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**Promoting Independence in Dementia (PRIDE):
A Feasibility Randomised Controlled Trial**

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Short title: PRIDE Feasibility RCT

Acronym: PRIDE

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SYNOPSIS

Title	Promoting Independence in Dementia (PRIDE): a feasibility randomised controlled trial.
Short title	PRIDE Feasibility RCT
Acronym	PRIDE
Chief Investigator	Professor Martin Orrell
Objectives	To investigate the feasibility and acceptability of conducting a randomised controlled trial (RCT) to compare the clinical and cost effectiveness of the PRIDE intervention delivered in addition to usual care with usual care only for people with mild dementia.
Trial configuration	Prospective, parallel group, two-arm, multicentre, feasibility, randomised controlled trial (RCT).
Setting	Services for people with dementia within NHS Secondary Care Trusts in England.
Sample size estimate	As this is a feasibility study, a formal sample size calculation for between group comparisons of a primary outcome is not appropriate. However a sample size of 75-80 randomised participants will allow estimation of recruitment fraction with a margin of error (half-width of 95% confidence interval) of around 8 percentage points, and retention of 12 percentage points.
Number of participants	A target sample size of 75-80 participants and up to 80 supporters will be sought from up to 6 sites over the recruitment period.
Eligibility criteria	<i>Inclusion criteria for the person with dementia</i> - Resident within the catchment area of one of the participating NHS sites. - Aged 18 or over; there is no upper age limit. - Meet the Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition (DSM-IV) criteria for dementia of any type, including Alzheimer's, vascular, Lewy body type and mixed. - Able to engage with and participate in the intervention in the judgement of the investigator or designee. - Able to provide informed consent in the judgement of the investigator or designee. - Able to read and communicate verbally in English. - Mild dementia, defined as a score of 0.5 or 1 on the Clinical Dementia Rating (CDR) Scale. The CDR will be completed as a post-consent screening assessment to determine eligibility for randomisation. <i>Exclusion criteria for the person with dementia</i> - Living in institutional care. <i>Inclusion criteria for supportive others (participation is optional)</i> - Aged 18 or over; there is no upper age limit. - Able to engage with and participate in the intervention. - Able to provide informed consent. - Able to read and communicate verbally in English.
Description of interventions	<i>PRIDE intervention</i> The PRIDE intervention is a social intervention encompassing social, physical, and cognitive dimensions for people in the early

	stages of dementia. It comprises a manual which is worked through with the support of a trained facilitator during three sessions of between 60-90 minutes, over two months. The objectives of the intervention are to promote independence and facilitate the person's access to opportunities to live well with dementia by supporting meaningful social, cognitive, and physical activities and healthy lifestyle choices and helping the person maintain their social roles. The PRIDE intervention will be delivered in addition to usual care. <i>Usual care</i> All participants will have access to the services and interventions usually available to people with dementia and their family at the participating sites. This will likely vary between and within centres and may change over time.
Duration of study	The expected recruitment period will be up to 10 months from enrolment of the first participant. Each participant will be in the trial for a maximum of 6 months, from randomisation to final follow-up. The duration of the trial is expected to be up to 24 months from recruitment of the first participant to reporting.
Randomisation and blinding	Participants will be individually allocated on a 1:1 ratio using minimisation with a probabilistic element. The minimisation variables will be study site, sex, age (< 80 or ≥ 80) and medication for dementia (any versus none). Clinicians delivering the intervention and participants and their supporters will be aware of treatment allocation. Outcomes will be collected by staff blinded to treatment allocation.
Outcome measures	Outcomes will be measures of the feasibility of conducting a full RCT related to participant recruitment and follow-up, intervention delivery including the recruitment, training and retention of PRIDE trained facilitators, clinical outcomes, intervention and resource use costs and the acceptability of the intervention and study related procedures.
Statistical methods	Data analysis will primarily be descriptive to address the feasibility aims of the study. All analyses to be conducted for the feasibility trial will be documented in a Statistical Analysis Plan which will be finalised prior to database lock.

ABBREVIATIONS

AE	Adverse Event
CI	Chief Investigator overall
CRF	Case Report Form
GCP	Good Clinical Practice
NDS	National Dementia Strategy
NHS	National Health Service
R&D	Research and Development department
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
TSC	Trial Steering Committee

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TRIAL BACKGROUND INFORMATION AND RATIONALE

Background

Impact of dementia

In the UK over 800,000 older people have dementia, which can lead to social exclusion, loss of identity and loss of independence due to deterioration in cognition and activities of daily living, the double stigma of age and dementia (Moniz-Cook, 2008), and the reduced capacity for social participation. In this way, dementia challenges society, and the individuals and their carers responding to it. Dementia has profound effects on family carers who, through their actions, save the UK government over £6 billion a year. In the UK the provision of health and social care services for people with dementia costs the nation over £17 billion a year. Despite the enormous costs to individuals and society, less than 10% of UK research funding is focused on health and social care research (EU Joint Programme Neurodegenerative Disease Research [JPND], 2012). The EU JPND research programme has highlighted the need for psychosocial interventions promoting social inclusion, dignity and the positive contributions to society that people with dementia can make (JPND, 2012).

Dementia is a national priority in the UK. The All Party Parliamentary Group on Dementia (APPGD, 2012) noted many people delay seeking help and highlighted the importance of better public awareness. While many people with dementia remain undiagnosed, the UK government's commitment to early diagnosis in the National Dementia Strategy (NDS) and the Prime Minister's Challenge on Dementia means that memory services often see very many people with early stage dementia who are largely independent and able to participate in community activities. This emphasises the need to strengthen community interventions including better information and support (APPGD, 2012). Key objectives of the NDS include reducing social exclusion and discrimination, and improved early diagnosis, intervention and better access to information and advice (Department of Health, 2009).

Key concerns of people with dementia (Mountain and Craig, 2012) include loss of power in the relationship with their family, the need to maintain a role outside the family, and a lack of basic information about diagnosis, prognosis and care. People with cognitive impairment and dementia can experience 'excess disability' due to stigmatisation, loss of independence and a sense that relatives seek to take over their tasks and run their lives. Low expectations mean that staff and carers often don't encourage people with dementia to use their skills or learn new things, further contributing to decline. Hobbies and interests are often lost early in the disease process (Muo *et al.*, 2005). A recent review indicated that provision of information and advice can improve quality of life in dementia (Corbett *et al.*, 2011). This help needs to be delivered as an easy to implement, low cost intervention to improve support and care.

Post diagnostic support for people with dementia and their carers

Post-diagnostic support is critical to enhancing and maintaining the functional capacity of people with dementia, with lack of effective or insufficient support being linked to failure to prioritise diagnosis rate (Knapp *et al.*, 2014). This study may offer a potential solution to the impoverished post-diagnostic experiences of many people with dementia and carers (Manthorpe *et al.*, 2013).

Self-management interventions

Self-management interventions are a core part of current UK health policy and provision for long term (chronic) conditions to enhance quality of life (Department of Health, 2010). They can be delivered and received in a variety of ways (individually and in a group) and may be computer assisted, mail-delivered, telephone-based or in a face-to-face format (Barlow *et al.*, 2002). The aim is to live well with chronic illness, managing one's condition and its emotional

impact, and maintain as active a life as possible (Barlow, 2001). The limited research from self-management programmes for people with dementia (Toms, Quinn, Anderson & Clare, 2014; Martin *et al.*, 2012; Barlow *et al.*, 2002) suggests they may address the current "care gap" supporting people living with early stage dementia (National Audit Office, 2007).

Background to the Promoting Independence in Dementia (PRIDE) Research Programme

The ESRC and NIHR Programme for Applied Research is funding a five year Research Programme: Promoting Independence in Dementia (PRIDE), grant number: ES/L001802/1 that commenced in March 2014 and has subsequently been extended by 12 months to end in February 2020. The PRIDE Programme aims to promote independence for people with dementia by (1) investigating how social and lifestyle changes may reduce risk of dementia, and understanding the social impact of dementia, in order to (2) develop and evaluate an effective social intervention to enhance independence and quality of life for people with mild dementia and the friends and family that support them. This programme's strong person-centred approach aims to maximise independence in all its critical aspects, by reducing stigma, and encouraging participation in mental, physical, and social activities. The present study is a feasibility randomised controlled trial (RCT) of the PRIDE social intervention for living well with dementia to determine the feasibility and inform the design of a large multi-centre RCT.

Rationale

A definitive trial comparing the clinical and cost-effectiveness of the PRIDE intervention offered in addition to usual care with usual care alone is needed. However, before this can be successfully delivered a feasibility trial is necessary to provide data to inform the design and conduct of a future trial.

TRIAL OBJECTIVES AND PURPOSE

PURPOSE

To investigate the feasibility and acceptability of conducting a randomised controlled trial (RCT) to compare the clinical and cost effectiveness of the PRIDE intervention delivered in addition to usual care with usual care only for people with mild dementia.

OBJECTIVES

The study will address the following feasibility objectives:

1. Determine the feasibility of recruitment to a large-scale RCT
2. Refine the eligibility criteria for a future definitive RCT
3. Determine the acceptability to patients / clinicians of randomisation
4. Determine the relevance and acceptability to patients / clinicians of the trial intervention
5. Determine the acceptability to patients / clinicians of the trial procedures
6. Assess the ability of NHS sites to deliver the intervention
7. Assess training and support needs for NHS staff delivering the intervention
8. Evaluate treatment fidelity when delivered through NHS services
9. Determine the services and interventions provided as usual care and evaluate methods for measuring this
10. Assess follow-up and outcome completion rates
11. Determine the relevance and acceptability of a range of clinical outcome measures and obtain data to inform selection of the primary outcome for the main trial
12. Evaluate the utility and acceptability of resource use questionnaires for use in an economic evaluation alongside a future RCT
13. Conduct a comparative micro-costing of the PRIDE intervention and usual care

14. Estimate the sample size required for a definitive study
15. Determine the resources required for a full trial

TRIAL DESIGN

TRIAL CONFIGURATION

This is a prospective, parallel, two-arm, multicentre, feasibility, randomised controlled trial (RCT).

Participants will be individually randomised on a 1:1 ratio, to usual care plus the PRIDE intervention, or usual care alone.

Endpoints

Feasibility outcomes

The primary outcome of this study is the feasibility of conducting a full RCT of the PRIDE intervention, determined by a range of measures related to the study objectives. The feasibility outcomes, which will be measured to meet the objectives of this study, are shown in Table 1.

Table 1: Feasibility Objectives and Outcomes

Feasibility Objectives	Feasibility Outcomes
1. Determine the feasibility of recruitment to a large-scale RCT	a. Aggregate data on potential participants within NHS services b. Number of patients assessed for eligibility / consented / randomised c. Number and proportion of potential participants identified through NHS services, Join Dementia Research and by self-referral who are eligible d. Reasons for non-inclusion / non-eligibility e. Monthly recruitment rate per site f. Barriers and facilitators to recruitment (Interviews/focus groups)
2. Refine the eligibility criteria for a future definitive RCT	a. Number of screening failures for eligibility, post-consent b. Participant and facilitator report (Interviews/focus groups)
3. Determine the acceptability to patients / clinicians of randomisation	a. Proportion of eligible patients that consent to randomisation b. Reasons for non-consent c. Participant and facilitator report (Interviews/focus groups)
4. Determine the relevance and acceptability to patients / clinicians of the trial intervention	a. Premature discontinuation or non-attendance of treatment and reasons b. Feedback from participants and site staff delivering the intervention c. Participant and facilitator report (Interviews/focus groups)

Feasibility Objectives	Feasibility Outcomes
5. Determine the acceptability to patients / clinicians of the trial procedures	a. Proportion of approached NHS sites that agree to participate in the trial and reasons for non-participation b. Proportion of eligible patients that consent to randomisation c. Reasons for non-consent d. Withdrawals and losses to follow-up and reasons e. Feedback from participants and staff (Interviews/focus groups)
6. Assess the ability of NHS sites to deliver the intervention	a. Measures of the feasibility of delivering the PRIDE intervention within NHS settings: i. Number / grade / experience of staff within the service ii. Staff turnover iii. Time to treatment initiation b. Measures of the recruitment and retention of PRIDE facilitators during the study treatment period c. Barriers to treatment delivery per protocol (Interviews/focus groups)
7. Assess training and support needs for NHS staff delivering the intervention	a. Feedback on training delivered (Interviews/focus groups) b. Support offered / accepted (e.g. log of calls and emails to central support lines) - c.
8. Evaluate treatment fidelity when delivered through NHS services	a. Measures of treatment fidelity including: i. Adherence to intervention manual ii. Uptake of activities b. Feedback from participants and staff (Interviews/focus groups)
9. Determine the services and interventions provided as usual care and evaluate methods for measuring this	a. Post-diagnostic care pathway b. Services available c. Uptake of services
10. Assess follow-up and outcome completion rates	a. Response rate to follow-up assessment b. Questionnaire completion rates c. Amount of missing questionnaire data at item and scale levels
11. Determine the relevance and acceptability of a range of clinical outcome measures and selection of the primary outcome for the main trial	a. Completion rates and reasons for non-completion / missing data b. Estimates of clinically important differences, variance and sensitivity to change for the clinical outcome measures c. Direct questions to participants regarding relevance of measures
12. Evaluate the utility and acceptability of resource use questionnaires for use in an economic evaluation alongside a future RCT	a. Completion rate and reasons for non-completion / missing data

Feasibility Objectives	Feasibility Outcomes
13. Comparative micro-costing of PRIDE intervention and usual care	a. Staff time and resources for delivery of PRIDE intervention b. Other service use
14. Estimate the sample size required for a definitive study	a. Primary outcome selection b. Variability in the outcome c. Withdrawals and losses to follow-up
15. Determine the resources required for a full trial	a. Sample size, recruitment rate (number of sites / recruitment period), staffing and resources (for recruitment, treatment and follow-up)

Clinical outcomes

Clinical outcomes will be measured to assess the relevance and acceptability of these outcomes for use in a future definitive RCT and to obtain information to inform selection of the primary outcome measure for a future trial. In addition to asking participants to complete a range of clinical outcome measures, participants will also be asked to rate the relevance and acceptability of these measures to their experience.

The following clinical outcomes will be assessed at baseline and at follow-up visits completed at 3 and 6 months post-randomisation (see Table 2):

Participants randomised after 30 June 2019 will not have a 6 month follow-up visit. For these participants the follow-up visit at 3 months will be their final visit.

Outcomes for the person with dementia

- Activities of Daily Living measured using the Lawton Instrumental Activities of Daily Living (IADL) Scale, Lawton & Brody (1969):
The Lawton Instrumental Activities of Daily Living (IADL) Scale assesses a person's ability to perform daily tasks which are reliant on cognitive and physical functioning. Performance is measured across eight domains, with a summary score from 0 (low function) to 8 (high function).
- Health related quality of life measured using the EuroQoL Quality of Life Questionnaire – 5 Domains, 5 Levels (EQ-5D-5L), EuroQoL Group (1990):
The EQ-5D-5L is a measure of self-reported health outcomes that is applicable to a wide range of health conditions and treatments. It consists of two parts: a descriptive system (Part I) and a visual analogue scale (VAS) (Part II). Part I of the scale consists of five single-item dimensions including: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has a 5-point response scale designed to indicate the level of the problem. Part II uses a vertical graduated VAS (thermometer) to measure health status, ranging from worst imaginable health state to best imaginable health state, giving a numerical score ranging from 0 (worst) to 100 (best).
- Quality of life measured using the DEMQOL, Smith *et al.* (2005):
The DEMQOL scale measures five domains of quality of life including health and well-being, cognitive functioning, social relationships and self-concept. The scale uses self-rated reports of quality of life administered to the person with dementia using a 4-point scale (1=a lot, 2=quite a bit, 3=a little, 4=not at all). Positive items are reverse scored. Scored items are summed to produce a total score. A higher score indicates better health related quality of life.

- Mood measured using the Geriatric Depression Scale (GDS) – short form, Yesavage *et al.* (1983):
The Geriatric Depression Scale (GDS) – short form is a 15-item self-report assessment used to identify depression in the elderly. Participants respond yes or no to questions asking how they have been feeling over the previous week. Of the 15 items, 10 indicate the presence of depression when answered positively, and 5 indicate depression when answered negatively. One point is scored for each answer indicating the presence of depression. Scores range from 0 to 15, with higher scores indicating more severe depression.
- Cognition measured using the Standardised Mini Mental State Exam (S-MMSE), Molloy and Standish (1997):
The SMMSE is a brief quantitative assessment of cognition widely used in clinical and research settings. The measure has adequate validation (Ridha & Rossor, 2005) and takes a short time to administer. Orientation (time and geographic), repetition, verbal recall, attention and calculation, language and visual construction are tested with possible scores ranging from 0 to 30 with a lower score indicating more cognitive impairment.
- Wellbeing measured using the Control, Autonomy, Self-realisation and Pleasure (CASP) questionnaire, Hyde, Wiggins, Higgs, & Blane (2003):
CASP is a 19-item scale measuring quality of life in older people across 4 domains; control, autonomy, pleasure and self-realisation. The scale has demonstrated good internal consistency and validity. Scores range from 0, which represents a complete absence of quality of life, to 57, which represents total satisfaction of all four domains.
- Quality of relationships measured using the Impact on Participation and Autonomy Questionnaire for older people (IPAQ-O), Hammar, Ekelund, Wilhelmson & Edlund (2014):
The IPAQ-O focuses on autonomy, participation and self-determination of older people. The five items from the social relations subscale will be used to measure quality of relationships. Higher scores represent more severe problems.
- Positive emotions measured using the Positive Psychology Outcome Measure (PPOM), Stoner *et al.* (2017):
The PPOM is a 16-item scale measuring aspects of positive psychology. Each item is rated on a 5-point Likert scale (0 = not true at all, 1 = rarely true, 2 = sometimes true, 3 = often true, 4 = true nearly all the time). Higher scores indicate better wellbeing. There are two subscales for the PPOM. Sub-scale responses can be summed to calculate hope scores and resilience scores.
- Social engagement measured using the number of social contacts and leisure activities per week:
Participants will be asked to provide a retrospective report of social contacts and leisure activities in the preceding 2 weeks.
- Global change (assessed by the person with dementia and the supporter):
At each follow-up time point, participants will be asked to provide a rating of their perceived change in relevant domains (wellbeing and sense of independence) since baseline, using a 5-point ordinal scale (1 = much better, 3 = no change, 5 = much worse). Responses will be used to categorise improvers / non-improvers for anchor-based analysis of minimum clinically important differences and responsiveness to change of relevant, related outcome measures.

Supporters will also be asked to independently provide a rating of their perceived change for the person with dementia in relevant domains (wellbeing and independence) from their perspective, during the course of the study, using a 5-point ordinal scale (1 = much better, 3 = no change, 5 = much worse). Responses will be used to categorise participants into improvers / non-improvers for anchor-based analysis of minimum clinically important differences and responsiveness to change of relevant outcome measures for the person with dementia.

Consistent ratings between the participant and supporter will increase confidence in the performance of the two external criteria for judging improvement.

Outcomes for supporters (if participating)

- Health related quality of life measured using the EuroQoL Quality of Life Questionnaire – 5 Domains, 5 Levels (EQ-5D-5L), EuroQoL Group (1990)

Health economic outcomes

- Resource use measured using a modified version of the Client Service Receipt Inventory (CSRI) for dementia, Beecham and Knapp (1992):
The CSRI collects information on the services and support study participants use, including any that have resource implications, such as accommodation, employment status and income, formal health and social care services used, and unpaid care. Participants and supporters will be asked to provide a retrospective report of resource use in the preceding 3 months.
- Quality Adjusted Life Years (QALYs) calculated using health related quality of life data collected through the EQ-5D-5L and DEMQOL:
We will base QALY calculations on the EQ-5D-5L and DEMQOL utility classification (DEMQOL-U, Mulhern *et al.* 2013). The DEMQOL-U classification system utilises 5 of the original DEMQOL items to derive dementia-specific health state classifications.
- Micro-costing of the PRIDE intervention determined by collection of information from participating sites regarding the staff time and resources for delivery of the PRIDE intervention, including implementation, training and delivery.

Qualitative outcomes

Interviews and focus groups with facilitators, participants and supporters (where present) will explore their perspectives on the intervention and investigate a range of themes including, but not limited to:

- Acceptability of the intervention (manual, sessions, facilitation)
- Barriers and facilitators to delivery of the intervention
- Experience of the intervention
- Factors that may mediate or moderate the effectiveness of the intervention
- Skills and competencies required to deliver the intervention
- Barriers and facilitators to continued use of the intervention
- Acceptability of the outcome measures (quantity, content, ability to complete)
- Acceptability of the trial procedures (recruitment, consent, randomisation and activities throughout the follow-up period)

Utilising a focus group approach will help people to identify and clarify their views in relation to others who have experienced the same intervention (Kitzinger *et al.*, 1995) and support sharing of their ideas and similar or different opinions.

A schedule of topics and questions will be developed f to help guide discussion to produce final themes (Stewart *et al.*, 2007). Field notes or flipcharts will be used to record discussions and agreement. Anonymous direct quotes, phrases and terminology from the group may be used in the analysis and report. Results will be used to explore potential explanations for the quantitative findings and identify emergent factors that influence the uptake and impact of the intervention and other trial procedures for a future large trial.

Table 2: Study Procedures and Assessments

Months	0	0 – 2	3	6 ⁶
Study Procedures and Assessments: Participants	Visit 1 Baseline	Intervention Period	Visit 2 Follow-Up	Visit 3
Initial eligibility screen ¹	X	RANDOMISATION <i>Intervention :</i> PRIDE intervention (3 sessions with a PRIDE facilitator) in addition to usual care <i>Control:</i> Usual care only		
Informed consent ²	X			
Demographic information	X			
Post-consent eligibility screen: Clinical Dementia Rating (CDR) Scale ³	X			
Lawton IADL Scale	X		X	X
EuroQoL Quality of Life (EQ-5D-5L)	X		X	X
DEMQOL	X		X	X
Geriatric Depression Scale (GDS)	X		X	X
Standardised Mini Mental State Exam (SMMSE)	X		X	X
Control, Autonomy, Self-realisation and Pleasure (CASP-19)	X		X	X
Impact on Participation and Autonomy (IPAQ-O) – Social Relations Sub-Scale	X		X	X
Positive Psychology Outcome Measure (PPOM)	X		X	X
Social Engagement Checklist	X		X	X
Global Change Measure			X	X
Client Service Receipt Inventory (CSRI)	X		X	X
Interviews/focus groups with facilitators and participants / supporters			X ⁴	
Study Procedures and Assessments: Supporters	Visit 1 Baseline		Visit 2 Follow-Up	Visit 3 ⁶
Informed consent	X			
Supporter questionnaire: EuroQoL Quality of Life (EQ-5D-5L) ⁵	X		X	X
Global Change Measure ⁵			X	X
Supporter questionnaire: Client Service Receipt Inventory (CSRI) ⁵	X		X	X

¹ Participants not included in the trial will be recorded on the trial screening log, with reasons for non-inclusion documented.

² All participants providing consent will be enrolled on the trial database, with demographic details and screening assessments recorded.

³ Participants who are identified as ineligible for randomisation during the post-consent eligibility screen will be defined as screen failures and will not proceed to randomisation. All data collected to this point will be entered onto the trial database.

⁴ Separate Interviews/focus groups will be completed with facilitators and a subset of participants and supporters.

⁵ Supporter questionnaires will be passed to supporters during participant visits (if present) for completion during the visit or will be posted with a prepaid envelope for return to the Coordinating Centre.

⁶ Participants randomised after 30th June 2019 will not have a 6 month follow up visit, and their last visit will be at visit 2.

Safety endpoints

There are no specific safety endpoints.

Stopping rules and discontinuation

The Sponsor reserve the right to discontinue this study at any time for failure to meet expected recruitment goals, for safety or any other administrative reason. The Sponsor shall take advice from the Trial Steering Committee and Funder as appropriate in making this decision.

RANDOMISATION AND BLINDING

Participants will be allocated at the individual level to intervention or control on a 1:1 ratio using minimisation with a probabilistic element. The minimisation variables will be study site, sex, age (< 80 or ≥ 80) and medication for dementia (any versus none). The allocation algorithm will be created by the Nottingham Clinical Trials Unit (NCTU) in accordance with their Standard Operating Procedure (SOP) and held on a secure server.

The investigator or authorised designee will use the remote, internet-based randomisation system to obtain the treatment allocation for each participant.

Due to the nature of the intervention, blinding of treatment allocation is impossible for participants and the staff delivering it. Outcome assessment and statistical analysis will be blind to allocation.

Maintenance of randomisation codes and procedures for breaking code

Access to the randomisation sequence will be confined to the NCTU IT staff.

Participants and clinical staff at each site, including those delivering the intervention, will not be blinded to treatment allocation.

To permit adequate monitoring and oversight, NCTU Trial Management staff will not be blinded.

The study outcome data at all the time points will be collected by members of the local research team who will be blind to group allocation. The local research team will record instances of unblinding at outcome visits. There is no foreseeable situation in which the members of the local research team collecting follow-up data would need to know the treatment allocation and therefore no specific procedures are required for breaking the code.

Members of the central research team conducting the fidelity and qualitative sub-study will not be blind to group allocation.

The trial statistician will remain blinded to treatment allocation until after database lock. Release of treatment allocation datasets will be controlled in accordance with the NCTU SOPs.

TRIAL MANAGEMENT

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

The data custodian will be the Chief Investigator.

Nottingham Clinical Trials Unit (NCTU) is the coordinating centre for this trial and will be responsible for all trial management activities. The Trial Manager, based at the NCTU will be responsible for the day to day management of the trial.

NCTU will be responsible for the delivery of study specific training / site initiation and for the ongoing support of the site staff in relation to research activities and trial delivery.

The PRIDE Programme Manager will be responsible for the delivery of training in the PRIDE intervention and the ongoing support of site staff delivering the intervention.

A number of committees will oversee the progress and conduct of the trial. An overview of the roles and relationships of these committees is provided here. A separate Charter will be in place for the Trial Steering Committee (TSC).

Trial Management Group (TMG)

The TMG will comprise members of the study team and will have overall responsibility for the trial, including the day to day management. The TMG will meet regularly (at least monthly during the recruitment period, wherever possible) for the duration of the trial.

Trial Steering Committee (TSC)

A TSC will be established to provide independent oversight of the trial. The TSC will have independent membership and an independent Chair but will also include members of the study team. The TSC will make recommendations about the trial to the TMG.

As the trial interventions and procedures have been assessed as low risk, safety oversight will be performed by the TSC without the need for a separate independent Data Monitoring Committee.

Independent members of the TSC are the only group with access to unblinded data during the course of the trial in closed sessions of the TSC, if required to consider safety issues. Study team members (the Chief Investigator, Trial Manager and Trial Statistician) will attend open sessions of the TSC only.

Site selection

Up to six NHS sites will be selected to participate in the trial. Site selection procedures will ensure sites are able to deliver the requirements of the study.

Records of the number of sites approached, site selection questionnaires returned, those deemed suitable for inclusion and opened to recruitment will be maintained in order to address the feasibility objectives of this trial.

Identification, recruitment and retention of PRIDE trained facilitators

Local site staff who will be trained and provide the PRIDE intervention during the study will be identified at a local level, on the basis of a Job Description and Person Specification prepared for the purposes of the study.

Potentially eligible staff will be nominated by the participating sites and will be reviewed for suitability prior to being accepted as PRIDE facilitators.

Records of the numbers of staff nominated, deemed suitable for inclusion, trained and delivering the intervention will be maintained in order to address the feasibility objectives of this trial.

DURATION OF THE TRIAL AND PARTICIPANT INVOLVEMENT

Study Duration:

The expected recruitment period will be up to 10 months from enrolment of the first participant. Participant follow-up will continue for a maximum of 6 months following the end of recruitment.

Participant Duration:

Each participant will be involved in the trial for a maximum of 6 months (+/- 4 weeks) from randomisation to final follow-up.

The active treatment phase of the trial will be approximately 2 months from the first to the final intervention visit.

Follow-up will be completed at 3 and 6 months post-randomisation for all participants randomised before 1 July 2019. Follow-up will only be completed at 3 months post-randomisation for participants randomised after 30 June 2019.

End of the Trial

The end of the study will be the last follow-up visit of the last participant.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Setting

Research activities, including participant recruitment, intervention delivery and follow-up will be carried out within secondary care NHS Trusts. NHS staff working within the participating sites, including clinical and research staff, Clinical Studies Officers (CSOs) and other relevant service providers, will be asked to support the trial. They will all act under arrangements agreed with the responsible NHS trust.

Identification of participants

There are three possible routes through which potential participants will be identified for recruitment into the trial:

1. NHS recruitment pathway

Participants may be identified and recruited from NHS services for people with dementia within participating secondary care trusts. To maximise generalisability we will recruit from a range of services across England.

Sites will also have the option to utilise GP practices to support recruitment who will act as Participant Identification Centres (PICs). PICs will be able to screen, identify eligible participants from databases and invite patients to join the trial.

Potentially eligible participants will be identified from patient lists of the participating services, including PICs, and records will be screened by a member of the usual care team in order to ascertain initial suitability for the trial. The initial approach will be from a member of the patient's usual care team (which may include the investigators), and will be made either face-

to-face or by invitation letter. Information about the trial will also be on display in the relevant clinical areas and potential participants may contact the local research team directly using contact details provided.

2. Join Dementia Research recruitment pathway

We will use 'Join Dementia Research' (JDR) as a recruitment tool to identify potential participants. This is an online 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. JDR is funded by Department of Health working in partnership with the charities Alzheimer Scotland, Alzheimer's Research UK and Alzheimer's Society and is Health Research Authority (HRA) endorsed. The online service and all associated documentation, methods of contacting volunteers and handling of data, were reviewed by a specially convened HRA committee which included experts in research ethics, data protection and information governance. Formal endorsement was issued by the HRA in a letter dated 20 May 2014.

There are two methods people with dementia can join the trial through JDR. First, potential participants may search the JDR database, identify the trial and contact the coordinating centre team themselves. In this case, the coordinating centre team will identify whether the participant is resident within the catchment area of the one of the participating sites, and if so, will request verbal consent to pass on the potential participant's contact details to the relevant site staff, who will contact them to discuss the study. The coordinating centre will record that verbal consent was obtained to pass on contact details and will send a copy of the Participant Information Sheet. Second, potential participants registered with JDR may give permission for their contact details to be made available to authorised users of JDR which may include local site staff and the coordinating centre team. In this case, potentially eligible participants identified through JDR will be screened in the first instance against the non-clinical eligibility criteria only (i.e., age, resident in catchment area of participating site), where these can be determined by the available information. Those who are resident within the catchment area of one of the participating sites will be sent an invitation letter and information about the study, and those who are interested may return the reply slip giving permission for the local research team to contact them directly using the contact details provided. Potential participants identified through JDR who are not resident within the catchment area of one of the participating sites will be advised that they do not meet the eligibility criteria for the study.

For people that have not responded to the invitation letter, a single phone call to enquire whether they remember receiving the invitation letter, and whether they would like further information about the study will be made, where possible. If they do not wish to have further information, no further contact will be made. If, however, they wish to have more information the local site staff will provide this. If the coordinating centre staff have made contact, they will request verbal consent to pass on the potential participant's contact details to the relevant participating site staff, who can provide them with more information about the trial. The coordinating centre will record that verbal consent was obtained to pass on contact details.

3. Self-referral recruitment pathway

Participants will also be able to self-refer directly to the local research teams or the coordinating centre. Potential participants may become aware of the study through relevant local and national charities and patient organisations and through general promotion of the trial through relevant organisations' newsletters, social media, mailing lists and websites. Potential participants finding out about the study in this way may contact the local site research team

directly using contact details provided, or may contact the coordinating centre. If the initial contact is with the coordinating centre, the coordinating centre staff will seek permission to pass on the potential participant's contact details to the relevant local research team and will also send out a copy of the Participant Information Sheet.

Recruitment

Whether identified in memory clinics, via PICs, through JDR or by self-referral, the investigator or their nominee, e.g. from the research team or a member of the participant's usual care team, will inform the potential participant of all aspects pertaining to participation in the study and a written Participant Information Sheet will be provided.

The consent forms and information sheets will not be available printed in other languages since the ability to read and communicate verbally in English is a requirement of participation in the trial.

It will be explained to the potential participant that entry into the trial is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Participants identified through JDR or by self-referral will be registered as outpatients of the memory clinic of the participating NHS trust at enrolment in the trial.

Identification and recruitment of supporters

When the study is explained to the potential participant, they will be advised that they can choose to take part either with a supportive other or on their own. If the participant chooses to take part with a supporter they will be asked to nominate a person, who if eligible, will be invited to join the study as the supportive other (note that it will also be possible for a supporter to assist the participant, without participating in the study in their own right). The potential supporter will be provided with written information about the study and the supporter role and be asked to attend the screening and baseline visit with the participant, where consent will be obtained.

Eligibility criteria

Inclusion criteria for the person with dementia

To be eligible for the trial participants must meet all of the following inclusion criteria:

- Resident within the catchment area of one of the participating NHS sites.
- Aged 18 or over; there is no upper age limit.
- Meet the Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition (DSM-IV) (APA, 1994) criteria for dementia of any type, including Alzheimer's, vascular, Lewy body type and mixed.
- Able to engage with and participate in the intervention in the judgement of the investigator or designee.
- Able to provide informed consent in the judgement of the investigator or designee.
- Able to read and communicate verbally in English.

In addition, to be eligible for randomisation, the following inclusion criteria must be met. This is ascertained by a formal screening assessment completed after consent:

- Mild dementia, defined as a score of 0.5 or 1 on the Clinical Dementia Rating Scale. The CDR will be completed during a face-to-face visit, as a post-consent screening assessment to determine eligibility for randomisation.

Exclusion criteria for the person with dementia

- Living in institutional care.

Inclusion criteria for the supportive other

Note that participation of a supportive other is not mandatory and will be at the discretion of the participant. If the participant chooses to identify a supportive other they wish to participate with, the following inclusion criteria will apply.

- Aged 18 or over; there is no upper age limit.
- Able to engage with and participate in the intervention.
- Able to provide informed consent.
- Able to read and communicate verbally in English.

Expected duration of participant participation

Study participants will be participating in the study for a maximum of 6 months from randomisation to final follow-up.

Participant withdrawal and discontinuation of treatment

Participants may choose to withdraw from the trial at any time. Participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis. The reason for withdrawal will be requested, and documented where given.

Participants in the intervention group may discontinue the PRIDE intervention at any time, either at their own request or at the discretion of the Investigator. A record of participants who discontinue the trial intervention prematurely will be documented, with reasons for discontinuation recorded. Participants who prematurely discontinue the trial intervention will be asked to remain in the trial for follow-up. If participants who prematurely discontinue the trial intervention choose to also withdraw from trial follow-up, the reason for withdrawal will be requested, and documented where given.

Supporters may also withdraw from the trial as a whole or choose to discontinue their involvement in the trial intervention. Doing so will not affect the participants continuation in the trial. The withdrawal or discontinuation of supporters will be recorded, with reasons for withdrawal or discontinuation requested, and documented where given. If the participant wishes to identify an alternative supporter to participate in the trial with them, they will be able to do so. The alternative supporter will provide consent to participate and the change of supporter will be documented.

Informed consent

Participant informed consent

All participants will provide written informed consent. The Informed Consent Form will be signed and dated by the participant before they enter the trial. The Investigator or their designee will explain the details of the trial and provide a Participant Information Sheet, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

Informed consent will be collected from each participant before they undergo any interventions (including screening assessments and history taking) related to the study. One copy of this will be kept by the participant, one will be kept by the Investigator, and a third will be retained in the patient's hospital records.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the trial, continuing consent will be obtained using an amended Consent form which will be signed by the participant.

Trial participants will be in the mild stage of dementia, and therefore would generally be expected to be competent to give informed consent for participation, provided that appropriate care is taken in explaining the research and sufficient time is allowed for them to reach a decision. If it is helpful for a family member or other supporter to be involved, we would aim to ensure that this is done wherever possible. It will be made clear to both participants and family carers that no disadvantage will accrue if they choose not to participate. In seeking consent, we will follow current guidance from the British Psychological Society on evaluation of capacity. In this context, consent has to be regarded as a continuing process rather than a one-off decision, and willingness to continue participating will be continually checked through discussion with participants during the assessments. If the participant's level of impairment increases during the course of their involvement in the study to the extent that, in the judgement of the Investigator (or designee), they do not have capacity to provide continued informed consent for their ongoing participation in the trial at that time, the research activity would be discontinued. Research activities would be resumed, should the participant regain capacity and agree to continue their involvement in the study.

Supporter informed consent

Where a supporter is also participating in the trial, the supporter will provide written informed consent for their own participation in the trial. The supporter Informed Consent Form will be signed and dated by the supporter before they enter the trial (e.g., complete questionnaires). The Investigator or their designee will explain the details of the trial and provide a Supporter Information Sheet, ensuring that the supporter has sufficient time to consider participating or not. The Investigator will answer any questions that the supporter has concerning study participation.

The supporter's decision to participate or not will not affect involvement of the participant. Supporters may decline consent to participate in the trial on their own behalf but continue to be present during research activities and intervention sessions in order to support the person with dementia, should they request this. In this case, their involvement will be recorded but no further details or data will be collected.

Should there be any subsequent amendment to the final protocol, which might affect a supporter's participation in the trial, continuing consent will be obtained using an amended Consent form which will be signed by the supporter.

TRIAL REGIMEN AND TREATMENT REGIMEN

TRIAL REGIMEN

The schedule of visits is shown in Figure 1.

Identification of participants

All potential participants who are invited or express an interest in the trial will be recorded on the Participant Screening and Enrolment Logs. Basic demographic data (age and sex) and the result of the pre-consent eligibility screen will be documented.

Visit 1: Screening & Baseline

At the first study visit, which will be in person with the researcher and conducted in the participant's home (or other suitable community or NHS venue, as appropriate, depending on participant preference), the researcher will confirm eligibility for enrolment in the trial, explain the trial and respond to queries, obtain informed consent and record the following demographic data:

- Gender
- Date of birth
- Ethnicity
- Educational attainment
- Living arrangements
- Marital status
- Type of dementia
- Use of dementia medication
- Availability of computer / internet access for use of web-based manual, should they be allocated to the intervention arm
- Supporter details (if participating)
 - o Relationship to participant
 - o Length of time in supporter role

The researcher will then conduct the post-consent screening assessment (CDR). The investigator will make clear that the initial screening assessment is required to check that the participant meets the inclusion criteria.

After consent, dementia severity will be assessed using the Clinical Dementia Rating (CDR) scale, Morris (1993):

- The CDR is often used in longitudinal studies and clinical trials for staging the severity of Alzheimer's disease. It rates impairment in each of six cognitive categories (Memory, Orientation, Judgment and Problem Solving, Community Affairs, Home and Hobbies, and Personal Care) on a five-point scale in which none = 0, questionable = 0.5, mild = 1, moderate = 2 and severe = 3.

The result of the CDR will be used to confirm eligibility for randomisation. Following screening, participants will be advised whether or not they meet the inclusion criteria.

Those who do not meet the inclusion criteria will be notified and thanked for their interest in the study. Feedback on the screening assessment may be provided, if requested.

Participants who are eligible to continue in the trial will proceed to baseline assessment completion.

The following measures will be collected at baseline:

- Lawton IADL Scale
- EuroQoL Quality of Life (EQ-5D-5L)
- DEMQOL
- Geriatric Depression Scale (GDS)
- Standardised Mini Mental State Exam (SMMSE)
- Control, Autonomy, Self-realisation and Pleasure (CASP-19)

- Impact on Participation and Autonomy (IPAQ-O) – Social Relations Sub-Scale
- Positive Psychology Outcome Measure (PPOM)
- Social Engagement Checklist
- Global Change Measure
- Client Service Receipt Inventory (CSRI)

Supporter questionnaires:

If the participant chooses to take part with a supporter, the designated supporter will be asked to complete the following baseline questionnaires after providing written informed consent:

- EuroQoL Quality of Life (EQ-5D-5L)
- Global Change Measure
- Client Service Receipt Inventory (CSRI)

Supporter questionnaires will be handed to the supporter (if present) during the screening / baseline visit for completion during the visit. If the questionnaire is completed during the visit it will be collected by the researcher and returned to the coordinating centre. If the questionnaire is not completed during the visit, it can be left with a prepaid return envelope and supporters will be asked to return the questionnaire to the coordinating centre. If the supporter is not present during the follow-up visit, the questionnaire may be posted to them. Supporters will be asked to return completed postal questionnaires direct to the coordinating centre using the prepaid return envelope provided.

Data entry:

All consenting participants will be enrolled on the trial database and assigned a trial ID number. Demographic data and the screening assessment result will be recorded for all enrolled participants. Ineligible participants who do not proceed to baseline data collection will be identified as screen failures and no further data entry will be required. All other participants should have baseline assessment data entered prior to randomisation. Enrolment, screening and baseline participant data will be entered by site staff.

Randomisation:

Following completion of screening and all baseline assessments, and entry of all required data onto the trial database, the investigator will randomise eligible participants using the web-based randomisation system. Participants will be randomised into either:

- a. Usual care
- b. PRIDE social intervention in addition to usual care

Randomisation should be completed promptly following the baseline assessment completion, within a maximum of 1 week or as soon as able, and only after all participant baseline data has been collected and entered onto the trial database. Receipt of completed baseline supporter questionnaires is not a mandatory requirement for randomisation.

Following randomisation, participants will be notified of their treatment allocation by an unblinded member of the research team. Participants randomised to the PRIDE intervention will be assigned to a local PRIDE trained facilitator, who should make contact with the participant to arrange the first intervention session. The first intervention session should be completed within a maximum of one month of randomisation.

Following randomisation, the participants' GP will be notified of their involvement in the trial.

Intervention:

Usual care will continue as normal for all participants. Participants allocated to receive the PRIDE intervention in addition to usual care will be offered up to 3 sessions with the PRIDE trained facilitator over a 2-month period.

*Follow-up visit 2 (3-months) and visit 3 (6-months):**

Follow-up visits will be completed at 3 and 6 months post-randomisation.

* Participants randomised after 30th June 2019 will not have a 6 month follow up visit, and their last visit will be at visit 2.

The following measures will be completed at follow-up visits:

- Lawton ADL/IADL Scale
- EuroQoL Quality of Life (EQ-5D-5L)
- DEMQOL
- Geriatric Depression Scale – short form (GDS)
- Standardised Mini Mental State Exam (SMMSE)
- Control, Autonomy, Self-realisation and Pleasure (CASP-19)
- Impact on Participation and Autonomy (IPAQ-O) – Social Relations Sub-Scale
- Positive Psychology Outcome Measure (PPOM)
- Social Engagement Checklist
- Global Change Measure
- Client Service Receipt Inventory (CSRI)

In addition, the researcher completing the visit will record the following information:

- Duration of visit
- Whether they were unblinded prior to or during the visit

Supporter questionnaires:

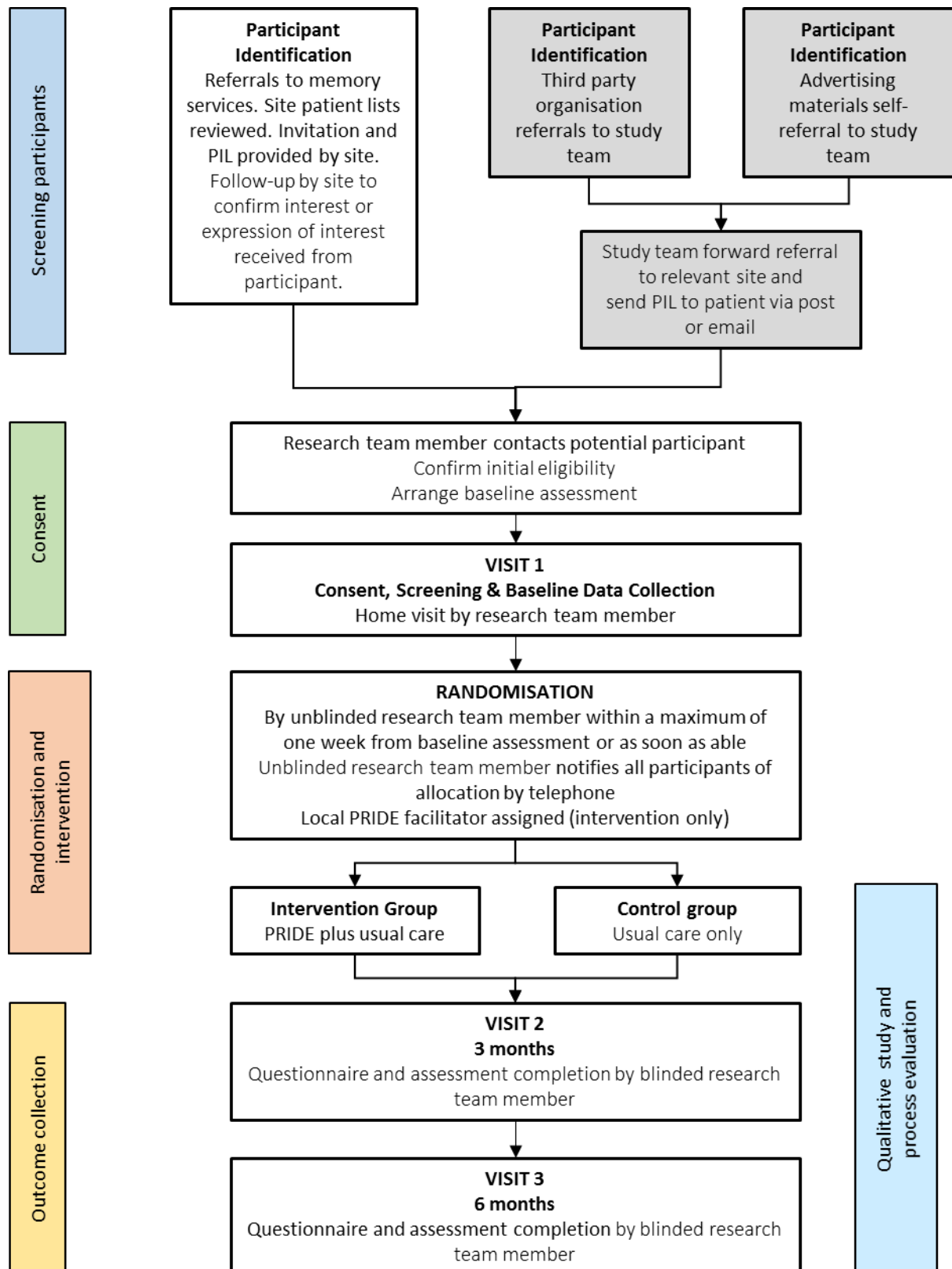
If a supporter is participating in the trial they will be asked to complete the following questionnaires at 3 and 6 months post-randomisation follow-up:

- EuroQoL Quality of Life (EQ-5D-5L)
- Global Change Measure
- Client Service Receipt Inventory (CSRI)

Supporter questionnaires will be handed to the supporter (if present) during the follow-up visit for completion during the visit. If the questionnaire is completed during the visit it will be collected by the researcher and returned to the coordinating centre. If the questionnaire is not completed during the visit, it can be left with a prepaid return envelope and supporters will be asked to return the questionnaire to the coordinating centre. If the supporter is not present during the follow-up visit, the questionnaire may be posted to them. Supporters will be asked to return completed postal questionnaires direct to the coordinating centre using the prepaid return envelope provided.

All follow-up visit data will be sent securely to the coordinating centre for data entry.

Figure 1: Participant flowchart



** Participants randomised after 30th June 2019 will not have a 6 month follow up visit, and their last visit will be at visit 2.*

TREATMENT REGIMEN

A summary is provided below, but PRIDE facilitators should always refer to the current PRIDE participant manual and PRIDE facilitator manual for full details.

The PRIDE Intervention

The PRIDE intervention is a social intervention encompassing social, physical and cognitive dimensions for people in the early stages of dementia. It comprises a manual which is worked through with the support of a trained facilitator during up to three sessions of between 60-90 minutes, held over approximately two months.

The objectives of the PRIDE intervention are:

1. To promote independence and facilitate the person's access to opportunities to live well with dementia.
2. To enable the participant to maintain an active lifestyle (e.g., participate in walking groups, swimming sessions).
3. To aid the participant to have a healthy lifestyle (e.g., smoking cessation).
4. To encourage the participant to maintain cognitive activities, including using computer games, the internet and/or computer based social media.
5. To provide sign posting to local services and resources about social, mental, and physical activities and healthy lifestyle opportunities.
6. To help the person maintain their social roles.

The PRIDE intervention manual

The manual includes chapters on communication, social connections, decision-making, keeping socially, mentally, and physically active, finding a balance in activities, receiving a diagnosis, and keeping healthy. Vignettes drawn from the qualitative literature have been incorporated into the chapters to demonstrate issues people might encounter, along with suggested ways to tackle them.

The manual will be available in paper or electronic (web-based) versions. All participants allocated to the PRIDE intervention will be provided with the paper manual, and will also be offered access to the web-based manual. Uptake and use of the electronic manual will be recorded.

The facilitator will:

1. Assist the person with dementia to maintain or re-engage in activities in one or more of the three lifestyle domains of their choice. To develop or reinforce their interpersonal skills 'modelling' of communication relevant to their circumstances will be used. This will focus on demonstrating how a person with dementia can be empowered to make independent decisions about activities and use of resources such as the internet and their social networks.
2. Help the person to select choices (Freund, 2002) to maintain or enhance their current social, mental, and physical activities and lifestyle, or try new activities / adopt new healthy living behaviours (e.g. smoking cessation).
3. Practice, using resources such as telephone support (e.g. texting, help lines), web-based support, and peer support groups.
4. Reflect with them how they might monitor and maintain their lifestyle activities in the future, and devise a plan to take into account future potential changes in personal and social circumstance.

Intervention session outline

Session one:

Based on the selective optimisation with compensation (SOC) framework (Baltes, 1997), the person will be encouraged to identify important aspects of their current daily lives and discuss how to maintain or enhance the activities/routines they value, as well as identifying new activities they might benefit from. The intervention will be tailored to individual preferences. The facilitator will explore whether the person feels they have agency in everyday decision-making, and how to create more opportunities for supported, but independent decision-making. Mapping of the participant's current social network will be conducted to identify the strengths and the areas where they may need extra support. They will explore ways to seek new resources (e.g. local walking groups) and consider activities that will support them in maintaining physical, social, and cognitive wellbeing. The facilitator will introduce the person to the intervention manual. Between each session, the person and the supporter will be encouraged to try out strategies and activities they have planned together.

Session two:

In the second intervention session scheduled approximately one month later, progress will be reviewed. Choices and activities may be refined according to the participant and supporters' experience of implementation and any needs which may have arisen in the first month. Barriers that prevented implementation of plans made in the first session will also be explored, and solutions explored. New options may also be set within the lifestyle domains. The second session may also involve the facilitator participating in activities out in the community with the person or participant and supporter based on their choices (e.g. attending a lunch club).

Session three:

At the third and final intervention session, scheduled approximately one month after session two, progress will be reviewed again, and a maintenance plan will be developed to encourage long-term change.

Usual Care

All participants will receive the services and interventions usually available to people with dementia and family at the participating sites. This will naturally vary between and within centres and may change over time. Any services and interventions offered as usual care will also be available to those in the PRIDE intervention group.

Adherence

Fidelity checks will assess how well the PRIDE intervention is being delivered according to the intervention protocol, facilitator training and manual. Checks will adhere to an intervention fidelity framework (see

Table 3) based on that identified by the Behaviour Change Consortium (Bellg *et al.*, 2004) and NICE guidance on behaviour change (NICE, 2007) using the following quality assurance parameters:

- training
- delivery and receipt

Training

Delivery and receipt of training will be observed and rated by two researchers (the lead for fidelity and one other member of the research team) using a bespoke training observation checklist. For the purposes of comparison, trainees will also be asked to rate the training according to the same criteria using a simplified checklist. The checklists will list core skills and key criteria identified out of the content of the training and the manualised intervention. Facilitator skills and understanding of the intervention will also be measured through training delivery techniques such as active participation as well as observed behaviours such as skill acquisition and reflection via the checklist.

Analysis of resulting data will determine inter-rater reliability between coders to establish the extent to which they attribute the same score to the same variable. Frequencies will be used to determine the extent to which the training maintained fidelity to what was intended. Similar methods have been used in previous studies (Mountain *et al.*, 2017).

Delivery and receipt

To ensure comparable treatment between sites and within dyads at sites, registers will be used to monitor adherence to the intervention. Quality of facilitation will be managed using a generic job description.

To assess facilitator adherence to the manualised intervention and participant receipt of the intervention, Interviews or focus groups will be held with a sample of facilitators and with participants and supporters respectively. Facilitators will also complete a register of attendance for each participant including number of sessions attended and topic covered during each session. This will demonstrate participant adherence to the intervention as well as adherence to the manual.

Table 3. Fidelity assessment strategy

Goal	Description	Fidelity
Monitoring facilitator training		
Standardised training	All facilitators receive the same training programme	• Training delivered by the same trainer(s) • Attendance registers for training • Training observation checklists
Facilitator skill acquisition	All facilitators participate in the training in a similar way Did training equip facilitators with required skills	• Completion of training exercises • Training observation checklist • Focus group
Monitoring intervention delivery		
Comparable treatment	All participants receive the same programme	• Offer of 3 sessions • Attendance register for 3 sessions • All participants receive a manual
Risk to implementation	Recruitment of suitable facilitators	• Facilitator job description
Standardised delivery	All facilitators using the same techniques and content from the manual and training	• Intervention delivery checklist • Focus group
Minimise drift in skills/delivery	Adherence to training content and delivery across sites	• Focus group
Monitoring receipt of intervention		
Participant attendance and engagement	Numbers of participants attending sessions Participants identifying a goal(s)	• Attendance register for 3 sessions • Register of topics/goals covered from the manual • Focus group

Criteria for terminating trial

The sponsor and Funder reserve the right to discontinue this study at any time for failure to meet expected recruitment goals, for safety or any other administrative reason. The Sponsor and Funder shall take advice from the Trial Steering Committee as appropriate in making this decision.

All participation may be stopped if the study sponsor or Research Ethics Committee (REC) terminates the study prior to the planned end date.

STATISTICS

Methods

Data analysis will primarily be descriptive to address the feasibility aims of the study. All analyses will be documented in a Statistical Analysis Plan which will be finalised prior to database lock. Feasibility outcomes will be estimated using descriptive statistics (with 95% confidence intervals [CI]) and will include recruitment rates, follow-up rates, amount of missing data, and intervention adherence. The rate of protocol adherence will be reported within the intervention group in terms of participants who adhere to the intervention they were allocated to receive and who comply with the scheduled treatment visits.

Key baseline characteristics (age, gender) will be compared between trial participants and the ineligible and non-consenting patients, to ascertain adequacy of inclusion/exclusion criteria and likely generalisability of the trial to the required targeted population. Similarly, we will compare the key patient characteristics between those followed-up and those lost to follow-up and investigate how similar this is across the treatment arms to assess possible attrition bias in data collection.

A baseline table will compare important demographic and clinical characteristics between the two treatment arms. It is not a primary objective of the feasibility study to obtain definitive estimates of intervention effect on clinical outcomes and so the clinical outcomes will be analysed descriptively.

Sample size and justification

A target sample size of 75-80 participants and up to 80 supporters will be sought from up to 6 sites over the recruitment period.

As this is a feasibility study, a formal sample size calculation for between group comparisons of a primary outcome is not appropriate. However a sample size of 75 randomised participants will allow estimation of recruitment fraction with a margin of error (half-width of 95% confidence interval) of around 8 percentage points, and retention of 12 percentage points.

Assessment of efficacy

This section is not applicable as the trial is a feasibility study and no assessment of efficacy will be undertaken.

Assessment of safety

There are no specific safety endpoints and no formal assessment of safety will be undertaken.

Procedures for missing, unused and spurious data

There will be no imputation for missing data at follow-up visits.

Definition of populations analysed

Baseline data and outcome data will be presented by allocated group, regardless of adherence with the intervention.

ADVERSE EVENTS

No adverse reactions have been identified in previous trials of social and psychological interventions for people with dementia, for example Cognitive Stimulation Therapy (CST) (Spector *et al.*, 2003), individual CST (iCST) (Orrell, Yates, Leung *et al.*, 2017), or Reminiscence groups for people with dementia and their family caregivers (REMCARE)

studies (Woods *et al.*, 2012). The risks of the current trial have therefore been assessed as low and there are unlikely to be adverse events resulting from the trial. For this reason Adverse Events (AEs) and Serious Adverse Events (SAEs) will not be routinely collected for this trial.

A record of premature discontinuation with the trial intervention and withdrawal from follow-up will be kept, with reasons, where these have been reported.

The assessments for participants will be limited in duration and not unduly long or stressful. Researchers and facilitators delivering the intervention will be trained to identify and deal with any distress exhibited by trial participants during trial activities and will make referrals (e.g., to the participant's GP) if needed.

ETHICAL AND REGULATORY ASPECTS

ETHICS COMMITTEE AND REGULATORY APPROVALS

The trial will not be initiated before the protocol, informed consent forms and participant and GP information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider's Research & Development (R&D) department, and the Health Research Authority (HRA) if required. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant, supporter and GP information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes should be notified to the HRA only and implemented according to the timeframe advised.

The trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the UK Department of Health Policy Framework for Health and Social Care, 2017.

INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant shall both sign and date the Informed Consent Form before the person begins their participation in the study.

The participant will receive a copy of the signed and dated form and the original will be retained in the Trial Master File. A second copy will be filed in the participant's medical notes and a signed and dated note made in the notes that informed consent was obtained for the trial.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No trial-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Informed Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Informed Consent Form by the REC and use of the amended form (including for ongoing participants).

RECORDS

Case Report Forms

Each participant will be assigned a trial identity code number, allocated at enrolment, for use on CRFs other trial documents and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available) and date of birth (dd-mmm-yyyy).

CRFs will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant's name, date of birth, local hospital number or NHS number, and Participant Trial Number (the Trial Recruitment Log), to permit identification of all participants enrolled in the trial, in accordance with regulatory requirements and for follow-up as required. CRFs shall be restricted to those personnel approved by the Chief or local Principal Investigator and recorded on the 'Trial Delegation Log.'

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated. The Chief or local Principal Investigator shall sign a declaration ensuring accuracy of data recorded in the CRF.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, current medical records, laboratory results and records. A CRF may also completely serve as its own source data. Only trial staff as listed on the Delegation Log shall have access to trial documentation other than the regulatory requirements listed below.

The location of source data may differ for each site, and therefore will be documented on a site specific Source Data Location Log.

Direct access to source data / documents

The CRF and all source documents, including progress notes and copies of laboratory and medical test results shall be made available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities (e.g. DH, Human Tissue Authority).

DATA PROTECTION

All trial staff and investigators will endeavour to protect the rights of the trial's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. The CRF will only collect the minimum required information for the purposes of the trial. CRFs will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the trial staff and investigators and relevant regulatory authorities (see above). Computer held data including the trial database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method). Information about the trial in the participant's medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information. Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

Consent will be sought for participant's personal contact details to be entered onto the secure trial database maintained and accessible by staff at NCTU. These details will be used by relevant members of the study team in order to send out study-related correspondence for the duration of their involvement in the trial. Participants may also optionally consent for their contact details to be retained beyond the duration of their participation in the trial, in order to be updated about the outcomes of the research or informed of future research.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

Insurance and indemnity for trial participants and trial staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but trial participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

TRIAL CONDUCT

Trial conduct may be subject to systems audit of the Trial Master File for inclusion of essential documents; permissions to conduct the trial; Trial Delegation Log; CVs of trial staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, correct randomisation, timeliness of visits); accountability of trial materials and equipment calibration logs.

TRIAL DATA

Monitoring of trial data and conduct will be in accordance with the study specific monitoring plan, to be finalised prior to the commencement of recruitment.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Research Code of Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all paper records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

Contact details of trial participants will be retained for a maximum of 3 years after which they will be securely destroyed.

The Trial Master File and paper trial documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all trial databases and associated meta-data encryption codes.

Electronic trial data (anonymised research data only) will be retained indefinitely.

DISCONTINUATION OF THE TRIAL BY THE SPONSOR

The Sponsor reserves the right to discontinue this trial at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice from the Trial Steering Committee as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above. Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

Such medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this trial will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

The trial results will be published in a peer reviewed journal, and presented at scientific meetings. Reporting will be in compliance with CONSORT recommendations. Results will be made available to participants through a newsletter (unless they have stated they do not wish to receive this).

The trial results will be published by named members of the trial team, on behalf of the Study Collaborative Group. Members of the collaborative group will be listed in the publication, based on contribution. Any secondary publications may be published by named individuals, but with appropriate acknowledgement of the collaborative group. All publications will be overseen by the Trial Management Group and Trial Steering Committee.

USER AND PUBLIC INVOLVEMENT

The PRIDE programme PPI group will oversee all aspects of carer/user involvement and reports directly to the Programme Steering Committee. The PPI group Chair and the carer co-applicants will ensure the involvement of supporters, people with dementia and members of the voluntary sector in study planning and implementation to encourage input, enhance experiences of participants in the study, and to maintain relevance to stakeholders and policy. People with dementia and supporters may act as consultants (opinions on information sheets/consent forms, focus groups), and collaborators (pilots of training packages, training project staff). We will work closely with Dementias and Neurodegenerative Diseases Research Network (DENDRON), PPI, Age Concern UK and Dementia UK.

STUDY FINANCES

Funding source

This study is funded by the Economic and Social Research Council (ESRC) and National Institute of Health Research (NIHR) (Ref. ES/L001802/1).

Participant stipends and payments

Participants will not be paid to participate in the trial. Participants are not expected to incur expenses for participation in the trial as study visits will usually be undertaken in their own home.

SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name) _____

Signature: _____

Date: _____

Statistician: (name) _____

Signature: _____

Date: _____

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