inclination to closely follow trial protocol (intrapersonal barriers) (Carroll et al., 2007; Lawton et al., 2011). Motivational issues may also arise from being allocated to the control condition or a non-preferred treatment condition, which can trigger disappointment, or even ‘resentful demoralization’ (intrapersonal barriers), thereby affecting

engagement and retention (Skingley et al., 2014, p.752). Organisational changes, such as staff turnover, working relationships and local priorities, also impact on stakeholder engagement and commitment (Wells, Williams, Treweek, Coyle & Taylor, 2012), particularly during longitudinal trials.

There is agreement within the implementation science literature that organisational influences within a site demand critical consideration within trials testing complex health interventions and that particular settings may be associated with specific concerns (e.g. Lewis et al., 2017; Moore et al., 2015; Wells et al., 2012). This chapter now concludes by considering challenges associated with conducting trials in one particular type of setting: schools.

1.4 The challenges of working with schools as cluster sites

For decades, health researchers have been drawn to collaborate with schools to improve young people's health. Schools are considered excellent sites for health promotion and prevention research (Bond, Glover, Godfrey, Butler & Patton, 2001; Hodder et al., 2011; Lee, 2009; Pearson et al., 2012; Wagner, Tubman & Gil, 2004). They are highly convenient, providing researchers with a captive audience, enabling them to reach a whole population in a target age group (Hodder et al., 2011). From a public health perspective, involving children in health interventions at school can help them establish positive health behaviours for life and even help them become agents of change within their own families and their community (Pearson et al., 2012). As children grow into adolescents and become increasingly exposed to health risk behaviours such as smoking, alcohol consumption and sexual activity, prevention interventions in school can help them make informed choices when they are most at risk (Hodder et al., 2011). For these reasons schools are considered a specialised form of community intervention (Wagner et al., 2004) and therefore one useful example of an organisational cluster.

Because school-based complex health interventions are often developed for whole year groups or schools, rather than for specific, individual students, cluster designs are commonly used during the testing phase (Moberg & Kramer, 2015): "entire schools or classes within schools are ready-made clusters" (Moberg & Kramer, 2015, p.3), and are in these cases the most natural unit of allocation (Rutterford, Taljaard, Dixon, Copas & Eldridge, 2015).

It is tempting to assume that schools welcome opportunities to 'road-test' new interventions that may benefit them (Witt, 1986). However, many researchers have noted that, despite the excellent potential of school-university collaborations (Lewis et al., 2017), schools can be extremely challenging sites with which to work (Befort et al., 2008; Drews et

al., 2009; Harrell et al., 2000; Midford, McBride & Farrington, 2000; Petosa & Goodman, 1991). Experienced researchers acknowledge that:

“There are many unique obstacles (..) including systematic barriers and practical and methodological challenges, in conducting and evaluating such programs” (Wagner et al., 2004, p.106).

Accessing the appropriate gatekeeper, for example, in just one school has been described as “difficult, frustrating and time-consuming” (Harrell et al., 2000, p.16) and becomes hugely “labor-intensive” when multiple schools must be recruited (Petosa & Goodman, 1991, p.428). Such negotiations are often hampered by heterogeneity amongst schools in terms of leadership structure, systems/procedures and organizational culture (e.g. Renes, Ringwalt, Clark & Hanley, 2007). Once secured, access and support cannot be taken for granted because significant gatekeepers or stakeholders may change roles or leave the school (Mukoma et al., 2009). Access and communication can suddenly cease, particularly if pivotal organizational members leave without securing a successor. As an ‘outsider’, it is extremely difficult to marshal the informational, material and human resources inside a school without supportive, influential staff on the inside.

A further obstacle is that schools juggling multiple competing priorities are often reluctant to surrender valuable time to research projects (Midford et al., 2000). In the face of overwhelming pressure to achieve academic results from education regulators, Senior Leadership Teams are increasingly de-prioritising activities targeting student health (Bonell et al., 2014). Time spent on wellbeing and health can be perceived as leading to “less time for academic learning and therefore lower attainment” (Bonell et al., 2014, p.348). Hence, timetabled lessons set aside for student health and wellbeing are increasingly re-allocated to core subjects such as Maths, English and Science to support academic achievement (Bonell et al., 2014). All this means that schools are less incentivised to engage in health research and they have fewer “windows” where such research could take place:

“Time is a real precious commodity, so if we’re going to deviate from the teaching and learning activities, we are going to have to have a real compelling reason” (School leader, Befort et al., 2008, p.584).

For a school to find a research programme compelling, it needs to demonstrate a tangible benefit for their school and support their school’s mission, and it must not be burdensome or clash with busy times in school (Befort et al., 2008). Being allocated the control condition often fails to provide that compelling reason schools need to take part: several researchers have found that school leaders are not happy to act as a control condition whilst their counterparts receive an innovative intervention/approach (Harrell et al., 2000; Petosa & Goodman, 1991). These factors present formidable engagement and retention

challenges for the cluster RCT researcher, whose study involves a reasonable chance of being allocated an undesirable control condition, and whose intervention may fail to align with individual school priorities and place high demands on staff for several years (Lewis et al., 2017).

1.5 Understanding the processes involved in the retention of clusters in trials

Qualitative research is playing an increasing role in understanding tacit, hidden processes at work within trials (Datta & Petticrew, 2013; Moore et al., 2015; Nelson, Macnaughton & Goering, 2015; O'Cathain, Thomas, Drabble, Rudolph & Hewison, 2013). During multi-site cluster trials evaluating complex health interventions, there is an acceptance that “the ‘same’ intervention may be implemented and received in different ways” (Oakley et al., 2006, p.413) across sites. The Medical Research Council advocates the use of process evaluations and recommend a framework to “assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes” (Craig et al., 2008, p. 3; Moore et al., 2015). Outputs from such evaluations provide valuable information about “how, for whom and under what conditions interventions will work” which can help policy makers/commissioners decide whether to adopt an intervention (Bonell, Fletcher, Morton, Lorenc & Moore, 2012, p. 2299).

Other authors, however, advocate the use of qualitative enquiry to examine wider aspects of trials (Trickett, Trimble & Allen, 2014), which “are not typically studied” within process evaluations, such as how stakeholders are motivated to plan and implement research programmes and how programmes are or are not sustained (Nelson et al., 2015, p. 377). Nelson and colleagues considered such questions when consulting with numerous stakeholders in a complex community mental health programme for rough sleepers in Canada and concluded that “what is taken for granted in traditional research reports actually entails a complex set of research practice skills and judgment” (Nelson et al., 2015, p. 382). Qualitative analysis has also recently shed new light on the issue of patient recruitment in multi-site trials, which has often been explained by logistical problems such as lack of time, or patient-related factors such as personal preferences (Elliott, Husbands, Hamdy, Holmberg & Donovan, 2017). Elliot and colleagues reviewed 35 qualitative studies which addressed healthcare professionals’ experiences of recruiting to trials. Their analysis revealed recruitment to be a “complex and fragile process”, with healthcare professionals commonly

experiencing “emotional and intellectual challenges” when trying to recruit patients (Elliot et al., 2017, p.796).

Qualitative studies examining these wider aspects of trials are revealing a more complex narrative about the interpersonal and intrapersonal skills and difficulties involved in managing trials. Informed by this approach, this thesis investigates the processes involved in longitudinal site-level engagement and retention, through a series of qualitative studies embedded within the RSIIYA pragmatic cluster RCT (2012-2017) (Conner et al., 2013). The research aims and an overview of chapters within the thesis are now outlined.

1.6 Thesis aims

The overall aims of this thesis are:

- (1) To synthesise and evaluate the available evidence surrounding strategies which facilitate site-level engagement and retention within longitudinal cluster trials (Chapter 2);
- (2) To understand the factors involved in site-level engagement and retention of school cluster sites in the RSIIYA trial, from the perspective of major stakeholders involved (Chapters 4, 5, 6 and 7);
- (3) To evaluate the adoption of an Engagement Promotion Programme to support site-level retention in the RSIIYA trial and determine its impact on trial outcomes (Chapter 8);
- (4) To explore the mechanisms underpinning the successful site-level retention of school clusters participating in the RSIIYA trial (Chapter 9).

1.7 Thesis overview

Chapter two reviews the available literature surrounding site-level retention. It firstly examines the current guidance within the retention literature, synthesising findings from systematic and non-systematic reviews. It then explores the extent to which site-level retention has been represented in this body of literature to date. The chapter then turns to the specific challenge of site-level retention, and reports a systematic review of articles which describe effective strategies to retain multiple sites within research studies. The review examines whether the recommended site-level strategies differ from individual-level strategies described in the broader literature. This chapter also explores why particular strategies seem to be effective, i.e. what are their mechanisms of action?

Chapter three contextualises the thesis by describing the RSIIYA trial, in particular the commitment involved by each of the 45 participating schools and the recruitment and retention strategies used. It then explains the methods used within this PhD research, including sampling of stakeholders, data collection and analysis.

Chapter four reports the design of and findings from an interview study (study one) involving individual trial-coordinators across participating schools. The study sought to understand these teachers' lived experiences of managing the RSIIYA trial in school. It explored the barriers they experienced whilst trying to sustain their school's commitment to the trial and its tasks, and how they responded to or overcame these. It also identified any facilitators or levers which supported them in maintaining site-level interest and managing the trial.

Chapter five contains findings from a smaller study (study two) which examined the research team's perspectives of managing the RSIIYA trial across 45 school sites. Secondary data were used as a basis for this study in the form of a transcript from an annual review meeting of the trial team. Within this meeting, the team reviewed their successes and failures with regard to maintaining site engagement and commitment to completing trial tasks. This study examined the meeting transcript to identify practical and personal strategies employed by the research team to sustain cluster site engagement, the challenges they faced and how they dealt with these.

Chapter six reports findings from interviews with the teachers who delivered the intervention or control lessons in participating schools (study three). This study sought to understand the contextual, intrapersonal and interpersonal factors affecting teachers' engagement with the trial, by exploring their personal experiences of being part of the research and of delivering the intervention or of being in the control condition. Analysis of intervention and control lesson feedback sheets completed by participating teachers is also discussed.

Chapter seven discusses findings from a series of focus groups with students based within the different cluster sites (study four). The focus groups accessed students' longitudinal, personal experiences, as primary stakeholders, of being part of the trial. This study investigated whether their engagement with the trial changed over their four-year involvement, and what factors influenced the degree to which they committed to the trial and completed its tasks. This chapter also includes a detailed analysis of intervention and control lesson feedback sheets completed by participating students.

Chapter eight examines the suite of engagement activities designed by the trial team to promote site-level retention in the trial. It presents an economic analysis of this approach, including design, production and delivery costs. It also discusses whether the adoption of this approach correlated with higher site-level engagement, and if higher engagement in the trial correlated with trial outcomes (i.e. decision to smoke).

Chapter nine concludes the thesis, synthesising the findings from each of the studies and presenting an overall discussion.

Chapter 2 Retaining research sites in studies: What evidence exists? A review of the literature

2.1 Chapter summary

Retention has long since been the poor relation to recruitment, which has received considerably more attention in the literature (Zweben et al., 2009). The dearth of information specifically regarding retention methodology in the literature has been highlighted across three decades by different researchers (e.g. e.g. Coday et al., 2005; El Feky, Gillies, Gardner, Fraser & Treweek, 2018; Ribisl et al., 1996). This chapter firstly reviews the literature surrounding retention broadly, then reports a systematic review of studies exploring effective strategies specifically for retaining research sites within studies (i.e. site-level retention, as opposed to participant-level).

The first section of this chapter comprises a review of the systematic reviews conducted to date of retention, supplemented by further evidence from a series of non-systematic reviews. It examines: (1a) What different retention strategies have been used within the literature? (1b) What evidence exists to support the effectiveness of particular strategies? (1c) To what extent has site-level retention been addressed in these reviews? The second section of this chapter then turns to the specific case of site-level retention within multi-centre studies and cluster trials. It reports a systematic review of studies which describe site-level retention strategies. The systematic review explores: (2a) Do the strategies employed by researchers to retain sites in studies differ from those recommended at the participant-level? (2b) What evidence exists for the effectiveness of different site-level strategies? The final section of this chapter presents a synthesis of the key findings presented, identifies 'gaps' in the retention literature and discusses how this PhD research aims to address some of these.

2.2 Reviews of retention strategies: what 'works'?

2.2.1 Findings from systematic reviews

Five comprehensive systematic reviews have been published to date of strategies to increase participant retention: two in the USA (Robinson et al., 2007; Robinson et al., 2015), two in the UK (Booker et al., 2011; Brueton, Tierney, et al., 2014) and one in Australia (Teague et al., 2018). A sixth is currently underway in Aberdeen, UK (El Feky et al., 2018). A number of other systematic reviews have dealt with the retention of specific participant groups, such as older adults (Lacey et al., 2017; Provencher, Mortenson, Tanguay-Garneau, Bélanger & Dagenais,

2014) and ICU survivors (Tansey, Matté, Needham & Herridge, 2007). Whilst it is acknowledged that specific participant groups may require slightly different approaches regarding engagement and retention (e.g. frail older adults particularly value personalized consideration (Provencher et al., 2014)), they are excluded from this review. This is because the review examined more generalized strategies appropriate to different study *designs* as opposed to specific strategies for particular *participant groups*.

The five comprehensive systematic reviews have differed in their study inclusion criteria. Robinson and colleagues (2007; 2015) in Baltimore, USA, included papers focusing primarily on **in-person follow-up studies** which *described* the retention strategies used and reported retention rates. Teague et al. (2018), in Australia, included papers published in the last 10 years focusing on **cohort studies** with at least one follow-up wave, in which both retention rates and strategies were reported. The remaining reviews (Booker et al., 2011; Brueton, Tierney, et al., 2014) were more selective in that they only included studies which *evaluated* retention strategies and provided retention rates. This latter approach is also the one adopted in the systematic review currently in progress in Aberdeen (El Feky et al., 2018). Booker et al.'s (2011) review included papers involving **prospective population-based cohort studies** with at least one follow-up wave, which *described and evaluated* at least one retention method and provided retention rates. Brueton, Tierney and colleagues (2014) in Glasgow, UK, focused their Cochrane review and meta-analysis on **RCTs** within a host RCT (i.e. a trial within a trial) which compared two or more retention strategies, or compared one or more strategies with none. The new review in progress (El Feky et al., 2018) will include **non-randomised studies** embedded within host randomised trials, which compare two or more retention strategies or one or more strategy with none.

What retention strategies have been used?

The reviews have revealed an extremely wide range of retention strategies. Therefore authors have sought to group individual strategies into higher order themes by considering any shared mechanisms of change between them. Robinson et al.'s (2007) review of 21 in-person follow-up studies revealed 368 different retention strategies, which they grouped into 12 themes (see Table 2.1). The two most commonly used and heavily populated themes in the review were 'contact and scheduling procedures' (e.g. maintaining systematic databases; used in 18/86% of studies) and 'visit characteristics' (e.g. reducing participant burden by offering an alternative interview location; used in 18/86% of studies), which contained 123 and 57 strategies respectively (Robinson et al., 2007).

Robinson and her colleagues (2015) updated their review to incorporate a further 67 newly identified studies and 617 additional retention strategies. This new review was based on the combined sample of 88 follow-up studies and 985 strategies. The same 12 themes emerged and once again, ‘contact and scheduling methods’ and ‘visit characteristics’ were the two most frequently used and densely-populated themes. ‘Financial incentives’ were also popular, used in 50/57% of studies. ‘Community involvement’ strategies were least commonly used (2% of the 985 strategies, used in 13/15% of studies).

More recently, Teague et al.’s (2018) review of 141 articles (involving 143 studies) featuring cohort studies published in the last 10 years revealed 95 different retention strategies, 44 of which had not been identified in previous reviews. These 44 ‘emerging’ strategies reflected advances in digital technologies to collect data and engage participants, and included social media, web-based advertising, electronic reminders, video conferencing, mobile/web surveys and devices such as ‘Fitbits’ (Teague et al., 2018). Teague et al. (2018) grouped the 95 identified strategies into four over-arching groups (see Table 2.1). The two most commonly used strategy groups, were ‘improving follow-ups/reminders’ (e.g. incentives, phone follow-ups, SMS reminders; used 306 times across 111/78% of studies) and ‘barrier reduction’ (e.g. alternative methods of data collection; used 268 times across 109/76% of studies).

Brueton, Tierney et al.’s (2014) review of 38 RCTs testing retention strategies within host trials generated six strategy themes (see Table 2.1). The strategies most commonly experimented with during trials were ‘incentives’ (14 trials; 19 trial comparisons), ‘communication approaches’ (14 trials; 20 trial comparisons) and ‘new questionnaire formats’ (eight trials). Behavioural, case management or methodology strategies were those least commonly evaluated within trials (four of the 38 trials).

Booker et al.’s (2011) review of 28 population-based cohort studies identified 45 different retention strategies, which they grouped into three broad themes (see Table 2.1). The most commonly evaluated strategies fell within theme two, such as sending reminder letters, conducting follow-up interviews in participants’ homes rather than at research sites, with 17/28 studies (61%) experimenting with at least one of these strategies. Incentives were also popular, evaluated in ten studies.

What evidence exists to support the effectiveness of *specific* strategies?

The systematic reviews have found evidence to support the effectiveness of incentives, flexibility, reminders, some communication approaches, and finally, combining multiple strategies in one study. These findings are now explained in more detail.

Table 2.1 Attempts by systematic reviews to date to ‘thematise’ retention strategies

Authors, study composition	Labels used to categorise individual retention strategies identified in the literature (i.e. themes/groupings)	
Robinson et al. (2007; 2015) In-person follow-up studies (N=21)	1. Financial incentives. 2. Reimbursement. 3. Non-financial incentives (e.g. pen). 4. Community involvement. 5. Study description. 6. Study identity. 7. Highlighting study benefits.	8. Study personnel (e.g. staff characteristics, training, management). 9. Contact and scheduling methods. 10. Visit characteristics (e.g. flexible appointments). 11. Reminders. 12. Special tracking methods.
Brueton, Tierney et al. (2014) RCTs (N=38)	1. Incentives (e.g. prize draws, cash, certificates). 2. Communication approaches (e.g. enhanced letters, phone/text/email reminders). 3. New questionnaire formats (e.g. shorter, changing question order).	4. Behavioural strategies (e.g. goal setting, information and time management). 5. Case management (e.g. advocacy to help keep planned follow-up). 6. Methodology strategies (e.g. open vs. blind trial).
Booker, Harding & Benzeval (2011) Prospective population-based cohort studies (N=28)	1. Incentives. 2. Reminder methods, repeat visits or repeat questionnaires, alternative modes of data collection.	3. Other methods (e.g. using handwritten envelopes, sending questionnaires by certified mail).
Teague et al. (2018) Cohort studies (in last 10 years) (N=141 articles/143 studies)	1. Reducing barriers to participation. 2. Creating a project community.	3. Follow-up/reminder strategies. 4. Tracing strategies.

Incentives: Within population-based cohort studies, Booker et al. (2011) found that the use of incentives was associated with increased retention rates, and additionally, that retention improved as the value of the incentive increased. However they were unable to reach a conclusion on whether cash is more effective than non-cash gifts of a similar value. Brueton, Tierney et al. (2014) also found that monetary incentives were a successful retention strategy in RCTs. Using monetary incentives, particularly those with higher valued incentives, increased responses to postal questionnaires and biomedical test kits, and electronic questionnaire responses increased when a monetary incentive was offered after completion (Brueton, Tierney et al., 2014). Robinson and colleagues (2015) were able to show that higher cash incentives were associated with higher retention rates in in-person follow-up studies, confirming tentative findings from their earlier review (2007). Brueton, Tierney et al. (2014) found no evidence that non-monetary incentives were effective within RCTs. Whilst using

cash or voucher incentives was the most common strategy across the 143 cohort studies in Teague et al.'s (2018) review (used in 59/41% of studies), the authors found no evidence that this strategy improved retention.

Flexibility: When collecting data by postal questionnaires within population-based cohort studies, Booker et al. (2011) found that offering a telephone interview to non-responders improved retention rates by 3%, and offering alternative locations or ways of collecting data (e.g. by phone) increased retention rates by 24%. Similarly, Teague et al. (2018) found that cohort studies offering alternative methods of data collection had significantly higher retention rates (86.1%) than those not using this strategy (76.3%). Offering flexibility around how data are collected also emerged as the strongest predictor of retention when compared to all other strategies used (Teague et al., 2018). In fact, Teague et al. (2018) found that cohort studies employing *any* kind of 'barrier reduction' strategy had higher retention rates than those using none. Of all four strategy groups Teague et al. (2018) identified, using any 'barrier reduction' strategy was the strongest predictor of retention (Teague et al., 2018).

Reminders: In population based cohort studies utilising questionnaires, issuing reminder letters was associated with 12% increase in retention, telephone reminders with a 5% increase and posting out a repeat questionnaire increased retention rates by 12% (Booker et al., 2011). However, Brueton, Tierney et al. (2014) found no clear evidence that additional reminders were effective within RCTs. Teague et al. (2018, p.11) found that cohort studies using phone calls to remind participants about follow-ups actually had significantly *poorer* retention rates (72.7%) than those not using this approach (80.6%), and it was a strong predictor of reduced retention rates. In fact, Teague et al. (2018) found that cohort studies using *any* form of follow-up/reminder strategy had significantly lower retention rates (76.4%) than those who used none (86.1%), and that using this group of strategies was predictive of reduced retention rates.

Communication approaches: Whilst acknowledging their conclusions are based on single trials, Brueton, Tierney et al. (2014) found that, in RCTs, sending questionnaires by recorded delivery and employing a package of postal communication were effective at increasing response rates. There was no clear evidence that shorter questionnaires, different structures, including enhanced letters by priority post, improved response rates/retention in trials (Brueton et al., 2014).

Multiple strategies: Robinson et al. (2007; 2015) found that researchers typically used a high number of retention strategies within in-person follow-up studies. Their 2007 review reported a median of 17 strategies (range 3-42) and six themes (range 3-10) per study,

followed by a median of 10 strategies (range 7-17) and six themes (range 4-7) per study in their updated 2015 review. The most successful follow-up studies achieving high retention rates used more strategies than those with low retention rates; the number of strategies used (but not the number of themes) explained 6% of the variation in retention rate (Robinson et al., 2015). Teague et al.'s (2018) review also revealed that multiple strategy use was common (mean 6.2 strategies across 143 studies) in cohort studies. However they found no association between higher retention rates and using a greater number of retention strategies across all their four identified groups (barrier reduction; community-building; follow-up/reminders; tracing) (Teague et al., 2018). They found that those cohort studies using a greater number of 'emerging' engagement and retention strategies (e.g. SMS, emails and social media) had higher retention rates than those using very few (Teague et al. 2018).

Summary and evaluation

In summary, the most consistent finding (across four of the five systematic reviews) is that (higher) monetary incentives are associated with higher participant retention rates. Robinson and colleagues (2007) concluded, "we are not able to provide specific guidance on what works for whom and under what circumstances. [...] The best advice to researchers designing protocols is use multiple strategies across multiple themes" (p.764). This was reiterated in 2015: "we cannot determine which particular strategies are most effective. However the existing research demonstrates that to improve participant retention, studies should use many different strategies across at least 5 to 6 different themes" (2015, p.6). The value of using multiple strategies is not refuted per se by Teague and colleagues (2018), but they do argue for a more nuanced approach to retention planning than 'use many different strategies'. Specifically, they recommend considering participants' needs carefully, anticipating potential issues and responding to these by selecting the most appropriate engagement and retention strategies (Teague et al., 2018).

The samples being scrutinised by Booker et al. (2011) and Brueton, Tierney et al. (2014) were very different from those examined by Robinson et al. (2007; 2015) and Teague et al. (2018) and smaller. Whilst Booker et al. (2011) and Brueton, Tierney et al. (2014) focused on the best available evidence, i.e. evaluative studies, to maximise internal validity, these types of studies clearly remain uncommon, have focused largely on increasing questionnaire responses rather than encouraging participants to return to sites and are "often poorly reported" (Brueton et al., 2014, p.18; Booker et al., 2011). Nearly 70% of the studies in Booker et al.'s (2011) review were postal/questionnaire based (N=15 studies) or telephone-based surveys/interviews (N=4 studies). Face-to-face (N=6) or mixed studies (N=3) formed less than

a third of the sample. Similarly, of 38 evaluative trials included in Brueton et al.'s (2014) review, 34 (90%) involved questionnaire designs. Accordingly, the results offer little guidance to the significant numbers of researchers whose studies do not involve questionnaires.

In focusing their reviews on evaluative studies of retention strategies, Booker et al. (2011) and Brueton, Tierney et al. (2014) have revealed that most of the evaluative work taking place in the field is tending to address discrete, more 'tangible' strategies which lend themselves well to randomisation/testing, such as monetary incentives, reminder letters or different mailing methods and primarily within questionnaire-based studies. Few of the evaluative studies to date have involved more complex, interpersonal strategies for encouraging participants to return to sites, "which are particularly needed because many trials collect outcome data this way" (Brueton et al., 2014, p.17). These more complex strategies were highlighted in Robinson et al.'s (2007; 2015) reviews, such as factors relating to study personnel (staff characteristics, interpersonal skills, training, team management) or providing participants and their families with benefits from being part of the study (e.g. creating and facilitating educational and support groups). However such strategies "are clearly more difficult to design interventions for and evaluate" (Brueton et al., 2014, p.10). Booker et al. (2011) also note that evaluation is expensive, which may firstly explain why there are so few studies, and secondly why strategy experimentation tends to occur largely within less expensive questionnaire-based studies rather than in complex, more costly in-person follow-up studies.

Perhaps due to their broader inclusion criteria, or perhaps due to the nature of in-person follow-up studies, Robinson and colleagues (2007; 2015) identified more retention methods and a wider range of themes than the Brueton, Tierney et al. (2014) and Booker et al. (2011) reviews, which involved predominantly questionnaire-based studies. Their finding that higher retention rates were associated with utilising a higher number of strategies within in-person follow-up studies suggests that a more complex, multi-faceted approach may be required to motivate participants to engage with and commit to research.

Whilst recognising the knowledge gained from these systematic reviews, other authors have commented on their limitations, in that they "did not allow for in-depth exploration of retention strategies and their implementation" (Abshire et al., 2017, p.1, p.1) and that they may have overlooked or disregarded other effective strategies or themes outside their inclusion criteria (El Feky et al., 2018). Face-to-face follow-up strategies are considered particularly under-researched, and there appears to be a reluctance in experienced practitioners to relinquish retention strategies they believe to be effective,

despite their lack of evidence in systematic reviews (Brueton, Stenning, Stevenson, Tierney & Rait, 2017). Therefore to supplement the systematic review findings and provide a more comprehensive review of the literature, this next section examines a series of papers which have sought to provide a more detailed exploration of the processes involved in successful retention. The first three papers discussed are non-systematic reviews of the retention literature (Davis et al., 2002; Hunt & White, 1998; Ribisl et al., 1996). These are followed by three expert consensus papers which draw upon interviews, focus groups and surveys conducted with experienced researchers (Abshire et al., 2017; Brueton, Stevenson, et al., 2014; Coday et al., 2005).

2.2.2 Additional findings from non-systematic reviews

Turning to the first of three non-systematic reviews of the literature, Ribisl et al. (1996) in Michigan, USA, extracted suggestions from the literature surrounding panel studies to improve participant tracking and retention, which resulted in eight strategies (see Table 2.2). A number of these have been identified in the systematic reviews: make involvement rewarding and convenient (noted in all the reviews); gathering comprehensive data at baseline, creating a project identity and study staff characteristics (all identified by Robinson et al., 2007; 2015); utilising multiple strategies for high retention rates (identified by Robinson et al., 2007). Ribisl and colleagues provide considerably more detail than Robinson et al. (2007; 2015) on the role study personnel play in retention. For example, they recommend that research staff are recruited for personal characteristics of “persistence, ingenuity, creativity and dedication” and “high tolerance for frustration” to handle the emotional demands of following up participants, and for their ability to demonstrate empathy and build trust, through listening skills and maintaining confidentiality (Ribisl et al., 1996, p.8). On a related note, one additional strategy not highlighted by the systematic reviews is their eighth recommendation: *tailor the approach to each individual study and participant*. They advise against a blanket retention strategy, instead urging researchers to consider the unique needs of each participant and record intelligence about what works for a particular participant. They stress that “a completely neutral and impersonal relationship in a long term follow-up is at best unlikely and at worst damaging to the study” (Ribisl et al., 1996, p.7).

A similar emphasis on relational/interpersonal skills is highlighted by Hunt and White (1998), in Seattle, USA, who analysed four longitudinal cohort studies providing detail of retention strategies used and retention rates. These studies involved the follow-up of four very different groups (registered nurses, men at risk of HIV, post-menopausal women and

intravenous drug users), and Hunt and White consider staff characteristics to be one of the most significant factors in longitudinal retention: “staff members must have skills that enhance the participant’s desire to participate, reflect the importance of the study and demonstrate enthusiasm and commitment to the project” (Hunt & White, 1998, p.61).

In addition to staff characteristics, Hunt and White identified seven other retention strategy themes (see Table 2.2). Three of these relate to tracking participants (6-8 in Table 2.2; with the need for tracking systems and gathering comprehensive baseline data also raised by Ribisl et al. (1996) and Robinson et al. (2007; 2015)). The remaining four strategies (1-4 in Table 2.2) relate to engaging and motivating participants. Whilst incentives (1) and bonding (2) have been identified in other reviews (all the systematic reviews and Robinson et al., 2007; 2017 respectively), the remaining two strategies (3 and 4) reflect Hunt and White’s (1998) belief that retention begins at recruitment: establishing a community advisory board creates a mutual understanding or bond between researchers and a study population and may be useful to identify potential retention issues before they arise. Hunt and White (1998) also argue that greater commitment and successful retention follow if researchers screen for commitment and clarify mutual expectations before the study commences (Hunt & White, 1998).

Support for Hunt and White’s (1998) argument that the foundations for retention are laid at recruitment can be found in a review of retention in community-based clinical trials (N=21) conducted by Davis et al. (2002) in Alabama, USA. Only trials which described retention strategies used and subsequent retention rates were included. Amongst the nine strategies identified by Davis and her colleagues (2002), similar advice emerged in this literature to reduce dropout: ‘conduct a run-in test’ (see Table 2.2, strategy 9), on the premise that if a participant performs poorly during the run-in test, they are unlikely to commit to and remain in the study, therefore should be ‘screened out’. Davis et al. (2002) also highlight the value of planning for retention when designing a trial by ensuring that there is an ‘appealing control group treatment’ (see Table 2.2, strategy 4).

Once again, consistent with Hunt and White (1998) and Ribisl and colleagues’ (1996) conclusions, Davis et al. (2002) identify high quality interactions between research staff and participants as “the critical factor in high retention studies” (p.49). In fact, ‘providing interpersonal skills training for project staff’ is one of their nine key retention strategies identified (see Table 2.2, strategy 6). A further four retention strategies are concerned with motivating participants to want to remain in the trial, i.e. they seek to make participation in the study a positive, worthwhile experience and minimise any burden (see Table 2.2,

Table 2.2 Attempts by non-systematic reviews and expert consensus papers to ‘thematise’ retention strategies

Authors, study composition	Labels used to categorise individual retention strategies identified in the literature (i.e. themes/groupings)	
Ribisl et al. (1996) Panel studies. (N=Not specified)	1. Gather comprehensive data at baseline. 2. Establish relationships with relevant agencies. 3. Use simplest & cheapest tracking methods first. 4. Expend greatest efforts at initial follow-up phase. 5. Create project identity <i>(e.g. badges, logo, newsletters, summaries).</i> 6. Study staff characteristics, training & support <i>(e.g. select for persistence, creativity, frustration tolerance, interpersonal skills; regular staff meetings).</i>	7. Make involvement rewarding and convenient <i>(e.g. go to high efforts to ensure pleasurable and convenient; provide tangible & intangible rewards; underline project’s value & participant expertise; minimize psychic & financial costs; flexibility).</i> 8. Tailor/customise efforts for each study and participant <i>(e.g. adolescents, cancer patients; then logging what works for a particular individual).</i>
Hunt & White (1998) Longitudinal cohort studies providing detail of retention strategies & rates (N=4)	1. Incentives <i>(Small tokens of appreciation, cash, feedback study progress).</i> 2. Bonding <i>(Create study logo, send cards, newsletters, updates; continuity of contact with study staff).</i> 3. Community Advisory Boards <i>(Health professionals, participant representatives, community figures, identify barriers to retention).</i>	4. Enrolment, consent and baseline activities <i>(Screen for commitment, inform of study requirements).</i> 5. Staff characteristics <i>(Well trained, enthusiastic; open communication; respond promptly, flexibility).</i> 6. Tracking systems <i>(To monitor follow-ups, record outcomes).</i> 7. Frequency of contact <i>(Maintain regular contact).</i> 8. Gather comprehensive data at baseline.
Davis et al. (2002) Community based clinical trials describing strategies used & rates (N=21)	1. Provide meaningful incentives. 2. Establish project identity. 3. Emphasise significance of study. 4. Appealing control group treatment. 5. Individualise data collection <i>(weighing up advantages of going “off-protocol” against risk of attrition due to rigidity).</i>	6. Provide interpersonal skills training for staff <i>(establishing trust, assertiveness, persistence, communication skills).</i> 7. Use participant tracking database. 8. Maintain contact between assessments. 9. Conduct a “run-in” test.
Coday et al. (2005) Strategies used by NIH Behavior Change Consortium (N=15 universities)	1. Provide incentives and small tokens of appreciation. 2. Be flexible with participants. 3. Give instrumental or tangible support <i>(e.g. reimbursements).</i> 4. Be patient but persistent with participants.	5. Maintain a good tracking system. 6. Emphasise benefits of participation. 7. Minimise respondent burden and give participants control. 8. Enlist support from others and provide social support <i>(e.g. contact between visits; sending get well soon card).</i>

Abshire et al. (2017) ¹ Thematic analysis of strategies used by teams achieving high retention rates in longitudinal clinical studies (N=19 interviews)	<ol style="list-style-type: none"> 1. Financial incentives. 2. Reimbursement. 3. Non-financial incentives – <i>offering pleasurable activities (e.g. creating artwork for a study).</i> 4. Community involvement. 5. Study description. 6. Study identity. 7. Highlighting study benefits. 	<ol style="list-style-type: none"> 8. Study personnel – <i>recruit for experience and knowledge of target population, persistence, communication and collaboration skills, staff consistency to create bonds.</i> 9. Contact and scheduling methods. 10. Visit characteristics. 11. Reminders. 12. Special tracking methods. 13. <i>Tailoring to individuals</i>
Brueton , Stevenson et al. (2014) Interviews with NHS staff who conducted primary care RCTs about strategies used to motivate participants to return to research sites. (N=29 interviews)	<ol style="list-style-type: none"> 1. Minimise participant burden. 2. Benefits of participation. 3. Engaging with participants: <i>establish good rapport and communication early on; personable, enthusiastic and persistent staff, good communicators.</i> 4. Tailoring retention strategies. 	<ol style="list-style-type: none"> 5. Working environment: <i>having an in-site staff member to champion the study (e.g. to ensure a smooth, welcoming experience for participants arriving to a site for follow-up meetings, such as rooms being made available, reception staff being informed about the study and knows where to direct them on arrival).</i>

¹ Of these authors (Abshire, Dinglas, Cajita, Eakin, Needham & Dennison Himmelfarb, 2017): Dennison Himmelfarb & Needham were co-authors of both Robinson et al. reviews (2007; 2015); Dinglas was co-author of Robinson et al. (2015) review. Strategies 1-12 in these cells are those identified by Robinson et al. (2007; 2015). Additional strategies/techniques identified in this 2017 study are in italicised text.

strategies 1-3 and 5), factors which have also been identified by Robinson et al. (2007; 2015) and Ribisl et al. (1996). The final two strategies identified by Davis and her colleagues (2002) relate to tracking/maintaining contact with participants (see Table 2.2, strategies 7 and 8), which has been identified as important in all the reviews. Once again, community-based clinical trials with the highest retention rates were those combining multiple strategies (Davis et al., 2002), supporting Robinson et al.'s (2007; 2015) and Ribisl and colleagues' (1996) findings.

In addition to these non-systematic reviews, a number of expert consensus papers have been published which draw upon interviews, focus groups and surveys conducted with experienced researchers. For example, in Memphis, USA, Coday et al. (2005) conducted a series of focus groups and surveys on barriers to retention and effective strategies across 14 universities with teams leading behavioural change intervention trials as part of a NIH Behaviour change consortium. The 61 strategies elicited were categorised into eight groups, all of which are consistent with recommendations already discussed (see Table 2.2, 1-8). Similar to Ribisl and colleagues' (1996) call for researchers to tailor their approach to participants to promote retention and engagement, Coday and his co-authors (2005) acknowledge that participants are not passive recipients, but have agency, and that their "participation is likely to be influenced by many factors" (p.63). They underline the need to be vigilant, responsive and adapt to participant needs, for example, paying close attention in the early stages of a project for any possible barriers, and developing appropriate strategies to prevent these becoming problematic (Coday et al., 2005).

Brueton, Stevenson, et al. (2014) in the UK conducted interviews with 29 primary care chief and principal investigators, trial managers and research nurses who had undertaken primary care randomised trials between 2000-2010, about strategies they used to motivate participants to return to research sites. These interviews revealed numerous strategies (see Table 2.2) which were not identified in their 2014 Cochrane review (which predominantly contained questionnaire-based studies). The dominant themes emerging from the trial staff interviews reflect the importance of interpersonal skills/qualities to engage with participants, to build relationships and maintain good rapport, in particular, "the need for a flexible approach, sympathetic, competent, personable, persistent, enthusiastic, good communicators, valuing the patient" (Brueton et al., 2014, p10). Tailoring approaches to meet individual needs was also considered important (supporting older recommendations by Ribisl et al., 1996 and Coday et al., 2005). The NHS interviewees in this study also highlighted the impact that the working environment had on retention, for example a study 'champion'

within the research site would increase the likelihood of the participant receiving a warm welcome on arrival for a follow-up appointment, and of facilities on site being made available for this meeting (Bructon et al., 2014).

More recently, in Baltimore, USA, Abshire and her colleagues (2017) contacted principal investigators from 22 published studies (with ≥ 200 participants, $\geq 80\%$ retention rate, over \geq one year follow-up), inviting them to participate in an in-depth interview to discuss effective retention techniques used. The 19 interviews conducted confirmed that the 12 retention strategy groups identified in Robinson et al.'s (2007; 2015) systematic reviews were utilised across all 19 studies featured, but also that additional, previously unidentified techniques were also considered crucially important (Abshire et al., 2017). These additional retention techniques are consistent with those raised by previous authors discussed earlier in this section: recruiting staff for their experience and in-depth knowledge of the target population, persistence, communication and collaboration skills; personalising/tailoring approaches to individual participants to help them feel valued, which in turn is believed to promote retention (Abshire et al., 2017). Finally, the importance of staff consistency was underlined, to create warm, enduring staff-participant bonds and offering pleasurable activities to engage participants in the research was considered effective (e.g. producing artwork related to the project) (Abshire et al., 2017).

Summary of the non-systematic reviews and evaluation

In contrast to the systematic reviews, all these non-systematic reviews have examined participant retention within face-to-face follow-up designs. There is generally broad consensus between these authors with regard to the key strategies for effective retention. Some of these recommended strategies are corroborated by all the systematic reviews, specifically:

- Make involvement rewarding;
- Make involvement convenient;
- Maintain good tracking/communication systems.

The advice to use *multiple strategies* to achieve higher retention (Davis et al., 2002; Ribisl et al., 1996) is also supported by Robinson et al.'s systematic reviews (2007; 2015).

Three additional, important groups of strategies not discussed within the systematic reviews have also emerged. Firstly, retention is acknowledged to be an interpersonally challenging and complex task, with the *researcher's interpersonal skills and qualities effectively considered as primary retention strategies* (e.g. Davis et al., 2002; Hunt & White, 1998; Ribisl et al., 1996). The reviewers argue that participant retention is more likely when a

researcher possesses strong interpersonal skills, selected for at recruitment or developed through training (e.g. Abshire et al., 2017; Brueton et al., 2014), because they facilitate trusting, relational bonds which lead to sustained commitment (Ribisl et al., 1996). In addition to interpersonal skills, particular staff characteristics, such as resilience, optimism and persistence, are underlined as important for retention (also identified by Robinson et al., 2007; 2015), so that frustrations can be resolved rather than spilling over into relationships with participants and triggering disengagement (Ribisl et al., 1996). For the same reasons, staff training and ongoing support are also recommended (Davis et al., 2002; Hunt & White, 1998; Ribisl et al., 1996).

The second additional, important strategy not discussed within the systematic reviews is an emphasis on *laying good foundations at recruitment* stage to support subsequent retention and commitment. Strategies here include devising an appealing control group, establishing community advisory boards, and conducting orientation and/or screening activities with prospective participants (Davis et al., 2002; Hunt & White, 1998). The final additional strategy identified uniquely within these non-systematic reviews is *tailoring the approach* to individual participants, which was highly recommended as a means of sustaining participant engagement (Brueton et al., 2014; Davis et al., 2002; Ribisl et al., 1996).

Whilst arguably not considered as methodologically rigorous as the systematic review (e.g. see e.g. see Moher et al., 2015), these non-systematic reviews have benefitted from greater freedom in not being bound by systematic review protocol when examining solutions to the perennial challenges surrounding retention. This has enabled the authors to explore challenges and solutions in more depth and explain their findings in more detail. Triangulating the data from these two sources (systematic and non-systematic), has revealed numerous overlaps/consistencies, and the appearance of common themes within both datasets supports the reliability of the findings (Thurmond, 2001). The three additional themes emerging from the non-systematic review dataset offer a more nuanced understanding of the retention process, which extend the systematic review findings. The next short section presents a synthesis of the two datasets (systematic and non-systematic).

2.2.3 Overall synthesis of the retention literature

Considerable challenges with the retention literature are the sheer volume and diversity of strategies described within published papers (Robinson et al., 2015). This necessitates some form of grouping or categorising, and inevitably different authors group individual strategies differently and decide upon different category names, which makes synthesizing retention methods difficult. For example, “visit characteristics” (Robinson et al., 2007; 2015) and

“flexibility with patients” (Coday et al., 2005) both appear to refer to the same principle of not being too rigid in the protocol and responding flexibly to participants’ needs to keep them engaged in the study. Therefore, in order to synthesize all the literature presented so far in this chapter, each retention category description has been studied carefully (including any specific illustrative examples provided), and close attention paid to patterns and relationships across the reviews. These groupings have then been ‘translated’ into a common rubric (as recommended in Popay et al., 2006) and a simple content analysis completed to indicate the prevalence of particular categories within the literature (see Table 2.3; strategies are listed from most to least prevalent).

With the exception of Brueton, Stevenson et al. (2014), it is notable that none of the key papers discussed has featured site-level retention. Whilst this is perhaps unsurprising where the review has ‘participant’ retention in the title (e.g. Robinson et al., 2015), other titles do not clearly specify a sole, individual-level focus. For example, readers drawn to titles such as ‘strategies to improve retention in randomised trials’ (Brueton et al., 2014) and ‘maximising retention in community-based clinical trials’ (Davis et al., 2002), hoping to find evidence on site-level retention, would be disappointed.

Table 2.3 Synthesis of retention strategy themes highlighted in the general literature

Retention Strategy	Description and examples from the literature	Identified in	
		SR	Non-SR
Make involvement rewarding	Invest heavily in making the research a pleasurable experience for participants. <input type="checkbox"/> Financial/non-financial incentives. <input type="checkbox"/> Provide meaningful incentives. <input type="checkbox"/> Highlight study benefits. <input type="checkbox"/> Emphasise significance of study. <input type="checkbox"/> Offer pleasurable activities.	1,2, 3,4, 11	5,6,7, 8,9,10
Maintain effective contact and tracking methods	<input type="checkbox"/> Gather comprehensive data at baseline. <input type="checkbox"/> Tracking systems. <input type="checkbox"/> Use simplest and cheapest tracking system first. <input type="checkbox"/> Expend greatest efforts at initial follow-up phase. <input type="checkbox"/> Use participant tracking database. <input type="checkbox"/> Maintain participant tracking system. <input type="checkbox"/> Contact and scheduling methods. <input type="checkbox"/> Special tracking methods. <input type="checkbox"/> Reminders/reminder methods. <input type="checkbox"/> Communication approaches (enhanced letters, phone/text/email reminders).	1,2, 3, 11	5,6,7, 8,9
Establish a project identity	To help the participant easily identify correspondence related to the study, to aid confidentiality regarding the nature of the study, to promote value in participating. <input type="checkbox"/> Study logos on incentives. <input type="checkbox"/> Establish project identity.	1,2, 11	5,6,7, 8,9
Invest in research staff as critical agents in the retention process	Recruit staff who are persistent, assertive, able to tolerate frustration, with strong interpersonal skills. Provide training and regular support. <input type="checkbox"/> Study staff characteristics, training & support.	1,2, 11	5,6,7, 9,10

	<input type="checkbox"/> Staff characteristics. <input type="checkbox"/> Provide interpersonal skills training for staff. <input type="checkbox"/> Study personnel. <input type="checkbox"/> Recruit for experience, and knowledge of target population, persistence, communication and collaboration skills. <input type="checkbox"/> Staff who are persistent, competent, personable, good communicators.		
Make involvement convenient	Minimise burden and psychic or financial costs, such as travel expenses, arranging childcare, be flexible in where and how data are collected. <input type="checkbox"/> Minimize respondent burden. <input type="checkbox"/> Flexibility with patients. <input type="checkbox"/> Reimbursement. <input type="checkbox"/> Visit characteristics. <input type="checkbox"/> New questionnaire formats (e.g. shorter). <input type="checkbox"/> Alternative modes of data collection. <input type="checkbox"/> Offer repeat visits or questionnaires.	1,2, 3,4, 11	8,9
Build relationships with participants	Create bonds with participants. <input type="checkbox"/> Build relationships and maintain good rapport. <input type="checkbox"/> Be reliable, trustworthy. <input type="checkbox"/> Bonding. <input type="checkbox"/> Staff consistency to create bonds. <input type="checkbox"/> Frequency of contact: keep communication channels open use newsletters, provide updates. <input type="checkbox"/> Maintain contact between assessments. <input type="checkbox"/> Remember details (e.g. important events). <input type="checkbox"/> Behavioural strategies. <input type="checkbox"/> Case management.	3, 11	5,6,7, 9,10
Clarify mutual expectations to minimise ambiguity /uncertainty	<input type="checkbox"/> Be clear about study requirements. <input type="checkbox"/> Study description. <input type="checkbox"/> Conduct a run-in test to screen for commitment/suitability.	1,2, 11	6,7,9
Formally involve the community throughout	<input type="checkbox"/> Community involvement <input type="checkbox"/> Establish community advisory board.	1,2, 11	6,9
Tailor approaches to individual participants	<input type="checkbox"/> Tailor/customise efforts for each study and participant. <input type="checkbox"/> Tailoring approaches to individuals. <input type="checkbox"/> Tailoring to individuals to help them feel valued.	11	5,7,9, 10
Use multiple strategies		1,2	5
Design an appealing control condition			7
Secure a “project champion” at the research site			10
Key: 1. Robinson et al. (2007) 5. Ribisl et al. (1996) 8. Coday et al. (2005) 2. Robinson et al. (2015) 6. Hunt & White (1998) 9. Brueton, Stevenson et al. (2014) 3. Booker et al. (2011) 7. Davis et al. (2002) 10. Abshire et al. (2017) 4. Brueton et al. (2013) 11. Teague et al. (2018)			

Studies involving multiple sites or clusters are unusual in that sites are not defined as the study participants: the participants are the individual members within them (Campbell et al., 2012). Consequently, it is unclear whether strategies considered effective for retaining individual participants are generalisable to the retention of sites within research studies. Two

of the review teams imply that different strategies may indeed be needed for retaining sites than those recommended for individual-level retention. Coday and his colleagues (2005) underline that they are not discussing site-level strategies, and Brueton et al. (2013) call for “more research on ways to [...] retain clusters” in RCTs (p.12). Therefore it is important to determine whether any specific literature exists on strategies to support site-level retention. The next section reports a systematic review of citations which address the issue of site-level retention in cluster trials (and multi-site studies) and describe strategies to maximise site-level engagement and retention. The findings from this review will then be discussed in the context of the synthesised participant-level retention literature, to provide a more comprehensive view of retention and identify gaps in the literature. The review will seek to answer the following questions:

1. Do the strategies employed by researchers to retain sites in studies differ from the participant-level strategies recommended in the literature?
2. What evidence exists for the effectiveness of site-level strategies?

2.3 Systematic review of studies exploring strategies for effective site-level retention

2.3.1 Method

Search strategy

Whilst this review was related to research methodology as opposed to a particular health care intervention, it was guided by the steps documented within the Preferred Reporting Items for Systematic Reviews and Meta-analyses statement (see see Moher, Liberati, Tetzlaff & Altman, 2009) for the purposes of transparency and rigour. Search terms used included combinations of variants of ‘cluster randomised trial’ AND ‘reducing attrition/withdrawal/drop-out’ OR ‘increasing retention/compliance/engagement’ (see Appendix 1). Utilised within the strategy were published electronic search strategies to increase the identification of reports of cluster randomised trials (Brierley, Brabyn, Torgerson & Watson, 2012; Moberg & Kramer, 2015; Taljaard et al., 2010). These have been published in response to authors’ inconsistent use of the term ‘cluster randomised trial’ in the title or abstract (Moberg & Kramer, 2015), a key recommendation in the adapted CONSORT statement for cluster trials (Campbell et al., 2012).

To maintain consistency with databases used in other systematic reviews of retention, the search strategy was applied to Medline, Embase, PsycINFO, Cumulative Index to Nursing and Allied Healthcare (CINAHL) and the Cochrane Library in July 2018. Diverging from previous systematic reviews, the strategy was also applied to the British Education Index

and Educational Resources Information Centre, to retrieve any education-focused, school-based cluster trials which may not appear in the other health-related databases. To maximise the likelihood of retrieving relevant citations, subject heading searches (e.g. MeSH terms) were combined with exact phrase/keyword searches wherever possible. No time restrictions/limitations were placed on the searches in order to maximise the number of potentially relevant articles retrieved.

Eligibility criteria and study selection

The eligibility criteria applied are defined in Table 2.4. In developing these criteria, careful consideration was given to the term ‘retention’. Within a systematic review, the noun ‘retention’ is problematic because it has multiple definitions. According to the online Oxford English dictionary, it is:

- The continued possession, use, or control of something;
- The fact of keeping something in one's memory;
- The action of absorbing and continuing to hold a substance;
- The failure to eliminate a substance from the body.

This lack of singular definition is reflected in the academic literature: ‘retention’ papers focus on a diverse range of topics, such as retaining knowledge after a training session, retaining employees at work, or urinary retention (i.e. incomplete evacuation of the bladder). A further complication arises from the fact that retention in treatment programmes and retention in research studies are very similar, and may be conflated (Zweben et al., 2009).

Table 2.4 Eligibility criteria for inclusion of articles in the systematic review

Inclusion Criteria	Exclusion Criteria
The article features a cluster trial or multi-site study.	Non-human sample.
Site-level retention/attrition/withdrawal is discussed.	Retention relates to therapy or treatment program.
Site-level strategies are described.	Retention/attrition is dentistry-related (e.g. teeth).
	Retention/drop-out relates to employees at work or students in education.
	Retention is in context of learning, memory, training, skills, information.
	Retention is associated with the body (e.g. biological/surgical, or faeces, urine etc.).
	Retention is discussed from the perspective of statistical/analytical treatment of data.
	Compliance/attrition/engagement/participation is not research study-related (e.g. compliance with wearing safety equipment).

Finally, the systematic review was not concerned with the statistical/methodological treatment of retention/withdrawal/dropout data. Therefore the exclusion criteria were developed to ensure that the retained papers focused purely on research retention. The titles and abstracts of identified citations were screened against the inclusion criteria and the full texts of potentially relevant citations were obtained and reviewed for inclusion by the author. A random sample of 20% of the citation titles and abstracts was screened independently against inclusion criteria by a second reviewer (CH). There were no discrepancies with regard to citation title inclusion, and following a discrepancy on two abstract inclusion decisions, a meeting was held during which a consensus was reached.

Data extraction and synthesis

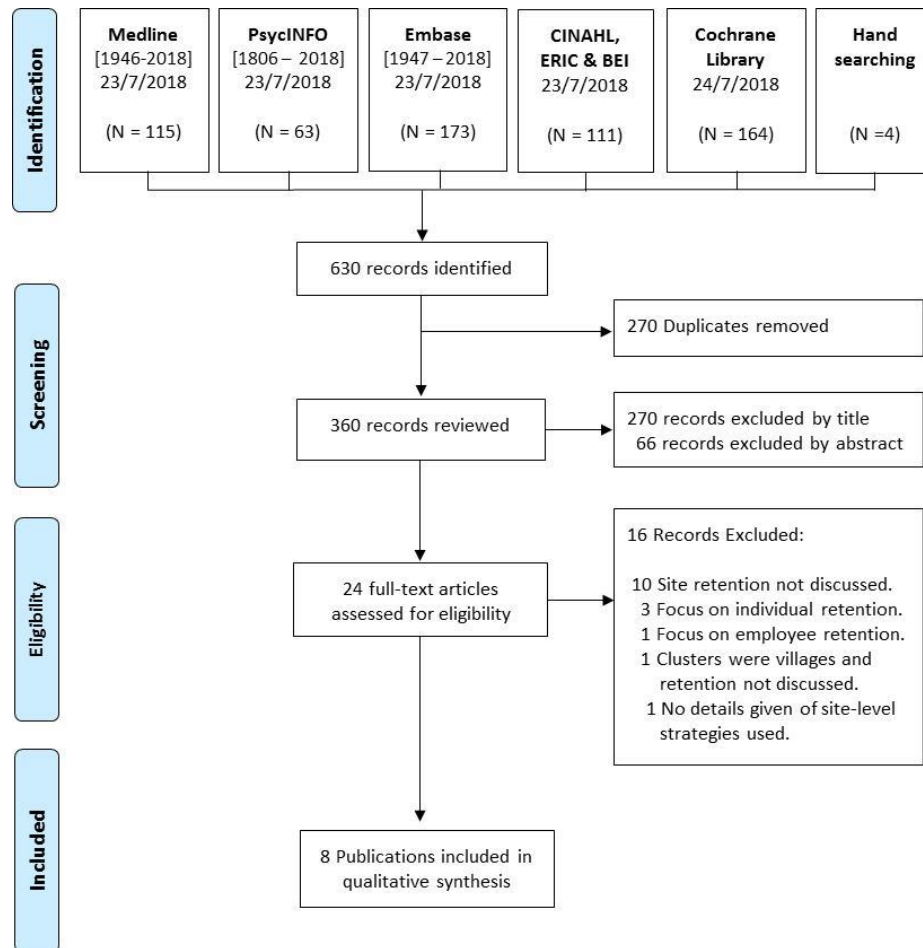
After full text screening, data were extracted from the final articles accepted into the review using pre-defined criteria (brief study outline; participants; setting; retention strategy; results; quality; other notes). An independent reviewer assessed the accuracy and completeness of data extraction (MC). Because the nature of the review question involved the inclusion of a wide range of designs, with narrative explanations of retention strategies, narrative data synthesis was used (Popay et al., 2006). Narrative data synthesis is a structured approach which helps the researcher summarise, organise and synthesise multiple studies, principally using text rather than numbers, effectively constructing a robust and defensible “story” about the data (Popay et al., 2006, p.5). This process began with producing textual descriptions of each citation’s findings, then organising the data into tabular form according to particular characteristics of each citation to more easily detect patterns and point of divergence (Popay et al., 2006). The data were then closely examined at this point, to explore relationships (Popay et al., 2006). During this stage, thematic analysis (based on Braun & Clarke, 2006) was used to study the authors’ descriptions of concepts/findings within each citation and ‘translate’ these where necessary to create a common rubric (Popay et al., 2006, p.18) to facilitate synthesis. Relationships between the data were also identified at this stage, and where appropriate new conceptual headings were created to explain the data. Borrowing from Framework Analysis (Ritchie & Spencer, 1994), the synthesised participant-level retention categories in Table 2.3 were applied to the data to determine whether the site-level strategies differed from these. Finally, content analysis was used to reveal the prevalence of particular strategies used within the sample.

2.3.2 Results

A total of 360 papers were identified after removing duplicates. After title and abstract screening, 24 citations potentially fulfilled the eligibility criteria. The full-texts of these

citations were acquired and reviewed. Of these, eight articles fulfilled the eligibility criteria and were included in the review (see Figure 2.1).

Figure 2.1 PRISMA flow diagram of the article review process in the systematic review



Most of the authors writing about site-level retention were based in the USA (four of eight articles: Berry et al., 2013; Drews et al., 2009; Markoe Hayes, Chapple & Ramirez, 2014; Pinto, Witte, Wall & Filippone, 2018), closely followed by the UK and Republic of Ireland (three of eight articles: Hindmarch et al., 2015; Leathem et al., 2009; Lloyd, McHugh, Minton, Eke & Wyatt, 2017) and one team of authors were based in New Zealand and Australia (Schoeppe, Oliver, Badland, Burke & Duncan, 2014). None of the articles included focused solely on retention: they all discussed retention alongside recruitment. Most of the articles discussed site-level retention strategies used within cluster RCTs (six out of eight articles: Berry et al., 2013; Drews et al., 2009; Hindmarch et al., 2015; Leathem et al., 2009; Lloyd et al., 2017;

Markoe Hayes et al., 2014¹) and one featured a longitudinal mixed-methods study (Pinto et al., 2018). One exception involved a literature review and Delphi study related to recruiting and retaining children in health risk factor studies (Schoeppe et al., 2014). Most of the authors had published their main study findings elsewhere (with the exception of Markoe Hayes et al., 2014 and Schoeppe et al., 2014) and their current article featured a descriptive report about how they achieved success in retention (see Appendix 2 for characteristics of included studies).

Schools were the featured sites in half of the articles. The remaining four articles featured general practices (Leathem et al., 2009), non-profit HIV-prevention agencies (Pinto et al., 2018), children's centres (Hindmarch et al., 2015) and community settings such as schools, childcare centres and youth-related organizations (Schoeppe et al., 2014). Most sites were participating in trials testing complex health- or injury-prevention interventions (six out of eight articles). The non-profit HIV prevention agencies were engaged in testing a training intervention to develop inter-professional collaboration skills between agency staff (Pinto et al., 2018), and 'community settings' were the target sites in a guidance paper outlining strategies for the effective involvement of children in health risk factor studies (Schoeppe et al., 2014).

The number of research sites being targeted with retention strategies was not always clearly presented in the six study-related articles. For example, Berry et al.'s (2014) abstract describes just eight elementary schools participating in the study, but it is later explained that a further 12 were recruited to boost the number of families involved. The precise number of schools involved in Markoe Hayes et al.'s (2014) teenage pregnancy prevention program is indeterminable from the paper. Specifically it is not explained whether cohorts one and two were drawn from the same pool of middle and high schools: cohort one were from six middle schools and six high schools and cohort two from four middle and three high schools (Markoe Hayes et al., 2014). Therefore the actual number of schools involved ranges from six to ten middle schools and six to nine high schools. The remaining five study-related articles clearly stated the number of sites involved, and these ranged from 32-48 separate sites (N=32 primary schools [Lloyd et al., 2017]; N=36 children's centres [Hindmarch et al., 2015]; N=36 HIV prevention service agencies [Pinto et al., 2018]; N=42 middle schools [Drews et al., 2009]; N=48 general practices [Leathem et al., 2009]).

¹ Although Markoe Hayes et al. (2014) do not use the term 'cluster', this is highly likely, therefore a decision was made to include in this group.

Do site-level strategies differ from participant-level strategies?

A total of 17 effective site-level retention strategies were extracted from the seven review articles (see Table 2.5 for a detailed description). These include five new site-level specific strategies and the same 12 retention strategies recommended in the participant-level literature (previously listed in Table 2.3), although two strategies require substitution of 'site' for 'participant', i.e. 'build relationships with *sites*' and 'tailor approaches to individual *sites*'. The degree of generalisability of the 12 previously identified retention strategies, and the five new site-level specific strategies are each now explored in turn.

Degree of generalisability of the 12 common retention strategies

Whilst the 12 previously documented strategies appear to be generalisable to sites, when the goal is site-level retention, two major differences emerged within the literature. Firstly, the methods used to execute these strategies at the site-level often differed from those at the participant-level. This was due to the scale of the tasks and the required reach of influence. For example, at the participant-level, a generic information sheet or presentation to potential participant groups may suffice to 'clarify mutual expectations to minimise any ambiguity/uncertainty'. At the site-level, however, multiple levels of stakeholders are involved, both inside and outside the organization (Drews et al., 2009), which dictates a more complex strategy. Particularly within cluster trials, stakeholders (such as children's centre managers, school principals and other site staff) are responsible for ensuring trial tasks take place at their site. Therefore it is vital that they fully understand the process, voice any concerns and receive reassurance that participation in the study is feasible. Early social gatherings, meetings and site visits with stakeholders are typically arranged to provide an opportunity to outline the study, including randomization, to highlight the associated requirements (e.g. facilities such as rooms), what to expect and to flush out any concerns so that these can be addressed (Drews et al., 2009; Hindmarch et al., 2015; Leathem et al., 2009; Markoe Hayes et al., 2014; Pinto et al., 2018; Schoeppe et al., 2014). Two studies underline the value of pilot work before commencing the full trial to identify potential retention issues and resolutions, which enabled the team to be proactive in this area (Hindmarch et al., 2015; Leathem et al., 2009).

Table 2.5 Cluster retention strategies extracted from the seven articles identified through the systematic review

Retention Strategy	Examples from the articles included in the review		Identified in
Make involvement rewarding	<ul style="list-style-type: none"> □ Free exercise equipment (1). □ Annually increasing monetary incentive- \$2,000 rising to \$4,000 final year/\$6,000 for control schools (2). □ Teaching activities designed to be fun to deliver, active input from the children (4). □ Financial incentive for site staff member acting as study co-ordinator on site; CPD points for staff attending events (6). 	<ul style="list-style-type: none"> □ £25 gift vouchers per children's centre (3). □ Describe the benefits of taking part, e.g. fun, improved student health; show enthusiasm and create interest when discussing the study (7). □ Social activities and refreshments, opportunities for networking, sharing experiences, researchers seeking organisations' views and ideas (6). □ £700 to compensate for phone calls, room use, time (8). 	<p>7/8</p> <p>¹ Berry et al. (2013) ² Drews et al. (2009) ³ Hindmarch et al. (2015) ⁴ Lloyd et al. (2017) ⁶ Pinto et al. (2018) ⁷ Schoeppe et al. (2014) ⁸ Leathem et al. (2009)</p>
Maintain effective contact and tracking methods	<ul style="list-style-type: none"> □ Recruiting an on-site study coordinator (paid for by trial) (4). □ Reminders about upcoming data collection sessions (letters to staff), posters around school, newsletter notices, school bulletins & school-wide notifications (2). □ Phone calls with children's centre managers at 1,3,8 and 12 months to collect activity logs and reiterate the importance of the trial (3). □ Comprehensive record keeping using Google calendar for appointments, standardised checklist developed for data collection, individualised notes recorded about each site enhanced efficiency (6). 	<ul style="list-style-type: none"> □ Establish optimal communication routes, e.g. noticeboards, emails, meetings. Record all contact details. If tasks are not completed, explore reasons collaboratively and identify barriers and potential workarounds/solutions (7). □ All site activity logged on database; Research Nurses rang sites to remind about patient appointments; created Practice Care Plans to log results of quality assurance observations, follow-up consultations and issues (8). □ Every semester, PI updated via email superintendents on progress; trial manager kept principals updated by phone and email (1). 	<p>7/8</p> <p>¹ Berry et al. (2013) ² Drews et al. (2009) ³ Hindmarch et al. (2015) ⁴ Lloyd et al. (2017) ⁶ Pinto et al. (2018) ⁷ Schoeppe et al. (2014) ⁸ Leathem et al. (2009)</p>
Establish a project identity	<ul style="list-style-type: none"> □ Study branding was used on all envelopes, communications and trial documents (3). □ SPHERE study folder was created and a newsletter was circulated to all participating general practices (8). 	<ul style="list-style-type: none"> □ Develop easily identifiable branding for your study. Create a study website, circulate posters at all sites, ensure research staff are easily recognisable by wearing study branded clothing/badges. Use appealing, professional-looking materials with branding (7). 	<p>3/8</p> <p>³ Hindmarch et al. (2015) ⁷ Schoeppe et al. (2014) ⁸ Leathem et al. (2009)</p>
Invest in research staff as critical agents	<ul style="list-style-type: none"> □ Trial manager introduced field coordinators to school principals so they felt comfortable about providing them with subsequent updates (1). 	<ul style="list-style-type: none"> □ Advisory group underlined the need for consistent, quality personnel with necessary skills and competencies to understand teachers' busy lives. Developed person 	<p>7/8</p> <p>¹ Berry et al. (2013) ² Drews et al. (2009)</p>

in the retention process	<ul style="list-style-type: none"> □ A recruitment and retention committee was established to develop strategies and monitor progress. Staff were employed for strong interpersonal skills and received training in local culture and customs. Over time at the sites they became attuned to local climate and anticipated potential obstacles (2). □ Use staff who are connected to the community. Ensure continuity for stability & trust, clear responsibilities. Foster strong team culture, cohesive team; provide training & manuals; (7). □ 'Crib sheet' was developed for Children's Centre visits to help research staff motivate managers (3). 	<ul style="list-style-type: none"> specification and coordinators were recruited, assigned to specific schools for continuity (4). □ Trained staff in using data collection standardisation checklist. Staff hired for tenacity, resilience, empathy to enable them to deal with DNAs, on-site emergencies, non-response to emails and calls (6). □ Characteristics of the Research Nurses established strong bonds: warmth, approachability, reassurance, encouragement. They made themselves easily accessible to staff and responded to site needs (8). 	<p>³ Hindmarch et al. (2015) ⁴ Lloyd et al. (2017) ⁶ Pinto et al. (2018) ⁷ Schoeppe et al. (2014) ⁸ Leathem et al. (2009)</p>
Make involvement convenient	<ul style="list-style-type: none"> □ Mainly non-school staff delivered the intervention. Envelopes, stamps, address labels were provided for admin staff to issue correspondence and study coordinator helped with tasks. Parental materials were translated if high proportion of English as second language, and adapted for parents with visual impairments (4). □ Red storage boxes were provided to general practices to store all study information; laminated A4 guide cards were produced with simplified visuals of consultation steps; Research Nurse helped with study admin when on-site and avoided phoning sites at busy times (Monday am and Friday pm) (8). □ Assured staff of low burden: showed them how study procedures slotted into the school calendar, accounting for exams/tests, Christmas and other significant school events (2). 	<ul style="list-style-type: none"> □ Ensured the study routine was flexible and convenient for staff (and families who staff would work with) (3). □ Reassured agencies that participation would be low burden: researchers visited at convenient times to collect data, saw multiple participants during the same visit and took no longer than 1 hour per person (6). □ Ensure parental study information/protocol is easy to follow to minimise issues the school has to field. Consider passive consent, use collection boxes as efficient ways of returning key paperwork, help site admin staff, limit the number of measures taken, avoid clashes with important school calendar events, pick up questionnaires from sites/provide stamped addressed envelopes (7). 	<p>6/8</p> <p>² Drews et al. (2009) ³ Hindmarch et al. (2015) ⁴ Lloyd et al. (2017) ⁶ Pinto et al. (2018) ⁷ Schoeppe et al. (2014) ⁸ Leathem et al. (2009)</p>
Build relationships with sites	<ul style="list-style-type: none"> □ Getting to know all levels of school staff, many of whom chose to become informal advocates of the study with students/parents. Personalised gifts and thank you notes to staff who allowed their 	<ul style="list-style-type: none"> □ Building relationships was central to delivering the intervention. Coordinator's photo on display in school reception (4). 	<p>8/8</p> <p>¹ Berry et al. (2013) ² Drews et al. (2009)</p>

	<p>classrooms to be used and helped the researchers pack up after sessions. Christmas newsletter to all stakeholders including students (1).</p> <ul style="list-style-type: none"> □ Regular meetings with school leaders and teachers to build rapport. Invested in control schools relationship (aware they had significantly less contact than intervention schools) – PI maintained personal contact with principals and other leaders, thanking for continued participation, underlining their importance, seeking feedback on data collection process. New Year cards to staff and personalised gestures (thank you notes, gifts and snacks at meetings) (2). □ Established strong relationships with children’s centre staff: prior to the study through meetings to discuss randomisation and how the study complemented existing injury prevention work; during the study through phone calls, meetings (3). 	<ul style="list-style-type: none"> □ Being on site helped build stronger relationships with school staff, who in turn voluntarily helped more with key tasks (e.g. reminding students of data collection). Provided regular updates to leadership team and staff and created feedback mechanism for continuous improvement (5). □ Invest in early collaboration with study partners, particularly face-to-face, personal contact – visits to sites. Maintain regular communication through site visits, emails, study website, newsletters. Ensure communication is open, clear and flexible, including nominated contact staff at each site. Fulfil promises made, such as providing reports or collecting data confidentially (7). □ Research Nurses offered a high degree of practitioner support and responsiveness; delivered multiple training sessions; conducted observations and engaged in supportive feedback/discussions; were easily accessible to staff; invested particularly in the primary relationship with the on-site study coordinator (8). 	<p>³ Hindmarch et al. (2015) ⁴ Lloyd et al. (2017) ⁵ Markoe Hayes et al. (2014) ⁶ Pinto et al. (2018) ⁷ Schoeppe et al. (2014) ⁸ Leathem et al. (2009)</p>
Clarify mutual expectations to minimise ambiguity/uncertainty	<ul style="list-style-type: none"> □ Provided schools with clear expectations about delivering the program and the associated requirements (e.g. classrooms). Also underlined the importance of their support in ensuring the girls turned up to the program weekly (5). □ Pilot work to understand potential barriers/difficulties with implementing the trial and intervention. Phone calls with prospective general practices, followed up with letters and information sheets detailing work involved, randomisation. Site visits to discuss the study and answer questions; obtained formal, signed participation agreements; provided extensive training in the intervention; held quality assurance observations, including feedback to ensure correct delivery of protocol; rapid response to queries (8). 	<ul style="list-style-type: none"> □ Schools signed a formal letter of understanding, which stressed their commitment to the study and the need to comply with procedures even if leadership personnel changed, and their agreement to randomisation and supporting data collection. The research team produced a study timeline for principals with key steps in the trial and a study overview brochure for staff with FAQs. (2). □ Highlighted centre obligations and what to expect with regard to randomisation, data collection and intervention delivery. The team met children’s centre managers before randomisation to explain the study and answer concerns (3). □ Obtained feedback on any barriers, clarified resources needed for the study in recruitment meetings (1). □ Gain signed consent from study partner leaders (7). 	<p>7/8</p> <p>¹ Berry et al. (2013) ² Drews et al. (2009) ³ Hindmarch et al. (2015) ⁵ Markoe Hayes et al. (2014) ⁶ Pinto et al. (2018) ⁷ Schoeppe et al. (2014) ⁸ Leathem et al. (2009)</p>

	<input type="checkbox"/> Used early stakeholder social gatherings/branches as opportunity to flush out and address practical concerns about time commitments if involved etc. (6).		
Formally involve the community throughout	<input type="checkbox"/> Established a community collaboration board which met monthly. Consisted of university researchers, HIV service users, agency managers and providers (e.g. counsellors, supervisors, educators). Involved in: developing the grant proposal which funded the research; designing the intervention training; co-designing survey questions; developing recruitment and retention strategies. At the end of the project, during dissemination events, providers, agencies and service-users 'member checked' the findings, helped interpret them, identified future research priorities and shared their experiences (6).	<input type="checkbox"/> Established a project advisory group which met regularly, consisting of teachers, parents, head teachers. Advised on: feasibility and acceptability of measures; optimal ways of engaging and interacting with parents; recruiting and engaging schools and teachers; person specification for school coordinators and subsequent interviews. Co-designed the intervention, parents and teachers were partners on research bid, acted as advocates at recruitment meetings (4).	2/8 ⁴ Lloyd et al. (2017) ⁶ Pinto et al. (2018)
Tailor approaches to individual sites	<input type="checkbox"/> Sites were able to tailor/adapt elements of the intervention to better suit their school and to respond to individual students' needs (4). <input type="checkbox"/> Through regular phone calls and visits to general practices, Research Nurses provided personalised support for different needs (8).	<input type="checkbox"/> Agencies found it difficult to release staff for the one-day training, or staff cancelled due to sickness/work pressures. Therefore the team produced a video version of training with accompanying activities (6)	3/8 ⁴ Lloyd et al. (2017) ⁶ Pinto et al. (2018) ⁸ Leathem et al. (2009)
Use multiple strategies	None of the articles explicitly advocated this, but all described multiple strategies.		8/8 ¹ Berry et al. (2013) ² Drews et al. (2009) ³ Hindmarch et al. (2015) ⁴ Lloyd et al. (2017) ⁵ Markoe Hayes et al. (2014) ⁶ Pinto et al. (2018) ⁷ Schoeppe et al. (2014) ⁸ Leathem et al. (2009)
Design an appealing control condition	<input type="checkbox"/> Wait list control were promised free exercise equipment and the intervention at the end of the trial. (1)	<input type="checkbox"/> Control arm received the intervention materials after final data collection (3).	2/8 ¹ Berry et al. (2013) ³ Hindmarch et al. (2015)

Secure a “project champion” at the research site	<ul style="list-style-type: none"> Secured a primary contact person in each school during previous academic year, but high turnover rates meant that they were no longer there when the study started. Researcher’s presence in the school to develop staff relationships was therefore more critical (5). 	<ul style="list-style-type: none"> Each agency nominated a contact person who would coordinate interview scheduling and secure internal approvals (6). A key contact was secured at each general practice. The Research Nurse liaised with these as a focal point for all study tasks and communication (8). 	<p>3/8</p> <p>⁵ Markoe Hayes et al. (2014) ⁶ Pinto et al. (2018) ⁸ Leathem et al. (2009)</p>
Identify & secure support from key stakeholders and champions	<ul style="list-style-type: none"> PI and study coordinator met superintendents and other key figures at district level to explain the study; followed up with presentations to school boards, faculty and staff on the study and type 2 diabetes; meetings with Head of PE department and food services manager (2). Identify key stakeholders (e.g. parents, school staff) and other influential figures who could champion the study and reassure sites about its value, such as community leaders, celebrities, GPs. Gain strong support from school principals (7). Children’s centre staff had a wealth of knowledge about families which was invaluable to study staff. They guided the team on who to approach/avoid, encouraged parental engagement with the intervention and gave additional, voluntary support such as providing a crèche and refreshments to motivate families to take part. They also delivered the intervention and reported on trial activity (3). A list of general practices was obtained from local health authority. Practices meeting study criteria were contacted by phone, those interested were followed up with letters and information sheets, and a further call 10 days later to arrange a lunchtime visit with all staff to explain the study and answer questions (8). 	<ul style="list-style-type: none"> ICC Board members took part in stakeholder recruitment events, using their own experience of being involved – supported/delivered presentations about the study. Secured senior influential figures from Division of AIDS research at NIMH as keynote speakers at the final study dissemination event who endorsed and validated the study (6). Early stakeholder social gatherings/brunches to allow time to discuss the study, including opportunities it would bring. Began with contacting agencies where had closest links (past collaborations or ICCB member worked there), then further session with less familiar agencies (6). Good relationships with staff led to them becoming informal study advocates/helpers (e.g. speaking to parents about the study, reminding students about data collection) (1). Advisory group members shared their experience of being involved in the study at a recruitment meeting with school leaders (4). Letters to children’s centres were followed up by meetings at interested sites (3). 	<p>7/8</p> <p>¹ Berry et al. (2013) ² Drews et al. (2009) ³ Hindmarch et al. (2015) ⁴ Lloyd et al. (2017) ⁶ Pinto et al. (2018) ⁷ Schoeppe et al. (2014) ⁸ Leathem et al. (2009)</p>
Involve and engage staff	<ul style="list-style-type: none"> Sought ideas from principals to improve data collection (2) and study activities (1). 	<ul style="list-style-type: none"> Children’s centre staff piloted questionnaires with parents and collected their feedback. Staff were interviewed across four study sites about what they considered to be the 	<p>7/8</p> <p>¹ Berry et al. (2013) ² Drews et al. (2009)</p>

	<ul style="list-style-type: none"> □ Got to know all levels of school staff which helped study run more smoothly (1). □ Optimised engagement with intervention by co-creating this with PAG (gave feedback to ensure acceptability & feasibility). Coordinator met with teachers to discuss study ahead of distributing parental packs. Teachers were encouraged to observe sessions to promote engagement. Teachers received regular email updates from coordinator; Information flyer was created for teachers (4). □ Use videos, slide shows and demonstrate gadgets to engage staff in the study (7). □ All general practice staff participated in initial study briefing, the Research Nurse invested in supporting the study coordinator, collaborative, supportive discussions took place after quality assurance observations and innovations/highlights emanating from these were shared with all sites via newsletters, extensive training took place on site (8). 	<p>barriers and levers to delivering health promotion and injury prevention interventions. Not only did this increase ownership for delivering the intervention, it also enhanced the researchers' understanding of the target audience and setting, which they were able to incorporate into the intervention (3).</p> <ul style="list-style-type: none"> □ Appealing to altruism and existing strong staff commitment to improving service and care for HIV community – stressing chance to be 'part of the solution' through the study– i.e. personal motivation/benefits to learning how to collaborate more effectively through the intervention (6). 	<p>³ Hindmarch et al. (2015) ⁴ Lloyd et al. (2017) ⁶ Pinto et al. (2018) ⁷ Schoeppe et al. (2014) ⁸ Leathem et al. (2009)</p>
Give back to the community	<ul style="list-style-type: none"> □ Provide summary reports, presentations at sites. Feed into/guide school curriculum with data collection and results; provide teaching materials (7). □ School-specific summary reports of student health data sent to school administrators and superintendents (2). □ Disseminating findings through community symposium and magazine distributed to all participating sites (6). 	<ul style="list-style-type: none"> □ The intervention itself was an engagement tool, meeting a local need (6). □ Highlighted how intervention activities fitted with PSHCE national curriculum (4). □ Explaining how intervention could support their usual health promotion activities and ongoing injury prevention work (3). 	<p>5/8</p> <p>² Drews et al. (2009) ³ Hindmarch et al. (2015) ⁴ Lloyd et al. (2017) ⁶ Pinto et al. (2018) ⁷ Schoeppe et al. (2014)</p>
Succession plan	<ul style="list-style-type: none"> □ Comprehensive record keeping helped in times of research staff turnover (In a longitudinal study this is not uncommon) – new staff were able to review site notes which helped maintain established relationships (6). 	<ul style="list-style-type: none"> □ Mindful of 25% turnover of Principals, met every new principal to describe the study and secure continued support of their school (1). □ Research Nurses trained new staff in the intervention and data collection procedures. 	<p>3/8</p> <p>¹ Berry et al. (2013) ⁶ Pinto et al. (2018) ⁸ Leathem et al. (2009)</p>

Be visible on site: invest “face time”	<input type="checkbox"/> Following poor recruitment and retention of Cohort 1, where the researcher only arrived on site to deliver the intervention, the researcher planned prior to the session at school site for Cohort 2. This greater visibility helped build staff and student relationships, and increased ability to remind students and anticipate problems. Led to higher retention in Cohort 2 (5).	<input type="checkbox"/> Invest in personal, face-to-face contact with sites and their staff, visit sites multiple times during recruitment (for visibility) and continue visits to maintain regular contact (7). <input type="checkbox"/> Research Nurses invested heavily in general practice site relationships through regular phone calls, visits, helping with study administration when on site, being on site for training and quality assurance observations (8).	3/8 ⁵ Markoe Hayes et al. (2014) ⁷ Schoeppe et al. (2014) ⁸ Leathem et al. (2009)
---	---	---	---

Another example of the same strategy, but executed at multiple, complex levels is ‘maintain effective contact and tracking methods’. At the site-level, this might involve: holding regular meetings with staff, exploring non-completion of study tasks and collaboratively negotiating potential ‘workarounds’ (Schoeppe et al., 2014); updating senior leaders on progress by phone and email (Berry et al., 2014); employing on-site study coordinators (Lloyd et al., 2017); maintaining individualised notes about each site, its staff and details of all contact (Pinto et al., 2018); extensive reminders about upcoming study tasks, via letters/emails to staff, posters around the site, newsletter notices, staff bulletins, noticeboards (Drews et al., 2009; Schoeppe et al., 2014) and introducing Practice Care Plans (Leathem et al., 2009) and study activity logs for site managers to complete (Hindmarch et al., 2015).

The second major difference between the site- and participant-level literatures in how the 12 common retention strategies were employed relates to prevalence (see Table 2.6). Whilst there was concordance in the use of some strategies (e.g. ‘maintain effective contact and tracking methods’; ‘make involvement convenient’), the use of others was polarized in the two datasets. For example, ‘use multiple strategies’ and ‘build relationships with sites’ were the most prevalent strategies in all the site-level literature (noted in all the articles), but recommended by just 30% and 60% of the participant-level retention papers respectively. Similarly, the strategy ‘clarify mutual expectations to minimise ambiguity/uncertainty’ was advocated by 88% of the site-level articles, compared to just half of the participant-level papers. Conversely, whilst ‘establishing a project identity’ was given high priority within the participant-level literature (70% of papers), just over a third of the site-level papers commented on the importance of this strategy.

Five newly identified site-level specific strategies

In addition to the modified use of the 12 common strategies, a further five new strategies were identified in the site-level retention literature, which did not feature in the participant-level literature. These were: (1) involve and engage staff; (2) give back to the community; (3) identify and secure support from stakeholders and champions; (4) succession plan; (5) be visible on site: invest in ‘face time’. These are now explained.

Identify and secure stakeholders and champions: The importance of securing the ongoing support of influential stakeholders and study champions, both inside and outside an individual site, was consistently stressed within the included review articles. Organisational stakeholders possess legitimate power to authorise participation, valuable knowledge of the people, processes and systems within a site and access to its resources, which University

researchers rarely possess. Influential study champions who can reassure sites of a study's value may be external and formal, such as GPs, a positive role model such as a community leader or sports player (Schoeppe et al., 2014). However, informal champions within a site are also considered valuable for site-level engagement and retention, such as PE teachers, administrators or other staff members who voluntarily promote the study's value and use their inside knowledge to support the research on-site (Hindmarch et al., 2015; Markoe Hayes et al., 2014). Ways of engaging stakeholders and champions include sending letters or emails, followed up by site meetings (Hindmarch et al., 2015; Leathem et al., 2009), holding social gatherings to discuss the study (Pinto et al., 2018), inviting them to be part of study advisory groups (Lloyd et al., 2017; Pinto et al., 2018), and asking informal champions to share their positive experiences within their own and other sites (Lloyd et al., 2017).

Table 2.6 Prevalence of retention strategies within the site- and participant-level literature (NB Bold text denotes a new strategy, not previously found in participant-level literature).

Retention Strategy	Prevalence	
	Site-level (N=8 papers)	Participant-level (N=10 papers)
Use multiple strategies	8/8 (100%)	3/10 (30%)
Build relationships with participants/sites	8/8 (100%)	6/10 (60%)
Involve and engage staff	7/8 (88%)	Did not feature
Maintain effective contact and tracking methods	7/8 (88%)	8/10 (80%)
Invest in research staff as critical agents in the retention process	7/8 (88%)	7/10 (70%)
Clarify mutual expectations to minimise ambiguity and uncertainty	7/8 (88%)	5/10 (50%)
Make involvement rewarding	7/8 (88%)	10/10 (100%)
Make involvement convenient	6/8 (75%)	6/10 (60%)
Identify and secure support from key stakeholders and champions	6/8 (75%)	Did not feature
Give back to the community	5/8 (63%)	Did not feature
Succession plan	3/8 (38%)	Did not feature
Tailor approaches to individual participants/sites	3/8 (38%)	4/10 (40%)
Establish a project identity	3/8 (38%)	7/10 (70%)
Be visible on site: invest in 'face time'	3/8 (38%)	Did not feature
Secure a "project champion" at the research site	3/8 (38%)	1/10 (10%)
Formally involve the community throughout	2/8 (25%)	4/10 (40%)
Design an appealing control condition	2/8 (25%)	1/10 (10%)

Involve and engage staff: Retention of a site is more likely when site staff are involved and engaged with the research (Schoeppe et al., 2014). Hindmarch et al.'s (2015) reflections on involving staff in the early stages of their trial were, firstly, that it had helped the research team to understand the target audience and setting, which influenced the design and implementation of the intervention, and secondly, that it led to increased staff ownership for

delivering the intervention. Similar experiences are described by Leathem et al. (2009) as a result of qualitative work from a pre-trial pilot.

Different levels of involvement and engagement were evident within the included articles. At the lower level of involvement, staff were provided with study details through flyers/posters meetings (Lloyd et al., 2017) and at formal presentations, where slide shows, videos and any interesting equipment were drawn upon to generate excitement and engage (Schoeppe et al., 2014). Moderate levels of involvement consisted of inviting staff to observe intervention sessions to promote engagement, regular email updates on study progress (Lloyd et al., 2017) and eliciting principals' feedback on how to improve data collection and study activities (Berry et al., 2014; Drews et al., 2009). Examples of higher levels of staff involvement included asking them to pilot questionnaires with potential participants and to participate in interviews to help the researchers understand the potential barriers and levers to delivering injury prevention interventions (Hindmarch et al., 2015). Study coordinators were secured at every site in three studies (Leathem et al., 2009; Markoe Hayes et al., 2014; Pinto et al., 2018), with the goals of having an 'insider' to support local, internal planning and delivery of the study and streamlining all study-related communication. Inspirational appeals were also used to enhance site staff agency, encouraging them to be part of the solution to important problems being addressed by the research (Pinto et al., 2018). Two studies (Lloyd et al., 2017; Pinto et al., 2018), both the most recent of all those included in the review, took an extensive participatory approach, involving staff and other stakeholders through advisory groups and committees. Staff members of these groups contributed to funding applications, helped identify research questions, advised on optimal ways of engaging with the target audience, the acceptability of proposed measures/materials, co-designed interventions and acted as study advocates at other sites when necessary (Lloyd et al., 2017; Pinto et al., 2018). Staff involved in testing the intervention within Pinto et al.'s (2018) longitudinal study took part in dissemination events to 'member check' the findings and identify future research priorities.

Give back to the community: Closely linked to 'make involvement rewarding', this strategy focuses not on offering immediate incentives (e.g. money), but on the researchers reciprocating the commitment shown by the organisational site. This could be achieved by leaving a positive 'footprint' behind, such as providing materials and equipment which can continue to be used (Schoeppe et al., 2014), by providing summaries of the research or school-specific reports of student data (Drews et al., 2009), or by disseminating findings at formal events and through magazines or websites (Pinto et al., 2018). A number of the articles

positioned the study intervention as meeting a local need, which they believed boosted retention. For example, Lloyd et al. (2017) highlighted how the intervention activities fitted within the PSHCE curriculum and Hindmarch et al. (2015) explained to children's centre staff how their intervention supported their ongoing injury prevention work and usual health promotion activities. Pinto et al. (2018) also considered their inter-professional collaboration intervention to be an engagement/retention tool in itself, in that it met a local need.

Be visible on site: invest in 'face time': As unknown, organisational outsiders, the articles stress the importance of researchers giving 'face time' to each research site to become familiar faces to site staff and to foster relationships. This was considered instrumental to securing the high retention rates in Leathem et al.'s (2009) general practice based trial: Research Nurses visited sites regularly and picked up administrative tasks whilst sitting with the team on site. Other recommendations include making the effort to call and collect completed documents in person rather than having them posted, holding meetings at the site wherever possible rather than by phone (Schoeppe et al., 2014) and arriving early to a site before an intervention delivery session to socialise with students in the dinner hall and become familiar with staff and school events (Markoe Hayes et al., 2014).

Succession plan: Affiliated with maintaining effective contact and tracking, this retention strategy specifically acknowledged the need to manage risks associated with staff turnover. From a staff perspective, retention is threatened by staff turnover: the continued participation of a previously stable site can become precarious following the departure of critical staff who have previously supported, championed and even authorized the research. For example, Drews et al. (2009) reported a 25% turnover of principals in their school-based study, which posed a retention threat at those associated sites because they had signed their formal participation agreement. To combat these risks, Drews and colleagues (2009) included wording in the participation agreement about the need to comply with procedures even in the event of personnel changes, and met any new principals as soon as possible to reinforce the value of the study and the school-university collaboration. Succession planning also featured in Leathem et al.'s (2009) general practice-based study: as staff moved on or retired, they re-delivered the training to that site.

Similarly, a number of the articles underlined the importance of continuity and consistency of research staff for building strong university-site bonds (Lloyd et al., 2017; Pinto et al., 2018; Schoeppe et al., 2014). Pinto et al. (2018) ensured that all site-level communication was carefully recorded within a shared database and that structured guidance sheets and training were provided for staff to manage the risks associated with staff

turnover. Such procedures allowed replacement staff to familiarise themselves with their newly allocated sites/cases before their first contact and present a seamless transition.

What evidence exists for the effectiveness of site-level strategies?

None of the included articles featured evaluations or trials-within-trials of particular retention strategies: they were all descriptive explanations of strategies believed to be effective. The common approach adopted within all the papers was multiple strategy use. Hindmarch et al. (2015) concluded that “no single strategy could be identified that, in isolation, optimised recruitment and retention; [...] a multi-faceted approach should be considered when undertaking trials of this kind” (p.12). Pinto et al. (2018) also attributed their success to a “community research-engagement model” which involved a “systematic combination of specific tasks and procedures over time” (p. 9).

With regard to site retention rates of the seven study-related articles, four reported 100% retention (Drews et al., 2009; Hindmarch et al., 2015; Leathem et al., 2009; Pinto et al., 2018). Whilst the remaining three study-related articles did not provide site-level retention rates, the narratives provided by Berry et al. (2014) and Lloyd et al. (2017) imply very high retention, and site withdrawals are not noted. Markoe Hayes et al. (2014) provided only student cohort retention rates for their 11 week after school programme and these are low-to-moderate (48-50% for cohort 1; 65-66% for cohort 2).

Although these were not evaluative studies testing retention strategies, the considerable concordance between the recommendations across these articles lends support to their reliability and validity. A central paper within this review is Schoeppe et al. (2014), whose site-level best practice recommendations are derived from a literature review of articles reporting effective recruitment and retention strategies in community-setting health intervention studies involving children (N=45 papers) and subsequent Delphi study with 27 internationally recognised public health researchers. Two articles in the present review cite Schoeppe et al.’s (2014) paper in their introductions (Hindmarch et al., 2015; Lloyd et al., 2017), and their findings support this paper’s recommendations. A further two articles also corroborate Schoeppe et al.’s recommendations (Berry et al., 2014; Drews et al., 2009 [included in Schoeppe et al.’s literature review]). It is perhaps worth highlighting that Markoe Hayes et al. (2014), who described the fewest number of site-level strategies, mentioned no explicit strategies either to make involvement rewarding for the school or to involve school staff. It is possible that their low-to-moderate cohort retention rates were a result of low site-level engagement with the study.

2.3.3 Summary and conclusion

The results of this systematic review suggest that there are generalizable retention strategies, appropriate for use with both participants and research sites. However these tend to be executed and prioritised differently when the goal is site- as opposed to participant-retention. In addition, five new strategies have been identified which appear to be unique to working with sites, reflecting the complex nature of multi-level stakeholder involvement. The overwhelmingly dominant approach to effective site-level retention appears to be a sustained, highly complex, labour- and time-intensive relationship building process:

“Time is required to develop trusting relationships. Viewpoints of all parties should be considered and all interests need to be heard” (Berry et al., 2014, p.86).

“Constantly fostering good will and buy-in was key to continued participation” (Drews et al., 2009, p.527).

“Time frames, efforts and costs [...] should not be underestimated (Schoeppe et al., 2014, p.800).

“We invested considerable effort in establishing and maintaining recruitment and retention, using resources which may not be available to others, but the importance of identifying resources for these aspects of research should not be underestimated” (Leathem et al., 2009, p.6).

Numerous meetings, social gatherings, presentations and site visits took place to engage key stakeholders with the research, incorporating meaningful discussions about what being involved would mean to identify and address any barriers/concerns, and secure their support. Attention was given to understanding organisational priorities, internal site-processes and staff demands, so that the study goals could be aligned with those of the organization and its staff, and study tasks could be designed/integrated into existing systems with minimal burden. Regular, open, flexible communication was prioritized to sustain interest and keep site-level tasks on track. Advisory groups and committees involving stakeholders were established and nurtured for prolonged periods of time, with responsibilities ranging from advising on potential barriers at the sites and acting as study champions, through to reviewing materials for feasibility/acceptability, co-designing interventions and partnering on grant applications. Significant investment was made in building site-level relationships with staff, through frequent site visits, warm rapport and expressing gratitude through personalised gestures. High efforts were made to involve and engage staff in the research through events, flyers/materials, soliciting feedback and more hands-on involvement such as implementing trial tasks. One likely motivation for these authors’ considerable level of investment in engaging cluster sites is that their studies involved multiple follow-ups across prolonged periods of time (with the exception of

Schoeppe et al. (2014) whose consensus paper recommends these comprehensive strategies for successful longitudinal research).

2.3.4 Review limitations

Whilst it would appear that how to achieve high rates of cluster/site-level retention is an under-reported topic, it is possible that such information is embedded within individual trial ‘lessons learned’ or trial process evaluation papers and therefore was not retrieved by the search strategy in this review. Unfortunately the scale of such a review would have been beyond the reach of this PhD, given that the other larger reviews were resourced by teams of multiple researchers. This could be an area for further research.

The term ‘retention’ is a nebulous concept, and appears in the literature in numerous contexts, from staff retention at work to urinary retention. It is also frequently conflated with *treatment* retention, i.e. complying with a particular treatment regimen/programme during a study (Zweben et al., 2009). Some researchers may not even use this term when discussing how to increase engagement of research sites. Although the terms within the search strategy were guided by those published in previous systematic reviews of retention methods (e.g. El Feky et al., 2018), given the variety of ways in which researchers describe this process/phenomenon it is possible that relevant articles were not captured by the range of terms used within the search strategy.

2.4 Discussion

The aims of this chapter have been to determine what different retention strategies have been used within the literature and to establish what evidence exists to support the effectiveness of particular strategies. In particular, it has sought to examine the evidence for strategies targeting site-level retention, and whether these differ from individual-level strategies recommended in the broader literature.

With regard to ‘what works’ in retention, systematic reviews have been unable to reveal a ‘magic bullet’ for individual participants: they have produced little tangible evidence about the effectiveness of individual strategies. In contrast, consistent findings from the non-systematic reviews attribute success in retention to using multiple strategies, personalizing or tailoring strategies to individual participants, and employing consistent, interpersonally skilled research staff who invest in building relationships with participants. The small number of articles retrieved within a systematic review of the site-level retention literature suggests that this is an under-researched area. The review revealed that a number of participant retention strategies are in fact generalisable to sites, although they are executed and prioritized differently in these contexts. For example, using multiple strategies, building

relationships and clarifying mutual expectations (to minimise ambiguity and uncertainty) were all considered more important for retaining research sites than when trying to retain individual participants. Finally, the review also identified five additional strategies that appeared to be unique to site-level retention: (1) involve and engage staff, (2) give back to the community, (3) identify and secure support from key stakeholders and champions, (4) be visible on site: invest in ‘face time’ and (5) succession planning.

Reflecting on the literature, it would seem that our knowledge and confidence surrounding ‘what works’ in retention has been hindered by a number of issues. Firstly, *research study* retention is not always clearly distinguishable in the literature from *treatment* retention (Zweben et al., 2009), which muddies the waters. Secondly, there is a tendency for published studies to omit details of any strategies used to retain and track participants (Ribisl et al., 1996), to rarely report successes and failures of different strategies tried (Davis et al., 2002) and to exclude retention/follow-up rates (Coday et al., 2005). Finally, where retention rates are provided for follow-up studies with multiple waves, the denominator for calculating these rates is often unclear, and the use of ‘refreshment samples’ to boost participant numbers in subsequent waves also clouds the true retention figure (e.g. Berry et al., 2014; Booker et al., 2011).

Researchers in the retention field continue to call for better reporting and description of retention strategies used (e.g. Davis et al., 2002; Robinson et al., 2015; Brueton et al., 2017). Studies with documented retention protocols continue to be a rarity, for example only 3/19 or 16% of studies in Abshire et al.’s (2017) survey included these. When retention protocols do exist, they tend to include broad principles rather than extensive detail of the often multiple strategies that were ultimately used (Abshire et al., 2017). Turning to the reporting of site-level retention protocols for cluster or multi-centre studies, whilst the CONSORT statement extension to cluster trials (Campbell et al., 2012) requires cluster ‘flow’ (i.e. any dropouts) to be reported, there is no requirement to report how cluster retention was achieved.

2.4.1 What is lacking in the retention literature?

In addition to the finding that site-level retention appears to be an under-researched area, there appear to be four notable gaps within the overall retention literature. Firstly, participants’ perspectives on why they stayed in a study are underrepresented: “findings are based on investigators’ perspectives rather than on participants’ opinions on reasons why participants stayed in the study” (Coday et al., 2005, p.64). Robinson et al. (2007) has called for “more papers on actual experiences with retention of participants in research” (p.764), and other

authors have highlighted the potential benefits of understanding some of the barriers and levers to successful retention from a participant perspective (Brueton, Stevenson et al., 2014; Coday et al., 2005).

Secondly, much of the research has focused on discrete, standalone strategies (e.g. offer an incentive), which lend themselves well to being evaluated in trials-within-trials. However, researchers are increasingly recognizing that successful retention in trials “goes beyond the use of standalone strategies and requires undertaking a ‘relational approach’” (Lloyd et al., 2017, p.2). Whilst the importance of developing warm, collaborative relationships is recognized within the literature, “*how to successfully build and maintain relationships with trial participants such that they are engaged with the research and happy to participate in the study overall are rarely reported*” (Lloyd et al., 2017, p.2). These ‘soft’ factors have been considered intangible and therefore hard to develop strategies for (Brueton, Stevenson et al., 2014) and less amenable to empirical, randomised evaluation (Bower et al., 2014). Using qualitative research to examine retention from a holistic, relational approach is likely to enhance the retention literature.

Thirdly, linked to the previous point, the tendency to focus on individual strategies within the research means that “little has been elucidated about retention from a methodological standpoint [...]. An understanding of the dynamics of effective retention methods from a theoretical perspective is currently lacking” (Coday et al., 2005, p.55). There is a need for a guiding framework or theory to inform the use of particular strategies.

Finally, the review has highlighted the critical role of the researcher in the retention process, and great emphasis is placed upon possessing the appropriate characteristics, qualities and skills to build relationships, be persistent and remain resilient. However, none of the papers discussed within this chapter have examined how researchers navigate the multiple inter- and intra-personal challenges involved, particularly with multi-site studies. This suggests that there may be valuable learning to be achieved by exploring researchers’ experiences of managing a trial.

2.4.2 How this PhD addresses gaps in the literature

This PhD seeks to add to the literature by addressing the four gaps identified. It adopts a mixed-methods approach, conducting an in-depth, case study examination of a cluster randomised controlled trial to:

- Understand retention from the perspectives of key stakeholders involved in the trial through focus groups and interviews;
- Explore trial staff’s experiences of managing a cluster trial across multiple sites;

- Document the interpersonal processes involved in engaging and retaining sites; and
- Provide methodological insight into, and theoretical explanation for, retention.

Chapter 3 Background and Method

3.1 Chapter summary

This chapter provides a background to the cluster RCT within which this PhD is embedded. It includes an overview of the RCT design and a description of the intervention and control condition. More detail is then provided on the engagement and task-related aspects of the trial given that these are drawn upon extensively within this thesis. These aspects include the cluster recruitment process and outcomes, cluster site responsibilities and the site-level engagement and retention programme which was devised. The chapter then outlines the methods used within the PhD research to examine the processes involved in site-level retention and engagement.

3.2 Background to the PhD: The Reducing Smoking Initiation in Young Adults (RSIIYA) cluster RCT

Outline of the trial

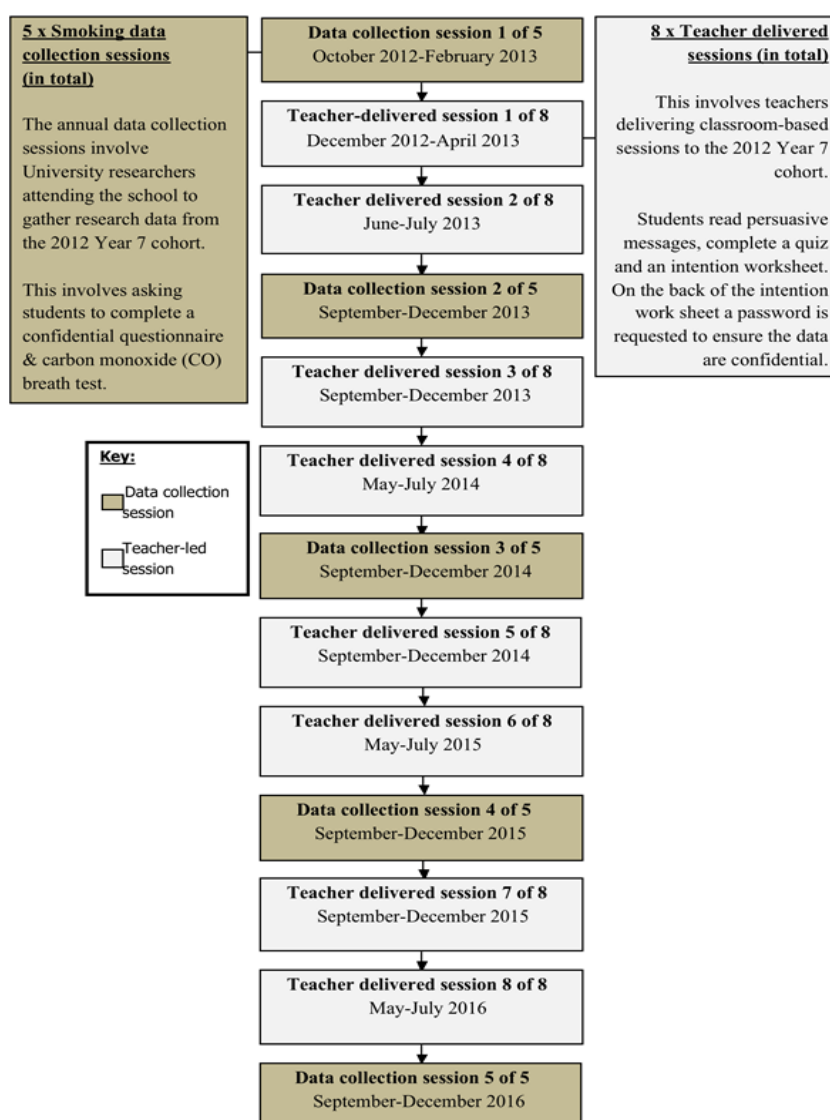
The RSIIYA cluster RCT (April 2012 - February 2017) was a collaboration between the University of Leeds and Staffordshire University funded by the National Prevention Research Initiative/Medical Research Council. The trial tested a classroom-based health intervention to reduce smoking initiation in adolescents and was delivered by trained teachers. Across Yorkshire and Staffordshire the trial involved 45 high schools. Forty-five teachers acted as study coordinators in school, with a further estimated 450 teachers annually delivering the intervention (or control), and over 7,000 student-participants.

The trial team comprised six research staff who were all Psychologists: two Principal Investigators (Professor of Social and Applied Psychology and Professor of Health Psychology), two Trial Managers (a Work Psychologist [the writer] and a Health Psychologist) and two part-time Research Assistants (a Health Psychologist and a Health Psychology Doctoral student). Whilst working together to plan, design study materials, and support each other, this team operated as two parallel teams of three at each university to manage their regional arms of the trial. A further five casual research assistants (a mixture of MSc and PhD Psychology students) were recruited annually in each region (50 in total) to support smoking data collection in schools across the trial.

A pragmatic cluster randomised control design was used. Schools were the unit of randomisation and students were the unit of analysis, taking into account clustering by schools (Conner et al., 2013). The primary outcome measure was objective smoking at 48

months compared to baseline, determined by breath carbon monoxide readings obtained from students using Micro⁺™ Smokerlyzer® CO monitors (Bedfont Scientific Limited, Kent, England). The secondary outcome measure was self-reported smoking at 48 months, which was collected using a Smoking Questionnaire. Both measures were completed at each site during annual visits arranged and facilitated by the research team, referred to as ‘smoking data collection sessions’. These visits took place at the start of each academic year before the smoking/homework lessons occurred for that year (see Figure 3.1).

Figure 3.1 RSIYA cluster RCT procedures for participating schools



(Taken from Conner et al., 2013, p.4).

Description of intervention and control conditions

The intervention comprised two elements: (1) exposure to motivational, anti-smoking messages, focusing on negative consequences of taking up smoking and benefits of remaining a non-smoker (Appendix 3), followed by (2) the formation of ‘implementation intentions’ (Gollwitzer, 1993), or personal plans, about how to refuse cigarette offers (Appendix 4). Implementation intentions are simple ‘if-then’ plans (e.g. if X happens, then I’ll do Y) and have proved to be effective in helping people achieve health goals and changing health behaviours (Sheeran, Milne, Webb & Gollwitzer, 2005). Presented as a short paper and pencil task to be read and completed in classroom time, the implementation intention element of the intervention was designed to give adolescents simple phrases for refusing a cigarette and to link them to situations where cigarettes might be offered (Conner et al., 2013). Five tick-box statements were provided for how they could refuse a cigarette offer (e.g., ‘No thanks, I don’t want to smoke’; ‘No, it’s bad for your health’). Participants were required to tick those they planned to use or record an additional response of their own. They were also asked to tick options related to where (e.g., ‘I will not smoke at school’; ‘I will not smoke with my friends’) and when they would not smoke (e.g., ‘I think I can make sure I don’t smoke this term’), followed by a final box to commit to their plan not to smoke (Conner et al., 2013).

The control condition dealt with the topic of homework completion, specifically: (1) exposure to motivational messages addressing the value and benefits of completing homework (Appendix 3) and (2) the formation of implementation intentions (i.e. personal plans) about completing homework (Appendix 4).

Participating students received eight ‘doses’ of the intervention/control in total in the form of two ‘doses’ every year from age 11/12 (as Year 7 students in 2012) until age 15/16 (as Year 10 students in 2016). This involved them forming repeated implementation intentions about smoking/completing homework, approximately every six months. The motivational messages changed every session to try and maintain interest and age-appropriateness. Response options within the Implementation Intention questionnaires (“personal plans”) changed slightly, but broadly remained similar each time point. All materials were validated through an independent teacher consultant and a small pilot group of students at a non-participating school.

Cluster recruitment process and outcomes

Sample size calculations indicated that at least 18 schools and 2160 students per condition needed to be recruited for the trial to have 90% power to detect a 5% difference in smoking rates between the two conditions (Conner et al., 2013). School recruitment took place

between April and July 2012. In each region, a list of secondary schools to approach was created using the local education authorities' websites. Collaboration was sought with each region's Healthy Schools and Wellbeing Services: a local council consultancy service which schools can buy to support their delivery of Personal, Social, Health and Economic education (PSHE). A PSHE consultant specialising in drugs, alcohol and tobacco in each region agreed to support the research team with access to schools with whom they had service level agreements (i.e. who had purchased their service). The recruitment procedure consisted of four communication stages:

- 1) E-mail and attached letter;
- 2) Posting a hard copy letter;
- 3) Follow-up phone call;
- 4) A meeting with a key stakeholder in school.

At any of the communication stages schools were able to agree or decline to take part in the study.

During stage one, a short recruitment email was devised advertising the research study with an attached, more detailed, University-branded letter which included the level of commitment involved and the benefits of taking part. The email notified the school to expect a formal personalised letter from the research team and a follow-up phone call to arrange a face-to-face meeting. The list of schools was separated into those who had service level agreements with the Healthy Schools and Wellbeing Service and those who did not. In those with service level agreements, initial contact was made by the service's PSHE consultants. They forwarded the email on the universities' behalf to named PSHE coordinators in each school with whom they had relationships, with a short covering email advocating the research initiative. Those schools without service level agreements (i.e. who managed their PSHE education independently) were telephoned directly by the researchers using contact details obtained from school websites. School receptionists, who typically received these calls, were asked if the head teacher or lead teacher for PSHE in school were available to discuss the research. If so, the researcher spoke directly to them about taking part in the research and followed this up with the standard recruitment email and letter. If they were not available, an email address was requested and the standard recruitment email was issued. If schools agreed to participate at this stage a face-to-face meeting was organised.

At stage two, the research team posted a hard copy, personalised version of the letter which had been attached to the e-mail to all schools, i.e. it was addressed to the PSHE coordinator (if known) or the Head Teacher/Principal. It also stated to expect a phone call

from a researcher to organise a face-to-face meeting. If schools agreed to participate at this stage a face-to-face meeting was organised.

Stage three took place one week after posting the letters, when the researchers contacted named individuals by phone to organise a face-to-face meeting.

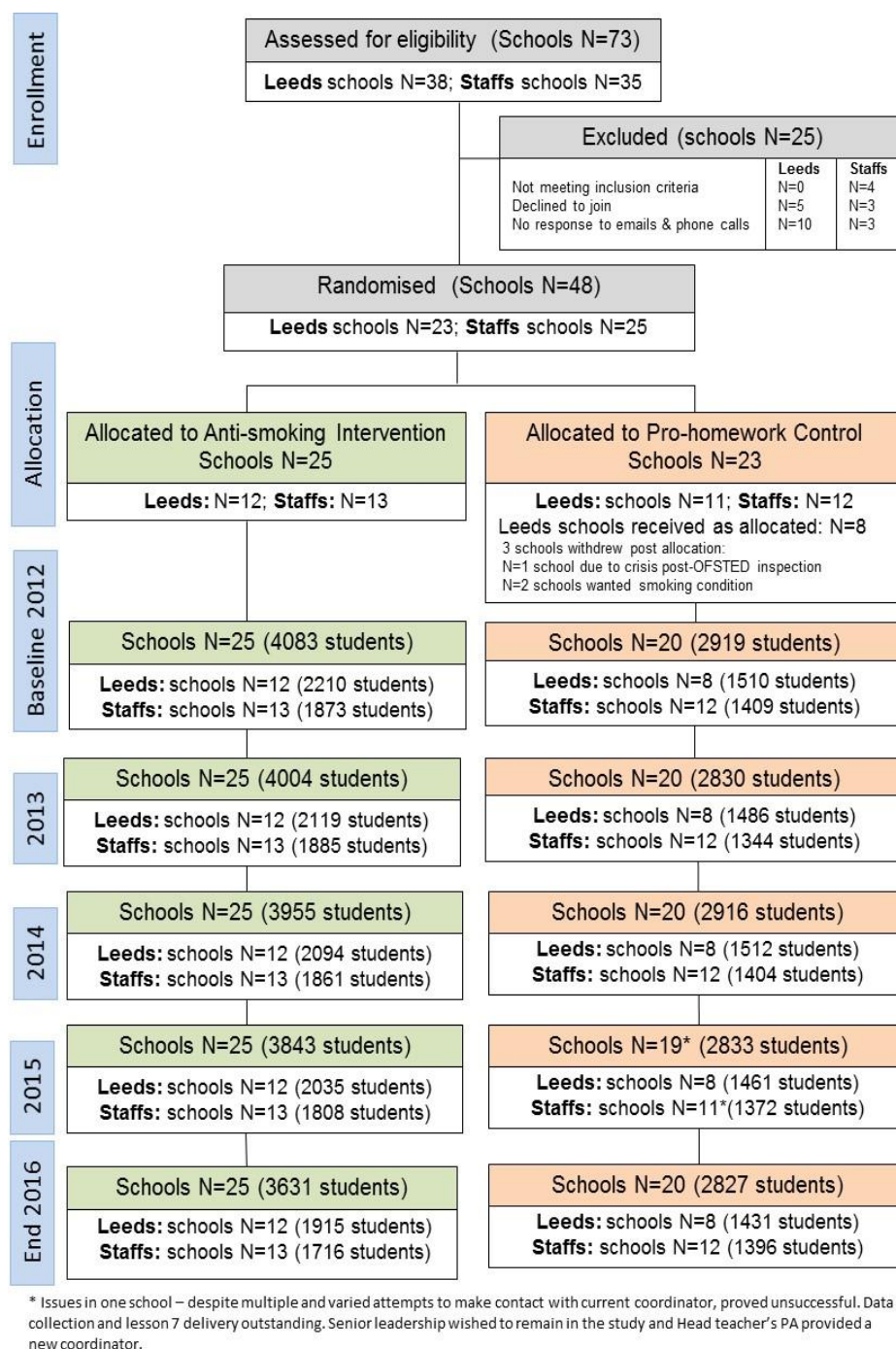
At stage four, the researcher attended a face-to-face meeting in the interested school to discuss and promote participation in the research. A short PowerPoint presentation was used to 'pitch' the research, including its importance, what was involved in the intervention and in taking part, and the benefits of participation. Examples of study materials, both intervention and control versions, were shown to these stakeholders (usually the teacher coordinating PSHE in school, and/or a member of the Senior Leadership team) to bring the study to life and help them engage with the research.

Recruitment outcomes: Seventy-three secondary schools across two regions were approached and 48 agreed to participate. Post randomisation but before any data were collected, three schools withdrew: two because they were allocated the control condition and one (reluctantly) because of an unfavourable Ofsted rating which meant urgent internal issues had to be prioritised above participating in the research. Ultimately, 45 schools (25 intervention; 20 control) and over 7,000 students (varying annually between 3631-4083 intervention and 2830-2919 control) took part in the trial, exceeding the target sample size of 18 schools and 2160 adolescents per condition (see Figure 3.2).

Cluster site responsibilities

A formal Participation Agreement was signed by Head teachers/Principals, which contained a clause confirming that they would not introduce any new anti-smoking initiatives during the trial period without first consulting trial staff. Schools were required to issue the University-provided parental consent letters (an opt-out procedure was used) and ensure that any students whose parents withheld their consent did not participate in any trial tasks. The repeated annual cycle of tasks applied only to the participating cohort year group for the duration of the trial. Tasks were related to (1) the researchers' visits to collect smoking data and (2) the delivery of the intervention/control lessons in school. The most significant task was identifying which lessons could be relinquished within the cohort year group's timetable for data collection (once a year) and delivering the intervention/control (twice a year). For the researchers' visits, schools were required to: book rooms, identify staff to

Figure 3.2 CONSORT diagram showing progress through the cluster RCT
(A version of this diagram appears in Conner et al., 2019, p.428).



support the process, notify staff and students about the sessions and ensure everyone attended according to plan. Tasks related to delivering the intervention/control lessons were more demanding. Schools were required to: identify teachers to deliver the lessons, arrange a training session for them with the research team, plan the lessons, distribute lesson

materials, ensure all planned lessons took place, retrieve completed research materials from teacher-deliverers and liaise with the research team regarding their collection.

3.2.1 Site-level engagement and retention programme

A multi-faceted school engagement and retention strategy was devised prior to recruitment, which continued to evolve as the trial progressed. This strategy was not detailed in the RCT grant application because it was conceived after funding was awarded. Therefore it needed to be economical and managed within the allocated budget. The strategy comprised two broad groups of strategies: one to promote stakeholder engagement at the site-level (e.g. offering free wellbeing workshops), and a second group to aid the researchers' facilitation of task completion (e.g. annual keep-in-touch meetings with the study coordinators; logging intelligence about each site on an Excel planning spreadsheet). Some elements within the retention strategy were flexible, allowing tailoring to combat particular challenges or respond to school requirements.

The different activities undertaken within the retention strategy are described below (see Table 3.1). They have been formalised after the trial according to the site-level retention categories identified through the systematic review in chapter two.

Table 3.1 RSIIYA cluster RCT retention strategy

Retention Activity	Description
Design an appealing control condition	During the trial design phase, feedback was obtained from a sample of teachers contacted to understand what topic would be valued as a control lesson. Boosting student motivation to complete their homework was identified. In addition, all intervention materials were issued to control schools at the end of the trial.
Identify and secure support from key stakeholders and champions	Presentations were delivered to school leadership teams during early recruitment meetings, to underline the importance of their support, the potential national impact of the trial outcomes and the associated benefits. Head Teachers/Principals were asked to identify a teacher to act as an internal trial coordinator. Teacher training sessions explained the aims of the trial and the critical role of teachers in delivering the lessons. Local council staff and public health teams specialising in tobacco were identified and collaborations were developed.
Secure a "project champion" at the research site	At each school a 'Smoking Study Coordinator' was identified to liaise with the trial manager to implement trial tasks in-site. This link with the school was considered to be the most important in the trial, therefore the trial manager prioritised and invested heavily in this relationship.
Clarify mutual expectations to minimise ambiguity and uncertainty	Early presentations delivered to school leadership teams outlined the tasks involved in the trial and emphasised its longitudinal nature. Details of involvement and commitment required were documented within the Participation Agreement signed by Head Teachers/Principals. The study

	coordinator tasks were formalised within a guidance folder, which was issued alongside a laminated flow chart to aid orientation at each stage of the trial.
Make involvement convenient	Every effort was made to support clusters and minimise burden. Lesson resources were packaged for convenience into the correct number of lesson packs for each school. Wherever possible, the research team were flexible, particularly with regard to their visits to collect smoking data: different school preferences were accommodated (e.g. conducting multiple, brief visits or during one single, long visit). If schools needed to deliver their smoking/homework lessons early, the researchers prioritised the preparation of their lesson resource packs.
Build relationships with participants/sites	The study coordinator relationship was valued highly and prioritised. Annual 'keep-in touch' meetings (30-40 minutes) took place with coordinators in each school to review collaboratively how the trial had run that year in their school, specifically: What had gone well? What had not gone well? What issues, concerns or ideas had arisen? Successes were celebrated, challenges were explored and support provided. Ideas for improvement were sought and acted upon wherever practical. Annually the trial managers gave coordinators a Christmas card and small gift. On completion of each academic year, a thank you card was issued in conjunction with a formal letter to their Head Teacher/Principal, highlighting their invaluable contribution to the trial.
Involve and engage staff	Annual staff training events took place to explain the trial, including slide presentations, distribution of the materials, discussing the activities and experimenting with the Smokerlyzer machines used by the researchers in data collection to generate interest. Feedback sheets were introduced to collect teachers' views of delivering the intervention/control lessons and of students receiving them. The researchers presented at year group assemblies to explain trial progress to date and upcoming data collection tasks.
Use multiple strategies	Different strategies were used across the trial and the approach developed as the trial progressed.
Make involvement rewarding	Each school was provided with: £500 vouchers across the term and an annual framed "Outstanding investor in student health and wellbeing" certificate. On conclusion of the trial, each school was provided with electronic copies of all lesson resources produced (intervention and control materials). They also received a final engraved plaque which recognised their named school as "an Ambassador for Health Research in Schools for their outstanding commitment to the Smoking Prevention in Young Adults study 2012-2017".
Give back to the community	Information and knowledge of progress were shared with schools through (1) a brief annual report on the whole cohort's smoking results issued to each school's Head Teacher/Principal; (2) a detailed report on trial outcomes at the end of the trial. The research team's psychological expertise was shared through: free workshops on wellbeing topics for staff (e.g. work-life balance) and students (e.g. keeping yourself well during exams); guest lectures as part of GCSE and A-level curriculae (e.g. Research Methods lesson); support for school health fairs and careers days. Schools were routinely alerted to university open days. Study coordinators and student representatives were invited to a final celebration event held at the host Universities, where personalised, engraved plaques were presented. Food and refreshments

	were provided, local press were in attendance and photographs of schools receiving their awards were later emailed to attendees.
Tailor approaches to individual participants/sites	The research team adapted their interpersonal approach to suit the school and coordinator; e.g. some schools were formal and others were more informal/friendly. Beyond the standard incentives (i.e. £500 vouchers and annual certificates), a suite of pre-designed workshops and ad-hoc wellbeing consultancy were also offered to all schools to meet local needs.
Maintain effective contact and tracking methods	Upcoming trial tasks were discussed during the annual keep-in-touch meetings with study coordinators. Emails from the researchers alerted them to activities requiring their attention/support, which were followed up by phone. Where a teacher could not be reached, a further contact attempt was diarised for the following week. All verbal agreements were confirmed by email. Every item of school contact was logged to increase intelligence about each cluster site on an Excel planning spreadsheet containing multiple tabs, including records of student numbers for printing, coordinators' names (including personalising information such as their partner and children's names), methods of delivering PSHE in school (e.g. dedicated weekly sessions or drop-down days), summaries of phone conversations, notes from annual keep-in-touch meetings, records of actions agreed, dates of emails issued and outcomes from attempts to contact coordinators by phone.
Invest in research staff as critical agents in the retention process	Each trial manager maintained ongoing contact with their Principal Investigator/line manager, with regular monthly meetings to discuss progress, concerns and resolve issues. The two trial field teams worked collaboratively to agree approaches, strategies and to design all materials and questionnaires. Regular contact was maintained by phone to reduce isolation, discuss highs and lows, share tips and exchange support. Bi-monthly both trial teams met in person to review progress and agree next steps. Casual data collection assistants were recruited annually (N=8 each region) to collect smoking data in schools, recruited for their warm interpersonal skills and experience of working with young people/in schools. Group training was provided in the trial aims, use of materials and equipment, study protocol and the importance of demonstrating values of collaboration, respect, empathy and gratitude with students and staff. Guidance was provided on how to deal with challenging students, the importance of demonstrating confidentiality and integrity when working with multiple schools, and of representing the University. A team culture was fostered, and annual Christmas social events took place where the trial manager provided the team with small gifts and cards.
Formally involve the community throughout	Two schools who chose not to participate in the trial volunteered to 'road-test' the intervention and control materials. They also contributed ideas for future materials. Tobacco, drugs and alcohol specialists within each local education authority remained collaborators on the trial, and annual meetings took place to update them on the trial progress. Regular feedback was sought from staff, students and study coordinators on how the running of the study could be improved. This was acted upon wherever possible and communicated to those involved.
Succession plan	The study coordinator guidance folder formalised the role and increased its visibility, which aided succession planning associated with staff turnover during the trial. Meetings were held with newly appointed coordinators to

	explain the study. When one of the trial managers became pregnant, she mentored a longstanding research assistant to cover her maternity absence.
Be visible on site: invest in ‘face time’	The trial managers collected all materials in person. Warm relationships were purposefully developed with school receptionists in person and by phone – e.g. names were obtained and noted. All keep-in-touch meetings were held on school premises. The trial manager attended every data collection session, and the team helped set up classrooms if this was necessary to support staff. Every opportunity was taken to visit school – e.g. assemblies, health fairs.
Establish a project identity	A study logo was devised and used on all correspondence. A specialised version of the lead University’s logo was developed to incorporate the wording “Building Healthy Communities”. This was emailed to all schools for use on their websites to publicise their partnership with the university. A branded guidance folder was produced for each study coordinator.

3.2.2 Trial cluster retention outcomes

Post-randomisation, but before any data collection commenced, three of the 48 recruited schools withdrew. Two of these were anticipated: they were allocated the control condition and explicitly wanted the intervention condition. However the third school, also allocated the control, withdrew unexpectedly after a poor Ofsted inspection placed them in ‘special measures’. This required them to urgently address a list of critical internal improvements, therefore they were unable to prioritise the trial. The 45 remaining schools (25 intervention: 20 control) were located in a range of communities: 31% (14) served disadvantaged communities (predominantly within the Yorkshire region; 69% (31) served moderate-to-affluent communities^{1,2}.

Despite demonstrating varying degrees of commitment, all 45 sites were successfully retained in the trial, from the first round of data collection to the very last. The trial managers’ efforts to keep every site engaged remained constant until the final data were collected. This PhD, which is now described in more detail, sought to understand what mechanisms were operating during this four-year retention process, and from the perspectives of major stakeholders involved, what seemed to be the critical levers and barriers to engaging with the trial.

¹ Categorised using eligibility for free school meal (FSM) data provided by local councils. A school’s FSM eligibility of >20% suggests lower socio-economic status within the community it serves.

² Of the three dropout schools, two served disadvantaged communities.

3.3 PhD Method

Differentiating the PhD from the RCT

Although this PhD was embedded within the RSIIYA RCT, it operated as a distinctly separate, parallel programme of research. The RCT ran from April 2012 to February 2017: this PhD began in October 2013 and its data were collected between March 2014 and March 2017. Whenever the RCT participants were approached about taking part in this additional research, it was underlined that, whilst it was linked to the main trial, it was a different PhD study which sought to understand how universities could engage more effectively with schools on health research. Separate ethical approval and participants' informed consent were obtained for each component of this PhD research, which are documented comprehensively in subsequent chapters.

3.3.1 Design

Because the aim of the PhD research was to generate an in-depth, multi-perspectival understanding of the retention process within and between numerous sites in the RSIIYA RCT, a collective case study design was used. This specific form of case study (termed 'collective': Stake, 1995) involves numerous component cases which are examined independently, then compared for similarities and differences to produce a holistic representation of the phenomena being studied (Crowe et al., 2011). This approach helps researchers to deconstruct and subsequently reconstruct phenomena under study to provide new insight (Baxter & Jack, 2008). Findings from case studies may contribute to theory development and theoretical generalisations beyond the individual case(s) under scrutiny (Crowe et al., 2011).

The importance of context is explicitly acknowledged within a case study approach (Wells et al., 2012) and a range of data sources or 'lenses' are used to examine complex phenomena in their natural context (Baxter & Jack, 2008). In this sense a case study is considered a triangulated research strategy because multiple sources are used to corroborate data (Denzin, 2010). Triangulation involves combining in one research project two or more data sources, researchers, methodological or theoretical approaches or forms of analysis (Thurmond, 2001) to enhance reliability (Denzin, 2010). Although data from multiple sources may converge and support notions of reliability, inconsistencies and contradictory data are considered equally valuable and can holistically "provide more and better evidence from which researchers can construct meaningful propositions about the social world" (Mathison, 1988, p.15). Triangulation therefore supports detailed and comprehensive examination of a phenomenon (Mathison, 1988; Thurmond, 2001). This collective case study comprised five component cases in the form of five individual studies, which were designed to examine

different perspectives on retention within the trial. Two main triangulation strategies were utilised: data source triangulation and methodological triangulation.

A summary of the five individual component studies within the collective case study can be found in Table 3.2. From a data source perspective, data were collected across the case study from *multiple settings* and from *multiple groups*. *Multiple settings* included a university and a range of schools, which included high performing and low performing schools, those allocated the intervention and control conditions and those serving disadvantaged and moderate-to-wealthy communities. The *multiple groups* involved study coordinators managing the trial in their individual schools (study one), researchers managing schools across the trial (study two), teachers delivering the intervention/control (study three) and students receiving the intervention/control (study four).

Methodological triangulation was used to extend the scope and nature of the data and enhance confidence in interpretation. The overarching approach adopted was qualitative, supplemented by complimentary quantitative elements. Multiple methods were used between the component cases to acquire data, consisting of interviews (studies one and three), focus groups (study four), documentation, specifically minutes of a research team review meeting (study two), lesson feedback sheets (studies three and four), and finally assessments of observed behaviour at different sites (study five). Between-methods triangulation, i.e. using both quantitative and qualitative methods, was utilised in two component cases (studies three and four).

Guidelines for the good reporting of a mixed methods study (O’Cathain, Murphy & Nicholl, 2008) were followed. These involve: providing a justification for using a mixed methods approach; describing the purpose and sequence of each method and specifying the process of integrating the mixed data; describing the sampling, data collection and analysis for each method; discussing any limitations with individual methods, and insights gained from integrating methods (O’Cathain, Murphy & Nicholl, 2008).

When interpreting multiple sources of data and developing plausible explanations for convergence, inconsistencies and contradictions, Mathison (1988) underlines the importance of the researcher possessing “a holistic understanding of the project itself, its history, the intentions of the developers, the ongoing relationships within the project” and a “store of knowledge and understandings about the social world” being evaluated (p.16). Crowe and colleagues (2011) and Mathison (1988) also recommend making this sort of ‘tacit’ knowledge more explicit by providing sufficient contextual information to enable a reader to understand how particular conclusions were reached. To this end, the next section provides contextual

information regarding my background and begins by explaining in more detail my epistemological standpoint for this PhD research.

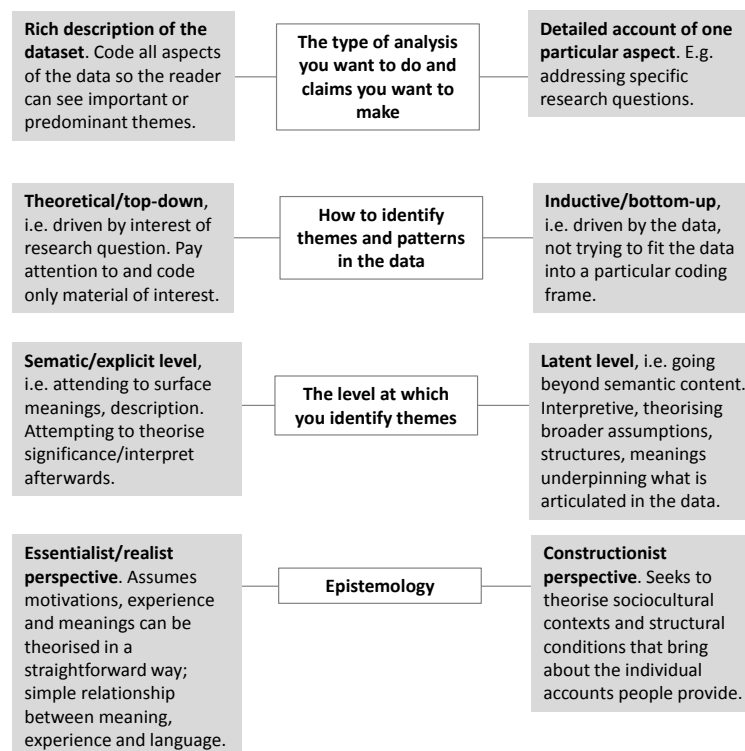
Table 3.2 Summary of component cases/studies within the collective case study

Study	Stakeholder Group	Sampling type	Method (including setting)
1	Study coordinators managing the trial in their individual schools	Opportunity sampling. Yorkshire region of the trial only.	Face-to-face semi-structured interviews on school premises to understand study coordinators' experiences (including barriers and facilitators) of managing the cluster RCT in their unique school context.
2	Researchers managing 45 schools across the trial	Purposive sampling. Staffordshire and Yorkshire regions of the trial.	Secondary data related to trial staff's experiences of retaining and sustaining cluster engagement towards the end of the trial. Use of an audio-recording of a trial team review meeting. Recording originally made to aid the typing of meeting minutes.
3	Teachers delivering the intervention/ control lessons to students in school	Semi-structured interviews: deviant case sampling - using teacher feedback sheets to identify teachers rating the lessons positively and negatively. Yorkshire region of the trial only.	Mixed methods to access teachers' understanding and experiences of the trial and of delivering the lessons. Using (a) data contained in teacher feedback sheets -completed immediately after delivering the smoking/homework lessons; (b) semi-structured interviews with teachers, conducted on school premises or by phone.
4	Students receiving the intervention/ control lessons in school	Opportunity sampling. Yorkshire region of the trial only.	Mixed methods to access students' understanding of the trial and experiences of the lessons. Using (a) focus groups with students in intervention and control schools; (b) data contained in student feedback sheets following smoking/homework lessons. Conducted in the School of Psychology at the University of Leeds.
5	Overall school	Use of secondary data. Staffordshire and Yorkshire regions of the trial.	To determine any correlation between the level of cluster site engagement during the RSIIYA trial, school characteristics (condition allocated; Ofsted rating; community served) and students' final smoking outcomes in the trial. An individual school 'engagement score' was generated using a specifically designed engagement assessment tool. Drawing on their experiences and observations within each school site across the duration of the trial, the researchers completed engagement assessments for each of the 45 participating schools. Secondary data (final smoking outcomes) were drawn from the trial.

3.3.2 Epistemological standpoint

For this PhD research, I took an overall essentialist/realist epistemological position. However, I adopted different approaches to the treatment of the data in each study. I frequently used thematic analysis (Braun & Clarke, 2006), but in deciding how to treat the data in each study, I was influenced by the meta-methodology proposed by Madill, Flowers, Frost and Locke (2018) for conducting pluralistic qualitative research. Madill and colleagues (2018) draw upon Braun and Clarke's (2006) extensively cited paper on using thematic analysis in psychology which describes a number of explicit choices that must be made before qualitative analysis begins. These choices relate to how data should be treated across four dimensions (see Figure 3.3). In answering my research questions in each study, I drew upon this four-dimensional framework when deciding how best to treat my participant data. The decisions I made are documented within each chapter's method section.

Figure 3.3 Four dimensions characterising different forms of qualitative analysis



Text from Braun & Clarke (2006), p.82-85.

Within this PhD, I was also influenced by Howe (2004) who emphasises the importance of democracy in case study work, including as far as possible all relevant stakeholders in the research, and actively involving them in dialogue about the topic being investigated. Influenced by this concept of democracy, I endeavoured to represent a range of voices and perspectives in this research. This was particularly important because each

stakeholder group held varying positions of organisational status and power (e.g. student, member of the leadership team, newly qualified teacher etc.) and undertook diverse roles within the trial (i.e. manager, in-site coordinator, lesson deliverer, lesson recipient).

Transparency and reflexivity are considered crucial in qualitative research to provide the reader with insight into (a) how analytical decisions were reached and (b) the degree of methodological rigour employed (Johnson & Cassell, 2001). This next section provides further detail about me as researcher and about my relationship with the participants.

The researcher's background

I am a Work Psychologist (BSc [Hons.] Psychology; MSc Occupational Psychology). I am also trained and qualified in Person Centred Counselling and Cognitive Behavioural Therapy, having worked clinically within a hospital setting with service users experiencing mental health issues. I have worked extensively outside of academia as a freelance psychologist, advising and supporting organisations and employees with wellbeing issues (e.g. stress), team functioning/efficiency and leadership development. These organisations have included charities, law firms, IT consultancies, local councils and schools. I have lectured both in Further and Higher Education (at A-level, undergraduate and masters levels), and worked intermittently as a predominantly qualitative researcher for the past 18 years. Before qualifying as a Psychologist, I worked as a Development and Training Consultant, designing and delivering training programmes and training trainers.

My experience in school settings is varied: in my freelance capacity I had a long-term relationship with a local education authority, facilitating numerous personal development workshops in schools, including counselling skills workshops to help staff support distressed students. I have also supervised pastoral care teams. As a mother, I have been an active member of Parent-Teachers Associations and have numerous friends and family members who are teachers. These experiences have made me aware of the daily pressures facing school leaders, teachers and students. Mindful of this challenging research setting, I recognised early in the trial the importance of minimising burden on schools and the need to not only establish respectful, collaborative working relationships, but also to offer something meaningful in exchange for their support. This led to the development of the strategy to promote site-level stakeholder engagement, followed by the inception of this PhD to understand more about stakeholders' lived experiences of working with universities on longitudinal research.

When developing working relationships with cluster site stakeholders I endeavoured to draw upon the humanistic core conditions of warmth, genuineness and unconditional

positive regard (Rogers, 1957) to build rapport and trust. I consistently tried to engage with stakeholders on their own terms and treat them as individuals rather than generically. For example, I noted names of study coordinators' children, details of significant events (e.g. a wedding) and sent bereavement cards. I tried to communicate that their views were valuable, for example by introducing a teacher and student feedback mechanism, and by annually reviewing trial tasks with study coordinators to discuss suggestions for improvement.

As the RCT trial manager responsible for 20 schools in the Yorkshire region of the trial, I had existing relationships with staff and students who additionally took part in my PhD research. Some of the teachers participating in my PhD research were well known to me, such as study coordinators and a small number of teachers who regularly helped with data collection visits. However most were largely unknown to me, in that we may have only met briefly through staff training to deliver the intervention/control lessons, if at all. Students participating in the PhD research were not known to me, due to a combination of the large numbers involved, brevity of annual contact and changing appearances as they grew older. I may have been familiar to them, however, due to my annual appearances in their school.

I maintained a personal, reflective journal during my PhD research, documenting lessons learned, ideas and potential theories/literature sources to explore. I recorded my reflections following interviews and focus groups, which included details of the setting, the mood of the participant(s) and my own, any significant occurrences during the interaction and the impact they had (e.g. interruptions, unanticipated time pressures) and general observations. Reflective notes were also recorded within the transcripts to aid analysis and interpretations were discussed with my supervisors.

3.3.3 Analysis

Numerous analytical approaches were used to examine the data, including Framework Analysis (Ritchie & Spencer, 1994), Thematic Analysis (Braun & Clarke, 2006), chi-square tests of independence/homogeneity, independent samples t-tests and correlational analyses. Details of the specific methods used in each study/component case are provided within individual chapters. Data within each individual, component case/study were analysed first before comparisons were made across cases, as recommended by Crowe et al. (2011) and Tellis (1997). Findings from each component case are presented within individual chapters and the amalgamation across cases and overall conclusions are contained with the final discussion chapter.

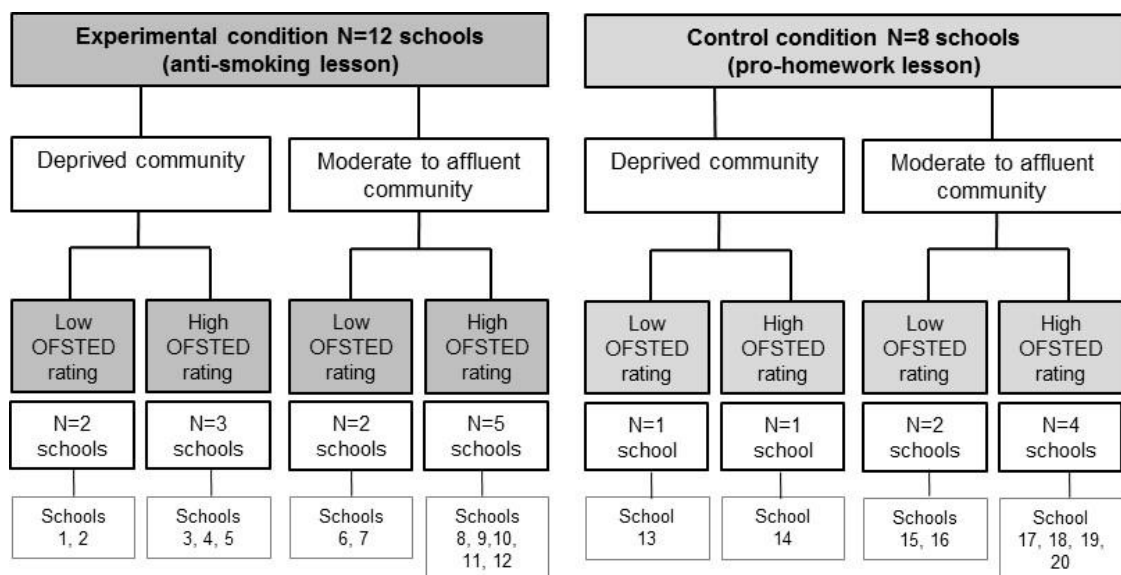
In collective case studies, the large volume of data typically generated across multiple cases can be overwhelming and loss of focus can be an issue for researchers (Tellis, 1997).

Therefore I was informally guided by a broad framework, as advocated by Yin (1994), to help me organise the data during analysis within and across components and retain focus. This simple framework consisted of two dimensions: (1) 'barriers to engagement and retention' and (2) 'levers to engagement and retention' and was applied across all cases. It facilitated the amalgamation and synthesis of individual component case data and allowed variations, similarities and relationships between cases to be seen more clearly (Tellis, 1997).

3.3.4 Sampling process

Study two employed purposive sampling: members of the RSIIYA trial research team were specifically targeted because of their knowledge and experience of managing 45 cluster sites (i.e. Staffordshire and Yorkshire regions of the trial). The three school stakeholder components of the case study (studies one, three and four) involved the Yorkshire region of the trial only. Opportunity sampling was used for these three studies, i.e. participants were recruited solely on the basis of being in the Yorkshire region of the trial. However I targeted recruitment to ensure that all varieties of school were represented in each study's sample. To do this, I created eight sampling groups from the 20 Yorkshire schools (see Figure 3.4), on the basis of randomisation outcome (intervention or control condition), socio-economic status (serving disadvantaged or moderate-affluent communities) and Ofsted rating (high or low).

Figure 3.4 Sampling groups for component cases/studies one, three and four



The socio-economic status of each school was determined using data provided by the Local Education Authority. These included a combination of eligibility for free school meals (FSM) and ACORN data. ACORN data is used to classify the social-demographic status of postcodes across England and considered more sophisticated than FSM data because it is

based on a wide variety of census and survey data. Ofsted ratings for each school were determined using the latest Ofsted inspections reported for each school. ‘High’ schools were those with an Ofsted rating of ‘1-outstanding’ or ‘2-good’; ‘low’ schools were those with an Ofsted of ‘3-Requires Improvement’ or ‘4-Unsatisfactory’. Whilst acknowledging that school standards and Ofsted ratings can change during a four year trial, I did not re-categorise schools if a new inspection awarded an improved or deteriorated rating: all schools remained in their original allocated category for sampling consistency.

3.3.5 Participants

Participant information is provided in greater detail within each individual study chapter, however an aerial view of all participants across the case study can be seen in Table 3.3. In total, this collective case study utilised data from 16,523 participants (15,923 students, 596 teachers and four researchers). Data for 16,457 of these were extracted from documentation (15,885 students, 586 teachers and four researchers). The remaining 66 participants provided data through interviews (28 teachers) or focus groups (38 students). Participants in studies one, three and four came from the Yorkshire region of the trial only. However studies two and five involved both the Staffordshire and Yorkshire regions of the trial. Study two examined researchers’ perspectives from both regions, in order to compare and contrast experiences of managing multiple cluster sites in different regions. Schools in Staffordshire were typically smaller buildings than those in Yorkshire, with fewer students in their year groups and were in more rural locations. As discussed earlier, study five involved analysis of secondary data in conjunction with assessments of individual schools’ engagement using behavioural indicator ratings.

Table 3.3 Total participants across the thesis by sampling group, study and role

			Experimental Condition (Anti-smoking)												Control Condition (Pro-homework)							
			Disadvantaged Community						Moderate-to-Affluent Community						Disadvantaged Community				Moderate-to-Affluent Community			
			Low OFSTED CELL 1 (n=2)			High OFSTED CELL 2 (n=3)			Low OFSTED CELL 3 (n=2)			High OFSTED CELL 4 (n=5)			Low OFSTED CELL 5 (n=1)		High OFSTED CELL 6 (n=1)		Low OFSTED CELL 7 (n=2)		High OFSTED CELL 8 (n=4)	
			School 1	School 2	School 3	School 4	School 5	School 6	School 7	School 8	School 9	School 10	School 11	School 12	School 13	School 14	School 15	School 16	School 17	School 18	School 19	School 20
Study	Method	N																				
One: School study coordinators	Interviews	16	1	1	2	2		1	1	1			1	1		1	1				1	1
	Interviews	12			1		1	1		1	1	2	1						1	1		
Three: Teacher deliverers	Documentation	568	28	12	32	16	33	33	17	52	19	22	33	27	27	27	40	34	34	33	28	21
	Focus Groups	38	11										11					10		6		
Four: Student recipients	Documentation	15885	693	527	747	659	711	988	653	962	717	695	859	647	795	813	1017	767	858	929	717	1131
Two: Trial researcher team	Documentation	4																				
Total data		16523	733	540	782	677	745	1023	671	1016	737	730	894	675	824	841	1059	811	893	969	746	1153

3.7 Thesis plan

The next five chapters deal with the individual component cases or studies within the collective case study, reflecting the chronological order in which they were executed, from study one to five:

- Chapter four – teachers’ experiences of coordinating/managing the trial as ‘insiders’ in their individual schools (study one).
- Chapter five – researchers’ experiences of managing the trial across 45 school sites as ‘outsiders’ (study two).
- Chapter six – teachers’ experiences of delivering the anti-smoking and pro-homework lessons (study three).
- Chapter seven – students’ experiences of participating in a longitudinal study (study four).
- Chapter eight – an investigation into potential correlations between the degree of cluster site engagement and trial outcomes (study five).

Chapter 4 What are teachers' experiences of coordinating the RSIIYA trial in school?

4.1 Chapter summary

This chapter reports an interview-based study which explored the experiences of teachers co-ordinating the RSIIYA trial within Yorkshire schools only. The study sought to understand how the trial coordinators experienced their role and to identify facilitating and impeding factors affecting their engagement with the trial. Participants involved teachers coordinating the trial in intervention and control schools to determine if and how the randomisation outcome affected their experiences.

4.2 Background

Once a research site has been recruited to a cluster trial, researchers need to determine how to 'bridge' or 'broker' ongoing relationships (Long, Cunningham & Braithwaite, 2013) between the project team and the site. Securing a key contact person or project champion at each research site has been identified as a positive factor in retention (Bructon, Stevenson, et al., 2014; Leathem et al., 2009; Pinto et al., 2018). As 'insiders', these figures have practical knowledge of organisational systems, processes, norms and culture, which can be invaluable to the 'outsider' research team when planning key tasks and communications on site. For example, key 'insider' contacts were secured to coordinate interview scheduling and the accompanying internal approvals in each of the 36 HIV-prevention service agencies in Pinto and colleagues' (2018) project to enhance inter-professional collaboration. Similarly, key contacts were nominated in 48 general practices to act as a focal point for all tasks and communication in Leathem et al.'s (2009) study evaluating a primary care-based coronary heart disease prevention programme.

In addition to their practical access to resources and systems, key contacts or champions may also hold valuable referent power which enables them to persuade site members and other important stakeholders that the research is worthwhile (e.g. Hindmarch et al., 2015; Lloyd et al., 2017; Schoeppe et al., 2014). This capacity to generate enthusiasm and commitment from within is particularly advantageous during pragmatic cluster trials, where complex health interventions are tested under real-world conditions, typically delivered by site staff. For example, during their trial evaluating a complex school-based intervention to reduce risk factors for type 2 diabetes, Drews and colleagues (2009) benefitted from the support provided by Heads of Physical Education departments in each

school, who promoted the trial and reinforced trial tasks with teaching staff and students.

Whilst schools are considered excellent sites for health promotion and prevention research (Bond et al., 2001; see discussion in Chapter one), researchers typically find them extremely challenging to work with (Befort et al., 2008; Drews et al., 2009). Schools are highly heterogeneous (Befort et al., 2008): each has its own “distinct society” (Caan et al., 2015, p.4), “norms, values, attitudes, behaviors and actions” (Christenson, Carlson & Valdez, 2002, p.473) and houses multiple classroom ecologies (Witt, 1986, p.41). Given their intimate knowledge of school personnel, internal politics and procedures, key contacts ‘on the inside’ are indispensable to research teams conducting schools-based research (Petosa & Goodman, 1991). They can also act as research champion in school, eliciting colleagues’ support for the study through their enthusiasm, belief and commitment (Bartlett et al., 2017; Robinson, 2014).

The key contact role within a multi-centre trial typically involves facilitating site members’ engagement with the research and supporting its local implementation on site (Leathem et al., 2009; Pinto et al., 2018), and the experience of undertaking these tasks is likely to be influenced by numerous factors. Process evaluations of trials testing school-based complex health interventions (e.g. Hazell, 2006; Langley, Nadeem, Kataoka, Stein & Jaycox, 2010; Mukoma et al., 2009) and consultations with researchers/intervention designers (e.g. Forman, Olin, Hoagwood, Crowe & Saka, 2009) have revealed numerous facilitators and barriers to site engagement. With regard to facilitators, a consistent finding is that schools are more likely to engage with an intervention if they consider it compatible with their goals and philosophy (Forman et al., 2009; Mukoma et al., 2009). The likelihood of teacher and student engagement with an intervention can be increased by involving teachers in the design, to help enhance its appropriateness and credibility (Mukoma et al., 2009). Strong leaders who publicly rate the intervention, demonstrate enthusiasm and support its implementation, such as helping find curriculum space for study-related tasks (Forman et al., 2009; Langley et al., 2010) also facilitate engagement with it. Having study coordinators in school who are committed to a study/intervention are also invaluable in “just making it work” (Langley, Nadeem, Kataoka, Stein & Jaycox, 2010, p. 109). At the delivery level, facilitators include having motivated implementers and coordinators who positively influence others and experiencing an intervention as easy to use and not a burden (Langley et al., 2010). This is more likely if the research team provide good teacher training, all materials (Mukoma et al., 2009), offer good technical and moral support and help the school plan for implementation (Forman, Olin, Hoagwood, Crowe & Saka, 2009; Mukoma et al., 2009). Continuity of teacher-

deliverers has also been found to enhance student and teacher engagement with an intervention (Mukoma et al., 2009).

Barriers have been identified at a number of levels. From a school-level perspective, barriers include low levels of senior leadership support (both in general, and specifically for the intervention/research), inadequate resources and poor investment in staff development (Hazell, 2006). Inadequate facilities, overcrowded classes and high teacher turnover has also been found to reduce lesson quality and student engagement with an intervention (Mukoma et al., 2009). The “low status” of PSHE education in many schools is also a barrier to testing health interventions (Mukoma et al., 2009, p.37): academic results are increasingly prioritised over student wellbeing, leading to a reluctance to release students from academic lessons (Forman et al., 2009). A lack of personal investment in the research/intervention is also problematic, and this may manifest in low stakeholder support or “passive resistance” from leaders, i.e. not wanting to be involved but ‘tolerating’ the process (Forman et al., 2009, p.32). Common practical barriers within school-based research include competing responsibilities (e.g. inadequate time/opportunity to deliver an intervention as planned) and overwhelming workloads (Forman et al., 2009; Langley et al., 2010). Finally, teachers’ protocol deviations have also been found to reduce quality of delivery and student engagement, including making considerable lesson adaptations (e.g. omitting role-plays, not following single-sex group recommendations) and not attending training (Mukoma et al., 2009).

The challenges for the researcher of working through a site representative or key contact during cluster or multi-site studies have been discussed within the retention literature. Site representatives or key contacts often undertake this informal, unpaid role in addition to their formal, paid responsibilities on site. Therefore, depending on how they acquired the role (i.e. through volunteering or by instruction) and the nature and volume of study tasks, they may be unable or unwilling to dedicate any significant time to the role. For example, Pinto and colleagues (2018) secured site representatives in every HIV prevention service agency participating in their multi-site study, specifically gaining their commitment to schedule staff interviews and deal with internal protocols. As the study progressed, Pinto et al. (2018) became quickly aware that these representatives were not completing the agreed tasks, therefore they took the decision to introduce a financial incentive to motivate staff and compensate them for their time. Financial incentives may not be appropriate or possible, however, therefore researchers must find other ways to motivate site representatives and support them in engage site staff and implementing study-related tasks.

In order to effectively support key contacts in school-based studies there is a need to

understand their experience. The present study examines the experience of teachers who acted as study coordinators for the RSIIYA trial in participating secondary schools in the North of England. The trial was implemented in each school through these study coordinators, whose responsibilities are detailed in Table 4.1. The Trial Managers prioritised the working relationship with coordinators in each school and invested considerable time in consultation, practical support and communicating their value to the study.

Table 4.1 Key contact responsibilities within schools participating in the RSIIYA trial

Planning smoking data collection sessions	Planning delivery of intervention/control lessons	Attending annual meeting with researcher
Securing timetable slot for researchers to visit school to collect smoking data.	Identifying teaching staff to deliver lessons.	Participating in 15 minute keep-in-touch meeting with researcher.
Informing appropriate staff about procedures for the smoking data collection visits.	Liaising with staff and researcher to plan teacher-training session.	Updating senior leadership team in school on study progress.
Meeting researcher on data collection visits.	Securing timetable slot for lesson delivery.	
	Distributing teaching materials to staff.	
	Ensuring lessons take place.	
	Collecting in and chasing up completed lesson materials.	
	Arranging researcher's collection of materials from reception.	

Given their extensive knowledge of the school context, and their leadership role for the study in school, these teachers were pivotal to the success or failure of the trial. Two key research questions were addressed within this present study:

- (1) What are teachers' experiences of coordinating the RSIIYA trial in their schools?
- (2) What factors facilitate and impede their and their schools' engagement with and implementation of the trial?

4.3 Method

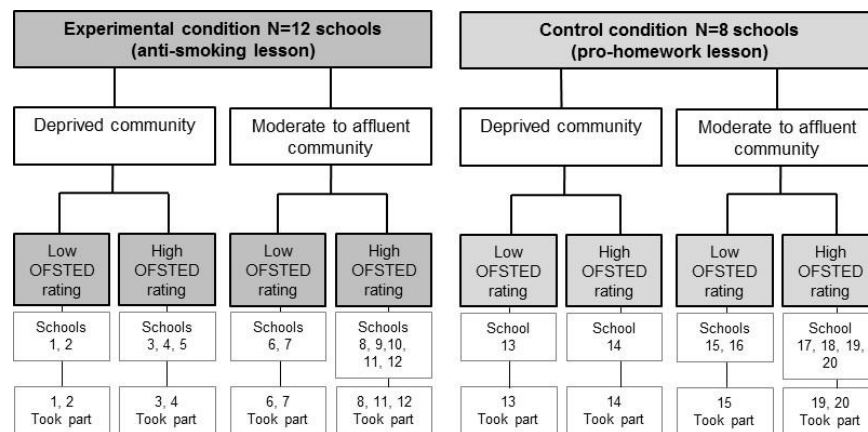
4.3.1 Design

Semi-structured interviews were used to explore coordinators' experiences of leading the trial in their school. This enabled them to recount their experiences in their own terms and to the depth they felt comfortable with, whilst allowing consistent areas of information to be collected and compared across interviews. Interviews were incorporated into annual review meetings to limit further burden.

Framework analysis (Ritchie & Spencer, 1994) was chosen to examine participants' accounts because of its applicability to applied settings, where researchers are often required to focus on specific issues or identify solutions, within short timescales and to present recommendations in an accessible way (Ritchie & Spencer, 1994). Because working through site contacts in multi-centre studies is already an identified issue in the literature, framework analysis was considered an appropriate method for this study since it tends to focus on a priori issues, which the researcher looks for and attends to within participants' accounts (Ritchie & Spencer, 1994; Gale, Heath, Cameron, Rashid & Redwood, 2013). From the transcripts, the researcher draws out important themes relating to these issues, then creates a thematic framework to both organise participants' material and act as a platform to interpret it and offer recommendations (Ritchie & Spencer, 1994). A more detailed account of the process is described within the analysis section (4.3.5).

4.3.2 Participants

Opportunity sampling was used, i.e. participants were recruited solely on the basis of being a study coordinator in school. However, as described in the previous chapter, the researcher targeted eight sample groups (see Figure 4.1) during recruitment to ensure that all varieties of school were represented. These groups were formed according to randomisation outcome (*smoking* or *pro-homework* condition), school socio-economic status determined using free school meal eligibility data (serving *disadvantaged* or *moderate-to-affluent* communities) and most recently awarded Ofsted inspection rating (*high* ['Outstanding' or 'Good'] or *low* ['Requires Improvement' or 'Unsatisfactory']). Figure 4.1 details the total number of Yorkshire schools within each sample group and those schools who agreed to participate in the interviews.

Figure 4.1 School key coordinators participating in the semi-structured interviews

Recruitment took place by email (Appendix 5). Eighteen of the twenty schools expressed interest to participate. Of these, two schools were unable to take part in planned interviews due to unforeseen events in school on the day of the interview. Of the six schools declining to take part, three were in the experimental/smoking condition and three were control/homework schools. Five were high Ofsted-rated (four in moderate-to-affluent communities; one disadvantaged) and one had a low Ofsted rating (serving a moderate-wealthy community). Five were also original coordinators who had helped sign their school up to the study.

The researcher had equally good relationships with coordinators in participating and non-participating schools. Sixteen teachers took part in the research, across fourteen schools (see Table 4.2). In two schools, two teachers were interviewed, due to their joint involvement in the trial. Nine were intervention schools and five were control (homework) schools. Two were Ofsted 'outstanding', seven were 'good', four 'required improvement' and one was 'satisfactory but improving'. Six schools served disadvantaged communities; the remaining eight were in moderate-to-wealthy locations. PSHE education was delivered as weekly/fortnightly lessons in half of the schools, three used 'drop-down' days only and the remaining four did not have dedicated PSHE lessons.

Of the 16 participants interviewed (across 14 schools), two did not provide full demographic data. Thirteen were female. Participants' mean age was 39 (range 26-54; SD 9.8) and there was a wide spectrum of years' teaching experience, from four years to 32 ($M=13.79$; SD 9.5). Seven teachers had worked in their current school since qualifying. Five were Senior Leaders: half were PSHE coordinators and two were PE teachers with dual

Table 4.2 Participant background information for semi-structured interviews

School (sample group code)	School Contextual Details				Personal details						
	Condition	Community served	Ofsted Rating	PSHE delivery	Role in school	Gender	Age	Years in teaching / in this school	Duration as key contact	Delivers lessons?	Smoking status
1	I	Disadvantaged	Low	Varies per year group	Geography teacher/Leader of applied learning (including PSHE)	F	33	7/7	Original	Y	Former smoker
2	I	Disadvantaged	Low	1 hour weekly	Year Leader (2012 cohort)	M	38	16/2	Year 2	N	Never smoked
3	I	Disadvantaged	High	1 hour weekly	Assistant Head	F	43	20/16	Original	Y	Former smoker
					PSHE Coordinator/PSHE teacher	F	45	Missing	Year 2	N	Never smoked
4	I	Disadvantaged	High	1 hour weekly	PE Subject Lead/Sixth Form Coordinator	F	29	5/5	Original	N	Never smoked
					Principal	F	50	Missing	Original	N	?
6	I	Moderate	Low	Form time	Assistant Head	F	33	11/11	Original	N	Former smoker
7	I	Moderate	Low	1 hour weekly	PSHE Coordinator/RE Subject Lead	M	30	5/1	Year 2	Y	Never smoked
8	I	Moderate	High	3 drop down days per year	PSHE Coordinator/DT Food Subject Lead	F	48	26/14	Original	N	Never smoked
11	I	Affluent	High	1 hour fortnightly	PSHE Coordinator/History teacher	F	40	14/11	Original	N	Never smoked
12	I	Moderate	High	Form time	Healthy Schools Coordinator/PE teacher	F	26	4/4	Year 2	N	Never smoked
13	C	Disadvantaged	Low	Fortnightly pastoral period	PSHE Coordinator/Technology teacher	F	28	4/2	Year 2	N	Trying to stop
14	C	Disadvantaged	High	3 drop down days per year	PSHE Coordinator/History teacher	F	27	4/4	Original	Y	Never smoked
15	C	Affluent	Low	1 hour weekly + 5 drop down days per year	PSHE Coordinator/PE & PSHE teacher	F	43	21/21	Original	Y	Former smoker
19	C	Moderate	High	1 hour weekly	PSHE Coordinator/Drama teacher	F	51	24/11	Original	N	Former smoker
20	C	Moderate	High	3 drop down days per year	Assistant Principal/History teacher	M	54	32/32	Original	N	Never smoked

Key: I=Intervention (smoking lesson); C=Control (pro-homework lesson)

responsibility for the Healthy Schools⁴ programme or teaching PSHE. Most coordinators (69% [N=11]) had initiated their school's sign up to the trial in 2012 and had managed it in school since. Five participants inherited the role when predecessors were promoted internally (N=3) or resigned (N=2). Nine were never-smokers, five were former smokers, and one was trying to stop (one participant provided no details). Twelve reported being "very strongly against" teenagers smoking, one was "against it" and one said they had "no problem with it at all".

4.3.3 Research Tools

A background information sheet (Appendix 6) was used to collect demographic data before the interviews. The interview schedule comprised largely open questions with various prompts (Appendix 7) to encourage the teachers to talk freely, but ensure key information was collected in a short timeframe. Factors informing the interview questions were identified as important after a review of the literature (especially Buston, Wight, Hart & Scott, 2002; Greenhalgh, Collard & Begum, 2005; Mukoma et al., 2009). The schedule was structured around three sections: the school's initial interest to participate in the trial, the reality of administering the trial in school and exploring any benefits being experienced. The questions were sometimes asked in a different order to better meet the needs of the teacher and the natural flow of discussion.

4.3.4 Procedure

To minimise disruption, the interviews were incorporated into established annual review meetings. These were designed to discuss the study's implementation that year, elicit suggestions for improvement and plan the next steps. Towards the end of year two of the trial, (May-June 2014), the researcher emailed all coordinators to request an annual review meeting. The email was warmly phrased and succinct to minimise time burden on these already busy teachers. It asked if they would consider extending the meeting by 20-30 minutes, on this one occasion, to answer some questions about their coordinator role in school. The email also mentioned audio-recording, outlined anonymisation procedures and that the researcher would be studying their responses in relation to other interviews. A consent form (Appendix 8) was attached to the email for completion prior to the interview, should they wish to take part. Interested coordinators contacted the researcher by

⁴ This is a joint initiative between the Dept of Health and Dept for Children, Schools and Families to improve student health, achievement, social inclusion. To be awarded 'Healthy School' status, schools must meet strict criteria for PSHE (including sex, relationships, drugs education), healthy eating (including nutritious catering in school canteens), encouraging physical activity and emotional health/wellbeing.

email/phone to book mutually convenient dates. The researcher then emailed by return a background information sheet for completion prior to interview. Interviews took place during work time in the coordinators' schools (locations included coordinators' offices, empty classrooms, drama theatres and unoccupied staff rooms).

The mean interview time was 15.7 minutes (range 10-22). Before the review meeting commenced, the researcher checked the coordinator was still happy to extend the meeting for the research interview, and for it to be recorded. Participants then signed the consent form and handed over their completed background information sheet. After the interview, the researcher re-iterated that their data would be treated confidentially, anonymised at transcription and stored securely. She also noted important information, such as details about the setting (e.g. disturbances), the mood of the interview (e.g. stressed), anything relevant mentioned beforehand or afterwards (e.g. previous bad experiences with research).

4.3.5 Analysis

With regards to the treatment of the data during analysis, a top-down/theoretical approach was adopted to identifying themes and patterns, driven by the research questions (for example, when coding the data, close attention was paid to identifying levers and barriers in conducting the key contact role). Themes were identified predominantly at a semantic level, i.e. focusing on explicit or surface meaning in participants' words. An essentialist/realist epistemological standpoint was adopted, in that the analysis concentrated on the key contacts' individual experiences, motivations and meanings.

All verbal aspects were transcribed verbatim to try to capture the nature of interview. I listened back to each interview, familiarised myself with each transcript, highlighting important/significant features line by line in pencil and allocating paraphrasing labels or 'codes' as I progressed (Gale et al., 2013). I then devised a working theoretical framework based on the codes emerging, key research questions and the topic areas within the interview schedule. Each code within the framework was systematically numbered for reference purposes. I applied this framework to each transcript, checking for the appearance of each code and recording its reference number in the margin (i.e. indexing). To generate a holistic view of the data, I then charted the total appearance of each code within the transcripts. Finally, I examined the results in the context of each school, sample group and participant to identify any patterns or relationships within the data and interpret their meaning/significance.

4.3.6 Ethical Considerations

Ethical approval was obtained from the University of Leeds School of Psychology Ethics Committee (reference: 14-0113; 9/6/2014). Participant consent was obtained before each interview. It was made clear there was no expectation to participate and that non-participation would have no detrimental effect on the ongoing working relationship. Participants were advised they could terminate the interview at any time if they became distressed, or refuse to answer any question without giving a reason. To secure anonymity, all names mentioned, including towns and schools, were changed. Interview recordings were erased following their transcription. Anonymised transcriptions and other participant data are being held electronically, confidentially and securely on a password-protected computer for up to five years, after which time these will also be deleted.

4.4 Results

The framework used to examine participants' accounts involved examining factors facilitating or impeding their engagement within four main themes: (1) at the point of deciding to join the trial or, if they were not the first coordinator, on inheriting the role; (2) at an organisational/contextual level; (3) at the personal level and (4) at a trial process level (see Table 4.3). When charting a holistic picture of the data, facilitating and impeding themes were recorded by school, according to their sample categories, to allow for comparison analyses. A summary of the findings is provided first, followed by an examination of the most common facilitators and impediments/barriers within each 'framing theme' and differences between the sample groups.

4.4.1 Summary

The teachers' overall experience of coordinating the study in their schools was positive and participating in it was perceived as worthwhile and valuable at both a personal and school level. Common reflections were that taking part in the study *met an identified need in school* (e.g. targeting smoking, helping with achieving the Healthy Schools award; theme 1.1.1) and that it was *a novel, noble, valuable educational experience* (theme 1.1.3). In many cases, their *Headteacher/Senior Leaders initiated participation or provided strong*

Table 4.3 Factors facilitating and impeding coordinators' engagement in the study: Framework Analysis results

Framing Themes	1. Facilitating factor themes	Schools				2. Impeding factor themes/barriers	Schools			
		Low Orsted Disadvantaged	Low Orsted Moderate-Affluent	High Orsted Disadvantaged	High Orsted Moderate-Affluent		Low Orsted Disadvantaged	Low Orsted Moderate-Affluent	High Orsted Disadvantaged	High Orsted Moderate-Affluent
1. Perceptions of being involved	1.1.1 It met an identified need in school (6)	1		<u>3</u> <u>4</u>	8 <u>19</u> <u>20</u>	1.2.1 No handover from outgoing coordinator (2)	<u>2</u>	7		
	1.1.2 Head teacher/Senior Leaders' initiation or strong support (6)	1	<u>15</u>	<u>3</u> <u>4</u> <u>14</u>	<u>20</u>	1.2.2 Reluctance/concern about responsibility after not choosing role (2)	<u>13</u>	7		
	1.1.3 Noble, novel, valuable educational experience (5)	1	<u>15</u>	4	8 <u>20</u>	1.2.3 Not recognising clear 'fit' with school plan (1)	<u>2</u>			
	1.1.4 Receiving school smoking statistics (4)		<u>6</u>	8	<u>19</u> <u>20</u>					
	1.1.5 Social proof (3)	1		<u>14</u>	<u>19</u>					
	1.1.6 Personal experience of cancer (3)	1	<u>15</u>		8					
	1.1.7 Establish links with local university (2)	1		<u>4</u>						
	1.1.8 Confirmed/reassured 'of value' during welcome meeting with researcher (2)	<u>13</u>	7							
	1.1.9 Handover from outgoing coordinator (1)		<u>6</u>							
2. Organisational/contextual level	2.1.1 Strong leadership support (8)	1	<u>6</u>	<u>3</u> <u>4</u> <u>14</u>	8 <u>11</u> <u>20</u>	2.2.1 In-house planning/bureaucracy complexities (5)	1	7 <u>15</u>	<u>4</u>	<u>19</u>
	2.1.2 Team cohesion and colleague support (8)	1 <u>13</u>	<u>15</u>	<u>3</u> <u>4</u> <u>14</u>	<u>12</u> <u>19</u>	2.2.2 Poor morale; overwork (4)	1 <u>13</u>	7		<u>12</u>
	2.1.3 Coordinator has high degree of control (7)	1	<u>6</u> <u>7</u> <u>15</u>	<u>3</u> <u>14</u>	<u>20</u>	2.2.3 Senior Leadership do not actively support (4)	<u>2</u> <u>13</u>	7		<u>19</u>
	2.1.4 PSHE is a priority (5)	<u>2</u>	<u>6</u>	<u>3</u> <u>4</u>	<u>20</u>	2.2.4 Lack of team coherence, support and vision (2)	<u>13</u>	7		
	2.1.5 Dedicated, regular PSHE timetable slots (4)	<u>2</u>	<u>6</u>	<u>3</u> <u>4</u>		2.2.5 Isolation in leading the study; invisibility (2)		7		<u>12</u>
	2.1.6 Consistency of staff delivering (especially if PSHE staff) (4)	1	<u>15</u>	<u>3</u>	8	2.2.6 Lack of specialist PSHE staff to deliver (2)	<u>13</u>	7		
	2.1.7 A good 'fit' was identified for the lessons (4)		<u>15</u>		<u>11</u> <u>19</u> <u>20</u>	2.2.7 PSHE is low priority (2)	<u>13</u>	7		
	2.1.8 School values external links with university (3)			<u>3</u> <u>4</u>	<u>11</u>	2.2.8 No perceived benefits (2)	1 <u>2</u>			
	2.1.9 The lesson structure/materials meet multiple needs (saves time) (3)		7 <u>15</u>	<u>14</u>		2.2.9 No timetable 'fit' established: inconvenient extra to squeeze in (1)	<u>2</u>			
						2.2.10 External links/opportunities with university not recognised/valued (1)		<u>6</u>		
						2.2.11 Within-school variability in teacher' delivery (1)		<u>15</u>		

3. Personal level	3.1.1 Belief in/commitment to study principles (10)	1 13	7 15	3 4	8 11 12 19	3.2.1 Feeling unsupported in PSHE/healthy school endeavours (3)	13			12 19
	3.1.2 Drive, resilience and persuasiveness (9)	1 13	6 7 15	3 4	12 19	3.2.2 Study not highly valued/meeting expectations (1)	2			
	3.1.3 Valuing research and external links (9)	1 13	7 15	3 4	11 12 20	3.2.3 Perceived as a burden (1)	2			
	3.3.4 Coordinating trial perceived as low burden (8)	13	6 15	3 4	8 11 20					
	3.3.5 Oriented to improving processes/adding value (5)	1 13	15		11 20					
4. Trial process level	4.1.1 Organisational efficiency of the study (8)	13	6 15	14	3 8 11 20	4.2.1 Lesson design: repetition, lack of variety and challenge (9)	1	6	3 14	8 11 12 19 20
	4.1.2 Working relationship with the researcher (6)	2 13	7 15	3 14		4.2.2 Inability to adapt smoking/homework lesson (3)	1	6	14	
	4.1.3 Positive spin-offs are highly valued (6)		6 7 15	3 4	11	4.2.3 Chasing up completed lesson material packs from teachers (2)			14	12
	4.1.4 Students' pride in being in the study (6)	13	7 15	3 14	19	4.2.4 Difficulties finding timetable availability for testing a full year group (2)		7	3	
	4.1.5 Pre-printed, quality resources (6)	13	6 7 15	14	8					
	4.1.6 Researchers delivering staff training is helpful (3)	13			8 11					
	4.1.7 Coordinating study is development opportunity (3)	13		4 14						
	4.1.8 Observations are confidence boosting (1)			3						
	4.1.9 Listening and responding to feedback (1)			14						

support (theme 1.1.2), in some cases influenced by the *social proof* of neighbouring or partner schools already signing up (theme 1.1.5). *Receiving school smoking statistics* (theme 1.1.4) and *establishing links with a local university* (theme 1.1.7) were cited as influential factors in deciding to join the study. Some coordinators were motivated to join the study by their *personal experiences of cancer* (theme 1.1.6). Some teachers who inherited the coordinator role (i.e. they were not involved at its inception) had to contend with *no handover from the outgoing coordinator* (theme 1.2.1), experienced initial *reluctance/concern about the responsibility of the role after not choosing it* (theme 1.2.2) or *did not recognise a clear 'fit' with the school plan* (theme 1.2.3). However, *most were reassured of the study's value during the welcome meeting with the researcher* (theme 1.1.8).

When discussing their management of the trial in school, coordinators mentioned facilitating factors (159 instances) more frequently than impeding factors (52 instances). A large proportion (65%; 34/52) of the impeding factors were raised by five coordinators, four of whom worked in low Ofsted-rated schools. The greatest number of barriers (N=11) was experienced at the organisational/contextual level. No clear outlier emerged with regard to facilitators: the highest number of facilitators (N=9) were found at the organisational/contextual level, trial process level and within perceptions of the trial.

Factors most frequently impacting on coordinators' engagement were those at the 'organisational/contextual' level (72 instances across 20 themes [9 facilitators/11 barriers]). However, whilst a greater number of barriers than facilitators was apparent at this level, coordinators spoke more frequently of facilitators (46 instances compared to 26 instances of barriers). These included *strong leadership support* (2.1.1), *team cohesion and colleague support* (2.1.2), and having a *high degree of control* as a coordinator (2.1.3). Further facilitating factors highlighted by the coordinators were school considering *PSHE as a priority* (2.1.4), providing *dedicated, regular PSHE timetable slots* (2.1.5), having *consistent staff delivering the lessons* (2.1.6) and *identifying a good 'fit for the lessons* (2.1.7). *School valuing external links with a university* (2.1.8) was also beneficial for some coordinators as they managed the project, and the *lesson structure/materials met multiple needs* which saved time (2.1.9).

The barriers associated with organisational/contextual level factors included difficulties with *in-house planning and bureaucracy complexities* (2.2.1), *poor morale and overwork* (2.2.2), *no active support from senior leaders* (2.2.3) and a general *lack of team coherence, support and vision* (2.2.4). These contributed to feelings of *isolation in leading the study, or invisibility* (2.2.5) for some coordinators. Other barriers included a *lack of specialist*

PSHE staff to deliver the lessons (2.2.6), *PSHE being a low priority in school* (2.2.7) and their school *perceiving no benefits* (2.2.8) in participating.

‘Personal level’ factors (46 instances across 8 themes [5 facilitators/3 barriers]) affecting engagement in the study were dominated by facilitators (41/46 instances; apparent in 79% [11/14] of schools). Facilitators featured: possessing a strong *belief in/commitment to study principles* (3.1.1); *drive, resilience and persuasiveness* (3.1.2); *valuing research and external links* (3.1.3). A high number of coordinators perceived *coordinating the trial as low burden* (3.3.4) and were generally *oriented to improving processes and adding value in their work* (3.3.5). In terms of barriers, some coordinators felt generally unsupported in the PSHE/healthy school endeavours (3.2.1).

Factors at the ‘trial process level’ were also discussed frequently by the coordinators (56 instances across 13 themes [9 facilitators/4 barriers]). Once again, they spoke more often of facilitators. These included the *organisational efficiency of the study* (4.1.1) and the *working relationship with the researcher* (4.1.2). *Positive spin-offs* (4.1.3), such as free wellbeing workshops, and the *pre-printed, ‘quality’ resources* (4.1.5) were highly valued, and the coordinators noted that *researchers delivering staff training is helpful* (4.1.6). Other facilitators were that *students had pride in being in the study* (4.1.4) and *coordinating the study was a development opportunity* (4.1.7).

The most commonly mentioned barrier at the trial process level was the *lesson design*, specifically *the repetition and lack of variety* (4.2.1). Linked to this was the *inability to adapt the smoking/homework lesson* (4.2.2). Practical barriers were also apparent. *Chasing up completed lesson material packs from teachers* (4.2.3) was sometimes challenging and *difficulties finding timetable availability for testing a full year group* (4.2.4) were also experienced.

The main facilitating and impeding factors, as discussed by more than 50% of schools interviewed, are now examined in more detail (see Appendix 9 for full details).

4.4.2 Main facilitating factors influencing trial engagement

The most frequently occurring facilitating factors were at the **personal level (theme 3)**: 3.1.1 *belief in/commitment to study principles* (10 schools), 3.1.2 *drive, resilience and persuasiveness* (9 schools), 3.1.3 *valuing research and external links* (9 schools) and 3.3.4 *coordinating the trial is perceived as low burden* (8 schools). The second most frequently occurring facilitators appeared at the **organisational/contextual level (theme 2)**: 2.1.1 *strong leadership support* (8 schools), 2.1.2 *team cohesion and colleague support* (8 schools) and

2.1.3 *coordinator has high degree of control* (7 schools). Facilitators at the **trial process level** (theme 4) were also prevalent: 4.1.1 *organisational efficiency of the study* (8 schools).

Theme 3: Personal level-facilitating factors

3.1.1 *Belief in/commitment to study principles* (71% [N=10] schools): Nearly three-quarters of the interviews contained evidence of teachers believing in the study and of being committed to seeing the required tasks through. The teachers expressed pride in being part of a national study and contributing as a collective with other schools to a shared health-related issue:

“Just a really important study, it was good to feel like we’re one of the schools that are part of something that’s obviously a national, nationally important thing. We need to get smoking sorted in adolescence. It needs.. it’s too.. it happens too often and anything we can do really to contribute to that, that’s great” (PE teacher/Healthy Schools coordinator, school 12: 31-34).

This personal investment in the trial was reflected in the effort the coordinators devoted to ensuring each stage went to plan. For example, the coordinators spoke of meeting with teachers prior to delivering the lessons to underline the study’s importance and of issuing numerous reminders to return lesson packs to them.

3.1.2 *Drive, resilience and persuasiveness* (64% [N=9] schools): Personal characteristics of the coordinators emerged as being particularly important for ensuring that trial tasks took place. It was clear from the interviews that the coordinators were confronted with numerous challenges and setbacks whilst planning and executing trial-related activities. This theme reflects coordinators’ individual determination to deliver to plan, and, in particular, how they dealt with setbacks or challenges.

Numerous coordinators used persuasion and other interpersonal approaches to ensure tasks were completed and goodwill was maintained. For example, one coordinator provided teachers who had delivered the lessons with a chocolate bar in their pigeonholes as thank-you/reward, which he paid for himself. On other occasions coordinators described having to using assertion to complete tasks. For example, the coordinator in school 1 outlined her frustration on returning from sickness absence that the smoking prevention lessons she had painstakingly negotiated with the timetable manager had been re-scheduled. She personally took responsibility for these lessons being implemented by reminding staff that school had signed a participation agreement, and by overseeing the process:

“I emailed round staff and like ‘I’m really sorry but you know, the study is going ahead. We’ve signed up for this, it’s part of what we agreed to do. It’s going to happen on this day and I need your support. You’re going to be coming down to the hall’. And staff came and I just chased them up on the morning because I was free, just went round all the classrooms” (PSHE/Geography teacher, School 1: 106-109).

The coordinator in schools 13 described initial difficulties when trying to secure a date for the researcher-delivered staff training, in that staff ‘avoided’ replying to her emails. She reflected during the interview that she had been ‘too tentative’ in these emails: “I phrased it, you know.. **if** you come there’s an incentive..” (line 205). She described subsequently adopting a more directive, assertive approach to communicate to staff that it was expected, not optional, that they attend the training.

3.1.3 Valuing research and external links (64% [N=9] schools): Viewing research as important and welcoming links with the University was another strong facilitator factor in coordinators’ engagement with the study. The two teachers interviewed in school 4, which served a disadvantaged community, each had equally positive but slightly different perspectives on the value of collaborating with universities:

“As a senior leader in a school you want to try and take every opportunity possible with people outside who have either the expertise or who want to use an evidence based research to help the country” (Principal, school 4: 71-73).

“Another exciting point for me though was making a link with Leeds University because obviously a lot of our students aspire to go to Leeds University. It was really good for me to get in a link, especially in my new role as the 6th form team (...) So as a maybe a selfish reason for the school I was really excited about forming that link as well” (PE Subject lead/Sixth form coordinator, school 4: 86-90).

Other teachers (e.g. school 1) also explained that in disadvantaged areas students benefit significantly from being exposed to universities and university staff because they may not have been encouraged at home to ‘aim high’. In this sense, many coordinators considered participation in the trial to have supplementary benefits beyond the research itself: it was believed to hold ‘kudos’, to raise the school’s profile and provide an important educational experience for students. Those coordinators who were also responsible for delivering PSHE in their school also spoke of the value of the trial for them personally, as a source of new ideas/information or support.

3.3.4 Coordinating the trial is perceived as low burden (57% [N=8] schools): Another key personal factor facilitating engagement and implementation was the coordinator’s perception that the activities within the study were clear, easy to manage and not labour-intensive:

“Everything’s made really easy and I’m not just saying that, cos it is. When I took it on, I thought it was going to be really onerous, but I still took it on because I thought it was going to be great. And it hasn’t been onerous at all. At any point.” (PSHE Coordinator/PE, school 15: 115-118).

“It’s not time-consuming in the slightest: handed them out, they did it, they handed them back to me. I kept them and then met up with you” (PSHE Coordinator/History, school 11: 179-180).

The coordinators particularly appreciated being provided with pre-prepared individual lesson packs because these saved them considerable time. In fact, two teachers described having to photocopy all the resources in a previous research study their school participated in. The experience was so time-consuming that they ultimately withdrew. In addition to receiving pre-prepared packs, the coordinators also appreciated that it was not incumbent on them to deliver staff training for the trial and the lessons. By the researcher delivering this training, coordinators felt that the trial's credibility and profile was raised in school and that staff were informed, involved and prepared:

"It's not been onerous because you've given us all the resources well in advance and the staff have been trained. They know what to expect" (PSHE/DT Food, School 8: 62-65).

Theme 2: Organisational/contextual level facilitating factors

2.1.1 Strong leadership support (57% [N=8] schools): Coordinators explained that having support from members of their school's leadership team considerably raised both their and the study profile in school, and helped key stages in the study take place:

"There's a member of senior team that wants this to go ahead, you know. They make sure that we do find the time. Sometimes it gets a bit squashed into the back end of the year, but you know it will get done so one way or another. I always find a way to fit it in" (Applied learning lead/Geography, school 1: 34-37).

A number of coordinators also explained that being acknowledged and supported by the senior leadership team contributed to their feeling that the role was worthwhile and valued. The Principal interviewed in conjunction with the coordinator in school 4 described perceiving the coordinator role as a personal and leadership development opportunity, which she felt provided another level of value for schools participating in the study. Some coordinators commented that their senior leadership team's initial minimal interest in the trial had significantly increased after receiving the annual framed certificate and formal letter from the university research team acknowledging the coordinator's valued support:

"The Headteacher started getting involved, particularly when we got our certificate and letters saying how brilliant it's been so now it's high profile within the school" (PSHE Coordinator/DT Food Lead, school 8: 39-41).

This was highly motivating for the coordinator involved, and the study was subsequently discussed in annual meetings with the Headteacher.

2.1.2 Team cohesion and colleague support (57% [N=8] schools): Being able to rely on trusted colleagues for their support in implementing key trial tasks was valued by coordinators:

"The form tutors were very, very supportive" (PSHE Coordinator/Technology, school 13: 72).

“I think the staff and tutors have absolutely been brilliant” (PSHE Coordinator/Drama, School 19: 47-48).

“We all work quite well in humanities, there’s no ‘I’m not doing that’” (PSHE Coordinator & teacher, school 3: 75-78).

The support was valued on two key levels. Firstly, it helped the coordinator feel that there was a collective school responsibility for the study, thereby reducing potential isolation in the role. Secondly, being able to call on colleagues to deliver the necessary tasks reduced the practical and emotional burdens associated with being responsible for these. For example, the coordinator in school 4 spoke of collaborating internally with the Head of RE to plan the lessons and data collection, which helped the activities to run smoothly.

Theme 4: Trial process level facilitating factors

4.1.1 Organisational efficiency of the study (57% [N=8] schools): During the interviews, coordinators underlined that teachers have to navigate multiple, competing demands daily, which seem to be in constant flux. Whilst some were initially unsure about how they would incorporate their coordinator role duties into their already busy schedule, they described how the organisational processes within the study reassured them that it was manageable. Specifically, the coordinators valued the pre-prepared lesson packs, the regular reminders/clear instructions and aide memoires which were produced, such as an A4 laminated flow-diagram detailing the steps in the trial:

“The big one (laminated flow chart) so that just took you through all the steps. It was really clear to me what the process was which was really, really helpful. And the fact that even you had little boxes next to it being like checked off. I mean I still use it so...” (PSHE Coordinator/Technology, school 13: 55-57).

Having a holistic view of the trial phases and understanding its cyclical nature allowed the coordinators to self-manage and plan ahead, which gave them a sense of control and reduced ambiguity:

“It’s very scheduled so I know exactly what’s coming up, when it’s coming up and when it needs to be completed by. It’s not a case of, you know, a week before you’re like, by the way, do this as well. It’s very much organised and the resources are always here weeks in advance” (PSHE coordinator/history, school 14: 140-143).

“The stuff you send through, the timings. (...) We know we’ve got a pattern, we can plan ahead.” (PSHE Coordinator/PE, school 15: 98-100).

Being given plenty of time, providing adequate notice of impending tasks requiring their attention, and routinizing processes seemed to be particularly valuable in minimising unnecessary stress within the coordinator role.

4.4.3 Main impeding factors influencing trial engagement

The most commonly experienced barrier influencing engagement was at the trial-process level.

4.2.1 Lesson design: repetition, lack of variety and challenge (64% [N=9] schools): A major impeding factor cited by coordinators was concern about the repetitive nature of the lesson design and materials. Some described receiving negative feedback from teacher-deliverers regarding students tiring of the repetitive process and lesson format:

“Teachers were saying that perhaps they are a little sick of the repetition and they’re getting a little bit bored with the tasks that they seem to be, they just remember doing six months previously.” (PSHE Coordinator/history, school 11: 129-131).

One coordinator (school 14) explained how she felt impotent after receiving teachers’ feedback, because “obviously I can’t say ‘oh right, well I’ll change that’ because that’s not my role. My role is to facilitate the project” (253-254). However the assertive approach she adopted, which was to reassure the teaching team that she would forward the comments to the research team, proved to be ultimately motivational for staff (i.e. the team’s suggestions were incorporated into the next set of lesson materials):

“What’s really helped this time is that you’ve obviously listened to what people are saying and you’ve fed back and you’ve changed it and I think they appreciate that”. (PSHE coordinator, school 14: 259-261).

During the interviews a number of coordinators made suggestions for how the research team could “keep looking at the lessons and how they might evolve a little bit” (Assistant Head, school 6: 219-222), such as incorporating more variety, time for discussion and exploration of issues, essentially “making them more challenging and maybe have some extension pieces” (PSHE coordinator, school 8: 258).

4.4.4 Differences between sample groups

The presence of facilitating and impeding factors’ was not related to randomisation outcomes. However some differences emerged between high and low Ofsted-rated schools, one factor had a greater facilitating effect in disadvantaged schools and some subtle effects of coordinators’ roles were observed. These are now discussed.

Ofsted-rating differences: Barriers associated with the lesson design (repetition, lack of variety/challenge) were raised predominantly in **high** Ofsted-rated schools (7/9). More high Ofsted-rated schools (5/8) commented on the organisational efficiency of the study and perceived the trial as low burden. A good fit for delivering the lessons had also been identified more frequently in these schools, and themes of strong leadership support, team cohesion

and colleague support were also more prevalent. The reverse was observed during interviews with coordinators in **low** Ofsted-rated schools: more of these were implementing the trial within a climate of poor morale/overwork (3/4) and lack of SLT support (3/4). This lethal combination was a major barrier to making the trial work. School 8's coordinator, for example, could not persuade staff to attend training to deliver the intervention: "if SLT was saying you had to do that but it, yeah, then it would kind of filter through". At other times, coordinators would feel guilty adding to colleagues' existing workload. All the coordinators describing a lack of team coherence, support and vision and an inability to recognise a clear fit in school worked in low Ofsted-rated schools, as did all those inheriting the role who described no handover and initial reluctance/concern about the responsibility. More low Ofsted-rated schools commented on valuing the pre-printed, quality resources (4/6).

Feature of schools serving disadvantaged communities: Most coordinators (4/6) commenting on the working relationship with the researcher worked in schools serving disadvantaged communities. This theme was not mentioned by coordinators in moderate-to-affluent, high Ofsted-rated schools.

Role differences: Coordinators in leadership roles made no reference to poor morale/overwork, and only one mentioned in-house planning issues (1/5). Only these leader-coordinators expressed that PSHE was a priority and dedicated PSHE timetabling made implementation straightforward. Most of the facilitating **personal** factors appeared in the accounts of coordinators without leadership roles, specifically: valuing research and external links (6/9); belief in and commitment to the study (8/10); drive, resilience and persuasiveness (6/9) and being oriented to process improvement and adding value (4/5).

4.5 Discussion

The aims of this study were to understand teacher-coordinators' experiences of the trial and to identify facilitating and impeding factors influencing their experiences of managing and implementing the trial in school. Facilitating factors were far more commonly experienced than impeding factors, which may explain why no school withdrew from the study.

The organisational climate and contextual factors within each school most frequently affected coordinators' experience of running the trial and their schools' overall engagement with it. The organisational/contextual barriers identified in the present study are consistent with previous findings, such as low leadership support/passive resistance, colleagues' reluctance to engage in the research, overwhelming workloads, logistical issues finding curriculum time to plan in study tasks (Forman et al., 2009; Langley et al., 2010; Hazell, 2006),

not attending training (Mukoma et al., 2009) and the low priority of PSHE education (Mukoma et al., 2009; Forman et al., 2009). Facilitating factors present within the present study also support previous findings: compatibility with school goals, finding a place for trial tasks within the curriculum, good technical support from the researcher, low burden, helping the school plan key steps in the trial (Forman et al., 2009) and strong leaders who believed in and supported the study (Forman et al., 2009; Langley et al., 2010).

Whilst the present findings add support for Caan and colleagues' (2015) 'distinct societies', they also suggest some "norms, values, attitudes, behaviors and actions" (Christenson et al., 2002, p.473) are shared by particular types of schools. MacNeil, Prater and Busch (2009) refer to a school's climate as its "organisational health" (p.75). Unhealthy schools have ineffective senior leadership teams and unhappy teachers who are dissatisfied with their roles and workplace colleagues (Hoy, Tarter & Bliss, 1990). Clearly some of the schools participating in the present trial could be described as unhealthy by this definition: coordinators in low Ofsted schools seemed to contend with more barriers, less support and less staff cohesion. Mukoma et al. (2009) also alluded to this when they observed poorer implementation in schools which had high staff turnover, were overcrowded, in more disadvantaged communities and with inadequate facilities.

By contrast, healthy schools consistently display clear goals and focus, good communication, cohesion, strong morale, propensity to innovation, problem-solving, autonomy and adaptability/resilience and optimal use of resources (Fairman, Clark & Corp, 1982). These criteria seem to map across to the facilitating factors within high Ofsted schools. Coordinators in high Ofsted schools in the present study could certainly be described as working within these healthier contexts. UK researchers commissioned by the Department for Children, Schools and Families, found that highly successful head teachers promote "an orderly and secure working environment" (Sammons, Gu, Day & Ko, 2011, p.93), set clear direction and display high expectations for teachers' work with students. They develop staff, encourage collaborative working and prioritise continuous improvement, such as "developing a culture of research and innovation" and "encouraging the use of data and research" (Sammons et al., 2011) Where such leadership qualities exist, Sammons and her team found a direct link with staff commitment, enthusiasm and also positive student behaviour and discipline. These factors appeared to be operating in high Ofsted contexts, providing a more settled, organised and supportive setting for coordinators running the trial. They also represent an ideal fit for research collaboration, and explain why such schools may approach research with high expectancies compared to low Ofsted schools.

An interesting finding in the present research was that more coordinators based in disadvantaged communities valued the working relationship with the researcher than those in moderate-to-affluent communities. This requires further investigation. One explanation might be that working in challenging communities places more emotional demands on staff, and having regular exclusive contact in school with an impartial, supportive psychologist is personally valuable. Alternatively, the benefits may surround the professional links and practical guidance the researcher can offer. These areas will be explored from the researchers' perspectives in study two.

The most consistent facilitating factor in trial engagement and implementation was the coordinators' personal investment in it. This supports earlier findings by Forman et al. (2009) and Langley et al. (2010) in particular, who found that successful trial implementation was not due to absence of barriers, rather the willingness of the coordinator/implementer to overcome them. If a researcher's representative in the trial organisation believes firmly in the intervention/study, sees it as low burden, invests energy to make it work, and influences colleagues positively, the likelihood of the trial running successfully seems high. Of particular interest is the finding that even when leadership support was absent, the study was implemented to plan because individual coordinators drove it through, indicating that local intermediaries or research champions' personal qualities may be more crucial than senior leadership support alone. These findings add further weight to Robinson (2014) and Petosa and Goodman's (1991) assertions regarding the importance of a local intermediary or research champion in school. They also suggest that the mechanisms through which leadership-role coordinators and non-leadership role coordinators exerted their influence were different. Those without leadership responsibilities used persuasion, drive, persistence/resilience to ensure key tasks were completed, implying the use of social influence (Cialdini, 2009; Ibarra & Andrews, 1993) and referent or expert power, given their PSHE role (French, Raven & Cartwright, 1959). Those coordinators in leadership positions, however, mentioned personal themes less, suggesting that they relied more upon their legitimate power as leader to ensure tasks were completed (French & Raven, 1959). In line with this, fewer leaders described difficulties with in-house bureaucracy and planning, suggesting that their status guaranteed fewer obstacles to overcome.

Another way of interpreting coordinators' drive and commitment is through their internal beliefs about the value of the study, and linking this to intrinsic motivation to make it succeed, despite setbacks (Gagné & Deci, 2005). It could be argued that the experience of being a coordinator provides variety beyond teaching (e.g. liaison with psychologists), visible

outcomes (monitoring smoking levels), significance (being involved in a nationally important study, with other local schools), autonomy (the coordinator is given wide parameters for completion of study tasks and some flexibility in how these occur) and regular feedback from a fellow professional. These factors are consistent with Hackman and Oldham's (1980) job characteristics model for facilitating high intrinsic motivation at work.

These overall findings of this study are consistent with elements of normalisation process theory (May et al., 2007; Murray et al., 2010). This framework is one way of understanding how participants make sense of interventions, during their development, evaluation and implementation. The framework involves examining the *coherence* surrounding the intervention, i.e. does it fit with organisational goals and tasks, have clear benefits and a sense of purpose; the level of *cognitive participation* by those using the intervention, i.e. believing in it and being prepared to invest energy in it; the *collective action* taken by those involved to make it work, influenced by factors such as its compatibility with current practices and whether it enhances or blocks work; finally, *reflexive monitoring* – which involves the consultation aspect, can users provide their feedback on the intervention and procedures.

The most commonly cited impediment was the lesson design itself, and this requires serious consideration, given user acceptability of an intervention is crucial for long-term adoption (Evans, Murphy & Scourfield, 2015; Witt, 1986). User acceptance will be explored in studies 3 and 4 with teachers and students. Throughout the trial, the researcher team continued to incorporate teachers' feedback wherever possible and stressed that a specific model was being tested, the precise format of which may change if successful and ultimately launched nationally.

Finally, in line with other research (e.g. Befort et al., 2008), schools' decisions to participate in the RSIIYA study were influenced mainly by the prospect of tangible benefits for the school and the practicality of it meeting a local need. As schools continue to be "inundated with requests to participate in research", which is "generally received as a disruptive intrusion with little benefit" (Mukoma et al., 2009, p.45-46), this repeated finding highlights the need for research to be mutually beneficial. Before approaching a school to participate in a trial, recruitment is likely to be more successful if researchers have carefully considered the local setting, what school's needs might be and what tangible benefits they could gain from participation. The reality is that schools manage too many competing priorities and complex demands to help universities simply because research is a noble endeavour.

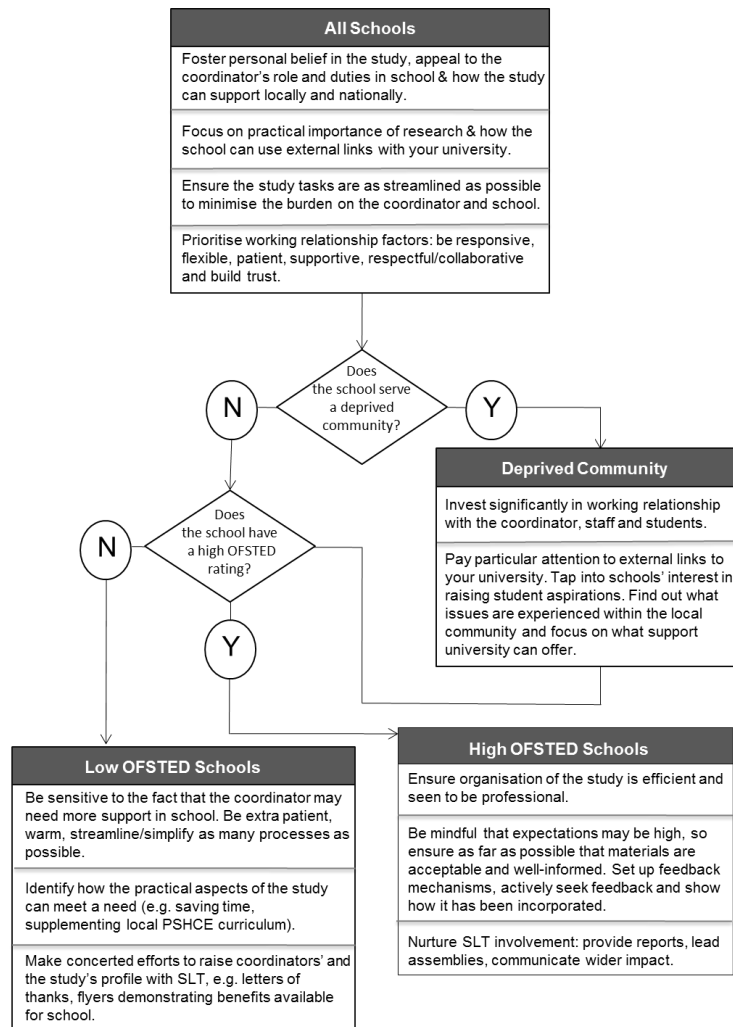
4.5.1 Strengths and limitations

There are a number of limitations to this study. One limitation is that the participants were known to the researcher and had an ongoing relationship with her. This may have led to reluctance to disclose extensive negative aspects, in that they did not want to offend her or impede their relationship moving forward. However, various negative comments did emerge; they were simply outweighed by facilitating factors. This study did not involve all the trial schools and it is possible that the six non-participating schools would have provided alternative perspectives. However, their profiles and the relationships with the researcher were no different to those who did participate, suggesting that their experiences may have been comparable. The study also benefits from the participation of schools within all sample groups, thereby reflecting a comprehensive range of experiences. A final limitation is that schools have been categorised according to their Ofsted rating and Ofsted's inspection and rating framework has attracted considerable controversy in recent years (Courtney, 2013). Ofsted ratings are also subject to change and represent just one way of assessing a school's effectiveness. The rating in the present study should not be taken as a definitive indication of each school's quality, rather as a pragmatic guide used to help meaningfully group and compare schools' experiences.

4.5.2 Implications

A promising avenue for future research would be to extend our understanding of how to tailor strategies to recruit and retain different types of schools to improve success in trials. Within the present study, the differential results emerging in relation to Ofsted-ratings and socio-economic status of the community schools serve suggest that recruitment and retention strategies may require greater refinement or tailoring for maximum effect. Of particular interest should be developing specific strategies to appeal to schools serving disadvantaged communities, whose children typically experience poorer health outcomes. Such tailored approaches may contribute to more mutually beneficial research outcomes. In the hope of aiding the school-based researcher, the flow-chart in Figure 4.2 details those strategies which seem to facilitate implementation and engagement in *most* schools, followed by those which may be additionally, *differentially* beneficial for (a) schools in disadvantaged areas and (b) those in high Ofsted and low Ofsted rated schools.

Figure 4.2 Flowchart of potential differential recruitment and retention strategies for school based research



4.5.3 Conclusion

In conclusion, this study offers some insight into the barriers and facilitators experienced by a large number of schools participating in a trial testing a complex health intervention. Although school-based research is challenging, and the organisational climate may not always be hospitable, this study has found that poor leadership support does not necessarily signal failure. In fact, the findings suggest that, although researchers cannot change an organisational context, they may still be able to guide successful implementation by developing a meaningful working relationship with an enthusiastic research champion on site.

Chapter 5 How do researchers contribute to cluster retention in the RSIIYA trial and what are their experiences of managing multiple sites?

5.1 Chapter summary

This chapter reports a qualitative study which examined the research team's experiences of managing 45 school site relationships for four years as part of the RSIIYA trial. An audio-recording of an annual project review meeting held in the final year of the trial was closely examined to explore: (1) the day-to-day challenges of maintaining effective relationships across multiple sites, and how these were navigated by the researchers, and (2) the behaviours, attitudes and strategies drawn upon by the researchers as they tried to positively influence cluster site retention and engagement in the trial.

The chapter outlines recent, novel attempts to improve recruitment and retention within trials by understanding the detailed processes involved in these broad tasks, from the perspectives of the researchers involved. A detailed analysis is then provided of the experiences of researchers working in the RSIIYA trial. Finally, the results are discussed with reference to sources of influence, power, relational work and social capital.

5.2 Background

Building relationships with research sites is considered critical for their retention in studies (Lloyd et al., 2017; Pinto et al., 2018; Schoeppe et al., 2014). Recommended strategies for building relationships range from discrete tasks such as giving site staff personalised gifts, thank you notes, Christmas newsletters (e.g. Berry et al., 2013), holding regular meetings with site staff (Drews et al., 2009) and being a physical presence on site (Markoe Hayes et al., 2014), through to more complex, continuous tasks such as ongoing collaboration through face-to-face contact, ensuring communication is open, clear and flexible and promises are kept (Pinto et al., 2018), seeking and responding to feedback (Drews et al., 2009), providing support, quality feedback and a high degree of responsiveness (Leathem et al., 2009). Despite these numerous recommended strategies for building relationships, remarkably little is known about the interpersonal and emotional work researchers must invest to successfully build and sustain such relationships over time (Daykin et al., 2018).

The pivotal, relational function of the researcher in the retention process has been highlighted across three decades of retention research (e.g. Abshire et al., 2017; Davis et al.,

2002; Ribisl et al., 1996). A collection of skills and personality traits is considered particularly useful for retention. The necessary skills have been described, in broad terms, as competence, communication (Brueton, Stevenson, et al., 2014), interpersonal and collaboration skills (Abshire et al., 2017) and, more specifically, as the ability to establish trust (Davis et al., 2002), to build rapport, communicate empathy, demonstrate respect and confidentiality, listening skills, and the capacity to attend to non-verbal cues and respond appropriately (Ribisl et al., 1996). Beneficial personality traits include those likely to motivate participants, such as enthusiasm, being personable, flexible and sympathetic (Brueton, Stevenson, et al., 2014), and those more closely associated with resilience, such as assertiveness (Davis et al., 2002), “persistence, ingenuity, creativity and dedication” and “high tolerance for frustration” (Ribisl et al., 1996, p.8). The identification of these characteristics reflects an acknowledgement that retention work can be challenging and emotionally demanding (Ribisl et al., 1996).

There is growing interest in understanding more about these emotional demands or the ‘burden’ associated with trial work, and the degree to which they influence a trial’s trajectory, by asking researchers about their personal experiences of this work (e.g. Skea, Treweek & Gillies, 2017). This reflects a departure from the longstanding focus on the comparative effectiveness of particular retention or recruitment strategies towards establishing a clearer understanding of the processes involved in these tasks. By identifying difficulties at a process level and targeting them with training and support, it is hoped that outcomes may be more reliably improved (Donovan, Paramasivan, de Salis & Toerien, 2014). Three examples of studies exploring researchers’ trial ‘work’ are now outlined. The first two examples focus on researchers’ experiences of recruiting patients (Donovan et al., 2014; Skea et al., 2017). The third specifically addresses retention experiences (Daykin et al., 2018).

Donovan et al. (2014) interviewed 72 doctors, chief investigators, nurses and other health professionals responsible for recruiting patients in clinical settings across six different RCTs about their experiences of the process. Their grounded theory analysis revealed that recruitment was experienced as a “complex and fragile process” (p.1). Practical issues emerged, such as logistical/ organisational difficulties with nurses being unable to attend clinics to recruit potential patients, low numbers of eligible patients and patients expressing strong preferences for a specific condition. However other “previously hidden issues” (p.1) also became apparent. For example, doctors felt conflicted by their roles as both trial recruiter and physician responsible for the patient’s management; nurses found deciding whether to discuss the trial with a patient so stressful that they often avoided talking about it altogether.

The “discomfort and emotion” offered a more nuanced (but improvable through support and training) explanation for low recruitment levels (Donovan et al., 2014, p.1).

The “hidden and complex work” surrounding recruitment in clinical trials was also highlighted more recently by Skea et al. (2017, p.1). A range of interpersonal difficulties was identified from eleven in-depth interviews with staff recruiting to a multi-centre trial comparing interventions for ureteric stones. Recruiters found clinical staff hard to engage, due to a low interest in research generally, high workloads and/or high staff turnover rates, and a major issue was having no control over which patients were approached or how they were identified (Skea et al., 2017). The recruiters engaged in multiple problem solving strategies to try and address these issues, such as using creativity to engage staff and raise the trial’s visibility, eliciting the Principal Investigator’s support to increase staff/site ‘buy-in’ and establishing databases, calendar notifications and reminders to prompt staff to approach every eligible patient (Skea et al., 2017).

Calling for more qualitative, process research into retention, Daykin and colleagues’ (2018) cross-sectional qualitative study examined the steps trial teams took to retain participants, the reasons behind using particular retention strategies, and “factors which may influence their retention behaviours” (p.2). Interviews with 22 trial staff members, including research nurses, trial managers, research assistants/fellows, administrators and chief investigators, across five trials revealed that their individual behaviour impacted on retention through a series of recognised and unrecognised influences.

‘Recognised influences’ were those acknowledged easily by interviewees, and comprised pre-planned retention strategies documented in study protocol (e.g. incentives), responsive/unplanned strategies initiated to problem solve threats to trial engagement and building and sustaining good relationships with participants (e.g. offering tea during appointments) (Daykin et al., 2018). Interviewees underlined that considerable time and energy were required to establish and maintain these relationships, yet such efforts were neither routinely valued by their wider trial teams nor acknowledged within funding applications (Daykin et al., 2018). This feeling was also compounded by a sense that the system’ (i.e. trial funders and national research networks¹) principally emphasised recruitment and neglected retention (Daykin et al., 2018).

‘Unrecognised influences’ on interviewees’ retention behaviour were largely implicit

¹ Daykin et al.’s (2018) participants were members of active trials within the UK National Institute for Health Research Health Technology Assessment portfolio.

and unconscious, therefore were less immediately obvious to them and only emerged as they discussed retention in more depth (Daykin et al., 2018). The first unrecognised influence was their individual “moral compass” (p.7) or personal values and beliefs, and their inability to “be hard-nosed” (p.7). As active agents, they described using empathy to make personal, ethical judgements about how far to pursue participants for data. For example, if a participant had cancer and was unwell, they might choose not to press them for follow-up data because it felt uncomfortable, inappropriate and insensitive. This was also the case if the interviewee experienced role-friction, for example, as one interviewee (SI_STM3) described, whilst a nurse’s role is to *give* their care, “as a research nurse, they’re *taking*, and they’re not used to, or comfortable with that” (Daykin et al., 2018, p.7).

A second unrecognised influence emerging from the interviews with trial staff was the positive impact that providing incentives had on their confidence, comfort and ability to maintain contact with participants (Daykin et al., 2018). This reciprocity of offering something in exchange for participation meant that the interviewees felt less indebted, awkward and more comfortable about pursuing data.

The final unrecognised influence on interviewees’ retention behaviour was their level of trial experience (Daykin et al., 2018). More experienced trial staff considered withdrawal to have a number of levels and were confident to negotiate some level of data from uncertain participants. For example, if a participant chose to withdraw from treatment, they would be confident to still pursue outcome measure data (Daykin et al., 2018). Less experienced interviewees reported a more definitive approach, assuming that wanting to discontinue treatment meant a desire to withdraw from all aspects of the trial (Daykin et al., 2018).

Taken together, these qualitative findings indicate that researchers are active agents in the recruitment and retention process, whose behaviour influences participants beyond the tangible, well-documented strategies such as incentives. However these studies have involved hospital settings and clinicians, and Daykin et al.’s (2018) study focuses on researchers’ experiences of retaining individual participants in trials. It is unclear whether these experiences are similar to those of researchers working in non-clinical cluster trials as they try to retain organisational sites.

Researchers within cluster trials are “boundary spanners” across numerous organisational boundaries (Long et al., 2013, p.2) and retaining sites involves developing successful inter-organisational relationships between research institution and research site. However, inter-organisational relationships are notoriously “difficult to manage as a result of the complexities involved”, and many “fall short of meeting the expectations of their

participants or fail for other reasons” (Barringer & Harrison, 2000, p.368). Despite these challenges, the importance of the inter-organisational relationship within cluster trials necessarily supersedes that of the individual relationship. This is because there are fewer clusters than individual participants, and the consequences of a whole site disengaging or withdrawing are more deleterious than those of an individual member’s withdrawal (as discussed in chapter one).

As inter-organisational boundary spanners, university researchers involved in school-based research must navigate substantial organisational, philosophical and cultural differences (e.g. Petosa & Goodman, 1991; White, 2012), neatly encapsulated by Sirotnik (1991):

“School systems and universities are not cut from the same cultural cloth. The norms, roles and expectations of educators in each of these educational realms could not be more different, e.g. in the regiment of time and space in the schools vs. the relative freedom of these precious commodities in the university setting; an ethic of inquiry in the university vs. an ethic of action and meeting immediate needs in the schools” (Sirotnik, 1991, p.19).

The qualitative study described in this chapter examined four researchers’ experiences of building and maintaining inter-organisational relationships between their two universities and 45 schools within the RSIIYA trial. Specifically, it focused on understanding how the researchers managed to successfully retain 100% of schools in the trial, from the first round of data collection in 2012 to its conclusion in 2017. The aims of this study were to explore:

- (1) The day-to-day challenges of maintaining effective relationships across multiple sites, and how these were navigated by the researchers;
- (2) The behaviours, attitudes and strategies drawn upon by the researchers as they tried to positively influence cluster sites’ retention and engagement in the trial.

5.3 Method

5.3.1 Design

To understand more about the strategies the trial researchers used to promote retention and engagement and the challenges they faced managing cluster site relationships, a simple case study approach was adopted using secondary data. An audio recording was analysed in detail of an annual progress review meeting held between the four field researchers working on the RSIIYA trial (one of whom was the author). These meetings were routinely audio-recorded during the trial to facilitate the writing up of meeting minutes. At the third meeting in Autumn 2015, the cluster RCT was moving into its final academic year, and a specific agenda item was to review cluster engagement to date, to reflect on successes, share difficulties/concerns and

ideas for improvement for the last 12 months of the trial. This discussion segment was located within the meeting audio recording and was transcribed verbatim. As a member of the trial team under examination within this study, I was present at the audio-recorded meeting, therefore my words appear as data in the transcript. In this sense I was in the position of insider participant observer for this study because I was both “the instrument of inquiry as well as the subject of that inquiry” (Labaree, 2002, p.107).

5.3.2 Participants

We were four researchers, all psychologists, working together on the RSIIYA trial (see Table 5.1). None of us had managed a cluster trial before. We operated as two satellite teams: two of us were based at the University of Leeds (the author and researcher four); two were employed at Staffordshire University (researchers two and three). Only researchers two and three knew each other before the trial, having worked together on a previous project. The author and researcher two were the trial managers, had been part of the trial since its inception and had been responsible for cluster site recruitment. Researcher three had worked on the trial as a casual research assistant and had recently been promoted to Research Officer to cover participant two’s imminent maternity leave. Researcher four was a newly appointed Research Assistant on the Leeds team, and therefore was less able to contribute in detail during the discussion. She involved herself in the discussion by tending to ask questions and summarising to clarify key points.

Table 5.1 Researcher background information

Researcher	Age	Qualification	Years in research	Experience in schools	Interpersonal and communication skills
The author	40s	PhD Psychology (in progress) MSc Occupational Psychology BSc Psychology	> 15 years	Worked for local education authority delivering workshops to teachers and support staff (e.g. Counselling Skills). Supervision/support of pastoral care teams in school. Mother of teenager and former member of Parent-Teachers Association.	Lecturing, small group teaching, conference presentations, consultancy skills (organizational psychology), workshops, workplace coaching and counselling, management development programmes.
2	20s	Doctorate in Health Psychology MSc Health Psychology BSc Psychology	10 years	None prior to the trial.	Lecturing, small group teaching, conference presentations, consultancy skills (Health Psychology), workshops.
3	20s	Doctorate in Health Psychology (In progress) MSc Health Psychology BSc Psychology	10 years	None prior to the trial.	Lecturing, small group teaching, conference presentations, consultancy skills (Health Psychology).
4	20s	PhD Health Psychology MSc Health Psychology BSc Psychology	10 years	None prior to the trial.	Lecturing, small group teaching, conference presentations.

We maintained regular email and phone contact and met quarterly to discuss the design of the trial materials and cluster engagement activity. We were all female. I was the oldest (in my 40s) and the remaining three researchers were in their mid-late 20s.

5.3.3 Procedure

I contacted my three female colleagues by telephone to explain how I would like to use the existing audio recording of our meeting in Autumn 2015 for this study, as part of my PhD. I explained the aims of the study and sought their formal consent to be considered as participants and for the recording to be examined in close detail. I followed this up by emailing an information sheet (Appendix 10) with a consent form (Appendix 11), in which my fellow researchers registered their willingness to be re-termed 'participants' and allow their data to be used for analysis. I reassured the trial team that, although they were colleagues, they would become participants after consenting, therefore the same ethical guidelines would be observed with regard to the treatment of their data.

The audio recording was transcribed by an independent, professional transcription company (university-approved). The company was instructed to transcribe only the first 57 minutes of the meeting, which contained discussion of the agenda item of interest, i.e. the review of cluster engagement to date as the trial approached its final year. The final transcript was issued to all participants for sign off, providing the opportunity to remove any data. No issues were raised and all data remained as per the original audio recording

5.3.4 Analysis

The goal of the thematic analysis was to provide a rich description of the dataset, therefore all aspects of the data were coded to try and reflect the predominant, salient themes. A broadly realist epistemological stance was adopted in that I was interested in individual motivations, experiences and meanings. However, in my treatment of the data, I was also cognisant of the impact on our realities and experiences of the different, complex socio-cultural contexts we encountered across schools.

The transcript was carefully examined to identify and analyse patterns within the data, following the six phases outlined by Braun and Clarke (2006). I firstly familiarised myself with the data by listening to the audio recording, then reading and re-reading the transcript. I generated initial codes by reading through the transcript, taking a line at a time and coding interesting features in the margin. I then searched for themes by reviewing all the codes. During this process, I attended to both semantic and latent themes. I tried to determine any patterns and links between codes and I collated similar codes into potential themes. I then reviewed the themes to check if they worked on two levels; whether they accurately reflected (1) the coded extracts and (2) the transcript as a whole. Although I primarily used an inductive/bottom-up approach, i.e. I drew upon our words for the theme names, at this stage I also accessed relevant literature to understand more about the emerging themes and drew

upon this developed understanding to conceptualise the theme more accurately. This ‘flip-flopping’ between the literature and data continued into phase five of the analysis, as I defined and named the themes more clearly. I generated paragraphs defining each theme to ensure clarity, and spent time refining the specifics of each theme. As the analysis progressed, three distinct levels became apparent: (1) themes, (2) sub-themes, and (3) higher-level themes. These higher-level themes were defined as ‘categories’. Whilst a ‘category’ is typically associated with grounded theory, it is also considered acceptable to adopt the term within thematic analyses where appropriate (Madill, 2008).

5.3.5 Ethical considerations

All four research staff had verbally consented to the meeting being recorded as an Aide Memoire when typing up minutes. This was normal procedure for our meetings. Approval was sought from the University of Leeds School of Psychology Ethics Committee (reference: 17-0020; 23/1/2017) to use the audio recording for research purposes. Consent was then obtained from participants for it to be transcribed verbatim and their personal data to be used. The consent form signified that the audio recording would be used in a different capacity from its original, informal intention, i.e. within a formal piece of research and subject to the required ethical protocols and professional standards.

Although the original audio recording of the meeting had been deleted from the recording device, the audio file remained stored in a shared folder accessible to all trial researchers and Principal Investigators. Following ethical approval and participant consent to use this file for research purposes, it was moved to the PhD researcher’s local-networked, password protected drive and renamed for anonymity/confidentiality purposes. The audio file was deleted after transcription.

During transcription all identifying information was anonymised so the participants and people and places they mentioned were unlikely to be identifiable within any publication or dissemination of the findings. Given the change of use of the material, all consenting participants were also asked to read the full transcript and to black out anything they would not like to be used before any analysis commenced. This allowed them to withdraw any particular aspects they were uncomfortable with and gave them final sign off of their words for analysis. None of the researchers took up this offer. However, had any researcher not consented, their data would have been removed from the transcript before it was sent to consenting participants for checking.

The anonymised transcript, in addition to other participant data, are being held electronically, confidentially and securely on a password-protected computer for up to five

years, after which time these will also be deleted. Consent forms are stored separately from the transcript to preserve anonymity further, and are being held securely in locked drawers for confidentiality. They will be kept securely for audit purposes up to 5 years after any final publication.

5.4 Results

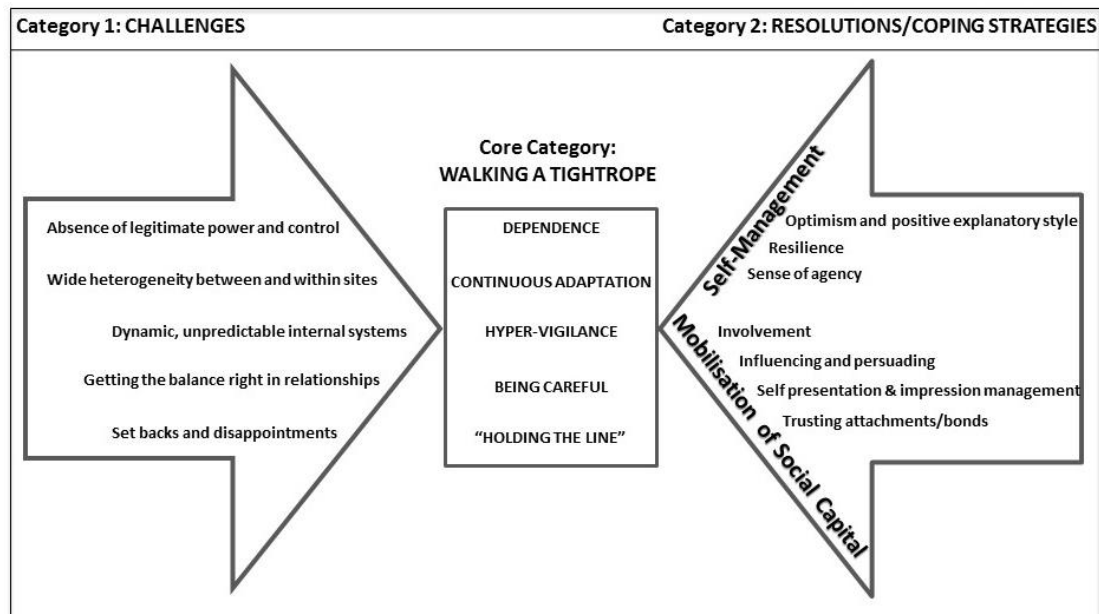
5.4.1 High level summary

‘Walking a tightrope’ was identified as the core category, representing our experience of navigating the perpetual risk of a school disengaging and withdrawing from the trial (see Figure 5.1). Five themes were associated with this core category: *dependence* upon site staff (theme 1), *continuous adaptation* to diverse situations (theme 2), *hyper-vigilance* (theme 3) to any potential retention threats, *being careful* (theme 4) to preserve site relationships and *‘holding the line’* (theme 5) in the face of setbacks.

The core category of **‘walking a tightrope’** and its themes were direct consequences of being confronted with particular **‘challenges’** (category 1): *an absence of legitimate power and control* (theme 1); wide *heterogeneity between and within sites* (theme 2); *dynamic, unpredictable internal systems* (theme 3); *getting the balance right in relationships* (theme 4); *dealing with setbacks and disappointments* (theme 5). **Resolutions/coping strategies** (category 2) were engaged to deal with the **challenges** and moderate the emotional impact of **‘walking a tightrope’**. This category consisted of two themes: *self-management strategies* (theme 1) and *mobilising social capital* (theme 2). *Self-management strategies* (theme 1) involved three sub-themes: *optimism and having a positive explanatory style* (sub-theme 1); *resilience* (sub-theme 2); *a sense of agency* (sub-theme 3).

Mobilising social capital (theme 2) between cluster site members and ourselves, reflected our relational investment at each site to help us implement the trial, given our limited access and control. It contained four sub-themes: *involvement techniques* (sub-theme 1), *influencing and persuading strategies* (sub-theme 2), *self-presentation and impression management* (sub-theme 3) and *trusting attachments/bonds* (sub-theme 4).

Figure 5.1 Representation of the relationship between categories and themes arising from the researcher review meeting analysis



The core category 'walking a tightrope' is now described in more detail, followed by categories one 'challenges' and two 'resolutions/coping strategies'.

5.4.2 Core category: Walking a tightrope

We were all cognisant of the importance of retaining the individual sites we were responsible for and of the need to engage school staff in the process. However, we found these two tasks to be complex, protracted and fragile. We harboured an enduring sense that we could not take site relationships for granted because schools were in a state of constant flux. Each site was a unique, continuously changing entity and working relationships required ongoing monitoring, risk-management and maintenance until the final data were collected. The five themes below are direct consequences or impacts arising from five challenges (core category 1) themes which then follow.

Core theme 1: Dependence

As university staff who were neither employed by nor based at the participating school sites, we were 'outsiders', unfamiliar with schools' people, processes and systems. In this sense we were entirely dependent on 'insider' cluster members to complete tasks:

"Rather than it being something you can just go ahead and do independently and have ticked off, you're relying on other individuals to get back" (The author: 83-85).

In particular, we had to trust that study coordinators would ensure tasks were implemented, whilst understanding that our trial-related tasks were less important to them than they were to us. We could never be sure if planned tasks were actually taking place in the manner we

agreed with the site, or indeed if they took place at all. We often felt uncertain or 'in the dark' about why our attempts to plan tasks at a particular site sometimes failed, and this was a source of frustration:

"You'll email dates, and try and get people to actually attend the training, and it might not happen because, for a number of reasons. And we don't fully know the underlying reasons. But it could be that, you know, the key contacts might not be pushing it enough or actually saying there's just not enough time" (Researcher 2: 295-298).

Core theme 2: Continuous adaptation

We experienced extreme variability in culture, resources, staff personalities, capacity and commitment both between and within sites. This demanded ongoing adaptation, both interpersonally and strategically. Adaptations were frequently required in the moment, in response to unexpected, isolated situations. For example, finding on arrival at a school for a meeting that the teacher only has 5 minutes, we had to quickly strip the meeting back to its bare essentials. On other occasions we encountered changes in school or staff characteristics which required a more fundamental, sustained adaptation. For example, finding that a school was moving from hourly PSHE lessons to drop down days we had to reconsider how to plan trial tasks. These continuous adaptations were challenging when multiplied across 45 sites:

"It's you know, high.. interpersonally demanding I would say. You've got to be quite tough" (Researcher 2: 613-614).

Continuous interpersonal adaptation was also necessary to provide personalised consideration to the diverse range of schools and their staff involved in the trial. We recognised the need to mentally prepare and adapt our approach to each site and each staff member, in order to build rapport and productive working relationships:

"It's not like just working in one school, where you kind of know the person, you know how they're going to be each time you go in. But working with twenty five, you kind of have to mentally readjust every time you go to a school: 'okay what am I going to expect this time? Who am I seeing? What are they like? What are their kind of, what is it, personality traits or foibles?'" (Researcher 2: 616-620).

Core theme 3: Hyper-vigilance

Each school was a complex system and challenges occurred daily, including student crises, urgent safeguarding issues, staff sickness absences, resignations and Ofsted inspections. These led to us becoming hyper-vigilant for any signs of potential risks to engagement and retention. If planned meetings or sessions were cancelled we had to ensure that these were re-arranged, and also be hyper-vigilant about any emerging patterns which might suggest disengagement, such as not replying to emails. A pivotal risk point was when a coordinator resigned:

“We’ve struck a relationship up with somebody and then that changes doesn’t it, sometimes when they move on” (Researcher 2: 217-218).

We were conscious of monitoring the situation closely in these particular schools and establishing whether a new coordinator had been nominated and when we could brief them about the trial. This constant hyper-vigilance sometimes resulted in stress and worry, particularly at certain task points in the trial, such as when trying to plan in data collection sessions:

“There are nights when you don’t sleep, where you think, ‘I haven’t heard from that school’” (Researcher 2: 380-381).

Core theme 4: Being careful

The phrase ‘being careful’ appeared frequently in the meeting transcript. It was used in relation to not wanting to overwhelm a particular school with requests, if we sensed that they were experiencing difficulties internally or were beginning to tire of tasks:

“So it’s just being really careful that we don’t, you know, start to...Overburden them” (The author: 118-119).

Being careful was also used in connection with ensuring tasks were completed: we needed to be assertive in our interactions with cluster site staff, but if this was perceived as too forceful we risked alienating sites:

“You’ve got to have the drive but then you can’t be too controlling” (The author: 379-380).

We needed to ‘be careful’ in our relationships, particularly with study coordinators. We were conscious of not crossing the professional boundary into friendship. Ultimately we were acting in a professional capacity to implement the trial and we needed to subtly resist the relationship becoming too informal without threatening their engagement:

“You’ve got to be careful going onto the friendship level I suppose, in some cases, because some people will say ‘oh, what gym do you go to, we could do a class together!’ [...] I had one person say that [...] It’s just being really careful and knowing how to get it back up to the professional but friendly level. It is, without damaging the relationship” (Researcher 2: 664-675).

We also had to be careful not to cross the boundary from trial manager into therapist if personal disclosures were made by staff. These had to be managed sensitively, and frequently led to feelings of tension about personal and professional boundaries:

“Because you don’t want them to disengage with you because, obviously, we need to keep these key contacts engaged. But it’s being careful to be abiding to our professional standards too, of what we can actually say” (Researcher 2: 70-72).

Theme 5: Holding the line

To preserve relationships, we understood the importance of suppressing negative emotions, such as frustration and disappointment, and displaying positive emotions, such as enthusiasm, even if these were not felt:

- The author: “You can’t just think they’re not interested I’m going to take my ball home, I’m just going to go through the motions, we can’t do that and we don’t feel like doing that but...
- Researcher 2: You just have to keep suggesting it, so every meeting you have you keep suggesting the workshops and different things and still maintain like a very friendly and positive approach with each one” (529-533).

In this sense, we felt we had to ‘hold the line’, i.e. not react negatively, but instead try to be resilient and remain focused on the ultimate goal of retaining a working relationship until the trial completed.

5.4.3 Category 1: Challenges

Challenges theme 1: Absence of legitimate power and control

This theme refers to the difficulties of managing the trial as invited guests, or outsiders, in 45 school sites. Without detailed knowledge of the people, processes and systems in each organisation, direct access to these resources or the legitimate power or authority to utilise/manipulate them (i.e. we were not members of the school leadership team), we needed to mobilise organisational resources within these diverse school sites to complete trial tasks. In this sense we were ‘managing’ without the traditional resources most managers have available to them in their own organisations.

This lack of access, formal authority and control caused considerable frustration throughout the trial. Because we were not based on site, we regularly experienced difficulties in accessing the necessary cluster members when we needed to discuss, plan or follow-up important tasks. These staff typically had heavy teaching commitments, multiple competing demands and often no formal office or direct/dedicated telephone number. This meant that completing a single trial task, such as planning a data collection session, would typically require multiple contact attempts even in one school, and these multiple attempts would be required simultaneously across all 45 sites:

“But that lack of control is a theme all the way through, isn’t it, because, you know, you want to be able to contact somebody and tick a job off, but if they’re not available you can’t do that, it’s out of your hands. So you’ve got to kind of go back” (Researcher 3: 376-378).

Having no formal authority to ensure teachers attended training sessions was also difficult: we were aware of the benefits for staff involvement and implementation quality if

they attended, and of the issues regarding protocol adherence if they did not. Frustration also emanated on occasions from a lack of control in how well the intervention/control lessons were delivered during fidelity observations. We could only watch as an impartial observer and offer supportive feedback at the end of the session:

“I felt the session wasn’t delivered as best as what it probably could have been. And that’s something that’s hard because you can’t always control teachers and the way they teach” (Researcher 2: 318-320).

Challenges theme 2: Wide heterogeneity between and within sites

Unexpectedly, we found the school cluster sites to be extremely different from each other, with their own particular internal systems, structures and culture:

“Some schools are a lot more kind of, I don’t know, engaging. And personal almost. Yeah, whereas some were very kind of to the point, very formal, in and out basically” (The author: 13-17).

The equipment and resources in each school also varied considerably, for example some schools were still using overhead projectors and acetates; others had electronic smartboards in each classroom.

The atmosphere of each site remained variable, depending on what had taken place prior to our visit. Within a single school there was often high variability between teachers’ attitudes towards the study and in their approaches to delivering the intervention or control lessons. Some teachers delivered the lessons with enthusiasm, conviction and engaged the students, whereas others would “just go through the motions and the kids just look bored in the lessons and don’t go with it” (the author: 330-331).

The range of staff we liaised with was diverse and each member had particular idiosyncrasies. For example, teachers in some schools hugged us on arrival, made us cups of tea and introduced us warmly to other staff members during our visits, seemingly proud of being part of the study. In other schools, we were met with a formal handshake and given just 15 minutes in the reception area. The personality, attitude and commitment of the appointed study coordinators were highly variable:

“Sometimes you’ll get a key contact that’s seeming to be really, you know, motivated about it, and excited about it, and almost wants to prove that they, you know, that they can do it, and organised and getting back to you straight away and putting it as a priority. And then you may get the other side of, you know, the scale where an individual is less likely to be pushing it and, because of other demands and just seeing it as something else that’s put on their to-do list” (Researcher 3: 158-163).

Challenges theme 3: Dynamic, unstable internal systems

This theme deals with the ever-changing, unpredictable nature of the school systems we interacted with. This instability took different forms, including staff turnover, changing internal priorities and increasing demands at different times of the academic year, and these were all potential retention risks. Some risks were moderate, such as when meetings were cancelled and had to be revised or rescheduled:

“I’ll email the week prior and just say ‘Is it still okay?’ and they’ve said ‘oh no, sorry, I forgot to book it in, I’ll let you know when I can’. So that can be a little hard, especially if you start preparing the sessions for that particular school and then they cancel” (The author: 483-486).

Some risks arising from the instability were high, such as when trusted, productive relationships with study coordinators unexpectedly changed due to increasing responsibilities or workloads in school. Staff resignations, promotions, maternity leave or illness were also sources of high risk. The process of establishing a working relationship had to start afresh, which could be difficult or straightforward depending on whether there was any succession planning.

Challenges theme 4: Getting the balance right in relationships

This theme reflects the tensions we experienced in negotiating long-term relationships and task completion during the trial. We had to strike a fine balance between maintaining warm, trusting relationships with school staff and assertively pursuing completion of trial tasks with them:

“It’s a kind of give and take and you’re trying to get the balance right” (Researcher 2: 122-123).

This was an ongoing challenge across the duration of the trial, as we weighed up the opposing costs and benefits of pursuing too hard with regard to site relationships and protocol adherence: push too little and tasks may not be prioritised; push too hard and sites may be alienated and withdraw:

“When they don’t get back to you, you’re really aware not to push them too much that they start to disengage and find the project demands too high” (The author: 116-118).

We also experienced challenges associated with establishing and maintaining ongoing, warm relationships with site staff whilst maintaining personal/professional boundaries. We particularly invested in the relationship with study coordinators and sought to build trust, communicate to them that they were important to us and make personal interactions enjoyable. In response, some staff responded to us on a very personal level, intimating that they would like to develop a friendship:

Other staff disclosed a high degree of personal information, such as work difficulties, body image issues and mental health problems. It was hard to determine whether this was due to the individual's natural openness, cues we may have given, or a lay understanding of the role of the psychologist as a form of counsellor:

"A couple of teachers they will start talking a little bit about their personal life and issues that they've got in their personal life and their work, professional life, which they've brought up and started to discuss. However I'm not sure whether they would just talk about that with anybody or whether it is because they know the psychological background, you know what I mean?" (Researcher 2; 61-65).

We were mindful that these micro-level exchanges posed retention/engagement risks from two perspectives. First, if we responded by encouraging too much elaboration of their problem, not only would this take the exchange beyond our role as trial manager, and our ethical limitations/professional capacity, but the study coordinator may also later feel embarrassed that they disclosed too much, which may alter the dynamics of the relationship and cause them to withdraw. Second, if we brushed off the comment or ignored it, we also risked relationship/trust damage.

Challenges theme 5: Setbacks and disappointments

This final challenges theme encapsulates the regular setbacks and disappointments we experienced whilst interacting with each cluster. Examples of setbacks and disappointments include poor student behaviour during data collection which went unchallenged by teachers, teacher resentment, disinterest or discourteous treatment (e.g. driving a long distance for a meeting with a teacher, who arrives to collect us from reception very late and then explains they only have 5 minutes). Disappointment was also experienced in response to discouraging feedback about materials we had spent considerable time designing, and the incomplete execution of tasks, despite extensive reminders and support:

"Sometimes we're having to keep them motivated, and keep them going, when actually sometimes we feel a bit run down with it and feeling a bit like 'tried to contact this particular school seventeen times, you know, in two weeks'. And I finally get there and, you know, it's not quite been done" (The author, line 593-596).

5.4.4 Category 2: Resolutions/coping strategies

Resolutions/coping strategies theme 1: Self-management

This theme reflects the intra-personal strategies used to cope with the challenges discussed (category 1) and their overall impact ('walking a tightrope'; core category). These were personality- and cognitively-based, associated with values, attitudes, beliefs and also with the interpretation and attribution of meaning given to external situations/events.

Sub-theme 1: Optimism and positive explanatory style: This sub-theme reflects the optimism that was present during the meeting about working with the cluster sites, despite the challenges. We all considered working with different schools, people and tasks to be enriching and interesting:

“I like visits, I like going to see them in their own environments and I like experiencing, I like the kind of challenge of what’s it going to be like in this school today” (The author: 126-127)

Having an optimistic outlook seemed to help us cognitively reframe some of the challenges into potential opportunities. For example, when one of the team became pregnant towards the end of the trial, instead of worrying about the impact of a temporary leave of absence, she viewed it as a human experience through which she and her school contacts could relate to each other:

“I actually thought, like a positive side of being pregnant is that it could engage!” (Researcher 2: 136).

Similarly, the potential opportunities resulting from a longstanding study coordinator’s departure from the school, was recognised:

“We can sometimes inherit a new person who’s much more enthusiastic than the other person who left” (Researcher 2: 176-177).

Our working relationships with schools enabled us to develop detailed insights into the challenges they faced. We quickly came to understand that the organisational/professional context for the trial was one of excessive demands on teachers, insufficient time, stress and low morale. Gaining this contextual knowledge helped us to consider the trial from their perspective:

“It’s another demand, isn’t it, on top of their role?” (The author, 570-571).

Whilst this challenging context was frustrating to work in as a researcher, being able to empathise with the teachers’ situations helped us explain some of the difficulties we were experiencing. For example, we sometimes experienced brusque interpersonal behaviour from teachers, and whilst in the moment this felt annoying, disrespectful or even shocking, we would try to reign in any negative thoughts/emotions about why they were behaving that way, and put ourselves in their position:

“Fortunately, my tricky lady is going to be moving on [...] and now somebody else is coming back. It wasn’t her choice to do it and I think that’s the difficult thing, when it’s not your choice and you’re being given an extra responsibility on an already busy role, it’s hard isn’t it?” (The author: 571-574).

If we could remain calm in this way, we were more likely to be able to negotiate and be assertive within the situation. Explaining or attributing negative events (e.g. tasks not being completed on time) to external factors (e.g. this teacher is incredibly busy) rather than to

internal, personal factors (e.g. this teacher couldn't care less about the research) represented a positive explanatory style. This positive explanatory style helped to limit negative emotions we experienced after a disappointment, and also helped us to feel hopeful about influencing the situation:

"Obviously it might not be anything to do with us, like it could be just her workload [...] you know, you've got to not take it personal" (Researcher 3: 546-547).

Sub-theme 2: Resilience: 'Walking a tightrope' was demanding and involved considerable resilience, persistence and problem solving. Examples of the daily obstacles we encountered included: schools deciding to change the way PSHCE was delivered (thereby limiting the timetable availability for delivering our trial tasks), study coordinators' sickness absence and cancellation of meetings/planned tasks. All these were threats/risks to the trial which had to be managed, and often required numerous attempts at problem solving to ultimately resolve:

"It's that kind of problem solving thing though, I think, that is really key though, isn't it, because you sort of try one strategy and that might not work, so you try something else and that might not work, you try something else, and it's that resilience to kind of keep going down other routes, isn't it, that I think is really important" (Researcher 2: 524-527).

Dealing with wide variability in terms of systems, culture and staff both within and between schools demanded flexibility, adaptation and persistence to increase the likelihood that tasks would be completed as per protocol. For example, we needed to invest more interpersonal effort in those less engaged study coordinators, such as showing empathy for their already high workloads, exploring what was particularly difficult for them with the trial, asking what additional help we could offer and following through on promises. Relationships with highly engaged coordinators also required investment and energy through ad-hoc emails, cards, letters of gratitude to their managers, remembering small but significant things such as birthdays, family events or illnesses.

Most importantly, the more experience we acquired through the trial, the more we came to accept that some issues could not be resolved, and that there were limits to our influence as outsiders:

"Then there's a certain time when you have to let it go because you can't control everything" (Researcher 2: 565-566).

Sub-theme 3: Sense of agency: Closely linked to resilience, this sub-theme reflects the sense of agency and personal responsibility we felt as a group towards the trial. We had been involved in recruiting the schools, developing protocol and an infrastructure, designing materials, building relationships and training staff, to the extent that:

"You feel like you've got an investment in making it work" (The author: 403).

Given that none of us had managed a cluster trial before, we reflected on the cumulatively positive effect on our sense of self-efficacy and confidence as we successfully navigated critical stages of the trial:

“Kind of proving each time that you can do it when you get through a phase. [...] And that gives you more confidence to keep going and, as you go through each phase, you kind of show that it can be done. So it gives you confidence in the future” (Researcher 2: 190-195).

“I think I feel like confidence to work with a range of people, so I think confidence and experience, in terms of developing my interpersonal skills and feeling confident to run such a big trial” (Researcher 2: 188-189).

Confronted with a lack of control and ambiguity/uncertainty, we found ourselves over time introducing informal systems to create the perception of order and control. These helped to reduce the cognitive load that would otherwise be required to continuously problem solve contact difficulties on an individual basis.

Having explored the use of self-management to cope with the challenges we experienced, this section now describes how we tried to resolve these through the mobilisation of social capital between site members and ourselves.

Resolutions/coping strategies theme 2: Mobilisation of Social Capital

This theme reflects the approach we took to try and manage engagement and implementation of trial tasks within the cluster sites, under the circumstances of being an outsider, without legitimate power/authority, knowledge of systems or access to site resources. Building warm, respectful relationships helped mobilise social capital, such as trust, cooperation and reciprocity, which increased our sphere of influence over the sites, despite our low control and legitimate power. As outsiders we sought to *involve* site members in the trial as collaborative partners, we drew upon *influencing and persuading* strategies to motivate staff and students, engaged in *self-presentation and impression management* and developing *trusting attachments and bonds*. Each of these four sub-themes is now explained.

Sub-theme 1: Involvement: As outsiders, managing the trial predominantly off-site, we were unable to personally oversee the completion of tasks in 45 schools. We were immediately aware that we needed to generate good will and interest from site staff, to want to be involved and therefore we attempted to create a sense of shared ownership for the project. This sub-theme reflects the approach we took to engage site staff in the trial by positioning it as a collaborative project between ourselves and schools, working together towards a shared, mutually important goal of reducing smoking in adolescents:

“We really need to work together with the professionals like you, you’ve got the students, you’ve got the teacher knowledge”, you know, “we’ve got the health

background, you know we would really love to work with you together on this, to be able to resolve it [smoking]”. That’s the kind of line we took, wasn’t it?” (The author: 268-271)

We delivered assemblies to outline the study to students, training sessions for staff, and introduced a system for students and staff to share their feedback with the universities after each intervention/control session. We held keep-in-touch annual review meetings with study coordinators where we also sought feedback, and updated them on what we changed as a result of previous feedback:

“I’ve had good feedback that they like to be able to have, there’s a mechanism for capturing what they feel about things, and that we’ve tried to incorporate things in. And we feed that back to the coordinators and then they pass that on to the staff, don’t they? And say: “you know, they can’t change it but they’re building this in”, or “they’re going to do this”, or “they’re going to do that”” (The author: 305-310).

Our hope throughout the trial was that by helping staff and students to feel involved, and by reinforcing that they were involved in something valuable and important, we would increase their sense of commitment to and ownership to it.

Sub-theme 2: Influencing and persuading: This sub-theme reflects the use of ‘pull’ as opposed to ‘push’ styles of influencing and persuading which we adopted during the trial. We endeavoured to position the trial as an important and valuable project to be part of, promoting its benefits, in a motivating, positive manner:

“I almost think it was almost acting like in a business role, when recruiting the schools, in a sense of selling it and making it sound straightforward and easy and that sort of thing. Not lying or anything like that but also making it... playing the strengths, almost like as if you’re selling something, like a businesswoman” (Researcher 2: 262-265).

We drew upon the principle of credibility to influence continued participation, by underlining the range of health experts involved in the trial, not just within our two universities, but also specialists in public health and smoking in the area. Similarly, we offered schools our psychology expertise through volunteering to support Health Fairs, Careers days, contributing to GCSE and A-level lessons on research methods, and delivering workshops to students on topics such as ‘looking after yourself during exams’, ‘revision tips’ and to staff on areas such as ‘work-life balance’, ‘self-harm’, ‘supporting students with mental health issues’. We provided regular reports on cohort smoking data, which were valued:

“They felt they could get something from it also, as well, you know, that they were going to get, exactly as you said, they were going to get the stats, they were attracted to that” (The author: 246-248).

These contributions also relate to the principle of reciprocity: in offering services which schools valued, we were able to reciprocate their commitment to the trial. This appeared to help retention because our continued partnership was mutually rewarding:

“It’s a kind of give and take” (Researcher 2: 122).

We recognised that site staff were managing multiple demands and across four years could not be expected to intrinsically retain knowledge and enthusiasm for the trial. Therefore we used motivational approaches during our interactions, particularly with our study coordinators, to reassure them, celebrate progress and help them prepare them for the next steps:

The author: “It’s making them see light at the end of the tunnel as well, so...

Researcher 3: You’re nearly there, yeah.

The author: ...we’re in the final push of the project, you know, you’ve only got four more things really to do, so keep going and then we’ll be out of your hair.

Researcher 2: I think that’s important, isn’t it, like stating that, that there’s just two more of this and two more of that, oh look how close we are to the end.

The author: So we're Mr. Motivator aren't we? We’re kind of adjusting their expectations and trying to motivate them” (583-591).

We found the annual review meetings very useful in motivating the study coordinators, and helping them to bring into focus the importance and value of the study:

“Because I think they lose track of why they're doing it and what's the main outcome” (Researcher 2: 495).

Sub-theme 3: Self-presentation and impression management: This theme reflects how we tried to adjust to the wide variety of situations we experienced by using social intuition, sensitivity to social cues and interpreting non-verbal behaviour of site staff. We used this information to adapt our own behaviour, in an attempt to present an appropriate self-image and thereby manage the impression we transmitted.

“You’ll have to kind of adapt your approach and the way you are to the person” (Researcher 2: 29-30).

Throughout the transcript, we used phrases such as “you get a feeling for that person”, “you feel it when you walk through the door”, which seemed to suggest a social intuition, a sensitivity to atmospheres or an ability to ‘read’ a situation. This helped us to be flexible in our approach, and personalise our interaction to meet the needs of the person and situation:

“I’ve got one key contact who’s quite formal in their approach and that sort of thing, so I will try and push other sides of the engagement activities, like to suggest that we can do things to keep them more engaged but not necessarily taking them up, so whereas others I will add more time, like I will ask more questions and try and, you know, I will try and put a bit more effort, you put a lot of effort into each one, don’t you?” (Researcher 2: 517-521).

Impression management was important during setbacks and unexpected events, because we engaged in self-monitoring to minimise any non-verbal ‘leakage’ of any strong emotions we felt:

“I’ve got to still put a smile on my face and say ‘well done for doing those three lessons, really appreciate it’” (The author: 596-597).

It was also important to help maintain personal-professional boundaries. Despite investing in warm relationships with staff and students, we were conscious of representing the university and maintaining a professional persona, particularly when staff disclosed personal difficulties. We supported them through non-verbal reassurance and initial empathy, but tried not to “get drawn into it”.

Sub-theme 4: Trusting attachments and bonds: This theme involves relational work invested to develop attachments and trust with site staff. When the trial began, the study coordinators, teaching staff delivering the intervention/control and students had no relationship with us, but were nevertheless asked to undertake, on our behalf, additional tasks beyond their usual workload, for four years. We considered it important to try and make the process rewarding for those involved, and to communicate that we valued their contribution to the trial. For example, with the students:

“When we’re out doing the data collection [...] it’s managing that in a way that we’re respectful to students, thanking them for what they’re doing, you know [...] people tell me, you know, in schools that goes a long way” (The author: 413-415).

We hoped that by building warm relationships during emails, phone calls and site visits, and by behaving consistently and reliably, we could earn site members’ trust and be considered less ‘outsiders’ and more collaborator-colleagues. By taking an interest in them as individuals, making ourselves human and relatable, we found that site staff and students were often more committed to completing tasks because they wanted to do it for us personally:

Researcher 3: “They’re more likely to be invested in the project, I think.

The author: Yeah, and have a connection with you, yeah.

Researcher 2: If they like you and they kind of want to do it for you in a way.

The author: I think that’s right, I get that vibe that some of it isn’t necessarily that they really value the lesson, it’s that they really like being in the study and they like, you know, the kind of contact

Researcher 2: The personal aspect” (679-685).

We particularly invested in building attachments and bonds with the study coordinators in each school, because they shouldered the greatest responsibility for the trial. It seemed important morally/ethically to do what we could to help them feel supported, appreciated and part of a team, otherwise they might fail to engage with the trial, lose motivation or give

trial tasks low priority. We built unique relationships with each coordinator, and personalised our contact to engage with them on a human level, for example:

- | | |
|--------------|---|
| Researcher 3 | “I think engaging the key contacts, you know, say the key contact's going on maternity leave, or they've had something happen |
| The author | Weddings |
| Researcher 2 | Yeah a wedding, if you give a little gift |
| The author | Bereavement cards I've sent as well” (655-660). |

Over time we experienced changes in trust levels between trial staff and cluster site members. For example during data collection sessions, students began to behave differently with us as the trial progressed. For example:

“The first year they were obviously asking a lot of questions and wondering what it was about and a bit nervous, thinking are their results going to be shared, even though you emphasise that they're not. But now, [...] they seem to know what it's all about, they're really happy to take part, some want to hang back and stay with us so they don't have to go back to class” (Researcher 2: 439-443).

Given our frequent school visits and phone calls, we built warm, effective working relationships with many school receptionists. This proved very useful when trying to contact staff members because they typically operated the school switchboard and would ‘go the extra mile’ to determine a teacher's location and availability if we needed to contact them. Some receptionists emailed teachers internally or spoke to them in the staffroom on our behalf to request that they contact us.

The bonds we developed were meaningful for us as researchers. We frequently looked forward to visits, and whilst these would remain professional, we connected with study coordinators as if we were team colleagues. We were often hugged on arrival, provided with cake and coffee at our meetings, we sometimes received a small gift at Christmas time and numerous teachers bought our pregnant trial manager gifts when she took maternity leave:

“I've had people saying, ‘can you please get in touch I want to know how it goes’, and then lots of people telling me about their experiences, so it's kind of connected me with some of them on a different level” (Researcher 2: 141-143).

At numerous points during the transcript, we all commented on the scope of relationships we needed to develop and maintain and on the intense interpersonal nature of being a cluster trial researcher

“I think you need to be a people person really, if not that would be a really difficult job, the amount of people that you interact with” (Researcher 2: 130-131).

5.5 Discussion

The aims of this study were to explore (1) the day-to-day challenges of maintaining effective relationships across multiple sites and how these were navigated by the researchers and (2) the behaviours, attitudes and strategies drawn upon by the researchers as they tried to positively influence cluster sites' engagement and retention in the trial.

The overall experience of maintaining effective relationships across sites was analogous to 'walking a tightrope', in that we navigated an ever-present risk of schools disengaging and withdrawing from the trial. The day to day challenges of maintaining effective relationships centred around an absence of legitimate power and control, wide heterogeneity between and within sites, dynamic, unpredictable internal systems and a need to appropriately balance relationships and handle set-backs. The impact of these challenges was a heavy *dependence* upon site staff, having to *continuously adapt* to diverse situations, *hyper-vigilance* to detect any potential retention threats, *being careful* to preserve positive site relationships and having to '*hold the line*'. To resolve or cope with these challenges we drew upon self-management strategies and invested in mobilising social capital between cluster site members and ourselves.

Our experiences of retention as a precarious, complex process, involving extensive hidden 'work' within this study are strikingly similar to other researchers' experiences of recruitment (Donovan et al., 2014; Skea et al., 2017). Our investing considerable time and energy in developing relationships and the need to problem solve retention threats, also reflects the researchers' retention experiences in Daykin et al.'s (2018) study. The finding that numerous researcher-factors and behaviours appeared to be important for retention, beyond the formal, documented retention strategies, supports earlier findings by Daykin et al. (2018). Many of the characteristics and skills we drew upon in this study have been previously highlighted as important in previous reviews (Abshire et al., 2017; Brueton, Stevenson, et al., 2014; Davis et al., 2002; Ribisl et al., 1996). Similar to Daykin et al.'s (2018) finding that being able to offer incentives had a positive impact on researchers' motivation to pursue participant data, we found that adopting a collaborative approach and offering psychological services helped us to reconcile the additional demands we placed upon staff. We also experienced difficulties with turnover rates of coordinators, struggled with a lack of control, had to be creative to engage staff and adopt systems to help prompt and remind staff, which reflect the experiences of those recruiting to clinical studies in Skea et al.'s (2017) study.

A number of the challenges we faced have been highlighted by other researchers working with schools, including wide heterogeneity between and within schools (Befort et al.,

2008; Caan et al., 2015; Witt, 1986), dynamic unpredictable systems (Christenson et al., 2002), loss of control when an intervention is trialled in a real-world setting (Lawton et al., 2011), and being dependent on already over-burdened teachers to deliver tasks (Forman et al., 2009). However, in a departure from much of this previous research, the current findings have revealed additional, relational challenges related to leading a trial as an outsider, such as how to influence cluster members to complete tasks with no legitimate power, striking the right balance in relationships and handling set-backs and disappointments, both publicly and privately. Furthermore, it has demonstrated the impact of these challenges on the researcher, specifically, having to continuously adapt, being hyper-vigilant for signs of disengagement, careful in relationships and managing emotional responses.

Risk and trust | Our experience of sustaining 45 school-university relationships as ongoing risk management is reflected in the literature surrounding inter-organisational collaborations (Bachmann, 2001; Barringer & Harrison, 2000). Inter-organisational relationships are widely acknowledged to be high-risk undertakings (Bachman, 2001). Uncertainty surrounds whether staff will cooperate ('relational risks') and whether the alliance objectives will be achieved, given the competence of those involved or unforeseen, adverse events ('performance risks') (Das & Teng, 2001). For the cluster trial researcher, relational risks include misaligned goals between the university and cluster site, and low commitment/engagement of site members.

Performance risks, particularly when testing a complex health intervention, include uncertainty over the completion of trial tasks, according to protocol. Relational and performance risks can be reduced by managing expectations between organisational members, through the development of trust and exertion of control (Bachman, 2001; Das & Teng, 2002). Establishing trust leads to positive expectations of each other, and exerting power or influence within alliance relationships can help to control behaviour (Bachman, 2001). Both control and trust were key themes within the current study, and these are now discussed in more depth.

Building trust reduces relational risk within inter-organisational alliance (Das & Teng, 2001) and is more likely to lead to successful outcomes and business performance (Liu, 2015). Trust between organisations (i.e. macro level trust) emanates from trust at the individual and team level (i.e. micro level trust) (Bachman, 2001; Das & Teng, 2002; Liu, 2015), and declining individual bonds are associated with a breakdown in inter-organisational relationships (Das & Teng, 2001). This suggests that a researcher's investment in building trusting, one-to-one

relationships with cluster site members (micro-level trust) may be rewarded with the retention of their cluster (macro-level trust).

Trust is established through a dynamic process of continuous learning on the parts of those involved (Liu, 2015). Liu (2015) describes three aspects of trust: competence (based on experience, qualifications, profession, work standards, ability), reliability (created by keeping promises, predictability, credibility) and goodwill (resulting from honesty, openness, integrity, shared values and emotional connection). These aspects of trust build cumulatively: the most basic level of trust, competence trust, is established first, followed by reliability trust, then, when people begin to have faith in each other and care about each other's welfare, the deepest level of trust has formed, i.e. goodwill trust (Liu, 2015). Establishing trust between organisations takes considerable effort and time as it moves through five distinct phases: initial building, confirmation/disconfirmation (e.g. promises are kept/not kept), developing, stabilising and sustaining (Huang & Wilkinson, 2014).

Investing in the deepest, strongest form of trust, goodwill trust, is recommended to reduce relational risk (Das & Teng, 2002). To do this, Das and Teng (2002) suggest establishing mutual interests, finding opportunities to confirm similar values and norms, and working through difficulties collaboratively. However there are calls for a better understanding of the in-depth activities involved in earning trust (Liu, 2015). One source of understanding may be usefully derived from the literature surrounding relational work. Relational work is considered vital within complex settings where uncertainty may be involved (DeFrino, 2009), and refers to "the ability to create, sustain and effectively manage relationships" (Cathcart, 2014, p.44). Broadly, relational work involves demonstrating values of mutuality and respect for others, being sensitive to the emotional context and effective listening skills, however four specific *practices* of relational work have been identified by Fletcher, Jordan and Miller (2000):

1. *Preserving* – taking responsibility, resolving conflict, anticipating problems and intervening, prioritising the needs of the project.
2. *Mutual empowering* – sharing information, providing support without making the recipient feel guilty, and being flexible when necessary.
3. *Self-achieving* – using relational skills to improve one's capacity to meet objectives. Using feelings about a situation as source of information to understand and anticipate reactions, responding appropriately to others' emotions using intuition.
4. *Creating team* – facilitating a team-oriented climate by treating people as individuals through being respectful and responsive, but also by establishing structural practices to encourage connections and interdependence.

Positive outcomes are more likely when people feel connected, supported, where relationships are prioritised, and there is a degree of interdependence and reliance upon one another, and these are the main goals of relational work (DeFrino, 2009). Leaders engaging in relational work engender higher relational trust in their teams, creating the conditions for collaboration, motivation and action which are associated with higher goal achievement (Helstad & Møller, 2013; Riggio & Reichard, 2008). The relational work undertaken by nurses with their patients to understand and support them as individuals with personal histories is linked to their recovery (DeFrino, 2009). Multi-disciplinary healthcare teams investing in relational work with each other tend to have higher quality communication and shared ownership of tasks, which are associated with high performance (Gittell, Seidner & Wimbush, 2010). Further evidence of a positive association between relational work and outcomes can be found within the psychotherapy research literature. A strong, collaborative ‘working alliance’ between therapist and client is reliably associated with positive therapeutic outcomes (Castonguay, Constantino & Holtforth, 2006; Muntigl & Horvath, 2014). A high quality ‘working alliance’ consists of shared *goals* sanctioned by both parties, shared *bonds*, i.e. trust, acceptance, strong attachments and confidence in each other, and shared *tasks*, where both take responsibility for the work involved in therapy (Muntigl & Horvath, 2014).

On close inspection, it could be argued that, as a group of researchers, we engaged in all four of Fletcher et al.’s (2000) relational practices, given there are numerous examples in the transcript. Taking these examples into consideration, it is possible that our engagement in these relational practices with individual cluster members, particularly the study coordinators, may have contributed to our high cluster retention rate. By building and sustaining individual relational trust and a sense of connection and support, we were able to reduce the relational risk within the cluster trial. The literature surrounding relational work and trust can also help to explain, firstly, why time is necessary to build relationships (e.g. Daykin et al., 2018) and, secondly, the particular value of researchers holding more advanced, relational skills. The literature suggests that if an organisational boundary spanner such as a researcher lacks relational skills, such as the ability to build rapport, demonstrate respect, empathy, confidentiality, to respond to non-verbal cues (Ribisl et al., 1996) and to establish a collaborative climate (Abshire et al., 2017), then the deepest level of trust, goodwill, may not be earned. Low levels of goodwill trust ultimately have implications for commitment, particularly within longitudinal cluster trials where uncertainty and complexity must be managed through relationships over extended periods.

Although relational work is acknowledged as extremely important for successful outcomes in leadership, team relationships, nursing and therapeutic work and inter-organisational collaborations, it also has a history of being undervalued or hidden within research (as highlighted by researchers within Dayton et al.'s (2018) retention study). Such relational work is intangible and therefore arguably falls outside the traditional medical model or positivist paradigm. From a retention perspective, parallels can be drawn between nurses' work and the cluster researchers' work (e.g. DeFrino, 2009). DeFrino (2009) differentiates between the visible and invisible nature of nurses' work. Visible work includes giving medication, setting up an IV and feeding the patient (DeFrino, 2009). Invisible work is relational, private, between people, and includes listening, responding appropriately, increasing one's knowledge about a person, connecting with them, building rapport and understanding and showing care (DeFrino, 2009). If we apply these distinctions to the cluster trial researcher, particularly to retention, visible retention work includes providing incentives, newsletters, update information, sending reminders and establishing tracking systems. The invisible retention work is represented by all the relational work highlighted within the current study (at the inter- and intra-personal level).

Control: Informal versus formal | Relational work also played a significant role in navigating the absence of legitimate power in each cluster site, and the corresponding issue of control. Control is considered vitally important within inter-organisational relationships to ensure that tasks are completed according to plan and that goals are met (Das & Teng, 2002). If behaviour can be 'controlled', uncertainty and complexity are reduced (Bachman, 2001) and relational and performance risks are minimised (Das & Teng, 2002).

Bachman (2001) and Das and Teng (2002) differentiate between formal and informal control, both of which have a direct impact on trust within inter-organisational alliances. Formal control involves the adoption of protocol, procedures, monitoring and rewards; informal control involves using personal power to influence people's behaviour (Bachman, 2001; Das & Teng, 2002). Employing strict, formal control during inter-organisational relationships can undermine goodwill trust, because those being 'controlled' are given little autonomy, which can make them feel untrustworthy (Das & Teng, 2002). In terms of outcome, this approach is more likely to lead to compliance (i.e. grudgingly complying and needing frequent prompting to complete) or resistance (i.e. outright refusal, stalling or making excuses) (Kreitner, Kinicki & Buelens, 2002).

Conversely, informal or social control involves interpersonal investment on the part of the 'controller' to encourage desirable behaviour through establishing norms, shared

values and internal adoption of mutual goals (Das & Teng, 2002). Whilst formal control is considered damaging to trust, informal control is seen as trust-enhancing (Das & Teng, 2002), with commitment being a more likely outcome, i.e. enthusiasm, demonstrating initiative and persistence to complete the task (Kreitner et al., 2002). Through “frequent meetings and communications, culture blending and socialization”, and “a recognition of each other’s competence”, social control engenders a sense of mutual goodwill trust (Das & Teng, 2002, p. 264)

As cluster trial researchers testing a complex health intervention, formal control mechanisms were necessary. For example, we required signed partnership agreements which underlined mutual expectations, clusters were required to follow documented protocol, staff were trained in how to deliver the intervention and we conducted monitoring observations. We were mindful of pushing too hard and damaging trust. This ‘push’ style approach was likely to lead to compliance or even resistance, rather than commitment to the study (Kreitner et al., 2002).

At face value, we had no legitimate power or “formal right to interfere in the teachers’ work” (Helstad & Møller, 2013, p. 260), and were dependent on study coordinators for access to information, people and resources within each school (Mechanic, 1962). It was necessary therefore to build goodwill trust, drawing upon interpersonal and relational skills, to help us personally influence behaviour at each site. By reiterating our shared goals, involving staff and students in the study, seeking and responding to their feedback, establishing rituals such as networking during school visits with staff, regular communication, annual review meetings, ceremonial presentations of annual framed certificates, each site and researcher benefitted from a ‘blending’ of organisational cultures or socialisation process, and we created our own norms for the trial (Muchinsky, 2003). This may have contributed to goodwill trust and informal control.

Sources of power | A person’s capacity to influence or exert social control over another’s behaviour is defined as social power (Kreitner et al., 2002). French et al. (1959) identified five bases of social power when individuals seek to influence others’ behaviour: reward power (promising or providing rewards), coercive power (using threats or actual punishments), legitimate power (based on authority), expert power (possessing knowledge or information) and referent power (based on personal charisma and attractiveness, and the influencee’s identification with the influencer). Expert and referent power are “attributed to one person by another”, i.e. they must be perceived by the person being influenced (Martin, 1978).

As researcher-outsiders, legitimate power to influence site staff was not available to us, and wielding coercive power would not only have been unethical, but there is also evidence that its use in the workplace has a negative impact on work outcomes (Podsakoff & Schriesheim, 1985). Fortunately, the most effective power bases for social influence, particularly within a work setting, have been identified as expert and referent power (Podsakoff & Shriesheim, 1985). Writing about the consulting role of school psychologists, Martin (1978) argues that expertise is a necessary, but not sufficient, characteristic, of a consultant, and that referent power is crucial. According to Martin (1978), accruing referent power takes time, because it requires “genuine liking or attraction for one another” (p. 53). Those you wish to influence need to get to know you, and you them, and this occurs through spending as much time together as possible, sharing small talk and more meaningful information and contributing to extra school activities (Martin, 1978). Over time, both parties begin to understand each other’s attitudes and personal qualities, which hopefully leads to identification and thus the acquisition of referent power (Martin, 1978). Skills and qualities needed to accrue referent power in these circumstances are intertwined with trust building, and once again, associated with relational work (Martin, 1978).

It could be argued that expert and referent power were both available to us as researchers. As psychologists with expertise in health and wellbeing we supported schools with stands at health fairs and careers events and delivered wellbeing workshops for students and staff, potentially increasing our ‘expert power’ base (and competence trust) within our schools. One indicator of this is that a number of teachers approached us about personal difficulties they experienced. We may have acquired ‘referent power’ during relational work undertaken to build goodwill trust, such as valuing cluster members’ opinions, involving them and creating warm attachments, and our ongoing self- and impression management during difficult situations.

Relational Social Capital | Collectively, the extensive relational work we undertook, as researchers, in seeking to build trustful relationships, foster collaboration, and our willingness to share our psychology skills beyond the immediate context of the study to reciprocate schools’ commitment to us, appeared to be successful in mobilising inter-organisational social capital. Social capital “reflects a primordial feature of social life – namely that social ties of one kind (e.g. friendship) often can be used for different purposes (e.g. moral and material support, work and non-work advice)” (Adler & Kwon, 2002, p. 17). Using Kwon and Adler’s (2014) assessment of how social capital is created, one interpretation of our high retention success is that our investment in building mutually rewarding relationships

helped to create a network of goodwill between ourselves and our 45 sites. Through frequent, sustained interactions during the study, a unique socialisation process occurred at every site between individual site members, and ourselves wherein we generated our own unique shared norms and values. Each goodwill network, comprising researcher and cluster members at each site, provided a rich source of mutually beneficial resources, qualities and skills (held by each individual within it), which could be drawn upon by those involved. Cluster members drew upon this social capital for psychological and academic advice, and for instrumental support (e.g. helping at health and careers fairs in school): as researchers, we fundamentally drew upon this social capital to help us achieve trial tasks (through social influence). As trial managers, it could be argued that we played a central role in each social network, and findings from the current study support Kwon and Adler's (2014) assertion that, people who occupy central roles in social networks usually possess strong social skills and impression management skills.

A large literature surrounds the importance of social capital for successful inter-organisational alliances (Adler & Kwon, 2002; Kwon & Adler, 2014; Steinmo & Rasmussen, 2018). Focusing specifically on university-industry partnerships to develop new technological innovations, Steinmo and Rasmussen (2018) underscore the need to be able to sustain collaboration over time, whilst negotiating multiple, complex processes. Steinmo and Rasmussen (2018) identify two key dimensions to social capital in the context of inter-organisational alliances: cognitive and relational. Cognitive social capital exists between organisations when they share goals and have similar cultures, whilst relational capital results from trust, mutual respect, warm attachments and perceptions of reciprocity or fair rewards for their efforts (Steinmo & Rasmussen, 2018). Relational social capital, otherwise known as 'being trusted' (Castelfranchi, Falcone & Marzo, 2006), is considered the most important ingredient for successful inter-organisational alliances (as previously highlighted by Bachman, 2001; Das & Teng, 2002; Liu, 2015): when relational social capital exists between organisations, members are more trusting, open and willing to share their information and resources (Steinmo & Rasmussen, 2018).

5.5.1 Strengths and limitations

This study offers a novel contribution to the retention literature on three fronts. Firstly, it adds to the knowledge surrounding the retention of cluster sites which has been given far less attention in the literature than participant retention. Secondly, it has used a case study approach to understand the lived experiences of successful trial staff as they approached the end of a longitudinal cluster trial, rather than the more common approach of seeking their

generic, accumulated knowledge about effective retention strategies. Because the researchers were still involved in the trial, this study was able to capture a moment in time which provided rich detail. It has been able to illustrate, not only the challenges experienced, but also how these were navigated at an inter- and intra-personal level. Thirdly, by firmly positioning the university-cluster site relationship as an inter-organisational alliance, it has been able to draw upon a rich body of organisational psychology literature to provide a more nuanced, in-depth insight into the complexities and uncertainties involved in sustaining inter-organisational relationships over time.

One potential limitation is that the two Principal Investigators of the RSIIYA trial were not present for the audio-recorded review meeting, and therefore their views are not reflected in the study. It is possible that they had different perspectives on or perceptions of our cluster work. However, the aim of the study was to explore the field researchers' experiences of navigating longitudinal relationships with cluster sites, and since the Principal Investigators had no contact with the schools, they were unable to contribute their experiences. Moreover, it is possible that, despite our trusting relationship with them, their presence may have tempered our discussion due to social desirability factors, meaning that we were less open and honest.

A second limitation is that this study reflects just one case, and the findings may not be generalisable to other researchers' experiences of managing different cluster trials. We were inexperienced in trial management, therefore the findings may be more a function of this rather than managing a cluster trial per se. For example, our experience of 'walking a tightrope' may be indicative of the higher risk we perceived as new trial managers without the confidence of previous trials behind us (see Siegrist, Gutscher & Earle, 2005). However, irrespective of our position, the findings reflect our initiation into cluster trial management, which is an equally valuable contribution to the literature. Further, similar studies would provide opportunity to corroborate our findings.

Thirdly, all the researchers were psychologists, therefore our experiences may not be representative of the community of researchers at large. Furthermore, we were four female psychologists, and it is unclear whether our gender influenced our approach to retention. For example, gender has been found to affect perception of risk, with females tending to express greater risk concerns than men, for example in relation to technologies and the environment (Siegrist, Gutscher & Earle, 2005). One hypothesis is that heightened awareness of or concern about the possibility of withdrawal may motivate females to use more strategies in the hope of minimising this risk. Some support for this hypothesis can be found in retention survey

conducted by Butler et al. (2013). Female researchers in their survey reported using significantly more retention strategies than male researchers. Given that most “US researchers tend to be male”, Butler et al.’s (2013, p.66) 79% female sample (N=249 respondents) may not have been representative of US researchers overall. However these findings raise the question of whether a researcher’s approach to retention, specifically their willingness to utilise multiple, complex strategies is influenced by gender. Furthermore, it is unclear whether our gender influenced our relational approach to retention: relational work has a long history of being considered ‘women’s work’, and being devalued accordingly (DeFrino, 2009; Fletcher et al., 2000).

A final consideration is my role as participant-observer in this study: how the data resonates with a researcher in this position inevitably influences the meaning-making process and the choice of themes highlighted in the data (Medico & Santiago-Delefosse, 2014). As an insider-participant observer, I have endeavoured to be transparent and reflexive throughout the analytic process. With regard to transparency, I wrote memos to (a) document key decisions I made to label, merge or break-up themes, and (b) record significant reading I had undertaken which had influenced my decisions or interpretation. I discussed the analytic process, interpretation of the data and personal reflections at numerous stages of development with an independent supervisor specialising in qualitative research (AM). I ensured that all participants were represented within the quotes selected as exemplars of each theme.

5.5.2 Implications

The findings from this study suggest that the longitudinal retention of cluster sites is a complex and uncertain process, and as a result places significant inter- and intra-personal demands upon trial staff. The inter- and intra-personal strategies used by the researchers appeared to be important for retention, and were used in addition to those well-documented retention strategies in the literature. This study also provides further support for the need to recruit staff to cluster trials who have strong interpersonal and relational skills, and who have characteristics associated with resilience and optimism, as recommended by researchers such as Ribisl et al. (1996). Such individuals are more likely to be able to build relationships and manage their wellbeing during challenging times. In addition, the findings also suggest a critical requirement to train cluster trial staff in the typical challenges of inter-organisational working, strategies to navigate these, the processes involved in building trusting relationships and in mobilising relational social capital. Similarly, providing ongoing, formalised support, such as regular team meetings, to share concerns, air frustrations and discuss alternative

techniques are likely to improve researcher self-efficacy, maintain wellbeing and contribute to successful cluster retention. This reinforces calls for better retention training and support of trial staff from the participant retention literature (e.g. Brueton, Stevenson et al., 2014; Ribisl et al., 1996).

5.5.3 Conclusion

The findings from this study suggest that formal retention strategies alone, such as incentives, reminders, effective tracking, are necessary but not sufficient for successful retention. Successful site retention depends on researchers investing in complex, hidden interpersonal and relational work, which adds an emotional burden to their role. This emotional burden must be moderated through self-management strategies and support, otherwise this stress/tension may 'leak' into site relationships and potentially affect engagement in the trial. There is growing acknowledgement that developing relationships and trust, requires considerable time and investment on the part of the researcher (e.g. Dayton et al., 2018; Drews et al., 2009; Schoeppe et al., 2014), particularly when forging new collaborative inter-organisational partnerships (Liu, 2015; Steinmo & Rasmussen, 2018). The findings from this study provide further support for calls to reflect this within grant applications, to increase the profile of and investment in retention work so it is comparable to that of recruitment (Dayton et al., 2018).

Finally, given that three decades of research into effective retention strategies have failed to reveal a panacea, there is a strong argument for a paradigm shift in how we research retention. Instead of focusing on *what* works in retention the findings of this study suggest that there is value in pursuing a more in-depth, qualitative understanding of the processes involved, i.e. studying *how* retention takes place.

Chapter 6 What are teachers' experiences of belonging to the RSIIYA trial and delivering the intervention and control lessons?

6.1 Chapter summary

This chapter reports a mixed methods study which examined teachers' experiences of being involved in the RSIIYA trial and of delivering the intervention or associated control lesson. Transcripts from twelve semi-structured interviews involving teachers from control and intervention schools and 568 teacher lesson feedback sheets were analysed to understand in depth and at scale how teachers experienced being part of the trial.

Given that the PSHE curriculum in schools was the intended delivery vehicle for the smoking prevention and control/pro-homework lessons, this study sought to understand whether and how teachers' perceptions of their school's PSHE provision shaped their experiences of delivery. Secondly this study explores teachers' perceptions of the trial and their experiences of delivering the intervention/control lessons. Drawing upon the implementation science literature, this chapter highlights some of the factors identified as moderating 'practitioner' engagement in delivering complex interventions. It also examines briefly the status of PSHE education in schools. A detailed analysis then follows of the experiences of teaching staff who, as cluster 'practitioners', were responsible for delivering the intervention and control lessons to students within the 20 participating Yorkshire high schools.

6.2 Background

People who participate in trials, including practitioners/implementers of interventions in pragmatic cluster trials, are not simply "passive recipients of assigned conditions" (Skingley et al., 2014, p.752). They are active agents (Coday et al., 2005), whose behaviour is influenced by their own cognition (i.e. knowledge, beliefs, thoughts, ideas, perceptions and memories (Hogg & Vaughan, 2005)), their emotions, the people around them and by their environmental context (Skingley et al., 2014). The ways in which people experience a trial, and make sense of being involved in it are likely to affect their engagement, which in turn affects their behaviour, their decision to remain in the trial, and, potentially, trial outcomes (Heaven et al., 2006; MacNeill, Foley, Quirk & McCambridge, 2016).

In pragmatic cluster trials, trial staff tend to have limited direct contact with participants and interact mostly with those implementing the trial on site. This means that

they have scope to impact the implementers *directly*, but are only able to impact on participants *indirectly*, through the implementers. These implementers are in a highly influential position to model positive, negative or neutral attitudes about the trial and the intervention (or control) to recipient cluster members. The ways in which these implementers understand and experience a cluster trial are likely to influence their commitment to it and their engagement in their delivery role, which ultimately impact on trial outcomes (e.g. Riley & Hawe, 2009).

The requirement to deliver an intervention (or control) may well be presented to individual practitioners within clusters as a ‘fait accompli’, which may have implications for their understanding of the trial, feelings of involvement, engagement and commitment. Cluster site recruitment efforts and discussions about the randomisation process typically target organisational gatekeepers and decision makers who can authorise a cluster’s participation (Walker et al., 2000). Within school-based trials, particularly those involving secondary schools which may have a vast teaching staff, logistical issues are likely to prohibit each teacher’s opinion being sought before a cluster-level decision is made to participate (for a discussion of ethical issues in cluster trials, see Campbell et al., 2012).

Despite a potentially low level of involvement in their cluster’s decision to participate in a pragmatic cluster trial, the cluster member practitioner delivering the associated intervention (or control) carries a high proportion of the responsibility for its success. They determine three of eight² dimensions of implementation which have been found to influence outcomes (Schoenfelder, 2012): (1) the quality of intervention delivery, (2) degree of adaptation made and (3) fidelity or adherence to protocol during delivery (Berkel, Mauricio, Schoenfelder & Sandler, 2011; Dane & Schneider, 1998; Durlak & Dupre, 2008). A fourth variable dimension, participant responsiveness (i.e. level of participation and enthusiasm), is determined by the intervention recipient/participant (Schoenfelder, 2012). Whilst the deliverer and recipient determine their particular variable dimensions, the four dimensions are inextricably linked (Berkel et al., 2011). *Participant responsiveness* to an intervention may well be influenced by the quality of delivery, adherence to protocol and choice of adaptations made (Berkel et al., 2011). Conversely, deliverers may find that recipients do not like their intervention, triggering an interpersonal barrier to their engagement with it, which may affect

² The remaining dimensions are: participant responsiveness; program differentiation or uniqueness; dosage; reach; monitoring of services or input received outside of the intervention/control conditions (Berkel et al., 2011; Dane & Schneider, 1998; Durlak & Dupre, 2008).

their quality of delivery, fidelity and potentially degree of adaptation (Carroll et al., 2007; Lawton et al., 2011).

The critical role played by the *quality* of delivery in influencing participant responsiveness has tended to receive less attention in the literature than *fidelity* of delivery (i.e. basic adherence to protocol) (Berkell et al., 2011; Low, Van Ryzin, Brown, Smith & Haggerty, 2014). Quality of delivery is defined as the “processes used to convey program material to participants”, and includes interactive teaching, enthusiasm, clarity, fostering a safe, supportive and cohesive environment and relational skills (Berkel et al., 2011, p.4). In trials testing classroom-based interventions in schools, teachers’ active engagement in and commitment to these lessons are considered vital for their successful delivery. For example, Pettigrew and colleagues (2015) found that the delivery of a substance use prevention programme within an ‘engaging classroom’ significantly predicted superior outcomes. Simple adherence to protocol was related to a significant reduction in alcohol consumption, but high quality delivery, featuring engaged teachers (defined by being attentive, enthusiastic, serious, clear and positive) and students (paying attention, participating) significantly “predicted reductions in *all* types of substance use” (Pettigrew et al., 2015, p.11). In other words, adherence is necessary but not sufficient for intervention success.

The enthusiasm and energy required to make trial-related lessons ‘work’ has also been identified in process evaluations of school-based prevention interventions. For example, teachers who delivered an HIV/AIDS intervention in South Africa underlined: “you had to be committed.. to think of ideas of making it interesting... it was not just a question of standing there and giving them the information, you had to be involved” (Mukoma et al., 2009, p.43). Experienced school-based researchers acknowledge that a teacher’s attitude can be “make or break... whether it went... how the class reacted to it” (Stallard et al., 2013, p.32). This association between students being engaged (due to teachers’ efforts) in interventions and their ultimate success has parallels within education research which reports a consistently positive relationship between student engagement and school achievement (Low et al., 2014).

Engaging individual teachers in delivering prevention education is far from straightforward: in comparison to new educational innovations (e.g. a new approach to language teaching), teachers’ individual motivation for delivering prevention interventions is highly variable (Haataja, Ahtola, Poskiparta & Salmivalli, 2015). It is not uncommon for aspects of a prevention intervention/programme to be disregarded or not delivered as planned (Haataja et al., 2015). Furthermore, whilst teachers’ use of a new educational innovation

typically becomes more efficient over time as their confidence and familiarity grows, fidelity when delivering prevention education programmes tends to decline (Haataja et al., 2015).

When participating in health-related research, teacher and student engagement is affected by the degree of importance senior leadership teams generally place on student health and wellbeing (e.g., Renes et al., 2007) and within UK schools this is highly variable (Glover, 2017). Most schools provide some form of personal, social, health and economic (PSHE) education, but it is a non-statutory subject with no formal structure, i.e. there is no national curriculum (Department for Education, 2015). This has led to wide variation in curriculae between British schools “even down to the name of the lesson” (Glover, 2017, p.157). In secondary schools, curriculum time allocated to PSHE education has declined by 30% since 2011 (Department for Education, 2015). The quality of PSHE provision is also inconsistent. In 2013, Ofsted issued their critical report of PSHE education provision in English schools which concluded that PSHE was “not yet good enough”. Student learning in PSHE in 40% of schools inspected was inadequate or required improvement; “subject-specific training and support were too often inadequate” and in 20% of schools teachers had “little or no training and teaching was not good in any of these schools” (The Office for Standards in Education, 2013, p.7).

These findings were echoed by English teachers contributing to a cluster trial which evaluated a school-based CBT intervention (Stallard et al., 2013). They spoke of PSHE being “undervalued and under-resourced”, “not given the proper priority it should be” and of students not taking PSHE lessons seriously (Stallard et al., 2013, p.32). These teachers also underlined the variable nature of delivery for PSHE, stressing that the quality of delivery of an intervention “would depend on individual teachers” (Stallard et al., 2013, p.33).

Many argue that this de-valuing of PSHE education emanates from education policy which drives schools to “maximize students’ academic attainment and ignore their broader wellbeing, personal development and health” (Bonell et al., 2014, p.348). However there is evidence that the low status perception of non-academic, personal life skills education is not confined to the UK. For example, this was also experienced by Mukoma and colleagues (2009) in South Africa.

The implementation science literature highlights numerous factors which have been found to moderate the engagement of those delivering interventions and the quality of implementation. These include characteristics of the person implementing the intervention (or control), characteristics of the intervention (or control) being delivered and factors within the delivery context (Durlak & Dupre, 2008).

Implementer characteristics: Characteristics of the implementer play a significant role in being engaged in a trial and delivering an intervention (or control) (Durlak & Dupre, 2008). Implementers are more likely to engage with and deliver an intervention well if they perceive that it meets a specific need and they have faith or belief that it will bring valued benefits (Carroll et al., 2007; Durlak & Dupre, 2008; Lawton et al., 2011). Teachers regarding a prevention programme as consistent with their personal beliefs and effective are more likely to dedicate more time and effort into helping it succeed (Haataja et al., 2015). Self-efficacy, or having confidence in one's ability to do what is required, and feeling appropriately skilled to deliver the intervention are also related to higher quality implementation (Durlak & Dupre, 2008).

Characteristics of the intervention (or control) are also important factors in engagement and implementation quality (Durlak & Dupre, 2008). In addition to personal beliefs about effectiveness noted above, interventions considered to be compatible with an organisation's priorities or goals, and which may be tailored to meet the needs of the deliverer and recipients are associated with higher quality implementation (Durlak & Dupre, 2008). Teachers are more likely to be engaged in an intervention or programme if they consider it easy to use (Haataja et al., 2015). Also related to the characteristics of the intervention are the recipients' views on its acceptability: an interpersonal barrier to engagement for those delivering an intervention is finding that the recipients do not like it (Carroll et al., 2007; Lawton et al., 2011). The less enthusiastic participants are, the less likely implementers are to embrace the intervention (or control) and deliver fully (Carroll et al., 2007).

The perception of personal gain has been cited as a major reason for participating in trials (Petersen, Zoffman, Kjærgaard, Stensballe & Greisen, 2014), therefore being allocated the control condition can be a significant barrier to engagement. Within schools, senior leadership teams are not happy to act as a control condition whilst their counterparts receive an innovative intervention/approach (Harrell et al., 2000; Petosa & Goodman, 1991). Disappointment is common, particularly in health research (Peterson et al., 2014) or "resentful demoralization" may be experienced (Skingley et al., 2014, p.752). As active agents in trials, people's reactions to being allocated to the control condition depend on how they make sense of the outcome and the extent to which they come to terms with it (Peterson et al., 2014). For example, in a Danish trial investigating the effects of the BCG tuberculosis vaccine on healthy newborns, parents' reactions when allocated the control (i.e. no vaccine/intervention) differed according to how important they considered their trial participation and the vaccine itself. If participating was important to them, 'control' parents

positively rationalized not receiving the vaccine with views such as “we’re supporting science with no risk” and “maybe our next child will benefit” (if the vaccine *was* important to them) or “we’re still getting special attention” (if the vaccine was *not* particularly important to them) (Peterson et al., 2014, p.5). Different appraisals were made if participating in the trial was *not* important to them. Control parents spoke of “not giving it any attention” since being informed of this, or expressed doubts that they were in a trial at all (if the vaccine was *not* important to them) or de-motivation and anger (if getting the vaccine had been important to them) (Peterson et al., 2014, p.5).

Factors within the delivery context: Contextual barriers may also impede an implementer’s engagement in a pragmatic trial, such as having insufficient time or support to deliver the required tasks (Carroll et al., 2007; Lawton et al., 2011). As a trial progresses, further barriers may emerge if completing intervention- or trial-related tasks become difficult to incorporate into existing systems, or if leadership teams and staff do not perceive the work as legitimate (Grant et al., 2013).

A different theoretical framework for encapsulating these factors, specifically for teachers delivering interventions, has been offered by Hall’s (2013) Concerns-based Adoption Model. Hall’s (2013) model posits that for teachers to engage with and deliver classroom-based interventions/programmes effectively, they must overcome three key concerns related to self, task and impact. As Hall (2013) describes, *self* concern relates to teachers’ capacity and competence to deliver an intervention (linked to implementer characteristics above), *task* concern relates to how it will be accommodated in the curriculum (linked to contextual factors above), and *impact* concern refers to whether it will benefit staff or students (linked to implementer and intervention characteristics above). Sufficient training and preparation tend to assuage teachers’ self concerns and task concerns may be reduced through leadership support for practical issues (e.g. creating timetable space) and reinforcing intervention messages around school (Haataja et al., 2015). However impact-concerns continue to influence teachers’ level of enthusiasm during delivery to students (Haataja et al., 2015). Typically, self and task concerns reduce once teachers begin delivering the intervention/programme in question, whilst impact concerns actually increase (Haataja et al., 2015).

Implementers as ‘active agents’ adopting roles and positions: Beyond the well-documented factors moderating implementer engagement and delivery quality, other researchers have argued that there is a need to study at a more nuanced level how

implementers in trials perceive, understand and evaluate of their role in a trial, within their specific organizational contexts. For example, Riley and Hawe (2009) argued that:

“Understandings are needed that appreciate the complexity of the phenomenon, taking into account the sometimes vexed experiences of practitioners at the coal face of intervention implementation. In particular, the practitioner’s viewpoint may be critical for illuminating theories of action that could strengthen intervention effectiveness” (para. 1).

Riley and Hawe (2009) sought to understand the different personal motivations and positions adopted by practitioners implementing a preventive community-based intervention for new mothers. Despite similar training and roles, and similar barriers/facilitators, each practitioner demonstrated personal agency by adopting a unique role and position within the trial (Riley & Hawe, 2009). From a narrative analysis of practitioners’ detailed field diaries kept over two years, Riley and Hawe created a typology of practice consisting of seven attributes, five of which were reported in their 2009 paper and now summarized very briefly.

The ‘romantic’ type of practitioner prioritises relationships over trial-related tasks or delivery of the intervention; the ‘technologist type’ is compliant and reliable with respect to management directives, and can be relied upon to “act as a conduit for the values and principles embedded in the design” of the intervention (Riley & Hawe, 2009, para. 50). The ‘against the odds’ type is likely to be optimistic and positive about the trial initially and about what the intervention can achieve, but over time this erodes as they begin to perceive obstacles and barriers too difficult to overcome (Riley & Hawe, 2009). The ‘satirist’ type is apathetic about delivering the intervention because it occupies a small space in their overall world, and adopts a passive role, seeing the ‘system’ as ruining their delivery of the intervention (Riley & Hawe, 2009). Finally, the ‘heroic’ type is imbued with a personal responsibility for making the intervention work and creates a narrative of others blocking their endeavours (e.g. related to decisions or resources) and themselves devising strategies to manage these blocking tactics (Riley & Hawe, 2009). In summary, these ‘types’ also serve to highlight the significant personal influence brought to bear by individual implementers upon their delivery of a trial-related intervention and how their personal influence determines the trajectory of a trial in their cluster.

Research Questions

It is clear that in pragmatic cluster trials implementers play a pivotal role in influencing outcomes. In school-based cluster trials, if positive outcomes are related to student responsiveness to an intervention (or control), student responsiveness is associated with high quality delivery, and high quality delivery is determined by teacher enthusiasm and

commitment (i.e. engagement), then it is important to understand factors affecting teachers' engagement. Furthermore, within trials testing prevention interventions, it is important to determine if and how any local ambivalence towards general student wellbeing and health education and specifically towards prevention education, affects teacher engagement. The aims of this study were therefore to understand:

- (1) To what extent did teachers adhere to lesson-related protocol within the trial (as a proxy for overall engagement)?
- (2) What are teachers' experiences of delivering the intervention/control lessons and what factors influence this?
- (3) What are teachers' perceptions of being part of the RSIIYA trial?
- (4) What are teachers experiences of the PSHE education context in their school and if/how do these affect their engagement with the lessons?
- (5) Do teachers' experiences differ according to condition?

Findings from study one with study coordinators in participating schools (chapter four) revealed tentative differences related to the characteristics of schools, specifically their Ofsted rating and community served. Specifically, study coordinators in low Ofsted schools reported more barriers and lower levels of organisational support and staff cohesion; coordinators in disadvantaged schools spoke more often about valuing the relationship with the researcher and the university. Therefore supplementary analyses were also undertaken to determine whether teachers' experiences of delivering the intervention or control lessons also differed according to their school's Ofsted rating (high/low) and community served (moderate-to-affluent/disadvantaged).

6.3 Method

6.3.1 Design

A mixed methods design was adopted to understand teachers' experiences of the trial, utilising lesson feedback data from teachers (N=568) collected as part of the RSIIYA trial and supplementary, semi-structured interviews with selected teachers (N=12) to obtain more in-depth data. These two methods were complementary in terms of the temporal nature of the data they provided. Lesson evaluations were completed as part of the RSIIYA trial after each anti-smoking and pro-homework lesson, representing an immediate reaction to delivering the lessons across four time points. In comparison, the interviews took place towards the end of

the trial, involving more detailed, retrospective reflections on their involvement as a whole. Each method is now explained in more detail.

Routinely collected lesson feedback data

After every lesson delivered, teachers were required by trial protocol to complete a simple 'Cover Sheet' for lesson identification purposes (i.e. school, teacher and class name, number of students participating). After completion, teachers were asked to attach the Cover Sheet to their students' completed Personal Plans for smoking/homework and return these to their smoking study coordinator in school. The trial manager (and writer) would then visit each school to collect all completed lesson packs. Lesson data recorded in the completed Cover Sheets were used when entering students' Personal Plan data into the Statistical Package for Social Sciences.

From lesson four onwards (in 2013, year two of the trial), the use of the Cover Sheet was extended by the writer to include teacher feedback items (see Figure 6.1) for the purposes of this present PhD study. The rationale behind this was twofold. Firstly, it created a vehicle through which teachers could communicate with the research team, sharing concerns or suggesting improvements. The research team hoped that consulting teachers and acting wherever possible on their feedback would facilitate their ongoing engagement and involvement in the study. Secondly, responses to the feedback items allowed a further level of analysis to be conducted about engagement with the lessons and the trial overall.


The extended Cover Sheet contained a 'Brief Feedback' section where teachers were able to rate their level of agreement with six statements about the group (e.g. I know this student group extremely well) and the lesson (e.g. the lesson was a pleasure for me to deliver). Ratings of 'strongly agree' scored 5 and 'strongly disagree' scored 1. There was also space to record additional handwritten comments. Finally, teachers were asked to indicate if they would be interested to share their experiences with a university researcher in confidence.

Semi-structured Interviews

Semi-structured interviews were used to develop a deeper understanding of teachers' experiences than the Cover Sheets alone could provide. For example, through the interviews, teachers were able to describe their perceptions of the trial overall and the school context within which the lessons were delivered. They also provided an opportunity to share any difficulties they experienced, if and how they overcame them, and also any ideas for improving the lessons. Using semi-structured interviews gave the teachers flexibility and a

degree of freedom in how they recounted their experiences, whilst allowing consistent areas of information to be collected and compared across interviews. To minimise burden, interviews were designed to be short (approximately 20 minutes) and flexible, conducted either in person or by phone. They took place towards the end of the trial to allow teachers time to reflect back on their experience

Figure 6.1 Cover Sheet

SMOKING PREVENTION STUDY 2012-2016 Anti-smoking Session					
COVER SHEET Please attach to front of all collected "My Personal Plan" sheets for each session then secure with an elastic band/place in folder provided.					
School Name	Teacher Name				
Class (e.g. 9a)	Date and Time				
This session was delivered in: <input type="checkbox"/> Form time <input type="checkbox"/> PSHCE lesson <input type="checkbox"/> Drop-down day <input type="checkbox"/> Other Please specify					
Brief Feedback					
I know this student group extremely well	Strongly disagree <input type="checkbox"/>	Disagree <input type="checkbox"/>	Neutral <input type="checkbox"/>	Agree <input type="checkbox"/>	Strongly agree <input type="checkbox"/>
I have a very warm rapport with this group	Strongly disagree <input type="checkbox"/>	Disagree <input type="checkbox"/>	Neutral <input type="checkbox"/>	Agree <input type="checkbox"/>	Strongly agree <input type="checkbox"/>
My students were highly engaged in the lesson	Strongly disagree <input type="checkbox"/>	Disagree <input type="checkbox"/>	Neutral <input type="checkbox"/>	Agree <input type="checkbox"/>	Strongly agree <input type="checkbox"/>
I followed the lesson plan to the letter	Strongly disagree <input type="checkbox"/>	Disagree <input type="checkbox"/>	Neutral <input type="checkbox"/>	Agree <input type="checkbox"/>	Strongly agree <input type="checkbox"/>
This lesson was a pleasure for me to deliver	Strongly disagree <input type="checkbox"/>	Disagree <input type="checkbox"/>	Neutral <input type="checkbox"/>	Agree <input type="checkbox"/>	Strongly agree <input type="checkbox"/>
Overall I'd say the lesson went incredibly well	Strongly disagree <input type="checkbox"/>	Disagree <input type="checkbox"/>	Neutral <input type="checkbox"/>	Agree <input type="checkbox"/>	Strongly agree <input type="checkbox"/>
If you have time, please feel free to expand on any of your answers:					
Would you be interested to share your experience with a University Researcher in confidence to help us improve future lessons? <input type="checkbox"/> Y / <input type="checkbox"/> N If yes, please provide your email address here:					
Any further comments? (e.g. rough size of group, disturbances like fire alarms or anything that might make the data less trustworthy)					

6.3.2 Participants

6.3.2.1 Routinely collected lesson feedback data:

A total of 587 Cover Sheets were available for analysis (Yorkshire region of the trial only), which, based on the number of lesson packs issued (N=875), represented 64.9% of the lessons expected to be delivered. This final sample comprised more anti-smoking (56.4% [N=331]) than pro-homework lessons (43.6% [N=256]), and higher proportions of Cover Sheets from schools in moderate-to-wealthy areas (69.7% [N=409], compared to 30.3% [N=178] from those in disadvantaged areas) and those with high Ofsted-ratings (67.2% [N=395] compared

to 32.7% [N=192] from low Ofsted-rated schools).

Examining the Cover Sheet returns as a percentage of what was expected, lower rates were observed in intervention schools (59.6% [331/555]) and those serving disadvantaged communities (52.4% [178/340]), in comparison to control schools (80% [256/320]) and those in moderate-to-wealthy areas (76.5% [409/535]). High Ofsted and low Ofsted-rated schools had similar return rates: 66.4% (395/595) and 68.6% (192/280) respectively.

On closer examination 19 Cover Sheets were incomplete (7 anti-smoking/12 pro-homework) so were excluded, resulting in a final sample of 568 Cover Sheets for analysis (see Table 6.1).

Table 6.1 Cover Sheets included in the analysis by lesson and condition

Lesson Number and Topic	Condition		Total
	Intervention	Control	
4. Smoking and appearance / Revising for tests	68	56	124
5. Secrets of motivation	65	50	115
6. Building your resilience to not smoke/complete homework	61	42	103
7. Looking after yourself during stressful times	67	43	110
8. Looking to the future	63	53	116
	324	244	568

6.3.2.2 Semi-structured interviews

Extreme/deviant case sampling was used to recruit teachers to these interviews. Teachers were recruited who had either a 'positive' or 'negative' experience of delivering the lesson, as determined by ratings for the final feedback item on the Cover Sheet, 'Overall I'd say the lesson went incredibly well'. It was hoped that interviewing teachers from these opposing groups would reveal any unique factors differentiating positive, successful experiences from negative, unsuccessful experiences. To identify relevant teachers to target in recruitment, a master list was first created of all teachers who had delivered the intervention or control lessons across the 20 Leeds schools in the trial (N=421), using names from returned lesson Cover Sheets to date. Teachers were allocated to the positive lesson rating group if they agreed/strongly agreed that 'the lesson went incredibly well' (58% [N=245]) to the negative lesson rating group comprised if they disagreed/strongly disagreed with this item (17% [N=71]) and excluded if they provided a neutral rating (25% [N=105]).

In recruiting teachers from the 'positive' and 'negative' lesson rating groups, the researcher sought to secure in the final sample representation from each of the eight sampling groups created for this PhD (see page 81, Chapter 2) and from those who delivered single and multiple lessons. Therefore, within the 'positive' and 'negative' lesson rating groups teachers were further grouped by school sampling group and whether they were single-lesson or multiple-lesson deliverers (defined as three or more). Finally, wherever

possible, teachers from the same school with opposing views were targeted to explore why their experiences differed.

Recruitment took place by email (Appendix 12). Between June and October 2016, twenty six teachers (15 positive rating; 11 negative rating) were contacted directly using email addresses provided on their completed Cover Sheets (indicating their willingness to be contacted by a researcher³), to invite them to take part in a short telephone interview. A more detailed information sheet was attached to the email to help them decide whether to take part (Appendix 13).

Six of the 15 'positive lesson rating' teachers and three of the 11 'negative lesson rating' teachers contacted agreed to participate. Wherever possible, when targeted teachers did not respond to the recruitment email, back-up teachers in the same school were invited by email to take part. Where no invited teachers responded in a targeted school, the researcher then contacted the appropriate Study Coordinators in those schools, who then circulated recruitment information on her behalf, with a personal appeal to help (between October 2016 - January 2017).

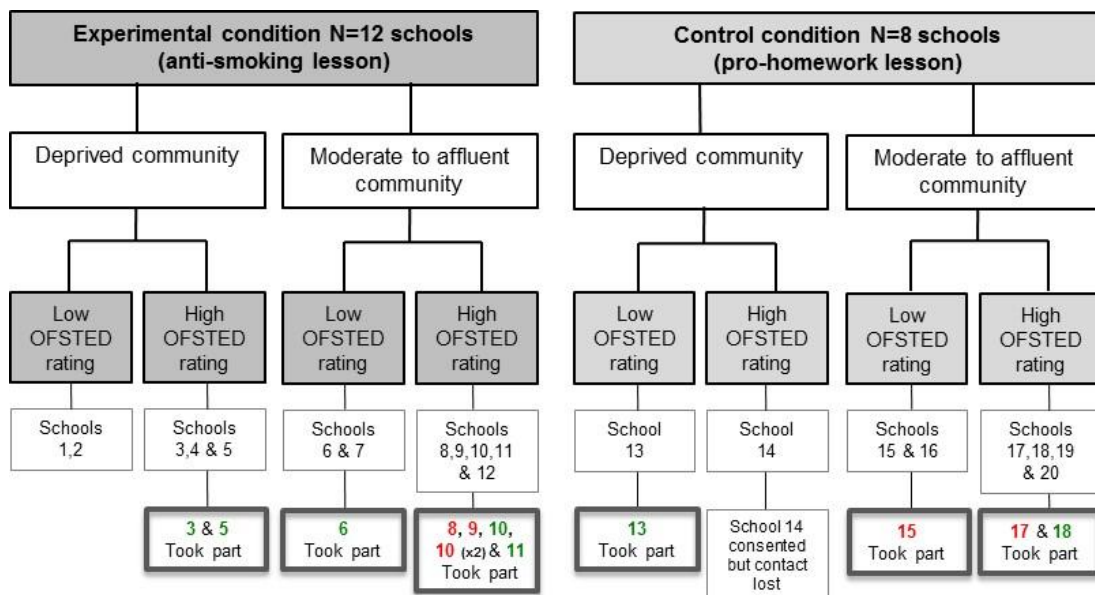
To boost recruitment, ethical approval was obtained to introduce a £10 gift voucher incentive and the email and information sheet were revised (Appendix 14,15). The researcher then targeted five non-responsive, unrepresented schools, asking the Study Coordinator to circulate her recruitment email to all teachers involved in the study. This resulted in five teachers coming forward from three schools. The researcher politely declined to interview one of these teachers because his name was on neither of the targeted lists. One other teacher was not interviewed, despite signing and returning a consent form and completing a background information sheet. Over a number of months, the researcher attempted to set up suitable interview dates by email and phone, but the teacher failed to confirm.

Despite considerable, extensive work to secure an equivalent number of control and intervention teachers, control school teachers were unfortunately less willing to be involved. The final sample consisted of eight intervention and four control teachers. All were interviewed between June 2016 and February 2017, eight by telephone and four face-to-face (see Table 6.2). Just over half of all schools participating in the Leeds region were represented in the final sample, three in disadvantaged and nine in moderate-to-affluent communities

³ N=98 Cover Sheets (70 intervention/28 control) indicated the completing teacher would be happy to discuss their experiences, representing 14.4% of the 683 Cover Sheets received. Three of these contained no name or initials and some teachers indicated their willingness to help on multiple Cover Sheets. Therefore the actual number of receptive teachers was 67.

(see Figure 6.2).

Figure 6.2 Schools participating in the semi-structured interviews



Key: red denotes negative experience group; green denotes positive experience group.

Seven teachers (5 intervention; 2 control) had provided positive and five (3 intervention; 2 control) had recorded more negative ratings (see Appendix 16). All were experienced at delivering Personal, Social, Health and Economic (PSHE) education, either as part of their role as Form Tutor or within off-curriculum ('drop-down') days in school. Seven were Subject Leaders (3 for PSHE; 3 for Science/STEM; 1 for Textiles). The mean age was 43 (range 30-60), the mean number of years in teaching was 16 years (range 3-40); 8 years (range 1-15) in the current school. Nearly all (6/7) of the positive experience teachers had delivered the lessons on multiple occasions (3+ times), whereas the frequency of delivery was more varied in the **negative** experience group. Throughout the rest of this chapter, negative experience participants are indicated by being **emboldened and underlined**.

Table 6.2 Composition of semi-structured interviews

School details			Personal Details					
School	Description	Participant	Role in School	Gender, Age	Years teaching (this school)	No of times lesson delivered	Smoker status	Familiar with smoking study?
3	Intervention/high Ofsted/disadvantaged	5	PSHE & Citizenship Lead	M, 55	30 (15)	4	Never	Quite
5	Intervention/high Ofsted/disadvantaged	8	History Teacher	F, 48	12 (11)	4+	Former	Very
8	Intervention/high Ofsted/moderate-affluent	<u>2</u>	STEM ⁸ Leader/Science Teacher	M, 43	12 (7)	4+	Never	Very
9	Intervention/high Ofsted/moderate-affluent	<u>3</u>	English & Drama Teacher	F, 31	5 (1)	2	Former	A bit
10	Intervention/high Ofsted/moderate-affluent	4	Subject Leader for Textiles	F, 50	19 (10)	4+	Never	Very
10	Intervention/high Ofsted/moderate-affluent	<u>6</u>	Science Teacher	M, 40	11 (2)	2	Former	A bit
11	Intervention/high Ofsted/moderate-affluent	1	PSHE Lead/PE Teacher	F, 60	40 (15)	2	Never	Quite
6	Intervention/low Ofsted/moderate-affluent	9	Science Teacher	F, 34	11 (10)	4	Never	Very
17	Control/high Ofsted/moderate-affluent	<u>12</u>	Subject Leader for Science	M, 48	25 (10)	4+	Never	Very
18	Control/high Ofsted/moderate-affluent	7	PSHE Lead/History Teacher	F, 35	10 (10)	3	Never	Very
15	Control/low Ofsted/moderate-affluent	<u>11</u>	Modern Languages Teacher	F, 42	19 (5)	4	Never	Not very
13	Control/low Ofsted/disadvantaged	10	Subject Leader for Science	M, 30	3 (3)	4	Never	Quite

Bold italicised underlined text denotes a participant in the negative experience sample.

⁸ Science, Technology, Engineering and Maths

6.3.3 Research Tools

In 2013, for the purpose of this study, the scope of the original Cover Sheet which teachers were required to complete after delivering an anti-smoking or pro-homework lesson was extended. Initially the Cover Sheet captured essential identifying information for lesson data entry into SPSS, however this was expanded to capture teachers' responses to the lessons (Figure 6.1). These Cover Sheet feedback data were collected routinely after every lesson.

With regard to the semi-structured interviews, a detailed information sheet was designed and attached to the recruitment email to help teachers decide whether to take part. A 'background information sheet' (Appendix 17) was used to collect demographic data before the interviews, so that the limited time available for the interviews could be utilised for obtaining experiences and opinions. An interview schedule was structured around five sections (Appendix 18): the teacher's contextual knowledge of the RSHYA trial, their level of training and confidence in delivering PSHE lessons, their experience of delivering the lessons (training, planning and acceptability of the materials/activities), contextual and personal factors (such as being a smoker themselves, their knowledge of the students) and finally their appraisal as to whether their school was experiencing any benefits from being part of the trial. The sequence of the questions was sometimes changed to suit the needs of the teacher and the natural flow of discussion. The interview schedule comprised largely open questions with various prompts to encourage the teachers to talk freely, whilst ensuring key information was collected in a short timeframe. The choice of interview questions was informed by the implementation science and process evaluation literature (Greenhalgh et al., 2005; Weiner, Lewis & Linnan, 2009), particularly those referring to schools' based complex health interventions (Buston et al., 2002; Mukoma et al., 2009), and also by the emerging comments in the returned Cover Sheets.

6.3.4 Procedure

The researcher emailed targeted teachers (as described earlier within the Participants section) directly using email addresses provided on their completed Cover Sheets (indicating their willingness to be contacted by a researcher), to invite them to take part in a short telephone interview. A detailed information sheet was attached to the email to help them decide whether to take part.

When a positive response was received from a teacher, the researcher contacted them to arrange a suitable interview time, confirming whether a telephone or face-to-face interview was preferred. If a telephone interview was agreed, the researcher underlined the

importance of privacy during the interview (e.g. not speaking in a busy staff room). Once a date had been agreed, the researcher posted the participant a consent form (Appendix 19) and background information sheet for completion and return (a stamped addressed envelope was provided), along with a single page handout reminder of all the appropriate condition lesson materials (smoking or homework) to re-familiarise themselves with before the interview. These were also sent electronically.

Interviews took place during the working day, largely by phone (8/12 interviews), during non-teaching periods, after the school day or during lunch breaks. The researcher always initiated the telephone interview by ringing the participant from a private research room. Participants were usually in an empty classroom or unoccupied staff room. One exception was a telephone interview with a part-time teacher, who was at home on her non-work day. Four interviews took place face-to-face due to participants' preference. Two were held in empty school classrooms and one took place in a meeting room, all after teaching had finished for the day. The fourth interview took place in a research room at the researcher's University because the participant was on campus completing a part-time Masters in Education.

The researcher emailed the teacher the day before the interview to confirm they were still happy to participate and that the agreed arrangements remained convenient. After initiating the telephone call, the researcher checked once again that the interview was still convenient, that they were in a quiet space where they would not be disturbed and that they were happy for it to be recorded. The researcher underlined that she was in a private room for confidentiality purposes and that all identifying names/places would be anonymised during transcription. Only after the participant confirmed they were comfortable did recording commence. For the face-to-face interviews, the researcher was met by the participant in their school reception area, who took them to their empty classroom or meeting room. The same reassurances were given regarding anonymity and confidentiality before asking for permission to start recording. At the end of the interviews, the researcher reiterated that their data would be treated confidentially, anonymised at transcription and stored securely.

The mean interview time was 25.5 minutes (range 18-45). All interviews were audio-recorded and transcribed. During transcription all verbal aspects were typed up verbatim to try to capture the nature of interview and facilitate comprehensive analysis (described in section 6.3.5.2).

6.3.5 Analysis

6.3.5.1 Routinely collected Cover Sheet data

The 568 completed Cover Sheets were analysed at a number of levels. Firstly, as a proxy for overall teacher engagement, teachers' protocol adherence was examined at the school level. This involved examining within each school the degree to which (a) smoking/homework lessons took place as expected and (b) fully completed Cover Sheets were attached to returned student Personal Plans.

A second level of analysis involved comparing lesson ratings between teachers in the intervention/control condition, high and low Ofsted-rated schools, and in schools serving disadvantaged and moderate-to-wealthy communities. A total score for each lesson was created from each Cover Sheet by combining scores for individual feedback items (Cronbach's $\alpha = .96$): (1) I know this student group extremely well; (2) I have a very warm rapport with this group; (3) My students were highly engaged in this lesson; (4) I followed the lesson plan to the letter; (5) This lesson was a pleasure for me to deliver; (6) Overall, I'd say the lesson went incredibly well. Using the Statistical Package for Social Sciences, the total scores for 568 Cover Sheets were first subjected to independent samples t-tests to detect any differences in teachers' experiences between conditions, school Ofsted rating and type of community served. Such analyses do not control for the fact that these data were clustered both by lesson and by school. Therefore in order to assess whether differences by condition, Ofsted rating or community type significantly influenced lesson rating controlling for lesson and school, the 'MIXED' command in SPSS was also used.

The third level of Cover Sheet analysis involved close examination of teachers' handwritten comments. Content Analysis was selected due to the brief nature and volume of these comments. With Content Analysis the researcher typically applies a low level of interpretation when coding the data (Vaismoradi, Turunen & Bondas, 2013) and aims to identify patterns and trends within a dataset to organize and distil the data into a more meaningful format (Shields & Twycross, 2008).

To facilitate the analysis, teachers' handwritten comments, which were entered as 'string' data in SPSS, were imported into Excel. This enabled comments to be more easily examined, managed and organised into themes. The first step in the content analysis involved the primary coding of each teacher comment as 'positive', 'negative' or 'mixed/balanced', to gain a macro view of the feedback. Next, each comment was read carefully, common threads and concepts were noted between similar comments, and meaningful labels were devised. The researcher then returned to individual comments and gave each comment the

appropriate label/code. Where a single teacher provided multiple comments, multiple labels/codes were applied. Finally, the researcher sought any patterns and relationships within and between codes, and through constant comparison synthesized these into a smaller number of organising themes. Within each theme, the number of instances of comments was recorded.

The researcher was mindful that the most frequently occurring topics might have been simply the easiest topics to talk about rather than the most important to teachers (Shields & Twycross, 2008). All themes were then considered alongside the more in-depth findings from the semi-structured interview analysis, contributing breadth, scale and triangulation of data. To determine any effect of condition on the type of comment teachers chose to record, Pearson's Chi-squared tests were applied to (a) the overall number of positive, negative and mixed/balanced comments and (b) the number of individual theme counts/appearances for intervention and control teachers.

6.3.5.2 Semi-structured interviews

The interviews were audio-recorded, transcribed and analysed for key themes using Thematic Analysis (Braun & Clarke, 2006). When examining the transcripts, the researcher sought to develop a detailed account of the specific research question areas, i.e. (a) teachers' experiences of the PSHE education context in their school and if/how these affected their engagement with the lessons, (b) perceptions of being part of the trial and (c) their experience of delivering intervention/control lessons and factors influencing this. This meant that a top-down approach was applied to the data when identifying themes and patterns, i.e. the researcher attended to and coded material pertaining to these three areas rather than coding the transcript line by line for any interesting item. A realist epistemological stance was adopted when interpreting the data.

The analytical procedure began with becoming familiar with the data (listening to the audio-recordings, reading then re-reading each transcript), generating initial codes relating to the specific research questions and reviewing patterns and relationships between all the codes to identify themes. Themes were identified predominantly at a semantic or explicit level (i.e. not going beyond what the students said) and consideration was given to whether a theme reflected an 'engagement-enhancing' or 'engagement-inhibiting' feature/factor. The initial themes were then reviewed to check if they accurately reflected the coded extracts and each transcript as a whole. Subsequently, initial themes were named and defined more clearly, through generating a descriptive paragraph for each with corresponding quotes. Finally, to facilitate the comparison of teachers' experiences by school-level characteristics,

the researcher drew upon the Framework Analysis method of 'charting' (Ritchie & Spencer, 1994), to illustrate the occurrence of all themes and sub themes by condition and focus group.

6.3.6 Ethical Considerations

Ethical approval was obtained from the University of Leeds School of Psychology Ethics Committee (reference: 14-0113; 9/6/2014). As noted earlier, due to poor recruitment a decision was made to introduce an incentive to offer some compensation for teachers' time. Approval was received by the University's Ethics Committee to introduce a £10 voucher incentive on 23 January 2017 (ref 17-0020), on the proviso that all participants recruited to date would be also furnished with a £10 voucher retrospectively.

Participant consent was formally obtained ahead of each interview, and again on the day verbally before recording began. Participants were advised they could terminate the interview at any time if they became uncomfortable, or refuse to answer any question without giving a reason. To secure anonymity, all names mentioned, including towns and schools, were changed. Interview recordings were erased following their transcription. Anonymised transcriptions and other participant data are being held electronically, confidentially and securely on a password-protected computer for up to five years, after which time these will also be deleted.

6.4 Results

6.4.1 Teachers' responses to delivering the lessons: *Cover Sheet analysis*

6.4.1.1 Utilisation of lesson resource packs and Cover Sheet protocol adherence

Between May 2013 (lesson 4) and July 2016 (lesson 8) 875 lesson packs were hand delivered to participating Leeds schools (see Table 6.3). Each lesson pack contained one lesson plan, 30 persuasive messages handouts and 30 Personal Plan handouts. Of these 875 packs issued, Personal Plans for 21% (N=184) lessons were not returned, therefore these were interpreted as non-delivered by the school. The remaining 79% (N=691) of packs were accounted for in returns to the research team. Eight of these lesson packs were returned unused, but 683 individual sets of completed Personal Plans were returned, indicating that at least 78% of the expected lessons were implemented.

Of the 683 sets of Personal Plans returned, teachers had followed trial protocol in 83% (N=568) of cases by fully completing and attaching a Cover Sheet (57% [N=324] intervention; 43% [N=244] control). Teachers violated protocol in 17% (N=115) of cases by

Table 6.3 Lesson pack utilisation and adherence to Cover Sheet protocol by school and condition, lessons 4 (May 2013) to 8 (July 2016)

					Utilisation of Issued Lesson Packs			Adherence to Protocol		
								Protocol Violated		Protocol Followed
School		Students in cohort	Lesson packs issued per lesson/ time point	Lesson packs expected by researchers lessons 4-8	Pack not returned/ unaccounted for N (%)	Pack returned unused N (%)	Pack used & returned N (%)	Cover Sheet missing	Cover Sheet incomplete	Cover Sheets completed fully N (%)
Intervention	1	216	8	40	11 (27.5%)	0 (0.0%)	29 (72.5%)	1	0	28 (70.0%)
	2	178	9	45	23 (51.1%)	2 (4.5%)	20 (44.4%)	8	0	12 (26.7%)
	3	217	8	40	5 (12.5%)	0 (0.0%)	35 (87.5%)	1	2	32 (80.0%)
	4	178	7	35	7 (20.0%)	1 (2.9%)	27 (77.1%)	11	0	16 (45.7%)
	5	240	20	100	56 (56.0%)	2 (2.0%)	42 (42.0%)	9	0	33 (33.0%)
	6	240	10	50	13 (26.0%)	0 (0.0%)	37 (74.0%)	4	0	33 (66.0%)
	7	200	7	35	12 (34.3%)	0 (0.0%)	23 (65.7%)	6	0	17 (48.6%)
	8	210	12	60	5 (8.3%)	0 (0.0%)	55 (91.7%)	3	0	52 (86.7%)
	9	205	7	35	11 (31.4%)	0 (0.0%)	24 (68.6%)	5	0	19 (54.3%)
	10	170	8	40	8 (20.0%)	0 (0.0%)	32 (80.0%)	6	4	22 (55.0%)
	11	197	7	35	0 (0.0%)	0 (0.0%)	35 (100%)	2	0	33 (94.3%)
	12	214	8	40	9 (22.5%)	1 (2.5%)	30 (75.0%)	2	1	27 (67.5%)
Control	13	195	7	35	4 (11.4%)	0 (0.0%)	31 (88.6%)	3	1	27 (77.1%)
	14	204	9	45	6 (13.3%)	1 (2.3%)	38 (84.4%)	11	0	27 (60.0%)
	15	232	8	40	0 (0.0%)	0 (0.0%)	40 (100%)	0	0	40 (100%)
	16	182	7	35	1 (2.9%)	0 (0.0%)	34 (97.1%)	0	0	34 (97.1%)
	17	210	8	40	0 (0.0%)	0 (0.0%)	40 (100%)	1	5	34 (85.0%)
	18	229	9	45	3 (6.7%)	1 (2.2%)	41 (91.1%)	8	0	33 (73.3%)
	19	191	7	35	0 (0.0%)	0 (0.0%)	35 (100%)	3	4	28 (80.0%)
	20	259	9	45	10 (22.2%)	0 (0.0%)	35 (77.8%)	12	2	21 (46.7%)
4167		175	875	184 (21.0%)	8 (0.9%)	683 (78.1%)	96	19	568 (64.9%)	

returning packs without a Cover Sheet (N=96) or with superficially completed Cover Sheets with only basic identification details and no lesson ratings (N=19).

Comparing use and return of lesson packs and protocol adherence

Rates of lesson pack use, return and protocol adherence by condition, community served and Ofsted rating can be found below in Table 6.4.

Table 6.4 Lesson pack use and return and protocol adherence by condition, community served and Ofsted rating

		Total Lesson Packs Expected	Lesson packs used and returned	Cover Sheets attached adhering to protocol
Condition	<i>Intervention</i>	555	389 (70.1%)	324 (58.4%)
	<i>Control</i>	320	294 (91.9%)	244 (76.3%)
Community Served	<i>Moderate-to-wealthy</i>	535	461 (86.2%)	393 (73.5%)
	<i>Disadvantaged</i>	340	222 (65.3%)	175 (51.5%)
Ofsted rating	<i>High</i>	595	469 (78.8%)	377 (63.3%)
	<i>Low</i>	280	214 (76.4%)	191 (68.2%)

By condition: Control schools (N=8) utilised and returned significantly more of their lesson packs (91.9% [294/320]) than intervention (N=12) schools (70.1% [389/555]), $\chi^2 (1, N=875) = 56.24, p<.001, \phi=-.25$. Control teachers' (76.3% [244/320]) adherence to Cover Sheet protocol was significantly better than that of intervention teachers (58.38% [324/555]), $\chi^2 (1, N=875) = 28.46, p<.001, \phi=-.18$.

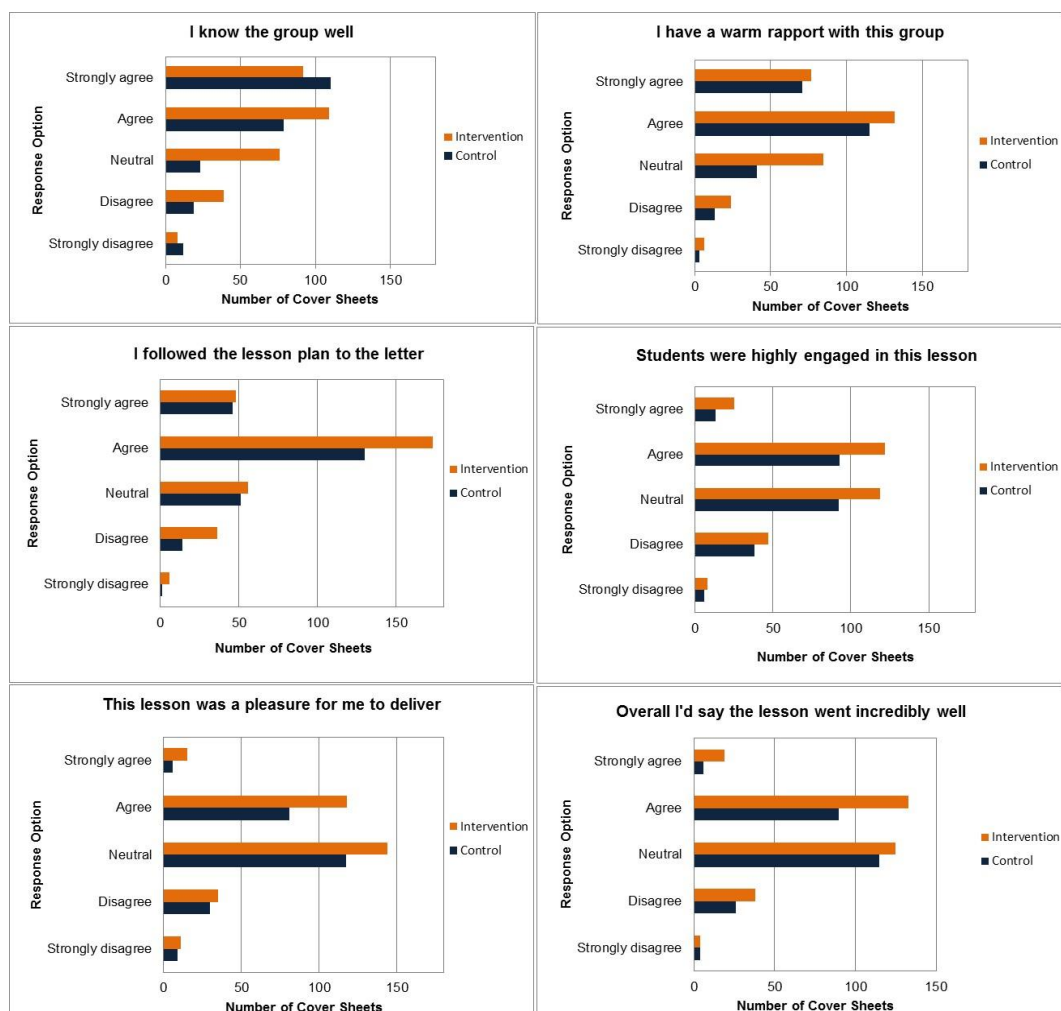
By community served: Schools serving moderate-to-wealthy communities (N=13) used and returned significantly more of their issued lesson packs (86.2% [461/535]) than disadvantaged (N=7) schools (65.3% [222/340]), $\chi^2 (1, N=875) = 52.89, p<.001, \phi=.25$. Moderate-to-wealthy schools (73.5% [393/535]) were also significantly better at adhering to Cover Sheet protocol than disadvantaged schools (51.5% [175/340]), $\chi^2 (1, N=875) = 44.13, p<.001, \phi=.23$.

By Ofsted rating: No significant effects of Ofsted rating were observed. Highly-rated Ofsted schools (N=13) used and returned a slightly higher proportion of their issued lesson packs (78.8% [469/595]) than low Ofsted-rated (N=7) schools (76.43% [214/280]). However, this association was not significant, $\chi^2 (1, N=875) = .64, p=.425$. Adherence to Cover Sheet protocol was similar in both high (63.3% [377/595]) and low Ofsted (68.2% [191/280]) schools, $\chi^2 (1, N=875) = 1.97, p=.161$.

6.4.1.2 Lesson feedback: *analysis of lesson ratings*

Frequencies for teachers' ratings of the six individual Cover Sheet items are presented in Figure 6.3. Examining individual item scores for the full sample ($N=875$), the items 'I know the group well', 'I have a warm rapport with this group' and 'I followed the lesson plan to the letter' attracted the highest mean ratings ($M=3.86$, $M=3.85$ and $M=3.71$ respectively; see Table 6.5). Teachers were less positive that 'Students were highly engaged in the lesson' ($M=3.28$) and the mean score was lower for the item 'Overall, I'd say the lesson went incredibly well' ($M=3.30$). Overall, teachers' lowest ratings were associated with their personal experiences of delivering the lesson, 'This lesson was a pleasure for me to deliver' ($M = 3.22$).

Figure 6.3 Frequencies for teachers' ratings of six Cover Sheet items



Mean ratings for 'I know the group well' and 'I have a warm rapport with this group' were higher for control teachers than intervention teachers. However intervention teachers' higher ratings for 'students were highly engaged in the lesson', 'the lesson was a pleasure for me to deliver' and 'overall I'd say the lesson went incredibly well' (see Table 6.5) suggest a

more positive overall experience for teachers delivering anti-smoking as opposed to pro-homework material. A lower mean rating for 'I followed the lesson plan to the letter' within the intervention teacher group indicates a more flexible approach towards the lesson guide.

Table 6.5 Mean scores by condition for Individual Cover Sheet feedback items

Feedback Items	Overall (N = 568)	Intervention (N = 324)	Control (N = 244)
I know the group well	3.86 (SD 1.13)	3.73 (SD 1.07)	4.04 (SD 1.17)
I have a warm rapport with this group	3.85 (SD 0.95)	3.77 (SD 0.96)	3.96 (SD 0.92)
I followed the lesson plan to the letter	3.71 (SD 0.97)	3.63 (SD 1.02)	3.80 (SD 0.88)
Students were highly engaged in the lesson	3.28 (SD 0.95)	3.31 (SD 0.96)	3.26 (SD 0.93)
This lesson was a pleasure to deliver	3.22 (SD 0.86)	3.27 (SD 0.87)	3.17 (SD 0.84)
Overall, I'd say the lesson went incredibly well	3.30 (SD 0.92)	3.34 (SD 0.92)	3.24 (SD 0.83)
All items combined	3.54 (SD 0.66)	3.51 (SD 0.66)	3.58 (SD 0.64)

Individual ratings for the six feedback items on each Cover Sheet were combined and a mean total score was calculated for each lesson. Mean total scores by condition and school characteristics, i.e. Ofsted rating and community-served, were subjected to independent samples t-tests. Whilst the mean total lesson score was higher in control than intervention schools (see Table 6.6) this difference was not significant, $t(566) = 1.29$, $p = .198$. Teachers working in disadvantaged communities rated their homework and smoking lessons significantly more positively than teachers in moderate-to-affluent schools, $t(566) = 2.59$, $p = .010$, $g = .24$. Similarly, teachers working in low Ofsted schools rated their homework and smoking lessons significantly more positively than those in high Ofsted schools, $t(566) = 4.92$, $p < .001$, $g = .44$ (see Table 6.6).

Table 6.6 Mean total lesson scores by condition, community served and Ofsted rating

		Cover Sheets	Mean Overall Score (6 items)
Condition	<i>Intervention</i>	324	3.51
	<i>Control</i>	244	3.58
Community Served	<i>Moderate-to-wealthy</i>	393	3.49*
	<i>Disadvantaged</i>	175	3.65*
Ofsted rating	<i>High</i>	377	3.45**
	<i>Low</i>	191	3.72**

* $p < .05$; ** $p < .001$

When controlling for clustering by school and by lesson, the effect for condition remained non-significant: the estimate for condition was $-.2626$, $SE = .309$, $t(17.98) = -.850$, $p = .406$. The effect for Ofsted remained significant: the estimate for Ofsted rating was $.7603$, $SE = .319$, $t(18.45) = 2.387$, $p = .028$. However, controlling for clustering by school and by lesson

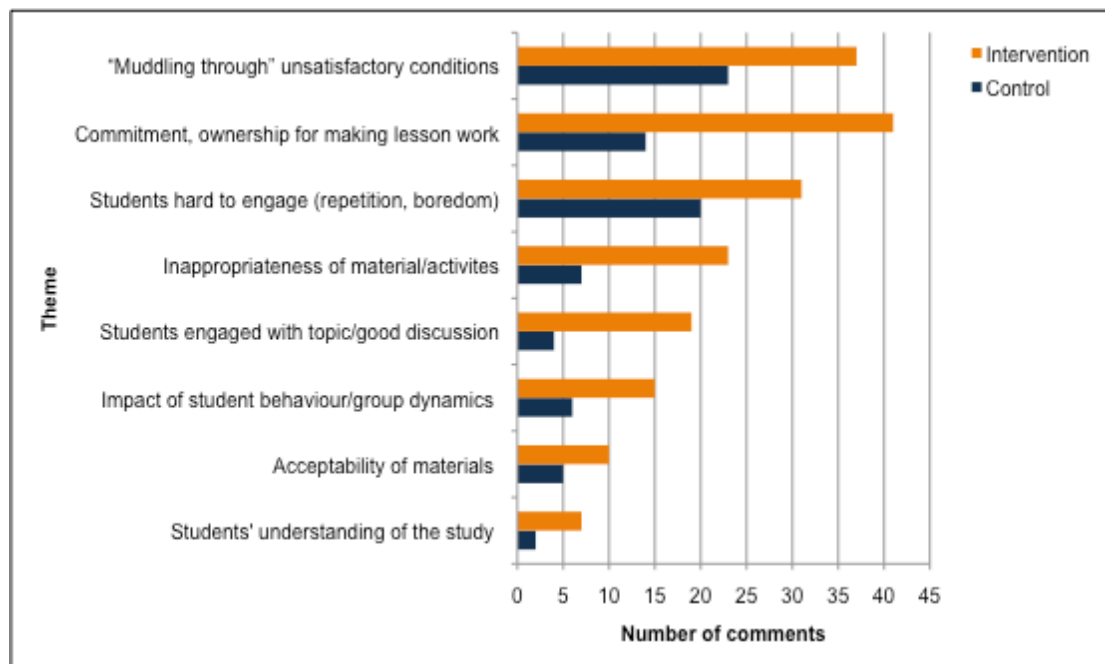
reduced the effect of community served to non-significance: the estimate for community was .1453, SE = .324, $t(18.78) = .448$, $p = .659$.

6.4.1.3 Lesson feedback: *Content analysis of handwritten comments*

Of the 568 completed Cover Sheets returned, 31.3% (N=178) contained a handwritten comment. Two-thirds of these (66.9% [119/178]) concerned the smoking lessons and a third (33.1% [59/178]) related to the homework lessons. For analysis purposes, comments were initially grouped and examined as three broad data corpuses: positive, negative and neutral comments. Over half the comments (57.9% [103/178]) were coded as 'negative' feedback (e.g. "kids were bored"), 15.2% (27/178) were coded as 'positive' (e.g. "thought the session was excellent easy to follow and allowed me to go into discussion with the kids") and 26.9% (48/178) were coded as 'neutral' (e.g. "only been their tutor 3 weeks"). The recording of positive, negative and mixed comments on their Cover Sheets was not related to condition, $\chi^2(2, N=178) = .85$, $p = .653$.

Comments consisting of multiple elements were separated out to allow them to be coded as individual comments. This resulted in a final sample of 264 comments (intervention 69.3% [N=183]; control 30.7% [N=81]) which were analysed. Once sub-themes had been determined from the three broad data corpuses, these then were examined together as a whole, synthesised where appropriate, and higher order themes were finally created.

Eight themes were created from the 264 handwritten comments (see Figure 6.4 for summary; see Appendix 20 for detailed table of themes). These themes, in order of most to least prevalent were: (1) "“muddling through” unsatisfactory conditions' (23% [60/264]); (2) 'commitment and ownership for making the lesson work' (21% [55/264]); (3) 'students were hard to engage due to repetition and boredom' (19% [51/264]); (4) 'inappropriateness of materials/activities' (11% [30/264]); (5) 'students engaged with the topic/good discussion' (9% [23/264]); (6) 'impact of student behaviour/group dynamics' (8% [21/264]); (7) 'acceptability of materials' (6% [15/264]); (8) 'students' understanding of the study' (3% [9/264]). Each of these themes is now summarised in turn.

Figure 6.4 Themes identified from teacher feedback comments (N=264) by condition

Theme 1 “muddling through” unsatisfactory conditions’ (60 instances: 37 intervention/23 control): A higher proportion of *control* Cover Sheets contained comments related to this theme (28% [23/81]) compared to intervention Cover Sheets (20% [37/183]), however this difference was not significant, $\chi^2 (1, N=264) = 2.14, p=.144$. Teachers commented on having to deal with numerous conditions which were unsatisfactory for delivering the lessons. These included having to deliver the lesson material within unsuitable timeslots, such as in a 20-minute form time, or in a 75-minute drop-down day session, rather than the recommended 50 minutes. This was often unsatisfying and stressful for the teachers as they had to engage in ‘work-arounds’. For example, with too little time, they had to rush through the material, make in-the-moment decisions to skip sections, cut discussions short, or simply ask students to read and complete the handout independently. With too much time, they had to stretch out the activities, such as giving students more discussion time, include additional activities/material or allow students to talk amongst themselves if they finished the lesson early. The main challenge for teachers with too much time was student boredom, which could descend into disengagement and poor behaviour.

Disengagement and poor behaviour were also caused by circumstances beyond the teachers’ control, such as being the last lesson on a Friday afternoon, immediately following an exam or “fire alarm at the start of the lesson so started 20 minutes late. Did not get to the back page. Group behaved poorly during this session”. Eleven teachers (8 intervention; 3 control) were cover staff or new teachers and had delivered the session with no knowledge

of the study or preparation time. Other teachers commented on delivering the lesson without the necessary materials (e.g. “I feel passionately about mental health so enjoyed the topic but there was no lesson plan”) or with technical issues (e.g. “Did not have access to PowerPoint so could not include in lessons”).

Theme 2 ‘commitment and ownership for making the lesson work’ (55 instances: 41 *intervention*/14 *control*): A higher proportion of *intervention* (22% [41/181]) than *control* (17% [14/81]) Cover Sheets contained comments related to this theme, but this difference was not significant, $\chi^2(1, N=264) = 0.89, p=.345$. Teachers commented on supplementing the lesson to engage students more in the material, and adapting the lesson to boost engagement. For example, “watched a short video to explain what a tracheotomy is as part of the discussion”; “I used additional resources and activities to engage students and ensure full time was used”; “it is easy to deliver, however pupils are not engaged fully unless I interject with personal tales/stories about smoking”. Linked to these adaptations, two teachers (both *intervention*) commented on the tension between adhering to protocol of the lesson plan, and also having to meet students’ needs. Two teachers (*intervention*) expressed resentment at delivering the lessons because in their schools they were delivered through RE and Science lessons, “the lesson interrupts our scheme of work”.

Theme 3 ‘students were hard to engage due to repetition and boredom’ (51 instances: 31 *intervention*/20 *control*): Comments related to this theme were more common proportionally in *control* (25% [20/81]) than *intervention* Cover Sheets (17% [31/183]). However, this difference was not significant, $\chi^2(1, N=264) = 2.16, p=.141$. Teachers commented on the difficulties associated with the repeated nature of the trial, in particular the standardised format of the lesson and requirement to complete the same style of Personal Plan twice-yearly, “class becoming de-motivated as they have done this so often”. When delivering the lesson they were often met with ‘moaning’, sometimes resentment at having to do it and disengagement, particularly as students were older.

Theme 4 ‘inappropriateness of materials/activities’ (30 instances: 23 *intervention*/7 *control*): Comments associated with this overall theme were more prevalent in *intervention* (13% [23/183]) than *control* (9% [7/81]) Cover Sheets, although this difference was not significant, $\chi^2(1, N=264) = 0.86, p=.354$. Teachers, given their professional training, provided a number of comments on the design of the lesson, the materials and activities involved. They felt that lessons needed to be more appealing “the lesson was very dry and not very engaging from the outset - it needed to have something wow to start and make activities interactive” and student-centred, “there was no independent or active learning for the pupils - this lesson

was very much teacher led which I didn't find engages pupils as much as a 'pupil' led lesson". Thirteen comments reflected feelings that the lesson materials were too difficult for low ability students, and one intervention teacher commented that they were not demanding enough for high ability students.

Theme 5 'students engaged with the topic/good discussion' (23 instances: 19 intervention/4 control): This theme was more prevalent in *intervention* Cover Sheets (10% [15/183]) than control (5% [6/81]), however this difference was not significant, $\chi^2(1, N=264) = 2.09, p=.148$. Teachers commented that students had been actively involved in the lesson, such as "good discussions were had", "we had a good Q and A session on the 'Activity Sheet'", "Students were engaged, many asked questions and others volunteered to share own experiences". These comments were spread evenly across all sessions, rather than referring to any in particular.

Theme 6 'impact of student behaviour/group dynamics' (21 instances: 15 intervention/6 control): Similar levels of comments related to this theme were identified in both intervention (8% [15/183]) and control (7% [6/81]) Cover Sheets, $\chi^2(1, N=264) = 0.05, p=.827$. Through their comments teachers provided an insight into how students' behaviour impacted on their experience of delivering the lesson. While a small number of teachers remarked positively on the class attitude and behaviour ("a lovely group"), most referred to the generally challenging nature of the group they were teaching, and how this affected their engagement. For example, "some students with regular behavioural issues could not be bothered - needed more motivating to complete," "behaviour is a real problem in this group hence why the lesson was not pleasure to deliver", "very difficult group - behaviour problems and several low ability pupils and these factors more influential than lesson plan/content", "not a particularly easy group to deliver guidance lessons to".

Theme 7 'acceptability of materials' (15 instances: 10 intervention/5 control): Once again, similar proportions of intervention (6% [10/183]) and control (6% [5/81]) lesson Cover Sheets contained comments related to this theme, $\chi^2(1, N=264) = 0.05, p=.819$. Teachers who had delivered the lesson more than once recognised and acknowledged improvements in the lesson design and materials over time, "much more engaging than previous tasks", "activity sheet forced students to apply the information - I felt the lesson was a big improvement on previous lessons". Others commented positively on the structure and design, "a good mixture of activities" and "good lesson - I enjoyed delivering this".

Theme 8 'students' understanding of the study' (9 instances: 7 intervention/2 control): The final theme consisted of just nine comments, and concerned the students'

conceptualisation of the lesson as part of an overarching study. This theme was equally prevalent in intervention (4% [7/183]) and control (3% [2/81]) lesson Cover Sheets, χ^2 (1, N=264) = 0.31, $p=.576$. Whilst three teachers wrote about students being familiar with the study and accepting of the process, the others felt that students struggled to understand the context of the lesson (“students find it hard to understand that this is an ongoing study”), particularly if it was delivered outside of PSHE education such as through the science or RE curriculum, “the students struggle, at times, to see how this fits in to their lessons”.

Following this Cover Sheet analysis of 568 lessons at scale, the next section presents more ‘depth’ findings from interviews with 12 teachers selected from this sample. Five of these were teachers who returned Cover Sheets with low ratings for their lesson(s) (3 intervention; 2 control) and seven had rated their lesson(s) highly (5 intervention; 2 control).

6.4.2 Teachers’ perceptions and experiences of the trial: *interview analysis*

When scrutinising the transcripts, themes were organised within the key research questions, namely: teachers’ experiences of the PSHE education context in their school and if/how do they affect their engagement with the lessons; their perceptions of the trial; experience of delivering the intervention/control lessons and factors influencing this (see Table 6.7). Close attention was paid to the appearance and prevalence of the resulting themes to determine whether there were any differences between intervention and control teachers’ experiences, and whether there were any unique factors differentiating positive, successful lesson experiences from negative, unsuccessful experiences. Throughout the following section, negative lesson experience sample participants are identifiable as emboldened and underlined.

(1) Teachers’ experiences of the PSHE education context in their school and if/how this impacted on lesson engagement

The PSHE education context in schools, through which the smoking prevention and pro-homework lessons were delivered, was a thorny issue within the interviews. Four themes were identified (themes 1-4) which related to: *feeling equipped to deliver PSHE lessons* (29 instances); the *adequacy of their school delivery model for PSHE education* (15 instances); the *importance of secure attachments for engaging students in PSHE* (12 instances); the “*validity*” of *PSHE as a subject* (11 instances) in their particular school and nationally.

Theme 1 - Feeling equipped to deliver PSHE lessons (29 instances/12 participants):

Poor provision of PSHE skills training was a common theme, with 8/12 participants commenting that there was no training available:

Table 6.7 Summary of themes resulting from Thematic Analysis of semi-structured interviews with teacher-deliverers

		Comments by participant number (<u>bold</u> denotes negative experience)								
Themes	Sub-themes	Total instances all interviews	Intervention Interviews	Control Interviews	Intervention High OFSTED Deprived	Intervention High OFSTED Moderate-Affluent	Intervention Low OFSTED Moderate-Affluent	Control Low OFSTED Moderate-Affluent	Control High OFSTED Moderate-Affluent	Control High OFSTED Moderate-Affluent
Experiences of the PSHE context in school	1 Feeling equipped to deliver PSHE lessons	29	18	11						
	1.1 Lack of training	8	4	4	8	3 4 6		11	7 12	10
	1.2 'Alien', daunting concept	7	5	2	5 8	1 2 6		11		10
	1.3 Confidence and passion	6	4	2	5 8	1 2			7 12	
	1.4 Supported by centralised PSHE Subject Lead	4	2	2		3 6			7 12	
	1.5 Abandoned, exposed by devolved "DIY" PSHE	4	3	1		3 6	9			10
	2 Adequacy of school PSHE delivery model	15	9	6						
	2.1 'Downgraded' to form time 20 mins/wk	5	3	2	8	4	9		12	10
	2.2 'Downgraded' to drop-down 3 days/yr	3	2	1		2 3		11		
	2.3 'Gold standard' PSHE lessons 1 hr/week	2	1	1	5				7	
	2.4 Supplementary events to enhance PSHE	5	3	2	8	1 4			7	10
	3 Importance of secure attachments for PSHE work	12	6	6						
	3.1 Earning students' trust for honest discussions	8	5	4	5	1 2 3 4		11	7 12	10
	3.2 Teacher enthusiasm to engage students in PSHE	3	1	2		1		11		10
	4 "Validity" of PSHE as a subject	11	8	3						
	4.1 Valid/Important	7	5	2	5 8	1 2 4			7 12	
	4.2 Invalid/Unimportant	4	3	1		3 6	9			10

Perceptions of the trial	5 Placing high value on being involved in university research		36	23	13							
	5.1 Positive experience (school/students/staff)		11	7	4	5 8	1 <u>2</u> <u>3</u> <u>6</u>	9	<u>11</u>	7 <u>12</u>	10	
	5.2 Invested as scientist/anti-smoking advocate		10	8	2	5 8 8	<u>2</u> <u>3</u> <u>6</u> <u>6</u>	9		<u>12</u>	10	
	5.3 Pride belonging to national study		6	3	3	8	1 <u>3</u>		<u>11</u>	7	10	
	5.4 Recognise benefits		5	3	2	5 8		9		7	10	
	5.5 Not aware of benefits provided		4	2	2		<u>3</u> <u>6</u>		<u>11</u>	<u>12</u>		
	6 Faith versus fatalism about health interventions		15	11	4							
	6.1 Can change lives (positive about starting young)		6	5	1	5 8	1 4	9		<u>12</u>		
	6.2 Shifting smoking norms anyway		4	3	1		<u>2</u> <u>3</u> 4				10	
	6.3 Can help make informed decisions		2	1	1		<u>3</u>			7		
	6.4 Fatalistic: can never change the “hard core”		3	2	1		<u>2</u>	9	<u>11</u>			
	7 Understanding and preparedness		11	7	4							
	7.1 High: involved and equipped via training/briefing		7	5	2	5 8	1 <u>2</u>	9		7 <u>12</u>		
	7.2 Low: confusion and sense-making (no briefing)		4	2	2		<u>3</u> <u>6</u>		<u>11</u>		10	
	8 Legacy and impact		5	3	2							
Experiences of delivery	8.1 Adoption of materials/approach		3	2	1	5 8					10	
	8.2 Desire to collaborate in further research		2	1	1	5				7		
	9 Coming to terms with being the control		2	0	2					7 <u>12</u>		
	10 Engagement threats		28	20	8							
	10.1 Repetition/boredom		11	7	4	8	1 <u>2</u> <u>3</u> 4	9	<u>11</u>	7 <u>12</u>	10	
	10.2 Mixed reaction to lesson content		8	6	2	5 8	1 <u>3</u> 4	9	<u>11</u>		10	
	10.3 Time-tabling decisions		7	5	2	5 8	<u>2</u> <u>6</u>	9		<u>12</u>	10	
	10.4 Vulnerability/suspicion		2	2	0		4	9				
	11 Comfort with responsibility for delivery		16	10	6							
	11.1 Well received; not burdensome, enjoyable		8	4	4	5 8	1 4		<u>11</u>	7 <u>12</u>	10	
	11.2 Limited planning/preparation		4	4	0	5	<u>2</u> <u>3</u> 4					
	11.3 Discomfort (trepidation/stress/dissonance)		4	2	2		<u>6</u>	9		<u>12</u>	10	
	12 Using strategies to boost		15	12	3							

	engagement	12.1 Personal disclosure	4	4	0	5	1 4 6	
		12.2 Interpersonal motivation (e.g. Chivvying)	4	2	2	8	4	<u>11</u> 10
		12.3 Inspirational/personal appeals	3	2	1		<u>2</u> 9	<u>12</u>
		12.4 Adaptations	3	3	0		1 4 9	
		12.5 Allocating experienced, resilient teachers	1	1	0		9	
	13 Acceptability of pre-designed materials		15	9	6			
		13.1 Quality materials, easy to deliver, usual practice	5	2	3	8	1 4	<u>11</u> 7 10
		13.2 Enhance variety (videos, artefacts, tasks)	5	3	2	5	<u>2</u> 4	7 <u>12</u>
		13.3 'Learning opportunity' not 'information provision'	4	3	1		<u>3</u> 6 9	<u>12</u>
		13.4 Lesson plan too formal	1	1	0		<u>3</u>	

“Every school I’ve been to I’ve never, ever, once had training from the school”
(Participant 3, English/drama, intervention, 342).

One teacher argued that teachers are forced to be independent when delivering PSHE: they may be given the materials but essentially they had to ‘muddle through’. This was echoed by another participant who also experienced delivering PSHE lessons as an isolated, individual endeavour. He felt incredibly unsupported, explaining that, not only was there no training, there were also never any team meetings to discuss upcoming difficult sessions, anticipate questions and develop responses collaboratively. Even one experienced teacher (participant 4) also felt there was little guidance and support, despite some lessons being hard, uncomfortable and demanding. Her colleague at the same school (participant 6) also explained that he did not always feel confident or comfortable to teach some of the topics, which left him feeling exposed.

Support was available in some schools. For example, in one school (participant 11) the PSHE coordinator offered drop in sessions if staff were delivering a topic they felt uncomfortable with, and in two other schools (participants 7, 12) there were specialist sex and relationships education (SRE) trained staff who were available to deliver these particular lessons/offer support. Participant eight had received specialist training in SRE as part of a local drive to reduce teenage pregnancies, but also acknowledged that any training was usually cursory.

Six participants expressed a confidence and passion for delivering PSHE lessons. They saw it as important, took pleasure in building relationships and found it personally rewarding work. One teacher highlighted that she and many colleagues enjoyed delivering personal, novel material, that it represented a welcome break from teaching their own subjects and preparing students for exams. It also gave teaching assistants an opportunity to teach, which was good for their development.

Most (7/12) teachers also described delivering PSHE lessons as a daunting, somewhat alien concept, stressful and uncomfortable at times, particularly when they had not designed the lesson themselves but were delivering someone else's materials:

“Even if someone developed an amazing set of resources and everything was absolutely spot-on you know, we’re never going to have the time to really sort of develop that in advance. So it’s always going to be kind of on the day. So however good it is, you’re still basing on what’s there and that can never cover everything, or it just comes across like you know a cover lesson in that way” (Participant 6, Science, intervention, 111-115).

There was an acknowledgement that teaching PSHE required confidence in yourself as a person to deliver material that is not your specialist subject that you were trained for:

"That's quite a nerve-wracking thing because, you know, essentially you're being asked to deliver something that, you know, is often..., it's not so much close to home, but you are talking about feelings and emotions and opinions and.. You know, that's, that's something that you're not necessarily well prepared for at all" (Participant 10, Science lead, control, 121-124).

Some of the teachers regarded life experience and personal characteristics such as age, wisdom and approachability as more important than formal training. For example, one participant commented that those who most enjoyed teaching PSHE in school and were most confident and approachable were older women and mothers. Being a parent also featured in a male teacher's account of why he valued teaching PSHE; he was personally motivated to support the whole child at school.

Responsibility for creating the PSHE education lessons varied. Five participants described responsibility being centralised, where a PSHE lead in school produced a scheme of work and materials. Two schools had small PSHE teams who acted as advisers on more specialist topics such as sex and relationships. Having a coordinator with centralised responsibility sometimes meant that materials were available on shared folders and could be freely accessed. However some teachers explained that, whilst the timetable may be planned in advance, materials were frequently only received on the day of delivery, or they contained only very basic information, which was "tough" (Participant 4, Textiles lead, intervention, 58).

Two teachers spoke about devolved responsibility for creating PSHE lessons, where individual teachers were required to design their own session plans and materials after being given topic titles only, and as described earlier, with no training. In one case this was due to the maternity absence of their PSHE coordinator, but in another this was because there was no coordinator. Finding time to design 'Do-It-Yourself' PSHE lessons in addition to teachers' primary subject responsibilities was difficult. This triggered feelings of being exposed and abandoned, particularly if the topic was challenging.

Theme 2 - Adequacy of school delivery model for PSHE education (15 instances/11 participants): Participants described wide variation in their schools' infrastructures for providing PSHE education. Eight teachers noted a significant change in their provision model in recent years. Most commonly they described losing their previous one-hour, weekly timetabled PSHE lesson, and PSHE being subsequently 'down-graded'. In five schools, PSHE was downgraded to 15-25 minutes in form time once a week, and in three schools it was reduced to a three times a year 'drop-down' day, where the whole school is off timetable and external speakers are invited to deliver sessions. Opinion was divided about the value of the stand-alone drop-down approach: one teacher (participant 2) believed this was more exciting

for students; others (participants **3**, **6**) believed that this infrequency and inconsistency communicated that PSHE was unimportant:

“A whole day of PSHE?! That not so great because the kids start going into a kind of relaxed mode of like “oh well it’s just a PSHE day”. A lot of them bunk off. Whereas if you just have an hour a week, it’s only a little snippet but they might remember, you know ” (Participant **3**, English/drama, intervention, 131-134).

Relationships were considered more difficult to develop within drop down formats, where teachers typically delivered lessons across different groups of often unfamiliar students. Although this gave them chance to refine a particular lesson they kept repeat delivering, it was not beneficial in terms of building rapport and trust within a session to explore the material meaningfully (see theme 3).

Just two teachers described their school delivering the ‘gold standard’ of a full hour each week of PSHE lessons. Five teachers described having ‘drop-down’ days as an additional extra to supplement lessons, which was considered positive. For example, four schools put on Health Fairs, another school offered Citizenship days 3 times a year and health-related ‘immersion curriculum experiences’ for a full week twice a year.

Theme 3 - The importance of secure attachments for engaging students in PSHE work (12 instances/9 participants): Most participants felt that PSHE lessons were more meaningful and effective if they knew the students and had a good relationship with them. The importance of establishing oneself as a positive, secure parental attachment figure for the students was also highlighted, because at home students may not get chance to discuss and share opinions. It was explained that students were more likely to be honest and engage with the material if they trusted, respected and liked the teacher.

“Just again engagement. but also I think, I just think that they’re more likely to be honest if you know them quite well or they know and trust you” (Participant 4, Textiles lead, intervention, 296-297).

Appropriate personal disclosure, sharing stories, was considered to be important to earn students’ trust, in addition to knowing students which allowed teachers to anticipate their needs, engage them better and be sensitive to any potential issues. For example, participant **11** when delivering a session on healthy eating was able to be sensitive to one student with an eating disorder.

All participants spoke of developmental changes in students as they progressed through school which affected PSHE. Younger students were considered more easily engaged in PSHE and open to the topics. As students grow older, teachers tend to experience students as more challenging, opinionated and more guarded in discussions due to peer pressure awareness. Teachers stressed that the student-teacher relationship acquired greater

importance the older the students became, because the safe space it created helped them to feel more comfortable to explore issues and allowed teachers to tailor the lessons to be meaningful.

A number of teachers believed that a student's appraisal of PSHE's value was derived from the teacher's attitude and approach, as an influencer, and that engaging students in a topic heavily depends on who is delivering:

"The kids will get a good deal or a bad deal depending on the personality of the teacher" (Participant 1, PSHE lead, intervention, 224-226).

As highlighted in theme 2, the delivery model adopted by the school (i.e. form time, PSHE lesson, or drop-down day) dictated whether teachers were able to utilise pre-existing relationships with students to enhance PSHE lessons, including the smoking and homework lessons.

Theme 4 - "Validity" of PSHE as a subject (11 instances/11 participants): 7/12 participants considered PSHE to be high on their school's senior leadership team agenda. Two of these working within disadvantaged communities stressed the importance of having regular PSHE lessons to support their community. They described common health issues such as obesity, smoking (which remained prevalent in local families) and Year 9/10 pregnancies, which they had been working hard to reduce through acquiring specialist training and delivering a targeted programme. One participant working within an affluent community described a comprehensive 'Personal Education Programme', which was themed and tailored for demands and ability levels of different year groups. This contained modules such as 'Personal Accounting' which supported students managing their pocket money, their time and organising themselves to complete homework. Another participant described recently being awarded the 'Healthy School' status.

The two teachers interviewed from school 10 interestingly held different perceptions about the importance placed on PSHE education. The positive-experience teacher described it as an integral part of school life, but this was not the view of the negative-experience teacher, who had recently joined the school. In fact, he was one of four participants who perceived that PSHE was unimportant in their school. These four teachers experienced incongruence between their Senior Leadership Team's public communication about valuing PSHE education and lack of support 'on the ground'. This led to cynicism:

"We're getting Ofstedded. We need to make sure PSHE's up and running and it looks good and, you know, we need to make sure we're running those lessons. And I think, you know, you always get the sense of or the feeling that the reason we're making it a priority or a focus is simply to tick those sort of boxes" (Participant 10, Science lead, control, 86-89).

There was a perception that their school did not consider PSHE education as a 'valid' subject, as demonstrated by time being easily 'stolen' from PSHE lessons for revision sessions, school photographs and enforcing disciplinary measures, such as 'isolation'. Two participants felt that many students did not perceive PSHE lessons as a valid or 'proper' lesson, as evidenced through comments such as "why aren't we in a normal lesson" (Participant 9, Science, intervention, 81). One participant stressed that the "invalid" nature of PSHE education was a national problem, underlining that the government needed to communicate its importance by increasing funding in this area.

(2) Teachers' perceptions of the trial

Teachers' perceptions of the trial were represented by five themes (themes 5-9) consisting of: *placing high value on being involved in university research* (36 instances); *faith versus fatalism* about the effectiveness of school-based health interventions (15 instances); *understanding and preparedness* (11 instances); *legacy and impact* of being involved (5 instances) and *coming to terms with being the control* (2 instances).

Theme 5 - Placing high value on being involved in university research (36 instances/12 participants): Without exception, all participants considered participating in a university research study to be extremely positive for the school, students and themselves:

"Well it was exciting to be a part of the research programme for the university and it was satisfying as a teacher that you felt that you were going to be doing something which was hopefully leading to better kids' health leading on into the future"
(Participant **12**, Science lead, control, 17-20).

Contributing to a nationally important study was a sense of pride. Teachers believed that students felt valued, listened to and being associated with a university was a novel experience for them, which gave the study credibility:

"From their point of view I think that, you know, it's quite an exciting thing as soon as you see the university is attached to something, you know, it has that sort of aspirational aspect to it which is important and, you know, they feel like, you know, someone's listening to them" (Participant 10, Science lead, control, 63-65).

Participant 7 explained that their school's participation in the study modelled good citizenship behaviour to the students and also provided an invaluable opportunity for them to contribute beyond their own school to helping others in the future.

A professional interest in the trial was expressed by five participants who were science teachers. They understood the importance of trials, expressed excitement at contributing to national data and statistics, and satisfaction at being able to do something to improve students' health:

"As a scientist, as I say, we, you know, scientific studies are massively important"
(Participant 9, science, intervention, 48)

Four participants expressed a personal investment in the study as an anti-smoking advocate. Two were former smokers, one a current smoker and a further participant had lost his father to lung cancer. All were aware of the highly addictive nature of cigarettes and were motivated to share their experiences with students.

Numerous teachers recognised the benefits of being involved. Those teaching within disadvantaged communities felt that trialling the smoking intervention supported them with their local agenda to reduce smoking and improve health outcomes (participants 5, 8). For one control school, there was a feeling that the homework lesson targeted a gap in their curriculum, as these skills/topics are not normally covered with students. The same teacher felt strongly that university-school collaborations are extremely beneficial in terms of reciprocal skill exchange:

“I think the universities working with schools is great anyway just in the fact of sort of sharing practices and knowledge and all of those things” (Participant 7, PSHE lead/history, control, 298-299).

Teachers spoke about the lack of money in schools and the significant benefits arising from working with universities. For example, receiving free, high quality, colour materials to support PSHE and enhancing PSE practice was highly valued. Four teachers were unaware of any benefits/incentives provided for participating in the study. For example, they had not seen the annual framed certificate or were unaware of the free workshops and other services available.

Theme 6 - Faith versus fatalism about health interventions (15 instances/10 participants): With regard to the intervention, half of the teachers felt strongly that this sort of school-based intervention could change lives and have a positive impact. Particularly in areas where smoking was still common in families, teachers recognised students’ potential to be agents of change:

“We had that a girl in my form went to her mum and said, “Will you just please stop doing that? I just, I don’t want you to smoke anymore.” So yeah it can have an impact” (Participant 1, PSHE lead, intervention, 232-234).

Teachers spoke of the power of the consistent, repetitive messages about smoking, where previously their school had covered smoking once across the student’s whole lifetime in school. Starting young, whilst students were still receptive, was also considered to be an effective approach.

Two teachers believed that an intervention can never wholly prevent students engaging in risky activity, but through discussion, they can be helped to make informed choices. Four teachers acknowledged that smoking attitudes and norms were continuing to shift, and through their careers they had witnessed a dramatic decline in the popularity of

smoking. The implication here was perhaps that the requirement for a smoking prevention intervention was less urgent/critical at this point in time. Two teachers were more ambivalent-to-fatalistic about the reach of a smoking prevention intervention, commenting that some students will always be resistant:

“By the time they're in Year 9, they've made their decision and anything you do isn't really going to change it because, you know, they're in their ways and they're in their habits” (Participant 9, science, intervention, 102-103).

When asked about the potential impact of homework lessons, participant **11** was quite fatalistic, arguing that parents were a bigger influence, and that it was impossible to convince students to do homework if they did not want to. However a different control teacher (participant **12**) stressed that such an approach had significant potential, if it was extended and developed.

Theme 7 - Understanding and preparedness (11 instances/11 participants): Just over half the participants (7/12) reported feeling clear about the study, its aims and how the data collection and lessons elements fitted together. One had received a briefing from the Head of Year, but the rest had attended the training, which they explained had helped them to feel involved and equipped:

“Yes you went into your lesson knowing exactly what you had to do and what methods you had to get over to the kids” (Participant 1, PSHE lead, intervention, 65-66).

The remaining five participants were less clear about the study overall. One of these had attended the training at the start of the study (but could not recall this), whilst the rest had not attended the training sessions. In one case, this was due to being new to the school. These teachers typically received a brief explanation by email, and delivered the materials ‘cold’, struggling to make sense of what they were being asked to do and why:

“I was never as clear with the sort of purpose of the lessons in advance because I was kind of looking at what was there and kind of looking at the information that had been sent out trying to patch it all together” (Participant **6**, science, intervention, 158-160).

In some cases, teachers admitted that the students knew more than they did and had to explain the process to them. For control teachers who had not attended the training, there was difficulty linking the smoking data collection with delivering the homework lessons:

“I had that confusion about the control and well, were we part of the smoking information?.. which it turns out we were, weren't we? You got data from our students over a number of years for smoking which I hadn't fully realised. [...] If you don't see the project the whole way through I think it can be a little bit confusing” (Participant **11**, Modern languages, control, 159-164).

Two teachers (participants 4, **11**) suggested that student engagement would have increased

if they had received the smoking 'survey' results each year, which was not possible because this would have confounded the study (this had been explained during the training).

Theme 8 - Legacy and impact (5 instances/4 participants): Reflecting on their time in the trial, four teachers (two intervention/two control) spoke about the positive impact of participating. Another control school teacher explained how his students had used the homework/study strategies, and proudly brought in, for example, MindMaps for him to see. The same teacher used the homework materials (which he originally delivered to his form) with his science classes to enhance their motivation and study strategies. The school had also incorporated the handouts and messages into their parent information evenings, to help parents support their children with homework and revision. One teacher explained that her school planned to adopt the repetitive messages and personal planning approach as standard protocol with their new Year 7s (participant 8) and one Head of PSHE planned to incorporate the smoking materials into his school's new PSHE curriculum:

“Well I was looking for like a new angle on things as well and already just glance reading over this there's stuff that I'm gonna put into my new scheme of work for the Year 8 smoking” (Participant 5, PSHE lead, intervention, 420-423).

Two schools particularly valued and enjoyed the university-school collaboration and stated that they were 'eager' to participate in future research.

Theme 9 - Coming to terms with being the control (2 instances/2 participants): Two participants commented explicitly on being allocated the control condition. One explained that, whilst he understood the need for a control group as a scientist, he was 'disappointed to get it'. One of the reasons for his disappointment became clear when he described the very different goals he perceived behind the pro-homework and anti-smoking lessons:

“Yeah I mean I often imagined that, if it was about smoking, the students in the school that were doing the equivalent smoking things that maybe they were thinking well you know, 'Our teachers are doing this because they care about us, they're concerned.' So you've got that dimension in there which is perhaps, it's in there a little bit with the homework isn't it, but maybe not quite as much. I might be just plugging homework because I'm a teacher and I want that homework to come in, whereas with smoking I'm looking at a bigger, a bigger wedge of care if you like for my students” (Participant 17, Science lead, control, 217-223).

Being in the control condition seemed to affect his personal motivation and enjoyment of the study, however he explained that he remained committed to it. This commitment to the study, regardless of being allocated the control, was also echoed by another teacher (participant 7). However she gave a more positive account and was still able to acknowledge the positives, commenting that their school already covered smoking well.

(3) Teachers' experiences of delivering the intervention or control lessons and factors influencing this

Teachers' experiences of delivering the standardised lessons were varied and four main themes (themes 10-13) were identified. Teachers' experiences were marked by having to contend with *numerous engagement threats* (28 instances) and they employed different *strategies to boost engagement* (16 instances). They expressed different degrees of *comfort with responsibility for delivering* the lessons (16 instances), but there was broad consensus regarding the *acceptability of pre-designed materials* (14 instances), although some teachers felt improvements could be made to the lesson design.

Theme 10 - Engagement threats (28 instances/12 participants): Whilst four teachers felt that students had engaged well with the study and saw it as important (participants 1, 5, 8, 10), others felt that engagement was more mixed. Students' reactions to the repetitive, standard format of the lesson featured strongly in teachers' accounts. Teachers explained that initially students were enthusiastic and engaged, but the repetitive format dampened their enthusiasm over time. Varying degrees of negativity were observed, from minor annoyance through to strong reactance. For example, some teachers felt that their students were unhappy about the repetition, but still applied themselves regardless and were not particularly challenging:

"It was never an issue as in "Oh we're doing this", you know. There wasn't really any moaning about the lessons or anything" (Participant 7, PSHE lead/history, control, 221-225).

"Well they certainly have engaged with them. I mean there's certainly an element of them going, "Oh, smoking again," you know. But I think they do recognise that it is important they look at it [...] there's not been any real kind of annoyance" (Participant 6, Science, intervention, 124-129).

Two control teachers observed their students disengaging as they grew older, i.e. they were "just going through the motions" (participant 12, Science lead, control, 172) and "weren't giving it the necessary thought towards the end" (participant 11, Modern languages, control, 130).

Other teachers experienced stronger psychological reactance from the students as they grew older. They described 'eyerolling' and groans from the students when they handed out the materials at the start of the lesson. One teacher delivering in a school undergoing considerable change/turbulence described a particularly difficult struggle to engage her students:

"By the time it got to Year 10, the kids were just, unfortunately they weren't engaged as much as you would want them to be. So it did become a bit of a, a bit of

a fight [...] They were all a bit like, "Can we not just get on with what we're, you know, what we're meant to do?" (Participant 9, science, intervention, 49-53).

Teachers in both the control and intervention groups spoke of students feeling angry that they were still 'made' to do the lessons, even though they were never going to smoke, or always did their homework, for example:

"Some are like 'well I'm not gonna do it anyway and I've got', you know, 'why am I still having to do this', you know" (Participant 2, STEM lead/science, intervention, 141-142).

Teachers also described mixed reactions from the students to the lesson content. Delivering a standardised lesson plan meant that it was difficult to wholly cater for different abilities, interests and changing ages. Teachers explained that whilst most students consistently enjoyed video clips when they were included in the lessons, they preferred discussions to filling in handouts/worksheets:

"I think the whole point of PSHE is that we're all discussing and we're talking in an open environment and I think when you start doing individual worksheets, they're just like "well what's the point? It's not going to get marked, it's not worth anything, why do I have to do this?" So I think that doesn't work, definitely not" (Participant 3, English/drama, intervention, 732-735).

There were competing teacher views about the lesson topics. For example, the "looking after yourself during stressful times" lesson was experienced as particularly valuable and enjoyed in a disadvantaged intervention school (participant 8) but "felt like overload" in a moderate-to-affluent control school (participant 11) who had done considerable work on this already.

Many teachers reiterated that student receptivity to PSHE material declines with age. In this sense there was some degree of acceptance that the waning student enthusiasm for the smoking/homework lessons was, to some extent, a function of age. However this was not a universal perception. Participant 8 described student engagement in the smoking intervention increasing with age, and that students became more open and willing to discuss smoking.

Teachers also explained that timetabling decisions made by the school regarding when the smoking/homework lesson would be delivered impacted on engagement. For example, a number of the teachers had to deliver the lesson in a 20-25 minute form period, in their capacity of form tutor. Knowing the students well enhanced openness and enabled teachers to make adjustments for their abilities and circumstances (participant 4, 10). However there was insufficient time to adequately complete all activities (which had been designed for a standard 50-60 minute lesson). Furthermore, the environment was more informal, relaxed and the teacher struggled to get students to write anything down

(participants 6, 10). Having *too much* time was a challenge for a teacher delivering the lesson within a 75 minute drop-down day period:

“Obviously delivering it in this amount of time that we have, you know, [...] that's sort of the main issue really actually for us. And obviously if somewhere else has had a half hour PSHE session it will be a lot more snappy and that will be fine I think. But it's just when you've got to keep it for 75 minutes in the room” (Participant 2, STEM lead/science, intervention, 175-179).

Whilst initially he allowed students more time for discussion, they soon became bored, therefore he began to supplement the lesson with additional material, or simply allow students time at the end for talking. A further challenge with the timetabling was that he delivered the lesson in the same room all day to multiple student groups he did not know, therefore he had no relationship with them.

In one control school (participant 12) the homework lesson was delivered within a comprehensive PSHE curriculum. The teacher felt that the homework lesson fitted perfectly in the early years module ‘Get yourself organised’. But in later years, as the scheme of work moved on, the homework lesson seemed incongruent. Students became confused and found it hard to understand why they were still having it.

Most of the teachers described delivering the lessons to mixed-ability classes, which posed challenges with regard to ensuring understanding, keeping students on task and maintaining an appropriate pace. However participant 5 delivered the smoking lesson within streamed PSHE lessons, which he felt had a positive impact on engagement because, for example, he was able to adjust more easily and completely for high and low abilities.

Two participants (4, 9) commented that some students felt vulnerable about committing their smoking habits to paper, suspicious that teachers or parents would find out and ‘hold it against them’. These teachers described reassuring them that all information was anonymous and in confidence in order to re-engage them in the material and tasks.

Theme 11 - Comfort with responsibility for delivery (16 instances/12 participants):

Diverse reactions to being responsible for the lessons were apparent during the interviews. Five teachers underlined that the responsibility was not burdensome, commenting that “there was no extra work involved at all” (Participant 8, history, intervention, 40), the lessons were straightforward to deliver:

“You made it easy and it wasn’t a tedious task that we think “Oh we’re doing the smoking thing”, you know, it’s not been a huge extra burden of work for anybody” (Participant 7, PSHE lead/history, control, 303-305).

These schools noted a good response from their colleagues towards delivering the lessons, and that staff involved were committed to the study.

Four participants (5,8,4,11) explicitly described enjoying delivering the lessons. One PSHE lead (in a disadvantaged community) was very receptive to using others' material:

"It's always nice to have material somebody else has produced to deliver in lessons and I thought because the material was relevant and because the material was attractive to the students that they would respond to it well, and without a doubt, you know, across the board, that's what they did" (Participant 5, PSHE lead, intervention, 26-29).

Another teacher working in a disadvantaged community described being responsible for delivering the lessons as a rewarding, enjoyable experience:

"I found it fascinating to teach and to be involved with and I thoroughly enjoyed doing it with my coaching group" (Participant 8, history, intervention, 284-285).

Four teachers described some discomfort at being responsible for the lessons. One of these was a relatively new teacher, who had neither participated in the training nor been briefed on the study. He felt worried about how students would react to the lessons and whether they would see it as a 'valid' lesson. He honestly explains, below, the difficulties of delivering and personally engaging in material that he has not designed:

"A little bit of trepidation in terms of getting them to engage when you don't know it that well because you've not written it, you've been given it. And you're gonna look through it but you're always gonna be much more superficial than if you were writing it yourself" (Participant 6, science, intervention, 29-33).

A related difficulty was experienced by a control teacher who delivered all eight of the homework lessons in his school. He felt increasingly compromised by persisting with the standardised lesson plan when his students were disengaging: this felt like he was betraying his teaching principles:

"It's not the sort of thing that I would ask them to do in terms of just going through the motions. I would always try and make the PEP session something which was of worth and it would stretch them somehow" (Participant 12, Science lead, control, 173-175).

Participant 9 was responsible for delivering the smoking intervention in a school undergoing a turbulent time, following an unsatisfactory Ofsted inspection. This included leadership changes, multiple staff resignations, stress-related sickness absences and high rates of cover staff. During this destabilising period, student behaviour deteriorated considerably. The teacher explained that the combination of high teacher stress levels and poorly-behaved students, who were openly dissatisfied with the repetitive nature of the lessons, meant that some staff refused to deliver the smoking lessons because they did not want the additional stress. She recalls numerous colleagues saying:

"I don't feel comfortable delivering it to them because I don't have the kind of relationship where I feel I can manage it" (Participant 9, science, intervention, 153-154).

In these cases, the coordinator had to re-allocate these classes to the more experienced or resilient teachers who were prepared to deliver them. Similarly, another intervention teacher also commented on how students' reactance to the repetitive nature of the study affected her, and on the effort she had to invest to engage them in the lesson:

"It's quite difficult because you still have to do it and try and be positive and try and get the best out of them" (Participant 4, Textiles lead, intervention, 108-109).

Through either choice or necessity, there was evidence of limited planning/preparation for the lessons. Two teachers commented that, although their schools were committed in theory, little support was practically available for lesson planning and preparation. One of these delivered a smoking prevention lesson with only a third of the resources (i.e. without a lesson plan or Personal Plan handouts) due to the study coordinator's error. Consequently, a follow-up lesson had to be planned to complete the Personal Plans with students (which were required by the research team). Teachers described the lesson packs often being placed in staff pigeonholes the evening before or the morning of delivery, which meant that adequate preparation was difficult. Three participants (2, 3, 4) spoke of preparing briefly for the lesson on the day/morning before delivery and one experienced PSHE teacher briefly scanned the resources immediately prior to the lesson. Teachers were accustomed to this short level of notice to prepare for PSHE lessons, therefore this did not overly concern them:

"You get used to doing it. I think the thought of it is a bit stressful but the minute you open up a PowerPoint or you just look at the material, it does tend to make sense, you know. But it doesn't take long to look through even, you know, half an hour or less even I would say, just to check that you know what you're doing. So no, we are used to doing that" (Participant 11, Modern Languages, control, 180-183).

Theme 12 - Strategies employed to boost engagement (15 instances/10 participants): Ten teachers described investing additional efforts to boost student engagement. The most common approach was to supplement the lesson plan with personal stories, particularly about smoking, such as sharing experiences of when they were young:

"Oh they love to hear your own stories [...] I talk about my dad who smoked all his life you know and had emphysema and what have you. I talked about when I was twelve I had a go as a girl guide but didn't like it" (Participant 1, PSHE lead, intervention, 211-214).

Tailoring the lesson to the group or making adaptations was also popular, such as introducing additional videos, engaging students to share their opinions in additional discussion, or reducing discussion time when behaviour was challenging. Those describing adaptations were all mindful of the controlled nature of the study, so were keen to stress that this only involved:

"Minor tweaking, 'cos obviously I realise, you know, you can't" (Participant 2, STEM lead/science, intervention, 221).

Four teachers described more interpersonal, motivational approaches to encourage students to apply themselves to the lesson materials. These included “chivvyng them along” (Science teacher, school 10, 138), keeping the atmosphere fun by “acting a little bit daft at the front of the room [...] as we went along to keep them going along with me” (Languages teacher, school 15, 124), “a lot of banter with them to try and kind of bring them round” (Science teacher, school 6, 162-163), “coaching them through it” (History teacher, school 5, 166), being “positive to get the best out of them, using encouragement” (Textiles teacher, school 10, 118).

Three teachers spoke of appealing to the students to encourage them focus on the lesson. For example, inspirational appeals were used in the hope that reinforcing the importance of the study during the lesson would enhance its credibility and positively influence the students:

“I try and promote it so, 'this is a real study, it's a pilot study, this might go national so you're involved in something very important'” (Participant 2, STEM lead/science, intervention, 150-152).

Two teachers (one control; one intervention) made personal appeals to the students, drawing on their trusting relationship with them, to encourage them to apply themselves to the lesson material. The control teacher, who had delivered all eight homework lessons in his school, explained:

“I’ve got to admit sort of the ones in the last year were, ‘It’s another one of these guys, I’m sorry, let’s, you know the routine, let’s do it’” (Participant 12, Science lead, control, 187-188).

The intervention teacher taught in the turbulent school where stressed teachers refused to deliver the lessons to difficult classes. She explains below how having a relationship with students can provide a teacher with personal influence or leverage to ‘get them on side’ when their engagement is low:

“I taught it to the class I knew, in which case it was quite easy to just kind of go, “Ha ha, very funny. Come on guys, think about this sensibly”, and bring them round. But I also taught it to a class I didn’t really know, but it was much harder, in that point of view, to try and bring them round, because I didn’t have the hook I needed” (Participant 9, science, intervention, 119-123).

Theme 13 - Acceptability of pre-designed materials (15 instances/12 participants):

Most (9/12) teachers were positive about being provided with a lesson plan and supporting materials. One PSHE lead commented, “I like the way it was delivered to us” (participant 1, PSHE lead, intervention, 309-310). The lesson pack was easily accepted by staff because it was commensurate with what they already received for PSHE education lessons. Teachers described the resources as “excellent” (participants 5, 8) and easy to use:

“Certainly the big thing that stood out was that the resources and the stuff that we’d got through was actually really comprehensive and really easy to follow and

use. Speaking to colleagues and other staff members, I don't think anyone's come across and said that they were particularly difficult to use or didn't enjoy teaching them" (Participant 10, Science lead, control, 401-405).

Views about the content and design of the lessons were more mixed. Some teachers described positive experiences of the lesson design, and discussions that arose from the material:

"It was so engaging, there was so much food for thought [...] I mean everything, part of it in terms of health, in terms of finance, in terms of various different things that came from it" (Participant 8, History, intervention, 219-222).

However, given the repetitive nature of the lessons, others felt that more varied learning opportunities, such as practical tasks/activities and focusing more on discussions without having to complete a worksheet, would have sustained students' engagement as they grew older:

"The format that there was in Year 7 and 8 was probably okay, but from 8, sorry, 9 to 10 they wanted something a bit more interactive [...], rather than just the same thing again" (Participant 12, Science lead, control, 242-244).

The inclusion of particularly 'nasty', 'hard-hitting' or shocking videos¹ and interesting, tactile objects or models, such as lungs containing tar, was also considered beneficial to spark interest.

Two teachers (3, 5) felt that the volume of information provided could be reduced, to make it less daunting for some, and allow more time for discussion, particularly when working with low-ability students:

"I could probably get about three or four lessons out of what's here which is why I'm, yeah, lots of, you know, different stances, information, pie charts" (Participant 5, PSHE lead, intervention, 243-245).

There was a view (participants 3, 6, 9) that the lessons were too simplistic or data-driven, and did not provide students with meaningful, challenging learning opportunities:

"It's fairly straightforward, there's nothing that's going to really challenge them, and I think that may be one of the elements with it. [...] Because it's more about information provision and then checking what they're going to do, they don't necessarily see it as a learning opportunity" (Participant 6, science, intervention, 131-134).

Finally, teachers emphasised that greater relevance and appropriateness would improve the lessons, such as focusing on the 'here and now' rather than the future. A number of teachers

¹ In response to feedback provided by teachers in their Cover Sheets during the trial, YouTube videos were introduced into the lesson design for the last 2 years of the trial.

reiterated that older students were harder to engage in PSHE, therefore it was critical that activities and discussions were “tweaked” to be more relevant and engaging to them.

Differences between intervention and control teachers’ accounts

Compared to control teachers, intervention teachers spoke *more frequently* about: being professionally (as a scientist) or personally (as an anti-smoking advocate) invested in the trial (8 vs. 2 instances); having faith that health interventions can change lives (5 vs. 1 instances); students’ mixed reactions to the lesson content (6 vs. 2 instances). Intervention teachers spoke *exclusively* about the need to focus on creating learning opportunities rather than simply ‘information provision and checking’. They also spoke exclusively about engaging in limited planning and preparation before delivering the smoking lessons, using personal disclosure/stories and making adaptations to boost student engagement. The main engagement boosting strategies described by control teachers were personal/inspirational appeals and interpersonal motivation, such as ‘chivvying’ students along.

Factors differentiating positive from negative lesson experiences

Teachers who rated their lessons *negatively* (participants 2, 3, 6, [intervention] and 11, 12 [control]) were more likely to work in schools supported by a centralised PSHE subject lead (3/4 instances) and exclusively in those which deliver PSHE through drop down days (3/3 instances). These participants were also heavily represented with regard to low understanding and preparedness about the trial – they were more likely to comment on confusion and sense-making, and none had been through the training or had a briefing (3/4). Teachers rating the lessons negatively spoke more about using inspirational appeals (2/3) rather than sharing personal stories or making adaptations (both these were science teachers so they may have been more conscious not to adapt, which might have contributed to their frustration/unhappiness with how the session went). The negative lesson rating teachers also commented more on limitations with the design – expressing the view that the lesson should be designed more as a learning opportunity than information provision and checking (2/3).

Teachers who rated their lessons *positively* commented exclusively on their school having supplementary events to enhance PSHE education (4/4). They were more likely to report having a good understanding of the trial and feeling involved and equipped to deliver the lessons (5/7), either through attending the training or being briefed. Linked to this, they also exclusively recognised benefits that were available as result of being in the study (5/5). They were more likely to comment on having faith in interventions and being positive about starting prevention education young (4/5). Positive rating teachers tended to draw upon personal disclosure and/or interpersonal motivation to boost student engagement (6/8) and

were the only group to comment on making lesson adaptations (3/3). They were more likely to rate the materials as good quality, easy to deliver and following usual practice (5/6) and commented exclusively that they or their school had adopted the materials and/or approach (3/3).

The following discussion section draws together the findings from the semi-structured interviews ('depth') and the analysis of the teacher Cover Sheets ('breadth') to provide an integrated representation of teachers' experiences, and sets this in context of previous research.

6.5 Discussion

This study sought to determine the extent to which teachers adhered to lesson-related protocol within the trial (as a proxy for overall engagement), and to understand their experiences of delivering the lessons, including whether their school's PSHE education context affected their engagement, and their experiences of the trial overall.

A high proportion (80%) of the lesson packs issued to schools were utilised and returned. Control schools and those in moderate-to-wealthy communities returned significantly more of their issued lesson packs than intervention schools and those in disadvantaged areas. Adherence to Cover Sheet protocol within all returned, used lesson packs was high across the 20 participating Yorkshire schools (83%), particularly from those in the control condition and in moderate-to-wealthy areas. Teachers delivering the intervention were more likely to deviate from lesson protocol than control teachers, as evidenced by their significantly lower ratings for the Cover Sheet item 'I followed the lesson plan to the letter'.

Analysis of the Cover Sheets revealed that intervention and control teachers' ratings of their lessons were not significantly different. However, irrespective of condition, teachers working in lower Ofsted-rated schools rated their lessons significantly more positively than teachers in high Ofsted-rated schools. The lowest rated Cover Sheet items were 'this lesson was a pleasure to deliver' and 'overall I'd say the lesson went incredibly well', indicating that the delivery of the lessons was not a particularly positive experience for the teachers.

Many of the experiences obtained at scale from the 568 Cover Sheets were similar to those shared by the 12 teachers interviewed, particularly with regard to the delivery of the lessons. The semi-structured interviews revealed a more positive experience for intervention teachers than those delivering the control lessons, however not all teachers were comfortable with having responsibility for delivering their lessons. Having to contend with students' dissatisfaction with the repetitive, unvarying format of the lessons was identified as a major

challenge in both data sets, and teachers across both data sets commented on taking steps to make the lesson work and boost engagement. Through the interviews, teachers were able to explain how personally difficult it was to be confronted with strong psychological reactance (e.g. some already stressed teachers refused to deliver the lesson), and provide more detail about the strategies they employed to keep the students on task during the lesson. Intervention teachers described using more active approaches to boost engagement, such as disclosing personal stories, extending discussions and tailoring the session to better meet the needs of the group (echoing the lower agreement to the Cover Sheet feedback item 'I followed the lesson plan to the letter'). Whilst teachers delivering the control lessons also described trying to boost engagement, their strategies were of a more interpersonal nature, such as 'chivvying' students along.

'Muddling through' unsatisfactory conditions was also a dominant theme across both data sets. Teachers described delivering the lessons with little/no contextual understanding of the study, with too much/too little time due to inappropriate timetabling by their school and sometimes missing key materials. Teachers were able to explain during the interviews that 'muddling through' was a common experience, particularly when delivering PSHE material, and that many teachers had grown accustomed to quickly adapting in less than ideal circumstances. The acceptability of the pre-designed materials was also highlighted in both data sets. Data from the interviews provided further understanding, as teachers explained that they were commensurate with their usual PSHE resources, attractive and well structured. Intervention teachers in particular commented more frequently than control teachers that students engaged well with the material and had good group discussions, but equally they also reflected more on the lesson content and made more suggestions for improvement (e.g. incorporating greater variety, artefacts and hands-on tasks). Finally, the need to cater more sensitively for lower abilities and to encompass more variety and genuine learning opportunities within the lessons was raised in both data sets.

This study has revealed that teachers' experiences of the PSHE context in their schools were very mixed. A high proportion had received no training to deliver this work, despite a wide acknowledgement that this often "alien", intensely personal work could be daunting. Numerous teachers seemed to be in a no-win situation due to their excessive workloads, and were used to 'muddling through' in PSHE topics: if they had a central PSHE coordinator designing the lessons, they had little time to sufficiently familiarise themselves with the content; if they were responsible for designing the lessons themselves, they had little time and guidance to create a confident lesson. Many teachers had witnessed an erosion in time

allocated to PSHE, to either 20-minutes' form time a week or three drop-down days per year, and these sometimes had consequences, such as being too informal (form time) or not being able to work with well-known students (drop-down day). The majority of teachers felt that their school leadership team valued PSHE, but others were more cynical that they were simply 'ticking' Ofsted boxes.

Teachers' perceptions of the trial overall were positive. Generally, school-university collaborations were held in high esteem, and considered a valuable experience for students, staff and the school. Half of the teachers had faith in the positive impact of school-based health interventions on students' lives. Teachers who had attended the training or been carefully briefed felt involved and equipped to play their part in it, and these teachers were more likely to rate their lessons positively. However numerous teachers delivered the lessons without the training or a briefing, and therefore delivered the lessons without being able to situate them in the context of the trial, or understand their important contribution to the trial and its outcomes. These teachers were more likely to rate their lessons negatively.

Many of these findings are reflective of previous research. For example, teachers' mixed experiences of PSHE, the need for the intervention to be more interactive, 'hands-on', more differentiated for age and academic ability, and students' declining interest in the intervention over time, were all also highlighted by teachers in Stallard et al.'s (2013) cluster trial testing a classroom-based CBT intervention. In line with the implementation science literature, many teachers found being faced with delivering the intervention or control to unenthusiastic students very challenging, and being in the control group was (at least for one teacher) disappointing.

An interesting finding was that differences in lesson ratings were attributable more to the characteristics of the school than the type of lesson being delivered (i.e. smoking or homework). Irrespective of condition, teachers in low Ofsted schools rated their lessons more highly than those in high Ofsted schools and those in moderate-to-wealthy areas. These Ofsted-related differences are similar to those found in the teacher-coordinators in study one (Chapter four). Together, these findings lend further support for the notion that, whilst each school may be a 'distinct society' (Caan et al., 2015), there may be comparable "norms, values, attitudes, behaviors and actions" (Christenson et al., 2002, p.473) within particular types of schools, specifically related to their Ofsted rating. For example, as discussed in chapter four, highly successful head teachers have been found to promote "an orderly and secure working environment" (Sammons et al., 2011, p.93), set clear direction and display high expectations for teachers' work with students. They prioritise continuous improvement, such as

“developing a culture of research and innovation” and “encouraging the use of data and research” (Sammons et al., 2011). This suggests that high Ofsted schools may approach research with high expectancies, compared to low Ofsted schools. These organisational-level differences will be explored further in Chapter eight.

Reflecting on Hall’s (2013) Concerns-based Adoption model: The broader findings can be interpreted using Hall’s Concerns-based Adoption model. From a *self-concerns* perspective, planning and preparation time generally helps teachers to feel more confident and equipped to deliver the material (Haataja et al., 2015). Students have been found to participate actively in lessons when teachers are well prepared and competent (Haataja et al., 2015). Almost all those teachers who rated their lesson experiences positively had a good level of understanding of the trial and of the lessons. Conversely, almost all of the teachers rating their lesson experiences negatively had delivered the lesson ‘blind’ with no training or briefing, and spoke of confusion, trying to make sense of what they were being asked to do, and of students sometimes knowing more than them. In conjunction with minimal preparation, which was a common feature, these teachers may have been unable to resolve their self-concerns in relation to delivering the material. This in turn may have had a reciprocal impact on student engagement in the lesson. *Task concerns* of the teachers were not always resolved: senior leadership support for the recommended timetable space (50 minutes) was uncommon, and a number of teachers commented on leadership ‘ticking boxes’ rather than supporting PSHE in a meaningful way. There were mixed beliefs about the potential effectiveness of the intervention (and control) which may have meant that *impact concerns* were not resolved. For example, 75% of teachers interviewed/11% of teachers in their Cover Sheets commented that the lessons needed to be more engaging, student-centred and differentiated for ability and age. Similarly, nearly all the interviewed teachers and 19% of teachers in their Cover Sheets commented on the repetitive aspect of the intervention/control lessons, and the negative impact on student engagement.

Acceptability of the intervention and adaptations: Teachers were charged with delivering a repetitive, unchanging format to students over a four-year period, which led to engagement challenges. It is clear that different approaches were used to try to encourage students to apply themselves to the lessons, particularly as they grew older. Urdan and Schoenfelder (2006) argue that teachers play a central role in enhancing student engagement through the learning climate they create and the learning opportunities they provide in the classroom. Student motivation is enhanced when teachers provide a strong ‘mastery’ goal structure in the classroom (Urdan & Schoenelder, 2006). This involves establishing a learning

climate, which builds on students' internal sense of competence and skills (have I *personally* learned?), rather than through their performance having to appear capable or better than others (did I do better than my classmates?) (Urda & Schoenfelder, 2006). To foster a mastery goal structure, teachers prioritise the valuing of learning and understanding of material in the classroom by providing "appropriately challenging and meaningful work", "opportunities for choice and autonomy" during lessons and evaluating students for their individual progress rather than by "social comparison and competition" (Urda & Schoenfelder, 2006, p.335).

Comments made by numerous teachers regarding students' (and indeed their own) declining motivation and engagement with the lessons indicate that repeatedly delivering a standardised lesson to all, under instructions not to deviate from the plan, which followed the same format each time, violated a number of mastery goal structure principles. Teachers adhering conscientiously to the plan expressed feeling compromised, that they were not sufficiently challenging their students, that it set a 'low-bar' of information provision and checking. Other teachers responded to the violation of mastery goal structure principles by taking action to adjust the lesson, using the plan and materials as a base, but adapting through additional videos, engaging students in further discussion. A further group of teachers appeared to pay surface commitment to the lessons, but did not dwell too heavily upon any dissonance or discomfort.

By making adaptations to make the intervention (or control lesson) more relevant to students, teachers may have helped them to feel that they were being heard and respected, a strategy which has been found to increase engagement with interventions/programmes (Berkel et al., 2011). Those teachers who listened to students' expressions of dissatisfaction, ventured off-lesson plan and invested in adapting the intervention may have contributed to sustaining their interest in the trial and the intervention's ultimate success. Rather than perceiving these as unhelpful deviations from protocol and interpreting that teachers may not have been committed to the study, on the contrary, teachers may have been committed to making it useful for the participants. Other teachers who were loyally committed to the protocol and followed the lesson plan to the letter may have exacerbated students' dissatisfaction and disengagement because they inadequately addressed their complaints. This in turn may have diminished their own engagement in the trial due to the unrewarding nature of the lesson.

Problems establishing a 'mastery goal structure' within PSHE: Fostering a mastery goal structure requires teachers to be confident in the material and relies upon meaningful

evaluation of this material and both aspects are problematic with regard to PSHE education in schools. To teach any other subject (e.g. Science), teachers train extensively to enable them to confidently support students learn their subject. However, the Department for Education (2015) emphasise that *all* teaching staff have responsibility for teaching PSHE, despite training being largely unsatisfactory or non-existent (Glover, 2017). Glover (2017) challenges this position, questioning why everyone should necessarily be a good PSHE teacher, and why it is considered acceptable to teach this topic with insufficient or no training. She argues that this position transparently highlights that, as a subject, PSHE is not considered commensurate with other subjects. From a personal perspective, teachers in the present study spoke repeatedly about confidence issues, inadequate training, receiving materials too late for adequate preparation, being unfamiliar with the lesson content because they had not designed/researched it or anxious because they had to construct a lesson with little specialist PSHE knowledge. Furthermore, teachers commented (e.g. participant **3**) that student progress is never evaluated in PSHE lessons/curriculum and that lessons do not consolidate or build logically, despite occasional exceptions (e.g. the Personal Education Programme in school 17, which was carefully structured to target students' developmental needs as they moved through school). Ofsted also highlighted these as deficiencies in their 2013 report "Not yet good enough".

Responses to being allocated the control group: Two teachers commenting on their experience of being control schools had different appraisals of their allocation. Similar to the parents in Peterson et al.'s trial (2014) whose children were allocated the control condition, each teacher interpreted their situation differently. Participant 7 (PSHE lead/history) was of the attitude that participating in the study was important in itself, that school-university collaborations were valuable. She felt that the school was modelling good citizenship behaviour to the students by participating (i.e. altruistically helping other students in future), that homework skills were a new topic they did not cover, whilst smoking was adequately covered in school anyway. Participant **12** (Science lead) had a different reaction. He expressed disappointment that their school was not randomised to the experimental condition, explaining that he would have liked to have had the chance to really affect his students' wellbeing and have been 'really participating'. Because his school covered homework/managing your time in their Personal Education Programme (PEP), the homework lesson was not satisfying an unmet need; rather it was difficult to schedule in their PEP as students progressed through school.

Evidence of ‘typologies’ of practitioners: These very different evaluations are evidence of the personal agency that teachers brought to bear on the trial and their delivery of the lessons. Across the sample there were very different teacher attitudes, personalities, values and interpretations of and reactions to common challenges. This was particularly evident within the interviews, where elements of Riley and Hawe’s (2009) typologies were visible. Participant 8 could be defined as the ‘romantic type’ because she spoke of running over on the lessons because her form students were so engaged in the discussions that she did not want to hurry them. The Personal Plans were completed, against protocol, on the next day rather than at the end of the lesson. Participants 2 and 12, both Science leads, could be considered ‘technologist types’. Both ensured they attended the training. As scientists, both were cognisant of the need for protocol adherence, did not engage in significant adaptations to the lessons (relying mostly on personal/inspirational appeals to complete the lessons) and reliably completed all their Cover Sheets. Incidentally both were in the negative lesson experience group.

Participant 9’s school was undergoing a turbulent, destabilising period, yet she retained a strong sense of commitment to the study, again partly due to being a scientist. She could be defined as a ‘heroic type’ because, whilst other teachers refused to deliver the smoking lessons due to poorly behaved students and high stress levels, she took responsibility for delivering these, in addition to her own classes, to ensure they were completed. Participant 11 may be described as an ‘against the odds’ type. Whilst she was initially optimistic when the study commenced, she found the obstacles she experienced over time (e.g. inconsistent involvement over the years, not being clear about the study, students dissatisfaction with the repetition and boredom) too overwhelming and her enthusiasm declined considerably. Finally, participant 3 could be regarded as the ‘satirist’ in the sample. She was dissatisfied with the general support of her senior leadership team in school, critical of their PSHE reductionist model of drop-down days, non-existent staff training and staff having to design their own PSHE lessons. The impression from her was that, in her school’s hands, the intervention was doomed.

6.5.1 Implications

Whilst all the lesson materials were overseen by a teacher who acted as a consultant to the study, they were designed by psychologists who were not trained in teaching high school students. Given that teachers had excellent suggestions for enhancing the design of the intervention (and control), involving teachers and students more extensively in the design of interventions and resources is likely to enhance their quality, relevance and acceptability.

Such collaborative, shared decision-making and involvement “has consistently led to better implementation” (Durlak & Dupre, 2008, p.338) of programmes. However, as Stallard et al. (2013) have already discussed, even if teachers want to be involved in such a collaboration, finding sufficient time and energy to do so is likely to be difficult: 57.5% of teachers recently reported working six days a week which is taking its toll on their families and health (Davidson, 2019). Morale is also low: a “growing sense of crisis” was highlighted in a recent UK House of Commons Public Accounts Committee report in response to almost 25% of teachers qualifying since 2011 having now left the profession (Public Accounts Committee, 2018, para 3).

The present study suggests any longitudinal approach taken to prevention work in schools needs to take into account students’ declining interest in PSHE as they grow older. As our teachers explained, the trial duration covered a significant developmental spectrum in students’ lives: what an 11/12 year old student just starting high school needs/engages with is very different from those of a 15-16 year old in the middle of GCSEs.

A more fundamental question is: should universities target PSHE lessons for health prevention interventions? There is an increasing lack of regular, quality lesson time for such interventions. We designed the intervention to fit into a 50 minute PSHE lesson, which we came to realise, is in fact a dying format. Consequently, most schools contended with numerous challenges and engaged in ‘work-arounds’: some had to try to fit the lesson into a 20-minute form time, where relationships were highly informal/non-teaching and administration had to be completed; others had to extend the lesson to fit a longer drop-down day session, which they delivered multiple times, to groups with whom they had no relationship. A further consideration is that delivering a new intervention, particularly a prevention intervention (towards which teachers tend to be ambivalent) through a vehicle that is not routinely highly valued is unlikely to be well received. As Stallard et al. (2013) concluded following their trial evaluating a CBT intervention delivered through PSHE:

“While PSHE provided a convenient way of fitting classroom-based CBT into the curriculum, a programme delivered in these lessons inevitably inherited negative expectations” (p. xvi).

6.5.2 Strengths and limitations

The findings from this study contribute to the literature surrounding the implementation of school-based prevention interventions, and, in conjunction with chapter four, provides support for the concept that school characteristics, specifically its Ofsted rating and type of community served, may impact on appraisal and delivery of an intervention. Lower-rated Ofsted schools and those serving deprived communities responded more positively to the resources and lessons than those in moderate-to-affluent areas and higher Ofsted rated

schools. This is an area to explore in future schools-based research.

The complimentary use of mixed methods was valuable in not only determining teachers' reactions to delivering the intervention and control lessons, but also in understanding their perceptions of belonging to the trial, and the PSHE education context within which the lessons were delivered. Through the interviews teachers had flexibility and freedom to explain their experience in their own words, to the depth they felt comfortable with. They also provided an invaluable retrospective account of their time in the trial. The Cover Sheets provided immediate reactions to individual lessons, across four different time points and greater insight into teacher responsiveness at scale. Together, these methods provide a comprehensive view of the teachers' experiences.

Recruitment to the semi-structured interviews was challenging, given the multiple demands most teachers are managing and the many extra hours they already work. Multiple efforts were unsuccessful to recruit teachers from schools which were underrepresented in this PhD collective case study (e.g. School 2: intervention/low Ofsted/disadvantaged community; School 14: control/high Ofsted/disadvantaged community). The final sample (N=12) was weighted heavily by high Ofsted (N=9), intervention schools (N=8) and those serving moderate-to-wealthy communities (N=9). This meant that the experiences of teachers in low Ofsted schools (N=3), serving disadvantaged communities (N=3) and in the control condition (N=4) were less well represented. Some caution is therefore required when making conclusions about the interview findings.

6.5.3 Conclusion

This study has underlined the high degree of responsibility carried by teachers for engaging students in interventions being tested within school-based pragmatic cluster trials. It is therefore important to acknowledge that teachers are active agents in a trial, whose own engagement will be affected by numerous factors. To increase the success of pragmatic cluster trials, trial staff need to effectively engage and involve teachers.

Chapter 7 How do students experience their participation in the RSIIYA trial?

7.1 Chapter summary

This chapter reports a mixed methods study which examined students' experiences of participating in the RSIIYA cluster RCT. Transcripts from four focus groups involving 38 students from control and intervention schools, and over 15,000 student lesson feedback sheets were analysed to understand in depth and at scale how students experienced being part of the trial. Specifically, the study investigated how well students understood the trial, how acceptable they found participating in it, and how they responded to the intervention or control lessons. The study also investigated whether there were any differences in experiences according to which lessons were experienced.

The chapter firstly discusses the active agency brought to bear by participants when they take part in trials and how their appraisals and understanding of the research influence their engagement with it. It draws upon findings from research that has investigated participants', and specifically adolescents', experiences of trials. A detailed analysis is then provided of the experiences of those adolescents who were members of 20 cluster sites (high schools) taking part in the RSIIYA trial.

7.2 Introduction

It has been suggested that the retention of child and adolescent participants in schools-based research may be superior to other methods because school attendance is compulsory and time is often made available within the timetable for the research (Bartlett et al., 2017). However, whilst these factors may increase the likelihood of a sustained physical presence in the research, they do not guarantee a young person's engagement with it. In fact, maintaining young people's interest and motivation towards a complex health intervention is incredibly difficult (Pereira & Marques-Pinto, 2017). Particularly within large-scale prevention or health promotion programmes, ambivalence toward targeted behaviours and/or perceptions that no behaviour changes are necessary are common challenges for researchers (MacNeill et al., 2016).

As discussed in the previous chapter, people who participate in trials are not simply "passive recipients of assigned conditions" (Skingley et al., 2014, p.752): rather they are active agents (Coday et al., 2005), whose behaviour is influenced by their cognitions, emotions, people around them and by their environmental context (Skingley et al., 2014). The ways in

which participants experience a trial, and make sense of being involved in it are likely to affect their engagement, which in turn affects their behaviour, their decision to remain in the trial, and, potentially, trial outcomes (Heaven et al., 2006; MacNeill et al., 2016).

Within trials evaluating behaviour change interventions, very little attention has been given to understanding how people engage with, not just the intervention, but all the different aspects of a trial, and which aspects are most important to them (MacNeill et al., 2016). Within clinical trials, qualitative research into adults' experiences has revealed that their decisions to participate and stay in a trial are based on multiple considerations of both intervention- and trial process-related factors (Locock & Smith, 2011; McCann, Campbell & Entwistle, 2010). Motivating factors include anticipating some personal benefit from taking part (Locock & Smith, 2011), such as seeing a specialist, having the chance to learn more about one's condition during personal consultations, receiving careful monitoring, access/faster access to surgery (McCann et al., 2010) and simply getting out of the house (Heaven et al., 2016). De-motivating factors include perceiving little personal benefit in participating, inconvenience or potential harm (Locock & Smith, 2011; McCann et al., 2010). Being allocated the control condition or a non-preferred treatment/intervention may also trigger confusion, disappointment or resentment, which can contribute to poor motivation, failure to commit to trial tasks or even withdrawal (Locock & Smith, 2011; Skingley et al., 2014).

A sense of altruism or civic duty has also been found to positively influence people's decisions to both sign up to clinical trials (e.g. Heaven et al., 2006) and to remain in a longitudinal study (Mein et al., 2012). However, rather than being an isolated driving force, altruism appears to be 'conditional' upon the additional perception of personal benefit (Locock & Smith, 2011; McCann et al., 2010). For example, civil servants participating in Mein et al.'s (2012) longitudinal Whitehall II study on the effects of social gradients on ageing described being motivated to remain in the study because of the associated benefits they perceived from undertaking the required, regular medical examinations. They spoke positively about the warm interactions with the research nurses/staff, their personalised treatment and the detailed information the examination offered them about their body and health (Mein et al., 2012). Participants even suggested to the researchers that offering further medical tests as they grew older (e.g. prostate tests) would motivate them to continue with the study (Mein et al., 2012). This demonstrates that they expected "a degree of implicit and explicit reciprocity" or fair exchange during their participation (Mein et al., 2012, p. 2345).

Personal expectations have also been discussed in the context of a role or 'identity' a participant adopts during a trial. Heaven et al. (2006) explored how participants made sense

of and responded to the DARTSII RCT, which tested a complex intervention to support stroke prevention treatment decisions. A spectrum of “participant identities” was identified through their qualitative research, and each identity determined participants’ sense-making processes and behaviour during the trial (Heaven et al., 2006, p.264). Participants who had prior experience with trials/research were identified as ‘professional volunteers’. ‘Professional volunteers’ saw themselves as supporting the advancement of medical knowledge, through their civic duty, and whilst they hoped to benefit, they retained an open mind, since the trial was not a priority in their lives (Heaven et al., 2006). Participants who identified as ‘patients’, however, saw the trial as an important chance to obtain tailored medical advice, as a ‘real’ patient (Heaven et al., 2006).

These identities acted as a lens through which participants viewed and interpreted the trial, which, accordingly, influenced their behaviour (Heaven et al., 2006). Their identity guided how relevant they considered the intervention, how satisfied they were with consultations in the trial, and what they believed to be the ‘right’ response to trial tasks (Heaven et al., 2006). For example, ‘professional volunteers’ regarded their personal needs as patients to be subordinate to the needs of the trial, therefore they tended not to behave in their usual, natural way (Heaven et al., 2006). This ‘filtered’ version of themselves made it hard for the intervention to have a genuine effect. Similarly, ‘patients’, who saw the consultation as a chance for extra medical support were more likely to be disappointed, confused or disengaged when they realised they were in ‘a trial world’, not the ‘real world’, and that their expectations would not be met (Heaven et al., 2006).

Whilst adults’ experiences of participating in trials have been explored to some extent within the literature, very few studies have examined how adolescents experience and make sense of being in a trial (Midgley, Isaacs, Weitkamp & Target, 2016). From an ethical perspective, exploring young people’s experiences and sense-making processes in trials is crucial to determining whether they understand and find acceptable the fundamental tasks involved, i.e. recruitment, randomisation and data collection (Midgley et al., 2016). Their perspectives are also vital for judging whether the impact of the intervention was related to something about the trial and its conduct, rather than purely the intervention (Midgley et al., 2016).

Midgley et al. (2016) explored adolescents’ understanding and experiences of participating in an RCT evaluating three psychological treatments for depression. They asked the young people about their reasons for taking part, how acceptable they found the trial, and whether they considered their experience of therapy and their outcome to be affected

by being in the trial. Understanding of the study was relatively poor: 42% of the 76 participants demonstrated an understanding, but the rest had little or a lack of understanding (Midgley et al., 2016). Just 20% (15/76) understood the randomisation process and half (38/76) were unable to recall there were three treatment options, felt that they all sounded the same or did not understand the difference between them. Some participants (20%, 15/76) expressed confusion about the two different elements of the trial, i.e. the therapy sessions (conducted by therapists) and the research assessment meetings (conducted by Research Assistants who completed depression measures) (Midgley et al., 2016). Although these were distinct aspects of the RCT for the researchers – i.e. the intervention and data collection – 20% of participants considered the assessment meeting to be linked to the therapy (Midgley et al., 2016).

The vast majority of participants (93%, 71/76) had a positive view of taking part, describing it as “interesting”, “a good experience” to be part of, which had helped them to recognise personal progress made (Midgley et al., 2016, p. 5). Similar to the adult participants’ experiences in Mein et al.’s longitudinal study (2012), most of the young adults (73%) spoke positively about valuing the one-to-one, relational time with the Research Assistants, but many (53%) found completing the questionnaires repetitive, time consuming, tedious and irrelevant, with some items too intrusive/invasive (Midgley et al., 2016). Some participants (18%) found the recording of the research meetings and therapy sessions “awkward”, “weird” or “scary”, and it made them self-conscious, however this improved with time (Midgley et al., 2016, p.7).

In terms of whether participating in the trial had contributed to their therapy outcome, 32% believed it had had no effect, with 15% of these stating that they were “going to therapy anyway” (Midgley et al., 2016, p.9). However 41% of participants felt that taking part in the study did contribute to their recovery, because it reduced their sense of isolation with their depression, the regular research assessment meetings helped them to feel ‘monitored’, and the clearly defined parameters or structure helped them to focus on their progress (Midgley et al., 2016).

As researchers, understanding participants’ experiences of trials helps us learn how to design, explain and implement key tasks in more acceptable and ethical ways (Midgley et al., 2016). It also helps us to distinguish between influences of trial participation and of the intervention itself (MacNeill et al., 2016; Midgley et al., 2016). However, within the implementation science literature, a more specific reason for seeking participants’ views has, historically, been to understand whether they consider a trialled intervention acceptable (e.g.

Durlak & Dupre, 2008). Participants' positive engagement with an intervention, referred to as 'participant responsiveness', is consistently associated with positive outcomes in prevention intervention trials (Dane & Schneider, 1998; Durlak & Dupre, 2008; Pereira & Marques-Pinto, 2017; Schoenfelder, 2012).

Participant responsiveness has been described as "the degree to which the program stimulates the interest or holds the attention of participants" (Durlak & Dupre, 2008, p.329), and "levels of participation and enthusiasm" (Dane & Schneider, 1998, p.45) and is one of eight variable dimensions of implementation found to influence outcomes (Schoenfelder, 2012). The remaining seven are: (1) fidelity or adherence to protocol during delivery, (2) quality of delivery, (3) degree of adaptation during delivery, (4) program differentiation or uniqueness, (5) dosage, (6) reach and (7) monitoring of services or input received outside of the intervention/control conditions (Berkel et al., 2011; Dane & Schneider, 1998; Durlak & Dupre, 2008).

Whilst dimensions (1)-(3) are determined by those delivering the intervention/program and participant responsiveness is determined by participants (Pereira & Marques-Pinto, 2017), these dimensions are also inextricably linked (Berkel et al., 2011). For example, if those delivering an intervention find that the recipients do not like it, an interpersonal barrier emerges to their engagement with it, which may affect their quality of delivery, fidelity and potentially degree of adaptation (Carroll et al., 2007; Lawton et al., 2011). Conversely, participant responsiveness to an intervention may be considerably influenced by the deliverer's quality of delivery, their adherence to protocol and choice of adaptations made (Berkel et al., 2011).

Traditionally, participant responsiveness has been measured using behavioural indicators such as the number of sessions attended, the degree of active participation in sessions (as reported by facilitators), satisfaction with the sessions (as reported by participants) and the proportion of homework tasks completed (Berkel et al., 2011). All these behavioural indicators are associated with intervention study outcomes (Berkel et al., 2011). However, researchers have become increasingly interested in participants' subjective, qualitative appraisals of receiving an intervention or program, such as how worthwhile they considered the skills being targeted and how they were affected by the group environment at play during the intervention sessions (Schoenfelder, 2012). For example, students considered positively the skills being targeted within a complex, school-based HIV/AIDS intervention in South Africa (Mukoma et al., 2009): instead of recycling well-known facts about HIV/AIDS transmission and prevention, the intervention helped them to clarify their

own values and morals to aid their decision-making (Mukoma et al., 2009). The 'group environment' incorporates a group's cohesiveness and expressiveness, and the facilitator's supportiveness, and all have been found to be positively associated with intervention engagement and outcomes (Schoenfelder, 2012). Again, using Mukoma et al.'s (2009) HIV/AIDS intervention as an example, students found it easier to discuss intimate details with teachers they became familiar with and trusted, than teachers they had no relationship with.

The participant 'voice' in research

Within the implementation science literature, participant responsiveness to interventions has traditionally received less attention than the dimensions of fidelity, dose and quality of delivery (Durlak & Dupre, 2008). Participants' views are also sorely under-represented in the retention literature; instead the field is dominated by researchers' perceptions of what keeps participants engaged in research (Coday et al., 2005; Robinson et al., 2007). However this approach may be flawed because there is evidence that researchers' and participants' views do not correspond. For example, the researchers in Mein and colleagues' (2012) longitudinal study explained participants' main motivation for taking part to be altruism, whilst participants themselves described comprehensive, personalised health information as most important to them.

There is a need to understand more from participants directly about their experiences of research (Evans, Scourfield & Murphy, 2015; Robinson et al., 2007). Understanding some of the barriers and levers to engaging with research from participants themselves is likely to be a useful contribution to the field (Brueton et al., 2014; Coday et al., 2005). This may be particularly important in trials testing complex health interventions targeting young adults, where relatively little is known about how this group make sense of being involved in trials and how their experience in turn affects their behaviour within them (Midgley et al., 2016).

The mixed methods study described in this chapter examined participants' experiences of being involved in the RSIIYA cluster RCT. Participants were young adults (aged 15 in 2017) taking part in the trial within an intervention school (testing the smoking prevention intervention) or control school (delivering a parallel pro-homework intervention). When this study took place, students had participated in a maximum of eight intervention/control lessons, delivered by teachers in their schools, and five smoking data collection sessions, facilitated by the research team who visited their schools. The present study sought to contribute to the increasing literature surrounding the participant voice, and to understand how the young people taking part in the trial understood it, made sense of associated tasks, responded to the intervention (or control) and the factors involved in this. Finally, given that

disappointment may be experienced as a result of being allocated the control condition in a RCT (e.g. Locock & Smith, 2011; Skingley et al., 2014) and randomisation may be poorly understood (Midgley et al., 2016), this study also sought to determine any differences between the experiences of control and intervention school participants. The aims of this study were to explore:

- (1) The students' understanding of the RSIIYA trial.
- (2) The extent to which the students found participating in the trial to be acceptable and what affected this.
- (3) How the students responded to the intervention/control lessons and what factors influence their experience.
- (4) Whether the students' experiences of the trial differed according to the condition they were allocated.

7.3 Method

7.3.1 Design

This study involved students in the Yorkshire element of the trial only (i.e. students within participating Staffordshire schools were not asked to take part). This was because the writer was the Trial Manager for these schools, therefore she was more likely to be able to draw upon her relationships with schools to secure students' release to take part in this additional PhD research. Mixed methods were employed within this study which allowed a depth and breadth of understanding of the students' trial experiences to be accessed. Routinely collected student feedback data from over 15,000 students (across all 20 participating Yorkshire schools, i.e. including those involved in the focus groups) were analysed to investigate at scale how students responded specifically to the intervention and control lessons, and explore any differences between conditions. A focus group design was also used to explore in depth the young people's understanding of the trial, how acceptable they found participating in it and how they experienced the lesson delivery (in four of the 20 participating Yorkshire schools). These two methods were complementary in the temporal nature of the data they provided: feedback sheets were completed straight after each lesson so the data contained within them represented an immediate 'frozen-in-time' reaction to multiple lessons, across four points in time. The focus groups, however, took place towards the end of

the trial and involved students' retrospective reflections on their experiences as a whole. Each method is now explained in more detail.

Routinely collected lesson feedback data

Lesson feedback sheets from students across all 20 participating Yorkshire schools were analysed at scale to understand reactions and responsiveness to lesson content, materials and teacher delivery. These feedback sheets were introduced in year two of the trial (i.e. 2013) for the purpose of this PhD (see Figure 7.1).

Figure 7.1 Student Feedback Sheets

My thoughts on the lesson

How did you find the lesson?

Very enjoyable Enjoyable

Not enjoyable at all Ok

Not very enjoyable

Please circle one of these options ↑

Please tick one of the boxes below to show us how much you agree or disagree with this statement:

"This lesson helped me think differently about smoking"

I strongly disagree I disagree I'm unsure I agree I strongly agree

☐ ☐ ☐ ☐ ☐

If you'd like to, please tell us why here:

My thoughts on the lesson

How did you find the lesson?

Very enjoyable Enjoyable

Not enjoyable at all Ok

Not very enjoyable

Please circle one of these options ↑

Please tick one of the boxes below to show us how much you agree or disagree with this statement:

"This lesson helped me think differently about homework"

I strongly disagree I disagree I'm unsure I agree I strongly agree

☐ ☐ ☐ ☐ ☐

If you'd like to, please tell us why here:

At the end of each lesson, from four through to eight, students completed their own feedback sheet anonymously, which was collected in and returned to the research team. The feedback sheet involved students rating on a Likert scale how enjoyable they found the lesson (where highly enjoyable scored '5' and not enjoyable at all scored '1') and the extent to which they agreed that the lesson helped them think differently about smoking or homework (where strongly agree scored '5' and strongly disagree scored '1'). It also provided space to record a handwritten comment. Student feedback ratings were analysed quantitatively to determine

the extent to which students enjoyed the smoking and homework lessons, whether they helped them to think differently about smoking or homework and whether experiences differed by condition. Students' handwritten comments were analysed qualitatively to provide a more comprehensive picture of why particular ratings had been recorded.

Focus Groups

Focus groups were selected because they are particularly suitable for exploring children's experiences: they mimic the small-group setting students are familiar with in their classrooms, where they have the support and safety of their peers (Hennessy & Heary, 2005). This typically facilitates deeper elaboration of ideas than single interviews, aiding children's self-expression and jogging their memories when their peers mention points (Hennessy & Heary, 2005). Additionally, the interpersonal format of the focus group "can highlight (sub)cultural values or group norms" (Kitzinger, 1995, p.300), which may reveal important inter- and intra- school differences contributing to the trial's success or failure in those sites.

The researcher consulted Trial Coordinators in participating Yorkshire schools when conceptualising this study to determine (a) how willing schools would be to release students from lessons for this research and (b) how to increase the motivation of schools, parents and students to take part. Resounding feedback was that schools would be more willing to participate and release students if the focus group took place on University premises, rather than within their school, and if it could be 'packaged' as an educational, aspirational visit. Therefore the focus group was embedded within a two-hour visit to the School of Psychology at the University of Leeds, which included refreshments on arrival, tailored research demonstrations and a tour of the University campus (45-minute focus group on arrival, then 40-minute research demonstrations/tour of the School of Psychology, concluding in 35-minute tour of campus). This supported schools' statutory obligations to raise academic and career aspirations, whilst providing a valuable educational experience. Taking part in the focus group research provided an opportunity to visit a Russell Group university, meet current students, ask questions, discuss the Psychology programme, and have a tour of the campus.

The researcher communicated to schools that students were valued as 'experts' whose opinions were sought, and their participation in the focus group would enable them to share their views, contribute to a national study, leave a lasting legacy for future students, gain experience in handling themselves independently with a professional researcher, rather than a teacher, practice their social skills within a group setting and increase their understanding of Psychology and what psychologists do. This approach also supported the University of Leeds's widening participation goals.

The focus groups took place towards the end of the trial, to allow the students time to reflect back on their entire experience. Each focus group involved one school only (i.e. schools were not mixed) and a maximum of 12 students was sought for each. This number ensured that group discussion was manageable and that individual students had space to express themselves.

7.3.2 Participants

Routine lesson feedback data: A total of 15,882 Yorkshire student feedback sheets were available for analysis (see Table 7.1): 55.7% [N=8852] of these related to the smoking/intervention lessons; 44.3% [N=7030] were homework/control lesson-related. Represented in these feedback sheets were lessons four through to eight, reflecting years two (session 4), three (sessions 5 and 6) and four (sessions 7 and 8) of the trial.

Table 7.1 Student feedback sheets subjected to analysis (by lesson, condition)

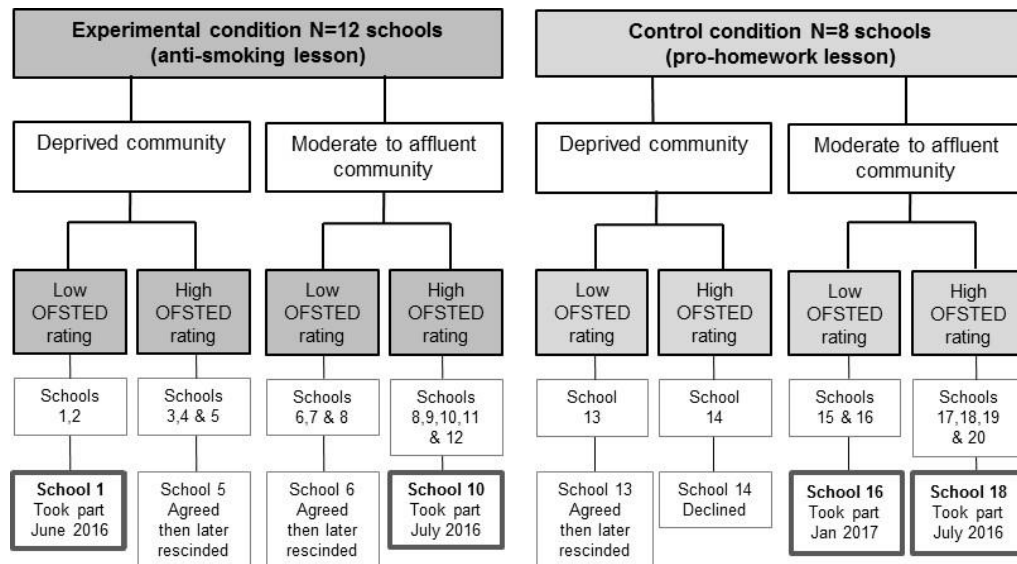
Condition	Lesson Number					Total
	4	5	6	7	8	
Intervention (Anti-smoking)	1908	1779	1668	1770	1727	8852
Control (Pro-homework)	1468	1514	1359	1430	1259	7030
Total	3376	3293	3027	3200	2986	15882
	21.3%	20.7%	19.1%	20.1%	18.8%	100%

Focus Groups: Recruitment for the focus groups took place by email through the Trial Coordinator in school. Eight schools were invited to take part (see Figure 7.2), which were selected using a maximum variation sampling approach to aid comprehensive, diverse coverage of participant views (as described in Chapter 2 method). The researcher selected one school from each sampling cluster. Selection within each cluster was based on ensuring diversity and comprehensive coverage across the overall PhD. In other words, schools were approached who had NOT taken part in study 1 or study 3 and for whom we had no qualitative ‘footprint’ to date.

If a selected school did not wish to participate, wherever possible a ‘next best’ school within the same sample group was selected, using the same criteria above. If a school did wish to participate, the researcher liaised with the Trial Coordinator in school to secure 10-12 student volunteers to take part, and an accompanying member of school staff. Recruitment took place between June 2016 and January 2017. Within one week of issuing invitations to the eight selected schools to participate in a focus group, six had expressed a desire to take part (1, 5, 6, 10, 13 and 18; see Figure 7.2). School 14 declined to participate soon after invitation because their senior leadership team did not want to students to miss lessons.

School 13 also declined for the same reason, despite the coordinator's best efforts to persuade school leaders of the benefits of participating. Both these schools served disadvantaged communities and were in the control condition, however one was highly rated by Ofsted whilst the other had a low Ofsted rating.

Figure 7.2 Recruitment outcomes for the student focus groups



Within one month of receiving the invitation, half of the schools who had expressed interest (1, 10 and 18) had planned a focus group date with the researcher and had secured student volunteers to participate. These took place during June and July 2016 as students reached the end of Year 10. Trial Coordinators in the remaining three interested schools (5, 6 and 16) continued to express an interest in taking part, however numerous difficulties emerged in trying to convert this interest into actual focus groups, despite extensive follow-ups. This was due to the resignations of trial coordinators (schools 6 and 5), followed by extensive bereavement leave of a successor (school 6, intervention, moderate-to-wealthy community, low Ofsted rating) and replacement of the entire leadership team due to poor academic performance (school 5, intervention, deprived community, high Ofsted rating) who subsequently refused to release students.

The trial coordinator also resigned in school 16 (control, moderate-to-wealthy community, low Ofsted). Despite their planning the focus group before leaving, it took time to establish a working relationship with his replacement. However this fourth focus group eventually took place in January 2017. In summary, of the eight schools approached four focus groups ultimately took place between June 2016 and January 2017 (see Figure 7.2). Represented within the four focus groups were: moderate-to-wealthy (N=3) and

disadvantaged communities (N=1), control (N=2) and intervention conditions (N=2), and highly rated (N=2) and low-rated Ofsted schools (N=2).

Within these schools individual students volunteered to take part. Schools were made aware that in order to participate, student volunteers would need to (1) have taken part in at least one anti-smoking (intervention) or pro-homework (control) lesson; (2) be willing and interested to share personal experience/reflections on being part of the study and the lesson and (3) be mature/responsible when off-site with minimal supervision from teaching staff. Underlined to schools was the importance of ensuring diversity within the final list of students they put forward, i.e. a range of academic and physical abilities, varied ethnicities and balance of male/female. Given that the trial involved a wide range of students, it was important for the focus group membership to reflect this diversity to capture a range of perspectives. It was also stressed to schools that the focus group should not be positioned as a reward for good behaviour, i.e. exclusively for hardworking or pleasantly behaved students. Equally, schools were asked to exclude any volunteers with known significant behaviour problems. This was because such behaviour may be harmful to other participants, difficult to manage during a focus group and the student could be at health/safety risk on campus. It may also be too challenging for one member of school staff to manage alone off site.

In total, 38 students took part (see Table 7.2), 14 males and 24 females. Ethnicity was determined from names on the consent forms and meeting the students in person: twenty two students (58%) were White British, six (16%) were Black African/British, three (8%) were Polish, four (11%) were Asian, two (5%) were of Middle Eastern origin, and one (3%) was Spanish. Ten students took part early in Year 11 (academic year 2016-2017), whilst the remaining 28 students were at the end of Year 10 (academic year 2015-2016).

Table 7.2 Composition of Focus Groups

Focus Group	Condition	Community served	OFSTED Rating	No of students	Ethnicity	Delivery format of RCT lessons
School 16	Control	Moderate	Low	10 (5 male)	2 Black African 2 Polish 6 White British	PSHE lesson
School 18	Control	Moderate	High	6 (2 male)	6 White British	Life Skills lesson
School 10	Intervention	Moderate	High	11 (2 male)	3 Asian 2 Black British/African 2 Middle Eastern 1 Polish 1 Spanish 2 White British	Form Time
School 1	Intervention	Dis-advantaged	Low	11 (5 male)	1 Asian 2 Black British/African 8 White British	Form time & Weekly PSHE lesson

7.3.3 Research Tools

The Student Feedback sheet (Figure 7.1) was created by the researcher for the purpose of this PhD study in order to capture immediate reactions to the lessons. It was incorporated onto the reverse of the 'My Personal Plan' handout which was the implementation intention aspect of the intervention/control lesson. These 'My Personal Plan' handouts were collected in routinely at the end of each lesson by the teacher-deliverers and returned to the research team. The Student Feedback Sheet was added for the first time to the Personal Plan at lesson number four, in year two of the RSIIYA trial (2013) and continued to be collected for the remainder of the trial.

With regard to the focus groups, personalised letters were devised for each invited school. The researcher reviewed each school's website and constructed an invitation letter designed to speak to the unique values of each school and addressed to the named Head Teacher/Principal. This letter accompanied a detailed two-page information sheet which explained the background to the study, the commitment involved, the benefits of taking part (Appendix 21, 22) and guidance on the selection of student volunteers. An abridged, more student-focused summary was created for form tutors (Appendix 23). This was designed for projection onto electronic classroom smartboards during form periods, with the aim of generating students' interest in volunteering for the focus groups. A parental information pack was also devised, comprising an adapted version of the school information sheet about the study (Appendix 24, 25) and a parental consent form (Appendix 26).

For the focus group itself, a schedule of questions was produced (Appendix 27) which was closely followed for each session to ensure consistency. This included agreeing to ground

rules of listening to each other, maintaining confidentiality beyond the focus group, and reiterating the anonymised, secure treatment of their data. All focus groups were recorded using an Olympus recording device. Cartons of fruit juice, jugs of water and biscuits were provided.

7.3.4 Procedure

The researcher approached the eight schools selected for the Focus Groups by posting out eight Head Teacher/Principal letters on university-headed paper and supporting information sheets and on the same day contacting their appointed RCT coordinators by email. Attached to the email were (1) the Head Teacher/Principal letter, (2) the detailed school information sheet and (3) shorter, student-focused summary, for circulation to Senior Leaders and Year 10 form tutors respectively. The trial coordinators raised the focus group invitation with key members of their Senior Leadership Team, either one-to-one or at the leadership team meetings, by asking if they had already received a formal invitation directly from the University, and seeking their commitment to take part. Schools were given two weeks after the email invitation and letter to make their decision.

Those schools expressing interest to take part managed their own recruitment of students, with minimal input from the researcher. This was because schools are familiar with arranging external events and have excellent knowledge of their students, internal processes and the formal paperwork required. Interested schools were given one month in which to submit to the researcher the names of up to 12 interested students. Twelve parental consent packs were posted directly to the trial coordinators in interested schools, which contained a stamped addressed envelope for return to them in school. Coordinators arranged for form tutors to raise the focus group invitation during form time and for interested students to be referred to them. From the list of all interested students, the coordinator selected a maximum of 12 students using the criteria provided by the researcher, and parental packs were sent home with these nominated students. These interested students had one week to decide if they still wish to take part and return their signed consent forms, before their place was offered to another student, if appropriate. It was underlined to coordinators that students could only be part of the study if consent forms were returned.

Mutually convenient dates for each focus group were arranged between the coordinator and researcher. It was made clear to trial coordinators in school that travel expenses would be paid and taxis arranged if required. The researcher then liaised with colleagues within her department to design a series of short research demonstrations and plan a tour of the department and campus. All schools utilised their minibuses to attend the

focus group and the students were accompanied and supervised by the trial coordinator in school. The school minibuses were met on arrival outside the School of Psychology building by the researcher, a research assistant and the Widening Participation lead for the School of Psychology. The accompanying teacher presented the researcher with the consent forms, which were checked against those students present, and the researcher gave the teacher coordinator a travel claim form. The researcher also obtained verbal consent from each student before escorting them to the focus group room, where refreshments were waiting.

To allow students to speak freely, the teacher coordinator accompanying the students was asked to not take part in the focus group. Instead, the Widening Participation lead made them comfortable in an adjoining room and arranged for coffee/tea. The researcher was accompanied by a research assistant during the focus group, who helped the participants settle, but did not ask any questions from the schedule. At the start of the focus group, ground rules were discussed and agreed. Students were asked to verbally confirm that they would respect fellow participants' opinions and keep all information discussed in the focus group in confidence. They were reassured that no-one would be forced to talk if they did not feel comfortable, and that the process was structured but informal and supportive.

The researcher asked open questions to promote discussion using the focus group schedule, and facilitated the group discussion to explore ideas, expand on disagreements/agreements etc. Questions involved asking about their experience and understanding of being in a research study for four years and of taking part in the annual smoking data collection process. They also explored students' responses to the intervention/control lessons and what factors influenced their experience of these. Samples of the appropriate lesson handouts (i.e. smoking lesson handouts for intervention schools) were placed on the focus group table to prompt students about the lessons if this was necessary.

Following the focus group, which lasted approximately 45 minutes, students were escorted on a 40 minute tour of the Psychology department which included research demonstrations, followed by a 35 minute tour of the University of Leeds campus by the Widening Participation lead for the School of Psychology, the researcher and the research assistant. After approximately two hours, the groups returned back to school on their minibus which collected them outside the School of Psychology.

All focus groups were audio-recorded and data were transcribed verbatim and analysed for key themes (see analysis section below). Qualitative data from the focus group

sessions were considered alongside the full students cohort quantitative ratings of the lessons.

Student feedback sheet data (N=15,882 sheets) were analysed using Statistical Package for Social Sciences and Excel. To facilitate the qualitative content analysis of students' feedback sheets, their handwritten comments (entered as 'string' data in SPSS) were imported into Excel from SPSS. This enabled comments to be more easily examined, managed and organised into themes and, ultimately, categories.

7.3.5 Analysis

7.3.5.1 Routinely collected student feedback sheet data

The 15,882 completed Yorkshire student feedback sheets were analysed at two levels. Firstly, using the Statistical Package for Social Sciences, student ratings for the two individual feedback items 'How did you find this lesson?' and 'This lesson helped me to think differently about smoking/homework' were first subjected to independent samples t-tests to detect any differences in student experiences between conditions, school Ofsted rating and type of community served. The 'MIXED' command was then used to examine the effects of controlling for clustering by school and by lesson. Scores for these two individual items were not combined into a total lesson score due to low internal consistency (Cronbach's $\alpha=.55$).

The second level of analysis involved close examination of students' handwritten comments where provided using Content Analysis. This allowed greater insight to be acquired into participants' reactions to the lessons, their experience of the lesson delivery, and the value they placed on the content of the lessons and skills being targeted. Content Analysis was selected due to the brief nature and volume of these comments. As outlined in the previous chapter, with Content Analysis the researcher typically applies a low level of interpretation when coding the data (Vaismoradi et al., 2013) and aims to identify patterns and trends within a dataset to organize and distil the data into a more meaningful format (Shields & Twycross, 2008).

To facilitate the Content Analysis, students' handwritten comments, which were originally entered as 'string' data in SPSS, were imported into Excel. This enabled comments to be more easily examined, managed and organised into themes. Comments were categorised on the basis of whether they were associated with a positive or non-positive appraisal of the lesson, using students' ratings for the item 'this lesson helped me think differently about smoking/homework'. Comments linked with agree' or 'strongly agree' rated lessons were categorised as 'positive'; those with any other response (neutral/disagree/strongly disagree/no rating) were categorised as 'non-positive'. A chi-

square test of independence was performed to examine the relation between condition and the provision of positive and non-positive comments.

All comments were initially examined within these two broad data corpuses. Within each data corpus, comments were examined initially by condition and given initial codes. These initial codes were then examined together more holistically. Common threads and concepts were noted between the codes and their comments, and clearer, more meaningful labels (i.e. themes) were devised. This was an iterative process which took place multiple times. The researcher continued to seek any patterns and relationships within and between themes, and through constant comparison synthesized these into a smaller number of organising themes.

The number of comment instances for each theme was tabulated, although the researcher was mindful that the most frequently occurring topics may have been simply the easiest topics to talk about rather than the most important to students (Shields & Twycross, 2008). To determine whether the distribution of themes differed by condition, a Pearson's Chi-squared test of homogeneity was applied to the number of individual theme counts/appearances for intervention and control comments.

The results of this Content Analysis supplemented the more in-depth findings from the thematic analysis of the focus groups, contributing breadth, scale and triangulation of data.

7.3.5.2 Focus groups

Transcripts from the four focus groups were analysed for key themes using Thematic Analysis (Braun & Clarke, 2006). In examining the transcripts the researcher sought to develop a detailed account of the specific research question areas, i.e. (a) students' understanding of the trial, (b) acceptability of their trial participation and what affected this and (c) their response to intervention/control lessons and factors influencing this. This meant that a top-down approach was applied to the data when identifying themes and patterns, i.e. the researcher attended to and coded material pertaining to these three areas rather than coding the transcript line by line for any interesting item. A realist epistemological stance was adopted when interpreting the data.

The analytical procedure began with becoming familiar with the data (listening to the audio-recordings, reading then re-reading each transcript), generating initial codes relating to the specific research questions and reviewing patterns and relationships between all the codes to identify themes. Themes were identified predominantly at a semantic or explicit level (i.e. not going beyond what the students said) and consideration was given to whether a theme reflected an 'engagement-enhancing' or 'engagement-inhibiting' feature/factor. The

initial themes were then reviewed to check if they accurately reflected the coded extracts and each transcript as a whole. Subsequently, initial themes were named and defined more clearly, through generating a descriptive paragraph for each with corresponding quotes. Finally, to facilitate the comparison of student experiences by school-level characteristics, the researcher 'borrowed' from Framework Analysis, using an adapted form of 'charting' to illustrate the occurrence of all themes and sub themes by condition and focus group.

7.3.6 Ethical considerations

Ethical approval was obtained from the University of Leeds School of Psychology Ethics Committee (reference: 16-0147; 23/5/2016). The main ethical concerns in this study related to ensuring informed consent, that any potential stress to participants was avoided (and their safety prioritised), freedom to withdraw, and that anonymity of data was maintained.

Informed consent: Parental consent was already in place for each student participating in the RSIIYA RCT. However, informed consent for this linked but distinct PhD research was obtained in writing from parents and verbally from participating students.

Avoiding stress: Whilst students may have felt a little nervous at the start of the focus group, the researcher had considerable experience of working with young people and sought to promote a warm, respectful and low-threat atmosphere, whilst providing clear structure/boundaries. She initiated and sought agreement to some initial ground rules at the start of the session to help the group feel secure, and reassured the group that no-one would be pressurised to talk.

Safety/minimising harm: During the focus group, there was also the potential that a student might disclose that they/someone they knew was being harmed, were at risk of harm or were harming/had harmed someone else. Before the focus group started, the researcher made the students aware that there are some limits to confidentiality in research. She explained that if any student revealed any criminal activity they were involved in or any intention to harm themselves or others, she would have to contact her supervisor so relevant action could be taken, potentially having to inform relevant authorities. However, she also reassured students that this research did not actively seek such information.

Freedom to withdraw: The students were told within the Parental information letter/consent form, and on arrival at university, that they were free to withdraw from the study at any time up to the focus group taking place. This was also re-iterated by the school before departing school for University on the day of the focus group, and by the researcher on their arrival. It was explained that after this point, withdrawal would not be possible because individuals would be difficult to identify/locate and therefore remove due to

anonymisation processes during transcription. This information was also included on the consent form. At the start of the focus group, the researcher explained as part of the ground rules that if anyone felt unhappy to contribute whilst it was underway, they could choose to remain silent. Plans were made that if the student was very reluctant to remain in the focus group, they may be escorted out of the room to wait with the teacher.

Confidentiality and anonymity: The teacher accompanying the students was asked to remain outside of the focus group (but nearby), for confidentiality reasons. Confidentiality was discussed at the start of each focus group. The researcher communicated to the group that comments made during the session would not be fed back/disclosed to any individual teachers or students concerned (i.e. no-one will get into trouble for being critical etc.). However she explained that their anonymised comments may be used in publications to illustrate points which were significant across groups or within a group. This was also made clear in the parental consent form.

The results are now described in two sections: students' understanding and experience of the trial, i.e. the focus group or 'depth' analysis, and students' responses to the lessons, i.e. the student feedback sheet or 'breadth' analysis.

7.4 Results

7.4.1 Students' responses to the lessons: *student feedback sheet analysis*

To understand at scale how the students responded to the homework and smoking lessons, feedback was analysed from 15,882 feedback sheets (see Table 7.1, previous section). Of these, 44.3% (N=7,030) were responses to homework lessons and 55.7% (N=8,852) to smoking lessons. Slightly more female students completed feedback sheets than male students (7,651 female; 7,561 male; 670 gender not recorded). Students' completion of feedback sheets declined as the trial progressed, with the exception of a slight increase at session 7. The lowest number of feedback sheets returned was for the final session (8 of 8), as students approached the end of Year 10, i.e. the summer break before GCSE year. The number of intervention schools returning smoking lesson feedback sheets remained fairly consistent, following a drop after session 4. Control schools' return of feedback sheets on their homework lessons was more inconsistent.

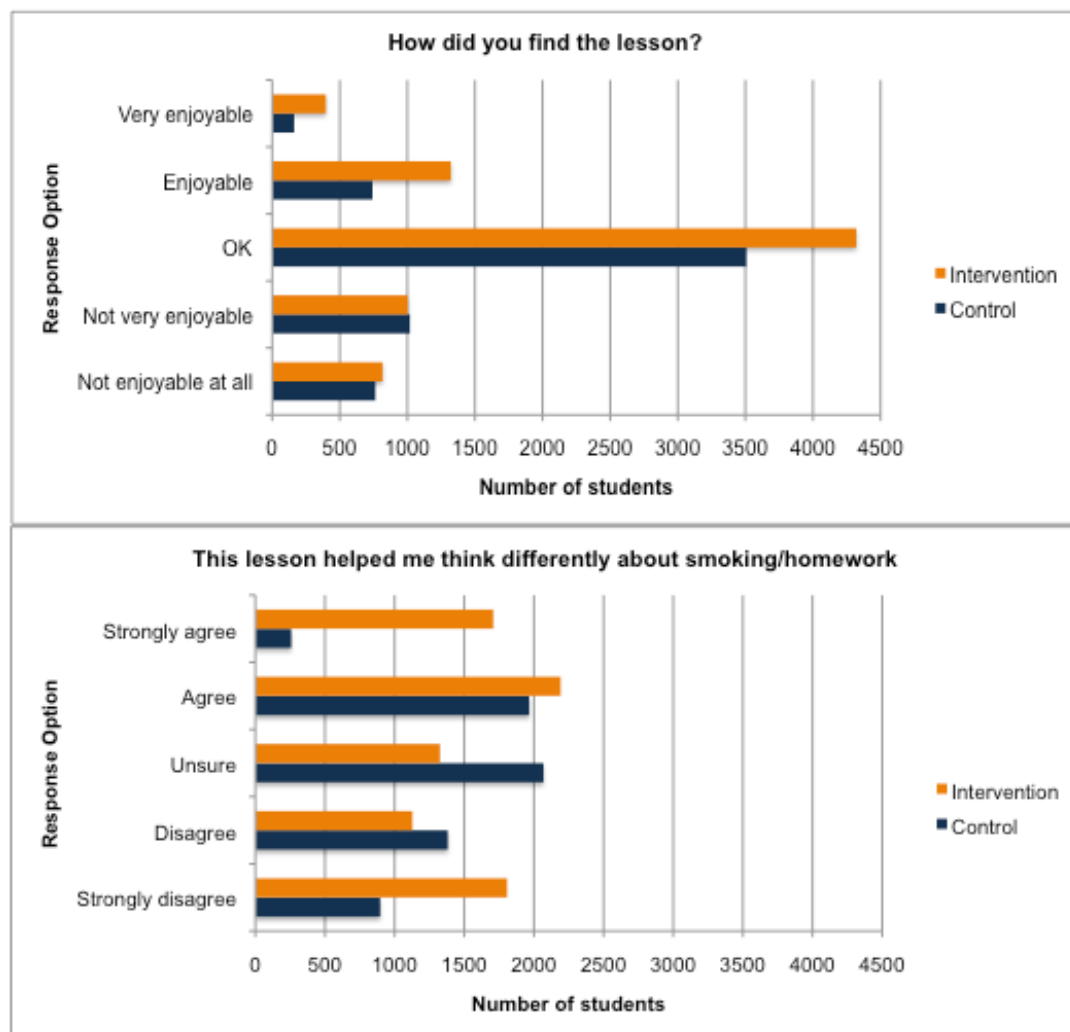
Analysis of lesson ratings

Of the 15,882 feedback sheets returned, ratings were available for the item 'how did you find the lesson' in 88.5% (N=14,054 [7,859 intervention; 6,195 control]) of cases and in 92.5%

($N=14,735$ [8,163 intervention; 6,572 control]) for the second item, ‘this lesson helped me think differently about smoking/homework’. Analyses for each item were conducted on 14,054 and 14,735 ratings respectively.

Frequencies for students’ ratings of the two feedback items are presented in Figure 7.3. As a full sample, students rated the impact of their lessons more highly than their enjoyment of them: ‘this lesson helped me think differently’ attracted a higher overall mean rating ($M=3.01$) than ‘how did you find the lesson?’ ($M=2.86$).

Figure 7.3 Frequencies for students’ ratings of the two feedback items



‘How did you find the lesson?’ responses

The modal student response (55.7% $N=7,828$) was that the smoking/homework lessons were experienced as ‘ok’ (see Figure 7.3). Intervention students rated their smoking lessons more positively ($M=2.93$) than control students ($M=2.76$) rated their homework lessons (see Table 7.3). This difference was significant, $t(13560) = 10.94$, $p < .001$, but represented a small effect, $g=1.8$. Students whose schools were in disadvantaged areas rated their lessons more

positively ($M=2.90$) than those who were in moderate-to-wealthy areas ($M=2.84$). However, whilst this was significant, $t(14052) = 3.78$, $p<.001$, the effect size was minimal, $g=.06$. Finally, students in low Ofsted schools rated their lessons more positively ($M=2.95$) than those in high Ofsted schools ($M=2.80$), $t(11763) = 9.64$, $p<.001$. However, again, the effect size was small, $g=.16$.

After controlling for clustering by school and by lesson (using the 'MIXED' command in SPSS), effects of condition and Ofsted rating for this item remained significant. The estimate for condition was $-.1665$, $SE = .063$, $t(19.78) = -2.66$, $p = .015$; the estimate for Ofsted rating was $.1573$, $SE .064$, $t(19.91) = 2.46$, $p = .023$. However, there was no effect of community served: the estimate for community was $-.0108$, $SE = .067$, $t(20.05) = -.162$, $p = .873$.

Table 7.3 Mean scores for each feedback sheet item by condition, community served and Ofsted rating

		Ratings (N)	How did you find the lesson?	This lesson helped me think differently about smoking/homework
Condition	<i>Intervention</i>	7859	2.93**	3.11**
	<i>Control</i>	6195	2.76**	2.89**
Community Served	<i>Moderate-to-wealthy</i>	9768	2.84**	2.95**
	<i>Disadvantaged</i>	4286	2.90**	3.15**
Ofsted rating	<i>High</i>	8623	2.80**	2.93**
	<i>Low</i>	5431	2.95**	3.14**

** $p<.001$

'This lesson helped me think differently about smoking/homework' responses

Students' responses to this item were more widely spread across the full rating range. A similar pattern to the previous item emerged with regard to students' ratings and condition, socio-economic status of the school community and school Ofsted rating. Intervention students ($M=3.11$) rated their smoking lesson impact significantly more positively than control students ($M=2.89$) rated their homework lessons (see Table 7.3), $t(14669) = 10.06$, $p<.001$ (although this reflected a small effect size, $g=.17$). Student ratings were also significantly more positive in *low* Ofsted than high Ofsted schools, $t(11912) = 9.45$, $p<.001$, and in schools serving *disadvantaged* as opposed to moderate-to-wealthy communities, $t(8110) = 8.84$, $p<.001$. However, once again effect sizes were small, $g=.16$ and $g=.15$ respectively.

Returning to differences between conditions, whilst nearly half of all intervention students (47.8% [$N=3,901$]) strongly agreed (20.9% [$N=1,709$]) or agreed (26.9% [$N=2,192$]) that the smoking lessons had helped them think differently about it, a greater proportion of

intervention (22.2% [N=1,808]) than control students (13.6% [N=897]) ‘strongly disagreed’ with this item. Analysis of handwritten comments on the feedback sheets revealed a more complex picture and added further understanding of the rationale for some of these students’ low ratings. These are discussed further in the next section.

Analysis of handwritten comments

Of the 15,882 feedback sheets received, 16.6% (N=2,639) contained a handwritten comment (70.6% [N=1,863] smoking; 29.4% [N=776] homework). Over half the comments (58.1% [N=1,534]) were provided to qualify a ‘strongly disagree’ or ‘disagree’ response to the statement ‘this lesson helped me think differently’ about smoking/homework. Students were less likely to provide a comment if they ‘strongly agreed’ or ‘agreed’ with (24.4% [N=643]) or were ‘unsure’ (15.3% [N=403]) about this statement. In 2.2% (N=59) of cases (mostly intervention students’ sheets [N=51]) a comment was provided without a lesson rating.

No significant relationship was found between the likelihood of providing a comment by condition and lesson ratings, χ^2 (1, N=2,580) = 1.33, $p=.249$. Students in both conditions were equally likely to provide a comment when rating a lesson either positively rated² (26.4% [N=203] control; 24.3% [N=440] intervention) or non-positively³ (73.6% [N=565] control; 75.7% [N=1,372] intervention).

Excluded from the content analysis were 168 illegible or unclear comments (97 smoking/71 homework; 62% linked to positive lesson ratings), which resulted in a final sample of 2471 comments.

Summary of themes from the Content Analysis

Seven themes were created from 2,471 legible and interpretable handwritten comments (see Figure 7.4 for summary; Appendix 28 for detailed counts by condition). The most common theme was having ‘pre-existing positive attitudes about the lesson content’ (30% [N=726]). In nearly three-quarters of cases (73.4% [N= 533]) this was used to explain why students did not rate their lesson positively (see Figure 7.5). For example, students wrote: “I already viewed homework as a good thing”; “I already know it’s bad and I wouldn’t smoke”. The next most common themes, ‘Already knew everything: opinion not changed’ (21% [N=527]), and ‘Boring and/or repetitive’ (19% [N=479]) were most likely to be recorded by students who did not

² Response to “This lesson helped me think differently” = Agree or Strongly Agree.

³ Response to “This lesson helped me think differently” = Unsure/Disagree/Strongly Disagree.

rate their lessons positively). Comments included: “we do the same thing every single time”, “we have had it about 500 times!” “we have done this lesson at least 4 times so I learn nothing new, and it's completely boring. A massive waste of school time. But it's RE so it would be s**t anyway”.

Figure 7.4 Themes from content analysis of student comments by condition

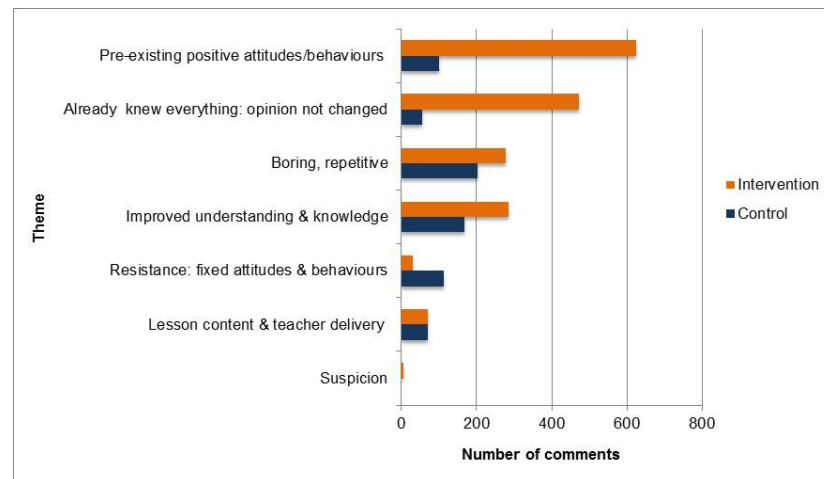
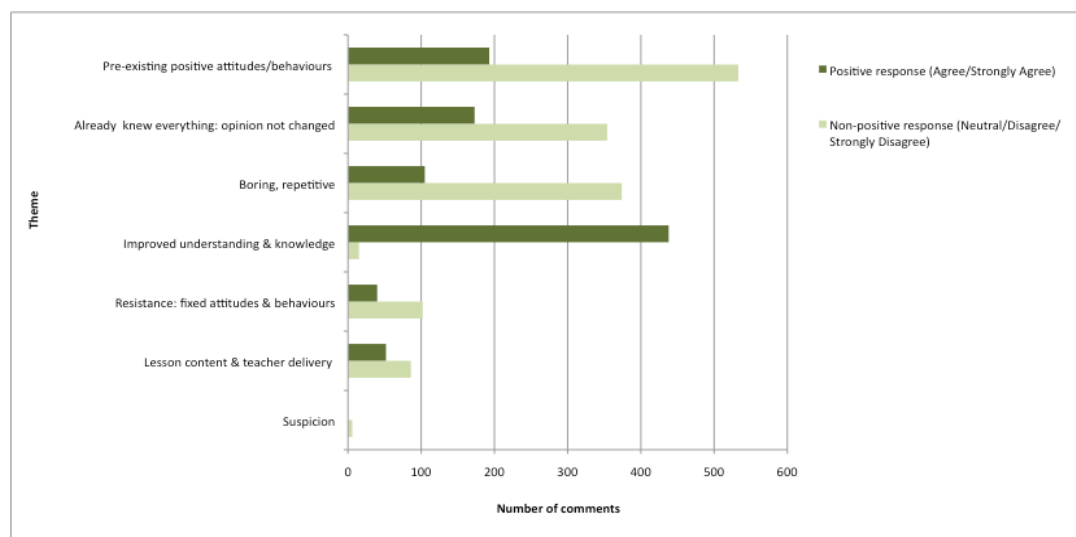


Figure 7.5 Themes from content analysis of student comments by ratings for ‘This lesson helped me think differently about smoking/homework’



The theme ‘Improved understanding and knowledge’ (18% [N=453]) was most commonly recorded by students who were positive about the lesson’s influence on them. Comments included: “it was a real eye opener”, “because it taught me about the benefits of doing homework and new strategies”. The final three themes were less densely populated. The theme ‘Resistance: fixed behaviours/attitudes which the lessons won’t change’ (6% [N=142]) was largely associated with students with less positive views of the lesson, and

included aspects of fatalism, such as “a lesson doesn't stop addiction” and “I will never like homework - you just have to do it.”

A further theme, the ‘Lesson content and teacher delivery’ (6% [N=138]), included engagement-facilitating and engagement-inhibiting comments about the teachers’ delivery, the classroom environment during the lesson and lesson materials and activities. For example, “I found the lesson fun based on the way it was taught”, “sick teacher 😊 Boring topic, but helped a lot”, “It was fun because we did group work”. In contrast, others wrote “my teacher was a bit rubbish”, “people was just spoiling it and messing about when sir was trying to talk”. There were multiple comments about protocol violation, with more of these being mentioned by control students: “we didn’t really have the lesson”, “my teacher didn’t explain it”, “we never actually talk about it”, “we just read off a sheet which didn’t make homework seem fun”. Some students thought that the homework lessons were at times too challenging, “it was very overwhelming and it seemed like you were forcing us to do it”, “I learned some things but it was a bit too much”. The final, minor theme ‘Suspicion’ (0.2% [N=6]) was only relevant to smoking lesson comments, for example, “you only did tests to see if we do smoke”.

Comparing distribution of themes by condition

Chi square tests of homogeneity revealed highly significant differences in the distribution of individual themes across conditions, although effect sizes were consistently small. Intervention students (35% [N=626]) were more likely to comment that they had pre-existing positive attitudes about the lesson content than control students (14% [N=100]), $\chi^2 (1, N=2471) = 109.8, p < .001, \phi = 0.21$. Intervention students (27% [N=473]) were also more likely than control students (8% [N=54]) to state that they already knew everything/their opinion had not changed, $\chi^2 (1, N=2471) = 109.8, p < .001, \phi = 0.21$.

Students receiving the homework lesson were more likely to comment that their lesson was ‘Boring and/or repetitive’ (28% [N=202]) than students receiving the smoking lesson (16% [N=277]), $\chi^2 (1, N=2471) = 54.2, p < .001, \phi = 0.15$. Control students (24% [N=167]) were also more likely to comment that they had acquired improved understanding and knowledge from the homework lessons, compared to their peers in the smoking lessons (16% [N=286]), $\chi^2 (1, N=2471) = 18.9, p < .001, \phi = 0.09$. Interestingly, control students (16% [N=113]) were more likely to comment on being resistant to and having fixed attitudes and behaviours about the messages contained in the lessons than intervention students (1.6% [N=29]), $\chi^2 (1, N=2471) = 192.5, p < .001$, and the effect size was considerably larger than for the other themes, $\phi = 0.28$ (approaching a moderate correlation). Control students wrote

about 'hating homework', not valuing it, never doing it, believing there was no point in doing it, or having their own preferred strategies. Finally, control students (10% [N=69]) were more likely to provide comments on their feedback sheets about lesson content and delivery than intervention students (4% [N=69]), $\chi^2(1, N=2471) = 33.0, p < .001, \phi = 0.12$.

7.4.2 Students' understanding and experience of the trial: *focus group analysis*

Themes were organised within the key research questions, namely: (1) students' understanding of the trial; (2) the acceptability of trial participation and what affected this; (3) responses to the intervention/control lessons and factors influencing this (see Table 7.4). Careful attention was then paid to the appearance and prevalence of the resulting themes to determine whether there were any differences between intervention and control students' experiences. The themes are now described in numerical order of the research questions.

(1) Students' understanding of the trial

The analysis revealed that, initially, some students' understanding of the trial was not strong. There were themes of *confusion* (theme 1) and attempts at *sense-making* (theme 4). As the trial progressed, *familiarisation with the routine over time* (theme 2) helped increase students' understanding and confidence in the process, *curiosity and interest* (theme 3) grew and there was a sense of *belonging to something important* (theme 5). Each of these themes is now described.

Theme 1 Confusion (11 instances/3 groups): The main source of confusion emanated from the annual smoking data collection process, rather than the smoking or homework lessons. Students in one of the control condition focus groups (school 16) in particular described being unclear about why they were providing data about their smoking attitudes, habits and those of people around them. There was confusion about the use of the Smokerlyzer/carbon monoxide breath monitor device, which students blew into during the annual data collection:

"Yeah, like if you knew you hadn't like smoked or taken any second hand smoke, you sort of thought like, why am I doing this, why do I need to do this, if you know that you've never like smoked in your life" (Control, school 16, 77-82).

Other students felt that they received no explanation about why they were being asked to provide information, and that it was not obvious to them that they were participating in research:

"I don't actually remember finding out that much about what it really was, just like here's a questionnaire, fill it in. And I don't think we were explicitly told. We weren't. This is a research thing" (Control, school 16, 159-174).

Table 7.4 Summary of themes extracted from the four focus groups

Themes		Sub-themes	Total instances all focus group	Intervention focus groups	Control focus groups	School 1 - Interv Low OFSTED Deprived	School 10 - Interv Low OFSTED Moderate-Affluent	School 16 - Control Low OFSTED Moderate-Affluent	School 18 - Control High OFSTED Moderate-Affluent
Understanding of the trial	1. Confusion		11	5	6	1	4	6	0
	2. Familiarisation with routine over time		10	6	4	2	4	3	1
	3. Curiosity and interest in the results		10	7	3	4	3	2	1
	4. Sense-making		9	4	5	0	4	4	1
	5. Belonging to something important		6	5	1	2	3	1	0
Acceptability of trial participation and what affected this	6. Repetitive, boring		18	10	8	4	6	2	6
	7. Feeling vulnerable		18	11	7	6	5	3	4
	8. Interesting, novel experience		9	3	6	1	2	4	2
	9. Trust in the study and team		3	2	1	1	1	0	1
	10. Escape from lessons		2	0	2	0	0	1	1
	11. Camaraderie		2	0	2	0	0	1	1
Response to intervention/ control lessons and factors influencing this	12. Teacher factors		38	17	21	11	6	14	7
		12.1 Enthusiasm (11 positive/16 negative)	27	11	16	7	4	11	5
		12.2 Familiarity and trust (4 positive/4 negative)	8	6	2	4	2	1	1
		12.3 Consistency (2 positive/1 negative)	3	0	3	0	0	2	1
	13. Lesson impact		22	7	15	2	5	7	8
		13.1 Internalised, adopted tips/content	12	4	8	1	3	6	2
		13.2 Sceptical lesson can change behaviour	10	3	7	1	2	1	6
	14. Lesson style/content		16	10	6	3	7	4	2
		14.1 Enjoyed group discussions	7	5	2	2	3	0	2
		14.2 Colour handouts seen as important	2	0	2	0	0	2	0
		14.3 Activities were irrelevant/hard	7	5	2	1	4	2	0
	15. Contextual factors		12	3	9	1	2	6	3
		15.1 PSHE lessons not taken seriously	4	0	4	0	0	2	2
		15.2 Lessons were rushed	4	0	4	0	0	4	0
		15.3 Too much time	4	3	1	1	2	0	1

Some of the students expressed being unaware (initially) that this smoking-related 'activity' was not just localised to their school, but was taking place in other schools around the country.

Whilst the smoking data collection sessions (facilitated by University researchers visiting the school) and the smoking/homework lessons (delivered by in-school teachers) were clearly distinct elements to the research team, they were not regarded in this way by the students. These two different elements seemed to merge in some of the students' minds:

"They kind of all like kind of linked to each other so you kind of remember them as like one whole thing rather than separate ones" (Intervention, school 10, 351-352).

Students used the term 'questionnaire' when referring both to the annual Smoking Questionnaire and also the Personal Plans about homework or smoking which they completed in their smoking/homework lessons. This caused some confusion during the focus groups, and required ongoing clarification when targeting particular aspects of their experience. When students were asked about specific homework or smoking lessons, it was hard for many of them to remember individual lessons, unless they reviewed the handout examples provided.

Theme 2 Familiarisation with the routine over time (10 instances/4 groups): A prevalent theme across all focus groups was a growing confidence and increased knowledge within the students about the study as it progressed, and as they came to trust the familiar routines each year. Suspicion and concerns about what they were being asked to do appeared to ease:

"Got used to it more. Yeah, you knew what you were doing. No, it just kind of became less of a worry, the more that we did" (Intervention, school 1, 32-37).

"At the start we were a bit, oh, we're in a room in the dark. Now we understand it more. Now we've got that, yeah.. the importance of like the research that you're doing" (Control, school 16, 572-574).

Students commented that they came to trust that their personal data were not shared with parents or teachers. Students' perceptions and concerns that the researchers were collecting their personal data on behalf of their school were also considerably reduced when they realised that they were part of larger network of participating schools:

"With other schools, it was sort of kind of all like... was less pressure, felt like it wasn't like focused on just our class or just our school. It was like quite a lot of people and it was a bigger study than we thought it was" (Intervention, school 10, 107-110).

Theme 3 Curiosity and interest in the results (10 instances/4 groups): Across all four focus groups, the students expressed considerable curiosity and interest in the outcomes of the trial, and in the overall goals of the research:

“It was interesting because like I always knew there’d be results, like at the end of it because I always knew it was a study, I remember being told, but maybe that’s because I was in a different classroom to everyone else, but I always wanted to know what the results would be” (Control, school 16, 550-552).

It seemed to be important to understand the impact of their extensive contribution, and to be able to ascribe meaning and value to their participation. This links to the next theme, “belonging to something important”.

Theme 4 Sense-making (9 instances/3 groups): Across the focus groups there was considerable evidence of students trying to make sense of their involvement. A common approach to making sense of what was happening was that deception was taking place, in other words, the reality was that the researchers were colluding with the school to identify and inform on smoking students. This led to suspicion and a mistrust of the motives behind external visitors coming into their school and asking for their smoking and other personal information:

“I know some people felt like they were trying to catch you out with it, like it wasn’t actually anonymous, and that they’d tell your parents or whatever” (Intervention, school 10, 35-36).

One student thought that the university researchers had actually been hired by his school to “pull a fast one” (Control, school 16, 266-267) on them. However, not all students were suspicious. Another student interpreted the involvement of the university quite differently. She explained that, whilst she had not fully understood what she was involved in, the university’s involvement signalled that she could trust the process and that it was worthwhile:

“At first I didn’t know what it was for but then when people came in I was like, okay, so that’s something important, whatever, ‘cos you’ve said you were coming from Leeds University” (Intervention, school 10, 221-226).

Other students reported happily complying with and accepting what they were asked to do without any concerns. They were not inclined to try to make sense of the tasks they were involved in and saw it as another routine part of school life.

Theme 5 Belonging to something important (6 instances/3 groups): Students described that, as the trial progressed, they experienced a growing realisation of contributing to something significant:

“It’s like, you always see it on, like, the telly and like everyone’s saying, ‘Statistics from, like, past research,’ and it’s a little bit weird how now, like, if something’s comes of it, you’ll be on it. A part of that” (Intervention, school 1, 83-90).

There was a sense of pride in being involved, and of leaving a legacy. Interestingly, this was mostly commonly expressed by students within the intervention focus groups (5/6 instances), rather than the control focus groups.

(2) Acceptability of trial participation and what affected this

When examining how acceptable students found their participation in the trial, and the factors involved, more engagement-inhibiting than engagement-enhancing themes were apparent. Students discussed finding the tasks within the trial **repetitive and boring** (theme 6) and **feeling vulnerable** (theme 7), themes associated with inhibiting their engagement with the trial. However, in contrast, they also found participating in the trial an **interesting, novel experience** (theme 8), they had **trust** (theme 9) in the study and researchers, perceived the tasks as a positive opportunity to **escape from lessons** (theme 10) and experienced a sense of **camaraderie** (theme 11) with their peers during the trial. These were identified as more engagement-enhancing themes.

Theme 6 Repetitive and boring (18 instances/4 groups): Students commented on the repetitive nature of both the annual smoking data collection process and the smoking/homework lessons over the four year duration of the trial. With regard to the completion of the annual Smoking Questionnaire, a number of students expressed some irritation that they were asked the same questions each time, and that their responses never altered:

“In Year 7 it was like, oh this is something new. But by Year 10 it’s just, ‘oh I didn’t smoke!’” (Control, school 16, 71-72).

The consistent format of the homework and smoking lessons were also identified as repetitive and by some as, “kind of boring, no offence” (Intervention, school 1, 126). This particularly related to the completion of the Personal Plan at the end of the lesson:

“I just think a bit repetitive. I think it was good but I just think like, like for example the different... like you have the different topics, but in the end it was the same questionnaire kind of thing” (Control, school 18, 326-328).

One student commented that he felt the lessons were too frequent, and like they were always taking place. But others were more forgiving of the repetition, viewing this as a positive feature because it helped to sustain the key messages from the lessons:

“These lessons just like reiterate what we already know but it’s good because it refreshes like what you need to do” (Intervention, school 10, 518-519).

Theme 7 Feeling vulnerable (18 instances/4 groups): The students experienced a degree of anxiety during the smoking data collection sessions, particularly with regard to the Smokerlyzer device (for a carbon monoxide reading). Students had a fear of the unknown with regard to device and worried what it would reveal about them. Even non-smokers felt exposed and vulnerable about what the machine might detect, and were fearful that they would be incorrectly labelled and judged as a smoker:

“Even though ... you know you don’t smoke, it’s kind of scary like to think what you might come up with, ‘cos you don’t know what it... ‘cos it was an unknown kind of thing so you weren’t sure what was going to happen” (Intervention, school 10, 28-30).

One student also commented that he considered some of the items on the Smoking Questionnaire to be ‘too personal’ and that he was ‘paranoid’ initially that his responses would not be confidential, leading him to be reprimanded by teachers. Some described the procedure with the researcher at the Smokerlyzer station as ‘formal’, and blowing into the device itself as ‘scary’ and ‘intimidating’. A number of students experienced performance anxiety whilst waiting their turn and following instructions for blowing into the device:

“I was just scared in case doing it wrong and just breaking the machine.” (Control, school 18, 116)

“It took me like three times. I couldn’t do it properly” (Intervention, school 1, 22-24).

One student also commented that she was frightened she was going to faint during the process.

Theme 8 Interesting, novel experience (9 instances/4 groups): Students talked about valuing the experience, as something uniquely interesting and different from their usual lessons:

“I think it was good, I think it’s been a good experience” (Intervention, school 10, 567).

“Knowledgeable, interesting experience” (Intervention, school 1, 291).

The scale of the study, i.e. that multiple schools were involved, also enhanced their interest in it, and gave it additional credibility:

“It was like kind of weird knowing like quite a lot of people around Leeds would also be doing it with us as well” (Intervention, school 10, 101-102).

The smoking data collection sessions were identified as particularly novel and ‘fun’, given that they had never previously encountered Smokerlyzer devices or provided biological data to a research team. Even though students found the process anxiety-provoking in the early stages of the trial, they came to enjoy and look forward to it:

“I think it was just intriguing because it was a new experience” (Control, school 18, 105).

Overall, control students contributed twice as many comments regarding the novel and interesting nature of the study than intervention students (6 instances vs. 3 instances respectively).

Theme 9 Trust (3 instances/3 groups): The acceptability of participating in the trial was enhanced by its association with a university. Students appraised it as a credible activity to be involved in, something to be proud of and taken seriously:

“‘Cos you’ve said you were coming from Leeds University and stuff, so like trusted the study more and thought we were doing something more important”
(Intervention, school 10, 225).

Despite initially feeling vulnerable and suspicious about the purpose of collecting smoking data in the trial, over time students grew to trust that the research staff would not disclose their personal information to teachers or parents. This trust helped them respond more openly when completing the smoking questionnaire:

“I think I’ve become like more honest over time, because in Year 7 I was like, oh they’re going to tell me off if I like say something that’s like or if I’m not honest, not as honest. And then like in Year 11 I’m more like, well in Year 10 I was like, oh well it helps them more, so my honesty is helping them, so just become more honest”
(Control, school 16, 590-593).

Theme 10 Escape from lessons (2 instances/2 groups): Students in the control school focus groups concurred that the most positive aspect of participating in the trial was being released from their usual lessons. Many participating schools utilised PSHE curriculum time for the completion of trial tasks, and the students described being happy to relinquish these PSHE lessons for the trial-related tasks:

“I enjoyed not doing PSHE lessons, because they were really bad and I’d rather do the smoking questionnaires than them [all agree]” (Control, school 16, 241-242).

Interestingly, this theme did not appear within the intervention condition focus groups.

Theme 11 Camaraderie (2 instances/2 groups): The fact that the whole year group participated in the trial was a source of support and reassurance, particularly in the early stages of the trial, when students experienced the greatest levels of worry and concern. For example, during the smoking data collection sessions, students joked with each other to alleviate their nerves, and compared figures they had observed on the Smokerlyzer device¹:

“It was sort of like afterwards we’d always joke about “oh yeah, I got like 100 on it” or “yeah, we were smoking every day all day”. Just like afterwards you just joke with your friends about it.” (Control, school 18, 41-43).

This was only evident within the control focus groups, and did not feature in the intervention student discussions.

¹ For ethical reasons, students were not given their Smokerlyzer reading during the data collection sessions. Once students had discharged all their held breath into the device, they were asked to immediately hand it back to the researcher. During particularly long exhalations students might sometimes see the initial Smokerlyzer reading before it increased and finally stabilised, and this is the figure they typically discussed with peers.

(3) Response to the intervention/control lessons and factors influencing this

During the focus groups, students contributed more negative (50 instances) than positive comments (38 instances) with regard to their reactions to the trial-related lessons. As discussed earlier, the repetitive nature of the trial was frequently highlighted as a barrier to fully engaging with it. This repetition related not only to the completion of smoking questionnaires as part of the annual smoking data collection process, but also to the twice-yearly Personal Plans about smoking and homework which formed part of the lessons. However, numerous **teacher** (theme 12) and **contextual factors** (theme 15) influenced their experiences and moderated their responses to the lessons. Despite this significant barrier of repetition discussed earlier, students nevertheless expressed both positive and negative views about the overall **lesson impact** (theme 13) and **lesson style and content** (theme 14). Each of these themes is described in turn, from the most to least prevalent.

Theme 12 Teacher factors (38 instances/4 groups): Perhaps unsurprisingly given teachers' central role in delivering the lessons, 'teacher-related factors' was the most frequently occurring theme in students' accounts of the lessons. *Teacher enthusiasm* (sub-theme 12.1), *familiarity and trust* (sub-theme 12.2) and *consistency* (sub-theme 12.3) were identified as sub-themes.

Sub-theme 12.1 Teacher enthusiasm (27 instances/4 groups): Students spoke at length about the impact of the teachers' level of enthusiasm on their enjoyment of the lesson and perception of the lesson's value:

"Well, with Miss Dawkins, seeing as how she started with us when we were in Year 7, the way like she introduced it and how enthusiastic she seemed about it kind of rubbed off on some of the students that were taking part. But with the teachers, you know, that are perhaps not as enthusiastic, that also kind of rubs off on students and to say, well, we're kind of here because we have to be here and do it because we have to do it" (Intervention, school 1, 266-270).

As this student explains, a high level of teacher enthusiasm was considered infectious. It helped the material to come alive and the teacher indirectly communicated that the lesson and study were of value/credible. The reverse was also true: those teachers unable to bring enthusiasm to their delivery of the lessons communicated to the students that the study had little value, which affected students' engagement with it. More often, students reflected on teachers being *unenthusiastic*, sensing and empathising that they too struggled with the repetitive nature of the trial:

"You could tell that they got sick of it, like they were like, yeah we're doing this again, form" (Intervention, school 10, 490-493).

Students explained that teachers were aware that "not everyone's overly excited" by the lessons, and their approach to completing the lesson varied from telling students they just

had to do it to using personal appeals, such as, “come on guys, you know, help them out” (Control, school 18, line 271).

Students described teachers who “just sit and read it out” and “don’t give you the opportunity to talk about it or ask questions” (Intervention, school 1, 149-151), who skipped elements of the lesson to keep the group interested or fit it into a 20 minute form period. Others also recalled that some teachers did not attempt to teach the smoking or homework lesson, but instead distributed the handouts and asked the class to complete independently whilst they caught up on administration. One student explained how the lesson effectively collapsed because it was not being led:

“So she was more concerned about doing that than what we were doing. Yeah, and then since she wasn’t driving it then other people weren’t doing it for themselves” (Homework, school 16, 419-422).

In this situation, students “didn’t actually read it properly” and “just talked to their friends” (Homework, school 16, 391).

Sub-theme 12.2 Familiarity and trust (8 instances/4 groups): Students reported engaging more with the lesson material and activities when they were delivered by a familiar, trusted teacher, and in the presence of peers they knew and had rapport with:

“Yeah, ‘cos when you kind of know people more and you’ve like been with the quite a while you kind of tend to trust them more, so you can like tell stories more honestly. Yeah, you don’t feel like you have to sort of like adjust your answer to sort of, not impress them, but to sort of like come across in the right way, that you’re more comfortable to be able to say what you actually think and feel” (Intervention, school 10, 439-443).

Students explained that where there was a trusting, warm relationship between the teachers and the class, the teacher took more of an interest in their wellbeing and shared personal stories to enhance the lesson, and encouraged more discussion and examination of the material. In this sense, the esteem in which the students held the teachers affected their satisfaction of the lesson. Students responded differently to the lesson material and contributed less in the group when it was delivered by unfamiliar teachers:

“Cos it’s not your usual teacher who you know and it’s just really awkward to share with” (Intervention, school 10, 460-461).

Students were aware of teachers delivering the anti-smoking lessons who smoked, and one student commented that this was ‘hypocritical’. Other students reported being motivated and inspired to never smoke by teachers sharing their personal stories of struggling to quit smoking but succeeding.

Sub-theme 12.3 Consistency (3 instances/2 groups): Students’ responses to the lessons were more positive when a consistent teacher delivered them. Having a consistent

teacher enhanced the feeling that the trial was a shared endeavour due to shared knowledge and experience. They also developed a cumulative understanding of previous lesson content which was valued. Students responded less positively to the lessons when they did not have “a proper teacher” (i.e. multiple, inconsistent teachers) because there was no shared experience, involvement or history between them, as one student explained:

“Yeah, the new teachers, they don’t really seem to be bothered. They don’t know the full thing we’ve been doing” (Intervention, school 1, 260-262).

Theme 13 Lesson impact (22 instances/4 groups): Students across all the focus groups reflected on the impact that the smoking and homework lessons had on them. Two sub-themes were associated with lesson impact: students *internalised and adopted lesson content* (sub-theme 13.1) and *tips and sceptical that an intervention can change behaviour* (sub-theme 13.2).

Sub-theme 13.1 Internalised/adopted lesson content and tips (12 instances/4 groups): Whilst students in all the focus groups commented that they had drawn on lesson content, this theme was most prevalent in the control group focus groups (8/12 instances) in connection with the homework lessons, for example:

“I think it’s made me want to do my homework because I didn’t used, I just used to just leave it and just get in trouble for not doing it” (Control, school 18, 184-186).

“It kind of, it just helped me from Year 7 to actually know how I should revise” (Control, school 16, 314-316).

Students in the intervention focus groups commented less on internalising and adopting lesson content from the smoking lessons (4 appearances). When they did, they referred primarily to those anti-smoking lessons which took an applied or novel approach, such as when smoking was discussed in relation to confidence (lesson 6, “Building your resilience to stay smoke free”) and stress (lesson 7, “Looking after yourself during stressful times”), for example:

“I think the ones where you like relate it back to like stress or stuff like that, that’s quite interesting, especially like when we’re like doing, we’re in high school and we’re at like our GCSEs. It kind of is more interesting to learn about stuff like that, than the whole like, the getting your health kind of thing, ‘cos we do know about a lot from primary school” (Intervention, school 10, 299-302).

As this last student underlined, the impact of smoking on health is covered in earlier years education, therefore the most memorable, impactful lessons within the trial appeared to be those offering something more. In contrast, students in the control focus groups commented that up until the trial began they had received little education about effective strategies for studying, revising and motivating themselves to complete homework.

Sub-theme 13.2 Sceptical that an intervention can change behaviour (10 instances/4 groups): Students across all focus groups also expressed some scepticism and resistance:

“You’re not really going to change how you do it [homework] because, you know, you work best the way that you do it” (Control, school 18, 168-169).

A number of students argued that the most powerful influence on people’s decisions to smoke was their family, rather than a lesson at school:

“I think what counts more is what you’re taught at home” (Intervention, school 10, 389).

These quotes indicate that some students had little faith in the lesson and accordingly, may have been less able/willing to engage with the material. This sense of fatalism was also implied by some control students who had tried new homework strategies. Despite numerous positive comments about adopting revision and homework strategies after the lessons, some students explained that they were not sustained:

“I kept up to it for about two weeks and I just went back to my normal way” (Control, school 18, 231).

Theme 14 Lesson style and content (16 instances/4 groups): A key theme within the focus groups featured students’ appraisals of the *style and content* of their homework and smoking lessons. This theme comprised a series of three subthemes. Two of these related to engagement-enhancing aspects: *enjoyed group discussions*, (*sub-theme 14.1*) and *colour handouts perceived as important* (*sub-theme 14.2*). One sub-theme related to features they disliked about the style and content (i.e. engagement-inhibiting): *activities were irrelevant/hard* (*sub-theme 14.3*).

Sub-theme 14.1 Enjoyed group discussions (7 instances/3 groups): Students in the intervention condition described appreciating that the smoking lessons focused on exploring and discussing smoking, rather than ‘preaching’ about anti-smoking. Their experience was that the lesson focused on “more sort of like giving your own reasons so that you can then decide” (Intervention, school 10, 395). In fact, students across both conditions valued the opportunity to discuss issues and activities as a group and found this a rewarding learning experience:

“I feel like, because we were sort of left more to sort of like discuss it with each other, it made us feel like more adult and not be, like when we were younger. We were sort of just like “oh what do you guys think?” sort of discuss it in your groups. You felt like when you were hearing what everyone else thought it’s sort of like that you were an adult and that you were being treated like one” (Control, school 18, 319-324).

Sub-theme 14.2 Colour handouts perceived as important (2 instances/1 group): Some students in the control focus groups felt that the lesson handouts being in colour signalled

that they were important, since only exam papers and important documentation were given to them in colour.

Sub-theme 14.3 Activities were irrelevant/hard (7 instances/3 groups): With regard to the homework lessons, some students commented that the activities felt irrelevant to them when they were younger because their school did not give out homework, or that the content was too challenging. Case studies were highlighted by a number of intervention students as unrealistic. They found it hard to relate to the person depicted on paper, and 'did not care about them', stating that they would have preferred real-life cases on a short film. Similarly, comments were made in the intervention focus groups that the options for refusing a cigarette in the Student Plans were often hard to relate to:

"It wasn't like you'd... like we'd had the answers of what a kid actually would say (Intervention, school 10, 144-5).

There was a sense from these students that the options were not realistic or were more akin to what an adult might say. In fact, one student explained that if he were offered a cigarette, he would just say no thanks and 'get out of the conversation', rather than providing any explanation for his refusal.

Theme 15 Contextual factors. Students spoke more frequently about contextual factors (12 instances/4 groups) impeding their enjoyment of the lessons in the control focus groups (9 instances), than during the intervention groups (3 instances). Included in the contextual factors theme were three small sub-themes: *PSHE lessons not taken seriously* (sub-theme 15.1), *lessons were rushed* (sub-theme 15.2) and conversely, *having too much time* (sub-theme 15.3) for the lessons.

Sub-theme 15.1 PSHE lessons not taken seriously (4 instances/2 groups): This sub-theme appeared only in the control focus groups with regard to their homework lessons. Many of the participating schools used their PSHE or 'Life skills' curriculum timetable in which to deliver trial tasks, however these lessons tend to have low credibility with students (and often schools themselves), as one student described:

"It's not like a maths lesson or English lesson, I mean so it's a bit more like lax, so some people might see that as an opportunity to perhaps not pay as much attention" (Control, school 16, 340-343).

By being delivered in these low-credibility timeslots, the homework lessons may also have been perceived as irrelevant or unimportant. Students spoke of their peers 'messaging about', sometimes to the extent that they could not hear the teacher.

Sub-theme 15.2 Lessons were rushed (4 instances/1 group): In one particular control school the homework lessons were squeezed into less than half the recommended time (i.e.

20 minutes rather than a full 50 minute lesson). This meant that the homework lesson material was inadequately delivered, processed and completed:

“I feel like the information on it was quite interesting, but like in one of them, it had like loads of, or a few of them they had like loads of activities and we’ve only got like 25 minutes of PSHE to read all of the information, to do all the things” (Control, school 16, 324-325) .

Sub-theme 15.3 Too much time (4 instances/3 groups): Interestingly, students receiving the intervention were more likely to discuss having too much time for their lessons, suggesting that it was given greater priority by schools. One student argued that this was not necessarily an issue, because it allowed more time for class discussion:

“I’d prefer to have much time, because we get to discuss and it’s like nicer to discuss with like your peers and your teacher, like on what your views are on smoking, rather than just filling out sheets” (Intervention, school 10, 551-553).

Other students commented that this protracted time allocated to the lesson meant that it became boring, there was little ‘pace’ to it and many students would use it as an extended chance to socialise if they finished early.

The next section summarises the notable differences arising from the analysis of the four focus groups between control and intervention students’ experiences.

Differences between intervention and control students’ experiences

On close examination of the identified themes, there are notable differences in how the intervention and control students described their experiences of the trial. Students in the intervention focus groups had a stronger perception of the importance of the study and their contribution to it than their control condition peers: they spoke more frequently about the sense of belonging to something important (5 instances vs. 1 instance). The theme of familiarity and trust in teachers was also stronger within the intervention focus groups (6 instances vs. 2 instances in the control focus groups), as they described the considerable difference this comfort and ‘being known’ made to their experience of the smoking lessons.

In contrast, control students commented twice as often as their intervention peers that they had adopted useful tips and strategies from their homework lessons (8 instances vs. 4), particularly since they explained that schools did not routinely teach this material within the curriculum. Control students also spoke more frequently about contextual-related factors impacting negatively on their experience of the homework lessons (9 instances vs. 3 in the interventions groups), implying that they were given low importance and value by their schools and fellow students. Only within the control groups did students mention that their lessons were not taken seriously because they were perceived as another low-value PSHE lesson. Control students were the only ones to comment that their lessons were squeezed

into shorter-than-recommended timeslots and rushed. Finally, only control focus group students mentioned 'getting out of lessons' as a major benefit of participating in the trial. This was not evident in the intervention students' accounts of taking part.

The following section draws together the findings from the focus groups ('depth') and the analysis of the student feedback sheets ('breadth') to provide an integrated, holistic representation of students' experiences.

7.4.3 Integrating feedback sheet and focus group findings

Overall experience: Many of the experiences shared by the 38 students across the four focus groups were similar to those obtained at scale from the 15,882 student feedback sheets (see Table 7.5). Being suspicious of the researchers' motives behind collecting smoking data was identified as a concern in both data sets, although in the focus groups, students were able to explain that, over time, they learned to trust us. Finding the trial tasks repetitive and boring was also a dominant theme in both data sets. In terms of responses to the lessons, teacher enthusiasm was repeatedly identified as a critical factor in students' engagement with and enjoyment and acceptance of them. Similarly, the pleasure and comfort of participating in the lessons with familiar teachers and classmates, and the joy of being able to discuss activities as a group were also consistently identified as important. At times, however, the lesson content was considered too challenging. Other themes from the focus groups which were corroborated at scale through the feedback sheets relate to lesson impact: students reflected on improved understanding and knowledge, but scepticism and resistance were also evident, as students explained they either always had healthy attitudes towards never smoking/ doing homework, or they already knew everything and learned nothing new. The students rated the overall impact of the lesson more highly (modal rating of 4 out of 5) than their enjoyment of it (modal rating of 3 out of 5).

Comparison by Condition: There were clear differences between the conditions in how students experienced the trial and the lessons (see Table 7.6). Compared to students in the control schools, intervention students rated their enjoyment of their smoking lessons more highly, commented more frequently that they felt like they belonged to something important and were more curious and interested in the study outcomes. They also

Table 7.5 Integrated view of students' experiences from the analyses of focus group transcripts and student feedback sheets

	Focus Groups (<i>N</i> = 4)	Student Feedback Sheets (<i>N</i> = 15,882)	
	4 Groups, 38 students (16 control; 22 intervention)	<i>N</i> = 2,471 handwritten comments (705/29% control; 1766/71% intervention)	<i>N</i> = 14,054 ratings for item 1 'how did you find the lesson' (6195/44% control; 7859/56% intervention); <i>N</i> = 14,735 ratings for item 2 'This lesson helped me think differently about smoking/homework' (6572/45% control; 8163/55% intervention)
Trial experience	Confusion Sense-making Familiarisation over time Curiosity and interest in results Belonging to something important Repetitive and boring Feeling vulnerable Interesting, novel experience Trust Escape from lessons Camaraderie	Suspicion Boring and repetitive	
Response to lesson	Teacher factors: - Enthusiasm - Consistency - Familiarity and trust	Lesson content and teacher delivery - Enthusiasm - Protocol violation - Classroom environment (e.g. "messaging about")	Item 1: 'How did you find the lesson?' (<i>enjoyment</i>): Modal rating = 3/"Ok".
	Lesson content & style: - Discussion - Activities irrelevant/hard - Colour handouts	"It was fun because we did group work". Homework lessons sometimes too challenging	
	Lesson impact: - Internalised & adopted content - Sceptical can change behaviour	Improved understanding and knowledge Resistance: fixed attitudes and behaviours Already knew everything: opinion not changed Pre-existing healthy attitudes/behaviours	Item 2: 'This lesson made me think differently about smoking/homework': Modal rating = 4/"Agree".
	Contextual factors: - PSHE not taken seriously - Too much time/Too little time		

Table 7.6 Comparison of students' experiences by condition

	Control Condition	Intervention Condition
Thematic Analysis	<p>Commented exclusively on:</p> <ul style="list-style-type: none"> - Getting out of lessons as a major benefit of participating in the trial. - Their homework lessons being rushed and squeezed into a shorter than recommended timeslot. - Homework lessons not being valued because they were delivered during PSHE which has low credibility. <p>Commented more frequently on:</p> <ul style="list-style-type: none"> - The impact of the lesson, particularly about internalising and adopting lesson content (i.e. homework/revision strategies). - Finding the study an interesting, novel experience (particularly with regard to the Smokerlyzer device during smoking data collection). 	<p>Commented more frequently on:</p> <ul style="list-style-type: none"> - Feeling like they belonged to something important and recognising their personal contribution to research. - Being curious and interested in the study outcomes. - The importance of having a known, trusted teacher to discuss personal issues during the smoking lessons.
Content Analysis	<p>Commented more frequently on:</p> <ul style="list-style-type: none"> - The boring and repetitive nature of the lesson. - Being resistant to the messages in the lesson due to fixed attitudes/behaviours (e.g. hating homework). - Improved understanding and knowledge. - Teachers' protocol violation during the homework lessons. 	<p>Commented more frequently on:</p> <ul style="list-style-type: none"> - Already having pre-existing healthy attitudes/behaviours towards not smoking. - Already knowing everything and therefore their opinion was not changed by the lesson.
Quantitative Feedback Item Analysis	<p>In comparison to intervention condition:</p> <ul style="list-style-type: none"> - Lower mean rating (2.76) for enjoyment of homework lessons (on item 1 'how did you find the lesson?'). - Lower mean rating (2.89) for perception of homework lesson impact (on item 2 'this lesson helped me think differently about homework'). 	<p>In comparison to control condition:</p> <ul style="list-style-type: none"> - Higher mean rating (2.93) for enjoyment of smoking lessons (on item 1 'how did you find the lesson?'). - Higher mean rating (3.11) for perception of smoking lesson impact (on item 2 'this lesson helped me think differently about smoking').

underlined the importance of having a known, trusted teacher to deliver the lessons, so they were able to be more open and honest.

Control students spoke more about the boring, repetitive nature of the homework lessons, and more frequently rated them as 'not enjoyable' or 'not at all enjoyable'. They were more likely to report being 'unsure' or 'disagreed' that the lessons helped them think differently about homework, and commented more on being resistant to the messages due to fixed attitudes about homework (e.g. they hated it). They spoke more of the lessons being devalued due to being delivered within PSHE timetable slots, and of protocol violations (e.g. delivered in too short a timeframe; teachers omitting material or not teaching the lesson at all). Some considered getting out of lessons a major benefit of taking part in the study. However, regardless of all this, control students still reported more than their intervention peers that they found the study an interesting, novel experience and that they had adopted numerous strategies and techniques introduced in the homework lessons.

7.5 Discussion

The aims of this study were to explore the students' understanding of the RSIIYA trial, the extent they found participating in the trial to be acceptable (and what affected this), how they responded to the intervention/control lessons and any key influencing factors and finally, whether experiences differed by condition.

This study has revealed that students' understanding of the trial was marked by initial confusion regarding their involvement and suspicion about the researchers' motives for collecting personal smoking data. However familiarisation with the routine over time built trust, there was a sense of belonging to something important and a genuine curiosity in the results. In terms of acceptability of participating in the trial, students overwhelmingly found the trial tasks to be repetitive and boring, and in the early stages, felt vulnerable and anxious when providing personal smoking data. However with time, trust increased and students reflected back on the trial as a novel and interesting experience to be part of. Students mostly thought the smoking and homework lessons were 'ok' rather than highly enjoyable, but lessons were rated highly for helping them to think differently about smoking and homework. That said, nearly a third (30%) of the 2,471 students providing handwritten feedback considered themselves to already have healthy attitudes towards smoking/homework, prior to the lessons.

Responsiveness to the smoking intervention and control lessons were predominantly influenced by individual teachers' enthusiasm and learning climate they created in each

classroom, which depended on the level of trust, knowledge of each student and support perceived. Control and intervention students experienced the trial differently. Control students communicated a sense that their schools did not value highly being in the control condition and the topic of homework was controversial in schools. Intervention students appeared to have a stronger sense of their contribution being of value, of their school belonging to something important. Student ratings for the intervention lessons were significantly higher than those for the control lessons.

These findings are similar to those of previous studies which have investigated participants' experiences of trials. For example, the adolescents in the present study and those participating in Midgley and colleagues' (2016) therapy trial both held mixed understandings of the trials, disliked completing questionnaires, found the formal use of technology initially 'scary' and felt self-conscious/vulnerable. The adolescents in the present study also engaged in sense-making, similar to the adult participants in the Heaven et al. (2006) and MacNeill et al. (2016) studies. Four key findings are now discussed in more detail: repetition, trial understanding, devaluing the control condition and the role of the teacher or 'learning climate'.

Repetition: In longitudinal trials, frequent, repetitive tasks represent a serious engagement threat for researchers. However this seems to depend on the nature of the repetitive tasks involved, and how enjoyable and valuable participants consider them to be. For example, participants in Mein and colleagues' (2012) longitudinal study considered the regular medical examination to be a positive, valuable experience, but completing a detailed health questionnaire every two years was a burden: they disliked completing the same questions, particularly having to select responses that failed to fully reflect their circumstances (Mein et al., 2012). A similar mixed pattern emerged in the present study. The adolescents found the questionnaires repetitive and tedious, sometimes struggled to find options that adequately reflected their views or feelings, or found questions they could not relate to which were 'obviously' written by adults. However breathing into the Smokerlyzer device during the annual smoking data collections sessions, the other repetitive tasks, was never described as 'repetitive' or 'boring'. Whilst initially perceived as formal and scary, it became regarded as 'fun'.

Whilst questionnaires are an enduring, important feature of longitudinal studies, their limitations are widely acknowledged (Robson, 2002). Being constrained by set responses and unable to accurately record one's feelings (i.e. a lack of personalisation) can be frustrating for respondents, as evidenced above. Within health assessment questionnaires in particular,

the perceived irrelevance of items, i.e. those that feel inapplicable or inappropriate, has been linked to respondent fatigue, poor engagement and attrition (Hochheimer et al., 2016; McCambridge et al., 2011; O'Reilly-Shah, 2017).

In designing materials within the RSIIYA trial, we were unable to personalise the annual Smoking questionnaire because it consisted of standardised items. However we did incorporate a personalisation element into the Student Plans by including a space for students' own responses. This seems to have been received positively, in that students in the focus groups commented that they preferred to do this. All materials within the RSIIYA trial were designed first by the research team, piloted through an uninvolved partner school and adjusted following student feedback. However, given the feedback from students, this seems to have been insufficiently thorough to ensure acceptability. There were likely to have been substantial benefits to involving young people in co-designing the materials, wherever possible, so that they reflected their voice and felt more relevant (Ashktorab & Vitak, 2016).

It is worth noting that it is, whilst children do report being bored as one of the negative aspects of taking part in research, even those who describe negative aspects of research are able to appraise their participation as positive overall (Crane & Broome, 2017).

Trial understanding: There is a well-documented ethical issue regarding consent within cluster trials relating to the fact that cluster members/participants are not typically involved in cluster-level decisions to participate in a trial (Taljaard et al., 2009). Whilst randomisation is explained to cluster site *leaders* and their consent is sought for randomisation, for logistical reasons, the consent of cluster site *members* is typically sought post-randomisation, to participate in the cluster's allocated condition (Taljaard et al., 2009). For these reasons it is particularly important to communicate as effectively as possible to cluster members (and in the case of minors, also their parents) a clear understanding of the trial so that they have the information they need to give their informed consent.

As a research team we were mindful of this, and felt we had gone to considerable lengths to provide students, their families and staff with important information about the study. For example, information letters and parental consent forms were sent home with students. Research staff were carefully recruited for their experience with children, approachability and warmth. At each step students were asked if they were happy to take part, reassured about confidentiality, and data were only collected from those who gave their consent. During teacher training sessions we reiterated the aims of the study and its different components. At every stage, assemblies were held to share the next steps of the study, and alert staff and students to upcoming tasks. For teachers delivering the intervention, we

incorporated into the session plans for delivering each homework/smoking lesson a consistent introduction to remind students about the study and how the lesson contributed to it. Consequently, the extent to which some students felt vulnerable and worried about providing smoking data and their initial low level of understanding about the trial were sobering findings, and a reminder that providing study information is no guarantee it is understood or that participants feel reassured.

Worries about personal data being shared with parents was highlighted in a recent systematic review of ethical issues surrounding children's participation in research, and were found to be particularly high and common during adolescence (Crane & Broome, 2017). Providing early information to young people themselves, not just their parents, may help allay concerns. Instead of liaising solely through parents, young people have suggested that they would like to be spoken to directly about participating in research, and have their own written information that is age-appropriate, easy to understand and attractive (Crane & Broome, 2017). To this end, Midgely et al. (2016) advocate involving young people in the design of information sheets. This early involvement may be particularly useful when technical devices or procedures are involved to anticipate any concerns and identify appropriate ways of explaining procedures to enhance participants' experience and reduce anxiety.

Devaluing the control condition: Students in the control schools had a different perception of the trial and experience of it than their peers in the intervention schools. This, at least in part, seemed to emanate from their schools' indirect communication that it was not highly valued. Within non-cluster trials it is not uncommon for participants to feel disappointed or resentful at being allocated the control or non-preferred treatment, and this understandably affects their engagement with the trial and experience of it (Locock & Smith, 2011; Skingley et al., 2014). Where schools are involved in cluster trials, senior leadership teams are not happy to receive a control condition whilst their neighbouring, often competitor schools are allocated an innovative intervention to test (Harrell et al., 2000; Petosa & Goodman, 1991). We were advised by local schools that an intervention encouraging homework completion would make an attractive control condition, and we treated all schools the same, regardless of condition (e.g. we met trial coordinators regularly, provided cohort smoking data annually, provided the same suite of incentives). However from the students' accounts it would seem that control schools were less engaged in the trial, and gave less consideration to planning and delivering the sessions than intervention schools, and these contextual factors had an impact on students' experiences.

Traditionally, less attention has been given contextual or external variables which

may impede or enhance participants' engagement and retention in a study (Coday et al., 2005). In the current study, students described homework lessons being regarded as another 'low-value' PSHE lesson, being rushed and a higher number of teachers violating delivery protocol (including not teaching the lesson, but distributing handouts for independent completion). From a student perspective, if the surrounding, contextual messages in school are that the study is low value, this is likely to negatively impact on their perceptions and motivation to engage with it (Urda & Schoenfelder, 2006).

A further explanation for students' lower levels of responsiveness towards the homework lesson may be the nature of the topic itself. The aims behind both conditions are arguably different. Whilst smoking prevention lessons are about students' physical health, the homework lessons are inevitably associated with academic attainment. In other words, the motives behind the smoking lessons were unambiguous, but the homework lessons may have been appraised as 'corporate', i.e. mostly beneficial to the school. However more control students reported being resistant to the messages in the homework lessons because they had fixed or fatalistic attitudes towards it: specifically, they hated it, thought it was futile or already had their own successful methods. In this sense, some students' evaluations of the lesson content may have been that it did not meet their needs and they believed the skills being targeted were not helpful.

The role of the teacher: As discussed earlier, this evaluation of content is an important component of participant responsiveness to an intervention and therefore their engagement with it (Schoenfelder, 2012). An additional, critical component of responsiveness concerns the perceived group environment in which the intervention is delivered, and the teachers' role is fundamental in this (Urda & Schoenfelder, 2006). Schools are highly heterogeneous (Befort et al., 2008), with each school representing a "distinct society" (Caan et al., 2015, p.4). Even within the same school, each classroom has its own micro-system or ecology, created through an interaction between a teacher's style/approach to managing learning and students' thoughts and behaviours (Witt, 1986, p.41).

Numerous authors have emphasised that classrooms are essentially social environments, where students interact and forge social relationships with their friends, peers and their teacher (Urda & Schoenfelder, 2006). Teachers have significant responsibility for the social climate in the classroom, such as establishing norms for interacting with each other, setting attitudes towards learning, and being accepting of students' ideas and mistakes (Urda & Schoenfelder, 2006). They are also responsible for attending to the academic learning environment, such as what material is covered, how it is presented and what is

considered an acceptable way of speaking to each other during lessons (Urden & Schoenfelder, 2006).

The participants' responsiveness to the lessons was influenced by the social and learning climate created by the teacher delivering them, including their quality of delivery, adherence to protocol and choice of adaptations made (Berkel et al., 2011). Students enjoyed the lessons more in the company of familiar, liked peers, delivered by enthusiastic, trusted teachers who supplemented the lesson with personal stories and engaged them in the discussion material. Students particularly disliked lessons which were delivered by teachers they had no relationship with, who were unenthusiastic, skipped sections of the lesson or distributed handouts for students to complete independently, or signalled their dissatisfaction with their repetitive nature.

These findings in relation to the smoking and homework lessons are reflective of those in the broader education literature: students perceiving teachers as uncaring or cold are less positively engaged in their lessons and have lower academic achievements; those who consider their teachers to be caring, respectful and interested in their opinions invest more effort at school and cooperate more productively with peers (Urden & Schoenfelder, 2006). The unfortunate reality of testing classroom-based complex health interventions in schools is that, given the high demands already on teachers, enthusiastic delivery and adherence to study protocol are hard to expect and achieve across multiple sites. This is a significant and well-documented issue in schools-based research, as discussed in Chapter one.

Turning finally to the control lessons specifically, students described fewer positive experiences of these during the focus groups. One consideration may have been that the teachers delivering the homework lessons were the ones setting it, therefore the students may have experienced a different power dynamic during the delivery of these lessons, compared to the more personal, health-related smoking lessons.

7.5.1 Implications

Whilst "it is unrealistic to aim for perfect understanding in every individual" (Locock & Smith, 2011, p.308), there is an argument for providing young people in cluster trials, in addition to their parents, with an easy to understand, appealing, written information sheet. Both Locock and Smith (2011) and Midgley and colleagues (2016) discuss the seemingly incompatible requirements of ethics committees and participants: ethics committees want participants to be given detailed, comprehensive information; participants want to receive information that is engaging, easy to understand and visually appealing. Given what we are beginning to learn

about young people's experiences and understanding of trials particularly, there is arguably a need to make a case for more user-friendly information and consent processes within ethics applications.

At the end of each focus group, students commented that they had enjoyed sharing their views and felt important because their opinions mattered. Whilst there is a danger of adding further burden to any trial, researchers may wish to consider seeking young people's views on participating in a trial as a matter of routine (e.g. Crane & Broome, 2017). Within school-based cluster trials, this may take the form of a short questionnaire, which could be done online, creative, interactive assemblies to gather experiences, focus groups, as in the present study or targeted interviews. Furthermore, incorporating a student advisory group in the trial protocol may be highly advantageous to ensure applicability of materials or to work as design partners (e.g. Midgley et al., 2016; Yip, Foss & Guha, 2012), to seek ad-hoc advice, and garner opinions about improving the experience of participating in research (e.g. Lloyd et al., 2017).

7.5.2 Strengths and limitations

The findings from this study contribute to an emergent literature which is endeavouring to represent children and young people's perspectives of being involved in research. The complimentary use of mixed methods were valuable in not only determining how students responded to the intervention (and control) lessons, but also in understanding how students experienced being in the trial overall. Through the focus groups, students had flexibility and freedom to explain their experience in their own words, to the depth they felt comfortable with. They also provided an invaluable retrospective account of their four years in the trial. The student feedback sheets provided immediate reactions to individual lessons, across four different time points and greater insight into responsiveness at scale. Together, these methods provide a comprehensive view of students' experiences.

The recruitment difficulties, in particular the resignations of trusted Study Coordinators, meant that only half of the desired focus groups took place. This had implications for the balance of schools in the final sample, which was a limitation of this study. Three of the four focus groups involved students from schools rated low in terms of their overall effectiveness (i.e. they received a rating of 'satisfactory' or 'requires improvement' following their last Ofsted inspection). 'Effective' schools (awarded 'good' or 'outstanding' by Ofsted) were underrepresented, with just one school/eleven students within the sample. Some caution is therefore required when making conclusions about the focus group findings. For example, some of the students' confusion may be symptomatic of a struggling school with

poor morale or leadership difficulties which had limited capacity to embrace the study fully. In fact, no student in the high Ofsted school focus group mentioned being confused, therefore there was less evidence of sense-making. Taking into consideration the national picture, according to 2018 government Ofsted figures (Department for Education, 2018), of 3,314 state secondary schools, 22% were outstanding, 53% were good, 17% satisfactory/requires improvement and 8% were inadequate. Therefore, most schools (75%) are either good or outstanding, which means that the sample does not quite reflect this larger picture.

A further limitation of the focus group sample was that 71% (27/38) of the students were from schools serving moderate-to-wealthy communities. Just one school (11/38 students) served a disadvantaged community. In England, people are four times more likely to smoke in areas of high social deprivation than those in the least deprived areas (Office for National Statistics, 2018). Therefore it could be argued that, given that the trial targeted smoking prevention, the voices of students who are most vulnerable with regard to smoking were not adequately represented within this sample. Given the recruitment challenges discussed earlier, it is difficult to determine how this situation could have been improved. On closer examination of the three moderate-to-wealthy schools, one was at the lower end of 'moderate' with regard to free school meals eligibility (school 10), and catered for a broad range of students. In fact this focus group was the most ethnically diverse including Asian, Black African, Middle Eastern, Polish and Spanish students. The involvement of diverse ethnicities within the sample increases the confidence in the representativeness of views and experiences (58% White British; 16% Black African/British; 11% Asian; 8% Polish; 5% Middle Eastern; 2% Spanish).

7.5.3 Conclusion

Despite these limitations, the results of this study has revealed that, whilst the retention of children and young people may be superior in schools when compared to other methods, young people are not passive recipients of their allocated trial conditions. Students within the RSIIYA trial often felt vulnerable, concerned about the limits of confidentiality and despite the researchers' best efforts, initially unclear about the nature of the trial. It has highlighted the likely benefits of involving young people in the co-design of intervention, materials and information sheets to enhance appeal, clarity of understanding and relevance.

This study also provides further evidence for the considerable influence of contextual effects on students' engagement in a trial, from the implicit messages communicated through school planning through to the microclimate messages transmitted by teachers within their classrooms. As other school-based health researchers have commented (e.g. Stallard et al.,

2013) it also highlights the complex difficulties involved in implementing classroom-based prevention interventions in schools.

Chapter 8 Does introducing a complex Engagement Promotion Programme impact on engagement and RSIYA trial outcomes?

8.1 Chapter summary

This chapter reports the final study in this PhD which examined multi-level engagement within the RSIYA trial. This study examined the costs associated with implementing an 'Engagement Promotion Programme', developed over time to sustain schools' commitment during the trial, the degree to which schools accessed this programme and any associated effect on engagement. This study also investigated whether there was differential engagement between schools according to characteristics at the school-level (e.g. Ofsted rating), and whether engagement of any particular stakeholder group was related to student smoking outcomes at the end of the trial.

8.2 Background

Engagement with an intervention is consistently associated with positive outcomes in prevention intervention trials (Dane & Schneider, 1998; Durlak & DuPre, 2008; Lawton, Mceachan, Jackson, West & Conner, 2014; Nix, Bierman & McMahon, 2009; Pereira & Marques-Pinto, 2017; Schoenfelder, 2012). Differential stakeholder engagement and commitment between and within sites are associated with trial outcomes (Lawton et al., 2014) and are consequently a serious concern for the cluster trial researcher. There is therefore a clear rationale for researchers to invest in promoting cluster site engagement.

The difficulties of developing and sustaining school engagement have been discussed extensively in this thesis. Schools receive frequent requests to participate in research projects, the majority of which are declined. For example, in a recent survey, almost half (26/56) of Australian teachers reported receiving 10 requests in the last year, and declining on average 80% of these (Prendergast & Rickinson, 2019). To engage with research, school leaders need to be persuaded, as a minimum, that the research will not be burdensome or clash with busy times in school and that it is credible and non-controversial (Befort et al., 2008). However, they also want to know "what's in it for us?" (Prendergast & Rickinson, 2019, p.26). School leaders are more likely to participate in research that meets a local need or supports their school's mission (Befort et al., 2008) and provides "tangible benefits, such as school-specific reports, staff professional learning workshops and sessions with students" (Prendergast & Rickinson, 2019, p.26). This expectation of "a degree of implicit and explicit reciprocity" or fair exchange for participation has also been identified as an important factor

in individual engagement and retention (Heaven et al., 2006; Locock & Smith, 2011; McCann et al., 2010; Mein et al., 2012, p.2345), as discussed earlier in this thesis.

Some of these ‘tangible benefits’, such as providing professional workshops and student teaching sessions, or establishing educational or support groups for participants (e.g. Robinson et al., 2015) can be considered complex engagement and retention strategies. When deciding whether or not to use such strategies, researchers are faced with a series of unknowns. The first unknown is: are they effective? Evidence to support their use is difficult to find in the retention literature: they tend to be under-researched and under-reported (Bructon et al., 2014; Robinson et al., 2015). One explanation for this is that complex retention strategies are harder to develop and evaluate in comparison to simpler strategies such as a cash incentive, which has been tested extensively in trials-within-trials (Bructon et al., 2014). A second unknown is: how much will using a complex strategy cost? Costs associated with implementing complex engagement and retention activities are difficult to determine. Published studies rarely even report retention protocols or any detail regarding the often multiple strategies they ultimately used (Abshire et al., 2017), therefore costs remain invisible. This situation is perhaps not helped by the research funding application process, which tends to emphasise identifying and presenting financial costs associated with recruitment strategies to meet recruitment targets (Daykin et al., 2018). As a result, it is possible that trials may be financially ill-equipped to invest in adequate retention and engagement activities, causing researchers to go to great personal lengths to retain participants by undertaking numerous unrecognised, informal activities (Daykin et al., 2018).

Measuring engagement

Whilst activities to promote engagement may be important for trial outcomes, there is also evidence that *measuring* different stakeholders’ engagement, for example as part of a process evaluation, can support the interpretation of outcomes (e.g. Bamberger, Coatsworth, Fosco & Ram, 2014; Wyatt et al., 2018). Researchers have adopted different methods and approaches to measuring engagement. For example, Bamberger et al. (2014) developed a short five-item scale to measure parental engagement across the seven week ‘Strengthening Families Programme’ described earlier. Five behavioural indicators were identified (“engagement/ participation, interest, resistance (...), positive affect toward leaders and positive affect towards other parents/group members”) and a behavioural statement was crafted for each (e.g. “parent was actively engaged and readily participated in parent session group discussions/activities”) accompanied by a four-point Likert scale (4 = “always or almost always”; 1 = “rarely or never”) (Bamberger et al., 2014, p.5). Parents were rated by individual

facilitators who discussed their ratings with co-facilitators and supervisors to reach a consensus, and a composite score was calculated for each parent (Bamberger et al., 2014). Ratings were conducted weekly to determine any changes in engagement as the trial progressed. Of the 1445 ratings available, Bamberger et al. (2014, p.5) were able to report that “the average parent was engaged “Often (3)” or “Always or almost always (4)”, and that engagement increased over time.

Multi-level stakeholder engagement was investigated as part of Wyatt et al.’s (2018) process evaluation of a trial testing a school-based obesity prevention intervention. The Healthy Lifestyles Programme (HeLP) targeted Year Five children (age 9-10) and involved physical activity workshops, drama sessions, teacher-delivered education sessions with short homework tasks, and setting goals to change behaviour with support from parents and HeLP coordinators in school (Wyatt et al. 2018). The trial involved 32 primary schools for one year in South West England. In the process evaluation, Wyatt et al. (2018) examined whether and the extent to which parents, children and the 16 intervention schools engaged with HeLP and the trial. Specific engagement indicators were developed for each stakeholder group, such as “*very enthusiastic, has discussed goals at home and has clear strategies for achieving them*” to assess a child (see Table 8.1 for the full scoring system), and ratings were conducted by HeLP coordinators employed by the trial to support schools with the intervention (Wyatt et al., 2018, p.75). These coordinators drew upon informal observational field note data to assess each stakeholder, who were ultimately dichotomised into an ‘engaged’ or ‘less engaged’ group (Wyatt et al., 2018).

Table 8.1 Scoring system used by Wyatt et al. (2018) to assess multi-level engagement within the HeLP trial

Child-level (N=676)	Parent-level (N=676)	School-level (N=16)
0 = <i>uninterested/unaware goals needed to be set</i>	0 = <i>did not attend any activity/did not sign the goal-setting sheet</i>	0 = <i>unengaged/uncooperative</i>
1 = <i>reluctant/needs a lot of prompting</i>	1 = <i>attended one or more events or signed the goal-setting sheet (but not both)</i>	1 = <i>supportive</i>
2 = <i>enthusiastic and happy to chat about goals and how they will achieve them</i>	2 = <i>attended one of more events and signed the sheet</i>	2 = <i>enthusiastic and supportive</i>
3 = <i>very enthusiastic, has discussed goals at home and has clear strategies for achieving them</i>		3 = <i>very enthusiastic and used HeLP in other aspects of teaching/school activities</i>
> 1 = engaged ≤ 1 = less engaged	≥ 1 = engaged < 1 = less engaged	0-3 = less engaged 4-9 = engaged

(Taken from Wyatt et al. 2018, p. 75-76)

Whilst the HeLP intervention was found *not* to be effective, engagement with it was generally high (Wyatt et al., 2018). There was however some variation across the three

stakeholder groups: engagement was highest at the child-level (92% of the 676 children were 'engaged') and lowest at the parent-level (77% were 'engaged') (Wyatt et al., 2018). The school-level engagement score (minimum 0; maximum 9) was a composite of individual ratings given to each school's (1) head teacher, (2) Year five teacher(s) and (3) administrator (Wyatt et al., 2018). Interestingly, whilst 80% of the 16 schools were classed as 'engaged' overall at the school-level, the Year five teachers represented the least engaged stakeholder group when considered independently (75% were categorised as 'engaged') (Wyatt et al., 2018).

Researchers working with schools are advised to engage stakeholders at all levels in their research to support retention and implementation of related tasks, i.e. senior leadership teams, parents, teachers, students and ancillary staff, such as kitchen staff and receptionists (Lloyd et al., 2017; Schoeppe et al., 2014). However it is unclear whether the engagement of a particular *level* of stakeholder is more important than another with regard to the success of a research programme, and therefore should be targeted more thoroughly. Senior leadership level commitment to research is consistently highlighted as necessary for sustaining cluster site engagement, effective trial task implementation and positive outcomes (e.g. Pinto et al., 2018). However, there is evidence to suggest that this level of commitment on its own may be insufficient to produce positive outcomes. For example, McEachan et al. (2011) successfully secured five organisations to participate in testing an intervention to increase physical activity in the workplace. In one of their five participating organisations (a bus company), leaders were highly engaged and committed to the project, however they struggled to find enthusiastic staff willing to facilitate the intervention and encourage others to participate in it (McEachan et al., 2011). Those staff who did come forward to be trained as facilitators sometimes faced unenthusiastic colleagues who were hard to motivate and deal with (McEachan et al., 2011). The lack of significant effect of the intervention was identified in post-hoc analyses as attributable to differential engagement both between and *within* sites (McEachan et al., 2011).

Numerous studies have highlighted the importance of staff-level engagement for trial outcomes within cluster trials testing complex interventions. In school-based trials, Stallard et al. (2013) in the UK and Mukoma et al. (2009, p.43) in South Africa both underlined the critical role of the teacher in influencing how students responded to their prevention interventions: a teacher's attitude could be "make or break...whether it went...how the class reacted to it" (Stallard et al., 2013, p.32). Similarly, Pettigrew et al. (2016) found that the delivery of a substance use prevention programme within an 'engaging classroom', fostered

by engaged teachers (defined by being attentive, enthusiastic, serious, clear and positive), significantly predicted superior outcomes. Staff engagement has also been found to be predictive of outcomes in non-school settings. For example, McEachan et al.'s (2011) workplace activity intervention had a significant effect in worksites whose staff demonstrated the highest levels of engagement and commitment towards it (Lawton et al., 2014).

Participant engagement with an intervention is more consistently related to programme outcomes than the number of sessions they attend, i.e. the 'dosage' they receive (Bamberger et al., 2014): simply attending an intervention session is no guarantee that the material will have meaning for an individual or that they will concentrate on related tasks (Bamberger et al., 2014; Dane & Schneider, 1998). Referring back to McEachan et al.'s (2011) workplace activity study, unenthusiastic, challenging employees were one explanation for a lack of significant effect in some sites.

Whilst individual-level factors, such as personal agency, play a crucial role in stakeholders' engagement with an intervention and trial (Coday et al., 2005; Riley & Hawe, 2009; Skingley et al., 2014), findings from earlier studies in this thesis tentatively suggest that school-level characteristics may have influenced stakeholders' engagement with the RSIIYA trial. These key characteristics include condition allocated, overall effectiveness Ofsted rating and deprivation levels within the community served. With regard to condition allocated, teachers commented more frequently in intervention schools (compared to control schools) on being personally or professionally invested in the trial and adapting the lessons to boost student engagement (study three, chapter five). Trial coordinators working in high Ofsted-rated schools spoke more frequently of *facilitators* when managing trial tasks, specifically of strong leadership support, team cohesion and support from colleagues (study one, chapter four). Coordinators in low Ofsted-rated schools, by contrast, spoke more of *barriers* when trying to engage staff and implement the trial tasks, such as a climate of poor morale/overwork and inadequate senior leadership support. Finally, with regard to level of socio-economic deprivation, teachers delivering smoking or homework lessons within disadvantaged communities in the RSIIYA trial rated them significantly more positively than teachers working in moderate-to-wealthy communities (study three, chapter six).

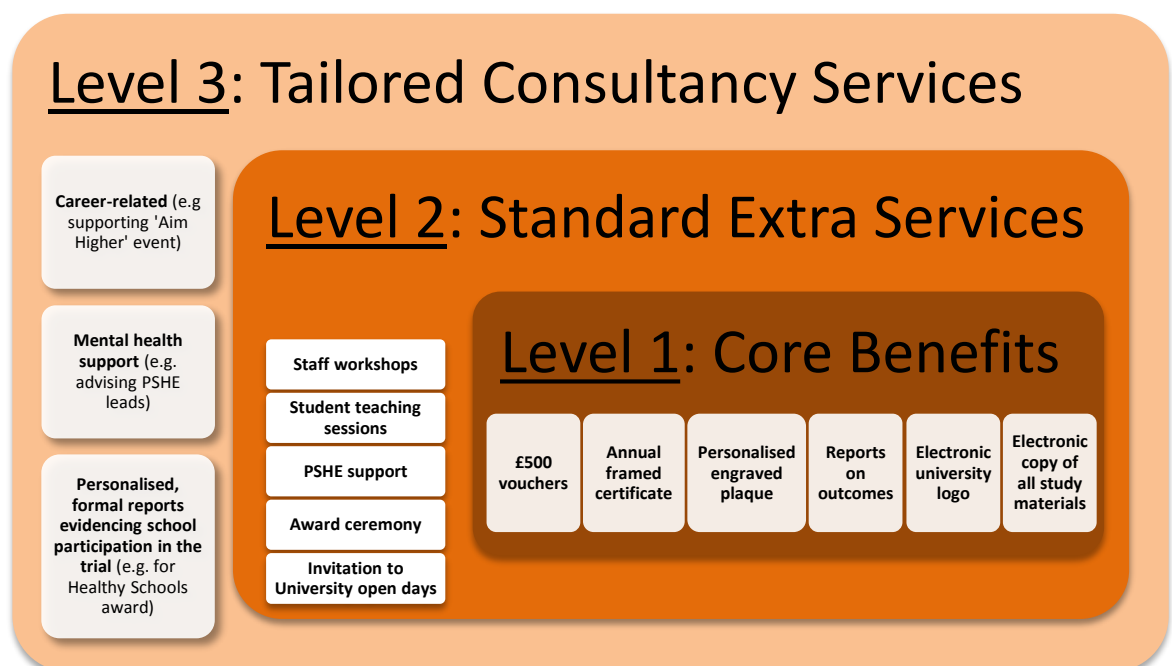
The present study

The present study examines work undertaken in the RSIIYA trial to promote and measure engagement in participating schools. The research team developed an 'Engagement Promotion Programme' which consisted of three levels of benefits offered to all schools and

the author devised a Measure of Engagement to formally assess engagement within and between participating schools. Each of these is now briefly described.

Engagement Promotion Programme: In the early months of the trial, the research team increasingly recognised that the initial benefits provided (£500 vouchers, annual framed certificate and report on student smoking outcomes) seemed disproportionate to the degree of organisation and effort required of each school to participate in the trial. There was concern that schools may disengage. Consequently, we began to explore additional benefits which would increase the likelihood that schools might view their contribution as a fair exchange. We consulted study coordinators in the annual ‘keep-in-touch’ review meetings to identify what additional benefits might appeal to their school and potentially sustain or increase their engagement with the trial. Coordinators’ suggestions involved benefits, such as use of the university logo, but also ‘services’ which included, for example, providing staff workshops and mental health advice. This feedback resulted in the research team developing a rolling, comprehensive ‘Engagement Promotion Programme’ consisting of three levels of benefit, which continued to evolve across the trial (See Figure 8.1).

Figure 8.1 The Engagement Promotion Programme developed for the RSIIYA trial



Level one consisted of ‘Core Benefits’ which were provided automatically to every school. Added to the original benefits were a specifically adapted university logo incorporating the phrase ‘Building Healthy Communities’ for school websites, and provided on conclusion of the trial, a personalised, engraved plaque, report on trial outcomes and an electronic copy of all study materials. Level two benefits were ‘Standard Extra Services’,

consisting of staff workshops, student teaching sessions, PSHE support, invitations to university open days and an award presentation ceremony (at the end of the trial). These were all designed and delivered by the trial managers (with the exception of the university open days) and promoted in schools through school coordinators. Following coordinators' feedback, a colour flyer of these benefits was produced (see Appendix 29) which could be used with their senior leadership team when discussing these free services. Level three benefits consisted of 'Tailored Consultancy Services', such as providing career-related or mental health support. Examples of these particular services were provided during annual review meetings with the study coordinator to generate additional local suggestions or ideas. Specific requests arose during or after these meetings, usually after study coordinators had had the opportunity to discuss the offer with their Senior Leadership Team.

Measure of Engagement: To help examine any impact of introducing the Engagement Promotion Programme, i.e. whether there was any relationship between a school's engagement in the trial and their utilisation of the programme, the author devised a Measure of Engagement. This was specifically designed for the purpose of this PhD study towards the end of the trial. Whilst the Staffordshire and Yorkshire research teams acquired an informal sense of each school's engagement through their frequent contact and visits, the Measure of Engagement enabled us to conduct a more formal, structured assessment of school engagement, thereby allowing meaningful comparisons to be made between the 45 participating schools.

The measure comprised three sub-scales to assess engagement at three key stakeholder group levels within each site: (1) peripheral staff/school; (2) directly involved staff; (3) student. 'Peripheral or school level' stakeholders were those staff on the periphery of the trial who were not directly involved in managing trial tasks or delivering the intervention or control lessons. These included the senior leadership team, receptionists and teachers who attended smoking data collection sessions with their students. 'Staff level' stakeholders were key cluster site members who were responsible for delivering trial tasks (study coordinators) and the intervention or control lessons (teacher-deliverers). The third stakeholder level consisted of the students receiving the intervention or control lessons and participating in smoking data collection sessions. Having these subscales allowed for a degree of analysis of differential engagement between stakeholders, whilst the overall composite of these subscale scores represented the degree of overall school-level of engagement in the trial.

Aims of the present study

The present study sought to determine whether investing in the complex ‘Engagement Promotion Programme’ was worthwhile, i.e. whether there was ultimately a relationship between schools’ use of the programme and their engagement in the trial. In addition, drawing upon the Measure of Engagement, the study sought to determine whether characteristics at the school-level (e.g. Ofsted rating, condition allocated, level of deprivation within the community) were predictive of engagement. Finally, the study drew upon secondary data from the RSIIYA trial to establish whether there was a relationship in intervention schools between students’ self-reported ever-smoking at the end of the trial and any particular stakeholder level of engagement. The specific research questions were:

- (1) What are the costs associated with implementing the ‘Engagement Promotion Programme’?
- (2) Does engagement differ according to utilisation of the ‘Engagement Promotion Programme’?
- (3) Do school-level characteristics (i.e. condition allocated, Ofsted rating or type of community served) predict engagement?
- (4) Is the engagement of a particular stakeholder group more important than others with regard to final smoking outcomes in intervention schools?

8.3 Method

To determine the costs associated with implementing the ‘Engagement Promotion Programme’ and the extent to which individual schools utilised it a retrospective analysis of field records was undertaken. Throughout the trial field notes were recorded in a shared planning document in Excel. These included details of any contact with schools, specifically the content and outcomes of meetings, number of attempts to contact key personnel and outcomes, feedback or comments received and issues experienced, discussions about Engagement Promotion Programme incentives and utilisation and delivery of incentives within the programme. Financial expenditure (e.g. travel claims, printing costs) was also itemised within this planning spreadsheet for budgetary and reporting purposes. The field notes were used to categorise schools according to their degree of benefit utilization: ‘low users’ (core level only); ‘medium users’ (two levels, i.e. core benefits and Standard Extra Services or Tailored Consultancy Services); ‘high users’ (all levels).

To generate an overall school engagement score for each participating school and to examine any impact of differential stakeholder engagement on final student smoking

outcomes, a 21-item Measure of Engagement was developed (see measure section) with three subscales relating to (1) peripheral school staff, (2) directly involved staff and (3) student engagement. Ratings were undertaken on one occasion only at the end of the trial, completed collaboratively by the research assistant and trial manager in each region.

To examine engagement in relation to the final trial outcomes, secondary data (in the form of students' self-reported smoking by school) were extracted from the RSIIYA trial dataset. Using the final trial dataset a new variable "percentage_school_smoke" was computed using students' responses to item 5 (see Figure 8.2) in the final Smoking Questionnaire (completed by 6,458 students, aged 15). The percentage of smokers in each school cohort was calculated by dichotomizing each student case into a 'never smoker' (score 0) if they ticked the first smoking statement "I have never smoked" or an 'ever smoker' (score 1) if they ticked any other statement below this. The number of 'ever smokers' was divided by the number of Smoking Questionnaire respondents in each school to create a smoking percentage. This variable and its data were then imported into the present study's SPSS dataset.

Figure 8.2 Smoking questionnaire item used to determine the trial final outcomes (i.e. percentage of students smoking)

- 5. Read the following statements carefully and tick the ONE that describes you.**
- ☐ I have never smoked
 - ☐ I have only ever tried smoking once
 - ☐ I used to smoke sometimes, but I never smoke cigarettes now
 - ☐ I sometimes smoke cigarettes now, but I don't smoke as many as one a week
 - ☐ I usually smoke between one and six cigarettes a week
 - ☐ I usually smoke more than six cigarettes a week

8.3.1 Measures

The process of generating items for the Measure of Engagement began by both trial managers meeting to develop an initial list of behaviours (positive/engaged and negative/disengaged) that they had observed during visits, different outcomes they had experienced of required trial tasks, and feedback they had received from study coordinators regarding their school's level of enthusiasm and support. The author also drew upon themes which had emerged from her previous PhD research with study coordinators, teachers and students. Using this initial list, the author then independently grouped the positive/engaged (e.g. students were well-behaved during data collection sessions) and negative/disengaged (e.g. study coordinator was uncommunicative/hard to contact) statements according to their relevance to the three specific stakeholder groups highlighted earlier (i.e. peripheral/school, staff and student level).

Each group of statements was then considered carefully and individual statements were collapsed and incorporated into one where appropriate. Each item was then written in the positive or as an exemplary, engaged behavioural statement.

The initial measure comprised 23 items requiring a simple yes or no response to indicate the presence or absence of the engagement behaviour. Following an iteration with the Staffordshire Principal Investigator and Trial Manager, it was agreed by consensus to replace the yes/no response with a five-point Likert scale, in order to provide a more sophisticated measure of engagement. Also by consensus, it was agreed that two items would be removed (because these related to smoking and homework lesson observations, for which we determined we did not have consistent data for all schools) and some item phrasing was enhanced for clarity. The final measure (see Figure 8.3) consisted of 21 items.

Multiple, independent ratings of the same school were not possible because the breadth and depth of stakeholder knowledge required to complete the measure was only available to the trial managers. The research assistants supported the rating process by offering their observations of staff and students during their data collection visits. This meant that a measure of inter-rater reliability of the scale (i.e. Cohen's Kappa) could not be determined.

Reliability analyses were performed on the full 21-item scale and two 10-item subscales, 'Peripheral school' and 'Staff', to determine the level of internal consistency with this sample of 45 schools (see Appendix 30 for SPSS output from the analyses). Using a single item to assess 'Student' engagement meant that this did not technically constitute a scale and therefore a reliability analysis for internal consistency was not possible. Cronbach's alpha showed the 21-item scale to reach good reliability, $\alpha=0.93$. Cronbach's alpha showed the sub-scale 'Peripheral school' engagement (items 1-10) to reach good reliability, $\alpha=0.80$. All the items appeared to be worthy of retention. All except two items would have resulted in a minor decrease in the alpha if deleted. Items 4 ('the Senior Leadership Team prioritised attendance at the award ceremony') and 10 ('Receptionist was aware that school was involved in study and knew who was the key contact') were somewhat weaker than the others with low item-total r values ($r=.25$ and $r=.18$ respectively). However their removal would have only marginally enhanced the performance of the sub-scale (to $\alpha=0.81$ in each case) so were retained (see Appendix 30 for reliability analyses SPSS output).

Figure 8.3 Final Measure of Engagement

Measure of Engagement: School _____

PERIPHERAL/SCHOOL LEVEL		SD	D	N	A	SA
1.	Senior Leadership Team showed interest in the study (e.g. asked the study coordinator for updates; mentioned it at assemblies, visited data collection sessions)	1	2	3	4	5
2.	Senior Leadership Team supported the coordinator when help was needed to plan in study tasks such as data collection	1	2	3	4	5
3.	School made use of free CPD workshops	1	2	3	4	5
4.	Senior Leadership Team prioritised attendance at the Award Ceremony	1	2	3	4	5
5.	Heads of Year/Departments (e.g. RE, Science) supported the coordinator by freeing up timetable slots for data collection, lesson delivery and staff training	1	2	3	4	5
6.	During data collection visits, teachers/staff seemed aware that school was involved in the smoking study	1	2	3	4	5
7.	During data collection visits, teachers/staff took an interest in the questionnaire and smokerlyzer and asked questions	1	2	3	4	5
8.	During data collection visits, teachers/staff expressed positive attitudes about the study	1	2	3	4	5
9.	During data collection visits, teachers/staff managed student behaviour to help the process go smoothly	1	2	3	4	5
10.	Receptionist was aware that school was involved in the smoking study and knew who was the key contact	1	2	3	4	5

STAFF LEVEL		SD	D	N	A	SA
11.	Study coordinator consistently replied to researcher emails in a timely manner	1	2	3	4	5
12.	Study coordinator was proactive, e.g. thought ahead about future study tasks, suggested how to improve processes, contacted the researcher about booking in engagement events, review meetings, new staff training.	1	2	3	4	5
13.	Study coordinator happily booked in annual meeting with researcher	1	2	3	4	5
14.	During staff training sessions, all relevant teachers attended, seemed willing to be involved, positive, asked questions and made suggestions	1	2	3	4	5
15.	Without needing to be chased by the researcher, the Study coordinator successfully negotiated timetable slots for smoking data collection	1	2	3	4	5
16.	Study coordinator made themselves available to actively support the research team during the data collection process	1	2	3	4	5
17.	Without needing to be chased by the researcher, the Study coordinator successfully negotiated timetable slots for the delivery of smoking/homework lessons	1	2	3	4	5
18.	Study coordinator made concerted effort to ensure teachers delivered all their lessons, chased up and collected in all completed materials.	1	2	3	4	5
19.	On the whole, teachers tended to deliver their planned smoking/homework lessons when asked by the coordinator	1	2	3	4	5
20.	On the whole, teachers tended to adhere to administrative protocol, i.e. returned their completed lesson materials on time to the coordinator, neatly arranged within the folders provided with completed cover sheets	1	2	3	4	5

STUDENT LEVEL		SD	D	N	A	SA
21.	Students behaved positively during data collection: got on with the questionnaire, asked thoughtful questions, listened to the researchers, were sensible, put up hands to ask questions/for help	1	2	3	4	5

Cronbach's alpha for the sub-scale 'Staff' engagement (items 11-20) also showed it achieved good reliability, $\alpha=0.93$. Again all the items appeared to be worthy of retention. The removal of all except two items would have resulted in a minor decrease in the alpha. Items 14 ('Teacher attended and engaged lesson training') and 16 ('study coordinator supported data collection') had the lowest item-total r values ($r=.41$ and $r=.31$ respectively), however their deletion would have only marginally enhanced the sub-scale performance (to $\alpha=0.94$ and $\alpha=0.95$ respectively). Therefore these were also retained. Inter-correlations between the three measures of engagement were substantial (see Table 8.2).

Table 8.2 Inter-Scale Correlations between ‘Peripheral school’, ‘Staff’ and ‘Student’ subscales in the Measure of Engagement (N=45)

		Engage Peripheral	Engage Staff	Engage Student
Engage Peripheral	Pearson’s r	--	0.683***	0.416**
	p-value	--	<.001	.005
Engage Staff	Pearson’s r		--	.0402**
	p-value		--	.006
Engage Student	Pearson’s r			--
	p-value			--

* P <.05, ** p<.01, *** p <.001

8.3.2 Sample

No participants were recruited to this study. It drew upon researchers’ appraisals and perceptions of the 45 schools (25 in Staffordshire; 20 in Yorkshire) participating in the RSIIYA trial and secondary data from the RSIIYA trial. The RSIIYA trial sample (see Table 8.3) comprised more schools from disadvantaged areas (N=24) than those from moderate-to-wealthy areas (N=21) and had a high proportion of high Ofsted-rated schools (62.2%). On average, participating student cohorts were significantly larger in Yorkshire schools (M = 208 students; range 170 - 259) than in Staffordshire schools (M = 146 students; range 56 - 232), $t(36.23) = 5.65, p < .001, g = 1.6$.

Table 8.3 School cluster sample characteristics for the RSIIYA trial

		Staffordshire (N=25)	Yorkshire (N=20)	Total Sample (N=45)
Condition	<i>Intervention</i>	13	12	25
	<i>Control</i>	12	8	20
Ofsted Rating	<i>High (1-2)</i>	15	13	28
	<i>Low (3-4)</i>	10	7	17
Community Served	<i>Disadvantaged</i>	11	13	24
	<i>Moderate-to-wealthy</i>	14	7	21

8.3.3 Data Analysis

To calculate design and delivery costs associated with implementing the ‘Engagement Promotion Programme’, assumptions were established (see Table 8.4) by consensus in collaboration with the Staffordshire Trial Manager. These assumptions were necessary to be able to calculate costs associated with designing and delivering services (e.g. workshops). Costs for producing object-related benefits (e.g. framed certificates) were extracted from trial invoices and expenditure records. Total cost to the trial and cost per school are provided for implementing each level of the Programme.

Table 8.4 Assumptions used to calculate design and implementation costs for individual benefits

Factor	Cost	Source
1 hour of researcher's time	£14.77	Based on Research Fellow annual salary of £36,000 gross/£28,800 net working 37.5 hours per week, 52 weeks per annum. $£28,800/52 \text{ weeks} = £553.84 \text{ per week}/37.5 \text{ hours}.$
1 day of researcher's time	£110.78	Based on Research Fellow annual salary of £36,000 gross/£28,800 net working 37.5 hours per week, 52 weeks per annum. $£28,800/52 \text{ weeks} = £553.85 \text{ per week}/5 \text{ days}.$
Researcher travel time per school visit	£22.16	Based on the mean university-school return journey of 1.5 hours.
Travel cost (mileage/petrol claim) per school visit	£15.00	Based on the mean university-school return mileage of 37.5 miles @ 40p per mile.
Design costs per workshop/student teaching session	£221.56	Based on 2 days of researcher's time to research, design slides and produce handouts.
Delivery costs per staff workshop	£29.54	Based on 2 hours of researcher's time.
Delivery costs per student teaching session	£14.77	Based on 1 hour of researcher's time (i.e. the standard duration of a timetabled lesson).

Independent samples t-tests were used to determine whether a school's allocated condition (intervention or control) and overall effectiveness Ofsted rating (high or low) predicted engagement (using total engagement scores). To establish whether school engagement was related to the socio-economic status within the community, a Pearson product moment correlation coefficient was computed between engagement scores and the percentage of students eligible for free school meals in each school.

To examine the effect of Engagement Promotion Programme use on engagement, schools were categorised as 'low', 'medium' and 'high' users of the programme. Schools using no further incentives beyond the Core Benefits were defined as 'Low Users'. Those using two levels of benefit, i.e. in addition to the Core Benefits they also utilised either the Standard Extra or Tailored Consultancy Services, were categorised as 'Medium Users'. Finally, schools accessing all levels of incentives available within the Engagement Promotion Programme were categorised as 'high users'.

A one-way between subjects ANOVA was used to analyse composite, 21-item engagement scores by category. Finally, to determine any relationship within intervention schools (N=25) between smoking outcomes and engagement at school and stakeholder group levels, a Pearson's product moment correlation was calculated between the percentage of students' self-reported 'ever smoking' and total engagement scores for the full 21-item scale and for the peripheral school staff, directly involved staff and students subscales.

8.4 Results

The cost of implementing the Engagement Promotion Programme

Implementing the three-level Engagement Promotion Programme within the RSIIYA trial cost £38,828.99. These costs resulted from providing all 45 schools with the Core Benefits in Level One and 28/62% of schools with services at Levels two and three. A high proportion (72.8%/£28,270.30) of the final costs were associated with providing the Core Benefits provided to all 45 schools (see Table 8.5). This was largely due to providing every school with £500 vouchers. Other benefits incurred relatively low costs: for example, producing an annual, framed certificate for the four years of the trial cost £2,751.38, equating to just £61.14 per school. Furthermore, two particular benefits (the university logo and an electronic set of all materials) were provided at no additional cost to the trial. The individual cost per school (N=45) of providing the Core Benefits was £628.23.

Table 8.5 Costs associated with Level 1 ‘Core Benefits’ (N=45 schools)

	Design cost per item A	Production cost per item B	Total produced (N) C	Total production costs D (BxC)	Total design & production costs E (A+D)	No of schools receiving F	Total cost per school G (E/F)
LEVEL 1: CORE ITEMS							
£500 vouchers	£0.00	£500.00	45	£22,500.00	£22,500.00	45	£500.00
Annual Framed Certificate (x4)	£110.78	£14.67	180	£2,640.60	£2,751.38	45	£61.14
Personalised engraved plaque	£221.56	£32.89	45	£1,480.05	£1,701.61	45	£37.81
Report on outcomes (x5)	£221.56	*£4.87	225	£1,096.75	£1,317.31	45	£29.27
Electronic university logo	£0.00	£0.00	1	£0.00	£0.00	45	£0.00
Electronic set of all materials	£0.00	£0.00	45	£0.00	£0.00	45	£0.00
Total Cost					£28,270.30	45	£628.22

**Calculated using the assumption of 2 days' (15 hours') researcher time to produce 45 tailored reports – populating the pre-designed report format with school-specific data. 15 hours/45 schools=0.33 hours per school per time point; 0.33 hours x £14.77 = £4.87 cost per school report per time point).*

Standard Extra Services (level 2), such as staff workshops and student teaching sessions, were accessed by 26 schools and providing these cost £9,508.58 (24.5%). These costs were largely attributable to the researchers' time spent in design and delivery (see Table 8.6). Each staff workshop or student teaching session typically required an initial two days for research, design and the production of slides and handouts. Subsequent costs were attributable to the researchers' travel time, mileage costs and delivery time associated with each recipient school. Some student teaching sessions were delivered to whole year groups across a school day, therefore travel time and costs were minimised.

Table 8.6 Costs associated with Level 2 ‘Standard Extra Services’ (N=26 schools)

	(A) Design cost	(B) Delivery cost per session	(C) Total delivered	(D) Total delivery cost (B x C)	(E) No of schools receiving	(F) Researcher travel time (E x £22.16)	(G) Travel cost (mileage) (E x £15.00)	(H) Total overall cost (A+D+F+G)	(I) Total cost per school utilising (H/E)
LEVEL 2: STANDARD EXTRA SERVICES									
Staff workshops									
Self-harm	£221.56	£29.54	9	£265.86	9	£199.44	£135.00	£821.86	£91.32
Stress and Wellbeing	£221.56	£29.54	3	£88.62	3	£66.48	£45.00	£421.66	£140.55
Work-life Balance	£221.56	£29.54	1	£29.54	1	£22.16	£15.00	£288.26	£288.26
Mental Health and Coping in Young Adults	£221.56	£29.54	1	£29.54	1	£22.16	£15.00	£288.26	£288.26
Student teaching sessions									
Stress and Wellbeing*	£221.56	£110.78	11	£1,218.58	11	£243.76	£165.00	£1,848.90	£168.08
Looking After Yourself During Exams*	£221.56	£110.78	11	£1,218.58	11	£243.76	£165.00	£1,848.90	£168.08
A-level Psychology: "Research Methods"	£221.56	£14.77	2	£29.54	2	£44.32	£30.00	£325.42	£162.71
Psychology as a Career	£221.56	£14.77	2	£29.54	2	£44.32	£30.00	£325.42	£162.71
Introduction to Psychology	£221.56	£14.77	2	£29.54	2	£44.32	£30.00	£325.42	£162.71
GCSE Business Studies: "Influencing Others"	£221.56	£14.77	1	£14.77	1	£22.16	£15.00	£273.49	£273.49
Confidence (2 hours)	£221.56	£29.54	1	£29.54	1	£22.16	£15.00	£288.26	£288.26
PSHE Support (Stand at Health Fair)	£221.56	£110.78	9	£997.02	9	£199.44	£135.00	£1,553.02	£172.56
Award ceremony	£221.56	£339.08	2	£678.16	24	N/A	N/A	£899.71	£37.49
Invitations to University Open Days	£0.00	£0.00	1	£0.00	1	N/A	N/A	£0.00	£0.00
Total Cost								£9,508.58	

*Delivered to a whole year group in one day (i.e. 5 x 1-hour lessons).

*Includes 4 hours' researcher time (£59.08) + £280 catering costs for sandwiches, cakes and drinks per trial region.

The most frequently requested and delivered staff workshop was ‘Self harm’, which meant that the design costs were retrieved, resulting in an implementation cost of £61.14 per school. Conversely, a number of staff workshops and teaching sessions were only delivered once (e.g. Work-life balance; GCSE Business Studies session “Influencing Others”), meaning that the implementation cost per school was much higher. The individual cost per school (N=26) of providing the Standard Extra Services was £365.71.

The lowest proportion of the overall costs (2.7%/£1,050.11) was associated with providing Tailored Consultancy Services (see Table 8.7). Costs were low because this level of service was the least-used by participating schools (eight schools only) and frequently involved meeting staff to discuss concerns and offer support, which required minimal or no researcher planning time. That said, a number of school requests within this level did involve considerable design costs (e.g. a two-hour CBT coping skills session for students experiencing panic attacks took two days to prepare) and because of their bespoke nature were unable to be re-used with other schools. This meant that the cost per school was high. The individual cost per school (N=8) of providing the Tailored Consultancy Services was £131.26.

Table 8.7 Costs associated with Level 3 ‘Tailored Consultancy Services’ (N=8 schools)

	(A) Design cost	(B) Delivery cost per session	(C) Total delivered	(D) Total delivery cost (B x C)	(E) No of schools receiving	(F) Researcher travel time (E x £22.16)	(G) Travel cost (mileage) (E x £15.00)	(H) Total overall cost (A+D+F+G)	(I) Total cost per school utilising (H/E)
LEVEL 3: TAILORED CONSULTANCY SERVICES									
Career-related									
Attending an Aim Higher event for able students and parents in disadvantaged school	£0.00	£59.08	1	£59.08	1	£22.16	£15.00	£96.24	£96.24
Lunchtime drop-in session on university and psychology	£221.56	£29.54	1	£29.54	1	£22.16	£15.00	£288.26	£288.26
Mental health support									
Meeting advising peer wellbeing mentors on establishing a school mental health magazine	£0.00	£14.77	1	£14.77	1	£22.16	£15.00	£51.93	£51.93
Meeting PSHE Lead to advise on improving mental health resources; putting them in touch with mental health charity contact	£0.00	£14.77	2	£29.54	2	£44.32	£30.00	£103.86	£51.93
CBT coping skills session with lunchtime nurture group suffering from panic attacks	£221.56	£29.54	1	£29.54	1	£22.16	£15.00	£288.26	£288.26
Personalised reports evidencing school participation in the trial	£0.00	£110.78	2	£221.56	2	N/A	N/A	£221.56	£110.78
Total Cost								£1,050.11	

Utilisation of the Engagement Promotion Programme

A large proportion of schools (28/62%) accessed the optional services offered within the Engagement Promotion Programme (see Table 8.8). Nearly half (22/45; 49%) were categorised as ‘medium users’. Schools within this group were evenly split with regard to condition (N=11 in each condition), but were more likely to be in moderate-to-wealthy communities (N=14 compared to N=8 disadvantaged), and have high Ofsted-ratings (N=14 high Ofsted compared to N=8 low Ofsted). Six (13%) schools accessed all levels of incentives available within the Engagement Promotion Programme, therefore were categorised as ‘high users’. These were all high Ofsted-rated (i.e. ‘outstanding’ or ‘good’), and four were in moderate-to-wealthy communities and in the intervention condition. Just over a third of schools (38% [17/45]) were categorised as ‘low users’. This ‘low user’ group had no discernible profile. It consisted of similar numbers of high (N=8) and low (N=9) Ofsted-rated schools, intervention (N=10) and control (N=7) schools and disadvantaged (N=8) and moderate-to-wealthy (N=9) schools. A detailed breakdown of all school characteristics according to incentive use can be found in Appendix 31.

This differential utilisation of the Engagement Promotion Programme also resulted in a range of individual costs per school: for 17 schools, this was £628.23 (i.e. Core Benefits only); for 20 schools, this was £993.94 (i.e. £628.23 for Core Benefits + £365.71 for Standard Extra Services); for two schools, this was £759.49 (i.e. £628.23 for Core Benefits + £131.26 for Tailored Consultancy Services); for six schools, the individual cost per school was £1,125.20 (i.e. £628.23 for Core Benefits + £365.71 for Standard Extra Services + £131.26 for Tailored Consultancy Services).

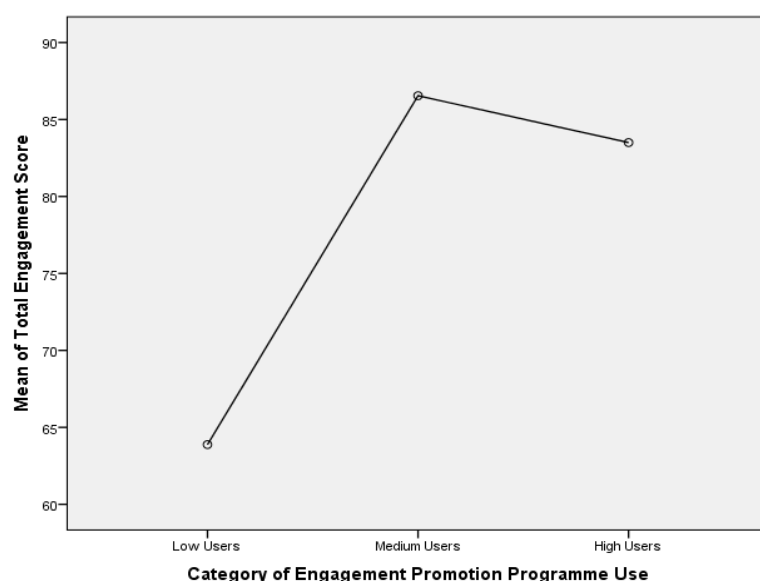
Table 8.8 Schools' 'Engagement Promotion Programme' incentive use by category

<i>Low Users</i>	<i>Medium Users</i>		<i>High Users</i>
Core Benefits Only	Core Benefits + Standard Extra	Core Benefits + Consultancy	All
School 1 School 2	School 3		School 4
	School 5		
School 6	School 7 School 8 School 9		School 10 School 11 School 12
	School 13		
School 14	School 15 School 16 School 17		School 18
	School 19 School 20		
School 21	School 22 School 23 School 24		
School 25 School 26		School 27	
	School 28 School 29		
School 30 School 31 School 32 School 33 School 34			
School 36	School 35		
School 38	School 37		
	School 39		
School 40 School 41 School 42			
	School 43		School 44
		School 45	
N=17	N=20	N=2	N=6

Engagement and utilisation of the 'Engagement Promotion Programme'

There was a significant effect of Engagement Promotion Programme use on engagement, $F(2, 42) = 20.877$, $p < .001$, $\eta^2 = .499$. Post-hoc comparisons using the Tukey HSD test indicated that the mean engagement score for 'low users' of the Programme ($M=63.98$, $SD=12.96$) was significantly different from 'medium users' ($M=86.55$, $SD=10.22$) and 'high users' ($M=77.58$, $SD=15.35$). However, there was no significant difference between the mean engagement scores of 'medium users' and 'high users' (see Figure 8.4).

Figure 8.4 Mean engagement scores for low, medium and high users of the Engagement Promotion Programme



Engagement of schools according to school-level characteristics

The engagement rating process resulted in a wide range of overall school engagement scores: the lowest 21-item composite mean score was 1.95; the highest was 4.90. The mean composite engagement score was 3.69 (SD 0.73)(see Table 8.9).

Table 8.9 Mean scores for Measure of Engagement scale and sub-scales

Scale Level	Mean Rating
Overall 21-item scale	3.69 (SD 0.73)
Engage Peripheral School	3.72 (SD 0.71)
Engage Staff	3.67 (SD 0.91)
Engage Student	3.91 (SD 0.95)

The more engaged schools (N=22) with composite scores above the mean were more likely to be high Ofsted-rated (72.2%; 16/22) in moderate-to-wealthy areas (63.6%; 14/22), and in the intervention condition (59.1%; 13/22). Specific characteristics associated with less engaged schools (N=23), i.e. those with summated scores below the mean, were less apparent. This group contained slightly more moderate-to-wealthy (56.5%; 13/23) than disadvantaged (43.5%; 10/23) schools, but similar numbers of schools in the intervention (52.2%; 12/23) and control (47.8%; 11/23) conditions and with high (52.2%; 12/23) and low (47.8%; 11/23) Ofsted ratings. On average, schools with higher Ofsted ratings were more engaged ($M=80.25$, SD 13.42) than those with lower Ofsted ratings ($M=73.18$, SD 17.63). Whilst this difference, 7.074, BCa 95% CI [-2.305, 16.453], was *not* significant $t(43) = 1.52$, $p=.136$, it did represent a medium-sized effect, $d=0.46$. Intervention schools were rated as

more engaged in the trial ($M=79.96$, SD 13.94) than control schools ($M=74.60$, SD 16.83). However this difference, 5.36, BCa 95% CI [-3.89, 14.61], was not significant $t(43) = 1.17$, $p=.254$ and represented a small effect size, $d=0.35$. There was no significant relationship between engagement in the trial and type of community served (using the percentage of students eligible for free school meals as a proxy measure for social deprivation), $r=-.08$, BCa 95% CI [-.406, .200], $p=.589$.

Engagement within intervention schools and students' final smoking outcomes

Analysis of the impact of intervention schools' engagement on trial outcomes revealed no significant relationship between the percentage of students reporting 'ever smoking' at the end of the trial and composite engagement scores ($r=-.13$, $p=.387$). Examining this at the level of stakeholder-group, there was no significant relationship between the percentage of students 'ever smoking' and total engagement scores for (i) peripheral school-level staff, $r=-.10$, $p=.518$, (ii) directly involved staff, $r=-.14$, $p=.346$, or (iii) students, $r=-.02$, $p=.918$.

Whilst none of these relationships approached significance, staff-level engagement was the most strongly negatively related ($r=-.14$) to self-reported ever smoking (i.e. higher engagement was associated with fewer students smoking) when compared to overall school-level engagement ($r=-.132$) and that of peripheral school staff ($r=-.10$) or students ($r=-.02$).

8.5 Discussion

This study examined the costs associated with implementing the 'Engagement Promotion Programme' and whether school engagement differed according to their utilisation of the Programme'. It also investigated whether school-level characteristics predicted engagement, and if the engagement of a particular stakeholder group was more important in intervention schools in relation to final smoking outcomes.

This study has revealed that the cost of implementing the Engagement Promotion Programme was £38,828.99. Providing the novel, optional extra services within the Programme (e.g. workshops, advice on supporting mental health in schools) was relatively inexpensive (£10,558.69) and they were popular, accessed by 62% of schools. Furthermore, the study found an effect of Programme utilisation on engagement: 'medium' and 'high users' of the programme who accessed these optional extra services had significantly higher engagement scores than 'low users' who did not. School-level characteristics were *not* predictive of engagement in the RSIIYA trial, with the exception of Ofsted rating: higher Ofsted ratings were associated with higher engagement overall. Finally, the study found no significant relationship between final smoking outcomes and engagement either at the school

level or at any particular stakeholder group level. Of all the stakeholder groups, however, staff-level engagement was the most strongly negatively related to the percentage of students smoking in intervention schools.

The findings from this study suggest that introducing a complex Engagement Promotion Programme impacted positively on cluster engagement: 62% of schools made use of additional support and services provided and this uptake was associated with higher school engagement in the trial, compared to schools who did not use these additional services. The £38,828.99 costs associated with implementing the Engagement Promotion Programme equated to 3% of the £1.3m RSIIYA trial budget, which would appear to represent value for money, given the high retention rate of cluster sites (100% of schools were retained after baseline data collection). The cost analysis revealed that a number of incentives within the Programme were provided for minimal or no expense, such as attending meetings to discuss school issues and providing the adapted University logo for school websites. It is notable that the highest users of the Programme were *not* the most highly engaged, despite incurring the highest costs (£1,125.20 per school) in the trial. The most engaged schools were medium users who made use of just one level of additional benefit beyond the Core Benefits. This suggests a ceiling effect of the Programme, that accessing one additional level of benefit may be sufficient for enhancing engagement, and that engagement does not increase as a function of the number of incentives used. Therefore, the most effective use of such a Programme may be to invest effort in ‘converting’ low users to medium users, rather than continuing to promote extra services to those who have already used them.

Whilst it would appear that providing this Programme was motivating for *schools*, it was also useful for us as Trial Managers. Echoing Daykin et al.’s (2018) research with trial staff (discussed in chapter 5), providing schools with something meaningful in exchange for their participation helped us to feel less indebted to them because we were able to cognitively appraise our partnership as mutually rewarding and beneficial. Through discussions with study coordinators we were able to develop services and object-related benefits (e.g. plaques) which met local needs, and demonstrated that we were responsive to their suggestions. In this sense, our ‘debt’ to schools (i.e. their having to complete numerous trial tasks) was discharged by providing beneficial services. In exchange, by making use of beneficial services offered to them, schools may have felt obligated to reciprocate positively towards the trial (Settoon, Bennett & Liden, 1996).

The concepts of social exchange (Blau, 2017) and norm of reciprocity (Gouldner, 1960) have been discussed extensively within the organisational psychology literature to

describe an employee's emotional commitment to their organisation (Settoon et al., 1996). Organisations benefit from having emotionally committed employees, because they are more likely to perform effectively and less likely to resign from their job (Rhoades & Eisenberger, 2002). Employees perceiving that their organisation values and supports them are more likely to be committed to their organisation (Rhoades & Eisenberger, 2002). There are clear parallels here between the organisation-employee relationship and the research team-cluster site relationship: cluster sites perceiving that they are valued and supported by universities or research teams are arguably more likely to be committed to their trial 'work'. This may explain the positive association between Programme use and engagement in the RSIIYA trial. It is worth noting here, however, that despite engagement scores being lower in control schools than intervention schools, we still experienced 100% retention. This could be interpreted as meaning that we actually provided more than was necessarily required to retain the schools.

The finding that higher Ofsted-rated schools were likely to be more engaged than lower Ofsted-rated schools in the RSIIYA trial indirectly supports earlier findings by Wyatt et al. (2018). Whilst they did not stipulate Ofsted ratings of their participating schools, Wyatt et al. (2018) found inadequate leadership and teacher absences were characteristics of poorly engaged schools in their Healthy Lifestyles Programme trial. A closer examination of the main Ofsted inspection criteria (see below) may provide a tentative explanation for the relationship between Ofsted ratings and engagement:

- i. *Quality of education*, e.g. The curriculum is ambitious and inclusive; teachers have good subject knowledge and create a positive learning environment.
- ii. *Behaviour and attitudes*, e.g. there are high expectations of behaviour. Learners' attitudes to learning are positive.
- iii. *Personal development*, e.g. students' characters are developed, including support with resilience, confidence, independence and how to keep physically and mentally healthy.
- iv. *Leadership and management*, e.g. there is a clear, ambitious vision for high quality education, strong shared values, policies and practice. Leaders engage with staff and focus on improving staff knowledge and skills (Ofsted, 2019).

These criteria and their examples suggest that higher Ofsted-rated schools may be more willing/able to participate in research because they are more receptive to research generally, they have a continuous improvement focus, there is good team cohesion and the leaders invest in staff. Conversely, if staff morale is low, there is inadequate leadership and student

behaviour is challenging, which are characteristics of lower Ofsted-rated schools, it may be more difficult for these schools to maximise research opportunities.

A number of the Ofsted criteria for high performing schools are reflected in Damschroder et al.'s (2009) 'inner setting' domain of their Consolidated Framework for Implementation Research. This pragmatic framework was developed to help researchers identify possible factors influencing implementation, following an extensive review and synthesis of the literature surrounding theories of effective implementation of innovations (Damschroder et al., 2009). Five key domains were identified, potentially impacting on implementation: characteristics of the intervention, outer setting, inner setting, individual characteristics and the implementation process (Damschroder et al., 2009, p.1). Certain 'inner setting' characteristics associated with successful implementation are strikingly similar to the Ofsted criteria listed above, specifically:

- Quality communication of organisational/team mission, goals and strategies and team cohesion;
- A "learning climate" in which new knowledge and approaches are embraced, and staff learning, growth and skill acquisition are supported;
- Clear staff goals and feedback;
- Leaders who are engaged, committed to implementation and "take the long view" (Damschroder et al, 2009, p. 9).

Whilst acknowledging that a macro Ofsted rating is unable to truly reflect the full, unique complexity of an individual school's culture and climate, it does appear in this study to provide an 'inner setting' level explanation of why higher Ofsted schools were likely to be more engaged in the research.

The lack of significant effect on trial outcomes of staff-level engagement in the present study was disappointing, particularly since numerous qualitative process evaluations have highlighted this level of commitment to be crucial (e.g. Mukoma et al., 2009; Stallard et al., 2013). Earlier studies reported in this thesis have also identified staff-level engagement as pivotal in ensuring that RSIIYA trial tasks were implemented and lessons were delivered enthusiastically to students. For example, trial coordinators took personal responsibility for ensuring tasks were completed and 'made it work', even when their senior leadership teams failed to actively support the trial (reported in study one, chapter four). Similarly, many teachers adopted a persuasive, influential role when delivering the smoking or homework lessons, demonstrating their commitment to boost student engagement with the material (reported in study three, chapter six). However, despite the lack of statistical significance of the

results, they were to some extent consistent with these findings, in that staff-level engagement was the most strongly negatively related to the final percentage of students' smoking, in comparison to the other stakeholder groups. It is possible that the limited range of engagement may have limited the power to detect any relationships, i.e. all schools were quite engaged, therefore all were retained, leading to all schools having reasonable rates of students refusing cigarettes. The small sample size of 25 schools may also have limited the power to detect any relationships.

8.5.1 Strengths and limitations

This study is novel in that it has sought to, firstly, clearly document the complex activities undertaken to support retention in a large cluster trial, and secondly, to reflect the financial cost of undertaking what was effectively a complex retention intervention. The findings contribute to the retention literature by providing tentative support for the use of complex retention strategies, which tend to be under-researched and under-reported (Brueton et al., 2014; Robinson et al., 2015). Furthermore, by documenting a complex, relational-based, retention intervention that was used successfully, and reporting its associated costs, this study contributes to elevating the visibility and status of retention work, which often goes unrecognised, as the 'poor relation' to recruitment (Daykin et al., 2018).

A further strength of this study is its attempt to develop and use a more comprehensive, sensitive measure of engagement. Resulting engagement scores facilitated direct analysis of the relationship between engagement and trial outcomes. Quantifying engagement allowed schools to be compared and contrasted, and revealed that our influencing attempts throughout the trial, including the Engagement Promotion Programme, resulted in a range of influencing outcomes: some schools were committed/engaged, others were compliant (i.e. needed more prompting to complete tasks) and some were more resistant (Yukl, Kim & Falbe, 1996).

There were a number of limitations associated with the Measure of Engagement. Firstly, 'engagement' is a construct. In order to make appropriate, meaningful and useful inferences from a composite score on an 'engagement measure', it is important to determine the construct validity of the measure, i.e. that its items actually measure the one factor of 'engagement' (Slocum-Gori & Zumbo, 2011). Typically the unidimensionality of a measure is assessed through factor analysis (Slocum-Gori & Zumbo, 2011). However the sample size in this study (N=45) was considerably smaller than the recommended minimum sample size for this analysis (Field, 2013; Slocum-Gori & Zumbo, 2011). However, internal consistency for two of the three subscales (the ones with multiple items) was high. It was not possible to establish

inter-rater reliability of the measure because only the Trial Manager in each region had sufficient knowledge to be able to complete assessments for their schools. One possible alternative may have been to examine test-retest reliability, i.e. for each Trial Manager to complete the assessments at two different time points, measuring internal consistency with Cronbach's alpha.

8.5.2 Implications and conclusions

The results of this study have revealed that a complex Engagement Promotion Intervention was able to be implemented at a relatively low cost (3% of the RSIIYA trial budget) and with a positive impact on cluster site engagement. This study has demonstrated that cluster sites appear to value more complex skills exchanges and other services, beyond simple incentive 'objects' (e.g. certificates or vouchers). The provision of such skills and services appear to contribute to engagement and cluster site retention, which may be explained using the concepts of social exchange and the norm of reciprocity. Therefore it may be beneficial for researchers to consider what specialities and skills they can offer cluster sites, and engage in discussions with cluster members to determine what they would find useful.

Findings from this study suggest that university collaborations with high Ofsted-rated schools on health research are likely to be successful: they are arguably more willing and able to be engaged because their particular 'inner setting' characteristics facilitate this process. Conversely, the inner characteristics of lower Ofsted-rated schools may mean that they have a reduced capacity to engage in research, and as a result may be more difficult to engage. However school-based prevention interventions require robust testing in 'real world' (i.e. not just highly functioning) environments. Given that higher Ofsted-rated schools are more likely to engage with research, and have higher commitment to it, it would seem important for researchers to do all they can to encourage lower Ofsted schools to participate and invest in building and sustaining strong relationships during a trial.

The next and final chapter within this thesis revisits the original thesis aims and outlines the key findings from each study with respect to the research question posed. It discusses key contributions made to the retention literature, limitations and directions for future research and highlights the implications of the research findings.

Chapter 9 General discussion

9.1 Chapter summary

This final chapter outlines the new, key findings of each study with respect to the research questions posed, followed by reflections on the contribution this work makes to the retention literature. Strengths and limitations of the thesis are discussed, and directions for future research are proposed. Finally, the implications of the research findings presented within the thesis are highlighted.

9.2 Original thesis aims

Achieving high rates of retention in cluster trials is a challenging and complex process. It has been unclear whether participant-level retention strategies, which dominate the literature, are generalisable to organisation/sites, or whether, in fact, different strategies are more effective. The evidence available on retention has remained unsophisticated, with no unifying theoretical framework to inform effective retention planning:

“We cannot determine which particular strategies are most effective (...) to improve participant retention, studies should use many different strategies” (Robinson et al., 2015, p.1487).

In response to these limitations, this thesis sought to augment the information available to support site-level engagement and retention within cluster RCTs. In doing this, it endeavoured to depart from the dominant discourse in the field of ‘*what* retention strategies work best?’ by examining ‘*how* does successful retention happen?’ in order to develop a theory-driven framework to conceptualise retention. A collective case study design was used to carefully scrutinise processes operating within a pragmatic cluster trial which had successfully retained 100% of its 45 organisational sites.

The specific aims of the thesis and a brief summary of the individual research studies undertaken to address these can be found in Table 9.1. The following section draws together the key findings from each study, reflecting the overall ‘collective case’, and examines how they address the thesis aims.

Table 9.1 Thesis aims and research studies undertaken to address these

Thesis aims	How these aims have been addressed
1. To synthesise and evaluate the available evidence surrounding strategies which facilitate site-level engagement and retention within longitudinal cluster trials	<p>A systematic review, described in Chapter 2 was undertaken to identify effective strategies to retain multiple sites within research studies. It also examined whether and how the recommended site-level retention strategies differed from individual-level strategies described in the broader literature.</p> <p>Study 1 (Chapter 4) examined teachers' experiences of <i>coordinating</i> the RSIIYA trial in their particular school.</p> <p>Study 2 (Chapter 5) explored the research team's perspectives of <i>managing</i> the trial across 45 schools.</p>
2. To understand the factors involved in site-level engagement and retention of school cluster sites in the RSIIYA trial, from the perspectives of key stakeholders involved	<p>Study 3 (Chapter 6) featured teachers who <i>delivered the intervention or control lessons</i> in participating schools. It explored their personal experiences of being part of the research and of delivering the intervention/control lesson, through interviews and the analysis of routinely collected lesson feedback data.</p> <p>Study 4 (Chapter 7) investigated student-recipients' personal experiences, as primary stakeholders, of <i>being part of</i> the RSIIYA trial, whether and how their engagement changed over time. This study also involved focus groups and analysis of students' lesson feedback sheets.</p>
3. To evaluate the adoption of an Engagement Promotion Programme to support site-level retention in the RSIIYA trial and determine its impact on trial outcomes	Study 5 (Chapter 8) examined the 'Engagement Promotion Programme' designed by the trial team to promote site-level retention in the RSIIYA trial. This study involved an economic analysis, explored any related impact on site-level engagement and examined relationships between different stakeholder groups' engagement and trial outcomes in intervention schools.
4. To explore the overall mechanisms underpinning the successful site-level retention of school clusters participating in the RSIIYA trial	Findings from the individual cases within studies 1-5 (Chapters 4-8) are examined collectively and synthesised within this chapter.

9.3 Summary of key findings

Aim 1: To synthesise and evaluate evidence surrounding strategies which facilitate site-level engagement and retention within cluster trials

With regard to 'what works' in retention generally, chapter 2 reported that systematic reviews to date have produced little tangible evidence about the effectiveness of individual strategies. In *systematic* reviews the most consistent finding is that higher monetary incentives are associated with higher participant retention rates. In *non-systematic* reviews, the most consistently reported strategies for effective retention are using multiple strategies, personalising strategies to individuals, and employing consistent, interpersonally skilled research staff who invest in building relationships with participants.

Site-level retention as a specific area appears to be under-researched. The systematic review of cluster site retention revealed that some participant retention strategies are in fact generalisable to sites, although they are executed and prioritized differently in these contexts.

For example, using multiple strategies, building relationships and clarifying mutual expectations are all considered more important for retaining sites than for retaining individual participants. In addition, five additional strategies appear to be unique to site-level retention: (1) involve and engage staff, (2) give back to the community, (3) identify and secure support from key stakeholders and champions, (4) be visible on site: invest in ‘face time’ and (5) succession planning.

Four notable gaps emerged within the overall retention literature:

1. Researchers’ *opinions* about what motivates participants to remain in a study dominate the field; participants’ personal experiences of being in a study and perspectives on why they stayed are underrepresented.
2. Research to date has mostly focused on discrete, standalone strategies (e.g. offer an incentive) and ‘soft’ interpersonal or relational approaches have been neglected. Possible explanations for this are that these approaches target intangible factors and tend to be more complex, which may make them harder to develop and less amenable to empirical, randomised evaluation. However, there is increasing recognition that successful retention relies upon a more relational approach rather than standalone strategies. The systematic review suggested that using qualitative research to examine cluster retention from a holistic, relational approach was likely to make a valuable contribution to the literature.
3. Although researcher characteristics (interpersonal and relational skills, assertiveness, persistence and resilience) are recognised as pivotal to successful retention, none of the papers discussed within this chapter examined specifically why these are necessary, more specifically *how* researchers navigate the multiple inter- and intra-personal challenges involved, particularly with multi-site studies.
4. There is little theoretical insight into the dynamics of effective retention in the literature.

Aim 2: To understand the factors involved in site level engagement and retention of school cluster sites in the RSIIYA trial, from the perspective of major stakeholders involved

Teachers’ perspectives of coordinating the trial were explored in **study 1**. Consistent with previous research, organisational/contextual barriers most frequently affected coordinators’ experiences and the extent to which schools engaged with it. These included, for example, low leadership support, colleagues’ reluctance to engage in the research, overwhelming workloads, logistical issues when planning study tasks and under-valued PSHE education. Facilitating factors reported also supported previous findings, such as

compatibility of the research aims with school goals, finding a place for trial tasks within the curriculum, researcher support, low burden and strong leadership support.

A key finding in this study was that the personal characteristics of the in-site coordinators appeared to be more crucial for retention and engagement than senior leadership support alone. The high degree of personal investment coordinators brought to the trial (i.e. strong belief in the study principles, drive, resilience, persuasiveness and personally valuing research and university links) kept the trial functioning in school, even when leadership support was absent. For some teachers, the unpaid coordinator role was experienced as an enrichment or development opportunity.

A second novel finding related to coordinators' differential experiences according to school Ofsted-rating and type of community served. Coordinators in low Ofsted schools contended with more barriers, less support and less staff cohesion and valued the quality, colour handouts. Those in high Ofsted schools raised more suggestions for improving the lesson design, perceived the study as low burden, experienced strong leadership/colleague support and team cohesion. Coordinators in disadvantaged communities expressed that they particularly valued the working relationship with the researcher. These emergent, differential results suggest that cluster site recruitment and retention strategies may require greater refinement or tailoring for maximum effect. This study's overall conclusion was that, whilst researchers cannot change an 'unhealthy' organisational context, they may still be able to achieve successful retention by individualising their interpersonal approach to sites, and particularly by investing heavily in a meaningful working relationship with a research champion on site.

Study 2 examined researchers' experiences of managing the RSIIYA trial, which was conceptualised as 'walking a tightrope'. We perceived an ever-present risk of schools disengaging and withdrawing from the trial and daily challenges centred around an absence of legitimate power and control, heterogeneity between and within sites, dynamic, unpredictable internal systems and a need to appropriately balance relationships and handle set-backs. Consequently, we were heavily dependent on site staff, had to continuously adapt to diverse situations, be hyper-vigilant to detect any potential retention threats, be careful to preserve positive site relationships and had to 'hold the line'. Our coping strategies involved drawing upon self-management techniques and investing in mobilising social capital between cluster site members and ourselves.

Whilst recent qualitative studies have started to explore researchers' experiences of recruitment and retention, this study was novel in making visible the invisible retention work

of the *cluster* trial researcher. Its findings suggest that formal retention strategies alone, such as incentives, reminders, effective tracking, are necessary but not sufficient for successful retention. Successful site retention seems to depend on researchers investing in hidden, complex relational work across protracted lengths of time. This emotional burden must be moderated through self-management strategies and support, otherwise this stress/tension may 'leak' into site relationships and potentially affect engagement in the trial. The need to recruit staff with strong inter- and intra-personal skills and providing ongoing support and training were identified as important for retention in cluster trials.

Teachers' perspectives of participating in the trial and delivering the anti-smoking or pro-homework lessons were explored in **Study 3**. This study revealed a high degree of personal responsibility carried by teachers for generating student engagement in the trial, within often unsatisfactory PSHE contexts in school. Consistent with previous research, a high proportion of teachers in this study had no PSHE training, despite a recognition that this personal work could be daunting, and routinely delivered PSHE topics with inadequate planning time and/or resources. Most had witnessed an erosion in allocated PSHE-time and there was widespread cynicism that schools were simply 'ticking' Ofsted boxes.

Also consistent with previous findings, teachers who had attended the training or been carefully briefed felt involved and equipped to play their part in the trial, and were most likely to rate their lessons positively. However for many teachers in practice, delivering the lessons was not a particularly positive experience. Being expected to 'muddle through' with no training or little/no contextual understanding, too much/too little time due to poor timetabling, and sometimes without key materials, meant that teachers were not universally comfortable with having this responsibility.

Having to contend with students' dissatisfaction with the repetitive, unvarying format of the lessons was identified as a major challenge and, consistent with previous findings, the degree of personal agency brought to making the lesson work varied considerably. Whilst some 'went through the motions' to complete the lesson, many more employed active strategies to keep students on task during the lesson. Those teachers who listened to students' expressions of dissatisfaction, ventured off-lesson plan and invested in adapting the intervention may have contributed to sustaining their interest in the trial and the intervention's ultimate success. Rather than perceiving these as unhelpful deviations from protocol signalling low trial commitment, teachers may have actually been committed to making it work for students. Indeed, teachers strictly adhering to protocol may have exacerbated students' dissatisfaction and disengagement by inadequately addressing their

complaints. This in turn may have diminished their own engagement in the trial due to the unrewarding nature of the lesson. Interestingly, this suggested an inter-dependent engagement relationship between teachers and students.

A particularly novel finding was that differences in how the lessons were appraised were attributable more to school characteristics than the type of lesson being delivered (i.e. intervention or control). Teachers working in low Ofsted-rated schools appraised their lessons more positively than those in high Ofsted schools. One explanation for this may be that, compared to low-Ofsted schools, high-Ofsted schools approach research with higher expectancies, for example they are more likely to prioritise continuous improvement, have higher expectations of staff, champion research and the use of data. Once again, the potential importance of personalising recruitment and engagement practices to school characteristics was highlighted.

Students' perspectives of being part of the trial and of the intervention and control lessons were examined in **study 4**. Consistent with previous research, students' understanding of the trial was marked by initial confusion regarding their involvement and suspicion about the researchers' motives for collecting personal smoking data. However familiarisation with the routine over time built trust, there was a sense of belonging to something important and a genuine curiosity in the results. In terms of acceptability of participating in the trial, students overwhelmingly found the trial tasks to be repetitive and boring, but they reflected back on the trial as a novel and interesting experience to be part of. Students mostly thought the smoking and homework lessons were 'ok' rather than highly enjoyable, but lessons were rated highly for helping them to think differently about smoking and homework.

Responsiveness to the smoking intervention and control lessons was overwhelmingly influenced by the climate they experienced within their classroom context. This emanated from the teacher's enthusiasm and the specific learning climate they created, based on mutual trust, knowledge of each student and perceptions of psychological safety. Students enjoyed the lessons more in the company of familiar, liked peers, delivered by enthusiastic, trusted teachers who supplemented the lesson with personal stories and engaged them in the discussion material. Students particularly disliked lessons delivered by teachers with whom they had no relationship, who were unenthusiastic, skipped sections of the lesson, distributed handouts for students to complete independently, or signalled their dissatisfaction with their repetitive nature.

Control students communicated a sense that their schools did not value highly being in the control condition and that the topic of homework was controversial in schools. Intervention students appeared to have a stronger sense of their contribution being of value, of their school belonging to something important.

The results of this study revealed that, whilst the retention of children and young people may be superior in schools when compared to other methods, young people are not passive recipients of their allocated trial conditions. It highlighted the likely benefits of involving young people in co-designing interventions, materials and information sheets to enhance appeal, understanding and relevance. Most importantly, it revealed that school cluster site engagement seems to build 'bottom up', classroom-by-classroom, and that student engagement in a trial is heavily dependent on the extent to which individual teachers are able/willing to create effective micro-climates within their classroom.

Aim 3: To evaluate the adoption of an Engagement Promotion Programme to support site-level retention in the RSIIYA trial and determine its impact on trial outcomes.

Study 5 revealed that introducing a complex Engagement Promotion Programme impacted positively on cluster engagement, at a cost of £38,828.99 or 3% of the £1.3m RSIIYA trial budget. Many (62%) schools used the additional support and services provided and this uptake was associated with higher engagement in the trial. Stronger school engagement was predicted by having a high Ofsted rating, but not by condition allocated or level of community deprivation. No significant relationship was found between final student smoking outcomes and engagement at either the level of school or individual stakeholder group.

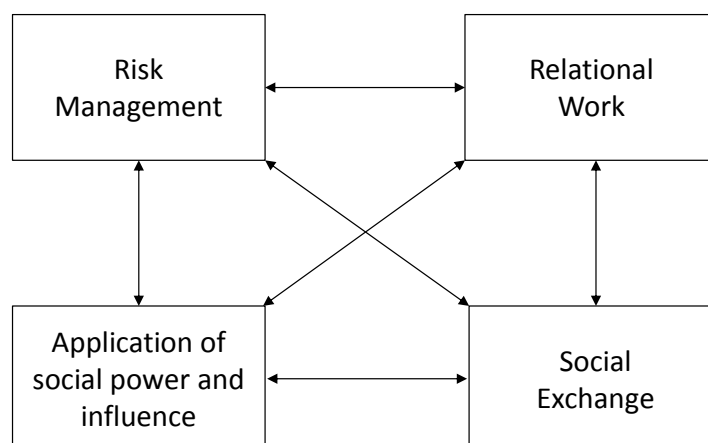
This study concluded that the cluster sites valued more complex skills exchanges and other services, beyond simple transactions or incentive objects (e.g. certificates or vouchers). These appeared to contribute to engagement and retention, which may be explained through social exchange theory and the norm of reciprocity. Therefore it may be beneficial for researchers to consider what specialities and skills they can offer cluster sites, and engage in discussions with cluster members to determine what they would find useful. Findings from this study also suggested that university collaborations with *high* Ofsted-rated schools on health research are likely to be successful: whilst they may have higher expectancies, they are arguably more willing and able to be engaged because their particular 'inner setting' characteristics facilitate this process. Conversely, the inner characteristics of *lower* Ofsted-rated schools may mean that they have a reduced capacity to engage in research, and, consequently, may be harder to engage.

This study was novel in documenting a complex, relational-based, retention intervention that was used successfully, and reporting its associated costs. Its findings contribute to elevating the visibility and status of retention work, which often goes unrecognised.

Aim 4: To explore the mechanisms underpinning the successful site-level retention of school clusters participating in the RSIIYA trial

This particular aim sought to make a novel contribution to the retention literature by offering theoretical explanations for retention and engagement. Across studies 1-5, four key inter-relating mechanisms were identified as useful in explaining significant processes operating during retention (see Figure 9.1): (1) risk management, (2) relational work, (3) social exchange, (4) application of social power and social influence. Each of these is now reviewed briefly.

Figure 9.1 Mechanisms underpinning successful retention



1) Retention as risk management

Particularly through research undertaken in study 2, the relationship between universities (or research unit) and organisational sites during a cluster trial was interpreted as a series of inter-organisational collaborations, with the job of retention more accurately defined as ongoing risk management. As an inter-organisational collaboration, each university-school relationship involved the researcher navigating risks at each school site of a relational (will staff cooperate, be engaged and committed?) and performance (will alliance objectives be met and tasks completed to plan?) nature. These relational and performance risks may be reduced by managing expectations between organisational members, through the development of trust and exertion of control (Bachmann, 2001; Das & Teng, 2001).

Within inter-organisational alliances, the establishment of micro-level trust, i.e. at the individual and team level, is the foundation upon which all inter-organisational alliances are built and therefore vital for successful outcomes (Bachmann, 2001; Das & Teng, 2001; Liu, 2015). Organisational or macro-trust emanates from micro-level trust, therefore declining *individual* bonds are associated with a breakdown in inter-organisational relationships (Das & Teng, 2001). This offers one explanation why building relationships and clarifying mutual expectations are regarded in the literature as more important for retaining sites than for retaining individual participants (as discussed in Chapter 2). This explanation is also applicable to the five additional, unique site-level strategies identified: ‘involve and engage staff’, ‘give back to the community’ and ‘be visible on site: invest in ‘face time’’ may be regarded as relational, micro-trust building strategies; ‘identify and secure support from key stakeholders and champions’ and ‘succession planning’ could be interpreted as strategies to manage performance risks. The critical role micro-level trust in successful inter-organisational collaborations suggests that a researcher’s investment in building trusting, one-to-one relationships with cluster site members (micro-level trust) may be rewarded with the retention of their cluster (macro-level trust).

2) Retention as relational work

Within this thesis, retention has also been interpreted as an outcome of successful ‘relational work’. Relational work offers an explanation for *how* effective in-site relationships are established and why this work facilitates micro-level trust and positive outcomes. Cluster trials involve considerable complexity and uncertainty on the parts of the researcher and site members, and relational work is considered vital for success under such circumstances (DeFrino, 2009).

Study 2 drew upon strong links identified between investment in relational work and outcomes in both the leadership (Helstad & Møller, 2013; Riggio & Reichard, 2008) and psychotherapy (Castonguay et al., 2006; Muntigl & Horvath, 2014) literature. This was used to theorise that engaging in relational work with cluster site members may have increased goodwill trust, by communicating to members that they were respected and valued as individuals, which may in turn have reduced relational and performance risks at each site and contributed to successful retention.

3) Retention as the application of social power and influence

Numerous examples emerged within this thesis of individuals exerting their social power at each site in an effort to influence the behaviour of others (Kreitner et al., 2002). The collective

endeavours of each individual in key positions, choosing to exercise their agency by influencing others to complete tasks, appear to have contributed to retention.

The *mechanisms* through which different individuals attempted to influence others differed according to their role in that site, according to 'the power base' they drew upon (as described by French and Raven, 1959). For example, study coordinators in formal leadership positions seemed to rely more upon their legitimate power as a leader to ensure tasks were completed. Those in non-leadership roles, however, had to work harder to manage cluster members' behaviour, drawing mostly upon referent (likeability, charisma) or expert power (given their PSHE role) to persuade cluster members that the study was valuable and ensure key tasks were completed.

Teachers used their referent power that existed between themselves and their students, directly and indirectly, to engage them in the lessons. Students enjoyed the lessons more when they were delivered by enthusiastic, trusted teachers who supplemented the lesson with personal stories and engaged them warmly in the discussion material. Engagement was typically low in circumstances where teachers had no referent power, i.e. where students perceived there was no relationship, or teachers were unenthusiastic and careless about their treatment during the lesson.

As researcher-outsiders, we had no legitimate power to influence site staff; therefore we invested in building relationships in the hope that we might increase the likelihood of cluster members wanting to complete tasks (i.e. generating referent power). As psychologists with expertise in health and wellbeing we supported schools with events and delivered workshops, which may have increased our 'expert power' base within our schools. It could be argued that expert and referent power were both available to us as researchers. The most effective power bases for social influence, particularly within a work setting, have been identified as expert and referent power (Podsakoff & Schriesheim, 1985), because these are more likely to generate commitment, rather than begrudging compliance or resistance (Yukl, Kim & Falbe, 1996). However expert and referent power do not exist within the influencer: they must be perceived by the person being influenced (Martin, 1978), therefore have to be earned. Referent power is particularly important in schools, but accruing it takes time, because it requires *authentic* liking and trust for each other (Martin, 1978). It involves spending time together, sharing small talk and more meaningful information, demonstrating commitment, so that over time an understanding and bonds grow, which ideally leads to identification (Martin, 1978). Skills and qualities needed to accrue referent power in these

circumstances are intertwined with trust building, and once again, associated with relational work (Martin, 1978).

4) Retention as social exchange

Retention has also been conceptualised within this thesis as successful social exchange, and parallels were tentatively drawn between employee-organisation and cluster site-university relationships. In the same way that employees who are emotionally committed to their organisations are more likely to perform tasks well and less likely to leave (Rhoades & Eisenberger, 2002), it could be argued that a trial should benefit from having cluster site staff who are emotionally committed to it. Employees are more likely to feel committed to their organisation if they perceive that their organisation values and supports them (Rhoades & Eisenberger, 2002), due to the norm of reciprocity (Gouldner, 1960) and social exchange (Blau, 2017). By offering a complex Engagement Promotion Programme and investing in relational work at an individual level at each site, it is possible that site members may have felt indebted or bound by the reciprocity norm to return something positive in exchange. From the researchers' perspective, offering additional benefits in reciprocity may have helped to minimise any guilt associated with placing additional burden on site staff.

Building relationships has been compared to "climbing a ladder" (Cropanzano & Mitchell, 2005p. 890). In the early stages, 'tangible' or material resources are usually exchanged, but with each successful exchange the relationship matures, rungs of the relationship ladder are climbed and 'intangibles' such as trust, support and commitment, become increasingly exchanged (Cropanzano & Mitchell, 2005). Therefore, offering cluster sites tangible benefits (e.g. vouchers) early in the relationship may have obligated them to reciprocate positively towards the trial, but then, accordingly, relationships matured as more intangible resources (e.g. warm relationship, support, commitment, expertise) were increasingly exchanged over time.

9.4 Strengths and limitations

Strengths and limitations of the research conducted within the thesis have been discussed in detail throughout the chapters. This section outlines some general, overarching considerations regarding strengths and limitations of the research and future directions.

A key limitation with the research presented in this thesis is that it used a case study design, findings from which are not conventionally generalisable (Hodkinson & Hodkinson, 2001p. 9). For example, the case focused on schools as cluster sites, therefore it is unclear

whether its findings are representative of other organisational settings (e.g. a hospital or an office-based workplace). With regard to the researchers involved, the team were inexperienced in trial management, therefore their experiences may not represent the research community at large. Furthermore, the team were all female psychologists, meaning that gender and professional background may have influenced perceptions and interpretations of processes within the trial.

Although “case studies can make no claims to be typical” (Hodkinson & Hodkinson, 2001, p.9), this collective case study has sought to identify more generic retention processes and theoretical approaches which may be transposed beyond the school setting and explored in further research. A further test of these findings will be the degree to which they resonate with cluster researchers working in other settings (e.g. within health services research).

As a collective case study, the particular strength of this research has been its comprehensive scale. It has drawn upon the experiences of four different stakeholder groups across every participating Yorkshire school site (studies 1-4), and all 45 participating schools were examined at an organisational level in study 5. However a further limitation is that the experiences of the Principal Investigators and Headteachers did not feature in the research. It is possible that the Principal Investigators may have been able to offer an additional, unique perspective which was not considered, particularly within study 2 (chapter 5). This may have also been the case with Headteachers, particularly with regard to their perceptions of benefits and difficulties associated with trial participation. The decision not to include Headteachers within the research was essentially due to practicality: they were very stretched, sometimes managing multiple school sites and it was virtually impossible to communicate with them directly because their secretaries guarded their time very diligently.

Each school site was unique in terms of how it was managed, organised and resourced, and the communities served also varied considerably. Despite this, similar processes were able to be observed across these very different sites, which suggests that the findings may not be idiosyncratic – a criticism often made of case studies (Hodkinson & Hodkinson, 2001).

A further limitation relates to the school setting itself. Given the multiple demands most teachers are managing and the many extra hours they already work, recruitment was a constant challenge. Multiple efforts were unsuccessful to recruit teachers and students from schools which were underrepresented in the research (see Table 9.2), which meant that the experiences of low Ofsted schools, serving disadvantaged communities and in the control condition were less well represented. Some caution may therefore be required when drawing

conclusions. The low value of PSHE in schools, coupled with teachers' low levels of training and confidence, were also problematic, and appeared to have affected perceptions of and motivation towards the research, which may also have impacted on results.

Table 9.2 Total participants across the thesis by sampling group and study (studies 1-4)

			Experimental Condition (Anti-smoking)												Control Condition (Pro-homework)							
			Disadvantaged Community						Moderate-to-Affluent Community						Disadvantaged Community				Moderate-to-Affluent Community			
			Low OFSTED CELL 1 (n=2)			High OFSTED CELL 2 (n=3)			Low OFSTED CELL 3 (n=2)			High OFSTED CELL 4 (n=5)			Low OFSTED CELL 5 (n=1)		High OFSTED CELL 6 (n=1)		Low OFSTED CELL 7 (n=2)		High OFSTED CELL 8 (n=4)	
Study	Method	N	School 1	School 2	School 3	School 4	School 5	School 6	School 7	School 8	School 9	School 10	School 11	School 12	School 13	School 14	School 15	School 16	School 17	School 18	School 19	School 20
One: School study coordinators	Interviews	16	1	1	2	2		1	1	1			1	1	1	1	1				1	1
Three: Teacher deliverers	Interviews	12			1		1	1		1	1	2	1		1		1		1	1		
	Documentation	568	28	12	32	16	33	33	17	52	19	22	33	27	27	27	40	34	34	33	28	21
Four: Student recipients	Focus Groups	38	11										11					10		6		
	Documentation	15885	693	527	747	659	711	988	653	962	717	695	859	647	795	813	1017	767	858	929	717	1153
Two: Trial researcher team	Documentation	4																				
Total data		16523	733	540	782	677	745	1023	671	1016	737	730	894	675	824	841	1059	811	893	969	746	1153

A further consideration relates to the staffing of the RSIIYA trial. This was atypical of other large cluster trials and may in itself have impacted on retention. One trial manager was solely responsible for all sites within their region (equating to 20 sites in Yorkshire and 25 sites in Staffordshire). Far more typical in cluster trials is allocating small groups of sites (e.g. 2-3) to particular researchers to spread the responsibility. Whilst managing a large number of sites was personally challenging, it allowed us to establish a cohesive approach. We were able to reflect on and compare behaviour across all sites, translate lessons learned in one site more easily to others, and provide schools with consistency. Where cluster sites are organised into sub-groups, a cohesive approach may be more difficult to achieve: lessons learned at one site are less easily translated to other sites, more variation is introduced in their management and responsibility for the whole trial is diffused.

Finally, given the dominant, qualitative nature of this research, it is important to critically reflect on my own situatedness in the research and the effect this may have had on the participants, the data collected and my interpretation (Berger, 2015). Many researchers maintain that complete objectivity in any inquiry, irrespective of paradigm choice, is a myth (e.g. Harper & Kuh, 2007), hence discussion of the PhD findings would not be complete without critically reflecting on the impact of my dual roles of Trial Manager and PhD student and my particular background and perspectives.

My role as Trial Manager and PhD student were inevitably connected. As a PhD student, I benefitted from the status, site knowledge and member relationships associated with my role as Trial Manager. I also recognise that my Trial Manager position may have also

shaped the researcher-participant relationship and the information participants wanted to tell me. Conscious of this dual role when approaching cluster members to participate in my PhD studies, I stressed that this work was linked to, but separate from, the trial and that they were not obliged to take part. However, given that the trial itself was poorly understood by staff and students (findings from chapters 6 and 7), it is possible that this nuance was unclear to them. For example, demand characteristics may have been a factor in how they described their experiences, i.e. they may have felt obliged to tell me what they thought I wanted to hear because they were keen to preserve ongoing trial relationships. This may have been a particular factor during interviews with key contacts in schools (study 1, chapter 4) where I knew participants quite well through established trial relationships: those new to the role (with whom I had no relationship) spoke more of issues managing the trial in their school, whilst those I knew better spoke more of facilitators. I interpreted this as due to environmental circumstances ('unhealthy', low-Ofsted rating; lack of handover from outgoing coordinator). However, it is possible that other participants also experienced this but did not feel comfortable to raise it, given our relationship.

I was mindful of such issues when recruiting for this study and took numerous steps to try and mitigate for this. For example, I endeavoured to do all I could to reassure coordinators that non-participation would not have consequences for our ongoing working relationship, that I was not expecting positive feedback and would welcome areas for improvement/learning. I reiterated at the start of interviews that I was looking for honest accounts, 'warts and all' and that this would be very useful. I followed up those who declined to participate and those coordinators whose accounts contained more negative content after the interviews with warm, friendly emails to communicate that our relationship remained unaffected.

Relationship factors/demand characteristics may also have been a factor within the student focus groups (study 4, chapter 7) and teacher interviews (study 3, chapter 6). However, I had no established relationships with either participant group, which could arguably have enabled them to express themselves more openly and honestly. Differences in status and power between the two groups may also have contributed to the information they disclosed to me. For example, teachers may have felt more confident to raise concerns during the interviews due to perceptions of equal status (given both our professional roles) and a lack of personal relationship with me. Conversely, it is possible that students within the focus groups may have perceived me as an authority/teacher-figure, and this status imbalance, in conjunction with not knowing me, may have made them more guarded in

what they told me. Again, I was sensitive to this and did all I could to mitigate the potentially negative impact. For example, I made them welcome, introduced supportive ground rules to promote psychological safety, had a young MSc student helping facilitate the session that they could more easily relate to. I also prompted them on the importance on flagging up negative aspects that we could learn from, and urged them not to just tell me what they thought I wanted to hear. The wide range of student feedback (including strong negativity and criticism) arising from the focus groups suggest that they did feel able to speak their mind.

My PhD student and Trial manager roles were inextricably linked and may have led to a beneficial, symbiotic relationship, inadvertently impacting on trial outcomes and my PhD results. The additional PhD work undertaken to garner stakeholders' views, through extended meetings, focus groups, interviews and feedback sheets, during a live trial, may also have indirectly strengthened their engagement in it. I communicated, through the PhD, that their views mattered on how the trial and lessons were operating. In this sense, my PhD work has arguably also functioned as retention work. Similarly, my PhD work benefitted from being able to utilise site relationships already established as the trial manager. I drew upon connections I had made within the trial to solicit help with recruitment, and gained a degree of 'insider knowledge' which was helpful in planning the PhD studies. An entirely unconnected, independent PhD student examining this particular trial would likely have found recruitment incredibly difficult, leading to entirely different outcomes.

Beyond my position as trial manager or PhD student, I recognise that my personal characteristics, background and training will have inevitably shaped my interactions and relationships with sites, and choice of retention approaches, my research, including design/method choices I made, interpretation of my findings and the trial outcomes and PhD conclusions. Another trial manager with a different background to me, conducting an embedded PhD in her trial, may have selected different methods for engaging and retaining clusters and also for investigating retention processes within the PhD. This may have resulted in different consequences and conclusions.

As someone valuing relationships with others, my approach to working with clusters was relational, influenced by my personality, training, background and experience. I used relational retention strategies: face-to-face workshops, meetings, assemblies, stands at careers/health fairs, personalised greetings cards and gifts, noting important personal details and referring to these. My particular training and experience in Occupational Psychology also influenced both the retention strategies I used in the trial, such as providing

mental health and wellbeing workshops for staff and students, and my interpretation of participants' accounts within the PhD. For example, I 'saw' in the data concepts related to organisational health, leadership and management and influencing and persuading. Valuing relationships may also have influenced my choice of research methods within the PhD, which were also predominantly relational (focus groups and interviews).

Given the heavy emphasis on relational work in the trial and the PhD, one could argue that my conclusion that relational factors are important in retention is unsurprising, or perhaps even a self-fulfilling prophecy. However, in defence of this, the critical role consistently highlighted across the retention literature (examined in Chapter 2) of relational work in retention suggests that my findings are unlikely to simply be an artefact of my choices. Furthermore, methodological decisions within my PhD were not based solely on my relational preference: there was justification for using these. For example, focus groups and interviews are commonly used in trial process evaluations (e.g. Oakley et al., 2006). Focus groups are considered particularly suitable for exploring children's experiences: they mimic the familiar classroom setting where students have the support, safety and input of their peers, which can facilitate deeper elaboration of ideas (Hennessy & Heary, 2005). My decision to use with teachers short interviews, for example as opposed to a questionnaire, was arguably more risky and challenging from a recruitment and planning perspective. However, consultations with teacher friends and family members revealed that interviews would likely be perceived as an interesting exchange experience for teachers, and that a questionnaire would be "faceless", deprioritised, seen as a chore or ignored.

9.5 Implications

This section considers, first, implication for theory and, second, implications for practice.

9.5.1 Implications for theory

Differentiating between transactional and relational factors in retention: The findings from this thesis suggest that formal retention strategies alone, such as incentives, reminders, effective tracking, are necessary but not sufficient for successful longitudinal retention of clusters in trials. Successful, long-term site retention seems to depend on relational factors: researchers are required to invest in complex interpersonal and relational work, beyond the provision of simple transactional objects such as vouchers or certificates.

This differentiation between transactional and relational factors has been discussed with regard to the retention and commitment of employees in organisations. Whilst employment relationships are formally defined by a legal employment contract, individuals

also hold their own unwritten expectations of the relationship, referred to as the ‘psychological contract’ (Rousseau, 1989). Expectations or obligations within a Psychological Contract may relate to transactional (i.e. financial or benefit-related) or relational (i.e. socio-emotional) exchanges between employee and employer, as illustrated in Figure 9.2 (Lee, 2001). The extent to which an individual perceives the psychological contract to be fulfilled defines the employee-employer relationship. If an employee perceives there are mutual, *relational* obligations, there will be a “tendency towards retention”, whereas if mutual obligations are considered to be more transactional or short-term, staff disengage easily (Lee, 2001, p.2). Perceptions that the Psychological Contract has been violated are associated with declining attitudes, work performance and turnover (Lee, 2001). Depending on the nature of the work, employer retention strategies may consist of ‘buying’ staff for the short term which ultimately involves minimum attachment, or ‘making’ retention more likely by developing and supporting staff, building attachments and thereby creating the conditions for loyalty (Lee, 2001).

Figure 9.2 Comparison of exchanges associated with transactional and relational contracts

Type of Psychological Contract	
Transactional	Relational
Obligations are relatively impersonal with little emphasis on relationships between those involved	Obligations are socio-emotional, emanating from ongoing relationship
Specified in advance, e.g. written contract	Emergent, less predictable, more intangible
Exchanges that support short-term capacity working	Exchanges that maintain long-term relationships
Extrinsic-reward based	Intrinsic-reward based
Exchanges are financially-oriented (e.g. pay, pension), benefits, flexible work schedules	Exchanges are associated with longer-term investment: trust, commitment, attachments, meaningful work, opportunities for advancement, job satisfaction

Adapted from Hausknecht, Rodda & Howard (2009, p.274-275) and Lee (2001, p.2).

Psychological contracts theory provides one theoretical explanation for why a more relational approach is necessary within longitudinal studies, where commitment is required for sustained time periods. It may also explain why transactional exchanges (e.g. certificate, vouchers) appear to be insufficient alone for long-term engagement. Cluster trials involve certain mutual obligation: from the university/research centre’s perspective, a participation agreement specifies explicit behaviours they require from the cluster site relationship, in exchange for documented, tangible benefits (e.g. vouchers). The extent to which cluster sites honour these obligations may be associated with whether they perceive this exchange to be

fair, mutually rewarding and beneficial under the circumstances. Part of the cluster researcher's role in retention may therefore involve establishing formally or informally what each site's expectations consist of, and ensuring that these are met wherever possible. This may be a fruitful area for future research.

Extending the parallels further between staff and study participants, there may also be value in drawing upon research addressing the reasons why staff stay with an employer/organisation. Hausknecht, Rodda and Howard (2009) identify 12 retention factors (see Table 9.3) associated with decisions to remain with a current employer. With perhaps the exception of 'lack of alternatives', 'location' and 'non-work influences', these factors may potentially be applicable to participants within a research context. For example, within this PhD thesis stakeholders have spoken of the rewarding nature of participation ('job satisfaction'), valuing the benefits offered ('extrinsic rewards') and the relationship with the researchers ('constituent attachments'), pride in belonging to the trial ('organisational commitment') and collaborating with a respected university ('organisational prestige'), acknowledging participation as a development opportunity ('advancement opportunities'), wanting to see the trial to the end ('investments'), being listened to/valued ('organisational justice') and appreciating flexibility around completion of trial tasks ('flexible work arrangements'). Whilst this clearly warrants further investigation, the work retention literature appears to be promising in increasing our theoretical understanding of participant and cluster retention.

Table 9.3 'Reasons for staying with your current employer' survey results (N=24,829)

Retention factor	Frequency	Representative quotes
Job satisfaction	50.9%	I really enjoy what I do
Extrinsic rewards	41.3%	All the benefits we are offered
Constituent attachments	33.5%	The people I work with are like family
Organisational commitment	17.4%	I am proud to work here
Organisational prestige	12.7%	Our company is highly respected
Lack of alternatives	9.8%	Slow economy and lack of other jobs
Investments	9.2%	Too much time invested here to leave
Advancement opportunities	8.3%	I like the opportunity to grow
Location	8.2%	It's really close to my house
Organisational justice	7.5%	I am treated as a trusted and valued team member
Flexible work arrangements	7.1%	I know that my manager will work with me and try to help our any scheduling difficulties I may have
Non-work influences	3.4%	My schedule allows a very nice home life

Adapted from Hausknecht, Rodda & Howard (2009), p.279-280.

Utilising inter-disciplinary literature: This PhD research has been novel in drawing upon and synthesising an inter-disciplinary literature in an effort to explain the potential mechanisms of retention. The fields of work/organisational psychology (e.g. inter-organisational collaboration, social capital, organisational commitment, the psychological

contract), social psychology (e.g. social exchange, the norm of reciprocity), social cognition (e.g. individual agency, social influence) and psychotherapy research (working alliance; relational work) have all been identified as having potential to explain *how* retention occurs. Further research is now needed to determine whether this and other inter-disciplinary literature has the potential to increase our understanding of retention processes.

Do we need a paradigm shift in retention research?: The research presented in this thesis represents a novel departure from the reductionist approach which appears to have dominated much of the retention literature. There has been an overriding concern with determining a cause-and-effect relationship between individual retention strategies and outcomes. For example, ‘if I phone a participant before issuing a follow-up questionnaire will they be more likely to complete it?’. In this examination of cluster site retention, a considerably more complex picture has emerged, in which retention outcomes have been found to depend on multiple inter-relational processes and contributory factors.

Given that three decades of research into effective retention strategies have failed to reveal a panacea, there is a strong argument for a paradigm shift in how we research retention. In this regard, tentative parallels may be drawn between research approaches to retention and to psychotherapy, given the relational complexity they both share. Barkham (2003) outlines four paradigms or ‘generations’ of psychotherapy research, of increasing sophistication, since the 1950s. First generation psychotherapy research (1950s-1970s) addressed the key question ‘*is* therapy effective’? Second generation psychotherapy research (1960s-1980s) was concerned with ‘*which* therapy is effective’, which subsequently evolved into generation three (1970s-to date) ‘what *components* are related to outcomes’. Since the 1980s, fourth generation research has concerned *users’ perspectives* of psychotherapy and the significance for the individual of particular aspects within it.

For some time, the dominant retention research paradigm has arguably been ‘which strategy is most effective’ (i.e. reminiscent of second generation psychotherapy research), given the considerable emphasis on improving trial efficiencies/avoiding unnecessary waste (e.g. the Trial Forge group at Aberdeen University). However there is an argument for a paradigm shift towards developing a more sophisticated understanding of what are the important components related to retention and participants’ experiences (i.e. the equivalents of third and fourth generation psychotherapy research). There are signs that this is beginning to happen. For example, Gillies et al. (2018) have been drawing upon the Theoretical Domains Framework (Cane, O’Connor & Michie, 2012) to firstly identify stakeholders’ perceptions of barriers and levers to improving retention in trials with poor retention and, secondly, to

design appropriate solutions or strategies.

Increasing the visibility and legitimacy of relational work: The introduction to this thesis drew upon Nelson and colleagues' (2015) reflections on the extensive, invisible work invested by researchers in stakeholder relationships within complex community programmes which tends to go unreported:

“What is taken for granted in traditional research reports actually entails a complex set of research practice skills and judgment” (Nelson et al., 2015, p. 382).

The work presented in this PhD supports these notions.

Whilst acknowledging that high retention is often used as a quality marker within trials, there appears to be a researcher perception that the 'system' (i.e. trial funders and national research networks) principally emphasises recruitment and overlooks retention (Daykin et al., 2018). The findings in this thesis specifically support those of Daykin et al. (2018): the provision of our pre-planned, tangible retention strategies (e.g. incentives) reflected only a fraction of the more prevalent 'invisible' relational work we undertook to keep sites engaged. Moreover, this work carried an emotional burden.

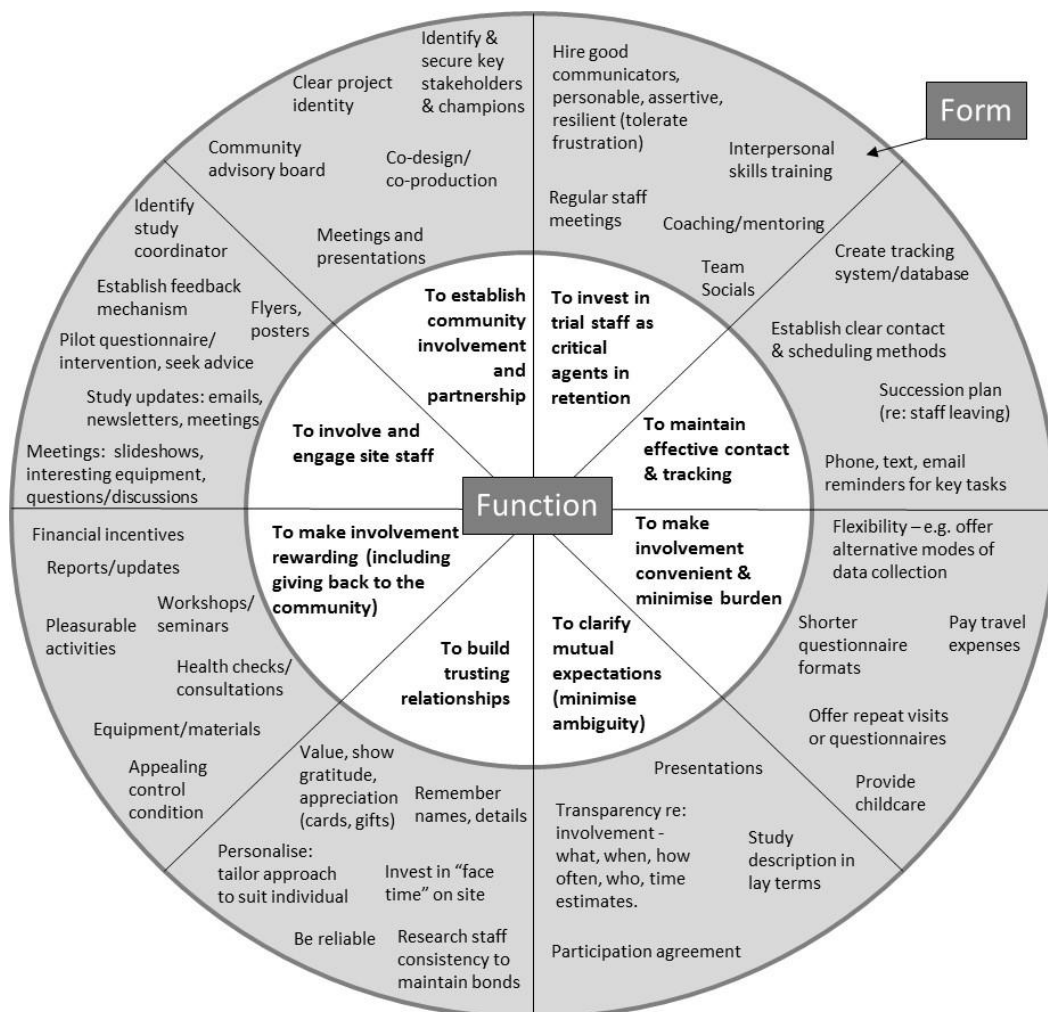
Perhaps because much of this work is intangible or typically considered 'women's work', there is a prevailing perception that it is not valued or legitimate. It is hoped that this thesis might contribute towards promoting the legitimacy of this relational work by making it more visible. In addition, defining cluster trials as inter-organisational collaborations further legitimises the importance of relational work, because trusting relationships are deemed essential for successful inter-organisational collaborations (Liu, 2015; Steinmo & Rasmussen, 2018). The inter-organisational collaboration literature is able to explain why trust is necessary for managing performance and relational risks inherent in these relationships (and similarly in cluster trials), and also why trust requires considerable time and investment on the part of the researcher (e.g. Dayton et al., 2018; Drews et al., 2009; Schoeppe et al., 2014). Organisational or site trust is built one person at a time, and it would seem that the cluster researcher must invest in this individual-level work to support site retention.

Differentiation in the literature between retention strategy functions and forms: Chapter 2's review of the general retention literature revealed the many hundreds of different, individual strategies that have been identified in systematic reviews to date. Each review team has thematised individual strategies into groups, but this has been done in a very inconsistent manner, which makes synthesising the evidence difficult. For example, Robinson et al. (2015) themed 985 strategies into 12 groups; Teague et al. (2018) themed 95 strategies into four groups. When too few groups are created, one could argue that granularity or complexity is lost; creating too many groups may be too complex/unwieldy.

A further difficulty with the retention literature is that strategy *functions* and *forms* (as defined by Hawe, Shiell & Riley (2004) with regards to complex interventions) are conflated in the reviews. For example, Robinson et al.'s (2015) 'financial incentives' are a *form* of strategy, whereas Teague et al.'s (2018) 'reduce barriers to participation' is a *function* or task. This conflation makes the literature hard to interpret and use effectively.

Examining more closely the recommended cluster retention strategies identified in Chapter 2's systematic review, these might be more usefully categorised or represented as *functions* or *forms*. In Figure 9.3, retention strategy *functions* are documented in the inner circle (e.g. to build trusting relationships), with examples of forms in the outer circle (e.g. invest in face time on site). Whether this approach to categorising retention interventions has utility for retention strategy planning warrants further investigation.

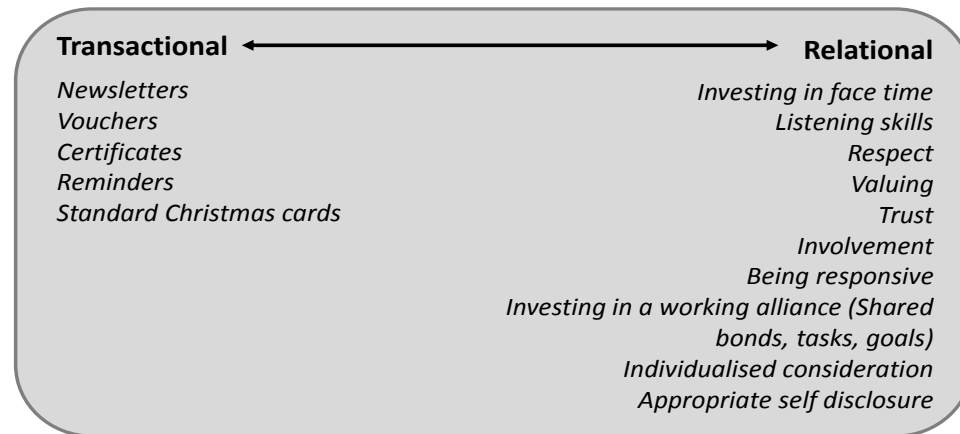
Figure 9.3 The retention wheel: Categorising cluster retention strategies/interventions by their function and form



Finally, there may also be value in categorising retention strategies/interventions in the literature as more or less transactional or relational, which may be of use when planning

retention strategies within different study designs (see Figure 9.4). For example attractive transactional strategies are likely to be more important in studies with short timescales; relational strategies are more critical in longitudinal studies.

Figure 9.4 Positioning retention strategies on a transactional-relational dimension



9.5.2 Implications for practice

Findings from the applied research conducted within this thesis have potentially a number of practical implications for researchers. These are now summarised below.

Continuing research into cluster retention: Retention research to date has overwhelmingly centred around participant retention. The retention of cluster sites is under-researched and more research is urgently needed. Research within this thesis suggests that cluster retention is distinct from participant retention. However, continuing work is required to substantiate this, and to explore, if so, how it is distinct.

Increasing the profile of retention work in publications: The visibility and importance of retention work is not commensurate with recruitment. There is a requirement to reflect more accurately in publications the extent of retention work conducted within trials to increase its profile and promote learning.

More comprehensive, visible retention planning during trial design: Instead of relying on researchers investing hidden, informal work, a comprehensive retention strategy should be developed during the trial design phase. The 'retention wheel' (Figure 9.3) has the potential to help researchers plan their retention strategy more comprehensively and effectively. Financial costings should also be taken into account during the retention planning phase. The finding reported in this thesis that a complex retention intervention was able to be implemented for 3% of the overall RSIYA trial budget may offer a guide for estimating costs. Full retention strategies and associated costs should ideally be requested within grant funding applications.

Recruiting, training and supporting cluster researchers for effective retention:

Within cluster trials there appears to be a need to recruit staff with strong interpersonal and relational skills, and who have characteristics associated with resilience and optimism. Such individuals are more likely to be able to build relationships and manage their wellbeing during challenging times. Providing development and training for cluster trial staff in these relational and self-management skills is also likely to be beneficial. The findings also suggest a critical requirement to prepare cluster trial staff in advance, through training, for the typical challenges of inter-organisational working, strategies to navigate these, the processes involved in building trusting relationships and in mobilising relational social capital. Providing ongoing, formalised support, such as regular team meetings, to share concerns, air frustrations and discuss alternative techniques is also likely to improve researcher self-efficacy, maintain wellbeing, develop team bonds and contribute to successful cluster retention.

Introducing practical tools to support strategic retention planning: The planning of cluster trials may be aided by developing a generic job description and person specification for cluster researchers, incorporating characteristics identified through the research within this thesis. These would potentially help principal investigators determine which skills they needed to recruit for. The retention wheel, which is evidence-based and explicitly identifies the retention tasks to consider, may also support cluster trial planning. Such tools would require further development and testing, and the challenges of disseminating new tools are well-known. For the author, seeking further funding (e.g. impact funding) may enable such work to take place. Future dissemination may involve, for example, webinars, a toolkit or book.

Investigating further the need to tailor retention strategies to different site characteristics: For maximum effect, retention strategies may require greater adaptation or tailoring to individual cluster sites. It will be interesting to determine whether differences observed between schools regarding their characteristics, circumstances and expectations of research are also observable between different workplaces or hospital wards/trusts.

Continuing investigations into the practicality and impact of involving stakeholders in research: Retention in cluster trials may be enhanced by actively involving stakeholders in their design and working in meaningful partnership, as opposed to tokenistically (see Crocker, Boylan, Bostock & Locock, 2017). Although students and teachers offered numerous suggestions for improving trial information and materials, it would be useful to determine the extent to which employees and employers in other organisational sites would be willing to do

so.

Tackling the issue of coercion of children to participate in school-based trials: In school-based cluster trials involving children, there is greater potential for coercion from teachers, peers and researchers to participate in research-associated activities. Therefore, in addition to parental consent, there is a strong argument for providing young people with an easy to understand, appealing, written information sheet which underlines that it is their decision to take part or not. This consistent message should be communicated to teachers and underpin the research team's approach in schools.

Raising awareness of the benefits of being a key contact on site for a trial/study: There is growing recognition that there are 'collateral' benefits from participating in research, beyond the nature of the study itself, for example, for healthcare staff being interviewed about their experiences/perceptions of a particular issue (Lawton, Budworth, Fylan & Sheard, 2020). Given that some study coordinators in the RSIIYA trial regarded the role as a development or enrichment opportunity, there may be value, during early conversations with senior leadership teams at organisational sites, in presenting an appealing, informal role description which identifies ideal qualities, the tasks/responsibilities and anticipated personal/professional benefits they might experience.

Careful consideration of where to intervene in cluster sites: When working with organisational cluster sites, careful consideration needs to be given to **where** to intervene with trial tasks. In workplaces, trial outcomes may be affected by agreements to deliver trial-related tasks during lunchtimes, breaks, formal working time or at the start/end of the day. For example, employers authorising research to take place during formal working time may signal to staff that it is valued or they may regard it as interfering with work. In schools, there are numerous opportunities, including general assemblies, individual classrooms, within form periods or particular subject streams (e.g. science, Religious Studies, PSHE, PE). As observed in the research presented in this thesis, there were implications associated with such decisions.

9.6 Concluding comments

Overall, the thesis has identified multiple inter-relational complexities within and between sites which seem to influence trial experience, engagement and retention. Whilst organisational/contextual factors certainly impacted on stakeholders' experiences of the trial (e.g. the school's organisational 'health', the degree to which PSHE was valued), individuals' personal commitment and agency appeared to be the most powerful moderators of

engagement and retention. The researchers committed to building trusting relationships with site staff, coordinators took personal responsibility for ensuring key tasks were delivered through their drive and personal influence with site staff, teachers took responsibility for 'making the lessons work' and engaging students.

Of particular importance to retention appeared to be the relational bonds established between the two organisational 'boundary spanners' (that is the researcher and the study coordinator), given the researchers' lack of legitimate power and access to each site's systems and resources. This relationship was especially valuable to the researcher within sites where leadership support had waned or was absent, and to study coordinators within schools serving disadvantaged communities.

A formal Engagement Promotion Programme, which sought to reciprocate schools' contribution to the trial by responding to local needs, was well received and enhanced school engagement. This may have helped to build long-term site commitment to the trial, whilst simultaneously aiding the researchers' motivation to pursue trial tasks by believing they were exchanging meaningful, professional skills/experience. The Programme may have performed a similar facilitative function for coordinators, as they planned trial tasks and attempted to persuade staff to undertake these.

This thesis contributes to the retention literature on three fronts. Firstly, it has highlighted that cluster retention is under-represented in the literature, and seems to require particular approaches which are distinct from individual participant retention. Secondly, it adds to the knowledge surrounding the retention of cluster sites, using a case study approach to understand engagement and retention specifically through the lived experiences of stakeholders during an active, longitudinal trial. This represents a departure from the more common approach of seeking researchers' generic, accumulated knowledge about effective retention strategies. It has also been able to offer theoretical explanations for why 'building relationships' is consistently identified as crucial in the sparse cluster retention literature that exists, and more broadly, for how retention occurs. Finally, it has presented a series of recommendations to enhance retention planning within cluster trials.

References

- Abshire, M., Dinglas, V. D., Cajita, M. I. A., Eakin, M. N., Needham, D. M., & Himmelfarb, C. D. (2017). Participant retention practices in longitudinal clinical research studies with high retention rates. *BMC Medical Research Methodology*, 17(1), 30.
- Adler, P. S., & Kwon, S.-W. (2002). Social capital: Prospects for a new concept. *Academy of Management Review*, 27(1), 17-40.
- Ashktorab, Z., & Vitak, J. (2016, May). Designing cyberbullying mitigation and prevention solutions through participatory design with teenagers. In *Proceedings of the 2016 CHI Conference on Human Factors in Computing Systems* (pp. 3895-3905).
- Bachmann, R. (2001). Trust, power and control in trans-organizational relations. *Organization Studies*, 22(2), 337-365.
- Bamberger, K. T., Coatsworth, J. D., Fosco, G. M., & Ram, N. (2014). Change in participant engagement during a family-based preventive intervention: Ups and downs with time and tension. *Journal of Family Psychology*, 28(6), 811.
- Barkham, M. J. (2003). Quantitative research on psychotherapeutic interventions: methods and findings across four research generations. In W. Dryden, R. Woolfe & S. Strawbridge (Eds.), *Handbook of Counselling Psychology* (Second ed., Vol. 25, pp. 25-73). London: Sage.
- Barringer, B. R., & Harrison, J. S. (2000). Walking a tightrope: Creating value through interorganizational relationships. *Journal of Management*, 26(3), 367-403.
- Bartlett, R., Wright, T., Olarinde, T., Holmes, T., Beamon, E. R., & Wallace, D. (2017). Schools as sites for recruiting participants and implementing research. *Journal of Community Health Nursing*, 34(2), 80-88.
- Baxter, P., & Jack, S. (2008). Qualitative case study methodology: Study design and implementation for novice researchers. *The Qualitative Report*, 13(4), 544-559.
- Before, C., Lynch, R., James, R. L., Carroll, S. L., Nollen, N., & Davis, A. (2008). Perceived barriers and benefits to research participation among school administrators. *Journal of School Health*, 78(11), 581-586.

- Bell, M. L., Kenward, M. G., Fairclough, D. L., & Horton, N. J. (2013). Differential dropout and bias in randomised controlled trials: when it matters and when it may not. *BMJ*, *346*, e8668.
- Berger, R. (2015). Now I see it, now I don't: Researcher's position and reflexivity in qualitative research. *Qualitative Research*, *15*(2), 219-234.
- Berkel, C., Mauricio, A. M., Schoenfelder, E., & Sandler, I. N. (2011). Putting the pieces together: An integrated model of program implementation. *Prevention Science*, *12*(1), 23-33.
- Berry, D. C., Neal, M., Hall, E. G., McMurray, R. G., Schwartz, T. A., Skelly, A. H., & Smith-Miller, C. (2013). Recruitment and retention strategies for a community-based weight management study for multi-ethnic elementary school children and their parents. *Public Health Nursing*, *30*(1), 80-86.
- Blau, P. (2017). *Exchange and power in social life*. London: Routledge.
- Bond, L., Glover, S., Godfrey, C., Butler, H., & Patton, G. C. (2001). Building capacity for system-level change in schools: lessons from the Gatehouse Project. *Health Education & Behavior*, *28*(3), 368-383.
- Bonell, C., Fletcher, A., Morton, M., Lorenc, T., & Moore, L. (2012). Realist randomised controlled trials: a new approach to evaluating complex public health interventions. *Social Science & Medicine*, *75*(12), 2299-2306.
- Bonell, C., Humphrey, N., Fletcher, A., Moore, L., Anderson, R., & Campbell, R. (2014). Why schools should promote students' health and wellbeing. *BMJ*, *348*(7958), g3078.
- Booker, C. L., Harding, S., & Benzeval, M. (2011). A systematic review of the effect of retention methods in population-based cohort studies. *BMC Public Health*, *11*(1), 249.
- Bower, P., Brueton, V., Gamble, C., Treweek, S., Smith, C. T., Young, B., & Williamson, P. (2014). Interventions to improve recruitment and retention in clinical trials: a survey and workshop to assess current practice and future priorities. *Trials*, *15*(1), 399.
- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77-101.

- Brierley, G., Brabyn, S., Torgerson, D., & Watson, J. (2012). Bias in recruitment to cluster randomized trials: a review of recent publications. *Journal of Evaluation in Clinical Practice*, 18(4), 878-886.
- Brueton, V., Stenning, S. P., Stevenson, F., Tierney, J., & Rait, G. (2017). Best practice guidance for the use of strategies to improve retention in randomized trials developed from two consensus workshops. *Journal of Clinical Epidemiology*, 88, 122-132.
- Brueton, V. C., Stevenson, F., Vale, C. L., Stenning, S. P., Tierney, J. F., Harding, S., . . . Rait, G. (2014). Use of strategies to improve retention in primary care randomised trials: a qualitative study with in-depth interviews. *BMJ Open*, 4(1).
- Brueton, V. C., Tierney, J., Stenning, S., Harding, S., Meredith, S., Nazareth, I., & Rait, G. (2013). Strategies to improve retention in randomised trials. *The Cochrane Database of Systematic Reviews*(12), 1.
- Brueton, V. C., Tierney, J. F., Stenning, S., Meredith, S., Harding, S., Nazareth, I., & Rait, G. (2014). Strategies to improve retention in randomised trials: a Cochrane systematic review and meta-analysis. *BMJ Open*, 4(2).
- Buston, K., Wight, D., Hart, G., & Scott, S. (2002). Implementation of a teacher-delivered sex education programme: obstacles and facilitating factors. *Health Education Research*, 17(1), 59-72.
- Butler, J., Quinn, S. C., Fryer, C. S., Garza, M. A., Kim, K. H., & Thomas, S. B. (2013). Characterizing researchers by strategies used for retaining minority participants: Results of a national survey. *Contemporary Clinical Trials*, 36(1), 61-67.
- Caan, W., Cassidy, J., Coverdale, G., Ha, M., Nicholson, W., & Rao, M. (2015). The value of using schools as community assets for health. *Public Health*, 129(1), 3-16.
- Campbell, M. J. (2014). Challenges of cluster randomized trials. *Journal of Comparative Effectiveness Research*, 3(3), 271-281.
- Campbell, M. K., Piaggio, G., Elbourne, D. R., & Altman, D. G. (2012). Consort 2010 statement: extension to cluster randomised trials. *BMJ*, 345(7881), e5661.

- Cane, J., O'Connor, D., & Michie, S. (2012). Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation Science*, 7(1), 37.
- Carroll, C., Patterson, M., Wood, S., Booth, A., Rick, J., & Balain, S. (2007). A conceptual framework for implementation fidelity. *Implementation Science*, 2(1), 40.
- Castelfranchi, C., Falcone, R., & Marzo, F. (2006, May). Being trusted in a social network: Trust as relational capital. *International Conference on Trust Management* (pp. 19-32). Springer, Berlin, Heidelberg.
- Castonguay, L. G., Constantino, M. J., & Holtforth, M. G. (2006). The working alliance: Where are we and where should we go? *Psychotherapy: Theory, Research, Practice, Training*, 43(3), 271.
- Cathcart, E. B. (2014). Relational work: At the core of leadership. *Nursing Management*, 45(3), 44-46.
- Chapman, S. J., Shelton, B., Mahmood, H., Fitzgerald, J. E., Harrison, E. M., & Bhangu, A. (2014). Discontinuation and non-publication of surgical randomised controlled trials: observational study. *BMJ*, 349. doi:10.1136/bmj.g6870
- Christenson, S. L., Carlson, C., & Valdez, C. R. (2002). Evidence-based interventions in school psychology: Opportunities, challenges, and cautions. *School Psychology Quarterly*, 17(4), 466.
- Cialdini, R. B. (2009). *Influence: Science and practice* (Vol. 4). Boston, MA: Pearson Education.
- Clark, A. M. (2013). What are the components of complex interventions in healthcare? Theorizing approaches to parts, powers and the whole intervention. *Social Science & Medicine*, 93, 185-193.
- Coday, M., Boutin-Foster, C., Sher, T. G., Tennant, J., Greaney, M. L., Saunders, S. D., & Somes, G. W. (2005). Strategies for retaining study participants in behavioral intervention trials: retention experiences of the NIH Behavior Change Consortium. *Annals of Behavioral Medicine*, 29(2), 55-65.

- Conner, M., Grogan, S., Lawton, R., Armitage, C., West, R., Siddiqi, K., . . . Simms-Ellis, R. (2013). Study protocol: A cluster randomised controlled trial of implementation intentions to reduce smoking initiation in adolescents. *BMC Public Health*, 13(1), 54.
- Conner, M., Grogan, S., West, R., Simms-Ellis, R., Scholtens, K., Sykes-Muskett, B., ... & Schmitt, L. (2019). Effectiveness and cost-effectiveness of repeated implementation intention formation on adolescent smoking initiation: A cluster randomized controlled trial. *Journal of Consulting and Clinical Psychology*, 87(5), 422.
- Courtney, S. J. (2013). Head teachers' experiences of school inspection under Ofsted's January 2012 framework. *Management in Education*, 27(4), 164-169.
- Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*, 337, a1655. doi:10.1136/bmj.a1655
- Crane, S., & Broome, M. E. (2017). Understanding ethical issues of research participation from the perspective of participating children and adolescents: a systematic review. *Worldviews on Evidence-Based Nursing*, 14(3), 200-209.
- Crocker, J. C., Boylan, A. M., Bostock, J., & Locock, L. J., (2017). Is it worth it? Patient and public views on the impact of their involvement in health research and its assessment: a UK-based qualitative interview study. *Health Expectations*, 20(3), 519-528.
- Cropanzano, R., & Mitchell, M. S. (2005). Social exchange theory: An interdisciplinary review. *Journal of Management*, 31(6), 874-900.
- Crowe, S., Cresswell, K., Robertson, A., Huby, G., Avery, A., & Sheikh, A. (2011). The case study approach. *BMC Medical Research Methodology*, 11(1), 100. doi:10.1186/1471-2288-11-100
- Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Science*, 4(1), 50.

- Dane, A. V., & Schneider, B. H. (1998). Program integrity in primary and early secondary prevention: are implementation effects out of control? *Clinical Psychology Review*, 18(1), 23-45.
- Das, T. K., & Teng, B.-S. (2001). Trust, control, and risk in strategic alliances: An integrated framework. *Organization Studies*, 22(2), 251-283.
- Datta, J., & Petticrew, M. (2013). Challenges to evaluating complex interventions: a content analysis of published papers. *BMC Public Health*, 13(1), 568.
- Davidson, G. (2019) Workload demands force Scots teachers to work 6 days a week. Available at <https://www.scotsman.com/news/politics/workload-demands-force-scots-teachers-to-work-six-days-a-week-1-4941936> [accessed 22nd June 2019].
- Davis, L. L., Broome, M. E., & Cox, R. P. (2002). Maximizing retention in community-based clinical trials. *Journal of Nursing Scholarship*, 34(1), 47-53.
- Daykin, A., Clement, C., Gamble, C., Kearney, A., Blazeby, J., Clarke, M., . . . Shaw, A. (2018). 'Recruitment, recruitment, recruitment' – the need for more focus on retention: a qualitative study of five trials. *Trials*, 19(1), 76. doi:10.1186/s13063-018-2467-0
- DeFrino, D. T. (2009). A theory of the relational work of nurses. *Research and Theory for Nursing Practice*, 23(4), 294.
- Denzin, N. K. (2010). Moments, mixed methods, and paradigm dialogs. *Qualitative Inquiry*, 16(6), 419-427.
- Department for Education (2015). Personal, social, health and economic (PSHE) education: a review of impact and effective practice. Crown 2015. <https://www.gov.uk/government/publications>.
- Department for Education (2018). *Official Statistics: State-funded schools inspections and outcomes* [Online]. Crown Copyright. Available at: <https://www.gov.uk/government/publications/state-funded-schools-inspections-and-outcomes-as-at-31-august-2018/state-funded-schools-inspections-and-outcomes-as-at-31-august-2018>
- Donner, A., & Klar, N. (2004). Pitfalls of and Controversies in Cluster Randomization Trials. *American Journal of Public Health*, 94(3), 416-422.

- Donovan, J. L., Paramasivan, S., de Salis, I., & Toerien, M. (2014). Clear obstacles and hidden challenges: understanding recruiter perspectives in six pragmatic randomised controlled trials. *Trials*, 15(1), 5.
- Drews, K., Harrell, J., Thompson, D., Mazzuto, S., Ford, E., Carter, M., . . . Rouillet, J.-B. (2009). Recruitment and retention strategies and methods in the HEALTHY study. *International Journal of Obesity*, 33, S21-S28.
- Durlak, J. A., & DuPre, E. P. (2008). Implementation matters: A review of research on the influence of implementation on program outcomes and the factors affecting implementation. *American Journal of Community Psychology*, 41(3-4), 327-350.
- El Feky, A., Gillies, K., Gardner, H., Fraser, C., & Treweek, S. (2018). A protocol for a systematic review of non-randomised evaluations of strategies to increase participant retention to randomised controlled trials. *Systematic Reviews*, 7(1), 30.
- Eldridge, S., Ashby, D., Bennett, C., Wakelin, M., & Feder, G. (2008). Internal and external validity of cluster randomised trials: systematic review of recent trials. *BMJ*, 336(7649), 876-880. doi:10.1136/bmj.39517.495764.25
- Elliott, D., Husbands, S., Hamdy, F. C., Holmberg, L., & Donovan, J. L. (2017). Understanding and Improving Recruitment to Randomised Controlled Trials: Qualitative Research Approaches. *European Urology*, 72(5), 789-798. doi:10.1016/j.eururo.2017.04.036
- Evans, R., Scourfield, J., & Murphy, S. (2015). Pragmatic, formative process evaluations of complex interventions and why we need more of them. *Journal of Epidemiology and Community Health*, 69, 925-926. doi:10.1136/jech-2014-204806
- Evans, R., Murphy, S., & Scourfield, J. (2015). Implementation of a school-based social and emotional learning intervention: understanding diffusion processes within complex systems. *Prevention Science*, 16(5), 754-764.
- Fairman, M., & Clark, E. (1982). Organizational problem solving: An organizational improvement strategy. *Fayetteville, AK: Organizational Health Diagnostic and Development Corp.*
- Field, A. (2013). *Discovering statistics using IBM SPSS statistics*. London: Sage.

- Fletcher, J. K., Jordan, J. V., & Miller, J. B. (2000). Women and the workplace: Applications of a psychodynamic theory. *The American Journal of Psychoanalysis*, 60(3), 243-261.
- Flynn, T. N., Whitley, E., & Peters, T. J. (2002). Recruitment strategies in a cluster randomized trial – cost implications. *Statistics in Medicine*, 21(3), 397-405.
doi:10.1002/sim.1025
- Forman, S. G., Olin, S. S., Hoagwood, K. E., Crowe, M., & Saka, N. (2009). Evidence-based interventions in schools: Developers' views of implementation barriers and facilitators. *School Mental Health*, 1(1), 26.
- French, J. R. P., Jr. & Raven, B. (1959). The bases of social power. In D. Cartwright (Ed.) *Studies in Social Power*. Ann Arbor, MI: Institute for Social Research, University of Michigan, pp. 150-167.
- Gagné, M., & Deci, E. L. (2005). Self-determination theory and work motivation. *Journal of Organizational Behavior*, 26(4), 331-362.
- Gale, N. K., Heath, G., Cameron, E., Rashid, S., & Redwood, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology*, 13(1), 117.
- Gillies, K., Bower, P., Elliott, J., MacLennan, G., Newlands, R. S., Ogden, M., . . . Young, B. (2018). Systematic Techniques to Enhance Retention in Randomised controlled trials: the STEER study protocol. *Trials*, 19(1), 197.
- Giraudeau, B., & Ravaud, P. (2009). Preventing bias in cluster randomised trials. *PLoS Medicine*, 6(5). doi:10.1371/journal.pmed.1000065
- Gittell, J. H., Seidner, R., & Wimbush, J. (2010). A relational model of how high-performance work systems work. *Organization Science*, 21(2), 490-506.
- Glover, S. (2017). PSHE: An opportunity to build an enduring relationship with health and social care or a waste of time. *International Journal of Perceptions in Public Health*, 1(3), 157-159.
- Gollwitzer, P. M. (1993). Goal achievement: The role of intentions. *European Review of Social Psychology*, 4(1), 141-185.

- Gouldner, A. W. (1960). The norm of reciprocity: A preliminary statement. *American Sociological Review*, 25(2), 161-178.
- Grant, A., Treweek, S., Dreischulte, T., Foy, R., & Guthrie, B. (2013). Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. *Trials*, 14(1), 15.
- Greenhalgh, T., Collard, A., & Begum, N. (2005). Sharing stories: complex intervention for diabetes education in minority ethnic groups who do not speak English. *BMJ*, 330(7492), 628.
- Gul, R. B., & Ali, P. A. (2010). Clinical trials: the challenge of recruitment and retention of participants. *Journal of Clinical Nursing*, 19(1-2), 227-233.
- Haataja, A., Ahtola, A., Poskiparta, E., & Salmivalli, C. (2015). A process view on implementing an antibullying curriculum: How teachers differ and what explains the variation. *School Psychology Quarterly*, 30(4), 564.
- Hackman, J. R., & Oldham, G. R. (1980). *Work redesign*. Reading, MA: Addison-Wesley.
- Hall, G. (2013). Evaluating change processes: Assessing extent of implementation (constructs, methods and implications). *Journal of Educational Administration*, 51, 264-289.
- Harper, S. R., & Kuh, G. D. (2007). Myths and misconceptions about using qualitative methods in assessment. *New Directions for Institutional Research*, 2007(136), 5-14.
- Harrell, J. S., Bradley, C., Dennis, J., Frauman, A. C., & Criswell, E. S. (2000). School-based research: Problems of access and consent. *Journal of Pediatric Nursing*, 15(1), 14-21.
- Hasson, H. (2010). Systematic evaluation of implementation fidelity of complex interventions in health and social care. *Implementation Science*, 5(1), 67.
- Hausknecht, J. P., Rodda, J., & Howard, M. J. (2009). Targeted employee retention: Performance-based and job-related differences in reported reasons for staying. *Journal of Human Resource Management*, 48(2), 269-288.
- Hawe, P., Shiell, A., & Riley, T. (2004). Complex interventions: how “out of control” can a randomised controlled trial be?. *BMJ*, 328(7455), 1561-1563.

- Hazell, T. (2006). *MindMatters: Evaluation of the professional development program and school-level implementation (Final report)*. Hunter Institute for Mental Health: Newcastle, New South Wales.
- Heaven, B., Murtagh, M., Rapley, T., May, C., Graham, R., Kaner, E., & Thomson, R. (2006). Patients or research subjects? A qualitative study of participation in a randomised controlled trial of a complex intervention. *Patient Education and Counseling*, 62(2), 260-270.
- Helstad, K., & Møller, J. (2013). Leadership as relational work: Risks and opportunities. *International Journal of Leadership in Education*, 16(3), 245-262.
- Hennessy, E. & Heary, C. (2005). Exploring children's views through focus groups. In S. Greene & D. Hogan (Eds.) *Researching Children's Experience: Approaches and Methods*. London: SAGE Publications, pp. 236-252.
- Hindmarch, P., Hawkins, A., McColl, E., Hayes, M., Majsak-Newman, G., Ablewhite, J., ... & Kendrick, D. (2015). Recruitment and retention strategies and the examination of attrition bias in a randomised controlled trial in children's centres serving families in disadvantaged areas of England. *Trials*, 16(1), 79.
- Hochheimer, C. J., Sabo, R. T., Krist, A. H., Day, T., Cyrus, J., & Woolf, S. H. (2016). Methods for evaluating respondent attrition in web-based surveys. *Journal of Medical Internet Research*, 18(11), e301.
- Hodder, R. K., Daly, J., Freund, M., Bowman, J., Hazell, T., & Wiggers, J. (2011). A school-based resilience intervention to decrease tobacco, alcohol and marijuana use in high school students. *BMC Public Health*, 11(1), 722.
- Hodkinson, P., & Hodkinson, H. (2001, December). The strengths and limitations of case study research. *Learning and skills development agency conference, Cambridge* (Vol. 1, No. 1, pp. 5-7).
- Hogg, M.A. & Vaughan, G.M. (2005). *Social Psychology*. Harlow: Pearson Education.
- House of Commons Committee of Public Accounts (2018) *Retaining and developing the teaching workforce*. 31st January 2018, HC 460: Seventeenth report of session 2017-2019.

- Howe, K. R. (2004). A critique of experimentalism. *Qualitative inquiry*, 10, 42-61.
- Hoy, W. K., Tarter, C. J., & Bliss, J. R. (1990). Organizational climate, school health, and effectiveness: A comparative analysis. *Educational Administration Quarterly*, 26(3), 260-279.
- Huang, Y. S., & Wilkinson, I. F. (2014). A case study of the development of trust in a business relation: Implications for a dynamic theory of trust. *Journal of Business Market Management*, 7(1), 254-279.
- Hunt, J. R., & White, E. (1998). Retaining and tracking cohort study members. *Epidemiologic Reviews*, 20(1), 57-70.
- Ibarra, H., & Andrews, S. B. (1993). Power, social influence, and sense making: Effects of network centrality and proximity on employee perceptions. *Administrative Science Quarterly*, 277-303.
- Johnson, P., & Cassell, C. (2001). Epistemology and work psychology: New agendas. *Journal of Occupational and Organizational Psychology*, 74(2), 125-143.
- Johnson, A. M., Jones, S. B., Duncan, P. W., Bushnell, C. D., Coleman, S. W., Mettam, L. H., . . . Rosamond, W. D. (2018). Hospital recruitment for a pragmatic cluster-randomized clinical trial: Lessons learned from the COMPASS study. *Trials*, 19(1), 74.
- Kitzinger, J. (1995). Qualitative research: introducing focus groups. *BMJ*, 311(7000), 299-302.
- Kreitner, R., Kinicki, A., & Buelens, M. (2002). *Organizational Behaviour*. London: McGraw-Hill Education.
- Kwon, S.-W., & Adler, P. S. (2014). Social capital: Maturation of a field of research. *Academy of Management Review*, 39(4), 412-422.
- Labaree, R. V. (2002). The risk of 'going observationalist': negotiating the hidden dilemmas of being an insider participant observer. *Qualitative Research*, 2(1), 97-122.
- Lacey, R. J., Wilkie, R., Wynne-Jones, G., Jordan, J. L., Wersocki, E., & McBeth, J. (2017). Evidence for strategies that improve recruitment and retention of adults aged 65

years and over in randomised trials and observational studies: a systematic review. *Age and Ageing*, 46(6), 895-903.

Langley, A. K., Nadeem, E., Kataoka, S. H., Stein, B. D., & Jaycox, L. H. (2010). Evidence-based mental health programs in schools: Barriers and facilitators of successful implementation. *School Mental Health*, 2(3), 105-113.

Lawton, J., Jenkins, N., Darbyshire, J. L., Holman, R. R., Farmer, A. J., & Hallowell, N. (2011). Challenges of maintaining research protocol fidelity in a clinical care setting: a qualitative study of the experiences and views of patients and staff participating in a randomized controlled trial. *Trials*, 12(1), 108.

Lawton, R., Budworth, L., Fylan, B., & Sheard, L. (2019, August). Beyond the outcomes: The benefits of the 'process' of doing applied health research.

<https://yhpstrc.org/beyondoutcomes/>

Lawton, R., McEachan, R., Jackson, C., West, R., & Conner, M. (2014). Intervention fidelity and effectiveness of a UK worksite physical activity intervention funded by the Bupa Foundation, UK. *Health Promotion International*, 30(1), 38-49.

Leathem, C. S., Cupples, M. E., Byrne, M. C., O'Malley, M., Houlihan, A., Murphy, A. W., & Smith, S. M. (2009). Identifying strategies to maximise recruitment and retention of practices and patients in a multicentre randomised controlled trial of an intervention to optimise secondary prevention for coronary heart disease in primary care. *BMC Medical Research Methodology*, 9(1), 40.

Lee, A. (2009). Health-promoting schools. *Applied Health Economics and Health Policy*, 7(1), 11-17.

Lee, G. (2001). Towards a contingent model of key staff retention: The new psychological contract reconsidered. *South African Journal of Business Management*, 32(1), 1-9.

Lewis, K. M., DuBois, D. L., Ji, P., Day, J., Silverthorn, N., Bavarian, N., . . . Schure, M. (2017). Meeting the challenges of longitudinal cluster-based trials in schools: Lessons from the Chicago trial of Positive Action. *Evaluation & the Health Professions*, 40(4), 450-482.

- Linnan, L., & Steckler, A. (2002). *Process Evaluation for public health interventions and research: An overview*. In L.Linnan & A. Steckler (Eds.) *Process Evaluation for Public Health Interventions and Research*. San Francisco: Jossey-Bass, pp. 1-23.
- Liu, Z. (2015). Trust between Organizations: A Review of Current Research and Recommendations for the Future. *Review of Contemporary Business Research*, 4(1), 40-48.
- Lloyd, J., McHugh, C., Minton, J., Eke, H., & Wyatt, K. (2017). The impact of active stakeholder involvement on recruitment, retention and engagement of schools, children and their families in the cluster randomised controlled trial of the Healthy Lifestyles Programme (HeLP): a school-based intervention to prevent obesity. *Trials*, 18(1), 378.
- Locock, L., & Smith, L. (2011). Personal benefit, or benefiting others? Deciding whether to take part in clinical trials. *Clinical Trials*, 8(1), 85-93.
- Long, J. C., Cunningham, F. C., & Braithwaite, J. (2013). Bridges, brokers and boundary spanners in collaborative networks: a systematic review. *BMC Health Services Research*, 13(1), 158.
- Low, S., Van Ryzin, M. J., Brown, E. C., Smith, B. H., & Haggerty, K. P. (2014). Engagement matters: lessons from assessing classroom implementation of steps to respect: a bullying prevention program over a one-year period. *Prevention Science*, 15(2), 165-176.
- MacNeil, A. J., Prater, D. L., & Busch, S. (2009). The effects of school culture and climate on student achievement. *International Journal of Leadership in Education*, 12(1), 73-84.
- MacNeill, V., Foley, M., Quirk, A. & McCambridge, J. (2016). Shedding light on research participation effects in behaviour change trials: a qualitative study examining research participant experiences. *BMC Public Health*, 16, 91.
- Madill, A., Flowers, P., Frost, N., & Locke, A. (2018). A meta-methodology to enhance pluralist qualitative research: One man's use of socio-sexual media and midlife adjustment to HIV. *Psychology & Health*, 33(10), 1209-1228.
- Madill, A. (2008). Core Category. In: L. M. Given (Ed.) *The SAGE Encyclopedia of Qualitative Research Methods*. London: Sage.

- Markoe Hayes, S., Chapple, S., & Ramirez, C. (2014). Strong, smart and bold strategies for improving attendance and retention in an after-school intervention. *Journal of Adolescent Health, 54*(3 Suppl), S64-69.
- Martin, R. (1978). Expert and referent power: A framework for understanding and maximizing consultation effectiveness. *Journal of School Psychology, 16*(1), 49-55.
- Mathison, S. (1988). Why triangulate? *Educational Researcher, 17*(2), 13-17.
- May, C., Finch, T., Mair, F., Ballini, L., Dowrick, C., Eccles, M., ... & Rogers, A. (2007). Understanding the implementation of complex interventions in health care: the normalization process model. *BMC Health Services Research, 7*(1), 148.
- McCann, S. K., Campbell, M. K. & Entwistle, V. A. (2010). Reasons for participating in randomised controlled trials: conditional altruism and considerations for self. *Trials, 11*, 31.
- McCambridge, J., Kallitaki, E., White, I. R., Khadjesari, Z., Murray, E., Linke, S., Thompson, S. G., Godfrey, C. & Wallace, P. (2011). Impact of length or relevance of questionnaires on attrition in online trials: randomized controlled trial. *Journal of Medical Internet Research, 13*(4): e96. doi:10.2196/jmir.1733.
- McDonald, A. M., Knight, R. C., Campbell, M. K., Entwistle, V. A., Grant, A. M., Cook, J. A., . . . Snowdon, C. (2006). What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials, 7*(1), 9. doi:10.1186/1745-6215-7-9
- McEachan, R. R., Lawton, R. J., Jackson, C., Conner, M., Meads, D. M., & West, R. M. (2011). Testing a workplace physical activity intervention: a cluster randomized controlled trial. *International Journal of Behavioral Nutrition and Physical Activity, 8*(1), 29.
- McMahon, N. E., Holland, E.-J., Miller, C., Patel, K., & Connell, L. A. (2015). Activities to support the implementation of complex interventions as part of routine care: a review of the quality of reporting in cluster randomised controlled trials. *BMJ Open, 5*(10). doi:10.1136/bmjopen-2015-008251
- Mechanic, D. (1962). Sources of power of lower participants in complex organizations. *Administrative Science Quarterly, 349-364*.

- Medico, D., & Santiago-Delefosse, M. (2014). From reflexivity to resonances: Accounting for interpretation phenomena in qualitative research. *Qualitative Research in Psychology, 11*(4), 350-364.
- Mein, G., Seale, C., Rice, H., Johal, S., Ashcroft, R. E., Ellison, G., & Tinker, A. (2012). Altruism and participation in longitudinal health research? Insights from the Whitehall II Study. *Social Science & Medicine, 75*(12), 2345-2352.
- Midford, R., McBride, N., & Farrington, F. (2000). Conducting research in schools: Lessons learnt from experience. *Health Promotion Journal of Australia: Official Journal of Australian Association of Health Promotion Professionals, 10*(1), 63.
- Midgley, N., Isaacs, D., Weitkamp, K., & Target, M. (2016). The experience of adolescents participating in a randomised clinical trial in the field of mental health: a qualitative study. *Trials, 17*(1), 364.
- Moberg, J., & Kramer, M. (2015). A brief history of the cluster randomised trial design. *Journal of the Royal Society of Medicine, 108*(5), 192-198.
- Moher, D., Liberati, A., Tetzlaff, J., & Altman, D. G. (2009). Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Annals of Internal Medicine, 151*(4), 264-269.
- Moher, D., Shamseer, L., Clarke, M., Ghersi, D., Liberati, A., Petticrew, M., . . . Stewart, L. A. (2015). Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews, 4*(1), 1.
- Moore, G. F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., . . . Baird, J. (2015). Process evaluation of complex interventions: Medical Research Council guidance. *BMJ, 350*. doi:10.1136/bmj.h1258
- Muchinsky, P. M. (2003). *Psychology Applied to Work*. USA: Wadsworth/Thomson Learning.
- Mukoma, W., Flisher, A. J., Ahmed, N., Jansen, S., Mathews, C., Klepp, K.-I., & Schaalma, H. (2009). Process evaluation of a school-based HIV/AIDS intervention in South Africa. *Scandinavian Journal of Public Health, 37*(2_suppl), 37-47.

- Muntigl, P., & Horvath, A. O. (2014). The therapeutic relationship in action: How therapists and clients co-manage relational disaffiliation. *Psychotherapy Research*, 24(3), 327-345.
- Murphy, E., Spiegel, N., & Kinmonth, A. (1992). 'Will you help me with my research?' Gaining access to primary care settings and subjects. *British Journal of General Practice*, 42(357), 162-165.
- Murray, E., Treweek, S., Pope, C., MacFarlane, A., Ballini, L., Dowrick, C., . . . O'Donnell, C. (2010). Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC Medicine*, 8(1), 63.
- Nelson, G., MacNaughton, E., & Goering, P. (2015). What qualitative research can contribute to a randomized controlled trial of a complex community intervention. *Contemporary Clinical Trials*, 45, 377-384.
- Nix, R. L., Bierman, K. L., & McMahon, R. J. (2009). How attendance and quality of participation affect treatment response to parent management training. *Journal of Consulting and Clinical Psychology*, 77(3), 429.
- O'Cathain, A., Murphy, E., & Nicholl, J. (2008). The quality of mixed methods studies in health services research. *Journal of Health Services Research*, 13(2), 92-98.
- O'Cathain, A., Thomas, K., Drabble, S., Rudolph, A., & Hewison, J. (2013). What can qualitative research do for randomised controlled trials? A systematic mapping review. *BMJ Open*, 3(6), e002889.
- Oakley, A., Strange, V., Bonell, C., Allen, E., Stephenson, J., & Team, R. S. (2006). Health services research: process evaluation in randomised controlled trials of complex interventions. *BMJ*, 332(7538), 413-416.
- Office for National Statistics (2018) *Likelihood of smoking four times higher in England's most deprived areas than least deprived* [Online]. Crown Copyright. Available: <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/drugusealcoholandsmoking/articles/likelihoodofsmokingfourtimeshigherinenglandsmostdeprivedareasthanleastdeprived/2018-03-14>.
- Office for Standards in Education (2013, September) The framework for school inspection: The framework for inspecting schools in England under section 5 of the Education

Act 2005 (as amended). Reference no. 120100.

<http://www.educationengland.org.uk/documents/pdfs/2013-ofsted-inspection-framework.pdf>

Office for Standards in Education (2019, May) The education inspection framework.

Reference no. 190015.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/801429/Education_inspection_framework.pdf.

O'Reilly-Shah, V. N. (2017). Factors influencing healthcare provider respondent fatigue answering a globally administered in-app survey. *PeerJ*, 5, e3785.

Patsopoulos, N. A. (2011). A pragmatic view on pragmatic trials. *Dialogues in Clinical Neuroscience*, 13(2), 217-224.

Pearson, M., Chilton, R., Woods, H. B., Wyatt, K., Ford, T., Abraham, C., & Anderson, R. (2012). Implementing health promotion in schools: protocol for a realist systematic review of research and experience in the United Kingdom (UK). *Systematic Reviews*, 1(1), 48.

Pereira, N. S., & Marques-Pinto, A. (2017). The Role of Participant Responsiveness on a Socio-Emotional Learning Program. *The Spanish Journal of Psychology*, 20, e2, 1-14.

Petersen, S. M., Zoffman, V., Kjærgaard, J., Steesballe, L. G. & Greisen, G. (2014). Disappointment and adherence among parents of newborns allocated to the control group: a qualitative study of a randomized clinical trial. *Trials*, 15, 126.

Peterson, J. C., Pirraglia, P. A., Wells, M. T., & Charlson, M. E. (2012). Attrition in longitudinal randomized controlled trials: home visits make a difference. *BMC Medical Research Methodology*, 12(1), 178. doi:10.1186/1471-2288-12-178.

Petosa, R., & Goodman, R. M. (1991). Recruitment and retention of schools participating in school health research. *Journal of School Health*, 61(10), 426-429.

Petticrew, M. (2011). When are complex interventions 'complex'? When are simple interventions 'simple'? *European Journal of Public Health*, 21(4), 397-398. doi:10.1093/eurpub/ckr084

- Pettigrew, J., Graham, J. W., Miller-Day, M., Hecht, M. L., Krieger, J. L., & Shin, Y. J. (2015). Adherence and delivery: Implementation quality and program outcomes for the seventh-grade keepin' it REAL program. *Prevention Science*, 16(1), 90-99.
- Pinto, R. M., Witte, S. S., Wall, M. M., & Filippone, P. L. (2018). Recruiting and retaining service agencies and public health providers in longitudinal studies: Implications for community-engaged implementation research. *Methodological Innovations*, 11(1), 2059799118770996.
- Podsakoff, P. M., & Schriesheim, C. (1985). *Leader reward and punishment behavior: A methodological and substantive review*. San Francisco: Jossey-Bass.
- Popay, J., Roberts, H., Sowden, A., Petticrew, M., Arai, L., Rodgers, M., ... & Duffy, S. (2006). Guidance on the conduct of narrative synthesis in systematic reviews: a product from the ESRC Methods Programme. *Lancaster: Lancaster University*, 10(2.1), 1018-4643.
- Prendergast, S., & Rickinson, M. (2019). Understanding school engagement in and with research. *The Australian Educational Researcher*, 46(1), 17-39.
- Provencher, V., Mortenson, W. B., Tanguay-Garneau, L., Bélanger, K., & Dagenais, M. (2014). Challenges and strategies pertaining to recruitment and retention of frail elderly in research studies: a systematic review. *Archives of Gerontology and Geriatrics*, 59(1), 18-24.
- Puffer, S., & Torgerson, D. J. (2003, June). Recruitment difficulties in randomised controlled trials. *Controlled Clinical Trials*, 24 (3S): S214-215.
- Puffer, S., Torgerson, D., & Watson, J. (2003). Evidence for risk of bias in cluster randomised trials: Review of recent trials published in three general medical journals. *BMJ*, 327(7418), 785-789.
- Puffer, S., Torgerson, D., & Watson, J. (2005). Cluster randomized controlled trials. *Journal of Evaluation in Clinical Practice*, 11(5), 479-483.
- Renes, S. L., Ringwalt, C., Clark, H. K., & Hanley, S. (2007). Great minds don't always think alike: The challenges of conducting substance abuse prevention research in public schools. *Journal of Drug Education*, 37(2), 97-105.

- Rhoades, L., & Eisenberger, R. (2002). Perceived organizational support: a review of the literature. *Journal of Applied Psychology*, 87(4), 698.
- Ribisl, K. M., Walton, M. A., Mowbray, C. T., Luke, D. A., Davidson li, W. S., & Bootsmiller, B. J. (1996). Minimizing participant attrition in panel studies through the use of effective retention and tracking strategies: Review and recommendations. *Evaluation and Program Planning*, 19(1), 1-25.
- Riley, T., & Hawe, P. (2009). A typology of practice narratives during the implementation of a preventive, community intervention trial. *Implementation Science*, 4(1), 80.
- Riggio, R. E., & Reichard, R. J. (2008). The emotional and social intelligences of effective leadership: An emotional and social skill approach. *Journal of Managerial Psychology*, 23(2), 169-185.
- Ritchie, J., & Spencer, L. (1994). Qualitative data analysis for applied policy research. In A. Bryman & R.G. Burgess (Eds.), *Analyzing Qualitative Data* (pp. 173-194) London: Routledge.
- Robinson, K. A., Dennison, C. R., Wayman, D. M., Pronovost, P. J., & Needham, D. M. (2007). Systematic review identifies number of strategies important for retaining study participants. *Journal of Clinical Epidemiology*, 60(8), 757-e1.
- Robinson, K. A., Dinglas, V. D., Sukrithan, V., Yalamanchilli, R., Mendez-Tellez, P. A., Dennison-Himmelfarb, C., & Needham, D. M. (2015). Updated systematic review identifies substantial number of retention strategies: using more strategies retains more study participants. *Journal of Clinical Epidemiology*, 68(12), 1481-1487.
- Robinson, O. C. (2014). Sampling in interview-based qualitative research: A theoretical and practical guide. *Qualitative Research in Psychology*, 11(1), 25-41.
- Robson, C. (2002) *Real world research: A resource for social scientists and researcher-practitioners*. London: Wiley-Blackwell.
- Rogers, C. R. (1957). The necessary and sufficient conditions of therapeutic personality change. *Journal of Consulting Psychology*, 21(2), 95.
- Roland, M., & Torgerson, D. J. (1998). Understanding controlled trials: What are pragmatic trials? *BMJ*, 316(7127), 285. doi:10.1136/bmj.316.7127.285

- Rousseau, D. M. (1989). Psychological and implied contracts in organizations. *Employee Responsibilities and Rights*, 2(2), 121-139.
- Rutterford, C., Taljaard, M., Dixon, S., Copas, A., & Eldridge, S. (2015). Reporting and methodological quality of sample size calculations in cluster randomized trials could be improved: A review. *Journal of Clinical Epidemiology*, 68(6), 716-723.
- Sammons, P., Gu, Q., Day, C., & Ko, J. (2011). Exploring the impact of school leadership on pupil outcomes: Results from a study of academically improved and effective schools in England. *International Journal of Educational Management*, 25(1), 83-101.
- Schoenfelder, E. (2012). *Behavioral and subjective participant responsiveness to a manualized preventive intervention*. PhD Thesis: Arizona State University.
https://repository.asu.edu/attachments/56813/content/Schoenfelder_asu_0010E_10774.pdf
- Schoeppe, S., Oliver, M., Badland, H. M., Burke, M., & Duncan, M. J. (2014). Recruitment and retention of children in behavioral health risk factor studies: REACH strategies. *International Journal of Behavioral Medicine*, 21(5), 794-803.
- Settoon, R. P., Bennett, N., & Liden, R. C. (1996). Social exchange in organizations: Perceived organizational support, leader–member exchange, and employee reciprocity. *Journal of Applied Psychology*, 81(3), 219.
- Sheeran, P., Milne, S., Webb, T. L., & Gollwitzer, P. (2005). Implementation intentions and health behaviors. In M. Conner & P. Norman (Eds.), *Predicting Health Behavior* (2nd ed., pp. 276-323). Buckingham, UK: Open University Press/McGraw Hill.
- Shields, L., & Twycross, A. (2008). Content analysis. *Paediatric Nursing*, 20(6), 38-39.
- Siegrist, M., Gutscher, H., & Earle, T. C. (2005). Perception of risk: the influence of general trust, and general confidence. *Journal of Risk Research*, 8(2), 145-156.
- Sirotnik, K. (1991). Making school-university partnerships work. *Metropolitan Universities*, 2(1), 15-24.

- Skea, Z. C., Treweek, S., & Gillies, K. (2017). 'It's trying to manage the work': a qualitative evaluation of recruitment processes within a UK multicentre trial. *BMJ Open*, 7(8), e016475.
- Skingley, A., Bungay, H., Clift, S., & Warden, J. (2014). Experiences of being a control group: lessons from a UK-based randomized controlled trial of group singing as a health promotion initiative for older people. *Health Promotion International*, 29(4), 751-758.
- Slocum-Gori, S. L., & Zumbo, B. D. (2011). Assessing the unidimensionality of psychological scales: Using multiple criteria from factor analysis. *Social Indicators Research*, 102(3), 443-461.
- Stake, R. E. (1995). *The art of case study research*. London: Sage.
- Stallard, P., Phillips, R., Montgomery, A., Spears, M., Anderson, R., Taylor, J., . . . Millings, A. (2013). A cluster randomised controlled trial to determine the clinical effectiveness and cost-effectiveness of classroom-based cognitive-behavioural therapy (CBT) in reducing symptoms of depression in high-risk adolescents. *Health Technology Assessment (Winchester, England)*, 17(47), vii.
- Steinmo, M., & Rasmussen, E. (2018). The interplay of cognitive and relational social capital dimensions in university-industry collaboration: Overcoming the experience barrier. *Research Policy*, 47(10), 1964-1974.
- Taljaard, M., Weijer, C., Grimshaw, J. M., Brown, J. B., Binik, A., Boruch, R., ... & Saginur, R. (2009). Ethical and policy issues in cluster randomized trials: rationale and design of a mixed methods research study. *Trials*, 10(1), 61.
- Taljaard, M., McGowan, J., Grimshaw, J. M., Brehaut, J. C., McRae, A., Eccles, M. P., & Donner, A. (2010). Electronic search strategies to identify reports of cluster randomized trials in MEDLINE: low precision will improve with adherence to reporting standards. *BMC Medical Research Methodology*, 10(1), 15.
- Tansey, C. M., Matté, A. L., Needham, D., & Herridge, M. S. (2007). Review of retention strategies in longitudinal studies and application to follow-up of ICU survivors. *Intensive Care Medicine*, 33(12), 2051-2057.

- Teague, S., Youssef, G. J., Macdonald, J. A., Sciberras, E., Shatte, A., Fuller-Tyszkiewicz, M., . . . Hutchinson, D. (2018). Retention strategies in longitudinal cohort studies: a systematic review and meta-analysis. *BMC Medical Research Methodology*, 18(1), 151.
- Tellis, W. M. (1997). Application of a case study methodology. *The Qualitative Report*, 3(3), 1-19.
- Thurmond, V. A. (2001). The point of triangulation. *Journal of Nursing Scholarship*, 33(3), 253-258.
- Trickett, E. J., Trimble, J. E., & Allen, J. (2014). Most of the Story Is Missing: Advocating for a More Complete Intervention Story. *American Journal of Community Psychology*, 54(0), 180-186.
- Urdu, T., & Schoenfelder, E. (2006). Classroom effects on student motivation: Goal structures, social relationships, and competence beliefs. *Journal of School Psychology*, 44(5), 331-349.
- Vaismoradi, M., Turunen, H., & Bondas, T. (2013). Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nursing & Health Sciences*, 15(3), 398-405.
- Wagner, E. F., Tubman, J. G., & Gil, A. G. (2004). Implementing school-based substance abuse interventions: Methodological dilemmas and recommended solutions. *Addiction*, 99(s2), 106-119.
- Walker, A. E., Campbell, M. K., & Grimshaw, J. M. (2000). A recruitment strategy for cluster randomized trials in secondary care settings. *Journal of Evaluation in Clinical Practice*, 6(2), 185-192.
- Weiner, B. J., Lewis, M. A., & Linnan, L. A. (2009). Using organization theory to understand the determinants of effective implementation of worksite health promotion programs. *Health Education Research*, 24(2), 292-305.
- Wells, M., Williams, B., Treweek, S., Coyle, J., & Taylor, J. (2012). Intervention description is not enough: evidence from an in-depth multiple case study on the untold role and impact of context in randomised controlled trials of seven complex interventions. *Trials*, 13(1), 95. doi:10.1186/1745-6215-13-95

- White, L. S. (2012). Reducing stress in school-age girls through mindful yoga. *Journal of Pediatric Health Care, 26*(1), 45-56.
- Witt, J. C. (1986). Teachers' resistance to the use of school-based interventions. *Journal of School Psychology, 24*(1), 37-44.
- Wyatt, K., Lloyd, J., Creanor, S., Green, C., Dean, S., Hillsdon, M., . . . Taylor, R. (2018). Cluster randomised controlled trial and economic and process evaluation to determine the effectiveness and cost effectiveness of a novel intervention [Healthy Lifestyles Programme (HeLP)] to prevent obesity in school children. *Public Health Research, 6*(1). doi:10.3310/phr06010
- Yin, R. K. (1994). *Case study research: design and methods*. Thousand Oaks, CA: Sage.
- Yip, J. C., Foss, E., & Guha, M. L. (2012). Co-designing with adolescents. In Designing Interactive Technology for Teens Workshop, NordiCHI, Copenhagen, Denmark. <http://www.chici.org/ditt2012/papers.html>.
- Yukl, G., Kim, H., & Falbe, C. M. (1996). Antecedents of influence outcomes. *Journal of Applied Psychology, 81*(3), 309.
- Zweben, A., Fucito, L. M., & O'Malley, S. S. (2009). Effective strategies for maintaining research participation in clinical trials. *Drug Information Journal, 43*(4), 459-467.

Appendices

Appendix 1 Database search strategy

Appendix 2 Characteristics of included studies

Chapter 3

Appendix 3 Persuasive messages element of the intervention and control lesson

Appendix 4 My Personal Plan element of the intervention and control lesson

Chapter 4

Appendix 5 Recruitment email for study coordinators (study 1)

Appendix 6 Participant background information sheet (study 1)

Appendix 7 Semi-structured interview schedule (study 1)

Appendix 8 Consent form (study 1)

Appendix 9 Summary of all Facilitating and Impeding Factors themes from the Thematic Analysis (study 1)

Chapter 5

Appendix 10 Information sheet (study 2)

Appendix 11 Consent form (study 2)

Chapter 6

Appendix 12 Original recruitment email (study 3)

Appendix 13 Original information sheet (study 3)

Appendix 14 Revised recruitment email with £10 incentive (study 3)

Appendix 15 Revised information sheet with £10 incentive (study 3)

Appendix 16 Interviewed teachers' lesson Cover Sheet ratings (study 3)

Consent form (study 3)

Appendix 17 Participant background information sheet (study 3)

- Appendix 18 Interview schedule (study 3)
- Appendix 19 Themes extracted from teacher Cover Sheets (study 3)

Chapter 7

- Appendix 21 Focus group information sheet for intervention schools (study 4)
- Appendix 22 Focus group information sheet for control schools (study 4)
- Appendix 23 Short information flyer for form tutors (intervention and control) (study 4)
- Appendix 24 Parental information letter for intervention schools (study 4)
- Appendix 25 Parental information letter for control schools (study 4)
- Appendix 26 Parental consent form (study 4)
- Appendix 27 Focus group schedule (study 4)
- Appendix 28 Results of content analysis of student feedback sheet comments (Study 4)

Chapter 8 – Engagement analysis

- Appendix 29 Flyer produced to share the Engagement Promotion Programme in schools (study 5)
- Appendix 30 Full Internal Consistency Reliability results for subscales within the 'Measure of Engagement' (study 5)
- Appendix 31 Degree of incentive utilisation by school characteristics (study 5)

Appendix 1: Database Search strategy

1	cluster analysis	MeSh term
2	small-area analysis	MeSh term
3	cluster*	Keyword
4	cluster randomi?ed trial	Keyword
5	cluster randomi?ed	Keyword
6	group randomi?ed	Keyword
7	community randomi?ed	Keyword
8	(randomi* or randomly) adj3 (group* or communit* or site* or district* or institution* or hospital* or ward* or unit* or clinic* or department* or facilit* or centre* or center* or school* or village*)	keyword
9	community adj3 intervention*	Keyword
10	level adj1 (cluster* or group* or communit* or site* or district* or institution* or hospital* or ward* or unit* or clinic* or department* or facility* or centre* or center* or school* or village* or organi?ation*))	Title
11	multi-centre or multi-center or multicent*	Title
12	multiple centre or multiple center	Title
13	multiple site or multi-site	Title
14	research adj1 (centre* or center* or site*)	Title
15	(cluster or study) adj1 site*	Title
16	stakeholder or gatekeeper	Title
17	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16	
18	attrition adj1 rate*	Title
19	attrition adj2 (minimi* or prevent* or lessen* or decreas* or reduc*)	Title
20	(dropout* or drop-out*) adj2 (minimi* or prevent* or lessen* or decreas* or reduc*)	Title
21	withdraw* adj2 (minimi* or prevent* or lessen* or decreas* or reduc*)	Title
22	difficult* adj2 (retain* or retention)	Title
23	retention adj1 rate*	Title
24	retention adj3 (strateg* or intervention* or method* or technique*)	Title
25	retention adj5 (increas* or encourag* or maximi* or promot* or influenc* or improv* or success*)	Title
26	compliance adj3 (strateg* or intervention* or method* or technique*)	Title
27	(increase* or maintain*) adj3 (engag* or participa* or compliance)	Title
28	strateg* adj2 (dropout* or drop-out*)	Title
29	strateg* adj2 attrition	Title
30	18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30	
31	17 and 30	
32	limit 31 to (English language and humans)	

Appendix 2: Characteristics of studies included in the systematic review

Reference	Study outline, participants.	Setting	Retention Strategies	Results
Berry, Neal, Hall, McMurray, Schwartz, Skelly & Smith-Miller (2012) USA	<p>Outline: Community weight management intervention. Nutrition and exercise education, coping skills training and exercise intervention.</p> <p>Control condition: wait list.</p> <p>Participants: Multi-ethnic, low SES elementary school children and their families (N=358 children; 358 parents).</p>	<p>Elementary schools with high ethnic diversity and 80-100% of students eligible for FSM.</p> <p>N=8 (across 2 school districts).</p> <p>But page 83 explains that 12 further schools were recruited to boost family and student numbers. Therefore it would appear that the total be 20 schools?</p>	<p>Orientation meetings and presentations: Enlisting superintendent support, feedback, access to schools & endorsement; presentations to all stakeholders -underlining benefits of participating, scope for questions, feedback on barriers; clarifying resources needed for study.</p> <p>Building relationships: Getting to know all levels of school staff who as a result self-initiated/chose to become informal study advocates/helpers. Personalised gifts and thank you notes to teachers who gave up their classrooms for the intervention, helped study staff clean up and lock up. Holiday newsletter to superintendents, principals, assistant principals, participants – also placed in schools staff lounge.</p> <p>Clear and consistent communication: Maintained amicable relationships with school administration and staff. Every semester, PI emailed both superintendents with update on study progress. Trial manager kept principals updated via personal phone and email contact.</p> <p>Staff training/supervision: Trial manager introduced field coordinators to school principals so they also felt comfortable providing them with updates. Underlined the importance of being familiar with the multiple levels within school systems and structure/hierarchies.</p> <p>Seeking feedback: Asked principals for suggestions on how to improve study activities.</p> <p>Incentives: Free exercise equipment for schools to keep. Wait-list control were promised these + intervention at end of trial.</p> <p>Highlighted benefits of participation: Free exercise equipment, free medical history and sports physical for parents and children, coping skills training, exercise sessions. [incentives for children and parents which may also be retention factor for school? \$20 each after each data collection, childcare & homework assistance for additional children accompanying parents, transport vouchers, refreshments].</p> <p>Succession planning: mindful of 25% turnover of principals, therefore met every new principal to explain the study and secure continued support of their school.</p>	<p>No specific retention figures provided for sites. However no mention is made of withdrawal, and the implication is that the strategies led to high retention / success rates.</p>

<p>Drews, Harrell, Thompson, Mazzuto, Ford, Carter, Ford, Yin, Jessup & Roullet (2009)</p> <p>USA</p>	<p>Outline: Multi-component intervention to reduce risk factors for Type 2 Diabetes. Changes in nutrition, physical activity, health education and promotion in school. Annual health screening over 3 years (2006-2009) to assess diabetes risk & other health problems.</p> <p>Control: not active. Data collection only. Materials & equipment at end of trial.</p> <p>Participants: Middle school students (6th through to 8th grade).</p>	<p>Middle schools with >50% ethnic minority representation (African American, Hispanic, American Indian) and >least 50% of students eligible for free or reduced price meals.</p> <p>N=42 (Six schools at seven centres: California, Maryland, Texas (Houston & San Antonio), Pittsburgh, Philadelphia, North Carolina).</p>	<p>Established recruitment & retention committee: To agree strategies and monitor.</p> <p>Met senior leaders and stakeholders (buy-in): PI and project coordinator in each centre met superintendents & other key figures at district level to provide overview of study [content not specified]. Presentation to school board, faculty & staff giving info on study & type 2 diabetes; sought feedback from principal re possible barriers & how to overcome. Meetings with food service manager and PE department head.</p> <p>Clear study description and highlighted benefits: Video encouraging school faculty and staff to participate; study timeline for principals with key study steps; school staff brochure with study overview, FAQs, benefits.</p> <p>Formal letter of understanding/participation agreement: Underlined commitment to study and need to comply with procedures even if personnel changes, agreement to randomisation, accommodating data collection.</p> <p>Created partnerships/relationships with faculty & staff: Regular meetings with school officials & teachers. Rapport. Aware control schools received much lower levels of contact than intervention schools: maintained personal contact with principal/ other officials to thank, reinforce importance of ongoing participation, & seek ideas to improve data collection. New year cards to faculty & staff and periodic personalised gestures: thank you notes, gifts & snacks at meetings.</p> <p>Staff characteristics and training: Good communication skills. Training on local culture & customs. Developed "heightened awareness of school culture and knowledge of possible pitfalls".</p> <p>Incentives: Staff T-shirts, study logo lanyard. Increasing monetary incentive: Intervention– Y1=\$2000, Y2=\$3000, Y3=\$4000; Control- Y1=\$2000, Y2=\$4000, Y3=\$6000.</p> <p>School-specific summary reports of student data collection results: sent to school administration and superintendents.</p> <p>Reminders/Alerts: Letter to faculty & staff re upcoming data collection dates & thanking for cooperation. Posters advertising data collection, notices in school newsletters, bulletins, school-wide communications.</p> <p>Assured of low burden: Showing faculty & staff how study procedures fit into school calendar, accounting for testing, holiday and other events.</p>	<p>100% retention of the 42 enrolled schools. None withdrew.</p>
---	---	--	---	--

<p>Hindmarch, Hawkins, McColl, Hayes, Majsak-Newman, Ablewhite, Deave & Kendrick (2015)</p> <p>UK</p>	<p>Outline: Fire-related injury prevention trial. Injury Prevention Briefing comprising guidance and exercises for use by children's centres to prevent fire-related injuries in pre-school children. Children's Centre staff supported recruitment and delivered materials. Researchers (NHS trusts and Universities) monitored and supported delivery and collected follow-up data.</p> <p>Control condition: normal practice on providing safety interventions, then provided with Injury</p>	<p>Children's centres at 4 English locations (Nottingham x9, Norwich x9, Newcastle-upon-Tyne x9, Bristolx9) N=36. 30 families per centre.</p>	<p>Pilot work: With sample of children's centres – to test questionnaires, user feedback on acceptability, usability; seek staff views on potential barriers and facilitators to this type of intervention.</p> <p>Visits to interested sites for information-giving sessions: Researchers followed up expressions of interest (after letters issued) with information-giving session [content not specified].</p> <p>Established strong relationships with CC staff: prior to intervention and developed during the study. Allowed researchers to keep close contact & monitor delivery and fidelity. Met CC managers in month before randomisation to describe study and explain how fitted with on-going injury prevention work. Reinforced commitment of CC staff by discussing how delivery of intervention would work in their CCs.</p> <p>Collaborated with Children's Centres (CC) staff: CC staff piloted questionnaires & collected feedback from parents on style etc. CC staff were interviewed across 4 study sites about barriers & facilitators to implementing health promotion & injury prevention interventions. Increased ownership for delivery and researchers' understanding of environment, context & parents, to take their needs into account.</p> <p>CC staff as research champions: staff had inside valuable knowledge which was harnessed, e.g. identified which parents should/not be approached, encouraged parental engagement with intervention, chose to give informal support (e.g. refreshments & crèche to encourage attendance). Delivered intervention & reported on trial activity.</p> <p>Regular communication: Phone calls with CC staff at 1,3, 8 & 12 months to collect activity logs, discuss attendance, reinforce trial importance.</p> <p>Study identity/branding: used on all envelopes, communications and trial documents.</p> <p>Minimised burden: Ensured the study routine was flexible and convenient for staff (and families).</p> <p>Clear study description: Highlighted obligations/what to expect re data collection, delivery and reportage of conditions.</p> <p>Highlighted win: win (also meets a CC need): intervention could support their usual health promotion activities (also minimising burden? Aligning goals?)</p> <p>Incentives: CC's received £25 gift voucher at end of participation. Enhanced Intervention arm also given contacts for local resources to support usual practice (e.g.</p>	<p>100% retention of Children's centres. All but one site returned all trial questionnaires over 12 month follow-up. That site did not return at 8 months, citing organisational restructure & staff pressures. Research staff support and reassurance led to CC remaining with the study and subsequently returned questionnaires at 12 months.</p>
---	--	---	---	--

	<p>Prevention Briefing materials at the end of the trial.</p> <p>Participants: 1080 families with pre-school age children in disadvantaged areas in England.</p>		<p>DVDs). Intervention only received the materials/intervention; control arm received intervention materials after final data collection.</p>	
<p>Leatham, Cupples, Byrne, O'Malley, Houlihan, Murphy & Smith (2009)</p> <p>UK & Republic of Ireland (RoI)</p>	<p>Outline: SPHERE cluster RCT – 2 year trial of a tailored intervention to enhance secondary prevention of Coronary Heart Disease within primary care/GPs. Randomisation at the practice level. Trialled in 3 regions: 1 in Northern Ireland; 2 in West & East RoI. Training was provided on intervention (2 x 90 minute sessions) and on standardised clinical measures</p>	<p>General Practices N=48</p>	<p>Pilot work: Intervention was piloted in a sample of 4 general practices, and included qualitative evaluation with practice staff, research nurses and patients. Highlighted issues such as the need for clearly structured protocol and the value of phoning practices to improve sign up to the study. Research Nurses observed sessions and noted patients' feedback/comments.</p> <p>Study champions: A key contact was nominated at each practice; the Research Nurse liaised with them as a focal point to streamline tasks/communication.</p> <p>Clear study description: If a practice was interested after an initial phone call from Research Nurse, a follow-up letter was issued with an information sheet detailing anticipated workload, randomisation process and the degree of patient involvement. Those still interested 10 days later were visited at lunchtime for convenience by research nurse to share details of project, deal with questions/ concerns. All staff invited. Practices signed a formal agreement (form) to indicate commitment to the study. Received a welcome letter. Practices received (1) SPHERE manual containing protocol and detachable A4 laminated cards with appealing visual representations of required consultation steps (2) A4 laminated, colour-coded sheet of reference medications to support accurate recording of patients' current medications.</p> <p>Incentives: £700 after recruitment phase per practice to cover time and recompense for allocating resources to the study (e.g. phoning patients, use of room for data collection).</p> <p>Staff characteristics: Research Nurses were rated highly by staff for their support, warmth, approachability, reassurance/ encouragement – and for being easily accessible and responsive to their needs.</p>	<p>100% retention of general practices.</p> <p>85% retention of patients</p> <p>Over 18 month trial.</p>

	<p>to collect data. Two baseline quality assurance observations were conducted by research nurses to provide support and ensure staff followed protocol correctly.</p> <p>Control: Unclear. It is just stated that intervention practices received more support for retention due to necessity – therefore implies not an active control. Data collection only?</p> <p>Participants: 903 patients.- eligible if some degree of CHD diagnosis, e.g. angina, prior acute myocardial infarction, coronary artery bypass graft.</p>		<p>Established strong, supportive relationships with staff (visibility): Before first patient consultation, Research Nurses offered high degree of practitioner support: visited to discuss consent; provided training in collecting baseline data using required standardised clinical measurements, for implementing the intervention (2x90 minutes, delivered in practices at convenient times); conducted two baseline quality assurance/fidelity observations in the early phase of the study to ensure staff were delivering correctly. Shared supportive feedback, discussed concerns. Regular communication: The nurses sustained regular contact with both practices and patients involved, through site visits and by phone.</p> <p>Tailoring/personalisation: Through regular phone calls and visits, Research Nurses provided personalised support for different needs of staff and patients.</p> <p>Minimise burden: Each practice was provided with – (1) a red storage box to keep all study-related materials in one place; (2) a handfile for trial paperwork. The Research Nurses picked up any admin duties when on site to ease staff burden and followed up patients who did not attend. They retrained any new staff and provided ad-hoc support as required.</p> <p>Tracking / monitoring /reminders: A ‘Practice Care Plan’ was created on which were recorded results of quality assurance observations, details of follow-up consultations and any issues – copy kept at the site and the research centre. All activity with a site was recorded on database, along with quality assurance visit results. Research Nurses rang site staff 2 weeks before patient appointments as a reminder, and to discuss any concerns/questions. Feedback from the quality assurance observations was sent to the Project Manager who shared highlights/learning via a newsletter (intervention sites only) to enhance smooth running of the intervention.</p>	
--	---	--	--	--

<p>Lloyd, McHugh, Minton, Eke & Wyatt (2017)</p> <p>UK</p>	<p>Outline: Multi-component, 4 phase Healthy Lifestyles programme (HeLP) to encourage healthy lifestyles. Targeting (1) decreasing consumption of fizzy drinks; (2) increasing ratio of healthy to unhealthy snacks eaten; (3) reducing screen-based activities.</p> <p>Participants: 1324 Year 5 students (age 9-10) across one academic year.</p>	<p>Primary schools</p> <p>N=32</p>	<p>Established Project Advisory Group (informal champions): teachers, headteachers, children, parents. Regular meetings- expenses paid, cover time paid for teachers, convenient times (4-6pm). Advised on: (a) feasibility & acceptability of proposed measures; (b) best way to communicate with & engage parents about the study; (c) recruitment & engagement of schools & teachers [e.g. headteacher advised tapping [i] a regional network of primary school headteachers during quarterly briefings (attended x2 of these & a teacher member of advisory group shared her experience of being involved) and [ii] Academic Learning Partnership meetings - clusters of approx 8 headteachers in particular locations (attended x2). Teachers & parents invited to be partners on research bids. Co-design of intervention/ feedback. Advice on person specification for school study coordinators and supporting recruitment.</p> <p>Highlighted win:win (also meets a school need): Intervention activities fitted in with PSHCE National curriculum.</p> <p>Pleasurable: Activities designed to be fun, active input from children.</p> <p>Flexibility/tailoring: Components could be adapted slightly to better fit the context of the school, respond to child's needs.</p> <p>Minimised burden: Mainly non-school staff delivered intervention components. Envelopes, stamps, address labels for school admin staff to communicate with parents. HC offered support with tasks. Parent correspondence translated if high proportion of English as 2nd language; adaptations made for visual impairments.</p> <p>Optimised engagement with intervention: co-created with PAG who gave feedback on activities, delivery methods to ensure acceptability & feasibility. PAG advised on necessary skills for intervention staff (see study personnel). HC met with teachers to discuss study ahead of distributing parental packs. Teachers encouraged to observe sessions to promote engagement. HC regular email updates with teachers; Information Flyer created for teachers.</p> <p>Study personnel: PAG underlined need for quality delivery by personnel able to engage school staff, children and families. Having <i>one key contact</i> person to help build relationships with <i>necessary skills and competencies</i> & understand teachers' busy lives. Therefore recruited HeLP Coordinators (HC) & assigned specific schools for continuity.</p> <p>Building relationships: 'At the heart of the intervention delivery'. HC contact details on all correspondence and contact details, photo in school reception, available to meet with parents if concerns/questions.</p>	<p>Retention rates given for the students (6% at 24 month follow-up), not school level.</p>
--	---	---	--	---

			Succession planning: HC contacted Year 6 transition staff at students' transitional secondary schools to ensure aware of study & info leaflet provided. Information leaflet given to non-trial schools that received trial children during course of study so were aware researchers needed to see these children at follow-up.	
Markoe Hayes, Chapple & Ramirez (2014) USA	Outline: After-school teenage pregnancy prevention program to empower girls to be "strong, smart and bold" through knowledge and activities (e.g. role playing assertion). Weekly, 90-minute sessions (5-20 students), over 11 weeks. Delivered by trained staff / program specialists Control condition: 'economic literacy' curriculum. Participants: 517 females: Cohort 1 N= 373	Middle and high schools serving disadvantaged communities in Los Angeles (identified using FSM data). Total number of participating schools = unclear, (Are cohort 2 from some of the same schools as cohort 1?). <u>Range:</u> 6-10 middle schools 6-9 high schools	Major stakeholder meetings: monthly calls past 3 years with funder (Office of Adolescent Health, part of Dept of Health & Human Services), its technical assistance contractor (Mathematica Policy Research), program staff (Volunteers of America, Greater Los Angeles - VOALA-girls inc), implementers and 3 rd party evaluator (Advanced Empirical Systems who collected data to evaluate). [But schools were not listed as being involved in these – unless the term "implementers" means school staff trained to deliver]. Identified primary contact person at each school: Whilst arranged previous academic year, high turnover rates meant they'd moved on. Researcher presence in school & establishing relationships with staff therefore more critical. On-site presence/visibility: Recruitment & retention poor in cohort 1. Program specialists were mostly off-site until arriving to deliver session, so unaware of school changes that made delivery difficult, often found classroom cancellations, had to find new classrooms last minute, unable to communicate with the girls, girls forgot. Decision taken in Cohort 2 for program specialists to prepare on site so were present more. Fostered buy-in: providing schools with clear expectations about program delivery process and needs. Emphasised to school staff the importance of girls returning to the program weekly & of their support. Building relationships with school personnel: Being on site helped research team build stronger relationships with school personnel. Then school staff displayed greater buy-in by helping with recruitment of girls and providing communication to students for implementation days + data collection. Collaboration more successful – able to be more responsive and flexible to needs. Providing regular program updates to school principals, administrators, staff to ensure feedback loop to share delivery status, challenges & successes.	School level data not provided. Cohort 1: 50% high school students; 48% middle school students. Cohort 2: 66% high school students; 65% middle school students.

	(6 middle schools [age 10-12]; 6 high schools [age 14-16]) <u>Cohort 2</u> N=144 students (4 middle schools; 3 high schools).			
Pinto, Witte, Wall & Filippone (2018) USA	Outline: Project ICI – Inter-professional Collaboration Implementation. A 5-year study to improve HIV prevention service provision by enhancing inter-professional collaboration between service providers through training (Counsellors, program workers, educators, supervisors) in non-profit agencies. Training in collaborative practices to spark inter-professional collaboration in resolving daily	Non-profit HIV Prevention Service agencies N=36	<p>Established Community Collaboration Board: uni researchers, providers (i.e. counsellors, supervisors, program workers, educators, supervisors), managers & consumers/service users. Involved in: developing grant which funded research, designing inter-professional collaboration skills training, co-design of survey questions, developing new recruitment & retention strategies. Met monthly, 2 hours, expenses paid & compensated for work outside meetings (e.g. drafting surveys, protocols). Discussion, support, problem solving to enhance project delivery & respond to potential recruitment & retention barriers.</p> <p>Social gatherings to secure stakeholders’ buy-in: Brunches, community-focused events, ensuring time to talk personally with agency personnel about opportunities study would bring, practical concerns about time commitments, share study goals & methods.</p> <p>Start with who you know: Began with agencies where had closest links (past collaborations or ICCB member worked there), then further session with less familiar agencies.</p> <p>Study champions: ICC board members attended stakeholder events & endorsed research, used own experience of being involved, supported or delivered presentations about project aims/methods. Dissemination events - keynote addresses with senior influential figures (e.g. Division of Aids research at the NIMH), endorsing and validating work.</p> <p>Ensured study was low burden: reassured agency representatives that participation would be low impact/burden. Research team went to agencies for data collection, convenient times for agencies/provider, saw multiple providers at each visit, 1 hour max each person.</p> <p>Identified a “point person”: each agency nominated a person to act as coordinator to schedule interviews and obtain internal approvals.</p>	<p>36 agencies retained over 5 years (although 2 pairs of agencies merged, so actual = 34)</p> <p><u>In depth interviews</u> 100% of participants taking part in in-depth qualitative interviews (n=20).</p> <p><u>Overall survey</u> 67.5% baseline-to-24 months: N=379 at baseline N=285 at 12 months N=256 at 24 months</p>

	<p>challenges. Baseline & follow up surveys with all staff (face-to-face interviews), 12 and 24 months post training– in depth qualitative interviews with subsample of 20. Capturing post-training changes in inter-professional collaboration and delivery of HIV-prevention services. Training between baseline and 12 months follow-up.</p> <p>Participants: 250 providers in 36 non-profit HIV prevention services New York City.</p>	<p>Flexibility/tailoring: Agencies struggled to release staff for 1 day training, or individuals cancelled due to illness/personal commitments. Responded flexibly by scripting and shooting a video version of the training.</p> <p>Modifying incentives: Point person given incentive for facilitating recruitment for 12 & 24 follow-up surveys in the agency. Doubled the incentive paid at 12 months at the 24month point. Social workers attending dissemination event were eligible for 6 hours CPD.</p> <p>Staff characteristics: Tenacity, resilience, empathy of researchers – sometimes turned up and provider ill, or called away to deal with crisis, rescheduling interviews not uncommon. Non-return of emails, calls from point person. Understanding people already burdened and handling empathically.</p> <p>Developing comprehensive record keeping: google calendar for appointments, standardised checklist for data collectors (+ training in its use), notes on data collection for each agency and providers, receipts for incentives. Supported fluid workflow. (Plus -see succession planning).</p> <p>Succession planning: Comprehensive record keeping helped when experienced researcher turnover - expected in longitudinal studies.</p> <p>Giving back to the community: respecting those who give their time to be involved in research, giving back to them. Three strategies:</p> <p><u>(1) Appealing to altruism¹ and stressing project benefits</u> – Making explicit the alignment of research & community goals. Drawing on loyalty and commitment to improve services/care for its users. Consistently underlined importance of reminding agencies & participants of all benefits of taking part & chance to impact lives of HIV community, through research staff training/ supervision. This enhanced personal benefits - individuals were motivated to be “part of the solution”.</p> <p><u>(2) Offering training as incentive</u> – i.e. the intervention: Served as an engagement tool, meeting a need within community of agencies & study providers.</p>	
--	---	--	--

¹ Altruism was also highlighted in NHS staff interviews within Brueton, Stevenson et al. (2014) qualitative paper: NHS staff felt that some participants signed up to participate to give the NHS something back for the treatment they had experienced. Not a retention strategy as such, but researchers could draw upon this when making inspirational appeals to take part – at individual- and site-level retention.

			<p>(3) Sharing research findings with the community – disseminating findings through different media, making available for service providers, managers, stakeholders and policy makers to use. Hosted 6-hour dissemination symposium to bring together community members, providers, administrators, researchers, participants. Social activities & refreshments, networking, comparing/contrasting experiences. Keynote addresses with senior influential figures (see above) endorsing and validating work. “Member checking” findings, and understand future areas for research. Small group discussions on issues uncovered by findings, help interpreting findings. Research Magazine of U of Michigan School of Social Work highlighted symposium and was distributed to all participants and agencies.</p>	
<p>Schoeppe, Oliver, Badland, Burke & Duncan (2014)</p> <p>NZ & Australia Psychology, Health, medical applied sciences</p>	<p>Outline: Two stages: (1) Literature search 1990-2012 papers reporting effective recruitment and retention strategies in cross-sectional, longitudinal, behavioural community setting health intervention studies involving 3-18 year olds (N=45).</p> <p>(2) Delphi study with 27 public health researchers, internationally</p>	<p>Community settings: schools, child care centres, youth related organisations</p>	<p>Support from key stakeholders/project champions: identify key stakeholders (e.g. parents, schools staff, government departments); identify local advocates such as PE teachers/leads, GPs, social workers, community leaders, celebrities who may champion the study, to explain benefits and reassure participants about its importance; gain strong support from school principals.</p> <p>Consider formative research and piloting: to flush out potential pitfalls and to test out materials and approaches with target audience.</p> <p>Explain purpose, requirements and benefits of study participation: hold information sessions before and during data collection phases (convenient times & venues) using videos and slide shows; describe the benefits of taking part (e.g. fun, improved student health); distribute attractive and informative handouts (plain English/appealing terms) about the study.</p> <p>Gain signed consent from study partners (e.g. school principal, child care centre director).</p> <p>Create interest in the study: Show enthusiasm and use simple language when explaining the study purpose; demonstrate gadgets/equipment that will be used to spark interest – e.g. pedometers, smokerlyzers.</p> <p>Invest time in developing relationships with study partners: collaborate early in the study; invest in personal, face-to-face contacts with study partners; maintain open, transparent and flexible relationships, including nominated contact staff at sites; resolve any concerns or questions about the study; visit sites numerous times whilst recruiting (for visibility); maintain regular contact through visits, emails, postcards, study website, newsletters.</p>	<p>Not applicable.</p>

	<p>recognised (Australia, NZ, Asia, Europe, North America) in 2012 to agree best practice in recruiting and retaining children in behavioural health risk factor studies. (Heavily features community setting interventions and working with study partners – extracted these aspects).</p>	<p>Study personnel: Use staff who have connections with the community, who are known. Sense of humour. Fulfil any promises made (e.g. incentives, collecting data discretely, providing reports about findings).</p> <p>Good leadership & cohesive team: create a positive team culture, where everyone has clear responsibilities. Ensure continuity of staff for stability and trust. Provide training, manuals and checklists/quality control measures.</p> <p>Minimise burden to staff: ensure study protocol is easy to follow to avoid issues arising from parents/carers etc. E.g. ensure consent forms & info are easy to understand, informative and attractive; set up efficient, convenient ways of returning consent forms and other correspondence, e.g. through collection boxes or supporting admin staff in site; consider passive consent process; limit how many measures are taken; be mindful of total time, days of the week or time of day needed for activities to avoid clashes between important events/activities and study activities. use pre-stamped envelopes or pick up questionnaires/equipment from sites.</p> <p>Create study identity: create easily recognisable branding of project; use study/organisational logos on all written communications, posters, presentations etc; create study website; circulate appealing posters in setting/sites; have study staff wear logos on their clothing so easily identifiable/branded; circulate pens with logos on at recruitment events.</p> <p>Include a fun component: use gadgets; ensure interventions are enjoyable; make children feel like they own the research and are being part of a research team; create positive experiences e.g. provide positive reinforcement and ensure children feel safe and comfortable (e.g. being weighed).</p> <p>Provide incentives/rewards for supporting recruitment and implementation: offer gift vouchers, equipment, teaching materials, monetary compensations; feed into/guide school curriculum with data collection and study results.</p> <p>Provide feedback about study results: provide summary reports, presentations at sites.</p> <p>Use appealing study materials: use easy to read, visually appealing, professional-looking information/materials – translate if setting is culturally diverse.</p> <p>Establish optimal communication channels: notice boards, emails, meetings.</p> <p>Use extensive follow-up procedures: Explore reasons for non-participation (or failure to complete tasks etc) by talking to partners and if possible identifying barriers. Record contact details.</p>	
--	---	--	--


			Use participatory approaches throughout: involve the target audience/community in developing interventions, understanding and tackling barriers, seek their help and engage them in the study.	
--	--	--	---	--

Appendix 3: Persuasive messages element of the intervention and control

Intervention

Smoking Awareness Top tips from scientists

**Health Masterclass:
Appearance and Health**




Smoking: What would happen to your body?
Studies have found that smokers experience bad health and are less able to fight off illnesses and diseases. The following could happen to your body if you smoked:

- **Cold and flu:** You will be unwell for longer compared to non smokers because your body is not as healthy. Remember how you felt when you were last unwell? It's not a nice feeling ☹️
- **Eyes:** You may experience eyesight problems which can even lead to **blindness**.
- **Hair:** Your hair will become **thinner**, also men can lose their hair quicker.
- **Diseases and illnesses:** You will increase your chance of getting: **lung**, mouth and **stomach** cancer; **heart** disease and increase likelihood of having a **stroke** (where smoking affects blood going to the brain). Most smokers do not think they will get a smoking related disease but they increase their chances every time they smoke.

Yellow, stained and missing teeth
Action → Next time you look in a mirror think about how smoking could affect your teeth. Think about your teeth being yellow, stained and rotten. Also imagine having missing teeth... Smokers' tend to get gum infections which leads to tooth loss.

Yellow, stained finger nails
Action → Take a good look at your hands and finger nails. Imagine that they are stained and **yellow** in colour... This is what smokers get.

Unhealthy skin
Action → Next time you look in a mirror think about how smoking could affect your skin, imagine having unhealthy looking skin because of smoking. Smoking reduces the amount of oxygen in your blood which can cause **wrinkles**, spots (pimples), uneven skin tone and unhealthy looking skin. The signs of smoking affecting the skin start at a young age. See the below image of two twin sisters (half of each twins face has been placed together). Which twin is a smoker? Twin A is a non smoker and Twin B is a smoker.



Think it won't happen to you?
If you start smoking you will most likely think "I will" and "I can" stop when I want to, or before smoking affects my health. However most smokers think they will be able to quit after starting but then find it **very difficult** because smoking is **addictive**. Although cigarettes are available legally-they are still a dangerous drug. Over 6 million people die every year in the world from smoking -possibly people that thought "I will" or "I can" stop when I want to...

Page 1

ACTIVITY SHEET: Choose one option below to work on with your group

1 How does smoking affect the body?
Fill in all the missing spaces below.
Answers are highlighted in red on the 'smoking awareness' sheet



Please feel free to list any other smoking impacts on the body that you know of. If you have time answer the questions below.

Questions:

- Which of these smoking-related health problems did you know about and which are new to you?
- Which of these health problems seem the most concerning to you?

2 Why do people smoke when it causes lots of health and appearance issues?
List below 3 reasons and discuss how it's not a good reason to smoke. Present your findings to the class.


- _____
- _____
- _____

Control

Homework Masterclass

Revising for Tests

Top tips from scientists





Engage different senses Need to learn something for a test? Try to put the info into your brain in a few different ways.

Make colourful mind-maps, pin them up and keep reading them (your brain makes a visual memory)

Read your notes into a voice recorder and listen back to them (your brain makes an auditory memory)

The more memory types you have of something, the more links your brain has and the more easily it remembers the information.





Total Recall When it comes to memory, your brain can do two things:

Recognise information it's presented with.

Recall information from scratch.

Got to remember info from scratch for a test? Practice recalling it from scratch. Just reading your notes trains your brain to recognise info when it's in front of you. In a test you might not be able to bring it up. If you practice recalling it by writing it out or telling someone, you're training your brain to be far more brilliant - recalling info from scratch ☺




Your memory in action: brain neurons firing

Can you really multi-task?

Your generation is the most hi-tech generation ever – every part of your world is filled with computers and gadgets. Scientists have found that, while studying, most students switch between different media sources 13 times in one hour! So, the TV's on, you're plugged into your iPod, you're checking Facebook every few minutes... and all whilst you're revising for a science test.

But is it ok and helpful to multi-task? Studies show it **ISN'T**. Your brain isn't set up to do all these things at once. It has a limited amount of attention and can only think properly about one thing at a time. Your brain is actually *switching* or jumping from task to task and scientists find this switching causes poorer learning, more mistakes and takes you almost **TWICE AS LONG** to finish your work.

You'll get far more work done if you study for 45 minutes then break for 15 minutes to check Facebook or watch some TV. After 40-45 minutes of concentrating/work, your brain's abilities go down hill. Give it a 10 minute break, return to work and it'll jump back to peak concentration. You might be interested to know that scientists have found students who spend loads of time on Facebook get lower grades than those who don't.....



What can divers tell us about memory? A famous study on memory got divers to try to learn a list of words under water. They then tested how well the divers remembered the words afterwards. First they asked them to sit on the boat and recall as many of the words as they could. They did ok – but not brilliantly. Then they got them back underwater to see if they remembered more words down there – where they'd learned them. What do you think happened? The divers remembered **FAR MORE WORDS** under water (they wrote them on a waterproof whiteboard) than they did on the boat.

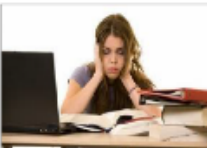
So what does this tell us? Your brain finds it much easier to recall information if your learning and recall environments are similar. So, if you have to recall information in a quiet classroom, at a desk, to pass a test, you'll remember better if you learn it in a quiet room, sitting up. Your brain uses the similarities in both settings (called "cues") to bring back the info more easily when you need it.

Page 1

ACTIVITY SHEET: Choose one option below to work on with your group

1 "Dani" – A Case Study

Dani is 13 and hates homework, but she has a History test next Thursday so knows she has to do some revision. On Wednesday night at 8.30pm she forces herself to sit down and do it.



The only way she can motivate herself is to have her iPod on with her favourite playlist, have Adventure Time on TV and lounge on the sofa. She has her History notebook in front of her and is trying her best to keep reading her notes over and over again. She sings along to some songs, glances up at the TV and keeps checking Facebook. But every now and again she's panicking inside....

1. What are your first thoughts on Dani's situation?
2. Using the information on the Revising for Tests page (p.1), can you identify 3 **unhelpful** strategies Dani's using?
3. Again, using the points on page 1, what changes might you suggest to help improve Dani's revision strategy?

2 Reviewing your own revision strategy

How good are you at revising? Use page 1 and the headings in the boxes below to help you evaluate your strategy. Note down any improvements you could make after today's lesson.

Good strategies	How I revise now	Poor strategies
What I'm going to do differently after today	How I can improve	Points on page 1 I found most interesting & why

Page 2

Appendix 4: My Personal Plan element of the intervention and control

My Personal Plan											
Now you've read the facts on smoking...											
To save yourself from the bad effects of smoking, will you make sure that you do not smoke this term? <input type="checkbox"/> yes <input type="checkbox"/> no											
How certain are you that you will not smoke this term? <table border="0"> <tr> <td>Very certain</td> <td>Certain</td> <td>Not sure</td> <td>Not certain</td> <td>Not at all certain</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>		Very certain	Certain	Not sure	Not certain	Not at all certain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Very certain	Certain	Not sure	Not certain	Not at all certain							
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>							
HOW could you refuse smoking this term?											
Tick ONE of the following things you could say if you were offered a cigarette or if you were tempted to smoke... <table border="1" style="width: 100%; text-align: center;"> <tr> <td><input type="checkbox"/> No thanks, smoking makes you smell awful</td> <td><input type="checkbox"/> No, I don't want yellow teeth</td> <td><input type="checkbox"/> No, I don't want to get addicted</td> <td><input type="checkbox"/> No thanks, if you're buying cigarettes you're buying cancer</td> <td><input type="checkbox"/> No it's really bad for my asthma</td> </tr> </table>		<input type="checkbox"/> No thanks, smoking makes you smell awful	<input type="checkbox"/> No, I don't want yellow teeth	<input type="checkbox"/> No, I don't want to get addicted	<input type="checkbox"/> No thanks, if you're buying cigarettes you're buying cancer	<input type="checkbox"/> No it's really bad for my asthma					
<input type="checkbox"/> No thanks, smoking makes you smell awful	<input type="checkbox"/> No, I don't want yellow teeth	<input type="checkbox"/> No, I don't want to get addicted	<input type="checkbox"/> No thanks, if you're buying cigarettes you're buying cancer	<input type="checkbox"/> No it's really bad for my asthma							
Now finish this statement → using your ticked option OR write your own if none of them suit you <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> *If someone offers me a cigarette, then I will say.. </div>											
WHERE can you make sure not to smoke this term?											
Tick ALL the places where you will not smoke <table border="0"> <tr> <td><input type="checkbox"/> I will not smoke at school.</td> <td><input type="checkbox"/> I will not smoke at home.</td> </tr> <tr> <td><input type="checkbox"/> I will not smoke at a party.</td> <td><input type="checkbox"/> I will not smoke with my friends.</td> </tr> <tr> <td><input type="checkbox"/> I will not smoke if I'm offered a cigarette.</td> <td></td> </tr> </table>		<input type="checkbox"/> I will not smoke at school.	<input type="checkbox"/> I will not smoke at home.	<input type="checkbox"/> I will not smoke at a party.	<input type="checkbox"/> I will not smoke with my friends.	<input type="checkbox"/> I will not smoke if I'm offered a cigarette.					
<input type="checkbox"/> I will not smoke at school.	<input type="checkbox"/> I will not smoke at home.										
<input type="checkbox"/> I will not smoke at a party.	<input type="checkbox"/> I will not smoke with my friends.										
<input type="checkbox"/> I will not smoke if I'm offered a cigarette.											
I think I can make sure I don't smoke this term: <input type="checkbox"/> Yes <input type="checkbox"/> No											
My Personal Plan											
Now you've read the facts on homework...											
Are you going to make sure you get maximum benefit and do all your homework this term? <input type="checkbox"/> yes <input type="checkbox"/> no											
How certain are you that you will do your homework this term? <table border="0"> <tr> <td>Very certain</td> <td>Certain</td> <td>Not sure</td> <td>Not certain</td> <td>Not at all certain</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>		Very certain	Certain	Not sure	Not certain	Not at all certain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Very certain	Certain	Not sure	Not certain	Not at all certain							
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>							
HOW could you get all your homework done this term?											
Tick ONE of the following things you could do to get your homework done.. <table border="1" style="width: 100%; text-align: center;"> <tr> <td><input type="checkbox"/> Do it the day I get it so it's fresh in my mind</td> <td><input type="checkbox"/> Work backwards from when it has to be in and plan it out.</td> <td><input type="checkbox"/> Make it fun and reward myself when it's done</td> <td><input type="checkbox"/> Have my music on in the background or on headphones</td> <td><input type="checkbox"/> Work in a quiet place without distractions</td> </tr> </table>		<input type="checkbox"/> Do it the day I get it so it's fresh in my mind	<input type="checkbox"/> Work backwards from when it has to be in and plan it out.	<input type="checkbox"/> Make it fun and reward myself when it's done	<input type="checkbox"/> Have my music on in the background or on headphones	<input type="checkbox"/> Work in a quiet place without distractions					
<input type="checkbox"/> Do it the day I get it so it's fresh in my mind	<input type="checkbox"/> Work backwards from when it has to be in and plan it out.	<input type="checkbox"/> Make it fun and reward myself when it's done	<input type="checkbox"/> Have my music on in the background or on headphones	<input type="checkbox"/> Work in a quiet place without distractions							
Now finish this statement → using your ticked option OR write your own if none of them suit you <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> *If I get some homework, then I will.. </div>											
WHEN will you make sure you do your homework this term?											
Tick ALL the times when you will do your homework <table border="0"> <tr> <td><input type="checkbox"/> When I get up in the morning.</td> <td><input type="checkbox"/> When I get home.</td> </tr> <tr> <td><input type="checkbox"/> In form time.</td> <td><input type="checkbox"/> After tea.</td> </tr> <tr> <td><input type="checkbox"/> At lunchtime at school.</td> <td><input type="checkbox"/> Weekends.</td> </tr> </table>		<input type="checkbox"/> When I get up in the morning.	<input type="checkbox"/> When I get home.	<input type="checkbox"/> In form time.	<input type="checkbox"/> After tea.	<input type="checkbox"/> At lunchtime at school.	<input type="checkbox"/> Weekends.				
<input type="checkbox"/> When I get up in the morning.	<input type="checkbox"/> When I get home.										
<input type="checkbox"/> In form time.	<input type="checkbox"/> After tea.										
<input type="checkbox"/> At lunchtime at school.	<input type="checkbox"/> Weekends.										
I think I can get all my homework done this term: <input type="checkbox"/> Yes <input type="checkbox"/> No											

Intervention

Control

Appendix 5: Recruitment email for key contacts (Study 1)

Recruitment email – Key contacts to Semi-structured interview

Key subject heading:

Smoking Prevention Study: firming up annual review meeting (& informal research interview?)

Main body message:

Dear [key contact's first name]

I hope all is well. I'm writing to set up our annual meeting to review how the study has gone this year, and to plan for next year. I wondered this time if you'd also consider extending our usual meeting by 20-30 minutes to answer some questions about your role in school with our study.

What would be involved?

As the key liaison between school and our university, your role is vital to the success of the study. I have a series of 5 questions I'd like to ask you (with some follow-up questions). I'm very interested to learn more about your perspective – to understand what support you get in school, how easy/difficult it is to manage the study in real life and to see what I can do to make things easier for you. I only need to ask you these questions once – this wouldn't be an annual event.

If you're happy for me to do so, I'd like to audio-record this short, informal interview. This frees me up from taking notes so I can pay more attention, and enables me to analyse your responses afterwards for key themes and compare these with key contacts in other schools/academies. All names will be changed so people and schools will not be identifiable.

The findings will enable me to:

- understand some of the common issues/challenges you face
- make more of any particular benefits and strengths you've experienced
- improve the running of the study

Ultimately, this should give us greater chance of success with the study.

Further details?

Further details are provided in the attached Consent Form, which we'll complete if you decide to take part. As ever, please feel free to contact me if you have any questions or concerns. I look forward to hearing from you.

With very best wishes

Ruth Simms-Ellis

Lead Researcher – Smoking Prevention in Young Adults

Institute of Psychological Sciences

University of Leeds

This research has been passed by the Institute of Psychological Sciences Ethics Committee at the University of Leeds (ref no: 14-0113; date approved: 09-June-2014). The Principal Investigator is Ruth Simms-Ellis (R.Simms-Ellis@leeds.ac.uk, 0113 34 31800). Professor Mark Conner is the lead supervisor (M.T.Conner@leeds.ac.uk, 0113 34 35720). Both are based in the Psychology Building, Lifton Place, University of Leeds, LS2 9JT.

Appendix 6: Consent form (Study 1)

Participant Consent Form: Semi-structured Interview

I have read the emailed information about the semi-structured interview and am aware of what my participation will involve.

I understand that:

1. My participation is voluntary and that I may withdraw at any time without giving a reason.
2. The recording device containing the interview will be held confidentially and securely, only accessed by the lead researcher.
3. Once uploaded the audio file will be deleted from the recording device and stored on the lead researcher's password protected-computer, with a numerical file name e.g. "Interview 1".
4. All names I mention in the interview will be changed during transcription of the recording to preserve anonymity (e.g. my own, colleagues', students', school).
5. My name and other identifying details will not be shared with anyone.
6. The overall findings may be submitted for publication to a scientific journal or presented at scientific conferences, which may contain anonymised extracts from the lesson.
7. My transcribed data will be kept in a locked filing cabinet for a period of at least two years after appearance in any associated publications.


All questions I have about the research have been satisfactorily answered.

I would like to take part in the interview group.

Participant's signature: Date:

Participant's name (please print):

Please note that this form will be kept separately from your data so you are not identifiable.

If you would like an Executive Summary of the research findings (in 2017 at the end of the study), please provide an email address here: 

This research has been passed by the Institute of Psychological Sciences Ethics Committee at the University of Leeds: (ref no: 14-0113; date approved: 09-Jun-2014). The Principal Investigator is Ruth Simms-Ellis (R.Simms-Ellis@Leeds.ac.uk, 0113 34 31800). Professor Mark Conner is the lead supervisor (M.T.Conner@Leeds.ac.uk, 0113 34 35720). Both are based in the Psychology Building, Lifton Place, University of Leeds, LS2 9JT.

Appendix 7: Participant background information Sheet (Study 1)

Participant	1 2 3 4 5 6 7 8 9 10 11 12 13 (Researcher to circle)	M / F	Age Range		Years in Teaching	
1. What is your role in school?						
2. How long have you worked at the school?						
3. How many staff (approximately) work in school?						
4. How many times have you delivered the Smoking Prevention/Pro-homework lesson materials?		<input type="radio"/> Never (i.e. you are key contact/liaison only) <input type="radio"/> Once <input type="radio"/> Twice <input type="radio"/> Three times <input type="radio"/> Four times <input type="radio"/> More than four times				
5. Do you deliver other PSHCE lessons?		IF YES: What does this involve? (briefly) 				
6. What is your smoking status?		<input type="radio"/> Smoker <input type="radio"/> Non-smoker (formerly a smoker) <input type="radio"/> Non-smoker (never smoked)				
7. How familiar are you with the Smoking Prevention Study overall?						

This research has been passed by the Institute of Psychological Sciences Ethics Committee at the University of Leeds: reference number X (??/??/2014). The Principal Investigator is Ruth Simms-Ellis (R.Simms-Ellis@Leeds.ac.uk, 0113 34 31800). Professor Mark Conner is the lead supervisor (M.T.Conner@Leeds.ac.uk, 0113 34 35720). Both are based in the Psychology Building, Lifton Place, University of Leeds, LS2 9JT.

Appendix 8: Interview Schedule (Study 1)

Understanding key contacts' experiences of managing the RCT in school

Opening: Thank you for doing this – I know it's busy in school and I do appreciate it. Just to reassure you, I'll be changing all the names you mention and you'll remain anonymous too. There won't be any records kept from the interview with your name on them. First of all, I need to check you're clear about what's involved in the research and that you're happy to take part. Were you happy with everything you read on the Consent Form I sent you..? (deal with any questions). Great if you could just sign here (participant signs consent form). Thank you. The interview should take no more than 30 minutes – is that okay?

If the original contact from 2012:

Can we start with the early stages of the study..

1. What was your role in the school signing up to it?

Follow-ups/prompts:

- ☐ What initially sparked your interest in it?
- ☐ What made you want to sign up?
- ☐ How easy was it to secure Senior Leadership Team agreement?

If NOT the original contact from 2012:

I know you inherited this liaison role..

1. How did that come about?

Follow-ups/prompts:

- ☐ How happy were you to take on this role?
- ☐ What was the handover like?

2. What's it been like running the study in school?

Follow-ups/prompts:

- ☐ How supportive of the study has the Senior Leadership Team been? How has this affected the running of the study?
- ☐ How does the study fit into everyday workloads here in school?
- ☐ Which aspects have you found demanding / straightforward? Why?
- ☐ How much time each year would you say you give the study?

3. How easily do our lessons fit into PSHCE in school?

Follow-ups/prompts:

- ☐ What level of priority does the Head give PSHCE education?
- ☐ What reaction have you had from staff delivering the lessons? How has this impacted you?
- ☐ **If smoker, in Smoking condition and been delivering materials:** I see you're a smoker. I wondered, what does it feel like delivering the anti-smoking lessons?

4. Do you think the school is experiencing any benefits from being in the study?

Follow-ups/prompts:

- ☐ Are we doing any particular things that you're finding really helpful?
- ☐ Are there things we're doing at the moment which are NOT helpful? What could we do to avoid this?
- ☐ What else can the team be doing to help you feel motivated and enjoy being in the study?

Ending: That's all my planned questions. Do you think there's any aspect of your experience of the study we've not covered? Thanks very much again for talking to me.

Appendix 9: Summary of Facilitating and Impeding Factors themes (Study 1)

Facilitating Factors Themes		Description	Total Instances
1. Trial Perceptions	1.1.1 It met an identified need in school	Being part of the study contributed to healthy schools award, it fit with local PSHCE curriculum or school has a smoking issue.	6
	1.1.2 Head teacher / SLT initiation or strong support	The head teacher or principal picked up the recruitment email and wanted it to go ahead; the Senior Leadership Team were enthusiastic and committed to proceeding when it was presented initially by the co-ordinator after the recruitment meeting.	6
	1.1.3 Noble, novel or valuable educational experience	Some schools decided to take part because they saw the bigger picture and wanted to contribute nationally to helping reduce teen smoking; others felt it would be a novel and interesting experience for students and staff to take part in; others thought the process of being in a study was educational in itself.	5
	1.1.4 Receiving school smoking statistics	Schools felt this data was highly valuable and desirable for use with future year groups, and for planning local PSHCE provision in the future. Following and receiving data on the smoking habits of an entire cohort through their high school years was seen as unprecedented and unique.	4
	1.1.5 Social proof	Schools took part because they saw which other schools had signed up in the locality. E.g. "it must be worthwhile" or "if they're doing it, we definitely are"; "we don't want to miss out".	3
	1.1.6 Personal experience of cancer	The initial staff member who picked up the recruitment email and met the researcher had been affected by a loved one who had smoking-related cancer.	3
	1.1.7 Establish links with local university	Such links were valued by a number of schools, for "aim higher" initiatives in more deprived communities, for the support they could access, and also for the prestige, kudos/credibility associated with working with Universities.	2
	1.1.8 Welcome meeting with researcher: confirmation and reassurance "of value"	For new coordinators inheriting the role, initial concerns were assuaged following the 30 minute welcome meeting with the researcher. The meeting outlined the rationale for the study, the aims/design, clarified the stages involved, confirmed the other schools taking part and reassured about the support available. The researcher left the coordinator with a folder and laminated flow chart.	2

	1.1.9 Formal, positive handover from the outgoing co-ordinator	When the new co-ordinator started the role, they had experienced a clear, supportive handover from the outgoing coordinator.	1
2. Organisational / contextual level	2.1.1 Strong senior leadership support for the study	Coordinators find having strong leadership backing helps their and the study profile in school, helps key stages in the study take place, and contributes to their feeling the role is worthwhile.	8
	2.1.2 Team cohesion & colleague support	Coordinators find it invaluable when they can call on and rely on colleagues to support the study and ensure the tasks are completed as required. This reduces feelings of isolation.	8
	2.1.3 Co-ordinator has high degree of control	Coordinators had most control where they were members of the Senior Leadership Team themselves (e.g. Assistant Head teachers; Heads of Year) or leaders of PSHCE. This gave them flexibility to make things happen, rather than relying on other people's decisions or authorisations.	7
	2.1.4 PSHCE is a priority	Coordinators who describe their schools as committed to PSHCE generally had fewer challenges. The study was accepted and supported more.	5
	2.1.5 Dedicated regular PSHCE timetable slots	Where PSHCE lessons have regular timetable allocation in school, the coordinator seems to find the study easier to accommodate.	4
	2.1.6 Consistency of staff delivering (especially if PSHCE staff)	If the same staff continue to deliver the lessons across the duration of the study, less work is needed by the coordinator: the co-ordinator does not need to plan teacher training each academic year, or persuade/cajole new staff to deliver the lessons. Staff delivering are also familiar with the process and are more likely to feel involved, which reduces the isolation that can be felt by the coordinator. This is particularly straightforward if the teachers are dedicated PSHCE staff as they are committed to supporting this sort of work and are skilled in dealing with such issues with students.	4
	2.1.7 A good "fit" has been identified for delivering the lessons	Numerous coordinators have thought creatively about where the homework or smoking lessons (and the smoking data collection sessions) would most appropriately fit. This seems to minimise the feeling that extra things are having to take place, and minimises burden as timetable slots are already secured for these things. It can also appear more meaningful/seamless for the students.	4
	2.1.8 School values external links with university	Schools and staff who value the external links generally were more open, supportive and flexible when it came to the implementation side of the research. This was because they saw the overall end goal, and considered the	3

		project an important collaboration worth investing in.	
	2.1.9 The lesson structure/materials meet multiple needs (saving time)	Some coordinators are positive/assured that the study has additional personal benefit – it saves them time/effort because lesson plans are designed, materials are printed and they would have been designing similar sessions in their own time. They then feel lucky to have extra time “freed-up” which can be used for other things.	3
3. Personal level	3.1.1 Belief in and commitment to the study principles	Coordinators personally believe the study is a sound concept and worth supporting, e.g. ahead of delivery of the lessons, they meet with teachers delivering to explain the process.	10
	3.1.2 Drive, resilience and persuasiveness	Coordinators have determination to drive through the implementation of the trial. They deal well with set-backs or challenges (e.g. timetable changes, less than enthusiastic delivering staff) using flexibility or creativity. They use persuasion and other interpersonal approaches (e.g. chocolate bars in pigeonholes) to ensure tasks are completed.	9
	3.1.3 Valuing research and external links	Coordinators see the greater benefit/bigger picture of being part of the study – i.e. for their local communities and for young people generally. They see research as useful, important, beneficial and/or place value in making external links with university. They see benefits for their students (aspirations, experience, variety) and themselves personally (new ideas, source of support/information) or for the school's profile.	9
	3.1.4 Co-ordinating the trial is perceived as low burden	Coordinator perceives the study is easy to manage in school and takes little time annually to be involved.	8
	3.1.5 Oriented to process improvement & adding value	Coordinator makes a personal investment in improving the flow of the study in school, e.g. types up students' password prompts to make things easier for the staff delivering. Willingly meets with the researcher annually to review the year. Contributes to improving processes by reading staff feedback and offering ideas/suggestions to the researcher.	5
4. Trial process level	4.1.1 The organisational efficiency of the study	The processes within the study and how they are organised/implemented are considered positive. E.g. clear instructions, laminated tick-box flowchart of stages involved, materials pre-sorted into teaching pack folders. The cyclical nature of the study allows co-ordinators to self-manage, plan ahead and gives control.	8
	4.1.2 Working relationship with the researcher	Coordinators feel supported by the researcher, enjoy the contact/professional relationship and appreciate the flexibility (e.g.	6

		how and when data collection takes place) and purposeful communication (e.g. reminders).	
	4.1.3 Positive spin-offs are highly valued	Coordinators like the rewards/incentives – such as vouchers, workshops, advice, aspirational aspect for students, putting schools in touch with other professional contacts (e.g. Mindfulness, Young Minds).	6
	4.1.4 Students' pride in being in the study	Students are proud to be in the study, are enjoying the process and like to feel valued by external people.	6
	4.1.5 Pre-printed, quality resources	Coordinators appreciated not having to photocopy handout or ask teachers to copy. They liked the high quality, colour printing – this kind of handout is not typical in school due to expense of producing it.	6
	4.1.6 Researchers conducting staff training is helpful	When the researchers deliver staff training, this is beneficial for coordinators because it saves them time briefing the staff themselves, helps the staff to feel valued/involved by improving their knowledge and adds weight/kudos to the study. This also helps the co-ordinator because knowledge of the study is diffused (they are not a lone voice) and the teachers are more likely to follow the protocol correctly.	3
	4.1.7 Coordinating the study is a development opportunity	The study is seen as a development opportunity, chance to build profile, work with University and demonstrate leadership potential to the Senior Leadership Team.	3
	4.1.8 Observations are confidence boosting	When the researcher observes one of the lessons, and provides feedback this is found to be motivating and reassuring.	1
	4.1.9 Listening to and responding feedback	One coordinator believed it was valuable that the researchers try to take on board teacher feedback regarding the materials.	1
		Total Facilitating Factor Themes	159
Impeding Factors Themes		Description	Total Instances
1. Trial Perceptions	1.2.1 No handover or footprint from outgoing co-ordinator	Some coordinators had received no handover from outgoing coordinators, knew little/nothing about the study and found no documents or trace of the study in school.	2
	1.2.2 Reluctance/concern about the responsibility after not choosing the role	Some coordinators were concerned about whether managing the study was going to be difficult on top of an already large workload, and were aware of the national scope and responsibility involved.	2
	1.2.3 Not recognising a clear "fit" with plans in school	One coordinator could not see how the study could fit with existing commitments and curriculum.	1

2. Organ-bisectonal/contextual level	2.2.1 In-house planning / bureaucracy complexities	Securing timetable slots can be very difficult – for e.g. data collection sessions and lesson delivery. Timetabling gatekeepers typically have to be approached, and justifications provided for why changes need to be made. This took considerable time, and then other challenges emerged, such as school trips, staff absence, inclement weather, and other urgent priorities such as Ofsted, mean that protected study timeslots are lost, and everything goes back to the drawing board.	5
	2.2.2 Poor morale; overwork	Some coordinators struggle to get the lessons delivered, but they understand how pressurised their colleagues are. They find themselves feeling guilty that they are putting more pressure on them and may for example, give small gifts to say thank you.	4
	2.2.3 Senior Leadership Team do not actively support	Numerous SLTs are unaware of the study; some make some accommodations but are not directly supportive; others tolerate it. Without this support or weight, lower ranking coordinators often find they do not have sufficient authority to (a) secure timetable slots for the smoking study; (b) inspire new staff to take on board delivering the lessons; (c) get staff to attend the training.	4
	2.2.4 Lack of team coherence, support and vision	Staff delivering the study may be working in silos, with colleagues who are unsupportive of the study, unhappy about attending training, delivering the lessons, late with delivering it or need lots of chasing to provide the coordinator with the completed materials.	2
	2.2.5 Isolation involved with leading the study; invisibility	Coordinators often feel that they are a lone voice, that they are receiving no acknowledgement or recognition for the work they are doing.	2
	2.2.6 Lack of specialist PSHCE staff to deliver	Some coordinators have different staff delivering at each timepoint, many of whom do not normally teach PSHCE or who do, but do not deliver PSHCE by choice and are not trained. This causes difficulties in terms of negotiating staff at each timepoint, getting them trained and feeling confident in the materials.	2
	2.2.7 PSHCE is low priority	Schools are focused mainly on academic subjects and PSHCE is not valued, given much timetable space, staffing or funding	2
	2.2.8 No perceived benefits	No benefits were apparent at this stage of the study.	2

	2.2.9 No timetable “fit” established: inconvenient extra to squeeze in	Where no clear curriculum “vehicle” has been identified for the study to slot into, co-ordinators find it difficult to plan in and find time to make the lessons and data collection happen.	1
	2.2.10 External links/opportunities with university not recognised/valued	Coordinators feel that where the senior leadership team and staff overall do not perceive the benefits of being linked to the University, there is a missed opportunity. This is demotivating and frustrating.	1
	2.2.11 Within-school variability in teacher-delivery of lessons	Some staff are enthusiastic; others go through the motions and this affects what students get out of the lesson.	1
3. Personal level	3.2.1 Feeling unsupported in PSHCE/healthy school endeavours	Coordinators feel unsupported in their work to improve student wellbeing and increase its profile on the curriculum. This leads to feeling frustrated, compromised in their ability to make a significant difference and resentful towards the Senior Leadership Team, because it feels shortsighted. They can also feel a sense of hopelessness and that they are not personally valued, which affects their morale. There is an element of contradiction/confusion – i.e. this is a valid role they have been given, yet it does not feel to be valid as not acknowledged/valued by SLT.	3
	3.2.2 Study not highly valued / not meeting expectations	Coordinator’s expectations are not being met by the study; they do not value participation highly.	1
	3.2.3 Perceived as a burden	The study is seen as one of many external bodies demanding something from schools. Workload is high and time pressures are keenly felt. The coordinator feels that the study takes too much time to engage with fully and would like it to take less time.	1
4. Trial process level	4.2.1 Lesson design: repetition, lack of variety and challenge	Coordinators were concerned about the repetitive nature of the intervention/control lessons and materials. They regularly received some negative feedback from the tutors regarding students growing tired of the process, and they were worried that the students would disengage. They requested more variety, time for discussion and exploration of issues.	9
	4.2.2 Inability to adapt the smoking/homework lesson	Coordinators confirmed that teachers expressed frustration at not being able to adapt the materials to meet the needs of their groups, or change the activities.	3
	4.2.3 Chasing up completed lesson material packs from teachers	Coordinators find it time consuming to chase up complete student plans from teachers who had delivered the lessons.	2

	4.2.4 Difficulties with timetabling slots to test an entire, streamed year group	Coordinators reported data collection was the most challenging aspect of the role. As students progress through school, it is difficult to find available timeslots to conduct this. SLT are increasingly reluctant to lose time from core subjects (maths, science, English). Also many students are streamed in different classes so this cannot be done lesson by lesson as some students may come twice to data collection or be missed.	2
		Total Impeding Factor Themes	52

Appendix 10: Information Sheet (Study 2)

Information Sheet

What is the rationale for the study?

Cluster RCTs are increasingly common in health-related research¹. Compared to non-clustered designs, they are also more expensive and complex². Cluster trials make many demands on researchers, particularly in terms of site **recruitment** and **retention**^{3,4} and their general **conduct**². Failure to reach **recruitment** targets in cluster RCTs is not uncommon: just 55% of trials in a recent review reached their recruitment target, almost half of which had been granted an extension to achieve this⁵. Once recruited, the ongoing engagement and **retention** of clusters within a trial is often precarious and drop-out is not unusual³. Drop-out can reduce power and introduce bias, particularly where different numbers result across trial arms³. Poor retention may require costly extensions to the trial, and if extreme, can lead to terminations⁴. **Conducting** trials across multiple clusters poses interpersonal challenges for researchers. From a position of little organisational power/control, they must try and influence stakeholders' adherence to trial protocol in organisations which are structurally, culturally and philosophically very different from their own research institutions.

The literature surrounding the retention of individual participants is emerging and growing, however we know far less about effective strategies to engage and retain cluster sites³. There is a need to develop our understanding of the barriers and facilitators to successful engagement and recruitment of cluster sites within trials and to expand the scope of the implementation science literature^{3,6}. This is the basis of my PhD and what you would be contributing to as a participant, should you decide to take part.

References

1. Campbell MJ and Walters SJ (2014) *How to design, analyse and report cluster randomised controlled trials in medicine and health related research*. UK:Wiley.
2. Christie J, O'Halloran P, Stevenson, M (2009) Planning a Cluster Randomized Controlled Trial: Methodological Issues. *Nursing Research* **58**(2),128-134.
3. Brueton VC, Stevenson F, Vale CL, et al. (2014) Use of strategies to improve retention in primary care randomised trials: a qualitative study with in-depth interviews. *BMJ Open* **2014**;4:e003835. doi:10.1136/bmjopen-2013-003835
4. Graffy J, Grant J, Boase S, Ward E, Wallace P, Miller J and Kinmonth AL. (2009) UK research staff perspectives on improving recruitment and retention to primary care research; nominal group exercise. *Family Practice* **26**: 48–55.
5. Sully BGO, Julious SA, and Nicholl J (2013) A reinvestigation of recruitment to randomised, controlled, multicenter trials: a review of trials funded by two UK funding agencies. *Trials*, **14**: 166
6. Treweek S, Altman DG et al (2015) Making randomised trials more efficient: report of the first meeting to discuss the Trial Forge platform. *Trials* **16**:261

Appendix 11: Consent Form (Study 2)

Study Title: The longitudinal engagement and retention of cluster sites within randomized controlled trials: what factors help and hinder according to trial research staff?

Participant Consent Form

For the use of an audio-recording of a project review meeting for research purposes.

The proposed change of use of the existing audio-recording has been clearly explained to me and I have had the opportunity to ask questions. I am aware of what my participation will involve.

I confirm and understand that:

1. My participation is voluntary and I will have the opportunity to read the meeting transcript and withdraw any of my material I do not want to be used in the research, without giving a reason.
2. The meeting audio file will be relocated from the research team's shared drive to the PhD student's personal, secure M drive, given a numerical file name and stored on her password protected-computer.
3. The meeting audio recording has already been deleted from the recording device.
4. All names I mention in the meeting will be changed during transcription of the recording to preserve anonymity.
5. My name and other identifying details will not be shared with anyone.
6. The overall findings may be submitted for publication to a scientific journal or presented at scientific conferences, which may contain anonymised extracts from the meeting.
7. My data will be kept in a locked filing cabinet for a period of five years after appearance in any associated publications.

All questions I have about the research have been satisfactorily answered.

I give my consent for the meeting material to be used for research purposes.

Participant's signature: Date:

Participant's name (please print):

Please note that this form will be kept separately from your data so you are not identifiable.

This research has been approved by the School of Psychology Ethics Committee at the University of Leeds (approved 9/11/2016, reference 16-0294). The lead researcher is Ruth Simms-Ellis (R.Simms-Ellis@Leeds.ac.uk, 0113 34 31800). Professor Anna Madill is the lead supervisor (A.L.Madill@Leeds.ac.uk, 0113 34 35750). Both are based in the Psychology Building, Lifton Place, University of Leeds, LS2 9JT.

Appendix 12: Original recruitment email (Study 3)

Recruitment email - Teachers telephone interview

Key subject heading:

Share your views on the smoking prevention study with health psychology researchers at the University of Leeds

Main body message:

Dear colleague

I'm writing to you as the lead researcher on the Smoking Prevention Study (2012-2016) because you've delivered our Anti-smoking/Pro-homework lesson materials to Year [7, 8, 9, 10 as appropriate] students in school.

Backed by the Medical Research Council/National Prevention Research Initiative, our goal is to design high quality lesson plans and materials to motivate students to do their homework/reduce smoking initiation in young people. Given your important role in delivering these on our behalf, your views on the materials and on your students' reactions to them are extremely valuable to us. Collecting your experiences from the field and sharing in your expertise at this stage will enable us to:

- enhance the design wherever possible
- increase student engagement
- identify factors crucial to the intervention's success

We would like to invite you to take part in a short telephone interview to help us understand how you, and the students, have found the lesson/materials and how you think we could improve them.

Further information can be found in the attachment to this email, and/or please feel free to contact me if you have any questions or concerns. I look forward to hearing from you.

With very best wishes

Ruth Simms-Ellis

Lead Researcher – Smoking Prevention in Young Adults

School of Psychology

University of Leeds

This research has been approved by the School of Psychology Ethics Committee at the University of Leeds (approved 25/11/2015, reference 15-0304). The Principal Investigator is Ruth Simms-Ellis (R.Simms-Ellis@Leeds.ac.uk, 07734 434 398, office 0113 34 31800). Professor Anna Madill is the lead supervisor (A.L.Madill@Leeds.ac.uk, 0113 34 35750). Both are based in the Psychology Building, Lifton Place, University of Leeds, LS2 9JT.

Appendix 13: Original information sheet (Study 3)

We would love to hear your views

Informal, short interview - Background Information

Our goal is to provide high quality lesson plans and materials which reduce smoking initiation in young people. To achieve this, it is crucial to consult with teachers delivering the materials in the field on our behalf. We would very much like to know how the lessons run, how the materials are received, and learn about any factors impeding or facilitating engagement with them. We would also value any suggestions for improvement you may have.

We would like to invite you to share your experiences with us, in a short telephone interview.

What is involved in the interview?

- Relaxed, informal 20 minute (max) discussion with the researcher leading the study.
- Arranging a convenient time (and private location in school with a telephone) when the researcher can ring and ask you about your experiences of: the materials, delivering the lesson, how the students respond, difficulties and opportunities that arise.
- Audio taping so the researcher can later analyse the discussion for key themes and compare with findings from other schools.

All information disclosed will remain confidential (it will not be revealed to other staff in school or Senior Leadership Team), and all names will be anonymised.

When could the telephone interview take place?

Any time that's most convenient for you, such as:

- After/before school
- During lunch period
- Within your non-teaching timetabled slots

Would you like further information?

Please contact Ruth Simms-Ellis by email or phone (see details below). I look forward to hearing from you.

This research has been approved by the School of Psychology Ethics Committee at the University of Leeds (approved 25/11/2015, reference 15-0304). The Principal Investigator is Ruth Simms-Ellis (R.Simms-Ellis@Leeds.ac.uk, 07734 434 398, office 0113 34 31800). Professor Anna Madill is the lead supervisor (A.L.Madill@Leeds.ac.uk, 0113 34 35750). Both are based in the Psychology Building, Lifford Place, University of Leeds, LS2 9JT.

Appendix 14: Revised recruitment email with £10 incentive (Study 3)

Recruitment email - Teachers telephone interview

Key subject heading:

Share your views on the smoking prevention study with health psychology researchers at the University of Leeds and receive a £10 LovetoShop voucher.

Main body message:

Dear colleague

I'm writing to you as the lead researcher on the Smoking Prevention Study (2012-2016) because you've delivered our Anti-smoking/Pro-homework lesson materials to Year [7, 8, 9, 10 as appropriate] students in school.

Backed by the Medical Research Council/National Prevention Research Initiative, our goal is to design high quality lesson plans and materials to motivate students to do their homework/reduce smoking initiation in young people. Given your important role in delivering these on our behalf, your views on the materials and on your students' reactions to them are extremely valuable to us. Collecting your experiences from the field and sharing in your expertise at this stage will enable us to:

- enhance the design wherever possible
- increase student engagement
- identify factors crucial to the intervention's success

We would like to invite you to take part in a short telephone interview to help us understand how you, and the students, have found the lesson/materials and how you think we could improve them.

In exchange you will received a £10 LovetoShop Voucher

Further information can be found in the attachment to this email, and/or please feel free to contact me if you have any questions or concerns. I look forward to hearing from you.

With very best wishes

Ruth Simms-Ellis
Lead Researcher – Smoking Prevention in Young Adults
School of Psychology
University of Leeds

This research has been approved by the School of Psychology Ethics Committee at the University of Leeds (approved 23/01/2017, reference 17-0020). The Principal Investigator is Ruth Simms-Ellis (R.Simms-Ellis@Leeds.ac.uk, 07734 434 398, office 0113 34 31800). Professor Anna Madill is the lead supervisor (A.L.Madill@Leeds.ac.uk, 0113 34 35750). Both are based in the Psychology Building, Lifton Place, University of Leeds, LS2 9JT.

Appendix 15: Revised information sheet with £10 incentive (Study 3)

Share your views with us and receive a £10 voucher

Information Sheet: taking part in a short research interview

Based in the School of Psychology at the University of Leeds, I am part of a team of Health Psychologists researching new ways of improving young people's health outcomes. Our research involves trying to understand how psychological, behavioural and cultural factors contribute to health and illness, and designing evidence-based interventions to enhance young people's health. We obviously share concern for student health and wellbeing with the nation's schools, so there is a strong case for universities and schools to work together on health research. We're mindful that we're very different sorts of organisations, with different priorities and demands, and such collaborations may not always be easy for schools to undertake. At the University of Leeds, we're actively trying to understand how to make such collaborations attractive, low-burden and rewarding for schools.

How can universities and schools work together better? Your school has worked with us for 4 years on the Smoking Prevention study, so your observations of being part of it are really useful. We'd therefore like to invite you to share your experiences with us, in a short telephone interview: what have you found interesting, enjoyable, beneficial or useful? What aspects have been difficult to relate to, hard to implement or dull? In exchange for your time and feedback, you will receive a £10 LoveToShop voucher.

What is involved in the interview?

- Relaxed, informal 20 minute (max) discussion with the researcher leading the study.
- Arranging a convenient time (and private location in school with a telephone) when I can ring and ask you about your experiences of: being in the study, the teaching materials, delivering the lesson, how the students respond, difficulties and opportunities that arise.
- Audio taping so I can later analyse the discussion for key themes and compare with findings from other schools.

All information disclosed will remain confidential (it will not be revealed to other staff in school or Senior Leadership Team), and all names will be anonymised.

When could the telephone interview take place?

Any time that's most convenient for you, such as:

- After/before school; During lunch period; Within your non-teaching timetabled slots.

Would you like further information? Please contact me, Ruth Simms-Ellis, by email or phone (details below). I look forward to hearing from you.

This research has been approved by the School of Psychology Ethics Committee at the University of Leeds (23/1/2017, reference 17-0020). The Principal Investigator is Ruth Simms-Ellis (R.Simms-Ellis@Leeds.ac.uk, 07734 434 398, office 0113 34 31800). Professor Anna Madill is the lead supervisor (A.L.Madill@Leeds.ac.uk, 0113 34 35750). Both are based in the Psychology Building, Lifford Place, University of Leeds, LS2 9JT.

Appendix 16: Interviewed Teachers' Cover Sheet Ratings and Comments (Study 3)

Total Cover Sheet Rating (out of 30) per Lesson Delivered - including comments where provided								
	Mean Total Lesson Rating	Participant	No of Cover Sheets	Lesson 4 Smoking and appearance/ Revising for tests	Lesson 5 Secrets of motivation	Lesson 6 Building your resilience to not smoke/ complete homework	Lesson 7 Looking after yourself during stressful times	Lesson 8 Looking to the future
Intervention	28	4 Textiles Lead	1	28	N/A	N/A	N/A	N/A
	26	5 PSHE Lead/ Citizenship	6	N/A	N/A	N/A	23; 23; 27	27; 28; 29 – "Students were highly engaged"
	25	8 History	1	N/A	N/A	25	N/A	N/A
	24	1 PSHE Lead/PE	1	24	N/A	N/A	N/A	N/A
	22	9 Science	3	N/A	23	N/A	21	22
	19	3 English/Drama	2	N/A	N/A	N/A	18 – "the group said they were fed up of doing this every year"	20 – "I took this group for the final lesson only. Students were involved and knowledgeable on the subject"
	18	2 STEM Lead	16	18; 18; 19	18; 18; 18 – "More activities needed for a 75 minute PSE lesson"	14; 19; 23	18; 18; 18; 19	17; 19; 21
Control	10	6 Science	1	N/A	N/A	N/A	10 (Rating incomplete)	N/A
	27	7 PSHE Lead/ History	1	27	N/A	N/A		N/A
	24	10 Science Lead	1	N/A	N/A	N/A	24 – "Good stress reliever tips"	N/A
	20	11 Modern Languages	3	N/A	N/A	21 – "I found it quite hard to enthuse year 9 and to encourage them to do homework. Many admitted they were just too lazy"	16	23
	19.5	12 Science Lead	3	No ratings	N/A	N/A	19 – "The form are getting tired of completing these forms now so may not have considered their answers carefully"	20 – "Students have done these tasks for a number of years now and are a little resentful of the messages the homework sessions are trying to get over"

Appendix 17: Background information sheet (Study 3)

Participant Number	Researcher to complete	M / F	Age		Years in Teaching	
1. What is your role in school?						
2. How long have you worked at the school?						
3. How many times have you delivered the Pro-homework lesson materials?		<input type="checkbox"/> Once <input type="checkbox"/> Twice <input type="checkbox"/> Three times <input type="checkbox"/> Four times <input type="checkbox"/> More than four times				
4. Do you deliver other PSHCE lessons?		IF YES: What does this involve? (briefly)				
5. What is your smoking status?		<input type="checkbox"/> Smoker <input type="checkbox"/> Non-smoker (formerly a smoker) <input type="checkbox"/> Non-smoker (never smoked)				
6. How familiar are you with the Smoking Prevention Study overall?						

This research has been approved by the School of Psychology Ethics Committee at the University of Leeds (23/01/2017, reference 17-0020). The Principal Investigator is Ruth Simms-Ellis (**R.Simms-Ellis@Leeds.ac.uk**, 07734 434 398, office 0113 34 31800). Professor Anna Madill is the lead supervisor (A.L.Madill@Leeds.ac.uk, 0113 34 35750). Both are based in the Psychology Building, Lifton Place, University of Leeds, LS2 9JT.

Appendix 18: Interview schedule (Study 3)

Understanding teachers' experiences of delivering the intervention/control lesson

Opening: I know how busy things are in school so thank you very much for giving me your precious time today. Can I underline that this study has been fully approved by the School of Psychology's ethics committee here at the University of Leeds on 23/Jan/2017 and is formally recorded by them under the number 17-0020. Just to reassure you, I'll be changing all the names you mention and you'll obviously remain anonymous too. There won't be any records kept from the discussions today with your name on them. First of all, I need to check you're clear about what's involved in the research and that you're happy to take part [confirm receipt of signed consent form and check still happy to proceed]. Thank you. I estimate the session will take no more than 30 minutes – is that okay? I am in a quiet, private room and won't be disturbed – are you in a private space where you can talk in confidence too? [Deal with any issues, e.g. noisy background, possibility of disruption by suggesting ways to improve the situation, such as identifying/moving to a quiet room and calling back in 10 minutes].

Contextual knowledge about the Reducing Smoking Initiation Study

1. To start us off, I'm really interested in whether you volunteered or were asked to deliver the lessons.

Follow-up questions if don't arise naturally:

- What made you volunteer?
- What were your thoughts when you were asked to deliver them? [explore workloads/morale here]
- How much did you or do you know about the overall Smoking Prevention Study these are linked to?
- How do you feel about the school being involved..?

Level of training and confidence to deliver PSHCE material

2. Obviously our lesson fits into PSHCE in schools. How important do you think PSHE is in your school?

Follow-up questions if don't arise naturally:

- What priority do the Senior Leadership Team give it would you say?
- What are your thoughts on that?
- How do you feel about delivering PSHCE material?
- Do you enjoy it or feel burdened/ uncomfortable with it?
- What training do you get? How does this impact?

Delivering the lesson materials: training, planning & acceptability of the materials/activities

3. Looking at the lessons themselves, can I turn to your experience of running them? How would you say they've gone?

Follow-up questions if don't arise naturally:

- What training did you have before running your first lesson? Was it enough?
- What preparation did you do beforehand?
- How do the lessons run? (Explore/follow-up issues as they arise)
- How do the students respond/engage with the materials?
- What particular aspects have they enjoyed/found boring or unengaging or complicated?
- What's it like to be asked to follow a lesson plan?
- Did you find you made adjustments? Why/what were these?

Contextual & personal factors: smoking status/views on smoking, relationship with students

4. Does it make a difference how well you know the students when you're delivering the lesson?

Follow-up questions if don't arise naturally:

- [If smoking school] Do you currently smoke? Do you think this has any impact on your delivery..?
- How much faith do you have in a lesson like this to be able to change students' behaviour?

What benefits, if any, are experienced? How could research team improve their experience?

5. What are your reflections on being part of the study?

Follow-up questions if don't arise naturally

- Would you say the school was experiencing any benefits from belonging to the study?
- Have you made of any of the additional benefits we offer, such as free workshops?
 - If yes, does this have an impact on your engagement with it?
 - If no, what has prevented you from taking up the incentives?
- What have you thought of Certificate, Newsletter
- Are there any ways in which the research team can help you more/reduce workload?
- How would you sum up the experience?

Ending: That's all my planned questions asked. Do you think there's any aspect of your experience of the study we've not covered? Thanks very much again for talking to me.

Appendix 19: Consent form (Study 3)

Participant Consent Form: Telephone Interview

I have read the emailed information about the telephone interview and am aware of what my participation will involve.

I understand that:

1. My participation is voluntary and that I may withdraw from the study at any time without giving a reason. I may withdraw at any point **before** or **during** the interview. Even **after** the interview, I may withdraw my data at any point up to 28 February 2017. [Beyond this point, the anonymised results may be submitted for publication, therefore withdrawal of my data will not be possible – see point 6 below].
2. The recording device containing the interview will be held confidentially and securely, only accessed by the lead researcher.
3. Once uploaded the audio file will be deleted from the recording device and stored on the lead researcher's password protected-computer, with a numerical file name e.g. "Interview 1".
4. All names I mention in the interview will be changed during transcription of the recording to preserve anonymity (e.g. my own, colleagues', students', school).
5. My name and other identifying details will not be shared with anyone.
6. The overall findings may be submitted for publication to a scientific journal or presented at scientific conferences, which may contain anonymised extracts from the lesson.
7. My transcribed data will be kept in a locked filing cabinet for a period of at least two years after appearance in any associated publications.

All questions I have about the research have been satisfactorily answered.

I would like to take part in the interview.

Participant's signature: Date:

Participant's name (please print):

Please note that this form will be kept separately from your data so you are not identifiable.

This research has been approved by the School of Psychology Ethics Committee at the University of Leeds (23/1/2017, reference 17-0020). The Principal Investigator is Ruth Simms-Ellis (R.Simms-Ellis@Leeds.ac.uk, 07734 434 398, office 0113 34 31800). Professor Anna Madill is the lead supervisor (A.L.Madill@Leeds.ac.uk, 0113 34 35750). Both are based in the Psychology Building, Lifton Place, University of Leeds, LS2 9JT.

Appendix 20: Themes Extracted from Teacher Feedback Sheets (Study 3)

Themes	Total Occurrences	Sub-themes	Sub-theme total	Intervention total	Cont total
"Muddling through" unsatisfactory conditions	60	Fitting material into a non-recommended time slot (too little/much time)	30	18	12
		Unfamiliar with study/lesson/students (new (7) /cover teacher (4))	11	8	3
		Not being provided with all planned materials (e.g. slides/lesson plan)	9	6	3
		Challenging lesson circumstances (e.g. Friday pm, exams)	7	4	3
		Technical issues (e.g. unable to use powerpoint slides, password issues)	3	1	2
				37	23
Commitment and ownership for making the lesson work	55	Supplemented/adapted the lesson to boost engagement	50	36	14
		Lessons disrupt learning/curriculum progress	2	2	0
		Tension between following lesson plan and meeting group needs	2	2	0
		Feeling greater confidence the more sessions delivered	1	1	0
				41	14
Students hard to engage due to repetition/boredom	51	Students hard to engage - repetition/boredom	51	31	20
				31	20
Inappropriateness of material/activities	30	More interaction/wow factor required	16	10	6
		Materials/activities too difficult for low ability students	13	12	1
		Not challenging enough for high ability students	1	1	0
				23	7
Students engaged with topic/good discussion	23	Students engaged with the material/topic (even spread across sessions)	13	11	2
		Prompted good discussion	10	8	2
				19	4
Impact of student behaviour/group dynamics	21	General behaviour/group dynamic-related	21	15	6
				15	6
Acceptability of materials	15	Acknowledging materials improved over time	6	3	3
		Well structured / designed	9	7	2
				10	5
Students' understanding of the study	9	Students struggle to understand lesson context	5	5	0
		Students are familiar with the study, accepting of the process	3	2	1
		Hard being the placebo group	1	0	1
				7	2
Total	264		264	183	81

Appendix 21: Focus Group Information Sheet for Intervention Schools (Study 4)

Information for Schools

Year 11 focus groups at the University of Leeds, Autumn 2016

Examining students' experiences of being in the Smoking Prevention Study



We are approaching the end of the Smoking Prevention Study after 4 years. This research has been testing the effectiveness of a simple smoking prevention intervention.

From our participating schools, we would like to talk to small, representative samples of students to learn more about:

- How have students perceived the smoking data collection process and Smoking prevention lesson?
- What improvements need incorporating into the intervention for a national launch?
- What are their experiences of participating in a scientific research project?
- How can we improve the quality of future school-based research?



What is involved in the focus group? A diverse selection of 10-12 Year 11 student volunteers from your school/academy visiting the School of Psychology on one occasion, for 2 hours (e.g. 1pm-3pm), accompanied by a member of school staff. We will reimburse travel expenses, such as petrol for minibuses or taxi fares. Following a 30-40 minute focus group with light refreshments, students and the staff member will be escorted on a guided tour of the Psychology Building and the University Campus by specially trained current Psychology undergraduates. University information packs will be provided for the students to take away.

What will happen in the focus group? The researcher will gain the students' agreement to some ground rules, such as allowing each other to speak and respecting each other's opinions. She will reassure the students that no-one will be forced to talk if they do not feel comfortable. The researcher will ask a series of questions to promote discussion and will facilitate the group to explore ideas and expand on disagreements/agreements etc. To allow students to speak freely, and for confidentiality reasons, the accompanying member of school staff will not be in the room for the focus group, but will be made comfortable just outside. We must make you aware that there are some limits to confidentiality in research. If a student reveals to the researcher any criminal activity they have been involved in or any intention to harm themselves or others, she would have to contact her supervisor so relevant action can be taken, potentially having to inform relevant authorities. However, we can reassure you that this research does not actively seek such information. The researcher holds an enhanced DBS certificate and has 15 years' experience working with young people. She will audio record the focus group to aid analysis at a later point. Information discussed in the focus group will be held in confidence. When the focus group

discussion is typed up, all names will be changed so no individual students, schools or teachers are identifiable, and all records will be stored confidentially on password protected computers.

What will happen to the information we collect in the focus groups? Once collected, we will store the focus group data securely in a locked filing cabinet for up to 6 years. Only the lead researcher and her supervisor will have access to it with a key. We may submit our overall findings to a scientific journal and it is usual practice to include extracts from focus groups to help readers understand the results. However any extracts will be anonymised so that no student or school can be identified.

Selecting Students to Take Part: To comply with our strict ethical standards, students need to volunteer to take part in the focus group (i.e. we request that it is not positioned as a reward for good behaviour). For these reasons, we would like to ask Year 11 form tutors to discuss the focus group with their Year 11 students. Any student meeting the following criteria is warmly invited to volunteer:

- | | | |
|---|---|--|
| 1. Have taken part in at least one of the University-designed Smoking Prevention Lessons. | 2. Are willing and interested to share their experience and reflections on being part of the study and the lesson | 3. Are considered responsible when off-site with minimal supervision from teaching staff |
|---|---|--|

We would leave the final selection of students to you, whilst requesting that the final group of 10-12 students includes a diverse selection, i.e. a balance of males/females and range of ethnicities and abilities. If you decide to go ahead with the focus groups, I will provide you with a short guidance sheet to help form tutors with this.

Parental consent: Once I have your approved list of interested students, I will drop off at your reception a parental information pack for each student. This will contain a Parental Consent Form which needs signing and returning to you in the first instance, and then ultimately to me, before students can participate. I will liaise with you on collecting these from you. A full risk assessment for these visits has been undertaken within our department.

Ethical approval: This research has been approved by the School of Psychology's ethics committee at the University of Leeds (ref: 16-0147; 23-May-2016). I, Ruth Simms-Ellis, am the Principal Investigator (✉ R.Simms-Ellis@Leeds.ac.uk, ☎ 0113 34 31800), under the supervision of Professor Anna Madill: (✉ A.L.Madill@Leeds.ac.uk, ☎ 0113 3435750).

We look forward to welcoming your students: We have planned an interesting and stimulating educational visit for those students kind enough to volunteer to help us. Specially trained undergraduates will show your students around and talk about university life, providing ample opportunity for questions. Students will bring back lots of information to share with others. Please do feel free to contact me if you have any further questions.

With kind regards

Ruth Simms-Ellis
Ruth Simms-Ellis,
Psychologist
School of Psychology
Faculty of Medicine and Health
University of Leeds
Lifton Place, Leeds, LS2 9JT
9 June 2016



Appendix 22: Focus Group Information Sheet for Control Schools (Study 4)

Information for Schools

Year 11 focus groups at the University of Leeds, Autumn 2016

Examining students' experiences of being in the Smoking Prevention Project

UNIVERSITY OF LEEDS
Building healthy communities

school of psychology

We are approaching the end of the Smoking Prevention Study after 4 years. This research has been testing the effectiveness of a simple smoking prevention intervention.

From our participating schools, we would like to talk to small, representative samples of students to learn more about:

- How have students perceived the smoking data collection process and Homework (control) lesson?
- What are their experiences of participating in a scientific research project?
- How can we improve the quality of future school-based research?



What is involved in the focus group? A diverse selection of 10-12 Year 11 student volunteers from your school/academy visiting the School of Psychology on one occasion, for 2 hours (e.g. 1pm-3pm), accompanied by a member of school staff. We will reimburse travel expenses, such as petrol for minibuses or taxi fares. Following a 30-40 minute focus group with light refreshments, students and the staff member will be escorted on a guided tour of the Psychology Building and the University Campus by specially trained current Psychology undergraduates.

University information packs will be provided for the students to take away.

What will happen in the focus group? The researcher will gain the students' agreement to some ground rules, such as allowing each other to speak and respecting each other's opinions. She will reassure the students that no-one will be forced to talk if they do not feel comfortable. The researcher will ask a series of questions to promote discussion and will facilitate the group to explore ideas and expand on disagreements/agreements etc. To allow students to speak freely, and for confidentiality reasons, the accompanying member of school staff will not be in the room for the focus group, but will be made comfortable just outside. We must make you aware that there are some limits to confidentiality in research. If a student reveals to the researcher any criminal activity they have been involved in or any intention to harm themselves or others, she would have to contact her supervisor so relevant action can be taken, potentially having to inform relevant authorities. However, we can reassure you that this research does not actively seek such information. The researcher holds an enhanced DBS certificate and has 15 years' experience working with young people. She will audio record the focus group to aid analysis at a later point. Information discussed in the focus group will be held in confidence. When the focus group

discussion is typed up, all names will be changed so no individual students, schools or teachers are identifiable, and all records will be stored confidentially on password protected computers.

What will happen to the information we collect in the focus groups? Once collected, we will store the focus group data securely in a locked filing cabinet for up to 6 years. Only the lead researcher and her supervisor will have access to it with a key. We may submit our overall findings to a scientific journal and it is usual practice to include extracts from focus groups to help readers understand the results. However any extracts will be anonymised so that no student or school can be identified.

Selecting Students to Take Part: To comply with our strict ethical standards, students need to volunteer to take part in the focus group (i.e. we request that it is not positioned as a reward for good behaviour). For these reasons, we would like to ask Year 11 form tutors to discuss the focus group with their Year 11 students. Any student meeting the following criteria is warmly invited to volunteer:

- | | | |
|---|---|--|
| 1. Have taken part in at least one pro-homework lesson. | 2. Are willing and interested to share their experience and reflections on being part of the study and the lesson | 3. Are considered responsible when off-site with minimal supervision from teaching staff |
|---|---|--|

We would leave the final selection of students to you, whilst requesting that the final group of 10-12 students includes a diverse selection, i.e. a balance of males/females and range of ethnicities and abilities. If you decide to go ahead with the focus groups, I will provide you with a short guidance sheet to help form tutors with this.

Parental consent: Once I have your approved list of interested students, I will drop off at your reception a parental information pack for each student. This will contain a Parental Consent Form which needs signing and returning to you in the first instance, and then ultimately to me, before students can participate. I will liaise with you on collecting these from you. A full risk assessment for these visits has been undertaken within our department.

Ethical approval: This research has been approved by the School of Psychology's ethics committee at the University of Leeds (ref: 16-0147; 23-May-2016). I, Ruth Simms-Ellis, am the Principal Investigator (✉ R.Simms-Ellis@Leeds.ac.uk, ☎ 0113 34 31800), under the supervision of Professor Anna Madill (✉ A.L.Madill@Leeds.ac.uk, ☎ 0113 3435750).

We look forward to welcoming your students: We have planned an interesting and stimulating educational visit for those students kind enough to volunteer to help us. Specially trained undergraduates will show your students around and talk about university life, providing ample opportunity for questions. Students will bring back lots of information to share with others. Please do feel free to contact me if you have any further questions.

With kind regards


Ruth Simms-Ellis,
Psychologist
School of Psychology
Faculty of Medicine and Health
University of Leeds
Lifton Place, Leeds, LS2 9JT

9 June 2016



The School of Psychology, the University of Leeds

Appendix 23: Short Information Flyer for Form Tutors (Study 4) (*intervention left; control right*)



JUNE/JULY 2016 STUDENT FOCUS GROUPS

Examining students' experiences of being in the Smoking Prevention Study

At the School of Psychology, University of Leeds

Researchers in the School of Psychology are seeking mature, responsible Year 10 students who have been involved in the Smoking Prevention Study for an informal focus group at the University of Leeds. After the focus group, students will be given a tour of the Psychology building and the University Campus by current Psychology Undergraduates. Students need to be willing to share their experiences of completing the Smoking Questionnaire and Smokerlyzer sessions and smoking prevention lessons. Their views will help researchers improve the lessons and the way universities work with schools on future research.

Interested students are asked to contact their form tutor in the first instance. From the final list of kind volunteers the Smoking Study Coordinator in school and Head of Year 10 will choose 10 names to attend the focus group. Decisions will be made on the basis of ensuring a diverse mix of students to fully represent your school/academy within the focus group. Thank you for your help.



45 MINUTE
FOCUS GROUP WITH
REFRESHMENTS

TOUR OF THE SCHOOL
OF PSYCHOLOGY

TOUR OF THE
UNIVERSITY OF LEEDS
CAMPUS

CHANCE TO TALK TO
CURRENT
PSYCHOLOGY
STUDENTS

This research has been approved by the School of Psychology's ethics committee at the University of Leeds (ref: 16-0147; 23-May-2016).

Ruth Simms-Ellis is Principal Investigator:
✉ R.Simms-Ellis@Leeds.ac.uk
☎ 0113 34 31800
She is supervised by Prof. Anna Madill:
✉ A.L.Madill@Leeds.ac.uk
☎ 0113 3435750



JUNE/JULY 2016 STUDENT FOCUS GROUPS

Examining students' experiences of being in the Smoking Prevention Study

At the School of Psychology, University of Leeds

Researchers in the School of Psychology are seeking mature, responsible Year 10 students who have been involved in the Smoking Prevention Study for an informal focus group at the University of Leeds. After the focus group, students will be given a tour of the Psychology building and the University Campus by current Psychology Undergraduates. Students need to be willing to share their experiences of completing the Smoking Questionnaire and Smokerlyzer sessions and homework lessons. Their views will help researchers improve the lessons and the way universities work with schools on future research.

Interested students are asked to contact their form tutor in the first instance. From the final list of kind volunteers the Smoking Study Coordinator in school and Head of Year 10 will choose 10 names to attend the focus group. Decisions will be made on the basis of ensuring a diverse mix of students to fully represent your school/academy within the focus group. Thank you for your help.



45 MINUTE
FOCUS GROUP WITH
REFRESHMENTS

TOUR OF THE SCHOOL
OF PSYCHOLOGY

TOUR OF THE
UNIVERSITY OF LEEDS
CAMPUS

CHANCE TO TALK TO
CURRENT
PSYCHOLOGY
STUDENTS

This research has been approved by the School of Psychology's ethics committee at the University of Leeds (ref: 16-0147; 23-May-2016).

Ruth Simms-Ellis is Principal Investigator:
✉ R.Simms-Ellis@Leeds.ac.uk
☎ 0113 34 31800
She is supervised by Prof. Anna Madill:
✉ A.L.Madill@Leeds.ac.uk
☎ 0113 3435750

Appendix 24: Parental Information letter for intervention schools (Study 4)

Information for Parents/ Guardians

Examining students' experiences of being in the Smoking Prevention Study



January 2017

Dear Parent/Guardian

Your son/daughter has recently expressed an interest to take part in a research focus group within Leeds University's School of Psychology. Only a small number of students from Year 11 has been randomly selected to take part, and your child is one of them. We require your formal, signed consent to allow them to take part. This letter provides you with further information to help you make an informed choice. If after reading this letter you are happy for them to participate, **PLEASE SIGN THE ATTACHED CONSENT FORM AND RETURN IN THE ENVELOPE PROVIDED.**

What is the Focus Group about? Your son/daughter's school and its students have been supporting our Smoking Prevention Study for the past four years. We would like to ask some of the students who have been involved about their perceptions and experiences of it. Their views will help us improve how we work with schools when developing new health interventions.

What will be involved in the Focus Group? The research focus group involves your son/daughter being released from school for approximately two hours, to come to the University by mini-bus with a member of teaching staff and around nine other students. Students will spend approximately 45 minutes in an informal meeting room with an experienced researcher who has worked with young people for a number of years and holds an enhanced DBS¹ certificate. The researcher will use open-ended questions to encourage students to share their experiences of being in the Smoking Prevention Study and in particular their views about the smoking prevention lessons. The discussion will be audio-recorded to help the researcher analyse in detail what was said at a later date. The member of school/academy staff accompanying them will **NOT** be present for the focus group session because it is important that students feel they can reply honestly and in confidence. However, they will remain nearby and accompany them for the remaining part of the visit. For everyone's safety, there are some limits to confidentiality in research. If your son/daughter reveals to me any criminal activity they have been involved in or any intention to harm themselves or others, I would have to contact my supervisor so relevant action can be taken, potentially having to inform relevant authorities. However, I can reassure you that my research does not actively seek such information.

¹ Disclosure and Barring Service. This process has replaced the Criminal Records Bureau Check.

What happens after the Focus Group? The students will be given a tour of the Psychology building by specially trained staff, followed by a tour of the campus. Students will have lots of opportunities to ask questions and will be given a University information pack on departure. Information discussed in the focus group will be held in confidence (i.e. will not be passed on to teaching staff). At a later date, the researcher will type up the focus group recording and analyse in detail what topics have been raised. When it is typed up, all names will be changed so no individual students, schools or teachers are identifiable after taking part, and all records will be stored confidentially on password protected computers.

What will happen to the information we collect in the focus groups? Once collected, we will store the focus group data securely in a locked filing cabinet for up to 6 years. Only the lead researcher and her supervisor will have access to it with a key. We may submit our overall findings to a scientific journal and it is usual practice to include extracts from focus groups to help readers understand the results. However any extracts will be anonymised so that no student or school can be identified.

A valuable educational experience The leadership team in school considers this to be a valuable educational experience and have therefore authorized your son/daughter's absence from school (providing that they catch up on any work missed afterwards). However, we also require your formal consent. If you would like your son/daughter to take part in this research, please complete the attached consent form and return it to school using the envelope provided. For ethical reasons, only those students who return a signed consent form will be permitted to come along on the day. Your son/daughter's participation in the focus group study is voluntary and they may withdraw at any time **prior** to the focus group date without giving a reason. If they change their mind **during** the focus group, they can choose to remain silent. Withdrawing their data **after** the focus group however will not be possible. This is because the researchers will be unable to identify them due to anonymisation processes used during transcription.

Ethical approval for this study This research has been approved by the School of Psychology's ethics committee at the University of Leeds (ref: 16-0147; 23-May-2016). I, Ruth Simms-Ellis, am the Principal Investigator (✉ R.Simms-Ellis@Leeds.ac.uk, ☎ 0113 34 31800), under the supervision of Professor Anna Madill (✉ A.L.Madill@Leeds.ac.uk, ☎ 0113 34 35750). Both Anna and I are based in the School of Psychology, Lifton Place, University of Leeds, LS2 9JT.

Please do feel free to contact me if I can be of further help. Alternatively, you can contact Ms Rosie Evans, our coordinator in school, who will be happy to answer any questions.

Yours faithfully



Ruth Simms-Ellis,
Psychologist
School of Psychology
Faculty of Medicine and Health
University of Leeds
Lifton Place
Leeds
LS2 9JT



The School of Psychology building at the University of Leeds

Appendix 25: Parental Information letter for control schools (Study 4)

Information for Parents/ Guardians

Examining students' experiences of being in the Smoking Prevention Study



January 2017

Dear Parent/Guardian

Your son/daughter has recently expressed an interest to take part in a research focus group within Leeds University's School of Psychology. Only a small number of students from Year 11 has been randomly selected to take part, and your child is one of them. We require your formal, signed consent to allow them to take part. This letter provides you with further information to help you make an informed choice. If after reading this letter you are happy for them to participate, **PLEASE SIGN THE ATTACHED CONSENT FORM AND RETURN IN THE ENVELOPE PROVIDED.**

What is the Focus Group about? Your son/daughter's school and its students have been supporting our Smoking Prevention Study for the past four years. We would like to ask some of the students who have been involved about their perceptions and experiences of it. Their views will help us improve how we work with schools when developing new health interventions.

What will be involved in the Focus Group? The research focus group involves your son/daughter being released from school for approximately two hours, to come to the University by mini-bus with a member of teaching staff and around nine other students. Students will spend approximately 45 minutes in an informal meeting room with an experienced researcher who has worked with young people for a number of years and holds an enhanced DBS¹ certificate. The researcher will use open-ended questions to encourage students to share their experiences of being in the Smoking Prevention Study and in particular their views about the homework lessons. The discussion will be audio-recorded to help the researcher analyse in detail what was said at a later date. The member of school/academy staff accompanying them will **NOT** be present for the focus group session because it is important that students feel they can reply honestly and in confidence. However, they will remain nearby and accompany them for the remaining part of the visit. For everyone's safety, there are some limits to confidentiality in research. If your son/daughter reveals to me any criminal activity they have been involved in or any intention to harm themselves or others, I would have to contact my supervisor so relevant action can be taken, potentially having to inform relevant authorities. However, I can reassure you that my research does not actively seek such information.

What happens after the Focus Group? The students will be given a tour of the Psychology building by specially trained staff, followed by a tour of the campus. Students will have lots of opportunities to ask questions and will be given a University information pack on departure. Information discussed in the focus group will be held in confidence (i.e. will not be passed on to teaching staff). At a later date, the researcher will type up the focus group recording and analyse in detail what topics have been raised. When it is typed up, all names will be changed so no individual students, schools or teachers are identifiable after taking part, and all records will be stored confidentially on password protected computers.

What will happen to the information we collect in the focus groups? Once collected, we will store the focus group data securely in a locked filing cabinet for up to 6 years. Only the lead researcher and her supervisor will have access to it with a key. We may submit our overall findings to a scientific journal and it is usual practice to include extracts from focus groups to help readers understand the results. However any extracts will be anonymised so that no student or school can be identified.

A valuable educational experience The leadership team in school considers this to be a valuable educational experience and have therefore authorized your son/daughter's absence from school (providing that they catch up on any work missed afterwards). However, we also require your formal consent. If you would like your son/daughter to take part in this research, please complete the attached consent form and return it to school using the envelope provided. For ethical reasons, only those students who return a signed consent form will be permitted to come along on the day. Your son/daughter's participation in the focus group study is voluntary and they may withdraw at any time **prior** to the focus group date without giving a reason. If they change their mind **during** the focus group, they can choose to remain silent. Withdrawing their data **after** the focus group however will not be possible. This is because the researchers will be unable to identify them due to anonymisation processes used during transcription.

Ethical approval for this study This research has been approved by the School of Psychology's ethics committee at the University of Leeds (ref: 16-0147; 23-May-2016). I, Ruth Simms-Ellis, am the Principal Investigator (✉ R.Simms-Ellis@Leeds.ac.uk, ☎ 0113 34 31800), under the supervision of Professor Anna Madill (✉ A.L.Madill@Leeds.ac.uk, ☎ 0113 34 35750). Both Anna and I are based in the School of Psychology, Lifton Place, University of Leeds, LS2 9JT.

Please do feel free to contact me if I can be of further help. Alternatively, you can contact Ms Rosie Evans, our coordinator in school, who will be happy to answer any questions.

Yours faithfully


Ruth Simms-Ellis,
Psychologist
School of Psychology
Faculty of Medicine and Health
University of Leeds
Lifton Place
Leeds
LS2 9JT



The School of Psychology building at the University of Leeds

¹ Disclosure and Barring Service. This process has replaced the Criminal Records Bureau Check.

Appendix 26: Parental Consent Form (Study 4)



UNIVERSITY OF LEEDS

Building healthy communities

Parental / Guardian Consent Form

For participation in the study: Examining students' experiences of being in the Reducing Smoking Initiation Project

Re: My son/daughter taking part in a Focus Group at the School of Psychology, University of Leeds

I have read the information provided about the focus group and I am aware of what my son/daughter's participation will involve.

I understand that:

1. The focus group will be audio-recorded to aid analysis.
2. Participation is voluntary and that they may withdraw at any time **prior** to the focus group date without giving a reason. If they change their mind about contributing **during** the focus group, they can choose to remain silent. Withdrawing their data **after** the focus group will not be possible because the researchers will be unable to identify them due to anonymisation processes used during transcription (see point 4).
3. The device containing the focus group recording will be held confidentially and securely, only accessed by the lead researcher. Once uploaded the audio file will be deleted from the recording device and stored on the lead researcher's password protected-computer, with a numerical file name.
4. All names mentioned in the focus group will be changed during transcription of the recording to preserve anonymity.
5. Their name and other identifying details will not be shared with anyone.
6. The overall findings may be submitted for publication to a scientific journal or presented at scientific conferences, which may contain anonymised extracts from my child's focus group.
7. The transcribed data will be kept in a locked filing cabinet for a period of at least five years after appearance in any associated publications.

All questions I have about the research have been satisfactorily answered.

I would like to my son/daughter to take part in the focus group event.

Child's name _____ Form: _____

Parent/guardian's signature: _____ Date: _____

Please note that this form will be kept separately from your child's data so they are not identifiable.

Appendix 27: Focus group schedule (Study 4)

Student Focus Group Schedule

Welcome and Introduction

- Welcome:** Thanks for agreeing to meet with me today. I really appreciate your willingness to do this.
- Introduction:** My name is Ruth and this is [insert Psychology member staff name].
- Purpose:** I'm meeting with people who've been part of the smoking prevention study in school. I'm particularly interested in what you've thought of our visits to gather smoking habit information and the [smoking or homework] lessons¹. You're the experts here and your opinions are really valuable for helping me work out improvements I need to make to these.
- Ground Rules:** I'd like you to do the talking: It would be great if everyone joins in and shares their views. I'll do my best to help everyone have their say. But no-one will be forced to say anything or made to feel uncomfortable if they're quiet.
There are no right or wrong answers: Every person's experiences and opinions are important. Please speak up whether you agree or disagree with what's said. It'd be great to hear a wide range of opinions.
Can we agree that what is said in this room stays here? I want everyone to feel comfortable sharing their opinions, and though we're not asking about really personal things, it's possible something sensitive might crop up. To make things easier, can I ask you not to mention teachers' actual names when we talk about the lessons: it's fine just to say 'the teacher'? I must make you aware that there are some limits to confidentiality in research. If you reveal to me any criminal activity you have been involved in or any intention to harm yourself or others, I would have to contact my supervisor so relevant action can be taken, potentially having to inform relevant authorities. However, I can reassure you that this research isn't actively seeking this information.
So I can remember everything you say, I'll be recording our discussion using this little recorder. If you don't want to be audio-recorded, it's ok to leave now and join your teacher outside, or decide just not to say anything. I won't use anyone's name when I talk or write about our discussion and your teachers won't know who said what.
- Opening:** Is everybody happy to get started then? Great. OK so the smoking study has been running for 4 years now and I've been into school 4 times with my researchers to collect your smoking information. How many of these sessions have you attended? [Check with each student and make a note of how many].

Questions

What factors facilitate & impede students' engagement in research?

1. What was your first reaction when you were asked to complete a Smoking questionnaire and take the Smokerlyzer test?
 Prompts
 Could you tell me a bit more about that?
 How did it make you feel?
 Did you understand what was happening?
 Do you have any questions about the questionnaire or the Smokerlyzer test?
2. Have you got used to these sessions over time?
 Prompts
 Do you ever worry about taking part in them? If so, can you tell me a bit about what worried you?
 Do you think any of the students stopped smoking for a while to avoid this being picked up by the Smokerlyzers? (You don't need to tell me names!)
3. Overall, what was it like for you being part of these sessions?
 Prompts
 What aspects did you enjoy / not enjoy? Can you tell me a bit more about that?
 Is there anything we can do to make the sessions more enjoyable?
 Is there anything we can do to reassure students more that no one will be told if they smoke?

¹ Select the lesson the focus group students have received: i.e. a control or intervention school.

Change topic: Brilliant. Thank you. I'm going to ask you about the [smoking or homework]¹ lessons now. Since the study started, 8 [smoking or homework] lessons have taken place. How many have each of you taken part in? [Check with each student and make a note].

What are students' subjective appraisals of the intervention [or control lesson if control school] and how acceptable is it to them?

4. How have you found the [smoking or homework]¹ lessons?

5. What aspects have you really enjoyed / not enjoyed about them?

Follow-up/prompt if required:

Have any particular sessions or materials really stuck with you the most? Why was that?

6. How much do you think the lessons have affected your decision about [smoking or doing your homework]¹? Can you tell me a bit more about that?

7. What could we do to make the lessons better?

How is the intervention implemented in real life?

8. How well did you know the teacher(s) delivering the lessons? (*Remind students you don't need names, "the teacher" is fine*).

Follow-up:

Do you think that made any difference to how much you got out of it? Can you tell me a bit more about that?

9. What did you like about the way your teacher delivered the sessions?

Follow-up/prompt:

What didn't go so well? Can you give me an example of that?

How enthusiastic/interested did they seem? Can you give me an example of that?

Did you have enough time to complete everything? Did you all have enough handouts?

What factors facilitate & impede students' engagement in research?

10. If you could choose one word to sum up your experience of being in the Smoking Study, what would it be?

Follow-up:

Why did you pick that word...?

Close

Well we're almost at the end now. Just to summarise: the aim of our discussion was to understand how you've found the Smoking Study overall and the [smoking or homework]¹ lessons in particular. Before we finish, is there anything we've missed? Have you had a chance to say everything you wanted about the lessons?

Thank you very much for coming today, it's been lovely to meet you all and so useful to hear all your views.

Appendix 28: Themes Extracted from Student Feedback Sheets (Study 4)

		This lesson helped me think differently about smoking / homework		
Category Description (with incorporated themes by condition below)		Agree/ Strongly Agree	Disagree/ Strongly Disagree / Neutral	Total
Pre-existing healthy attitudes/behaviours about smoking/homework		193	533	726
Intervention	I was never going to smoke anyway	162	464	626
Control	Already do my homework and see its use	31	69	100
The lessons contained information I already knew and didn't change opinion		173	354	527
Intervention	I think the same - no change (not specifying that this was "I will never smoke")	152	321	473
Control	Already knew the information/wasn't new, didn't change my views	21	33	54
Boring, repetitive		105	374	479
Intervention	Repetitive, boring	57	220	277
Control	Boring, repetitive	48	154	202
Improved understanding and knowledge		438	15	453
Intervention	Improved understanding of impact of smoking	275	11	286
Control	Learning new skills/strategies	77	0	77
Control	Showing value of homework	65	4	69
Control	Improved motivation & self-regulation (stress)	21	0	21
Resistance: fixed behaviours/attitudes which the lessons won't change		40	102	142
Intervention	Smoking already	5	11	16
Intervention	Fatalistic: if people are going to smoke, you can't stop them	5	8	13
Control	Fatalism: no point, won't make any difference	10	2	12
Control	Homework is hated/not valued/not done	20	62	82
Control	Won't change how I do things: have my own ways	0	19	19
Content and delivery of the lesson		52	86	138
Intervention	Delivery protocol	7	18	25
Intervention	Printing error confusion	12	32	44
Control	Protocol deviation	13	2	15
Control	Lesson design	11	19	30
Control	Teacher lesson delivery	9	13	22
Control	Negative effect (making me more stressed)	0	2	2
Suspicion		0	6	6
Intervention	Suspicion	0	6	6
Total comments		1001	1470	2471

Appendix 29: Flyer produced to share Engagement Promotion Programme in schools (Study 5)

Smoking Prevention Study



As our valued research collaborator, your school is entitled to **FREE support from Psychologists** at the University of Leeds

Staff CPD workshops:

- Body Image issues
- Helpful responses to self-harming
- Staying well during stressful times (we also deliver this to students directly)

Support for health fairs and drop down days

"Psychology as a career" talks

Help with promoting student wellbeing in school

Invitations to University Open Days




Here are just some of the ways we've supported our schools so far:

Body Image stands at health fairs: School K; School A; School D; School F.

Self-harm workshops (staff): School K; School I; School H.

Stress & wellbeing workshops: School H; School I; School J; School K. For staff - twilight sessions & staff training days. For students - drop down days.

Careers talks, aim higher events & university open days: School D; School E; School F; School G.

Delivering specialist lessons to support curriculum activities: School A (GCSE Business Studies – Influencing & persuading); School B (A level Psychology – Research Methods).

Ad-hoc support: group support session with students experiencing panic/stress; advice to schools council on developing a student mental health magazine.

Appendix 30: Full internal consistency reliability results for subscales within the 'Measure of Engagement' (Study 5)

(1) 'Peripheral School' Engagement Sub-Scale

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.803	.831	10

Item Statistics

	Mean	Std. Deviation	N
Item11_Study_coord_replied_promptly_to_researcher_contact	3.56	1.289	45
Item12_Study_coord_was_proactive	3.49	1.408	45
Item13_Study_coord_happily_booked_annual_meeting	4.27	1.031	45
Item14_Teachers_attended_and_engaged_lesson_training	3.76	.957	45
Item15_Study_coord_timetabled_data_collection_without_chased	3.20	1.272	45
Item16_Study_coord_supported_data_collection	4.22	.951	45
Item17_Study_coord_timetabled_lessons_without_chased	3.18	1.267	45
Item18_Study_coord_ensured_lessons_delivered	3.60	1.156	45
Item19_Teachers_delivered_lessons_to_plan	3.67	1.066	45
Item20_Teachers_adhered_protocol	3.53	.968	45

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Item1_SLT_showed_interest	33.64	38.189	.666	.878	.761
Item2_SLT_supported_key_contact	33.36	40.962	.611	.861	.772
Item3_School_used_Workshops	34.16	37.771	.517	.422	.785
Item4_SLT_prioritised_award_ceremony_attendance	33.87	42.209	.247	.294	.831
Item5_Headsofyear_supported_key_contact	33.07	41.882	.589	.585	.775
Item6_Teachers_staff_aware_smoking_study	33.22	42.995	.564	.614	.779
Item7_Teachers_staff_interest_data_collection	33.53	43.073	.607	.847	.777
Item8_Teachers_staff_positive_attitudes_study	33.42	42.613	.610	.862	.776
Item9_Teachers_staff_managed_behaviour	33.33	43.727	.516	.554	.784
Item10_Receptionist_aware_study_and_key_contact	33.20	47.436	.182	.311	.813

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
37.20	50.845	7.131	10

(2) 'Staff' Engagement Engagement Sub-Scale**Reliability Statistics**

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.934	.931	10

Item Statistics

	Mean	Std. Deviation	N
Item11_Study_coord_replied_promptly_to_researcher_contact	3.56	1.289	45
Item12_Study_coord_was_proactive	3.49	1.408	45
Item13_Study_coord_happily_booked_annual_meeting	4.27	1.031	45
Item14_Teachers_attended_and_engaged_lesson_training	3.76	.957	45
Item15_Study_coord_timetabled_data_collection_without_chased	3.20	1.272	45
Item16_Study_coord_supported_data_collection	4.22	.951	45
Item17_Study_coord_timetabled_lessons_without_chased	3.18	1.267	45
Item18_Study_coord_ensured_lessons_delivered	3.60	1.156	45
Item19_Teachers_delivered_lessons_to_plan	3.67	1.066	45
Item20_Teachers_adhered_protocol	3.53	.968	45

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Item11_Study_coord_replied_promptly_to_researcher_contact	32.91	62.765	.895	.904	.919
Item12_Study_coord_was_proactive	32.98	61.340	.879	.913	.920
Item13_Study_coord_happily_booked_annual_meeting	32.20	69.209	.725	.676	.928
Item14_Teachers_attended_and_engaged_lesson_training	32.71	75.028	.408	.313	.941
Item15_Study_coord_timetabled_data_collection_without_chased	33.27	64.109	.834	.902	.922
Item16_Study_coord_supported_data_collection	32.24	76.643	.310	.426	.945
Item17_Study_coord_timetabled_lessons_without_chased	33.29	64.346	.825	.908	.923
Item18_Study_coord_ensured_lessons_delivered	32.87	65.936	.822	.824	.923
Item19_Teachers_delivered_lessons_to_plan	32.80	67.255	.819	.799	.924
Item20_Teachers_adhered_protocol	32.93	68.200	.849	.806	.923

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
36.47	82.709	9.094	10

(3) Inter-scale Correlation

		EngagePeripheral	EngageStaff	EngageStudent
EngagePeripheral	Pearson Correlation	1	.683**	.416**
	Sig. (2-tailed)		.000	.005
	N	45	45	45
EngageStaff	Pearson Correlation	.683**	1	.402**
	Sig. (2-tailed)	.000		.006
	N	45	45	45
EngageStudent	Pearson Correlation	.416**	.402**	1
	Sig. (2-tailed)	.005	.006	
	N	45	45	45

** . Correlation is significant at the 0.01 level (2-tailed).

Appendix 31: Degree of incentive utilisation by school characteristics (Study 5)

Incentive Use	School Identifier	Region	Condition	Ofsted rating	Community served
Low User	1	Leeds	Intervention	Low	Disadvantaged
	2	Leeds	Intervention	Low	Disadvantaged
	21	Staffs	Intervention	Low	Disadvantaged
	6	Leeds	Intervention	Low	Moderate-to-wealthy
	25	Staffs	Intervention	Low	Moderate-to-wealthy
	26	Staffs	Intervention	Low	Moderate-to-wealthy
	30	Staffs	Intervention	High	Moderate-to-wealthy
	31	Staffs	Intervention	High	Moderate-to-wealthy
	32	Staffs	Intervention	High	Moderate-to-wealthy
	33	Staffs	Intervention	High	Moderate-to-wealthy
	34	Staffs	Control	Low	Disadvantaged
	36	Staffs	Control	Low	Disadvantaged
	14	Leeds	Control	High	Disadvantaged
	38	Staffs	Control	High	Disadvantaged
	40	Staffs	Control	High	Disadvantaged
	41	Staffs	Control	Low	Moderate-to-wealthy
	42	Staffs	Control	High	Moderate-to-wealthy
	<i>N</i> = 20		Intervention = 10 Control = 10	High = 14 Low = 8	Disadvantaged = 8 Moderate = 14
Medium User	22	Staffs	Intervention	Low	Disadvantaged
	23	Staffs	Intervention	Low	Disadvantaged
	3	Leeds	Intervention	High	Disadvantaged
	24	Staffs	Intervention	High	Disadvantaged
	5	Leeds	Intervention	High	Disadvantaged
	7	Leeds	Intervention	Low	Moderate-to-wealthy
	27	Staffs	Intervention	Low	Moderate-to-wealthy
	8	Leeds	Intervention	High	Moderate-to-wealthy
	9	Leeds	Intervention	High	Moderate-to-wealthy
	28	Staffs	Intervention	High	Moderate-to-wealthy
	29	Staffs	Intervention	High	Moderate-to-wealthy
	35	Staffs	Control	Low	Disadvantaged
	13	Leeds	Control	Low	Disadvantaged
	37	Staffs	Control	High	Disadvantaged
	39	Staffs	Control	High	Disadvantaged
	15	Leeds	Control	Low	Moderate-to-wealthy
	16	Leeds	Control	Low	Moderate-to-wealthy
	17	Leeds	Control	High	Moderate-to-wealthy
	19	Leeds	Control	High	Moderate-to-wealthy
	20	Leeds	Control	High	Moderate-to-wealthy
	43	Staffs	Control	High	Moderate-to-wealthy
	45	Staffs	Control	High	Moderate-to-wealthy
	<i>N</i> = 20		Intervention = 10 Control = 10	High = 14 Low = 8	Disadvantaged = 8 Moderate = 14
High User	4	Leeds	I	High	Disadvantaged
	10	Leeds	I	High	Moderate-to-wealthy
	11	Leeds	I	High	Moderate-to-wealthy
	12	Leeds	I	High	Moderate-to-wealthy
	18	Leeds	C	High	Moderate-to-wealthy
	44	Staffs	C	High	Moderate-to-wealthy
	<i>N</i> = 6		Intervention = 4 Control = 2	High = 6 Low = 0	Disadvantaged = 2 Moderate = 4