The feasibility of undertaking a complex intervention trial in English care homes

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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.

Chapter 1: Section 1.2 Thesis Context: The PATCH trial - is based on the 'posture and mobility in care homes' (PATCH) trial protocol publication*, for which I was lead author.

Chapters 4 and 6 include some of the quantitative data included in the PATCH trial results publication**, for which I was also lead author. Statistical summaries of data return rates and intervention compliance were mostly produced by statistical colleagues at the Clinical Trials Research Unit, University of Leeds. It is made clear within each chapter where this is the case or where I have produced new summaries from the raw data.

My qualitative findings reported in Chapter 6 (generated solely by me as part of my PhD studies) were included in a jointly authored paper*** examining the inter-rater reliability of staff proxy ratings of residents' quality of life compared to residents' own reports of their quality of life.

* Graham L, Cicero R, Clarke D et al. PATCH: posture and mobility training for care staff versus usual care in care homes: study protocol for a randomised controlled trial. Trials 19, 521 (2018). https://doi.org/10.1186/s13063-018-2863-5

** Graham L, Ellwood A, Hull K et al. A posture and mobility training package for care home staff: results of a cluster randomised controlled feasibility trial (the PATCH trial). Age and Ageing, afaa046, https://doi.org/10.1093/ageing/afaa046

*** Kelly C, Hulme C, Graham L et al. Inter-rater reliability of care home staff's proxy judgements with residents' assessments of their own health-related quality of life: an analysis of the PATCH trial EQ-5D data. Age and Ageing, *50*(4), pp.1314-1320

I was co-applicant and project lead for the PATCH trial; and my PhD was nested within it. I managed trial delivery - overseeing all trial procedures. Specifically, my role included: writing the protocol; applying for research ethics committee approvals; identification and recruitment of care homes, as well as on-going communications with care home managers and staff; leading the design of data collection forms, tools and approaches; collecting data (alongside other trial researchers - AE, IP); working with the trainers (KH, JF) to develop materials and co-ordinate intervention delivery; designing and testing a tool to monitor intervention adherence; monitoring trial progress; and managing team and oversight group meetings.

The researchers (AE, IP) recruited residents to take part in the trial; the data management team (MG) at the Clinical Trials Research Unit (CTRU) entered and cleaned the data collected by the researchers and myself from care homes; the statistical team (BC, MH, AFa) at CTRU provided statistical summaries of the data collected, in order to report the main feasibility findings.

Other authors of the above publications were responsible for aspects of the project that are not included in my PhD: DC, RH and RW led the process evaluation interviews with staff; CH and CK were responsible for the health economics analysis; and AFo was the Chief Investigator for this project.

Acknowledgements

Abstract

Background: The health and well-being of care home residents is under-researched, but studies in care home settings are complex and many researchers report methodological challenges.

Aims: 1) identify systematically the challenges in conducting intervention research in care homes in the British Isles; 2) explore empirically, within a trial, the research challenges in this setting and thereby make recommendations for research practice.

Literature review: To frame my empirical studies I systematically searched the literature for methodological and practical challenges that intervention-researchers have faced in care homes.

Empirical study methods: I adopted a pragmatic perspective, using a multi-method approach to explore identified challenges. Qualitative and quantitative data were collected to: understand the challenges of intervention delivery; explore how to monitor intervention uptake in care homes; investigate data collection methods; investigate people's experiences of providing data; and explore alternative data collection approaches.

Study findings: Modifiable factors were identified which influence staff engagement with training; monitoring staff members' use of new skills through non-expert observation was difficult. Data acquisition worked well when researchers collected data directly from care notes or from staff, but return rates were poor for self-completed data. Good compliance masked inaccuracies in the dataset due to: staff having difficulty making proxy judgements about residents; outcome measures being inappropriate for residents; and care notes being complex to navigate, misaligned with research requirements, and incomplete when compared to NHS-derived data. Many residents could not provide data due to cognitive impairment; better data return rates came from researcher observation, although there were some concerns about accuracy.

Implications: I explored reported challenges in care home research in more detail, identifying reasons behind some of these difficulties. I suggest ways to adapt and refine methods to enhance care home engagement, optimise staff training, and tailor data collection approaches to the needs of the care home environment.

Table of Contents

Table of Figures

Table of Tables

List of Abbreviations

6-CIT	Six-item Cognitive Impairment Test
A&E	Accident and Emergency
ADL	Activities of Daily Living
AUASR	Academic Unit for Ageing and Stroke Research
BGS	British Geriatrics Society
CCAM	Continuing Care Activity Measure
CENTRAL	Cochrane Central Register of Controlled Trials
CH	Care Home
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CONSORT	Consolidated Standards of Reporting Trials
CQC	Care Quality Commission
cRCT	Cluster Randomised Controlled Trial
CRF	Case Report Form
CSP	Chartered Society of Physiotherapy
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTRU	Clinical Trials Research Unit
DNA	Did Not Attend
ENRICH	Enabling Research In Care Homes
EPR	Electronic Patient Record
EQ-5D-5L	EuroQoL-5 Dimension-5 Levels
FAC	Functional Ambulation Classification
GP	General Practitioner
HRA	Health Research Authority
ID	Identity
KCES	Kiersma-Chen Empathy Scale
LIHS	Leeds Institute of Health Sciences
MCA	Mental Capacity Act

MRC	Medical Research Council
NC	Nominated Consultee
NICE	National Institute for Health and Care Excellence
NICHE	Nurturing Innovation in Care Home Excellence
NIHR	National Institute for Health Research
NHS	National Health Service
PAM-RC	Physical Activity and Mobility in Residential Care scale
PAT	Postural Assessment Tool
PATCH	Posture And mobility Trial in Care Homes
PC	Personal Consultee
P-CAT	Person-centred Care Assessment Tool
PPI	Patient and Public Involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QUALYs	Quality Adjusted Life Years
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SCTP	Skilful Care Training Package
SD	Standard Deviation
SoA	Statement of Activities
SoE	Schedule of Events
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SSCR	School for Social Care Research
UC	Usual Care
UK	United Kingdom
UPRN	Unique Property Reference Number
VAS	Visual Analogue Scale

Chapter 1 Introduction

In this thesis I identify the challenges that researchers face when undertaking intervention research in care homes in the UK, investigate these challenges within the context of a cluster randomised controlled trial (cRCT) in English care homes, and make recommendations for the conduct of future research in this setting. This chapter presents the background to my work, the context within which it was undertaken, and my aims and objectives. Part 1 of this chapter provides an introduction to and rationale for my studies, whilst Part 2 describes the cRCT within which my studies were situated.

1.1 PART 1 - Introduction and rationale

1.1.1 Background

1.1.1.1 The care home sector

The Office for National Statistics predicts that the number of persons aged 85 and over will double between 2016 and 2041, from 1.6 million to 3.2 million (1). One consequence of this growth is an increase in demand for long-term care (2) and the commensurate need to ensure that optimal care is achieved in this setting. In the United Kingdom (UK) more than 410,000 older people live in 11,300 care homes (3) which vary in size from fewer than 20 to more than 100 beds. Care homes provide long-term residential care (4, 5) for people who require assistance with activities of daily living and personal care, with some homes also providing nursing care. Residents of care homes are amongst the frailest members of our population, with complex health and social care needs (6). Length of stay is variable, with life expectancy shorter for nursing compared to residential home residents (7).

Care homes are widely recognised to be complex, heterogeneous settings: although described as a collective entity, care is provided by multiple independent, mostly for-profit or voluntary (not-for-profit) organisations (8). In England 75% of care home providers own just one home, with these homes providing 38% of the total number of available resident beds. (9) There is also diversity in the physical nature of care homes: some are large, purpose-built facilities of varying ages (which thereby offer a varying quality of infrastructure), whilst others were originally private homes that were converted and adapted to provide care. (10)

A report published by the British Geriatrics Society in 2011 (6), stated that health care for care homes in the UK is characterised by "unmet need, unacceptable variation and often poor quality of care"; whilst a Healthwatch publication (11) more recently reported variable and often poor access to health services, especially to a comprehensive range of services to meet residents' needs. Despite the levels of frailty and health needs within care homes, there has been no standard model of co-ordinated health care to meet residents' needs. In some regions of England, an Enhanced Health in Care Homes (EHCH) programme (12) has been trialled over recent years, with local successes (13) informing the inclusion of this initiative in the NHS Long Term Plan. (14) This framework for providing care to residents aims to increase integration between care homes, NHS and voluntary service providers, thereby offering the standard of care for residents that would be expected if they lived in their own homes. This approach is not yet routinely available across the country, nor is it straightforward to implement, and the British Geriatrics Society have made recommendations for the NHS to work with care homes to support roll out of this initiative. (10)

Care staff working in care homes are poorly paid, earning little over the minimum wage (15); they receive minimal training, which is not standardised, and they have no career structure with few options for progression (16). Concern has long been expressed about the quality of care provided to residents, with suggestions that training provision should be improved and that there should be a requirement for minimum qualifications for care assistants (17). There is great difficulty with recruitment and retention of care and nursing staff in care homes (9, 17), and this high staff turnover adds to the difficulty of providing quality care for residents. The British Geriatrics Society have again recently highlighted this problem, (10) recommending more government funding to support care home staff training - to improve their knowledge, skills and competencies.

1.1.1.2 Care home residents

The care home population has changed dramatically over recent years to include far more people with severe frailty and illness (18, 19). Typically, residents are aged over 80 years, and have high levels of dependency and multiple morbidities - with a high prevalence of dementia (around 62%) (4). It is estimated that over three-quarters of residents need help with their mobility or are immobile (17); this dependency includes difficulty performing every-day self-care tasks such as washing, dressing and eating. Regardless of physical dependency, residents generally tend to spend most of their time inactive (20-22), spending up to 13 hours of their waking day sitting or lying (23).

They have many healthcare needs, but they are often not satisfactorily met by the health care system: residents have limited access to allied health professionals (24), access to medical care is variable and uncoordinated (25), and ways to establish effective healthcare in these settings remain poorly understood (5). The EHCH aims to address these problems but, as yet, integrated and co-ordinated care is not well-established.

1.1.2 Rationale for my studies

I had previously been a co-applicant and trial manager on two large care home trials (26, 27), and had experienced first-hand the challenges of conducting research in care homes. Many of the complexities of the setting described above (for example, uncoordinated health care, high staff turnover, and a frail population with high levels of cognitive impairment) also create challenges for research. Intervention research, particularly in the form of randomised controlled trials, is vital for the advancement of care practices to support residents' health and well-being; however, it requires considerable engagement from the care home community (for example, involvement in intervention training, use of new skills, and repeated provision of data) - much more so than for observational or other non-interventional research such as surveys or interviews. This research complexity, in the context of sector-related complexities, appears to have deterred researchers from working with care homes. This avoidance is evidenced by the relatively few intervention studies undertaken in care homes compared to NHS settings, despite more than twice as many people residing in care homes than in hospital at any given time (19).

Over the last 10 years national funding bodies have included social care research in their remit (19) following the public expression of concerns that care home residents were under-represented in research (28). There are now an increasing number of research studies taking place in care homes (29), but the research base is still relatively under-developed (19), with recent studies still reporting challenges that suggest the need for enhanced or adapted research methods.

A scoping review I undertook in preparation for my PhD confirmed to me that researchers recognise the challenge of undertaking research in care homes. This review identified some existing summaries of care home research challenges and solutions - for example, findings and recommendations from NIHR-funded studies (19),

and a detailed report designed to aid understanding of the complexities of care home life (17). Individually reported challenges include difficulties with: the recruitment and retention of a frail and cognitively impaired population (30); care home staff's lack of engagement with research; and the uniqueness (19) and heterogeneity of the care home environment. Researchers have also discussed the need for interventions (31) and for data collection approaches (19) to be adapted specifically to care homes, noting that what may work in a hospital or community setting does not necessarily translate to the care home environment. I found published methodological observations and advice based on the experience of care home researchers (8, 32), with solutions intended to improve care home research mainly focusing on field researchers requiring excellent interpersonal skills, knowledge of the sector, and time and flexibility to approach and manage research effectively in this setting (8, 19, 30, 33).These articles were mostly based on qualitative researchers' experiences and are not based on systematic review. Whilst there was discussion of implementation difficulties across many individual reports of intervention research in the care home setting (29, 34), a review and synthesis of these methodological challenges had not been undertaken. A comprehensive review of the literature was thus an important first step to fully understand the difficulties of implementing intervention research in care homes.

Given the many individual reports of problems, but the limited reported solutions to these problems, it also seemed timely and important to explore these difficulties in more detail in specifically designed empirical studies. I was able to do this within the context of the 'posture and mobility in care homes' (PATCH) trial which I describe in the second part of this chapter (Section 1.2)

1.1.3 Aims and objectives

The aims and objectives of my PhD work were as follows:

Aims:

- To identify systematically the challenges that researchers face when conducting intervention research in care homes in the British Isles.

- To explore empirically, within the context of the PATCH trial, the challenges identified - in order to make recommendations for future research.

Objectives:

My first objective was to undertake systematically a review of the literature to identify the challenges of conducting intervention research in care homes in the British Isles.

The objectives for my subsequent empirical studies are outlined below; however, these were clarified following my review of the literature, so are specified more clearly by articulating the associated research questions in Chapter 3.

1. To identify the challenges of providing intervention training to care home staff, and the difficulties of monitoring and reporting the use of new skills.

2. To understand researchers' and care staff members' experiences of collecting and providing data for care home research.

3. To explore the acceptability of various methods of obtaining trial data in care home research.

An overarching objective was to make recommendations, based on my literature review and empirical findings, for the future conduct of intervention research in care homes.

1.1.4 Thesis overview

<u>Systematic review</u>

My first step was to review systematically the care home literature to identify the range of challenges that researchers have faced in their conduct of intervention research in care homes. My literature review examines two kinds of publication: 1) papers reporting the results of individual projects - included because I expected that the discussion sections might mention the challenges experienced by the team during research implementation, and 2) papers specifically focussed on reporting the challenges encountered. I took this approach in order to establish a representative picture of the complexity of research in British care homes. My findings describe this complexity, and I identify challenges related to: research design in this setting, research team engagement with care home staff and residents, available data collection tools and approaches, intervention uptake by residents and staff, participant recruitment, and participant retention. The literature review is reported in Chapter 2.

<u>Empirical studies</u>

My empirical studies were situated within the PATCH trial and framed by my review of the literature. Chapter 3 describes the methodology and methods of my empirical studies. First, I explain why I adopted a pragmatic perspective and then go on to describe the multi-method approach that aligned with this perspective. I collected data from multiple sources - using data obtained for the purposes of the PATCH trial as well as data collected solely for my work. I used these data to explore research processes deemed challenging by the authors identified in my review of the literature, and which I was able to investigate during the conduct of the PATCH trial. Qualitative and quantitative data were collected to: understand the challenges of intervention delivery (Study 1) and explore how to monitor intervention uptake in care homes (Study 2); and investigate data collection methods (Study 3), people's experiences of providing data (Study 4), and alternative approaches to data collection (Study 5). Participants involved in my studies were: those taking part in the PATCH trial (residents and staff); care home staff who provided data for the trial; researchers who recruited residents then collected data from and about them; and the physiotherapists who delivered the intervention training.

In the final chapter I consider the findings of my literature review and empirical studies, and their implications for future research and practice in care homes.

1.2 PART 2 - Thesis context: the PATCH trial

The empirical studies outlined above were undertaken within the context of the 'posture and mobility in care homes' (PATCH) trial. In this section I summarise the PATCH trial rationale, intervention, methodology, design and methods - to explain the setting within which my PhD was situated - and briefly summarise the trial findings. It is important to establish this context here for a number of reasons: participants included in each of my studies were also participants in the PATCH trial; discussion of my findings sometimes relates back to the PATCH trial design and conduct; and methodological underpinnings of the PATCH trial are referred to in my later discussions and critical appraisal.

The trial design and methods are also explained comprehensively in the protocol publication (35), for which I am lead author.

1.2.1 Trial background and rationale

Physiotherapists working in care homes have observed residents' lack of opportunity for activity, as well as the poor posture of many (36). Poor sitting positions, unsatisfactory positioning in bed, along with unskilled movement assistance are, at least in part, a consequence of the lack of training available to care staff. Physical activity can be improved through targeted interventions, but these are often time-limited, provided by external professionals, and are resource-intensive (37). To address these observations of poor posture and mobility amongst residents, and to try to overcome the problem of existing interventions being impracticable and unsustainable in care homes, a group of physiotherapists in our locality developed a training programme for care staff - the Skilful Care Training Package (SCTP) (36).

In 2016 my colleague Anne Forster (AF) and I were approached by these physiotherapy colleagues to provide methodological expertise to evaluate this intervention. Working closely together we developed a grant application to the Chartered Society of Physiotherapy Charitable Trust (OPA/14/03). The application was successful and we were awarded funding to conduct a cluster-randomised feasibility trial to explore the delivery of the SCTP to care home staff - the 'posture and mobility in care homes' (PATCH) trial (35). Together with colleagues in the Clinical Trials Research Unit (CTRU) at the University of Leeds, we designed the trial to examine the feasibility of intervention delivery and evaluation design - so it served as an effective platform from which to investigate prospectively the range of challenges experienced in the undertaking of intervention research in care homes.

1.2.2 Intervention - The Skilful Care Training Package

The training package focusses on skilled handling techniques (to facilitate movement) and techniques to promote good positioning (to maintain functional posture). Throughout training, emphasis is placed on person-centred care and the development of empathy towards residents. Course content is manualised to ensure standardisation, but flexibility is allowed in order to adapt the focus of the training to the particular needs of a home and its staff members and residents. The format of delivery combines educational sections with practical exercises to demonstrate and try out new skills - for example, supported eating, and facilitating sit to stand. It is delivered by expert physiotherapists to small groups of care staff over a 7½ hour period split over three 2½ hour sessions. The course is designed to be delivered to all those providing care (care assistants and nursing staff) rather than to be cascaded down to staff via the training of

'champions'. The intention is for new skills to become embedded into care staff's routine practice, with the training thereby providing a sustainable approach to improving and supporting residents' posture and mobility.

The Medical Research Council's (MRC) guidance for developing and evaluating complex interventions (38) emphasises the importance of programme theory (39) to inform the evaluation of an intervention. A programme theory lays out how an intervention is expected to lead to its effects, and it can illustrate what mechanisms are expected to generate the outcomes, and what features of the context (in this case, the care home environment) might affect those mechanisms. Development of the programme theory had not been undertaken by the physiotherapists who had developed the present intervention, so it was an important step in designing the feasibility trial. I worked with the physiotherapists to establish the preliminary programme theory - laid out as a logic model (40) (Appendix 1) - that described the component parts of the Skilful Care Training Package (SCTP), proposed mechanisms of action, and specified outcomes that might be expected for staff and residents. It is expected that the programme theory developed during feasibility work will be refined on the basis of emerging evidence and, accordingly, I later consider the implications of my PhD study findings for the SCTP programme theory, as well as their wider implications.

1.2.3 Trial methodology and design

The PATCH trial was designed, by me and the trial co-applicants, in accordance with the MRC Guidance (38). This guidance emphasises the need to explore uncertainties, some of which are identified from the programme theory, before proceeding to a definitive evaluation of an intervention; an approach that reduces the likelihood of failure that is attributable to sub-optimal design. The trial aimed to explore the feasibility of intervention design because the intervention had not been delivered at scale in care homes, so it was not known for certain whether the content and format would be acceptable to care staff, nor whether delivery was feasible in the care home setting. We also aimed to assess the feasibility of the evaluation design - to explore whether participants were willing and able to take part and to provide data for the trial at baseline and follow-up time-points - as well as to explore the suitability of data collection tools and data sources.

Since the planned intervention delivery approach involved the training of all eligible care and nursing staff, the most appropriate design was a cluster randomised

controlled trial (cRCT), as it would have been very difficult to train some staff and not others, or to ask staff to use their newly learned skills with some residents but not others - as would be required for an individually randomised trial design. Thus, cluster sampling was used to include care homes, their staff and residents, and then each care home was randomised to receive or not receive the intervention.

As recommended by the MRC (38), a set of criteria for progression to a full cRCT were devised at the start of the trial to indicate the success (or failure) of each uncertain element: intervention delivery, participant recruitment, data collection and follow-up. Whilst progression criteria set a standard to meet which would indicate the feasibility of the various uncertain components, it is suggested (41) that they should not be taken as strict thresholds; rather they are guidelines which indicate varying levels of acceptability and feasibility. In line with this thinking, we devised a categorical scale of success which took the form of a 'green, amber, red traffic light system' for each uncertain element - where green criteria represented success; amber criteria indicated the need to review and revise procedures for a future trial; and the meeting of red criteria was to be viewed as potential failure. Taking the 'intervention delivery' criteria as an example, the trial management group and I agreed the required number of staff who would need to attend the Skilful Care Training (the required 'intervention dose') to effect a home-wide change in care practice. This change would of course depend upon the staff who had attended training going on to enact their new skills, but the measurement of attendance at training was a first step to understanding the success of intervention delivery. The full progression criteria for the PATCH trial and the specified cut points for success are described later in this Chapter in Table 1 (section 1.2.4).

The PATCH trial included an embedded process evaluation that was designed to explore the proposed mechanisms of action in our logic model, and to consider the elements laid out in the MRC guidance (40). Process evaluation supports an understanding of the barriers and facilitators to intervention delivery and use in practice which, in turn, enables adjustment and optimisation of its design. The PATCH trial process evaluation aimed to: understand the barriers and enablers to delivering and implementing the SCTP; understand trainers' and care home staff's views of delivery and receipt of the training; and obtain insight from residents regarding intervention acceptability.

1.2.4 Trial Methods

<u>Sample</u>

Ten care homes in the north of England were included (seven nursing homes and three residential homes). Care homes were eligible if the managers were able to release staff to take part in the intervention training and to provide data for the trial, and where there was the expectation that there would be sufficient eligible residents to join the trial.

Residents were eligible if they were permanently resident at the participating homes, were aged 65 years or over, and were likely, due to their limited mobility and their need for support when mobilising (defined as a score of 1-4 on the Functional Ambulation Classification (FAC)) (42), to benefit from skills that staff acquired during SCTP training.

It was hoped that, should the intervention be effective, it would benefit residents regardless of mental capacity. The exclusion of those lacking capacity would have affected the generalisability of the trial results, so all eligible residents, with and without capacity, were to be included in line with the provisions of the Mental Capacity Act (MCA) (43).

Following a care home's agreement to participate, all residents who were permanently residing there were screened for eligibility, assessed for their capacity to provide consent, and then consultee agreement or consent was sought for trial participation. Of the 348 residents screened across all ten homes, 250 were eligible and 146 took part in the trial.

All nursing and care staff were invited to take part, except for bank or agency staff who had worked in the home for less than one month during the preceding six. All eligible staff (299 at baseline) were asked to provide data about themselves and their role, with some also asked to provide data about participating residents (proxy data).

<u>Registration and randomisation</u>

Following confirmation of residents' eligibility and consent (or consultee agreement), and after completion of baseline data collection, residents were registered as trial participants. Once all participating residents at a care home were registered, the home

was randomised (1:1) to receive either the SCTP or to continue to provide UC only. Five homes were randomised to receive the SCTP, as planned. Four physiotherapists (usually individually, occasionally in pairs) delivered the intervention.

<u>Data collection</u>

Outcome measurement tools were selected to measure the intended consequences of the intervention (as described in the logic model - see Appendix 1), capturing for residents: pain, mobility, activity levels, independence (for example, feeding and dressing), posture, and quality of life (including anxiety and depression). Data were also collected from care notes to describe residents' health outcomes such as falls and pressure ulcers - occurrences that might be reduced following changes to care practices. Staff measures were selected to measure elements of the staff's care practices that might be expected to change following receipt of the intervention training.

Data were collected by study researchers at baseline (prior to randomisation) and at three- and six-months post-randomisation. Data were obtained in a variety of different ways: self-completion of measures (all staff); researcher administration of measures with residents and staff proxies (i.e. those providing data about participating residents); observation of residents; collection of data from care notes; and obtaining data directly from managers. In addition, written accounts of intervention delivery processes and experiences were collected from the trainers during the intervention delivery period, and observations and interviews were undertaken as part of the process evaluation during and immediately after the completion of training in each home in receipt of the SCTP.

<u>Analysis</u>

PATCH trial data analysis was performed by statistical colleagues at the Clinical Trials Research Unit (CTRU), University of Leeds. Summary statistics were produced to describe PATCH trial feasibility outcomes. Where I present data in this thesis in tabular format, I either attribute these summaries to statistical colleagues, or describe my use of the raw PATCH trial data to answer different questions to those explored within the trial.

<u>Findings</u>

I published the main findings of the PATCH trial elsewhere (44), and these are presented briefly below as bullet points and in tabular format; Table 1 illustrates the findings alongside the pre-specified progression criteria and indicates where these criteria were and were not met.

We were able to draw the following conclusions:

- Resident recruitment was feasible, although it required considerable time and effort from the researchers.
- Intervention training success was mixed. The proportions of staff attending all training sessions varied greatly between homes; so whilst some homes met or nearly met pre-defined success criteria, others fell short of the required attendance rate.
- Resident attrition rates were higher than expected (mainly due to death). Coupled with high levels of cognitive impairment, this attrition meant that measures designed for residents to complete themselves were poorly completed. However, where staff members provided proxy data, completion rates were excellent for those residents who were available for follow-up.
- The intervention was safe: it did not result in any serious adverse events amongst residents.

These findings are briefly summarised here to show how this thesis and the wider feasibility trial are inter-related; some of the findings are expanded upon in later chapters where they form the basis for my empirical studies.

Table 1 Pre-specified progression criteria and observed results

Feasibility outcome		Pre-specified progression criteria			Feasibility trial observations
		Green (proceed)	**Amber (revise)**	**Red (major revisions)**	
Recruitment	No. care homes recruited	**10***	8-9	< 8	10
	No. residents recruited (average)	**≥12**	8-11	Not specified	14.6
Intervention delivery	Proportion staff attending all training sessions	≥65%	<65% and ≥ 50%	**< 50%**	67/155 (43.2%)
	Proportion staff attending ≥1 session	**≥ 75%**	<75% and ≥ 60%	< 60%	119/155 (76.8%)
Data collection and follow-up	Loss to follow-up (including deaths) at 6 months	≤ 25%	**>25% and ≤ 35%**	> 35%	42/146 (28.8%)
	No. residents with PAM-RC and EQ-5D-5L proxy data at 6-months	≥ 75%	**<75% and ≥ 65%**	< 65%	104/146 (71.2%)
	Safety concerns around intervention delivery or trial processes	**None**	No major concerns	Major concerns	None

Bold indicates progression level (green, amber or red) met for each outcome

* * * * * * * *

In this chapter I have described the complexities of the care home setting, and how challenges within the sector make the undertaking of research difficult. I have explained that many researchers have reported challenges in the conduct of their research, but that these challenges had not been systematically reviewed, and there are few published solutions. I have laid out the aims and objectives of my studies: to investigate these challenges and generate recommendations for future research. I have provided a necessary overview of the PATCH trial, within which my studies were situated. This context is integral to understanding the work I undertook, the interpretations I have made, and the conclusions drawn. Next, I present the findings of my literature review which provided a framework and context for my empirical studies.

Chapter 2 A systematic literature review to identify the challenges of conducting intervention research in care homes in the UK and Ireland

2.1 Rationale and aim

The purpose of my literature review was to identify the methodological challenges and solutions reported during the implementation of a wide range of intervention research in care homes.

The aim was to identify:

a) the range of challenges that researchers have experienced in their conduct of intervention research in care homes in the UK and Ireland,

b) suggested solutions for improvement in research conduct in this setting, and challenges that were reported to be intractable.

2.2 Methods

I conducted an overview (45) of the literature to provide a broad and comprehensive summation of the topic area. I took a systematic approach to searching the relevant reference databases for reports of care home research. It was important to be comprehensive in my search, to ensure that all publications relating to my aims were included, thereby enabling robust conclusions to be drawn.

2.2.1 Eligibility for the review

Articles were eligible for my review if they met the following criteria:

Inclusion criteria

- Participants: studies involving participants who were either care home residents (older adults) or staff.

- Intervention: all types of intervention.

- Design: Randomised controlled trials (RCTs) (definitive, feasibility and pilot trials), cluster RCTs or non-randomised trials.

Qualitative studies were included where they were exploring processes relating to research conduct - for example process evaluations, or interview studies exploring participants' experiences of their involvement in intervention research.

- Location: British Isles (UK and Ireland).

Exclusion criteria

- Observational studies, case studies, cross-sectional studies, and longitudinal studies without an intervention component.

- News articles, commentaries and letters (not direct reports by research teams).

My search was limited to the British Isles (UK and Ireland) to focus the review on research conducted in settings operating under a similar structure. I expected my review to include many studies because I intended to include all intervention research in care homes - not only publications reporting challenges - so, limiting it to the British Isles would include ample data relevant to other countries, but would exclude many studies where cross-national differences might influence the results. In short, I wanted to be sure that my findings were grounded in the care home sector in the UK.

2.2.2 Search methods

Search expertise was provided by an Information Specialist based at Leeds Institute of Health Sciences at the University of Leeds. She provided search terms (Appendix 2) for identified concepts following discussion between her and I of requirements, and refinement after I tested early searches.

The following reference databases were searched because they cover most of the health literature concerned with research within the care home setting:

- Medline

- Embase

- PsycINFO

- CINAHL

- CENTRAL

Databases were searched between 2007 and January 2018.

2.2.3 Selection of studies

I assessed search results for inclusion against the eligibility criteria specified above. Obviously irrelevant titles were screened out (for example where it was clear that the research was not in a care home setting), with abstracts then reviewed for the remaining articles. Those not explicitly mentioning the inclusion criteria were excluded. Abstracts were classified as included, uncertain and excluded. Full text papers were obtained for 'included' and 'uncertain' abstracts, and a record kept of the reasons for all exclusions.

2.2.4 Data extraction, management and analysis

I read all full text papers in detail to confirm eligibility and, for those that were eligible - to establish the study design, study population and sample, intervention, and outcomes - in order to set the papers' discussions in context. In practice, it was usually the discussion and conclusion that warranted the most attention, as experiences of challenges and solutions were the focus of my review.

I designed a data-extraction form to document challenges reported in the included articles. This form was initially based on the requirements for good research design, known to me through the literature and my experience working on trials, but also framed by formalised checklists that logically document required processes - for example, elements from the SPIRIT checklist (46) and the CONSORT statement (47). I revised the data extraction form to accommodate newly emerging categories (or themes), and I kept a record of all changes.

Final categories in the data extraction form were:

- Study design - description and challenges

- Intervention description

- Engagement

- Recruitment successes and challenges

- Data collection approaches and challenges

- Intervention uptake

- Retention successes and challenges

I also recorded any other major implementation problems, solutions or successes mentioned by the authors.

I used a thematic synthesis approach (48) to summarise the challenges and solutions that were reported within each category of my data extraction form. I carefully read each included article - extracting relevant data and allocating an initial code to each piece of extracted text. Over time I identified patterns and themes in the data, returning to earlier articles to re-code text in accordance with identified themes.

Themes within each category were documented in Excel, including the reference to the papers in which they appeared. Over time I identified few new themes so, at that point, it was agreed with my supervisors that the formalised (and time consuming) approach of extracting verbatim data for each paper was no longer required; rather I would read papers, highlighting content relating to existing themes on the paper, and assign an existing code (e.g. 'inappropriate outcome measures'). These new examples relevant to existing themes were documented as an additional reference to that theme in the Excel spread sheet. If new themes were identified, they were added to the Excel spread sheet in full.

We decided that the repeated occurrence of a theme (cited >10 times by different authors) indicated reasonable consensus about its importance, so further recording of the theme's occurrence was not required. In this way a weighting (how many times cited) was assigned to a theme until it was at saturation (cited > 10 times). Reported findings include these main themes and related sub-themes.

2.2.5 Additional reviews

As well as reports of individual studies, the search returned a systematic mapping review of RCTs in care homes by Gordon et al (29). I reviewed all references in the Gordon et al. paper to check my search had not missed any UK care home RCTs included in this review - it had not. My search also returned articles that described the challenges of care home research as the main focus of their report (49-59). I undertook a citation search for these articles to identify recent papers that specifically discussed

the challenges of care home research, and that were not already included in my search - this yielded 11 relevant articles.

Earlier scoping work around care home methodology highlighted publications external to my review, but clearly of relevance: i) the NIHR Dissemination Centre Themed Review entitled 'Advancing Care: Research with Care Homes' (19), ii) the My Home Life literature review entitled 'Quality of Life in Care Homes' (17), iii) the School for Social Care Research Care Homes Methods Review (32) and iv) a Guide to Research with Care Homes (8). I read each of these articles to identify these authors' themes and conclusions, to augment my findings and for comparison purposes. I also cross-checked the references in the NIHR Dissemination Centre Themed Review (findings for which came from recently completed and on-going NIHR-funded care home studies) with my search results, and I identified a further five articles that met my eligibility criteria.

2.3 Results

2.3.1 Articles reviewed

I ran the searches on 8th January 2018. The numbers of articles meeting search criteria are shown in Table 2.

I excluded articles listed without authors - mainly letters and news articles from magazine publications. This excluded 155 articles, leaving 2798 to review. By reviewing titles, I excluded those that obviously did not meet the inclusion criteria. This procedure led to the identification of 265 titles that appeared to meet the inclusion criteria, 2489 that did not, and 44 about which I was uncertain. In the event, I did not return to these 'uncertain' titles as I had sufficient eligible articles to explore research challenges thoroughly. I read the abstracts for the 265 potentially eligible articles, resulting in the further exclusion of 112 studies, leaving 153 requiring full text review. A flow of articles through the review process is illustrated in Figure 1. This figure also includes the additional 16 articles identified through reference and citation searching, as described above (section 2.2.5).

Table 2 Number of articles

Database	Number of articles
CINAHL	1341
Medline	883
PsychInfo	222
Embase	1224
CENTRAL	45
Total (prior to de-duplication)	**3715**
Total (after de-duplication)	**2953**

Figure 1 PRISMA diagram of the record review process

```
┌─────────────────────┐      ┌─────────────────────┐
│ Additional records  │      │ Records identified  │
│ identified through  │      │ through database    │
│ other sources       │      │ searching           │
│ (n = 16)            │      │ (n = 3715)          │
└─────────────────────┘      └─────────────────────┘
                                        │
                                        ▼
                             ┌─────────────────────┐      ┌─────────────────────┐
                             │ Records after       │      │ Records excluded    │
                             │ duplicates removed  │─────▶│ (n = 155)           │
                             │ (n = 2953)          │      │                     │
                             └─────────────────────┘      └─────────────────────┘
                                        │
                                        ▼
                             ┌─────────────────────┐      ┌─────────────────────┐
                             │ Titles screened     │      │ Records excluded    │
                             │ (n = 2798)          │─────▶│ (n = 2533*)         │
                             │                     │      │                     │
                             └─────────────────────┘      └─────────────────────┘
                                        │
                                        ▼
                             ┌─────────────────────┐      ┌─────────────────────┐
                             │ Abstracts screened  │      │ Records excluded    │
                             │ (n = 265)           │─────▶│ (n = 112)           │
                             │                     │      │                     │
                             └─────────────────────┘      └─────────────────────┘
                                        │
                                        ▼
                             ┌─────────────────────┐
                             │ Full text articles  │
                             │ accessed for        │
                             │ eligibility         │
                             │ (n = 169)           │
                             └─────────────────────┘
                                        │
                                        ▼
                             ┌─────────────────────┐
                             │ Articles included in│
                             │ review              │
                             │ (n = 139)           │
                             └─────────────────────┘
```

Full-text articles excluded
(n = 30)

Reasons:

- Not in care homes (4)
- No intervention (6)
- Qualitative work not linked to an intervention study (6)
- Methodological work (6)
- Commentary (1)
- Not UK research (5)
- HTA monographs** (2)

* Includes 'uncertain' articles as well as those definitely excluded

** Eligible, but the related primary publications had been reviewed

2.3.2 Findings

2.3.2.1 Setting the scene

Authors concurred with the established view that care home culture is complex, with some homes more open to change than others (60, 61), and that there is a wide variety of management styles, staff attitudes, knowledge, skills and care practices. In addition, they reported wide variability in residents' physical and mental health within and between care homes. Although cultural variability across organisations is a challenge not unique to care homes, there was a general message from the literature that care home studies are particularly complex due to the many factors that affect intervention implementation and quality, expanded upon in the themes detailed below.

2.3.2.2 Literature review themes

I identified the following themes from the literature and include exemplar references to illustrate the points discussed.

i) Difficulties with planning and design

There were multiple observations that the methodological quality of research has been generally poor in the care home setting (29, 34, 37), with heterogeneity across studies in terms of interventions of the same 'type' (e.g. various exercise interventions for the same condition and population), outcome measures used (e.g. different measures of physical activity across similar studies), and populations studied (e.g. variable inclusion of residents with / without capacity who would otherwise be eligible). In addition, studies were often small (62-64) and samples were potentially biased (51, 58).

Selection bias: The selection of care homes to participate in research can be a difficult and time-consuming process (see recruitment section, below), and it is suggested that those homes that ultimately take part in research have a qualitatively different profile, with more stable staffing, stable management and a willingness to change (32).

Resident heterogeneity: Within and between care homes heterogeneity is a recognised factor which often affects successful implementation (65, 66); one paper noted that the variation between residents at baseline was bigger than the anticipated intervention effect (67). Rather than exploring interventions for a patient group defined by a

particular disease or condition, care home researchers seek to involve those who happen to reside in a particular location. This leads to wide participant variability (68, 69) where research aims to be inclusive or, conversely, to relate only to a small eligible population - generating evidence that is less generalisable (70, 71) to residents as a group.

Resident multi-morbidities: Coupled with the often-inevitable decline of residents who are nearing the end of life, it is suggested that complex needs of residents may mask any benefits specific to an intervention (72, 73). In addition, complex health and emotional needs are seen to affect residents' ability to engage with an intervention (69, 74) (directly or indirectly through changes in staff practice) and with data collection (75, 76).

Follow-up too short: Follow-up periods are thought to be too short (34, 62, 77) to see any intervention effects - explained in part by residents' short life expectancy and limited research funding - precluding the prolonged data collection typical of longitudinal cohort studies.

Data collection biases: Care home staff who attend training in an intervention may also provide proxy outcome measures for residents unable to self-report. Researchers suggest (73, 78, 79) that staff may view resident outcomes differently post-randomisation in light of skills and knowledge gained through intervention training. This could be a favourable bias if they feel that the intervention is beneficial; conversely it might bias their assessment to be more critical if they increase their awareness of residents' lived experiences following intervention training (for example, a greater understanding of the nuances of seated posture may lead to more observations of poor posture).

Another form of potential bias relates to researcher blinding. There are multiple opportunities for un-blinding due to the many participants involved, a lack of understanding of research design amongst participants, the amount of time that researchers spend in the care homes, and the observable nature of many interventions (72, 73) - for example, if materials are displayed or new practices are obvious. However, engagement of researchers is critical (see next section), and they need to

weigh the benefits of methodological rigour with the importance of establishing relationships that facilitate ongoing participation.

ii) Engagement

The need for comprehensive, clear, two-way engagement to enable successful working with care home staff and residents came out strongly as a theme.

Engagement with the care home manager: The most frequently cited message was that engagement and collaboration with care home managers is essential for the effective implementation of research (80-83). Managers are critical to the success of a project: to facilitate researcher access to residents, staff and records; to allow staff time to attend training, implement new interventions and provide data; and to empower staff to make changes. Goodman et al., in their review and consensus work around care homes' readiness (84) to take part in research, identify a 'capable and confident care home manager with the autonomy to make decisions' as one of the top five characteristics likely to affect 'readiness'.

Benefits, relevance and 'fit': Many researchers note that, for homes to engage effectively, the research question needs to be relevant and have perceived benefits (51, 65, 85) - for individual homes, staff and their residents. Care homes are pressured environments, where research and development has low priority compared to the needs of residents; thus research needs to be of potential benefit, and lead to minimal disruption (32).

Consequently, the research needs to 'fit in': with relevant national or organisational policies (86), with usual care delivered at the home (33, 51), and with staff workload (87). The research should also avoid duplicating any current practices and should ensure that researchers' visits are discreet and impose minimal additional burden on staff.

Importance of researcher time and communications: Researcher contact is crucial to building rapport (53, 57), and communication is very important to establish good relationships, mutual respect, and clarity of requirements and roles (33, 51, 88). A substantial investment of time, on the part of the research team, is required to explain the project and its implications to managers, staff and residents. Care home staff may

be sceptical of research and unwilling to engage (57, 60), so investment of time to provide appropriate information is important. Similarly, researchers must take time to understand staff and their roles and routines, which may be usefully achieved by spending time in the home before the research begins (8). This may mean multiple visits to care homes, the time and cost of which should not be under-estimated.

Collaborative approach: Mutual understanding is important, extending to shared ownership and a collaborative approach to research design and implementation (19, 32, 89, 90), and to improve engagement with recruitment, intervention development, and data collection.

Staff turnover: It is well known and often reported (66, 82, 85, 91) that staff turnover is high within this sector. This inevitably affects engagement, such that many of those initially engaged in the research leave the home over the course of a project, and new staff can feel less wedded to or less informed about the research. The problem with turnover reduces the quality of the data (less follow-up data from staff who provided it at baseline) and decreases any potential intervention effect - due to lost knowledge and new staff's non-attendance at training.

Resident multi-morbidities: At the resident level, cognitive, physical and sensory impairments all impede engagement with the intervention and data collection (67, 88).

All the above elements constituting the theme 'engagement' are inextricably linked to the themes that follow; such that lack of engagement is detrimental to the success of data collection, intervention uptake, recruitment and retention.

iii) Data collection

Lack of appropriate outcome measures: Many researchers report that there are very few appropriate outcome measures for care home residents (66, 73, 81, 92). This problem can be split out into a number of separate points:

a) Due to high levels of moderate-to-severe cognitive impairment, residents often don't understand the questions included in existing measures, even where those measures are specifically developed for those with dementia (93) (e.g. DEMQOL (94)).

b) Residents have needs and experiences that differ from those of community-dwelling older people, which means that some component questions of existing measures are not relevant to care home life (66).

c) As a consequence of the lack of relevance of some questionnaires or measures, there are reports of missing data (85, 95), ceiling effects (73), and questionable reliability of the data that are collected (96). Few tools are specifically validated for this population (66, 73, 92).

d) It is difficult to find sufficiently sensitive tools for this population and there is a need for development of appropriate tools (97).

Poor choice of measures: There is suggestion that, as well as tools not being validated for the population, the choice of measures is sometimes inappropriate (33, 56). It is repeatedly observed that data collected need to be relevant to residents' everyday life - for example, measuring balance and gait is not appropriate where many residents are unable to stand (75). It is also reported that tools may not adequately measure the full range of intended effects of an intervention (74, 98, 99) - in part due to poor selection of outcome measurement tools and to the lack of available, reliable measures.

Lack of agreed core outcome set: There are no agreed core outcomes for residents of care homes, and there are calls for the development of a core outcome set (34, 37) to standardise measurement across trials, thereby reducing heterogeneity and contributing to useful meta-analysis. The NIHR Themed Review (19) concurs with the view that new tools are needed and that a lack of appropriate outcome measures is a problem.

Residents' health and mood fluctuate: Researchers have observed daily fluctuations in residents' health ("good days and bad days") (19), and the NIHR review concludes from this that "any measure that takes just a snapshot of residents' lives is going to be limited". Gridley et al (93) report that time of day influenced answers provided by residents, with some, for example, being more cheerful in the morning but having lower mood in the afternoon, or that mood was contingent upon a particular activity. They also note that an intervention effect might be noticeable 'in the moment' but is not sustained.

Time-intensive, resident-centred approach required: It is apparent from the literature that the way in which data collection is approached needs to be sensitive to residents' needs, aiming to avoid distress and burden associated with questions, as well as minimising complexity for those with cognitive, physical and sensory impairments (65, 71, 100). Consideration needs to be given to data collection times that fit with residents' daily routines (56) - for example, some residents may be more alert in the morning and sleepy or agitated in the afternoon. The practicalities of undertaking data collection can be a challenge: finding the right time to visit (researchers need to be flexible to fit with daily activities and fluctuations in health); finding an appropriate, private location to speak to residents (56, 88); and finding times when staff are not too busy to facilitate residents' involvement (for example, assisting a resident to move to a different room). Multiple visits to see a resident, sometimes with limited returns, are inevitable.

Resident capacity and communication difficulties: There is agreement that residents' perspectives are important (76, 97), but it is difficult to collect information from residents with severe cognitive impairment and limited communication skills (66, 70), so data are often obtained by proxy from a member of care staff, which may present a differing view point to that of the resident (69, 82). Including families' perspectives is suggested by some but it is observed that a high proportion of relatives rarely visit or get involved in research (60), limiting the viability of this option from the perspective of data quality. Proxy provision of outcome data by staff is thus a frequently-used method in the absence of direct collection from residents with advanced cognitive impairment, physical frailty and sensory impairments.

Poor quality data from care home staff: Data requested from staff are often missing or of poor quality, without comparative measures at follow-up time points (67, 89, 98, 100). Some authors have noted difficulties with language (101) and educational levels, which may impede engagement and questionnaire completion. Further work is required to improve the provision of data by staff.

Routine data collection is complex: Although not a substitute for self-reporting of subjective experience, the collection of routine data appears, in principle, to be a promising way of collecting standardised health and care data without creating additional burden to staff and residents. The data are those available in care plans and other routinely documented notes within each care home, and information recorded by NHS practitioners and organisations when a resident requires health care. Routine

data are collected in different ways and with differing levels of detail and quality across care homes (56, 60, 73). This inconsistency affects researchers' ability to collect good standardised, trial data. Some success has been reported where chosen outcomes closely align with data collection that is already mandated for reporting across the sector (for example, reporting of residents' falls to the local authority) (95, 100); however, data are not always available even when supposedly 'routine' for daily care (e.g. fluid charts, residents' weight) (75, 100, 102). Success has also been observed with the collection of NHS data directly from NHS Trusts and GP practices, although there can be problems with completeness and access (66, 72). There is the suggestion that multiple data sources are required to obtain a representative and comprehensive picture of a resident's health (89, 103), although this process would, at present, be a complex and time-consuming undertaking.

iv) Intervention uptake

Inadequate intervention dose: A number of researchers report the inadequacy of intervention dose in care home trials - brought about by many factors, including study design, participant engagement and data-collection challenges. Ideally residents and staff will engage fully with an intervention, implement it enthusiastically, and sustain any changes, but this does not often happen in practice (53, 67, 74, 104).

Dose problem - resident engagement: Intervention uptake in care homes is particularly impeded by resident frailty, cognitive impairment and mortality - so that residents cannot, rather than will not, engage (67, 72). There are reports of interventions being unsuited to the resident population, requiring greater understanding or activity levels than is possible for the majority of participants (67, 72, 88) - and of resident adherence to an intervention being limited by others (for example, family and staff) (69) where residents need assistance to participate. Residents often have days where they don't feel well, or have other activities scheduled which further reduces participation (74, 81). Flexibility and perseverance are thus required to maximise residents' uptake of an intervention (105) where it involves their engagement in a particular activity (for example, an exercise class). It is suggested (19) that interventions need to be better tailored to residents' specific needs, and that more 'reality checking' and collaboration with staff and residents is required to ensure appropriateness of an intervention - for residents and for staff.

Dose problem - staff engagement: There are multiple reports of poor staff engagement with interventions (55, 81, 90), with reasons including time, turnover, resources, morale, and difficulty releasing staff from usual care duties to attend intervention training sessions (53, 78, 95). It is noted that flexibility needs to be built into intervention delivery (53, 89), adjusting training timetables to fit with the availability of care home staff, and perhaps providing shorter sessions to fit more realistically with care pressures. On the other hand, intervention training programmes are often seen as too short (86) and, following training, practice changes are not sustained (106, 107).

Lack of sustainability: Aside from suboptimal attendance at training sessions (the 'dose problem'), this underperformance is attributed to multiple factors including: staff not fully understanding the intervention (108), not having protected time to carry it out in addition to their normal job role (95), and not feeling empowered to make change (90). It is suggested that, for an intervention to be implemented and sustained, senior staff and management need to be involved and to engage with the intervention (109), endorse and legitimise associated practice changes (61, 78), and communicate effectively with their staff about training and implementation plans (90, 110). There is also a suggestion that the identification of intervention 'champions' amongst staff members, on-going supervision, and follow-up training sessions help to maintain skills and motivation (17, 91). High staff turnover inevitably means that skills are lost over time, but this can potentially be countered by a rolling programme of training (109, 111).

Adherence not well reported: Uptake and sustainability are poorly understood because measurement of intervention adherence is not routinely carried out well (34, 62), with limited reporting of enactment of new skills (76, 112) and low recording of reasons for poor uptake (113). A number of authors recommend the development of adherence and fidelity measures to examine the extent to which an intervention is implemented and sustained (79, 86). Reported methods for monitoring adherence are mostly straightforward descriptions: 'counts' for example, of staff logging the delivery of a session (76), researchers reviewing reports that set out elements of the intervention within care plans (112), or staff questionnaires reporting on knowledge (90, 114) and skills. None of these simple descriptions is a direct measure of enactment, and self-reported knowledge or skills cannot be attributed unequivocally to the intervention in question. A few researchers have undertaken observations of care practice (82, 114) to obtain more detailed reports of enactment, which may be a more fruitful approach, albeit a time consuming one.

v) Recruitment

Whilst involvement in research is an essential activity laid out in the NHS constitution (115), with its comprehensive research infrastructure support, care homes exist in a largely independent sector where research has not been widely or routinely championed. Recruitment operates at the level of the organisation and the care home, and it is dependent on owners' and management's enthusiasm and the willingness of staff, residents and relatives to take part; as a consequence it is more uncertain, complex and time-consuming in this setting.

Care home recruitment is difficult: Many researchers report difficulty engaging homes to take part in their research. There is a high level of non-response to postal invitations (78, 111, 116), with researchers often needing to follow up these invitations with multiple phone calls. Where contact is made with a home's staff, researchers can face gatekeeping and poor communications from staff when trying to speak to managers to introduce their project (53, 57). Even when communication with managers is established, they are often too busy and sometimes simply not interested in research (76, 117). However, a proportion of homes <u>are</u> willing to take part, with researchers reporting the importance of taking time to engage with managers (110) and staff to answer questions and establish trust (100) - with the researcher showing flexibility to fit around staff workload and care home routines (53, 101).

Resident recruitment is time-consuming and complex: Given the high proportion of residents with cognitive impairment, researchers regularly need to work in accordance with the Mental Capacity Act (MCA) (43), which requires assessment of capacity and consultation with identified 'consultees'. Inevitably, recruitment is complex and time-consuming (33, 51, 59, 88), as researchers need to involve not only the resident but also staff and residents' families in the recruitment process. Researchers need to support the process as much as possible (66), whilst being mindful of data-protection regulations (118) - for example, staff will need to add personal details to study invitation letters and information sheets, but researchers can provide all required paperwork in 'ready to send' packs. Staff need to approach residents initially to establish their willingness and capacity to speak to the researcher (109) and consider the research, but thereafter the researcher can engage with residents directly. When judging the best time of day or how best to engage with a resident (for example, preferred conversation topics), staff support is essential (8). Throughout a research project, researchers also

need to be vigilant for changes in capacity (119), and may need to involve a consultee later if a resident loses capacity. These processes are time-consuming for researchers and for staff.

Involving personal consultees can be difficult: As alluded to previously, the involvement of personal consultees is not straightforward. Relatives may not be easily contacted - many do not visit regularly, and responses to study invitation letters are not always forthcoming (33, 60, 120). Researchers have adapted their approaches (in line with MCA requirements) to accommodate these difficulties: involving families as early as possible in the research process (33), and setting time frames for response after which a nominated consultee is approached as an alternative to a personal consultee (120, 121). Even where personal consultees do respond, there is sometimes concern that they are expressing their own views rather than those of the residents (120), and some do not see the benefit of their relative's participation in research (98).

Involving nominated consultees can be difficult: Nominated consultees are usually care staff who know the residents well, and there are often no other suitable visiting professionals to take on this role. It can be difficult to find someone who is willing and able to take on the role and, where a nominated consultee is identified, they can be reluctant to make a decision on a resident's behalf (58, 120). Linking back to the earlier theme of 'engagement', high staff turnover can also diminish the availability of a nominated consultee, with researchers sometimes needing to identify new consultees during a project to ensure continued resident participation (122).

Low recruitment rates: Low recruitment rates are reported in a number of research projects (49, 60, 68, 88), variably attributed to fewer residents being eligible than expected, low willingness to take part, and low uptake for those without capacity. This scenario accords with methodological difficulties reported earlier, supporting the assertion that samples may be too small and potentially biased.

Where staff involvement as research participants is required, recruitment rates are also low (80, 104), with workload often cited as the reason.

Tailor participant information: Many researchers recommend the provision of clear and tailored information for all potential participants (33, 51, 57, 59) (residents, staff and

relatives), with a format appropriate to each individual's needs (85, 119) (for example, audio, large print, simplified, appropriate length). It is noted that personal consultees do not always understand the information provided about a study (75) (for example, that the intervention is non-invasive and not about new medicines) or their role, and that long information sheets may burden older, frail relatives - this is particularly unjustified for low-risk studies. Provision of short, clear information may improve recruitment.

vi) Retention

High resident loss to follow-up: Although some researchers report low drop-out of residents (92), there are many reports of high resident attrition rates (53, 70, 104, 123) due to mortality, illness, moving away from the participating care home, and no longer wanting to take part.

Loss of care homes: In some projects whole homes have dropped out (72, 77, 98) due to closure, organisational pressures, change of manager or because all participating residents have died. Some researchers have noted that 'control' homes do not comply with research protocols to the same degree as homes receiving an intervention. They suggest that provision of the intervention to the control group at the end of a trial might increase compliance and reduce drop-out (124).

Poor staff compliance with research procedures: Care staff often cite lack of time and difficulty incorporating research processes into their workload as reasons for poor compliance (33, 51, 88). Engagement with the research process is also influenced by staff turnover, affecting intervention dose and sustainability, and data quality (49, 67, 112, 125).

All challenges discussed above are summarised in Table 3 below.

Table 3 Challenges - themes and sub-themes

Theme	Sub-themes / details
Planning and Design	Selection bias - Care homes - Residents
	Resident heterogeneity - Wide variability in sample (or) - Small eligible population
	Resident multi-morbidities - Inevitable decline = don't see change - Complex needs mask any benefits - Difficult to engage (with intervention / with data collection)
	Follow-up too short - Short life expectancy
	Data collection biases - Staff who have intervention training provide resident data - Researchers often un-blinded
Engagement	Engagement with care home manager critical
	Researcher engagement critical - Good communication = good relationships - Allow lots of time
	Research needs to be relevant for staff to engage - Perceived benefits for home - Fit with daily home life
	Collaborative approach and shared ownership important
	Staff turnover is high - Affects engagement with all research processes
	Resident multi-morbidities - Difficult to engage (with intervention / with data collection)
Data collection	Poor choice of measures - Lack of valid, reliable, sensitive tools
	Existing measures inappropriate - Residents don't understand questions - Not relevant to care home life
	No core outcome set - Lack of standardisation
	Difficult to collect meaningful data from residents - Resident health / mood fluctuates regularly - Resident capacity and communication difficulties
	Time intensive / flexible approach - To accommodate resident needs - To fit with care home life
	Poor quality data from staff - Lack of engagement / time
	Routine data collection not straight forward - Concerns over accuracy and quality
	Dose inadequacy

Intervention uptake	- Poor staff engagement
	- Poor resident engagement
	Intervention not sustained
	- Staff turnover / lack of engagement
	- Resident capacity / physical ability
	Intervention adherence not well measured or reported
Recruitment	Care homes
	- High level of non-response
	- Time consuming process
	Residents
	- Capacity = multiple parties involved
	- Time consuming
	- Low recruitment rates
Retention	High loss to follow-up (residents)
	- Mortality, illness, moves
	Loss of whole homes
	- Change in manager, loss of residents, engagement
	Poor staff compliance (with intervention, with data collection)
	- Fit with workload / time
	- Engagement

2.3.2.3 Updated search

I re-ran my search (identical to that described in Section 2.2) on 9th November 2020, and again on 6th June 2022 to ascertain whether new care home research challenges or solutions had been reported since January 2018. After de-duplication, the November 2020 search returned 933 articles of which 115 were eligible; whilst the June 2022 search returned 1381 articles of which 83 were eligible. This number of eligible articles is considerably better than my initial search - which returned 123 from a total of 2953 - suggesting that there has been an increase in intervention research taking place within the care home sector over recent years. That there were 198 eligible articles over a period of less than five years, compared to 123 over nearly 11 years, illustrates a surge in research to improve the care of care home residents. This increase may reflect the completion of projects initiated following the UK Government's focus on, and investment in, social care research (19, 28) over the last 10 years.

Following my review of eligible articles, I did not identify any new challenges, and I found that researchers continue to report difficulties conducting research within this complex environment. For example, authors discuss the difficulties of: recruiting care homes and engaging with managers (126), involving residents without capacity in their research (127), obtaining outcome data directly from residents (128, 129), accessing

data from care notes within care homes (130), there being a paucity of high-quality outcome measures validated for use in care homes (131), high levels of resident loss to follow-up (132, 133), poor rates of staff questionnaire completion (134), variable staff engagement with intervention use (135, 136), and the unsustainability of interventions over time (128, 137), as well as some interventions' incompatibility with care home practices. (136)

Since I undertook my original review, articles have been published that identify care home research challenges from an international perspective; two via systematic review of the literature (138, 139), and two linked papers reporting the opinions of experts with experience (of research in and working with and for care homes) who attended a virtual consensus conference that aimed to address the complexities of undertaking pragmatic trials in long-term care settings. (140, 141) Although not specific to the British Isles, the authors identify similar challenges to those I have reported, including difficulties with: recruitment, involving as participants those who lack capacity to consent, staff availability, staff engagement, resident and staff attrition, poor outcome measurement tools, and difficulties with data collection. The authors put forward suggestions that: good communication with care home managers and staff is important; staff should be more involved in research design; and that staff diversity, including ways to maximise their inclusion in research, should be considered. The need to consider the compatibility of interventions with existing care home practices is also mentioned, as is the relevance of interventions to staff and residents, and the need to assess each care home's capability to take part in research.

2.4 Discussion

My review builds on previous work (8, 17, 19, 30, 32) because I used a systematic approach and focussed on all intervention research reported in the British Isles since 2007. I have brought together individual reports of intervention research in care homes in the British Isles to provide a clear picture of researchers' experiences, reflections and opinions concerning the main challenges they face.

2.4.1 Summary of findings

I identified the following themes: i) difficulties with planning and design, ii) the importance of engagement and collaboration between care homes and researchers in all aspects of research implementation, iii) multiple difficulties with data collection

(subjective and objective), iv) concerns regarding intervention implementation (insufficient dose, lack of sustainability and inadequate adherence monitoring), v) the time-consuming nature of recruitment and potential selection biases, and vi) high attrition rates amongst residents and staff. Engagement, whilst a theme in its own right, is central to all themes - such that lack of engagement of one or more stakeholders inevitably affects recruitment, retention, intervention implementation and data collection; it is the challenge of sub-optimal engagement in each of these areas that creates the multiple methodological difficulties that often affect researchers' ability to draw meaningful conclusions from their research.

Where it was possible, some of the themes identified were addressed in the design and conduct of the PATCH trial - for example, we aimed to minimise bias through the use of broad selection criteria, and we tried to maximise engagement with care homes through regular researcher contact and support - to facilitate recruitment and retention. Other challenges identified could not be addressed within the PATCH trial as there were no reported or obvious solutions to these problems. It was these challenges that I investigated in the empirical studies reported in this thesis.

2.4.2 Methodological considerations

I chose to focus on care home research within the British Isles because I thought that the challenges faced in care homes there would be sufficiently similar to those experienced elsewhere in the world to be generalisable; at the same time, I hoped to avoid inclusion of research in other countries that reported on difficulties specific to that nation. I acknowledge as a limitation the exclusion of a large body of research from the rest of the world, but my search - inclusive and with a high return of eligible papers - was detailed, focussed, and manageable. I also had concerns that attempts to appraise critically any research undertaken in countries where I am unfamiliar with the health and social care systems might have led me to misinterpretation or overgeneralisation - for example in relation to staffing structures, funding or regulation, which vary between countries (126).

2.4.3 Comparison with other literature

At the time of my initial search no existing review reported the challenges of conducting research in care homes, although there were a number of related reviews focussing on certain aspects of care home research - for example (142-144) - and a review by Maas

(30) looking at "issues in conducting research in nursing homes"; this review was not, however, systematic, and it was published as far back as 2002.

The School for Social Care Research (SSCR) Care Home Methods review (32) (published at the time of my initial search) includes *some* themes occurring in my review but draws on predominantly qualitative projects. Consequently, they concentrate on the lived experience of researchers in the field - emphasising the importance of researcher reflexivity, flexibility and interpersonal skills, as well as investments in partnership working. These are important considerations for all research that involves resident and staff contact, not just qualitative projects - and additional researcher skill and time requirements must be carefully considered before and during a project.

Since I undertook my initial search, Lam et al. (139) have published a paper entitled "Challenges of conducting research in long-term care facilities: a systematic review". They used the same databases that I searched but search terms were different (with the inclusion of articles that specifically reported challenges or barriers in long-term care research), the time frame larger, and all types of research design were included, with no limitation to the older adult or to the British Isles. Their published review comprised 39 articles, far fewer than I included for the British Isles alone during my initial search (N=139). My search, whilst perhaps over inclusive, has ensured that a wide spread of authors' viewpoints have been included - not only the views of those who chose to publish specific 'challenges' papers (as were included in the Lam et al. review), but also those where descriptions of challenges are embedded within research reports. I can thus assert that my review is representative of a wide range of intervention researchers' opinions in the British Isles.

There is overlap in the findings of Lam et al.'s review (139) and the present one - particularly in terms of difficulties with: recruitment (of homes and residents), resident capacity and associated consent processes, staff time constraints, attrition (residents and staff), and outcome measures being unsuitable. However, their focus is more on clinical trials of investigational medicinal products (CTIMPs) than non-CTIMPs or complex interventions, so there is emphasis on regulatory barriers and the difficulty of engaging external physicians, as well as residents' preferences for active treatment over placebo. They include little detail about: the importance of engagement and relationship building, problems with intervention delivery and uptake, and

methodological challenges (for example, selection bias, short follow-up periods) - all important points identified by the authors of the papers that I reviewed.

Very recently (2022) a further three papers (138, 140, 141) have been published that report challenges of undertaking research in care homes and offer recommendations for future research. Two linked papers, published by US authors, (140, 141) report the opinions of experts in the field of care home research, so conclusions drawn and recommendations made, whilst valid, are not based on systematic review of the evidence. Their opinions resonate to some degree with my own findings. As they did, I identified the need to engage well with care home staff, adopt a collaborative research approach, ensure research 'fit' with daily care home life, and I found there to be reported difficulties with intervention uptake - poor engagement, lack of sustainability, and poor measurement and reporting of adherence to intervention tasks. Their suggestions for consideration of staff diversity to support their inclusion in research, assessment of care homes' ability to participate (their 'readiness'), and better specification of the core components of interventions are good proposals, that are compatible with the areas I identified.

The third recently published paper reports a systematic review of 'process evaluations of care home complex interventions'. (138) The authors included international reports from high-income countries, published in English between 2005 and 2019, so there will be some overlap with articles included in my review - those published by UK authors from 2007 onwards. Indeed, I see some similarity between our findings: their reported challenges include a lack of staff engagement with research processes, a need for good communication (particularly with managers) and good relationships with staff, a clear rationale for the intervention, and the compatibility of the intervention with the care home's existing work routine. The authors' focus is on contextual factors that affect implementation, so they mainly report recommendations relating to staff engagement and intervention uptake; however, they do suggest that other research processes, such as simplifying data collection as much as possible, be considered in the study design phase. My review, whilst perhaps less detailed in relation to intervention processes, is broader in its consideration of the challenges that affect the implementation of complex intervention trials in care homes.

Finally, a recent care home collection has been published in Age and Ageing with an accompanying commentary. (145) This collection revisits care home articles published

in their journal since 2015, bringing together 42 relevant papers. The commentary authors draw attention to the fact that only three included articles are RCTs, (26, 44, 73) and that there is a predominance of observational studies which describe rather than 'fix' the problem - although there are articles describing projects which adopted alternative designs such as realist evaluation. The authors suggest that the publication profile reflects the immaturity of care home research and the difficulty of conducting trials research in this sector. Alternatively, it may be that care home RCTs are not predominantly published in Age and Ageing, with authors choosing, or being directed, to publish elsewhere. Whatever the reason, I found 198 eligible articles published by UK authors since 2017; admittedly not all of these were RCTs as I included all intervention evaluation designs, as well as articles describing researchers' experiences of conducting intervention research; but I believe there to be more care home trial research being undertaken than is suggested by the Age and Ageing commentary. What I do agree upon is the ongoing challenge that researchers face in their implementation of such research designs.

2.4.4 Literature review findings as a conceptual framework

The findings of my review provided a conceptual framework (146) for my subsequent empirical studies - grounding them in the current understanding of the challenges of care home research. I focussed on the challenges for which there were limited solutions reported, but which were not intractable - areas that could be adapted usefully by future researchers to improve their research processes and outcomes. For example, data collection methods can be adapted and developed by research teams to improve validity and reliability of outcomes, whereas care home or resident characteristics cannot be influenced by researchers. The literature review's themes map to my research questions which, in turn, clarify my stated objectives (Chapter 1), and are described in Figure 2 below.

Figure 2 Mapping of literature review themes to research questions

THEMES FROM THE LITERATURE

Data collection

Poor choice of measures

Existing measures inappropriate

Poor quality data from staff

Difficult to collect data from residents

Routine data collection not straightforward

Research question:
How might posture be measured in a care home resident population?

Objective 3

Research question
What are staff and researchers' experiences of providing and collecting data for research in care homes, and what are the implications for future data collection?

Objectives 2 and 3

Research question: Can routine NHS data be used as a reliable data source in the provision of health outcomes for care home residents?

Objective 3

Retention

Poor staff compliance with intervention and data collection

Intervention uptake

Dose inadequacy

Intervention not sustained

Adherence poorly measured and reported

Research question:
How could the enactment of new skills learned in training be comprehensively measured in care homes?

Objective 1

Research question:
What are the challenges faced by trainers in the organisation and delivery of a training intervention in care homes?

Objective 1

Chapter 3 Methodology and methods

In this chapter I provide a rationale for my methodological choices; and describe the methodological orientation of my empirical studies, the design of each study, the data collection methods I employed, and my approaches to the analysis of the quantitative and qualitative data generated.

3.1 Introduction

Whilst the authors of articles I had reviewed often described the problems they had experienced with the conduct of their care home research, none reported exploratory work to understand these problems in more detail. I set out to understand reported difficulties: I explored care home and staff engagement with training, the acceptability of data collection methods, and alternative approaches to data collection. To do this I needed to examine quantitative data collected during the PATCH trial - which I could use to illustrate challenges with research processes (for example, poor data return rates) - and then collect qualitative data from those involved in data collection or intervention provision, to explore the reasons for the observed challenges. This is known as a mixed-methods approach - one which uses qualitative data to explain quantitative observations or, conversely, to explore a topic via qualitative methods to establish and build a quantitative study (147).

In simplistic terms, quantitative research measures an event or outcome (a numerical and often 'closed question' approach), whilst qualitative research uses words (or an 'open-ended question' approach) to understand people's experiences and views in more depth (147, 148) - the how, what and why of research (149). Use of quantitative, qualitative or mixed methods is widely known as the *research approach* (147). The chosen approach is influenced by the researcher's *philosophical world view*, as well as the *research design* and *research methods* that are appropriate to the research question. I briefly describe each of these concepts below, to set later explanations of my methodological approach in context.

3.1.1 Philosophical world view, research design and methods

3.1.1.1 Philosophical world view

A researcher's philosophical world view includes, as a basis for their approach, their understanding of how we come to know the world as we do - a theory of knowledge (149), also known as an *epistemological* stance. A well-established philosophical view-point is that of *positivism* which assumes that there is a reality that exists regardless of who views it or attempts to explain it. This often aligns with quantitative experimental methodologies, which aim to find the objective, observable truth of a situation, attributing cause and effect. The assumption here is that research observations and findings generated via the scientific method are entirely separate from the perspectives of individuals involved (as participants or observers) in the research. This has been somewhat modified in the *post-positivist* viewpoint: for post-positivists, whilst there is a belief that causes determine outcomes and that there is a truth to be found, there is also an acceptance that evidence is fallible and may later be disproved by further observations. Positivist assumptions do not sit well with researchers who wish to explore the nature or influences of human behaviour. Those who reject the positivist/post-positivist view, instead often align with an *interpretivist* standpoint, which argues that the complex and unpredictable nature of human behaviour means that we need to focus on understanding how human behaviour influences outcomes, rather than being able to identify and explain a universal truth of knowledge. Knowledge is created by exploring and understanding the meanings placed on activities or events by the people who experience them within their particular social context (150). As Green and Thorogood (149) note, interpretivists believe that "…the most interesting questions are not about the 'reality' of the world, but about people's interpretations of it." This approach is often associated with qualitative research methods. There are other philosophical views that have similar roots to interpretivism, such as *phenomenology* (understanding the 'essence' of an experience or situation) and *social constructionism* (assuming that reality is socially constructed on the basis of each individual's experience): all these views counter the possibility that there is an unchanging reality out there to be discovered.

An alternative world view is that of *pragmatism*. Pragmatism has its origins in a philosophical movement of the latter half of the 19th century, with early proponents of this way of thinking being Peirce, James and Dewey (151). Their claim was that a proposition or social reality could be said to be true if it could be seen to work or to have positive practical consequences. The approach does not give weight to debates

about the nature of truth and reality, and instead focusses on the practical understanding of real-world experiences (152). In research terms, the emphasis is on the research problem and solutions to that problem; so a pragmatic approach is adopted, involving the selection of the most suitable of all available methods to best answer the question. There is no particular allegiance to one philosophy, rather a practical focus on applying the most appropriate methods to answer the research question(s).

3.1.1.2 Research design

The *research design* is influenced by the researcher's philosophical world view, which directs them to use a qualitative, quantitative or mixed methods approach. Within each approach there are a number of possible research designs (or 'types of enquiry' (147)) from which a researcher will choose to address the research question most appropriately. Quantitative designs include experimental research, such as randomised controlled trials which seek to assess whether a treatment (or intervention) leads to a particular outcome when compared to a control group. Qualitative research includes designs such as phenomenological research, grounded theory and ethnography (149).

Phenomenologists mainly focus on people's lived experiences; grounded theory seeks to generate theory - grounded in real-world social settings - to explain social processes; and ethnography is often concerned with the in-depth study of social groups and social processes within those groups. These designs draw on participants' perceptions, experiences and interactions in the social world, exploring them in detail via, for example, observational or conversational methods of data gathering.

Mixed methods designs do as they say - they mix quantitative and qualitative methods to address the research questions posed. They are often associated with a *pragmatic* philosophy in that they employ a diverse range of methods to establish efficiently 'what works', rather than requiring a particular design. For example, interview data may be gathered to understand people's views on a particular health service, whilst quantitative data are collected to build up a picture of service use (how much it is used, by how many people, and what types of people). Where mixed methods are used, researchers must adhere to the principles that underpin each method employed, to ensure rigour in their approach.

3.1.1.3 Research methods

The *research methods* used are the tools of the design - the ways in which the researcher appropriately gathers and analyses data to meet their aims. Different methods are appropriate to different research designs: for example, 1) an experimental design might involve the use of standardised data collection forms to obtain numerical data at specified time points pre- and post-intervention, with planned statistical analyses undertaken once all data are collected; whilst 2) a qualitative study to explore participants' beliefs and understanding of a topic might involve open-ended interviews, with ongoing sampling and thematic analysis throughout data collection.

In the next section I describe the influences on my studies and the rationale for my choice of design and methods.

3.1.2 Methodological orientation for PhD studies

I have a quantitative background, having spent many years working as a trial manager, mainly on multi-centre RCTs of complex interventions similar to the PATCH trial. I therefore began my PhD studies with an embedded *post-positivist* view of research - that is, as previously described, holding the assumption that there is a reality out there which is mostly unaffected by research processes so knowledge can be gained by testing hypotheses about causal relationships empirically against observations (150). Whilst I retain this view in part, I have become aware of the difficulty of applying a solely *post-positivist* approach to the understanding of the effects of complex interventions - where there are multiple contextual and individual factors that can affect implementation and outcomes (153).

For my PhD studies, I aimed to understand the challenges associated with the undertaking of intervention research in care homes - particularly focussing on methodological elements that are part of experimental research designs such as our cluster randomised controlled trial (cRCT). I realised that I needed to revise my stance as I began to understand the nuances, detail and subjectivity of the challenges I was to investigate. I had initially thought it appropriate to adopt a post-positivist position for my investigations: for example, exploring challenges relating to the provision and collection of data seemed practicable and indisputable - matters that could be observed and the truth established. I had also thought that a deductive approach to understanding the difficulties encountered in the PATCH trial could be appropriate: from my literature

review I had developed a detailed framework of challenges reported by many researchers (see Chapter 2), which I thought could lead directly to hypotheses to guide my analyses. However, although these standpoints might be appropriate for some of the procedures I investigated, I realised that they were not necessarily so for others. People's experiences of providing data were by no means an objective reality to be understood but, rather, the subjective experience of individuals - dependent upon their own knowledge, experience and attitudes, as well as the setting in which they worked - which in turn influenced their interpretation of the research tasks required of them. In this situation an *interpretivist* approach, in which lived experiences are explored, would be more appropriate for an understanding of subjectively meaningful experiences (150).

As my research questions varied between the observation of a (mostly) known reality - for example, the availability of routine data or staff attendance at training sessions - and the understanding of subjective experiences (of those providing training or providing data), I came to the conclusion that a *pragmatic* perspective best described my view and would be the best 'fit' for the questions I set out to answer. In line with a pragmatic stance, I chose a mixed-method approach (154, 155) - applying specific and differing research designs to each research question. As I describe in more detail in the next section, for each of my empirical studies I collected quantitative and qualitative data, in combination and on their own, to answer my research questions in the most appropriate way. The use of multiple data sources is a strength of this approach (156), as qualitative data can confirm or explain quantitative findings; however, as I alluded to earlier, the use of multiple methods requires skill in more than one approach to ensure rigour in the undertaking of each element of the research. I thus needed to consolidate and expand my understanding of qualitative research methods prior to undertaking data collection and analysis, which I achieved via attendance at relevant training courses, and through consultation with qualitative experts.

The conceptual framework which I developed from my review of the literature, combined with my own experience of delivering the PATCH trial, underpinned my understanding of the challenges faced by care home researchers and informed my approach to each of my empirical studies. I did not feel it appropriate to set my work within the constraints of a particular theory as I was exploring a diverse range of challenges that were predominantly practical in nature. It is accepted practice that the application of theory is not always required (147, 150): whilst it is important to be aware of the substantive issues associated with a topic (in the present work, from my

comprehensive review of the relevant literature) - and to have clarity of purpose via aims, objectives and design - having a fixed theory to guide the work is not always helpful or necessary, particularly where theories might arise from analysis of the data collected.

3.1.3 Aims and objectives of empirical studies

The aim of my empirical studies was to explore the challenges of conducting intervention research in care homes by collecting and generating prospective data during the implementation of the PATCH trial. My objectives were clarified following my literature review, which led me to formulate research questions that could be explored within the PATCH trial. These research questions are stated in Figure 2 (Chapter 2) and presented alongside my study objectives below. The study that addresses each research question is also specified below and included in Figure 3.

Objectives were:

1. To identify the challenges of providing intervention training to care home staff, and the difficulties of monitoring and reporting the use of new skills.

    Associated research questions:

 -   *What are the challenges faced by trainers in the organisation and delivery of a training intervention in care homes?* (Study 1)
 -   *How could the enactment of new skills learned in training be comprehensively measured in care homes?* (Study 2)

2. To understand researchers' and care staff members' experiences of collecting and providing data for care home research.

    Associated research question:

 -   *What are staff and researchers' experiences of providing and collecting data for research in care homes, and what are the implications for future data collection?* (Study 4)

3. To explore the acceptability of various methods of obtaining trial data in care home research

    Associated research questions:

 -   *How might posture be measured in a care home resident population?* (Study 3)

- *Can routine NHS data be used as a reliable data source in the provision of health outcomes for care home residents?* (Study 5)

3.2 Study Design

The fieldwork was undertaken during the PATCH trial, and involved the gathering of interview, conversation and documentary data from care home staff, researchers and trainers; as well as observational data obtained during observation periods in each care home. Health service use data were obtained from routine NHS sources and were compared with data obtained for the trial from care home records. Some data collected for the purposes of the PATCH trial were also reviewed and summarised to illustrate the presence and extent of the challenges further explored in my fieldwork. Below I summarise the design of my studies, then in subsequent sections describe in detail the methods I used.

Figure 3 illustrates the design of my PhD studies and how they related to, and were conducted alongside, the PATCH trial.

Figure 3 PhD Fieldwork

PATCH trial design	**PhD fieldwork**

PhD studies were conducted in parallel to each other, and alongside the PATCH trial - to explore the challenges faced in the conduct of the trial.

Care homes, residents and staff recruited

Randomisation

Usual care

Usual care + SCTP

Data collected at 3m and 6m post-randomisation:

- Via observation of residents

- From residents about their QoL

- From staff about residents' QoL

- From staff about themselves

- From care home records about residents' health service use

Study 1. Challenges of delivering training

- Staff attendance data

- Documentary data from trainers

Study 2. Measuring the use of new skills

- Developing & trialling an observational tool

Study 3. Development and testing of a postural assessment tool

- Iterative development of a new tool

Study 4. Feasibility of measuring outcomes

- Data return rate summaries

- Interviews & conversations with staff and researchers

Study 5. Feasibility of use of routine NHS data for trial outcomes

- Comparison of routine NHS data with data obtained from care homes

Study 1: Challenges of delivering training

Poor care home staff engagement with intervention training was often highlighted in the literature (53, 81, 90). I wanted to explore the practical difficulties associated with arranging training sessions and the problems encountered with attendance, through review of the quantitative data collected for the PATCH trial and written accounts provided by the trainers after each training session.

The PATCH trial process evaluation aimed to: understand the barriers and enablers to delivering and implementing the SCTP; understand trainers' and care home staff's views of delivery and receipt of the training; and obtain insight from residents regarding intervention acceptability. Some of these aims were met by another researcher

undertaking observations of training sessions and interviews with staff, trainers and residents. I focussed on understanding staff attendance rates, the practical challenges associated with planning and delivering the sessions, and trainers' reflections on the organisation and delivery of sessions - elements that might influence fidelity of intervention delivery and receipt, as well as support process evaluation conclusions. I particularly attended to elements that were reported to be problematic in the literature.

I examined summary statistics generated from the quantitative data to illustrate the range of staff compliance with planned training sessions. I also examined the quantitative data to explore the organisational processes undertaken, training group composition, whether training sessions took place as planned, and the sustainability of training over time. Qualitative data obtained from the trainers then allowed exploration of their experiences of these processes.

I designed data collection forms for the PATCH trial for the trainers to record training attendance and difficulties encountered with the arranging and conduct of training sessions. I used these data to explore in detail the problems experienced with staff training in the PATCH trial.

Although interviews often yield richer data (148), I thought that the trainers' written accounts of their experiences after each session would be the best way to capture data about the practical challenges that occurred at each care home 'in the moment', rather than relying on later recollections of such challenges; such delayed recollections might have lacked the detail I required of the specific experiences trainers had with each group of staff at each home. The possibility of interviewing the trainers every time they had delivered a training session was not a practicable alternative due to the time it would have taken out of their clinical work and the difficulty scheduling multiple conversations.

Study 2: Measuring the use of new skills

There are detailed checklists (157) and frameworks (158) that have been developed to elucidate the important elements of intervention fidelity, prescribing what should be monitored and reported; these elements were incorporated into the PATCH trial process evaluation and my design of Study 1. However, there is less guidance on what should be done in practice to measure fidelity (159), in particular how the use of new

skills should be measured. It is important to understand the degree to which new skills are used in practice (enactment) to inform the decision to progress to a definitive trial and, within a definitive trial, to inform the interpretation of results (40, 153).

My literature review revealed that observational approaches have been used in other care home research to identify the enactment of new skills - for example, an audit of activities that were included in intervention training sessions (114) - but there is no standard approach that can be applied to all skills-based interventions. Indeed, the measurement of intervention fidelity and enactment is often poorly reported and, where it is reported, methods used are wide-ranging with no agreement on a gold standard approach (159, 160). I thus needed to explore the development of a bespoke approach to the measurement of care staff's use of skills learned during training.

I worked with the physiotherapists who designed the intervention (and who were providing the training) to develop a structured observational approach (161) to the measurement of care staff's use, in practice, of skills learned during the Skilful Care Training sessions. We decided to develop a structured checklist because it would be the researchers and I who would use it - being non-experts, we needed guidance on what behaviours to look for and how to record them - and it forces each observer to look systematically for the presence of the same behaviours, so potentially improving the reliability of the measurement process (162). An iterative approach to developing and testing the checklist was adopted.

The physiotherapists provided expert advice on the required content of the checklist; they defined staff behaviours that would clearly demonstrate their use of techniques learned in training - for example, specific ways of helping a resident to stand. Those behaviours also needed to be easy for a researcher to identify and observe in a public area such as a care home's living room. As a starting point, the physiotherapists generated a list of activities (for example, help with eating), which I converted into a checklist on which we could record whether each activity had been observed. If it had, there was an option to record whether the supportive techniques used by staff were correct - those taught during training - and whether there was appropriate communication from the staff member to the resident to explain the activity. I included a free text section to describe the location in which the observation was undertaken (for example, living room) and the current environment (for example, how many residents and staff were in the room, researcher's impression of residents' postures). This

contextual section was later updated, following discussion with a colleague with expertise in process evaluation, to follow a standard format that prompted comprehensive reporting of the environmental conditions (163). We agreed to observe for around 20-30 minutes because we were assessing the feasibility of the approach, rather than collecting extensive data, and we thought that longer observations might be intrusive. This timeframe also aligned with recommendations provided for other observational tools (114, 164), which suggest that 20 minutes is the optimal duration for a researcher to maintain concentration.

We encountered several uncertainties that could only be answered by testing the checklist: whether observation of a number of residents at the same time - producing a 'count' of observed behaviours - or more detailed observation of only one resident at a time was more meaningful or feasible; whether there would be too much or too little activity to observe; and whether short observations would yield sufficient data.

Before using the checklist for the first time, the physiotherapists provided training to the researchers and me - to explain in detail the behaviours we would be looking for. During this training we agreed to rate staff and resident interactions preferentially over observations of posture, although posture could be commented upon if there was no activity to observe. In this way we would be providing evidence for the active use of skills. The checklist was then tested in participating care homes by me, the physiotherapists, and other researchers working on the project. Testing the checklist on different occasions and in different locations provided preliminary information about the feasibility of its use. I met with the physiotherapists several times to discuss difficulties with completion and suggested changes that would improve the ease of use of the checklist; I made detailed notes during these discussions, later re-designing the checklist to incorporate agreed changes - thereby undertaking an iterative process of testing and re-design.

Study 3: Development and testing of a postural assessment tool

It is always important to select reliable and valid tools for the measurement of participant outcomes in research to ensure that results are meaningful (165): a reliable tool is one which has been shown to produce the same results regardless of how many times it is completed or by whom; a valid tool has the proven ability to measure what it is intended to measure (166). It is also important that the chosen tools are sufficiently sensitive to changes expected in the population under study, and that they are

measuring outcomes that are important and relevant to that population. Ideally a limited number of robust outcome measures would be available for use across trials assessing similar interventions or involving similar populations (167) to ensure quality and standardisation, so enabling meta-analysis. However, there were multiple reports in the literature I reviewed of available measures being inappropriate for care home residents (49, 56, 123) (for example, not validated in this population (66)), and indeed for the PATCH trial our choice of measures was limited and we had to use some that were not validated for our population (168, 169). In particular, we were not able to identify any existing observational tools or approaches that could be used by non-expert researchers (i.e. not physiotherapists) to measure residents' posture - a key outcome (see Appendix 1 - logic model) for an intervention designed to improve staff awareness of good posture. I thus worked with the physiotherapists who had designed the intervention to develop a bespoke tool for this purpose and to assess its preliminary validity, acceptability and feasibility. Such a tool needed to measure all relevant aspects of posture (content validity), be easy to use, and be acceptable to those whose posture was assessed.

The physiotherapists and I agreed that a hands-on approach to assessing posture, one that might be used by healthcare professionals, was not appropriate for researchers who would have no clinical reason (or training) to use it; we therefore needed to develop an observational tool. Colleagues and I had searched the literature systematically to find a suitable existing tool to measure residents' posture without success. The search returned 1568 potential papers, of which 123 abstracts were suitable for review, with five of these eligible for full text review. None of the existing tools reported in these five papers was suitable for our study population as they were either designed for a specific group - for example, wheelchair users (170, 171) or stroke survivors (172), or they required professional expertise and equipment (170, 173).

I organised a number of consultation meetings, attended by two physiotherapists, a researcher and me. At these meetings the physiotherapists considered the required content of a postural assessment tool, and we all discussed the appropriate format of the tool and the feasibility of completing it in a care home environment. We also consulted with a small group of physiotherapists who work with care home residents to seek agreement on the body areas considered to be clinically important when assessing posture. This consultation with experts was a robust method for establishing the content validity (174) of the tool: ensuring that it was fully representative of the

range of postures to be measured in the care home population. I worked with a graphic designer to translate the suggested content into pictorial format. Multiple iterations of the tool were produced, with each iteration developed through my discussions with the physiotherapists, other researchers and the PATCH trial's Patient and Public Involvement (PPI) group. I and another researcher field tested the tool, first completing it by observing each other, with the physiotherapists' guidance, and later by observing participating residents, as part of the PATCH trial data collection procedures. Once the final version of the tool was in use, we trained a further researcher to complete it, to ensure sufficient resource (two researchers and me) for data collection purposes. Where possible we obtained residents' opinions on the acceptability of our use of the postural assessment tool for the observation of their seated posture. Our experiences and residents' feedback also contributed to development of the tool's content.

A mixed methods approach to testing the newly developed tool - collecting quantitative data (multiple completions of the tool for PATCH trial participants) to illustrate the feasibility of completion, and qualitative feedback from researchers and residents - contributed to the validity of the findings: triangulation of data sources helped me to understand completion rates in the context of the researchers' and residents' experiences.

Study 4: Feasibility of measuring outcomes

Aside from the postural assessment tool, selected trial outcomes were as follows:

A) Completed by a staff member (a 'proxy') about each resident, in discussion with a researcher:

- Functional Ambulation Classification (FAC) (42)
- Physical Activity and Mobility in Residential Care (PAM-RC) scale (175)
- Barthel Activities of Daily Living (ADL) Index (168)
- Continuing Care Activity Measure (CCAM) (176)
- EuroQol 5-Dimension (EQ-5D-5L) proxy (177)

B) Completed by the participating residents (in discussion with a researcher):

- Iowa Pain Thermometer (178)
- EQ-5D-5L (self-report) (177)

C) Completed by all care staff about their own working practices and knowledge:

- Person-centred Care Assessment Tool (PCAT) (179)

- Kiersma-Chen Empathy Scale (KCES) (180)
- A trial-specific posture and movement questionnaire.

These questionnaires for care staff were provided in booklet form for ease of completion so, collectively, they are referred to as the 'staff booklet'.

D) We also collected data directly from managers and from care notes about residents' health and use of health care services. These data were provided in the form of the 'care notes booklet'.

All measures are included for information in Appendix 3.

All outcome measurement tools were chosen to align as closely as possible with the expected outcomes following intervention delivery, as laid out in the logic model (Appendix 1) which describes the component parts of the intervention, proposed mechanisms of action, and expected resident and staff outcomes. However, as mentioned above, some of these tools were validated in different populations (e.g. stroke survivors (168)) or were suitable only for those with mild cognitive impairment (181). It is the experience of administering these outcome measures and the perceptions of those providing data that I explored in Study 4 to try to understand the difficulties faced.

First, I reviewed measures' completion rates at each trial time point (baseline, 3 months and 6 months) to give an indicator of feasibility and acceptability over the course of the trial: was it possible to complete the measures, and were people willing to provide the information asked of them?

Second I explored, via interviews, the acceptability to the staff proxies and researchers of the tools used to assess residents' well-being (measures listed in A and B above). I also interviewed managers about their experiences of providing data about residents' health and health resource use. Looking only at overall completion rates of each measure or 'booklet' tells us little about the accuracy or completeness of the *content* or the reasons for non-completion, so interviews were chosen because they generate detailed accounts of people's experiences (149, 182). These interviews enabled me to explore the range of difficulties experienced by individuals in the administration or completion of particular tools, and any problems with the questions within the tools. Asking researchers about their experiences of the administration of measures with residents was also an indirect way of accessing residents' views and experiences of

answering the questions posed in each measure. To increase rigour, I collected written accounts from researchers after each data collection visit, inviting comments about any difficulties experienced with data collection. Notes taken in team and oversight group meetings by myself were also scrutinised for any reported detail about data collection difficulties. *Triangulation* (149, 156) of these data sources increased the validity of my findings: that is, each source provided a different perspective, and the use of multiple sources (triangulating - see below) is a way of confirming the truth, or validity, of subsequent findings.

I also aimed to speak to care staff about their experiences of completing the staff booklet. Since many of these staff would not have been directly involved in the research in the same way as the staff proxies - who had met regularly with a researcher to provide data about each participating resident - I thought that they might be daunted by 'interviews' and reluctant to engage in this way.(183) I was also aware of the difficulty of care staff finding time to take part in research whilst they were on shift (60, 97), and the fact that I was only asking them to comment on completing a few questionnaires about themselves. For these reasons I decided to undertake short conversations rather than formal interviews. These were focussed conversations, in that I wanted to explore staff members' perceptions of the booklets, but there was no topic guide to structure the conversation as there was for the interviews with staff proxies and researchers. Conversations can generate useful data when one aims for a more informal approach or wishes to take the opportunity to talk to people during chance encounters (184). This strategy enables data collection without the need for pre-planning as it is possible to obtain in-the-moment agreement for anonymised data to be used.

Study 5: Feasibility of use of routine NHS data for trial outcomes

As mentioned above, data were collected on residents' health and health service use. These data enabled examination of the impact of the intervention on health-related outcomes which resulted in health service use (for example, hospital admissions for falls or other reasons). These objective outcomes are frequently collected in care home research but are often reported to be of variable quality when collected from care home records (73, 100, 112), or difficult to access from routine data sources (68). I contacted the NHS Trusts to which our participating care home residents would be referred in the event of serious illness and obtained their routinely available data from either a researcher situated within each hospital, or directly from the Trust's information

systems team. My aim was to compare these quantitative data with data obtained from care homes to identify similarities and differences between the data sources, with the intention of making recommendations for the potential use of NHS data for future care home research. Should NHS data prove to be as reliable as or more reliable than care home-derived data, its use may reduce the need for resource-intensive data collection from care homes.

3.2.1 Sampling methods

3.2.1.1 Participant sampling

Quantitative research is usually concerned with ensuring recruitment of a representative sample of the population of interest (165). For example, a study population might comprise residents at 50 English care homes, with the intention of generalising findings to all care home residents in England (the target population). It is necessary to make population inferences from a study sample, because it clearly would not be possible from a time or cost perspective to recruit an entire population to a study.

Randomised controlled trials (RCTs), and other experimental designs, have defined sampling criteria, inviting participation only from eligible participants (those for whom an intervention is designed to provide benefit).(185) This sampling may be of individuals or of clusters - in which a group of individuals is seen as one unit (e.g. patients registered at a GP practice, residents in a care home). Cluster sampling would be the strategy of choice when an intervention was designed to act at the cluster level (186) - for example, a care home-wide initiative to change practice. There would be eligibility criteria for the cluster (e.g. care homes) and often for the individuals (e.g. residents) within it. Measures are put in place to minimise bias in the selection of participants in order to maximise the representativeness of the sample: for example, this may be achieved by offering all potentially eligible care homes within a particular region the opportunity to participate, rather than targeting only those homes known to the research team. The sample size is determined by statistical calculations which recommend a sample that is sufficiently large to support statistical analysis that can detect significant differences between groups.(185)

RCTs also aim to minimise bias in participant allocation to the arms of the trial - to ensure that results are attributable to the intervention and not to any special

characteristics of the participants. There are different methods of allocation, the most rigorous being random allocation in which participants are randomly assigned to an arm of the trial using techniques to eliminate bias in this process: a table of random numbers might be used to allocate participants to one arm or the other (*simple randomisation*), or a more sophisticated approach would be to employ *stratified randomisation* to ensure that participants with characteristics which might influence outcomes (e.g. gender, age) are included equally in each trial arm. Another form of allocation is *cluster randomisation* in which clusters (as described above) are randomly allocated to each trial arm.

Unlike quantitative sampling, qualitative sampling is not intended to generate statistical significance, but rather it should ensure representativeness of the population under study (150). Representativeness in this case refers to the selection of a range of subjects who provide in-depth accounts of the research topic. Sampling is non-probabilistic, and it is mainly classified as either *purposive* or *convenience* sampling (187). *Purposive* refers to a deliberate or purposeful selection of subjects - they are chosen by the researcher to ensure that certain types of subjects with particular experiences or views are selected. How subjects are chosen will depend on the research question: it may be that the researcher wishes to understand the full spectrum of views on a particular subject from a diverse range of people (e.g. men, women, old, young, rural, city-dwellers), in which case a *maximum variation* (148) purposive sampling strategy would be employed to ensure representativeness of all people of interest. Alternatively a researcher may wish their sample to comprise similar individuals (a *homogenous* sample (187)) in order to explore a shared experience that relates to their similarity of, for example, gender or culture. A further strategy is *critical* or *typical* case sampling (147) in which particular subjects are chosen on the basis of their being critical to a particular function (for example, the implementation of an intervention where intervention delivery is being explored): it is these subjects' views that are critical to the understanding of the process.

Convenience sampling is not driven by the needs of the researcher; rather it is based on selecting those who are available. By definition, it is not an ideal strategy and is open to criticism that it does not allow the gathering of a diverse and meaningful range of data that might otherwise be seen with purposive sampling. In short, conclusions are difficult to draw when there is a lack of representativeness of the wider population within the sample, so even with a large sample there may still be concerns about representativeness.

Sample sizes in qualitative research are usually small, partly because statistical variables do not play a part in the nature or purpose of qualitative research - the aim is not to report, for example, frequencies or proportions, but rather to understand a topic in depth - so statistical calculations are not necessary (150). In generating large amounts of detailed data from interviews for example, it is not always feasible to include large numbers of subjects because there may not be the resource or time to undertake analysis. Detailed accounts from even a few participants can generate vast amounts of data; that, coupled with an appropriate sampling strategy, means that after a time there is little new information generated. This is known as reaching data *saturation* (150), at which point there is no need to recruit further subjects to a study. Saturation can be reached sooner or later, dependent on the research question, the complexity of the selection criteria, and the diversity of the population; it is not possible to specify, a priori, a precise sample size, as is the case with experimental research designs.

I employed a number of different sampling approaches to select participants for my studies, tailored to my research questions and the availability of potential participants.

To understand the difficulties with scheduling and delivering training sessions (Study 1), I needed to capture information from the trainers involved in providing training to staff at each of the five homes allocated to receive the SCTP. It was important to obtain information about training successes and difficulties at all homes - to capture the overall attendance rates, and any variation between homes. Similarly, I wanted to collect information from each of the trainers, in case they experienced the training differently. Critical case sampling was thus the strategy of choice, as the trainers were critical to my understanding of the challenges related to staff attendance at training sessions.

The observation of residents and staff (Study 2) were made for all those present in public areas of the care homes when we visited (a convenience sample), providing there was no objection from anyone within each area. It is necessary to work in this way to observe care practices as they occur routinely, without any prior sampling of those to be observed.

To explore staff and managers' experiences of providing research data (Study 4), I wanted to capture any variation that might exist between homes, and therefore between staff members' perceptions of the provision of data. By doing this I would improve the *credibility* (described below) of my findings through the inclusion of a range of viewpoints. For example, some homes had electronic records that were more easily interrogated than paper notes (these tended to be the larger, 'chain' homes); I thought that nursing staff might have different perceptions of residents' health and well-being to care staff in residential homes, and that staff at the homes allocated to receive the SCTP might have had more exposure to research procedures. I thus purposively sampled homes on the basis of size (registered to care for < 40 and ≥ 40 residents), type (residential or nursing), and intervention allocation (SCTP or usual care) - aiming for maximum variation in the sample from the staff population contributing to the PATCH trial. The total number of managers and staff proxies who provided data about the residents was 23 across 10 care homes - 13 informants and 10 managers. I hoped to engage at least four homes, and from those homes recruit 8-10 managers or staff proxies to take part in interviews about their experiences of providing data. Although it is well known that there is heterogeneity across care homes (9), and I could have undertaken the larger task of interviewing all 23 managers and staff, the subject of my enquiry was limited to a practical task, so I thought that interviewing a small sample would yield sufficient diversity of viewpoints to ensure saturation of the topic area (150).

As well as interviewing staff proxies (those providing data about the residents), I also wanted to understand the researchers' experiences of obtaining information for the trial from residents and staff. Researchers were critical to the data collection process, facilitating the provision of information from all participants, so it was important to have their views to obtain a wider understanding of any challenges faced by themselves, the residents and staff. My researcher selection strategy was thus one of critical case sampling, as it was for the trainers (detailed above).

My planned *conversations* with care staff related to a specific task - their completion of questionnaires about their own working practice, knowledge and skills - so I expected a narrow range in the diversity of views about the acceptability of the questionnaires' content and its completion time. Thus, I thought that a smaller sample (N=20) would appropriately reflect a range of experiences. (Overall >140 staff completed questionnaires during the PATCH trial.) I also thought this to be a realistic number to expect from a pool of busy care staff, and that any larger sample would not be feasible. Mindful of the reported difficulties of accessing staff, I adopted an opportunistic

approach when I visited care homes - I invited those who were available at the time of my visit to provide brief, conversational feedback about their experience of completing the staff booklet. In this way I planned to include a convenience sample of care staff from our PATCH homes. As mentioned earlier, this is not an ideal strategy from the perspective of representativeness, but it seemed to be the best option to capture views from a hard-to-reach population.

Finally, the quantitative elements of each of my studies used data from the full PATCH trial resident sample. Although there was not the requirement for statistical significance (I was not conducting a further experimental, comparative study), it was nevertheless important to have as large a sample as possible to maximise the strength of my findings.

3.2.1.2 Inclusion criteria

<u>Trainers</u>

All trainers provided feedback on their experiences of arranging and delivering training sessions (Study 1).

<u>Staff</u>

Staff were eligible to take part in interviews (Study 4) if they were:

- the manager of a care home participating in the PATCH trial, or

- a member of staff who had provided 'proxy' data about residents' quality of life in discussion with a study researcher.

Staff were eligible to take part in conversations (Study 4) about their experience of the 'staff booklets' if they had been provided with one of these on at least one occasion during the conduct of the PATCH trial.

<u>Researchers</u>

I aimed to invite researchers to be interviewed (Study 4) who were involved in data collection at most of the participating care homes to maximise my understanding of variation between and similarities across care homes.

All researchers collecting data from care homes participating in the PATCH trial were included in elements of my work requiring written feedback to ensure as complete a picture as possible of the diversity of experience (Studies 2, 3, 4 and 5).

<u>Residents</u>

Residents' consent (or consultees' agreement) to take part in the PATCH trial included agreement to their data to be used for my studies. All participating residents' data were thus included in my work (Studies 3, 4 and 5), unless they (or their Consultee) had later withdrawn consent to trial participation. It was important to maximise the amount of data available for any quantitative data summaries to improve the validity of my findings.

Observation of residents and staff to understand the use of new skills (Study 2) were not limited to those who had provided consent (or consultee agreement); rather all residents and staff present in public areas of the care homes were observed to enable an understanding of routine practice.

3.2.1.3 Participant identification and recruitment

The identification and recruitment of PATCH trial participants (residents and staff), whose data were also used for some elements of my work, is described elsewhere (35, 44) and in Chapter 1. Here I describe how I identified and recruited participants for my prospective empirical studies.

Trainers and researchers were part of the trial team. I obtained verbal agreement for use of their data collected during the PATCH trial for my PhD studies. After completion of data collection in all homes, I approached the researchers, requesting their verbal agreement to be interviewed about the research process (Study 4).

At the end of their involvement in the trial, I approached care home managers to find out whether they would be willing for me to talk to them and to their staff. Where they agreed, I provided the manager with copies of information sheets about the proposed interviews and conversations (Study 4) - for themselves and to pass on to staff members. I spoke to interested staff over the telephone to explain what would happen

during an interview and to arrange a convenient time to visit their care home to carry this out. Written consent was obtained prior to all interviews.

For informal conversations about the staff booklets, I approached staff who were on shift when I visited their care home for pre-arranged staff interviews. Staff I had interviewed directed me to those who were on shift and available, and I subsequently asked those I spoke to if they could direct me to others. Prior to speaking to each staff member, I provided a short (one-page) information leaflet and obtained verbal agreement to speak to them and make anonymised notes directly afterwards.

It was important to speak to researchers and staff *after* PATCH trial data collection was complete to ensure that the topics raised in our discussions did not influence the way data were later collected for the trial. Interviews conducted before completion of the trial might have resulted in biased data provision - for example, after our interview, a staff member might have considered residents' experiences in a different way and so expressed different opinions about their perceptions of a resident's well-being.

3.2.2 Setting

Data were collected from and about residents within their care home. I spoke to managers and staff in their care homes, in a private space wherever possible. Researchers were interviewed in a private room at the Academic Unit for Ageing and Stroke Research.

3.3 Ethical considerations

Ethical approval was required for my studies as they involved secondary use of the data collected from and about vulnerable older adults residing in care homes. Approval for my PhD work was included in the approvals obtained for the PATCH trial. A favourable ethical opinion for the PATCH trial was provided by Yorkshire and the Humber - Leeds East Research Ethics Committee (REC) (Reference: 16/YH/0114). I was responsible for writing and submitting the IRAS application and all protocol amendments occurring during the trial period, including amendments to allow the use of trial data for my PhD studies, and additional permissions to undertake interviews and conversations with staff about data collection processes. Copies of all information sheets and consent forms are available on request.

At the start of the trial I had obtained only REC approval, as the Health Research Authority (HRA) approval and associated individual site review required for NHS studies were not needed for research undertaken solely in care homes. However, in order to obtain data from NHS Trusts for Study 5, I later needed to request HRA approval for the project in order to proceed with approvals at a local Trust level. In accordance with standard procedures, each Trust then had to confirm their capacity and capability to undertake the required elements of the research - namely the provision of routinely available data about care home participants. This meant that I needed to provide each site's R&D team with a 'local document package' which included all documentation submitted to and received from the REC and HRA, a part-completed Statement of Activities (SoA), and a Schedule of Events (SoE). These last two documents are required for all NHS research projects - they describe where research activities will take place, who will be involved, when and for how long, and the amount of time and resource required to deliver the project locally.

My work was conducted in accordance with the UK Policy Framework for Health and Social Care Research. The main ethical considerations are detailed below.

3.3.1 Informed consent

A core principle of research is that informed consent should be obtained from participants. This has a basis in good clinical practice (188) and ethical standards that promote the expectation of autonomy and privacy of research participants (189). There is also a legal requirement for consent through the common law duty of confidentiality (190). To ensure consent is valid, all potential participants must be fully informed about the rationale, processes, risks and benefits involved in a research project and have time to ask questions prior to making a decision about whether to participate. Thereafter, consent must be voluntarily given by a person with capacity (189). Where a person does not have capacity to provide consent, a consultee should be identified to make a decision and provide agreement (or not) on his or her behalf, in accordance with the principles of the Mental Capacity Act (MCA) (43).

A large proportion of the residents living in the care homes participating in the PATCH trial did not have capacity to provide consent, so we followed the principles of the MCA, obtaining agreement for each resident's participation from a suitable representative

who knew them well - a relative, friend or member of staff (a 'consultee') (35). In all research, participants or their representatives have the right to withdraw from their involvement at any time after they have provided consent or agreement. I remained vigilant for any such withdrawals during my work to ensure that I only included resident data in accordance with their or their consultees' wishes. In the event, there were no individual participant withdrawals during the trial.

All staff members in each care home were provided with information sheets explaining the PATCH trial and the elements of the research in which they might be asked to participate. Staff members providing data about themselves (in the 'staff booklet') were not asked to sign consent forms; instead, agreement to use of their data was assumed by their return of questionnaire booklets. However, we preserved the anonymity of their responses by using an ID number rather than any personal identifiers. This anonymisation was achieved by keeping a *staff tracker* in each care home which comprised a list of all direct care staff by name, including a unique ID for each person.

Using this same tracker, names and IDs were added to the forms completed by the trainers after each training session, with names removed prior to any data being sent to the research offices. All those attending training signed a *training attendance sheet* at the start of their first session, in which they agreed, amongst other statements, to "the trainers collecting some information for the research (e.g. attendance) at each training session [which would be] sent directly to the research office. It would not include your name."

Consent was obtained from care home staff who participated in interviews (Study 4), following provision of an information sheet and the opportunity to discuss the interview process and subsequent use of data with me. In my undertaking of interviews it was important to remind staff that they could stop the discussion at any time if they felt uncomfortable or did not wish to continue; however, this did not happen, perhaps because we were not discussing a particularly sensitive or personal topic.

For Study 2 (measuring the use of new skills), a process consent approach (191) (an ongoing process of consent throughout the project) was used for these observations, with researchers explaining their purpose to all individuals present on each occasion when observations took place. Observations were only recorded in public areas of the

care homes, and only when there was no objection from anyone within that area. No identifiable information was recorded.

3.4 Data collection

Quantitative and qualitative data collected for the PATCH trial and additional data acquired for the sole purposes of my PhD studies contributed to different elements of the findings reported in this thesis.

3.4.1 PATCH trial data

I used the following data collected during PATCH trial intervention delivery and data collection visits to contribute to the answering of my research questions.

For Study 1

For the PATCH trial I had designed forms for the trainers to complete to report the planning and delivery of training sessions - for completion after every session at each of the five homes that were in receipt of the SCTP.

As well as prompting for planned session dates and attendance at these sessions, the forms included space for written reflections from the trainers on the difficulties they experienced with planning and delivery. For example, I prompted for reasons as to why practical sessions did not take place as planned, or why content was modified. I also asked them to express in writing their initial impressions of the suitability of the care home for training (before any training sessions had taken place), and their experience of the training in each home once it was complete - prompting them to reflect on any context-specific issues that affected training, or that they thought would influence implementation; there was also space to provide any other feedback they might wish to report. I wanted to use these data to explore the practical difficulties encountered by the trainers when attempting to deliver the intervention at each home.

At the end of the trial, intervention planning and delivery data were returned to me in raw form in Excel spreadsheets, so I could summarise attendance rates and explore the written reflections provided by the trainers. These 'reflections' were exported from the trial database to an Excel spreadsheet and then uploaded by me to NVivo for data

management and analysis. Staff attendance rates in conjunction with the trainers'
reflections enabled me to explore the difficulties of providing intervention training in
care homes.

For Study 2

The development of the observational tool is presented solely in this thesis; data
obtained - collected by myself and other researchers - were not used in the analysis
and reporting of the PATCH trial.

For Study 3

I used Postural Assessment Tool (PAT) data collected by myself and researcher
colleagues to explore the feasibility and acceptability of using the PAT with residents.
The CTRU returned the raw data to me so I could calculate completion rates and
scrutinise the data to understand any difficulties with particular questions. Written notes
(comments within the PAT) provided by me and other researchers were also included
in this dataset, including comments on what was difficult and why, and feedback from
residents regarding their experiences of being observed. These data contributed to my
understanding of the ease of use or difficulty with the completion of an observational
postural assessment tool within the care home setting.

For Study 4

Data return rates for resident and staff informant measures (except the postural
assessment tool) were summarised by statistical colleagues at CTRU and health
economist colleagues at the Leeds Institute of Health Sciences (LIHS) at the end of the
trial. I reviewed these data and I present relevant completion rates in Chapter 6 (the
feasibility of measuring outcomes) alongside my qualitative findings. Completion rates
point towards the ease or difficulty of obtaining data from different types of participants,
so provide context for the exploration of researchers' and care staff members'
experiences of collecting and providing data for care home research. For example,
where data return rates were low, I explored the reasons for this with staff and
researchers.

For Study 5

Residents' health and care data were collected from care notes held within each home, and from the manager - with the manager also providing home-wide data on health service use. These data included hospital out-patient visits, A&E attendances, in-patient admissions and engagement with community practitioners such as district nurses. I received the raw data collected for the trial so that I could later compare it with data I obtained from the relevant NHS Trusts. The purpose was to consider whether routinely available NHS data was a suitable alternative data source for obtaining outcome data for care home research.

3.4.2 Empirical study data

Here I describe additional data collected specifically for my empirical studies. I used some methods of data collection across studies so, in order to avoid repetition, I have grouped this section by methods used; I indicate for each method the studies to which they apply.

3.4.2.1 Documentary data (studies 3, 4 and 5)

After each visit to a care home (a visit defined as the one- or two-week period of data collection at each time-point at each home) all the researchers and I provided written feedback on our experiences on a form I had designed. This form included prompts for feedback on any difficulties with: data collection, recruitment, access to the home and to staff, and challenges relating to the residents. There was also space for an explanation of how data were stored and accessed, and any general comments about our experiences at the home.

I kept detailed notes from: all team meetings with the researchers, meetings with the physiotherapist experts regarding development of the postural assessment tool, trial management group meetings (all co-applicants), and meetings of the Trial Steering Committee (independent experts reviewing trial progress). I also made field notes after each visit to a care home during which I had had conversations with the manager or staff, and after speaking to hospital-based staff about the availability of routinely-recorded health data. I typed up these notes for future review and analysis.

These documentary data contributed to Studies 3, 4 and 5 by providing information and insights about: the iterative development of the PAT, data collection processes, and the feasibility of obtaining different types of data. This information complemented other data sources (quantitative data, interview data) by providing additional detail to help answer my research questions regarding the acceptability, feasibility and challenges of data acquisition for care home research.

3.4.2.2 Observational data (study 2)

For study 2 I developed a checklist that other researchers and I used to document care staff's use of new skills in routine practice. In my reporting of this work I do not present the observational data (this was not the primary focus, and was not sufficiently comprehensive), but rather the feedback that informed iterative development of the checklist and led to agreement of the most feasible approach for future observational work. Detailed field notes were made by me and other researchers immediately after each observational session. I also made notes during each meeting or informal discussion held to further the development of the checklist. It is these notes and feedback that form the dataset for this work.

3.4.2.3 Interviews (study 4)

For Study 4, I developed an interview topic guide (Appendix 4) to be used during my interviews with the managers and staff who had provided data about the residents participating in the trial. In creating the topic guide I drew on the findings from my literature review relating to data collection from care home residents and staff (for example, that some measures were not relevant to residents, or that data are sometimes not available). I drew also on experience from the PATCH trial as observed by me and discussed with the other researchers. A topic guide acts as an aide-memoire to ensure standardisation of the topics to be discussed, but it is sufficiently broad (topics rather than questions) to ensure flexibility in the discussions with individual participants (150). I wanted to elicit staff's opinions on the ease of use and relevance of each questionnaire administered for the PATCH trial, so I asked them to look again at the questionnaire booklet during the interview to remind them of the data that they had been asked to provide. I covered the following topics: the ease or difficulty of answering the questions in each proxy questionnaire and its perceived relevance to the residents; how home-level data, such as falls, were collated - and what types of data were collected routinely; the relevance and time taken to provide home-level data; suggestions for alternative ways to collect data; and thoughts or

feedback received about the staff booklet (in which staff provided data about their own knowledge and working practices).

Similarly, I explored researchers' views on the data collection tools, using each questionnaire booklet as the structure for discussion - prompting for feedback with questions such as 'how did you find this?' and 'what sort of feedback did you have from staff?'. I audio-recorded all interviews and these were transcribed verbatim by a trusted external transcription service.

3.4.2.4 Conversations (study 4)

I used prompts to facilitate conversations with care home staff, asking if they remembered being given the staff booklets, if they had completed them (if not, why not) and what they thought of them. I made anonymous notes immediately after conversations with staff. Where informal conversations (out-with planned conversations or interviews) yielded important and relevant information, I made anonymous notes, after verbal agreement from the person(s) involved. I typed up these notes so that they were in a suitable format for analysis.

Data derived from interviews and conversations contributed to my understanding of researchers' and care staff members' experiences of collecting and providing data for care home research (Study 4).

<u>Interview and conversation conduct</u>

Prior to commencing each interview, I reminded the interviewees that our discussion would be confidential, that they had the right to withdraw during or after the interview, and that it would be recorded to ensure that an accurate record of the discussion was obtained. Similarly, for conversations, I was clear about the principles of confidentiality and withdrawal. I reassured all participants that there were no right or wrong answers, and that I was interested in their opinion and to understand their experiences during the PATCH trial. I was careful to limit my use of research terminology, using plain English terms to facilitate staff members' understanding of the topic - I was aware that there were many words in everyday research parlance that were not clear in their meaning to non-researchers. For example, 'intervention', 'randomisation', 'baseline', 'follow-up', 'outcome measure'.

3.4.2.5 Routine NHS data (study 5)

As mentioned above, PATCH trial data collected from care home records included information about residents' hospital and community health care contacts. I sought to collect these same data from the relevant NHS Trusts to allow comparison with data collected from care homes, and so to explore the availability and usability of routine NHS data to inform trial outcomes (Study 5).

During their participation in the trial I asked each care home manager which hospital(s) their residents would attend for emergency and routine care - to ensure that I obtained research governance approvals for, and requested data from, the correct Trusts. I excluded one of the ten participating homes completely from this work as research staff collecting data had been based at the hospital to which the home referred residents, and they had thus already been able to access routine data from hospital records to provide trial outcome data - thereby contaminating the research method if included in the present study.

Once approvals were in place, I identified and communicated with staff members at each NHS site who were to access and provide trial-residents' routinely available health data. I either met them in person or spoke to them over the telephone to explain what was required, to explore how the hospital data were coded and stored, and to understand the data extraction and transfer process. I investigated whether it would be easier to provide data manually or via electronic querying and download of participant records and, for the latter, whether this process would compromise content. I made detailed notes after each meeting to provide a record of processes and potential challenges at each Trust. Where NHS staff preferred to provide data manually rather than via an automated data download, I gave them the relevant trial case report forms (CRFs), highlighting the data items required on these forms, so that they could transcribe data in a standardised way onto paper. These CRFs were those that had been used during the PATCH trial by researchers to collect health and care data from care home records.

Figure 4 illustrates the data I requested from the acute trusts where a direct data download was to be the method of data provision; Figure 5 illustrates the data requested from the Community Trust.

Figure 4 Data requested from acute trusts

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1. Participant level data

Hospital admission details

- Date of admission
- Reason for admission
- Ward description (e.g. general, orthopaedic)
- Discharged (yes, no, died)
    - o Date of discharge (if applicable)
    - o Date of death (if applicable)
    - o Cause of death (if applicable)

Other hospital contacts

- Attendance at out-patient clinic(s)
    - o Reason
    - o Clinic name/type
    - o Date(s) of attendance -
- Hospital day centre attendance
    - o Date(s) of attendance
- A&E attendance
    - o Date(s) of attendance
    - o Reason for attendance
    - o Outcome (discharged, admitted, died)
        - ▪ Date of discharge (if applicable)
        - ▪ Date of admission (if applicable)
        - ▪ Date of death (if applicable)
        - ▪ Cause of death (if applicable)

2. Care home level data (anonymous)

- Number of residents admitted to hospital from this care home
- Number of admissions to hospital from this care home (this can 'double count' individuals)
- Number of admissions to hospital where reason for admission = fall
- Number of deaths

Figure 5 Data requested from community trust

Type of contact*

- District nurse
- Tissue viability nurse
- Advanced nurse practitioner
- Community matron
- Health visitor
- Community mental health team
- Speech and Language Therapist
- Occupational therapist
- Podiatrist
- Community pharmacist
- Chiropodist
- Physiotherapist
- Palliative care team
- Dementia assessment unit

* For each of these I requested total no. of face-to-face contacts, location of visit and total no. telephone or email contacts (as had been included on the trial CRFs)

I asked site staff to search for hospital attendances for participating residents living at the care homes within their catchment area (as identified by managers). I also asked these staff to search for attendance records for residents living at some additional participating homes that did not report routinely referring residents to the hospital in question, in order to estimate whether data would be missed if I focussed solely on the hospitals identified by the care homes.

I sent each participant's NHS number, initials, date of birth and trial ID securely to site staff to enable accurate data extraction. On receipt of NHS data sets I checked data for completeness and then sent any queries regarding missing or ambiguous data items to site staff. Once all queries were satisfactorily resolved, I anonymised the final data set from each Trust to include only care home and trial IDs. Retaining trial ID with the hospital data allowed the later comparison of these data with the trial data collected from care homes - to enable me to explore the availability and usability of routine NHS data to inform trial outcomes. I entered data received on paper CRFs into an Excel spreadsheet for review purposes. Where I received electronic data outputs (also

downloaded to Excel) from staff who had queried electronic notes systems, I reviewed and formatted these to facilitate analysis - for example, where multiple rows of data related to one admission, I combined them to allow comparison with trial data.

3.5 Data Analysis

Data that had been stored in the trial database at CTRU were transferred back to me at the end of the trial data collection period. I then saved these data in secure electronic files in linked anonymised form, including only participants' trial identification numbers (IDs). Similarly, data obtained from NHS Trusts were saved securely, with all identifiers removed except participants' trial IDs. All documentary data that I had collected or produced were saved securely in electronic form. Interviews were transcribed verbatim and anonymised, with participants allocated an ID and pseudonym.

All analyses were conducted at the end of the data collection period. This was essential where quantitative data were required, as I needed to wait for a full, clean dataset to be available. I might have begun analysis of my interviews whilst these were ongoing, to inform the direction and content of later interviews (a form of constant comparison (192, 193)); however, I needed to fit my work around staff availability at the end of the trial, which gave little time between interviews for detailed analysis. I did, however, reflect on my interview style between interviews by listening back to the recordings to refine my approach. I was also able to update the topic guide to focus in later interviews on areas that had been discussed in earlier ones: for example, the observation that residents' health and well-being varies from day to day was raised by staff in the first few interviews, so I included prompts designed to explore this concept in subsequent interviews.

3.5.1 Quantitative data

For Studies 1, 3 and 4, I summarised relevant data collected for the purposes of the PATCH trial to produce descriptive statistics that include:

- Counts and proportions of training uptake by care homes (individually and overall), and attendance at sessions by staff.

- Data completion rates - for the postural assessment tool (overall and item-level completion rates) and for staff outcome measures, including for the proportions of staff remaining in post over time and thereby able to contribute to data collection.

For Study 5, I reviewed in detail the data provided by each Trust - to understand the data fields that were available and to ascertain how they compared to the data item descriptions I had requested. I was then able to map hospital-provided data fields to trial data fields, thereby establishing rules for which fields were comparable when assessing agreement between hospital and trial data for each resident. I also needed to identify individual events that were reported in both data sets - achieved by ordering each data set by Trial ID (as assigned to each resident) and then by date of hospital attendance - which allowed further essential comparison between the two data sets. Finally, I needed to apply additional categorisation to the hospital data set, identifying which hospital attendance dates fell within the trial-defined baseline, 3-month and 6-month periods. I was then able to produce counts, for each resident, of the number of events (for example, A&E attendances) occurring during each time-period in the hospital data set, for comparison with trial data that were grouped in this way. Detailed description of the processes undertaken is provided in Chapter 7.

Data quality

The *validity* and *reliability* of study results are important concepts in the conduct and reporting of credible research findings (194). In quantitative research, *internal validity* refers to the accurate measurement of outcomes within the study - establishing a trustworthy 'cause and effect' relationship between treatment and outcome; whilst *external validity* refers to the generalisability of findings to a wider population (195). *Reliability* refers to the consistent repeatability of a measure so that, for example, the measurement of a person's mobility is the same each time it is measured by different people using the same tool or measure.

These concepts were considered in the design of the PATCH trial by selecting, wherever possible, outcome measurement tools that had established validity and reliability, training researchers in their use to minimise measurement error, and blinding researchers to treatment allocation to minimise the possibility of biased assessment. I was involved in the collection of baseline outcome data, but not follow-up data as I was the un-blinded member of the team, so my involvement in data collection post-randomisation would have been open to the criticism of bias (165). The application of eligibility criteria that were sufficiently representative of the England-wide care home population provided assurances regarding external validity.

Maintaining data validity was achieved by rigorous data management procedures, both at the CTRU and by me. Data were entered and checked by separate individuals to ensure accuracy of transcription from paper to database. Where I received data back from CTRU, it had already undergone data checking procedures, but I also cross-checked with my records to ensure I had data for the full population and that there were no discrepancies between my records and those maintained by CTRU. Similarly, data received from the NHS Trusts for Study 5 were cross-checked against data collected for the trial, with any discrepancies queried with the CTRU team to ensure I was able to draw robust conclusions from all available data.

3.5.2 Qualitative data

3.5.2.1 Approach to analysis

I used the *thematic analysis* method described by Braun and Clarke (196) to make sense of the documentary, interview and conversation data. This is a structured method for systematically organising data into codes and categories, and for identifying patterns of meaning across a data set (197). Thematic analysis can be used to produce either a rich thematic description of an entire dataset or a more detailed account of particular themes identified within the data (196). When including the entire dataset, some depth and complexity is inevitably lost, but it is a useful way of generating an understanding of an under-researched area where the views of participants are not known. Themes can vary in complexity, from purely descriptive accounts of a concept to more interpretative themes that aim to understand the deeper meanings within the data. Because I was investigating practical tasks associated with intervention delivery and data collection, and because there is little known of people's experiences of these tasks, most of my themes are descriptive in nature. In my analysis of the interview data, however, some of the themes include more interpretative content. For example, when talking about the difficulty of providing proxy data, staff members discussed their conceptualisation of dementia and how this affects their ability to make a judgement about residents' own experiences of well-being.

Thematic analysis can be undertaken using an *inductive* or *deductive* approach. (196) Inductive analysis involves coding the data without trying to fit a pre-existing coding framework; the analysis is data driven and is not underpinned by theoretical hypotheses. Conversely, deductive analysis is top-down - based upon an existing framework that is theoretically driven; in analysing the data the researcher would be

looking for evidence to support or refute particular hypotheses generated prior to data collection. An inductive approach benefits from not engaging with the literature prior to or during analysis, so in this respect my approach was somewhat deductive in terms of having existing expectations originating from my literature review; however, my aim was to identify themes from the data rather than fit them to an existing framework, so the intention was to take an inductive approach (as far as was possible) so that I was open to newly expressed concepts.

Separate thematic analyses were undertaken for Studies 1, 3 and 4. I used a form of data triangulation, combining in my analyses data from different sources - interview, conversation and documentary data, as appropriate - to understand as fully as I could the views and experiences of my participants.

Braun and Clarke (196) describe a six-phased approach to thematic analysis, which is flexible - it can be adapted by the researcher to suit the research question - and which is not intended to be linear, with movement back and forth between phases throughout analysis. In summary, these phases are: 1) familiarisation with the data, 2) generation of initial codes, 3) searching for themes, 4) reviewing themes, 5) defining and naming themes and 6) producing the report.

First, I familiarised myself with the data by reading and re-reading the transcripts of interviews with staff and researchers, and all documentary data - making notes of potential data categories. For Study 4, I uploaded transcribed interviews and conversations to NVivo (QSR International 2012) to facilitate management and analysis of the data set. The volume of documentary data was less than that generated from interviews and conversations, and included shorter pieces, some already in an easily manageable format (on Excel, or in summary meeting notes), so I chose not to use NVivo to manage this part of the dataset. For Studies 1 and 3, however, I uploaded the trainers' written accounts and the researchers' written comments, respectively, to NVivo, as described above. For each study I systematically reviewed the whole dataset, generating initial codes from the data to produce a long list of codes, and then I sorted them to produce a candidate set of themes, which I then reviewed by reading all coded extracts to check for coherence. I reached my final version by refining codes and themes, creating new ones, and moving codes between one theme and another. During interpretation of the coded data I used a form of constant comparison (192, 193) - to revise my coding in line with newly identified themes. After re-reading and re-

coding the dataset, I then created a thematic map to assess whether my identified themes adequately described the whole dataset and were sufficiently distinct from one another. This process resulted in the splitting and re-naming of some themes to improve clarity, and my consideration of the essence of each theme - what it was trying to say - rather than just setting out a description of the theme's content. I then set about writing the analytic narrative and selecting data extracts to illustrate each theme, at this stage returning to my aims and to the literature to set my findings in context.

3.5.2.2 Trustworthiness

Whilst it is necessary to demonstrate that quantitative research findings are reliable and valid, qualitative research is judged in terms of its *trustworthiness*. The aim in both cases is to provide evidence for the accuracy of research findings - demonstrating that the research procedures and analysis have been undertaken rigorously, are methodologically sound and thus that results are understood to be legitimate and worthy of attention (198). It is more the case in qualitative than quantitative research that the findings are influenced by the researcher, and there are often many interpretations that could be applied to qualitative data (199), so it is particularly important that the trustworthiness of the approach taken to analysis is transparently reported. Whilst there is no consensus on a single approach to defining rigour in qualitative research, trustworthiness is commonly referred to in qualitative reports. Trustworthiness criteria were first defined by Lincoln and Guba (200) who provided definitions to parallel those of validity, reliability and generalisability in quantitative research. The criteria that they suggest contribute to the trustworthiness of research findings are: *credibility*, *transferability*, *dependability* and *confirmability* (200).

Credibility refers to the accuracy with which a researcher elucidates participants' experiences - the fit between participants' views or experiences and the researcher's representation of them (198, 200). It can be established via a number of means including: prolonged engagement with participants to ensure an in-depth understanding of their experiences; persistent observation to ensure, for example, a large quantity of observations; data collection triangulation (multiple data sources); and peer debriefing, or checking back with participants to confirm whether they have been accurately represented.

I established credibility through purposive sampling, data collection triangulation, peer debriefing and checking back with participants. By sampling purposively I hoped to

ensure that I captured a range of views from staff working in different types of home and in different roles, thereby creating a rich dataset for analysis. I collected data from a variety of sources - contemporaneous field notes, meeting documentation, written feedback immediately after an activity (data collection or training) had taken place, and interviews and conversations with staff and researchers. I considered that triangulating these different types of data and perspectives would add credibility to my findings by building a coherent justification for my themes (147). I presented the preliminary findings of Study 3 to an independent and experienced qualitative researcher, who provided an objective assessment of the processes undertaken and the themes I had identified. I also discussed my coding framework and initial findings with an independent qualitative researcher and my supervisors who made suggestions for expansion or amalgamation of existing themes, and alternative interpretations. These critical reviews helped me to shape my approach - allowing me to become more embedded in the meaning of the data; rather than pursuing my initial tendency to categorise data items in a more quantitative manner, I moved on to a more interpretative approach to the identification of codes and themes. This change in approach led, I believe, to a more robust analysis and conclusions.

I discussed my findings with the researchers who had taken part in the interviews, and with one of the trainers who had provided the written feedback after each training session. They concurred with the conclusions I had drawn; however, on reflection, I realise I should also have taken my findings back to care home staff for them to comment on their accuracy.

Transferability refers to the extent to which findings could be transferred to other situations (a parallel to generalisability in quantitative research), and it is assessed by researchers providing a rich description of the context or setting of their work (200, 201). There also needs to be sufficiently detailed description of the phenomenon under study to ensure a full understanding on the part of the reader who can then judge whether the findings are transferable. I spoke to a range of care home staff (managers, nurses, carers) and researchers who worked in or had collected data from care homes of different types and sizes; thus, it can be argued that my findings are transferable to other care home settings given the diversity of my sample. I have also provided detailed descriptions in my analytic narrative, including quotes from a range of participants to endorse my findings. This detailed presentation allows the reader to judge the transferability of my findings to other care home settings with which they may be familiar.

Dependability refers to the research process being logical, traceable and clearly documented (198, 202). Lincoln and Guba (200) suggest that dependability can be established if the research is seen to be credible; my explanation above, regarding the credibility of the processes I undertook, also illustrates elements of the dependability of my findings. In addition, I maintained a clear audit trail of my data management and analytic processes, using NVivo to facilitate this, as well as the writing of memos whilst undertaking analysis of both NVivo-based data and other documentary data.

Confirmability relates to the concept of researcher neutrality and their being free from biases that might influence data collection and analysis. Before undertaking participant interviews, I attended qualitative interviewing and analysis skills training, which equipped me with the techniques to approach my interviews in a way that would maximise unbiased participant responses - for example, asking open-ended questions and exploring participants' responses without directing the subject matter. It is suggested (203) that triangulation of data from a number of different sources allows for reflection on the neutrality of a researcher's interpretations; by using this approach I was able to minimise bias during my analysis.

The detailed reporting of methods is also an important element of confirmability; it allows others to understand how and why processes were undertaken and decisions were made (204). This transparency of reporting provides evidence that researchers' conclusions are drawn directly from the data (198). I have clearly laid out my methods and decisions that underpinned my choice of methods, thus enabling the confirmability of my findings. In demonstrating the credibility, transferability and dependability of my data, this also establishes confirmability (198).

3.5.2.3 Reflexivity

A separate but linked point is that of researcher *reflexivity*. Whilst the aim of all researchers should be to provide an unbiased account of the data (as described above), it is almost impossible in practice to attain total neutrality (149): all researchers have prior experience and beliefs which may influence the way in which they collect and interpret data. It is thus important for researchers to be transparent about their beliefs and values to enable others to understand their findings in the context of these

potential biases. I provide reflexive statements considering biases I may have brought to my analyses in chapters 4, 5 and 6.

* * * * * * * *

In this chapter I have described the methodological orientation of my empirical studies; and the design, data collection methods, and my approaches to the analysis of the quantitative and qualitative data generated for each study. Chapters 4 to 7 report the findings of my studies; whilst the final chapter (Chapter 8) draws my findings together to consider their implications for future research and practice.

Chapter 4 The challenges of delivering training to care home staff and measuring their use of new skills

In this chapter I present the findings of my empirical studies designed to identify the challenges of providing intervention training to care home staff, and the difficulties of monitoring and reporting their use of new skills. The research questions associated with this aim were:

- What are the challenges faced by trainers in the organisation and delivery of a training intervention in care homes?
- How could the enactment of new skills learned in training be comprehensively measured in care homes?

Details of the methodology and methods used are described in Chapter 3.

First, I present quantitative findings describing the organisation and delivery of training; second, I present my thematic analysis of the written accounts of the trainers' experiences, documented before, during and after training; and third, I present a narrative description of work undertaken to develop an observational tool to measure care staff's use of new skills in practice.

4.1 Participants

4.1.1 Trainers

Four trainers delivered the training sessions across the five care homes randomised to receive the SCTP intervention. All trainers were qualified physiotherapists with specialist expertise in neurological conditions and training qualifications such as 'Preparing to Teach in the Lifelong Learning Sector'. Data provided by each of these trainers contributed to my quantitative summaries describing the planning and delivery of training sessions, and my qualitative analysis of their narratives describing their experiences of these processes.

4.1.2 Staff

Data regarding each staff member's attendance at training sessions across the five care homes that received the SCTP intervention are included in my quantitative summaries. There were 155 care staff working across these five care homes at the

baseline data collection time point, all of whom could have been expected to attend training; this is the denominator used for attendance summaries.

4.2 Organisation and delivery of training - quantitative findings

4.2.1 Arranging training sessions

Although the trainers and I worked with the manager at the start of their involvement in the trial, to plan a programme of training dates for groups of staff, sessions did not always go ahead as planned: 71% (49/69) of planned sessions were delivered (see Table 4).

Of the 20 sessions that were cancelled, six were called off at the last minute due to too few staff members being available for training (see Table 5). Insufficient attendees also accounted for 5/6 of the cancellations that occurred within 24 hours of the scheduled sessions. Longer notice periods were given when a manager needed to re-arrange training sessions, mainly due to conflicting training requirements in one home.

Trainers experienced difficulties contacting managers to confirm or re-arrange sessions, which resulted in more time than expected being spent on administrative work. As well as setting out the proportion of sessions that went ahead, Table 4 also includes the time spent by the trainers (or a member of their administrative team) emailing or telephoning the care home managers to re-arrange training sessions. On average, they spent 50 minutes in contact with each home over the course of the training period.

The time spent travelling to sessions that were cancelled with no prior notice (six such sessions - see Table 5) was not recorded but can be estimated, from successful training sessions, as approximately two hours on each occasion - a total of around 12 hours of wasted travel time. Where these last-minute cancellations occurred, trainers also had unexpected 'spare' time available that could not readily be used for other clinical purposes.

Table 4 Training session planning and delivery

Care Home	No. planned sessions*	No. (%) sessions delivered	Admin time (minutes)**
4	13	6 (46%)	56
5	17	11 (65%)	40
7	7	7 (100%)	25
8	18	15 (83%)	45
10	14	10 (71%)	85
Total	**69**	**49 (71%)**	**251**

* Includes additional sessions required following cancellation of others

** Arranging and re-arranging session dates

Table 5 Reasons for sessions not taking place as planned

Reason	No. homes	No. times	Notice period given		
			None*	≤ 1 day	≥ 2 days
Insufficient attendees	3	9	5	4	0
Insufficient attendees due to heavy snow	1	2	1	1	0
Other training at care home took precedence	1	7	0	0	7
Rescheduled by home	1	1	0	0	1
Miscommunication**	1	1	0	1	0

* On such occasions, trainers had travelled to the care home as arranged

** Manager thought training was cancelled when it was not

4.2.2 Staff not attending training as expected

To ensure all staff were fully trained, we had planned to establish several groups of staff at each home, with staff remaining together in their allocated group to attend each of the three sessions. In this way trainers could tailor sessions to the individuals within the group, ensure that all staff received all elements of the training course, and monitor

attendance easily by marking as present those staff included on a list of expected attendees. Maintaining group composition did not, however, always work in practice. In the event, there were no homes at which all groups were convened as planned (see Table 6); instead, between 27% and 100% were <u>not</u> convened as planned. This unpredictable attendance by staff is explored further in section 4.3.

Table 6 Group composition <u>not</u> as expected - as a proportion of all group sessions delivered

Care Home	4	5	7	8	10	Total
Total no. sessions delivered	6	10*	7	15	10	**48**
Sessions where group composition was not as expected	5 (83%)	9 (90%)	7 (100%)	4 (27%)	3 (30%)	**28 (58%)**

* This data item does not match data presented in Table 11. I produced Table 11 from the raw data provided by the trainers. Data in this table were provided by CTRU in aggregate form, so I cannot check the raw data for accuracy.

4.2.3 Staff training attendance rates

Table 7 sets out the proportion of staff who attended i) all training sessions and ii) at least one training session. Cells are highlighted in green, amber or red to indicate the meeting of progression criteria described in Chapter 1 (see Section 1.2.3 and Table 1). Briefly, green represents successful intervention delivery; amber represents the need to review and revise training procedures for a future trial; and the meeting of red criteria is viewed as unsuccessful intervention delivery (less than 50% staff attendance at all sessions, or less than 60% attendance at ≥ one session).

Table 7 Staff attendance at training sessions

CH ID	No. expected to attend*	Attended all sessions (%)	Attended ≥ 1 session (%)	Attended none (%)
4	28	6 (21.4%)	15 (53.6%)	13 (46.4%)
5	40	5 (12.5%)	25 (62.5%)	15 (37.5%)
7	22	14 (63.6%)	19 (86.4%)	3 (13.6%)
8	38	25 (65.8%)	35 (92.1%)	3 (7.9%)
10	27	17 (63.0%)	25 (92.6%)	2 (7.4%)
Total	**155**	**67 (43.2%)**	**119 (76.8%)**	**36 (23.2%)**

* Working at care home at baseline. Excludes those known to be non-direct care staff and staff noted as not expected to attend the training (e.g. on maternity leave, no longer in post)

Staff attendance varied widely between care homes, ranging from 13% to 66% attendance at all required sessions, and 53% to 93% attendance at one or more sessions. Across all homes, satisfactory numbers of staff attended at least one session (77%), but only a minority completed the full training course (43%). A marked difference in attendance at all sessions can be seen between the first two care homes and the last three - accounted for, in part, by competing mandatory training and home closure at the first two homes, respectively. Collectively, the last three homes only just fell short of meeting green criteria.

4.2.4 A note about denominators

A comparison of staff denominators presented in this chapter with those presented later in Chapter 6, reveals a discrepancy between the total 'number expected to attend' (included in Tables 7, 8 and 9 of this chapter) and the total number expected to complete booklets presented in Table 20 in Chapter 6. A few weeks elapsed between the provision, by the manager, of the list of care staff to include on the staff tracker - and to whom questionnaire booklets were distributed at baseline - and the start of training. In the meantime, some staff members left or took extended leave (sick leave or maternity leave); where these absences were reported to the trainers, the relevant staff members have been removed from the 'number expected to attend'. In addition, some staff were later added to the training attendance sheet because they were newly in post. These changes explain the discrepancy between denominators presented here and in Chapter 6. This experience of fluctuating staff numbers points to a wider

difficulty with the accuracy of denominators: whilst the 'number of expected booklets' or 'number expected to attend' is as accurate as was possible at baseline or at the first training session, respectively, using this denominator to calculate proportions providing data or attending training over time becomes less meaningful when the total number of staff working in the home changes, or when the numbers of those present in the home at baseline declines.

4.2.5 Sustainability of training

I explored the sustainability of training, using the progression criteria set for the trial (Chapter 1 - Section 1.2.3 and Table 1) to consider whether homes that met 'green' or 'amber' criteria at the end of training remained in these categories over the six-month follow-up period; I did so by looking at how many of the staff members who had attended training were still working at their care home at the end of the trial. These numbers and proportions are laid out in Table 8 and Table 9, including a coloured representation of the level of success achieved. There are two problems with these tables. First, it was not possible to match all staff IDs on the training attendance forms with those recorded on the staff tracker form (a log of staff working in the care home at each time point): the trainers could not find all staff members' names and IDs on the attendance forms - mainly where staff started in post after the baseline visit and were thereby not recorded on the tracker - so they created a new ID for these staff on the attendance form, which did not correspond with the tracker at any point in time. These staff members with trainer-allocated IDs are the 'unknown' staff included in Table 8 and Table 9 so it is not possible to tell from the tracker whether they were still working at the home at six months. Second, as mentioned in the previous paragraph, there is the denominator problem: proportions are based on the total number of staff present in the care homes at baseline, but there might have been different numbers working in the home at six months. As it was not possible to reconcile all staff IDs, an accurate denominator at six months could not be calculated.

If I were to assume that 'unknown' staff were still in post at 6-months post-randomisation and the denominator was correct, the staff attrition rate would be less than it appears to be from the 'yes' columns in Table 8 and Table 9. Accordingly, I have highlighted each cell in the 'unknown' column with the relevant 'success' colour to illustrate the best-case scenario in relation to the retention of trained staff at 6-months.

Few staff left the homes but enough, in nearly all homes, to diminish the proportion of trained staff so as to downgrade the home to a lesser category of success (amber or red) than that recorded immediately after training.

Table 8 Proportion of staff, of those who attended <u>all</u> training sessions, working at each care home at 6 months

CH ID	No. expected to attend	No. attended all sessions	Still working at home at 6 months		
			Yes (% expected to attend at baseline)	No	Unknown
4	28	6 (21.4%)	6 (21.4%)	0	0
5*	40	5 (12.5%)	-	-	-
7	22	14 (63.6%)	9 (40.9%)	2 (9.1%)	3 (13.6%)
8	38	25 (65.8%)	23 (60.5%)	2 (5.3%)	0 (-)
10	27	17 (63.0%)	13 (48.1%)	0 (-)	4 (14.8%)

 * Home closed at 3 months

Table 9 Proportion of staff, of those who attended ≥ 1 training session, working at each care home at 6 months

CH ID	No. expected to attend	No. attended ≥ 1 session	Still working at home at 6 months		
			Yes (% expected to attend at baseline)	No	Unknown
4	28	15 (53.6%)	14 (50.0%)	0	1 (3.6%)
5*	40	25 (62.5%)	-	-	-
7	22	19 (86.4%)	13 (59.1%)	3 (13.6%)	3 (13.6%)
8	38	35 (92.1%)	33 (86.8%)	2 (5.3%)	0 (-)
10	27	25 (92.6%)	20 (74.1%)	0 (-)	5 (18.5%)

 * Home closed at 3 months

4.3 Organisation and delivery of training - qualitative findings

I thematically analysed the written accounts provided by the trainers (see Chapter 3 for details of methodology and methods used), identifying the following themes related to the challenges associated with training provision in care homes:

- **Staff training attendance - expect the unexpected**. Despite attempts to pre-arrange groups of attendees for each session, staff attendance was ad hoc, with trainers attributing this to unavoidable, but also potentially avoidable, reasons.
- **Staff engagement with training varies**. Trainers experienced variable engagement from staff; they saw this variability as partly inevitable, but also suggested ways to improve engagement based on their experiences.
- **It's a home, not a training venue**. The variability of facilities available for training affected its delivery, and trainers needed to be mindful that they were working within residents' homes.
- **Adapting to the situation**. The difficulties trainers experienced with attendance, engagement and facilities for training led them to adapt session content, order and duration.
- **Organisational factors out of our control**. Trainers were unable to train staff in some homes due to unexpected organisational changes; in other homes they speculated that staff might have difficulties using their new skills because of the layout of or facilities within the homes.

Staff training attendance - expect the unexpected

In their meetings with the home managers prior to the start of training, the two lead trainers formed largely positive impressions of how training would unfold at each home, noting that managers seemed enthusiastic about the training and were convincing in their accounts of the organisational processes that would be put in place to ensure staff attendance.

> *"Well organised. Aim for 90% staff to be trained for all in-service training." (Care Home 8)*

> *"Well organised home. Manager provided list of staff." (CH9)*

> *"Manager proactive and keen to engage. Wants to develop a way of sustaining learning and practice after the training. Mentioned linking SCTP to their standard manual handling training." (CH10)*

Sadly, these positive impressions were not often reflected in practice. Despite the trainers working with the managers (or delegated member of staff - for example, the deputy manager or administrative team) to obtain listings of staff groups to attend pre-arranged training sessions, there were multiple reports of staff not attending as expected: either more or fewer staff than anticipated, or sometimes staff who had not been on the list of expected attendees at all.

> *"Was expecting 5 people from session 1 group. 2 DNA but 1 person who should have attended session 1 came today." (CH9, Session 2)*

> *"5 extra unexpectedly present, unsure why - appeared to have decided themselves…" (CH6, Session 1)*

> *"Variation in staff planning to attend and those who did attend." (CH7, reflection at end of training)*

Often sessions were missed for unavoidable reasons such as sickness, providing cover for other staff who were unexpectedly on leave, or when there were staff shortages; however, the trainers speculated that other absences could have been avoided with better communication. They reported deficits in communication between the management team and staff - so that staff were not always aware of the requirement for them to attend a particular training session - as well as poor communication between the management team and the trainers themselves. Trainers were often not informed of staff absences, so would sometimes arrive to deliver training when only 1 or 2 staff were available to attend the session. In such cases training was not feasible, so trainers' time was wasted.

> *"Some staff didn't know they had been allocated to certain training slots." (CH9, reflection at end of training)*

> *"Poor communication between us and manager to arrange training sessions. Two cancellations of sessions - not advised in advance about one of these. No pre-populated list of attendees so not clear who was due to attend." (CH6, reflection at end of training)*

Trainers also felt that managers could have planned the staff groups better: sometimes staff were scheduled to attend sessions when they were on leave, or when they had just come off a night shift, so it seemed that the allocation of staff to groups for training was not undertaken in a considered way. Some staff had to leave sessions early due to personal reasons (for example, collecting a child from school), which again could have been factored into the planning of the sessions had the trainers known about these commitments. This poor planning led to fewer people attending sessions, or it meant that sessions had to be cut short.

> *"…being allocated to attend when they were at other training or on holiday, allocated to training when shifts made it inappropriate (e.g. afternoon training pre night shift)." (CH9, reflection at end of training)*

> *"One member of staff very tired - come from night duty - more than 24 hours awake at start of course." (CH10, Session 1)*

> *"Participants required to pick up children from school - session shorter than initially planned. However, feedback was that this was the right length." (CH10, additional session)*

All these difficulties with training attendance had implications for trainers' time: wasted visits for training sessions that did not go ahead, time spent arranging and re-arranging sessions, as well as checking who had and had not been trained. One of the trainers noted at the end of the training period in one home that: *"Dealing with the home became very admin intensive". (CH9, reflection at end of training)*

There were also implications for the success of the training. Staff attending ad hoc sessions rather than following the training session plan meant that some attended sessions out of order, which made learning more difficult.

> *"Lack of continuity of groups compared to what was planned. A few attended sessions out of order which is not ideal." (CH9, reflection at end of training)*

Staff engagement with training varies

The trainers found there to be variability in staff members' engagement with training

within and across homes. Whilst there were many reports of positive staff engagement, trainers also reported some difficulties engaging certain staff members or groups.

"Very good engagement. Very good discussion on empathy and receptive." (CH9, session 2)

"Pleased with engagement, participation, practice. One learner demonstrated a marked change in attitude to client, expressing more understanding of 'difficult' behaviour." (CH8, session 3)

"Difficult group - one very vocal attendee - not engaged especially at end of session. Session too long for this group to maintain concentration." (CH7, Session 1)

"[name of trainer]'s group in particular were difficult and did not engage well and were reluctant to take part in practical sessions." (CH7, reflection at end of training)

The trainers reported various medical problems that limited some staff members' participation in training sessions - mainly musculoskeletal conditions, back pain or minor injuries. Whilst there was some acceptance that variable levels of engagement were inevitable, due to these physical limitations, or due to staff members' individual differences, the trainers suggested other reasons for poor engagement that were not intractable. They found that the longer sessions in care home 7 were problematic (this home's training was split over two four-hour sessions for each group, rather than the standard three x 2.5-hour sessions), with a number of staff losing concentration during the lengthy training sessions.

"Engagement needed to get them involved - did so, but decision to respond to group with shorter session as felt would 'lose them' if not. They did participate quite well but took effort to get 'on board'." (CH7, Session 2)

"Longer session times were a problem as they found it hard to maintain concentration." (CH7, reflection at end of training)

They also observed some staff being very tired during training sessions which took

place directly after a long shift, concluding that those staff shouldn't have been scheduled to attend that particular group because their fatigue obviously affected engagement.

"One member of staff very tired, come from night duty - more than 24 hours awake at start of course." (CH10, session 1)

"2 staff doing session had just come off nights - therefore very tired. Suggest they do a different session." (CH10, session 2)

The trainers noticed differences in the engagement of staff with varying roles, and that group dynamics affected participation in practical work. There were observations that senior staff were sometimes more engaged, taking part in more in-depth discussion, whilst some staff had difficulty understanding some of the terminology used. The trainers reflected on the need to amend the training to facilitate the understanding of concepts by all staff.

"Initially limited feedback from group perhaps because 2 new staff attended one was team leader, perhaps because researcher observing. Perhaps because student present - a new person - and I forgot initially to introduce the group." (CH8, session 2)

"1 member of staff shy to speak out. 2 others were seniors + not effective learning of practical skills." (CH7, session 1)

"Very engaged group. Deputy manager attended who is obviously keen to improve quality of residents' care." (CH6, session 2)

"Had to explain the word 'expansion' […] Understanding of 'expansion' and 'mortality' may be difficult." (CH9, session 2)

So although some variability in engagement is inevitable, the trainers made useful observations about factors that could potentially be modified to improve engagement in future.

It's a home not a training venue

Trainers reported wide variability between homes' facilities for, and staff members' attitudes towards, training. Practically, there were repeated comments about the rooms used for training being inappropriate in terms of size and comfort, which affected the ease of training and probably contributed to the lack of staff engagement reported earlier - for example, if staff were uncomfortable in the available chairs they were less likely to be able to concentrate. Sometimes a residents' sitting room needed to be used as there was no private space available.

> *"Training room being too warm impacted efficiency of some of the training. Some of the seating not ideal for sitting and attending to training." (CH9, reflection at end of training)*

> *"Training room small, and variable chairs - some course members sitting on chairs not ideal for facilitating attention and learning (easy chairs)." (CH7, reflection at end of training)*

> *"5 extra unexpectedly present, unsure why - appeared to have decided themselves. Therefore 11 in session which was difficult in size of room, and stuffy." (CH6, session 1)*

However, some homes had dedicated training spaces which made training easier (for example, more space and facilities available for PowerPoint presentations) and, as one might expect, the staff working at these homes were more familiar with undertaking training, so were more accepting of their attendance at the sessions. Staff at other homes seemed less familiar with training, and some were less inclined to view it positively, seeing it as an unnecessary distraction from their job.

> *"Staff were very used to training - designated training room." (CH8, reflection at end of training)*

> *"Home did not seem to have a culture of training. Some staff resentful of being 'made to' attend training when they should be doing 'useful work'." (CH7, reflection at end of training)*

In those homes without dedicated training spaces, trainers had to adapt to the facilities

available, but had also to be mindful of the fact that they were working within residents' homes. Some of the practical work required use of beds; whilst there were often opportunities to use a spare room, sometimes a resident's room needed to be used, with their permission. Trainers needed to be considerate of residents' space and staff members' wishes. There were reports of residents being present during training sessions, as well as training groups needing to move rooms to accommodate residents' daily schedule - for example, where training was to take place in a dining room, this could not be used if lunch overran. There was often no option but to change plans at short notice to accommodate the residents' and staff's needs; the fact that training was taking place in their home added to the unpredictability of each training session.

> "Training was in sitting room that residents used. One man [male resident] *sat and listened intently to one of the sessions." (CH7, reflection at end of training)*

> "Was anticipating having two rooms for practical, however one room contained possessions of resident who had very recently passed away. Participants refused to use room as they felt it inappropriate so all participants did practical in single bedroom." (CH10, session 3)

Adapting to the situation

The variability of staff attendance and engagement, and the variable facilities for training within each home meant that the trainers sometimes had to adapt their approach to training to deliver the planned session content successfully. They reported changing the order of training, repeating content covered in earlier sessions to allow staff to catch up who had missed these sessions, or they moved content to a later session when there had not been time to cover this in an earlier one. They also responded to staff needs by covering some elements in more detail where they could see that certain principles had not been completely understood.

> "Changed order slightly. Only 1 participant had attended session 1 so spent some time reviewing principles therefore as wasn't sure whether time would allow or not I moved importance of activity practical to the end." (CH9, session 2)

"Increased emphasis on principles of sit to stand as initial comments from staff showed some key principles missed." (CH8, session 3)

Flexibility was required to fit with staff needs and availability. Some staff arrived late to sessions, whilst others had to leave early; as alluded to earlier, some had commitments such as child care, which limited the time they could spend in a training session that was scheduled to finish later than their usual hours. Others wanted to complete training as quickly as possible, so the trainers sometimes made the decision to shorten sessions by omitting content where groups were not engaging well.

"Participants required to pick up children from school - session shorter than initially planned. However, feedback was that this was the right length." (CH10, additional session)

"Session too long for this group to maintain concentration. Did not do quiz - for benefits of activity - went up to walking." (CH7, session 1)

"Shorter time needed to deliver because they didn't want a break." (CH7, session 2)

As mentioned earlier, there were variable facilities available for training. Whilst these created some problems for the trainers, they were also able to use the less-than-ideal training environment to their advantage. Where chairs were uncomfortable for staff, this was seen as a good opportunity to discuss the disadvantages of poor seating (an important element of the training), and where residents were nearby they were able to observe and discuss their posture during the sessions to illustrate the points being covered.

"Some of the seating not ideal for sitting and attending to training. Although different seating and comfort was used as a learning point." (CH9, reflection at end of training)

"Training was in sitting room that residents used. One man sat and listened intently to one of the sessions - his posture was poor because of the chair and the discussion around the chairs residents frequently use was actually helpful." (CH7, reflection at end of training)

Organisational factors out of our control

One home was unable to continue with the planned training sessions following the home's management unexpectedly requiring their staff to train in new electronic care systems, which took precedence over our research; there was not the time or staff capacity to continue with the Skilful Care Training. Another home closed during its involvement in the trial. No matter how many steps a research team might put in place to optimise training uptake, the needs of the home will come first, and sometimes this means that training may not prove possible.

> *"Though initially positive, only arranged two full training courses (6 sessions in total). Other courses were arranged but then cancelled by the home because other training which was statutory had to be completed in a fixed time period." (CH8, reflection at end of training)*

Trainers sometimes thought that the building layout was not ideal for residents with limited mobility or cognitive impairment. They suggested that these environmental factors might limit staff's attempts to encourage or support greater mobility - for example, corridors were long, or layout was confusing. Some homes had limited access to appropriate seating, affecting staff's ability to seat residents correctly - for example, uniform chair size meant that chairs were too high or too wide for smaller residents, which could result in them slipping out of a good seated position. They felt that no matter how engaged staff were, and how readily they understood the training concepts, the lack of appropriate home-wide facilities might limit the implementation of newly learned techniques in practice.

> *"Advised purchase of different seating would be very helpful to give more opportunities for seating appropriately." (CH7, reflection at end of training)*

> *"..environment that I would say is very positive in keeping people with moderate or good level of mobility mobile with spacious corridors and interesting places to walk to - could be a disadvantage for people with low levels of mobility as distances too much to manage so potentially leading to people being put into chairs for the whole journey - though hopefully training will impact on that." (CH 8, reflection at end of training)*

Considering all themes, it seemed that there were areas where adaptation to the trainers' approach to session organisation, intervention delivery or content could usefully improve intervention uptake. Some elements could be adjusted with relative ease (for example, course length), whilst others were intractable factors of care home life (e.g. lack of training facilities) that would need to be carefully considered in order to optimise the training approach. All themes also incorporate the need for flexibility and engagement that is required for research procedures to mesh with care home life, and demonstrate that the environment and culture are major factors in intervention success.

4.4 Measurement of the use of new skills

Researcher colleagues and I completed non-participant observations (161) of staff and residents engaging in their daily routines, after training had taken place, in six care homes on 12 occasions. The aim was to trial a bespoke checklist designed to record whether newly learned skills were being incorporated into care practices.

4.4.1 Completion of the first version of the observational checklist

A researcher, physiotherapist and I completed the first version of the checklist in two care homes, and then met to discuss our experiences. It had been difficult to complete the checklist, particularly the staff-resident interactions, in such a structured format; we initially invited selection from a list of behaviours, some of which did not occur in the order specified, and some not at all. I amended the checklist to be structured around lunch as this involves many of the skilled activities included in training: staff support for residents when walking (or being transferred by wheelchair), transferring to sitting, and feeding. The plan was to follow through the expected course of events: entering the dining room, sitting down, eating, standing or transferring to a wheelchair, and leaving the room. Observations of activities associated with each of these stages would be recorded as a free-text description, which could later be coded to identify positive (skills learned in training) or negative staff-resident interactions.

In group discussions between the physiotherapists, a researcher and me, questions were raised about whether observations could be accurately made without an understanding of each resident's functional abilities. For example, staff might not have encouraged independent eating (a skill learned in training) because they knew a resident was not capable of holding a spoon, but this was not necessarily obvious to an

uninformed observer. We concluded, however, that it was not feasible to obtain contextual detail for all residents so the reported observations would have to be based upon information available in the present moment.

4.4.2 Completion of the second version of the observational checklist

We tested the next iteration of the checklist in five care homes - observations were structured around expected lunchtime activities, and we used a free-text approach to the documenting of our observations. This was easier to complete, but we still found that it was too structured - breaking up activities into segments rather than describing the flow of events as they happened was not feasible, in our view. Other problems encountered included: difficulty documenting, in a structured way, the individual activities of multiple residents at the same time; and possible over-reporting of expected (taught) activities, with under-reporting of omissions of activity - for example, not reporting instances where certain support should have been provided but was not. Identifying omissions was especially difficult for non-experts.

4.4.3 Final observation

A final observation period was undertaken in one home to try out an unstructured approach - documenting all observed behaviours within a defined location within the home over a fixed time. Although unstructured, the observer had a guide to refer to, which listed the behaviours of particular interest - those acquired through training. This approach worked well, but we remained concerned that it would not always be possible to classify behaviour as appropriate or inappropriate if the observer did not fully appreciate the resident's functional abilities.

In undertaking this observational work, I was unable to answer definitively the research question regarding how to measure staff members' enactment of new skills; however, I did meet my objective of identifying the difficulties of monitoring and reporting the use of new skills.

4.5 Discussion

4.5.1 Summary of findings and their implications for future research and practice

As other researchers have described, I found that the trainers reported problems with the organisation and delivery of training: variable staff attendance due to poor communication from the management team about the sessions (53), the unavailability of staff (78, 80, 114), and variable staff engagement (205). Many researchers have reported problems with intervention uptake, particularly where staff members are required to take time out of their busy schedules (90, 97) to attend non-mandatory training. A few authors have suggested solutions to the problems encountered - for example allowing more flexibility in the scheduling and format of sessions (109) to fit with staff availability, making a training plan with the manager at the outset (111), involving senior staff in the training programme (79) to foster engagement, and using a good training venue (95). We had incorporated some of these proposed solutions into the PATCH trial design (a meeting with the manager, planning training dates with the manager, inviting ALL staff to training) but I did not find evidence that these adjustments supported good engagement with training. Whilst my findings endorsed the challenges reported by many other authors, I had not found in the literature satisfactory solutions to the problem of poor staff engagement with training; nor had I found detailed reports of the reasons for the problems encountered. I suspect many trials, particularly those with process evaluation, have explored in detail the barriers and facilitators to intervention uptake, but there were limited reports in my literature review of the specific reasons behind poor staff uptake of training interventions. My findings offer some detailed descriptions and analysis of the challenges that contribute to a lack of staff engagement, thereby providing a basis for the exploration of pragmatic solutions to improving intervention uptake. These findings contribute to the refinement of the SCTP programme theory, as well as having wider implications for the delivery of staff-training interventions in care homes.

Training attendance and communication

Quantitative data illustrate the poor attendance of staff at the full complement of required sessions (43%). This proportion fell short of our pre-specified (green) success criteria (≥65%) when considered across all five homes; however, there was a marked difference between attendance rates at the first two homes (21%, 13%) - they experienced unexpected and unavoidable reasons for non-compliance - compared to the last three homes (63 - 66%), which were able to proceed as planned. This suggests

that, without external factors impeding engagement, the training could be successfully achieved. 'Success' here, however, simply reflects the number of staff who were trained in relation to pre-specified success criteria; the overall picture was more nuanced, as revealed through the collection and analysis of qualitative data provided by the trainers.

Considering the recommendations of other researchers (79, 109), and the best methods to involve staff in the SCTP training sessions, the trainers and I had thought that working with the manager to identify specific groups of staff to be trained at particular times would facilitate attendance. However, this approach often did not work, and attendance was patchy despite these detailed arrangements having been made. Inevitably, there were last minute drop-outs due to sickness, and due to staff providing cover for those on sick leave, but reasons were not provided for much of the non-attendance. Consequently, it became clear that planning the attendance of particular individuals was not a productive use of the trainers' time. However, the trainers observed that some staff were scheduled to attend at inappropriate times (for example, following a night shift, or when they had other personal commitments), so it would be useful to plan session times to meet the needs of staff members.

Communication was poor between all parties - some staff were unaware of their required attendance at particular sessions, and the management team did not always communicate with the trainers to cancel sessions when staff were unavailable. Trainers reported difficulties with the organisation of training sessions, spending more time than expected arranging and re-arranging sessions. An improvement in communication, as suggested by many other researchers (76, 79, 81, 125), would probably increase staff attendance at appropriate sessions, despite intractable problems such as sick leave; however, *how* to improve communication has not been set out by others. From the themes I identified, I would suggest that detailed discussions with staff as well as with the management team, at the outset and throughout the training period, would support the appropriate arranging of sessions to fit with staff members' needs, and the changing needs of the homes. This ongoing communication and adjustment to training schedules on the basis of feedback is a new mediator to include in a revised version of the SCTP logic model (Appendix 1), as well as being an important consideration more widely for interventions that involve care home staff training.

Staff engagement

Staff engagement with training was variable - some staff members were enthusiastic and saw the potential benefits of newly learned principles for supporting their residents, whilst others did not feel the sessions were a good use of their time. In hindsight the trainers thought that staff engagement might have been improved by having shorter sessions, scheduling them to fit better with staff shifts, and by having certain types of staff (e.g. all carers, all seniors) trained together so that the content could be tailored to their experience. A reduction in session length has been suggested by other researchers (53, 74, 89) as a necessary adjustment, and perhaps the trainers should have been less rigid in their requirement for a fixed session duration; however, the SCTP had been developed as a structured training package including standard content in the form of educational materials and practical exercises. To reduce the session length during the trial would have compromised the content, potentially changing the intervention we were testing and reducing the scientific integrity of the feasibility trial.

The suggested changes above have implications for the SCTP programme theory (illustrated in the logic model - Appendix 1), which could be modified to include shorter sessions. In addition, shift patterns and staff roles could be included as mediators to facilitating intervention mechanisms, which when appropriately considered would result in the desired staff outcomes. Lack of engagement has been reported as a pervasive problem (205), so any attempts to accommodate staff's needs might be beneficial. Such flexibility would require detailed understanding of staff roles, shifts and needs in order to tailor training to fit with care home culture and working patterns.

The care home environment

The trainers experienced some difficulties working in the care home environment. A lack of training facilities in some homes made training difficult. Although other researchers have mentioned the need for a good training venue (95), there is often little that can be done to adapt the care home facilities to the requirements of formal training sessions; rather, the provision of training needs to be adapted to the venue. As observed by others (33, 71), trainers found that it was of paramount importance to be mindful of the fact that they were working in people's homes, and respectful of the needs of residents and staff when using and working within shared spaces. It was clear that the physical environment in which training took place (i.e. the care home) was another factor that affected the success of intervention delivery and is thus a further mediator to include in the SCTP programme theory, as well as an important

consideration for all training interventions. It may even be the case that, following an evaluation of the care home environment, the decision is reached that certain care homes are unsuitable for training due to a lack of essential elements required. This potential exclusion of unsuitable homes would be something to consider in future trialling and implementation of the SCTP, and more widely as an implementation consideration for other training interventions.

Flexibility and adaptation

Trainers could perhaps have been better prepared for the delivery of training in environments quite unlike a formal training setting. Over time they adapted their approach to work less rigidly to the prescribed training plan, but I would suggest that more time could be dedicated to the evaluation of the environment at the outset, and to the consideration of how training might be tailored to fit with available facilities. In delivering the SCTP, trainers also found they needed to adapt their approach and session content to fit with staff members' needs. In refining the SCTP, consideration needs to be given to accepted variation in training content that can occur without affecting intervention fidelity.

All my findings indicate that further work is needed to refine the SCTP to fit better with care home facilities and culture, as well as with staff availability. It may be more appropriate to train staff whilst they work, enabling them to try new techniques to support residents during care duties, with expert support and guidance (so-called on-the-job training); this should be explored via participatory work with care home staff.

I have identified difficulties with intervention implementation from the perspective of the trainers; focussing on participant engagement with the intervention, and the contextual factors which limit engagement with training. Consideration of these areas should be incorporated into the SCTP programme theory with the aim of improving future intervention fidelity. The importance of context is central to the new MRC guidance for developing and evaluating complex interventions, (206) and is seen as a moderator in implementation fidelity frameworks (207); the care home environment (structure and culture) is a complex and variable context which needs prime consideration in the implementation of all intervention research if this is to be successful.

Observation of enactment

Researchers (34, 79, 112) have commented that intervention enactment is poorly measured and reported, probably because there is no standard approach (159), despite there being prescribed frameworks (157, 158) for the elements of intervention fidelity that should be considered and incorporated into all evaluations. I developed a checklist for the observation of interactions between staff and residents in an attempt to capture their use of new skills learned during training. The completion of this checklist proved difficult, particularly for non-experts, like me, who were not always able to assess the *omission* of appropriate behaviours (the *presence* of behaviours was easier to observe); there was suggestion that observation should be undertaken by an expert to minimise the likelihood of incorrect observations. A structured approach to observation did not work because it did not necessarily align with residents' activities during the observation period. There was also concern that in-the-moment observations, undertaken without knowledge of each resident's usual abilities, might render the assessment inaccurate if documented staff behaviours which appear to be demonstrating the appropriate skill set were in fact inappropriate for a particular resident.

To obtain a true understanding of a resident's needs to enable correct assessment of staff-resident interactions might take many hours of observation. I failed to develop a final checklist that could be used during the trial, but the iterative development approach with in-depth discussion amongst team members in-between each iteration was invaluable to my understanding of the complexities of this approach. It endorsed other researchers' views of there being poor measurement and reporting of enactment (208), probably because it is very difficult to do well. It also identified ineffective approaches which can thereby be avoided in future evaluation of the SCTP. Further work is needed to develop a valid approach to the measurement of the use of new skills. Success in this respect would support the measurement of adherence in a definitive trial of the SCTP, and it would enable the recommendation of an observational approach to adherence measurement and reporting for other trials of similar interventions.

Sustainability

Staff turnover rates in care homes are generally high (80, 109, 125, 209). Of those who attended our training sessions, some staff had left the care homes by the time of the six-month follow-up, but not in large numbers. I found that it was hard to track which

staff members remained in post; where staff left or joined the home in-between recruitment and training it was very awkward to identify that this was the case, and consequently to track their retention in the home over time. This made assertions about the proportions trained who remained in post at six-months impossible with any precision. The setting out of proportions of trained staff who remain in post over time - to depict the sustainability of training - might not be accurate, and indeed may be an arbitrary measure of success as those trained might not be those most involved in relevant aspects of care (e.g. part-time staff, night staff). Identifying the number and type of staff who need to be trained to effect change (and remain in the home at any one time) might be a better way of defining sufficient intervention 'dose'. I would recommend that a future definitive trial of the SCTP establishes a minimum intervention dose, decided upon through exploratory work with the trainers and with care home staff. Consideration would also need to be given to the frequency, content and format of repeated training sessions to maintain this 'dose'.

4.5.2 Methodological considerations

In this chapter I have reviewed the quantitative data reporting staff attendance at sessions, and the qualitative data derived from the trainers' written accounts of their experiences of delivering training. Using more than one type of data (objective reports of attendance, and subjective reflections on training sessions) increases the trustworthiness of my findings, such that the two types of data complement and confirm each other: for example, poor attendance rates are confirmed by trainers' accounts of the difficulty with staff drop-outs.

I collected written accounts from the trainers of their experiences of training after every training session. Had I also interviewed them at a later date to explore their experiences in more detail I might have generated a richer dataset. It is possible that, by collecting only written feedback, I might have missed important points that would explain certain findings in more detail, and there may be staff perspectives that I have not taken into account; however, my focus was on staff attendance, and the practical challenges associated with intervention delivery. I might have missed nuanced and expanded explanations for lack of attendance or engagement, but the main conclusions I have drawn are credible; they are derived from the repeated completion of written feedback by trainers after every session (N=49) - many data items from which to draw my conclusions. I also checked back with one of the trainers, sending

her a copy of my findings; she confirmed that their experiences had been accurately represented.

The questions posed to trainers were negatively biased, asking for details about challenges and problems experienced. This might have provided an overly pessimistic view of the training, but the trainers were given the opportunity to provide non-directed ('other') feedback; in doing so they commented on positive elements of the training sessions - in particular the good engagement of some staff with the learning process. The trainers also reported instances of staff considering the ways in which they could apply their new skills to support specific residents, and they were pleased to report that some staff talked about using new skills with good effect. There is good evidence in this respect that the trainers were not limited to the reporting of difficulties.

Reflexive statement

I was closely involved with the organisation of intervention delivery. I supported the trainers to meet with the managers at the start of their involvement in the trial, and I liaised with them regarding the organisation of training sessions. I also visited the homes to provide intervention materials and spoke to managers about the intervention and data collection elements of the trial. Through this involvement I had insight into the challenges faced by the trainers throughout the intervention delivery period, and I had personal experience of the difficulty of contacting managers - so I had expectations of what I might find before I received the data. I had a good relationship with the trainers who, as a consequence, spoke to me on a number of occasions about the challenges they were facing. Inevitably this level of involvement and prior knowledge will have affected my analysis of the data; however, I kept these influences in mind as I reviewed the data, checking and re-checking my interpretations in an attempt to minimise bias.

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An improvement in residents' posture was a hoped-for outcome following training, detailed in our logic model / programme theory; there was, however, no existing tool or approach to measure the posture of care home residents (see Chapter 3, section 3.2). Consequently, with the help of the trial's trainers, we developed a postural assessment tool - which I describe in the next chapter.

Chapter 5 Development, usability and acceptability of a new postural assessment tool

In this chapter I present the findings of Study 3, which was designed to answer the research question: "How might posture be measured in a care home resident population?" This question aligns with objective 3: to explore the acceptability of various methods of collecting and reporting trial data in care home research. (Methods employed for this work are described in Chapter 3.)

My aim was to evaluate the ease of use and acceptability to researchers and residents of a tool to measure care home residents' posture. I developed this tool in conjunction with the trainers (expert physiotherapists) and a researcher colleague. First, I report the development and refinement of the postural assessment tool, providing a descriptive narrative of the iterative approach to development, testing and revision of content which led to the production of a final version of the tool for use in the PATCH trial. Whilst development work could arguably be badged as 'methods', the narrative I report, based on my detailed notes documenting the iterative development process, provides helpful insights into the difficulties faced by non-experts (researchers) in the completion of a physiotherapist-informed tool. Thus, these findings merit reporting and discussion, alongside reporting of the acceptability (to researchers and residents) and usability of the final version of the tool - measured by: completion rates, reported reasons for non-completion and written feedback from researchers.

5.1 Development of the PAT

<u>Format and content</u>

During our consultation meetings we decided that a pictorial tool would be the best format for non-experts because images can easily convey postures without the need for an understanding of clinical terminology. The physiotherapists thought that assessing posture in bed would not be possible, as it would be very difficult to make an accurate assessment without being hands-on in a situation where someone was partially covered, so the tool was designed to assess seated posture only.

The physiotherapists agreed on an initial list of body areas that they believed should be assessed individually: head, shoulders, trunk, pelvis, thighs, knees and feet. For some of these areas they thought that assessment should be made from various angles: the

pelvis, for example, would be viewed in the coronal and sagittal planes. Thus, the first version of the tool included assessment of: head tilt (front view), shoulder shift (front view), kyphosis of trunk (side view), trunk tilt (front view), pelvic anterior-posterior alignment, pelvic lateral alignment, knee assessment to determine alignment of pelvis, knee assessment to determine alignment of thigh, and positioning of the feet. We decided to include categorical questions at the end of the tool to capture the type of chair and seating environment (for example, resident's own room, communal living area) to provide context for the observed posture. I also added a question about 'additional supports' (for example, pressure cushions), as suggested by members of the PPI group.

Upon review of the first pictorial version of the tool, the physiotherapists decided that pelvic alignment in the coronal plane was also important so should be included - resulting in a 10-item tool.

Field testing

After the researcher and I had tried completing the first version of the tool (completing it with each other and the physiotherapists), we agreed on a number of changes to improve its clarity and content. As it stood, we had found some items to be difficult to rate if a person had their legs crossed, so I added a question to indicate when a resident had their legs crossed. The researcher and I thought that the completion of items would be easier in a different order, so I reordered the questions to flow more logically from head to foot. Chair-fit was amended to include the suitability of its height, width and depth, after we observed that postures were affected by these dimensions, and we agreed that this context was important. I added a notes section to each question as the researcher and I thought that it was important to further contextualise the data - for example, 'resident keeps slipping down chair'. During the tool's testing we had found that some postures were easier to rate than others, so I added a measure of confidence (very confident, moderately confident, uncertain) to each question to allow evaluation of the rater's perception of an item's difficulty. Finally, I added a 'comments' section at the end of the tool for the researchers and me to make any other observations that we felt were important to support understanding of the residents' posture, or to report difficulties completing the tool.

During administration of the next iteration of the PAT (the first use with residents), the researcher and I found it difficult to make a judgement on lower body postures when

the pelvis, knees and feet deviated from the 'ideal' posture because a resident's legs were crossed. The physiotherapists agreed that the PAT should be amended to include 'unable to assess' for all questions relating to the lower body when a resident's legs were crossed.

The PAT content was amended again following our experience in a further four care homes. Sometimes residents had moved (usually head or legs) whilst we were trying to rate their posture, which left us uncertain how to record the data. We decided, in consultation with the physiotherapists, that movement should be documented, but that a resident's 'best' observed position be recorded as the best representation of their functional ability.

The researcher and I continued to have difficulty distinguishing between upper trunk curve and shift: the physiotherapists felt that the clinical response to curve or shift would be similar, so the group agreed that these two items could be merged. We observed that some residents' knees were lower than their hips so added it as an additional level for this item (shown in Figure 6 below). These changes were incorporated in the next iteration of the PAT, with a final version including only minor changes, such as the addition of an extra chair type and some final re-ordering of the items.

Figure 6 Postural Assessment Tool - example question

5.2 Acceptability and usability of the Postural Assessment Tool

5.2.1 Completion rates and reasons for non-completion

The PAT was administered at least once (across all time points) with 121/146 (83%) residents. The average assessment time was five minutes; the majority (83%) of assessments took place in a day room or other communal room such as the dining room.

Table 10 sets out the number of residents (of those available) who had one or more PAT assessment (using any version of the PAT) completed at each time point. Over three quarters (79% - 115/146) of residents had at least one assessment at baseline,

reducing to 68% (71/104) having been assessed at least once at the six-month follow-up time point.

Table 10 PAT completion rates for available residents

	Baseline	3-month follow-up	6-month follow-up
Number of residents available*	146	124	104
No assessments completed	31 (21.2%)	33 (26.6%)	33 (31.7%)
At least one assessment completed	115 (78.8%)	90 (72.6%)	71 (68.3%)
1 assessment completed	*28 (19.2%)*	*17 (13.7%)*	*12 (11.5%)*
2 assessments completed	*87 (59.6%)*	*73 (58.9%)*	*59 (56.7%)*
Missing**	0 (-)	1 (0.8%)	0 (-)

* Those who had not died or moved away from the care home

** Data on whether or not the PAT was completed was missing

Table 11 and Table 12 illustrate the reasons for non-completion of the PAT where it was not completed at both attempts or at one attempt, respectively, at baseline, three-months or six-months. In most cases, non-completion was due to a resident being in bed, either permanently or temporarily, and thus not suitable for assessment by our 'seated' tool. There were very few instances where non-completion was due to a resident's refusal to be observed - eight refusals overall.

Table 11 Reasons for non-completion - for residents with *no assessments* completed

Reason	Baseline (N) ǂ	3 months (N) ǂ	6 months (N) ǂ
Resident bed-bound	19	20	21
Resident in bed	7	11	11
Resident asleep	3	0	0
Resident mobilising	0	0	0
Out of the unit / home	1	1	1
Resident did not wish to be observed	1	0	0
Unavailable	0	0	0
Other*	0	1	0
No reason given	0	0	0
Total	**31**	**33**	**33**

* Other = too unwell (1)

ǂ Some of the same individuals are included in the count at >1 time point

Table 12 Reasons for non-completion - for residents with *one assessment* completed

Reason	Baseline (N) ǂ	3 months (N) ǂ	6 months (N) ǂ
Resident bed-bound	0	0	0
Resident in bed	12	7	7
Resident asleep	2	3	1
Resident mobilising	1	1	0
Out of the unit / home	4	1	1
Resident did not wish to be observed	1	4	2
Unavailable	2	0	0
Other*	3	0	1
No reason given	3	1	0
Total	**28**	**17**	**12**

*Other = had visitors (2), agitated (1), researchers missed resident (1)

ǂ Some of the same individuals are included in the count at >1 time point

5.2.1.1 Item level completion rates, reasons for non-completion, and researcher confidence levels

I looked at all instances of completion of versions 4 and 5 of the PAT - the versions that were used for most participants: 400 assessments across 101 participants. I did not review instances of completion of versions 2 and 3, since the PAT changed more substantially after these iterations.

The researchers and I found it more difficult to complete lower body items, with 'unable to assess' rates of 15-20%, mainly because residents' legs were often crossed or elevated. Table 13 illustrates completion rates for each assessment item, where residents were available for assessment; Table 14 provides the reasons we were unable to complete certain questions.

Table 13 Completion rates for each item

Assessment item	Completed	Unable to assess	Missing*
	N (%)	N (%)	N (%)
Head	398 (99.5%)	0 (-)	2 (0.5%)
Upper Trunk Shift/Curve	398 (99.5%)	0 (-)	2 (0.5%)
Trunk Anterior-Posterior	398 (99.5%)	2 (0.5%)	0 (-)
Pelvic Anterior-Posterior Alignment	367 (91.8%)	28 (7.0%)	5 (1.3%)
Pelvic Lateral Alignment	376 (94.0%)	19 (4.8%)	5 (1.3%)
Pelvic Alignment in the Coronal Plane	324 (81.0%)	69 (17.3%)	7 (1.8%)
Knee to Hip (R)	331 (82.8%)	65 (16.3%)	4 (1.0%)
Knee to Hip (L)	328 (82.0%)	57 (14.3%)	15 (3.8%)
Alignment of the Thigh (R)	318 (79.5%)	76 (19.0%)	6 (1.5%)
Alignment of the Thigh (L)	316 (79.0%)	75 (18.8%)	9 (2.3%)
Feet (R)	318 (79.5%)	80 (20.0%)	2 (0.5%
Feet (L)	314 (78.5%)	71 (17.8%)	15 (3.8%)

* PAT question left blank

Table 14 Reasons unable to assess for each item

Reason*	Legs crossed ‡	Legs elevated ‡	Clothing / material obscuring view	Furniture / equipment obscuring view	Resident size / positioning	Other / no reason	Total
Head	-	-	-	-	-	-	0
Upper Trunk Shift/Curve	-	-	-	-	-	-	0
Trunk Anterior-Posterior	-	-	1	-	1	-	2
Pelvic Anterior-Posterior	-	-	13	10	3	5	31
Pelvic Lateral	-	-	14	4	2	4	24
Pelvic - in Coronal Plane	69	-	-	-	-	-	69
Knee to Hip (R)	65	-	-	-	-	-	65
Knee to Hip (L)	57	-	-	-	-	-	57
Alignment of the Thigh (R)	56	20	-	-	-	-	76
Alignment of the Thigh (L)	55	20	-	-	-	-	75
Feet (R)	57	23	-	-	-	-	80
Feet (L)	50	21	-	-	-	-	71

* Reasons not mutually exclusive.

‡ Unable to assess due to 'legs crossed' or 'legs elevated' was a response option for the questions where this reason is reported. All other reasons were derived from researcher comments after each question.

We were more confident when assessing the head and feet of residents, and least confident evaluating the position of the pelvis. For example, 86% of head assessments were very confident, 10% were moderately confident and only 3% were uncertain; whereas for pelvic anterior-posterior alignment only 41% of assessments were made with confidence, 23% with moderate confidence, and the remaining 35% were uncertain.

Table 15 sets out researchers' level of confidence in the answers we chose for each item. Reasons for uncertainty were similar to those reported in Table 14 and, in the case of pelvic alignment, clothing obstructing the view of the pelvis caused particular difficulty. For some items, researchers were more confident when assessing severe deviations from optimal posture.

Table 16 includes a breakdown of confidence ratings for each level within the 'pelvic anterior-posterior alignment' item - the item completed with the least confidence. This illustrates the increased difficulty experienced when postural deviations are moderate, rather than 'normal' or 'extreme'.

Table 15 Researcher confidence (all items)

Level of certainty	Very	Moderately	Uncertain	Missing	Total possible*
Head	342 (85.9%)	41 (10.3%)	11 (2.8%)	4 (1.0%)	398
Upper trunk	316 (79.4%)	57 (14.3%)	21 (5.3%)	4 (1.0%)	398
Trunk anterior-posterior	220 (55.3%)	116 (29.1%)	57 (14.3%)	5 (1.3%)	398
Pelvic anterior-posterior	152 (41.4%)	83 (22.6%)	129 (35.2%)	3 (0.8%)	367
Pelvic lateral alignment	186 (49.5%)	95 (25.3%)	87 (23.1%)	8 (2.1%)	376
Pelvic - in coronal plane	272 (84.0%)	21 (6.5%)	26 (8.0%)	5 (1.5%)	324
Right knee to hip	265 (80.1%)	42 (12.7%)	20 (6.0%)	4 (1.2%)	331
Left knee to hip	263 (80.2%)	41 (12.5%)	20 (6.1%)	4 (1.2%)	328
Alignment of the thigh	281 (88.9%)	22 (6.7%)	7 (2.2%)	6 (1.9%)	316
Right foot	305 (95.5%)	6 (1.9%)	4 (1.3%)	3 (0.9%)	318
Left foot	299 (95.2%)	6 (1.9%)	4 (1.3%)	5 (1.6%)	314

* This excludes those where it was not possible to rate the item, and thus where a measure of confidence is not applicable.

Table 16 Researcher confidence (pelvic anterior-posterior alignment)

How confident	Pelvis extremely tilted back		Pelvis tilted back		Pelvis level		Pelvis tilted forwards		Total
Missing	0	0.0%	2	1.1%	1	0.9%	0	0.0%	3
Very	43	56.6%	42	23.6%	67	60.4%	0	0.0%	152
Moderately	11	14.5%	53	29.8%	19	17.1%	0	0.0%	83
Uncertain	22	28.9%	81	45.5%	24	21.6%	2	100.0%	129

5.2.2 Feedback from researchers and residents

I analysed the written comments that the researchers and I had provided at the end of each completed PAT, categorising the challenges and observations we made in order to understand its ease of use and its acceptability to researchers and residents. I identified the following themes:

About completing the PAT:

- Impediments to postural assessment (related to residents' posture, the chair or the wider environment)
- Impediments to assessment of chair fit (related to residents' posture, chair type and chair accessories)
- Completing the PAT contrary to instruction. (Researchers sometimes felt able to complete certain PAT items where instructions provided advised them not to.)
- Acceptability of observation to residents and staff.

Other observations:

- Demonstrating knowledge of postural correction. (Researchers sometimes commented on poor posture and how it might be corrected, going above and beyond the requirements of the PAT and demonstrating their knowledge of how to achieve good posture.)
- Identifying residents' needs and behaviour.

Impediments to postural assessment

The researchers and I often reiterated and expanded upon challenges that we had already reported in quantitative form through the completion of binary questions within the PAT - such as: 'is the resident sitting with their legs raised?' and 'are there any cushions or other supports?' - noting when particular positions or supports made rating difficult because they impeded our view of the resident's posture, or because the posture was particularly complex to assess.

Accurately assessing the position of certain parts of the body was impeded by: items covering the resident (loose clothing, blankets, other types of cover); the view being obscured by furniture (for example, if they were sitting at a table) or another person; a complex chair set up (for example, a 'tilt-in-space' chair made difficult the assessment

of pelvic anterior-posterior alignment moves as body angles were not relative to the ground); and a resident's own physical attributes or behaviour.

> *"Due to position of the chair quite difficult to assess. Tilted but looks like all at 90 degree angles (hip / knee)." (CH6, Resident 549*, Researcher 1)*

> *"Had rug on lap and hard to tell posture around pelvis due to this and weight / clothing." (CH1, Resident 45, Researcher 2)*

* To note: assigned resident ID is arbitrary and not indicative of the number of residents participating in the trial

In relation to a resident's physical attributes, researchers reported that when a resident had very poor and unusual posture (e.g. contractures, severe deviation from the mid-line), was overweight, moved throughout the assessment, or sat unsupported by their chair, then accurate rating was impeded. The placement of the resident in relation to the chair back was often used as a pointer towards good or poor posture, so being unable to assess pelvic angle in relation to the gap between a resident's bottom and the back of the chair - for example, if the resident was sitting forward in the chair or the view was obscured - sometimes made it more difficult to make a judgement.

> *"Resident is sat onto right side, head in right hand, right leg is bent up, hips tilted right? Very difficult to assess." (CH3, Resident 123, Researcher 1)*

> *"Resident has two dolls on her lap, she chats to them and leans over them to kiss and cuddle them making some of the PAT difficult." (CH10, Resident 422, Researcher 1)*

In addition, accurate observation of posture was more difficult when residents were agitated causing regular shifting of their position, or when researchers worried that they were exacerbating the agitation.

> *"Resident agitated - fidgety - difficult to observe" (CH6, Resident 559, Researcher 1)*

> *"Resident difficult to observe - gets agitated when watching." (CH7, Resident 383, Researcher 2)*

Impediments to assessment of chair fit

Researchers were asked to make a judgement on the appropriateness for the resident of their chair's height, depth and width. We often found this difficult to do, and there were many reports of problems with this assessment. Certain chair types were difficult to assess - for example, we found that wheelchairs with footplates could be assessed in two ways; use of the footplates could make the chair height too low, but not using the footplates made it the right height, so we were uncertain which judgement to make. The presence of cushions sometimes changed a resident's position relative to the chair back or sides, making it hard to assess the appropriateness of chair depth or width. A resident's position in the chair and, as with the assessment of posture, the presence of loose clothing or blankets sometimes obscured our view.

"Difficult to tell if chair too deep - sat at the edge but cushion is at the back of resident." (CH2, Resident 68, Researcher 1)

"Arms of chair are very low - not supportive. Could be due to being sat on a cushion. Chair is deep / tall? Resident sat very far forward towards front edge - almost laid in chair." (CH8, Resident 203, Researcher 1)

"Chair maybe a little wide - but resident wearing bulky clothing." (CH5, Resident 492, Researcher 2)

"Height unsure. Footplates would make it too low? Has feet on floor." (CH2, Resident 77, Researcher 1)

Completing the PAT contrary to instructions

Although the PAT was designed to be completed in particular circumstances to avoid ratings that might be inaccurate or meaningless, on occasion we reported completing items regardless of these instructions. We were supposed to complete the PAT only when residents were awake, and not to complete certain items when a resident's legs were crossed or raised, and to assess residents only in their usual position (e.g. their usual chair or type of chair). However, without always having staff to consult during assessments, we found it difficult to know whether residents were in their usual chair, and we sometimes assessed residents when they were seated in a transit wheelchair, which ought not to be their usual seating arrangement. There were a number of reports of residents being sleepy during assessments, and of some falling asleep; however,

given residents were often asleep in the lounges, it was difficult to avoid this problem when assessments needed to be completed during a particular time period (for example, a two hour visit in-between lunch and tea).

> *"Resident fell asleep during assessment - but did not change position." (CH8, Resident 211, Researcher 3)*

Residents often moved their legs during an assessment, raising them and crossing and uncrossing them, so again it was difficult to avoid completion of the PAT for these residents because the prohibited (by instruction) posture may be attained only after we had started completing it. Researchers also made personal judgements that, despite instruction to the contrary, some items *could* be rated with legs crossed or raised.

> *"Resident is fidgeting legs a lot - keeps crossing legs over each other and moving during assessment" (CH6, Resident 565, Researcher 1)*

> *"Resident has ankles crossed but I have ticked boxes anyway as some can be rated." (CH1, Resident 43, Researcher 1)*

Acceptability of observation to residents and staff

Those residents who were able to have a conversation with us about the PAT agreed that good posture (being in a comfortable position and a chair that fitted well) was important to them. Some talked about being comfortable, whilst others recounted that they were often in pain or had difficulty maintaining a good position. One resident who was feeling unwell did not want us to continue with the assessment, but most who were able to converse said that they did not mind being observed by researchers to enable completion of our tool.

We reported that a few residents appeared agitated whilst the PAT was being completed, and in some cases we attributed this agitation, or exacerbation of it, to our observation of them. Occasionally observation proved more difficult in communal settings when some of the residents were agitated. In such instances, we found that sitting or standing less obtrusively (in one of the living room chairs, or at a distance) at least partially resolved any anxiety that our presence caused. Agitated residents were

those without capacity so we were unable to ask them directly whether they were concerned by our presence.

> *"Resident is quite agitated today - keeps shuffling and lifting legs - could be* [because s/he is] *being observed." (CH7, Resident 380, Researcher 1)*

> *"Really difficult doing PAT today due to 'Korsakoff's' environment - lots of paranoia, people don't like being looked at." (CH5, Researcher 1)*

Demonstrating knowledge of postural correction

Although the researchers' remit was to assess and document posture within the confines of the PAT, we also made additional comments about residents' posture, particularly when this was affected by the use of cushions. The researchers and I were aware of the purpose of the Skilful Care Training, and that adaptations to a resident's seating arrangement could be made to improve posture. Comments on the effect of cushions and staff adjustments to residents' posture illustrated this knowledge.

> *"Resident should not be sat on sofa - doesn't provide sufficient support - cushion has been put in place to provide some support." (CH8, Resident 205, Researcher 1)*

> *"Chair a little wide perhaps - cushion at back, might be better at side?" (CH8, Resident 211, Researcher 2)*

> *"After assessment a member of staff came in and adjusted resident position - adding cushion to support on right and uncrossing ankles." (CH10, Resident 443, Researcher 1)*

Identifying residents' needs and behaviour

We documented observations of residents' behaviours, health and posture; in particular noticing when residents were agitated and upset, and when they appeared to be in pain. There was also mention of some residents resisting care attempts by staff members (e.g. resisting re-positioning), and repeated behaviours such as sliding down the chair or trying to get out of the chair when unable to do so.

"Chair is too high due to the propad cushion - staff report attempting to adjust resident's position but not accepted by resident - who is capable of moving and making her own choices. She just repositions herself." (CH6, Resident 564, Researcher 1)

Opportunistic discussions with staff and relatives were reported when these provided context or explanation for certain behaviours or seating arrangements.

"Resident has been very agitated today. Staff report as a general decline - normal behaviour for participant at this time." (CH8, Resident 224, Researcher 1)

"Participant's wife explained he usually sits in a wheelchair due to distress at being hoisted to an armchair." (CH1, Resident 12, Researcher 2)

At other times we did not have information from staff about residents' usual position or behaviour, so speculated as to whether action could be taken to improve a resident's well-being.

"Resident has a specialised wheelchair but currently sat in normal chair - legs very far out and pelvis / thorax curved - appears slumped. Unsure if this is her physical condition - whether this could be changed?" (CH8, Resident 192, Researcher 1)

"Often in wheelchair when not in bed. Needs help to learn how to transfer to chair." (CH2, Resident 73, Researcher 2)

Observations were made about problematic conditions for residents, noting where seating arrangements were not ideal and where improvement was required. There were many reports of residents sitting on hoist slings which should be removed when not in use, and of sub-standard wheelchair set-ups.

"Son has provided piece of wood to use as footplate. Await assessment for wheelchair with footplate." (CH3, Resident 129, Researcher 2)

"With foot plates chair would support resident's feet and legs. However these

have been removed to prevent catching other residents." (CH8, Resident 194,
Researcher 1)

Finally, there were comments about residents' apparent health status - there were many reports of residents being frail - as well as information about their health gleaned from the residents themselves or from staff.

"Chair is built for resident, however very frail and has quite severe
contractures." (CH6, Resident 570, Researcher 1)

"[Resident] *telling us that she fell and fractured her hip very severely and now has ulceration to both lower legs." (CH9, Resident 243, Researcher 1)*

"Moved at end of assessment. Appeared to be some pain on moving." (CH2,
Resident 89, Researcher 2)

5.3 Discussion

5.3.1 Summary of findings

I led the development of a postural assessment tool which required an iterative approach - consulting with physiotherapists and PPI colleagues, and trialling the tool within the care home environment - to refine its content and format. Without this development work with experts and *in situ*, the PAT would have been weaker: testing allowed us to establish what it was possible to measure in everyday care home life, enabling us to adapt the tool following unexpected difficulties with completion (e.g. rating a moving resident) or difficulties with non-expert understanding of posture (e.g. differentiation between trunk curve and shift).

The PAT appeared, from completion rates, to be acceptable to care home residents: only eight PAT completions were lost because residents refused to be observed. Most residents who were able to speak to us confirmed that they did not mind being observed; however, some residents with cognitive impairment appeared agitated. Whilst this agitation was probably pre-existing, there was speculation that it might be increased by our observations, so it was important to be as unobtrusive as possible.

PAT completion rates reduced over time, possibly explained by more residents being available for assessment at baseline, and there being more residents in bed at later follow-ups due to a deterioration in their health - the researchers and I often reported the frailty of residents, which supports this assertion, and the poor and declining health of residents is well-known (4, 210); however, there were still 68% residents (of those remaining in the trial) with at least one PAT completed at the 6-month follow-up time-point. This is a much higher data completion rate than the residents' self-report measures during the trial (as will be reported in the next chapter) - suggesting that an observational method may be more appropriate for this frail population who are often cognitively impaired (4), and who can struggle with the completion of measures due to their sensory impairments (211). Indeed, other authors (212, 213) have pointed towards the difficulty of obtaining self-report measures from people with dementia and have suggested that observational approaches to understand quality of life might be more productive.

Our written observations extended beyond the requirements of the PAT, including mention of agitation, pain, and physical disabilities, indicating that this observational approach could perhaps be used to obtain health and quality of life outcomes. Observations also included commentary on residents' posture and poor seating arrangements which displayed an understanding of the expected outcomes of the skilful care training. The provision of these unasked-for observations suggests that researcher time spent in the care home for PAT completion could be used productively to identify staff's enactment of new skills. I would suggest that researchers spending extended time in each care home observing posture, resident health and wellbeing, and staff's use of new skills would be a good use of their time, and it would contribute data that might be more credible (200) due to the large quantity of observations gathered over a longer period of time. Of course, appropriate, validated tools would be needed for this to be an effective method and, whilst some exist (214), there are few that are suited to care home residents.

If we had been able to visit the participating care homes on a more frequent basis it might have been possible to achieve higher PAT completion rates - to include those who were in bed only temporarily on the days when we visited; and to adhere more closely to the requirements of the PAT. Despite instruction to the contrary, we completed the tool for some residents who were asleep or in positions which prohibited rating. This was probably because there was insufficient time to wait for residents to meet the criteria for assessment.

Where residents were permanently in bed, it was not possible or relevant to administer the PAT as it was designed to assess seated posture. Over time, the proportion of participating residents who were in bed increased, suggesting that a tool to assess posture in bed would be helpful - to ensure that postural assessment is not limited to those who are more able.

Despite developing a tool that achieved high data-completion rates and appeared acceptable to most residents, there were unresolved problems with certain elements of postural assessment: we were less confident when rating more subtle postural deviations or very unusual postures; we had difficulty rating the central, pelvic area of the body; and we were unable to rate a number of postural items due to an impeded view, a resident's legs being crossed or elevated, and the presence of additional supportive items such as cushions. These difficulties indicate that further refinement of the tool could improve the accuracy of completion of all items; and more comprehensive training to identify postures correctly may be needed.

5.3.2 Methodological considerations

Whilst a sample size calculation is not necessary for feasibility work, the large dataset available from PATCH trial participants is a strength of this work as it improves the validity of my findings. A mixed methods approach to testing the newly developed tool - collecting quantitative data (multiple completions of the tool) to illustrate the feasibility of completion, and written feedback from researchers - also contributed to the validity of my findings: triangulation of data sources helped me to understand that, whilst overall PAT completion rates were good, there remained difficulties with the accurate completion of the items within the tool. These difficulties pointed towards the need for further refinement of the tool.

Rather than obtain written accounts of the difficulties with PAT completion, I could have interviewed the researchers to explore these challenges in more detail. However, I was aiming to understand the difficulties with a practical task that might vary from resident to resident and between care homes; interviews at a later date would probably have lacked the detail required to allow a complete understanding of the range of difficulties faced. For the purposes of refining the PAT, written accounts after each completion provided a more thorough understanding. However, I did go on to interview

researchers at the end of their involvement in the PATCH trial to ask them more generally about their experiences of data collection (see Chapter 6), which included the completion of the PAT as well as all other outcome measures.

<u>Reflexive statement</u>

I collected a proportion of the PAT data, which I then subsequently analysed, so I am not impartial in my understanding and review of researcher accounts of the difficulties faced in completion of the postural assessments. My experiences, as well as my discussions with the researchers throughout their involvement in the PATCH trial, probably influenced my interpretation of researcher comments; however, this was a practical task with practical difficulties documented, so there was limited chance of misinterpretation. Nevertheless, my expectations of what I might find prior to review of the data will have influenced my interpretations.

5.3.3 Implications

Measuring posture as a non-expert, and without a hands-on approach, is challenging. This was preliminary work to establish the ease of use of a postural assessment tool, and to assess its acceptability to residents and its fit with the care home environment. Further work is required to refine the PAT's content to improve its usability and to assess formally its: content and concurrent validity; inter-rater reliability when used by non-experts (researchers and care staff); and acceptability when used by staff rather than researchers. A valid and reliable tool could inform the provision of care and be a useful outcome measure for research. One of the project's physiotherapists and I applied for, and were successful in receiving, a grant from The Chartered Society of Physiotherapy Charitable Trust (PRF/18/B10) to undertake this work, which will be completed in 2022. We have also, more recently, been successful in a second application (PRF/20/C07) to the same funder to develop a postural assessment tool for residents who are in bed. Given the high proportion of residents who are bed-bound or spend long periods of time in bed, such a tool will be an important addition to enhance comprehensive assessment of posture for all residents, regardless of their mobility levels.

Observation as an approach to assessing residents' quality of life is an important method to explore in more detail. High rates of cognitive impairment often preclude completion of outcome measures which require resident responses whereas we

achieved good PAT completion rates through observation. In the next Chapter I discuss the use of *existing* resident- and proxy-completed outcome measures selected to assess the intended consequences and impact of the Skilful Care Training Package. I look at the feasibility of their use in care homes, and staff and researchers' perspectives on their suitability for residents.

Chapter 6 The feasibility of measuring outcomes

In this chapter I present my findings from Study 4, in which I aimed to assess the feasibility of measuring trial outcomes using standard outcome measurement tools and bespoke trial data collection forms. My objective (Objective 2) was to understand researchers' and care staff members' experiences of collecting and providing data for care home research, and to then consider the implications for future research data collection in care homes. Details of the methodology and methods used are described in Chapter 3.

First, I report PATCH trial data completion rates to set in context my qualitative findings (Section 6.2) - which explore reasons for the observed completion rates, as well as other experiences of data collection not captured by these quantitative data.

6.1   Data completion rates

6.1.1 Resident data

Tables 17, 18 and 19 illustrate data return rates for data provided by staff informants about participating residents, whole-home measures (also provided by staff informants), and resident-provided data, respectively.

Provision of data by staff informants was excellent where residents were available for follow-up (99-100% if partially completed questionnaires are included) but resident attrition (following death or moving out of a care home) meant that data capture for the full cohort declined over time, with only 69-71% completed at the 6-month follow-up (Table 17).

Anonymised data, collected for all residents living in each care home at each time point, had similarly high completion rates for the PAM-RC and FAC outcomes (Tab;e 18). The PAM-RC was fully completed for 99% residents at baseline, 98% at 3 months and 100% at 6 months follow-up. The FAC was incomplete for just one resident at 3 months follow-up.

Table 17 Completeness of data provided by staff informants at each time point

(registered residents as denominator)

	Baseline	3 month follow-up	6 month follow-up
Number of registered residents	146	146	146
Number of questionnaires expected†	146	124	104
EQ-5D-5L Proxy			
Completed EQ-5D-5L + VAS	146 (100%)	122 (83.6%)	104 (71.2%)
Partially completed EQ-5D-5L	0 (0.0%)	1 (0.7%)	0 (0.0%)
Physical Activity and Mobility in Residential Care (PAM-RC)			
Fully Completed	146 (100%)	118 (80.8%)	104 (71.2%)
Partially Complete	0 (0.0%)	5 (3.4%)	0 (0.0%)
Functional Ambulation Classification (FAC)‡			
Completed	146 (100%)	123 (84.2%)	104 (71.2%)
Barthel Index of Activities of Daily Living			
Fully Completed	145 (99.3%)	121 (82.9%)	102 (69.9%)
Partially Complete	1 (0.7%)	2 (1.4%)	2 (1.4%)
Continuing Care Activity Measure (CCAM)			
Fully Completed	140 (95.9%)	121 (82.9%)	101 (69.2%)
Partially Complete	6 (4.1%)	2 (1.4%)	3 (2.1%)

† Number of registered residents minus those who have died or moved away from the home

‡ The FAC is a classification tool providing a single score and therefore partial completion and missing items are not possible

Table 18 Completeness of whole home (anonymised) resident data, provided by staff informants at each time point

	Baseline	3 month follow-up	6 month follow-up
PAM-RC			
Fully Completed	346 (99.4%)	318 (98.1%)	318 (100%)
Partially Complete	2 (0.6%)	5 (1.5%)	0 (0.0%)
FAC			
Completed	348 (100%)	323 (99.7%)	318 (100%)

Resident data return rates were poor, with only 49-51% of residents able to complete measures at baseline, declining to 31-43% of those available for follow-up at 6 months. As a proportion of the whole cohort, only 31-35% were able to provide data at the 6-month follow-up visit (Table 19). Reasons for non-completion of the measures were predominantly the residents' inability to communicate, engage or understand the questions being asked of them. Completion of the 6-item Cognitive Impairment Test (6-CIT) was so poor that, for this reason as well as the distress of some residents during its administration, its use was discontinued after completion of the baseline visit in the sixth care home.

Table 19 Completeness of data provided by residents at each time point

(Expected data as denominator)

	Baseline	3 month follow-up	6 month follow-up
Number of registered residents	146	146	146
Number of questionnaires expected†	146	124	104
EQ-5D-5L (of expected)			
Completed EQ-5D-5L	71 (48.6%)	43 (34.7%)	36 (34.6%)
Partially completed EQ-5D-5L	15 (10.3%)	17 (13.7%)	12 (11.5%)
Completed EQ VAS	57 (39.0%)	26 (21.0%)	27 (26.0%)
Completed EQ-5D-5L and EQ VAS	56 (38.4%)	25 (20.2%)	24 (23.1%)
Pain Thermometer Scale‡ (of expected)			
Completed	74 (50.7%)	57 (46.0%)	45 (43.3%)
6-CIT*			
Assessment completed or partially completed	26 (31.3%)		
No assessment	57 (68.7%)		

Notes:

† Number of registered residents minus those who have died or moved away from the home

‡ The pain thermometer scale is a classification tool and therefore partial completion and missing items are not possible

* Administration of the 6-CIT was discontinued after its use in the first 6 care homes at baseline - thus the denominator is the total no. registered residents in these 6 homes (N=83).

6.1.2 Care notes data

Booklets for the recording of data about the care home environment and residents' contacts with health and social care services were completed for all homes (except the home that closed during follow-up) and participating residents.

6.1.3 Care staff data

Table 20 sets out return rates for the staff booklets, which consisted of the posture and movement questionnaire, the empathy scale, and person-centred care scale. As a proportion of the care staff working at the homes at each time point, 48% completed a booklet at baseline, 41% at 3-months, and only 27% at 6-months. There was wide variation in booklet completion rates between homes, with no discernible pattern explaining non-completion. The best performing homes (care homes 6 and 7) achieved >60% compliance at every time point, whilst two homes returned only 5% of the expected booklets at the final follow-up time point.

The staff tracker was lost at care home 2, so staff booklet compliance is not presented for this home; although I can report that 7, 3 and 3 staff members completed a booklet at baseline, 3-months and 6-months, respectively; and the number of staff reported to be working at the home at baseline was 27.

I also reviewed staff booklet completion rates for the sub-set of staff (N=13) who took on the staff informant role in each care home. As they were more familiar with the research and had spent time with the researcher, I wondered whether their completion rates would be better than the overall levels of staff compliance. Table 22 shows that this was indeed the case - with return rates of 69% at baseline, 54% at 3-months, and 50% at 6 months.

Table 20 Completeness of staff measures

CH ID	Baseline			3 months			6 months			Average return rate
	No. booklets expected*	No. booklets completed	Return rate (%)	No. booklets expected*	No. booklets completed	Return rate (%)	No. booklets expected*	No. booklets completed	Return rate (%)	
1	52	29	55.8%	52	24	46.2%	50	13	26.0%	42.9%
3	31	8	25.8%	29	11	37.9%	26	3	11.5%	25.6%
4	31	18	58.1%	30	12	40.0%	29	4	13.8%	37.8%
5^	38	17	44.7%	0	0	-	0	0	-	-
6	32	24	75.0%	29	18	62.1%	33	27	81.8%	73.4%
7	19	12	63.2%	16	13	81.3%	23	14	60.9%	67.2%
8	33	13	39.4%	38	6	15.8%	37	2	5.4%	19.4%
9	37	5	13.5%	39	10	25.6%	37	2	5.4%	15.0%
10	26	18	69.2%	29	14	48.3%	29	7	24.1%	46.4%
Total	**299**	**144**	**48.2%**	**262**	**108**	**41.2%**	**264**	**72**	**27.3%**	

* Based on the number of care staff listed on the staff tracker as working in the care home at each time point. Booklets were circulated to all these staff.

^ Home closed just after 3-month visit, so staff booklets not collected.

Note: care home 2 is excluded from this table as the staff tracker was lost for this home.

Table 21 Staff remaining in post for the duration of the project

(as a proportion of average staffing levels)

CH ID	Average staffing level	Staff members working at care home at all time points
1	51	42 (82%)
3	29	22 (75%)
4	30	27 (90%)
6	31	26 (84%)
7	19	14 (74%)
8	36	31 (86%)
9	38	33 (87%)
10	28	21 (75%)

Note: Data for care homes 2 and 5 are not included as the staff tracker was lost, and the care home closed at 3-months, respectively

Table 22 Staff informants' completion of staff measures

	Baseline	3-months	6-months
No. staff informants	13	13	12
No. completing booklets	9 (69.2%)	7 (53.8%)	6 (50.0%)

6.2 The feasibility of measuring outcomes - qualitative findings

6.2.1 Participants

6.2.1.1 Researchers

I interviewed two researchers who were based at the Academic Unit for Ageing and Stroke Research (AUASR) in Bradford in June 2018; they were selected because of their high involvement in the project - undertaking data collection at nine of the ten participating care homes - so they could reflect on similarities and differences between homes. This joint interview lasted nearly two hours.

I did not interview the two researchers who had collected data from only one care home each; however, their written feedback provided after each visit to the care home was part of the documentary evidence that I included in my analysis.

6.2.1.2 Care home staff

Interviews with staff were completed during October and November 2018 - involving seven members of staff at five participating care homes: two managers and five staff informants, as set out in Table 23. Interviews took between 30 and 60 minutes. Two homes (care homes 2 and 4) did not respond to my requests for interviews, and one (care home 5) had closed during the trial. A further two homes (care homes 3 and 9) did not engage, probably because one manager was on long-term sick leave and the other had left the home.

Although I had intended to sample purposively, in the event I had to contact all homes to achieve the required sample - meeting with staff at homes where the managers were willing to participate. Despite this change in approach, the sample was sufficiently varied, including: four nursing homes and one residential home; three homes that had received the intervention and two that had not; and three homes with fewer than 40 beds and two with more than 40 beds (see Table 23). Those interviewed tended to be more senior members of staff, reflecting the type of staff member who had been willing to engage with the provision of data. The staff sample included two managers, three deputy managers (two with a nursing background and one with a background in social care), one nurse and one senior carer.

My greater difficulty was finding care staff available to have informal conversations (rather than be interviewed) about completion of the staff measures. I only managed to speak to three members of staff - in addition to the staff I interviewed who had also completed the staff measures - reflecting their availability when I visited the homes. I tried to find staff to speak to when I was visiting to interview the manager or staff informant, but most were busy and unavailable for conversations. I made plans to go to a staff meeting at care home 9, but this was repeatedly cancelled.

Table 23 Staff interviews and conversations

Care home ID	Residential / Nursing	Allocation*	No. beds	Interviewed Manager	Interviewed staff informant	Staff member conversations	Notes
1	Nursing	Usual Care	48	No	Yes	No	Manager left prior to interviews
2	Nursing	Usual Care	44	No	No	No	
3	Nursing	Usual Care	33	No	No	No	Manager left prior to interviews
4	Residential	SCTP	46	No	No	No	
5	Nursing	SCTP	20	No	No	No	Home closed prior to end of trial
6	Nursing	Usual Care	40	No	Yes	No	
7	Residential	SCTP	30	Yes	Yes	Yes x 1	
8	Nursing	SCTP	38	No	Yes	Yes x 2	Manager left prior to interviews
9	Residential	Usual Care	41	No	No	No	Manager on long-term sick leave
10	Nursing	SCTP	36	Yes	Yes	No	

* SCTP = the Skilful Care Training Package

6.2.2 Findings

I aimed to explore researchers' and care staff members' experiences of collecting and providing data for research through analysis of interview and documentary data (see Chapter 3 for analytic approach). I identified the following themes which exemplified these challenges:

- **An unrecognised reality** - staff felt that they were not always able to make an accurate judgement about residents' quality of life and well-being, particularly those with dementia.

- **Capturing the nuances of residents' daily lives** - staff and researchers felt that the data collection tools did not always accurately capture residents' lived experiences.

- **The proxy paradox** - although staff members thought they were ideally placed to understand and report on residents' quality of life, this was not always easy to do.

- **Understanding care home life** - staff and researchers reported a mismatch between the data we ask for in research and the information they collect to support resident care.

- **Complexities of the research process** - researchers had to adapt their approach to data collection, so that residents and staff understood what was being asked of them.

Each of these themes is described in detail below.

An unrecognised reality

Residents with dementia were often unable to provide researchers with the data that we needed, with researchers reporting few successful completions of questionnaire booklets. Where residents with dementia were able to engage with researchers, their accounts of observable aspects of their health and well-being were often inaccurate; researchers speculated that this was probably as a result of being unable to remember, or providing a learned, socially acceptable answer. Researchers reported conversations with staff confirming that residents' self-reported data were inaccurate. One member of staff was clear that the only way to obtain 'the truth' was by asking a caregiver who knew the resident well.

> *"I get a lot of people say, "I'm fine, I can walk," and staff have quite often like, you know, they can't walk, or they don't do, you know…" (Researcher 1)*

On the whole researchers felt that residents who did not have dementia understood the questionnaires, and that relevant answers could be elicited with appropriate prompting, but they found that residents with capacity were also prone, on occasions, to provide inaccurate responses. Researchers and staff speculated that residents were sometimes reluctant to voice their limitations for personal reasons - be that embarrassment that they needed help, that they were perhaps too proud to say that they were in pain, the 'British stiff upper lip', or that they just did not want to talk about how they were feeling. Researchers reported that residents would sometimes just say 'I'm alright', and that they struggled to get them to go beyond this to categorise their well-being on a Likert or numerical scale.

> *"…and even some people are too proud to say they're in pain..." (Staff informant 1)*

> *"A lot of them find it difficult to give numbers, again their health is like, "well I can't put a number to it but I'm fine"." (Researcher 1)*

Staff informants were asked to report quality of life from the perspective of each resident. They said that reporting residents' abilities in relation to activities of daily living tended to be relatively straightforward since the provision of support with residents' mobility and personal needs is a key element of care - so they were well-equipped to report levels of dependency. On the other hand, staff and researchers reported that people with dementia are sometimes less mobile or less engaged in activities of daily living because they don't remember or understand how to do certain things, or perhaps are not given the opportunity, rather than being physically incapable. An example given was that someone may need to use a wheelchair most of the time because they rarely move independently, but they might occasionally stand up and walk. Similarly, someone talked about residents being capable of holding a cup to drink but that they are not given the opportunity because staff know that they will not know how to use it. So it seemed that there were two elements to some residents' abilities - activities that

they were physically capable of doing, however infrequently, and their usual level of dependency upon which staff had to base care decisions.

> *"…but like somebody like with your dementia, they sometimes will forget*
> *that they can, which you know they're physically able to walk but they just*
> *won't, either stand up, think they can't…" (Staff informant 3)*

> *"…every now and again he's beggared off down the corridor, but he's*
> *officially not able to walk." (Researcher 1)*

This created confusion for staff and researchers on how to complete a questionnaire. Should it reflect the predominant reality for the resident, or should they report residents' true (or 'best') ability, even if this happened only occasionally?

> *"So then they're like, okay, so how do we answer this, does that mean*
> *again going back to their ability, or they're just not doing it, or there's just no*
> *chance of them for doing, you know, propelling." (Researcher 2)*

Staff found the assessment of subjective states, such as mood and general well-being, particularly difficult. They reported that the rating of residents' well-being on a numerical scale such as the EQ-5D Visual Analogue Scale (177) was hard to do; they were unsure how to provide a rating for someone else's subjective health state. Staff members suggested that it often felt like a guess, and researchers talked about staff members rating residents against each other, rather than considering each individual separately. Thus, obtaining a true understanding of a resident's emotional and physical well-being was often difficult.

Capturing the nuances of residents' daily lives

The outcome measures used for this project asked about residents' health and well-being over various time frames: 'right now', 'today', 'over the last week' and 'current ability' - the last of these assuming a consistent or 'steady state' ability. Most staff talked about residents' abilities varying from day to day - as a consequence of dementia, but also related to residents' poor health. They mentioned residents' mobility and dependency being affected by varying levels of pain, periodic limitations of a

chronic condition such as arthritis, acute illness, or being inhibited by medical equipment such as a catheter. Staff also commented that sometimes residents just didn't want to engage in activities, preferring staff to help them - perhaps because this was easier, was available, and because there might be some levels of apathy and depression amongst residents. Staff explained that, on some days, residents were able to do some of the activities we asked about, but on other days they were not. The difficulty for staff and researchers arose with the longer time frames in the questionnaires as they found it hard to represent adequately or accurately residents' variable health status. They also expressed some frustration that we missed this variation in our reporting of trial outcomes.

> *"…it's difficult some things because sometimes it depends from day to day. Yeah, you can't really say that's, you can't just put a tick and say he's like that because sometimes one time you realise these, other time you're like this. Maybe today might be very good at walking, the other day he's not able to walk depending on the condition." (Staff informant 2)*

As well as some questionnaires failing to capture the variability of residents' health status, researchers found that some questions were difficult to ask because they did not align with care home life. For example, one question asked about engagement with 'usual activities', with associated prompts (work, housework, leisure activities) that were more relevant to a community-dwelling person. In contrast, activities in the care home were often extremely limited due to residents' physical and cognitive impairments, as well as there being infrequent opportunities to engage in every-day events. Consequently, questions asking about engagement in usual activities felt meaningless, as well as having the potential to upset residents.

> *"On that sort of, you know, assessment that they go through, what they've written is example work, study, housework, family, which none of them they do, they're at a care home, they don't work, they don't study, they don't have housework, you know, leisure activities maybe, if they're out, then yeah, you do ask, "Do you join in with activities?" and if they're very immobile, mostly, might like to go or…" (Researcher 2)*

Some questions, although relevant to residents, were thought to include pre-defined categorical answers that did not reflect the way in which residents experienced life. Staff and researchers suggested that some of the questionnaires did not include enough question categories to reflect accurately the subtle differences in ability between residents. For example, the Barthel Index - Activities of Daily Living (168) includes questions about residents' level of dependency in several categories, including 'grooming', 'feeding' and 'dressing'. For these categories, residents can be graded as 'unable', 'needs help' and 'independent'. Some staff and researchers felt that the 'needs help' category was too broad (that the questionnaire was insufficiently sensitive) such that subtleties relating to limited levels of dexterity were missed. This was also the case for several other questionnaires.

"…your slight and moderate maybe might like, be the hand movements, you know, being able to move their arms and things or being actually being able to use their fingers… [….] …we've got some that can brush their hair but they can't hold the toothbrush to do their teeth." (Staff informant 1)

Researchers felt that the lack of sensitivity of the tools affected the accuracy of the data collected because staff needed to select options that they felt did not adequately describe the residents' abilities.

Staff and researchers made suggestions for ways to improve reporting to reflect residents' actual experiences - for example, the collection of contextual data to describe variable abilities, collection of the range of residents' abilities (best and worst over the time frame), or reporting for shorter time frames and more frequently. They also thought that questionnaires with more categorical options, or the inclusion of free-text description, would result in more accurate resident profiles.

The proxy paradox

Staff felt that the only way to obtain accurate information about residents without capacity was to ask them: "we know the residents" was a repeated assertion, with staff expressing the view that they were in a good position to provide information about residents' well-being because they had learned to understand their needs through observing their behaviour over time. They believed that it was an understanding of these needs that was fundamental to providing good care. They also monitored specific

components of residents' health and well-being as part of their every-day care - for example, mobility, feeding and skin integrity.

> *"…we know them, we know how they behave, when they, say, for example, when they're in pain we know what, you know, what kind of behaviour will tell us that so-and-so is in pain, we know how, you know, how they, you know, they interact with other people, you know, even if they don't, they can't speak to you, or some of them can speak to you, but obviously cannot formulate a sentence and things like that, we sort of anticipate their needs, we know what they need." (Manager 1)*

However, the research questions asked did not necessarily align with the information that staff would need or use to inform care. Some staff said that they might be able to judge when a resident is in pain and respond promptly, but rating the severity of pain from a resident's perspective is quite different. Reporting observable aspects of health, such as mobility, was thought to be more straightforward - despite the difficulties with day-to-day variability described previously - but when it came to rating subjective states such as pain, depression and anxiety, staff found it difficult.

Staff and researchers commented on how residents' and staff members' individual differences and differing perceptions of their health and well-being affected their responses to questionnaires. Staff pointed out that there are some residents who will always say that they are 'fine' when they are not and that, conversely, there are those who will think that they are ill when the staff think that they are doing reasonably well.

> *"… some will say "oh I'm fine" but no they're not fine, you know they're not fine, they'll be in pain but they don't say that they're in pain, or then you've got the others at the other end of the scale saying "oh my back's killing me today" and the next minute they're around building and they're fine…" (Staff informant 3)*

Variability in residents' expressions of their health and well-being meant that staff and researchers were not always confident that the answers provided by staff to proxy questionnaires would necessarily reflect the answers a resident might offer. Staff's answers might more accurately reflect residents' well-being, but the purpose of proxy

reporting is to understand a resident's perspective. Staff therefore faced conflict between providing an accurate assessment and adopting the resident's view-point.

> *"…where I were putting somebody they would completely put their self somewhere different, you know, it's, it is quite hard that one." (Staff informant 1)*

As well as the discrepancy between staff and residents' ratings of their quality of life, researchers noted differences in the way ratings were made by individual staff. Staff role and experience might affect answers, and individual members of staff might themselves have a more positive or negative bias in the way they considered someone's well-being.

> *"…sometimes you get a different point of view from if you've got a nurse, they come at it more clinical, so like they go, "Oh, no, they've not had anything for depression," or, "They have pain relief regularly"…" (Researcher 1)*

> *"….like Brian* was putting everyone down this end, and then Judith* puts everybody up this end…" (Researcher 1)* [talking about how they rate residents on a scale from 0 - 100]

* pseudonyms

Staff questioned whether people with dementia experience their health and well-being in the same way as those with capacity. They differentiated between anxiety and depression, and dementia - suggesting that the behaviours we might usually associate with mood disorders were part of the dementia, so not 'true' anxiety and depression. They also spoke about anxiety in terms of it being contingent upon health or particular activities, rather than it being a separate state of mind.

> *"Somebody with dementia and it's, you know, they'd have a total different concept to how it really was, you know, they see things totally different don't they?" (Staff informant 5)*

Coupled with the idea that quality of life is different for those with dementia, some staff also commented on the difficulty of making an accurate judgement about a resident's quality of life when they were not able to communicate with the person:

"…you don't know how a person's feeling if they can't tell you how they're feeling, so that can be quite difficult." (Staff informant 3)

Understanding care home life

Staff talked in detail about how they care for residents and the regular processes they were required to undertake and to document. Where the data that we asked for were routinely recorded in care home records, or where our questions aligned with standard care practices, it was relatively easy for staff to provide, and researchers to collect, those data. For example, staff reported that they monitored falls and hospitalisations on a monthly basis - to ensure they picked up any problems that would influence future care, and because there was a requirement to report serious incidents to head office and to CQC; thus falls and hospital attendance data were easily found in care notes. Care staff also reported to us that the content of some of the questionnaires largely reflected the areas of residents' health and well-being that they would monitor on a daily basis.

"…I do, for my monthly manager's report, that's one of the things that comes on the report. I need to know how many falls, how many of them have gone into hospital, how many of them have been admitted because of that, and yeah, so that, to me, isn't very bad." (Manager 1)

"…that's all in the care plans and they're all sort of separate sheets on how it has to be done […] The information probably is all there that you've got in yours as well." (Staff informant 3)

Some information was easily provided because staff reported that they 'just know' the answers without having to refer to any notes or records. Here they were referring to certain aspects of residents' health that would be of concern (for example, development of a pressure ulcer), or events that are easy to recall because they are familiar, such as routine staff training. Sometimes, though, data collection was difficult,

particularly where the data required for the research did not reflect standard processes or care practices.

The two home managers I interviewed took the view that it was impossible to provide certain information because we were asking for something that they just did not know, or about events that did not happen (for example, health visitors never came to the homes).

> *"…that was one of the things I found a bit difficult, so, for example, you're asking me about the price of certain equipment, I don't know … some of it actually comes from the NHS, because we get some equipment from loan stores, like the big, bulky chairs and, you know, I don't know how much they cost, I just put in a request through the occupational therapist and the physio, and then we get it. So it is very difficult for, you know, for me to know the costs of that." (Manager 1)*

In their feedback, researchers noted that sometimes care home notes did not include the detail required for the research. Health care professional visits were not always clear - records showing only 'nurse' rather than 'district nurse' or 'tissue viability nurse' - and the specific details about a health problem were sometimes lacking. For example, type of stroke, pressure-ulcer grading, and type of hospital ward for admitted residents were not always included in the care notes. Similarly, some of the contextual information we asked for around a health episode was not documented - for example: *"…private and NHS, it's difficult for us to know from the notes…" (Researcher 2)*

Staff and researchers talked about how the trial's data collection forms asked for data in a different format to that routinely documented by the homes. The predominant problem cited was failed attempts to gather data in aggregate form (for example, the number of hospital admissions over a one- or three-month period, or total GP callouts in the last three months), when homes recorded these items in individual records.

> *"…so that's not an easy task either, I'd have to look at care plans then, so each individual care plan for the person who's in hospital to see when they were admitted and when they were discharged." (Manager 2)*

Researchers noted that it was extremely difficult to obtain summary data about the care staff at a home: working hours were not recorded centrally, information about rotas and sickness was recorded for each individual staff member rather than aggregated, and it was difficult to collect data exclusively about care staff rather than all staff employed by the home. Some homes aggregated data for their own reporting purposes but did so using different time frames to those specified for the trial. Researchers found that summary data about hospital admissions or falls was often collated monthly, whereas we hoped to obtain this over a three- or six-month period; the combining of monthly figures was awkward as individual residents could easily be double-counted across months.

Staff commented that our question categories did not always reflect care or working practices, which made some questions difficult to answer.

> *"…because you've got like the GP, daily, twice a day, twice a week, once a week, once a fortnight, once a month. To me, these are quite vague, not really vague, GP would visit when we need them." (Manager 1)*

Similarly, some difficulties with the completion of standard outcome measures arose from pre-defined question categories not accounting for care home practices. For example, so-called profiling beds provide mechanical support for residents' movement to reduce the physical support residents need from carers; standard questionnaires, however, only ask about personal assistance requirements as a measure of dependency. Thus, reported levels of dependency did not accurately reflect residents' needs. Staff and researchers commented that contextual detail would have been helpful to describe why residents were or were not able to undertake certain activities, noting that additional information could have been provided about types of chair, profiling beds and regular re-positioning of residents to minimise pressure ulcer risk.

The mismatch between questions posed for the research and the data available in care homes (the available data items and the way in which they were documented) made data collection difficult for staff and researchers.

Complexities of the research process

Some processes worked well: researchers reported developing good rapport with residents, managers and staff members - particularly with those who regularly provided data - and staff praised researchers for their professional, friendly and non-intrusive approach. Staff members mostly didn't mind providing data, even though it was sometimes a lengthy and slightly repetitive process. However, because of the difficulties with the collection of some data, there were challenges and adaptations required throughout the project.

Some staff and researchers reported that they were uncertain of the meaning of some questions, affecting the answers they gave and the quality of the data provided. Difficulties arose for staff with research terminology, or wording that didn't fit with their working practices - for example, one staff member didn't understand what was meant by the care home introducing 'new initiatives' or 'voluntary measures' - and the researchers reported having to explain certain questions to staff when they themselves didn't quite understand what was required. Researchers also found the interpretation of medical information in the care notes difficult at times.

> *"Because sometimes when you see it written down it can be quite a lot of jargon and you think "what are they asking of me here?" " (Staff informant 3)*

> *"I never knew really what is the difference between transfer and sit to stand, and because they're sort of, essentially they're the same, they would say, "I've just answered that," and you go, "Mm, yeah, you have…"." (Researcher 1)*

Researchers found that they sometimes had to spend a long time deciphering information in care records and calculating figures required for the research where this was not directly available in the notes - for example, deducing the presence of a medical condition on the basis of prescribed medication, and calculating the number of hospital visits over a period.

It was apparent that researchers were skilled and flexible in their approach, adapting the ways in which they collected data to be sensitive to staff's and residents' needs and

levels of understanding. In particular they talked about never just asking the 'prescribed' questions within the questionnaire booklets; rather they would have a chat with residents and introduce topics within natural conversation, translating and explaining difficult terminology so that a resident would understand, prompting on a few occasions when answers were not forthcoming. Both researchers felt that this was a preferable approach and that it resulted in more information from residents.

> *"…you wouldn't sit and, you know, with a pen and, you know, with the tick list, you just have a natural conversation and within that conversation I manage to get that question in, so you know, you just say, "Oh how have you been today, did you have a nice weekend, did you have family members over?" and then, "How have you been over the weekend?", they say, "Oh I've been feeling okay, not too bad," and you're just putting, "So have you been feeling any pain?" and then you get that answer that way."* (Researcher 2)

Similarly, they adapted their approach with staff informants - to explain what was required, to clarify the meaning of questions, to elicit information from a general discussion, and to go back to questions if needed (for example, when later answers contradicted earlier ones).

Other information

I had little success engaging care staff to talk about the staff booklet; however, from those I did speak to, they had no strong views about the questionnaires included in the booklet. There was some indication that alternative methods of obtaining information, such as focus groups or online questionnaires, might be an acceptable way to improve engagement. Staff were ambivalent about the use of incentives such as a prize draw - for which there is currently little evidence of effectiveness.(215)

During the course of the interviews I accumulated factual information from the care home staff and researchers: they described, as part of our conversation, the types of resident data that would be routinely monitored and documented, and the electronic systems that supported their recording of residents' health interventions and care plans. This information does not add anything in particular to this chapter, but it is a potentially useful resource for future research - to be used as a practical starting point

when deciding which data can be reasonably expected to be available for research, and where and how to access it. Consequently, I have included a table of available data items in Appendix 5, and I describe the electronic systems used in the care homes we worked with at the start of Chapter 7 - to set the scene for my work looking at the use of routinely available data.

6.3 Discussion

6.3.1 Summary of findings

To examine the feasibility of measuring outcomes in care homes, I first looked at data return rates from different types of participants and from different data sources. I observed excellent return rates where data were gathered from care records by a researcher, or where a researcher obtained data from a member of care home staff through direct questioning. Researchers had trouble collecting data directly from residents due to high levels of cognitive impairment, as well as sensory impairment in some cases. Where care staff were required to complete questionnaires about themselves without researcher support, completion rates were poor. Poor compliance is often attributed, in part, to high staff turn-over (80) but more than 70% of staff were working at their care home for the duration of the project - a proportion not reflected in staff booklet completion rates. Completion rates for staff informants were better than those for the general population of care staff, probably because they had more engagement with the research, and because most held more senior roles so perhaps had a greater understanding of the questionnaires' content and purpose. However, completion rates by informants were not nearly as good as the almost 100% provision of proxy data, suggesting that face-to-face contact with a researcher is the best way to ensure completion of measures.

To understand these successes and challenges, I spoke to care staff who had: provided health and demographic data about the care home and its staff, provided quality of life data about the residents, and completed questionnaires about their own working practices. I also spoke to researchers who had collected data from residents, staff and care notes. Analysis of these interviews and conversations gave rise to explanations for the challenges in providing data and identified further difficulties that could not have been discovered if only crude data compliance figures were reported. Researchers' and proxy staff members' data return rates were excellent, but that did not mean that the data provided were of consistently good quality or were easy to

obtain: for example, proxies were not always confident that they had answered questions correctly or appropriately, and researchers found it difficult to obtain some information from care notes. Staff who had acted as proxies for residents (to describe their health and well-being) found it difficult to answer some of the questions in the standard quality of life measurement tools for a number of reasons.

I identified themes which captured these difficulties. Staff discussed how residents often couldn't articulate their status (accurately or at all), that they found it difficult to understand how residents were feeling, and that residents were sometimes capable of more than their regular behaviours would suggest. For all these reasons, the reality experienced by residents often went unrecognised in the research dataset. In a trial looking to improve posture and mobility, there was uncertainty around whether to rate ability, even if it rarely occurred, or the more commonly observed behaviours. Staff and researchers suggested that reporting more contextual information would make their task easier, to explain why a resident doesn't engage in a certain activity, and to indicate what they are <u>able</u> to do as well as what they <u>actually</u> do. Which of these it would be more important to report would depend on the outcomes an intervention is aiming to influence, but taking this into account might allow a more meaningful and informed analysis of the data.

Researchers and staff also talked about residents' day-to-day variation in their abilities and how the questions posed did not capture these because of the time-frames imposed. Researchers felt that some of the questions were not relevant to people in care homes - in particular, questions asking about engagement in 'usual activities' where there may be little available activity that residents are capable of undertaking. Questions about activities of daily living were largely seen as appropriate, aligning with care plans provided for residents. Staff and researchers, however, regarded some questions as insufficiently sensitive to residents' limited abilities. They felt that current categorisation might miss small differences in motor capabilities that could be important for residents' independence. These challenges with the existing measures meant that the reported profile of residents did not always reflect the nuanced differences within and between residents. When reviewing the care home literature (see Chapter 2), I found that other researchers had reported this problem (97, 216), with wide agreement that many existing tools were not valid for this population.

Staff felt they were ideally placed to act as proxies because they knew the residents well, however, the questions posed did not always align with the *way* in which they knew the residents. A few care staff talked about their perception that the quality of life of someone with dementia is quite different from that of someone who is not cognitively impaired - for example, staff interpreted anxious behaviours as being a part of the dementia or a short-term response to confusing situations, rather than being anxiety disorder.

Staff found it difficult to empathise in the manner required for proxy completion of a questionnaire - they didn't feel that some of the questions reflected the person with dementia's reality, or indeed that they understood that reality. Similarly, concerns were expressed about individual differences - that residents with similar health states might rate themselves quite differently, and that staff with differing backgrounds or attitudes might rate the same resident in a different way. Despite these concerns, staff felt that they knew the residents well and could (mostly) understand their needs from their behaviours, to enable appropriate care. This was easier for activities of daily living such as mobility, dressing and eating but there remains the difficulty of accurately identifying the less tangible elements of emotional well-being. This inconsistency poses serious questions around the usefulness of existing methods of collecting proxy data, and points to the need for the development of tools or approaches that more accurately capture residents' experiences of their quality of life. Other researchers have reported poor agreement between staff proxy and resident ratings on the EQ-5D-5L and other measures (217), as well as variability between raters (218), suggesting that further work is needed to explore how quality of life is conceptualised by different types of participants (219). My work begins to address staff proxies' understanding of residents' QoL, with further work needed to consider how best to understand and capture residents' lived experiences.

Aside from questionnaire-based data, the researchers and I collected data from care notes about residents' health conditions and use of health care resources. The provision of these data was straightforward when the required data items aligned with care home recording and reporting procedures; however, on other occasions we asked for research data that were not routinely recorded. A lack of standardisation of record keeping and the presence of multiple records for each resident often made locating data items a long and inefficient process. Although we managed to gather most of the data that we sought, there were concerns about accuracy due to difficulties finding, categorising and understanding some information held by the care homes, particularly

where data held in care notes were recorded in a different format to that required for the research. This inconsistency suggests that we had not sufficiently investigated or understood the care home environment when selecting outcomes and designing the data collection forms. This mismatch between questions asked and data availability meant that information about care home life might have been missed or inaccurately reported.

The research process, although facilitated by good relationships, was time-consuming for researchers. They needed to be adaptable, flexible and patient in their approach: explaining the meaning of questions, taking time to talk to residents, and deciphering complex care records. In part, this reflects the complexity of the environment, but it also illustrates the difficulty caused by sub-optimal data collection tools in this setting.

6.3.2 Methodological considerations

My failure to engage staff to talk about completion of the staff questionnaire booklets limits any conclusions or suggestions for alternative approaches. Most of my reporting is based on interviews with the members of staff who had more senior roles in their care homes and who were most involved in the research - through face-to-face provision of information with a researcher over several hours and several occasions. These senior staff gave the impression that they felt involved in the research - that they had 'buy in' through their time spent with the researchers - and most of them reported a positive experience working with the researchers. Thus, there may have been bias to the feedback I received, as those who viewed the research positively were the ones who agreed to talk to me.

A limitation of the interviews was their timing. I spoke to staff a few months after they had completed their involvement in the project; some noted that they couldn't remember all the information we had asked for, which made it difficult to offer definite opinions. That said, I took along copies of the booklets as a reminder of what had been asked and I drew attention to them during my interviews. Interviewed staff mostly said that they could not think of any other data we could have usefully collected. This view aligns with my understanding from the interviews that our questionnaires largely reflected the content of care plans, but it may have been difficult for staff to think of 'what else to collect' from a research perspective; without specific prompts they may not know what else we would be interested in or what would be an important outcome.

A potential limitation of this work is that I did not interview residents to obtain their perspective on the questions we asked them; their involvement may have added an additional useful perspective to my findings. However, very few residents had capacity, so I would not have been able to talk to many of them, and it was mainly the data collection difficulties caused by lack of capacity that I considered in my analysis.

<u>Reflexive statement</u>

As the project lead for the PATCH trial, I had a relationship with most participants because I had trained and managed the researchers and had regular communications with the care home managers throughout the research. I knew the staff informants less well as they had mainly worked with my co-researchers. All participants were aware of my role as the project lead, which may have influenced the narrative they provided; however, since the purpose of this work was to understand their views of a process (data collection) - which was a practical rather than personal matter - I did not feel that there would be any undue pressure to provide the 'right' answers. I made it clear at the start of each interview that I hoped for an honest account to improve future research in care homes; I found participants to be open about how they viewed the research process. I acknowledge that there may have been a discrepancy between my own and the care home staff's understanding of research that might have affected the responses provided, although I was careful to avoid using research terminology. I also acknowledge that I did not come from a neutral position and, inevitably, I had preconceived ideas about the ease or difficulty of data collection - from my own experiences of undertaking this task, and from talking to the other researchers. This standpoint will have influenced the way I asked questions and the perspective I took during analysis.

6.3.3 Implications

Despite allowing plenty of time for data collection, collecting information face to face with residents, and providing only a short booklet for care staff to complete within their working hours, we still observed poor data return rates from residents and from the full cohort of care staff at each home. This persistent difficulty with data provision indicates that we need to consider alternatives for the collection of data from these groups - methods that are more suitable for residents with reduced mental capacity and for busy care staff who simply may not complete questionnaires. I reported in Chapter 5 that

researchers were more successful obtaining data through observation than through conversation with residents. It might be that an observational approach proves more successful, particularly as the staff I interviewed were clear that they often understood the residents' needs by observing their behaviour.

It is well known that asking care staff to complete questionnaires can be unsuccessful (73, 98, 112) - a finding in this trial, despite efforts to enhance completion. Often staff will not spend time providing inessential data when they are busy caring for residents. It is also thought that staff may not always understand the questions because of their educational levels, that they may not be comfortable with the written word, and may not have English as a first language (101). My lack of success in obtaining feedback from staff (N=3 who were not staff informants) also illustrates the obstacles in engaging staff in research processes. The suggestion of focus groups or provision of online questionnaires needs to be explored further through feasibility work with groups of care home staff.

Researchers' completion of questionnaires with staff proxies was more successful, suggesting that face-to-face work improves data quality - although, as suggested earlier, perhaps the staff, mostly fairly senior, who agreed to take on the proxy role were more committed to the research. However, compliance was not necessarily indicative of complete or accurate content; although they provided answers, staff proxies sometimes felt uncomfortable with the answers they gave about residents' abilities when that ability fluctuated on a regular basis. Researchers and staff also felt that some questionnaires did not include options or categories pertinent to the resident population. Consideration needs to be given to the time frame for assessment - for example, providing answers about a resident's health or well-being 'today' rather than over 'the last week' - and to the frequency of assessment: more regular assessments might give a more accurate picture of ability and variability. It is also important to acknowledge variable ability - perhaps recording best and worst functioning over a specified time. Questionnaires need to be adapted, or new tools developed, to include categories more suited to older people living in care homes. There remains the problem of how to assess the emotional well-being of those with dementia who are unable to express this for themselves. Regular observation, as suggested earlier, is one possibility.

Aside from missing data due to staff non-compliance or residents' cognitive impairment, there were problems with sample retention across the resident cohort - mainly due to death. Regardless of measures introduced to improve data quality, there remains the problem of loss to follow-up and its impact on outcome measurement. Alternative trial designs (220), or perhaps alternative methods such as realist evaluation (221), might be better suited to this setting, and work is needed to explore the feasibility and suitability of different approaches.

Careful preparatory work is required in the design of data collection forms, which would do well to ask for data in a way that aligns with the availability and format of routine data collection in each care home. I have produced a table of data items that were available in the PATCH trial care homes (Appendix 5), and I have described the difficulties that researchers faced when collecting these data. I recommend detailed exploration, through conversations with care home staff before a project starts, of the way in which care homes document and report data items. An appropriate mix of homes would need to be consulted as I found, for example, differences in the accessibility of information between smaller and larger homes. Consultation with care homes would allow tailoring of data collection approaches in order to decrease the burden placed on care home staff and researchers, and to increase the accuracy of the information provided. Such a step would allow researchers to assess homes' suitability for a project in relation to their ability to provide the required data.

Even with the improved design of data collection forms, there will always be instances where researchers have trouble interpreting medical notes or understanding care practices, so comprehensive guidance would be useful for future researchers. It should be based on expert knowledge and perhaps predicated on pilot data collected at the start of a project.

* * * * * * * *

As well as collecting data directly from care homes, it is possible to access routine hospital and community data records that set out information about residents' health care contacts. This may be a promising alternative or complementary source of information for research, in the absence of other current options. In the next chapter I explore the accessibility and usefulness of these sources of routine data.

Chapter 7 Routine NHS data: accessibility, availability and accuracy

In this chapter I report my findings from Study 5, in which I aimed to explore the ease of access, availability, variability and comparability of routine data available from NHS Trusts with data obtained from care home records. My research question was: "Can routine NHS data be used as a reliable data source in the provision of health outcomes for care home residents?" My question was linked to Objective 3, to explore the acceptability of various methods of obtaining trial data in care home research. Details of the methods used are described in Chapter 3.

First, I provide a short introduction to the concept of routine data, including a summary of our experiences of collecting these data from care home records in the PATCH trial. This description illustrates the complexities of health data collection from care homes, providing further justification for the exploration of routine NHS data sources. I then report the results of my study, describing the processes for data access and the accessibility and availability of NHS data. Finally, I present summaries that compare data obtained from care homes with data provided by NHS Trusts, allowing conclusions to be drawn about the accuracy and usability of routine NHS data for future research.

7.1 Background

Routine data are collected habitually in a standardised manner to inform good quality and safe health and care practices. As reported in Chapter 6, we found difficulties in obtaining data that one would expect to be routinely recorded by care homes, as they were not always easy to access or interpret. Other researchers have reported similar experiences - with data either unavailable (75, 112) or difficult for researchers to find (68). Where the required information is available, its accuracy is sometimes questionable (100), it may not be sufficiently precise (73), it can be difficult to interpret (216), and it can be very time consuming to collect.

An added complexity is a lack of standardisation of data-recording procedures in care homes, with some using multiple paper records and others adopting a variety of electronic systems. Electronic care records are a potential source of data that can be interrogated more efficiently to provide data for research participants (with appropriate

permissions), but this can be difficult because systems used in care homes are not standardised, are implemented in a piecemeal fashion and are set up to collect different types of data. This was described first-hand by the PATCH trial researchers in their documentary feedback and in the interviews I conducted (Chapter 6). They reported that they accessed electronic systems to collect data in five of the ten participating homes. Only one home stored all their residents' and staff's data electronically. One home used an electronic system for all resident data, but staff data were on paper. Often we accessed data across different platforms - for example, an electronic system might be used for the reporting of incidents such as falls or hospitalisations, whilst another database was used for staff data, and paper notes for residents' care plans. Where electronic systems were used there was little standardisation: two homes used CQUINS to report incidents, but otherwise different systems were used in each home - these included: the Care Management System (a system designed for care homes), Nourish, Medicare, E-MAR, E.Compliance, Person-centred software.com, Fusion, Datix and SAGE. These systems variably recorded incidents (falls, accidents, hospital admissions), daily care notes, care plans, medications, staff rotas, and staff sickness. One care home manager reported the recording of staff employment on the National Minimum Data Set, which is reviewed and incentivised by CQC and NHS Choices.

This lack of standardisation raises concerns regarding data quality, and it was therefore important to consider alternative methods of obtaining the data required for the PATCH trial. For health and care activities undertaken by care home staff, there is no alternative data source; however, where residents are seen or treated by NHS health professionals, contacts will usually be documented and stored in NHS patient record systems. For the PATCH trial we wanted to collect data regarding residents' hospital attendances (A&E, admissions and outpatient appointments) and engagement with community practitioners such as District Nurses. I sought to collect these data from the relevant NHS Trusts, as well as from care home records, to explore the robustness of collection from care homes or Trusts alone.

7.2 Results

7.2.1 Approval to access NHS Trust data

Each Trust's R&D department reviewed the 'local document package', Statement of Activities (SoA) and Schedule of Events (SoE), and consulted with relevant staff in

order to agree local participation. In addition to these standard documents, Trusts requested various other review processes before agreeing to their involvement (see Table 24). For example, one Trust asked for completion of a 'finance feasibility form' and a 'site feasibility form', and another requested a 'capacity and capability assessment form'. Agreement to proceed was then issued in various ways - confirmation via: email and return of the completed SoA, a formal permission letter, and a Caldicott approval letter focussing on compliance with data protection legislation.

That I only needed one data download, or one instance of manual data collection, from each Trust - which would take someone from half a day to a whole day to accomplish (all Trusts confirmed this time frame) - did not diminish the amount of paperwork or time required to formalise the process. Some Trusts seemed to be set up, procedurally, to approve only studies that involved full research participation - recruitment, treatment and follow-up of their patients - rather than requests only for routine clinical data.

The time taken to obtain approval to proceed with the collection of routine data from NHS Trusts varied enormously - from a minimum of 56 days to nearly 8 months (see Table 24). Data provision following approval was relatively quick in the acute Trusts - between two to five weeks post-approval - but took much longer (a further seven months) in the community Trust, where access to data appeared more complex.

Although it would have been helpful to receive data from Acute Trust 4, I decided not to pursue my requests following multiple unsuccessful attempts to facilitate the approval process. I had established that this Trust used the same electronic records system as Acute Trust 1 and so I could reasonably assume that the data items available at Acute Trust 1 would mirror those recorded at Acute Trust 4. Unfortunately, I was thereby unable to compare fully the home's data provision (the trial data set) with that of the hospital for participants at homes that referred residents to Acute Trust 4.

Table 24 Trust approval process

Trust	Date first contacted R&D	Date approved	Forms required for approval*	Date data provided
Acute Trusts				
Acute Trust 1 (AT1)	22.02.18	21.05.18	Site feasibility form, finance feasibility form. Informatics Manager needed a 'patient level data request form' and to liaise with Information Governance team.	22.06.18
Acute Trust 2 (AT2)	05.04.18	31.05.18	None	12.06.18
Acute Trust 3 (AT3)	04.04.18	15.11.18	Capacity and Capability Assessment form.	03.12.18
Acute Trust 4 (AT4)	04.04.18	Not approved - did not pursue after lack of response	Did not progress to this stage.	N/A
Community Trust				
Community Trust	16.04.18	11.12.18	None. Nor did they complete the SoA or SoE - agreed that this was a data-sharing approach rather than approval of a study.	10.01.19 (incorrect data output). Next output provided 09.07.19

* In addition to the standard 'local information package'

7.2.2 NHS Trust data access and availability

7.2.2.1 How data were accessed and by whom

Data were accessed in different ways at each Trust (see Table 25): by a researcher already working on the PATCH trial who had an honorary contract with the Trust; by a research nurse employed by and working at a Trust but who had not previously been involved in the trial; and by Trust data analysts who were able to query their electronic systems to produce data outputs for trial participants. Where databases were queried, the raw data were extracted and provided by Acute Trust 1, whilst summary data (e.g.

each participant's total number of contacts with district nurses over the required time frame) were provided by the Community Trust.

Table 25 NHS Trust systems and access

Trust	System used	How accessed	By whom
Acute Trusts			
AT1	Electronic Patient Record (EPR) - bespoke system	Database queried directly and provided output files	Data analyst
AT2	SystmOne	Review of individual records in electronic system	Research nurse
AT3	PPM+ - bespoke system	Review of individual records in electronic system	Trial researcher
Community Trust			
CT1	SystmOne	Database queried directly by database team. Outputs reviewed and summarised by IS and Governance officer before sending to me.	Data analyst + IS/governance officer

7.2.2.2 Electronic systems used - data accessibility and availability

SystmOne

SystmOne is an electronic health record system, widely used by GP practices (>2,700) in England, with modules also used by some secondary and community care services. This system was in use at both Acute Trust 2 and the community Trust (see Table 25).

I met with the research nurse who had agreed to provide data at Acute Trust 2 - to explore the type of patient information recorded and stored in this system, and to establish how she would interrogate it to obtain trial participants' data. She searched for records using the NHS number I provided for each trial participant. However, it was also possible to search by postcode or date of birth if the NHS number was not available, with more than one of these identifiers used where possible to be sure that the correct record had been identified. Where residents had been to the hospital (at

any time) they would have a record on the system, so it was possible to ascertain whether or not the resident had attended within the required time frame for the trial (six months pre-randomisation and the six month follow-up period for each care home). There would be no record for those who had never visited the hospital.

Where a patient record existed, it was possible to access information about all hospital contacts within the Trust (for example, letters, medications, admissions, and attendance at appointments). Limited access to A&E records was available (staff within the Trust held varying levels of access dependent on their role), and it was possible to view information provided by GPs and community services where these services also used SystmOne. However, information from external NHS service providers was only accessible if patients had consented to information sharing between NHS organisations. This could work both ways - so, for example, patients could consent to their GP sharing information with the hospital, but not vice versa.

As the research nurse who manually searched SystmOne worked in the hospital in a clinical and research capacity and was familiar with the electronic system, I could be reasonably confident that the information she provided would be comprehensive. As a one-off exercise to gather information for a relatively small number of residents (N=20 - see Table 29) for the whole trial period, the task was not onerous - it took about half a day - although using individual record interrogation as a data collection strategy throughout a large trial would be more time-consuming. I therefore investigated whether direct data downloads from SystmOne would be possible and, if so, similarly comprehensive.

I communicated with the Information Manager at the same Trust who reported that - with provision of the NHS number - hospital admissions, A&E attendances and out-patient visits could be retrieved for a specified time period although some data would not be available - such as cause of death and reasons for hospital attendances. The difficulty appeared to be a) with the way in which data were coded (a mis-match between the data required for research and the data available in medical records) and b) whether or not they were coded at all. For example, 'primary diagnosis' or 'chief complaint' was coded on SystmOne, but 'reason for admission or attendance' was not - the patient's reason for attendance may have been a symptom such as 'stomach pain', but the chief complaint that was ultimately coded and recorded on the system was 'appendicitis'. Reason for outpatient attendance was not coded at all.

As only coded data could be downloaded, the conclusion was that it would be possible to download some of the required data items, but there may be less detail available using this method of data retrieval. To obtain a full data set for research purposes it might be necessary to look within discharge letters (for example) to obtain reasons for a patient's admission - these records would contain information that may not be available from an automated search. However, my understanding of data availability in SystmOne was from discussion with the Information Manager at Acute Trust 2 rather than first-hand experience: since the data I needed had been obtained by the research nurse, there was no justification for obtaining the data again via SystmOne - and such an approach had not been included in our REC approval. This explanation alerted me to the difficulties that there may be in obtaining data for research if the required information did not align with the way in which data is recorded in electronic systems.

At the community Trust, the preferred method of data provision was a data download rather than individual interrogation of notes (it was thought to be much quicker to download data in bulk - from multiple records for multiple patients), so I was able to explore a SystmOne data-output from this Trust (see section 7.2.3).

The community Trust required the NHS number for an accurate search of the database, and it needed to search discrete 'units' within the system: each department or service had a separate area (unit) in which they recorded their patient contact information, and the Trust insisted that each department needed to approve access to their area. The Information Systems Officer confirmed that he could provide data on appointments with community services, and that he could filter out administrative contacts in order to provide a summary of clinical contacts for each participant; however, he noted that "calculating contacts from SystmOne activity reports is a bit of an imprecise art so I'd take these figures as being indicative of the levels of activity rather than being an exact count". This suggested that automated downloads of summary data would not provide accurate data at a patient level, but could be useful if one wished to see trends in service use across whole care homes over time.

Electronic Patient Record (EPR)

The EPR was a bespoke system in place at Acute Trust 1. Prior to obtaining data I met with a data analyst at the Trust to discuss my request. She confirmed that it was

quicker for the informatics team to query the database and download the data, rather than for a researcher to interrogate individual records within EPR. She indicated that most participant-level data requested (see Figure 4 in Chapter 3) would be recorded in EPR, and that reports could be produced listing individual patients' in-patient admissions, out-patient appointments and A&E attendances. She would be able to link the data so that, for example, all in-patient admissions were grouped for each patient. NHS number was needed in order to identify and link individual data - it would be too time consuming to undertake data linkage without this identifier. Using NHS number also ensured accuracy compared to other identifiers - she noted that there are a lot of people with the same name and that some people do not know or divulge their date of birth so their medical records assign them a birthday of 1st January.

The data analyst reported that the following information was among what was available:

- Rather than 'reason for admission', 'primary diagnosis' and up to 14 'secondary diagnoses' are recorded - this would include co-morbidities.

- Ward on admission (including day hospitals), as well as transfers to other wards. There would be diagnoses and dates for each ward. She would be able to provide overall length of stay, or length of stay in each ward - known as an 'episode'.

- Date of discharge and its nature, such as 'died', 'home', 'transferred to another ward'.

- For out-patient appointments, the date and type of clinic attended would be recorded (e.g. dialysis). A reason for the appointment was not recorded, but the type of clinic would provide indicative context.

- A&E data were also available on a similar basis to the admission data above.

I explored whether it would be possible to obtain anonymised data for each care home - indicating the total number of residents, admissions and deaths from each participating care home. The analyst reported that it was not routine practice to report data for care homes, and that there are no specific codes for 'care home'; the resident's source of admission is often documented as 'usual place of residence'. She proffered a strategy that was complex and uncertain in value: a query of all the required fields with the addition of 'address', then filtered for address, anonymised, and provided for the whole data set. Unfortunately it might include (or exclude) residents whose

address is not up to date. For example, a resident may have attended hospital during the baseline period (six months prior to care home randomisation), but may not have been living at the home at that time - thus his or her attendance would not be identified.

<u>PPM+</u>

This was a bespoke system used at Acute Trust 3. I did not have direct contact with the data team at Acute Trust 3 because a trial researcher who was familiar with the PATCH study collected these data. The researcher was trained by hospital staff on how to use PPM+ and where to find the relevant data items within a patient record. NHS number was required to access data for each patient and the researcher reported that the system was easy to navigate following training. For each patient, various sections within their record could be selected and viewed for different types of service contact such as admissions, outpatient visits and medications, as well as links to community and GP consultations.

7.2.3 Data items provided by NHS Trusts

Table 26 compares the data items I requested with those provided by Acute Trust 1, to illustrate the level of information available from a direct data download. Most information requested was available or could be inferred from the information provided by this Trust.

For SystmOne and PPM+, the researchers gathering the data recorded on the paper CRFs the information they found in the hospital records. They were able to complete all relevant fields on the CRFs; however, because the CRFs only counted attendances at out-patients and A&E over the trial period, it was not always clear when these visits occurred in relation to trial follow-up time points. Unprompted, the research nurse at Acute Trust 2 provided additional information about the dates of A&E attendances, which was helpful for later analysis.

The data provided by Acute Trust 1 is coded information that can be downloaded. For a large trial with multiple follow-up points this could potentially provide a quick and bias-free method of obtaining data. However, I needed to manipulate the EPR data to fit with the format required for the trial. For example, there were often multiple rows (episodes) for the same hospital admission - a row of data for each ward occupied by

the patient during that admission. These rows had to be made into a single row for the duration of each admission to enable comparison between Trust and trial data - to understand the number of times a resident had been admitted to hospital, the reason for the admission, and their length of stay. The EPR download included multiple diagnoses for each patient's admission - a primary diagnosis and up to 14 secondary diagnoses that included co-morbidities such as hypertension and dementia, but also mentioned acute conditions such as delirium, urinary retention or pressure ulcers. I took 'primary diagnosis' to be the reason for admission, but also reviewed secondary diagnoses for further information and for mention of falls (another trial outcome).

Table 27 shows the service-use data provided by the Community Trust. In addition to the length of time it took to permit data access, there were difficulties allocating Trust staff time to dedicate to this task. At the time of my request the Trust were changing over from an older electronic system to SystmOne, which did not run smoothly and meant that my request was further delayed. When I did receive a data download in January 2019 it was for incorrect time parameters, with a corrected version not received until July 2019. Further queries relating to this final data set were not answered. It remains unclear why only certain data items were provided - for example (see Table 27), some services, such as occupational therapy, for which data were not provided sit within the Community Trust, so data on the Trust's contact with care home residents should have featured. I suspect, from initial discussions with the Information Governance Officer, that it proved too difficult or time-consuming to obtain data from separate teams - he had told me that he would need to contact each individual service department (or 'unit') to request data outputs.

Whatever the reasons, this whole process was more complex than obtaining acute Trust data, and the data provided were of limited use: I received a summary of the total number of contacts over the full 12 month period, rather than the number of service contacts by time-point, as would be needed for the trial. In addition, data pertaining to district nurse, tissue viability nurse, and continence team contacts were provided collectively rather than individually. I was told that it would have been very difficult to separate out different types of contacts from the same 'unit' - this would have needed manual review and a lot of time. Perhaps if I had been provided with the raw data this is something I could have undertaken, but the Trust wished to provide only summarised data.

Table 26 Data provided by Acute Trust 1

Data items requested	Data provided in direct data download from EPR
Hospital admissions	
Date of admission	Date of admission
Reason for admission	Diagnosis (primary and multiple secondary)
Ward (e.g. general, ICU)	Ward name and specialty description (e.g. Geriatric Medicine, Urology)
Discharged (yes, no, died)	Discharge method (e.g. 'with consent', 'on clinical advice')
Date of discharge	Discharge date
Date of death	Included in 'discharge date'
Cause of death	Not specified in output provided
Out-patient clinic visits	
Reason	Not specified, but can be inferred from clinic details below
Clinic name / type	Clinic session description (e.g. trauma and ortho) + specialty description (e.g. cardiology)
Date of attendance	Attendance date
Hospital day centre	
Date of attendance	Not specified separately, but would be included in in-patient activity
Accident and Emergency	
Date of attendance	Arrival date
Reason for attendance	Diagnosis description (multiple)
Outcome (discharged, admitted, died)	Attendance disposal (admitted, discharged, died)

Table 27 Data provided by the community Trust

Data requested	Available from SystmOne?	Notes
District nurse (DN)	Yes	Output from the DN 'unit' on SystmOne includes DN, out of hours DN, TVN and Continence team.
Tissue viability nurse (TVN)	Yes	Included in DN above.
Advanced nurse practitioner	Not provided	This is a role rather than a specific team or service, so I suspect it would be difficult to run a comprehensive search for this type of contact.
Community matron	Not provided	This service sits within the Trust
Health visitor	Yes	
Community Mental Health Team	Not provided	This service sits within the Trust
Speech and Language Therapist	Yes	
Occupational therapist	Not provided	This service sits within the Trust
Podiatrist	Yes	
Community pharmacist	Not provided	Not a Community Trust service
Chiropodist	No	Not a Community Trust service
Physiotherapist	No	Not a Community Trust service
Palliative care	Not provided	This service sits within the Trust
Dementia assessment unit	Not provided	This service sits within the Trust
Other		Health Trainers and Falls Prevention Team data were available.

7.2.4 Participant data provided by NHS Trusts

7.2.4.1 Data availability

As can be seen in Table 28, there were no significant discrepancies from my expectations - data were available for trial participants at the hospitals I expected them

to attend, with no attendances retrieved from the hospitals at which participants' attendance seemed unlikely. I requested a search for all participants at all participating homes (N=9) at the Trust providing an automated data download; however, at the other Trusts I asked for data for residents at homes within their catchment area - with the exception of Care Home 8 which was located on the border between two catchment areas.

Table 29 sets out for each care home: the number of records searched in each hospital (this equates to the number of resident participants at each home); the number of participants for whom records were found; and the number of hospital admissions and A&E visits within the specified trial date parameters (six months pre- and six months post-randomisation for each home). The cells shaded green show the homes for which participant records were found at each Trust. 39 attendances for 22 participants from five homes were found at Acute Trust 1; 11 attendances for seven participants from two homes were found at Acute Trust 2; and 19 attendances for 12 participants from three homes were found at Acute Trust 3. Since residents of some homes were consistently referred to one hospital, whilst other homes referred to more than one hospital, it is not possible to draw conclusions about expected proportions of residents who may attend hospital over the course of one year. For example, individual residents from Care Home 2 may have attended Acute Trusts 1 and 2 (and so could be double counted in Table 29), whilst residents from Care Home 4 may have attended other hospitals that are not included in my data set, and so be under-represented. Of interest is that there were records for participants from Care Home 1 at Acute Trust 2, and for Care Home 8 at Acute Trust 3 but no hospital attendances for any of these participants. I surmise that this reflects residents having lived within the hospitals' catchment areas before they moved to their current care home, rather than none of these residents requiring hospital care. Few residents attending hospital from Care Home 8 (two residents from a sample of 19) lends weight to the likelihood of this home referring to another hospital (or hospitals) from which I did not collect data.

On the basis of the information provided by care homes about which hospitals they referred to (Table 28), and the numbers of records found at each hospital (Table 29), I decided to exclude homes 4, 8 and 10 from all analyses comparing hospital attendance 'counts'. This was because the hospital data set would not be complete for these homes, so comparisons with trial data would not be meaningful. Comparing the substance or meaning of data items provided - for example 'reason for admission' or

'ward type' - did not, however, require exclusion of these hospitals as the purpose was to review the comparability of the content provided by each source.

It should be noted that Acute Trust 1 did not specify whether the absence of any hospital attendance data for a participant was due to there being no record for a participant (i.e. they had never attended the hospital), or that they had not had an admission during the required time frame. For Acute Trusts 2 and 3, researchers specified when they were unable to find a participant's record. They would search by NHS number and if this was not recognised (no records returned) they could be confident that the participant had not been a patient at that Trust.

Table 28 Records requested and data found

CH ID	Acute Trust 1				Acute Trust 2				Acute Trust 3			
	Distance to hospital	Records requested	Data expected^	Attendances found	Distance to hospital	Records requested	Data expected^	Attendances found	Distance to hospital	Records requested	Data expected^	Attendances found
1	1 mile	Yes	Yes	Yes	11 miles	Yes	No	No	12 miles	No	No	-
9	2 miles	Yes	Yes	Yes	12 miles	Yes	Yes&	Yes	10 miles	No	No	-
2	5 miles	Yes	Yes	Yes	8 miles	Yes	Yes	Yes	15 miles	No	No	-
4*	5 miles	Yes	Yes	Yes	17 miles	Yes	No	No	13 miles	No	No	-
8**	7 miles	Yes	Yes	Yes	18 miles	Yes	No	No	8 miles	Yes	Equivocal	No
7	10 miles	Yes	No	No	20 miles	No	No	-	4 miles	Yes	Yes	Yes
5	16 miles	Yes	No	No	24 miles	No	No	-	3 miles	Yes	Yes	Yes
6	16 miles	Yes	No	No	24 miles	No	No	-	3 miles	Yes	Yes	Yes
10***	12 miles	Yes	No	No	20 miles	No	No	-	20 miles	No	No	-

* Some residents also go to Acute Trust 4

** Residents mainly go to Acute Trust 1, but may go elsewhere (not fully established from home where this might be - home centrally placed for various hospitals in the region)

*** Residents mainly go to Acute Trust 4

^ Expected on the basis of information provided by care homes

& Only occasionally attend this hospital (99% elective = Acute Trust 1, 100% emergency = Acute Trust 1)

Table 29 Number of records searched and hospital attendances (A&E and admissions) found

| CH ID | NHS Trust | | | | | | | | | | | |
| | Acute Trust 1 | | | | Acute Trust 2 | | | | Acute Trust 3 | | | |
	No. records searched	No. ppts with records^	No. ppts with hospital visits	Total no. visits*	No. records searched	No. ppts with records	No. ppts with hospital visits	Total no. visits*	No. records searched	No. ppts with records	No. ppts with hospital visits	Total no. visits*
1	16	-	3	9$	16	4	0	-	0	-	-	-
9	10	-	6	9	10	2	1	2	0	-	-	-
2	15	-	4	4	15	14	6	9	0	-	-	-
4	14	-	7	15	14	0	0	-	0	-	-	-
8	19	-	2	2	19	0	0	-	19	11	0	-
7	12	-	0	0	0		-	-	12	11	6	9
5	8	-	0	0	0		-	-	8	8	5	9
6	14	-	0	0	0		-	-	14	14	1	1
10	22	-	0	0	0		-	-	0	-	-	-
Total	**130**	**-**	**22**	**39**	**74**	**20**	**7**	**11**	**53**	**44**	**12**	**19£**

* Where an in-patient stay follows an A&E admission, this is counted as one attendance (or 'visit')

^ Not known - output was not clear whether the participant was not on the system or was on the system but had no admissions within the time frame

$ A further five cases for two participants were found, but these have been excluded as they were day cases (i.e. fitting of a device x 3, blood sampling x 2)

£ Dates of A&E attendances were not provided for this Trust. Only two A&E visits were reported, one for a resident with no reported hospital attendances; the other I have not included as it may have been linked to an included admission.

7.2.5 Comparison of trial data with NHS Trust data

7.2.5.1 Hospital admissions data

Table 30 sets out the number of instances where trial data collected from the six care homes with complete hospital data sets (Care Homes 1, 2, 5, 6, 7 and 9) corresponded to the data provided by the Trust. It should be noted that the data include the total number of hospital admissions - in some cases multiple admissions for individual participants - rather than the total number of residents. There was a low match rate with only 13/45 (29%) admissions reported in both the trial data set and the hospital records (including full and partial matches); rising to 36% (16/45) if the 'uncertain' cases are included. In total, 25 (56%) admissions recorded in the hospital data set had not been found in care home notes; whilst 4 (9%) hospital admissions were recorded by the care homes but not found in hospital records. Thus the poor match rate can mainly be attributed to missing trial data - some admissions were either not recorded in care home notes or could not be found there by researchers. This suggests that using hospital records to obtain outcome data is the more accurate way of obtaining a comprehensive and accurate data set.

Table 30 Number of hospital admission matches (includes the six care homes with comprehensive hospital data sets)

Time point	Full match	Partial match*	Uncertain**	No trial record	No hospital record	Total
Baseline	4	1	2	10	4	**21**
3 months	4	0	0	10	0	**14**
6 months	2	2	1	5	0	**10**
Total	**10**	**3**	**3**	**25**	**4**	**45**

* Discrepancy between either discharge or admission dates

** Probably a date data entry error - event reporting similar in other respects

Table 31 lists the admissions for all homes where there was a corresponding (by date) record in the trial and hospital data sets. The cells highlighted in green indicate where the description of the admission or ward concurs across data sets: the reason for admission does not always align with the diagnosis made in hospital, which might be expected - care home staff will be aware of presenting symptoms whilst hospitals will record the diagnoses that require treatment or monitoring. Type of ward collected from

care home records was rarely known or correct but was nearly always available from the hospital data sets.

Table 31 Comparison of trial and hospital data for matched admissions

Res ID*	Trial data		NHS data	
	Reason for admission	Ward type	Primary diagnosis	Specialty / ward description
1	Abdominal Surgery	Surgical Ward	Malignant neoplasm of rectum	General surgery
1	Urinary Retention	Urology	Urinary retention	Urology
2	Pneumonia / chest infection	General	Haematemesis	Geriatric medicine
3	Pneumonia / chest infection	Ward 6	Pneumonia	General medicine *(not ward 6)*
3	Confusion and high temp	-	Septicaemia due to other specified staphylococcus	Geriatric medicine
4	Pneumonia / chest infection	Ward 2	Collapse	General
5	Fall - soft tissue injury	-	Unspecified acute lower respiratory infection (secondary diagnosis = open wounds to upper limbs and head)	Geriatric Medicine
5	Pneumonia / chest infection	Not known	Lobar pneumonia, unspecified	Geriatric medicine
6	Low O2 levels - general decline	-	Urinary tract infection	A&E, then CDU
7	Blood clots / DVT	-	Iron deficiency anaemia ('deep vein' mentioned in secondary diagnoses)	Geriatric medicine
8	Urinary tract infection	General	No details	A&E
9	Pneumonia / chest infection	General	Urinary tract infection	General
10	Fall - fracture		Fracture - unable to weight bear and mild thigh pain	Not specified
11	Pneumonia / chest infection	General	Shortness of breath	General
12	Fall - soft tissue injury (wound to back of head)	-	Minor traumatic brain injury	CDU
13	Fall - fracture	-	Fracture - found on floor	-
14	Pneumonia / chest infection	Not known	Lobar pneumonia, unspecified	Geriatric medicine
15	Fall - fracture	-	Fracture of neck of femur; closed	Trauma & Orthopaedics
16	Pain in leg	General	Sepsis, unspecified	Geriatric medicine

* Resident ID has been altered from that allocated in the PATCH trial, and individual residents' IDs are not consistent across tables to maximise anonymity

7.2.5.2 Accident and Emergency data

For the trial we collected data regarding the number of times each participant had attended an A&E department at baseline (in the six-month period before the start of the trial in each home), and again at each follow-up visit - for the three-month period preceding each visit. I counted the number of A&E attendances listed in the hospital data sets provided by Acute Trusts 1 and 2, categorising them as baseline, 3-months or 6-months to allow comparison with trial data. For Acute Trust 3 this procedure was impossible because the researcher had provided a count of A&E visits for each resident for the total pre- and post-randomisation period. (There was just one instance where the date of an attendance at the Clinical Decisions Unit, situated within A&E, was reported.) Providing a count of attendances was as specified on the CRF; in retrospect I should not have provided CRFs for provision of these data, but rather a request for the details and date of each hospital contact, as I had done to the Trust providing a data download.

Table 32 sets out the trial- and hospital-reported A&E attendances at each time-point for all participants at the six care homes with complete hospital data sets where A&E data existed in one or both data sets. Table 33 summarises these data to illustrate the number of times attendance reporting at a data collection time-point matched when comparing the trial and hospital data sets, and where there were more reported attendances in one data set than the other. There were only 2 exact matches, 5 instances of more reported attendances in the trial data set compared to the hospital data set, and 17 instances of greater A&E attendance reporting in the hospital data set. The low match rate and high levels of missing data suggest that care home notes contain unreliable A&E details, or that they are difficult to interrogate to find this information. As with hospital admission data, A&E attendance reporting was more comprehensive when obtained directly from hospital records, than from care home notes. All five instances of less A&E attendance reporting in hospital notes can be attributed to Acute Trust 3 - for which data were provided solely on trial CRFs. It is possible that reported hospital admissions included an initial A&E attendance that was not separately reported; or it could be that A&E attendances were hard to find in PPM+ - only three were reported from the records of the 12 residents with hospital attendances over a 12-month period. When compared to A&E attendances found at Acute Trusts 1 and 2 - nine in the records of seven residents, and 31 in the records of 22 residents with hospital attendances - this seems surprisingly few.

Table 32 Comparison of trial- and hospital-reported A&E attendances by participant

(for residents at the six care homes with complete hospital data sets)

CH ID	Res ID*	Time point	No. times attended A&E	
			Trial data	**Hospital data**
1	1	Baseline	0	1
1	2	6 months	2	2
1	2	Baseline	1	2
2	3	6m	0	1
2	4	Baseline	0	1
2	5	Baseline	0	1
2	5	6m	0	1
2	6	Baseline	2	1
2	6	Baseline	0	1
2	7	Baseline	0	1
2	8	3m	0	1
5	9	Baseline	1	0
6	No records for this home found in trial or hospital data sets			
7	10	3 months	2	0
7	11	Not known	0	1
7	12	Baseline	1	0
7	13	Not known	0	1
7	14	6 months	1	1
7	14	Baseline	1	0
7	15	6 months	1	0**
9	16	3 months	0	1
9	17	Baseline	0	1
9	18	Baseline	0	2
9	19	3 months	0	2
9	20	Baseline	0	2
9	21	Baseline	0	1
		Total	**12**	**25**

* Resident ID has been altered from that allocated in the PATCH trial, and individual residents' IDs are not consistent across tables to maximise anonymity

** Hospital data set includes a reason for attendance that indicates possible A&E attendance, but this is not explicitly stated

Table 33 Match rate for reporting of participants' A&E attendances

Time-point	Matched A&E attendance reporting	Fewer attendances in trial data set	Fewer attendances in hospital data set	Uncertain	Total
Baseline	0	10	4	0	**14**
3 months	0	3	1	0	**4**
6 months	2	2	0	1	**5**
Missing	0	2	0	0	**2**
Total	**2**	**17**	**5**	**1**	**25**

7.2.5.3 Falls data

For the trial we collected data about residents' falls separately from the A&E and admissions data - asking whether a resident had fallen during the baseline or follow-up periods and, if they had, whether it had resulted in hospitalisation. Most falls reported (209/220 - 95%) did not result in hospitalisation, with researchers identifying from care home records only 11 falls across the whole cohort that were severe enough to warrant hospital care. Here I report data for the six care homes with complete hospital data sets - for these homes the trial data set includes eight falls that led to hospital attendance. Table 34 sets out the data reported for each of these falls, as well as additional falls data from the hospital A&E and admissions data sets. The table shows four matched records (green), and one that might be a match (amber) as it seems possible that the date could have been transcribed incorrectly. There were an additional eight reports of falls within the hospital data set that were not reported for the trial. Three reports in the trial data set were not found in hospital records; each was a superficial injury or no injury at all, so it is possible that residents were treated in a minor injuries unit or similar satellite clinic. Again, data derived from care home records do not seem to offer a comprehensive account of residents' hospital attendances following a fall.

We collected falls data separately to hospital admissions data, and then excluded falls from the reporting of admissions, in an attempt to avoid 'double counting'. However, if one were to use routinely collected hospital data in future trials, this separation would not be required - falls could be extrapolated from the A&E and admissions data sets for outcome reporting. As well as the potentially improved accuracy of hospital-derived data, this step would eliminate the possibility of the double-reporting of hospital attendances following a fall. Examination of the EPR data output from Acute Trust 1, which included up to 14 secondary diagnoses, indicated that some residents were admitted to hospital following a fall, but also with other medical problems (for example,

delirium) that might have caused the fall, so separating falls from other reasons for admission does not always make sense.

7.2.5.4 Outpatient data

We asked, at baseline, 3-months and 6-months, whether participating residents had visited hospital outpatient clinics and, if they had, how many times. I compared the trial data with hospital outpatient attendance data for residents at the six homes where provision of hospital data was comprehensive. Table 35 sets out the number of outpatient visits reported in the trial and hospital data sets. The cells highlighted in green indicate matches between data sets: as can be seen, there were few matches (7 participants out of 25), with no discernible pattern to the discrepancies. The especially high number of outpatient visits reported from the care home's records for Participant 4 gives some cause for concern - it may be that regular visits to community services were inaccurately reported as out-patient visits, but confirmation is not possible from the data.

7.2.5.5 Other service use

As well as residents' hospital admissions, A&E attendances and outpatient visits, we aimed to collect data regarding day centre use and stays in nursing units and hospices. Such use of services was not, however, reported for any residents in either the trial or hospital data sets, so it seems not to be relevant to this population, and collection of information about its use might therefore be excluded from future trial data collection forms.

Table 34 Comparative falls data reported for the trial and from hospital records (for care homes with complete hospital data)

CH*	Res ID**	Time point	Trial data			Hospital data				
			Date of admission	Date of discharge	Severity	Date of admission	Date of discharge	Primary diagnosis (on admission)	Additional fall details (admissions data)	Data from A&E records
1	1	6 months	-	-	-	24/12/17	24/12/17	N/A - not admitted	-	Closed fracture of shoulder
2	2	Baseline	-	-	-	31/03/17	07/04/17	Fall, UTI	-	-
2	2	Baseline	07/05/17	07/05/17	Soft tissue injury	-	-	-	-	-
2	2	Baseline	-	-	-	11/06/17	11/06/17	N/A - not admitted	-	Closed fracture of ankle
2	3	Baseline	19/07/17	19/07/17	Soft tissue injury	-	-	-	-	-
5	4	Baseline	20/06/17	20/06/17	Fracture	-	-	-	-	-
5	4	Baseline	-	-	-	20/07/17	20/07/17	Fracture	-	-
7	5	3 months	18/01/18	12/02/18	Fracture	18/01/18	12/02/18	Fracture	Unable to weight bear, mid-thigh pain	
7	6	Baseline	28/05/17	29/05/17	No injury	-	-	-	-	-
7	7	Baseline	-	-	-	25/06/17	26/06/17	Closed fracture	-	-
7	7	6 months	12/03/18	14/03/18	Soft tissue injury	13/03/18	14/03/18	Minor traumatic brain injury		
7	8	6 months	07/05/18	18/05/18	Fracture	08/05/18	08/05/18	Fracture		
9	9	Baseline	01/11/17	10/11/17	Fracture	01/11/17	10/11/17	Fracture of neck of femur; closed	Unspecified fall; Residential institution	-
9	10	Baseline	-	-	-	16/11/17	17/11/17	Pain in joint; Pelvic region and thigh	Unspecified fall; unspecified place	Pain in left leg
9	11	Baseline	-	-	-	30/07/17	08/09/17	Fractured hip	-	-
9	11	Baseline	-	-	-	31/10/17	31/10/17	N/A - not admitted	-	Forearm fracture
9	11	Baseline	-	-	-	24/11/17	24/11/17	N/A - not admitted	-	Superficial bruising of thigh

* No falls data were reported for residents at care home 6 in either data set

** Resident ID has been altered from that allocated in the PATCH trial, and individual residents' IDs are not consistent across tables to maximise anonymity

Table 35 Comparison of trial- and hospital-reported outpatient visits by participant

(for residents at the six care homes with complete hospital data sets)

CH ID	Res ID*	No. outpatient visits	
		Trial data	Hospital data
1	1	8	11**
1	2	1	1
1	3	2	0
1	4	121	7**
1	5	2	2
1	6	1	0
2	7	1	1
2	8	2	2
5	9	6	2
5	10	1	3
5	11	1	0
5	12	1	1
5	13	0	2
6	14	1	2
6	15	1	1
7	16	3	4
7	17	0	1
7	18	2	4
7	19	2	0
7	20	0	1
7	21	1	0
7	22	1	0
9	23	1	1
9	24	4	3
9	25	9	1
		172	**50**

* Resident ID has been altered from that allocated in the PATCH trial, and individual residents' IDs are not consistent across tables to maximise anonymity

** Includes day cases reported in Acute Trust 1's admissions data set

7.2.6 Identifying those residing in a care home from NHS Trust data

Whether participating residents were recorded as living at the correct care home is worth exploring to assess the accuracy of hospital records. During my initial discussions with the data analyst at Acute Trust 1 and the research nurse at Acute Trust 2, they expressed doubts about the reliability of the address recorded for each person, suggesting that it was not always up to date; however, if it were accurate, it would be a useful way of identifying residents for the collection, for research purposes, of anonymised whole home data, without researchers needing to obtain any personal details for those who were not research participants (which of course would not be legal or ethical without appropriate justification and approval). The data output provided by Acute Trust 1 for this project included 'address' in the A&E and outpatient data sets - this allowed me to explore the accuracy of the documenting of address for residents taking part in the trial.

Table 36 summarises whether residents who had attended this hospital's A&E department or out-patient clinics (as reported in the hospital data set) during the trial time-frame were recorded as living at their participating care home. In all instances where attendances occurred during the follow-up period, residents were correctly assigned the address of their care home. It was only at baseline that not all residents were recorded as living at their care home, which probably reflects hospital attendances that took place before they moved to the home. It seems likely that 'address' is accurately recorded for hospital attendances occurring whilst a resident is living at a care home although, for certainty, further exploration would be needed.

Table 36 Address recorded in Acute Trust 1's A&E and out-patient data sets

Time-point	No. participants with A&E or OP data	No. recorded as living at CH	No. with different or no address recorded
Baseline	18	11	7
3 months	10	10	0
6 months	8	8	0

7.3 Discussion

7.3.1 Summary of findings and their implications

In this chapter I have reported: the process of accessing routine data from Acute and Community NHS Trusts for PATCH trial participants, my exploration of the comprehensiveness and accuracy of these data, and comparisons between trial- and hospital-provided data.

Obtaining R&D approval for access to routine data varied in complexity, taking longer at some Trusts than others, with procedures seemingly tailored to the approval of studies requiring active recruitment and follow-up - there did not seem to be a standard process for dealing with more simple requests to access only routinely available data. With advances in the use of electronic systems across the NHS and increasing interest in the use of routine data for research,(222-224) it would be advantageous were this type of governance approval to be streamlined. Once approved, data receipt from the acute Trusts was quick - a matter of weeks - but it was protracted from the Community Trust.

Some Trusts were able to query their records to provide electronic data extracts, whilst others preferred a researcher to collect the data manually by reviewing electronic notes. In all cases NHS number was the required identifier to ensure accurate data retrieval and, using this identifier, data collection or provision took only a few hours. Electronic systems varied - two Trusts used SystmOne (a widely-adopted system, at least in primary care), and the other two used bespoke systems. Investigation of the availability of data required for the trial revealed differences in the way data were recorded for clinical purposes compared to data items requested for the research - for example, trial CRFs asked for 'reason for admission' whilst hospital records documented 'primary diagnosis'. This difference alerts us to the need for carefully considered choices of research outcomes in the context of clinically available information. I explored the available data fields with hospital staff and, in doing so, was able to establish which fields would return the data required for the trial; however, without this preparatory work it would have been difficult to understand the usefulness of available data.

Detailed review of the hospital data set confirmed that it provided the information needed for collection of the trial's outcome data, although data received electronically

following an automated database search required considerable re-formatting to allow comparison with trial data. Where it was possible to compare trial and hospital data for specific admissions, hospital data were often more comprehensive in their descriptions, including information that was frequently missing from the trial data set - for example, 'ward type'. The only data item that was often missing from the hospital data set was date and cause of death, but this is information that may not be best collected from NHS data sets as many residents die at their care home.

The raw data from the electronic search included multiple diagnoses (primary and secondary) for each resident and for each admission. Secondary diagnoses included useful information about other acute and chronic conditions that might contribute to more comprehensive and efficient collection of trial outcomes - for example, a resident might have been admitted with a fractured shoulder as the primary diagnosis - with delirium, a pressure ulcer and diabetes listed as secondary diagnoses. For the trial we collected only one reason for hospital admission, and we collected falls and pressure ulcer data separately, which increased the risk of missing potentially important health data.

Six homes referred residents exclusively to the Acute Trusts from which I obtained data. For these homes I established that the agreement between hospital and care home-derived admissions data (29%), and hospital and care home-derived A&E attendances data (8%) was poor, attributable to the reporting of fewer hospital attendances in the trial data set. There were far fewer instances of trial-reported data being missing from hospital records, leading to the conclusion that hospital-derived data are a more comprehensive and accurate source than are care home records. Even some serious falls that resulted in hospitalisation were not found in care home records. If the reporting of more severe falls is inaccurate (where reporting is mandated by CQC and local authorities), it raises doubts over the accuracy of the less severe, non-hospitalised falls data, and their usefulness as a trial outcome. Of course, missing data in the trial data set could also be explained by a researcher's inability to find those data in care home records, but this difficulty also points to the need to avoid reliance on care home records for the collection of outcome data.

Analysis and review of out-patient and community data did not point to one data source being more comprehensive than the other; indeed it was impossible to understand which data set was the more accurate. That there were more out-patient contacts

recorded in the trial data set suggests that homes were either accessing different hospitals for outpatient care or that they were mistakenly reporting to the researchers healthcare contacts that would not constitute hospital outpatient appointments. Whatever the reason for the observed differences, it seems likely that outpatient data collected for the trial are unreliable. I would recommend that future trials clearly define 'outpatient appointments' to ensure that data provided are consistent and meaningful. Outpatient visits cover such a wide range of health care contacts and interventions that it might also be helpful to specify which particular contacts are relevant for the purposes of the trial - that is, those that might be affected by the trial intervention. This would enable targeted data collection from the appropriate sources.

Acute Trust 1 provided addresses associated with each A&E and outpatient contact. I found that they were accurately recorded during the follow-up period - with all residents correctly assigned their care home's address. However, at baseline there were residents for whom the care home was not correctly listed as their address - probably because of hospital contacts before they became resident in the care home, although this would need further investigation. The consistent accuracy of address recording during follow-up (when we know all residents are living at their care home), suggests that address is correctly updated on admission, and could thus be used to identify all residents from a specific care home without the need for any personal identifiers. Using address to search records would allow retrieval of accurate data regarding hospital attendances from a whole home. This procedure would be particularly useful for cluster trials where an intervention is designed to affect the health or well-being of all residents, as it would provide data about the impact of the intervention home-wide - not just for the sub-set of participating residents but for all those living in the care home before and after randomisation. I have misgivings about the setting of a long baseline period for hospital attendance data as there is increasing likelihood of including a period when residents were living elsewhere. A change in living environment might have a significant impact on residents' well-being and could lead to false conclusions about the impact of an intervention.

Other researchers have reported that it is difficult to identify care home residents from hospital records because 'care home' is not routinely documented as an indicator in electronic records (225). Where such problems are reported, it will often relate to identification of 'all residents from care homes' to draw conclusions about the population as a whole - for example, the number of hospital admissions from care homes in England. The difficulty for these researchers in ensuring comprehensive

collection of data lies with the identification of which addresses are indeed care homes (226). However, in a trial we work with a limited number of known care homes and can thereby establish to which hospitals they refer. With this information in place it should be possible to collect comprehensive, accurate, anonymous data relating to specific care homes' residents. Other researchers working with a trial sample of care homes have used other methods to identify care home residents for whole-home analysis - for example, by using postcode (73) to identify those living at a care home, but this tactic might have reduced positive predictive value as it is likely to include other residences with the same postcode. Using the full care home address seems to be a more reliable way of accurately identifying care homes. Of course, some care homes change their name (for example when there is a change of ownership), which will impede identification, but can be mitigated by keeping up close communications with care home managers.

7.3.2 Methodological considerations

My exploration of the availability of hospital data and the comparison with trial data seems robust as it was set within a randomised controlled trial, including all participating residents (N=130) at nine care homes - a reasonably sized sample from which to draw conclusions. Residents had consented (or consultees had provided agreement) to the collection of data from their hospital records, so I was able to obtain accurate information about their hospital attendances through the use of NHS number as a unique patient identifier.

At the three Acute Trusts involved in this work, resident data were available, as expected - with care home residents attending the hospitals specified by the care home managers. However, I was unable to collect data from one Trust so was unable to verify this finding definitively for all nine homes. This limitation also meant that my sample, for the comparison of the number of hospital attendances, was smaller than expected (N=6 care homes), so results are less generalisable than they might have been. It may be that data from the 'missing' Trust are not as comprehensive or easily accessed; although I am relatively confident that this would not be the case as the same electronic system was in place at that hospital as at Acute Trust 1. What these findings draw attention to is the need for uniform engagement from all hospital Trusts to which participating care homes refer - to ensure comprehensive data collection, should routinely available information be the primary source of data.

Data collection from the Community Trust was unsuccessful due to limited staff availability, coupled with the complexity of accessing data segmented by specialty; agreement proved to be needed from each department for their section of the Trust database to be accessed. Data, once received, were not appropriately grouped by time-point, nor complete; I was, therefore, unable to review these data or draw any conclusions about accuracy. As a consequence, I suggest that it would be prudent in future to obtain approval for researchers themselves to search Community Trust systems for individual consenting participants' records.

Methods of data provision varied between acute Trusts. I relied upon a research nurse at Acute Trust 2 and a researcher at Acute Trust 3 to extract data from electronic records, and they may have missed some data; however, they were both experienced and familiar with the systems used so this is unlikely. I had met face to face with both researchers before they collected data - to explain the data required - so I can be confident that they understood what was needed. In retrospect I realise that I should have asked for specific data fields so that the data they extracted were similar to those provided by automated data download; using trial CRFs to collect routine data resulted in some inadequate information from Acute Trust 3.

I only received a useable electronic extract from one Trust so the conclusions I have drawn in relation to the accuracy and extended content of electronic records are limited. Further work with a larger sample of Trusts with a variety of electronic systems would be needed to draw more robust conclusions about the reliability of routine Acute Trust data.

Chapter 8 Discussion

8.1 Introduction

This final chapter brings together the previous chapters by: summarising my key findings; discussing these findings in relation to the literature; considering the methodological strengths and weaknesses of my work; and making recommendations for intervention research practice in care homes, for care homes and for areas where future research is required.

The aims of my PhD studies were to identify systematically the challenges that researchers face when conducting intervention research in care homes in the British Isles, and to explore empirically the challenges identified in order to make recommendations for future research. I met my aims by, first, conducting a systematic review of the literature to identify challenges already reported by researchers undertaking intervention research in care homes in the British Isles. This review led to clarification of my empirical study objectives, which were to:

1. Identify the challenges of providing intervention training to care home staff, and the difficulties of monitoring and reporting the use of new skills.

2. Understand researchers' and care staff members' experiences of collecting and providing data for care home research.

3. Explore the acceptability of various methods of obtaining trial data in care home research.

Each of the empirical studies was designed to answer a research question related to the above objectives:

- Study 1: What are the challenges faced by trainers in the organisation and delivery of a training intervention in care homes?

- Study 2: How could the enactment of new skills learned in training be measured comprehensively in care homes?

- Study 3: How might posture be measured in a care home resident population?

- Study 4: What are staff and researchers' experiences of providing and collecting data for research in care homes, and what are the implications for future data collection?

- Study 5: Can routine NHS data be used as a reliable data source in the provision of health outcomes for care home residents?

I summarise the key findings from each of these studies below, considering where my studies align with other researchers' reported experiences, and where I have generated new knowledge that could contribute to research practice or point towards areas requiring further research.

8.2 Summary of key findings

8.2.1 Systematic literature review

I aimed to identify the range of challenges reported by researchers who had undertaken intervention research in care homes, as well as any solutions that they might have put forward to address the challenges reported. I sought to direct my studies towards challenges for which there were no reported solutions so that I might usefully explore areas requiring improvement.

The volume of research conducted in the care home setting has increased markedly over recent years; despite this, my literature review identified that researchers continue to report challenges in many areas of research conduct and methodology. These ongoing difficulties lead to findings that are often inconclusive or based on weak methodology. I identified a number of themes which encapsulated the difficulties repeatedly reported by the authors included in my review - difficulties which, prior to my review, had not been systematically considered together in this way. Themes relate to difficulties with: research planning and design (for example, sample heterogeneity, residents' complex needs making outcome measurement difficult); the need for intensive engagement with staff and residents; data collection challenges (for example, poor choice of measures, difficulties collecting meaningful data from those with cognitive impairment); intervention uptake (for example, poor staff engagement); and recruitment and retention. Challenges within each of these themes fall into two groups. First, there are research processes that can be modified - such as recruitment approaches, data collection tools and procedures, and intervention design and implementation. Second are contextual factors that cannot be altered, or ones that are certainly more intractable - for example, resident capacity, resident mortality, and staff turnover - and which thereby necessitate changes to research designs to

accommodate the limitations of participant understanding and availability. It is mainly the former of these two sets of challenges that I focussed on in my empirical studies, and for which I am able to offer insights and recommendations.

8.2.2 Empirical studies

Intervention delivery and monitoring the use of new skills

In the PATCH trial, staff attendance at SCTP training sessions did not meet our pre-specified criteria for successful training delivery. My analysis of the written accounts provided by the trainers after each session indicated that this poor attendance was often due to poor communication between managers and staff about the training schedule, and last-minute unavailability of staff due to unforeseen care duties or leave. The trainers also found it difficult to contact managers; where managers did facilitate training session attendance, this was sometimes ill-considered - for example, pre-planned sessions included staff who had completed a night shift and were too tired to concentrate. More often it became apparent that it was impracticable to pre-plan group composition due to the variable availability of staff - a standard feature of care home life.

Where staff did attend sessions, their engagement with the content varied; the trainers felt that improving the scheduling of sessions (to fit with staff shifts) and composition of groups (including staff with similar roles) might improve engagement, as might reducing the length of training sessions. They also felt that the care home environment itself affected engagement - adversely so when there were inadequate training facilities such as small rooms, limited private space and uncomfortable chairs - and positively so when staff were familiar with training, and homes had dedicated training spaces.

In order to assess whether skills taught were used in practice, I tried to develop a method for measuring the enactment of skills learned during training. The use of a structured observational checklist proved awkward: it was difficult to record comprehensively staff-resident interactions when the checklist-defined activities were not relevant during the particular observational period. It was also hard for a non-expert such as myself (not a physiotherapist) to identify where there were omissions of required actions to support residents' posture and mobility; a physiotherapist would know when certain skills should be put to use, but a non-expert would not necessarily be able to make that judgement. In discussion with the expert group, the

physiotherapists were also concerned that the use of newly learned techniques might not always be appropriate for an individual resident, and that more contextual detail about a resident's abilities would be needed to judge the suitability of skill use. In short, I was able to uncover some of the difficulties associated with the measurement of enactment, but I failed to develop a definitive approach.

Development and testing of a postural assessment tool

In the absence of an appropriate existing outcome measure, I convened a development team (physiotherapists, a researcher and me) to develop a postural assessment tool (PAT) to measure residents' posture. We used an iterative development approach - trialling it in care homes, then making adjustments in consultation with the expert physiotherapists - in an effort to ensure that the tool was usable by non-experts and in the care home environment. It appeared acceptable to residents, with very few refusing to be observed, and it had good completion rates that were much better than those for the self-report questionnaires (such as the EQ-5D-5L), which we asked residents to complete through discussion with a researcher; the tool was mainly uncompleted for those who were in bed at the time of our visits and thereby not suitable for assessment. I analysed the written accounts of our experiences of completing the PAT; these accounts illustrated difficulties with assessing certain postures and greater difficulty with particular body areas (for example, the pelvic area) due to the complexity of a resident's position, or due to our view being obscured by items such as furniture or clothing. Whilst these accounts provided descriptions of the practical challenges of completing the PAT, they also revealed that researchers' observations went beyond the requirements of the tool; we made notes about residents' behaviour, apparent mood, health and poor postural set-up.

Feasibility of measuring outcomes

My review of data return rates in the PATCH trial revealed excellent rates for data collected by researchers from care home records, and for data collected by researchers in face-to-face meetings with staff who provided proxy data for residents. Researchers struggled, however, to collect questionnaire data directly from residents due to high prevalence of cognitive impairment. There were also low return rates for questionnaires completed by care home staff in their own time. I explored, through interviews, researchers' and staff members' experiences of providing data for the trial. Although proxy data return rates were good, discussions with researchers and staff revealed that some answers provided were not accurate representations of residents'

well-being; staff found it difficult to make a judgment on residents' quality of life when they were unable to converse with them. They also felt that the measures used did not always capture the subtleties of residents' abilities or content of their daily lives. Whilst staff members felt they were ideally placed to provide a view on residents' well-being, the questions we asked them could be hard to answer because they required a subjective judgement and did not align with the way staff considered residents' needs when providing care. They found it particularly difficult to make an accurate assessment of residents' emotional well-being.

Researchers and staff also reported that the data requested for the trial from care home records was sometimes unavailable or had been recorded in a format that made its retrieval awkward or impossible. Researchers, consequently, needed to support the complexities of data collection by being flexible and adaptable in their approach, explaining what was required to staff and residents, and taking extra time to find and interpret information detailed in care records.

Use of routine NHS data for care home research

I obtained routinely available data about hospital attendances and admissions from three NHS acute Trusts that served nine of the care homes that participated in the PATCH trial, with a complete NHS-derived dataset available for six of these homes. I was able to compare these data with those collected directly from care home records during data collection visits for the trial. I found that hospital data were often more comprehensive in their description of a hospital episode, and that they included primary and secondary diagnoses which were relevant to the required trial dataset. Agreement between hospital and care home derived data was poor, attributable to lower reporting in the trial dataset; even some severe falls were missing from the trial dataset, showing that important outcomes can be either poorly documented or difficult to find in care home records. There was little agreement between out-patient and community Trust data and the care home derived data, making it impossible to draw conclusions regarding which data source was better placed to provide accurate information. For one acute Trust I was able to explore the accuracy of their recording of patient addresses. I found that all residents were correctly assigned the address of their care home during the follow-up period; this was not the case during the baseline period, but this discrepancy could be explained by their having moved to the care home during this time.

In summary, I observed poor engagement by care home staff in those research procedures that were not facilitated by a researcher (training and data provision), whilst procedures worked well when researchers were directly involved - collecting data directly from care notes or from staff members (those providing proxy data about residents). However, good compliance masked probable inaccuracies in the content of the dataset due to: staff finding it difficult to make proxy judgements about residents; some outcome measures being inappropriate for residents; and care notes being complex to navigate, misaligned with research requirements, and incomplete when compared to NHS-derived data. Many residents were unable to engage with data provision due to cognitive impairment, and we found that collecting data by observation yielded better data return rates, but again there were concerns regarding accuracy. In short, the research was fraught with difficulties in the engagement of participants and the reliability of the data that could be obtained.

8.3 The relation of findings to the literature

Many care home researchers have reported poor intervention uptake by staff (53, 60, 61, 67, 90); I found similar problems, with trainers reporting various reasons for poor attendance at training sessions. As other researchers have found, in our trial staff members dropped out from sessions at the last minute because they needed to prioritise residents' needs (60) and, on occasions, did not attend because of poor communication - staff were sometimes unaware that they had been scheduled to attend particular sessions. Our trainers reported that the practical arranging of sessions with the manager (or management team), whilst recommended by other (111) researchers, did not help much; managers were asked to provide a list of named staff to attend particular groups, but often this did not work in practice because their scheduling did not take account of staff members' shifts, other commitments or planned absences.

As recommended by others (79, 109) we aimed to involve all staff (including managers and other senior staff) in the training sessions, but the trainers found that managers did not engage with the sessions (none attended), and that the presence of senior staff sometimes undermined the cohesion of the group. They felt that groups where staff in similar roles attended together were more engaged because staff felt more comfortable with their peers. The care home environment also affected staff engagement with training; others have reported inadequate facilities (67) for training, and we found this to be the case - small stuffy rooms, uncomfortable chairs, and a lack of private space

affected comfort and concentration. Whilst others recommend the need for a good training venue (95), this isn't always possible - particularly in smaller care homes with limited or no space for training.

My findings align with those of other researchers - we agree that training in care homes is problematic; however, I have gone further - I have established which of these challenges can potentially be overcome (better planning of sessions to take into account staff commitments), and which may be intractable (lack of facilities, lack of time, last-minute drop-outs from sessions). Our employment of some of the solutions suggested by others did not lead to good attendance or engagement, which suggests that formalised sessions might not be the best method to train staff (discussed further below).

It is well-established that intervention adherence is often poorly measured and reported (34, 62, 104, 157, 227), with many studies failing to report adequately the quality (delivery of the intervention as intended) and use of the intervention in practice (76, 112). Some researchers have reported a variety of approaches to measuring intervention fidelity and adherence, but many of these reports do not result in a full understanding of the use of the intervention, instead recording that something was done (112, 228) (e.g. a care plan was completed, facilitators appropriately contributed to the running of a group), or including a retrospective audit of completed intervention materials (229) (such as logs detailing procedures that were undertaken). My review of the literature revealed few approaches to the monitoring of the use of new skills, but there were indications (114, 162) that structured observation might be a reasonable method to capture the use of an intervention; only through observation is it possible for the research team to understand first-hand whether skills are being employed to support care.

Completion of the checklist I had developed was not straightforward, and whilst the use of a structured form has been reported by others - for example, observing hand hygiene (114) or observing exercise classes (67) - I found it to be unsuitable for the observation of 'Skilful Care' care practices. This unsuitability was because the care practices we were trying to assess are not a mandated set of actions to be undertaken on every occasion, as would be the case for hand washing, but rather a 'toolkit' of supportive approaches to be used as required for each resident dependent on their needs at any one point in time. I would suggest that a checklist might only appropriate

when a fixed set of actions would always be expected within a limited time period (e.g. during an exercise class).

My findings were probably most useful where they elucidated the difficulties associated with observing the use of skills that form part of routine care: it was difficult to identify omissions of care, and hard for a non-expert to know what was and was not appropriate or expected. In addition, it seemed important to understand the abilities of each resident to know whether support was required; for example, omissions of support may well be appropriate. Other researchers have used more detailed approaches, such as ethnographic observation of daily life (67) and researcher field notes to identify positive changes since baseline (82). These time-consuming, and thereby costly, approaches may well be the only true way to understand the use of new skills. It is also important to consider whether only experts in the intervention - where that intervention requires the application of specialist skills - can be the ones to assess its use. Other studies of skills-based interventions have used non-experts (for example, researchers without clinical expertise) to assess intervention fidelity, with limited success. (162) Further exploration of the most effective and efficient method for robustly measuring intervention adherence is needed.

We were often unsuccessful in our attempts to collect data directly from residents, illustrating what many other researchers have reported: that the completion of outcome measures with residents who have cognitive impairment is difficult and sometimes impossible (85, 95), leading to incomplete or missing data (66, 70). Yet, researchers continue to pursue the collection of data from residents using standard tools that the majority cannot complete; my observation of this problem, coupled with my drawing together of the many reports of this difficulty, indicates that this data collection approach should not continue in its current form.

Similarly aligned with other researchers' observations (67, 73, 89, 98) were our poor data return rates from care staff who were asked to complete data in their own time. Again, by reviewing multiple researchers' reports, and through my own experience of trying a range of methods to enhance return rates, I have shown this to be a pervasive problem which should be addressed by consulting with staff and testing alternative approaches. I was unable to explore this in any detail due to my difficulty accessing staff for a discussion of their involvement in the completion of questionnaires - a weakness of this work, and something which requires further exploration in future

studies. Nevertheless, my inability to engage with staff confirms other reports of staff being too busy to take part in research (73, 101).

Staff members who completed measures on behalf of residents (proxy data provision) concurred with other reports (49, 82, 123) - that measures were not sufficiently sensitive in their ability to detect small but meaningful differences in residents' abilities or quality of life. My findings expanded on these reports by clarifying particular areas where this was the case - for example, small differences in dexterity can be important to residents' independence in their activities of daily living. Researchers and staff also talked about some components of the measures being inappropriate for residents, a challenge mentioned by others (49, 92, 122) who note the difficulty of finding reliable and valid tools for the care home population: a problem which needs to be addressed with some urgency to improve the reliability of trial results. As well as the problems caused by these inappropriate questions when staff tried to provide their opinions on residents' well-being, they also felt unable to judge with accuracy residents' subjective experiences - because they could not discuss these with the residents, and because they thought that residents with dementia might experience their wellbeing differently. Whilst other researchers have reported discrepancies between proxy-rated and resident-rated quality of life (217-219), there are no published reports of proxy raters' views on the difficulties they face in this role; my work provides insight into what proxies find difficult and why.

The observational approach to collecting data about residents' posture was more successful, in terms of data completion rates, than was asking residents to verbalise their wellbeing in response to researchers' administration of questionnaires. Other researchers have suggested that the use of observational approaches might be preferable (213, 230) to the verbal administration of questionnaires, to maximise data return and minimise burden or distress to residents with cognitive impairment. A number of observational tools have been developed (214, 231), or bespoke observational approaches used for individual projects (232), but these are not widely used to collect outcome data in clinical trials in care homes. Given the difficulty that proxy data providers expressed with their assessment of residents' quality of life, and the limited data that can be obtained directly from residents, it would seem sensible to pursue the collection of data by observation as a more widely acceptable approach. New tools are required, and these could be developed to incorporate observational techniques for data-gathering.

Our researchers experienced difficulty finding outcome data in care notes, some of which were reported in a different format to that required for the research, and some of which could not be found or were not recorded at all. Other researchers' (56, 73, 111), have reported the difficulty of finding data unless it aligns precisely with care notes or is mandated for care home reporting. Even then, researchers have reported that data they would expect to find (e.g. fluid charts) can be inaccessible (68), missing (60, 75, 112) or inaccurate (100). I compared NHS-derived and care home-derived hospital attendance data, finding that the NHS-provided data were more comprehensive. Whilst other studies have suggested that NHS routine data are useful and accessible sources of the outcomes required (73), they have not compared the accuracy of the two sources as I have done.

There is current focus in the UK on how to identify care home residents in order to create population-level datasets (225, 233), but this is different to considering the accuracy of NHS data for consented residents for whom identifiers, care homes and hospitals will be known. One acute Trust involved in my work provided participant address data, and I found that the care home address was accurately recorded for all participating residents who had attended hospital during the follow-up period. This was, however, a small sample and would need further exploration although it is a promising indicator of the accuracy of hospital data for residents taking part in a trial. Other researchers have used postcode to identify home-level data on hospital admissions (73); but a postcode will usually include other households in addition to the care home, so reducing the reliability of the data. Should full address be found to be accurate, then this identifier would be a profitable method for obtaining whole-home data on hospital admissions. Other work is ongoing to incorporate a Unique Property Reference Number (UPRN) for every addressable location (233) in routine datasets, and this could provide a definitive method for correctly identifying a care home and its residents, both for individual research studies and at a population level. On the other hand, this UPRN is not widely used or updated at present, so in the meantime, address would seem to be the most practicable means of identifying care home residents in NHS datasets.

8.4 Methodological considerations

I have considered the methodological strengths and weaknesses in each of the earlier chapters reporting my findings. Here I summarise the strengths and limitations of my

work as a whole, qualifying the conclusions I have drawn and the recommendations I make.

The quantitative data used for my studies are derived from the PATCH trial, which included an eligible population of 146 residents living at 10 care homes in England. My exploration of data-return rates for resident outcome measures and the Postural Assessment Tool is thereby based on a reasonably sized population from which to draw conclusions. Similarly, my comparison of hospital data with trial data seems robust as it included participating residents (N=130) at nine of these care homes; however, I only received a useable *electronic* dataset from one Trust, so the conclusions I have drawn in relation to the accuracy of electronic records are limited.

For each of my empirical studies (except for study 5's scrutiny of routine data) I used a mixed methods approach; using more than one type of data (for example, objective reports of staff attendance at training, and subjective reflections from trainers on the organisation and delivery of training sessions) increases the trustworthiness of my findings and contributes to their validity.

For elements of some of my studies I relied upon written accounts of trainers' and researchers' experiences, rather than undertaking interviews to explore the topic areas. I may therefore have missed more detailed, and perhaps more nuanced, information that might have been elicited from interviews. However, my intention was to explore practical challenges associated with research implementation, so the obtaining of written information after every encounter with a care home provided accounts of the range of experiences that might have been lost in later interviews.

My failure to engage staff to talk about their self-completion of outcome measures limits any conclusions I can draw about the wider involvement of care home staff in research (beyond those who were more engaged in the provision of proxy data).

I did not interview residents about the nature of the questions we asked them; their involvement might have enriched my findings. However, very few residents had capacity, so I would not have been able to talk to many of them, and it was mainly the data collection difficulties caused by lack of capacity that I considered in my analysis.

In developing and implementing the PATCH trial I worked closely with the researchers, trainers and care home managers throughout the delivery of the project. Because I was a data collector and I designed the new tools, I was not an impartial observer of research processes, nor distanced from the subjects I interviewed and whose data I reviewed. There will thus inevitably be bias in my analysis and interpretation of qualitative data. On the other hand, I had a greater understanding of the difficulties faced in a number of areas through my direct experience of the situations I explored, which will have provided additional context for my analyses. In turn, however, my experience could have affected my interpretation of trainers', researchers' and staff members' accounts, although I consciously held in my mind this potential bias during my analyses, in an attempt to minimise it. In addition, I arranged for independent researchers to check my analyses, and I cross-checked with one of the trainers my interpretations of the difficulties with training.

8.5 Recommendations

8.5.1 Recommendations for research practice

Understanding and engaging with care homes

I gained a detailed understanding of the difficulties of undertaking an intervention trial in care homes, breaking the challenges down into intractable and avoidable problems, thereby identifying areas that can and should be considered to improve future intervention research. Researchers need to be aware of the potential for intractable problems such as competing training and insurmountable events such as home closures, factoring these unexpected occurrences into their project timelines and sample size calculations. No matter how many steps a research team might put in place to optimise training uptake and other research procedures, the needs of the home will always come first, so sometimes training or data collection may not be possible.

Avoidable problems of a practical nature (those relating to integrating the research to fit better with the care home environment) can be addressed with foresight and the inclusion of additional methods to support and amend research processes. I identified the need to tailor training to staff needs (e.g. to fit around shifts) and to the care home

environment (e.g. where training rooms were not available). I also found that researchers experienced problems obtaining data from care notes, and that care staff did not engage with data provision when this involved self-completion. There will be unique considerations for each home relating to intervention delivery and data provision, so more time might be spent at the start of engagement with a care home to map their staff structure and working patterns, environment, routines, notes systems, and other factors that might limit intervention uptake or data collection.

Other researchers recommend that research staff take time to understand care homes and staff routines (33, 51, 53); I certainly agree and suggest that a pre-study observational and engagement period would be of great benefit - to understand how research procedures would work best in each care home, considering: if and how the intervention would fit with existing care practices and the home environment; whether the required trial data are available in care notes; and the routines of the residents' and staff in relation to appropriate data collection strategies.

Establishing an understanding of research 'fit' aligns with recommendations from Goodman et al. (84) who explored how care home context affects uptake of health care innovation. They suggest that it is important to explore: whether an intervention aligns with care home priorities, the engagement of the manager and staff, and available time for the work. This engagement effort should increase the likelihood of success through the researcher's assessment of a home's suitability for the research, in which they would also establish whether the staff and residents were sufficiently interested and able to dedicate the time required for research procedures. I would go further than promoting this level of engagement only at the start of a research project: I would suggest that observations and discussions take place within the home throughout trial participation to ensure an ongoing 'fit' of the research in the care home.

In this way, initial and evolving practical constraints of the care home environment could inform flexible intervention delivery and data collection procedures, with observation and conversational findings feeding back to the care home team to effect corrections to emerging impediments to research processes. Very recent publications endorse this approach: Levy et al (140) following a consensus conference of care home experts (researchers and those working in and with care homes), suggested the need to assess organisational strain and readiness to participate in research prior to and throughout the implementation of a project, adapting to the varying needs of a care

home over time. Peryer et al (138) also recommend that time is allocated to assessing suitability and readiness to participate in research, and they point to a need for monitoring of implementation activities to detect 'procedural drift'.

This process of observation and discussion would point to any challenges for intervention implementation; it is important to consider implementation during intervention trialling (153) so that the research delivers evidence to support mechanisms for routine uptake of an intervention should it prove to be effective in the more controlled trial conditions. This level of engagement and observation would certainly be time- and therefore cost-intensive, but it could have a triple purpose - finding solutions to problems with research processes, supporting implementation, and also observing enactment of intervention use in routine practice - so it could be an effective use of researcher time.

Staff training

As discussed above, greater consideration of individual staff members' needs is required to improve attendance at training sessions, ensuring that they are invited to sessions that fit with their availability and working pattern. This process requires a better understanding of staff commitments, alongside improved communications with staff by the research team and the home's management team. Alternatively, due to the frequently experienced last-minute requirements for staff to cover others' duties or to care for residents, it may not be possible to plan for specific staff to attend particular sessions; rather, planning a number of 'open' sessions at various times of the day and week might work better for staff where planning ahead is difficult. Certainly, other researchers suggest the need for flexibility (109) in the offer of training, and perhaps the only viable way to offer such flexibility is to consider further tailoring of training through ongoing consultation with all involved staff members at each home.

Defining intervention 'success'

Research teams agree criteria, at the start of a trial, that reflect sufficient exposure to or engagement with an intervention (234); this exposure or engagement must be deemed sufficient to be likely to result in change. These criteria are often based upon expert opinion rather than fact, and they are usually expressed as proportions of staff engaging with an intervention. As I have discussed in Chapter 4, proportions can be misleading, and I would suggest that a defined number and type of staff to be trained,

probably representative of staff roles within the care home, might be a more useful measure of success. Even so, successful implementation of an intervention in routine practice might be achieved with fewer staff having received training, so progression criteria should perhaps be less quantitatively prescriptive, focussing more on qualitative observations and interviews, and contextual information, to inform progression. This aligns with newly revised MRC guidance (153) on the development and evaluation of complex interventions, which promotes the combined use of quantitative and qualitative data to inform progression.

Routine data

I recommend the use of routinely collected hospital data where hospital admissions and A&E attendances are trial outcomes. For the PATCH trial participants, the hospital dataset identified more hospital contacts than did the care home records, missing very few of those reported by the care homes. Another benefit of using routine data is comprehensive provision of all hospital attendances between the date parameters, thereby avoiding any gaps or repetitions in data reporting that might occur when a researcher visits a care home at specific time-points. For example, data could be missed between the baseline visit and randomisation if there were delays, and hospitalisations on the cusp of the three- and six-month follow-up periods could be missed or double-counted.

Where the decision is taken to use routinely available NHS data to establish trial outcomes, I would recommend a service mapping exercise at the start of the trial to establish which hospitals serve each participating care home, and to ensure that all identified Trusts are willing and able to provide data. Without these assurances, data quality would be compromised. It is also important to align trial outcomes to the available hospital data to ensure ease of access and unambiguous collection of outcomes.

There is much focus at present on the need to improve systems to collect electronically a minimum dataset for residents, and the linking of this data to NHS and community datasets. (10, 235) Until this ambition is realised, the processes I suggest could provide an accurate and comprehensive alternative.

8.5.2 Recommendations for care homes

In the section immediately above I suggest that researchers need greater understanding of and engagement with care homes. Equally care home managers, staff, and residents (where possible) would benefit from engagement with researchers before committing to a research project - to understand what it would involve, and to decide whether the proposed intervention and data collection approaches are suitable for their home. While researchers are assessing the suitability of a home for their research during an initial engagement period, care home staff would have the opportunity to decide whether the research was something that they could adopt. Informed consent procedures require that a fully informed decision is made but, given the problems experienced with limited staff attendance at training and poor data compliance, I would suggest that a full appreciation of requirements is often not established with all parties. This suggestion aligns with other researchers' recent recommendations which include consideration of enhanced communication with care home staff, (138) and the need to adopt a more collaborative approach. (138, 140)

I found that researchers had difficulty finding in care notes some of the data required for the research. A lack of standardisation of record keeping across homes not only affects the ease and accuracy of data collection for research, but also has implications for accurate reporting of mandated information to CQC and variability in homes' ability to use their data to inform resident care. I would suggest that there needs to be standardisation of recording and reporting of important data (for example, falls, which were variably reported across homes participating in the PATCH trial) to support resident care. This standardisation would also facilitate integrated care across social care and the NHS in line with the government's proposals for health and care integration (236). The government's aim is to join up data and information to ensure integration of services to optimise care, but what constitutes core data for care homes is not well established (237). The ongoing DACHA study (Developing research resources and minimum dataset for care homes' adoption and use) (235) aims to develop a UK minimum data set for care homes in consultation with care staff to ensure it is fit for the home's purposes, as well as piloting the linking of health and social care data to inform service planning, integrated care and to support research (238). Comprehensive work is thus underway to standardise and link to NHS sources information about residents, which is critical to improving their care.

In the next section I discuss recommendations for future research. All work to improve research procedures should involve care home staff to ensure that suggested approaches are fit for purpose.

8.5.3 Recommendations for future research

Much work is needed to adapt and refine research methods so that they are better suited to the care home environment, so that research outputs provide more accurate reports of care home life and intervention effects. This work includes: 1) improving intervention uptake and the monitoring of its use in practice; 2) development of new measurement tools that are relevant to residents' daily lives, and that are more easily completed by (or for) residents or staff; 3) development of new methods of obtaining data from care staff; and 4) optimising the use of routinely available data for research.

Intervention recommendations

My findings, along with those of the interviews conducted for the PATCH trial process evaluation, will be used to adapt and refine the Skilful Care Training Package (SCTP). Consideration needs to be given to the number and type of staff who should be trained, group composition, and the format and timing of training. Our employment of some of the solutions suggested by other researchers did not lead to good attendance or engagement, which suggests that formalised sessions (or at least lengthy sessions) might not be the best method to train staff; rather, alternative approaches, such as on-the-job training, may be more effective in their ability to engage staff. These alternatives should be explored with the trainers and care home staff, using participatory methods, to ensure the intervention aligns with care home priorities, and is compatible with care homes' facilitates, their staff availability and their residents' needs. My findings and the proposed further development work have implications for an evolving SCTP programme theory; this would need to be regularly revisited and refined during an exploratory intervention development phase (153). As well as informing the SCTP, working with the trainers and care home staff to refine the intervention would have wider implications - elucidating methods of intervention delivery that would make training more acceptable and accessible to care home staff.

Further work is needed to explore approaches to observing and documenting the use of new skills following intervention training. Consideration needs to be given to who is best placed to undertake these observations, and the duration of observation -

balancing the collection of sufficient data to provide a meaningful representation of skills use with the complexity of analysis. These observations could also contribute to improved understanding of the care home environment - describing 'usual care' and identifying any barriers or facilitators to intervention use. Exploration should include alternative methods for observing use of new skills in practice - for example, videos of care practices over specific time periods for later coding and analysis.

Improved methods for collecting resident data

The work in this thesis begins to address the degree to which staff can understand a resident's perspective on their quality of life, and the implications this has for the reliability of proxy measures. Further work needs to consider how best to understand and capture residents' lived experiences.

The development of new outcome measurement tools is needed if research findings are to become more meaningful. Work should focus on the development of measures that: more accurately reflect the reality of residents' daily life (content), include categories that capture small changes in quality of life (sensitivity), can be more easily understood by residents and staff (accessibility), and are completed in a way that makes for more reliable data collection (administrative approach). There is suggestion in the literature (239) that standard scales that require the choosing of an option are not appropriate; the suggestion (211) is that a conversational approach might be easier - with answers categorised later by a researcher, using a standard coding system. This was endorsed by the PATCH trial researchers who felt that asking the questions included in a questionnaire did not work well for residents. We found that completing the Postural Assessment Tool through observation was more successful than the verbal administration of questionnaires; I also found that researchers observed more than posture alone, providing comments about in-the-moment behaviour, mood and health state. The use of observation might therefore be a better method for some researcher assessments, and for staff providing proxy data about residents' well-being: staff repeatedly asserted during my interviews with them that they understood the residents' needs through observing their behaviours, so tools that tap into this understanding are more likely to be valid.

In order to develop effective outcome measures there should be consultation with residents, their relatives and care home staff so that the outcomes prove of relevance to residents. This approach would lead to the development, for the first time, of a core

outcome set for care home residents. There are existing core outcome sets for specific interventions (for example, optimising prescribing in nursing homes (240)), but not a general core outcome set for residents' quality of life that could be used consistently across projects.

Work is underway to identify "internationally comparable common data elements that can be used to measure essential aspects of long-term care" via the WE-THRIVE project (241) (an international consortium of researchers identifying potential domains and data collection standardisation for long-term care). This collaboration is, however, focussed on the identification of *existing* outcome measures that fit with areas of importance identified by health care professionals - for example, person-centred care, and organisational context. The international collaborators are not involving residents and staff in the identification of important outcomes, nor are they seeking to develop new measures. The DACHA study (235), mentioned earlier, will look at routinely available data to develop a standard, recommended data set, but their work does not include the identification of subjective resident outcomes. The Covid-19 pandemic has brought into focus the need for easily accessible data about UK care home residents (242), and it has lent urgency to the endeavour to develop a minimum data set (237) that can support planning and delivery of care, as well as research. I believe that the development of a core outcome set for care home residents - developed with them and by those who know them well - will complement this work.

<u>Improved data collection from care staff</u>

Alternative approaches and methods for obtaining data from staff need to be considered, probably avoiding written materials, which have failed on numerous occasions to provide sufficient data for meaningful analysis. Focus groups are one possibility - these and other options should be explored through feasibility work with care home staff.

<u>Optimising the use of routinely available data</u>

As for hospital attendances more generally, data derived from care home records do not seem to offer a comprehensive account of residents' hospital attendances following a fall. If care home records of more severe falls are inaccurate (where reporting is mandated by CQC and local authorities), there must be doubt about the accuracy of the recording of less severe, non-hospitalised falls data, and their usefulness as a trial

outcome. Of course, missing falls-data in the trial data set could also be explained by the researcher's inability to find those data in care home records. Work is needed to optimise and standardise the collection of data on falls - a common trial outcome.

Collection of whole-home data might be particularly useful for cluster trials where it is important to understand an intervention's impact on all residents and not only those directly participating in the trial; indeed, we had approval to do this for PATCH trial care homes - obtaining, from care home managers, a summary of the total number of falls, hospitalisations and deaths across their home. I concluded from my review of Acute Trust 1's data that hospital records accurately record a resident's care home address where we know that they are living at a particular home; this identifier could thus be used to collect anonymised data from NHS records for all residents - data that would be more reliable than what can be obtained from care homes. This assertion needs further investigation - for example by conducting a prospective observational study to monitor the number of hospital admissions from one or more care homes and later comparing these data with those recorded by the hospitals to which residents were referred. Further work with a larger sample of Trusts with a variety of electronic systems would be needed, to draw more robust conclusions about the reliability and usability of routine Acute Trust data.

8.6 Conclusions

Care homes are quite different to NHS settings - they are the homes of people with multiple health needs; they are a workplace; and often they are private businesses. We need to respect these differences - designing interventions, outcome measures, and participant engagement methods that are tailored to, and designed in collaboration with, care home staff and residents. Current methods and approaches fall short of these ideals.

Methodological challenges discussed here are underpinned by the separation that exists between researchers and care homes - physically and collaboratively. In NHS-based intervention research, investigators are mainly clinicians who take on a dual clinical and research role within their service; they are embedded within the care-system and thereby understand patient needs from first-hand experience. Although clinician-researchers lead most intervention research in care homes, those researchers often have limited contact with care homes and have only partial knowledge of

residents' and staff members' daily life. It seems intuitive that care home managers and staff - the people who best know their residents' needs and capabilities - should be the ones to identify research questions, or at least work in close partnership with researchers to do so. To date, however, there has been little collaborative work with care homes to prioritise and design new research projects.

My recommendations for future research must involve care home managers, staff, residents and their relatives as partners to support the development of research methods that are practicable in a busy care home environment - to identify the best methods for engaging staff and residents with new interventions, and to develop outcome measurement tools and approaches that are suited to residents and staff. Some of the recommendations I put forward would be costly to implement (and a few may raise ethical issues), but repeated efforts to establish effectiveness in trials where intervention delivery and data collection are sub-optimal are themselves costly and unethical. Until care home research methods are improved, there will be limited impact on residents and staff from intervention research in this setting. The title of my thesis is "The feasibility of undertaking a complex intervention trial in English care homes". I conclude that, whilst it may well be feasible to work with care homes to a degree, not all current methods or tools result in adequate outputs from which robust conclusions can be drawn - so, at present, feasibility is questionable.

Collaboration needs to be structured, perhaps via a national network of care home researchers - to ensure that priority research questions can be investigated at scale, and that standard approaches for care home research conduct are agreed. The many published reports, by individual research teams, of methodological challenges point to a lack of cohesion amongst researchers - in the past and at present. Care homes have little research infrastructure, unlike that afforded to the NHS - where research is supported by the Clinical Research Network and associated NIHR funding structures. Researchers suggest (243) that national capacity needs to be built for geriatric medicine research (including that undertaken with care home residents); and it seems sensible that improvement in research in care homes should be underpinned by a national, multi-centre approach to research, involving clinical, academic and care home stakeholders. Lately, a group of UK care home researchers has once again emphasised the need for greater collaboration, and for a national research infrastructure for care homes (244) following their attempts to set up a platform for national care home research during the Covid-19 pandemic.

High quality intervention research is essential to improve the health and care of this underserved population. Only through major changes to research methods - to tailor approaches and tools to this unique setting - and more collaborative working with care home staff and residents, can such high quality research be achieved.

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Appendix 1 Logic model

The problem	Evidence base	Resources	Activities	Intervention mechanisms	Staff outcomes	Resident outcomes	Impact
Residents in care homes are amongst the frailest in our population, and spend the majority of their time sedentary. Improving physical activity and optimising posture is important for maintaining health, but interventions are patchily realised. Training on postural care including feeding training, is rarely given to care workers, and is limited to nurses working in care homes. Training on giving skilled assistance to assist people in keeping as independent and active as possible is limited.	Inactivity is associated with chronic disease risk factors and all-cause mortality. Decreased mobility and poor postural management can lead to an increased incidence of pressure sores, pain, contractures, cardio-vascular deconditioning, urinary infections, loss of independence, and reduced opportunities to participate in social activities. Care and nursing staff in care homes can be trained to improve their knowledge and skills - to impact on residents' well-being.	Expert physiotherapists (Trainers) Structured training programme (slides) Handouts for staff (to keep) Pocket book for staff (for daily reference) Staff time to attend sessions Training space in care home Certificates Biscuits!	Trainer meeting with care home manager to discuss content, time requirements, and to tailor the programme if required. 7.5 hours training* provided to all care and nursing staff in the care home (split into 1, 2 or 3 sessions and run on multiple occasions to keep group size to around 8 participants) (*training includes practical training exercises and quizzes, as well as theory and discussion elements.)	Understanding new information relating to posture and movement in the context of the care home environment Observing, imitating and mastering new skills Modelling residents' limitations to gain empathy and change attitudes Understanding and appreciating the importance of new skills for staff and resident well-being.	Understanding residents' needs (Empathy Scale, P-CAT) New understanding and skills relating to positioning, moving and promoting independence (posture and movement questionnaire) Demonstrate new knowledge and skills in every day work (observation)	Improved posture (PAT) Improved mobility and independence (PAM-RC, FAC, ADL, CCAM, EQ-5D) Reduced pain (Pain thermometer, EQ-5D) Improved mood (EQ-5D) Reduced incidence of pressure ulcers Fewer hospital attendances & admissions Health resource use	Change in staff skills and culture of the care home - in relation to improving residents' posture and mobility / independence Improved resident posture, mobility and well-being – sustained at the whole home level

Mediators

Time to attend training	Learning needs
Medical conditions	Proportion of staff who attend training
Time to implement changes	
Barriers / facilitators to implementing changes (staff or home-level changes)	
Access to chairs / equipment	

Appendix 2 Search strategy

Example from Medline Search

Database: Ovid MEDLINE(R) <1996 to January week 1 2018>

----

1   Nursing home/ (4199)

2   nursing home?.tw. (18346)

3   Long-Term Care/ (14898)

4   ((geriatric or elderly or convalescent or retir* or life care or continuing care) adj2 (facility or facilities or institution* or residence* or centre* or center*)).tw. (2644)

5   ((long-term care or longterm care) adj2 (facilit* or institution* or setting* or resident* or provision)).tw. (5396)

6   (long-stay adj2 (facilit* or institution* or resident*)).tw. (218)

7   (Institutionali* or institutional care or care home? or rest home? or formal care or dementia care unit* or convalescent home? or retir* home?).tw. (13213)

8   residential facilities/ (2746)

9   ((skilled or intermediate) adj2 (nursing facility or nursing facilities)).tw. (1478)

10   intermediate care facilities/ (372)

11   skilled nursing facilities/ (2445)

12   Institutionalization/ (2803)

13   Assisted Living Facilities/ (1251)

14   assisted living.tw. (1586)

15   (extended care adj2 (facility or facilities)).tw. (228)

16   sheltered care.tw. (3)

17   group homes/ (771)

18   (group? adj (home? or living)).tw. (1843)

19   halfway houses/ (265)

20   halfway hous*.tw. (44)

21   (residential adj3 (care or healthcare or facilit*)).tw. (3936)

22   or/1-21 [care home terms] (60327)

23   exp aged/ (2167153)

24   Geriatrics/ (9122)

25   Geriatric Nursing/ (7750)

26   health services for the aged/ (11582)

27   exp Medicare/ (29461)

28   Geriatric Assessment/ (23112)

29   (geriatric patient* or elderly or gerontolo* or seniors or senior citizen* or pensioner* or later life).tw. (174056)

30   ((older or elder*) adj (person or people or adult* or patient* or inpatient* or resident* or men or women)).tw. (166983)

31   (ageing or aging or "65+" or "75+" or "80+" or "very old" or "oldest old").tw. (1011648)

32   (over adj2 ("65" or "66" or "67" or "68" or "69" or "70" or "71" or "72" or "73" or "74" or "75" or "76" or "77" or "78" or "79" or "80" or "81" or "82" or "83" or "84" or "85" or "86" or "87" or "88" or "89" or "90" or "91" or "92" or "93" or "94" or "95" or "96" or "97" or "98" or "99" or "100") adj years).tw. (9346)

33   (("65" or "66" or "67" or "68" or "69" or "70" or "71" or "72" or "73" or "74" or "75" or "76" or "77" or "78" or "79" or "80" or "81" or "82" or "83" or "84" or "85" or "86" or "87" or "88" or "89" or "90" or "91" or "92" or "93" or "94" or "95" or "96" or "97" or "98" or "99" or "100") adj "years or over").tw. (572)

34   (("65" or "66" or "67" or "68" or "69" or "70" or "71" or "72" or "73" or "74" or "75" or "76" or "77" or "78" or "79" or "80" or "81" or "82" or "83" or "84" or "85" or "86" or "87" or "88" or "89" or "90" or "91" or "92" or "93" or "94" or "95" or "96" or "97" or "98" or "99" or "100") adj "years and over").tw. (2850)

35   or/23-34 [old people] (2894132)

36   22 and 35 [care home and old people] (37383)

37   Homes for the Aged/ (8500)

38   (aged adj2 (care or nursing or healthcare or residential) adj2 (facility or facilites or setting* or provision* or institution*)).tw. (344)

39   or/37-38 [old age care homes] (8676)

40   36 or 39 [all old people care home terms] (39989)

41   clinical trial/ or clinical trial, phase i/ or clinical trial, phase ii/ or clinical trial, phase iii/ or clinical trial, phase iv/ or controlled clinical trial/ or multicenter study/ or randomized controlled trial/ (818634)

42   exp Clinical Trials as Topic/ (255619)

43   Evaluation studies/ (253395)

44   Validation studies/ (96150)

45   research design/ or cross-over studies/ or double-blind method/ or matched-pair analysis/ or random allocation/ or "reproducibility of results"/ or sample size/ or exp "sensitivity and specificity"/ or single-blind method/ or Early Termination of Clinical Trials/ (1050068)

46   (pre post or pre test or post test or non ramdomi?ed or quasi experiment).tw. (14934)

47   Feasibility studies/ (61250)

48   Pilot projects/ (99211)

49   exp program evaluation/ (65750)

50   placebo*.tw. (154763)

51   (random* adj3 (study or studies or trial or trials)).tw. (336767)

52   (random* adj3 (allocation or assign* or allocate*)).tw. (107200)

53   (study adj (pilot or feasibility or evaluation or validation)).tw. (988)

54   (studies adj (pilot or feasibility or evaluation or validation)).tw. (219)

55   ((blind or mask*) adj2 (singl* or doubl* or trebl* or tripl*)).tw. (104429)

56   (control adj group*).tw. (310212)

57   ("outcome study" or "outcome studies" or quasiexperimental or "quasi experimental" or quasi-experimental or "pseudo experimental").tw. (14107)

58   (crossover* or "cross over*" or cross-over*).tw. (54794)

59   ((trial or trials) adj2 (clinical or controlled or cluster or factorial)).tw. (410835)

60   intervention.tw. (407075)

61   exp Great Britain/ (239479)

62   (national health service* or nhs*).ti,ab,in. (131108)

63   (english not ((published or publication* or translat* or written or language* or speak* or literature or citation*) adj5 english)).ti,ab. (38073)

64   (gb or "g.b." or britain* or (british* not "british columbia") or uk or "u.k." or united kingdom* or (england* not "new england") or northern ireland* or northern irish* or scotland* or scottish* or ((wales or "south wales") not "new south wales") or welsh*).ti,ab,jw,in. (1246957)

65   (bath or "bath's" or ((birmingham not alabama*) or ("birmingham's" not alabama*) or bradford or "bradford's" or brighton or "brighton's" or bristol or "bristol's" or carlisle* or "carlisle's" or (cambridge not (massachusetts* or boston* or harvard*)) or ("cambridge's" not (massachusetts* or boston* or harvard*)) or (canterbury not zealand*) or ("canterbury's" not zealand*) or chelmsford or "chelmsford's" or chester or "chester's" or chichester or "chichester's" or coventry or "coventry's" or derby or "derby's" or (durham not (carolina* or nc)) or ("durham's" not (carolina* or nc)) or ely or "ely's" or exeter or "exeter's" or gloucester or "gloucester's" or hereford or "hereford's" or hull or "hull's" or lancaster or "lancaster's" or leeds* or leicester or "leicester's" or (lincoln not nebraska*) or ("lincoln's" not nebraska*) or (liverpool not (new south wales* or nsw)) or ("liverpool's" not (new south wales* or nsw)) or ((london not (ontario* or ont or toronto*)) or ("london's" not (ontario* or ont or toronto*)) or manchester or "manchester's" or (newcastle not (new south wales* or nsw)) or ("newcastle's" not (new south wales* or nsw)) or norwich or "norwich's" or nottingham or "nottingham's" or oxford or "oxford's" or peterborough or "peterborough's" or plymouth or "plymouth's" or portsmouth or "portsmouth's" or preston or "preston's" or ripon or "ripon's" or salford or "salford's" or salisbury or "salisbury's" or sheffield or "sheffield's" or southampton or "southampton's" or st albans or stoke or "stoke's" or sunderland or "sunderland's" or truro or "truro's" or wakefield or "wakefield's" or wells or westminster or "westminster's" or winchester or "winchester's" or wolverhampton or "wolverhampton's" or (worcester not (massachusetts* or boston* or harvard*)) or ("worcester's" not (massachusetts* or boston* or harvard*)) or (york not ("new york*" or ny or ontario* or ont or toronto*)) or ("york's" not ("new york*" or ny or ontario* or ont or toronto*)))))).ti,ab,in. (914587)

66   (bangor or "bangor's" or cardiff or "cardiff's" or newport or "newport's" or st asaph or "st asaph's" or st davids or swansea or "swansea's").ti,ab,in. (35347)

67   (aberdeen or "aberdeen's" or dundee or "dundee's" or edinburgh or "edinburgh's" or glasgow or "glasgow's" or inverness or (perth not australia*) or ("perth's" not australia*) or stirling or "stirling's").ti,ab,in. (135100)

68   (armagh or "armagh's" or belfast or "belfast's" or lisburn or "lisburn's" or londonderry or "londonderry's" or derry or "derry's" or newry or "newry's").ti,ab,in. (16038)

69   or/61-68 (1537171)

70   (exp africa/ or exp americas/ or exp antarctic regions/ or exp arctic regions/ or exp asia/ or exp australia/ or exp oceania/) not (exp great britain/ or europe/) (1897228)

71   69 not 70 [UK only filter] (1440407)

72   or/41-60 [intervention studies] (2847608)

73   40 and 72 [all old people care home terms and intervention studies] (11628)

74   71 and 73 [old people care home terms and intervention studies UK only] (1437)

75   limit 74 to last 10 years (938)

Appendix 3 Outcome measures used in the PATCH trial

The following pages include all measures completed by:

- Staff informants (administered by a researcher)
- Residents (administered by a researcher)
- All staff - about their own working practices and knowledge
- Researchers - obtaining data about the care home from managers and from care notes

PATCH
Posture and mobility in care homes

Proxy version of the EQ-5D-5L: 2

Please write today's date |Day|Month|Year| ☐ Or tick if same day as Section 1

Under each heading, please tick the ONE box that the resident would choose to describe his/her health TODAY if he/she could tell us.

MOBILITY

No problems in walking about	☐
Slight problems in walking about	☐
Moderate problems in walking about	☐
Severe problems in walking about	☐
Unable to walk about	☐

SELF-CARE

No problems washing or dressing him/herself	☐
Slight problems washing or dressing him/herself	☐
Moderate problems washing or dressing him/herself	☐
Severe problems washing or dressing him/herself	☐
Unable to wash or dress him/herself	☐

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

No problems doing his/her usual activities	☐
Slight problems doing his/her usual activities	☐
Moderate problems doing his/her usual activities	☐
Severe problems doing his/her usual activities	☐
Unable to do his/her usual activities	☐

PAIN / DISCOMFORT

No pain or discomfort	☐
Slight pain or discomfort	☐
Moderate pain or discomfort	☐
Severe pain or discomfort	☐
Extreme pain or discomfort	☐

ANXIETY / DEPRESSION

Not anxious or depressed	☐
Slightly anxious or depressed	☐
Moderately anxious or depressed	☐
Severely anxious or depressed	☐
Extremely anxious or depressed	☐

PATCH
Posture and mobility in care homes

- We would like to know how good or bad you think the resident would say his/her health is TODAY, if he/she could tell us.

- This scale is numbered from 0 to 100.

- 100 means the best health imaginable.
  0 means the worst health imaginable.

- Mark an X on the scale to indicate how good or bad you think the resident would say his/her health is TODAY, if he/she could tell us.

- Now, please write the number you marked on the scale in the box below.

The resident would rate his/her OWN HEALTH TODAY AS: |___|

The best health imaginable

```
— 100
— 95
— 90
— 85
— 80
— 75
— 70
— 65
— 60
— 55
— 50
— 45
— 40
— 35
— 30
— 25
— 20
— 15
— 10
— 5
— 0
```

The worst health imaginable

Time taken to complete (in minutes) |___|
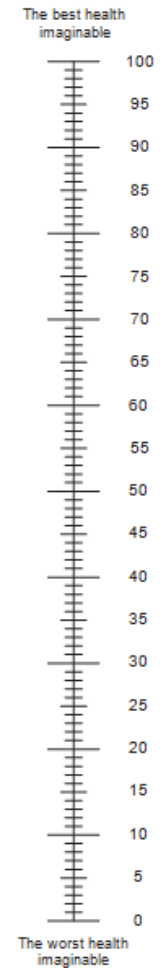
PATCH
Posture and mobility in care homes

FAC (Functional Ambulation Classification)

Please write today's date [Day | Month | Year]   ☐ Or tick if same day as Section 2

Use the definitions below to classify the resident to a category

Category	Definition
1 Nonfunctional Ambulation	Patient cannot ambulate, ambulates in parallel bars only, or requires supervision or physical assistance from more than one person to ambulate safely outside of parallel bars.
2 Ambulator-Dependent for Physical Assistance – Level II	Patient requires manual contacts of no more than one person during ambulation on level surfaces to prevent falling. Manual contact is continuous and necessary to support body weight as well as maintain balance and / or assist coordination.
3 Ambulatory-Dependent for Physical Assistance – Level I	Patient requires manual contact of no more than one person during ambulation on level surfaces to prevent falling. Manual contact consists of continuous or intermittent light touch to assist balance or coordination.
4 Ambulator-Dependent for Supervision	Patient can physically ambulate on level surfaces without manual contact of another person but, for safety, requires standby guarding of no more than one person because of poor judgment, questionable cardiac status, or the need for verbal cuing to complete the task.
5 Ambulator-Independent Level Surfaces Only	Patient can ambulate independently on level surfaces but requires supervision or physical assistance to negotiate any of the following: stairs, inclines, or nonlevel surfaces.
6 Ambulator-Independent	Patient can ambulate independently on nonlevel and level surfaces, stairs, and inclines

Category = [ ]

Time taken to complete (in minutes) [ ]

PATCH
Posture and mobility in care homes

PAM-RC (Physical Activity and Mobility in Residential Care Scale)

Please write today's date [Day | Month | Year]   ☐ Or tick if same day as Section 3

Score the following five questions based on the resident's usual activities in the last week.

ABILITY

Mobility	Score (Tick one only)
Bedbound	☐ 0
Wheelchair bound (transfers with hoist)	☐ 1
Wheelchair bound (standing transfers with assistance)	☐ 2
Wheelchair bound (standing transfers without assistance)	☐ 3
Able to walk short distances within room (<3 m) with / without aids / assistance	☐ 4
Walks longer distances (>3 m) using walking aid / assistance / supervision	☐ 5
Walks longer distances (>3 m) independently	☐ 6

Balance	Score (Tick one only)
Immobile	☐ 0
Needs assistance of one or two people to maintain balance	☐ 1
Needs to use walking aid (stick / frame) to maintain balance	☐ 2
Uses no walking aid but unsteady	☐ 3
Uses no walking aid but gait is steady	☐ 4

ACTIVITY

Walking frequency	Score (Tick one only)
Doesn't walk at all	☐ 0
Walks in room to help with personal care (i.e. to the toilet or commode)	☐ 1
Walks in the room and around the home only when necessary (toilet / dining area)	☐ 2
Walks around the home more often than for necessary functions but spends majority of time sitting	☐ 3
Walks around the home more often than for necessary functions spending only short times sitting	☐ 4

Wandering	Score (Tick one only)
Wandering not exhibited in last 7 days	☐ 0
Wandering occurred 1–3 days out of last 7	☐ 1
Wandering occurred 4-6 days out of last 7	☐ 2
Wandering occurred daily	☐ 3

Outdoor mobility	Score (Tick one only)
Doesn't go out (except for hospital appointments)	☐ 0
Only goes out in wheelchair	1
Goes for short walks <50 m with assistance of carer (i.e. around the garden)	2
Goes for longer walks >50 m with assistance of carer (i.e. to local shops)	☐ 3
Goes out longer distances >50 m without carers (includes absconding)	☐ 4

Time taken to complete (in minutes) [ ]

236

PATCH

Barthel Index (Activities of Daily Living)

Please write today's date [Day | Month | Year]   ☐ Or tick if same day as Section 4

Choose the scoring point for the statement that most closely corresponds to the resident's CURRENT level of ability for each of the following 10 items. Record actual, not potential, functioning. Information can be obtained from the resident's self-report, from a separate party who is familiar with the resident's abilities (such as a relative), or from observation.

	Score
Bowels 0 = incontinent (or needs to be given enemata) 1 = occasional accident (once/week) 2 = continent	☐
Bladder 0 = incontinent, or catheterized and unable to manage 1 = occasional accident (max. once per 24 hours) 2 = continent (for over 7 days)	☐
Grooming 0 = needs help with personal care 1 = independent face/hair/teeth/shaving (implements provided)	☐
Toilet use 0 = dependent 1 = needs some help, but can do something alone 2 = independent (on and off, dressing, wiping)	☐
Feeding 0 = unable 1 = needs help cutting, spreading butter, etc. 2 = independent (food provided within reach)	☐
Transfer 0 = unable – no sitting balance 1 = major help (one or two people, physical), can sit 2 = minor help (verbal or physical) 3 = independent	☐
Mobility 0 = immobile 1 = wheelchair independent, including corners, etc. 2 = walks with help of one person (verbal or physical) 3 = independent (but may use any aid, e.g., stick)	☐
Dressing 0 = dependent 1 = needs help, but can do about half unaided 2 = independent (including buttons, zips, laces, etc.)	☐
Stairs 0 = unable 1 = needs help (verbal, physical, carrying aid) 2 = independent up and down	☐
Bathing 0 = dependent 1 = independent (or in shower)	☐

Time taken to complete (in minutes) [ ]

Collin et al., 1988

PATCH

CCAM (Continuing Care Activity Measure)

Please write today's date [Day | Month | Year]   ☐ Or tick if same day as Section 5

To be completed via staff report rather than resident observation. Refer to the CCAM completion guidelines.

Function:	Score:
1. Rolling from supine to side lying (Right)	
2. Rolling from supine to side lying (Left)	
3. Moving up in bed (reposition)	
4. Lying to sitting	
5. Sitting to lying	
6. Sitting at the bedside (feet supported)	
7. Sitting ability (seating needs)	
8. Reposition in wheelchair/lounge chair	
9. Supported sitting duration	
10. Sitting to standing	
11. Transfer (bed/ wheelchair)	
12. Ambulation	
13. Ambulation distance (indoors)	
14. Wheelchair mobility (indoors)	
15. Upper extremity function (Right)	
16. Upper extremity function (Left)	

Walking device used: _____

Wheelchair: power ☐   manual ☐

PATCH
Posture and mobility in care homes

Staff Informant Booklet

CCAM (Continuing Care Activity Measure)

1 & 2 ROLLING RIGHT/LEFT	10 SITTING TO STANDING
1 = Total assist/one person maximum	1 = Total assist (no weight bearing)
2 = One person moderate	2 = Two people/one person maximum
3 = One person minimum	3 = One person moderate
4 = Supervision/verbal cue	4 = One person minimal
5 = Independent with device	5 = Supervision/verbal cue, stands 30 seconds
6 = Independent, no device, slow	6 = Independent with device, slow, stands 30 seconds
7 = Independent, no device, timely	7 = Independent, no device, slow, stands 30 seconds
3 MOVING UP IN BED	11 TRANSFER
4 & 5 LYING-SITTING & SITTING-LYING	1 = Mechanical/assisted lift
1 = Total assist	2 = Two people client bears weight
2 = One person maximum	3 = One person maximum or moderate with standby
3 = One person moderate	assist
4 = One person minimal	4 = One person moderate
5 = Supervision/verbal cue	5 = One person minimal
6 = Independent with device, slow	6 = Set up chair
7 = Independent, no device, slow	7 = Supervision/verbal cue
6 SITTING AT THE BEDSIDE	12 AMBULATION (± device)
1 = Unable	1 = Non-ambulatory
2 = Assistance or < 30 seconds	2 = Three people (3, or 2+1)
3 = < 2min (transfer); supervision allowed	3 = Two people (2, or 1+1) or wall/parallel bars or
4 = < 5min (washing) supervision allowed	high walker
5 = < 10min (dressing) supervision allowed	4 = One person maximum
6 = < 15 min (eating meal), independent	5 = One person moderate
7 = > 15 min, independent	6 = One person minimal
	7 = Supervision
7 SITTING ABILITY	13 AMBULATION DISTANCE
1 = Bed bound	1 = Non-ambulatory
2 = Lounge chair, back angle <120	2 = Ambulates < 5 m
3 = Adapted tilt/reclining wheelchair	3 = Ambulates < 10m
4 = Tilt/reclining wheelchair	4 = Ambulates <30 m
5 = Adapted standard wheelchair	5 = Ambulates < 50 m
6 = Standard wheelchair	6 = < 100m or > 100 m + rests
7 = Regular chair	7 = Ambulates > 100 m
8 REPOSITION IN WHEELCHAIR	14 WHEELCHAIR MOBILITY
1 = Three people/mechanical lift/bed bound	1 = Unable to propel
2 = Total assist	2 = In room < 5m
3 = One person maximum	3 = < 10m
4 = One person moderate	4 = < 30m + doorways
5 = One person minimum/set up chair	5 = < 50m + doorways
6 = Supervision/verbal cue	6 = < 100M + doorways
7 = Independent, slow	7 = Institution and elevators
9 SUPPORTED SITTING DURATION	15 & 16 UPPER EXTREMITY RIGHT/LEFT
1 = Bed bound/lounge chair back angle > 120	1 = No active movement
2 = >5 min < 10 min	2 = Movement not functional
3 = < 30 min	3 = Stabilize/weight bear
4 = < 2 hours	4 = Points at objects
5 = > 2 hours	5 = Assist in dressing (lifts arm)
6 = ≥ 3 hours (half day)	6 = Finger food/touch face
7 = < 6 hours (full day)	7 = Drinks from cup/utensils to eat/comb hair, brush teeth

Time taken to complete (in minutes) [ ]

PATCH
Posture and mobility in care homes

Resident Booklet

EQ-5D-5L

Please write today's date

| Day | Month | Year |

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ☐
I have slight problems in walking about ☐
I have moderate problems in walking about ☐
I have severe problems in walking about ☐
I am unable to walk about ☐

SELF-CARE

I have no problems washing or dressing myself ☐
I have slight problems washing or dressing myself ☐
I have moderate problems washing or dressing myself ☐
I have severe problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ☐
I have slight problems doing my usual activities ☐
I have moderate problems doing my usual activities ☐
I have severe problems doing my usual activities ☐
I am unable to do my usual activities ☐

PAIN / DISCOMFORT

I have no pain or discomfort ☐
I have slight pain or discomfort ☐
I have moderate pain or discomfort ☐
I have severe pain or discomfort ☐
I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION

I am not anxious or depressed ☐
I am slightly anxious or depressed ☐
I am moderately anxious or depressed ☐
I am severely anxious or depressed ☐
I am extremely anxious or depressed ☐

☐

PATCH Pack v4.0 31/10/2017

238

PATCH
Posture and mobility in care homes

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health
you can imagine

— · 100
— 95
— 90
— 85
— 80
— 75
— 70
— 65
— 60
— 55
— · 50
— 45
— 40
— 35
— · 30
— 25
— 20
— 15
— · 10
— 5
— · 0

The worst health
you can imagine

Time taken to complete (in minutes)

PATCH Pack v4.0 31/10/2017

PATCH
Posture and mobility in care homes

Pain Thermometer Scale

Please write today's date [Day | Month | Year]   ☐ Or tick if same day as Section 1

Ask the resident to circle the words on the thermometer to indicate the intensity of current pain.
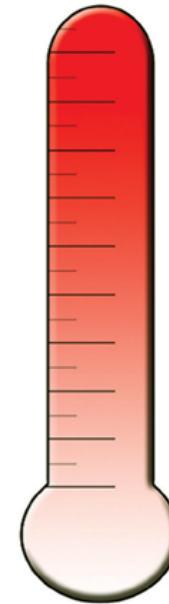
Pain as bad as could be

Extreme pain

Severe pain

Moderate pain

Mild pain

No pain

Time taken to complete (in minutes)

PATCH Pack v4.0 31/10/2017

PATCH

Person-Centred Care Assessment Tool

Please write today's date [Day] [Month] [Year]   ☐ Or tick if same day as Section 1

This questionnaire aims to measure the extent to which the care within a facility is experienced by staff as being person-centred. The questionnaire consists of 13 statements about the care. You are asked to decide to what extent you think the statements correspond to your own experiences working in your current facility.

Please **put a cross in the box** for the alternative that you think best describes your experience. It is important that you answer all the statements, so if you feel uncertain, pick the alternative closest to your experience.

	Disagree completely 1	Disagree 2	Neither agree or disagree 3	Agree 4	Agree completely 5
1. We often discuss how to give person-centred care.	☐	☐	☐	☐	☐
2. We have formal team meetings to discuss residents' care.	☐	☐	☐	☐	☐
3. The life history of the residents is formally used in the care plans we use.	☐	☐	☐	☐	☐
4. The quality of the interaction between staff and residents is more important than getting the tasks done.	☐	☐	☐	☐	☐
5. We are free to alter work routines based on residents' preferences.	☐	☐	☐	☐	☐
6. Residents are offered the opportunity to be involved in individualised everyday activities.	☐	☐	☐	☐	☐
7. I simply do not have the time to provide person-centred care.	☐	☐	☐	☐	☐
8. The environment feels chaotic.	☐	☐	☐	☐	☐
9. We have to get the work done before we can worry about a homelike environment.	☐	☐	☐	☐	☐
10. This organisation prevents me from providing person-centred care.	☐	☐	☐	☐	☐
11. Assessment of residents' needs is undertaken on a daily basis.	☐	☐	☐	☐	☐
12. It is hard for residents in this facility to find their way around.	☐	☐	☐	☐	☐
13. Residents are able to access outside space as they wish.	☐	☐	☐	☐	☐

PATCH

Kiersma-Chen Empathy Scale

Please write today's date [Day] [Month] [Year]   ☐ Or tick if same day as Section 2

The following questions relate to your attitudes and feelings **towards residents in care homes**. Please mark the number on the scale below that indicates your level of agreement or disagreement with each statement, where 1=strongly disagree, 2=disagree, 3=somewhat disagree, 4=neutral, 5=somewhat agree, 6=agree, and 7=strongly agree.

	Strongly Disagree 1	Disagree 2	Somewhat Disagree 3	Neutral 4	Somewhat Agree 5	Agree 6	Strongly Agree 7
1. It is necessary for a healthcare practitioner to be able to comprehend someone else's experiences.	O	O	O	O	O	O	O
2. I am able to express my understanding of someone's feelings.	O	O	O	O	O	O	O
3. I am able to comprehend someone else's experiences.	O	O	O	O	O	O	O
4. I will not allow myself to be influenced by someone's feelings when determining the best treatment.	O	O	O	O	O	O	O
5. It is necessary for a healthcare practitioner to be able to express an understanding of someone's feelings.	O	O	O	O	O	O	O
6. It is necessary for a healthcare practitioner to be able to value someone else's point of view.	O	O	O	O	O	O	O
7. I believe that caring is essential to building a strong relationship with residents.	O	O	O	O	O	O	O
8. I am able to view the world from another person's perspective.	O	O	O	O	O	O	O
9. Considering someone's feelings is not necessary to provide patient-centered care.	O	O	O	O	O	O	O
10. I am able to value someone else's point of view.	O	O	O	O	O	O	O
11. I have difficulty identifying with someone else's feelings.	O	O	O	O	O	O	O
12. To build a strong relationship with residents, it is essential for a healthcare practitioner to be caring.	O	O	O	O	O	O	O
13. It is necessary for a healthcare practitioner to be able to identify with someone else's feelings.	O	O	O	O	O	O	O
14. It is necessary for a healthcare practitioner to be able to view the world from another person's perspective.	O	O	O	O	O	O	O
15. A healthcare practitioner should not be influenced by someone's feelings when determining the best treatment.	O	O	O	O	O	O	O

Staff Booklet — PATCH

PATCH — Posture and mobility in care homes   **Staff Booklet**

Posture and Movement Questionnaire

Please write today's date   Day   Month   Year   ☐ Or, tick if same day as Section 3

Please answer each question by circling a number between 1 to 5 on the scale; where 1 = not at all, and 5 = a lot /very

	Not at all				A lot / Very
How well do you understand what good sitting posture is, and why it is important for the comfort and wellbeing of residents?	1	2	3	4	5
How confident are you that you can help residents get into a good position in a chair when they can't do this for themselves?	1	2	3	4	5
How confident are you that you can help residents get into a good position in bed when they can't do this for themselves?	1	2	3	4	5
How well do you understand the physical benefits of activity for older adults?	1	2	3	4	5
How well do you understand how activity can help a resident to feel better?	1	2	3	4	5
How confident are you that you have the practical skills to help residents keep active and move well?	1	2	3	4	5
How confident are you that you can skilfully help residents to roll over in bed?	1	2	3	4	5
How skilfully do you feel that you can help residents to eat and drink when they need assistance?	1	2	3	4	5
How confident are you that you have the knowledge and skills to help residents avoid pressure sores?	1	2	3	4	5
How confident are you that you have the knowledge and skills to help residents to reduce their changes of falling?	1	2	3	4	5

Care Home Booklet — PATCH

PATCH — Posture and mobility in care homes   **Care Home Booklet**

About the Care Home

Please write today's date   Day   Month   Year

Has there been a change in home ownership since the last researcher visit? ☐ Yes ☐ No

If yes, home ownership ☐ Independent
☐ Part of a chain
☐ Local Authority

Please inform CTRU and the Trial Manager of the new owner's details

Number of beds in the whole home ☐ Beds

Does the home have any specialist units? ☐ Yes ☐ No

If yes, specify ☐ Nursing ⟶ Number of beds ☐ Beds
☐ Dementia ⟶ Number of beds ☐ Beds
☐ Rehabilitation /intermediate care ⟶ Number of beds ☐ Beds
☐ Other, please specify ⟶ Number of beds ☐ Beds

Does the home use telemedicine facilities? ☐ Yes ☐ No

PATCH
Posture and mobility in care homes

Has the care home been inspected by the CQC since the last researcher visit? ☐ Yes ☐ No

If yes, date of inspection [Day | Month | Year]

Has the care home had any outbreaks of D&V or any other communicable illnesses since the last researcher visit? ☐ Yes ☐ No

If yes, please give details

Has the care home been temporarily closed since the last researcher visit? ☐ Yes ☐ No

If yes, please give details

Has the care home agreed to take part in any other research since the last researcher visit? ☐ Yes ☐ No

If yes, please give details
(E.g. name of project, name of researcher/ Chief Investigator etc.)

PATCH
Posture and mobility in care homes

About the Care Home Manager

Please write today's date [Day | Month | Year] ☐ Or tick if same day as Section 1

Is the manager the same as at the last researcher visit?

☐ Yes ⟶ Skip to section 3

☐ No ⟶ Please record the new manager details in this section

New home manager initials [ ]

New home manager date of birth [Day | Month | Year]

Manager trial number [ ]
(To be completed from the Staff Tracker)

Date started in manager role [Day | Month | Year]

Previous roles within this home
(Tick all that apply)
☐ None – joined as home manager
☐ Worked previously as deputy manager or equivalent
☐ Worked previously as direct care worker
☐ Worked previously here in another role, please specify
[ ]

Length of time working as a care home manager overall
☐ ≤2 years
☐ 2 – 5 years
☐ 5 – 10 years
☐ >10 years

Length of time working in care homes overall
☐ ≤5 years
☐ 5 – 10 years
☐ >10 years

Highest qualification
☐ None
☐ O Level / GCSE / NVQ 2 / QCF level 1 or 2
☐ A Level / NVQ 3 / QCF level 3 / Registered nursing qualification
☐ NVQ 4 / Certificate or Diploma of Higher Education/ Foundation degree / QCF level 4 or 5
☐ Advanced diploma / Bachelor degree / QCF level 6
☐ Postgraduate Certificate, Diploma or Master's degree / QCF level 7
☐ Doctorate (PhD) / QCF level 8
☐ Other, please specify [ ]

Usual Care Details

Please write today's date [Day | Month | Year]   ☐ Or tick if same day as Section 2

Training in Manual Handling / Moving and Handling of People

Has there been a change in training provider or policy since the last researcher visit?

☐ Yes ➤ Please record the details below

☐ No ➤ Please skip to Other Training section

Most often used training provider [   ]

Total number of external training providers [   ]

What is the training policy?
☐ Provided upon appointment *(e.g. within first week)*
☐ Provided within 1 month of appointment
☐ Provided within 3 months of appointment
☐ Other, please specify [   ]

How often is a refresher provided?
☐ Every 6 months
☐ Every 12 months
☐ Other, please specify [   ]

Is there a dedicated lead? ☐ Yes ☐ No

Other Training

Is training provided in health and safety? ☐ Yes ☐ No

Is training provided in safeguarding? ☐ Yes ☐ No

Note:
• The following two questions are asking about training other than the Skilful Care training
• Please remind the manager/delegate that you are blind to the care home's allocation

Has any other training been provided to staff since the last researcher visit? ☐ Yes ☐ No

If yes, what was the training? [   ]

Do any health professionals regularly visit the home to provide guidance on posture and mobility? *(E.g. physiotherapist, occupational therapist)* ☐ Yes ☐ No

If yes, please give details [   ]

Current Initiatives at the Home

Does the home engage with any **service-level special initiatives**? ☐ Yes ☐ No
(E.g. for pressure care, dementia care, falls, increasing mobility, provision of activities)

If yes, please give details [   ]

Have any **new procedures or care processes started** since the last researcher visit? ☐ Yes ☐ No

If yes, please give details [   ]

Recent Care Home Changes

Have there been any **organisational changes** since the last researcher visit? ☐ Yes ☐ No

If yes, please give details [   ]

Have there been any **new staff roles introduced** since the last researcher visit? ☐ Yes ☐ No

If yes, please give details [   ]

Have any **voluntary measures to improve standards** been introduced since the last researcher visit? ☐ Yes ☐ No

If yes, please give details [   ]

PATCH

About the Residents in the Care Home Unit(s) participating in the trial

Please write today's date | Day | Month | Year | ☐ Or tick if same day as Section 3

About ALL Residents

Number of beds in the participating unit(s)	☐ Beds
Number of **temporary** residents	☐ Residents
Number of **permanent** residents	☐ Residents
Number of **self-funded** residents	☐ Residents

Cost of a standard self-funded nursing place without top up £ ☐ Per week

Cost of a standard self-funded residential place without top up £ ☐ Per week

On average, how many residents were present on the unit(s) since the last researcher visit?
(i.e. how full was the unit(s)?) ☐ Residents

About the Permanent Residents

How many **unplanned GP call-outs** have residents had since the last researcher visit?	☐
How many residents does this relate to?	☐ Residents
How many **falls** that **did not** result in hospitalisation have residents had since the last researcher visit?	☐
How many residents does this relate to?	☐ Residents
How many **falls** that **did** result in hospitalisation have residents had since the last researcher visit?	☐
How many residents does this relate to?	☐ Residents
Total number of hospital bed days	☐
How many **unplanned hospital admissions (excluding falls)** have residents had since the last researcher visit?	☐
How many residents does this relate to?	☐ Residents
Total number of hospital bed days	☐
How many **pressure ulcers** have there been since the last researcher visit?	☐
How many residents does this relate to?	☐ Residents
How many **referrals to wheelchair services** have there been since the last researcher visit?	☐
How many **referrals to chair services** have there been since the last researcher visit?	☐
How many residents have **died** since the last researcher visit?	☐ Residents

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PATCH

About the Care of the Residents

Has care of the residents resulted in any other additional resources being used since the last researcher visit? (E.g. additional staffing required if they needed intensive one-to-one care; special aids or equipment such as chairs, wheelchairs, hoists or mobility devices.)   ☐ Yes ☐ No

If yes, please give details

Details of the additional resources	Who paid for this?
Additional resource or equipment: .... Total cost (if known): £.........	☐ NHS ☐ Social care ☐ Care home ☐ Resident or family
Additional resource or equipment: .... Total cost (if known): £.........	☐ NHS ☐ Social care ☐ Care home ☐ Resident or family
Additional resource or equipment: .... Total cost (if known): £.........	☐ NHS ☐ Social care ☐ Care home ☐ Resident or family
Additional resource or equipment: .... Total cost (if known): £.........	☐ NHS ☐ Social care ☐ Care home ☐ Resident or family

Has any equipment ceased to be used in the care of the residents since the last researcher visit?   ☐ Yes ☐ No

If yes, please give details

Time taken to complete (in minutes) ☐

PATCH
Posture and mobility in care homes

About the Staff in the Care Home Unit(s) participating in the trial

Please write today's date [Day | Month | Year]   ☐ Or tick if same day as Section 4

Staffing Levels

Total number of staff (ALL staff including domestic, catering, etc.)	[ ]
Total number of staff who have direct resident care contact	[ ] → The Staff Booklet should be given to all these staff

Of the staff who have direct resident care contact:

Number of **permanent** staff	[ ]
Number of **agency** staff	[ ]
Number of **bank** staff	[ ]
Number of staff who have **left** the home since the last researcher visit	[ ]
Number of staff who have **joined** the home since the last researcher visit	[ ]
Number of days lost due to staff sickness since the last researcher visit	[ ]
How many staff does this relate to?	[ ]
How many staff have had sickness episodes due to joint and/or muscle pain since the last researcher visit? (E.g. lower back, upper back, neck)	[ ]

} Update the Staff Tracker

PATCH
Posture and mobility in care homes

Staff Profile – Contracted Staff

NB: This is just the staff in the care home unit(s) participating in the trial

Please indicate in the boxes below the number of staff and their contracted hours for each staff role, for the last week.

Example

If the unit(s) has 5 agency nurses that work 6–15 hours and 3 that work 30–40 hours you would write the following:

Role	0–6 hrs	6–15 hrs	15–30 hrs	30–40 hrs	40+ hrs
Agency Nurse		5		3	

Role	0–6 hrs	6–15 hrs	15–30 hrs	30–40 hrs	40+ hrs
Administration (e.g. reception, office staff)					
Ancillary (e.g. laundry, catering, domestic, handyperson)					
Nurse manager					
Nurse					
Nurse (agency)					
Senior carer					
Senior carer (agency)					
Carer					
Carer (agency)					
Activities coordinator					
Activities coordinator (agency)					
Physiotherapist					
Physiotherapist (agency/freelance)					
Deputy manager					
Manager					

Other please list:

	0–6 hrs	6–15 hrs	15–30 hrs	30–40 hrs	40+ hrs

Staff Profile – Visiting Staff

NB: This is just the staff in the care home unit(s) participating in the trial

Please indicate (tick) the frequency of visits for each role, for the last 3 months.

Example

If the unit(s) has twice weekly visits from an NHS occupational therapist (not necessarily the same person each time) you would tick the following:

Role	Daily	Twice a week	Once a week	Once a fortnight	Once a month	Other	If other, please specify:
NHS Occupational Therapist	☐	☑	☐	☐	☐	☐	

Role NHS & Social Care Staff	Daily	Twice a week	Once a week	Once a fortnight	Once a month	Other	If other, please specify:
GP	☐	☐	☐	☐	☐	☐	
Practice nurse	☐	☐	☐	☐	☐	☐	
District nurse	☐	☐	☐	☐	☐	☐	
Tissue viability nurse	☐	☐	☐	☐	☐	☐	
Advanced nurse practitioner	☐	☐	☐	☐	☐	☐	
Community matron	☐	☐	☐	☐	☐	☐	
Health visitor	☐	☐	☐	☐	☐	☐	
Member of community mental health team	☐	☐	☐	☐	☐	☐	
Social worker	☐	☐	☐	☐	☐	☐	
Speech and language therapist	☐	☐	☐	☐	☐	☐	
Occupational therapist	☐	☐	☐	☐	☐	☐	
Podiatrist/Chiropodist	☐	☐	☐	☐	☐	☐	
Physiotherapist	☐	☐	☐	☐	☐	☐	
Community pharmacist	☐	☐	☐	☐	☐	☐	
Other please list:							
	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	
Private Staff *(e.g. private physiotherapist)*, please list:							
	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	

Appendix 4 Interview topic guide

Opening questions

- Could you tell me a little about your role here at .....[care home]?

- Could you tell me about how you got involved in providing information for the PATCH study?

- How did you feel about doing it?

- What's it been like for you? (time, fit with workload, etc.)

- What did you think about the types of questions we were asking?

Resident data collection

For staff informants

I'd like to go through the study questionnaires and ask for your thoughts on them please. *(Reference staff informant booklet)*

For each questionnaire (EQ-5D-5L proxy, FAC, PAM-RC, Barthel ADL, CCAM):

- Could you tell me how you found this?

- How relevant were the questions to the residents? (*prompt for thoughts on anything that might be missing that is relevant, which questions are and which aren't relevant*)

Care home level data collection

For managers

- How did you find the care home booklet? (G*o through each section of the booklet - what was easy, what was difficult and why.*)

- Did we ask about anything you didn't think was important?

- …and not ask about anything that you think **is** important?

- How did you feel about the time spent completing this?

For staff informants and managers

- What resident information do you collect (and report) on a routine basis?

- What are your thoughts on how we might better collect data for research?

Staff data

We asked all care staff to fill in a questionnaire booklet about themselves (Person-Centred Care Assessment Tool, Empathy Scale, Posture and Movement Questionnaire).

- Did you complete this? If so, how did you find it?

- Either way, did you hear anything from staff about their thoughts on the booklet?

  (*e.g. Did they understand what it was for? How relevant did they think it was to their daily work? How easy was it to understand? Was it quick to do?*)

- What are people's thoughts on completing the same booklet more than once (*i.e. at the start and at the follow-up time points*)?

- Do you think there are other ways we could collect information from staff that would work better?

Closing questions

- Is there anything else you think I need to know about collecting data for research in care homes?

- Do you have any questions for me?

Appendix 5 Data available in care homes

This table illustrates the data reported by care staff and researchers as being routinely available in care home records.

Routinely collected data	Notes
Data about individual residents	
Falls and other serious injuries	
Hospital admissions - including admission and discharge dates	
Care plans - multiple plans for daily care including eating / feeding, drinking (fluid charts), hearing, vision, mobility (including use of assistive equipment), moving and handling, personal hygiene, pressure care (skin integrity, turning requirements), sleep, dementia, other illnesses, medication, need for external HCPs. Also includes personal history.	One home mentioned having tools to measure anxiety and depression. This information would be kept in the care plan.
Daily care notes (ADL) - personal care (including colostomy and catheter care), independence, mobility, continence, fluid intake, diet, weight monitoring (if needed).	
Nursing notes	Includes medications
Professional visit records - GP and other HCP visits	This is not always recorded in care home records - for example, district nurses might record visit details in their NHS Trust records.
Data aggregated for the whole home	
Incidents / accidents (infections, falls)	Reporting time frame and dates for collating this information varied by home.
No. hospital admissions	As above for incidents. One home noted that this doesn't include admission and discharge dates.
Complaints	
Safeguarding incidents	
Equipment	Some homes had an equipment log book
No. of staff who have received mandatory training	
No. agency staff	
Staff who leave	
Staff sickness	Not all homes documented this, and it was often in individual rotas rather than centrally collated.