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Maintaining independence in individuals with dementia at home after a fall: a protocol for the UK pilot cluster randomised controlled trial MAINTAIN

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ABSTRACT

Introduction Individuals with dementia face an increased risk of falls. Falls can cause a decline in the individual's overall functionality. All types of falls, including those that do not result in injury, can lead to psychosocial consequences, such as diminished confidence and a fear of falling. Projections indicate a rising trend in dementia diagnoses, implying an increase in fall incidents. Yet, there is a lack of evidence to support interventions for people living with dementia who have fallen. Our objective is to test the feasibility of a falls intervention trial for people with dementia.

Method and analysis This is a UK-based two-arm pilot cluster randomised controlled trial. In this study, six collaborating sites, which form the clusters, will be randomly allocated to either the intervention arm or the control arm (receiving treatment as usual) at a 1:1 ratio. During the 6 month recruitment phase, each cluster will enrol 10 dyads, comprising 10 individuals with dementia and their respective carers, leading to a total sample size of 60 dyads. The primary outcomes are the feasibility parameters for a full trial (ie, percentage consented, follow-up rate and cost framework). Secondary outcomes include activities of daily living, quality of life, fall efficacy, mobility, goal attainment, cognitive status, occurrence of falls, carer burden and healthcare service utilisation. Outcome measures will be collected at baseline and 28 weeks, with an additional assessment scheduled at 12 weeks for the healthcare service utilisation questionnaire. An embedded process evaluation, consisting of interviews and observations with participants and healthcare professionals, will explore how the intervention operates and the fidelity of study processes.

Ethics and dissemination The study was approved by the NHS and local authority research governance and research ethics committees (NHS REC reference: 23/WA/0126). The results will be shared at meetings and conferences and will be published in peer-reviewed journals.

Trial registration number ISRCTN16413728.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ We will use rigorous quantitative and qualitative methods during the pilot trial with an embedded process evaluation.
⇒ The intervention is tailored to the individuals needs and abilities.
⇒ This study is a small-scale pilot and, as such, does not allow us to draw conclusions about the effectiveness and cost-effectiveness of the intervention.
⇒ It is not possible to conceal healthcare professionals, participants or study team members (bar statisticians) to the study arms.

INTRODUCTION

In the UK, falls and fractures incur an approximate annual cost of £4.4 billion.[1] People with dementia are up to 10 times more likely to experience falls compared with those without dementia.[2 3] Following a fall, people living with dementia are often less likely to recover well compared with individuals without dementia,[4] leading to a loss of independence.[5] Falls, including those that do not result in injuries, can lead to psychosocial consequences, such as diminished confidence and a fear of secondary falling.[6 7] Recent estimates indicate that up to 850 000 individuals in the UK are living with dementia,[8] of whom approximately 60% reside in the community.[9] Although projections indicate a rising global incidence of dementia in the future,[10] coupled with the escalated susceptibility to falls and resultant injuries in people living with dementia,[2 3] there is a paucity of empirical support for interventions to mitigate the consequences of falls among individuals with dementia.[11]

Current research has demonstrated effectiveness in preventing secondary falls using a range of interventional strategies, including exercise, medication optimisation/review and multifaceted programmes in individuals without dementia,[12–15] but their efficacy for individuals with dementia remains uncertain.[16] There have been limited pilot and full trials focusing on improving physical activity in people living with dementia, yielding mixed findings.[17–22] To date, no published trials have specifically investigated the effectiveness of interventions aimed at enhancing independence following a fall in individuals with dementia. Notably, the current National Institute for Health and Care Excellence (NICE) guidelines for dementia do not identify any evidence of effective interventions specifically tailored to address falls.[23] Nonetheless, they recommended referring individuals with dementia to falls services, with the acknowledgement that such services may not be suitable for individuals with more advanced dementia.[23] Consequently, there is a pressing requirement for further trials in this field.[11]

In a prior research programme, we developed an intervention, named DIFRID (Developing an Intervention for Fall-Related Injuries in Dementia), aimed at maintaining independence in people living with dementia in the community.[24] In the present study, we are conducting a pilot cluster randomised controlled trial (c-RCT) involving a modified version of the DIFRID intervention. The current trial is named MAINTAIN.

Objectives

The main objective of the present study is to assess the feasibility of conducting a research trial on an intervention for falls in individuals aged over 50 with dementia. Secondary objectives include:

1. Examination of the implementation and acceptability of the intervention for participants and healthcare professionals, and mechanisms of impact via a process evaluation.
2. Investigation of the cost-effectiveness framework for the full trial.
3. Iterative refinement of the intervention for the full trial.
4. Assessment of 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 and whether loss to follow-up differs markedly between the trial arms.

METHODS, DESIGN AND ANALYSIS

Design

This protocol was designed in accordance with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials 2013) statement[25] and the TIDieR (Template for Intervention Description and Replication) checklist.[26] The study is a pilot c-RCT of a rehabilitation falls intervention, accompanied by an embedded qualitative process evaluation. Cluster design facilitated the implementation of the intervention at a service level, mirroring real-world scenarios and offering a pragmatic approach to delivering the intervention. The study recruitment window runs from 1 September 2023 to 30 April 2024.

Study setting and recruitment

The study will be carried out in six healthcare sites that range in services, such as acute units, virtual wards and memory clinics. Each site will be a cluster (ie, six clusters in total). Study sites reflect a range of healthcare services to allow for generalisability. Table 1 outlines the available routes for participant identification. Sites will use the identification routes accessible to their service. There are several identification streams. Identification from primary care can occur through two streams, a retrospective case search and during clinical consultations. In addition to primary care, other community settings, such as admiral nurses and paramedics, will also be able to identify participants. Sites may also use pre-existing research registers, if available. Please refer to online supplemental file 1 and 2 for further details on participant identification and recruitment.

Study population and participant eligibility criteria

The study will involve individuals aged 50 years or older who are diagnosed with dementia and registered on the Primary Care Quality Outcomes Framework dementia register. The diagnosis of dementia must be confirmed by the primary care team within 4 weeks of study identification. The individual with dementia must have experienced at least one fall in the past 6 months. 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. The individual with dementia 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. People living in a care home are not eligible for this trial. Individuals with dementia must also have an unpaid carer willing to take part in the research and either have the capacity to consent to participation, or a personal or nominated consultee (see online supplemental file 3 for consent/consultee form). Unpaid carers will be invited to participate in the study as part of a dyad with the person with dementia. It will be determined by the person with dementia and their family members or friend who will be identified as the carer for the study. To be eligible, carers must be in contact with person with dementia for at least 1 hour per week and have capacity to provide informed consent. All participants must be able to communicate in English.

Cluster randomised controlled trial

For the c-RCT, people living with dementia and carers will be recruited as dyads (pairs) and these participants will

Table 1 Community and secondary care settings to identify potential participants for the MAINTAIN trial

Community services	Secondary services	Research registers
Primary care Individuals who have a confirmed dementia diagnosis and have experienced a fall within the past 6 months, within the healthcare practices that are part of the Clinical Commissioning Groups (CCGs) participating in the research.	**Emergency departments** Individuals with possible dementia presenting with a fall in the last 6 months to any of these services in participating sites will be eligible if they are cared for by the healthcare provider.	**Join Dementia Research (JDR)** JDR is an online self-registration platform designed for individuals dealing with memory problems or dementia and their carers. Researchers can reach out to volunteers through their preferred method of contact to explore potential participation further. People living with dementia registered with the service will be eligible for the study if they have had a fall within the last 6 months.
Paramedics Responding to incidents involving individuals who may have dementia and have fallen. This will be relevant for incidents occurring within the postal code areas covered by the collaborating CCGs.	**Supported discharge teams** Individuals with possible dementia presenting with a fall in the last 6 months to any of these services in participating sites will be eligible if they are cared for by the healthcare provider.	**Local research case registers** If recruitment sites have the capability to access local research registries, we will use these for the recruitment process. People living with dementia registered with the service will be eligible for the study if they have had a fall within the last 6 months.
Admiral nurses Determine individuals who may have dementia and live within the postal code regions covered by the involved CCGs, and who have sought or are seeking medical care due to a fall in the last 6 months.	**Rehabilitation outreach teams** Individuals with possible dementia presenting with a fall in the last 6 months to any of these services in participating sites will be eligible if they are cared for by the healthcare provider.	
	Memory clinics Individuals with possible dementia presenting with a fall in the last 6 months to any of these services in participating sites will be eligible if they are cared for by the healthcare provider.	

either be offered the intervention (intervention arm) or receive usual care (control arm).

Training for healthcare professionals

Healthcare professionals responsible for implementing the intervention include qualified and experienced physiotherapists and occupational therapists (OTs) as well as rehabilitation support workers (RSW). The formal qualification for an RSW is dependent on the trust/post but experience of working in a healthcare setting is required. Healthcare professionals will receive training alongside the utilisation of a manual. Training options will be provided through online e-learning modules and/or in-person sessions. This training will be conducted by experienced physiotherapists and OTs who specialise in working with individuals with dementia. See online supplemental file 4 for the training curriculum.

Description of intervention

The intervention constitutes a multidisciplinary approach that is administered in the participant's home. The intervention is individualised, taking into consideration physical capabilities, activity preferences and goals mutually established by the healthcare professional, the participant and their carer. The number of sessions a participant receives will be adjusted to their specific requirements. A clinical researcher will conduct a baseline assessment to collect outcome measure data. The first intervention session will be a clinical home assessment by a healthcare professional to identify necessary actions for fall risk reduction and improved independence. This will be followed by a potential series of up to 19 therapy sessions distributed across 12 weeks, with additional booster sessions at 16, 20 and 24 weeks. The control arm will receive treatment as usual. Follow-up data will be collected at 28 weeks with an additional assessment scheduled at 12 weeks for the healthcare service utilisation questionnaire. See online supplemental file 5 for a list of outcome measures and figure 1 for the schedule of events for the intervention and control arms.

Intervention home assessment

After the baseline visit, a qualified physiotherapist or OT will visit the participants at home to conduct a holistic home assessment (see box 1). This assessment will incorporate input from the participant and their carer, in addition to consultations with professionals who are

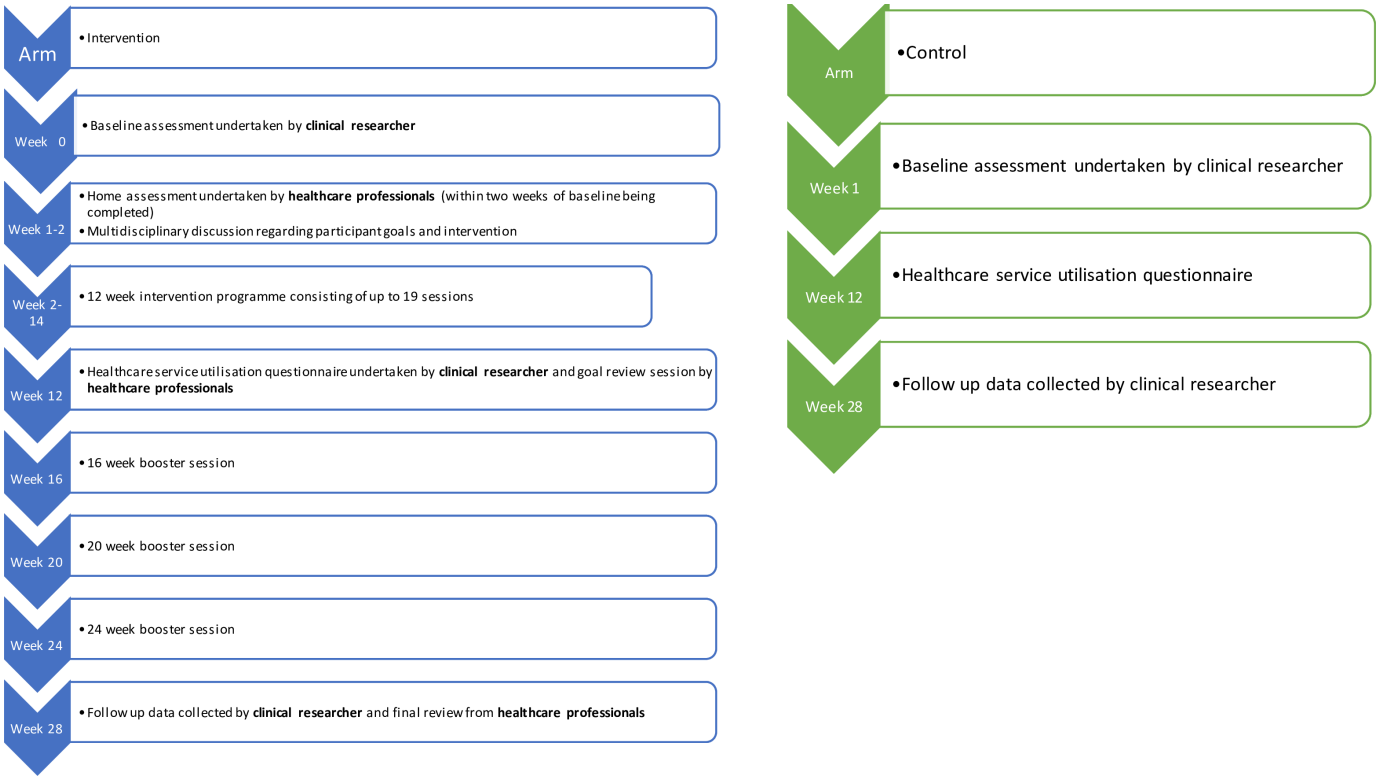

Figure 1 Schedule of events for the MAINTAIN cluster-randomised control trial.

already engaged in the participant's care. At the end of the assessment, a list of identified challenges and a set of tailored goals, chosen by the person with dementia and their carers and agreed with the healthcare professional, will be formulated. These challenges and goals will be reviewed by the multidisciplinary team (MDT) which includes physiotherapists, OT and RSW. The MDT will devise an action plan with recommendations for activities to be undertaken during therapy sessions. One therapist will be designated as the primary point of contact for the participants. Before the 12th week, the primary point of contact may review and modify the goals and action plan if necessary. The MDT will also pinpoint onward referrals to healthcare professionals such as the general practitioner (GP), geriatrician or mental health nurse.

During the home assessment, the capacity and willingness of the carer to engage in the intervention will be confirmed, along with an assessment of their knowledge and understanding of dementia and falls, including their attitudes towards risk. Additionally, an evaluation of carer stress will be conducted, using data from the Zarit burden interview 12 (ZBI-12)[27] as a reference. The MDT will also consider the needs of the carer and determine how to address those needs.

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Intervention therapy sessions

Therapy sessions will be up to 60 min, with a maximum of 19 sessions over a 12 week timeframe. Booster sessions are also scheduled at weeks 16, 20 and 24. In total, during the 28 week follow-up period, participants have the potential to receive a maximum of 22 sessions, which includes the booster sessions. The quantity and frequency of these sessions will be personalised to meet the needs of the participants. Up to six sessions can be carried out by the physiotherapist or OT. All remaining sessions will be facilitated by a RSW.

Session activities encompass both functional and physical exercises, including strength and balance exercises, as well as dual-task activities. Participants have the option to either follow a separate exercise programme distinct from their daily routines or integrate the exercises into their daily lives, such as practicing balance while standing at the sink during dishwashing. Functional activities will be identified during the goal-setting session, encouraging participation in both community and social activities. Carers will be supported to promote the activities by joining in where appropriate as well as engaging in the goal setting process. Visual aids, such as images illustrating physical activities, may be provided to assist participants in carrying out activities. Cueing cards may be integrated into the participant's daily routine to prompt increased activity. A structured form will be used during each visit to document the activities undertaken and

Box 1 Intervention home visit assessment sessions undertaken by healthcare professionals

Intervention home assessment

⇒ 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.
⇒ Medical history and comorbidities.
⇒ Medication.
⇒ 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 for example, 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 for example, ability to make a cup of tea.
⇒ Assessment of home adaptations and need for new adaptations.

provide recommendations for activities to be completed between visits. This form will review the participant's adherence to previous recommendations and, if not followed, assess the reasons and reevaluate goal setting. Additionally, the participant may be referred to other local services designed for individuals at risk of falling, such as falls prevention classes. A summary of the interventions conducted during the study, along with recommendations for continued service involvement as needed, will be forwarded to the GP after the final therapy visit.

Randomisation

Study sites will be randomly assigned in a 1:1 ratio to one of two groups: either the intervention along with standard care (intervention arm) or simply continuing with standard care (control arm) to create six 'clusters'. Participants will be randomised at the cluster level rather than individually, and the assignment of clusters will take place before participant recruitment. This approach provides the needed preparation time for sites in the intervention arm. The allocation sequence will be generated by the trial statistician using a random seed and entered into REDCap Academic.

The procedure for replacing sites will be as follows. Any withdrawn sites will be replaced in a 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 the study and a completed site questionnaire has been received. 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.

Blinding

Given the nature of both the intervention and usual care treatment, it is not feasible to implement blinding for clinicians and participants involved in the intervention regarding treatment allocation. Additionally, due to the nature of discussions between participants and researchers during follow-up visits, it is also impractical to blind researchers who collect data regarding treatment allocation during follow-up. This is due to the likelihood that healthcare service utilisation data obtained at the 12 week mark would reveal the treatment allocation, thus necessitating that all clinicians involved in this trial remain unblinded throughout. To prevent any undue influence on potential participants considering enrolment in the trial, participants will remain blinded until they have been screened and given their consent. However, they will subsequently be unblinded as the intervention cannot be concealed during delivery. Statisticians will maintain blinding until the completion of the statistical analysis plan (SAP) to ensure that proposed analyses and any subgroup analyses are not biased.

Trial outcomes

Given the multifaceted nature of this comprehensive intervention, multiple outcome measures will be investigated. Including several outcome measures will allow us to determine the most appropriate primary outcome measure for the definitive trial. See online supplemental file 5 for a comprehensive list.

Sample size

We are aiming to recruit six healthcare sites. Randomisation will allocate three sites to the intervention arm and three sites to the control arm. Over a 6 month recruitment period, each cluster will enrol 10 dyads (10 individuals with dementia and 10 accompanying carers) resulting in a combined sample size of 60 dyads. We will aim for an even distribution of 30 dyads in the intervention arm and 30 dyads in the control arm. Based on observations in our feasibility study,[24] a recruitment rate of 1.7 dyads per site per month is anticipated.

The required sample size was calculated based on obtaining sufficiently precise estimates of the feasibility parameters. We anticipate approaching 150 eligible

individuals, with an expected consent rate of 40% (60 participants). A total of 150 screened individuals is large enough to estimate the consent rate with a 95% CI of 29% to 51%. Assuming an 80% follow-up rate among those who consent, the 60 recruited participants is large enough to estimate this with a 95% CI of 66% and 91%. Furthermore, the intervention arm, consisting of 30 participants, is large enough to estimate the percentage (assumed to be 80%) of those attending at least three-fifths of the allocated sessions with a 95% CI of 60% to 93%. These CI account for clustering and are based on an assumed intracluster (intraservice) correlation coefficient of 0.05, which quantifies the variability across clusters of feasibility parameters, including the percentage consenting, the percentage of participants who are followed up, and the percentage of participants in the intervention arm that attend at least 60% of the sessions.

Data analysis

The analyses will adhere to a fully predefined SAP, which will receive approval from both the Trial Steering Committee and the Trial Management Group (TMG). The progression of participants through the trial will be summarised using a CONSORT (Consolidated Standards of Reporting Trials) flow diagram[28] for reporting cluster randomised controlled trials. To provide an overview of the baseline characteristics of both the services and participants, continuous variables will be summarised using means and SD, while categorical variables will be presented in terms of frequencies and percentages. We will present the following parameters with 95% CI that account for clustering: the percentage of screened individuals meeting eligibility criteria, the percentage of eligible individuals consenting to participate, the percentage of participants providing data at the follow-up and the percentage of intervention arm participants attending at least 60% of the sessions.

To estimate these parameters, we will use mixed-effects logistic regression models with Satterthwaite's df correction, fitted to binary outcomes representing consent status, follow-up status and attendance of at least 60% of scheduled sessions. The constant derived from these models is the log odds of these parameters, and the results (including 95% CIs) will be converted to and reported as percentages. Additionally, we will provide estimates of the SD for continuous outcomes measured at baseline, 12 weeks and 28 weeks. To assess the potential impact of cluster randomisation on recruitment bias, particularly with unblinded researchers, we will report the percentage of eligible individuals participating in both the intervention and control arms and examine participant characteristics between the two trial arms.

In ancillary analyses, we will also present intention-to-treat estimates of the intervention's effect on continuous outcomes at 12 and 28 weeks, along with 95% CI to gauge potential effectiveness. The comparison between trial arms will involve the use of mixed ('multilevel') linear regression models with Satterthwaite's df correction to account for the limited number of clusters in the study. These comparisons will be adjusted for the baseline outcome scores. All analyses will be carried out using Stata software. Given that this is a pilot study, we will provide estimates from these comparisons along with 95% CI, but no p-values will be reported.

Process evaluation

The process evaluation will examine the implementation of the intervention, its acceptability to participants and healthcare professionals, the underlying mechanisms of its impact and any contextual factors. Eighteen people with dementia and their carers, and up to 15 healthcare professionals will be interviewed. Observations of therapy sessions, healthcare staff supervision and MDT discussions will also be conducted. A logic model will be used to structure the process evaluation and will be adjusted in response to study findings. NVivo software[29] will assist in organising qualitative data. Thematic analysis[30] will be used to analyse qualitative data, which will be underpinned by a critical realist approach.[31 32] Interviews about the acceptability and feasibility of study processes (eg, randomisation) will also be conducted with the clinical researcher at all six sites. See online supplemental file 6 for further details.

Economic evaluation

The health economics aspect of the study will examine the cost-effectiveness framework within the pilot c-RCT. This component aims to evaluate the gathering of resource and outcome data, which will be used in a future comprehensive cost-effectiveness analysis. The analysis will adopt a societal perspective, considering potential indirect effects.[33] Both the individual with dementia and their carers outcomes will be assessed, as recommended by the National Institute of Health and Care Excellence (NICE), which advises the inclusion of all direct health effects, whether for patients or, when applicable, caregivers, in cost-effectiveness analyses.[23] Additionally, in line with NICE guidance, the cost-effectiveness analysis will utilise a preference-based measure. Specifically, within the pilot c-RCT, we will employ the EuroQol-5 Dimensions-5 Levels (EQ-5D-5L).[34] The measure will be completed by individuals living with dementia with the capacity to complete the items. The proxy version of the EQ-5D-5L will be completed by the carer on behalf of the individual with dementia, and the carer will also complete their own EQ-5D-5L to assess their health-related quality of life. The English value set for the EQ-5D-5L, recommended by NICE at the time of analysis will be used to generate index scores based on the EQ-5D-5L domains for everyone. The study will provide information on the number (percentage) of partially completed and non-completed questionnaires, and the number (percentage) of missing scores due to incomplete individual question items for both participant and caregiver EQ-5D-5L.

A participant-completed healthcare service use questionnaire (HUQ) will be developed based on similar

studies involving comparable populations.[35 36] This questionnaire will be assessed for completion and data quality to capture information about healthcare, social care, informal care and out-of-pocket expenses. We will calculate the average per-participant cost over the 28 week duration for each randomised arm. Unit costs will be sourced from various references, including the Personal Social Services Research Unit.[37] We will also monitor the completion of the HUQs.

Data management

Data management will adhere to the Data Protection Act 2018. Data will be collected via paper consent forms and case report forms (CRFs). An electronic data capture (EDC) system will allow consent forms to be scanned in and will mirror paper CRFs. CRFs will be pseudonymised to protect participant identities. Paper consents and CRFs will be sent to the study site by the clinical researcher for transcription into the EDC system. Paper CRFs will be securely stored at study sites until they are posted to the Exeter CTU at the intervention's end. Participating sites will handle the storage of their data in alignment with their respective local NHS trust/institution procedures. Access to the EDC system will be controlled through individual logins and permissions assigned by the trial management team. Regular reports will be generated for missing data, and data entry reminders will be sent to sites.

Methods to promote participant retention and complete follow-up include clear communication via participant facing documents and the research/therapy team, tailored scheduling of home visits and, fostering a trusting relationship between participants and study staff. For participants who discontinue, we will ask if it is possible to continue collecting information about their health from central NHS and GP records.

Qualitative interviews will be transcribed verbatim (see online supplemental file 7 for the discussion guide). Audio recordings and transcriptions will be managed exclusively by the qualitative team or authorised transcribers with confidentiality agreements. Secure file transfer systems will be in place. Personal identifiers such as names and locations will be omitted from transcriptions, and a unique code will identify each study participant, with the code list stored in a separate, secure location from the transcripts. Given the detailed nature of qualitative data, complete anonymisation of interview transcripts may not be feasible, as excessive redaction could render the data unusable for analysis. Folders containing transcripts will only be accessible to identified research team members engaged in qualitative analysis. Audio recording files will be deleted at the conclusion of the study, while interview transcripts, observation notes and analysis files will be securely archived with the MAINTAIN study documents. Healthcare professional consent forms will use DocuSign, and the qualitative researcher will have a secure account. Completed forms will be securely saved and deleted from download folders and recycle bins.

Table 2 Success criteria and barriers to success for the MAINTAIN trial

Definite go ('green light')	Definite stop ('red light')
≥40% of eligible patients consenting to the pilot trial.	<10% of eligible participants consenting to the pilot trial.
≥80% of participants attending ≥60% of planned sessions.	<30% of participants attending ≥60% of planned sessions in each intervention arm.
Retention of ≥70% of consented participants for key outcome data at 28 weeks.	Retention of <50% of consented participants for the provision of key outcome data at 28 weeks.
Qualitative feedback indicating that the intervention is perceived as acceptable to both participants and professionals.	Process data from participants and professionals indicating low fidelity in intervention procedures (content, frequency, duration and quality), or the intervention being deemed infeasible to deliver.

The trial master file and EDC system data will be archived in accordance with the Exeter CTU standard operating procedure. Study documents will be archived for 5 years poststudy completion. After this period, all personally identifiable data will be securely disposed of. The anonymised data set will be retained indefinitely for future ethically approved research purposes.

Serious adverse events and monitoring

This is a low-risk, non-drug trial. As dementia is progressive and associated with comorbidity, intercurrent illness will be common. We will only be recording and reporting safety data for individuals living with dementia. Non-serious adverse events (SAEs) will not be documented or reported in the study, as the intervention components are not novel, and safety is not an outcome measure. All deaths (regardless of cause) and hospitalisations resulting from falls, fractures or musculoskeletal injuries will be recorded. Other SAEs will not be documented or reported. An authorised delegate will assess causality for reportable SAEs. SAEs possibly, probably or definitely related to the intervention will be categorised as 'related.' If causality cannot be determined within 24 hours of awareness, the SAE will be treated cautiously and subject to expedited reporting.

Success criteria and barriers to success

Success criteria serve as progression benchmarks for advancing to a full trial, outlined in table 2.

Intermediate targets will be categorised as amber, and study refinement will be carried out in collaboration with our Patient and Public Involvement and Engagement (PPIE) panel and other key stakeholders. The Trial Steering Committee will deliberate on whether to proceed with planning a full trial.

Ethical considerations and dissemination

The study has received approval from both NHS and local authority Research Governance and Research Ethics Committees (NHS REC reference: 23/WA/0126). All protocol modifications will be communicated to relevant parties though appropriate systems/channels. The trial results will be published in peer-reviewed journals and presented at various meetings and conferences. Findings will be available in an open-access journal within 24 months of study completion, following CONSORT guidelines. The International Committee of Medical Journal Editors definition of the role of authors and contributors will be used during publications. A lay-accessible summary of results will also be made available and will be developed in collaboration with our PPIE panel. Participants can choose their preferred format (post or email) to receive the lay summary. Results will be posted on the International Standard Randomised Controlled Trial Number website, and a summary will be submitted to the Health Research Authority within 12 months of study completion.

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