Optimising the implementation of complex healthcare interventions in trials involving older people

Sadia Nisar Ahmed

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Intellectual Property and Publication Statements

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.

My own contribution and that of members of the PROSPER team, as well as other contributors to specific publications/chapters are clearly articulated below.

Chapter 3

Contributions: Sadia Ahmed (SA) sampled a subset of studies from a previously conducted systematic review which was conceived by Andrew Clegg (AC), Thomas Crocker (TC), John Gladman (JG), and Richard Riley (RR). This systematic review was designed by AC, TC, JG, RR, Joie Ensor (JE), Anne Forster (AF), Magda Jordão (MJ), Natalie Lam (NL), and Eleftheria Patetsini (EP). Deirdre Andrew executed the database and trial register searchers. TC, MJ, NL, EP, John Green (JGr), Jessica Morgan (JM), Ridha Ramiz (RRa) and Rebecca Walford (RW) conducted the study selection. AC, TC, AF, JG, MJ, NL, and Alison Ellwood (AE) conducted intervention grouping. SA conceived, designed and applied the MOSAIC tool to the sample of studies selected from the systematic review. SA completed data extraction of the studies selected for the systematic methods overview. SA synthesised findings of the systematic methods overview and wrote this up.

Chapter 4

Contributions: SA designed the SWAT, randomised and trained the intervention deliverers, and collected and analysed qualitative data through interviews with service users and intervention deliverers. SA led the analysis of both the quantitative and qualitative data. Ellen Thompson (ET) and Bethan Copsey (BCo) provided advice and assistance to aid with the statistical analysis of quantitative data. Suzanne H Richards (SHR) contributed to the analysis of qualitative interview data by independently coding a sample of interview transcripts and discussing themes generated with SA.

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Contributions: SA conceived the idea for the paper and led the PROSPER SWAT as part of her PhD research. SA led the write up of the paper.

Jennifer Airlie (JA) was involved in the design of the RECREATE SWAT. JA contributed to drafts of the article, critically reviewed and revised different versions of the paper.

AC is Principal Investigator of the PROSPER Trial, an academic supervisor on SA's doctoral studies and contributed to the development of the SWAT methods. AC reviewed article drafts.

Bethan Copsey (BCo) was involved in the design of the RECREATE SWAT. BCo contributed to drafts of the article, critically reviewed and revised different versions of the study.

Bonnie Cundill (BC) was involved in the design of the PROSPER SWAT and is the statistical lead for the PROSPER host trial. BC critically reviewed and revised different versions of the article.

AF is Principal Investigator of the RECREATE Trial, contributed to the development of the SWAT methods and assisted with the development of this paper. AF critically reviewed and revised different versions of the study.

Anne Heaven (AH) is the PROSPER Programme Manager and was involved in the instigation and development of the PROSPER SWAT video animation. AH reviewed and contributed to article drafts.

Jessica F Johansson (JFJ) was involved in the design of the RECREATE SWAT and is leading the nested process evaluation described in the manuscript. JFJ contributed to drafts of the manuscript, critically reviewed and revised different versions of the article.

Nicola Kime (NK) led the analysis and write up of the PROSPER feasibility study and was instrumental in the development of the PROSPER SWAT video animation. NK reviewed and contributed to article drafts.

Lauren Moreau (LM) was involved in the design of the RECREATE SWAT. LM critically reviewed different versions of the article.

Seline Ozer (SO) was involved in the design of the RECREATE SWAT. SO contributed to drafts of the manuscript, critically reviewed and revised different versions of the article.

Catriona Parker (CP) was involved in the delivery of the PROSPER SWAT study. CP contributed to drafts of the manuscript, critically reviewed and revised different versions of the article.

SHR was involved in the design of the PROSPER SWAT, and is an academic supervisor on SA's doctoral studies. SHR contributed to drafts of the article, critically reviewed and revised different versions of the article.

Ellen Thompson (ET) was involved in the statistical design of the PROSPER SWAT, contributed to discussions around the statistical considerations, and reviewed different versions of the article.

Amanda J Farrin (AJF) conceived the idea for the paper, designed the host trials and embedded SWATs and is the lead supervisor on SA's doctoral studies. AJF co-led article writing.

Presentations

International Conference (oral)

Sadia Ahmed. A new opportunity for enhancing trial efficiency: Use of SWAT methodology to investigate intervention implementation processes – Case studies of two trials. International Clinical Trials Methodology Conference, Harrogate, October 2022.

International Conference (poster)

Sadia Ahmed. Methods used to measure implementation of complex interventions within trials and the strategies employed to optimise their implementation: a systematic methods overview. International Clinical Trials Methodology Conference, Harrogate, October 2022.

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Sadia Ahmed. How does the use of a video animation to introduce a complex intervention affect participant engagement and uptake within trials? International Clinical Trials Methodology Conference, Harrogate, October 2022.

Planned Future Presentations

International Conference

Sadia Ahmed. How does the use of a video animation to introduce a complex intervention affect participant engagement and uptake within trials? Results. International Clinical Trials Methodology Conference, Edinburgh, October 2024.

Sadia Ahmed. Development of MOSAIC toolkit. International Clinical Trials Methodology Conference, Edinburgh, October 2024.

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Abstract

Background

When clinical trials of complex interventions fail to demonstrate intervention effectiveness, this may be attributable to poor implementation rather than an ineffective intervention. Implementation methods and strategies can support implementation of complex interventions within trials, but these are often under-researched and poorly reported. By improving their reporting, we can address weaknesses, reduce research waste and improve quality of clinical trials.

Aim

The aim of this PhD was to investigate methods used to measure implementation and strategies employed to optimise implementation of a complex intervention within the context of trials involving older people, and their potential to impact on participant outcomes.

Methods

This was addressed through a mixed-methods approach, consisting of a broad systematic methods overview across all populations and disease areas. This was followed by a focused methods overview involving complex interventions targeted at older people with frailty. Subsequently, a mixed-methods study within a trial (SWAT) was undertaken to investigate use of an animated video as a strategy to optimise the implementation of a complex intervention in a trial involving older people.

Results

The first systematic methods overview found that most studies reported methods used to measure implementation, however there was little focus on strategies for optimising intervention implementation. This informed the development of the MOSAIC tool which was tested and refined through the second systematic methods overview, which found the tool useful and easy to use. The mixed-methods SWAT found no difference between uptake and engagement rates in the SWAT intervention and control groups. Qualitative

interview data found the Personal Independence Coordinator (PIC) to be a motivating factor for service user uptake and engagement.

Conclusion

The MOSAIC tool provides a useful framework for researchers to report implementation of complex interventions within trials. The SWAT showcased a novel use of this methodology for investigating intervention implementation within a trial.

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Abbreviations

CFIR	Consolidated Framework for Implementation Research
CTRU	Clinical Trials Research Unit
HTA	Health Technology Assessment
MOSAIC	Methods for measuring and OptimiSing the Implementation of Complex Interventions
MRC	Medical Research Council
NIHBCC	National Institute of Health's Behaviour Change Consortium
NIHR	National Institute for Health Research
PARIHS	Promoting Action on Research Implementation in Health Services
PIC	Personal Independence Co-ordinator
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
PROMETHEUS	PROMoting THE USE of SWATs
PROSPER	PeRsOnaliSed care Planning for oldER people with frailty
RCT	Randomised Controlled Trial
RDE	Remote Data Entry
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance
REC	Research Ethics Committee
SWAT	Study Within A Trial
TMRP	Trials Methodology Research Partnership

Chapter 1
Introduction

1.1 Background

In the year 2021/2022, the National Institute for Health Research (NIHR) for England awarded around £400 million of funding to research programmes, many of which are clinical trials testing new, complex interventions[4] as the preferred method for testing their effectiveness. However, a trial may fail to demonstrate intervention effectiveness due to poor implementation rather than the intervention being ineffective [5]. To be able to differentiate between an ineffective intervention and poor implementation, there is a need for a concerted effort into investigating implementation, both the methods used to measure implementation within trials and also the strategies employed to optimise the implementation of a complex intervention within a trial. By doing this, we can ensure better translation of research into practice, minimise the number of trials failing to demonstrate intervention effectiveness due to poor implementation rather than the intervention being ineffective, and increase the evidence base for efficient trial design and conduct. Addressing methodological weaknesses in the design, conduct and analysis of clinical trials can help reduce research wastage and improve the quality of clinical trials[6].

This thesis explores the use of methods to measure complex intervention implementation and strategies to optimise implementation of a complex intervention within the context of a randomised controlled trial (RCT).The term ‘implementation’ can be used both to describe post-evaluation scale-up and also delivery of an intervention during a trial[5]. In this thesis, ‘implementation’ refers mostly, unless stated otherwise, to delivery of an intervention during a trial.

The overarching aim of this PhD was to investigate methods used to measure implementation and strategies employed to optimise implementation of a complex intervention within the context of trials involving older people, and their potential to impact on participant outcomes. This was addressed through a mixed-methods approach, consisting of a broad systematic methods overview across all populations and disease areas. This was followed by a more focused methods overview involving complex interventions targeted at older people with frailty. Subsequently, a

study within a trial (SWAT) was undertaken to investigate the use of a specific strategy employed to optimise the implementation of a complex intervention in a trial involving older people. This chapter covers the background, definitions of terms that are used in this thesis, and aims and objectives of the thesis.

1.1.1 Complex interventions

Complex interventions consist of multiple interacting components, often selected by intervention developers based on existing evidence-based intervention components which are then combined to create a more complex intervention. Complex interventions also have several other features that deem them to be complex[7]. They often target multiple groups or organisational levels, for example a hospital-based intervention may target hospital staff, patients and their family members. Often, complex interventions require a number of different behaviours to be enacted as part of delivering and receiving the intervention. These behaviours then target and impact upon various different outcomes which are measured as part of testing the effect of the complex intervention. Finally, some complex interventions allow a degree of tailoring or personalisation of the intervention to suit individuals within the target population.

A complex intervention can be described as a 'black box', meaning that we cannot always be clear about precisely what is contained within the intervention and how it works[8]. Furthermore, if the intervention is shown to be effective, we may not be clear about the reasons behind its effectiveness, partly due to the fact complex interventions are made up of different components, some of which may be 'active' and others less so[9]. An active component is one which makes the intervention effective, though it is not always easy to precisely identify these.

The effectiveness of complex interventions is usually formally evaluated through the 'gold standard' method of RCTs[10], which are generally large in scale and costly to conduct. RCTs test the overall effectiveness of the 'black box' and cannot necessarily determine the relative contributions of the different components of the complex interventions. When RCTs fail to show the effectiveness of a complex intervention, we cannot be sure if this is due to the lack of a treatment effect arising from the intervention or another factor, such as poor implementation [11]. Due to the complex nature of the intervention and the context within which it is being tested, it

can be difficult to tease out the reasons for ineffectiveness [12]. Context, as used here, can be defined as the setting or environment within which the intervention is being implemented [13, 14]. The complex intervention and its components, the context in which it is implemented, and its implementation are closely linked, and all interact with one another, making it difficult to separate what constitutes each of these [15].

Establishing evidence on the effectiveness of complex interventions is built up over several stages or phases[2], which employ different methods at each stage (Figure 1). The pre-clinical phase is where researchers establish the theory behind the complex intervention and this involves reviewing existing evidence and theories and identifying the kind of intervention and study design required. Following this, the complex intervention is modelled in Phase I, by outlining the various components and how they may interact with one another. Phase II precedes a formal RCT and may involve a pilot trial or mixed-methods work in order to begin to test the potential effectiveness of the intervention. Pilot, or feasibility studies, provide the opportunity to test the feasibility of a larger scale and more expensive definitive trial[16]. At this stage, the intervention can be optimised or refined based on findings of a pilot trial or qualitative work. Though these terms are often used interchangeably, a feasibility study questions whether something can be done, how and whether to proceed to a definitive trial. In comparison, a pilot study asks the same questions whilst conducting something on a smaller scale than what is eventually planned for a definitive trial[17].

Phase III is where the definitive trial takes place, often on a much larger scale than the pilot study, in order to evaluate effectiveness of the complex intervention. Finally, Phase IV is concerned with the long-term and real-life effectiveness of the intervention. Over the course the complex intervention is optimised, and it becomes more fixed and less open to adaptation of its components. The context within which the complex intervention is implemented also changes from one phase to the next and the process of implementation may well change too. Crucially, there could be a failure of implementation at any point within this framework, which would in turn impact upon intervention effectiveness. Therefore, it is equally important to study implementation of a complex intervention within the context of a trial alongside evaluating the complex intervention and its components.

In the UK, the Medical Research Council (MRC) guidance for developing and evaluating complex interventions is a widely used and influential framework for researchers in this field[18]. This guidance, first published in 2000[2], and consequently updated in 2008[7], 2014[5] and 2021[3], was developed through consensus workshops involving groups of experts. The 2008 update of the MRC guidance addressed limitations of the previous version such as a lack of emphasis on piloting and development, linearity of the model, and a disregard for context in which the intervention is implemented. Figure 2[7] depicts the key elements of this guidance in the four phases: development, feasibility and piloting, evaluation and implementation. It is not necessary that they would follow each other in a linear or cyclical fashion, in practice, although the diagram may suggest this[7]. Within this guidance, implementation followed evaluation of the complex intervention and referred largely to wider scale-up of the complex intervention in the real-world. The guidance did, however, suggest that a process evaluation conducted alongside a trial would enable investigation of fidelity and quality of intervention implementation. Fidelity is defined as the degree to which an intervention is implemented as intended[19].

This was followed up by the MRC guidance for process evaluation of complex interventions, published in 2014, which provided a more thorough framework for investigating implementation of a complex intervention during a trial[5]. The MRC guidance from 2008 suggested a ‘step wise’ model, with methods changing along each stage until this culminated in trials and post-trial evaluations. In comparison, more recent versions of the MRC guidance propose a more iterative cycle.

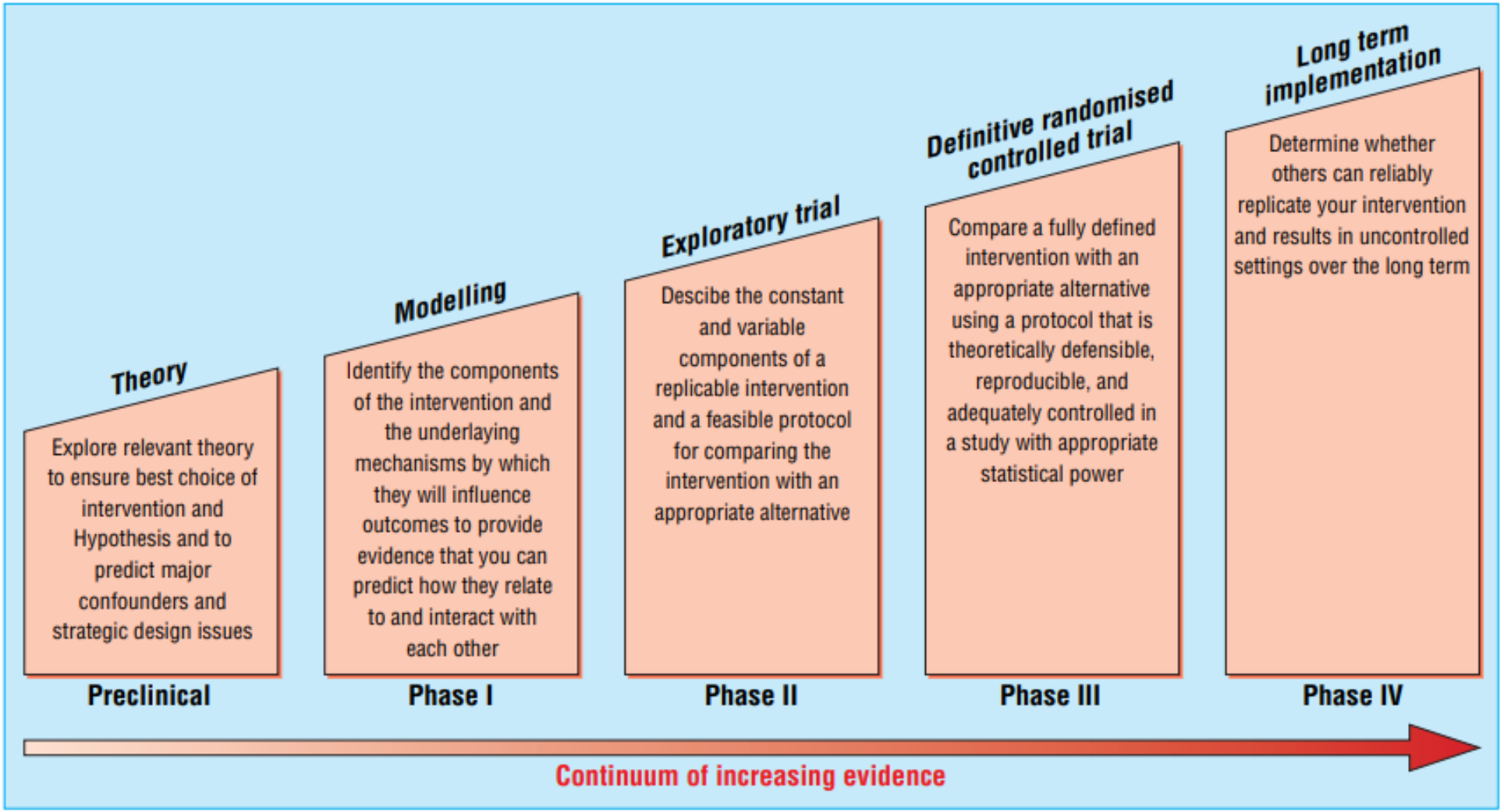


Figure 1 A framework for development and evaluation of RCTs for complex interventions to improve health[2]

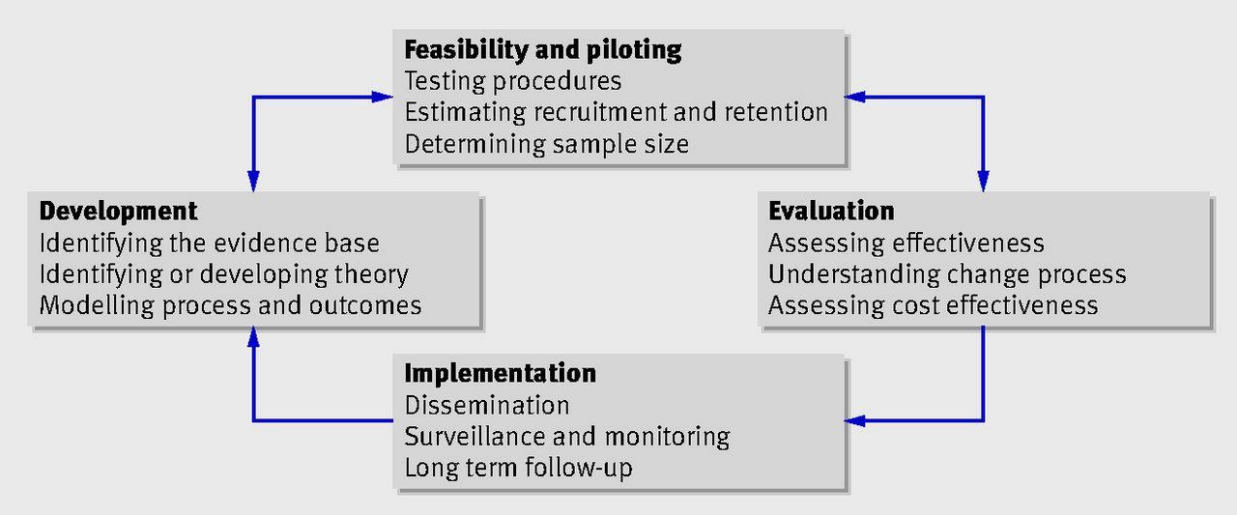


Figure 2 Flowchart of the key elements of the development and evaluation process [7]

This PhD project commenced in 2019, therefore the MRC guidance for process evaluation of complex interventions published in 2014 was the operational framework against which this project was undertaken. The most recently updated MRC guidance for developing and evaluating complex interventions, published in 2021 reiterates the four phases of complex intervention research: development, feasibility, evaluation and implementation. It goes on to identify six core elements which should be considered and revisited within each phase, as depicted in Figure 3[3]. It suggested that implementation should be considered as early as possible within the process of development and evaluation, with some emphasis on process evaluations for investigating intervention failure or unintended consequences. Thus, over the past decade, within the guidance literature, there has been a steady shift from sequential through to more iterative cyclical processes whereby important core elements are considered at every stage from intervention development to feasibility testing to definitive trials.

Whilst there are strengths to the MRC guidance and it is widely adopted, there remain many grey areas regarding its operation. The latest iteration (2021) was proposed in response to challenges reported when operationalising the previous versions. Whereas previously the focus was on effectiveness, there has now been a shift towards understanding acceptability of the intervention, how it will be implemented, whether it is cost effective, scalable and transferable to different

contexts[3]. The new iteration is an attempt to address these issues, acknowledging the complexity of evaluating complex interventions, but is mostly untested in the ease of application. This PhD is focussed on understanding the methods used to measure and optimise implementation of a complex intervention within the context of a trial. It is important to be clear of the definitions of these terms before discussing further.

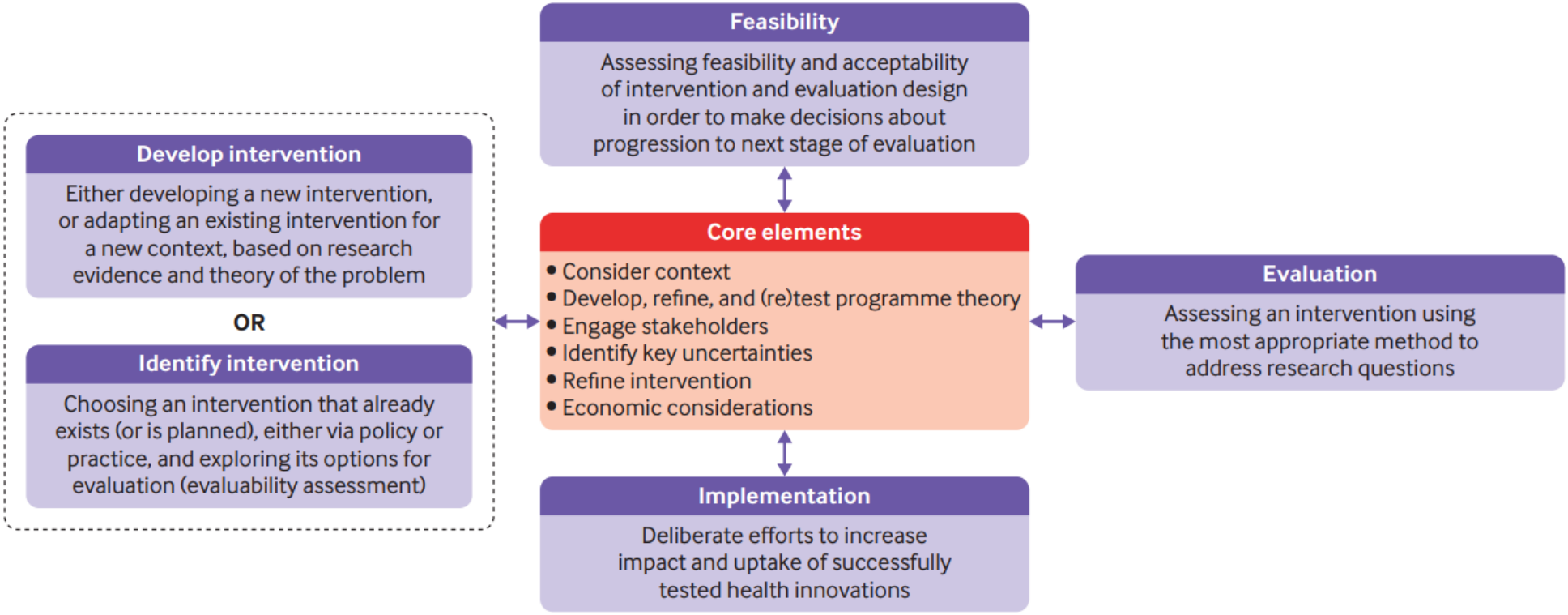


Figure 3 Framework for developing and evaluating complex interventions[3]

1.1.2 Optimisation

Optimisation, also referred to as enhancement or maximisation, is defined as “a deliberate and data-driven process to improve a health intervention and/or its implementation to meet stakeholder-defined public health impacts within resource constraints”. [20] Optimisation is also used to refer to the process of improving the efficiency of a complex intervention [21], by identifying the most promising components and conditions of the intervention [22], before evaluation. Efficiency in this context, refers to achieving the best outcome, whilst using the least effort or expense.

Feasibility studies are often used as a vehicle for optimising complex interventions before they are evaluated in a full scale RCT. In the earlier versions of the MRC guidance, optimisation sat firmly within the feasibility and piloting section of the flowchart (Figure 2)[7]. Though not referred to as optimisation, the guidance referred to ‘refinements’ that may be made to the design of an intervention prior to full scale evaluation. Refinement, in this context, can be defined as ‘the process of fine tuning or making changes to the intervention once a preliminary version (prototype) has been developed’[3]. The process of optimisation or refinement of a complex intervention is an iterative process[21] which may well take place a number of times during the life cycle of a trial. Through optimisation, it should be possible, in theory, to separate those components which are likely to show little effect and remove them prior to a full scale RCT. However, there are questions yet to be answered, about when an intervention is optimised enough, or ready for full scale evaluation in an RCT[23]. The MRC guidance from 2021 outlined intervention refinement as a core element that is common across all four phases of the framework: intervention development, feasibility, evaluation and implementation (Figure 3)[3].

Intervention optimisation is a key concept within the field that overlaps considerably with implementation of a complex intervention within a trial. However, in this thesis, when referring to optimisation, the focus primarily is on optimising the implementation of a complex intervention within a trial. Thus, for the purpose of this PhD, optimisation is defined as the process through which the implementation of a complex intervention has been refined. This may well include refinements made to the delivery of the intervention, such as an alternative mode of delivery being made available in order to optimise the implementation and improve its effectiveness.

1.1.3 Implementation

The term ‘implementation’ traditionally refers to the process by which an evidence-based intervention is brought into routine practice [24, 25] . However, it can also be used to describe the delivery of a complex intervention during a trial [5], though this is a less common use of the term, which is indicative of the lack of research in this area. The focus of this PhD project is concerned with the latter definition, referring to implementation of a complex intervention within the context of a trial. Since there is no universally accepted definition of intervention implementation, for the purpose of this PhD project, intervention implementation is defined as *‘the structures, resources and process through which delivery of the intervention is achieved and the quantity and quality of what is delivered.’* [5]

One key concept relating to implementation is fidelity. There is a degree of ambiguity surrounding the concept of fidelity and a lack of guidance for how it may be addressed in complex intervention trials [26]. It is important to emphasise that fidelity is just one aspect of implementation and implementation is broader than just measuring fidelity, although there is considerable overlap between the two terms within the context of complex interventions in trials. Generally, in trials, more resources are dedicated towards evaluating effectiveness and cost-effectiveness of complex interventions, than into measuring or optimising complex intervention implementation [27]. Therefore, there is a lack of evidence on intervention implementation processes within the context of trials. Hence, the methods used to implement complex interventions within trials are based on experiential knowledge rather than being evidence-based. Researchers may utilise one or more of a number of frameworks for implementation of a complex intervention in a trial.

1.1.4 Frameworks for implementation

There are two distinct types of frameworks for implementation; those for implementing evidence-based interventions into practice and those for implementing interventions during research, for example within the context of a trial. Examples of these are discussed below.

The Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework for adoption and implementation of evidence-based interventions outlines five steps to translate research into action [28]. These are: reach, effectiveness or efficacy, adoption, implementation and maintenance. Reach can be defined as the number, proportion and representativeness of individuals willing to participate in the intervention and reasons why[29]. Effectiveness refers to the impact of an intervention on individual outcomes, such as quality of life. Adoption was defined as the number or proportion of settings and intervention deliverers who were willing to initiate the intervention and why. The implementation step here is concerned with fidelity to the intervention, as well as consistency of delivery, time and cost of the intervention. It is also concerned with the participant's use of the intervention strategies. Finally, maintenance refers to the extent to which the intervention becomes part of routine practice. Originally developed to encourage consistency in reporting of research, the RE-AIM framework is now used for translating research into practice, i.e. implementation in real-world settings.

The PARIHS framework (Promoting Action on Research Implementation in Health Services) describes how successful implementation may be achieved through nature and type of evidence, the context and ways in which the process of implementation is facilitated [30]. In this framework, 'evidence' is defined as "knowledge derived from a variety of sources that has been subjected to testing and found to be credible"[30]. This may include research, clinical experience, patient experience and local data or information. Context refers to the setting or environment in which the implementation takes place, and facilitation describes the process by which implementation is made easier. Similarly to the RE-AIM framework, the PARIHS framework is used when implementing research into practice.

Despite these frameworks being intended for use when implementing research into practice, they are still useful to refer to within the context of trials as similar concepts may apply. However, other frameworks are designed specifically for implementation during research. One example is the Conceptual Framework for Implementation Research (CFIR) from Carroll and colleagues [19]. The CFIR focuses mainly on fidelity, referred to as 'implementation fidelity.' In this framework, adherence to the content, coverage, frequency and duration of the intervention, as described by the

intervention designer(s) is emphasised as the main requirement to achieve fidelity [19]. As noted earlier in this chapter, the term fidelity can be ambiguous, and is often used interchangeably with terms such as ‘adherence’ and ‘implementation’ [5].

In this thesis, ‘fidelity’ is used to describe the degree to which an intervention is implemented as intended[31]. Thus, it is just one of the elements which sits under the umbrella term of implementation. Carroll and colleagues proposed that for an intervention to be implemented with fidelity, it should adhere to the content, coverage, frequency and duration as described by the intervention designers. They also refer to ‘moderators’ which are factors that may affect the degree of fidelity. These include intervention complexity, facilitation strategies, quality of delivery and participant responsiveness.

Some frameworks for implementation research refer to process evaluation, which can be used to assess fidelity and other aspects of intervention implementation, as well as exploring mechanisms and contextual factors which impact outcomes [7]. Process evaluation can refer to the intervention itself, methods used in the trial or both. Process evaluations are increasingly used alongside trials to explore implementation issues, but the degree to which intervention implementation is examined is unclear. Often, the scope of the process evaluation is constrained due to the availability of resources, therefore intervention implementation may not be thoroughly examined if it is not prioritised within constrained resources.

The MRC developed a framework for conducting process evaluations of complex interventions (Figure 4) [27]. Although previous MRC guidance established the value of process evaluations, there was a distinct lack of specific guidance on how to conduct a process evaluation of a complex intervention. This framework addresses this gap by building on the 2008 MRC guidance, and providing clear recommendations for researchers. As emphasised in the framework, the focus of the process evaluation may differ depending on the stage of the research programme [27]. Within implementation, they suggest researchers should consider the implementation process, what is delivered, fidelity, dose, adaptations and reach.

Saunders and colleagues also proposed a framework through which they demonstrate how to develop a process evaluation plan which can be used to assess

implementation [32]. Within this framework, they present a step-by-step plan for the development of process evaluations (Figure 5) [32]. They suggest the consideration of steps 3-5 in an iterative manner, which is key, as emphasised in the MRC guidance for developing and evaluating complex interventions[3, 7]. Saunders and colleagues also include detail on how the various aspects of implementation may be measured, including possible questions to consider and information needed. These aspects include fidelity, dose (delivered and received), reach, recruitment and context.

Similarly, Grant et al proposed a framework for the design of process evaluations, specifically for cluster RCTs [33]. A cluster RCT is a randomised controlled trial in which groups of individuals are randomly allocated to treatment arms[34]. The groups are termed clusters. There was a lack of clear guidance for process evaluations of cluster RCTs prior to this framework being developed by Grant and colleagues. Recruitment, reach and delivery, to clusters and to the target population, alongside maintenance, effectiveness and unintended consequences were included in this framework. Maintenance is a key term which refers to whether the processes such as recruitment, reach and delivery are maintained over time. This is important, especially for trials with longer durations. Unintended consequences of an intervention are also important, though often overlooked. Identifying and measuring unintended consequences, particularly in terms of knowing whether these are helpful or harmful for the trial participants can be done through process evaluation[33].

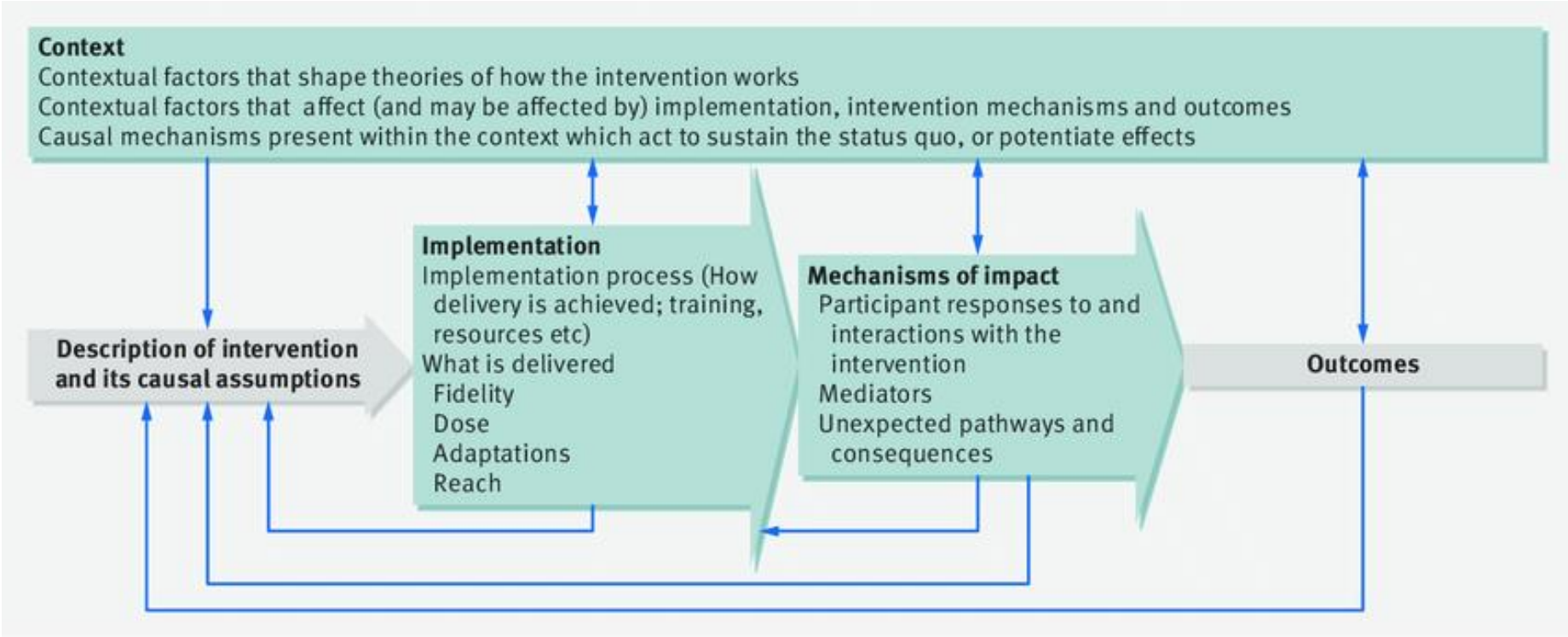


Figure 4 Key functions of process evaluations[27]

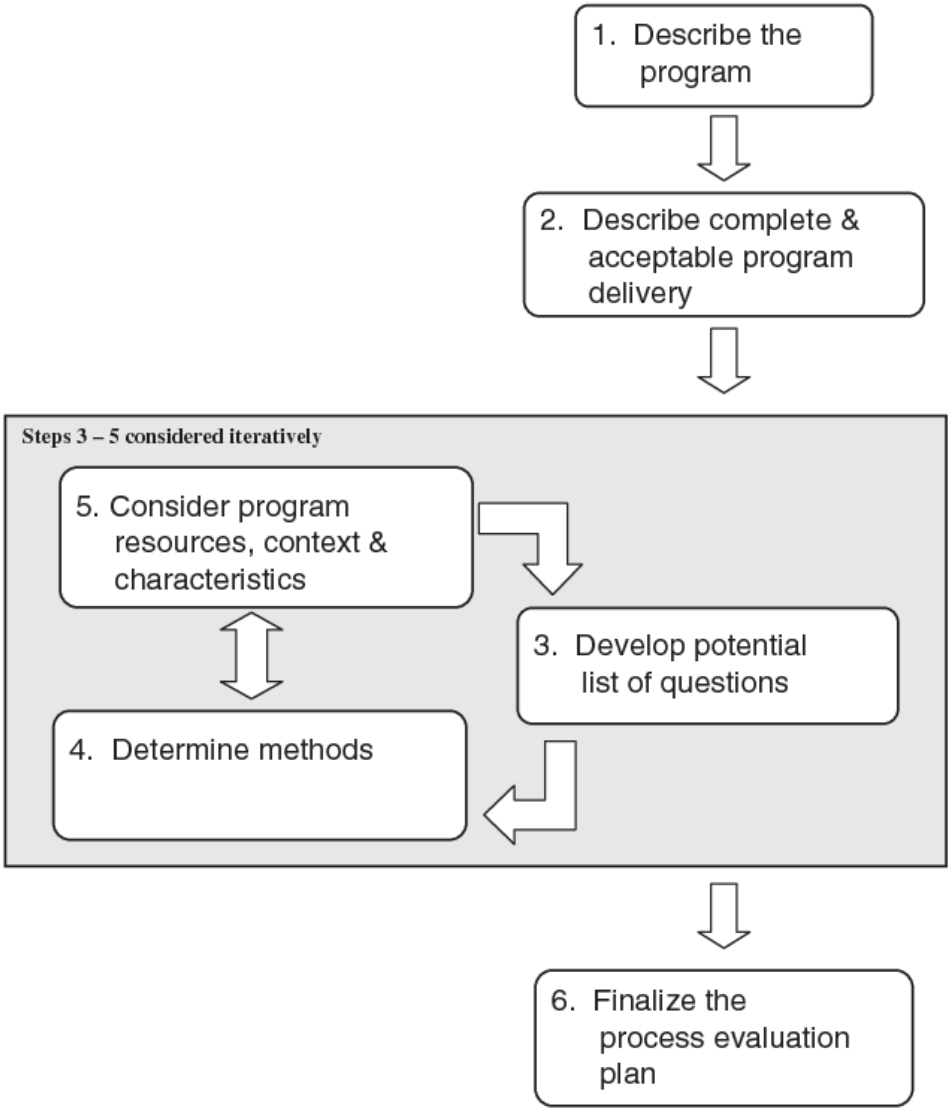


Figure 5 Steps in the process evaluation planning [32]

Though there is some variation in the content of implementation frameworks in the literature, one thing that is widely agreed is that to establish the reason for effectiveness of an intervention, there is a need to evaluate fidelity [1] and the implementation process as a whole. It is possible that the frameworks in this area are missing guidance on how to optimise the implementation process. The CFIR developed by Carroll and colleagues includes a number of strategies that may be used to facilitate implementation such as training, feedback and the provision of

manuals[19]. However, there is a need for guidance on how to operationalise these facilitation strategies.

Similarly, Borrelli and colleagues from the National Institute of Health's Behaviour Change Consortium (NIHBCC) developed a treatment fidelity framework which proposes guidelines for assessing, monitoring and enhancing treatment fidelity[1]. These guidelines are arranged in five domains: *study design, provider training, treatment delivery, treatment receipt and treatment enactment*. Study design refers to ensuring a study can test its hypotheses in relation to its underlying theory and clinical processes[35]. This includes operationalising active components of the intervention in order to ensure fidelity[1]. Training of intervention providers includes educating and providing those delivering the intervention with the necessary skills to do so. Treatment delivery relates to ensuring that the intervention is delivered as intended by those who developed it. Receipt of the intervention refers to what the participant receives, focusing on their ability to understand and perform the necessary behaviours. Similarly, enactment focuses on the participant and their ability to continue performing the necessary behaviours from the intervention outside the context of intervention delivery, i.e. in a real-life setting[35].

Although the NIHBCC treatment fidelity framework is focused more closely around 'treatment fidelity' as opposed to implementation as a whole, it remains relevant to implementation when intervention fidelity is conceptualised as a sub-component i.e. this framework can be applied to specify the domains and strategies proposed to optimise intervention implementation. The NIHBCC treatment fidelity framework and its five domains are used in Chapters 2 and 3 of this thesis as a backdrop against which to present findings from systematic methods overviews. The diagram in Figure 6 demonstrates how the five domains from the NIHBCC treatment fidelity framework have been used to break down implementation of a complex intervention within a trial for the purpose of this thesis. As shown in the diagram, context runs throughout implementation across all five domains. The elements beneath each domain demonstrate examples of potential aspects to measure or optimise, though these are not exhaustive and may be referred to using varying terminology in the literature. For example, 'participant engagement' may be termed 'participant responsiveness'.

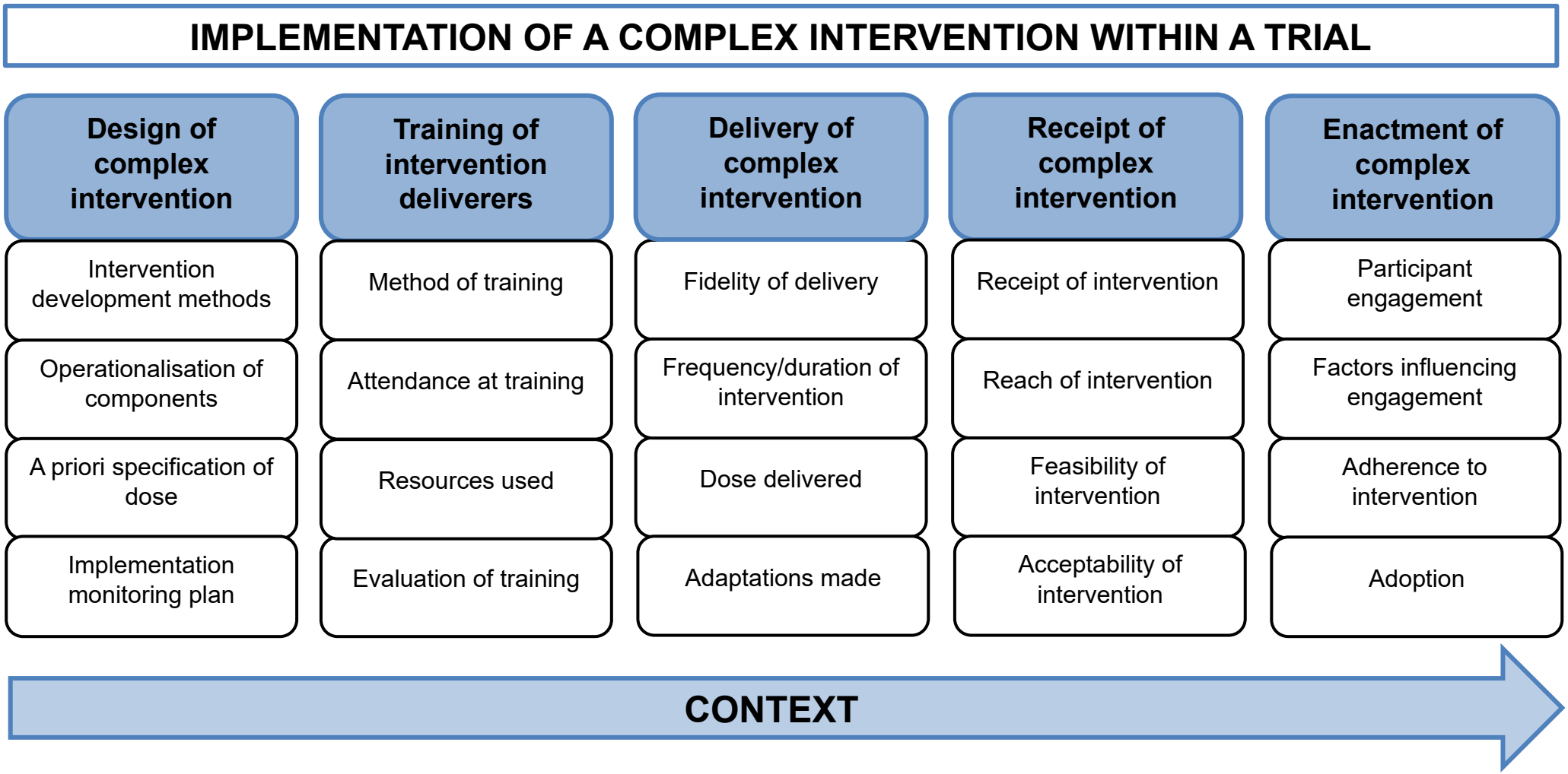


Figure 6 A breakdown of complex intervention implementation using the five domains from the NIHBCC treatment fidelity framework[1]

Though Borrelli and colleagues use the term ‘enhancing’, this is essentially interchangeable with ‘facilitating’ as used by Carroll and colleagues, or ‘optimising’, as used in this thesis. Both the CFIR[19] and the NIHBCC treatment fidelity framework[1] offer worthwhile strategies for optimising implementation of a complex intervention, but further and more detailed guidance is needed to outline and describes ways in which these strategies can be operationalised. As well as this, there needs to be a concerted effort made to test optimisation strategies, potentially through the use of a study within a trial (SWAT).

Strategies for optimising implementation of a complex intervention may well be transferable from the context of a trial to the implementation of a complex intervention in a real world setting, particularly for pragmatic trials. This thesis focuses on implementation optimisation strategies within the context of a trial but it is worth noting that it could be argued that the same strategies could be applied in the real world setting. Another point to consider about strategies for optimising implementation of a complex intervention is whether they are actually just part of the complex intervention. In this case, employing optimisation strategies would equate to changing the complex intervention which could lead to a failure of trial validity. It could be argued that it depends entirely on the nature of the intervention and the optimisation strategy to which degree they are both simply part of the complex intervention itself. Also, it would depend on the degree to which the optimisation strategy alters the intervention i.e. whether it is a minor refinement or changes the intervention entirely. There is no one rule for all complex interventions, therefore these considerations would apply differently depending on the nature of the intervention and the optimisation strategies used.

1.1.5 Study within a trial

A SWAT is a self-contained research study embedded within one or more host trials to explore or evaluate alternative methods of delivering or conducting a particular trial process[36]. Conducting SWATs alongside trials allows researchers to answer questions surrounding trial conduct and delivery to fill gaps in evidence about the best ways of conducting trial processes. To date, most SWATs are focused around improving trial methods (e.g. trial recruitment and retention procedures) (PROMoting THE USE of SWATs (PROMETHEUS) programme)[37], and do not test options for

maximising implementation processes to bolster intervention fidelity. SWAT methodology can also be utilised to investigate minor refinements to implementation processes of a complex intervention within a trial[38]. This thesis proposes a novel use of SWAT methodology for investigating intervention implementation processes, and the effects of a strategy employed to optimise implementation (Chapter 4). This is also one of the first examples of a mixed-methods SWAT, including a nested cluster RCT and a qualitative interview study. Previous research described the use of a video as a strategy to optimise fidelity of delivery, however the video was used to train the intervention deliverers to deliver the intervention [39]. Though there is some overlap, the video animation in the SWAT described in this thesis was targeted at optimising service user uptake and engagement with the intervention. Engagement is important because it is a pre-requisite to fidelity. Without service user engagement, changes in outcomes cannot be attributed to the intervention since the intervention was never engaged with fully [40].

1.2 How I plan to address this knowledge gap

Clinical trials are large scale, often expensive endeavours. It is estimated that 85% of research activity leads to research waste [6]. To reduce this, we should aim to fill in knowledge gaps to maximise the usefulness of the gold standard RCT. The gap identified here is that there is a lack of research into the methods for intervention implementation during a trial. There are currently no existing methods overviews published to guide our understanding of the methods used by research teams when measuring intervention implementation within a trial. Similarly, there are no reviews of the strategies employed to optimise implementation of a complex intervention within the context of a trial.

1.2.1 Systematic methods overview 1

In my first study, I conducted a systematic methods overview to address both of these gaps in the literature. This systematic methods overview reviewed existing complex intervention trials and associated literature to identify the methods used to measure and the strategies employed to optimise the implementation of a complex intervention within the context of a trial. It was not restrictive in terms of the target population, disease areas or health conditions included, thus allowing for a broad range of methods and strategies utilised across trials involving people of all ages

with all types of health conditions to be captured. The systematic methods overview informed my development of the MOSAIC (Methods for measuring and OptimiSing the Implementation of Complex Interventions) tool to aid the reporting of implementation processes of complex interventions within trials (Section 2.4.3).

1.2.2 Systematic methods overview 2

This was followed by a second, more focused systematic methods overview which involved a sample of trials investigating community-based complex interventions for older people with frailty, accessed from a recently completed National Institute for Health Research-Health Technology Assessment (NIHR-HTA) funded evidence synthesis[41]. This methods overview aimed to test, refine and update the previously developed MOSAIC tool using trials involving the population of interest - older people, including those living with frailty. There are a number of reasons for focusing on trials involving older people. This population has historically been excluded from research[42]. Secondly, the UK NHS Long Term Plan [43] identifies the increasingly ageing population as a key driver of service demand. The Plan emphasises development of community services to help people age well. These often take the form of complex interventions with multiple interacting components that can be tailored to the needs of older people. Through the process of conducting this focused methods overview, the methods used to measure implementation and strategies employed to optimise implementation of complex interventions within the sample of trials identified, were documented using the MOSAIC tool, allowing for this tool to be tested rigorously. Previously identified methods and strategies from the first overview were sought out, as well new methods and strategies that were not already captured in the MOSAIC tool.

1.2.3 Study within a trial

Finally, a SWAT was embedded within the PeRsOnaliSed care Planning for oldER people with frailty (PROSPER) host trial, consisting of a nested RCT and a qualitative interview study. This SWAT was embedded within the PROSPER host trial (funded by an NIHR Programme Grant for Applied Research RPPG-0216-20003) [44]. The PROSPER trial aims to assess the effectiveness and cost-effectiveness of a personalised care planning intervention in improving quality of life

for older people (aged 65 years and over) living with frailty. The PROSPER trial and embedded SWAT are described in more detail in Chapter 4.

This SWAT compared the effect of an animated video to optimise service user uptake of and engagement with the intervention versus a no video control. The SWAT demonstrated a novel use of the methodology for investigating implementation of a complex intervention within a trial. It took a mixed-methods approach to investigating this, through an RCT and a qualitative interview study. Mixed-methods research involves collecting and integrating qualitative and quantitative data to draw interpretations from both datasets to answer research questions [45].

In summary, the research in this thesis focuses on the methods used to measure and the strategies employed to optimise the implementation of a complex intervention within the context of a trial, with a focus on a trial involving older people as the exemplar. This is an important and evolving area of trials methodology research, in which this thesis provides a novel contribution.

1.3 Aims and objectives

The overarching aim of this thesis was to investigate methods used to measure implementation and strategies employed to optimise implementation of a complex intervention within the context of trials involving older people, and their potential to impact on participant outcomes. This was addressed through the following objectives:

1. To systematically review the existing literature: to (a) identify and describe qualitative and quantitative methods used for measuring implementation of complex interventions within trials, and (b) identify and describe the strategies employed to optimise implementation of complex interventions within trials.
2. To develop a tool (MOSAIC) to aid with reporting of implementation processes of complex interventions with trials.
3. To systematically review a sample of complex intervention trials involving older people to: (a) identify and describe the qualitative and quantitative methods used to measure implementation, and (b) identify and describe the strategies employed to optimise implementation.

4. To test, refine and update the previously developed MOSAIC tool using a sample of complex intervention trials involving older people.
5. To conduct a SWAT embedded within the PROSPER trial to investigate the effect of an animated video versus no video on optimising the implementation of the PROSPER intervention, through increasing servicer user uptake of, and engagement with, the intervention.
6. To undertake a qualitative interview study, within the SWAT, to understand the views of service users and staff surrounding the use of an animated video as a strategy to optimise implementation of the PROSPER intervention.

Chapter 2
A Systematic Methods Overview of the Methods used to Measure Implementation and Strategies to Optimise Implementation of Complex Interventions within Trials

2.1 Rationale

To date, there are no reviews of the methods used to (1) measure complex intervention implementation, or (2) strategies employed to optimise complex intervention implementation within trials. Understanding the strengths and weaknesses of different methods for measuring and strategies for optimising complex intervention implementation is necessary to ensure efficient trial conduct and reduce research waste.

This systematic methods overview therefore aimed to review the methods used to measure implementation and strategies to optimise implementation of complex interventions within trials reported over the past five years (2015-2020). Reviewing the methods literature on a given topic is a relatively new approach to evidence synthesis [46], and was selected over a traditional systematic review as the area of interest is in methods used rather than research findings (e.g. intervention effectiveness). The key methodological difference is that methods overviews do not require exhaustive searching nor are they meant to include all relevant literature. Rather, it is expected that a range of methodological approaches are used repeatedly in the literature and therefore appear multiple times within searches.

The overview sought to capture a wide range of methods, not necessarily estimate the number of times a method is used within complex intervention trials. With this method, there are the potential risks of missing methods which are used infrequently as well as being unsure as to whether all methods within the topic have been captured. Although this is not a traditional systematic review, a systematic approach was taken to report the findings of this overview, since it is more rigorous [47].

This overview was not restricted to a specific population as the same methods to measure implementation and strategies to optimise implementation can be applied to different populations. The focus was on primary research papers reporting findings

from trials of complex interventions, since this overview is about methods used in trials.

It is important to have clear and concise definitions for the key terms included in this overview, especially since I refer to many overlapping constructs. All key terms are defined in the introductory chapter; however it is useful to refer back to some of these here.

A complex intervention consists of multiple interacting components, as well as having other features such as allowing for tailoring or personalisation [7]. Components have been defined as “active ingredients”, “intervention techniques”, or “elements of an intervention that have the potential to causally influence outcomes” [48]. The term implementation, when used in this overview, refers to delivery of a complex intervention during a trial [5].

Within implementation, there are various key concepts. Commonly referred to in the field, fidelity is one key concept which can be defined as the degree to which an intervention is implemented as intended [19]. Measuring fidelity provides an indication of how well the intervention has been implemented. The National Institute of Health’s Behaviour Change Consortium (NIHBCC) provide a treatment fidelity framework for measuring fidelity in intervention implementation [1]. They propose five domains of fidelity: *study design, training, delivery, receipt, and enactment*, which provide a useful framework for discussing fidelity of a complex intervention. This framework can be used both for measurement of intervention fidelity within the context of a trial and for enhancement, or optimisation, of the intervention under evaluation. For a detailed outline of optimisation, refer to 1.2.2 Optimisation.

2.1.1 Aims and objectives

The aim was to provide an overview of (1) the methods used to measure implementation and (2) the strategies employed to optimise implementation of complex interventions within trials.

I addressed this aim through the following objectives:

1. To systematically review the existing literature to identify and describe qualitative and quantitative methods used for measuring implementation of complex interventions within trials.
2. To systematically review existing literature to identify and describe the strategies employed to optimise implementation of complex interventions within trials.
3. To develop a tool to aid with reporting of implementation processes of complex interventions within trials.

2.2 Methods

2.2.1 Study design

This evidence review took the design of a systematic methods overview[46], documenting and describing the range of methods used to measure implementation of complex interventions within trials.

2.2.2 Eligibility criteria

The eligibility criteria for this overview are displayed in Table 1.

Table 1 Eligibility criteria for study selection in the systematic methods overview

Study designs:	Any primary research, qualitative or quantitative presenting empirical data from a comparative trial, including RCTs, non-randomised controlled trials, feasibility and pilot trials. Any descriptive papers about methods for measuring implementation processes.
Participants:	Human participants (no age restriction).
Interventions:	Complex healthcare interventions (as defined in Section 1.1.1, by Craig and colleagues) [7]

Comparators:	Any type of control condition, such as usual care or another intervention.
Outcomes:	Implementation measures such as fidelity, adherence, dose, reach and quality of delivery. No restrictions on measures used. If a study described strategies for optimising implementation but did not report methods for measuring implementation, it was to be included in this systematic methods overview.
Setting:	No restrictions according to setting in which the complex intervention is evaluated (e.g. can include health, social care, education).
Language:	English language only.

2.2.3 Identifying eligible studies

Search strategy:

Electronic databases (Medline, EMBASE, CINAHL and PsycINFO) were searched from 1st January 2015 to 15th January 2020. It was anticipated that there would be a large number of articles, therefore searches were limited to a 5-year period, with the potential to extend this by a further five years if insufficient studies were identified.

Search strategies were developed iteratively after testing a portion of the search results using different keywords, until the search found key papers previously identified as relevant to the topic (Appendix 1). The search strategy (Appendix 2) was adapted to the syntax requirements of each database. Searches were limited to English language articles published since 1st January 2015. No study design filters were employed. Additional publications linked to eligible trials were identified (e.g. protocol papers, companion papers). This could include publications that pre-dated the 5-year search period. Citation tracking through reference lists of included trials to

identify additional eligible trials was considered, in case relevant studies were not identified in the initial searches. But this was not completed due to the volume of relevant studies identified in the initial searches.

2.2.4 Selection process

I completed title and abstract screening, supported through discussion with supervisors for papers where there was uncertainty. I completed full text screening, with assistance from supervisors to reach consensus on papers where there was uncertainty about inclusion. If a study described strategies for optimising implementation but did not report methods for measuring implementation, it was to be included in this systematic methods overview. During the selection process, papers arising from the eligible trial were linked into a study dataset, with the study considered as the unit of analysis. The selection process for this overview followed preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines [49].

2.2.5 Data extraction

To standardise the data extraction process, I developed a form in Microsoft Excel and piloted by extracting data for several studies. This was then reviewed in conjunction with the supervisory team to assess the usefulness and completeness of the data extracted and the efficiency of the process. I completed all data extraction from eligible studies. There was no checking of data extraction by any other researcher. Where information was not available in the study, this was indicated using the phrase ‘not reported.’ The data extraction form (Appendix 3) includes the following headings:

- First author
- Year of publication
- Identifier
- Title of paper
- Country
- Design of study (e.g. RCT, cluster RCT)
- Authors’ stated aim

- Target population (e.g. older people, pregnant women, people with diabetes)

The form also included a section for intervention characteristics informed by the template for intervention description and replication (TIDieR) checklist [50]. The TIDieR checklist and guide aims to improve the reporting of interventions, providing a template for structuring descriptions of interventions. Using this template, the following headings were selected for the data extraction form:

- Intervention name
- Intervention delivery details (provider, delivery mode i.e. face to face or remote, and group or individual)
- Duration of intervention (short (four weeks or less), medium (five weeks to six months) or long (more than six months) and one off or continuous)
- Tailoring or personalisation of intervention (allowed or not)

Only the items from the TIDieR checklist which were deemed relevant for this topic were selected for the data extraction form. Finally, the following data were extracted on information relating to the implementation processes:

- Use of a framework to inform implementation of the complex intervention (yes, no or not reported - if yes list which framework)
- Methods for measuring implementation (Free text – detail the methods used to measure implementation. If none reported or the focus is on optimising implementation, state none reported)
- Strategies for optimising implementation (Free text – detail the strategies used to optimise implementation. If none reported, or the focus is on measuring implementation, state none reported.)
- Aspects of implementation that were measured (e.g. adherence, fidelity, reach, dose, frequency)
- Methodological approach to evaluating intervention implementation (i.e. qualitative, quantitative, both or mixed-methods)
- Data collection method (e.g. interviews, surveys, questionnaires)
- Degree to which the intervention was implemented as planned (as detailed in the paper, e.g. X% received the required dose of the intervention)

There are currently no universally agreed standards for assessing the risk of bias when conducting a methods overview [46]. There was also no value in documenting the risk of bias for the included studies by extracting quality appraisal data using recommended checklists [51], as this overview was focused specifically on synthesising the methods used and does not synthesise the evidence regarding effectiveness.

2.2.6 Data management

Search results were exported into an EndNote file, where duplicates were removed. Title and abstract screening were conducted against the eligibility criteria using EndNote. Articles to be included were collated for full-text screening using EndNote. Full-text screening was conducted using an Excel spreadsheet, where reasons for exclusion were recorded.

2.2.7 Data synthesis

A narrative approach was taken to synthesise and report the findings. The unit of analysis was the study as opposed to a trial, therefore allowing protocols and output papers to be linked prior to analysis. Analysis was restricted to trials reporting empirical findings, rather than protocols for ongoing studies. This decision was made due to the volume of studies included, and the consideration that protocols may not be operationalised fully.

The data were extracted and descriptive analysis used to report study characteristics and details of the complex interventions. Data extracted on frameworks used in each study were presented in tabular form to allow for comparisons between different frameworks and the elements they refer to.

Data were extracted, and the analysis was stratified based on whether or not the studies reported (1) methods used for measuring implementation or (2) strategies employed for optimising implementation of complex interventions. It is possible for individual studies to include data relevant to both categories (measuring and optimising). Within these categories, data were organised into themes. The themes selected were based on the domains from the treatment fidelity framework provided by the NIHBCC[1]: *study design, training, delivery, receipt and enactment*. These

themes were selected as they provide a good framework for categorising the methods and strategies identified in this overview. It is important to note that although the initial themes used were coded deductively[52] based on the NIHBCC treatment fidelity framework domains, the scope of this overview is broader (i.e. about measuring and optimising complex intervention implementation). Thus, some inductive coding[52] was undertaken, allowing for new themes to be identified outside of the initial coding frame.

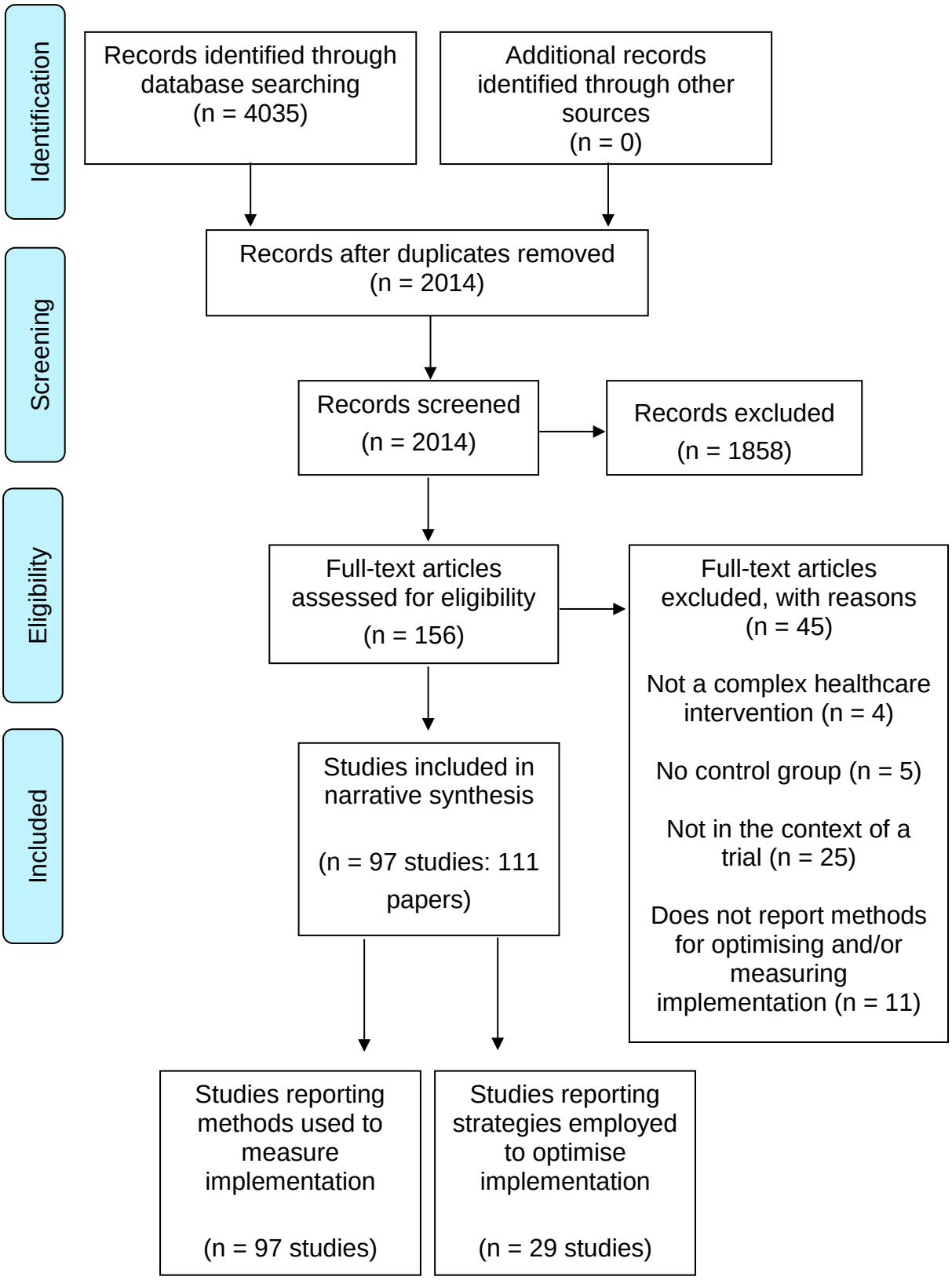
Within the category of methods used for measuring implementation, data were extracted on the type of methods used i.e. quantitative, qualitative or mixed-methods. For the purposes of this thesis, these terms have been defined as follows. Quantitative methods are those which have been used to collect numerical or statistical data, for example measuring the number of intervention sessions delivered[53]. Qualitative methods allow researchers to understand and explore the meanings individuals or groups ascribe to an issue, for example through the use of interviews[54]. Mixed-methods research involves collecting and integrating qualitative and quantitative data to draw interpretations from both datasets to answer research questions[45].

2.3 Results

2.3.1 Search results

The initial search yielded 4035 articles, which after duplicates were removed, comprised 2014 articles. (Figure 7). 1858 articles were excluded at the title and abstract screening stage due to being deemed ineligible for inclusion. After linkage, 97 studies (111 papers) were deemed eligible and included for analysis.

Figure 7 PRISMA flow diagram of study selection



2.3.2 Study characteristics

Of the 97 included studies, twenty-nine [27, 55-82] were conducted in the United Kingdom, thirteen in the United States [83-95], ten in Australia [96-105], nine in the Netherlands [106-114], six in Denmark [115-120], three each in Norway [121-123], Belgium [124-126] and India [127-129], and two each in Ireland [130, 131] and Sweden [132, 133]. Single studies were conducted in Argentina [134], Austria [135], Bangladesh [136], Canada [137], China [138], Germany [139], Spain [140], Switzerland [141], Uganda [142], Vietnam [143] and Zambia [144]. Some studies were conducted across multiple countries. One of these was conducted in Scotland and Australia [145], another was conducted in Zimbabwe, Ethiopia and India [146], whilst three studies were conducted across several European countries [147-149].

Regarding study designs, forty studies were RCTs and forty were cluster RCTs. Other designs included quasi experimental study [77, 113, 116, 139], non-randomized quasi-experimental design [141], non-randomised controlled trial [125, 130], quasi randomised trial [92], randomised multi-factorial design [83], observational case control study [107], non-randomised pre-test and post-test study [87], and parallel arm pre-test and post-test study [112]. Three of the 97 included studies were not evaluating an intervention but describing implementation frameworks or guidance [27, 72, 85].

2.3.2.1 Intervention descriptions

In terms of interventions tested, sixty-six interventions were delivered by healthcare professionals such as general practitioners, nurses and occupational therapists; nine were delivered by teachers and other professionals such as sports or drama coaches [67, 75, 77, 115-117, 120, 138, 142]; five were delivered by nursing home staff [73, 110, 121, 139, 148], and the rest by other intervention deliverers, such as ‘Family Partners’ - a paraprofessional community member trained to support families of children with behavioural health needs, locally trained facilitators, lifestyle coaches, peer mentors and student representatives. Nineteen of the studies focused on children [66, 67, 75, 77, 80, 83, 84, 92, 95, 105, 113, 115-117, 120, 132, 135, 138], nine on community dwelling older people [69, 93, 106, 109, 111, 112, 147], eight on nursing home residents [73, 110, 121, 123, 126, 139, 141], eight on healthcare staff, seven on stroke survivors, five on pregnant women, three on patients with dementia, and two on patients with heart disease. Other studies focused on people

with schizophrenia, rheumatoid arthritis, epilepsy and those undergoing intensive care.

Intervention delivery locations included; hospitals (n=22) [55, 57, 63, 65, 70, 71, 81, 88, 89, 98-100, 102, 103, 109, 114, 124, 127, 128, 132, 145, 149], participants' homes (n=17) [56, 58, 59, 64, 70, 79, 92-94, 106, 112, 122, 125, 127, 130, 136, 144], schools (n=15) [66, 67, 74, 75, 77, 80, 105, 113, 115-117, 120, 135, 138, 142], nursing homes (n=9) [86, 110, 121, 123, 126, 139, 141, 148, 150] and other healthcare environments such as general practices and rehabilitation centres (n=16) [64, 68, 69, 76, 78, 87, 91, 96, 101, 107, 111, 119, 129, 133, 137, 140]. Seven studies did not report the delivery location [60, 62, 82, 104, 108, 131, 146]. Seventy-seven interventions were delivered exclusively face to face, with a further ten also utilising telephone, radio and email. Four interventions were delivered remotely through a website, television and telephone. Regarding the level of intervention, forty-two interventions were delivered to individuals, thirty-seven were delivered to groups, eleven were delivered to both individuals and groups, and three were delivered to dyads (stroke patients with nominated family member or friend; dementia patients with nominated family member or friend; couples who have recently given birth). Most interventions had a duration of seven months or longer (n=45), some lasted between one and six months (n=34) and few lasted four weeks or less (n=9). The duration was not reported for five interventions. Most interventions were continuous (i.e. delivered over more than one session) (n=87) and few had one session only (n=6). Most interventions were designed to allow for some tailoring or personalisation (n=76) when being delivered to the target population.

2.3.3 Frameworks guiding intervention implementation

Sixty-nine studies referenced the use of an existing framework to inform the implementation process and nineteen of these referenced the use of more than one framework. Three studies reported on the development of new frameworks[27, 72, 85] that could be used to inform intervention implementation.

2.3.3.1 Existing frameworks

The most commonly referenced frameworks were: MRC guidance for process evaluations [27] (n=25 studies), RE-AIM framework [28] (n=12), Consolidated Framework for Implementation Research (CFIR) (n=10), Steckler and Linnan's

framework [31] (n=7), Carroll and colleagues' conceptual framework for implementation fidelity [19] (n=6), Saunders and colleagues' process evaluation plan for assessing implementation of a health promotion program [32] (n=6), Grant and colleagues' framework for the design and reporting of process evaluations for a cluster trial [33] (n=5) and the Promoting Action on Research Implementation in Health Services (PARIHS) framework [30] (n=5). Other frameworks referred to were the treatment fidelity framework from the NIHBCC [1], Normalisation Process Theory (NPT) [151], and the Interactive Systems Framework (ISF) [152].

As discussed in Section 1.1.4, these frameworks fall under one of two categories, either used for (1) implementing evidence-based interventions into practice; or (2) for implementing interventions during research, for example, in the course of a trial. The RE-AIM and PARIHS frameworks are both examples of the former, used for implementing interventions into practice. Some frameworks which are designed specifically for use during research are the CFIR [19], and a number of frameworks intended to help researchers plan process evaluations. These include the MRC guidance for process evaluations [27], Saunders and colleagues' framework for developing a process evaluation plan [32], Steckler and Linnan's framework for process evaluations of public health interventions[31], and Grant and colleagues' framework for the design and reporting of process evaluations for a cluster trial [33]. Table 2 summarises the aspects of implementation referred to in these different frameworks.

2.3.3.2 Development of new frameworks

Three of the studies included reported on newly developed frameworks [27, 72, 85] that could be used to inform implementation of complex interventions. Dy et al adapted the CFIR for care transition interventions [85]. Moore et al outlined the MRC guidance for process evaluations of complex interventions [27] which built on the previous guidance for developing and evaluating complex interventions, published in 2008 [7]. Rapley et al[30] reported on the development of the NoMAD (Normalisation Measure Development Questionnaire) instrument for assessing implementation, as based on the NPT[153].

Within the ‘Care Transitions Framework’, there is a domain entitled ‘measures of implementation’[85]. The measures of implementation domain included the following constructs:

- Acceptability
- Adoption/abandonment
- Appropriateness: degree of fit and relevance
- Intervention cost
- Fidelity
- Reach: within the population and organisation
- Penetration: depth of integration
- Replicability
- Sustainability
- Evolvability: capability of being sustained through adaptation and refinement

In the MRC guidance for process evaluations of complex interventions[27], implementation was described as a key component of a process evaluation. Within this, the following aspects of implementation were highlighted as being important:

- Implementation process (How delivery is achieved; training, resources etc)
- What is delivered
- Fidelity
- Dose
- Adaptations
- Reach

As well as these, Moore et al also noted the important of context affecting implementation and mechanisms of impact, including participant responses to the intervention and unexpected consequences. They offered definitions of terms such as fidelity and dose to facilitate understanding and use of this guidance.

The NoMAD instrument, developed as part of the NoMAD study[72], focuses specifically on the implementation participants’ experience, i.e. those delivering or receiving the intervention. The NoMAD instrument is concerned with implementation of a complex intervention into practice, as opposed to implementing a complex intervention in the context of a trial.

Table 2 Frameworks referenced in studies and the aspects of implementation they refer to

	Aspects of implementation assessed in the framework													
	Implementation	What is delivered/quality of delivery	Fidelity/ adherence	Dose (delivered and/or received)	Adaptations	Reach	Participant response/ interaction	Mediators	Unintended consequences	Context	Recruitment	Effectiveness	Adoption	Maintenance
MRC PE guidance [27]	✓	✓	✓	✓	✓	✓	✓	✓	✓					
RE-AIM [28]	✓					✓						✓	✓	✓
Updated CFIR [154]	✓				✓					✓				
Steckler & Linnan[31]	✓		✓	✓		✓				✓	✓			
Saunders et al[32]			✓	✓		✓				✓	✓			
CFIR[19]			✓				✓			✓				
Grant et al[33]		✓				✓	✓		✓	✓		✓		✓
PARIHS [30]	✓									✓				
NPT [151]	✓									✓				✓
NIHBCC [1]			✓	✓			✓							
ISF [152]	✓													

2.3.4 Methods for measuring intervention implementation

2.3.4.1 Approaches to data collection

Seventeen studies [76, 79, 82, 88, 89, 93-95, 99, 105, 111, 113, 114, 118, 138, 142, 149] reported the use of quantitative methods to measure implementation of the complex intervention, eight used qualitative methods [69-71, 73, 75, 81, 133, 145] and 47 used a mixed-methods approach [56, 58-61, 63, 66-68, 74, 77, 78, 86, 87, 90-92, 97, 101, 102, 104, 106-110, 112, 116, 119, 120, 122, 124, 126-129, 131, 132, 134, 136, 137, 139, 141, 146, 147, 155, 156]. A further twenty-one studies reported use of both quantitative and qualitative methods but did not report formal integration of either the methods or results [55, 57, 64, 65, 80, 83, 84, 96, 98, 100, 103, 117, 121, 125, 130, 135, 140, 143, 144, 148, 157].

Methods of data collection varied amongst the studies. Some studies used qualitative methods of data collection such as interviews (n=63) [55-64, 66-70, 73-75, 77, 78, 80, 81, 83, 84, 86, 90-92, 97, 98, 100-102, 104, 106-110, 116, 117, 119, 120, 122, 124, 127-132, 134, 135, 137, 139, 141, 143-148, 157], observations (n=34) [58, 61, 62, 64-67, 69, 70, 75, 80, 81, 87, 98, 99, 101, 102, 114, 116-120, 124, 127, 129, 131-133, 136, 138, 144, 146, 147] and focus groups (n=25) [63, 65, 66, 75, 77, 91, 97, 106, 116, 117, 119, 122-124, 126, 129, 130, 133, 136, 137, 141, 143, 144, 146, 147] . Others used quantitative methods such as questionnaires or surveys (n=44) [56, 61, 66, 68, 77, 84, 86-88, 90, 91, 94, 97, 100, 104, 105, 107-110, 112, 114, 116, 117, 120, 123-126, 128-130, 134, 135, 138-140, 142-144, 146, 148, 149, 157], and activity logs (n=22) [60, 61, 66, 70, 77, 83, 86, 90, 99, 102, 109, 112-114, 118, 121, 130, 138, 143, 144, 147, 149].

2.3.4.2 Measuring intervention implementation

Although only four studies referenced use of the NIHBCC framework to inform the implementation process [58, 89, 131, 155], ninety-seven studies either measured different aspects of implementation or included these within a framework they reported (Section 2.3.4.1). These findings can be categorised according to the NIHBCC treatment fidelity framework domains: *design, training, delivery, receipt and enactment* (Section 1.1.4) [1]. Table 3 shows a visual representation of the number of studies which measured aspects from each of these domains.

Table 3 Methods used to measure intervention implementation categorised into NIHBCC framework domains

NIHBCC Framework Domains		Number of studies
Design	Active components of intervention operationalised	●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●
	Intervention developed through co-design	●●●●●●●●●● ●●●●
	A priori specification of treatment dose	●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●●● ●●●●
	Monitoring of intervention implementation throughout	●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●●● ●
Training	Participation/attendance at training	●●●●●●●●●
	Fidelity of training delivery	●●●●
	Views and experiences of intervention deliverers	●●●●●●

	Readiness of intervention deliverers	●
	Adaptations made to training	●
	Whether there were any problems with the training	●
	Reach of the training	●
	Training components and process	●
	Perceived appropriateness of training	●
	How the training was performed	●
	Understanding of training materials	●
	Evaluation of training	●
	Satisfaction with training	●
	Resources used for training and their usefulness	●●
	Intervention deliverers' confidence to deliver	●
	Availability of training opportunities	●
Delivery	Fidelity of delivery	●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●●●●●●●
	Dose delivered	●●●●●●●●● ●●●●●●●●● ●●●●●●●●● ●●●
	Frequency/duration	●●●●●●●
	Intervention delivery	●●●●●●●●●
	Quality of delivery	●●●●●●●●●
	Adaptations	●
	Impact of intervention delivery	●

	Number and length of visits	●
	Intervention content	●
Receipt	Receipt of the intervention	●●●●
	Reach of the intervention	●●●●●●●●●● ●●●●●●●●●● ●●●●●●●●●● ●
	Feasibility and acceptability	●●●●●
	Feasibility	●●●
	Acceptability/acceptance	●●●●●●●●●● ●●●●
	Attendance	●●●
Enactment	Participant responsiveness	●●●●●●●●●● ●●●●●
	Engagement	●●●●●●●
	Factors influencing engagement	●
	Intervention adherence	●●●●●●●●●● ●●●●●●●
	Adoption	●●●●●●●●●● ●●●●
Other domains		
Context		●●●●●●●●●● ●●●●●●●●●● ●●●●●●●
Maintenance		●●●●●●●●●●
Sustainability		●●●●
Appropriateness		●●●●●
Penetration		●●

2.3.4.2.1 Design

According to the NIHBCC treatment fidelity framework, assessment of fidelity to study design can be conducted through assessing the active components of the complex intervention to ensure they are fully operationalised, co-designing the intervention alongside members of the target population, with a priori specification of the treatment dose and monitoring implementation throughout. The majority of

studies in this overview reported how the active components of the intervention were operationalised (N=88). Fourteen studies reported that the intervention was developed through co-design with the target population [58, 59, 61, 73, 103, 116, 118, 120, 124, 129, 134, 141, 147, 155]. Of these, six studies reported the use of focus groups or interviews to gather data during the intervention development process [58, 116, 120, 124, 134, 147]. Most studies reported a priori specification of the treatment dose (N=84), for example in the intervention manual. Similarly, most studies reported monitoring of intervention implementation throughout (N=91).

2.3.4.2.2 Training

The majority of studies in this overview did not report any evaluation of training. Thirty-eight studies measured at least one aspect of training [56, 58, 66, 68, 69, 74, 75, 77, 79-81, 86, 90, 95, 99, 102, 105, 109, 110, 119, 123-131, 133-135, 142, 145, 146, 148, 155]. Of these, ten studies measured participation or attendance at training [56, 75, 77, 90, 95, 99, 109, 119, 126, 134], and most of them used attendance logs or forms to collect this data.

Sixteen studies measured some aspect of training using only quantitative methods [64, 66, 86, 95, 99, 105, 119, 124, 125, 127-129, 134, 135, 142, 158] whereas ten used only qualitative methods [68, 69, 75, 79, 81, 102, 133, 145, 148, 155]. Five studies used both quantitative and qualitative methods [74, 77, 90, 109, 126] and five adopted a mixed-methods approach (5/38) [56, 58, 80, 110, 146].

In terms of data collection methods, thirteen studies used interviews as a method of measuring some aspect of the training process [56, 58, 69, 74, 75, 77, 80, 81, 90, 109, 145, 148, 155]. Of these studies, some used interviews to measure whether training was delivered as planned i.e. the fidelity of training delivery [56, 58] whereas others used interviews as a tool to gather data on the views and experiences of the intervention deliverers with regards to the training [74, 77, 80, 81, 90, 145].

Eight studies used observations as a data collection tool when measuring training [58, 68, 69, 75, 80, 81, 129, 146]. Three of these studies used observations to measure the fidelity of training delivery [58, 80, 129]. Other studies measured readiness of intervention deliverers [68], attendance at training [75], adaptations made to training to fit context [146] and whether there were any problems with the training [81].

Six studies used questionnaires to measure training [56, 66, 110, 125, 135, 146]. Di Lorito et al used questionnaires to assess the reach of the training [56], whereas Jong et al used

questionnaires to assess the training components and process [66] and Kien et al assessed the perceived appropriateness of training [135]. Pieper et al assessed how the training was performed using questionnaires [110]. Van den Branden et al evaluated training including whether it was sufficient in terms of the content, extensive enough and the practical applicability of the training using questionnaires [125]. Vousden et al used questionnaires to measure the understanding of training materials amongst intervention deliverers [146].

Five studies used surveys to measure some aspect of training, such as satisfaction [126], resources used and their usefulness [105, 130], intervention deliverers' confidence to complete delivery expectations [90] and availability of training opportunities [128].

Three studies used field notes or documents to measure training [66, 110, 133]. Two studies used audio [79] or video recording [56] to measure training. Two studies used focus groups [126, 133]. Two studies used delivery or training records [56, 58].

2.3.4.2.3 Delivery

Within the *delivery* domain, fidelity was the most commonly reported measure of the delivery of an intervention. Fifty-nine studies measured fidelity [56-61, 63-66, 68-70, 73-80, 82-84, 87, 88, 90, 92, 93, 95-98, 103, 106, 107, 110, 112, 114, 118-120, 124, 127, 129-132, 136, 138, 140, 141, 143, 144, 146, 147, 149, 155, 159]. Of these, twenty-four studies used quantitative methods to measure fidelity [57, 59, 61, 65, 74, 76, 79, 82-84, 93, 95, 96, 106, 110, 112, 114, 118, 127, 129, 138, 141, 147, 149]. A further seventeen studies utilised mixed-methods to measure fidelity [56, 58, 63, 66, 68, 77, 78, 87, 90, 107, 119, 120, 124, 131, 132, 136, 155]. Nine studies used qualitative methods to measure fidelity [69-71, 73, 75, 80, 130, 140, 143]. Four studies used a mix of qualitative and quantitative methods to measure fidelity [64, 98, 103, 144]. The remaining five studies did not provide sufficient detail regarding methods used to measure fidelity of delivery.

The most commonly reported method to measure fidelity was through the use of a checklist. Seventeen studies used checklists to measure fidelity [59, 63, 65, 67, 71, 78, 79, 82-84, 87, 90, 92, 93, 119, 129, 147]. Eight studies used audio or video recording, often alongside a fidelity checklist or protocol [56, 59, 84, 87, 96, 119, 131, 140].

Thirty-three studies measured dose [56, 60, 61, 63, 66, 67, 74, 77, 92, 93, 95, 97, 99, 104, 106-108, 110, 112, 114-118, 127, 130, 132, 138, 139, 143, 144, 149, 155]. Of these 33 studies, ten [66, 74, 97, 106, 107, 117, 118, 138, 149, 155] reported measuring both dose delivered and dose received, whereas five only reported measuring dose delivered [60, 95, 108, 132, 144]. Dose received also fits within

the theme of receipt (below) – one study reported measuring dose received alone [112]. Seven studies measured frequency and duration, which is very similar to dose [59, 97, 99, 109, 122, 125, 126]. Twenty-one studies used quantitative methods to measure dose [60, 61, 67, 74, 77, 92, 93, 95, 99, 104, 110, 112, 114, 118, 127, 130, 138, 139, 143, 144, 149], whereas ten studies adopted a mixed-methods approach [56, 63, 66, 97, 106-108, 116, 132, 155]. Three studies used a mix of both quantitative and qualitative methods [98, 115, 117]. Dose was most commonly measured using questionnaires (N=10) [61, 66, 77, 108, 112, 115-117, 138, 149] and observations (N=10) [77, 98, 99, 114, 116, 117, 127, 132, 138, 155]. Other methods of measuring dose included attendance or activity logs (N=8) [60, 67, 99, 112, 114, 130, 144, 149], interviews (N=6) [63, 98, 107, 108, 115, 132], checklists (N=4), [63, 92, 93, 143], and delivery records (N=3) [56, 97, 118].

Ten studies measured intervention delivery [55, 76, 99, 101, 102, 116, 119, 129, 131, 142]. Within these, some studies reported 'fidelity of delivery' [76, 119, 131], whereas others reported factors influencing delivery [99]. A further ten studies specifically referred to and reported quality of delivery [65, 67, 75, 96, 97, 106, 115, 122, 125, 139]. Donkers et al also termed quality of delivery as fidelity, which they measured alongside adaptations (defined as changes that undermine delivery) and impact of intervention delivery [106]. Di Lorito et al reported measuring the number and length of visits, as well as intervention content [56].

2.3.4.2.4 Receipt

Four studies measured receipt [91, 118, 119, 129]. Ferm et al did this through the use of delivery records and observation [118]. Jensen et al used focus groups and interviews to measure receipt [119]. Ridgeway et al used administrative data, interviews and questionnaires [91]. Similarly, Srinivasapura et al also used a questionnaire to measure receipt of the intervention [129].

Thirty-one studies measured reach [55, 56, 61, 63, 66, 74, 75, 77, 84, 88, 91, 93, 95, 97, 102, 103, 106, 110, 112, 116, 117, 120, 130, 132, 134, 137, 138, 142, 144, 146, 148, 149, 159]. Di Lorito et al defined reach as "the extent to which participants come into contact with the intervention" [56], hence this element was categorised under the theme of receipt. Five studies measured reach and recruitment alongside one another [66, 102, 106, 149, 155]. A further six studies reported measuring recruitment alongside implementation measures [55, 57, 90, 122, 130, 144]. Donkers et al reported measuring recruitment through qualitative interviews to explore reasons for participation and reasons for declining participation, as opposed

to the traditional quantitative measurement of recruitment [106]. Similarly, Jong et al reported the measurement of recruitment and reach under mechanisms of impact through the qualitative methods of observations, focus groups, interviews and written logs [66].

Five studies measured feasibility and acceptability of the intervention [80, 83, 90, 140, 141], whilst three measured feasibility alone [103, 110, 124] and fourteen measured acceptability alone [57, 60, 61, 68, 75, 77, 92, 94, 112, 121, 132, 134, 143, 144], or as it was termed in some cases, acceptance [68, 121].

Three studies measured attendance [80, 84, 108]. White et al also termed this engagement, which overlaps into the theme of enactment, and they measured this using participation records [80]. Davis et al measured attendance using delivery records [84], whereas Leenen et al measured attendance using a registration form [108]. Fifteen studies used attendance logs or forms to measure aspects of implementation such as acceptance [121], participation [126, 143], reach [61, 130, 137, 148], dose [56, 60, 61, 99, 130], adherence [56, 160], fidelity [64, 119], implementation according to protocol [134] and engagement[100].

2.3.4.2.5 Enactment

Fifteen studies measured participant responsiveness to the intervention [67, 97, 109, 115, 122, 125, 139], though in some cases it was referred to as responsiveness [104, 118], response [55, 80, 102, 130, 144] or participation [84]. Lloyd et al referred to this concept as both participant responsiveness and engagement [67]. Seven other studies also reported measuring engagement [78, 80, 84, 97, 100, 116, 144]. Of these, Coorey at al also reported factors influencing engagement [97].

Participant responsiveness was measured in a variety of ways; some studies took a mixed-methods approach [67, 97, 109, 122], whereas others utilised both qualitative and quantitative methods [80, 115, 125, 144]. Some studies used exclusively qualitative methods such as interviews [55, 102, 130] and some used exclusively quantitative methods such as questionnaires [139] and fidelity scores [104].

Seventeen measured intervention adherence [65, 67, 68, 82, 89, 96, 99, 104, 106, 108, 115, 122, 125, 132, 134, 139, 147]. Donkers et al also termed this as ‘dose delivered’ and dose received.’ Fourteen studies measured adoption [84, 90, 91, 93, 98, 120, 123, 134, 137, 140-142, 146, 148].

2.3.4.2.6 Other

Some of the aspects measured in the studies in this overview do not fit neatly under the domains from the NIHBCC framework during deductive coding[52]. Through the process of inductive coding, it was possible to further categorise measurement into the following domains: *context, maintenance/sustainability, appropriateness,* and *penetration.*

Twenty-seven studies measured context [55, 63, 66, 70, 74, 88, 92, 97, 98, 100, 102-104, 106, 107, 116, 117, 122, 129, 133, 138, 139, 143, 144, 146, 147, 155]. Context, as previously defined in Section 1.1.1, refers to the setting or environment within which the intervention is being implemented[13, 14]. It is an important aspect of implementation but was only reported to be measured in less than a third of the studies in this overview. Of the 27 studies, 13 used qualitative methods to measure context[55, 70, 74, 92, 102-104, 106, 122, 129, 133, 143, 147], 12 studies used both qualitative and quantitative methods[63, 66, 97, 98, 100, 107, 116, 117, 139, 144, 146, 155] and two studies used quantitative methods[88, 138].

Ten studies measured maintenance [55, 84, 93, 102, 120, 123, 130, 134, 137, 148]. Of these, five used qualitative interviews to measure maintenance of the complex intervention [55, 84, 102, 134, 148] and two studies used questionnaires [120, 148]. Maintenance can be defined as the extent to which a behaviour is sustained 6 months after the intervention ends[28]. This is often referred to as sustainability. Four studies measured sustainability [77, 88, 94, 128]. Two of these used qualitative methods such as interviews and focus groups [77, 128], whereas two used quantitative methods to measure sustainability such as surveys and questionnaires [88, 94].

Five studies measured appropriateness [90, 94, 124, 140, 143]. Appropriateness can be defined as the relevance and perceived fit of the intervention within the context[161]. Three of these used qualitative methods such as interviews [124, 143] and surveys with open-ended questions [90], whereas two studies used quantitative surveys [94, 140].

Two studies measured penetration [94, 141], one of which used a survey [94] and the other measured penetration by identifying the proportion of professionals who integrated the intervention into their usual practice following completion of the intervention [140]. Penetration can be defined as the integration of the intervention into the setting[162].

2.3.5 Strategies for optimising intervention implementation

Twenty-nine studies (30%) reported optimisation of the implementation process through various strategies which can be categorised into a number of themes. These themes are based around the domains in the treatment fidelity framework from the NIHBCC: design, training, delivery, receipt and enactment [1], interpreted through an intervention optimisation lens.

2.3.5.1 Design

Eleven studies [61, 80, 89, 90, 98, 100, 103, 113, 137, 148, 155] reported optimising implementation of the intervention through the design of the intervention. The design strategies reported have been grouped into the following categories:

- *Stakeholder involvement:* Five studies [61, 90, 103, 113, 137] reported involvement of participants or other stakeholders in the design of the intervention in order to minimise implementation issues arising later.
- *Piloting the intervention:* Two studies [80, 155] reported prior testing of the intervention to allow researchers to work through issues in a similar setting to that in which the intervention will be implemented.
- *Manualising procedures:* Three studies [89, 103, 137] reported manualising procedures which involves writing out the procedures in a manual or producing some other resources to help ensure that the intervention is implemented as intended.
- *Fixed core components with tailoring allowed:* Five studies [90, 100, 103, 137, 148] reported having fixed core components with some degree of tailoring or personalisation to the participant allowed. This strategy is useful for complex interventions which may need some tailoring to specific participants or groups. For example, different participants may have different needs or goals which need to be met through the intervention. Hence the intervention deliverer can tailor the intervention to best meet these needs, whilst ensuring the core components remain standardised.
- *Documenting implementation issues:* Two studies [98, 155] reported documenting or predicting implementation issues during the design stage. Doing this prior to implementation is another technique of predicting potential problems that may arise and thinking of solutions beforehand.

2.3.5.2 Training

Optimisation strategies pertaining to training of intervention deliverers were utilised in 11 studies [39, 55, 65, 80, 83, 89, 90, 121, 122, 146, 155], though many more reported training of intervention deliverers. The training strategies have been grouped into the following categories:

- *Train-the-trainer approach:* Two studies [121, 146] reported training champions who then trained other intervention deliverers.
- *Standardised training scheme:* Five studies [55, 89, 121, 122, 155] used a standardised approach to train the intervention deliverers. Pastva et al[89] standardised intervention training through a number of strategies including careful selection of intervention deliverers and having a critical number of deliverers per site as well as a leader, having a manual of procedures, training being conducted on-site and refresher training in the form of webinars.
- *Booster session:* Four studies [83, 89, 90, 121] had additional booster or refresher training sessions to optimise intervention implementation. Aasmul et al [121] referred to this as a 'midway seminar' taking place halfway through the four month intervention delivery period. Broder-Fingert et al [83] and Pastva et al [89] reported the booster training took place once a year. Porter et al [90] reported the use of a video developed to act as a recap for intervention deliverers to watch before delivering to the second cohorts, 10 months after the initial training.
- *Manual or other resource:* Four studies [39, 65, 89, 122] reported providing intervention deliverers with an intervention manual, handbook or video to aid with training. Walton et al [39] reported the use of a video to show the intervention deliverers how to deliver the intervention.
- *Expert trainers:* Gossage-Worrall et al[155] reported use of expert trainers to deliver training.
- *Web-based training:* Chesworth et al[55] reported using largely web-based training to facilitate easy access and flexibility for the intervention deliverers.
- *Interactive training:* Two studies [80, 146] used interactive training methods such as animated films and interaction with deliverers to clarify uncertainties in operationalising the intervention.

2.3.5.3 Delivery

Twenty-three studies [39, 55, 64, 65, 67, 70, 73, 89, 90, 95, 98-100, 103, 110, 121, 122, 133, 137, 141, 145, 155, 159] reported optimisation strategies under the theme of intervention delivery. The delivery strategies have been grouped into the following categories:

- *Support or supervision:* Nine studies [39, 73, 99, 100, 110, 121, 122, 155, 159] reported use of ongoing support or supervision during intervention delivery for intervention deliverers as a strategy to optimise implementation. This included peer support, support from researchers e.g. through regular phone calls, and individual or group supervision to facilitate uniform delivery.
- *Monitoring:* Six studies [64, 89, 90, 95, 155, 159] utilised monitoring and providing feedback on intervention delivery as a strategy to optimise implementation. According to Pastva et al, this included assessing intervention competency (whether intervention deliverers maintained the skills learned in training), intervention differentiation (whether they delivered only the target intervention and not others), and intervention adherence (whether the intervention was delivered as intended) [89].
- *Interdisciplinary teams:* Three studies [137, 141, 145] used interdisciplinary teamwork or experts to optimise intervention implementation. Interdisciplinary teams are made up of healthcare professionals from a range of backgrounds such as doctors, nurses, physiotherapists and psychologists. Luig et al [137] reported the use of interdisciplinary experts to “foster collective sense-making”, which was key in driving successful implementation. They report how interdisciplinary team members shared experiences to aid implementation. Luker et al [145] reported interdisciplinary teamwork as a key strategy for ensuring the intervention was implemented as intended.
- *Stakeholder involvement:* Four studies [67, 73, 110, 141] used stakeholder groups to optimise intervention delivery for example, holding discussion groups with stakeholder to discuss barriers and facilitators for implementation.
- *Facilitation:* Three studies [55, 98, 100] reported use of facilitation as an optimisation strategy. It is based on the principle that ownership is with the group [163, 164]. Hence, the facilitator’s role is to guide the group towards achieving their goals, helping them to identify problems and think of solutions to overcome these. Similarly, in the CHERISH study [100], facilitation was

reported as a central element, which they actioned by tailoring strategies to the target population and local context of the intervention.

- *Champions:* Three studies [65, 137, 159] reported use of a 'champion' to optimise implementation. This is different to the train-the-trainer approach under the theme of training. James et al [65] reported that the champions would lead the implementation of a certain components of the intervention and report back with regular updates on progress to research. Similarly, Luig et al[137] reported that the clinical champions provided ongoing feedback between participants and researchers as well as keeping records of communications. In Sutherland et al [159], it was reported that school champions embedded the intervention practices within the school.
- *Technological aids:* Two studies [89, 103] used technology to optimise implementation of the intervention for example through the use of a touchscreen computer or electronic database. The electronic database was used to collect data and generate reports which provided flexibility needed for successful implementation of the intervention.
- *Tailoring and flexibility:* Six studies [70, 99, 100, 133, 137, 141] reported use of tailoring strategies, or allowing flexibility to adapt the intervention, to make the intervention appropriate for local recipients, whilst ensuring fidelity is preserved. Murdoch et al [70] describe an innovative approach termed 'context-mapping' whereby they identified factors which may impede intervention implementation beforehand and then consider ways in which the intervention could be adapted during implementation.

2.3.5.4 Receipt

Only three studies [89, 137, 155] reported optimisation strategies relating to the theme of intervention receipt. The strategies included:

- Intervention deliverers used scripted summaries designed to help participants with understanding and comprehension, encourage identification of problems and think of solutions. Self-monitoring was encouraged and 1:1 support was provided to participants by intervention deliverers [155].
- Co-creation of tools by participants with researchers and compilation of resources by researchers with input from clinicians and participants [137]. This

strategy was implemented in response to an identified need for tools which did not already exist. Through an iterative process with intervention providers and graphic designers, the tools were created.

- Participant commitment agreement signed at enrolment, comprehension facilitation through return demonstration and teach-back techniques, facilitating attendance through clear schedule and reminders, participant progress report and shared decision making [89].

2.3.5.5 Enactment

Only three studies [39, 89, 155] reported optimisation strategies relating to intervention enactment. The strategies included:

- Use of interviews to explore learning and use of skills by intervention participants. Also, support was provided by telephone for 12 months after the end of the intervention delivery period [155].
- Ensuring participants used the skills taught in the intervention by conducting a home evaluation within a week after discharge and a maintenance exercise phase using phone calls [89].
- Finally, Walton et al reported four strategies for improving engagement with the intervention: use of a session summary document, clear instructions for participants, sufficient time to practice activities and regular support over the telephone [39].

2.3.5.6 Other

Unlike the methods for measuring implementation, there were no optimisation strategies that did not fit under the categories taken from the NIHBCC domains [1].

2.4 Discussion

2.4.1 Summary

This systematic methods overview identified 97 studies which used methods to measure and/or strategies to optimise implementation of a complex intervention within the context of a RCT. The studies varied widely in terms of the methods they used to measure, and the strategies employed to optimise implementation of the complex intervention. The majority of studies reported the methods used to measure

implementation, whereas less than a third of the studies reported strategies employed to optimise implementation. The component most focused on throughout the studies included in this review was fidelity. There are a range of frameworks surrounding fidelity of complex interventions in trials and how best to measure fidelity of complex interventions[1, 19, 27, 32, 165]. Therefore, it was not surprising that fidelity was the most commonly reported component of implementation in this overview.

2.4.2 Key findings

Most of the studies report a framework or set of guidance which they used to inform the implementation process. The most commonly used framework is the MRC guidance for process evaluations of complex interventions. Some of the frameworks applied by triallists are designed to support implementing evidence-based interventions in practice, as opposed to those designed for implementation during research (Section 2.3.3). This overview is concerned with the latter of these categories. However, studies were not excluded on the basis of the framework used to inform the implementation of the complex intervention in the study.

There was a lot of variation between the studies in this overview, in terms of the methods and strategies they report. More studies used both quantitative and qualitative methods to measure implementation, than those that used exclusively qualitative or quantitative methods. Some studies used a mixed-methods approach and reported how one type of data informed the other i.e. explicitly integrated within the design or analysis phase. A mixed-methods approach can facilitate a better understanding of the connection between quantitative and qualitative findings, compared to using both of these paradigms alongside one another without some form of triangulation or integration [166].

The NIHBCC framework was used to categorise the methods of measuring implementation and the strategies of optimising implementation, into the following categories: *design, training, delivery, receipt, and enactment*. Since the studies included in this overview did not all use this framework to inform implementation, it was not straightforward to organise the findings into these categories. Nonetheless, through discussion with my supervisors, it was decided that the NIHBCC framework domains provide a good structure for reporting the methods to measure, and strategies to optimise implementation identified in this overview. More studies in this

overview report methods of measuring implementation than strategies to optimise implementation.

Of these five domains (*design, training, delivery, receipt, and enactment)*, *delivery* was the most commonly reported aspect of implementation, both in terms of reporting methods to measure *delivery* and for strategies to optimise *delivery*. Within this domain, fidelity was the most commonly reported aspect of implementation measured in the studies in this overview. It was most commonly measured using a checklist, often alongside audio or video recording. Some studies used terms such as 'quality of delivery' [106] or 'fidelity of delivery' [76, 119, 131] to refer to fidelity. Similarly, engagement, which fits under the NIHBCC domain of *enactment*, was referred to in multiple different ways: participant responsiveness, response and participation. In terms of strategies employed to optimise implementation, these were reported to a lesser degree than methods used to measure implementation. The strategies that were reported pertained mainly to optimising the *delivery* of the intervention, and the *training* of intervention deliverers. There was substantially less focus on strategies to optimise *design, receipt* and *enactment* of the intervention, which are critical components of implementation, essential for the intervention to have the intended effect.

2.4.3 Development of the MOSAIC tool

As part of this systematic methods overview, the MOSAIC (Methods for measuring and OptimiSing the Implementation of Complex Interventions) tool was developed to aid the reporting of complex intervention implementation within a trial. Though the development of this tool was not always intended as part of this PhD, the need for a tool to facilitate data extraction and standardise reporting was identified through the process of conducting the systematic methods overview.

This tool was informed by the TIDieR checklist for intervention description[50] and the NIHBCC fidelity framework domains[1] (d*esign, training, delivery, receipt and enactment*). This tool was developed iteratively during the process of data extraction for this methods overview, from the data extraction form. The tool was first applied to the primary reference paper i.e. RCT paper to extract information. If any fields remained blank following this, any accompanying papers such as process evaluations were then accessed.

The columns in the data extraction form about the intervention characteristics such as the target population, intervention name and intervention deliverer formed Part A of the MOSAIC tool. The items in Part A of the tool were informed by the TIDieR checklist for intervention description[50]. Not all the items from the TIDieR checklist were deemed relevant to be included in the MOSAIC tool since the focus of the MOSAIC tool is on intervention implementation rather than intervention description. However, it was deemed necessary to include some items in order to provide context.

Parts B and C were informed by the NIHBCC fidelity framework domains[1] (d*esign, training, delivery, receipt and enactment*). For part B, within each of these domains, there were a number of questions formulated, to aid with data extraction. For example, in the domain *training*, there was the question *'What did training entail?'*. These questions were used as prompts to aid with the data extraction process. The prompts were then listed under each of the domains to form part B of the MOSAIC tool.

Part C of the MOSAIC tool lists a number of strategies which could be employed to optimise implementation of a complex intervention. These strategies were extrapolated from the strategies used in the studies included in this systematic methods overview. Through an iterative process, similar strategies were pooled and categorised into the same domains used in part B. Each of the domains also includes an 'Other' category since it is understood that the list of strategies was not exhaustive. The MOSAIC tool was then tested in a second systematic methods overview (Chapter 3).

The MOSAIC tool could be used in multiple ways by researchers. Firstly, it could be used to extract data for a systematic methods overview. It provides a helpful framework against which to extract data most relevant for intervention implementation. Secondly, the MOSAIC tool could be used when developing an implementation plan for a complex intervention trial. In this situation, the tool could be used at various stages of the trial since the strategies in part C of the tool could be employed during a trial to optimise intervention implementation. Finally, the MOSAIC tool could be used when writing up a scientific paper about the implementation of a complex intervention within a trial to ensure that all aspects of implementation are reported. The MOSAIC tool is displayed below in Figures 8-10.

A: Intervention Characteristics
• Target population • Intervention Name • Intervention Deliverer Profession e.g. Nurse • Delivery Mode: Face to face or remote • Delivery format: Group or individual • Duration: Short (four weeks or less), Medium (five weeks to six months), Long (six months or more) • One-off or continuous • Tailoring or personalisation allowed (Yes/No)

Figure 8 MOSAIC Tool - Part A: Intervention characteristics, as informed by the TIDieR checklist for intervention description[50]

B: Methods used to Measure Intervention Implementation				
Design	**Training**	**Delivery**	**Receipt**	**Enactment**
• Framework used to inform implementation • How were active components of the intervention operationalised? • Was the intervention co-designed with the target population? (Yes/No) • Was there apriori specification of the treatment dose? (Yes/No) • Was implementation monitored throughout the trial? (Yes/No) • Were there any adaptations to the intervention during the trial? (Yes/No)	• What did training entail? • Was training evaluated in some way? (Yes/No) • Qualitative and/or quantitative or mixed-methods approach? • What data collection methods were used? E.g., interviews, surveys, trial data	• What components of delivery were measured? E.g., fidelity • Qualitative and/or quantitative or mixed-methods approach? • What data collection methods were used? E.g., interviews, surveys, trial data	• What components of receipt were measured? E.g., reach • Qualitative and/or quantitative or mixed-methods approach? • What data collection methods were used? E.g., interviews, surveys, trial data	• What components of enactment were measured? E.g., engagement • Qualitative and/or quantitative or mixed-methods approach? • What data collection methods were used? E.g., interviews, surveys, trial data

Figure 9 MOSAIC Tool - Part B: Methods used to measure intervention implementation, as informed by the NIHBCC fidelity framework domains[1]

C: Strategies employed to Optimise Intervention Implementation				
Design	**Training**	**Delivery**	**Receipt**	**Enactment**
• Stakeholder Involvement • Piloting the intervention • Manualising procedures • Fixed core components with tailoring allowed • Documenting or predicting implementation issues • Other – provide detail	• Train-the-trainer approach • Standardised training scheme • Booster session • Manual or other resources • Expert trainers • Web-based training • Interactive training • Other – provide detail	• Support or supervision • Monitoring • Interdisciplinary teams • Stakeholder involvement • Facilitation • Champions • Technological aids • Tailoring and flexibility • Other – provide detail	• Scripted summaries • Self-monitoring • Co-creation of tools • Participant commitment agreement • Teach-back techniques • Clear schedule and reminders • Progress report • Shared decision making • Other – provide detail	• Post-intervention support • Home evaluation after intervention ended • Maintenance phase using phone calls • Session summary document • Clear instructions • Time to practice • Regular telephone support • Other – provide detail

Figure 10 MOSAIC Tool - Part C: Strategies employed to optimise intervention implementation, as informed by the NIHBCC fidelity framework domains[1]

2.4.4 How findings relate to previous research

To my knowledge, this is the only overview to date of methods used to measure implementation, and strategies employed to optimise implementation, of a complex intervention within the context of a trial. There was a review previously conducted of the measures used to assess fidelity and engagement with complex interventions [167], which found that fewer than half of the studies in the review measured both of these aspects of implementation. Fidelity of delivery was measured mostly by assessing the delivery of intervention components against the intervention protocol. It was assessed in most cases by either observation or self-report measures. This is different from what was found in my systematic methods overview, where the majority of studies used a checklist to assess fidelity of delivery. Walton et al also reported that around 20% of the included studies that used a framework or model to inform the method they used to assess fidelity and/or engagement. Many of the frameworks referenced were also referenced in my systematic methods overview, for example Steckler & Linnan's framework (2002)[31], the NIHBCC treatment fidelity framework[1], the RE-AIM framework[28], and Saunders et al (2005)[32]. This systematic review, published in 2017, also reported details about the psychometric and implementation qualities of these measures. Regarding this, they found that implementation qualities were reported less frequently than psychometric qualities.

There has also been a scoping review of strategies used to optimise a complex intervention before an RCT [23] which provided a classification of the optimisation strategies, as well as raising a series of questions for researchers to consider. This scoping review refers specifically to optimisation of interventions prior to a full-scale RCT whereas my systematic methods overview focuses on optimising intervention implementation within the context of a trial. Optimisation is an important aspect of clinical trials, which should be considered throughout the life cycle of a trial, from design to piloting to evaluation and to implementation. In this review, Levati et al reported that just over half of the included studies used the MRC framework for developing and evaluating complex interventions[7] to

guide their intervention development process. This was in line with my systematic methods overview. This shows that the MRC guidance is useful and researchers do utilise this guidance throughout the life cycle of a trial from development, through to implementation.

2.4.5 Strengths and limitations

This systematic methods overview aimed to provide an overview of the methods used to measure and optimise implementation of complex interventions within trials. The decision was taken to conduct a systematic methods overview rather than a systematic review or a narrative review since the area of interest is in the methods used rather than research findings such as intervention effectiveness. A comprehensive search was conducted with broad eligibility criteria in order to capture a wide range of methods and strategies. The search strategy was tested and refined in an iterative process to ensure key papers were found in the search.

Conducting one broad search for the two topics ensured efficiency as it allowed for the coding of two related sets of findings covering implementation of complex interventions in the context of trials. The first of these focused on methods for measuring implementation and the second on strategies for optimising implementation of complex interventions. This was challenging, since the separation of these two process (measuring implementation and optimising implementation) was not always clearly reported in studies. Therefore, I undertook an iterative process with my supervisors to reach conclusions surrounding the distinctions between measuring and optimising implementation. Similarly, there was a challenge around mapping terminology and definitions against one another. This was a subjective process and it was not possible to have a second reviewer to consult with regarding each new term used.

This overview focused on studies published since January 2015 in order to identify studies most likely to be designed following the publication of relevant guidance on complex interventions and their implementation within a trial, such as TIDieR[50] (published in 2014) and the MRC guidance for complex interventions[7] (published in 2008). It was intended that this would provide the most realistic picture of current practice. A limitation of this is that it does not allow conclusions to be drawn about research published prior to 2015, however

it is likely that reporting would be less detailed in studies published before guidance became available[168].

Upon reflection, the number of studies identified and included in this overview suggests the scope was wide. It may have benefitted from a more focused scope. The reason for keeping the scope so broad had been to capture a wide range of methods, which was achieved. Due to this, the MOSAIC tool which was developed through this systematic methods overview will have wider applicability to different populations. However, focusing the scope of this overview may well have allowed the identification of methods and strategies more relevant to the context of older people with frailty, which was the population of interest. Having said this, a later, more focused overview was conducted focusing only on trials involving older people with frailty.

Conducting this systematic methods overview also highlighted that methodological details pertaining to implementation of a complex intervention may not always be reported in the main trial report or publication, and it may be necessary to access companion papers such as process evaluations. Since this was an overview of methods, there was no consideration or categorisation of the quality of the methods employed; the analysis is narrative aiming to summarise what methods are being used by research teams. This could be investigated in the future, as it would be useful in this field, however it was beyond the scope of the systematic methods overview.

2.4.6 Implications

There are a number of useful implications from this overview for researchers working in clinical trial methodology. There is a need for clear, concise operationalised definitions of terminology used in implementation of complex interventions within the context of trials. The results of this overview demonstrated the extent of variation in terminology whereby different researchers use the same terminology to mean different things. This overview has further demonstrated the gaps in reporting of clinical trials, in particular the reporting of strategies to optimise implementation. Only around a third of the studies in this overview reported any strategies employed to optimise implementation of the complex interventions being tested. Within these, the majority were focused around training of intervention deliverers and delivery of

the intervention. There was a distinct lack of focus on receipt and enactment of the intervention, which are vital aspects of implementation, since most complex interventions require these to have the intended effect. It may be that strategies are used in trials to optimise these aspects of intervention implementation, but they are not being reported, in which case reporting of these needs to be improved.

Though the NIHBCC framework provides a useful backdrop against which to map the methods used to measure the and strategies employed to optimise implementation, it does have some limitations. The NIHBCC treatment fidelity framework domains are broad and can be further broken down into categories, as demonstrated in this overview, for the purposes of documenting the strategies employed to optimise complex intervention implementation within a trial. There is also some overlap of strategies across domains, for example 'support or supervision' has been categorised under the *delivery* domain, but it could also fit within *training,* as it relates to support for intervention deliverers.

There are a number of recommendations that emerge from this overview for researchers. Firstly, researchers must aim to be comprehensive in the reporting of methods used to measure and strategies employed to optimise implementation of a complex intervention within a trial. Secondly, they must consider all aspects of implementation including those which align with receipt and enactment of the intervention. Thirdly there is a need for a tool which can be used to aid reporting of methods used to measure and strategies employed to optimise implementation of a complex intervention. As outlined in Section 2.4.3, the MOSAIC tool provides a framework which researchers can use to ensure comprehensive reporting of implementation methods of complex interventions in trials. This tool also suggests potential strategies which can be employed to optimise the implementation of complex interventions. Accurate and complete reporting of implementation issues allows us to make better, more informed decisions about estimates of effectiveness of complex interventions. If an intervention is found to be ineffective in a trial, this could be due to poor implementation. Without measuring and reporting implementation, the intervention would be deemed ineffective and therefore discarded for use, when it could be due to a failure of implementation.

Chapter 3

A Systematic Overview of the Methods used to Measure Implementation and Strategies to Optimise Implementation of Complex Interventions within Trials involving Older People

3.1 Rationale

The UK NHS Long Term Plan (2019)[43] identified the increasingly ageing population as a key driver of service demand. The Plan emphasises development of community services to help people age well. These often take the form of complex interventions with multiple interacting components that can be tailored to the needs of older people.

Complex interventions have the potential to yield different outcomes in different contexts, therefore they need to be evaluated in a certain population before being implemented on a wider scale. They are usually evaluated through the 'gold standard' methodology of RCTs, which are generally large in scale and costly to conduct. RCTs often fail to show effectiveness, and we cannot be sure if this is due to failure of the intervention or another factor such as poor implementation. Due to the complex nature of the intervention and the context within which it is tested, it can be difficult to tease out the reasons for ineffectiveness (Section 1.1.1).

Some of the processes within RCTs are not very well understood, for example implementation processes do not have a lot of evidence to indicate what the best methods may be (Section 1.1.3). The methods for implementing complex interventions within trials are largely based on experiential knowledge, as opposed to selecting evidence-based methods to optimise the implementation of the intervention for different populations, settings or contexts. Understanding the methods for measuring intervention implementation and strategies for optimising intervention delivery is necessary to translate research into practice and to help reduce research waste (Section 1.2).

It is estimated that 85% of research activity leads to research waste [6]. To reduce this, we should aim to fill in knowledge gaps so we can maximise the usefulness of the gold standard RCT. Since community services for older

people were identified as an area of focus in the NHS Long Term Plan (2019)[43], there is a need for more research into the implementation of complex interventions within trials involving older people. In particular, there is a knowledge gap within methods of measuring implementation and strategies to optimise implementation of complex interventions within trials. Therefore, this overview was conducted to address the knowledge gap by identifying and describing the methods used in trials involving older people to measure and optimise implementation of complex interventions.

This systematic methods overview utilised a subset of the included studies from a previously conducted systematic review and network meta-analysis [41] of community-based complex interventions to sustain independence in older people, stratified by frailty (HTA Reference: 18/143 NIHR128862). The previous systematic review aimed to synthesise evidence on the effectiveness of these interventions, including the effect of frailty and pre-frailty, and group interventions to identify the best configurations, or categories of interventions. The interventions identified in this systematic review were grouped as part of a three-stage process by Thomas Crocker and colleagues, in which a number of intervention components were generated. My systematic methods overview sampled studies from this systematic review which included 'health education' as a component of the intervention. These were selected as it was anticipated that interventions which included health education as a component would be well reported. Also these interventions were deemed to be most similar to personalised care planning, which is at the centre of the PROSPER intervention, an important focus point for this PhD (Section 4.1.1).

Chapter 2 reported on a systematic methods overview which encompassed a broad and thorough search of trials investigating complex interventions (any setting, or population) published between 2015-2020. The systematic methods overview synthesised the types of methods used in trials to measure complex intervention implementation, and strategies employed to optimise complex intervention implementation. The MOSAIC (Methods for measuring and OptimiSing the Implementation of Complex Interventions) tool was developed in Chapter 2 (Section 2.4.3) to aid with the reporting of information regarding the implementation of a complex intervention within the context of a trial. The systematic methods overview reported in this chapter tests the value and

completeness of the MOSAIC tool by exploring how well it captures information regarding implementation methods within a sample of trials from the NIHR-HTA systematic review.

3.1.1 Aims and objectives

The aim of this systematic methods overview was to test the MOSAIC tool using a sample of complex intervention trials involving older people, with health education as a component of the interventions. This aim was addressed through the following objectives:

1. To systematically review a sample of complex intervention trials involving older people to identify and describe the qualitative and quantitative methods used to measure implementation of complex interventions.
2. To systematically review a sample of complex intervention trials involving older people to identify and describe the strategies employed to optimise implementation of complex interventions
3. To test, refine and update the previously developed MOSAIC tool using a sample of complex intervention trials involving older people.

3.2 Methods

3.2.1 Study design

This overview takes the design of a systematic methods overview (Section 2.2.1 for full description) [46].

3.2.2 Eligibility criteria

The eligibility criteria for this systematic methods overview were:

RCTs and cluster RCTs (and where available, associated papers reporting findings of process evaluations) of community-based complex interventions to sustain independence for older people living at home (mean age 65+), compared with usual care or another complex intervention.

Only those studies categorised under the intervention component of ‘health education’ were sampled. Studies published before the MRC guidance for process evaluations of complex interventions was published in 2008 [7] were excluded to manage capacity and workload. Also, it was presumed that studies

published after this guidance was published would be more likely to include detailed information regarding implementation processes.

3.2.3 Identifying eligible studies

3.2.3.1 Search strategy

As part of the aforementioned NIHR-HTA funded systematic review and network meta-analysis [41], the following electronic databases and trial registers were searched between 9th and 11th of August 2021: Cochrane Central Register of Controlled Trials (CENTRAL) Wiley (1992-); MEDLINE Ovid (1946-); Embase and Embase Classic Ovid (1947-); CINAHL EBSCO (1981-); APA PsycINFO Ovid (1806-); US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov); World Health Organization International Clinical Trials Registry Platform (https://trialsearch.who.int). The reference lists of included studies were also scanned.

There were no separate searches undertaken for this overview as part of this PhD, since the studies sampled were to be retrieved from the search detailed above.

3.2.4 Selection process

Title and abstract screening were completed by two researchers working on the NIHR-HTA funded systematic review and meta-analysis [41]. I was not involved in this part of the screening process. Due to the size and scope of the dataset, it was deemed appropriate to focus on a subset of trials from the aforementioned systematic review, for the purposes of this systematic methods overview.

The trials selected for this overview had previously been categorised to include ‘health education’ as a component of the intervention by the researchers undertaking the systematic review and network meta-analysis[41]. I further screened these trials to exclude those conducted before the MRC guidance for process evaluations of complex interventions was published, in 2008 [7].

Similarly to the methods overview discussed in Chapter 2, the unit of analysis here was the trial and associated companion papers. Therefore, papers arising from the same study, such as protocol papers or process evaluations were linked to eligible trials. The primary reference for each study was always

accessed first, followed by the other papers in cases where information was not found in the primary reference.

3.2.5 Data extraction

The MOSAIC tool (Section 2.4.3) was developed in Microsoft Excel and piloted before being used for the data extraction process of the overview. This tool has been designed to aid reporting of implementation processes of complex interventions within trials. Following some changes to the tool, informed by my first systematic methods overview (Chapter 2) and the NIHBCC fidelity framework domains [1] (*design, training, delivery, receipt and enactment*), the MOSAIC tool was also used to extract data for this methods overview.

The MOSAIC tool was first applied to the primary reference i.e. RCT paper to capture the relevant information. If the information was not found in the primary trial report, accompanying papers such as process evaluations or protocol papers were reviewed to extract further details. There was no checking of data extraction by any other researcher.

3.2.6 Data management

Full text screening to establish trial eligibility and intervention type was conducted by researchers working on the NIHR-HTA funded systematic review [41]. For the purpose of this overview, I accessed the relevant studies, i.e. those testing interventions with health education as a component, published after 2008. Files were obtained containing the primary reference papers such as trial results for each of these studies, as well as associated papers such as protocols and process evaluations. These files were imported into Endnote for the purpose of this methods overview.

3.2.7 Data Synthesis

A narrative approach was taken to synthesise and report the findings. Descriptive analysis was used to report study characteristics and details of the complex interventions. A similar approach to that used in the first systematic methods overview in Chapter 2 (Section 2.2.7) was taken to synthesise the data, using the MOSAIC tool. The use of this tool for data extraction and synthesis was tested in this systematic methods overview, by assessing the comprehensiveness of the tool and its ability to capture new data.

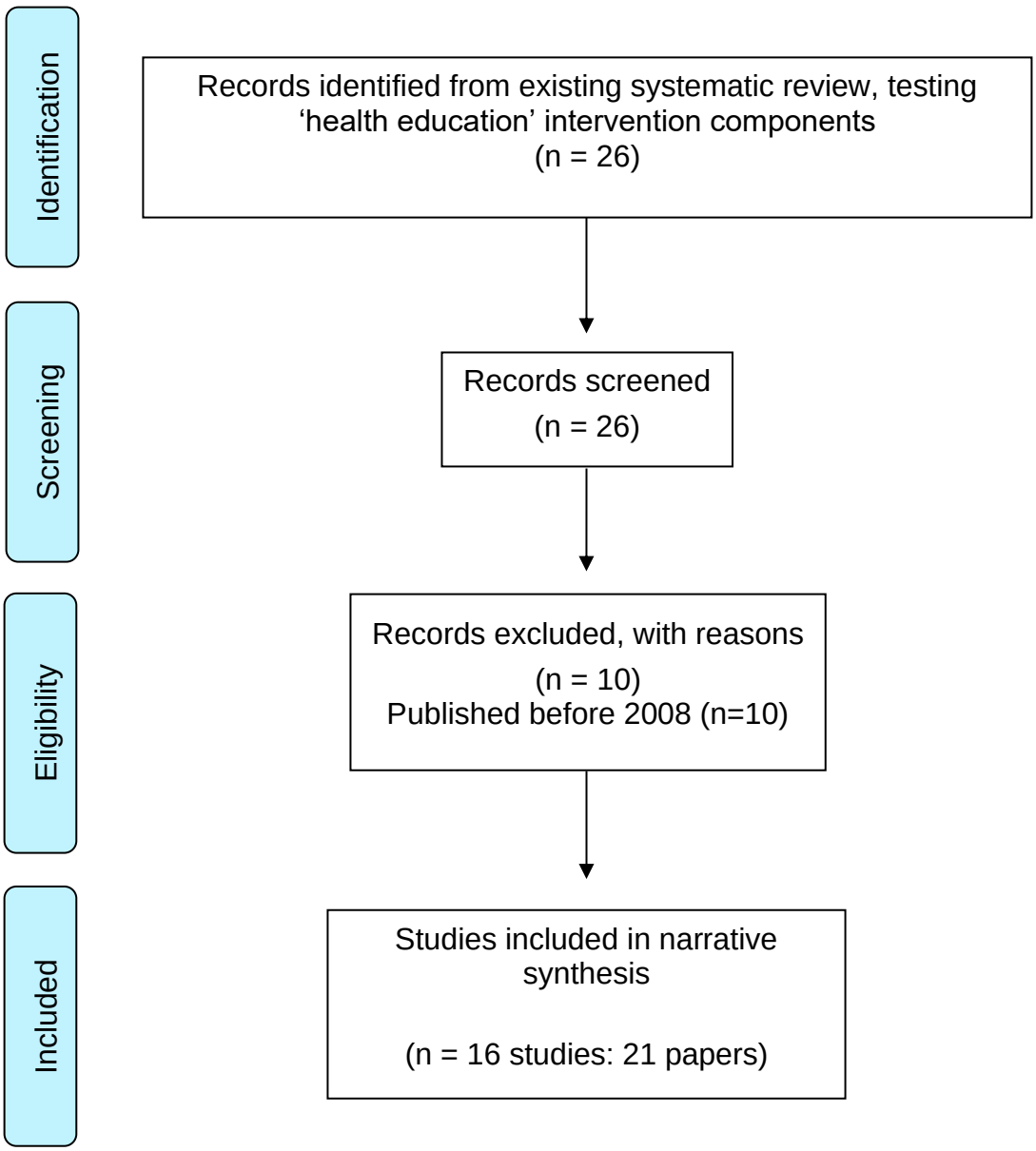
3.3 Results

3.3.1 Search results

For the NIHR-HTA funded systematic review and meta-analysis [41], the researchers generated 19 intervention components: Formal homecare, physical exercise, health education, ADL training, providing aids and adaptations nutritional support, psychological therapy, technology for communication and engagement, cognitive training, engagement in meaningful activities, care voucher provision, alternative medicine e.g. homeopathy, social skills training, welfare rights advice, multifactorial-action from care planning, routine review following multifactorial action from care planning, medication review, routine risk-screening and monitoring.

For the purpose of this systematic methods overview, I screened a sample of 26 studies where the interventions included health education components. Of these 26 studies, 10 were excluded as they were conducted prior to the MRC guidance for process evaluations of complex interventions being published in 2008. Figure 11 outlines the screening and identification process.

Figure 11 Screening and identification of studies



3.3.2 Study characteristics

Of the sixteen included studies, five were conducted in the United States [169-173], three in Sweden [174-176,] two in the Netherlands [177, 178] and one in each of the following countries: Switzerland [179], Germany [180], Canada [181], Spain [182], Australia [183] and Japan [184]. Thirteen of the studies were RCTs [169, 171-176, 179-184,] two were cluster RCTs [177, 178], and one had a quasi-experimental pre-post test design [170].

3.3.2.1 Intervention descriptions

All the interventions, except one which was an internet programme [171,] were delivered by healthcare professionals. Seven interventions were delivered by more than one healthcare professional, often a multidisciplinary team such as occupational therapists, nurses, physiotherapists, rehabilitation specialists, dietitians, dental hygienists, and social workers[170, 174, 175, 177, 179, 180, 184]. Two interventions were delivered by one person from a group of healthcare professionals including nurses, physiotherapists, occupational therapists and social workers [175, 176]. Three interventions were delivered exclusively by occupational therapists [169, 172, 173], two interventions were delivered exclusively by nurses [178, 181], and one intervention was delivered by 'nursing personnel' and a geriatrician [182]. One intervention was delivered via an Internet programme and had been developed by a group of experts including older adults, caregivers and community partners[171].

All the studies included in this methods overview had a target population of community-dwelling older people however some specified additional inclusion criteria. For example, two studies were targeted specifically towards older people who had migrated to Sweden [174, 176], another two were focused on low income adults with disabilities [172, 173]. Some specified age-related criteria, for example targeting older people over 75 years of age [182], or those between the ages of 70 and 78 years [178], or pre-frail 80 year old people living at home [175]. Other studies specified criteria relating to service use, for example one study focused on older adults who reported current use of long-term care services [184], another on older people referred for assistance with domestic or personal care tasks [183], and another on those aged 75 or over not receiving home care services [181]. Lastly, one study targeted ethnically diverse older people at risk of

health-related decline [169], one focused on older adults with chronic illnesses [170], and another on older adults and their informal caregivers [171],

Most of the interventions were delivered face-to-face, however one was delivered over the phone [170], another over the internet [171] and one both face-to-face and over the phone [179]. Most interventions were delivered to participants individually [170, 172, 173, 177-181, 183], three in a group setting, [169, 175, 184] three through a combination of both individual and group settings [174, 176, 182] and one was delivered to older people and their caregivers together (dyad) [171]. Most interventions were delivered over a duration between one month and six months, categorised for the purpose of this overview as 'medium' [169, 170, 172-174, 176, 183, 184]. Five interventions were delivered over a period longer than six months, categorised here as 'long' [171, 178, 179, 181, 182] and one was categorised as 'short' in duration, lasting 4 weeks or less [180]. The duration of the intervention was not reported in one study [177]. One study compared two interventions of short and medium duration [175].

Most interventions were continuous (i.e. delivered over more than one session) [169-174, 176-179, 181-184], but one had one session only [180]. One study compared a continuous intervention with a one-off intervention [175]. Most interventions (n=14) were designed to allow for some tailoring or personalisation, when being delivered to the target population. Two studies did not report whether tailoring or personalisation of the intervention was allowed [175, 180].

3.3.3 Frameworks guiding intervention implementation

Most of the studies in this overview did not reference the use of a framework or set of guidance to inform the implementation process (n=14) [169-173, 175, 176, 178-184]. No studies referenced the MRC guidance for process evaluation of complex interventions[7]. Only two studies included in this overview reported the use of a framework to inform implementation of the complex intervention [174, 177].One study used the Knowledge to Action model to inform the implementation process [185]. This model uses knowledge creation and action to improve health. Barenfeld et al used the action cycle element of this model, which involves identifying components that support or inhibit implementation of an intervention, to implement the intervention into practice. Metzelthin et al [177] used the

following frameworks to inform the implementation process: Baranowski and Stables 2000, Linnan and Steckler 2002 and Saunders et al 2005 [31, 32, 186].

3.3.4 Accessing companion papers

For eleven of the studies in this systematic methods overview, implementation data were extracted from the main paper i.e. trial report or results papers. Five studies required linkage to other papers such as protocols to complete data extraction[173-175, 180, 183].

3.3.5 Methods for measuring intervention implementation

Seven of the studies included in this systematic methods overview did not report any methods used to measure implementation of the complex intervention [170-172, 175, 176, 182, 184]. Nine studies (56%) reported the methods used to measure implementation of the complex intervention [169, 173, 174, 177-181, 183]. Of these, six studies used quantitative methods to measure implementation of the complex intervention [169, 173, 179-181, 183]. Two studies used both quantitative and qualitative methods [174, 178] and one study adopted a mixed-methods approach [177]. Table 4 shows a visual representation of the number of studies which measured aspects from each of these domains.

Table 4 Methods used to measure intervention implementation categorised into NIHBCC framework domains

NIHBCC Framework Domains		Number of studies
Design	Active components of intervention operationalised	None
	Intervention developed through co-design	●
	A priori specification of treatment dose	None
	Monitoring of intervention implementation throughout	None
Training	Training received	●●●●●●●
	Intervention manual used	●●
	In-person training	●

	Evaluation of training	●
Delivery	Fidelity of delivery	●●●●
	Dose delivered	●●
	Barriers to intervention delivery	●
Receipt	Receipt of the intervention	●●●
Enactment	Meaningful activity participation	●
	Motivators for participation and barriers and facilitators for continuation	●

3.3.5.1 Approaches to data collection

Methods of data collection varied amongst the studies. Some studies used quantitative methods such trial data and documentation (n=5)[169, 173, 174, 178, 183], questionnaires or surveys (n=6) [172, 174, 177, 179-181], logbooks (n=1), assessment scales (n=1)[187] and audiotapes alongside fidelity checklists (n=1)[173]. Others used qualitative methods such as interviews (n=4)[171, 174, 177, 178], observation (n=1)[174], focus groups (n=2)[171, 177] and diaries (n=1)[177].

3.3.5.2 Design

According to the NIHBCC treatment fidelity framework, assessment of fidelity to study design can be conducted through assessing the active components of the complex intervention to ensure they are fully operationalised, co-designing the intervention alongside members of the target population, with a priori specification of the treatment dose and monitoring implementation throughout [1]. Only one study reported that the intervention was co-designed alongside members of the target population [171]. No studies reported details about operationalising active components of the complex intervention, or a priori specification of the treatment dose, or monitoring implementation.

3.3.5.3 Training

Seven studies reported that intervention deliverers received some form of training [173, 174, 177, 179, 180, 183, 184]. Two studies did not report the training in detail [174, 180]. Another two studies reported that the intervention manual was used for

the purposes of training [173, 179]. Hattori et al reported that intervention deliverers received in-person training at a 4-day workshop led by occupational therapists [184]. Lewin et al reported details about the training such as the resources used: presentations, case studies, role plays, activities, take home exercises, and prereading. They also reported that training was delivered by Senior Allied Health Professionals working within a multidisciplinary team, and that training was followed by a competency assessment [183]. This was the only study in this overview reporting any evaluation of training (i.e. the post-training competency assessment) [183].

3.3.5.4 Delivery

Fidelity of delivery was the most commonly reported aspect of intervention implementation in the studies included in this overview, with four studies reporting fidelity measures [173, 174, 177, 184]. Two studies measured dose [173, 177]. One study measured barriers to intervention delivery as experienced by healthcare professionals through a process evaluation[177].

Most of these studies utilised quantitative methods to measure aspects of the intervention delivery [173, 178, 181, 183]. For example, Szanton et al utilised audiotapes and fidelity checklists, alongside electronic documents to measure fidelity, dose and costs of delivery [173]. Ploeg et al used surveys to measure costs to deliver the intervention [181]. Moll van Charante et al used trial data from participants to measure adherence[178].

One study utilised a mixed-methods approach [177], using interviews and focus groups to measure fidelity and barriers to intervention delivery, as well as logbooks to measure dose. Another used both qualitative and quantitative methods [174], using interviews, observations and study documentation to measure intervention fidelity. One study did not report the methods used to measure intervention delivery [184].

3.3.5.5 Receipt

Three studies measured some aspect of receipt of the intervention[177, 179, 180]. Of these, two studies used quantitative methods of data collection such as telephone surveys[180], and questionnaires [179] to measure acceptance [180], and uptake [179] respectively. One study adopted a mixed-methods approach, using

logbooks and evaluation forms to measure reach and dose received (exposure), and interviews and focus groups to measure satisfaction [177].

3.3.5.6 Enactment

Only two studies reported measuring enactment in some way[169, 178]. One of these measured 'meaningful activity participation' through the use of a new tool, developed specifically for the study, called the Meaningful Activity Participation Assessment (MAPA) [169]. The MAPA is a checklist used by participants to self-report the frequency of performance for each activity. Another study measured motivators for participation and barriers and facilitators for continuation using qualitative interviews[178].

3.3.6 Strategies employed to optimise implementation

Of the sixteen studies included in this overview, nine studies (56%) reported strategies employed to optimise implementation[171, 173, 174, 176, 183]. These can be categorised into a number of themes, based around the domains in NIHBCC treatment fidelity framework [1]: *design, training, delivery, receipt and enactment*. Within these themes, strategies reported have been mapped against the categories taken from the MOSAIC tool, as discussed in Section 3.2.5 of this overview. There is some overlap of these categories across domains, for example *stakeholder involvement* spans both design and delivery of the intervention. Tables 4-7 show the strategies employed to optimise implementation of complex interventions in each of the nine studies, as categorised under the five themes: *design, training, delivery, receipt and enactment*.

3.3.6.1 Design

Six studies reported strategies to optimise the implementation of the intervention, relating to the design[171, 173-176, 183] (Table 5). No studies reported having fixed core components with tailoring allowed, or predicting implementation issues to optimise implementation of the intervention. There were no additional strategies, relating to *design*, reported in the included studies.

Table 5 Design: Strategies employed to optimise implementation

Design		
Strategy	**Employed by**	**Method of employment**
Stakeholder Involvement	Barenfeld et al 2018[174]	Recruited a steering committee to aid with implementation
	Lood et al 2015[176]	Used reference groups with whom they consulted prior to making adaptations
	Gustafson et al 2022[171]	Used Asset-Based Community Development to develop and test intervention technology
Piloting the intervention	Gustafson et al 2022[171]	Tested paper prototypes and onscreen iterations of the intervention technology
	Lood et al 2015[176]	Piloted the study in a feasibility pilot study
	Gustafsson et al 2013[175]	Tested the intervention with involvement from the target population in a pilot study
Manualising procedures	Szanton et al 2019[173]	Used an intervention manual to optimise implementation of the intervention
	Lewin et al 2013[183]	Used an intervention manual to optimise implementation of the intervention
Fixed core components-tailoring allowed	No studies reported this as a strategy used for optimising the implementation.	
Documenting/ predicting implementation issues	No studies reported this as a strategy used for optimising the implementation.	

3.3.6.2 Training

Though seven studies reported training of intervention deliverers, only two studies[179, 183] detailed exact methods or strategies used to optimise implementation of the complex intervention through training (Table 6). No studies reported using the following strategies to optimise training of intervention deliverers: train-the-trainer approach, standardised training scheme, booster sessions, expert trainers, web-based training, or interactive training. There were no additional strategies, relating to *training*, reported in the included studies.

Table 6 Training: Strategies employed to optimise implementation

Training		
Strategy	**Employed by**	**Method of employment**
Manual	Stuck et al 2015[179]	Provided intervention deliverers with an intervention manual to aid with training
	Lewin et al 2013[183]	
Competency Assessment	Lewin et al 2013[183]	Training was followed by a competency assessment.
Train-the-trainer approach	No studies reported using the train-the-trainer approach to train intervention deliverers.	
Standardised training scheme	No studies reported using a standardised training scheme to train intervention deliverers.	
Booster session	No studies reported having booster training sessions.	
Expert trainers	No studies reported using expert trainers to train intervention deliverers.	
Web-based training	No studies reported using web-based training to train intervention deliverers.	
Interactive training	No studies reported using interactive training methods to train intervention deliverers.	

3.3.6.3 Delivery

Nine studies reported strategies to optimise the delivery of the intervention[170, 171, 173, 174, 176-178, 181, 184]. The most commonly used strategies, used in three studies each, were support or supervision[173, 177, 184], monitoring[173, 178, 181] and stakeholder involvement[171, 174, 176]. One study reported the use of interdisciplinary teams[170], another study reported the use of technological aids[171] and a third reported the use of tailoring and flexibility[174] as strategies to optimise delivery of the interventions. Although, tailoring and flexibility was not reported as a specific strategy to optimise intervention delivery, almost all studies reported allowing some degree of tailoring or personalisation of the intervention to each participant. For many complex interventions, this is simply a feature of the intervention itself. No studies reported facilitation or the use of champions to optimise delivery of the intervention (Table 7). There were no additional strategies, relating to *delivery*, reported in the included studies.

Table 7 Delivery: Strategies employed to optimise implementation

Delivery		
Strategy	**Employed by**	**Method of employment**
Support or supervision	Szanton et al 2019[173]	Feedback provided to intervention deliverers through supervisory sessions.
	Metzelthin et al 2013[177]	Optional supervision of intervention delivery.
	Hattori et al 2019[184]	Intervention deliverers had consultations with supervisors to maintain intervention fidelity.
Monitoring	Ploeg et al 2010[181]	Nurses monitored and encouraged patient adherence through follow-up phone calls and home visits.
	Moll van Charante et al 2016[178]	Monitored delivery of the intervention through visits to the intervention deliverers (nurses).

	Szanton et al 2019[173]	Used monitoring checklists to maintain fidelity of intervention delivery.
Interdisciplinary teams	Faul et al 2009[170]	Used an interdisciplinary team to deliver intervention. No further details reported.
Stakeholder involvement	Barenfeld et al 2018[174]	Use of steering committee to transform the intervention into practice
	Gustafson et al 2022[171]	Used Asset-Based Community Development to help improve the intervention during implementation.
	Lood et al 2015[176]	Use of reference groups to consult with regarding adaptations to the intervention at all stages of implementation.
Technological aids	Gustafson et al 2022[171]	Used digitally collected data to test and improve the intervention technology during implementation
Tailoring and flexibility	Barenfeld et al 2018[174]	The intervention protocol, though predetermined, allowed adaptation by answering to any contextual needs.
Facilitation	No studies reported the use of facilitation to optimise intervention delivery.	
Champions	No studies reported the use of champions to optimise implementation.	

3.3.6.4 Receipt

Five studies reported strategies to optimise the receipt of the intervention[169, 171, 173, 176, 181]. Of these, two studies reported the co-creation of tools[171, 176] and another two studies reported use of a clear schedule and reminders[169, 181] to optimise receipt of the intervention. One study reported the use of checklists[173], another reported the use of financial compensation[169] and a third reported home visits[181] as strategies employed to optimise the receipt. A number of strategies from the MOSAIC tool were not reported to have been employed in these studies: scripted summaries, self-monitoring, participant commitment agreement, teach-back techniques, progress reports and shared decision-making (Table 8). There were some additional strategies, relating to *receipt*,

reported in the included studies, which were consequently added to the MOSAIC tool. These were: use of checklists, financial compensation, and home visits.

Table 8 Receipt: Strategies employed to optimise implementation

Receipt		
Strategy	**Employed by**	**Method of employment**
Co-creation of tools	Gustafson et al 2022[171]	The intervention was co-created in conjunction with the target population.
	Lood et al 2015[176]	There were partnerships between the target population and research group during all stages of development and implementation, though there was not enough detail to determine whether there was co-creation of any intervention elements.
Clear schedule and reminders	Clark et al 2012[169]	Intervention deliverer would regularly contact patients to inform them of upcoming events as well as sending reminders and repeatedly contacting those who failed to attend.
	Ploeg et al 2010[181]	Nurses encouraged patients to adhere to the intervention through the use of follow-up phone calls and home visits.
Checklists	Szanton et al 2019[173]	Use of a checklist to monitor participants' engagement with the intervention.
Financial compensation	Clark et al 2012[169]	To encourage adherence, participants were compensated for their time and effort with a financial incentive.
Home visits	Ploeg et al 2010[181]	To encourage adherence to the intervention.

Scripted summaries	No studies reported the use of scripted summaries to optimise receipt of the intervention.
Self-monitoring	No studies reported the use of self-monitoring to optimise receipt of the intervention.
Participant commitment agreement	No studies reported the use of participant commitment agreement to optimise receipt of the intervention.
Teach-back techniques	No studies reported the use of teach-back techniques to optimise receipt of the intervention.
Progress reports	No studies reported the use of progress reports to optimise receipt of the intervention.
Shared decision-making	No studies reported the use of shared decision making to optimise receipt of the intervention.

3.3.6.5 Enactment

Only two studies in this overview reported the use of strategies to optimise the enactment of the intervention[173, 181]. One of these reported allowing time to practice[173] and the other reported employing regular telephone support[181] to optimise the enactment of the intervention. A number of strategies from the MOSAIC tool were not reported to have been employed by the studies included in this overview, including: post-intervention support, home evaluation, maintenance phase using phone calls, session summary document and clear instructions (Table 9). There were no additional strategies, relating to *enactment*, reported in the included studies.

Table 9 Enactment: Strategies employed to optimise implementation

Enactment		
Strategy	**Employed by**	**Method of employment**
Time to practice	Szanton et al 2019[173]	Participants were provided opportunity to demonstrate the exercises to the intervention deliverer to optimise enactment of the intervention.
Regular telephone support	Ploeg et al 2010[181]	Follow-up phone calls to encourage adherence. No further information provided about how often the participants were called or the nature of the calls.
Post-intervention support	No studies reported provision of support following the intervention end date to optimise enactment of the intervention.	
Home evaluation after intervention ended	No studies reported conducting any home evaluation after the intervention period ended to optimise enactment of the intervention.	
Maintenance phase using phone calls	No studies reported the use of a maintenance phase to optimise enactment of the intervention.	
Session summary document	No studies reported the use of a session summary document to optimise enactment of the intervention.	
Clear instructions	No studies reported the use of clear instructions to optimise enactment of the intervention.	

3.4 Discussion

3.4.1 Summary

This methods overview aimed to test the MOSAIC tool within a sample of studies investigating community-based interventions that included a 'health education' component, targeted at older people with frailty. The MOSAIC tool was used for the data extraction process and to synthesise the findings. This overview identified 16 studies published after the 2008 MRC guidance for process evaluations of complex interventions[7]. These studies were then reviewed for data reporting on methods used to measure implementation processes and strategies employed to optimise implementation. Only around half of the included studies reported some degree of detail on implementation processes, either measurement or optimisation of implementation or both. Of these, around half required additional papers such as process evaluations to be reviewed for the details. Most of the studies in this overview did not report a framework or set of guidance which they used to inform the implementation process. The MOSAIC tool appeared comprehensive, with some new strategies for optimising intervention implementation identified in this dataset.

3.4.2 Key findings

The MOSAIC tool provided a useful method for capturing the data extracted from the studies in this overview. It was easy to use and allowed the data from the studies to be presented against a framework. Of the five domains included in the MOSAIC tool, taken from the NIHBCC fidelity framework [1], many studies in this overview focused mostly on the *delivery* domain. There was a distinct lack of focus on *design, training, receipt,* and *enactment* of the intervention, both when measuring intervention implementation and when optimising the intervention. For example, although almost half of the studies in this overview reported training intervention deliverers, only one study evaluated the training, as evidenced by a competency assessment. It is important for training to be evaluated since, without effective training, intervention deliverers may not be delivering the intervention in the correct way. Also, evaluation of training or the effect of training can also be classified as an optimisation strategy since this can elicit improvements in the intervention implementation.

Very few studies reported details surrounding the design of the intervention. Often this information may not be reported in trial results papers; instead it may be found in papers detailing intervention development. However, additional papers were accessed to allow for a thorough data extraction process. Despite this, there remained a lack of detail surrounding intervention design. Within the *delivery* domain, most studies focused on fidelity of delivery as the main aspect of intervention implementation that was measured.

Around half of the studies in this overview reported strategies they used to optimise the implementation of the complex intervention. Using the MOSAIC tool, these were categorised under the domains of *design, training, delivery, receipt,* and *enactment* and further categorised into sub-categories within each domain. Most strategies reported to optimise intervention implementation related to the domains *design, delivery* and *receipt.* There was a distinct lack of strategies reported relating to the domains of *training* and *enactment.*

There were some strategies for optimising implementation identified through this systematic methods overview and added to the MOSAIC tool. These were categorised under the theme of *receipt*: use of checklists, financial compensation, and home visits (Section 3.3.4.3). Similarly, to the methods of measuring implementation, most of the strategies identified aligned with the domain 'delivery' of the complex intervention.

3.4.3 How findings relate to previous research

This systematic methods overview reported fewer strategies and methods used compared with my first systematic methods overview (Chapter 2). This could be attributable to the fact there were fewer studies in this systematic methods overview, whereas my first systematic methods overview included almost 100 studies. Fewer studies in this systematic methods overview reported the use of a framework to inform the implementation process than in my first systematic overview. These systematic methods overviews are the first, to my knowledge, in the area of intervention implementation within the context of a trial.

As discussed in Section 2.4.4, Walton and colleagues conducted a systematic review of measures used to assess fidelity and engagement with complex interventions[167]. Whereas this systematic review found that 20% of studies reported the use of a framework to inform implementation, my systematic

methods overview reported that only 12.5% of studies reported the use of a framework to inform implementation. Consistently with this systematic review, and my first systematic methods overview, it was found that fidelity of delivery was the most commonly reported aspect of intervention implementation in this systematic methods overview. Very few studies measured aspects of enactment, such as engagement, in my systematic methods overview. This was different to the findings from Walton and colleagues, where almost half of the included studies reported some measure of engagement.

Through conducting this overview, there were some additional strategies identified which were subsequently added to the MOSAIC tool. As with all the strategies listed in the MOSAIC tool, these may well be used in trials but they may not always be reported. Under-reporting of intervention details was previously identified by the researchers involved in developing the TIDieR checklist[50], which was developed to help address this issue. The checklist and guide is now widely used and cited for intervention description, leading to an improvement in reporting. Similarly, researchers must aim to improve reporting of implementation methods and optimisation strategies, and ensure better linking to outcome reporting. Further benefits of improving reporting come from researchers being able to learn from and replicate successful intervention implementation methods and strategies to optimise across trials. This can potentially be done using the MOSAIC tool. Though this tool has not yet been extensively tested, it provides a useful framework for researchers to apply surrounding implementation of a complex intervention within the context of a trial. It indicates potential strategies that can be employed to optimise implementation of a complex intervention within a trial as well as providing questions for researchers to consider when reporting the methods they used to measure intervention implementation.

Similarly to the findings from my first systematic methods overview, strategies relating to *receipt* and *enactment* of the intervention (Sections 2.3.5.4 & 2.3.5.5) were not often reported, compared with strategies relating to the *design* and *delivery* of the intervention (Sections 2.3.5.1 & 2.3.5.3). However, in contrast to my first systematic methods overview, there were few strategies reported that aligned with the *training* theme (Section 2.3.5.2). In my first systematic methods overview, there were a number of strategies identified such as the use of expert

trainers, the train-the-trainer approach. However, none of these were reported to be used in the interventions identified in this systematic methods overview. There were no new strategies relating to optimising training identified from the studies included in this overview. This may be attributable to inadequate reporting of training procedures, or may indicate of a lack of strategies employed to optimise training of the intervention in these studies. Since training depends on the intervention type, some interventions require different types and extents of training for intervention deliverers. Therefore, some variation between training provided is expected. As mentioned previously, the studies included in this systematic methods overview were conducted outside of the United Kingdom, so this may reflect a difference in practices between trials conducted in the United Kingdom and elsewhere around the world.

3.4.4 Strengths and limitations

This overview aimed to test the previously developed MOSAIC tool through the process of data extraction of a subset of studies investigating complex ‘health education’ interventions for community-dwelling older people with frailty. The overview has demonstrated the usefulness of the tool in extracting methods used to measure implementation of these complex interventions, and strategies employed to optimise their implementation. The MOSAIC tool allows the researcher to go beyond the intervention descriptions, which the TIDieR checklist[50] facilitates. The methods and strategies identified have been categorised under the domains in the MOSAIC tool, as informed by the NIHBCC fidelity framework domains. There were no domains or concepts found through this systematic methods overview which did not fit within the domains in the MOSAIC, therefore the tool was not modified.

The approach taken to address the aims of this overview was a thorough approach, whereby 21 papers were accessed linking to the 16 studies sampled for this overview. Additional papers, where available, for each study were accessed to pool all the available information regarding implementation of the complex intervention.

Due to the small number of studies sampled for this overview, the methods and strategies identified were not extensive and this is one limitation of this overview. However, it was not intended that a broad set of studies would be

included in this overview. Instead, the aim was to test the MOSAIC tool, which was achieved through the small subset of studies included. Further there was no search strategy or screening process undertaken solely for the purpose of this overview since the studies sampled already accessed from an existing systematic review. This approach was taken since the interventions and target population were the same. Therefore, accessing a sample from the existing systematic review minimised workload whilst still allowing for the objectives of this PhD to be met. A limitation however, is that the studies sampled for this overview only related to interventions including health education as a component, which may report different methods and strategies to interventions which include other components.

This systematic methods overview excluded studies that were published before the MRC guidance for developing and evaluating complex interventions in 2008[7] to manage capacity and workload implications in this doctoral study. This restriction was deemed reasonable as it was assumed that studies published after 2008 would have better reporting of implementation processes post-publication of the MRC guidance. But, it is worth noting that studies published before 2008 may have included methods for measuring implementation and strategies for optimising implementation of complex interventions. Therefore, important data for this systematic methods overview could be missed due to this exclusion.

Also, none of the studies included in this systematic methods overview referenced the MRC guidance, which may be due to the fact that none of the studies were published in the United Kingdom. Since the studies sampled for this systematic methods overview form a specific subset within a niche area, there is a chance that the findings may not be generalisable beyond studies investigating complex interventions involving health education for older people with frailty. The identified methods for measuring implementation and strategies for optimising implementation may only apply within this subset rather than translating to other areas. Therefore, if this systematic methods overview was to be extended in future, it would be worthwhile to access a larger sample of studies, particularly those published before 2008 and those testing interventions with other components, i.e. not just health education.

3.4.5 Implications

There are a number of useful implications from this systematic methods overview for researchers working in clinical trial methodology. This systematic methods overview has highlighted that intervention implementation methods and optimisation strategies are not carefully considered by researchers. The existing frameworks in implementation research are not utilised in the studies included in this systematic methods overview. Despite the limited information reported in the included studies, the MOSAIC tool was successfully tested in this systematic methods overview.

The MOSAIC tool was tested by extracting data from the studies included in a sample of studies investigating complex interventions for older people. Through this process, additional strategies to optimise implementation of the complex interventions were added to the MOSAIC tool. It was shown to be a useful tool for extracting information but also holds value for being used to plan intervention implementation and select optimisation strategies. The MOSAIC tool could be used alongside the TIDieR checklist for intervention descriptions[50], to allow for completeness in data reporting on complex interventions and their implementation. In the future, the MOSAIC tool could undergo further development through which it could become a resource for researchers reporting on the implementation of complex interventions within trials. There is no existing tool to aid reporting of implementation methods and strategies for optimising complex interventions within trials.

The recommendations that emerge from this systematic methods overview relate to reporting in detail what methods were used to implement an intervention within the context of a trial and strategies employed to optimise intervention implementation. When reporting these details, it would be helpful to utilise a framework such as the MRC guidance for process evaluations[5] or the NIHBCC treatment fidelity framework[1]. This allows researchers to ensure they have considered all important aspects of intervention implementation and also prompts researchers with strategies to optimise intervention implementation. Training of intervention deliverers was one aspect that

The MOSAIC tool can aid with this process of reporting since it provides useful categories against which to report aspects of intervention implementation. This

overview supports many of the findings and implications from my first systematic methods overview in Chapter 2 (Section 2.4.6).

Chapter 4

Study Within a Trial (SWAT) to investigate whether use of a video animation improves' service users' uptake and engagement with the intervention

4.1 Introduction

A study within a trial (SWAT) is a self-contained research study embedded within one or more host trials to explore or evaluate alternative methods of delivering or conducting a particular trial process [36]. SWATs contribute to the evidence base for improving trial efficiency, without affecting the scientific integrity of the host trial. There is an extensive evidence base of SWATs exploring refinements to trial processes concerning recruitment and retention [188-191]. SWATs investigating refinements of other trial processes, such as data quality, monitoring risks or dissemination are becoming more common [192, 193].

SWATs usually employ trial designs such as RCT or cluster RCTs, but are not always randomised [36]. The decision to randomise a SWAT depends on the research question under investigation in the SWAT. If the research question is focused on evaluating the effects of trial processes (e.g. using a pen as an incentive for recruitment), the alternative processes should be randomly allocated. Trial processes may include recruitment of participants, retention of participants, or indeed intervention implementation processes such as training of intervention deliverers or delivery of the intervention. Conversely, if the research question is focused on understanding why a trial process is conducted in the way it is, this does not require random allocation. In cases like this, qualitative methods or a mixed-methods design may well be more appropriate for the research questions under investigation. Randomisation of the SWAT does not need to follow the same process used in the host trial. It is worth noting that there is currently limited guidance on using qualitative methods in SWATs. Although qualitative research is often nested within a definitive trial for the purposes of process evaluation (Section 1.1.4), this is different to attaching qualitative studies to SWATs.

There are some challenges related to conducting SWATs identified in the literature. One of these relates to SWATs often being underpowered. This is

due to the fact that the sample size for a SWAT is constrained by the host trial sample size. It is recommended are SWATs evaluating the same intervention within the same population be meta-analysed to address the issue of individual SWATs being underpowered [36]. Other challenges relate to costs, obtaining ethical approval and ensuring that the SWAT does not undermine the host trial.

To date, SWATs are not widely used to evaluate competing trial processes relating to an aspect of intervention implementation ('*the structures, resources and process through which delivery of the intervention is achieved and the quantity and quality of what is delivered')* [5]. There are only a few SWAT examples identified within the Northern Ireland SWAT repository [194] which report investigation of intervention implementation. Some of these used a randomised trial design, for example to investigate reminders to intervention recipients to improve adherence[195]; and the use of additional virtual follow- ups and automatic, rather than manual, intervention adjustments on intervention compliance [196]. Others used a non-randomised design with a qualitative component in the SWAT to investigate the influence of different healthcare professionals on intervention delivery [197]. These SWATs are crucially different to SWATs testing trial recruitment or retention processes in that they can only operate within the intervention arm(s) of the host trial.

It is unclear, however, if these studies have systematically assessed whether embedding a SWAT within only the intervention arm of a randomised trial compromises the scientific integrity of the host trial, or presents other methodological or conduct challenges. These challenges have been identified and explored through conducting the SWAT, and subsequently discussed in my paper published in the journal Research Methods in Medicine and Health Sciences [38]. In this paper, written by myself and colleagues, we proposed that such SWATs are an informative and potentially important methodology for the understanding and refinement of implementation processes of complex interventions.

This paper presented two case studies of SWATs which aim to test the use of video animations to improve intervention implementation, with particular focus on enhancing understanding, engagement and compliance. These are important aspects of intervention implementation as they are directly linked to intervention effectiveness, and therefore important to study. One of the case

studies discussed in the paper was the PROSPER SWAT, which is the focus of this chapter.

In this thesis, I used SWAT methodology to test a minor refinement to the implementation process of a complex intervention within the context of the PROSPER trial (Section 4.1.1). It is important to highlight the use of the term 'minor refinement' as the extent of the refinement to the implementation process determines whether this can be investigated using SWAT methodology or if indeed, it lies outside the parameters of a SWAT. Though there is no specific method for identifying whether the refinement is minor or major, it is important to consider whether the refinement could indeed qualify as a separate intervention itself, in which case it would be better to investigate in a definitive trial, or as a separate arm within the trial.

4.1.1 Host trial - PROSPER

The PROSPER trial aims to assess the effectiveness and cost-effectiveness of a personalised care planning intervention designed to improve quality of life for older people (aged 65 years and over) living with frailty. The PROSPER intervention aims to improve self-management skills, incorporating shared decision making to provide linkages to wider mechanisms including care coordination and linkage to community resources and increase social networks of older people living with frailty. Shared decision making and related goal setting/action planning give the older person control over decisions that impact their life, health and wellbeing. The PROSPER intervention is delivered to service users in their own homes by Personal Independence Co-ordinators (PICs), employed by the charitable organisation Age UK.

Recruitment to the PROSPER feasibility trial, a multi-centre, two-arm cluster RCT, was conducted between March 2019 and January 2020[44], with 12 month follow-up. The process evaluation of the trial examined implementation of the key components of the intervention using qualitative methods including observations, semi-structured interviews and reviewing the trial monitoring data. This process evaluation[198] identified concerns about service users dropping out at or after the initial intervention visit took place. Through the process evaluation work conducted alongside the feasibility study, it was found that most of the service users who dropped out reported concerns regarding the

appropriateness of the intervention for them. Through discussions at the Programme Management Group (PMG) meetings, it was concluded that this may have been due to a perception amongst service users that their level of independence did not align with the examples provided by the PICs, despite potential service users being carefully sampled as the target population for this intervention. To address these concerns, a video animation was developed to improve service users' uptake of, and engagement with the intervention. I worked alongside the PROSPER trial team to embed a SWAT into the trial, to test the effect of this video on service users' uptake of, and engagement with the intervention. Unless otherwise described, I undertook all the empirical work for the SWAT.

In this context, intervention uptake is defined as the service user proceeding with the intervention following the initial visit from a PIC. Engagement is an important aspect of intervention implementation, which in this context, refers to a service user's understanding and responsiveness to the intervention, encompassing 'intervention receipt' and 'intervention enactment' [1, 19, 167]. Engagement is an important component to focus on as it forms the basis for interpretation of intervention effects. Without service user engagement in the intervention, changes in outcome are not plausibly attributable to the intervention.

4.1.2 SWAT aims and objectives

The aim of this SWAT was to investigate whether the use of a video animation improved servicer users' uptake of, and engagement with the PROSPER intervention. This was explored through the following objectives:

1. To embed a study within the PROSPER host trial to investigate the effect of an animated video versus no video on optimising the implementation of an intervention.
2. To undertake a qualitative interview study to understand the views of service users and staff surrounding the use of an animated video as a strategy to optimise implementation of the PROSPER intervention.

4.2 Methods

4.2.1 Design: nested cluster RCT and embedded qualitative study

A two-arm cluster randomised SWAT (addressing Objective 1) was undertaken with an allocation ratio of 1:1, together with an embedded qualitative study (Objective 2). The SWAT protocol is registered on the SWAT repository [199]. Consistent with the mixed-method convergent design [200], both strands were implemented at the same time with equal emphasis. The results of each method (SWAT trial and qualitative interview study) were analysed separately and then converged in a final analysis.

4.2.2 Service users

4.2.2.1 Eligibility criteria

All service users in the intervention arm of the PROSPER host trial were eligible to be included in the SWAT. For the qualitative study, the following criteria were applied:

- Service users without the capacity to consent were excluded from the qualitative interview study
- Only service users in the intervention arm of the SWAT were eligible to be included in the qualitative interview study
- Only PICs randomised to use the video were eligible to be included in the qualitative interview study

4.2.3 Intervention and comparator

4.2.3.1 Intervention: Video

An animated video clip was developed by a team of animators, informed by an intervention development group consisting of public and patient involvement (PPI) members and researchers including myself. The animation was developed through participatory methods whereby discussions between researchers and PPI members and story boarding informed the development. Therefore, the developers did not identify a specific theory, or use a specific intervention development method. This approach is broadly consistent with pragmatic, participatory methods[21] whereby the intervention was developed to

address concerns identified during the PROSPER process evaluation of the feasibility study[198]. Since I had not yet started this PhD project when the intervention was developed, my role in the intervention development group meetings was purely as an observer. Hence, I did not have any input in the intervention development itself.

The video aims to inform the service user about the intervention and ways in which it may be useful for them using example fictional characters who act as service users and PICs. A transcript of the video can be found in Appendix 4. The video clip is around 2.5 minutes long. The video was designed to supplement the existing information sheet and verbal explanation of the intervention provided as standard. A video not only standardises information given to service users but also allows them to see an example of ways in which the intervention might help them. It is intended that the video covers a broad range of potential issues that could be addressed through the PROSPER intervention. The video was intended to act as a prompt, the idea being that the service user and PIC can discuss the video allowing the service user to make an informed decision about whether the intervention is suitable for them. This enabled them to better engage with the intervention as they were aware of the range of what was on offer through the intervention. This video was not piloted with anyone.

Box 1: Narrative summary of the video animation

The video begins by introducing a 78-year-old female character by the name of Maggie and goes on to explain how she used to spend most of her time at home and was left feeling alone by the death of her dog. Although her sons visited, her impaired vision meant the television was no use to her and she did not feel confident enough to use the bus anymore, especially since her medication had recently been changed leaving her feeling 'wobbly'. This was all changed by a visit from an Age UK worker, called Andy, who initially rang Maggie and asked if he could visit. During the visit, the two had a conversation about Maggie's hobbies and some of the insecurities she was feeling. They also discussed any improvements Maggie felt she could make to her life and how Andy could make her life easier. Eventually, the two drew up a plan which included new medication for Maggie that left her with no side effects and also a visit to the opticians to address her vision. These two improvements meant she was now able to take the bus and because of the money saved by changing her gas supplier, she could now indulge in treats like the hairdresser and gardener. Her bathroom was also changed to help suit Maggie by introducing grab rails. The intervention included 12 weeks of regular contact through visits and telephone calls. After 2 months, the two reviewed the initial plan they had drawn up to assess their progress. When the service ended, Maggie was left with contact details for Age UK and other groups. The confidence developed through the intervention meant Maggie could now go alone to these groups if she felt the need. The video concludes by asking 'What could you do with PROSPER support?'

Some important features of the video include the use of animation as opposed to actors, the change from black and white or faded images to full colour images and the use of characters from diverse backgrounds. The progression from black and white images to full colour was a feature selected by PPI members to illustrate the PROSPER intervention bringing the colour back into the life, or improving the life of the service user in the video. The animation script was based on case studies from the PROSPER process evaluation of the feasibility study[198] which illustrate the types of support available in the intervention. The animation is stored on the hard drive of the PIC's laptop to avoid connectivity issues and is shown at the start of the initial meeting with service users.

4.2.3.2 Comparator: Verbal explanation accompanied with information sheet

The PROSPER PIC provided a verbal explanation of the intervention to the service user, as well as providing an information sheet (Appendix 5) for them to read.

4.2.4 Training

The PICs randomised to the intervention group, who would use the video in their intervention delivery, were trained at a group training session, delivered online via Teams by myself. In this training session, they were introduced to the concept of a SWAT and why we conduct SWATs as well as being taught about the PROSPER SWAT and some key considerations for them when delivering the intervention. There was an interactive exercise in which the PICs incorporated the video into their scripts which they had previously prepared for their first session with the service users. Following this, there was a brief discussion in which any questions they had were answered. The Powerpoint slides used during the training were shared with the PICs after the session ended, along with the video animation. These slides can be found in Appendix 6. This training session was developed with a lay audience in mind and thus it was tailored to the PICs as they all came from non-research backgrounds.

4.2.5 Outcomes

Both primary and secondary outcomes were documented on trial case report forms by the PIC during intervention delivery. They then entered this information onto a database to be accessed by staff at the clinical trials unit for analysis.

Primary outcome

- Proceeding with the intervention following the initial visit (Yes/No)

The primary outcomes was obtained from the PROSPER trial case report forms (CRFs), which documented whether the video was played within the initial meeting; and whether the service user chose to proceed with the intervention. If the service user later changed their mind and decided to drop out, this would also be documented by the PIC. However, for the purpose of the primary outcome, only decisions made during the initial visit were analysed since they were most probably attributable to the video. See Appendix 7 for CRF.

Secondary outcomes

- Goals set (Yes/No)
- Number of goals set
- Evidence of action plan (Yes/No)

The secondary outcomes were also obtained from the PROSPER trial CRFs, which documented evidence of the development of an action plan and number of goals jointly set by the service user and PIC. The CRFs were completed by PICs delivering the intervention, then uploaded onto the trial database where this information could be accessed by the relevant parties. See Appendix 8 for CRF.

4.2.6 Sample size

As is common with a SWAT, we (myself and a statistician at the CTRU - Ellen Thompson) did not undertake a formal power calculation to determine the sample size, since the sample size was constrained by the number of service users recruited into the host trial and allocated into the intervention arm [36]. The target recruitment expected for the PROSPER intervention arm was 80 service users per month, with the SWAT initially expected to run for nine months, therefore a total of 720 service users were expected to be included in the SWAT. Overall, the trial expected to recruit 15 PICs each seeing on average 50 service users. However, due to issues with recruitment and the COVID-19 pandemic, there were 522 service users recruited in total.

A post hoc power calculation was performed using a projected sample size of 720 service users (360 per arm). This sample size was found to provide 80% power to detect a relative difference of 22% (absolute difference of 16%) in uptake between the two arms, and assume 75.7% uptake in the control arm from the PROSPER feasibility study. The calculations account for 13% loss to follow-up, 0.03 ICC (intraclass correlation coefficient), an average of 58 service users per PIC, 0.28 coefficient of variation to account for varying number of service users per PIC, and an allocation ratio of 1:1.

4.2.7 Randomisation

Randomisation for this SWAT occurred at a different level and time-point to randomisation for the host trial PROSPER. Whereas PROSPER randomised at the level of the individual, this SWAT used cluster randomisation at the level of the intervention deliverer, i.e. the PICs. PICs were randomly assigned (ratio 1:1) to either intervention (video) or control (no video). Allocation was stratified by

the PIC WTE (full time or part time) and four localities. These stratification variables were selected as they may impact upon the outcome variable and potentially create unequal numbers in each arm. Intervention delivery may vary across localities. Ensuring that full time and part time PICs were spread across both arms helped to avoid unequal numbers of service users in each arm.

Randomisation of each PIC took place following completion of the PICs training and prior to the PIC receiving any PROSPER trial participants. Once a service user was randomised to the intervention and a PIC, it was also known whether the PIC they were allocated to would be using the video or not. PICs used the video in their initial meetings with service users, or verbally explained the intervention without the use of a video, if in the SWAT control group. All service users randomised to the intervention group of the PROSPER trial were included in the SWAT.

The minimisation method was used to conduct the randomisation incorporating a random element of 0.8 and stratified by the PIC's locality and working time equivalent (WTE). I developed the SWAT randomisation schedule, which was then independently checked by a trial statistician for any errors before PICs and the trial staff were informed of their allocation. Minimisation was used to minimise imbalance between the two arms. PICs in the SWAT intervention arm were then contacted via email to arrange training online via Microsoft Teams.

Allocation concealment was not possible since I performed the randomisation and also trained the PICs randomised to the intervention arm of the SWAT. Therefore, I was aware of the PICs in each arm. Blinding could not be achieved in this SWAT as it was clear which arm PICs were randomised to due to the nature of the intervention.

4.2.8 Data collection

Quantitative data were collected using trial case report forms as part of the host trial processes. These forms documented whether the service user chose to proceed with the intervention following the initial visit. Trial data about intervention discontinuation rates and reasons given was also collected across the two groups. This data were collected by the PICs and entered onto a remote data entry (RDE) database which researchers could access. A full description of the PROSPER trial dataset is beyond the scope of this thesis. Here I describe

variables captured in trial CRFs which were used for the purpose of the SWAT analysis. Service user characteristics such as age, gender, living arrangements (whether they live alone or with somebody), electronic frailty index (eFI) score and ethnicity were collected through routine trial data collection procedures. The eFI is a clinically validated tool which was used to assign a score to service users[201], deeming them to have mild (0.12 to 0.24), moderate (0.24 to 0.36) or severe frailty (0.36 and above).

4.2.9 Statistical analysis

Quantitative data has been analysed using descriptive statistics and logistic regression. The analysis plan was not pre-registered. Descriptive statistics were used to summarise the characteristics of service users in the SWAT intervention (video) and control (no video) groups.

Due to the nature of the cluster randomised design of the SWAT and the small number of clusters (PICs) per randomised group, the primary and secondary outcomes were compared between the randomised groups using a cluster-level analysis, adjusting for the stratification factors [202].

Logistic regression was used to explore uptake and engagement whilst adjusting for variables including which PIC delivered the intervention, service users' eFI score, their living arrangements and the locality in which the intervention was delivered.

Initially, a summary measure was calculated for each outcome by randomised group and for each cluster. The primary outcome summary measure was uptake, defined as the proportion of service users who continued with the intervention following the initial visit. The secondary outcome summary measures were: whether service users set goals or not, the number of goals they set and whether or not they created action plans. The summary measures were calculated for each PIC in both intervention and control groups. Since the distribution of these cluster-level summaries were skewed, an appropriate transformation of the summary measure was calculated for each cluster prior to analysis.

Adjustment for the following stratification factors was carried out using a two-stage process:

- PIC assigned to the service user
- Service user's eFI score
- Service user's living arrangements - whether they live alone or with somebody
- Locality - Area in which the intervention is delivered

The first stage involved performing a logistic regression model ignoring the clustering of the data i.e. all covariates of interest are entered into the regression model except for the intervention effect. The summary measure for each cluster is the residual based on comparison of the observed outcome in that cluster and the predicted outcome, in the absence of an intervention effect.

In the second stage the covariate-adjusted residuals take the place of the cluster-level summaries. An unpaired t-test of the cluster-level summaries was performed at the 5% significance level using the pooled estimate of variance of the cluster summaries. This provided a measure of the intervention effect which is adjusted for the stratification factors listed above. A corresponding 95% CI for the intervention effect was also calculated.

Exploratory analyses were also conducted to investigate factors related to the PIC and the effect of these on engagement with the intervention. Line graphs were created in Microsoft Excel to assess whether there was a temporal effect, or a learning curve whereby the PICs had higher levels of service user engagement over time.

4.2.10 Qualitative interview study

4.2.10.1 Selection of qualitative approach

There are a range of qualitative methods which can be used to design a study and analyse data. Depending on the research question, different methods can be appropriate. Thematic analysis (TA) was selected as the most appropriate approach for analysing the data for a number of reasons [203]. When seeking to understand experiences, thoughts or behaviours across a data set, TA is an appropriate method to use [204]. Since the intervention under investigation in this SWAT was developed without the use of theory, it is appropriate to use a method of analysis that does not require the use of theory to inform analysis. TA can be conducted inductively, through a data-driven approach, without a theory

to inform the process. It is simple to learn and apply for a relatively inexperienced researcher, whilst still being a powerful and widely applied method of analysis [205].

4.2.10.2 Sampling and recruitment

4.2.10.2.1 Service users

PICs randomised to the video group were contacted to identify potential service users to purposively sample for interviews. The criteria for sampling were as follows: service users seen by PICs for their initial visit within the past week who had viewed the video and agreed to continue participation with the intervention.

After verifying with the process evaluation team that the service users had not already been approached for interviews as part of the wider PROSPER research programme, invitation letters were posted to the service users, along with the service user information leaflet and consent form as well as a prepaid envelope for returning the consent form. Following this, the service users received a telephone call to invite them to participate in a short, phone interview about participation in the intervention and their initial meeting with the PIC. During this phone call, the purpose of the research was explained, along with what participation would involve, and the voluntary nature, including the freedom to withdraw without providing a reason. It was emphasised that involvement in this qualitative study was independent from the main trial and that their involvement would not affect receipt of the intervention or their relationship with the PROSPER trial. Opportunity to ask questions was provided and they were offered a call back to give them time to consider participation.

Whilst the original plan was to interview between 25 and 30 service users, around halfway through the interviews, it was found that there was considerable repetition in service users' answers and that data saturation[206] was reached. Therefore, recruitment for interviews was halted. Sixteen service users were purposively sampled from the pool of service users who received the video intervention, for interviews. The aim was to sample service users from all four localities, and from all PICs randomised to the intervention arm of the SWAT, as well as ensuring variability in terms of the service users' demographic characteristics (Table 10). I sought to obtain diversity in terms of ethnicity, age and gender of service users. These variables were considered the most

relevant when sampling for interviews since experiences and perspectives of the PROSPER service and the video may vary for service users from different groups. I sought to conduct interviews with service users from as many of the descriptor groups as possible.

Table 10 Summary of the demographic characteristics of service users purposively sampled for qualitative interviews

Demographic Characteristics	Descriptors
Ethnicity	White, Mixed, Asian, Black, Other
Age	65-74, 75-84, 85-100
Gender	Male, Female

With a view to minimise service user burden and confusion, service users sampled for SWAT interviews were highlighted to the PROSPER process evaluation team so they would not approach the same service users. Of the sixteen service users interviewed, one audio recording was lost due to a fault in the audio recording device, leaving fifteen recordings which were transcribed and analysed.

Once the service users were happy to proceed, a time was arranged for the interview, and it was requested that service users fill in and return the consent form they had received in the prepaid envelope enclosed in the pack. As a precautionary measure, informed consent was obtained before the commencement of the interview by going through the statements on the consent form with the service user and recording their responses.

4.2.10.2.2 Personal independence coordinators (PICs)

For the PIC interviews, those PICs randomised to the intervention arm of the SWAT, i.e. those who had used the video, were sampled through quota sampling. Quota sampling, whereby it was decided during the design of the study how many people with which characteristics would be sampled[207]. It was intended that all PICs in the intervention arm of the SWAT would be approached for interviews. One PIC had ended their employment with Age UK therefore they could not be interviewed. Another PIC did not reply to emails

inviting them to be interviewed. This left a sample of four PICs who were initially contacted via email to invite them to take part in an interview over the phone about use of the video in their initial meetings with service users.

They were also sent the information leaflet and consent form via email, and asked to fill in and return the consent form if they were happy to take part. Once the consent form was returned, they were then contacted to arrange a time for the interview to take place.

4.2.10.3 Data collection

Semi structured interviews were conducted with a sample of service users to assess the impact on engagement with the intervention. After the initial visit, service users were invited to participate in a short, semi-structured interview, taking place over the phone. Interviews were selected as the most appropriate method of data collection, as opposed to a focus group or observation, due to a number of reasons including capacity of researchers, causing minimal disruption to the host trial, ethical issues and minimising service user burden as well as being the most appropriate for the research question.

Since the aim of the interview was to investigate the effect of the video, and in light of the video being short in duration and a small part of the intervention as a whole, it was crucial that interviews be conducted as soon as possible following the initial visit. Due to the Covid-19 pandemic, interviews took place over the phone, and were recorded using an encrypted audio recording device, before being transferred onto a secure server. A topic guide was developed for use in the interviews, whilst allowing flexibility for additional relevant information from service users. The topic guide explored recall of the video, acceptability of the video, whether or not it encouraged service users to engage with the intervention and service users' motivations to continue with the intervention. The topic guide was piloted with a member of the PROSPER PPI group in order to test the questions. Following this pilot interview, the topic guide was redrafted. Interviews were relatively short in duration, usually lasting less than fifteen minutes. With permission from service users, interviews were audio recorded and transcribed verbatim.

Similarly, semi-structured interviews were conducted with PICs who were invited via email and interviews were conducted over the phone, whilst

recording using the same encrypted audio recording device and saving on a secure server. A topic guide was developed for use in the interviews. It explored PICs views on the use of a video during their initial visits with service users focusing in particular on whether or not the video helps to introduce the intervention and engage service users. See Appendix 9 for topic guides used for interviewing service users and PICs.

4.2.10.4 Qualitative data analysis

Interview data were transcribed verbatim by myself. Interview data were analysed using thematic analysis [203]. Braun and Clarke (2006) proposed six stages of thematic analysis: 1) familiarising with data, 2) generating initial codes, 3) identifying themes, 4) reviewing themes, 5) defining and labelling themes, and 6) interpreting the findings.

For stage 1, familiarising with the data, interview recordings were listened to and transcribed, and transcripts were read several times before coding. Initial codes were generated deductively, in stage 2, using the areas of interest and interview questions. These codes were then applied independently to 3 transcripts by myself and my supervisor Suzanne H Richards (SHR). These codes were then compared and differences were discussed and resolved. Minor changes were made to the codes during this process. The same coding frame was initially applied to the transcripts for the PIC interviews. As the PIC interviews were richer than service user interviews, additional codes were generated using the data. Stage 3 involved searching for themes. This was done inductively by deriving themes from the coded data and using Microsoft Excel to organise the data according to the identified themes. The themes were reviewed in Stage 4, by myself and my supervisor SHR through an iterative process. Since the PIC interviews were richer, sub-themes were also generated for each of the themes. In stage 5, the themes and sub-themes were defined and labelled. Finally, the analysis was written up in stage 6. As part of this, findings from the service user and PIC interviews were synthesised, whereby commonalities in the data were drawn out and discussed.

4.2.10.5 Positional reflexivity

Since the SWAT intervention training for intervention deliverers was delivered by myself, and I conducted interviews, it is recognised that this may well have

influenced responses to the interview questions. Intervention delivery staff (PICs) may have perceived me to be involved with intervention development and thus may have responded more positively regarding the video, due to social desirability effects. My prior perceptions, experiences and background may have in some way influenced the interview topic guides and the manner of interviewing with both intervention delivery staff and service users. As the service users had not previously met me and given the differences in age and ethnicity, they may not have felt completely comfortable providing all information, especially any negative comments about the intervention or their experience. To mitigate this, I endeavoured to develop good rapport with both service users and intervention delivery staff in the short time available.

4.2.10.6 Converging quantitative and qualitative results

As described by Creswell [200], a mixed-method convergent design has been applied to converge the data. Using this method, the researcher implemented both qualitative and quantitative strands at the same time with equal emphasis. The results of both the SWAT trial and qualitative interview study were analysed separately and then integrated (or 'converged') in a final analysis. This method was selected because it was not possible for one dataset to inform the design of the other in any way since both sets of data were collected in parallel. Therefore, this SWAT utilises a mixed-methods approach.

4.3 Data management

4.3.1 Primary data

All primary data were analysed and stored at the Leeds Institute of Clinical Trials Research (LICTR). Audio files were uploaded to a secure platform. Data are stored on secure servers at the LICTR and removed from the recording device.

Research data were stored in password protected Word/Excel files on password protected encrypted laptops until such time that they could be uploaded to a secure server at CTRU. They were then removed from the portable device.

4.3.2 Secondary data

Secondary data i.e. required fidelity and other quantitative data were stored and analysed by the LICTR. Data from service users taking part in this SWAT were made available to myself via secure electronic transfers. This included contact details that were stored at the LICTR.

4.3.3 Paper records

Paper records e.g. consent forms for the SWAT, were stored in a locked filing cabinet at the LICTR. Only the research team members have access to this data. Both electronic and paper data will be stored for a period of 10 years, when paper data will be disposed of with confidential waste and electronic data no longer required for analysis will be deleted.

4.4 Ethical considerations

4.4.1 Ethical approval

Ethical approval for this SWAT was obtained through Substantial Amendment 05 on 19th January 2021 by Yorkshire and Humber – Bradford Leeds Research Ethics Committee (REC reference: 20/YH/0108).

4.4.2 Potential vulnerable adults

Service users without the capacity to consent were excluded from interviews. Since consent to participate is an on-going process, capacity was assessed at the point of contact. The fieldwork period was relatively short, therefore it was only necessary to assess capacity and gain consent once.

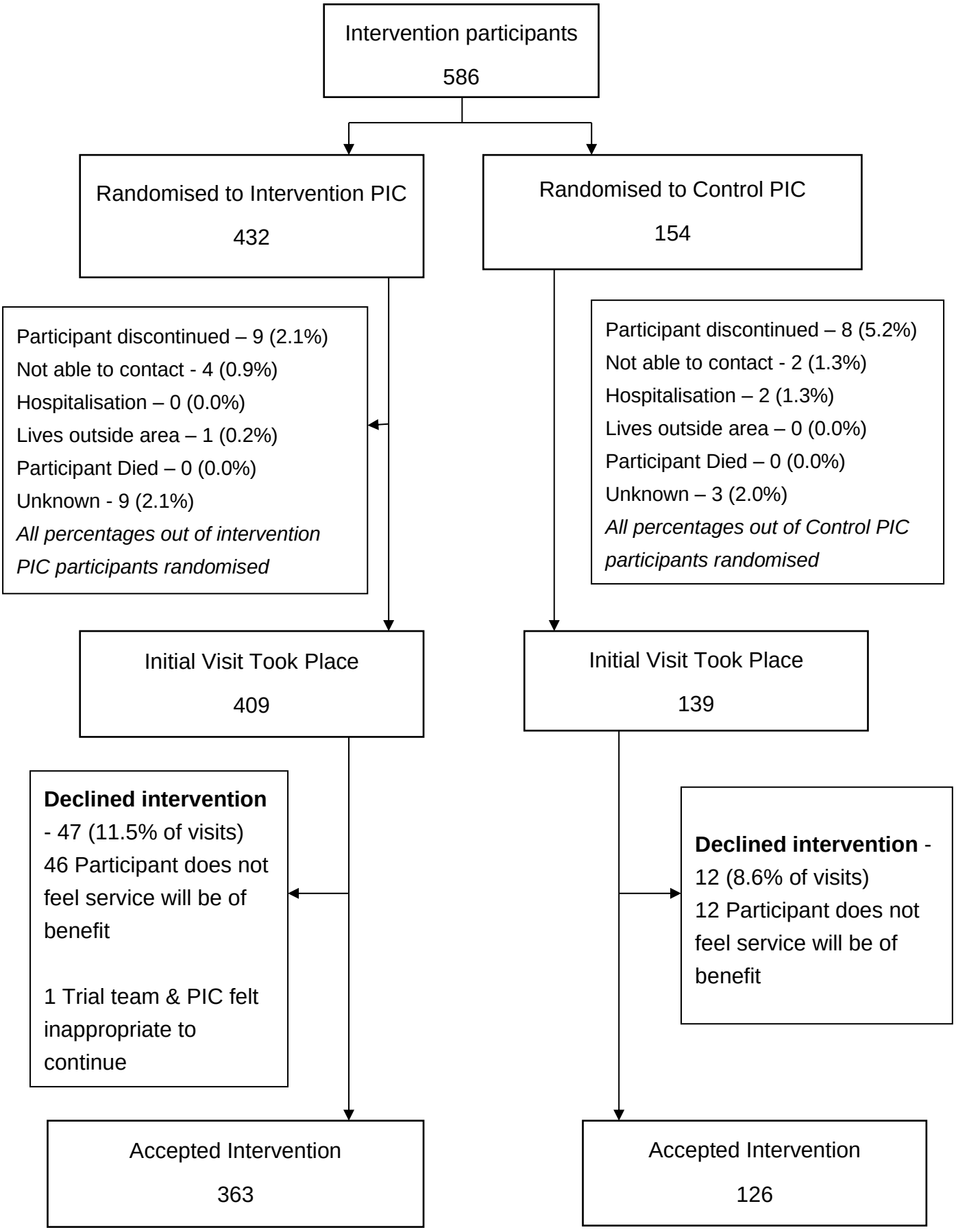
4.5 Results

4.5.1 Recruitment and participant flow

Recruitment for the PROSPER host trial took place through invitation letters sent out via general practices. Recruitment began in May 2021, and at the point of this thesis being submitted, was still ongoing. PICs were continually being randomised for the SWAT as they were recruited. However, for the purposes of this thesis, the data were downloaded at two points. The first was 17th March 2023, and included the service users randomised for the PROSPER trial up to this data. The second download was 15th June 2023, which collected the

intervention data for all those randomised up to 17th March 2023, as the duration of the PROSPER intervention was three months. The analyses presented in this chapter will be updated as more data becomes available and prior to publication of the SWAT findings. Within the downloaded data, there were 548 participants in this SWAT. See Figure 12 for participant flow.

Figure 12 PROSPER intervention delivery for participants randomised as of 17 March 2023



4.5.2 Baseline data

Table 11 Baseline characteristics of participants in both SWAT intervention and control groups

Characteristic	SWAT Intervention group (N=409)	SWAT Control group (N=139)	Total (N=548)
Age: Mean (SD) [1]	78.00 (6.74)	77.44 (7.24)	77.86 (6.87)
Median (Range)	78 (65-96)	78 (65-96)	78 (65-96)
Gender: Male	172 (42.05%)	60 (43.17%)	232 (42.34%)
Female	237 (57.95%)	79 (56.83%)	316 (57.66%)
Ethnicity: White	405 (99.02%)	133 (95.68%)	538 (98.18%)
Mixed	0	3 (2.16%)	3 (0.55%)
Asian	2 (0.49%)	2 (1.44%)	4 (0.73%)
Black	1 (0.24%)	1 (0.72%)	2 (0.36%)
Other	1 (0.24%)	0	1 (0.18%)
Living arrangements:			
Living alone at home	165 (40.34%)	74 (53.24%)	239 (43.61%)
Living with another person at home	244 (59.66%)	65 (46.76%)	309 (56.39%)
eFI: Mean (SD) [1]	0.29 (0.08)	0.29 (0.08)	0.29 (0.08)
Median (Range)	0.28 (0.22-0.67)	0.28 (0.21-0.61)	0.28 (0.21-0.67)

[1] SD - standard deviation; eFI - electronic frailty index

4.5.3 SWAT intervention groups

There was an imbalance between the number of PICs randomised to the SWAT intervention group and those randomised to the SWAT control group, despite using minimisation to randomise. This led to an imbalance in the number of service users in the groups. Table 12 summarises the number of service users assigned to each PIC in both the SWAT intervention and SWAT control groups, as well as PICs' WTE. One reason for the imbalance in the number of service users is that many of the PICs randomised to the SWAT control group dropped out of the trial either before visiting any service users, or after having visited a small number of service users. In comparison, PICs randomised to the SWAT intervention group generally visited more service users and were part of the PROSPER trial for a longer period of time.

Table 12 Number of service users assigned to PICs in SWAT intervention and SWAT control group

SWAT Intervention Group N=409			**SWAT Control Group N=139**		
PIC ID	**Number of service users (%)**	**WTE**	**PIC ID**	**Number of service users (%)**	**WTE**
3	0 (0%)	PT	4	0 (0%)	PT
6	0 (0%)	PT	5	25 (18.71%)	PT
8	65 (15.89%)	PT	7	10 (7.19%)	PT
10	56 (13.69%)	FT	12	0 (0%)	PT
11	110 (26.89%)	FT	18	0 (0%)	PT
13	12 (2.93%)	PT	21	0 (0%)	PT
16	44 (10.76%)	PT	22	8 (5.76%)	PT
17	25 (6.11%)	PT	24	45 (32.37%)	PT
20	51 (12.47%)	PT	25	39 (28.06%)	FT
27	21 (5.13%)	PT	26	11 (7.91%)	PT
28	17 (4.16%)	PT			
29	8 (1.96%)	PT			

4.5.4 Outcomes and estimation

4.5.5 Primary outcome

Uptake of the intervention was generally high across both the intervention and control groups in this SWAT. The primary outcome, the proportion of service users who proceeded with the intervention following the initial visit, did not differ significantly between the groups (adjusted risk difference = 0.07%, *95% CI*= -0.15%, 0.30%, *p*=0.477) (Table 13). In the logistic regression model, the PIC was the only significant predictor, at the 0.05 level, with a p-value of 0.005. Table 14 shows the unadjusted results for the primary outcome.

Table 13 Primary outcome: Uptake - outcome proportions and risk differences (RD) adjusted for stratification factors

	Adjusted[2] model estimates		
	Outcome % (N)	**RD (*95% CI*)**	**p-value**
Control (no video)	90.8 (N=126)	0.07 *(-0.15,0.30)*	0.477
Intervention (video)	88.2 (N=361)		

Table 14 Primary outcome: Uptake - outcome proportions and risk differences (RD) unadjusted for stratification factors

	Unadjusted model estimates		
	Outcome % (N)	**RD (*95% CI*)**	**p-value**
Control (no video)	91.8 (N=126)	0.04 *(-0.17,0.25)*	0.676
Intervention (video)	88.0 (N=361)		

4.5.6 Secondary outcomes

4.5.6.1 Service user engagement

There was a high level of service user engagement with the intervention in both the intervention and control arms of this SWAT. There was no evidence of any SWAT intervention effects for the secondary outcomes of proportion of service users who set goals, number of goals set and proportion of service users who

developed action plans (Table 15). Table 16 shows the unadjusted results for the secondary outcomes.

Table 15 Secondary outcome: Goals set - outcome proportions and risk differences (RD) adjusted for stratification factors

Goals Set: Yes/No			
	Adjusted[2] model estimates		
	Outcome % (N)	**RD (*95% CI*)**	**p-value**
Control (no video)	73.1 (N=101)	-0.03 *(-0.32,0.27)*	0.852
Intervention (video)	73.5 (N=301)		
Numbers of Goals Set			
	Adjusted[2] model estimates		
	Outcome (Mean)	**RD (*95% CI*)**	**p-value**
Control (no video)	2.95	0.27 *(-0.39,0.93)*	0.393
Intervention (video)	2.87		

Table 16 Secondary outcome: Goals set - outcome proportions and risk differences (RD) unadjusted for stratification factors

Goals Set: Yes/No			
	Unadjusted model estimates		
	Outcome % (N)	**RD (*95% CI*)**	**p-value**
Control (no video)	74.9	0.03 *(-0.29,0.34)*	0.855
Intervention (video)	72.2		

[2] This model was adjusted for working time equivalent (WTE) and locality

Numbers of Goals Set			
	Unadjusted model estimates		
	Outcome (Mean)	**RD (*95% CI*)**	**p-value**
Control (no video)	2.56	-0.55 *(-3.02,1.92)*	0.636
Intervention (video)	3.11		

All service users in both the SWAT intervention and control groups demonstrated evidence of action planning, hence there was no difference between the two groups. Therefore, it was not necessary to conduct a regression analysis for this outcome (Table 17).

Table 17 Secondary outcome: evidence of action planning in both groups

	Evidence of action planning	
	Yes - N (%)	**No - N (%)**
Control (no video)	139 (100%)	0 (0%)
Intervention (video)	409 (100%)	0 (0%)

4.5.7 Ancillary analyses

Exploratory analyses were conducted to explore the proportion of service users who proceeded with the intervention for each PIC in the SWAT intervention group. Figure 13 is a line graph demonstrating whether the service users each PIC saw proceeded with the intervention or dropped out during the initial visit. Each coloured line represents a different PIC, and each dot represents a service user. The graph shows the cumulative proportion of service users proceeding with the intervention per PIC.

The majority of the PICs appear to have experienced a learning curve whereby over time, the proportion of service users proceeding with the intervention increased steadily. A minority of PICs were found to have much lower levels of uptake in the service users they were assigned, for example PIC 10 averaged between 60% and 70% uptake. It was worth noting that there was a degree of

variation in the number of service users seen by each PIC, with PIC 29 seeing the fewest (9 service users) and PIC 11 seeing the most (99 service users). Some PICs (8, 13, 29) demonstrated a 100% uptake rate in all the service users they saw.

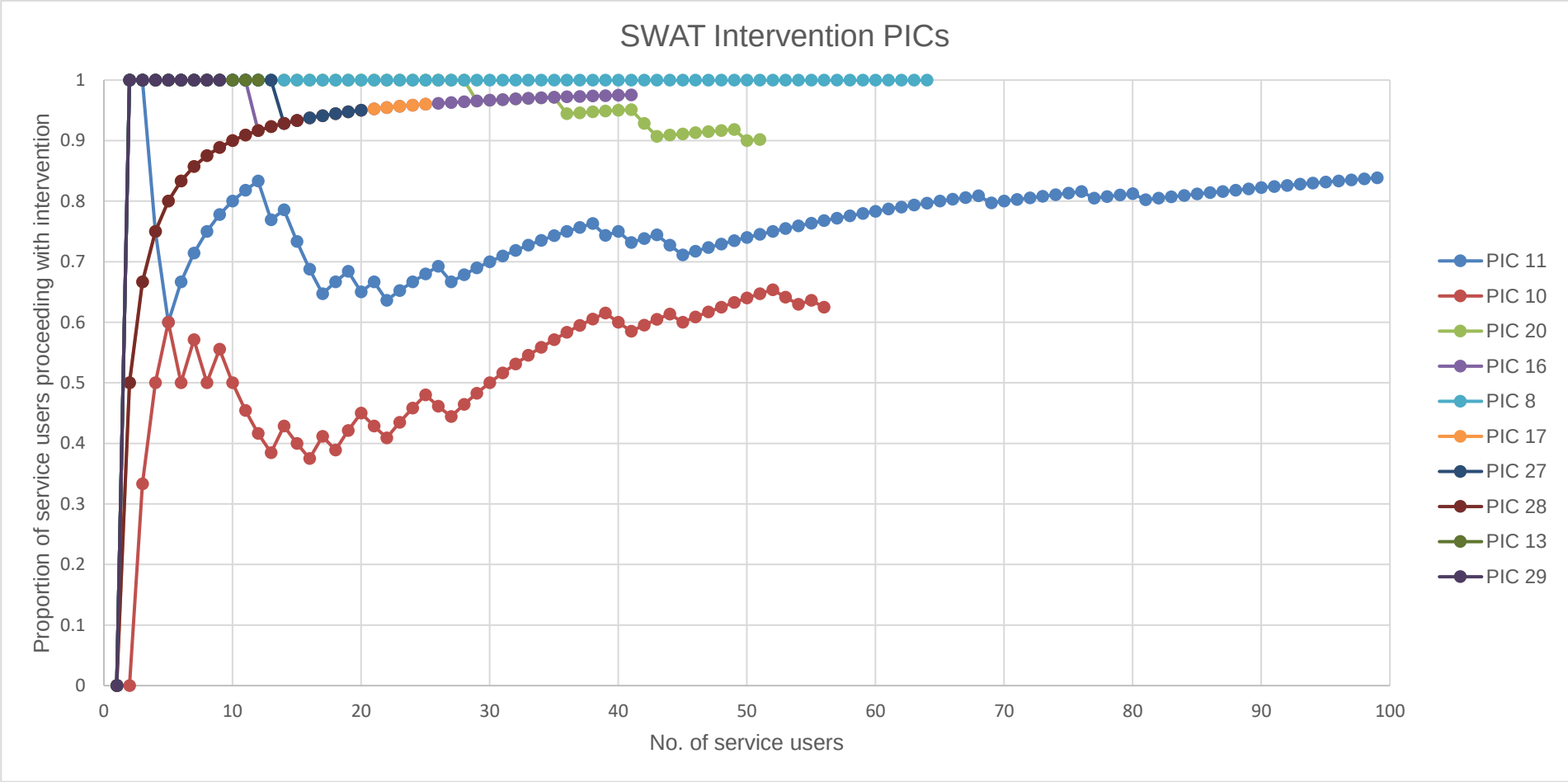


Figure 13 Service user uptake of the intervention over time, per SWAT intervention PIC

1

[1] This graph shows for each PIC, the cumulative proportion of service users they saw who proceeded with the intervention at the initial visit stage.

4.5.8 Qualitative interview findings

4.5.8.1 Sample characteristics and timing of interviews

Twenty-seven service users were approached for telephone interviews, through a letter posted to them which was followed up by a phone call to ask if they were happy to be interviewed. Of these, sixteen service users agreed to be interviewed. The sample included six males and ten females from three different localities who were seen by six different PICs. Their ages ranged from 69 to 87 years old and most of them were scored as mild to moderate in terms of frailty, as assessed using eFi score. Three service users were rated as severe frailty. All service users interviewed were white. Timing of interviews ranged from one to ten weeks after the initial meeting with the PIC.

Five PICs were approached for telephone interviews of which, four agreed to be interviewed. The sample included one male and three female PICs of white ethnicity, from three different localities. Interviews took place after around six months of them delivering the PROSPER intervention to service users.

4.5.8.2 Service user findings

Using thematic analysis four main themes were identified from the interviews with PROSPER service users: “Value of the PROSPER Service,” “Relationship with PICs,” “Motivating factors,” and “Usefulness of Video.” There was a degree of overlap across these themes.

4.5.8.2.1 Theme one: Value of the PROSPER service

This theme was defined by service users’ impressions of the PROSPER service, including how well they understand the service, the appropriateness of the service for them, how useful it had been for them, and what the service helped them with. This was explored further through the use of illustrative quotes from interviews with service users. Since the interviews took place as early as one week into the PROSPER intervention delivery, service users had had limited exposure to the intervention. This may help to contextualise service users’ responses to some of the interview questions.

Most service users felt they understood the purpose of the PROSPER service well, and backed this up with examples of what they thought the service intended to do:

> *"The service enables older people, whether living with someone or on their own umm to obtain the, the monetary needs you know if they if they (inaudible) in their income or pension or the aids that are available to people like us."* (Service user 4)

> *"Umm that it's doing... just like people like myself... elderly and with health problems making sure that we're aware of benefits we can claim and can claim on our behalf, basically helping people like myself that are relatively isolated and may not be aware of what's out there."* (Service user 10)

Some service users felt that the PROSPER service was not appropriate for them, due to their level of independence, financial security or having family support. They felt it may well benefit other people, for whom the service may be more appropriate:

> *"Err at this point in my life, I'm quite, I'm really fit and well. It probably wouldn't benefit me, but it might benefit other people."* (Service user 2)

> Interviewer: *"Was there anything that put you off taking up the service?"*
>
> *"Just that I thought it was more geared up to people that needed more help than I do."* (Service user 13)

There were mixed responses regarding the usefulness of the PROSPER service for service users. Some felt the service was not very useful for them, whereas others felt it was:

Interviewer*: "Do you feel like these plans so far have been useful for you?"*

"Umm not so far. Other than information wise, I haven't actually done anything that's beneficial to me." (Service user 2)

"I find it hard standing... for any length of time, so... through [PIC], I might be able to get some hand holds in the shower, which would be very very useful to me." (Service user 11)

As well as the usefulness of the PROSPER service, many service users discussed ways in which the service had helped them:

"Yes, we highlighted I think it was 5 things that we needed to do. One was the fire brigade because my alarms weren't working so I got those replaced, the second was my step wasn't safe, so they've been out to do that, that's now fine […] Thirdly, I can't chop vegetables so I've been shown a catalogue… that could help me there. Fourth, try to find me a dog that I can either adopt or foster. And I don't know what the fifth one was […] Well she's [PIC] helped me with all, with everything. She's helping me now with everything. […] Just trying to find out what the fifth one was. Oh! A blue badge!" (Service user 6)

"Well, I mean that was... it was quite helpful because... one of the problems that I have faced since I had my stroke in April when I was in hospital for over 4 weeks.. umm .. is the complete absence of people coming and talking to me." (Service user 7)

In contrast, some service users did not find the service to be helpful:

Interviewer: *"Would you like to tell me any ways she [PIC] has helped you?"*

"I can't think of…" (Service user 3)

Interviewer: *"What did they [PIC] tell you the PROSPER service can offer you?"*

"Not very much." (Service user 11)

Service users reported mixed responses on being selected for the PROSPER service. One service user reported feeling positive about being selected:

"Umm, you know I think if I hadn't have been one that was chosen, I would've felt a bit down." (Service user 10)

Whereas, another service user felt guilty, as they reported they felt there were people who may need the service more than them:

"Yeah, I think they're useful, as I say I think, umm there's so many people who could benefit from it.. that aren't doing at the minute.. but you know, I just feel, a bit guilty at being one of the chosen few." (Service user 15)

4.5.8.2.2 Theme two: Relationship with PIC

This theme explores service user relationships with PICs and the rapport building between service user and PIC. All service users reported positive feelings about their assigned PIC. For example, some service users reported that their PIC was friendly:

"She [PIC] was just so friendly, we hit it off straight away... umm both being Welsh... umm it's a bonus really." (Service user 9)

"Yeah, as I say he's very, very friendly and very I don't know... he's umm... you can tell that he enjoys what he does you know what I mean, it sounds silly, but he is just a lovely man and he's really well suited for the job actually." (Service user 14)

Many service users highlighted personal qualities they valued about their assigned PIC. For example, some service users reported that their PIC was easy to talk to:

> *"Oh definitely, very friendly... and you know we've got gardening in common you know she's [PIC] very easy to talk to…"* (Service user 9)

> *"Oh she's [PIC] lovely, so easy to talk to."* (Service user 10)

Others reported that their assigned PIC made them feel at ease, particularly when asking personal questions that may be difficult to answer:

> *"Yes, yes I've had two visits from [PIC] so far, she's a lovely person. She puts you at your ease umm and she doesn't... I mean a lot, quite a few of the questions are personal questions and she puts it to you in such a way that you don't feel embarrassed to answer."* (Service user 4)

As well as this, some service users reported that the PIC was helpful, and that they valued the information provided to them by the PIC:

> *"Umm, then she just started asking a couple of questions, umm and it just like branched off from there... it was really helpful, the information she was coming out with."* (Service user 10)

> *"Ohh, [PIC] gives you more information than you can find out normally. She's told me a lot of things that I would never have known."* (Service user 2)

Many service users felt the PIC was knowledgeable and good at their job:

> *"Umm, and then we just got on really well, umm she took down details of things that I weren't too sure about and clarified various things on the spot and then said that she'll find out various other things by the next time she came, which she did. So that was good."* (Service user 15)

4.5.8.2.3 Theme three: Motivating factors for taking up the service

This theme explores the different factors reported by service users' as their reasons for taking up the PROSPER service. Service users reported various different factors which influenced or motivated them to take up the service. Many service users saw the potential benefits of PROSPER for themselves, such as finding out about things they are interested in partaking in, getting adaptations to their living environment or improving their confidence. No service users reported the video as a motivating factor for taking up the service.

> Interviewer: *"What encouraged you or put you off?"*
>
> *"Nothing put me off, umm I'm in favour of things like this because you do get isolated when you're retired and I mean, like my husband has Alzheimer's so I'm restricted to going out, so you do get a bit isolated. I, for one tend to lose my confidence umm finding out things, and you lose the knack of... oh god I sound like an old idiot... you lose the knack of filling forms and things like that so knowing that somebody's going to be there to assist you umm and know what they're talking about..."* (Service user 10)

> Interviewer*: "What motivated you to continue with the service?"*
>
> *"Yeah… 'cause, before it started, I didn't think anything would apply to me but then he suggested the handrail and the fire... the alarm thing."* (Service user 13)

Some service users also commented on the potential future benefits of being involved with PROSPER:

> *"Well what motivated me was, and I never really realised at the time. I've got arthritis. I'm managing it, it's not, not crippled yet with it or anything. She was saying we'll carry on if you want to cause it might be relevant to you in a couple of months, you might need some assistance or... I don't think I will, but... She was very umm, she's*

very positive and I would recommend it to anybody. Especially somebody that really needed it." (Service user 5)

"Err... Nothing except that I am 87 years old and err I'm reasonably getting back to where I was err but I am getting older, so I'm... I accept that I'm going to need more help in the future." (Service user 7)

Some service users reported that they wanted to help out, whether that was by helping the NHS, or their perception that they would be helping the PIC by taking part. This may also be a reflection of service users' trust in the healthcare workers and the NHS, embodied by service users' not wanting to reject the referral as it came from a trusted source.

"As I said, you know the NHS has done plenty for me since 1996, so I'm hoping to give a little bit back and help someone in research to make it better." (Service user 8)

"Mainly because I liked [PIC] and I thought she was doing a good job and I thought it would help her." (Service user 15)

Some service users reported that they agreed to take up the service, to have someone to talk to. This links to, and overlaps with, the previous theme in which service users' relationships with the PICs were explored.

"I know I talk to... my son lives at home umm but that isn't' easy because he has split up so he has his children here, so I just feel my home isn't my home anymore. So that has caused problems as well. And so, with [PIC] coming here, it has given me somebody else to talk to and get sort of some of my concerns and frustrations off my chest really." (Service user 9)

Other service users reported that they were curious to find out more about the service, or generally happy to continue with the service, for no reason in particular:

Interviewer: *"Was there anything in particular she said that encouraged you to take up the service?"*

"Umm, not particularly, no. I just go along with it you know the PROSPECT [sic: PROSPER] thing. It came from PROSPECT first, and then I had an interview with somebody from there and they said they'd send somebody out which they did. She [PIC] was very helpful, the girl." (Service user 5)

Interviewer: *"So, was there anything in particular [PIC] said that encouraged you to take up the service? Or anything that put you off?"*

"Umm, no I were just curious to see what it was all about really." (Service user 15)

One service user cited the recommendation from their general practitioner as their reason for taking up the service.

"I'd been recommended by my GP. […] So obviously he thought it would benefit me." (Service user 4)

Another service user reported that the PIC persuaded them to take up the service.

"The lady presenting it, she presented it that well." (Service user 12)

4.5.8.2.4 Theme four: Usefulness of the video

This theme explores service users views on the video, the degree to which service users recalled the video, how useful they found the content and how well it motivated them to take up or engage with the PROSPER service. Although the qualitative interview study was designed to explore the impact of the video, it became clear during interviewing that most of the service users did not have a clear or detailed recollection of the video, and the interviewer often had to prompt the service user to elucidate more detail. Indeed, three service

users had no recollection of the video. Only two service users mentioned the video without being prompted.

> Interviewer: *“Did she [PIC] show you a video clip on the laptop?”*
>
> *"God, I can’t remember"* (Service user 15)

However, many service users reported that whilst they did recall watching a video, they did not remember its content and they often had to be prompted by the interviewer providing them with a brief description:

> Interviewer: *“Ok, and was there any information that the, that [PIC] showed you that helped you decide, any leaflets or…”*
>
> Service user: *"There was a leaflet and a movie, a video as well showed me a video."*
>
> Interviewer: *“Do you remember much about the video?”*
>
> Service user: *"No, I don't, not now."*
>
> Interviewer: *“That’s okay.”*
>
> Service user: *“I knew you were gonna ask me that as soon as I’d said it. But I can’t remember what was on it. I thought it was very useful at the time.”* (Service user 4)

> Interviewer: *“Okay and did you watch anything on the laptop?”*
>
> Service user: *“Yes.”*
>
> Interviewer: *“Okay, do you remember what you saw on the laptop?”*
>
> Service user: *"I can’t now to be honest... but I know it was interesting."* (Service user 14)

In contrast, some service users recalled watching the video, and reported that it helped them to understand the service, either by clarifying what the service offered or adding something over and above the written information supplied:

Interviewer: *“Did the video help you to understand the service better?”*

"Yes, it did and, I mean for me Age UK was just a name, I didn’t really... didn’t know what it entailed... umm you know she offered me if I wanted… services and stuff like that which I didn’t realise you could get help with." (Service user 9)

Interviewer: *“Did the video help you to understand the service?”*

"Umm, yeah ‘cause it was just backing up the written information that I’d received from PROSPER." (Service user 10)

Some service users also reported that the video played a part in motivating them to take up the service:

Interviewer: *[after watching the video] “Did you feel you’d benefit from the service?”*

"Ohh, definitely. Definitely." (Service user 9)

Interviewer: *“After watching the video, did you feel you would benefit from taking up the service?”*

"That, in conjunction with the written information that came through yes." (Service user 10)

Other service users reported some more general positive feedback about the video:

Interviewer: *“Any other comments on the video?”*

"No, only that it just makes you feel like there is somebody else out there and you’re not alone." (Service user 9)

“I think the overall [aim] was to get the point over and that did that more than adequately to be honest." (Service user 12)

One service user reported negative views surrounding the video, finding the content of the video somewhat juvenile:

> Interviewer: *"What did you think of the cartoon?"*
>
> *"Umm slightly juvenile. Well, the... I mean they tended to sort of indicate they were speaking to somebody of low intelligence, well I... perhaps I don't know I might be... I'm not at the present time... I've not noticed any deterioration in my intelligence really."* (Service user 7)

Another service user who could not recall the content of the video clip, but when prompted with a brief description, also suggested it could be patronising:

> *"Mmm, that sounds a bit patronising as well, sorry."* (Service user 15)

Some service users reported that they could not relate to the character in the video:

> *"Well, at the time when I was looking at it [video]… to me it was more to do with someone who was on their own, lonely, needing a lot of assistance. So much assistance to get on with their life… umm and I didn't really think that was relevant to me at the time."* (Service user 5)
>
> *"It doesn't really apply to me, because I've got a wife, two daughters here, I'm the chauffeur so I'm always out and about. I've got a son by a previous marriage, living a couple of miles away, so I'm always going to see him or he's coming here. So, I've got quite a bit going on."* (Service user 11)

One service user discussed how the paperwork given to them by the PIC was more helpful as a resource as they didn't find the video relevant to their personal situation:

> Interviewer: *"What was the most impactful resource?"*

> *"Umm, I think it might have been the paperwork really. It just sort of explained things more, than what the video did. Cause the video just wasn't relevant to me."* (Service user 5)

Another service user supported the usefulness of the written resources, with the video acting as a reinforcement:

> Interviewer: *"Do you think the video on its own is detailed enough?"*
>
> *"No, you need the written information as well because then you can go at that in your speed and I think the fact that that came first and you given ample time to go through it, it just reinforced what I'd read."* (Service user 10)

Whereas, other service users reported that they could relate to the character in the video:

> *"Yes, she showed me umm an interview of a lady and that you know.. was isolated like I am and how she got out into the community. […] Definitely, I just felt I was in her shoes."* (Service user 9)

However, some of these service users did report that the video may be helpful for somebody who was in a similar situation to the character in the video. One service user also felt the video may be more appropriate for them in the near future:

> Interviewer: *"Would you say it would be helpful for somebody who was in that situation?"*
>
> *"Oh definitely. […] That might be relevant to me in a couple of years' time, that video."* (Service user 5)

Some service users referenced the length of the video in a positive manner:

"It was a short video, you know quite... I've seen worse umm and that was... it was a few minutes, and it was interesting." (Service user 12)

Others provided feedback on the technical qualities of the video, such as visuals and sound:

Interviewer: *"Could you hear the video clearly and understand it?"*

"Yes, yes very clearly." (Service user 9)

Interviewer: *"Could you see it all okay?"*

"Oh yeah, yes it's very clear." (Service user 10)

Regarding the storyline in the video, many service users reported that it was easy to follow and understand:

"Yeah it was ok as well, easy to understand." (Service user 5)

4.5.8.3 PICs findings

Using thematic analysis, three key themes were identified from the data: "Content of the PROSPER Service," "Uptake of the PROSPER service" and "Usefulness of Video." There were also several sub-themes within each theme. There was a degree of overlap across these themes. These interviews were conducted with four PICs, from three different localities.

4.5.8.3.1 Theme one: Content of the PROSPER service

This theme explores the way in which PICs introduce the PROSPER service to service users, including the content of the initial meeting, the effects of training and any barriers faced during this first session with service users.

4.5.8.3.1.1 Sub-theme one: Content of the initial meeting

PICs discussed how they introduced the PROSPER service to service users within the initial conversation, emphasising the importance of building rapport. This was achieved using a variety of strategies, including clarifying the wide

range of assistance that could be accessed through the PROSPER service. PICs described the need to explore the service user's current interests, activities and lifestyle so that discussion could be tailored around aspects of the PROSPER service that might be most relevant to the service user:

> *"Yeah absolutely, so I try to explain to them you know, we help with a variety of things it's not just walking aids or going on a bus or things like that. I said I often sort of said to them the video is a simple example of what we might offer. So let's talk a little bit about what other service we might be able to offer you, what other help, what do you think to this and would you like getting involved in that and it's about sort of using those persuasion techniques almost and getting them sort of interested, focusing on things that might appeal to them, you know?"* (PIC 1)

> *"I usually say well ok, let's have a conversation about you and your daily life then we'll start the guided conversation.. I say tell me a little bit about yourself, about your day and it leads.. it can lead onto various things. There are times when people have said no, nothing, it's not me at all that but as you progress with the conversation you find that there is something that we can do with them, or for them."* (PIC 4)

In addition to the PICs tailoring information on PROSPER services to build rapport, another important feature was to ensure that the service could offer the service user tangible support that aligned to these interests:

> *"Whether they want any more support in the home, have they thought about that. That's it... I do actually say have you had any thought about what you might need some help and support with, if anything? And sometimes they've got a big long list, and other times no... So some people have actually you know had a think about it, but then we need to make it clear to them what we can help them with. To be honest with you, we don't say we can't do anything, we'll pretty much find that we are supporting them with anything that they*

ask... unless it's a social services referral... But we do try to support with most things ourselves. (PIC 3)

As a consequence of the need to build rapport and tailor information giving, one PIC reported that it could take a long time to get through everything they need to in the first meeting:

"And then we kind of go through the questionnaire as much as there's general areas that we talk about but a lot of it.. it's definitely not sort of question and answer, it's more sort of a chat with them about everything to do with their lives and depending how much they talk, the meeting can be anything from just under an hour, probably about the fastest, you know it can be two hours plus if they like to reminisce a lot and they're happy to carry on talking." (PIC 2)

Whilst an important first step in the PROSPER service is to ascertain service users needs of offer tailored support, one PIC described allowing service users to talk freely, without time restriction or a set structure, with the conversation guided to cover the relevant information whist remaining enjoyable and centred around the service user:

"I never kind of shut anybody up and stop the meeting after a certain point unless I can tell they're you know flagging or something if they're struggling to breathe or anything like that. But otherwise I just let them carry on talking. Sometimes, I might be the only person that's been all week so I just let them get on with it and you pick up a lot more information that way." (PIC 2)

The PICs received training delivered by researchers who developed the PROSPER intervention. The training facilitated intervention delivery by explaining the aims of PROSPER and what it could offer for service users. One PIC discussed how this training helped to facilitate intervention delivery:

"Actually quite natural and quite easy because I feel like we've had plenty of training from the start from obviously Leeds Uni, Bradford

Teaching Hospitals, so I think we had a really good understanding of what the project's aims and objectives were, explaining it to service users for me like wasn't a problem and especially when I'm so passionate about a subject as well." (PIC 1)

4.5.8.3.1.2 Sub-theme two: Resources

PICs also commented on the resources they used in the first meeting, including those used to guide the conversation or collect information from service users and those provided to the service users such as leaflets they could read after the visit. They were asked to comment on resources used other than the video being tested in the SWAT, which was covered separately:

"So, umm first meeting so obviously we have used the LEAF assessment (Life Essentials Assessment Framework), the actual initial assessment, err we take the umm PROSPER service booklet with us." (PIC 1)

"No.. in the first meeting it's just the PROSPER leaflet which we had printed up at the start of the project." (PIC 2)

The resources referred to by PICs 1 and 2, the 'PROSPER service booklet' and the 'PROSPER leaflet' are part of a manual provided to the PICs during their training process. These resources act as a guide for PICs to refer back to during their delivery of the intervention, as opposed to being a resource given to service users. It is very likely that PICs use these to help explain the intervention to service users, however their intended audience was the PICs.

Some PICs reported that they did not use as many resources and expressed their dislike towards too many resources. PICs discussed how they selected resources specific to the service user's needs, after having had the initial meeting with the service user. This suggests that resources such as leaflets did not feature heavily in the initial meeting.

"Oh sorry yes, oh yes.. I wouldn't normally.. right if I'm being honest, I wouldn't normally take a big bag of leaflets with me, no. But yes we do, umm Age UK leaflets. Depending on what they're looking for, a lot of the time, I would take leaflets along with me to the next visit so for example, they're asking for aids, adaptations referral.. I'll do the referral but I will also take along .. whilst we're waiting on the referral to come through, they'll have a look at how the process works, what I've done basically, what sorts of things they can expect from that referral when it does take place.. when social services do call them." (PIC 3)

"I wouldn't say I use any other resources really other than.. my knowledge of what's available and umm I sometimes right at the beginning leave contact details for other services depending on how the service has gone, how I've thought it's gonna go.. but that's the predominant tool that I use as guidance for how the conversation's going to go." (PIC 4)

The leaflets referred to by PIC 3 are resources intended for service user use, in that the service users can keep these and refer to them later after the visit from the PIC. These leaflets often describe and illustrate opportunities the service user may be interested in and are an information resource for them as opposed to a tool for PICs to aid intervention delivery.

4.5.8.3.1.3 Sub-theme three: Barriers

Some PICs discussed barriers they faced during the initial meeting with the service users. The main barrier reported by PICs was service users who did not feel the service was not appropriate for them:

"You know I'm okay, or I'm not like Maggie in the video. I don't need that help but I think initially when we first started out we were kind of like oh okay then that's kind of your choice and perhaps we were

discontinuing people when we shouldn't have, looking back …" (PIC 1)

"It's getting that first phone call, umm because obviously a lot of older people are very proud and the minute you suggest any sort of help, that what's I'm going to be coming for and they don't need any umm so the first barrier really is that first phone call umm to actually get to the visit, on occasions I've even said would you humour me? Would you humour me and just let me come out and see you and if it does... if it's definitely something that you're not interested in…umm you know we're not going to try and force anything you know onto you that you don't want." (PIC 3)

One PIC reported that service users may be refusing the service as they may want to hold on to their independence:

"Umm, I wouldn't say barriers as such.. the main barrier for some people is that they're so determined to hang onto their independence or as they see their independence, they really don't want any help.. even if I think that there is help there.. I think sometimes they see it as giving in if they accept the service." (PIC 4)

Another barrier faced by PICs during the initial meeting with service users was the lack of understanding of the service, potentially partially attributable to hearing impairments:

"I do feel that a lot of people that we see are not totally understanding what the service is.. they may have got the wrong idea, they may.. there's been some barriers with the older service users with their hearing." (PIC 3)

4.5.8.3.2 Theme two: Uptake of the PROSPER service

This theme explores the motivating factors for service users taking up the PROSPER service as well as the degree of engagement, from the perspective of the PICs. PICs often asked service users why they were interested to take up the service and hence this theme explores the different reasons service users may or may not take up the service and reasons for their varying levels of engagement with the service.

4.5.8.3.2.1 Sub-theme one: Motivations

Of the four PICs interviewed, two of them reported that service users were motivated to take up the PROSPER service in order to help their GP or the NHS. This could be interpreted as being an integral part of the reciprocal relationship between doctor and patient whereby when referred to a service, it is expected that the patient would take up the service. Some service users wanted to help the NHS, considering it to be their duty in a way.

> *"Some people were only signing up because they wanted to help the NHS and things like that and not necessarily had any needs that needed sort of interventions putting in place."* (PIC 1)

> *"And I'll be… oh well why did you sign up for it then? Is there anything in particular you were thinking of? Oh no no, I just wanted to help out the NHS really, or Doctor so and so's been really good to me so I thought this would help them."* (PIC 2)

4.5.8.3.2.2 Sub-theme two: Engagement

PICs discussed how they encouraged service users to engage with the intervention. One strategy to convert interest into engagement was to use the needs assessment to set goals which could be used to support making an action plan. This plan was seen as an important tool to clarify what support could be put in place, and as a tool to support sustained engagement with the PROSPER service beyond the initial meeting:

> *"Umm and then at the end we sort of take a bit of time to summarise well okay, these are the issues that I think you know have come out of it that I think we can maybe help you with and what about yourself,*

what do you think, what's important to you? Then I'll get… once we've agreed some sort of steps we can look at, some goals as it were then I'll get them to prioritise what's important to them." (PIC 2)

4.5.8.3.3 Theme three: Usefulness of video

This theme explores PICs views on the video (SWAT intervention), how useful they found the content and how acceptable they perceived the video to be for the service users.

4.5.8.3.3.1 Sub-theme one: Content

All PICs reported that positive views regarding the content of the video. For example, some PICs reported that they felt it was easy to understand and follow:

"…and the service users do seem to… yeah… they do seem to take on board what it is and can understand where it's going. I don't find I have too much of a problem. But I do like showing the video, I like the fact I can say… but this actually summarises everything… you know sets out exactly what it's about and I do like that because I do think it helps people to understand." (PIC 2)

"Because it's set out in such an easy way for people to understand. I just think obviously it can only cover so many things in the video, otherwise you'd be there all day." (PIC 1)

PICs reported that they found the video was helpful for service users to better understand the intervention.

"I think it helps, it's certainly helped me with explaining because umm I've… I think I sort of explain it reasonably well these days and that people understand. But I do think that really helped summarise things." (PIC 2)

When discussing the length of the video, PICs felt it was an appropriate length:

"I think it's about the right length, I think if it went on for much longer, people wouldn't really… might start to get a bit ughh hasn't it finished type of thing?" (PIC 4)

Most PICs reported that video and audio quality were good, however one PIC reported one occasion when the audio malfunction and how they managed this:

"and I usually say can you hear that to the person? And they usually say yeah, and I say are you okay with reading? Because obviously some people aren't and they'll say yes or no. And if they aren't, obviously I would read that to them." (PIC 1)

"Umm, it played without sound once and I couldn't work out why, there was no mute or the sound wasn't turned down. Umm but I kind of… as it went along, gave… because I've heard it so many times now, I can almost do it… so I kind of gave a running commentary on what was happening and basically they were okay with that." (PIC 4)

This demonstrated how the video became memorable for PIC 4 and thus they were able to relay the content of the video to service users. Since service users only watched the video once, it would not have the same effect for them. This suggested that the video may be multipurpose in that it could be a tool for PICs to familiarise them with the intervention and to standardise their description of PROSPER to service users.

4.5.8.3.3.2 Sub-theme two: Acceptability

PICs reported that service users had a range of positive and negative reactions to the video. Whereas some service users found it acceptable or amusing, others did not like the video much. PIC 4 relayed one negative reaction to the video, perhaps due to the use of animation.

"Only one person's ever commented on the fact that it's animations. They said did you get it from the cartoon network, that's the best place for it. But generally people have either been amused by it or encouraged by it… generally speaking, they seem to think it's ok.

> *Apart from that one comment, I've not heard anything negative about it being animation."* (PIC 4)

Some PICs reported that they felt service users did not find the video to be appropriate or relevant to themselves and their needs:

> *"So I think, umm the video clip sometimes can alarm people in one sense because they think what? I'm not as frail as that, this isn't me. So it sorts of gets them on the footing that this isn't me, I'm not like that person."* (PIC 1)

> *"Umm, and then after you show them the video, they might turn around and say oh well no actually I'm nothing like Maggie…"* (PIC 2)

PICs also reported how they responded to service users who felt that the intervention may not be appropriate for them, by trying to suggest ways in which the intervention could benefit the service user. One PIC also reported that they explained the generic nature of the video, and that it was not targeted specifically to the service user:

> *"…so then you've got to try and say well, actually it's not just for people who are immobile or lost the confidence or whatever, there is other things we can support people with."* (PIC 1)

> *"And yep then we will have a little chat about the video. I usually say was there anything there at all that you identified with, it's fine if you didn't. I explain to them it's generic and everybody is shown that video, not just for them. There may be bits in it that they don't feel… I've had various responses to the video."* (PIC 3)

On the other hand, some PICs reported how some service users felt they could relate to the video:

> *"Yeah, they actually relate to it, so it makes them actually feel quite emotional watching it."* (PIC 3)

"Yes, because sometimes the person has said, oh the bit that they said about getting adaptations for the bathroom that's something that I could use so…" (PIC 4)

Barriers when using the video were also discussed. One potential barrier that may arise this was the possibility of service users finding the video to be condescending and not wanting to continue with the PROSPER service as a result of this:

"A possible barrier with the video is.. some of the more able people might find it a tad condescending but umm, but I never.. I don't try and paint it that way because I don't think it is. I think it's really good. But I've never had anybody turn around and say that video's awful, you shouldn't be showing that." (PIC 1)

4.5.8.3.3.3 Sub-theme three: Prompt to discuss PROSPER

As well as finding the video helpful for the service users, PICs also discussed how they used the video as a tool to prompt the discussion about the PROSPER service. Since the video provided examples of ways in which PROSPER could support the service user, the PIC used it as a springboard to tailor the discussion with the service user to their individual needs.

"We'd go in and visit somebody and the first thing that I was doing with people was explain what PROSPER was and possibly how it could help them and then what I was sort of saying to them is we've got a video of an example of a person who perhaps might use PROSPER service. Would it be okay for me to show you that video?" (PIC 1)

"… that's when I introduce the video, I say we've got a short video that's two and a half minutes that we'd like to show you that gives a full explanation or an overall explanation of how the PROSPER service works." (PIC 4)

4.5.8.3.3.4 Sub-theme four: Uptake

PICs discussed the perceived effect of the video on service users' uptake of the PROSPER service. Some PICs felt it encouraged service users to think more about whether they would like to continue with the service:

> *"I think it sows the seed with people. I think it gets their mind working and thinking I could probably do with some help with that. Or yeah, perhaps I'm not like that but I might need that. So, it does sow the seed. I think it gets people thinking a little bit before you start the assessment process and start setting goals with them and you know planning your work."* (PIC 1)

> Interviewer: *"Ok, so then do you think the video does make a difference in terms of helping them decide whether to use the service?"*

> *"I think so yes."* (PIC 2)

One PIC felt the conversation with the service user after watching the video was important in helping service users to make that decision rather than just the video alone. This supports the usefulness of the video as an additional tool to use in the initial meeting between PIC and service user.

> *"I don't think it hinders… I don't think it does hinder at all… I think it's how you explain that video to them is the key, not just the video on it's own… It's the explanation. It's not generic, everybody has different needs and hopefully that's something they identify with. So yeah, it's how you approach the video… we've been to people who have more needs than others, if that makes sense."* (PIC 3)

One PIC reported that they did not feel the video was pivotal in service users' deciding whether or not to take up the PROSPER service:

> *"Umm I think it certainly helps them make that decision… umm I don't think anyone's rejected it on the basis of seeing the video… I*

think some people before we go and see them have already got it in their head… when I ask why are you taking part or why did you agree to take part in the PROSPER trial, a lot of them just say… one of the most familiar answers is oh I just wanted to help the surgery…" (PIC 4)

4.5.8.4 Synthesis of PIC and service user interviews

There were some commonalities found between interviews with service users and those with the PICs. For example, some service users felt the intervention was not appropriate for them due to their level of independence and this was reported as a barrier faced by PICs who said they encountered service users for whom the intervention was not appropriate.

Similarly, there were commonalities regarding service users' motivations for taking up the PROSPER service. Some service users reported that they took up the service as they saw this as a way to help the NHS, and some PICs also reported that service users mentioned this as a reason for why they accepted the service.

Regarding the video, PICs reported that some service users had positive reactions to the video and others exhibited negative reactions. This was mirrored in the service user interviews. Whereas some service users reported positive feedback such as finding the video useful in helping them to understand the PROSPER service, others felt it was not applicable to their personal situation and somewhat patronising in some cases. PICs also discussed the acceptability and appropriateness of the video for the service users, reporting that the video was not always appropriate for every service user they visited.

4.5.9 Synthesis of qualitative and quantitative data

Statistical analysis of the quantitative data showed no effect of the video animation intervention on service user uptake or engagement with the intervention in this SWAT. However, service user uptake of, and engagement with the intervention was high in both the intervention and control groups. This was supported by the qualitative interview data, which suggested that whilst the video was, for the most part, acceptable to service users, it was not that

memorable. Rather, qualitative data suggested that the motivation to engage with PROSPER was much more driven by the interpersonal relationship with the PIC, and or through ‘wanting to support the NHS’ if referred by a health professional. This is consistent with the lack of intervention effect observed in the quantitative data.

There were no differences in secondary outcomes (goals set, number of goals set, evidence of action planning) in the quantitative data. This appeared somewhat conflicting with the qualitative data, where some service users reported that the video animation showed them activities that they might not have otherwise considered. This could be explained by the fact that PICs were trained to cover all bases, so the video complemented, rather than replicated information given by PICs. This was also consistent with qualitative data from PIC interviews as there were some instances where they did not utilise the video (N=27) and reported that they felt it was unsuitable for some service users. In some of these cases, this was due to technical issues such as the audio not functioning.

Qualitative data about service users’ relationships with their assigned PICs were overwhelmingly positive, reaffirming this relationship as a key driver of uptake of the PROSPER service. Many service users reported that their PIC was friendly, easy to talk to, helpful and knowledgeable. No service users reported any negative feelings about their relationship with their assigned PIC.

In contrast, service users reported varied opinions about the value of the PROSPER service. Whereas some felt it was useful and helpful, for example in applying for blue badges or acquiring a new shower rail, other service users reported that it was not useful for them thus far. This was often attributed to a misalignment of the PROSPER service with the service users’ level of independence. Hence, in these cases, service users felt the PROSPER service could be beneficial for others in need of help but was not necessarily appropriate for themselves due to factors such as their independence, financial security and family support. This was reinforced by data from the PIC interviews which also suggested that many service users felt the intervention was not appropriate for them. Similarly, some service users reported feeling guilty about being selected for the PROSPER service since there may well have been people for whom the service was needed.

These findings, coupled with the video being immemorable for many service users, provide further explanation for the lack of effect of the video on service user uptake of and engagement with the PROSPER intervention. The rate of intervention uptake was higher in both arms of the SWAT than the PROSPER feasibility study. This implies that there may be other factors to which this effect was attributable, for example changes in the design of the trial or better training for PICs. Since uptake and engagement rates were so high in both groups, there was little opportunity for the video to have an additional effect. The video was used in training both PICs in the SWAT intervention group and those in the SWAT control group, therefore this may have influenced intervention delivery in both groups, contributing to the improvement in uptake from the feasibility to the main trial. This observation could be reinforced by qualitative data from the PIC interviews which suggests the video was a valuable training tool for PICs, particularly useful as a prompt to discuss the PROSPER service.

4.5.10 Harms/ unintended consequences

Although the intervention in this SWAT was not expected to be especially burdensome for the service users, it is worth noting that all interventions can lead to unintended consequences[33] or potentially harm the participants. Having said this, there were no identified harms to the service users taking part in this SWAT. There were some unintended consequences of the intervention including the fact that a minority of service users expressed negative emotions relating to the video and having been shown this. As noted, in some cases, PICs made the decision not to show the video to certain service users, for whom they believed it would not have been suitable.

4.6 Discussion

4.6.1 Main findings

The aim of this mixed-methods SWAT was to test whether the use of a video animation, as compared with an information sheet and verbal introduction to the intervention, increased service users' uptake of the intervention, and engagement with the intervention. This was explored through a randomised SWAT alongside a qualitative interview study.

Qualitative interviews were conducted with service users and PICs who were part of the intervention group in this SWAT. The data generated allowed for some interpretation of these service users' experiences of watching the video and the influence of the video on service user engagement with the PROSPER intervention. The data were not sufficiently rich for in-depth interpretation; however, this was as expected since the SWAT intervention formed only a small component of the PROSPER intervention delivery process. Despite this, there were still some key findings that arose from the interview data. Many service users did not recall the video, especially not without being prompted. Those who did recall the video did not have any strong views about it playing a key role in motivating them to take up the intervention. In contrast, many PICs reported that they found the video a useful tool which aided delivery of the PROSPER intervention.

There were also some key findings regarding the use of SWAT methodology in a novel way to investigate implementation of a complex intervention within a trial, in particular the use of qualitative interviewing within this. Semi-structured interviews were selected as an appropriate method for answering the research questions though in a post-pandemic climate, pragmatism had to be applied and interviews were thus conducted over the telephone. The method was successful in generating the data required to adequately answer the research questions, however it is worth considering whether other methods might have yielded different results. For example, the use of think aloud methods[208], whereby participants speak out loud whilst completing a task may have been beneficial for this research question. For this SWAT, think aloud methods could have been used to observe service users whilst they are watching the video and ask them to say their thoughts aloud during the video, as well as asking questions after to explore the usefulness of the video.

Statistical analysis of the quantitative data collected showed that the video animation was not superior to the control group in which service users' were provided with a verbal introduction to the intervention and an information sheet. Therefore, there was no effect of the video on uptake of the intervention. The secondary objectives were to explore engagement with the intervention, through assessing the number of goals set and whether action plans were made in the intervention and control groups. It was found that there was also no effect of the

video on engagement with the intervention. However, service user uptake of, and engagement with the intervention was very high in both the SWAT intervention, and SWAT control group, therefore there was little opportunity for the video to have an additional effect. Additionally, the uptake and engagement rates were much higher than those reported in the PROSPER feasibility trial. This may be attributable to the fact that the video was also used as a training tool for PICs in both SWAT intervention and control groups.

PICs in the intervention group generally saw more service users than those in the control group. Cluster sizes varied massively in both intervention and control groups, with the smallest cluster consisting of just nine service users and the largest consisting of 110 service users. The reason for this is that service users were being continually recruited as were PICs and hence some PICs had been delivering the PROSPER intervention for longer than others. Also, ten PICs terminated their employment with PROSPER due to various reasons, such as delays with the trial (due to COVID-19) and changes in personal circumstances. Therefore, these PICs did not make contact with many service users before they left the trial. The issue of clusters being small was addressed by performing an adjusted cluster-level analysis [202].

The logistic regression analysis demonstrated that the only significant predictor in the model was the PIC. This was supported by findings from the qualitative interviews with service users, in which service users discussed their primary motivations for continuing with the intervention as being the PIC and the rapport built with them. This is consistent with the ‘therapist effect’, whereby variability in participant outcomes is attributable to differences between intervention deliverers, after controlling for other variables[209].

Exploratory analyses were conducted to further assess what factors relating to the PIC improved engagement with the intervention. Line graphs were created in Microsoft Excel to identify whether there was a temporal effect, or a learning curve, whereby as the PIC saw more service users, they improved their delivery and hence the service users’ uptake of and engagement with the intervention improved. This was not the case, however some PICs had service users with higher uptake and engagement rates than others. Generally, the PICs who had seen more service users overall, having had the most experience delivering the intervention also had the highest rates of service user uptake of the

intervention. This was consistent with data from qualitative interviews, suggesting that the rapport with the PIC was critical to engagement with the intervention.

It is worth noting that there were some changes made from the PROSPER feasibility study to the main trial which could well have influenced the differences in service user rates of uptake and engagement with the PROSPER intervention. For example, there was a change in the design with the feasibility study adopting a cluster randomised design and the main trial being randomised at the level of the participant. As well as this, the PROSPER main trial intervention delivery took place following the COVID-19 pandemic, which likely had an effect on service user uptake and engagement, with many older people having had extended periods of social isolation over the duration of the pandemic. Finally, there were changes made in terms of training for PICs, particularly a new video that had not been used in the feasibility study which likely influenced the intervention delivery.

4.6.2 Strengths

The use of SWAT methodology in this novel way to investigate intervention implementation processes is a key strength of this SWAT. At the time of conducting this SWAT, there were few SWATs focusing on intervention implementation processes within trials. These SWATs have the potential to systematically and robustly test minor refinements to intervention delivery, such as those aimed at improving participants' uptake of the intervention or their engagement with the intervention. It may well be the case that refinements have been identified during feasibility or pilot stages of trials, if trial conduct issues were identified through process evaluation[38]. For example, trial teams may have taken action to improve participant engagement, compliance or fidelity, by providing extra information to intervention participants, implementing additional reminders to intervention participants, deliverers or both, delivering booster training or increasing the frequency and/or duration of supervision. These actions may or may not have been introduced systematically and equally across all those delivering (or receiving) the intervention. However, the value of such amendments may have been explored within a process evaluation, or with a post-hoc quantitative analysis, such as through the use of causal modelling.

What is proposed here is that minor amendments to the implementation of the trial intervention could be evaluated systematically through randomised SWATs, as these studies are designed to provide a robust, unbiased assessment of the effect of such changes. Feasibility or pilot studies identify refinements to either the intervention or trial processes before proceeding to a definitive trial, however these changes are largely untested for effectiveness in bringing about the desired improvements. Therefore, SWATs provide a method for testing these minor refinements, systematically. There are still questions surrounding defining a ‘minor refinement’ and whether they can be adequately investigated through a SWAT.

Furthermore, it is proposed that SWATs of this type could increase trial efficiency by maximising the number of trial participants receiving (more of) the intervention as intended. This could help avoid diluting the potential to detect treatment effects, which could arise with reduced intervention implementation or with lower levels of intervention compliance. Trials, in which intervention delivery is better optimised, require fewer numbers of patients than those where treatment effect dilution is accounted for in power calculations.

The use of mixed-methods to investigate intervention implementation processes in a single study as described here provides a superior understanding of the issues at play than using either quantitative or qualitative methods alone. Creswell describes the use of mixed-methods in research to involve collecting, analysing and integrating qualitative and quantitative data in one study. This SWAT has utilised both qualitative and quantitative methods from data collection through to analysis. For example, the quantitative data demonstrated no impact of the video on uptake and the qualitative data provided important insights into why this might be the case.

This SWAT has used robust methods to address the research question, from randomising PICs using the minimisation method to collecting trial data from CRFs and conducting qualitative interviews with service users and PICs. Analyses of the data were conducted in a thorough and in-depth manner. Qualitative interview data were analysed using thematic analysis, through an iterative process of coding and reviewing codes with supervisor SHR. Statistical analysis of the quantitative data was equally exhaustive and involved consulting

with statisticians throughout conducting the cluster level analyses as well as conducting further exploratory analyses.

4.6.3 Limitations

The video animation tested in this SWAT was developed in response to concerns arising from the PROSPER feasibility trial in which service users questioned the suitability of the intervention for themselves. The quantitative data showed that service user uptake of the intervention was much higher in the PROSPER definitive trial than the PROSPER feasibility trial. This was the case in both the intervention and the control group of the SWAT, hence there was little opportunity for the video to have an effect. Consequently, there was no effect of the video on service user uptake of, and engagement with the intervention.

During development, it was also anticipated that the video could be used as a tool for training PICs, therefore it was shown to all PICs in both the SWAT intervention and control group. The use of the video for training of PICs may explain the increase in service user uptake from the PROSPER feasibility trial to the PROSPER definitive trial. The fact that PICs in both the SWAT intervention and the SWAT control group viewed the video may also have reduced the potential for the video to have an effect on service user uptake since the PICs may have used examples from the video in their intervention delivery. The effect of the video as a training tool was not investigated in this SWAT, but this may have been worth exploring.

Since PICs randomised to the SWAT intervention group received training, they were aware of the SWAT. PICs randomised to the SWAT control group were not explicitly made aware that they were in a SWAT however it is likely that many of them became aware of this over time as they may have engaged in conversations with their colleagues about intervention delivery. This may have had consequences for the results of the SWAT as it could have influenced the PICs' delivery of the intervention, in particular it may have left PICs in the control group feeling that their intervention delivery was lacking something or inadequate in some way. Due to the nature of the intervention, blinding could be not achieved. This may well have had consequences for the outcomes of this

SWAT, for example through performance bias or through PICs and service users exhibiting demand characteristics in interviews.

Findings from qualitative interviews with service users showed that many of them did not remember the video animation for very long after having watched it. Therefore, it could be argued that this intervention is not the most appropriate form of information for this target population of older adults with frailty, who may well have existing memory problems. The video was viewed by the service user during the same visit in which they decided whether or not to proceed with the intervention. So, it could also be argued that service users did not need to hold the video in their memory beyond the first visit. This would be the case if uptake was the only outcome, which it was not. Service user engagement with the intervention was also measured, through secondary outcomes, as number of goals set and action plans made over a number of visits. Therefore, it may well be worth considering whether a different resource, one that service users could refer back to during intervention delivery, would be more appropriate for this target population and the outcomes investigated. Alternatively, well trained PICs may be the key to improving service user uptake and engagement with the intervention, in which case the value of the video lies in its use as a training tool.

The use of qualitative interviewing to address the research questions in this SWAT had some limitations. The interviews were very brief and focused mostly around the video animation. In cases where the service user did not recall the video, there was little data generated. Upon reflection, other methods may have been better suited towards the research questions, and the population group of interest. Researcher observation of the first PROSPER visit may have provided a better indication of the service users' reactions to the video in live time, and the influence of the video on their decision to continue with or end their participation with the PROSPER service. This could be supplemented with a short survey immediately after the decision was made to ask service users about the role of the video in their decision to continue or not continue with the intervention. Similarly, think aloud methods[208] could have been utilised as an alternative to qualitative interviewing and in this case, a survey would not be necessary.

Due to the interviews taking place over the phone and the processes involved in arranging the interview, it was often not possible for interviews to be conducted

until sometime after the PIC visit had taken place. Observations would circumvent the issue of service users' not being able to recall the video as this delay would not exist. Despite this, use of an alternative methodology would almost certainly have other considerations or potential risks. For example, having two visitors (PIC and researcher) during an initial meeting may be overwhelming for service users and may in turn, impact upon their decision to continue with the PROSPER service.

Another point to consider when using qualitative interviewing is the timing of these interviews and whether the interviews may have been more beneficial at an earlier stage of research, for example during intervention development. After the video was developed, a formal evaluation could have been undertaken prior to its use in the trial. However, there are logistical reasons for why this may not have been possible such as the lack of time between the feasibility trial and the definitive trial and the lack of resources to test the video.

Qualitative interviews were conducted with service users in the intervention arm of the SWAT only. It may have been beneficial to interview service users in the control arm of the SWAT to try to understand how their experience may have differed from those in the intervention arm. This may have allowed further elaboration of the qualitative interview data and aided with evaluating the value of the video animation by interviewing service users who had not been shown the video.

4.6.4 Implications and considerations for research

4.6.4.1 Implications

The findings of this SWAT are clear, showing that although there was no effect of the video animation on service user uptake and engagement with the intervention, these rates were very high in both the intervention and control groups, particularly when compared with the PROSPER feasibility trial. This has implications for future complex intervention trials involving older adults with frailty since it can inform trialists who may wish to consider the use of a video animation to improve service user uptake of an intervention or optimise service user engagement with the intervention. The value of a video animation may lie in its use as a training tool for intervention deliverers rather than a tool to

engage participants. Although, the findings cannot be generalised too broadly as this may vary for a different intervention or target population.

It is recommended that a video animation is not the most appropriate tool for optimising service user uptake or engagement with the intervention, within this target population of older adults with frailty. Many older adults do not recall the content of the video animation long enough for it to have an effect on uptake of the intervention or engagement with the intervention. Instead it is worth investing efforts to explore the use of a video as a training tool for intervention deliverers. There are a number of additional considerations for researchers considering the use of a mixed-methods SWAT for investigating some aspect of implementation of a complex intervention within a trial.

4.6.4.2 Broader considerations for research

4.6.4.2.1 SWAT intervention choice

There are some methodological considerations for researchers conducting a SWAT investigating intervention implementation processes. Selecting the intervention to investigate can present challenges. The intervention under evaluation must present a minor refinement to the implementation of the host trial intervention. It must not change the trial intervention itself. The SWAT intervention can be developed, through learning from earlier host trial intervention development and evaluation work, such as feasibility or pilot studies. Any uncertainties arising from this earlier work can be discussed whilst finding potential ways to address these uncertainties. Hence, a SWAT can be designed to evaluate minor refinements to the particular aspect of the implementation where uncertainties have been identified. Since intervention implementation is a broad concept, encompassing various aspects including uptake, engagement and compliance with the intervention, refinements can be made to address any of these aspects. It is recommended that refinements be minor and also targeted to specific aspects as opposed to generally addressing intervention implementation.

4.6.4.2.2 Delivery of the SWAT intervention

Intervention implementation SWATs are different to SWATs exploring recruitment or retention in that the central trial team have more limited control of

the delivery of the SWAT in the former than in the latter. In SWATs evaluating intervention implementation, such as the SWAT discussed in this chapter, delivery of the SWAT intervention is often executed by a third party such as a clinical team or a voluntary sector organisation. With this, comes additional challenges such as ensuring that the SWAT intervention is delivered to the correct participants, at the correct time and in the correct manner. Where the SWAT is dependent on technology, such as investigating the use of a video animation, this creates further challenges, especially in multi-centre trials if the software and equipment varies across sites. Ensuring there is no contamination is another consideration for intervention implementation SWATs, since PICs may share resources or methods for delivery. This makes it complex for the trial team to identify and minimise contamination threats. One way to maximise adherence and prevent contamination is to highlight and emphasise the importance and value of the SWAT during training with PICs.

Training of PICs brought about some of its own challenges as there had to be separate training sessions for PICs in the SWAT intervention and control arms. This led to some confusion with those in the control arm unsure about why they were not invited to attend the training session intended for those in the intervention arm.

4.6.4.2.3 Randomisation level

Another thing that required careful consideration was about the most appropriate level at which to randomise for the SWAT. In individually randomised host trials, randomisation for the SWAT does not have to automatically follow the host trial randomisation. Since the intervention implementation process was modified, randomisation had to be undertaken at the PIC level as opposed to the service user level. By doing this, it maximises correct use of the alternative implementation process and avoid contamination between the SWAT arms. Conversely in cluster randomised host trials, when both the trial intervention and the alternative implementation process tested in the SWAT are delivered at the cluster level, cluster-level randomisation should also be used for the SWAT.

4.6.4.2.4 SWAT outcomes

Another difference to be highlighted between recruitment or retention SWATs and intervention implementation SWATs is that outcomes of interest can vary significantly in the latter, depending on the aspects of implementation that are the focus of the SWAT. SWATs investigating recruitment or retention processes typically adopt simple outcomes such as recruitment rate or follow-up rate which are relevant to all trials and hence, data is collected through routine trial data collection. In contrast, intervention implementation is a broad concept, encompassing both the quality and quantity of intervention delivery. Therefore, there are no common simple outcomes which can be used across all SWATs investigating intervention implementation. The SWAT outcome should be carefully aligned to the aspect of implementation under investigation in the SWAT.

4.6.4.2.5 SWAT sample size

As with all SWATs, the sample size of the SWAT is constrained by that of the host trial which can lead to SWATs being underpowered. This issue is exacerbated in SWATs conducted only in the intervention arm of the host trial, since it further restricts the sample size. However, a post-hoc power calculation was performed which identified that 720 service users would provide 80% power to detect a relative difference of 22% between uptake in the two arms.

Meta-analyses are one way of increasing the power of the analyses of SWATs, by combining SWATs of the same type to provide better estimates of the effect of changes in trial processes. Performing meta-analyses of SWATs investigating intervention implementation may prove more challenging than that for recruitment or retention SWATs as there may be a high degree of heterogeneity in the host trials, for example the delivery settings, outcomes or type of implementation process may vary too much. As well as this, the SWAT interventions themselves may also vary considerably. However, it may be possible to plan coordinated SWATs for two or more host trials simultaneously and thus increase the evidence base for replicated SWATs investigating intervention implementation processes. Although, this would require the preceding research from feasibility or pilot studies to have identified similar areas of uncertainty for the SWAT to address.

4.6.4.2.6 Host trial considerations

Conducting a SWAT should not affect the integrity of the host trial in any way[36]. Where SWAT outcomes are related to the outcomes of the host trial, the analysis of the SWAT may need to be delayed until the end of the host trial follow-up. However, if outcomes are not directly related, analysis can be performed earlier. This has the added benefit of allowing any findings showing improved implementation processes to be implemented for the remainder of the host trial. For example, in the PROSPER SWAT, it had been previously agreed that if the video showed an added benefit, in the SWAT, it would be used for all participants once the SWAT analyses had been performed. Data collection for the SWAT is still currently ongoing and will be analysed again when all service users have been randomised.

There are also practical issues to consider to ensure that the SWAT does not disrupt the host trial. For example, randomisation and data management processes may need to be adapted to accommodate for the SWAT. However this should be done in a way that minimises disruption to the host trial. Careful planning in advance helps to ensure this and also avoid confusion for participants, staff and researchers. Embedding a SWAT in a host trial has financial and workload implications, therefore this needs to be costed for in funding applications. Additional costs could be minimal relating to postage, printing and phone calls or they could be substantial costs relating to staff, video animation production and training.

As well as these, there are considerations pertaining to the host trial analysis. When undertaking SWATs investigating intervention implementation processes, the statistical analysis must account for the possibility of an interaction effect between the intervention in the host trial and the SWAT intervention. The analysis approach should be chosen to reflect the key research question that the trial is looking to answer, for example, whether to assess the host trial intervention effect averaged over the two SWAT arms or whether the groups should be assessed separately. The analysis plan for the host trial should pre-specify how the SWAT will be accounted for in the host trial analysis. The impact of the SWAT intervention on intervention delivery should also be accounted for during secondary analyses, and when examining mediating effects, for instance when adopting causal inference approaches.

Additionally, health economic evaluation methods are often embedded within definitive trials to estimate the cost and cost-effectiveness of new technologies[210]. Embedding a SWAT investigating intervention implementation may have implications for the resources costed. For example, the new intervention delivery method being evaluated may incur additional upfront costs to develop it (for example, designing and producing a video animation), as well as affecting the ongoing costs associated with intervention implementation (e.g. staff time taken to deliver intervention may be increased, or decreased depending on the change to delivery processes). The costs and resources used within the context of a SWAT should be documented within the health economic evaluation, and subsequent analysis adjusted accordingly. The analysis approach may mirror that taken for the statistical analysis. Additionally, the economic evaluation may require sensitivity analyses with varying assumptions relating to the extent to which the SWAT intervention is adopted within the trial intervention if it were to be implemented into clinical practice.

4.6.4.2.7 Process evaluations within the host trial

Process evaluations are valuable for further understanding the complexities of intervention implementation and are therefore complementary to conducting a SWAT. Whereas a SWAT is used to evaluate one specific change in the trial process, process evaluations take a broader view and can investigate in other ways, multiple changes in the trial. Process evaluations typically incorporate qualitative aspects such as interviews and observations where researchers can get a more in-depth understanding of the factors that influence engagement and compliance, and how much the participants understand the intervention[5].

When planning the SWAT, researchers should consider developing a separate programme theory and logic model which includes the aspect of delivery under evaluation e.g. video animation. This will assist in understanding the mechanisms by which the additional intervention aspect may or may not have an effect. Researchers will also need to consider what will be examined as part of a process evaluation as this may influence the data collection methods. For example questions specific to the SWAT may need to be added to some of the topic guides for semi-structured interviews.

Depending on the trial design, there can be challenges involved when conducting a SWAT alongside a process evaluation. If participants are individually randomised as part of the trial, researchers should be mindful of potential burden if participants are asked to take part in separate interviews, for

the host trial process evaluation and the SWAT. To minimise the potential burden on participants, process evaluation researchers and SWAT researchers could ensure they do not contact the same participants for interviews. However this does reduce the pool of potential participants available for each element which can be problematic when trying to purposively sample. Where possible, this could be avoided entirely by adding additional questions relevant to the SWAT to process evaluation interview topic guides, thus eliminating the need for separate interviews.

4.6.4.2.8 Ethical approval

As with all trials, gaining ethical approval must be considered in advance to avoid difficulties or delays. For this SWAT, the process was straightforward since ethical approval was obtained through a protocol amendment, but it could be more complicated depending on the nature of the SWAT.

4.6.5 Conclusion

To conclude, this SWAT showed no effect of using a video animation on improving intervention uptake or service user engagement with the intervention, however uptake and engagement were high in both groups, leaving little opportunity for the video to have an effect. There was an effect of the PIC, supported by both the quantitative data and the qualitative interview data which suggested that the PIC was the primary motivating factor for service users' uptake of the intervention. As is consistent with the 'therapist effect' phenomenon, the heterogeneity between different intervention deliverers leads to some intervention deliverers facilitating better participant outcomes than others[211].

This mixed-methods SWAT demonstrated a novel approach to investigating intervention implementation processes within trials. Using SWAT methodology in this way provides a systematic approach to testing minor refinements which may enhance the intervention implementation process. If these refinements are shown to enhance intervention implementation, they could be used in future as evidence-based strategies to facilitate implementation of complex interventions within trials.

There are methodological considerations associated with the design and conduct of the SWAT pertaining to intervention choice and delivery, as well as statistical considerations surrounding randomisation, outcomes and analysis. Considerations for the host trial relating to statistical analysis and health economics have also been discussed alongside unique considerations associated with conducting a process evaluation alongside a SWAT.

The methodological recommendations of this work are as follows: SWATs investigating intervention implementation processes should supplement, rather than replace evidence from process evaluations embedded in trials. Together these pieces of work enable researchers to address key uncertainties about the best ways to implement interventions into practice. Researchers should consider the value of SWATs to systematically explore minor amendments to implementation processes when evaluating complex interventions, whilst being mindful of methodological implications.

Chapter 5
General Discussion

5.1 Summary of key findings

5.1.1 Aims and objectives

The overarching aim of this thesis was to investigate methods used to measure implementation and strategies employed to optimise implementation of a complex intervention within the context of trials involving older people, and their potential to impact on participant outcomes. This was addressed through a number of specific objectives which were:

1. To systematically review the existing literature: to (a) identify and describe qualitative and quantitative methods used for measuring implementation of complex interventions within trials, and (b) identify and describe the strategies employed to optimise implementation of complex interventions within trials.
2. To develop a tool (MOSAIC) to aid with reporting of implementation processes of complex interventions with trials.
3. To systematically review a sample of complex intervention trials involving older people to: (a) identify and describe the qualitative and quantitative methods used to measure implementation of complex interventions, and (b) identify and describe the strategies employed to optimise implementation of complex interventions.
4. To test, refine and update the previously developed MOSAIC tool using a sample of complex intervention trials involving older people.
5. To conduct a SWAT embedded within the PROSPER trial to investigate the effect of an animated video versus no video on optimising the implementation of the PROSPER intervention, through increasing servicer user uptake of, and engagement with, the intervention.
6. To undertake a qualitative interview study, within the SWAT, to understand the views of service users and staff surrounding use of an animated video as a strategy to optimise implementation of the PROSPER intervention.

5.1.2 Systematic methods overview 1

To achieve objectives 1 and 2, a systematic overview of methods was conducted to identify methods used to measure implementation and strategies employed to optimise implementation in existing trials and associated literature (Chapter 2). This overview was broad in nature as it was not focused on any particular target population or disease area. This approach was taken since methods for measuring implementation and strategies for optimising implementation of complex interventions within trials are not specific to any population or disease, rather they can be transferable across these.

Findings indicated much variation between the 97 studies in terms of the methods and strategies reported to measure and optimise implementation of complex interventions. Studies also varied in terms of the frameworks they used to inform the complex intervention implementation process. However, the most commonly cited framework was the MRC guidance for process evaluations of complex interventions[27]. More studies reported the methods used to measure implementation (Section 2.3.4), than those that reported strategies employed to optimise implementation (Section 2.3.5).

Findings were categorised under the five domains taken from the NIHBCC treatment fidelity framework[1] (*design, training, delivery, receipt* and *enactment)*. Of these domains, *delivery* was most commonly reported in terms of both the methods reported to measure, and strategies employed to optimise intervention implementation. Within the domain *delivery*, fidelity was the most commonly measured aspect of intervention delivery. The least reported domain was *enactment,* which was measured by capturing participant responsiveness, engagement or intervention adherence. This is an important part of intervention implementation, without which changes in participant outcomes cannot be attributed to the intervention if it was not engaged with fully [40].

Strategies to optimise intervention implementation were reported to a lesser degree than the methods used to measure intervention implementation. As with methods to measure intervention implementation, strategies relating to the *delivery* domain were reported in more studies than those relating to the other domains. There were also many strategies relating to *training* of intervention deliverers.

Through the process of conducting this overview, the MOSAIC tool was developed to systematically capture the methods used to measure, and the strategies employed to optimise implementation of the complex interventions (Section 2.4.3). Development of this tool emerged through the process of conducting the systematic methods overview; it was not initially intended as a part of this PhD. The MOSAIC tool was used as a data extraction tool but could also be used to aid reporting or design of implementation processes of complex interventions within trials. The tool was informed by the TIDieR checklist for intervention descriptions[50], from which the relevant subheadings were captured in the first part of the MOSAIC tool. The subsequent parts were informed by the domains in the NIHBCC treatment fidelity framework[1], however these were applied to implementation as a whole, rather than just to fidelity. This tool is a key output of this body of work which was then tested in another systematic methods overview.

5.1.3 Systematic methods overview 2

To achieve objectives 3 and 4, a second systematic methods overview was conducted (Chapter 3). This overview aimed to test the previously developed MOSAIC tool using a sample of complex intervention trials, with a health education component, involving older people, collated as part of a wider NIHR-HTA funded evidence synthesis. Through this systematic methods overview, the MOSAIC tool was tested in its use for data extraction, alongside an investigation into the methods reported in this sample of complex intervention trials involving older people to identify patterns of reporting or methods within this population sub-set.

The sample was obtained from a recently completed HTA funded systematic review and network meta-analysis of community-based complex interventions to sustain independence for older people, stratified by frailty[41]. Since the population of interest was the same for both the NIHR-HTA systematic review and the systematic methods overview for this PhD, the decision was made to sample a subset of studies from the NIHR-HTA systematic review and extract data relevant for the systematic methods overview reported in this thesis.

It was found that the MOSAIC tool was useful for systematically gathering information about methods used to measure implementation and strategies employed for optimising complex intervention implementation. The second systematic methods overview supported the findings of the previously conducted, and broader systematic methods overview in Chapter 2 of this thesis. It was found that *delivery* was the domain most methods and strategies reported, related to. There was a distinct lack of focus on the other four domains of the NIHBCC fidelity framework: d*esign, training, receipt and enactment*[1] (Section 3.4.2). There were three strategies added to the MOSAIC tool through the second systematic methods overview. These were use of checklists, financial compensation, and home visits, all categorised under the domain of *receipt.* The final draft of the tool can be found in Appendix 10.

5.1.4 Study within a trial

To achieve objectives 5 and 6, a mixed-methods SWAT was conducted consisting of a nested cluster RCT and a qualitative interview study (Chapter 4). The SWAT was embedded in the PROSPER host trial which investigated a personalised care planning intervention for older people with frailty. This SWAT aimed to empirically test a strategy to optimise the implementation of the PROSPER intervention. The strategy employed was a video animation to introduce the PROSPER intervention, targeted to improve service users' uptake of the intervention and engagement with the intervention. The primary outcome for the cluster randomised controlled SWAT was whether or not the service user chose to proceed with the intervention following the initial visit. Secondary outcomes were number of goals set, evidence of action planning and service users' and staff views on the video animation and its impact on service user engagement with the PROSPER intervention. The quantitative data were analysed using descriptive statistics and logistic regression. Qualitative data collected were analysed using thematic analysis.

The findings of the RCT showed there was no effect of the video animation on improving intervention uptake or service user engagement with the PROSPER intervention, however service user uptake of, and engagement with the intervention was high across both the intervention and control groups (Section

4.5). The qualitative interview study found that many service users did not recall the video, unless prompted. Those who did recall the video found it acceptable, though did not report the video as a key motivating factor for their uptake of the intervention. In contrast, many PICs reported that they found the video to be a useful tool which aided delivery of the PROSPER intervention (Section 4.5.8). Synthesising data from the RCT and the qualitative interviews, this is a key finding from this SWAT as it indicates that some interventions such as the video tested in this SWAT may be useful in improving elements of implementation other than those they intended to. Although this video was intended to improve service user uptake and engagement by providing information to service users, it was found to be more useful as a tool for intervention deliverers.

Both the quantitative data and the qualitative interview data showed that the PIC was a motivating factor behind service users' uptake of the intervention (Section 4.5.9). These findings suggest that perhaps the key in improving participant engagement with an intervention may be in a tool to aid delivery aimed at the intervention deliverer. The systematic methods overviews reported in this thesis found that *enactment* is the least reported domain of intervention implementation. Enactment encompasses engagement and participant responsiveness, all important elements necessary for an intervention to be effective. Therefore, this further highlights the need to invest efforts into developing strategies to optimise participant engagement with complex interventions.

This SWAT showcased both a novel use of SWAT methodology for investigating intervention implementation as well as a mixed-method RCT and qualitative study combined for the SWAT, which elicited a number of recommendations and considerations for researchers. These considerations relate to the following issues: SWAT intervention choice, delivery of SWAT intervention, randomisation level, SWAT outcomes, sample size of SWAT, host trial considerations and process evaluation consideration. These issues have been described in more detail with recommendations in Section 4.6.4.2.

5.2 How findings relate to previous research

The MRC guidance for process evaluation of complex interventions[5] and the MRC guidance for developing and evaluating complex interventions[3] both emphasise the importance of considering implementation throughout the process from development through to evaluation of a complex intervention. Various frameworks emphasise different aspects of implementation that should be considered (Section 1.4). The NIHBCC treatment fidelity framework proposes these five domains, in relation to which fidelity should be considered: *design, training, delivery, receipt and enactment*[1]. In this thesis, I have proposed that these domains can be applied to implementation as a whole rather than just to fidelity. When designing and reporting the implementation of complex intervention within the context of a trial, the use of a framework to inform this process is very important and useful. A framework can help to ensure that researchers have considered all aspects of implementation. As shown in the systematic methods overviews, previously reported trials do not always utilise a framework to inform implementation, and consequently, not all aspects of implementation are given thought. Researchers can select the implementation framework they consider most applicable and useful for their intervention.

There is a distinct lack of research covering intervention implementation within trials as a whole. Much research in implementation tends to be focused on implementing an effective intervention in the real world, as opposed to within the context of a trial. For example, there are a number of frameworks which focus on implementing evidence-based interventions into practice, such as the RE-AIM framework[28] and the Promoting Action on Research Implementation in Health Services (PARIHS) framework[30].

The research outlined in this thesis has extended this reported knowledge by reviewing and evaluating other aspects of implementation of complex interventions in trials. The overviews conducted in this PhD have provided an outline of the methods used to measure aspects of implementation such as adherence, reach, dose. Further, strategies employed to optimise implementation of complex interventions within trials were also reviewed. Both the methods used to measure and strategies employed to optimise implementation of complex interventions within trials were categorised

according to the domains proposed by Borrelli and colleagues within the NIHBCC treatment fidelity framework[1]. The TIDieR checklist was also utilised in the systematic methods overviews to aid data extraction of intervention details[50]. The findings from the overview described in Chapter 2 informed the development of the MOSAIC tool which can be used to aid reporting of methods used to measure implementation, and strategies employed to optimise implementation, of a complex intervention within a trial.

As well as this, a mixed-method SWAT was conducted (Chapter 4) to explore service user engagement and uptake of a complex intervention within the context of a host trial investigating personalised care planning for older people with frailty. This was a previously unexplored area in SWATs, since the majority of SWATs tended to focus on recruitment and retention of participants, prior to this[212, 213]. To my knowledge, this was one of the first SWATs to utilise a mixed-methods approach to explore a minor refinement to a trial process relating to intervention delivery through a SWAT.

There are some examples of SWATs reported on the Northern Ireland SWAT repository[194] which report investigation of intervention implementation, however none of these incorporate a nested RCT alongside a qualitative interview study as demonstrated here. Some of the SWATs do utilise a randomised trial design, to investigate aspects of implementation such as adherence[195] and compliance[196]. BenSaaud and colleagues used telephone reminders to enhance adherence to the intervention, randomising participants in the intervention arm of the host trial to SWAT intervention and control[195]. They compared the effects of a telephone reminder with no telephone reminder on adherence to the protocol of the host trial. This intervention is perhaps quite simplistic in comparison to the video animation investigated in the PROSPER SWAT.

Pufulete and colleagues had a more complex design, whereby they used a 2x2 factorial design to investigate the effect of additional follow-up via telephone or video call on compliance with the intervention[196]. Although the design of this SWAT is more complex, the intervention is once again, fairly simple. As is consistent with the PROSPER SWAT, these SWAT interventions aim to optimise the implementation, or delivery of the host trial intervention.

Cullinan and colleagues utilised a non-randomised mixed-methods SWAT design with a qualitative component to investigate the effect of different healthcare professionals delivering the intervention on the uptake[197]. The qualitative component involved qualitative analysis of the reasons provided for difference in uptake rates. This differs from the qualitative component of the PROSPER SWAT where qualitative interviews with service users and intervention delivers were undertaken.

These SWATs differ from those investigating recruitment and retention because they can only operate within the intervention arm(s) of the host trial. There are of course, methodological and conduct considerations to explore when embedding a SWAT within the intervention arm of a trial, and a number of challenges may arise. These have been discussed fully in Section 4.6.4.2.

5.3 Implications for research and practice

The research presented in this thesis holds important implications for research and practice. Trials methodology research is vital for improving the way we conduct clinical trials and developing and testing new methods for conducting trial processes[214]. Despite this, it is only during the last 15 years that there has been a concerted effort made towards developing, testing and improving trials methodology research. The NIHR-MRC programme for methodology research established a network of centres dedicated to trials methodology research in 2008 (Hubs for Trials Methodology Research). In 2016, the MRC-NIHR-TMRP (Trials Methodology Research Partnership) was established to further build on the methods research conducted through the HTMR network, and to continue to progress trials methodology research and work towards reducing research waste[215]. The Trial Forge network was developed in 2014 to address the lack of an accessible evidence base around trial efficiency and quality[216]. With the aim of building evidence on trial processes, the SWAT network was set up in 2021 to help coordinate and keep track of SWATs being done. This work allows us to move closer towards the goal of reducing research waste and improving the efficiency of trials.

Many implications of this work have been discussed in the earlier chapters: Sections 2.4.6, 3.4.5 and 4.6.4.1. Here the focus is on the following areas: inconsistent use of terminology, focus on fidelity of intervention delivery,

strategies employed to optimise implementation, frameworks to report intervention implementation, novel methods, and implications from the SWAT.

5.3.1 Inconsistent use of terminology

There is a lot of variation in terminology used within research pertaining to implementation of complex interventions within trials. The variation in terminology was introduced in Chapter 1 and is a recurrent theme in both of the systematic methods overviews in this thesis. Hence, there is a need for clear, concise, operationalised definitions to be agreed upon for the field going forward. For example, 'fidelity' is often referred to as 'quality of delivery' or 'fidelity of delivery'. Similarly, 'engagement' is sometimes termed 'participant responsiveness', 'response' or 'participation'. Through conduct of both systematic methods overviews reported in this thesis, it transpires that these terms are largely referring to the same concept. However, this is not always clear, hence creating confusion amongst researchers working in complex intervention trials. This lack of consensus also means that methods to measure implementation of complex interventions are not standardised, and this limits our ability to pool data and learning across trials. Without this consensus, it is difficult to build knowledge on the impact of intervention implementation. This issue could potentially be addressed through consensus procedures involving a wide range of researchers working in complex intervention trials from those conducting methods reviews to statisticians and qualitative researchers.

Inconsistent terminology and varying definitions creates challenges for researchers, particularly when reviewing the literature. Since different terms were used to refer to the same concepts and terms such as implementation and optimisation have been defined in different ways, it was challenging to determine the relevant literature for this thesis and particularly, for the systematic methods overviews. One example of this is the fact that behaviour change techniques utilised to optimise implementation of complex interventions were not identified within the systematic methods overviews. This could potentially be due to the differences in terminology used for reporting.

Similarly, in this field there are challenges of determining what constitutes implementation and what is simply part of the intervention itself. This raises the question of whether strategies to optimise implementation of a complex

intervention are simply strategies to optimise complex interventions. It is difficult to separate these two concepts and this issue is worth noting, although beyond the scope of this thesis.

5.3.2 Focus on fidelity of intervention delivery

The focus in this area tends to be around fidelity of delivery (Section 2.3.4.2.3 and Section 3.3.3.3), with far fewer studies investigating other aspects of implementation such as measuring dose delivered or received, or enactment of the intervention. This finding was consistent across both the systematic methods overviews conducted here. The implication of focusing solely on fidelity when measuring intervention implementation is that this would provide an incomplete depiction of the implementation since it does not necessarily explore aspects within other domains such as receipt or enactment of the intervention. Exploring intervention implementation more wholly and encompassing all domains from the NIHBCC fidelity framework[1] (*design, training, delivery, receipt and enactment*) in the reporting and evaluation of implementation could allow for a broader and more complete representation.

5.3.3 Strategies employed to optimise implementation

Complex intervention trial findings published in journal articles tended to report methods used to measure implementation over and above strategies employed to optimise intervention implementation. This may be attributable to a lack of reporting which may, in part, arise through word count limitations imposed by journals, rather than an indication that these strategies are not being employed. For example, many trials include some element of training of intervention deliverers and this process may involve optimisation strategies such as the use of booster sessions or interactive training methods. However, researchers may fail to report these optimisation strategies especially if they did not consider the approach taken to be an ‘optimisation strategy’ and thus did not highlight it in the publications. Alternatively, details surrounding optimisation strategies may be reported in other papers not found in the search such as intervention description papers. Although, in the systematic methods overviews in this thesis, the search was comprehensive and additional papers such as intervention description papers were accessed, where found.

In alignment with the finding that fidelity of delivery was the most commonly evaluated aspect of implementation, optimisation strategies reported in the overviews tended to focus on intervention delivery, as opposed to the other domains from the NIHBCC treatment fidelity framework. Particularly, strategies pertaining to receipt or enactment of the intervention require more attention in future since it is vital to ensure that participants' are receiving and engaging with interventions as intended before interpreting intervention effects. Perhaps PPI is needed in order to explore potential strategies to optimise engagement with interventions. SWAT methodology provides a useful way to investigate the use of these strategies, however PPI is key for the first step of identifying creative strategies.

This systematic methods overview highlights a need for researchers to take a more rounded approach to measuring and optimising implementation of complex interventions within trials. There is a need to consider more than just one aspect of implementation and a need to explore other domains as well as delivery of the intervention. As emphasised in the MRC guidance for process evaluations of complex interventions[3], implementation must be considered from the earliest point i.e. intervention design and development through to the point of evaluating outcomes.

5.3.4 Frameworks to report intervention implementation

In terms of reporting information about implementation of complex interventions within the context of a trial, there is currently no consensus for a single framework that can be used to aid this process. Therefore, different studies undertake different approaches to reporting the methods they used to implement the intervention and any strategies they may have employed to optimise the intervention. Hence, there is a gap in the literature for a tool to aid reporting in this area. The MOSAIC tool, outlined in Section 2.4.3, provides a framework which researchers can utilise to ensure comprehensive reporting of implementation details. The tool also describes a number of strategies that can be employed across a range of complex interventions to optimise their implementation. This tool could encourage better reporting of implementation information, potentially allowing researchers to make more informed conclusions about intervention implementation within trials.

The TIDieR checklist was developed in response to a problem identified within intervention reporting whereby the quality of intervention description was poor thus replication of interventions was difficult to achieve[50]. Hence, the TIDieR checklist was developed through a process involving literature reviewing and a Delphi survey. The checklist and guide is now widely used and cited for intervention description, leading to an improvement in reporting. The development of the MOSAIC tool follows a similar process, with the systematic methods overviews described in this thesis informing the early stages and consensus procedures to follow in the pathway to impact. The tool could in future, undergo independent testing to investigate its acceptability and ease of use. The MOSAIC tool could be utilised alongside the TIDieR checklist for intervention description, to allow for more completeness in reporting on complex interventions and their implementation within trials.

5.3.5 Novel methods

The systematic methods overviews described in this thesis (Chapters 2 and 3) utilised a new approach for a systematic review, focusing on methods, following guidance published by Gentles and colleagues.[46] This is a relatively new approach in systematic reviewing and there does not yet exist a quality assessment tool or approach for appraising the studies included in the overviews. [21]

As demonstrated in Chapter 4 of this thesis, SWAT methodology can be used successfully to investigate a minor refinement to the implementation process of a complex intervention within the context of a trial. This SWAT can act as an example or case study for future SWATs in this area, which allows the investigation of minor refinements in a systematic and rigorous way, prior to the refinements being made across the trial.

5.3.6 Implications from the SWAT

The mixed-methods SWAT described in Chapter 4 demonstrated that a video animation did not have an effect on service user uptake and engagement with a complex intervention. Instead, the value of this tool may lie with its use as a strategy to optimise training for intervention deliverers. In order to draw robust conclusions about the use of a video animation as a training tool, there would need to be an empirical study conducted to investigate this. However, the

recommendation from this SWAT is that a video animation is not the most appropriate tool for optimising service user uptake or engagement with the intervention, within this target population of older adults with frailty. There are a number of additional considerations for researchers considering the use of a mixed-methods SWAT for investigating some aspect of implementation of a complex intervention within a trial, which have been described in Section 4.6.4.2.

5.4 Strengths and limitations

Throughout this thesis, the approaches taken to explore the literature and investigate outcomes have been thorough and rigorous. The methods overviews undertaken in this PhD provided a broad representation of the methods and strategies used to measure and optimise implementation of complex interventions across a variety of populations and disease areas. Further, the rigorous and systematic approach taken, by which additional papers were always tracked and accessed for data extraction enabled me to present an accurate portrayal of the data, since protocols and other linked papers were accessed. One limitation of this thesis is that I was unable to manually search reference lists of included studies to identify additional eligible trials for inclusion in the systematic methods overviews. Due to workload issues, it was not possible to use this method to identify further relevant studies for inclusion in the overviews. However, the searches were comprehensive and the findings support this. The studies that were included in the overviews allowed a number of conclusions to be made and demonstrated a broad summary of the methods used to measure implementation and strategies employed to optimise implementation in complex intervention trials.

The two systematic methods overviews described in this thesis also informed the development of the MOSAIC tool, which was demonstrated to be useful to aid reporting of implementation processes of complex interventions in trials. One limitation of the process under which the tool was developed is that it was not informed by theory and did not follow a formal process of testing. Further, due to capacity issues, there were no other researchers involved in this process of developing and testing the MOSAIC tool, which brings into question the reliability of the tool. In future, the MOSAIC tool will undergo further testing,

involving a wider team of researchers who will input their feedback into future development (Section 5.5).

The second systematic methods overview in this thesis (Chapter 3) was considerably smaller and more focused than the first (Chapter 2). This approach was taken to present a more focused view of the methods and strategies utilised within the specific population of older people with frailty, focusing on interventions involving health education components. This sample was selected as it was anticipated that interventions which included health education as a component would be well reported. Therefore, it was surprising that implementation methods and strategies were not better reported in this sample of studies. It was intended to further extend the sample of studies included if considered necessary, however due to capacity of workload, and the fact that the included studies allowed for the research questions to be sufficiently answered, the sample was not extended. This may be something that could be addressed in future work, by extending the sample of studies. Furthermore, this systematic methods overview aimed to test the usability of the MOSAIC tool by testing its application in this sample of studies and using the findings to refine the tool. The sample of studies selected had its own limitations since different interventions would likely utilise different methods for measuring implementation and strategies for optimising implementation. A broader sample would likely yield more methods and strategies. If this systematic methods overview was to be conducted again, it would be beneficial to expand the sample of studies to include a range of interventions, not only those with health education components.

To my knowledge, the SWAT described in Chapter 4, is the first to use mixed-methods involving a nested cluster RCT and a qualitative interview study to investigate the implementation of a complex intervention within a trial involving older people. Therefore this SWAT presents a novel use of the methodology to investigate intervention implementation within a trial. The SWAT used robust methods, both quantitative and qualitative to address the research questions, providing a superior understanding of the findings than using either method alone.

Findings from the feasibility study were utilised to inform a minor refinement to the intervention delivery, which was then systematically tested through a SWAT.

Randomising participants in the intervention arm of the host trial allowed for a robust way of testing the effect of this minor refinement, which was a video animation to introduce the intervention to service users. There are questions surrounding the degree to which a minor refinement can be tested through a SWAT before it is considered a completely different intervention. Applying this consideration to this SWAT, it is worth questioning whether the video animation was a minor refinement to an existing intervention or indeed a separate intervention in itself. The PROSPER intervention itself took place over a period of 12 weeks and a number of in person weeks and phone calls between service users and their assigned PICs. In comparison, the video animation was a short clip played to the service user in their first visit from the PIC, therefore making up a small part of the PROSPER intervention. Hence, it can indeed be considered a minor refinement to a complex intervention.

SWATs of this design could increase efficiency of the host trial by maximising the number of participants receiving the intervention as intended. This SWAT intended to improve service user uptake of, and engagement with the intervention. However, the video had the potential to be beneficial as a tool to aid intervention deliverers instead. Having access to SWAT findings whilst the host trial is ongoing, could vastly improve the implementation of the intervention, maximising the potential of resources such as a video animation.

The video animation was developed through participatory methods involving discussions between PPI group members and researchers. My role in this process was purely as an observer, therefore I did not have any input in the intervention development, particularly since this took place before the commencement of my PhD. If I was to undertake this process as part of my PhD, I would question the suitability of the intervention for the population group and I would test the video animation with a group outside of the PPI group who developed it. This intervention may not necessarily have been the most appropriate strategy for addressing issues raised in the PROSPER feasibility study. The key to addressing the barriers raised in the feasibility study may lie in other solutions such as different training methods for PICs or changing the design of the trial. Furthermore, this video animation was used in training both PICs in the SWAT intervention and control groups which is not appropriate since it creates the potential for contamination between the arms.

5.5 Future research

There is a need for the MOSAIC tool to undergo further development and testing, in order to ensure that it is fit for purpose. This was not within the scope of this PhD, however could be achieved through future research. Experts in complex intervention research such as trial methodologists could test the tool and provide feedback regarding the suitability of this tool to aid reporting of methods and strategies used in implementation of complex interventions within trials. Alongside this, there could be a systematic process through which additional methods and strategies to be included in the tool could be identified.

This could be followed by a consensus procedure, such as the Delphi survey used by researchers during the development of the TIDieR checklist for intervention description[50]. The experts could be recruited for this process through utilising communication channels already in place, for example the LUCID (Leeds Unit for Complex Intervention Development) mailing list, advertising on social media platforms such as Twitter and signposting at the end of relevant seminars. From those interested, 30 experts would be selected for the panel as this is the minimum requirement to provide rigour for statistical analysis[217]. The aim would be to purposively sample experts from a range of backgrounds, who use a mix of methods. Round 1 of the Delphi survey would be qualitative, with open-ended questions enabling the experts to express their opinions on the current version of the MOSAIC tool. The survey would be administered online.

Through the Delphi survey, experts such as trial methodologists and complex intervention development groups could highlight which of the methods and strategies suggested should be prioritised for inclusion in the MOSAIC tool and of these, which should be given the most weight. The methods and strategies included in the MOSAIC tool should be carefully operationalised using worked examples, with consensus, by some of these experts. This process could follow the Delphi survey as an additional optional aspect.

These findings could then be used to inform the agenda for more intervention implementation SWATs which need to be conducted in order to create an evidence base for the optimisation strategies included in the MOSAIC tool. As demonstrated by the mixed-methods SWAT reported in Chapter 4 of this thesis,

there is a need to systematically evaluate minor refinements to intervention implementation processes before employing these optimisation strategies across a wide range of complex intervention trials. This would not only ensure that the methods used in trials are evidence-based, but also save trialists time and money alongside helping to minimise research waste.

Following further refinement, the MOSAIC tool could be applied to studies such as the mixed-methods SWAT reported in Chapter 4 to examine whether the details reported about intervention implementation were sufficient according to the MOSAIC tool. Part A of the MOSAIC tool would be used to identify in gaps in reporting details about the intervention. Part B of the MOSAIC tool would be used to ascertain whether the relevant details pertaining to the methods of measuring implementation were reported. Finally, part C of the MOSAIC tool could be used to identify any strategies for optimising intervention implementation utilised in the SWAT, other than the video animation reported.

5.6 Impact of COVID-19 pandemic

As a result of the Coronavirus pandemic, the timeline for this PhD has been affected. Recruitment to the PROSPER trial, in which the SWAT was embedded, was hugely delayed due to the pandemic. Further, the pandemic caused a disruption to my routine and impacted upon my work. Coupled with the stress of being in lockdown, using sub-standard equipment led to inevitable delays with this PhD project.

5.7 Conclusion

The research presented in this thesis aimed to investigate the methods used to measure implementation and the strategies employed to optimise implementation of complex interventions within the context of trials involving older people, and their potential to impact on participant outcomes. The systematic methods overviews outlined in this thesis have successfully addressed part of this aim, by reviewing the methods used to measure implementation and strategies employed to optimise implementation of complex interventions within the context of trials, both across a range of populations, and focusing specifically on older people living with frailty. These overviews were conducted against a challenging backdrop of a lack of consensus in

terminology, resulting in the proposal of a new reporting tool which aims to simplify this challenge. The MOSAIC tool for reporting implementation processes of a complex intervention within a trial addresses a gap in the literature and provides a useful framework for researchers to use.

Further, the mixed methods SWAT outlined in this thesis investigated one example of a refinement strategy to optimise implementation of a complex intervention targeting older people living with frailty and explored the impact of this on participant outcomes. This SWAT aimed to investigate whether the use of a video animation, as compared with an information sheet and verbal introduction to the intervention, increased service users' uptake of the intervention, and engagement with the intervention. This demonstrated a novel use of SWAT methodology and a number of considerations and recommendations for researchers have been highlighted. The work carried out in this thesis has been a large body of rigorous research, carefully delivered and reported.

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Appendices

Appendix 1 Iterative development of search strategy for Systematic Methods Overview 1

1) Keywords: Complex intervention **AND** (implementation **OR** dose **OR** delivery **OR** reach **OR** fidelity)
   - ⇨ Carried out in Medline = 1988 references
   - ⇨ Screened approx. 1/3 of these references and identified around 35 relevant papers

2) Keywords: Complex intervention **AND** (implementation **OR** dose **OR** delivery **OR** reach **OR** fidelity) **AND** trial
   - ⇨ Medline = 803 references
   - ⇨ Contained around 2/3 of the relevant papers identified in search 1

3) Keywords: Complex intervention **AND (**implementation **OR** delivery)
   - ⇨ Medline = 1858 references
   - ⇨ Contained all of the relevant papers identified in search 1

4) Keywords: Complex intervention **AND** implementation **AND** trial
   - ⇨ Medline = 494 references
   - ⇨ Contained around 1/3 of the relevant papers identified in search 1

5) Keywords: Complex intervention **AND** implementation
   - ⇨ Medline = 1265 references
   - ⇨ Contained all of the relevant papers identified in search 1
   - ⇨ Decided to take this and replicate it in other databases
   - ⇨ Exported results to Endnote and deduplicated

Appendix 2 Search syntax for Systematic Methods Overview 1

((complex or multicomponent* or multi component or multiphase or multi phase or multi step* or multi factor* or multifactor* or multifac* or multi facet* or multidimension* or multi dimension*) adj5 intervention*).tw.

AND

Implement*

Appendix 3 Data Extraction Form for Systematic Methods Overview 1

First author	Year	Identifier	Title	Linked papers	Country	Design	Aim	Name of intervention	Who provided	Delivery mode	Delivery mode 2	Where was it mainly delivered	Duration of intervention	Duration 2
	Year of publication	ISRCTN or NCT number	Title of the paper		Where was the study carried out	Study design	Aim of the study/paper	A name or phrase to describe the intervention	List intervention provider/s (e.g. psychologist, nursing assistant)	Was it delivered Face-to-face, over the internet or via phone, or a combination of the above?	Was it delivered to participants individually or in a group?	Main location/s e.g. home, hospital or nursing home	Categorise as short, medium or long based on these definitions: Short = 4 weeks or less, Medium = 1 month to 6 months, Long = 7 months +	One-off or continuous

Tailoring	Target population	Use of a framework or approach for implementation process	Strategies for optimising implementation	Strategies for measuring implementation	What components of implementation were measured? What were the implementation outcomes?	Qual/quant/mixed	How was implementation data collected?	How well the intervention was delivered
Was the intervention allowed to be personalised, titrated or adapted, answer YES or NO.	Was the intervention targeted towards a specific population e.g. adolescents or patients with heart disease?	Did they use a framework or approach to inform the implementation process? If so, what was it? Or list, if more than one. E.g. MRC guidance for process evaluations	What methods or strategies have been used to optimise implementation. If none reported, or the focus is on measuring implementation, state none reported	What methods or strategies have been used to measure implementation. If none reported, or the focus is on optimising implementation, state none reported	E.g. adherence, fidelity, dose, reach etc	Is the approach quantitative/qualitative or mixed methods	E.g. questionnaires, interviews, surveys etc	Describe the extent to which the intervention was delivered as planned - e.g. % received the required dose

Appendix 4 PROSPER Animation Video Transcript

PROSPER Animation Video Transcript

PROSPER, helping you to get the most out of your life.

This is Maggie. She's 78 and lives alone, although her sons live close by and visit weekly. She's on her way into town to get her hair done, perhaps pop into the library. Afterwards she'll meet some friends for coffee before going home to a nice hot bath and a good book.

Not so long ago, Maggie spent her days indoors, watching the world go by. She was lonely since her dog Alfie died but she enjoyed visits from her boys and counted herself lucky. She couldn't really see the television anymore but there was always the radio to keep her company. Maggie wasn't sure why she stopped meeting up with friends. Some had passed away, and since her eyes had got worse, she wasn't confident getting on the bus anymore. She'd also been feeling a bit 'wobbly' after they'd changed her medication.

What happened to change Maggie's life was a visit from an Age UK worker. A letter from her GP first told her about PROSPER, a free service to help older people get the most out of their lives. Then, Andy, from Age UK called to ask if he could come and visit. Maggie and Andy had a really good chat about all kinds of things, including her love of books and gardening, the support from her sons, and how her fear of falling keeps her indoors and has stopped her getting a bath as often as she'd like. They also talked about what Maggie would like to

be different and how that might happen with a little bit of help. Together, Maggie and Andy made a plan.

Andy asked the GP to review Maggie's medication and she was prescribed new tablets that didn't make her feel dizzy. Next Maggie and Andy visited the opticians for an eye test. Able to see better and not feeling dizzy, Maggie and Andy took some bus trips to build her confidence. Maggie now has a bit more to spend since Andy helped her change her gas supplier. She uses this for treats like the hairdresser and gardener. Andy also arranged for an Occupational Therapist to assess Maggie's bathroom. Now she has grab rails fitted so she can use the bath and shower more safely.

Andy worked with Maggie for 12 weeks. He kept in contact with visits and by telephone. After two months, they reviewed the plan to see how things were going. At the end of the service, Andy left contact details for Age UK and other local groups. With new found confidence, Maggie felt able to go along by herself, happy in the knowledge that further support was available if she needed it.

What could you do with PROSPER support?

Appendix 5 PROSPER Participant Information Sheet

PROSPER
Personalised care planning for older people

PROSPER: A randomised controlled trial of PeRsOnaliSed care Planning for oldER people

Participant Information Sheet

We would like to invite you to take part in a research study called PROSPER

- Your GP surgery is taking part in a new study to test personalised care planning in older people.
- Your GP thinks that you are suitable to take part in the study, on the basis of information recorded in your medical records
- Before you decide whether to take part, we would like you to understand what this involves.
- Please read this information carefully and take time to decide whether or not you would like to take part. You can also discuss it with your relatives or friends if you wish.
- You are free to decide whether or not to take part. If you choose not to, it will not affect the care you receive from your GP in any way.
- You can keep this information sheet to remind you about the study.
- If you have any questions, please contact the study team using the details on this page.

Thank you for reading this information sheet

Contents

How to contact us

If you have any questions about this study, please contact:

Name: <<INSERT NAME >>
Telephone: <<INSERT NUMBER>>
Email:<<INSERT EMAIL>>

Chief Investigator: Prof Andrew Clegg

Tel: 01274 382096

1 Why are we doing this study?

As people get older, they can be more likely to have multiple long-term health conditions, need assistance or have challenges in their daily lives.

The aim of the PROSPER study is to look at how older people can possibly be helped to maintain and improve their wellbeing so they can get the most out of their lives.

This study is randomised, so some people will receive the PROSPER intervention (service), but others will continue with their usual form of care. Older adults in the intervention group will initially meet with an Age UK worker at home. They will then work together for around 12 weeks. The Age UK worker will identify areas that are important to the individual and work with them to develop a plan to achieve agreed goals. All the support offered is aimed at enabling individuals to live independent, enjoyable, and healthy lives for longer. Individuals will be contacted by letter and phone by an Age UK worker and an appointment for a home visit will be arranged.

Due to the design of this study, there is a chance you will not be offered the PROSPER intervention. You have around a 3 in 5 chance of being offered the intervention. Which people will be offered the intervention is decided by chance. This means that neither the GP surgery, nor the researchers who run the study, can influence this. Those not in the PROSPER intervention group will continue with their usual care and support. We will follow up people in both groups. In this way, we can compare the two groups of people at the end of the study.

We work closely with a group of independent lay people like you to ensure the design of this study is relevant and appropriate.

2 Why am I being asked to take part?

Your GP surgery has agreed to take part in this research. Based on your medical records, your GP has identified you as someone who would be suitable for the study. We are asking you to take part in order to find out whether the intervention is better than the usual way of providing care. We hope to involve around 1300 other people across Yorkshire and the North West

3 What will happen if I take part?

Do I have to take part?

No, your participation is voluntary, and you may withdraw your consent to take part at any time, without giving us a reason.

What will happen to me if I agree to take part?

If, after reading this information, you are interested in taking part, you will be asked to complete a reply form or text / call us and a researcher will telephone you to talk more about the study. They will ask you some

questions to make sure you are eligible to take part. They will also ask if we can collect some details such as the name of your GP Practice and your date of birth (for identification purposes only). They will then arrange a visit in your own home at a time convenient for you.

At the visit, the researcher will discuss the study in more detail and ask you to sign a consent form to document your willingness for us to collect your information.

If you are willing to take part:

1. If you are eligible, you will complete some short questionnaires about your general health and quality of life, day-to-day activities, and use of care services. This first visit is likely to last 1-2 hours. If we need to keep to short home visits due to COVID19, we may leave a booklet for you to complete in your own time. A researcher will then call you to collect the answers over the telephone.
2. We will ask you to complete follow up questionnaires 6 and 12 months later. The research team will send you a £10 gift voucher before the 12-month questionnaire as a token of appreciation for your help in completing the questionnaires.
3. We will collect information about your health and care from electronic health records, for example hospital attendances and admissions.
4. If you are randomly allocated to the "intervention" group of the study, you will be contacted first by letter, and then by telephone by a team member from Age UK to arrange a visit in your own home. The Age UK worker's name will be made known to you before their visit in case you are worried about a stranger coming to your home.
5. We will also ask a small selection of participants if they would be willing to discuss their experience of the PROSPER intervention with a researcher. If selected, we would contact you separately and give you full information before asking if you want to take part. You do not have to do this but can still take part in the study.

4 What are the advantages and risks of taking part?

We hope that this study will improve quality of life for older people in the future. If you are in the intervention group, you may benefit by having a personalised care plan, but we cannot say that you will definitely experience an improvement

Agreeing to complete questionnaires will mean giving up some of your time to do this.

We do not expect there will be any direct risks or disadvantages to taking part.

5 What information will you collect about me?

As part of the PROSPER study we will:

1. Ask you to complete some questionnaires about yourself.
2. Collect information about you from electronic health records for example hospital attendances and admissions.

3. If you agree to take part, we may also ask you some questions about your experience.

How will you collect this information?

Personal Data

Questionnaires:

We will ask you to complete 3 sets of questionnaires over a total of 12 months. These questionnaires will ask you about your general health, day-to-day activities, quality of life and use of care services. The first set would be completed in your own home once you have agreed to take part, with the support of your local researcher. These questionnaires are likely to take between 40-60 minutes to complete.

We will also contact you again 6 and 12 months after you agreed to take part in the study to ask you to fill in another set of questionnaires. These will be posted to you at your home address or you will be sent a link by email to complete online if you prefer. If you would like any help to complete these questionnaires we can arrange for a researcher to contact you to either complete them over the phone, or possibly visit you at home.

Electronic Health Records:

Your medical records are held electronically by your GP practice and hospital. There are different systems that can be used to hold data, dependent upon your care provider.

We would like to access these systems so we can ensure we are able to collect the information we require. This may be from:

Hospital records: NHS Digital holds details of all admissions, reasons for admissions, outpatient appointments, and A&E attendances at NHS hospitals in England – this data is known as 'Hospital Episode Statistics' or 'HES'. NHS Digital also holds information on date and cause of death.

GP records: Most GP practices hold electronic health records (in systems called SystmOne, or EMIS Health) with information about your care provided by your GP (number and type of appointments, care home admissions and medications).

With your agreement we would like to access your data held in these electronic records to avoid asking you more questions about your recent care. To do this we need to send your identifiable data (for example your initials, sex, date of birth, NHS number, and postcode) to each system provider to obtain the correct information from these records.

The data from these sources will be sent via secure methods to the Clinical Trials Research Unit (CTRU) at the University of Leeds (where the study is being centrally coordinated) for processing and analysis.

6 Will my information be kept confidential?

Bradford Teaching Hospitals NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for

this study. This means that we are responsible for looking after your information and using it properly. Bradford Teaching Hospitals NHS Foundation Trust will put arrangements in place to keep the collected identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

The Clinical Trials Research Unit (CTRU) at the University of Leeds will collect information from you and/or your medical records for this research study in accordance with our instructions.

Most of the information needed for the study will be collected online; some information will be collected on paper forms and sent directly to the study team at the CTRU using standard Royal Mail post. In some cases we send information by secure email. You will be allocated a unique study number, which will be used along with your date of birth and initials to identify you instead of your name.

The CTRU will hold a copy of the consent form that you sign, which will have your name on it. Your name, address, phone number(s) and email address (if you have one) will also be given to the study team at the CTRU and to the researcher(s) on the study. This is so they can contact you about the study, when they need to.

Your data will be entered onto a secure database held at the CTRU. All access to data and databases will be restricted to the staff who require access to process and analyse the data.

Your data may be used in future by the organisations involved in this research for evaluation, teaching and training purposes relating to the provision of NHS care and treatment and for academic and non-commercial research purposes. If this happens, the information would be anonymised so that no-one would be able to identify you from it.

How will my information be stored?

Information collected about you will be processed by a study data manager and study statisticians at the CTRU and entered and stored on CTRU systems. Your information will only be accessed by the research team.

Identifiable data will not be accessed by any third parties outside the research team. All the data you give us, including personal details such as name, date of birth, address, postcode, NHS number will be securely stored for up to 10 years after the end of the study and then destroyed.

Will you share any of my information?

Although the information we collect about you is confidential, should you disclose anything to us which we feel puts you or anyone else at risk, we may feel it

necessary to report this to the appropriate persons. In these circumstances, the researcher or Age UK worker would report their concerns to their manager and consider contacting the person responsible for adult safeguarding in their organisation. In addition, we would inform your GP if you scored highly on the depression measure.

It is possible that the information collected about you might be shared with other research teams to answer new research questions in the future. If this happens, the information would be anonymised so that no-one would be able to identify you from it.

We will share identifiable information when requesting information from Electronic Health Records to ensure we collect the correct information. Information will be securely shared with these system providers and in accordance with the Data Protection Act 2018.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- a leaflet is available from www.hra.nhs.uk/patientdataandresearch
- by contacting Anne Heaven, PROSPER Programme Manager, Tel: 01274 382815, Email: anne.heaven@bthft.nhs.uk
- Bradford Teaching Hospitals NHS Foundation Trust Privacy Notice is available to read at https://www.bradfordhospitals.nhs.uk/privacy-statement/

7 More information about taking part

What will happen if I do not want to carry on with the study?

You are free to withdraw from the study at any time and without giving a reason and without affecting your care in any way. If you did wish to withdraw, you would need to tell us (contact details can be found on the first page of this information sheet). We would then stop collecting information about you. Data already collected would remain on file and will be included in the final study analysis.

What happens to my care when the research stops?

Your help with this study is complete once we receive your 12-month follow-up questionnaire. You will continue with your usual care as before. It is up to your GP surgery if they make any continuing changes to the service they provide.

What if there is a problem?

If anything about your care, treatment or health worries you, you should speak to your GP. If you have a concern about any aspect of this study, you should speak to the Programme Manger or study team (contact details on first page) who will do their best to answer your questions. Alternatively, you can ask to speak to the practice manager at your GP surgery who can advise on local NHS complaints procedures or contact the customer contact centre/patient feedback

service at your local Clinical Commissioning Group (CCG). Details can be found on the NHS Choices website. There are no special compensation arrangements in place for this study.

What happens if new information about the study becomes available?

Sometimes during the course of a study, new information becomes available. If this happens your GP will let you know about it and you can decide if you want to continue in the study.

We will also keep you updated regarding study progress via newsletters. If you wanted to speak to anyone in the study team at any point about your participation, please use the contact details on the first page of this information sheet.

What will happen to the results of the research study?

When the study is complete, the results will be published in a medical journal and all GP surgeries will be sent a summary of the results, but no individual participants will be identified. We will also include a summary of the results in a newsletter sent to people who took part.

Who is organising, funding and reviewing the research?

The study is being organised and supervised by the Bradford Teaching Hospitals NHS Foundation Trust. It is funded by the Department of Health. All research is looked at by an independent group of people called a Research Ethics Committee to protect the safety, rights, wellbeing, and dignity of those taking part. This study has been reviewed and approved by Bradford Leeds Research Ethics Committee.

What do I need to do now?

Please let us know if you would like to take part in the study by completing the attached reply slip – **YES**- you would like to take part, **MAYBE** - you would like more information, or **NO** - you would not like to take part. Place this form in the pre-paid and addressed envelope included and post it back to us. You can also call or text the research team.

If we do not hear from you within 7 days, we may try to call you to find out if you are interested in taking part.

8 Questions?

If you have any questions or would like more information, please contact us using the contact details on page 1 of this information sheet.

If you would like further information about research in general, the UK Clinical Research Collaboration (a partnership of organisations working together on research in the UK) have published a booklet entitled 'Understanding Clinical Trials', you can access this here: www.ukcrc.org.

Thank you for taking the time to read this information sheet.

Appendix 6 PROSPER SWAT Training Materials

1

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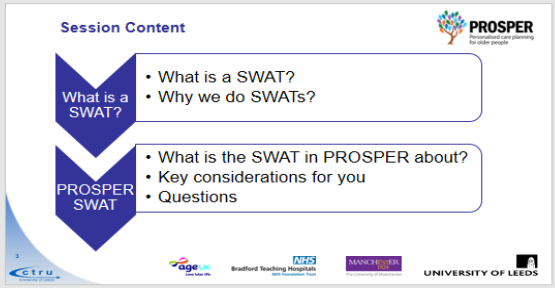

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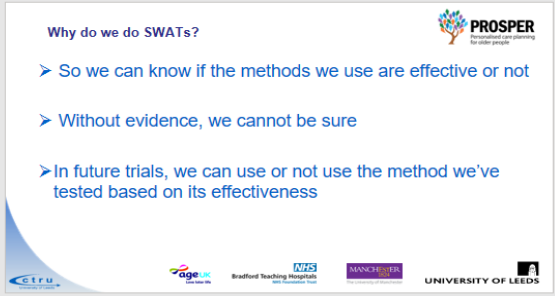

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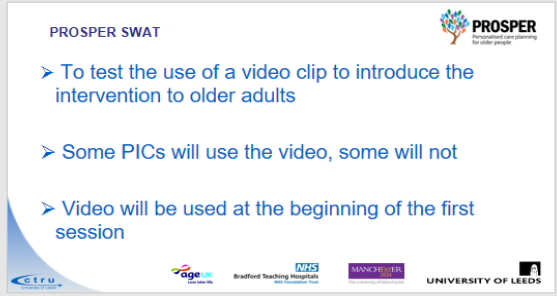

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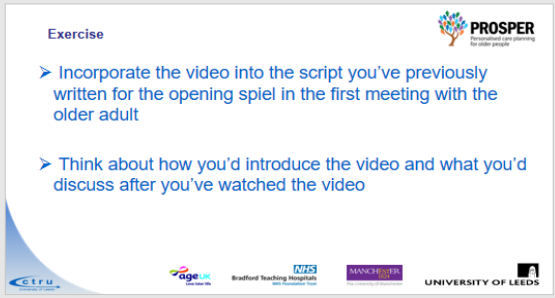

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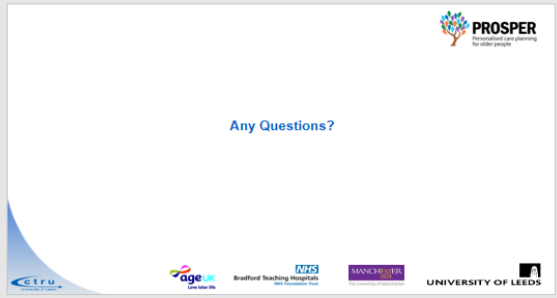

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Appendix 7 CRF for Primary Outcome

ISRCTN16123291

PROSPER
Personalised care planning for older people

FORM 50
Page 1 of 2

Making Contact & Initial Visit

Participant Initials		Participant Date of Birth	Day Month Year	Participant ID	Site Code	Trial No

- **To be completed for every intervention participant**
- **Return to the CTRU within 1 week of form completion**

Age UK Worker Allocation

Name of Age UK worker leading the case

CTRU use only — Age UK ID

Were you the original named Age UK worker for this case? ☐ Yes ☐ No

If no, please give reason for change in Age UK worker

Named worker on leave	☐ Yes	☐ No
Named worker case load too high	☐ Yes	☐ No
Clinical reasons	☐ Yes	☐ No
Other reason	☐ Yes	☐ No

Please specify

Making Contact

Date intervention letter sent — Day Month Year

Was telephone contact successful?

☐ Yes

☐ No → **STOP, sign and date the footer**
Complete **F56 Intervention Discontinuation**

Was a date for the initial visit arranged?

☐ Yes → Planned date of initial visit — Day Month Year

☐ No → **STOP, sign and date the footer**
Complete **F56 Intervention Discontinuation**

Did the initial visit take place on the first attempt?

☐ Yes *(no rescheduling required)*

☐ No → Number of unsuccessful visits

Did the initial visit eventually take place? ☐ Yes → Please continue completing the form

☐ No → **STOP, sign and date the footer**
Complete **F56 Intervention Discontinuation**

Completed by — Date — Day Month Year

Form continues on next page ►►

Entry into MACRO — *Computerised* — *Date* — *Initials*

ISRCTN16123291

PROSPER
Personalised care planning for older people

FORM 50
Page 2 of 2

Making Contact & Initial Visit

Participant Initials		Participant Date of Birth	Day Month Year	Participant ID	Site Code	Trial No

Visit Details

Date of initial visit: Day Month Year

Start time: Hours : Minutes

End time: Hours : Minutes

Was the video played?

- ☐ Yes
- ☐ No → Please give reason
- ☐ N/A *(Age UK worker not selected to implement video)*

Were the following components of the intervention explained?
(Tick yes or no for each)

	Yes	No	**If not explained**, please record reason
Service time limits	☐	☐	
Key contacts	☐	☐	
What is and is not available	☐	☐	
Goal setting and action planning	☐	☐	

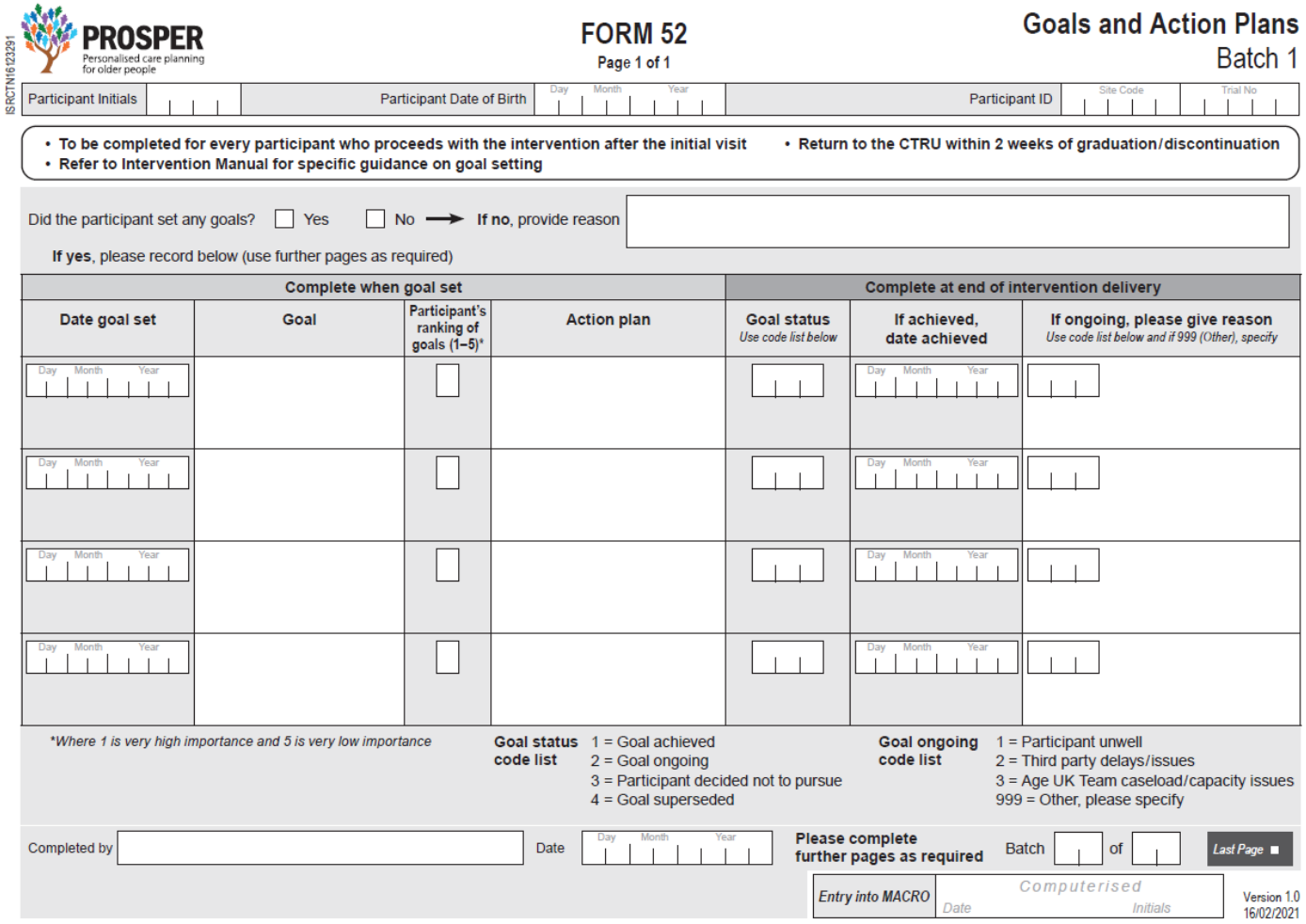
Is the participant going to proceed with the intervention?

- ☐ Yes → What is the estimated date of graduation? *(12 weeks from date of first visit)* Day Month Year
- ☐ No → Complete **F56 Intervention Discontinuation**

Completed by | Date: Day Month Year | Last Page ■

Entry into MACRO	Computerised Date	Initials

Appendix 8 CRF for Secondary Outcomes



PROSPER
Personalised care planning for older people

ISRCTN16123291

FORM 52
Page 1 of 1

Goals and Action Plans
Batch 1

Participant Initials		Participant Date of Birth	Day Month Year	Participant ID	Site Code	Trial No

- **To be completed for every participant who proceeds with the intervention after the initial visit**
- **Refer to Intervention Manual for specific guidance on goal setting**
- **Return to the CTRU within 2 weeks of graduation/discontinuation**

Did the participant set any goals? ☐ Yes ☐ No → **If no**, provide reason

If yes, please record below (use further pages as required)

Complete when goal set				Complete at end of intervention delivery		
Date goal set	**Goal**	**Participant's ranking of goals (1–5)***	**Action plan**	**Goal status** *Use code list below*	**If achieved, date achieved**	**If ongoing, please give reason** *Use code list below and if 999 (Other), specify*
Day Month Year					Day Month Year	
Day Month Year					Day Month Year	
Day Month Year					Day Month Year	
Day Month Year					Day Month Year	

*Where 1 is very high importance and 5 is very low importance

Goal status code list
1 = Goal achieved
2 = Goal ongoing
3 = Participant decided not to pursue
4 = Goal superseded

Goal ongoing code list
1 = Participant unwell
2 = Third party delays/issues
3 = Age UK Team caseload/capacity issues
999 = Other, please specify

Completed by | Date Day Month Year | **Please complete further pages as required** | Batch ☐ of ☐ | *Last Page* ■

Entry into MACRO | *Computerised* Date Initials

Version 1.0
16/02/2021

Appendix 9 Qualitative Interview Topic Guides

Semi-structured Interview Topic Guide

Older Adults

Introduction

Thank you for agreeing to take part in this interview. I would like to talk to you today about your experience with the PROSPER service so far and the sessions you have had with your Age UK worker. I am interested in particular in what factors have influenced people such as yourself to take up the PROSPER service.

If at any point you would like to stop or take a break, just let me know. Don't worry if you feel like you can't think of anything to say, there are no right or wrong answers. I may ask you to talk about some things in a little more detail, but don't worry if you feel you don't have anything else to say, or don't wish to say any more.

Although I will be audio recording this interview, everything you say is confidential, and nothing will be linked back to you. You can also let me know if you wish to stop the interview at any time.

Do you have any questions? Is it OK to start the interview? I am starting the recording now.

Questions:

- Please can you tell me about what happened at the first meeting with your Age UK worker, in as much detail as you can remember?

  Prompts:
  What sort of things did you discuss with the Age UK worker?
  In particular, what did you discuss in relation to the PROSPER service?

- How did you feel about taking up the PROSPER service, following that initial meeting with your Age UK worker?

  Prompts:
  Was there anything in particular they said that encouraged you to take up the service? Or anything that put you off?

- What information, if any, did the Age UK worker show you to help you decide?

  Prompts:
  Were you given any handouts/leaflets?
  If they don't mention the video, ask if they remember being shown anything on the laptop i.e. a video

Did you get a chance to look at the cartoon/video clip that Age UK have prepared that explained the service?

- How did you go about making the decision? What motivated you to take up the PROSPER service?

  Prompts:
  What information was most useful to you?
  What helped you to make the decision?
  Did you talk to anyone else about it?

- **If they remember the video:** What do you remember about the cartoon/video?

  Prompts:
  Did the video clip help you to understand the PROSPER service/ decide whether to take up the service or not?
  Did you feel you would benefit from using the service?
  Did you feel you could relate to the character Maggie? In what ways?

- **If they remember the video:** What did you think of the cartoon/video?

  Prompts:
  How easy was the speech to understand? Could you hear it clearly?
  How did you find the storyline? Was it easy to follow?
  Did you feel it was too fast or too slow?
  How did you find the video visuals? Did you notice for example that it switched from black and white to colour?
  Was there anything you disliked about the video or anything you would change?

- How well do you feel you understood the PROSPER service after the first session?

  Prompts:
  If you had to describe the PROSPER service to a friend or family member, how would you describe it?

- How are you getting on with the PROSPER service so far?

  Prompts:
  How many sessions have you had with your Age UK worker? Has it been helpful?
  What kinds of things have you discussed?

- **If relevant:** It sounds like you have got a plan going on – can we talk a little about that?

  Prompts:

What do you think lies ahead in the next few sessions?

- **If they mention any plans/goals:** How do you feel about the plans you have made?

  Prompts:
  Have you had to make plans like this before?
  Do you feel it's helpful or useful for you?

- Focusing in particular on the first session with your Age UK worker and the way in which the service was introduced to you, do you have any suggestions for things we could improve?

  Prompts:
  Was there anything that did not help you to understand the service?
  Was there anything that put you off taking up the service?

- Is there anything we haven't covered about your experiences with PROSPER that you'd like to talk about now?

Thank you for your time in talking to me. I am going to turn off the audio recorder now.

Just to let you know a little bit about what happens next. The information you've given is very valuable and I will now write it up for my PhD. Would you be interested in receiving a short summary of the results when they are ready?

Please keep your information sheet so you have my contact details in case you have any questions or need to get in touch for any reason.

Semi-structured Interview Topic Guide

Age UK Workers

Introduction

Thank you for agreeing to take part in this interview. I would like to talk to you today about your experience working for the PROSPER service so far and the sessions you have had with the older adults. I am interested in particular in what factors have influenced people to take up the PROSPER service.

If at any point you would like to stop or take a break, just let me know. Don't worry if you feel like you can't think of anything to say, there are no right or wrong answers. I may prompt you to talk about some things in a little more detail, but don't worry if you feel you can't or do not wish to answer any further.

Although I will be audio recording this interview, everything you say is confidential, and nothing will be linked back to you. Your employer will not know who made what comment. You can also let me know if you wish to stop the interview at any time.

Do you have any questions? Is it OK to start the interview? I am starting the recording now. [date, time]

Questions:

- Please can you tell me a little bit about what typically happens during the first meeting with the older adult?

  Prompts:
  How did you find explaining the PROSPER service to the older adults?

- Can you tell me about any barriers you experience when discussing the PROSPER service with the older adult?

  Prompts:
  Do older adults ever indicate that they feel the service is not appropriate for them?
  What reasons do they give for this?

- What resources do you use in your first meeting with the older adult?

  Prompts:
  Do you use handouts or leaflets?
  Do you show them anything on the laptop?

- How do you feel the video clip helps or hinders the process?

  Prompts:
  Does it help the older adults to understand the service? Why?
  Does it make things confusing or complicated? Why?

- How do the older adults react to the video clip?

  Prompts:
  Do the older adults generally react positively or negatively to the video?
  Do you think the video makes a difference in them deciding to use the service or not?

- Were there any issues that arose when using the video?

  Prompts:
  Any difficulties with playing the video?
  Was the audio loud enough?
  Any problems with visuals?

- Do you have any suggestions for how the video could be improved?

  Prompts:
  Slow down or speed up?
  Addition of more characters/examples?
  Made simpler?

- From your experience, what other things would help to introduce and explain the intervention?

Thank you for your time in talking to me. I am going to turn off the audio recorder now.

Just to let you know a little bit about what happens next. I will be analysing the data and writing up findings. Would you be interested in receiving a short summary of the results when they are ready?

Please keep your information sheet so you have my contact details in case you have any questions or need to get in touch for any reason.

Appendix 10 MOSAIC Tool

A: Intervention Characteristics
• Target population • Intervention Name • Intervention Deliverer Profession e.g. Nurse • Delivery Mode: Face to face or remote • Delivery format: Group or individual • Duration: Short (four weeks or less), Medium (five weeks to six months), Long (six months or more) • One-off or continuous • Tailoring or personalisation allowed (Yes/No)

B: Methods used to Measure Intervention Implementation				
Design	**Training**	**Delivery**	**Receipt**	**Enactment**
• Framework used to inform implementation • How were active components of the intervention operationalised? • Was the intervention co-designed with the target population? (Yes/No) • Was there apriori specification of the treatment dose? (Yes/No) • Was implementation monitored throughout the trial? (Yes/No) • Were there any adaptations to the intervention during the trial? (Yes/No)	• What did training entail? • Was training evaluated in some way? (Yes/No) • Qualitative and/or quantitative or mixed-methods approach? • What data collection methods were used? E.g., interviews, surveys, trial data	• What components of delivery were measured? E.g., fidelity • Qualitative and/or quantitative or mixed-methods approach? • What data collection methods were used? E.g., interviews, surveys, trial data	• What components of receipt were measured? E.g., reach • Qualitative and/or quantitative or mixed-methods approach? • What data collection methods were used? E.g., interviews, surveys, trial data	• What components of enactment were measured? E.g., engagement • Qualitative and/or quantitative or mixed-methods approach? • What data collection methods were used? E.g., interviews, surveys, trial data

C: Strategies employed to Optimise Intervention Implementation				
Design	**Training**	**Delivery**	**Receipt**	**Enactment**
• Stakeholder Involvement • Piloting the intervention • Manualising procedures • Fixed core components with tailoring allowed • Documenting or predicting implementation issues • Other – provide detail	• Train-the-trainer approach • Standardised training scheme • Booster session • Manual or other resources • Expert trainers • Web-based training • Interactive training • Other – provide detail	• Support or supervision • Monitoring • Interdisciplinary teams • Stakeholder involvement • Facilitation • Champions • Technological aids • Tailoring and flexibility • Other – provide detail	• Scripted summaries • Self-monitoring • Co-creation of tools • Participant commitment agreement • Teach-back techniques • Clear schedule and reminders • Progress report • Shared decision making • Checklists • Financial compensation • Other – provide detail	• Support post intervention end date • Home evaluation after intervention ended • Maintenance phase using phone calls • Session summary document • Clear instructions • Time to practice • Regular telephone support • Other – provide detail