Full title: An intervention to maintain independence in People living With Dementia, living in their own homes, who have already fallen: a multi-centre, two-arm pilot cluster randomised controlled trial

Short title: Maintaining Independence in People with Dementia who had a fall: a pilot cluster randomised controlled trial (the Maintain Study)

IRAS ID: 323555

Sponsor ref: 2307452

ISRCTN No: ISRCTN16413728

Sponsor:

Royal Devon University Healthcare NHS Foundation Trust

Barrack Road

Exeter, EX2 5DW

Email: Rde-tr.RDEResearch@NHS.net

Tel: 01392 406075

Funder:

This study is funded by the Alzheimer's Society and has been awarded a project grant with a grant period of 36 months. The views expressed are those of the author(s) and not necessarily those of Alzheimer's Society.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies and serious breaches of GCP from the study as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:

Signature: DocuSigned by: EF9FA00DF8A9463... Date: 14 November 2023 | 00:41 P

...../...../.....

Name (please print):

Alison Kerridge

Position: Sponsor Representative

Chief Investigator:

Signature: DocuSigned by: Louise Allan 950AAA26F8F547D... Date: 14 November 2023 | 09:21 G

...../...../.....

Name: (please print):

Louise Allan

(Optional)

Statistician:

Signature: DocuSigned by: Obi Ukoumunne CE39F71F1C3642A... Date: 15 November 2023 | 19:58 G

...../...../.....

Name: (please print):

Obi Ukoumunne

Position: Professor in Medical Statistics

KEY TRIAL CONTACTS

Role	Contact details
Chief Investigator	Prof Louise Allan, Professor of Geriatric Medicine University of Exeter, EX1 2LU Tel: 01392726025 Email: L.Allan@exeter.ac.uk
Clinical trials unit	Bethany Whale Trial Manager Exeter Clinical Trials Unit University of Exeter, EX1 2LU Email: MaintainStudy@exeter.ac.uk
Sponsor representative	Alison Kerridge Royal Devon University Healthcare NHS Foundation Trust Exeter, EX2 5DW Email: Rde-tr.RDEResearch@NHS.net
Funder representative	Julia Collins Research Grants Officer Alzheimer's Society Julia.Collins@alzheimers.org.uk
Co-investigator	Prof Rowan Harwood Professor of palliative and end of life care/ Clinical Consultant Geriatrician University of Nottingham Email: Rowan.Harwood@nottingham.ac.uk
Co-investigator	Professor Victoria Goodwin Professor of Ageing and Rehabilitation University of Exeter Email: V.Goodwin@exeter.ac.uk
Co-investigator	Prof Obioha Ukoumunne Professor in Medical Statistics University of Exeter Email: O.C.Ukoumunne@exeter.ac.uk
CTU Statistician	James Connors Research Fellow in Medical Statistics Exeter Clinical Trials Unit University of Exeter, EX1 2LU Email: J.Connors@exeter.ac.uk
Co-investigator	Prof Adam Gordon

	Professor of the Care of Older People University of Nottingham Email: adam.gordon@nottingham.ac.uk
Co-investigator	Dr Thomas Jackson Clinician Scientist in Geriatric Medicine University of Birmingham Email: T.Jackson@bham.ac.uk
Patient & public involvement and engagement lead	Ms Rachael Litherland Director, Innovations in Dementia CIC PO Box 616, Exeter, EX1 9JB Email: rachael@myid.org.uk
Co-investigator	Dr Sarah Morgan-Trimmer Senior research fellow, qualitative researcher University of Exeter Email: S.Morgan-Trimmer@exeter.ac.uk
Co-investigator	Professor Claire Hulme Professor of Health Economics University of Exeter Email: c.t.hulme@exeter.ac.uk
Physiotherapist	Dr Abi Hall Research Fellow Physiotherapist University of Exeter Email: a.hall4@exeter.ac.uk
Co-investigator	Dr Robert Barber Consultant Old Age Psychiatrist Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust Email: robert.barber@cntw.nhs.uk
Co-investigator	Dr Steve Parry Consultant Acute Physician and Geriatrician/ Honorary Senior Lecturer Newcastle upon Tyne Hospitals NHS Foundation Trust Email: steve.parry1@nhs.net
Co-investigator	Prof Simon Conroy Honorary Professor of Geriatric Medicine Central and North West London NHS Foundation Trust Email: simon.conroy@ucl.ac.uk
Co-investigator	Prof Chris Fox Professor of Clinical Psychiatry

	University of Exeter Email: christopher.fox@exeter.ac.uk
Occupational therapist	Ashima Sharma Research Fellow Occupational Therapist University of Exeter Email: ashima.sharma@nhs.net
Chair of the Trial Steering Committee	Prof Cherry Kilbride Professor of Neurorehabilitation and Applied Clinical Research Brunel University Email: Cherry.Kilbride@brunel.ac.uk

i. Table of contents

Contents

ii. List of abbreviations

ADL	Activities of Daily Living
AE	Adverse Event
CAPA	Corrective And Preventative Action
CCG	Clinical Commissioning Group
CI	Chief Investigator
CRF	Case Report Form
CRN	Clinical Research Network
CTU	Clinical Trials Unit
DAD	Disability Assessment for Dementia
DMP	Data Management Plan
ED	Emergency Department
EDC	Electronic Data Capture
EQ-5D-5L	European Quality of Life Instrument (EuroQol)
ExeCTU	Exeter Clinical Trials Unit
FES	Falls Efficacy Scale
GAS	Goal Attainment Scaling
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
HRQoL	Health Related Quality of Life
HUQ	Health Utilisation Questionnaire
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trials Number
JDR	Join Dementia Research
MDT	Multidisciplinary Team
Mini-ACE	Mini-Addenbrooke's cognitive examination
MRC	Medical Research Council
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NHS	National Health Service
OT	Occupational Therapist
PI	Principal Investigator
PIS	Participant Information Sheet

PPIE	Patient and Public Involvement and Engagement
PT	Physiotherapist
PWD	Person or people with Dementia
QOF	Quality Outcomes Framework
QOL-AD	Quality of Life in Alzheimer's Disease
RCT	Randomised Controlled Trial
R&D	Research and Development
REC	Research Ethics Committee
RSW	Rehabilitation Support Worker
RUSAE	Related Unexpected Serious Adverse Event
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
TMF	Trial Master File
TSC	Trial Steering Committee
TUG	Timed Up and Go
USM	Urgent Safety Measure
ZBI-12	Zarit Burden Interview-12 item

iii. STUDY SUMMARY

Table 1 Study summary

Study Title	An intervention to maintain independence in People living With Dementia, living in their own homes, who have already fallen: a multi-centre, two-arm pilot cluster randomised controlled trial	
Internal ref. no. (or short title)	Maintain Study	
Clinical Phase	II	
Study Design	Pilot cluster randomised controlled trial, two-arm, multidisciplinary intervention with a process evaluation	
Participants	People with dementia aged over 50 years old living in their own homes, who have sustained at least one fall in the last six months, their unpaid caregivers and professionals caring for them.	
Planned Sample Size	60 people with dementia and carer participant pairs 24 healthcare professionals 6 research nurses	
Treatment duration	12 weeks with booster sessions at 16, 20 and 24 weeks	
Follow up duration	6 months	
Planned Study Period	7-month set-up, 6 months recruitment, 7 months follow-up, 3 months analysis and intervention refinement (23 months total)	
	Objectives	Outcome Measures
Pilot cluster RCT study	The primary objective is to deliver a pilot cluster RCT of an intervention to maintain independence in PWD, living in their own homes, who have already fallen.	1. Activities of daily living (ADL) will be assessed with the Disability Assessment for Dementia (DAD) 2. Patient participant quality of life assessed with the European Quality of Life Instrument (EQ-5D-5L) 3. Quality of Life - Alzheimer's Disease (QOL-AD) 4. International short form Falls Efficiency Scale (FES) 5. Timed Up and Go test 6. Goal Attainment Scaling (intervention only) 7. Falls diary

		8. Carer burden assessed with the Zarit burden interview 12 (ZBI-12) 9. Carer participant quality of life assessed with the European Quality of Life Instrument (EQ-5D-5L) completed by the carer 10. Carer rated Patient participant quality of life assessed with the EQ-5D-5L proxy 11. Carer rated patient participant quality of life QoL-AD Proxy 12. Health and social care Utilisation Questionnaire (HUQ)
Intervention	A rehabilitation programme delivered in participants' homes. The programme consists of physical exercises and goal directed activities. The rehabilitation programme will be manualised and delivered by trained healthcare professionals with the assistance of an unpaid carer who is taking part in the study with the patient participant.	
Process evaluation	A sample of 18 persons with dementia/carer dyads and 24 healthcare professionals will be interviewed to explore their views on the intervention.	
Stop/Go criteria for progression to full trial	Definite Go ('green light'): • ≥ 40% of eligible patients consenting to pilot trial • ≥ 80% participants attend ≥ 60% of sessions as planned • Retention of ≥ 70% of consented participants for key outcome data at 6 months • An indication from qualitative work that the intervention is perceived as acceptable to both participants and professionals. Definite Stop ('red light'): • < 10% of eligible participants consenting to pilot trial • < 30% participants attend ≥ 60% of sessions as planned in a given intervention arm • retention of < 50% of consented participants for provision of key outcome data at 6 months • It is clear from the process data from participants and professionals that the intervention procedures have low fidelity in terms of content,	

	frequency, duration and quality and/or that the intervention is not feasible to deliver. Intermediate targets will be defined as amber and refinement of the study will be undertaken in conjunction with our PPIE panel and other key stakeholders. A decision as to whether to progress to planning a full trial will be discussed by the Trial Steering Committee.

iv. FUNDING AND SUPPORT IN KIND

The Alzheimer's Society is providing financial support for the research costs of this study. The University of Exeter is providing support for the investigators.

v. ROLE OF TRIAL SPONSOR AND FUNDER

The Royal Devon University Healthcare NHS Foundation Trust is the sponsor for this study. The sponsor has had input into the design of the study but overall responsibility for the design lies with the chief investigator (LA). The sponsor is responsible for authorising the initial submission to the research ethics committee (REC) and health research authority (HRA) and subsequent amendments, ensuring appropriate agreements and indemnity arrangements are in place, overseeing the conduct of the study and ensuring it adheres to the principles of good clinical practice (GCP) and the UK Policy Framework for Health and Social Care Research and for archiving at the end of the study. The sponsor is not responsible for and has no involvement in the data analysis or interpretation, or for writing manuscripts.

The Alzheimer's Society as funder is responsible for providing funds to cover the agreed research costs as part of a programme grant. The funder is not responsible for and has no involvement in data analysis or interpretation, or for writing manuscripts.

vi. ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Trial Steering Committee

The trial steering committee (TSC) will be composed of an independent chairperson with expert knowledge in the subject area and a minimum of two additional independent professional members and a minimum of one independent lay representative. The chief investigator and lead statistician will join the TSC as non-independent members.

The trial manager and representatives of the sponsor and the funder will be invited to attend TSC meetings as observers but will not be voting members.

The roles and responsibilities of the TSC are documented in the TSC charter, available upon request to the trial manager. The TSC will fulfil the roles of a trial steering committee and data monitoring committee for this study.

Trial Management Group

The trial management group (TMG) will be composed of the chief investigators, trial collaborators, the statisticians, qualitative researchers, health economist, co-applicants at regional sites, patient and public involvement (PPIE) lead, , a PPIE group member lay representative and the trial manager.

The TMG will write the protocol, statistical analysis plan (SAP) and participant-facing materials, obtain relevant approvals from an NHS research ethics committee (REC) and the Health Research Authority (HRA), coordinate with NHS Trusts or research providers to set up sites and ensure the study is conducted according to the principles of GCP and the UK Policy Framework for Health and Social Care. The TMG will meet quarterly to monitor safety, key performance indicators and discuss and resolve emerging issues. A sub-set of the TMG will meet at least monthly to manage the day-to-day running of the study.

Members of the TMG will analyse the data, interpret the analyses, write reports to the funder and write and submit manuscripts to peer-reviewed journals.

Patient and Public Involvement and Engagement Group

A Patient and Public Involvement (PPIE) group, led by Rachael Litherland of "Innovations in Dementia", will inform the development of participant-facing materials, Health and social care

Utilisation Questionnaire and the intervention. The PPIE group will provide ongoing support for the duration of the study and will co-produce lay summaries of the results and advise on public dissemination.

vii. KEY WORDS:	Dementia, RCT, rehabilitation, multidisciplinary intervention

1. Background

PWD are ten times more likely to fall than people who do not have dementia [1]. After a fall they may have a poorer recovery than people without dementia and have an increase in dependency and poorer quality of life. In a previous NIHR Health Technology Assessment (HTA) project we developed an intervention for helping people living with dementia (PWD) to recover after a fall and preventing further falls [2]. In the present study we aim to carry out a pilot cluster randomised controlled trial (RCT) of a modified version of this intervention. This will enable us to determine whether it is feasible to proceed to a full definitive cluster randomised controlled trial of the intervention. We define decision rules for progression to the main trial.

2. Rationale

Falls and fractures cost the UK more than £2 billion per year [3]. Recent estimates suggest that there are 850,000 people living with dementia (PWD) in the UK, of whom 70% live in the community. PWD living in their own home sustain almost 10 times more incident falls than other older people and their falls are more likely to result in injury. They are less likely to recover well than cognitively intact older people. For older people without dementia, there is good evidence that a multifactorial intervention delivered by a specialist falls service will reduce incidence of falls. However, effectiveness for PWD is unclear. After a fall, there is little evidence for how to help PWD recover, with most studies having focussed solely on hip fracture, with inconsistent benefits reported. The current NICE guidelines for dementia did not find any evidence of effective interventions for falls specific to PWD, but nevertheless recommended that PWD are referred to falls services, with the caveat that such services may not be suitable for people with more severe dementia [4]. Given that the effectiveness of falls interventions for PWD has not been demonstrated, it is important that appropriate, well designed trials are carried out to avoid ineffective and non-cost-effective interventions continuing in the NHS.

There is a range of ways in which improved management of falls might reduce adverse sequelae for PWD and carers. Firstly, if physical recovery from the fall itself is poor, further restriction of mobility may occur and independence in activities of daily living (ADLs) may decline. These restrictions may then result in reduced social participation, increased burden for carers and increased need for formal care. Such problems lead to reduced wellbeing and quality of life for PWD, and substantial costs to both health and social care systems. A successful falls intervention may support the maintenance or reduce the degree of physical decline and loss of independence. Secondly, any fall in older people, whether injurious or not, is known frequently to result in fear of falling and psychological morbidity which may lead the person to restrict their mobility, resulting in deconditioning and a cycle of further loss of mobility and frailty [5]. A successful intervention may reduce psychological morbidity and improve wellbeing in PWD [6]. Thirdly, the cost of further falls to health and social care is very high. Prevention of further falls may reduce the further decline in independence and risk of institutionalisation in PWD.

There have been no published trials which have aimed to investigate the effectiveness of interventions to improve independence after a fall in PWD. There have been a number of trials of interventions to increase physical activity in PWD which have shown improvements in mobility and physical functioning [7]. There are few trials which have aimed to prevent falls in PWD [8]. Of four published

randomised controlled trials (RCTs), two were pilot studies [9, 10] and two were large RCTs of good quality [11, 12]. Three of these trials did show some evidence of reduced fall rates with exercise training programmes in PWD. One trial did not report a significant reduction in the rate of falls; however, the intervention significantly reduced the rate of falls in participants with better baseline physical function and the proportion of multiple fallers [12]. One further trial of a falls intervention programme is ongoing, but this is a primary prevention study in people with early dementia or mild cognitive impairment who have not necessarily already fallen [13]. There are even fewer studies in PWD who have already fallen. The only RCT of an intervention which aimed to reduce falls in people with cognitive impairment who had had a fall did not show a significant reduction in falls, but the intervention in the trial was not specifically tailored to PWD and did not aim to promote independence in activities of daily living [14]. There is good reason to believe that the outcomes of fall intervention programmes may be different in PWD who have already begun to fall than those who have not fallen. Such individuals are likely to be more cognitively impaired and their future risk of falls is higher [1]. Their cognitive impairment makes them less likely to be suitable for falls programmes that have not been adapted for PWD and specific adaptations of the approaches to exercise may be required.

The participant population are PWD living in their own homes, who have sustained at least one fall in the last six months, their unpaid caregivers and professionals caring for them. Participants could be vulnerable and may lack the capacity to provide informed consent.

In our previous NIHR HTA-funded project, we undertook extensive development work for a novel intervention for PWD who had sustained a fall requiring healthcare attention. In a realist review [15] we identified key principles for the intervention which included ensuring that the circumstances of rehabilitation are optimised for PWD, compensating for the reduced ability of PWD to self-manage, and equipping the workforce with the necessary skills and information to care for this patient group. Using a Delphi approach, we developed a 12-week complex intervention delivered to PWD in their own homes by a multidisciplinary team. Risk factors for falls were identified and addressed and an activity programme was developed, tailored to goals chosen by the PWD in conjunction with their carers. Exercise activities were tailored to the individual, embedded in their usual activities and are low risk. The intervention was successfully tested in 11 PWD, with the intervention being well received and outcome measurements also successfully collected. We identified two areas where we will refine the intervention before proceeding to the pilot trial: clarifying the involvement of Geriatricians in the intervention and improving carer support. In order to reduce the burden on participants, the intervention is designed to work alongside usual care. Before recruitment commences, a risk assessment will be completed and maintain throughout the duration of the study.

We propose to test the modified intervention in a pilot cluster RCT in preparation for a full trial.

3. Assessment and management of risk

3.1. Potential risks

As the patient population is made up of people living with dementia, they may lack the capacity to give informed consent and therefore be considered vulnerable.

The intervention is comprised of physical activity which could result in injuries being sustained.

Patient participants will undertake the intervention at their home without medical assistance available if injuries occur, such as if the participant falls.

There is the potential impact of increased burden on both the patient participant and the carer participant when taking part in this study compared to usual care.

Visits from research support workers and therapists to the patient participants home introduce the risk of COVID-19 infection during these home visits.

3.2. **Potential benefits**

Structured physical exercise rehabilitation could lead to improved physical functioning and independence with a reduced prevalence of falls.

The intervention will be undertaken at patient participant's homes, eliminating the need for travel to community or hospital appointments.

Inclusion of carers in the intervention could lead to long term benefits for both patients and carers as a result of having a greater understanding of their condition and the rehabilitation activities.

3.3. **Mitigation of risk**

Potential patient and carer participants will be fully informed of the risks and potential benefits before deciding whether to take part in the study, and will be required to provide informed consent before undertaking any research activity. Patients who lack capacity to provide informed consent will not be recruited into the study without obtaining a positive opinion from a consultee.

In collaboration with our PPIE group we have designed participant information sheets that are accessible to patients with dementia.

All participants must have an unpaid carer such as a family member or friend who normally spends at least one hour a week with the participant to be eligible to take part. The carer will have an integral role in supporting the patient participant with the intervention.

Expert healthcare professionals, including a physiotherapist and occupational therapist will deliver comprehensive training to rehabilitation support workers (RSW) who will deliver the intervention in the participant's home. RSWs will be provided with a comprehensive manual describing the intervention procedures.

The intervention will be tailored to the individual based on an initial assessment of physical function. Activities will be graded so that they remain challenging enough to encourage interest, motivation and improvement, without being so challenging that they are overwhelming and discourage participation.

To minimise patient participant burden, if a participant is receiving rehabilitation as part of usual care, the RSW will review the care package and choose activities from the intervention manual that complement rather than replicate the usual care activity.

The research team have considerable expertise in working with the patient population involved in this study in both a clinical and a research capacity and will undertake the study in full compliance with the

Mental Capacity Act 2005, the opinion of an NHS REC and the UK policy framework for health and social care research.

Each NHS Trusts' infection control policy and government guidelines will be followed at all times to minimise the risk of COVID-19 infection. Our patient population are likely to already receive home care as part of standard care, or have regular visits to healthcare settings so the risk of catching COVID-19 will never be zero but we will minimise the risk as much as possible.

4. Objectives and outcome measures

Primary research question: Is it feasible to conduct a research study of an intervention, in people with dementia aged over 50 years old, whilst demonstrating benefits in other patient-reported, professional-reported and cost-effectiveness outcomes.

4.1. Aim and primary objective

Aim: The aim of the study is to test the feasibility of conducting a research study of the intervention

Objective A: Deliver a pilot cluster RCT of an intervention to maintain independence in PWD, living in their own homes, who have already fallen

4.2. Secondary objectives

Objective B: to examine the implementation and acceptability of the intervention for participants and professionals, and mechanisms of impact, including the roles of geriatricians and carer support via a process evaluation.

Objective C: to test the cost-effectiveness framework for the full trial

Objective D: to perform iterative refinement of the intervention for the full trial.

Objective E: to assess potential threats to allocation concealment based on: whether the participants were unblinded prior to consent; whether more or fewer participants are recruited in the intervention arm than the control arm; whether the characteristics of the participants differ markedly between the trial arms; whether loss to follow-up differs markedly between the trial arms.

4.3. Outcome measures

The following outcomes will be assessed:

1. Activities of daily living (ADL) will be assessed with the Disability Assessment for Dementia (DAD) completed by an unpaid carer
2. Patient participant rated quality of life assessed with the European Quality of Life Instrument (EQ-5D-5L) completed by the PWD
3. Patient participant rated Quality of Life - Alzheimer's Disease (QOL-AD) completed by the PWD
4. International short form Falls Efficiency Scale (FES) completed by the PWD
5. Timed Up and Go test completed by the PWD
6. Goal Attainment Scaling (intervention only) completed by the PWD
7. Falls diary completed by the PWD with the aid of an unpaid carer if required
8. Carer burden assessed with the Zarit burden interview 12 (ZBI-12)
9. Carer participant rated quality of life assessed with the European Quality of Life Instrument (EQ-5D-5L) completed by the carer
10. Carer rated patient participant quality of life assessed with the EQ-5D-5L proxy
11. Carer rated patient participant quality of life QoL-AD Proxy
12. Health and social care Utilisation Questionnaire (HUQ)

See Table 2 for a list of objectives matched with the outcomes.

4.4. Success criteria and barriers to success

Success criteria are the progression criteria for proceeding to a full trial as given below.

Definite Go ('green light'):

- ≥ 40% of eligible patients consenting to pilot trial
- ≥ 80% participants attend ≥ 60% of sessions as planned
- Retention of ≥ 70% of consented participants for key outcome data at 6 months
- An indication from qualitative work that the intervention is perceived as acceptable to both participants and professionals.

Definite Stop ('red light'):

- < 10% of eligible participants consenting to pilot trial
- < 30% participants attend ≥ 60% of sessions as planned in a given intervention arm
- retention of < 50% of consented participants for provision of key outcome data at 6 months
- It is clear from the process data from participants and professionals that the intervention procedures have low fidelity in terms of content, frequency, duration and quality and/or that the intervention is not feasible to deliver.

Intermediate targets will be defined as amber and refinement of the study will be undertaken in conjunction with our PPIE panel and other key stakeholders. A decision as to whether to progress to planning a full trial will be discussed by the Trial Steering Committee.

Barriers to success include:

- Insufficient participants – mitigated by using several recruitment settings.
- Insufficient therapy time - mitigated by engaging with sites to ensure therapists will be available before randomisation.

4.5. Outcomes for the pilot cluster RCT

Table 2 Pilot cluster RCT outcomes

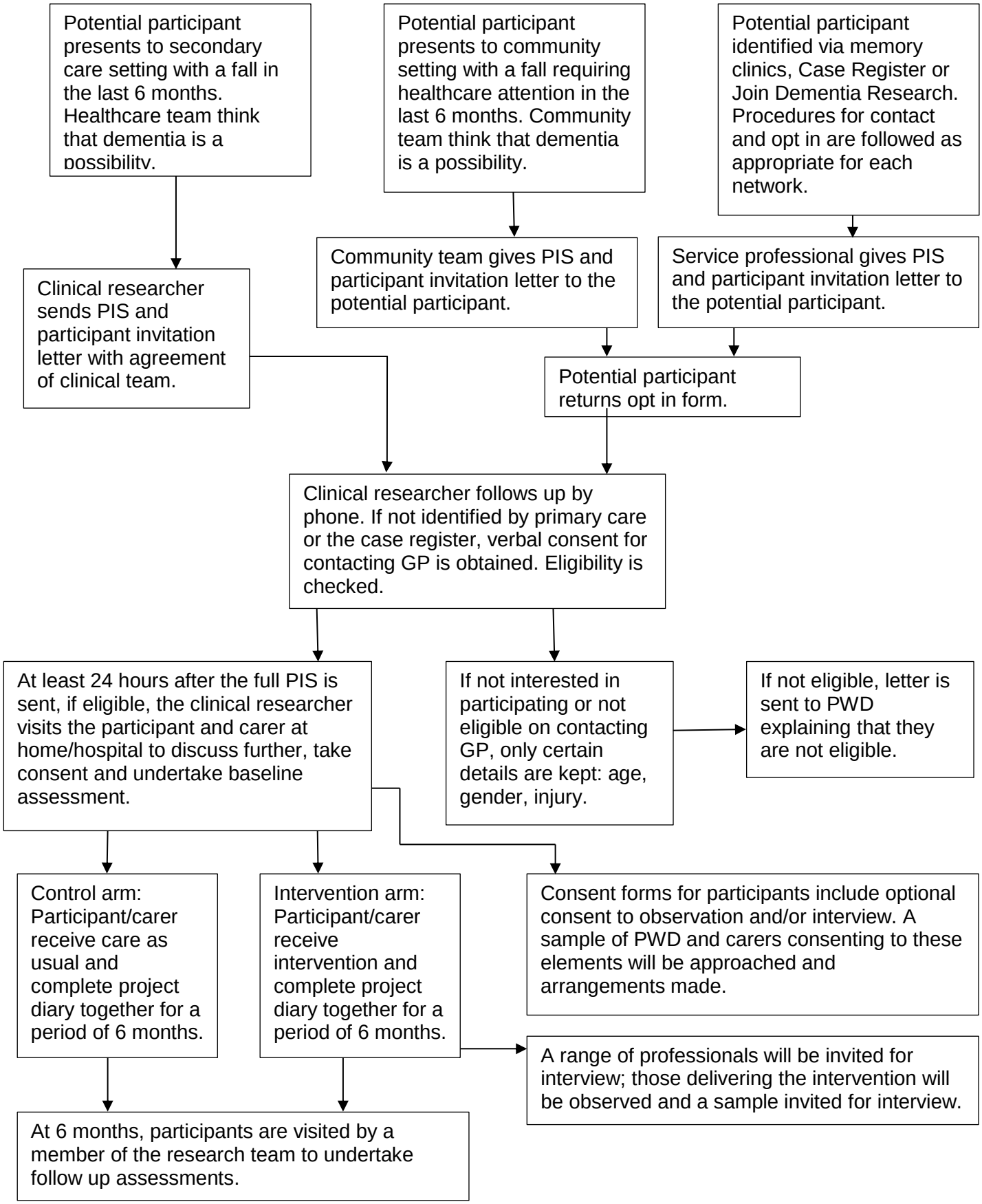
Measure	Description	Time point
Primary		
Activities of daily living (ADL) assessed with the Disability Assessment for Dementia (DAD)	The DAD is a standardised instrument measuring the functional ability of PWD in activities of daily living (ADLs) [16]. It is 40-item scale regarding the subject's involvement in ADL. Seventeen items address basic ADL (hygiene, dressing, continence, and eating), and 23 items relate to instrumental ADL (meal preparation, telephoning, going on an outing, finance and correspondence, medications, and leisure and housework). Items can be categorised as part of initiation, planning and organization, and effective performance subscales, with the total score used most frequently, as is proposed as the primary outcome. Non-applicable items (e.g., those that a patient did not participate in even before the onset of their illness) are excluded from scoring, with the final scores being converted to a percentage. Scores thus have a potential range from 0 to 100%, with higher percentage scores representing greater competence in ADL. It will be completed at baseline and 6 months. Each item can be scored: 1 point = Yes 0 point = No or non-applicable = N/A. A total score is obtained by adding the rating for each question and converting this total score out of 100. The items rated as N/A are not considered for the total score. For example: A score of 33 on 40 (maximum score) converted out of 100 = 82.5% A score of 33 on 38 (max. score with 2 N/A) converted out of 100=86.8% This will result in a final score, a percentage which provides an appreciation of global function in ADL. Higher scores represent less disability in ADL while lower scores indicate more dysfunction.	Baseline, 6 months
Secondary **Patient participants**		
European Quality of Life Instrument (EQ-5D-5L)	The EQ-5D-5L is a standardised instrument used to measure generic health-related quality of life [17]. It will be completed at baseline and 6 months by PWD with the capacity to complete the items.	Baseline, 6 months

Quality of Life - Alzheimer's Disease (QOL-AD)	The QOL-AD is a standardised instrument for measuring quality of life for PWD [18, 19]. It is a 13-item scale administered via an interview. It includes the domains of physical condition, mood, memory, functional abilities, interpersonal relationships, ability to participate in meaningful activities, financial situation, and global assessments of self as a whole and QOL as a whole. It will be completed at baseline and 6 months by PWD with the capacity to complete the items. Points are assigned to each item as follows: poor (1), fair (2), good (3), and excellent (4). The total score is the sum of all 13 items.	Baseline, 6 months
International short form Falls Efficiency Scale (Short-FES-I)	The psychological consequences of falling will be determined using the Short-FES-I [20]. This is a 7-item measure of falls efficacy (or fear of falling). It will be completed at baseline and 6 months by PWD with the capacity to complete the items. Points are assigned to each item as follows: not at all concerned (1), somewhat concerned (2), fairly concerned (3), and very concerned (4). To calculate the Short FES-I score when all items are completed, simply add the scores for each item together to give a total that ranges as follows: Short FES-I: minimum 7 (no concern about falling) to maximum 28 (severe concern about falling) Scoring with missing items If responses are missing on more than four items on more than two items (i.e.≥3) for Short-FES-I then the questionnaire scores cannot be used. If responses are missing on 2 or less on Short FES-I then it is possible to calculate a Short FES-I score. To do this first calculate the total score of the items which have been completed. Divide that score by the number of items completed and then multiply by 7. The new total score should be rounded up to the nearest whole number to give the score for an individual. For example, if scores on Short FES-I were: Item 1=2 Item 2=3 Item 3=missing Item 4=3 Item 5=2 Item 6=4 Item 7=missing Then 2+3+3+2+4=14/5 = 2.8×7= 19.6 which is rounded up to 20.	Baseline, 6 months
Timed Up and Go test	Patient participants stand up and walk 3 metres, turn around and walk back. The time taken to complete it is recorded. The test is scored as time in seconds. 10 seconds or less = normal 10 to 20 seconds = good mobility 20 to 30 seconds = problems with mobility	Baseline, 6 months

	A score of 14 or more seconds has been shown to indicate high risk of falls.	
Goal Attainment Scaling (GAS) (intervention only)	As part of the intervention, therapists will set individualised goals with participants. The goals will be agreed with the PWD by the therapists at the initial assessment and assigned 'weights'. GAS is a method of scoring the extent to which these goals are achieved in a way that is standardised for analysis [21, 22]. Progress towards goals will be measured at the final intervention visit, allowing a numerical score to be calculated at 6 months. Each goal is rated on a 5-point scale, with the degree of attainment captured for each goal area: If the patient achieves the expected level, this is scored at 0. If they achieve a better than expected outcome this is scored at: +1 (somewhat better) +2 (much better) If they achieve a worse than expected outcome this is scored at: -1 (somewhat worse) or -2 (much worse) Goals may be weighted to take account of the relative importance of the goal to the individual, and/or the anticipated difficulty of achieving it. Normally 3-4 goals are identified, which are incorporated into the single GAS score. Overall Goal Attainment Scores are then calculated by applying a formula: Overall GAS = 50 + $\frac{10\,\Sigma(w_i\,x_i)}{\sqrt{(0.7\,\Sigma w_i^2 + 0.3(\Sigma w_i)^2)}}$ Where: wi = the weight assigned to the *i*th goal (if equal weights, wi = 1) xi = the numerical value achieved (between –2 and + 2) A simple spreadsheet calculator is available for use.	Baseline, 6 months
Cognition assessed with mini ACE (Mini-ACE)	The Mini-ACE consists of 5 items and has a maximum score of 30	Baseline
Falls diary	Number of falls will be assessed through prospective completion of a diary during the 6 months of follow-up. Aid of an unpaid carer can be utilised if required. For each day, participants will be asked to record if they had any falls and, if so, explain the context and consequences of the fall. The data from the falls diary will be used to calculate the proportion of participants with one or more falls and the fall rate per person per year.	During the 6 months of follow up

Secondary **Carer participants**		
Carer burden assessed with the Zarit burden interview 12 (ZBI-12)	Carer burden will be measured using ZBI, a series of 12 questions designed to elicit the impact of the patient's disabilities on the life of the caregiver [23]. This will be completed with an informal carer at baseline and follow-up. 5-point scale from 0 to 4 Items. Items 1 to 21: Never (0) to Nearly always (4) Item 22: Not at all (0) to Extremely (4) Total scores are calculated as a summation of the 12 items with a range from a possible 0 to 48. A higher score indicates a greater caregiver distress/burden.	Baseline, 6 months
Carer participant quality of life assessed with the European Quality of Life Instrument (EQ-5D-5L)	The carer will assess their own HRQL using the EQ-5D-5L.	Baseline, 6 months
Carer rated Patient participant quality of life assessed with the EQ-5D-5L proxy	The carer will assess the patient's HRQL using the Proxy version 2 of the EQ-5D-5L.	Baseline, 6 months
Carer rated patient participant quality of life QoL-AD Proxy	The carer will assess the patient's HRQL using the Proxy version of the QOL-AD.	Baseline, 6 months
Health and social care Utilisation Questionnaire (HUQ)	Data on the use of health, social care and wider resources will be collected via the HUQ.	Baseline, 3 months and 6 months

5. Study schema



6. Study design

The study is a multi-centre, pilot cluster RCT of a rehabilitation programme intervention with embedded qualitative process evaluation. The PWD who have had a fall in the last six months are the patient participants; unpaid family members or friends of the patient participant are the carer participants. Patient participants and carer participants will be recruited in pairs, undertake the intervention, receive follow-up assessment at 28 weeks post-baseline assessment for the control group and 26 weeks after the initial assessment for the intervention group. The point at which follow-up assessment occurs varies between the control and intervention groups due to the assessment visits taking place for the intervention group during week 1 (see table 3). Each study site (cluster) will be randomly allocated to receive either the intervention or usual care. The intervention will include an assessment to identify any actions which need to be carried out to reduce the risk of falling or improve independence. This will be followed by a 12 week programme of activities facilitated by a team of therapists. Additional (booster) sessions will take place up to 6 months. The activities will be targeted at achieving personal goals chosen by the participants. We will follow participants up at 6 months to measure their independence in daily activities, mobility, fear of falling, falls, whether they achieved their goals, quality of life, caregiver burden and the health services and care they required. At the end of the trial we will know whether we should carry out a full trial to assess whether the intervention works and is good value for money.

6.1. Study setting

The study will be carried out in six research sites (clusters), reflecting a range of National Health Service (NHS) practice to allow for generalisability.

6.1.1. Community settings

Three community services will be used for recruitment:

- Primary care
- Paramedics
- Admiral nurses

The first setting will be in primary care: patients with a known diagnosis of dementia presenting with a fall in the last 6 months, at participating practices in the Clinical Commissioning Groups (CCGs) involved in the study.

Potential participants will also be identified by paramedics attending calls to a person with possible dementia presenting with a fall. This will apply to calls within the postcodes served by the participating CCGs.

Admiral nurses will identify patients with possible dementia, resident within the postcodes served by participating CCGs, who seek or have sought healthcare attention regarding a fall within the past 6 months.

6.1.2. Secondary care settings

Four secondary care services will also identify potential study participants:

- Emergency departments
- Supported discharge teams
- Rehabilitation outreach teams
- Memory clinics

Patients with possible dementia presenting with a fall in the last 6 months to any of these services in participating Trusts will be eligible if they are resident within the postcodes served by participating CCGs.

6.1.3. Research registers

We will also recruit potential participants from local research case registers. Participants on the case register have already given consent to be approached about potential research projects. Those registered with either service will be eligible for the study if they have had a fall within the last 6 months.

Join Dementia Research (JDR) can be utilised for participant recruitment. JDR is an on-line self-registration service that enables volunteers with memory problems or dementia, carers of those with memory problems or dementia and healthy volunteers to register their interest in taking part in research. The purpose of JDR is to allow such volunteers to be identified by researchers as potentially eligible for their studies. Researchers can then contact volunteers, in line with the volunteers preferred method of contact, to further discuss potential inclusion.

6.2. Participant eligibility criteria

Participants are PWD on the Primary Care Quality Outcomes Framework (QOF) Dementia register who have sustained at least one fall within six months prior to identification as a study participant. Recruitment will include patients presenting to community settings (primary care, admiral nurses, paramedics), patients presenting to secondary care settings (emergency departments, rehabilitation teams, mental health services) and patients listed on research registers. Carers will be screened and recruited to the study as a pair with the patient participant.

Carers are either a close family member or friend who receive no financial compensation for the care they provide to the patient participant. The PWD and their family members or friends will determine who will be identified as the carer for the study.

See Section 7.1.3 for details of professional participants who will be invited to take part in the embedded qualitative process evaluation.

6.2.1. Inclusion criteria patient participants

1. A diagnosis of dementia made prior to entry into the study. PWD must be on the Primary Care Quality Outcomes Framework (QOF) Dementia register.

2. Must have sustained at least one fall within 6 months prior to identification as a potential study participant. A fall is defined as an event whereby a person comes to lie on the ground or another lower level with or without loss of consciousness.
3. Must be dwelling in their own home at the time of the index fall and returning to their own home at the time of the intervention.
4. Must have an unpaid carer available to assist with completion of the diaries.
5. Either has capacity to consent to participation, or a personal or nominated consultee who is able to give an opinion on the participation of the PWD.
6. Able to communicate in English
7. Aged over 50 years.

6.2.2. Exclusion criteria patient participants

1. Diagnosis of dementia cannot be confirmed by the primary care team within 4 weeks of their being identified.
2. PWD found to be dwelling in a care home, or to have been a hospital inpatient at the time of the index fall.
3. PWD refuses consent, or lacks capacity and does not have personal or nominated consultee, or their personal or nominated consultee declines participation.
4. Unpaid carer declines participation in the study

6.2.3. Inclusion criteria carer participants

1. Family member or friend of the PWD patient participant.
2. In contact with patient participant for at least one hour per week.
3. Able to communicate in English sufficiently well to complete the proxy outcome measures.
4. Has capacity to provide informed consent.

6.2.4. Exclusion criteria carer participants

There are no exclusion criteria for carer participants.

7. Trial procedures

7.1. Recruitment

7.1.1. Participant Identification

The following settings will be available as routes for participant identification. Study sites will determine which settings are logistically available and do not have to utilise all settings. If the routes outlined do not fall under the study site's trust, they will be set up as PIC sites i.e. paramedic, admiral nurses, memory clinic, rehabilitation outreach teams and primary care. PICs will be identified as site set-up commences.

7.1.1.1. Community Services

Within primary care services, a retrospective search will take place at the beginning of the study to identify potential participants who have had a fall in the last 6 months. An invitation letter and a participant information sheet (PIS) will be sent to the potential participant, explaining what the study is about and that they are eligible to take part. Dementia QOF registered patients will have a flag applied to their records. During primary care consultations with these potential participants, the professional will be alerted to determine if the patient's fall occurred within the last 6 months and if so, the patient can be given an invitation letter and PIS. Potential participants will be approached no more than once about the study. District and practice nurses will be included in the Site Initiation Visit (SIV) to ensure they are prepared to discuss the study with patients who are seen in their homes. Any potential participants who receive the invitation letter can complete and return an opt-in form to the clinical researcher if they are interested in taking part.

Other community settings include admiral nurses and paramedics. Patients presenting with a history of memory problems and a fall requiring healthcare attention will receive the introductory letter and PIS from the relevant service. Potential participants with a history of memory problems can be self-reported, reported by an informal carer, recorded in service records, or on observation. Potential participants can complete and return an opt-in form to the clinical researcher if they are interested in taking part. Potential patients taken to hospital by paramedics will be identified at the emergency department (ED) by the secondary care team. Therefore, paramedics will only identify and give the introductory letter and PIS to potential participants that are not taken to hospital to avoid multiple contacts with the patient. If the potential participant is in a distressed state, paramedics will be asked to use their discretion when considering giving the patient the letter and PIS as it may be inappropriate at that time. If a potential participant lacks capacity to understand the PIS and introductory letter from undue stress, and a carer is not present, these documents will not be given.

The research team will keep in regular contact with all participating services to make sure they remain aware of the study and are able to identify and resolve any issues to recruitment.

7.1.1.2. Secondary care services

Clinical researchers embedded in the healthcare teams at each site will communicate with professionals in each secondary care settings to identify potential participants for recruitment. Secondary care services include EDs, outreach rehabilitation services, supported discharge teams and memory clinics. When attending a person with a fall, professionals will be asked to question whether it is possible the person may have dementia. This information may also be received via a direct history of known dementia or confusion from the person or their informal carer. This information may not be available if the opinion of the professional is that the person appears to be confused. All persons who have sustained a fall and have possible dementia will be recorded so that the clinical researcher is able to send out an introductory letter and PIS. The responsibility of whether an introductory letter and PIS should be sent out lies with the responsible clinician from the referring service. The clinical researcher embedded within the clinical team will keep in regular communication with the participating professionals to ensure they remain aware of the study and so they are able to identify and resolves any obstacles. The clinical researcher at each site will record any duplicates presenting via more than one route to ensure they are only approached once. The introductory letter and PIS will be sent by post to the person as soon as possible after the person is identified as a potential participant. This would typically be the day after their attendance at the relevant service, or the Monday after attendance during a weekend. Where it is not possible to embed a clinical researcher within the clinical team the attending clinician will seek consent for the person to be approached by a clinical researcher.

7.1.1.3. Research registers

At some sites a database of research interested patients with a diagnosis of dementia who have given consent to be approached about research studies is maintained. Staff will identify potential participants from the Case Register. The initial approach will be made by phone by a member of the research staff who will introduce the study and check whether the person has had a fall in the last 6 months. If the patient has had a fall and is potentially interested in taking part, their verbal consent will be sought to pass their contact details to the clinical researcher. The clinical researcher will then send out the introductory letter and PIS and follow this up with a telephone call approximately one week later. The clinical researcher will answer any questions and check whether they are still interested in taking part in the study having had time to consider the information in the PIS. If appropriate, a home visit will be arranged at which consent will be sought and the baseline assessment completed.

7.1.2. **Identification and recruitment of informal carers**

In cases in which PWD seeking healthcare are accompanied by an informal carer, the carer will be aware of the study from the outset. The informal carer will receive an informal carer PIS by the clinical researcher at the earliest opportunity. In most cases, this will be when the follow-up call occurs to seek verbal consent from the PWD to contact their GP practice to confirm eligibility. It is probable that the informal carer will answer the telephone, instead of the PWD. If the PWD is not accompanied by an informal carer, we will ask the PWD to identify whether they have an informal carer who helps with day to day activities and who might be interested in being involved in the study. If the PWD can provide a name and address, the clinical researcher will send the informal carer and invitation letter and PIS. If the PWD provides a name and phone number, the informal carer will be contacted for an address. If

the PWD can only provide a name, the clinical researcher will send the invitation letter and PIS addressed to the informal carer, c/o the PWD to the PWD's address.

7.1.3. Identification and recruitment of professionals

The process evaluation will examine implementation, acceptability of the intervention for participants and practitioners, mechanisms of impact, and context. The process evaluation will be structured using a logic model, representing an initial theory of how the intervention works and will be revised according to study findings. The datasets for the process evaluation are: 18 paired interviews with people with dementia and their carers; 24 interviews with practitioners delivering the intervention; six interviews with study research nurses; observations of six intervention sessions; observations of four supervision sessions; and observations of four multidisciplinary team (MDT) meetings. Trial records of fidelity, dose, reach and attrition will also be collected to inform the process evaluation and to assess the feasibility of the study processes.

7.1.3.1. Participant sampling, recruitment and consent

Recruitment and consent for people with dementia aged over 50 years old and their carers (referred to here as 'participants') in the process evaluation will be included in the consent process for the overall study. Information about the process evaluation will be included in the Participant Information Sheet, and participant consent forms will include an optional section for consent to (1) a face-to-face, paired interview with a qualitative researcher (2) one or more intervention sessions to be observed by a qualitative researcher. Consent forms will include an item explaining that participants can withdraw their qualitative data from the study up to the point at which analysis is conducted, giving an approximate date for this.

Patient-carer pairs will be sampled for maximum variation (such as gender, site) by the study qualitative researcher, drawing on trial records. The researcher will then contact participants by email or telephone to invite them to take part in an interview, which will be conducted around the end of the intervention to avoid Hawthorne effects. A total of 18 interviews will be conducted. Consent will be re-confirmed verbally at the beginning of the interview.

7.1.3.2. Practitioner sampling, recruitment and consent

One or two clinical research nurses will be located at each of the six sites. The study qualitative researcher will liaise with the clinical research nurses to identify intervention practitioners from the six sites to invite for interview and to take part in MDT meeting observations, supervision observations and intervention session observations. Interviews will include geriatricians, physiotherapists, occupational therapists and support workers. Only geriatricians who are not co-applicants (i.e., not members of the research team) will be invited to interview. Approximately four practitioners from each site will be interviewed, with a total of 24 practitioner interviews conducted overall. The clinical research nurse will invite practitioners verbally or by email, and will provide practitioners with a participant information sheet and consent form at this stage. Contact details of practitioners agreeing to take part will be sent by the research nurse to the study qualitative researcher who will then contact the practitioner to arrange the return of the consent form and a time to conduct the interview or observe a session. Practitioners will have an opportunity to consent to an interview, session observation, supervision observation, MDT meeting observation, or all four.

A clinical research nurse from each of the six sites will be invited by the study qualitative researcher to take part in an interview about the research processes (e.g., participant recruitment). An invitation, participant information sheet and consent form will be emailed to the research nurse, after which the study qualitative researcher will contact the research nurse to arrange the interview.

Consent forms will be sent out and returned to the study qualitative research electronically where possible. Paper copies with an SAE will be sent to potential interviewees where requested. All consent forms will include an item explaining that interviewees can withdraw their qualitative data up to the point at which analysis is conducted, giving an approximate date for this. Consent will be re-confirmed verbally at the beginning of interviews.

7.1.3.3. Interviews

Eighteen semi-structured, face-to-face interviews will be conducted with participants receiving the intervention and their carers (paired interviews). Interviews will address feasibility, mechanisms of impact, contextual factors, and acceptability of the intervention. Questions about acceptability and feasibility of research processes such as recruitment, attitudes to randomisation and burden of data collection will also be included. Where face-to-face interviews are not possible, due to Covid restrictions for example, they will be conducted online.

Twenty-four semi-structured telephone or online interviews with professionals across the six study sites will be conducted to examine implementation, feasibility, mechanisms of impact and contextual factors. Questions about experience of training, and the feasibility of research processes will also be included, where practitioners have been involved in these aspects of the study. Interviews will be conducted with four types of professional: geriatricians, physiotherapists, occupational therapists and support workers.

Six clinical research nurses will be interviewed about research processes for MAINTAIN. Interviews will be semi-structured, and conducted online or by telephone. Interviews will explore views on trial recruitment, attitudes to randomisation, reasons for any attrition, feasibility of qualitative and quantitative data collection processes, and research burden on participants.

Interviews will take no longer than around 60 minutes and will be video/audio recorded with participants' permission. If permission is not given, notes will be taken. Participants with dementia and carers will be offered the option to have a break during the interview if required. Encrypted voice recorders will be used to record interviews where conducted face-to-face or by telephone.

7.1.3.4. Observations

Six non-participant, semi-structured observations of interventions sessions will be conducted to investigate feasibility, implementation and contextual factors affecting the intervention. Sessions will be sampled to include those delivered by physiotherapists, occupational therapists, and research support workers, across different sites.

Four supervision meetings between support workers and either physiotherapists or occupational therapists will be observed, to assess feasibility and implementation factors. Four multidisciplinary team meetings between physiotherapists, occupational therapists and support workers will also be observed to further investigate implementation. These observations will also be non-participant and semi-structured.

Observations of intervention sessions, supervisions and MDTs will take place in person where possible. The study qualitative researcher may record the session using an encrypted voice recorder, and will take notes during and immediately after observations. Where in-person observation is not possible (e.g. due to participant consent for only audio-recording, or Covid restrictions) the recording will be carried out by a practitioner using an encrypted recorder, and sent to the study qualitative researcher via secure file transfer system at the earliest opportunity. The study qualitative researcher will then listen to the recording and take notes. Selected sections of recordings may be transcribed in full for more detailed analysis where necessary.

7.1.4. **Confirmation of PWD eligibility**

The research team will confirm that the PWD is on the primary care QOF dementia register prior to formal recruitment to the study, with the exception of potential participants identified through primary care. Once the potential participant has received the PIS they will be contacted by the clinical researcher via telephone call. During this initial telephone call to discuss participation, the clinical researcher will obtain verbal consent from the PWD to contact their GP practice to check whether the potential participant is on the dementia QOF register. For those referred directly by primary care, we will already know that the participant is on the dementia QOF register.

If the potential participant is on the QOF register, the clinical researcher will contact them again to confirm eligibility and, if the PWD is still interested, to arrange a home visit to take consent and undertake baseline assessment. Potential participants who are not on the dementia QOF register will be sent a letter explaining that they are not eligible by thanking them for their interest.

The clinical researcher will be asked to keep a list of all potential participants who have had contact with the research study team at each stage of the recruitment process. If the potential participant has declined or not responded to a contact from the research team, or if they have not been recruited for any other reason, they will not receive any further contacts from the research team.

7.2. **Consent**

Informed consent will be required for PWD to participate in the study in accordance with the Declaration of Helsinki. Some participants may lack the capacity give full informed consent due to the nature of dementia. In this case, the provisions of the Mental Capacity Act (2005) will apply. PWD will be asked to give consent appropriate to their level of understanding, this could range from written informed consent to account being taken of verbal and non-verbal communication in determining willingness to participate. The clinical researcher will identify a personal consultee for individuals who lack the capacity to give full informed consent. The personal consultee will be sent a letter explaining the role of a consultee and will be asked for their advice regarding the PWD's participation. If the consultee is not available at the home visit they will instead be contacted by telephone by the clinical researcher to receive their advice about the PWD's participation. If the consultee feels the PWD would not have wanted to participate, the PWD will not be recruited into the study and they will not be contacted any further about the study. If they do not give any opinion it will be assumed that the consent is withheld and the PWD will not be recruited or contacted any further about the study. If a PWD appears distressed by participation or withdrawing consent, they will be excluded from the study without prejudice to clinical care.

Consent will also be sought from all professionals involved in the study to participate in observation and/or interviews and informal discussions. Consent will be required from all professionals involved in

the study. A PIS will be provided to make these expectations clear and describe the rationale for the qualitative aspects of the study.

7.3. **Randomisation**

Participating services (clusters) will be randomised in a 1:1 ratio to receive either the intervention plus usual care (intervention arm) or continue with usual care services (control arm). Randomisation will be undertaken based on computer-generated random numbers with no stratification factors.

After the baseline assessment, the clinical researcher will inform the central research team. If the participant is in a service (cluster) that is randomised to the intervention arm, the research team will send a referral to the intervention team using a structured referral form with details of the baseline assessments of the PWD and unpaid carer. The intervention team will then arrange an initial intervention assessment within 2 weeks.

7.3.1. **Method of implementing the randomisation/allocation sequence**

In this trial, participating services (clusters) will be randomised prior to recruitment of participants in order to account for the necessary preparation time required for services within the intervention arm. The allocation sequence will be produced by the trial statistician using a random seed and inputted into RedCap Academic. Randomisation of initial sites will then be completed in RedCap Academic, ensuring concealment of the allocation sequence from sites prior to them being randomised. Any sites that act as a replacement for an already randomised site that drops out from the study will be allocated to the treatment group of the site they are replacing. Any additional sites added at a later stage specifically to compensate for slow recruitment of participants, rather than for site drop-out, will be randomised in the same way as initial sites. Allocation concealment will also be ensured for potential participants prior to them consenting to the trial in order to prevent influence on recruitment from participants knowing allocation prior to joining the trial. The research nurses discussing the study with potential participants at each site will not let the participant know which arm the site has been randomised to until after consent has been taken. The participant information sheet will contain information about both arms of the study.

After randomisation is completed a member of the trial team will inform each site of their allocation.

The procedure for replacing sites will be as follows. Any withdrawn sites will be replaced in chronological order with the first site to withdraw being replaced by the first replacement site that has been confirmed as ‘ready’. A site will be deemed 'ready' when they have confirmed availability of a therapy team to participate within a study. In the event of no sites needing replacing but where there has been provision to open additional sites, the same procedure will apply as with replacement sites for the order in which they are accepted to randomisation.

7.4. Blinding

Due to the nature of the intervention and usual care treatment, clinicians and participants involved in the intervention cannot be blinded to treatment allocation. Furthermore, due to the nature of the discussions that patients and clinicians may have during follow-up visits, it is not possible to blind clinicians undertaking data collection to treatment allocation at follow-up. This is because health utilisation data collected at the 3 month time point will likely unblind the clinician to the allocation. As a result, all clinicians involved in this trial will be unblinded throughout.

In order to prevent influence on potential participants joining the trial, participants will be blinded until they are screened and consented but will become unblinded subsequently, as the intervention cannot be delivered as concealed.

Statisticians will be blinded until the completion of the Statistical Analysis Plan in order to prevent bias in proposed analysis or any subgroup analysis sets.

7.5. Emergency Unblinding

In this trial, the treating clinicians and participants are already unblinded to intervention, so it is not expected that there will be any need to unblind any blinded team members to ensure emergency care.

7.6. Baseline Assessments and Data

Baseline data for PWD and their informal carers consenting to the study will be collected by a clinical researcher within two weeks of confirmation of eligibility. For PWD, this will include the DAD, EQ-5D-5L, QOL-AD, Short-FES-I and Timed Up and Go test. GAS will be collected by the intervention therapist at baseline for those randomised to the intervention (Table 2). Informal carers will be asked to complete EQ-5D-5L proxy, QOL-AD proxy, HUQ, EQ-5D-5L and ZBI (Table 2).

After the baseline assessment, the clinical researcher will inform the central research team. If the participant is in the intervention arm, the referral will be sent to the intervention team using a structured referral form with details of the baseline assessment of the PWD and the unpaid carer. The intervention team will then arrange an initial intervention assessment within two weeks. If the participant is in the control arm, usual care will continue.

7.7. Follow up Assessments

The clinical researcher will carry out a second visit to repeat most of the outcome measures completed at baseline with the PWD and their informal carer (see Table 2). For those in the intervention arm, this will take place 26 weeks after the start of the intervention. For those in the control arm, this will take place 28 weeks from baseline. The HUQ will also be completed at three months follow up by phone call. A fidelity checklist will be used to measure intervention fidelity.

7.8. Quantitative assessment of falls

PWD will be asked to complete a prospective falls diary for the duration of the six month follow up period with the aid of an unpaid carer if required. These will be used to calculate:

- the fall rate per person per year
- the proportion of participants with one or more falls
- injury and fracture rates

7.9. Process evaluation and Qualitative assessment of study procedures

The process evaluation will examine implementation and the acceptability of the intervention for participants and professionals, and mechanisms of impact, including the roles of geriatricians and carer support identified in the previous study as being important. The process evaluation will be structured using a logic model, representing an initial theory of how the intervention works. Eighteen semi-structured, face-to-face interviews will be conducted with PWD receiving the intervention and their unpaid carers (paired interviews) to identify factors affecting acceptability and mechanisms of impact. Patient-carer pairs will be sampled for maximum variation, and interviews will be conducted around the end of the intervention to avoid Hawthorne effects.

Twenty-four semi-structured telephone interviews with professionals will be conducted to examine implementation, implementability (including fidelity, and mechanisms of impact, behaviour change, contextual factors). Interviews will be conducted across the 3 intervention sites and with four types of professional: geriatricians, physiotherapists, occupational therapists and support workers.
During the trial delivery phase, six observations of professionals will be conducted to further investigate implementation and contextual factors. Four supervision and four multidisciplinary team meetings will also be observed. Field notes will include a reflexive perspective.

Interviews will also include questions about the acceptability and feasibility of study procedures, such as recruitment and randomisation, where professionals have been involved in these aspects of the study.

The consent process with PWD and unpaid carers will also include consent for optional participation in the qualitative aspects of the study. Interviews will take no longer than around 60 minutes and will be audio recorded with participants' permission (as documented on the initial study consent form; consent to recording will be verbally confirmed at the time of the interview).

Table 3 Schedule of Events

	Baseline assessment (clinical researcher)	Week 1 (intervention)	Weeks 2-28 (intervention)	Week 12 follow-up assessment (clinical researcher)	Week 28 follow-up assessment (clinical researcher)
Informed consent (including consent for observation and/or interview)	X				
Baseline data collected (see Table 2)	X				
2 Assessment visits by Intervention team including Timed Up and Go Test		X			
Up to 22 visits by Intervention team Final visits will include Goal attainment scaling and Timed Up and Go test			X		
Completion of diary		X	X		
Completion of HUQ	X			X	X
Informed consent of professionals and participants and observation of interventions received		X	X		
Informed consent and qualitative interview with some professionals regarding views on intervention.			X		
Qualitative interview with patients, informal carers and professionals views on intervention (subset of participants who consent to qualitative study)			X		
Follow up outcome data collected					X

7.10. **Withdrawal Criteria**

Both PWD and their unpaid carers have the right to withdraw from any and all aspects of the study without giving a reason at any time. Investigator sites should attempt to determine the reason for withdrawal and document this within the CRF and participant's medical notes. PWD and their unpaid carers will be able to withdraw from the optional qualitative component, intervention delivery and/or outcome assessment. It is the responsibility of the site to communicate with the participant to determine which aspect of the study they wish to withdraw from. This information will be documented on a study withdrawal form.

The investigator may withdraw a participant form the study at any time if they consider it necessary for any reason, including:

- Participant withdrawal of consent
- Significant protocol deviation or non-compliance
- Investigator's discretion that is in the best interest of the participant
- An adverse event (AE) that causes the participant to be unable to continue in the study
- Termination of the study by the sponsor

Due to the nature of dementia, some participants may become ill or die before completion of the study. Routinely, participants who withdraw will not be replaced in the trial.

Professionals will have to the right to withdraw from the study at any time without having to give a reason.

7.11. **End of Study**

The end of the study will be defined as the completion of all data collection, all data recorded in the study database, all data cleaned, and the database locked. A declaration of end of study form will be submitted to the NHS REC who awarded the favourable opinion within 90 days of the end of study.

If the study is terminated early, the end date will be the date that the Sponsor formally declare the study terminated in writing. The NHS REC will be notified of early termination within 15 days of the Sponsor deciding to end the study.

8. Maintain Intervention

8.1. Description of the Intervention

The Maintain intervention is a multidisciplinary complex intervention which is delivered in the patient participant's home. The intervention will be personalised to each participant, taking into account their physical abilities, their preference for activities and goals agreed by the therapist, the patient participant and their unpaid carer. The number of sessions the participant receives will also be tailored to their needs. The first two sessions will be assessment sessions which will be followed by up to 19 therapy sessions delivered over 12 weeks and booster sessions at 16 weeks, 20 weeks and 24 weeks. An intervention manual will detail the assessment and therapy procedures for the professionals.

8.1.1. Training

Use of the manual will be accompanied by training sessions for professionals responsible for the delivery of the intervention prior to enrolment of the first participant. Training will be offered online as e-learning modules and/or face-to-face. The physiotherapist and occupational therapist with expertise in working with PWD will deliver the training. Training will include:

- Dementia awareness
- Dementia identification, assessment and diagnosis
- Dementia risk reduction and prevention
- Person-centred dementia care
- Communication, interaction and behaviour in dementia care
- Health and well-being in dementia care
- Assessment and management of pain
- Pharmacological interventions in dementia care
- Living well with dementia and promoting independence
- Families and carers as partners in dementia care
- Equality, diversity and inclusion in dementia care
- Law, ethics and safeguarding in dementia care
- End of life dementia care
- Research and evidence-based practice in dementia care
- Setting SMART goals
- Goal Attainment Scaling (GAS)

8.1.2. Assessment sessions

The PT and/or OT will visit the participant during week 1 to complete a structured holistic assessment proforma assessing the below items. This assessment will include perspectives of the participant and their unpaid carer as well as discussion with professionals already involved with the participant.

- History and circumstances of index fall(s) and any injuries sustained
- History of additional falls to determine any patterns in falling
- Details of treatment offered so far and services already involved
- Past medical history and comorbidities
- Medication
- Osteoporosis risk

- Living arrangements
- Details of current informal and formal carer input
- Current levels of activity, routines and likes and dislikes for activities
- Current mobility (bed mobility, bed and chair transfers, walking and stairs)
- Assessment of risk factors for falls
    - Fear of falling
    - Dizziness
    - Nutrition and fluid intake
    - Pain
    - Continence
    - Footwear
- Identification of challenging behaviours and sleep disturbance
- Identification of informal carer stress
- Identification of informal carer's willingness to be involved in promoting the activities
- Physical examination
    - Objective body examination including focus on areas of pain
    - Timed Up and Go test
    - Use of walking aids
    - Functional movements e.g. reaching, carrying and bending
    - Lying and standing blood pressure
    - Visual assessment
- Functional examination
    - Assessment of home safety environment including a walk around the home to see where actual falls have occurred
    - Assessment of functional activities e.g. ability to make a cup of tea
    - Assessment of home adaptations and need for new adaptations

A problem list and set of goals to achieve will be compiled at the end of the assessment which will be agreed with both the participant and their unpaid carer. The goals and problem list will then be discussed at a multidisciplinary team (MDT) meeting with the physiotherapist, OT and support worker. The MDT will create an action plan including recommendations for activities to be carried out during the therapy sessions. One therapist will be identified as the participant's key worker. At week 6, the goals and action plan will be reviewed and adjusted by the key worker if required.

Onward referrals to the GP, geriatrician, mental health nurse, old age psychiatrist, continence adviser, podiatrist, optician or dietitian will also be identified by the MDT.

The initial assessment session will also confirm the unpaid carer's capacity and willingness to take part in the intervention, their knowledge and understanding of dementia and falls (including attitudes to risk) and an assessment of carer stress (using data from the ZBI as a guide). The MDT will also consider the needs of the unpaid carer and how to address these needs. An action plan for the unpaid carer's needs will be made where appropriate.

8.1.3. **Therapy sessions**

Each therapy session will be 60 minutes with up to 19 sessions occurring over a 12 week period. Booster sessions will also take place at weeks 16, 20 and 24. In total the participant could receive a maximum of 22 sessions (including the boosters) over the course of the 6 month follow-up period. The number and frequency of the sessions will be tailored to the participants needs and if the participant is making good progress they may wish to have fewer than 19 sessions during the 12 week period. Up to 3 sessions will

be delivered by the physiotherapist and up to 3 sessions will be delivered by the occupational therapist. All remaining sessions will be delivered by a rehabilitation support worker (RSW).

The participant's comfort, nutritional needs and pain assessment will be considered before each activity session with tools to assess non-verbal signs of pain used if appropriate. Activities include both functional activities and/or physical exercises (which may include strength and balance exercises and dual task activities). Participants can either follow an exercise programme separate from their daily activities or have the exercises embedded into their daily life e.g. practicing balancing whilst standing at the sink washing up. Functional activities will be identified during the goal setting session and will include encouragement to engage in both community and social activities. Unpaid carers will be asked to promote the activities by joining in where appropriate as well as engaging in the goal setting process. Pictures of physical activity to be carried out may be provided to the participant to support them with the activity. Cueing cards will be embedded into the participant's daily life to encourage them to increase activity throughout the day. A structured proforma will be used during each visit to record the activities undertaken and recommendations of activities to be performed between visits. The proforma will include a review of whether the participant undertook the recommendations set out at the previous visit. If the participant has not adhered to the recommendations the reasons will be discussed with the participant and the goal setting will be reviewed.

The participant may also be referred to other local services for people who fall such as falls prevention classes. The GP will be sent a summary of the interventions carried out during the study after the final therapy visit as well as recommendations regarding ongoing service input where needed.

8.2. Adverse events

8.2.1. Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant to whom a medicinal product has been administered, including occurrences which are not necessarily caused by or related to that product.
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
Related and Unexpected SAE (RUSAE)	A related and unexpected SAE is an event which is related to the intervention; and 'unexpected' – that is, the type of event is not listed in the protocol as an expected occurrence.

Table 4 Adverse Event definitions

8.3. **Recording and reporting AEs, SAEs and RUSAEs**

The Maintain study is a low risk, non-drug intervention trial. The interventions may be offered as part of a routine physiotherapy intervention. As dementia is progressive and associated with comorbidity, inter-current illness will be common. We will only be recording and reporting safety data for patient participants.

Adverse events (AE)

Non-serious AEs will not be recorded or reported for the study. The components of the intervention are not novel and safety of the intervention is not an outcome measure.

Serious adverse events (SAE)

All deaths (from any cause) and hospitalisations due to falls, fractures or musculoskeletal injury will be recorded. Other SAEs will not be recorded or reported. Only related SAEs will be subject to expedited reporting.

Causality of reportable SAEs will be assessed by the site PI (or authorised delegate). All SAEs which are possibly, probably or definitely related to the intervention will be categorised as 'related'. If the PI or delegate is unable to assign causality within 24 hours of the site becoming aware of the event, the SAE will be treated cautiously and subjected to expedited reporting.

Related unexpected serious adverse events (RUSAE)

Death is an unexpected event. Deaths related to the intervention will be categorised as RUSAEs and subjected to expedited reporting.

Not related or improbable

A clinical with temporal relationship to trial intervention which makes a causal relationship incompatible or for which other treatments, chemicals or disease provide a plausible explanation. This will be counted as "unrelated" for notification purposes.

Possible

A clinical event, with temporal relationship to trial intervention which makes a causal relationship a reasonable possibility, but which could also be explained by other interventions, chemicals or concurrent disease. This will be counted as "related" for notification purposes.

Probable

A clinical event, with temporal relationship to trial intervention which makes a causal relationship a reasonable possibility, and is unlikely to be due to other interventions, chemicals or concurrent disease. This will be counted as "related" for notification purposes.

Definite

A clinical event, with temporal relationship to trial intervention which makes a causal relationship a reasonable possibility, and which can definitely not be attributed to other causes. This will be counted as "related" for notification purposes.

Not assessable

There is insufficient or incomplete evidence to make a clinical judgement of the causal relationship.

Reporting procedure

1. If an adverse event is not classified as serious, no recording or reporting is required.
2. If an adverse event is classified as serious, but it is not a death or hospitalisation due to fall, fracture or musculoskeletal injury, no recording or reporting is required.
3. If the adverse event is serious, a death or hospitalisation due to fall, fracture or musculoskeletal injury, but not related to the intervention the Investigator must record the SAE on the CRF and no further reporting by site is required. The Exeter Clinical Trials Unit (ExeCTU) will report 3-monthly to the TMG, 6-monthly to the TSC and annually to the REC.
4. If the adverse event is serious, a death or hospitalisation due to fall, fracture or musculoskeletal injury, and related to the intervention the Investigator will report the SAE to ExeCTU within 24 hours of becoming aware of the event. ExeCTU will report to the sponsor within 24 hours of becoming aware of the event. If the event is death, the Sponsor or delegate will report to the TSC and REC within 7 days.

8.4. Responsibilities

At the 28 week follow-up visit the clinical researcher conducting the visit will ask if the patient participant has had a reportable SAE. Members of the research team at the site will also record all reportable SAE events into the EDC system before the 28 week follow-up time-point.

The principal investigator (PI) at site, or their authorised delegate, is responsible for assigning the severity and causality of an event, recording the SAEs as detailed in Section 8.3 of this protocol, and entering the data into the EDC system. The EDC will be set up with a role-restricted task to allow only the PI or delegate to sign off the reportable SAEs within the system.

The chief investigator (CI) or authorised delegate SAEs on a monthly basis and confirm their agreement or disagreement with the PIs judgement on causality. The CI will only upgrade, not downgrade, any decision made by the site PI. Disagreements will be discussed with the Sponsor, CI and PI and the Sponsor will be responsible for a final decision.

The TSC will review SAE data to identify if there are any patterns of events and to identify safety issues.

8.5. Notifications of deaths

Deaths will be recorded in the EDC system with the cause of death recorded. RUSAEs will be reported to the TSC and the REC within 7 days of the Sponsor being made aware of the event.

8.6. Pregnancy reporting

Pregnancy is considered very unlikely, but if a participant becomes pregnant during their participation in the trial it will not be recorded or reported.

8.7. Urgent safety measures

In the event of an immediate risk to participant safety, the Sponsor, CI, PI and/or TSC will make a decision to implement an urgent safety measure (USM).

PIs will implement USMs at sites and must be notified to the CI within 24 hours. The CI must notify the Sponsor within 24 hours of being made aware of an USM.

If the CI and the Sponsor consider the USM to affect all participants, all PIs must be informed of the USM.

A protocol amendment must be submitted to the HRA and REC within three days following implementation of the USM. If the USM requires a temporary halt to the study, this will be notified by an amendment.

8.8. **Annual report to the REC**

An annual report will be submitted to the NHS REC who issued the favourable opinion using the appropriate form provided by the Health Research Authority.

9. **Statistics and data analysis**

9.1. **Sample size calculation**

We will randomise six rehabilitation services (clusters), one in each of 6 sites, and aim to recruit 60 PWD altogether (3 services and 30 PWD to each of the intervention and the control arms). Each service will recruit 10 PWD during the 6-month recruitment period, based on a recruitment rate of 1.7 PWD per service per month as achieved during our feasibility study. If recruitment is slower than expected, we will consider adding 2 additional sites.

The sample size calculation was based on the precision for estimating the proportion of eligible people that consent to participate in the study. We anticipate that we will have to approach 150 eligible people and 40% (60 participants) of these will agree to take part. The 150 who are screened is a large enough number to estimate the percentage that consent with a 95% confidence interval 29% to 51%. If the percentage that is followed up is 80%, 60 recruited participants is large enough to estimate this with a 95% confidence interval 66% to 91%, and the 30 participants in the intervention arm is large enough to estimate the percentage that attends at least 60% of the allocated sessions with a 95% confidence interval 60% to 93%. These confidence intervals take clustering into account [16] and are based on an assumed intra-cluster (intra-service) correlation coefficient of 0.05 to quantify variability across clusters in the feasibility parameters (i.e., percentage consented, followed-up, attending at least 60% of sessions).

9.2. **Statistical analysis**

Analyses will be fully pre-specified in a statistical analysis plan that is signed off by the Trial Steering Committee and the Trial Management Group.

Participant flow through the trial will be summarised using a CONSORT flow diagram for cluster randomised controlled trials.

Baseline characteristics of the services and participants will be described using means and standard deviations for continuous variables and numbers and percentages for categorical variables. We will report the following parameters with 95% confidence intervals that are widened to allow for clustering: % of screened people that are eligible; % of eligible people that consent to participate; % of participants that provide data at the 6-month follow-up; and % of intervention arm participants that attend at least 60% of

scheduled sessions. To estimate these parameters, mixed logistic regression models with Satterthwaite's degrees of freedom correction will be fitted to binary outcomes that represent eligibility status, consent status, follow-up status and whether attended at least 60% of the scheduled sessions. The constant from these models will represent the log odds of the parameters which will (along with the 95% CIs) be converted to the percentage scale.

We will also report estimates of the standard deviations for continuous outcomes measured at baseline, 3 months and 6 months.

In order to assess the extent to which randomisation of clusters before recruiting participants may have resulted in recruitment bias due to the research nurses being unblinded, we will report the percentage of eligible people that participate in each of the intervention and control arms and examine the characteristics of the participants between the trial arms.

Finally, in ancillary analyses, we will report intention-to-treat estimates of the effect of the intervention on the continuous outcomes at 3 and 6 months, using 95% confidence intervals to quantify potential effectiveness. The comparison between trial arms will be undertaken by fitting mixed ("multilevel") linear regression models using Satterthwaite's degrees of freedom correction to recognise the small number of clusters in the study. Comparisons will be adjusted for the baseline score of the outcome. No p-values will be reported as it is not an objective of this study to conduct a definitive test of the intervention effect. Analyses will be undertaken using Stata software.

9.3. Interim analysis and criteria for the premature termination of the trial

There are no planned interim analyses.

9.4. Participant population

People with dementia, over the age of 50 years old, who have had a fall in the past 6 months. Participants must be living in a private dwelling and have a family member or friend willing to take part with them.

Intention-to-treat comparisons of the outcome between the trial arms will be undertaken with participants analysed according to the trial arm their site (cluster) was randomised to. As this is a pilot study estimates from these comparisons will be reported with 95% confidence intervals only and no p values.

9.5. Procedure(s) to account for missing or spurious data

Every attempt will be made to collect a complete record of data during the trial, with queries being raised for missing data to collect these within a reasonable time window if available. All data that are missing should be appropriately coded with the reason, if known, for why the data is missing.

Missing data will not be imputed for analysis. Complete case analyses of the outcome will be undertaken when comparing them between trial arms.

9.6. Other statistical considerations.

Analyses will be fully pre-specified in a statistical analysis plan that is signed off by the Trial Steering Committee and the Trial Management Group. As this is a pilot study we do not anticipate marked deviations from the analysis plan. If any aspects of the analysis potentially require alteration the Trial Steering Committee will be consulted.

9.7. Economic evaluation

The health economics component will test the cost-effectiveness framework within the pilot cluster RCT; it will assess collection of resource and outcome data for a future large-scale cost-effectiveness analysis (CEA). The analysis will take a societal perspective. Given potential spillover effects [24], outcomes for both the participant and their carer will be assessed (the National Institute of Health & Care Excellence (NICE) recommend that all direct health effects, whether for patients or, when relevant, carers, are included in cost effectiveness analyses [25]).

NICE guidance also recommends that cost-effectiveness analysis is undertaken using a preference-based measure (NICE 2013). Following this guidance, within the pilot RCT, we will use the EQ-5D-5L [17]. The proxy version of the EQ-5D-5L will be completed on behalf of the trial participant by their carer. The carer will also self-complete an EQ-5D-5L pertaining to their own health related quality of life (HRQoL). Both will be collected by the clinical researcher at baseline and 26 weeks. The English value set for the EQ-5D-5L recommended by NICE at the time of analysis, will be used to create index scores using the results of the EQ-5D-5L domains for each individual. The study will report the number (percentage) of partially completed and non-completed questionnaires (where the denominator is the expected number of questionnaires) and number (percentage) of missing scores due to missing individual question items for participant and carer EQ-5D-5L. Summary tables will be produced with the percentage of missing data for each of the EQ-5D-5L domains, EQ-5D index scores and EQ VAS scores for each of the time points for both participant and carer and by randomised arm.

A participant completed resource use questionnaire (HUQ) will be developed based on previous studies with similar populations [26] [15] and assessed (completion/ missing data) to collect data on health care, social care, informal care and out of pocket expenses. The questionnaires will be collected at baseline, 12 weeks and 26 weeks by the clinical researcher. The pilot RCT will also be used to hone methods of data collection for the intervention – in particular to determine the optimal

method to collect details of the intervention delivery. In order to provide consistent results to the EQ-5D-5L outcome measures we will report the number and percentage of partially completed and non-completed HUQs (denominator expected number of questionnaires). Summary tables will be produced with the percentage of missing data for each of the HUQ cost variables for each of the time points and by randomised arm. We will also estimate the mean per patient cost over the 26 weeks duration by randomised arm. Unit costs will be obtained from a variety of sources including the Personal Social Services Research Unit [27].

10. Data management

10.1. Data collection tools and source document identification

Data will be handled, computerised and stored in accordance with the Data Protection Act 2018. Patients' will be given a copy of their signed consent form to keep, a copy will be filed in the patients' medical notes and a copy will be filed in the investigator site file. A scanned copy will be uploaded to the secure online EDC system by site staff, in which only authorised members of the trial team will be able to access. The consent forms will be checked by an authorised member of the trial team and then deleted after the check is complete.

Paper case report forms (CRFs) designed by Exeter Clinical Trials Unit will be used to collect data which will then be input into a secure online study EDC system. CRFs will capture the date of completion and name of the person completing the CRF. The EDC system will mirror the paper CRFs and will be able to audit the users entering data, amending data and any other data changes. The eCRFs will be validated to query discrepancies in the data as well as querying missing data. SAE data will be the only exception to this method and will be entered into the EDC system directly (medical records will be used for source data). Audio recordings from qualitative interviews will be transcribed and the transcriptions will be saved as source data.

When data are captured on a CRF as the first recording of the data (e.g. participant reported outcome measures), the CRFs are the source data. Where data are accessed from medical records, the medical records will be the source data. Data on standardised outcome measures will be collected on the CRFs by clinical researchers. Data for the health economics component (HUQ) will be integrated into the CRFs. CRFs will be pseudonymised to protect the identity of the participants. Paper CRFs completed at the 6-month visits in participants' homes will be transferred to the participating site by the research nurse (or equivalent) where the data will be transcribed into the EDC system. Paper intervention CRFs will be stored securely at the relevant Trust premises and posted to Exeter CTU at the end of the intervention period. Data will then be entered into the EDC by an authorised member of the research team. Diaries will be returned to the research team at the end of the intervention. Data from the diaries will also be entered on to the EDC system.

A clinical researcher at each site will maintain the screening log. The lists of potential patients from secondary care will include NHS/hospital number, date of birth and name and contact details to facilitate retrieval of notes and enable us to send or provide information about the study. This information will be recorded in the Investigator Site File and kept in a password protected file on a NHS Trust computer or research provider computer. The Investigator Site File will be stored in a locked room. Each patient will be allocated a unique study identifier. All data extracted from the case notes and recorded for the study will be identified only by the unique study identifier. The diagnosis of known dementia will be confirmed by the patient being on the primary care dementia QOF registers. Where the patient is not on the dementia QOF register but other information suggests they should be the GP will be asked to review the patient's Read codes and advise whether they believe the register should be revised to include the patient. For those who do not consent to be in the study the only data to be retained by the University of Exeter will be age, gender, confirmed diagnosis of dementia if confirmed and type of injury, if injury is present. For those non-participants, no patient identifiable information will be retained.

The intervention will be delivered according to manuals developed for the study with intervention documentation designed to facilitate collection of clinical data relevant to each component of the intervention. Proformas will be used by clinical staff to record baseline assessment and delivery of each component of the intervention at intervention visits. Intervention records will be returned to the research team for data extraction by secure courier services. Data will be extracted using a unique identifier and entered on to a bespoke database for analysis with an auditable data trail. The database will be held on a secure server maintained by the University of Exeter and access will be password protected.

A restricted EDC CRF will be used to store personal identifiable data (i.e. names, addresses, email addresses, telephone numbers) that will be separate from the research data. Personal data will be collected to facilitate the sharing of newsletters and study results and monitoring of consent forms by the Exeter CTU trial team and assist with retention and follow-up activities. Access to the contact details will be restricted to individuals authorised by the chief investigator. Recruiting NHS Trusts or research providers will also use the information to securely refer the participants to other NHS services or research providers involved in delivery of the study if applicable to the site.

All EDC system users will require individual log-in credentials and authorisation from an approved member of the trial management team before access is granted. The EDC system will incorporate role restriction such that individual users will only be able to access and enter or edit data as their individual permissions allow.

The Exeter CTU trial management team will run regular reports for missing data and remind sites at least monthly to enter data that is expected and document any reasons for missing data.

Healthcare professional consent forms will be signed using DocuSign provided by the University of Exeter. The qualitative researcher will have a DocuSign account with secure individual log in credentials that are not shared with other members of the study team. Completed consent forms will be downloaded and saved on a secure server with restricted access. All documents will be deleted immediately from download folders and computer recycle bins.

The study team will collect trial data on recruitment, number of sessions each participant received, details of referrals to geriatricians, type of therapist delivering intervention (OT or physio), withdrawals from the study (and reasons for this where given), and usual care services being accessed by participants. These data will be summarised to assess fidelity, feasibility, reach and dose of the

intervention for the process evaluation, and also to assess the feasibility of research processes. Where participants contact a member of the study team or clinical research nurse to withdraw from the study, permission to record the reason for withdrawal will be requested and this information will be treated as data for study records.

All audio-recordings of interviews will be fully transcribed, with identifying information such as names and locations removed. Interview transcriptions will be uploaded to NVivo, together with observation field notes. Qualitative data will be analysed using adapted thematic analysis, underpinned by a critical realist perspective. Analysis will combine a deductive and inductive approach, drawing on existing programme theory but also identifying novel factors. Analysis of implementation will be informed by Normalisation Process Theory constructs. The study qualitative researcher will keep reflexive field notes during interviews and observation, which will inform initial codes and themes in the analysis.

In a final stage of analysis, qualitative and quantitative findings will be triangulated using a joint display table, to examine implementation and mechanisms of impact in more depth. Data and findings about how the intervention operates (the process evaluation) will be kept conceptually distinct from data and findings about how well the trial and research processes operated, since these are separate research questions. Findings from the process evaluation will be used to develop a refined theory of how the intervention operates, and both sets of findings will be used to inform a definitive trial.

All data collected for the process evaluation will be stored in restricted-access computer folders on secure servers maintained by the University of Exeter.

Interviews recorded on encrypted voice recorders and any audio recordings of observations will be uploaded onto secure university folders at the earliest opportunity. After confirmation that uploads have been successful, the recordings on the voice recorder will be deleted. Where interviews are conducted on Zoom or Teams, recordings will immediately be stored in restricted-access folders on secure university servers.

Qualitative interviews will be fully transcribed. Audio-recordings and transcripts will be handled only by the qualitative team and transcribers who have signed appropriate confidentiality agreements, or by transcription companies with adequate confidentiality policies. Any recording or transcription files will be transferred to and from transcribers using a secure file transfer system. Identifying information such as names and locations will be removed from transcriptions, and an identifier code will be used to indicate the study participant, with the list of codes stored in a separate, secure file location to the transcripts. Due to the detailed nature of qualitative data, it may not be possible to fully anonymise interview transcripts (since removing too much detail can render the transcript unusable for data analysis). Folders containing transcripts will therefore only be accessed by identified research team members involved in qualitative analysis.

Audio recording files will be destroyed at the end of the study. Transcripts of interviews, observation notes and analysis files will be securely archived with the MAINTAIN study files.

10.2. **Data handling and record keeping**

A data management plan (DMP) will be implemented prior to starting recruitment and will be updated throughout the study as appropriate. Working instructions will be provided to the central study team, site teams and intervention delivery teams on record keeping and data entry processes. Electronic

systems will be validated, tested and documented before starting recruitment. The DMP and validation documents will be available upon request to the Exeter CTU.

10.3. **Access to Data**

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections- in line with participant consent.

10.4. **Archiving**

The trial master file and EDC system data will be archived following the Exeter Clinical Trials Unit standard operating procedure. This will require authorisation from the Sponsor following submission of the end of trial report.

Participating sites will be responsible for archiving their investigator site files, including paper CRFs and consent forms, following their local NHS Trust or research provider archiving procedure. Sites will be required to notify the Sponsor of their archiving arrangements.

Study documents will be archived for 5 years after the end of the study. After 5 years, all personal identifiable data will be securely destroyed upon authorisation from the Sponsor. The anonymised dataset will be stored indefinitely for the purposes of future ethically approved research.

11. **Monitoring, Audit & Inspection**

A detailed monitoring plan will be agreed between the CI, Exeter Clinical Trials Unit and the Sponsor and will be based on the trial risk assessment. The risk assessment will be reviewed periodically and in response to amendments to the study protocol.

Monitoring will be conducted by a combination of remote and central monitoring, led by the Exeter Clinical Trials Unit. On-site monitoring will be conducted if one or more triggers are met, as detailed in the monitoring plan, or if concerns are raised by an individual with knowledge of the study.

Sites will be expected to cooperate with remote and onsite monitoring procedures by provision of copies of requested documents in a timely manner and the completion of self-audit checklists. In the case of triggered on-site monitoring visits, sites will be expected to provide a space for the monitor(s) to work on the Trust premises and provide access to all documents requested in the notification of monitoring visit letter. The PI or a delegated member of the study team must be available during on-site monitoring visits. The Exeter Clinical Trials Unit will provide sites with sufficient notice to prepare for a monitoring visit.

The Sponsor and/or regulatory authorities may audit or inspect any aspect of the study, including on-site visits, at any time during the study.

A separate data monitoring committee will not be convened for this study. The TSC will fulfil the role of a data monitoring committee and will review data completeness, data quality and accumulating safety data at agreed intervals throughout the study.

A copy of the monitoring plan and risk assessment is available upon request to Exeter Clinical Trials Unit.

12. Ethical and regulatory considerations

12.1. Research Ethics Committee (REC) review & reports

Before the start of the trial, the study protocol and supporting documents will be reviewed by an independent NHS REC in England. Recruitment will only commence following the issue of a favourable opinion letter. Substantial amendments that require review by the REC will not be implemented until the REC grants a favourable opinion for the trial.

The study will also receive approval from the HRA prior to commencing recruitment.

Details of the favourable opinion of the RECs and the HRA will be added to this protocol as part of the next protocol amendment. All correspondence with the REC will be retained in the TMF.

The chief investigator will submit an annual progress report (APR) to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended. The CI will follow HRA guidance on notifying the REC of the end of the trial and submission of the final report. If the trial is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination

12.2. Peer review

The study has undergone peer review as part of the funding process.

12.3. Public and Patient Involvement and Engagement

The research question was identified by the HTA with patient and public involvement. The DIFRID feasibility study shared the brief and plans for this project with older people and informal carers of PWD participating in Voice North - an organisation to facilitate the involvement of the public in research and product and service development. Voice North exists to harness the skills and experience of the public - currently over 1000 people are involved from across the North East. The participants concurred with the HTA's view that this is an important area for research into the care of PWD. Two participants were informal carers of PWD and one had experience of caring for their father following a fall and fractured neck of femur. The participants identified that the views of people who have been recent informal carers of PWD are often overlooked in this area of health care and identified them as potential sources of learning.

Our collaborator, Rachael Litherland, oversees PPIE on this study and has convened a group of people with lived experienced of dementia who have had a fall, including carers, who have given input on the participant facing materials, intervention design and health resource use questionnaire. Two PPIE representatives will be invited to join the trial management group and an independent lay representative sits on the PSC.

The PPIE group will meet regularly throughout the study to advise the research team of study conduct and at the end of the study they will be involved in interpreting and disseminating the results. The

research team will regularly feedback progress with the study to the PPIE group, including specific information on how their input has informed decision making.

12.4. Regulatory Compliance

Recruitment will commence at participating sites once the local NHS or university R&D department has confirmed capacity and capability to deliver the study and signed a model non-commercial agreement with the Sponsor.

The latest HRA guidance will be followed at all times with regard to notification and implementation of amendments at sites.

12.5. Protocol compliance

All staff undertaking research activities outlined in the protocol will be trained prior to commencing work on the trial.

The CRFs and EDC system will be designed to assist in adherence to the protocol by guiding study personnel through the assessments and data collection, as well as reminding staff when follow-ups are due. The EDC system will also be validated to minimise protocol deviations, e.g. blocking off access to baseline and follow-up form groups if a patient does not meet the eligibility criteria.

Exeter CTU will conduct regular central monitoring of key data items, including consent details and follow-up adherence to identify protocol deviations. Study personnel will be trained to notify the trial manager in the event of a protocol deviation or suspected or actual serious breach. A deviation log will be maintained by Exeter CTU and reviewed regularly by the CI and the Sponsor. Recurrent deviations will be discussed with the study management group and PSC, as appropriate. We will work with study personnel to identify the cause of the deviations and put in place steps to mitigate them, as appropriate.

Rehabilitation support workers will complete a CRF for intervention sessions to record the planned and actual intervention activities undertaken, and any issues arising which prevented the intervention from taking place.

Protocol compliance will be reported at the end of the trial.

12.6. Notification of Serious Breaches to GCP and/or the protocol

A serious breach is a breach that is likely to affect:

(a) the safety or physical or mental integrity of the participants of the study; or

(b) the scientific value of the study

Serious breaches may be identified through routine or triggered monitoring, inspection by the regulatory authorities, by chance or by direct report to Exeter CTU and/or the Sponsor by a member of the study team or other party.

All suspected serious breaches will be notified to the Sponsor by a member of the Exeter CTU study team following Exeter CTU standard operating procedure. Research sites may notify Exeter CTU in the first instance who will onward report the suspected breach to the Sponsor.

The suspected breach will be logged on the Exeter CTU quality management system. The Sponsor representative will decide if the event constitutes a serious breach. The sponsor will report serious breaches to the REC within 7 days of becoming aware as per the SOP for Research Ethics Committees.

In the event of a serious breach, the Sponsor, Exeter CTU and the individuals involved will work together to agree and implement a corrective and preventative action (CAPA) plan, and follow up on the plan at agreed intervals to ensure effective implementation.

12.7. Data protection and patient confidentiality

This study will be conducted in a way that protects the rights and dignity of the participants. We will adhere to the Data Protection Act 2018 when collecting, storing and reporting data. Study data will be reported anonymously so that it will not be possible to identify any individual taking part in the study.

Each participant will be assigned a unique ID number. Personal identifiable data will be collected and stored separately to research data and will only be accessible to authorised members of the research team. Personal data will only be used for reasons relevant to the research as outlined in the participant information sheets and will be stored for 5 years after the end of the study before being destroyed.

Data will be managed by the UKCRC registered Exeter Clinical Trials Unit (ExeCTU) following UK General Data Protection Regulation. Data will be collected and stored in accordance with the Data Protection Act 2018 and ICH GCP E6 R2. Access to the EDC system (REDCap Academic) web interface will be over Hyper Text Transfer Protocol Secure (HTTPS) / Transport Layer Security (TLS) version 1.2 as a minimum and it will be ensured that web traffic to and from the REDCap server is encrypted. We will host REDCap Academic in Amazon Webservices (AWS). Amazon Relational Database Service (RDS) will be encrypted. Amazon RDS encrypted database instances use the industry standard AES-256 encryption algorithm to encrypt the data on the server that hosts the Amazon RDS database instances. The AWS global infrastructure is designed and managed according to security best practices as well as a variety of security compliance standards. AWS provides on-demand access to security and compliance reports and select online agreements through AWS Artefact. Standards include ISO 27001 and ISO 9001.

Only principal investigators or their authorised delegates who are suitably qualified and trained will access the patients' medical notes to gather the required information for the study. Investigators will hold substantive or honorary contracts with the NHS Trust or research provider at which the patient is recruited and will therefore be bound by the confidentiality clauses that all NHS staff adhere to. Referrals made to other NHS service providers will be made using only nhs.net to nhs.net email.

Data collected at sites on paper such as participant contact information and consent forms (conforming to local policies on infection control), will be stored and archived at site. Data collected on paper in participants' homes during intervention and follow-up sessions will be pseudonymised with the unique participant ID number to protect the identity of the participant.

Audio-recordings of interviews and intervention sessions will be initially stored on an encrypted audio-recording device and then transferred to a secure area on University of Exeter servers accessible only to authorised members or the research team. Every effort will be made not to identify participants in the audio-recordings but this is not always possible due to the nature of the work. A third party

transcription service, Victoria Pink, will be used to transcribe the audio-recordings. A data sharing and confidentiality agreement is in place between Victoria Pink and the University of Exeter.

The data controller for the study is the Sponsor, the Royal Devon University Hospitals NHS Foundation Trust.

12.8. Financial and other competing interests

The chief investigator does not have any competing interests. Members of the TSC will complete conflict of interest forms declaring any competing interests that will be filed in the trial master file (TMF). Independent members of the TSC are approved by the funder as being independent of the study. PIs will be provided with a PI declaration form as part of the model non-commercial agreement in which competing interests will be identified.

12.9. Indemnity

This is an NHS-sponsored research trial. If an individual suffers negligent harm as a result of participating in the trial, NHS indemnity covers NHS staff and those people responsible for conducting the trial who have honorary contracts with the relevant NHS Trust. Research providers will be required to have appropriate clinical trial insurance in place. In the case of non-negligent harm, the NHS is unable to agree in advance to pay compensation, but an ex-gratia payment may be considered in the event of a claim. Any harm arising from the design of the research is covered by the RDUH insurance policy. There are no arrangements for the Sponsor to pay compensation in the event of harm to research participants where no legal liability arises.

12.10. Amendments

All substantial amendments and relevant non-substantial amendments will be discussed by the TMG and with the PPIE group if appropriate. The chief investigator will be responsible for the final decision on making an amendment to the protocol. The approval of the TSC chairperson will be sought for substantial amendments to the protocol in advance of submitting them to the REC and/or HRA, and if necessary, a meeting of the TSC will be convened to discuss the amendment. The funder representative will be notified of relevant substantial amendments in advance of submission, and a full list of all substantial and non-substantial amendments will be provided as part of regular funder reports.

The Sponsor will decide if an amendment is substantial or non-substantial following HRA guidance.

All amendments will be submitted to the NHS REC that issued a favourable opinion (if appropriate) and the HRA following the appropriate HRA amendment process in place at the time of submission. Amendments will be communicated by the trial manager to R&D departments, PIs and research teams at participating sites as soon as possible upon receipt of approval to do so from the HRA.

The chief investigator or delegate will inform the trial registry of changes to the study.

An amendment log will be maintained by the trial manager and filed in the TMF. The protocol version history will be recorded in an appendix to the protocol. Research sites will be provided with an updated document version control list where applicable following an amendment.

12.11. Post trial care

The study will end for a participant after the 6 month assessment data collection is complete. After this point, patient participants will continue to receive standard NHS care with no special arrangements made in relation to the study.

12.12. Access to the final trial dataset

We will store anonymised research data and outputs in the University of Exeter's Open Research Exeter repository (https://ore.exeter.ac.uk/repository/) in order to facilitate open access to, and the impact of, our research. All future research proposals must obtain the appropriate ethical and regulatory approvals.

13. Dissemination policy

13.1. Dissemination policy

The results of the trial will be disseminated regardless of outcome. We aim to publish the findings in peer reviewed scientific and clinical journals and via presentations at local, national and international meetings. We aim to publish the results in an open access journal within 24 months of study completion. Outcome papers will adhere to CONSORT guidelines. We will work with the PPIE group to provide a lay-accessible summary of the results to all study participants. Participants will be asked to provide their contact method preferences so that they receive the results in a format of their choice (i.e. hardcopy by post or digital copy by email). Participants will not be provided with copies of their individual data, due to the nature of the study the data collected would not be relevant to their continued care. Clinical data recorded in medical records irrespective of their taking part in the research will be available to participants through normal processes for accessing medical records.

The results will be posted on the publicly available registry (ISRCTN). A summary of the results will be submitted to the HRA within 12 months of the end of the study in line with HRA guidelines.

The study protocol will be published in a peer-reviewed journal before the end of the recruitment stage.

13.2. Authorship eligibility guidelines and any intended use of professional writers

We will follow the International Committee of Medical Journal Editors (ICMJE) authorship criteria for outcome papers:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND

- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

An authorship plan will be agreed prior to the drafting of outcome papers. We do not plan to engage the use of professional writers for this study.

14. References

1. Allan, L.M., et al., Incidence and prediction of falls in dementia: a prospective study in older people. PLoS ONE [Electronic Resource], 2009. 4(5): p. e5521.
2. Allan, L.M., et al., An intervention to improve outcomes of falls in dementia: the DIFRID mixed methods feasibility study. Health Technology Assessment (Winchester, England). 23(59): p.1-208.
3. Treml J.., et al., Falling standards, broken promises: report of the national audit of falls and bone health in older people 2010. 2011.
4. NICE, Dementia: assessment, management and support for people living with dementia and their carers. 2018, National Institute for Health and Care Excellence: London.
5. Deshpande, N., et al., Activity restriction induced by fear of falling and objective and subjective measures of physical function: a prospective cohort study. J Am Geriatr Soc, 2008. 56(4): p. 615-20.
6. Vaapio, S.S., et al., Quality of life as an outcome of fall prevention interventions among the aged: a systematic review. European Journal of Public Health, 2009. 19(1): p. 7-15.
7. Pitkala, K., et al., Efficacy of physical exercise intervention on mobility and physical functioning in older people with dementia: a systematic review. Experimental Gerontology, 2013. 48(1): p. 85-93.
8. Burton, E., et al., Effectiveness of exercise programs to reduce falls in older people with dementia living in the community: A systematic review and meta-analysis. Clinical Interventions in Aging, 2015. 10: p. 421-434.
9. Suttanon, P., et al., Feasibility, safety and preliminary evidence of the effectiveness of a home-based exercise programme for older people with Alzheimer's disease: a pilot randomized controlled trial. Clinical rehabilitation, 2013. 27(5): p. 427-438.
10. Wesson, J., et al., A feasibility study and pilot randomised trial of a tailored prevention program to reduce falls in older people with mild dementia. BMC Geriatrics, 2013. 13: p. 89.
11. Pitkala, K.H., et al., Effects of the Finnish Alzheimer disease exercise trial (FINALEX): a randomized controlled trial. JAMA Internal Medicine, 2013. 173(10): p. 894-901.
12. Taylor, M.E., et al., Tailored Exercise and Home Hazard Reduction Program for Fall Prevention in Older People With Cognitive Impairment: The i-FOCIS Randomized Controlled Trial. The Journals of Gerontology: Series A, 2020. 76(4): p. 655-665.
13. Bajwa, R.K., et al., A randomised controlled trial of an exercise intervention promoting activity, independence and stability in older adults with mild cognitive impairment and early dementia (PrAISED) - A Protocol. Trials, 2019. 20(1): p. 815.
14. Shaw, F.E., et al., Multifactorial intervention after a fall in older people with cognitive impairment and dementia presenting to the accident and emergency department: randomised controlled trial. BMJ, 2003. 326(7380): p. 73.
15. Wheatley, A., et al., Developing an Intervention for Fall-Related Injuries in Dementia (DIFRID): an integrated, mixed-methods approach. BMC Geriatrics, 2019. 19(1): p. 57.
16. Gélinas, I., et al., *Development of a Functional Measure for Persons With Alzheimer's Disease: The Disability Assessment for Dementia.* American Journal of Occupational Therapy, 1999. 53: p. 471-81.

17. Herdman, M., et al., *Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L).* Qual Life Res, 2011. 20(10): p. 1727-36.
18. Logsdon, R.G., et al., *Assessing Quality of Life in Older Adults With Cognitive Impairment.* Psychosomatic Medicine, 2002. 64: p. 510-19.
19. Logsdon, R.G., et al., *Quality of Life in Alzheimer's disease: Patient and Caregiver Reports.* Journal of Mental Health and Ageing, 1999. 5(1): p. 21-32.
20. Tinetti, M.E., D. Richman, and L. Powell, *Falls Efficacy as a Measure of Fear of Falling.* Journals of Gerontology, 1990. 45(6): p. P239-P243.
21. Stolee, P., et al., *An Individualized Approach to Outcome Measurement in Geriatric Rehabilitation.* Journal of Gerontology Series A: Biological Sciences and Medical Sciences, 1999. 54A(12): p. M641-M647.
22. Kiresuk, T.J. and R.E. Sherman, *Goal Attainment Scaling: A General Method for Evaluating Comprehensive Community Mental Health Programs.* Community Mental Health Journal, 1968. 4(6): p. 443-53.
23. Zarit, S.H., K.E. Reever, and J. Bach-Peterson, *Relatives of the Impaired Elderly: Correlates of Feelings of Burden.* The Gerontologist, 1980. 20(6): p. 649-55.
24. Al-Janabi H, van Exel J, Brouwer W, Coast J. 2016. A Framework for Including Family Health Spillovers in Economic Evaluation. Medical Decision Making https://doi.org/10.1177/0272989X15605094
25. National Institute of Health and Care Excellence. Guide to the methods of technology appraisal. National Institute for Health and Clinical Excellence (NICE) London, UK. 2013.
26. Bruce J, Hossain A, Lall R, Withers EJ, Finnegan S, Underwood M, et al. Fall prevention interventions in primary care to reduce fractures and falls in people aged 70 years and over: the PreFIT three-arm cluster RCT. Health Technol Assess 2021;25(34) https://doi.org/10.3310/hta25340
27. Jones, K. & Burns, A. (2021) Unit Costs of Health and Social Care 2021, Personal Social Services Research Unit, University of Kent, Canterbury. DOI: 10.22024/UniKent/01.02.92342