*Journeying through Dementia

* A randomised controlled trial of the clinical and cost-effectiveness of the Journeying through Dementia intervention compared to usual care

JOURNEYING through DEMENTIA

RESEARCH PROTOCOL-
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Sheffield Clinical Trials Research Unit (CTRU)

Journeying through Dementia- A randomised controlled trial of the clinical and cost-effectiveness of the Journeying through Dementia intervention

This document describes a clinical trial, and provides information about procedures for entering participants. The protocol is not intended for use as a guide to the treatment of other patients. Amendments may be necessary; these will be circulated to known participants in the trial (as appropriate).

Contents

Abbreviations

AE	Adverse Event
CACE	Complier Average Causal Effects Analysis
CI	Confidence interval
CONSORT	CONsolidated Standards Of Reporting Trials (i.e. flowchart)
CRF	Case Report Form
CRN	NIHR Clinical Research Network
CSO(s)	Clinical Studies Officer(s)
CTRU	University of Sheffield's Clinical Trials Research Unit
DMP	Data Management Plan
DEMQOL	Dementia related quality of life measure
DMEC	Data Monitoring and Ethics Committee
EQ-5D-5L	Measure of Health Status
GAD7	Measure of Generalised Anxiety Disorder
GCP	Good Clinical Practice
GLM	General Linear Model
GP	General Practitioner
GSE	General Self-Efficacy Scale
HCP	Health Care Professional
HRQoL	Health Related Quality of Life
HSCRU	Health and Social Care Resource Use questionnaire
HTA	Health Technology Assessment
IADL	Instrumental Activities of Daily Living
ICC	Interclass Correlation
ITT	Intention to Treat
MMSE	Mini Mental State Examination Score
MP	Monitoring protocol
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NHS	National Health Service
PHQ-9	Patient Health Questionnaire
PIC	Participation Identification Centre
QALY	Quality Adjusted Life Year
R&D	Research and Development
RCT	Randomised Controlled Trial

REC	Research Ethics Committee
SAE	Serious Adverse Event
ScHARR	School of Health and Related Research, University of Sheffield
SD	Standard Deviation
SHSC	Sheffield Health and Social Care NHS Foundation Trust
SMA	Self-Management Ability Scale
SOP	Standard Operating Procedure
SCQ	Measure of Sense of Competence in caregivers
TMG	Trial Management Group
TSC	Trial Steering Committee

Definition of terms

Participant- This refers to a person with dementia who is participating in the trial.

Participating supporter- This is a family member, friend or neighbour that provides support to a person with dementia. They may be known as a 'carer'. In the trial, participating supporters are people that have consented into the trial to complete outcome measures. They may also help a person with dementia participate in the trial, such as liaising with researchers to organise visits; and participating in the intervention if allocated to receive it.

Supporter- This is a family member, friend or neighbour that provides support to a person with dementia. They may be known as a 'carer'. In the trial, supporters are people that may be helping a person with dementia participate in the trial, such as liaising with researchers to organise visits or attending the intervention if allocated to receive it. However supporters are not participating in the trial themselves, for example no outcome data is collected from them.

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Protocol amendments since Version 1.0

Version number	Change (s) made	Date of REC approval*	Amendment number
2.0	• Updating of contact details • Professor Tom Dening replaces Professor Martin Orrell as lead at the University of Nottingham. • Throughout the protocol the ordering of outcome measures has been changed to the order in which they will be administered. • The IADL measure has been added to the trial summary as had been omitted in error. • The planned analysis part of the summary has been updated to reflect what was contained in the main part of the protocol. • The Stop/Go criteria has been altered at the request of the HTA who are funding the trial. • Changes to figure 2 and text on P29 to provide more flexibility for participating supporters to be consented and have their baseline outcome measures at separate visits. • Removed the reference to health care professionals only discussing the trial at post-diagnostic appointments. • Providing more options for how health care professionals can signpost people to the trial. • Adding in collection of written permission to conduct the eligibility assessment. • Proposed that an unblinded member of the research team can conduct randomisation rather than naming the specific roles. • Changed from trial support officer to an unblinded member of the research team who will inform the intervention staff that a participant has been randomised to receive the intervention. • Added that supervisor must be trained in the JtD intervention. • Provision for outcome measures from participating supporters to be collected via the telephone. • Correcting the assessment table for participating supporters because the EQ-5D-5L had been missed from the table (it has been specified in the text). • References 45 and 46 were the wrong way round and have been corrected. • Updating the PPI section, in that the PPI group will link in with the TMG.	11/10/2016	1.0

	• In the qualitative section, more flexibility has been given for the timing of the interviews. • Flagging of the PHQ score has been changed from '3 and 4' to '2 and 3' to reflect the scoring on the outcome measure. • The sequencing used for randomisation has been amended to reflect that randomisation needs to be by delivery site.		
3.0	• Inserted ISRCTN registration. • The addresses of some members of the TMG have been changed. • Ellen Lee replaces Munya Dimairo as the trial statistician. The senior trial statistician and co-applicant: Professor Stephen Walters remains the same. • Katherine Ludwin has left the study so is no longer a member of the TMG. • Inserted date of approval for REC approval of Version 2.0. • Section 6.1 The wording has been changed to explain that the randomisation schedule will be produced before recruiting participants not before the trial starts. • Section 7.1- The wording has been changed to make it clearer that one of the individual sessions will be held after the group sessions have finished. • Section 7.1 Reference to specific Agenda for Change bands for facilitators has been caveated with 'usually' to take into account that each NHS Trust has a different configuration of staff. • A reference for the EQ-5D-5L has been inserted. Consequently other reference numbers have been amended. • Section 9.2- A paragraph has been removed regarding secondary outcomes as this paragraph is repeated later on in the section.	24/01/17	2.0
4.0	• Inserted date of approval for REC approval of Version 3.0. • Amended Trial Manager name to Jessica Wright • Added new member of staff to TMG	25/07/17	3.0

	• Outlined that the gap between baseline and intervention is ideally <2 months, rather than a strict requirement, and noting that central research team approval required to start baselining. • Process for completion of MMSE for visually impaired individuals outlined (section 8) • Added details of a further sub-study in section 4.3 – developing the JtD intervention. • To clarify that the research supervisor will receive individual/group sheets during the intervention for supervision purposes (section 4.2) • Update on the fidelity section which will now not include video recordings (section 4.2) • Included information in the risk section about actions to be taken with a score of moderate/severe anxiety or depression (section 8.9) • Updates to the randomisation and statistical analysis sections in relation to inclusion of couples, both with dementia, into the study (sections 6.1 and 9.2) • Minor text corrections		
5.0	• Updates to the fidelity sub study. Originally interviews were planned for staff at the fidelity sites at the beginning and end of them delivering the intervention to monitor their change in outlook based on their experience of delivering the intervention. However, since many of the facilitators they propose to interview have actually delivered it before in a previous wave, there is less value in doing two interviews. We suggest an amendment to the protocol so that one interview is now conducted, looking more broadly at the facilitator experience of delivering the intervention. We now propose to interview staff at one time-point at the 4 fidelity sites and 3 additional sites.	28/11/17	4.0
6.0	• Inserted date of approval for REC approval of Version 4.0/5.0. • Update to TMG table to replace TMG member (Jules to Michelle at Bradford) and other small administrative changes to addresses.	24/10/18	5.0

	• Changes in relation to a small number of participants potentially not receiving the 12 month follow-ups (N.B primary measures are taken at 8 months). The Protocol has been updated to indicate that will now only take place when possible within project timescales, through changes to: the trial summary, figure 1 on flow of participants (Section 3), Section 8.3 (12 month post randomisation visit), Table 2, on assessments for the person with dementia, Section 8.6, Lost to follow-up, • Updates to the fidelity sub study. Minor changes to section 4.2 of the protocol, including a change to who completes individual session check-lists (amended to apply only to facilitators, p21), a clarification on where participants are sampled from for the qualitative interviews (p22), a clarificationthat the qualitative findings will be triangulated with results obtained from the fidelity assessment as well as the qualitative analysis (p23). • Section 7 clarification on who may deliver the training course. Sentence added: In some cases, for example if the individual is to be a reserve facilitator, or the group to be trained is small, they may receive a shortened course supported by online resources created for this purpose. • Update to S8.2 to explain that some measures may be taken from the participant on the telephone at the 8 and 12 follow-up visits if this is the only feasible way of collecting the data. • Update to Serious Adverse Event (SAE) procedures (Section 8.8), to indicate that the local principal investigator, not the CI, will assess SAEs to judge as to whether they are unexpected and related.		

7.0	Update to include information on the plans for involving people with dementia in validating qualitative analyses (section 4.2)..		7.0

**For non-substantial amendments the date relates to notice of acknowledgement

Trial Summary

Trial Design: Journeying through Dementia (JtD) is a pragmatic, two-arm, parallel group, individually randomised controlled trial, intended to determine the benefit of an occupational therapy based self-management intervention compared to usual care for people in the early stages of dementia.

Setting: NHS and community settings.

Recruitment: Recruitment for JtD will be through specialist NHS services such as memory services; signposting through third sector organisations and recruitment through the Join Dementia Research database. People with dementia can also involve a family member or friend as a 'participating supporter' in the trial.

Intervention: Groups of 8-12 participants randomised to the intervention arm will be invited to attend 12 weekly facilitated meetings at local venues. The group will be assisted by the facilitators to select, explore and engage with activities that are relevant to them. Each participant will also be offered four individual sessions with one of the facilitators where they will be encouraged to pursue personal goals. Participants can choose to have a supporter attend some of the sessions with them (i.e. the supporter cannot attend alone). The intervention will be in addition to usual care.

Sample size: The sample size is 486 participants (243 participants will be randomised to usual care and 243 randomised to receiving the intervention in addition to usual care) assuming a 20% loss to follow-up. The sample size would have over 90% power to detect a 4-point difference in the DEMQOL at 8 months post randomisation (and assuming SD=11, ICC=0.03 and average cluster size=8).

Measurement of outcomes: The primary outcome measure is the DEMQOL at 8 months post randomisation. Secondary outcome measures include the EQ-5D-5L; PHQ-9; GAD-7;General Self-Efficacy scale (GSE); Diener's Flourishing Scale, Self-Management Ability scale (SMA), Instrumental Activities of Daily Living (IADL) and the Health and Social Care Resource Use (HSCRU) questionnaire. Participating supporters will be asked to complete the PHQ-9, EQ-5D-5L and the Sense of Competency questionnaire (SCQ).

Follow-up: Follow-up of the participant with dementia will occur at 8 months, with some of the measures repeated at 12 months post randomisation, where possible within project timescales. Follow-up of participating supporters will take place 8 months post randomisation.

Planned analyses: Analyses will compare the two arms of the trial on an as allocated basis. The primary analyses will compare the mean DEMQOL scores of the participants with dementia at 8 months between the two arms using a mixed effects linear regression model adjusted for DEMQOL baseline score and delivery site and allowing for the clustering of the outcome by the JtD intervention. Secondary outcomes between the intervention and control groups will be compared at 8 months and 12 months post randomisation. A cost-effectiveness analysis will be undertaken of the incremental cost per Quality Adjusted Life Years (QALYs) of the JtD intervention compared with treatment as usual.

Additional sub studies: Embedded qualitative and fidelity sub-studies will be conducted to explore the underlying mechanisms of the intervention.

1. Introduction

The Journeying through Dementia (JtD) randomised controlled trial (RCT) will be conducted through collaboration between Sheffield Health and Social Care NHS Foundation Trust (SHSC), the Universities of Sheffield, Bradford, Hull, Nottingham, Sheffield Hallam and Manchester, and in partnership with NHS dementia related services. It will test the effectiveness and cost-effectiveness of a manualised self-management intervention called Journeying through Dementia (JtD intervention). This intervention has been designed to improve the quality of life for people in the early stages of dementia by promoting self-efficacy and assisting them to continue to participate in life and maintain their independence.

Rationale

The increasing prevalence of dementia within the UK and globally is widely recognised [1,2]. The importance of dementia research (both for cure and for care) for the NHS (and for social care) cannot be underestimated. Dementia is a global and national priority; in 2009 the estimated world-wide cost was $422 billion dollars [3] and it has been predicted that costs to the UK alone will be £24 billion by 2026 [4]. Approximately 820,000 people in the UK have a diagnosis of dementia. Prevalence increases with age rising from 1 in 100 for people aged 65-69 to 1 in 6 for people aged 80 or more [1]. The resultant impact for individuals living with the condition and their family carers, for services and for economies is higher than for all other long-term illnesses in people aged 60 and over (including cancers) [2]. Two thirds of people with dementia live in the community, with half of these requiring some form of support [5].

In 2009, the UK Government announced a National Dementia Strategy, which included a number of priorities including increasing the rates of early diagnosis and improving support for people in the early stages of dementia. As part of this strategy, the UK Government mandated the establishment of memory services in each health locality. The aim of these services is to enable people experiencing symptoms of dementia to access expert diagnosis and help, with a particularly focus on earlier diagnosis [6,7]. The National Audit of Memory Services found there had been a fourfold increase in numbers presenting since 2010/11. In 2010/2011, services saw an average of 317 patients, with this increasing to approximately1206 patients in 2013 [8]. It also highlighted that 49.3% of patients were in the early stages of the condition. Despite these numbers, the type of help that memory services offer people who are in the early stages of dementia is inconsistent.

The potential value of psychosocial interventions for people in the early stages of dementia is recognised [9,10,11] and is also driven by the knowledge that a cure for dementia is unlikely in the near future. Psychosocial interventions are diverse but their common theme is that they do not involve the use of medication and instead focus on supporting people to overcome challenges and maintain good mental health. Such interventions can promote self-management, help people to continue to enjoy life and decrease reliance upon carers for longer. However, whilst there has been some shift, the use of psychosocial interventions within dementia care has been a neglected area in both research and practice. For example there has been little investment made into intervention development and testing. Current policy is now focussed upon the treatment and support required by people following

diagnosis, and memory services are being strongly encouraged to provide post diagnostic treatment and support [12]. The planned research will go some way to addressing these acknowledged research and practice gaps.

Self-management is one example of a psychosocial intervention that might be provided to people post diagnosis. It is an established concept for those living with long-term conditions [13,14] and will remain a cornerstone of health policy in the UK and internationally. It involves people with long-term health conditions identifying strategies and knowledge (in partnership with professionals), which can enable them to take responsibility for their own health as far as they are able to. People with dementia were not included in the 2001 and 2005 self-management policy [15]. In recent years however there has been a radical shift in thinking and work is now taking place to explore how people with dementia might be supported to manage their own symptoms for as long as possible.

There is a growing body of evidence to demonstrate how individuals with dementia can be supported to use self-management based techniques (sometimes in combination with other interventions such as cognitive rehabilitation and occupational therapy) [16-19]. A recent pilot trial of a dementia self-management intervention found that amongst the 24 people that participated, there were small positive gains in self-efficacy at 6 months for those that received the 8 week group self-management intervention [20]. A qualitative study which interviewed people with dementia who attended a self-management programme reported that participants found it enjoyable and useful. Several benefits were identified by participants, including the opportunity for peer support. However, they felt the programme could be improved by having more emphasis on maintaining activities and relationships and improving positive wellbeing [21]. In addition to these studies, the Healthbridge evaluation [22] and the Mental Health Foundation evaluation [23], both considered the role of peer support for people with dementia. In each case there was evidence that people with dementia and their carers benefitted from receiving group based peer support.

Whilst existing research has provided insights into the potential benefits of promoting self-management for people with dementia, there is an absence of robust evidence through full-scale RCTs. This means that it is difficult to establish the effectiveness and cost-effectiveness of such interventions, particularly in comparison to usual care.

The JtD intervention is a manualised intervention designed to support people with dementia to continue to participate in life, maintain their independence and promote self-efficacy. The content of the intervention was developed in consultation with people with dementia [24]. It involves individuals in the early stages of dementia participating in 12 facilitated weekly group sessions and in 4 individual sessions with one of the facilitators. It is anticipated that the timing of the individual sessions will be one before, one after and two during the course of the group sessions. The group is encouraged to select the content of their sessions from a range of topics including strategies to manage memory challenges, engaging in hobbies/interests and ways of maintaining physical and mental wellbeing. An essential component is the enactment of activities in the community with support from each other. During individual sessions people with dementia are assisted to work on individual needs and goals. Participants are not necessarily required to nominate a supporter (family member or friend who provides them with support) to take part, but if supporters are involved they are

invited to join group sessions one, six and twelve and can participate in the individual sessions with the person with dementia if agreed.

The JtD intervention was tested in a feasibility study [25]. The intervention was found to be acceptable to both people with dementia and their supporters. Reported benefits included increases in confidence and self-efficacy, engagement in activities and re-engagement with fun and friendships.

Funding has been obtained through the National Institute of Health Research (NIHR) Health Technology Assessment theme (HTA) to conduct a RCT to test the effectiveness and cost-effectiveness of the JtD intervention.

This protocol describes the processes and procedures for undertaking the RCT of JtD. The trial will be conducted in compliance with the protocol, Good Clinical Practice (GCP) and regulatory requirements.

2. Aims and objectives

The primary aim of the JtD trial is to determine the clinical and cost-effectiveness of the JtD intervention for people in the early stages of dementia.

To meet this aim, the objectives are:

1. Conduct an internal pilot RCT of the intervention to check the feasibility of rates of recruitment at scale.

2. Proceed to a full pragmatic RCT evaluating the clinical and cost-effectiveness of the JtD intervention.

3. Conduct fidelity checks regarding the delivery of the JtD intervention.

4. Undertake an embedded qualitative sub-study to explore issues concerned with intervention delivery.

5. Identify how the intervention might be realistically delivered through services.

3. Trial Design

The trial is a pragmatic, two-arm, parallel group, individually randomised RCT, comparing the JtD intervention with usual care to determine benefit for people in the early stages of dementia. The trial will contain an internal pilot study during the first 8 months of active recruitment. Feasibility will be assessed against stopping rules (see below).

The internal pilot will assess the feasibility of conducting the trial using a formal stop/go criteria. This criteria is:

- Recruitment of a minimum of 113 participants across the six pilot sites by the end of the fifth month of active recruitment (75% of the 150 target).
- Recruitment of a minimum of 12 facilitators (two facilitators identified at each of the six pilot sites by the start of active recruitment to deliver the intervention).
- No more than two of the six planned groups in the internal pilot with less than four participants registered for the group by the sixth month of active recruitment.

At the end of the internal pilot, the Trial Steering Committee (TSC) will assess whether the trial should continue, using the results of the stop/go criteria. The TSC will inform the HTA of their decision.

The fidelity of delivery of the training and supervision received by facilitators will be assessed as will intervention delivery.

A qualitative sub-study will be embedded into the trial. The key purpose will be to explore the mechanisms of the intervention, for example what elements of the intervention appear to support people to improve their self-management and what promotes good facilitation.

Design measures to minimise bias

To minimise bias, there will be allocation concealment through the use of a centralised web-based randomisation service.

The trial will be co-ordinated from the Clinical Trials Research Unit (CTRU) in the School of Health and Related Research (ScHARR), University of Sheffield. Researchers and Clinical Studies Officers (CSOs) based in the collaborating universities and participating NHS trusts and staff from the NIHR Clinical Research Network (CRN) will seek consent.

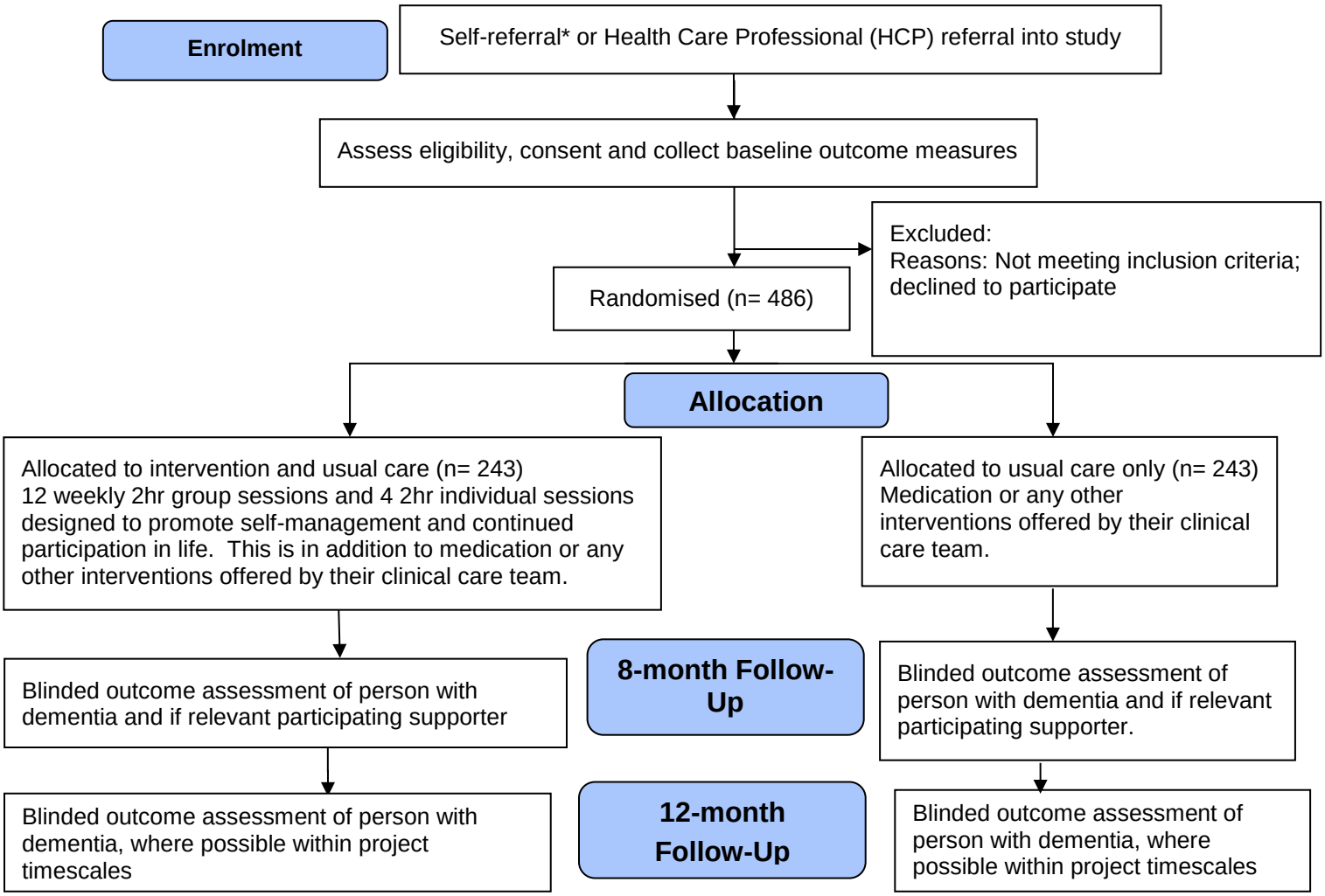
The TSC, study statisticians, health economists and outcome assessors will be blinded to treatment allocation whilst the trial is ongoing. For practical reasons, some members of the research team will not be blinded. This includes the trial manger, trial support officer, clinical research assistant, the lead of the qualitative study/fidelity assessment, the data management team, the chief investigator and NHS site staff involved in intervention delivery such as facilitators.

Participants will be randomised using the CTRU's web-based randomisation system. A member of the trial team, not blinded to treatment allocation, will inform participants of their allocation. Due to the nature of the intervention, participants will not be blinded. Participants will be advised that the outcome assessors collecting their outcome assessments are blinded to their allocation. If the outcome assessors know (or suspect) they have been unblinded this will be recorded on the Case Report Form (CRF) and reported periodically to the trial oversight committees.

Analysis will be on an as allocated basis (i.e. intention-to-treat). Where individuals are lost to follow-up or data is missing, imputation methods will be employed. These will be described in the statistical analysis plan.

Figure 1 shows the CONSORT diagram of participants' flow through the trial.

Figure 1: Flow of participants through the trial (CONSORT diagram)



*Self-referral includes signposting via third sector organisations and potential participants contacting the research team directly. This is detailed later in the protocol.

4. Ancillary sub-studies

4.1 Health economics evaluation

A trial based economic evaluation will be undertaken of an intention-to-treat comparison of the costs and outcomes of the two trial arms. A cost-effectiveness analysis will be undertaken of the incremental cost per Quality Adjusted Life Year (QALYs) of the JtD intervention compared with usual care provided through NHS memory services. QALYs will be calculated using the EQ-5D-5L preference-based index administered at baseline, 8 and 12 months. A sensitivity analysis will be undertaken using utility values from the DEMQOL-U, which can be derived from responses to the DEMQOL questionnaire [26]. The total cost of the intervention will be estimated at the individual participant level and will include the costs of providing the intervention and the subsequent consequences for the use of routine health and social care services. The facilitated group and individual sessions will be costed including administration, hire of local community venues, facilitator salaries and travel, refreshments, and any materials used. The number of participants attending each session will be recorded and an average level of capacity used to estimate an average cost per attendance. Finally, this estimate will be applied to the actual number of group and individual sessions that each participant attended.

The use of services by trial participants will be collected in detail using a Health and Social Care Resource Use (HSCRU) questionnaire administered at 8 and 12 months post randomisation devised from data collection tools developed in ScHARR and those collated by the Database for Instruments for Resource Use Measurement [27]. We anticipate that participants may have difficulty in completing the resource questionnaire themselves due to the recollective nature of the questions and, in this case, will therefore ask supporters (if appropriate) to complete the questionnaire on behalf of the participants. Service use will be costed using the most recent National Reference Cost Data and Unit Costs of Health and Social Care [28,29]. Missing data will be dealt with using multiple imputation for EQ-5D-5L, DEMQOL-U and resource use data [30]. A random effects linear regression model, accounting for clustering will be fitted, the model will include baseline scores for EQ-5D-5L and baseline costs. This model will be varied in sensitivity analysis using alternative models such as generalised linear models (GLM) and seemingly unrelated regression. The central analysis of mean incremental costs per QALY will be subjected to a full sensitivity analysis of key parameters including the measure used to estimate QALYs and number of participants at the weekly sessions. A full probabilistic sensitivity analysis will be performed to examine the probability of cost-effectiveness of the intervention for the NHS for different levels of costs and QALY gains [31]. We will follow the Consolidated Health Economic Evaluation Reporting Standards for reporting cost-effectiveness studies [32].

4.2 Fidelity Assessment and qualitative sub-study

Fidelity assessment

Fidelity checks will assess how well the JtD intervention is delivered according to the intervention protocol and manual. Checks will adhere to an intervention fidelity framework, see Table 1, based on that identified by the Behaviour Change Consortium [33] and NICE guidance on behaviour change [34].This provides quality assurance parameters based on intervention design, training, delivery, receipt and enactment.

Table 1: Fidelity assessment strategy for JtD

Goal	Description	Fidelity
Trial Design		
Comparable treatment	All participants receive the same programme tailored to the needs of the group/ setting.	• Attendance at group sessions (Register) • Attendance at 1-1s (Register) • Facilitator – Meeting checklist (Sample) • Facilitator – 1-1 session checklist (Sample) • Group observation checklist (Sample)
Risk to implementation	Plan for potential issues that could affect the delivery of the intervention.	• Implement a range of recruitment strategies to maximise uptake • Recruit and run intervention at different geographical areas
Monitoring facilitator training		
Standardised training	All facilitators receive the same training programme in a similar way. All supervisors receive the same training programme in a similar way.	• Training delivered by the same trainer(s) • Attendance registers for training • Observer training checklist (facilitator training only) • Trainee training checklist (facilitator training only)
Facilitator skill acquisition	All facilitators understand and engage with the intervention programme training in a similar way.	• Completion of training exercises by facilitators • Observer training checklist (facilitator training only) • Trainee training checklist (facilitator training only)
Monitoring intervention delivery		
Standardised delivery	All facilitators using the same techniques and content from the programme.	• Use of manual & supporting materials • Facilitator – Meeting checklist (Sample) • Facilitator – 1-1 session checklist (Sample)

		• Group observation checklist (Sample) • Facilitator semi-structured interviews (Sample) • Participant semi-structured interviews- people with dementia and supporters (Sample) • Supervisor semi-structured interviews (Sample)
Minimise drift in skills/delivery	Adherence to training content and delivery across sites.	• Group observation checklist (Sample) • Provision of supervision • Supervision checklist (Supervisors and Facilitators) • Support provided by research team • Facilitator semi-structured interviews (Sample) • Supervisor semi-structured interviews (Sample)
Monitoring receipt of intervention		
Participant attendance and engagement	Numbers of participants attending the programme each week. All participants taking part in the group meetings and activities. Impact of intervention on participant in terms of wellbeing.	• Attendance at group sessions (Register) • Attendance at individual sessions (Register) • Use of manual and supporting materials • Facilitator semi-structured interviews with (Sample) • Participant semi-structured interviews- people with dementia and supporters (Sample) • Supervisor semi-structured interviews (Sample) • Patient reported outcomes

Adapted from Bellg et al (2004) [33]

Training

Examination of the fidelity of facilitator training at each site will involve facilitators and supervisors receiving the same two day training delivered by the same trainer. Supervisors will also be able to attend a further half day day training session specific to the role. Training delivery and receipt of the 2 day training will be observed and rated by the same two researchers (the lead for fidelity and one other member of the research team) for inter-rater reliability using a bespoke ***training observation checklist***. For the purposes of comparison, trainees (the facilitators and supervisors) will also be asked to rate the training according to the same criteria using a simplified ***training trainee checklist***. The checklists will list core skills and key criteria identified out of content of the training programme, and the index and

text of the manualised intervention. Facilitator skills and understanding of the intervention will also be measured through training delivery techniques such as role play and active participation as well as observed behaviours such as skill acquisition, group work, self-awareness 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, using the Kappa statistic [35]. Frequencies will be used to determine the extent to which the training programme received by facilitator's maintained fidelity to what was intended. Comparison of training across sites will also be conducted to check for consistency.Similar methods have been used in previous studies, for example the Lifestyle Matters Trial [36].

Intervention

To assess facilitator adherence to the manualised intervention and participant receipt of the intervention, a purposive selection of group meetings across sites will be observed by two researchers (the fidelity lead and one other member of the research team). Observations will take place in the location of the group meeting. Consent from participants for the observations will be obtained. Where possible observations will be of meetings at approximately week 3 and week 8 of approximately 20% convenience sample of groups to monitor implementation and adherence to the programme and to identify any facilitator drift over the intervention delivery lifespan. The two researchers will use a ***Group observation checklist*** based on the contents of the manualised intervention and the two day training to assess each meeting. Facilitators of this sample will also be asked to complete a simplified ***group checklist*** from the observed sessions for comparison to the independent coders. Findings (validated by the two researchers) will be used to identify ability (or inability) to deliver the intervention as per protocol; including an examination of inter-rater reliability as before.

Observations of the individual sessions is considered to be too intrusive, instead a sample of approximately 20% of facilitators will be asked to complete ***individual session checklists*** to evaluate their experience of the individual sessions (participants will be supported with this). They will be asked to complete these at the end of each of the four individual sessions they deliver. Findings will be used to identify ability (or inability) to deliver the intervention as per protocol as well as potential differences in delivery between sites.

Facilitators will complete a ***weekly register*** of group meetings and ***individual register*** for individual sessions to record adherence.

Facilitators will also complete weekly and individual worksheets as part of the manual to record reflections on the content of the session and goal achievement.

As this is a pragmatic study, feedback will only be provided to facilitators by their supervisors during supervision sessions. Direct feedback will only be taken by the research staff if a serious issue is identified from the fidelity study such as the group observations which indicates a risk to participants.

Supervision

An additional important factor in preventing facilitator drift is supervision. A supervisor

protocol will be developed to guide sessions. All facilitators will therefore receive regular supervision by experienced qualified staff recruited at sites. These individuals will undertake training in the intervention and be supported by members of the trial team throughout the duration of the intervention delivery at each site. The delivery and quality of the supervision will be assessed in terms of the number of sessions delivered and facilitator satisfaction measured using Likert scales. A ***supervision checklist*** will be developed to collect data on aspects of the supervision sessions. This will be completed at the end of the first, sixth and twelfth weeks of supervision with approximately 20% of the sample. Satisfaction with supervision will also be assessed via the semi-structured interviews with a subsample of facilitators.

Supervisors will receive supervision from members of the research team who are experienced in delivering the JtD intervention and other similar interventions. Supervisory meetings will be recorded using a ***supervisor support contact sheet*** which will be completed by the research team supervisor and will record details of the issues discussed and how they were resolved.

While the trial is in progress the research supervisor will review the individual session and group recording sheets to check the documents are being completed properly and the intervention is being delivered according to the manual and training. The research supervisor may contact supervisors at sites if the documentation is not being completed correctly or if issues are identified which raise concerns about intervention delivery.

Embedded qualitative sub-study

In line with Medical Research Council guidance, an embedded qualitative sub-study will be undertaken to investigate the impact of the JtD intervention upon the quality of life and wellbeing of people with dementia, upon the experience of caregiving by supporters and upon the facilitator role of staff. Discrepancies between observed and expected outcomes will be evaluated in order to explore the implementation of the intervention [37].

<u>Participants and their supporters</u>

Individual qualitative semi-structured interviews will be conducted with a purposive sample of approximately 20 participants from participants at sites who are part of the fidelity assessment. All interviews will be conducted as soon as possible after the last group meeting. Separate semi-structured interviews will be conducted with approximately 12 participating supporters. It is preferred to interview supporters of participants who are also being interviewed. A ***participant interview schedule*** and ***supporter interview schedule*** will be developed to cover the following themes:

- range and nature of issues that influence experiences of the intervention
- perceived advantages and disadvantages of taking part
- factors that may mediate or moderate the effectiveness of the intervention
- perceived skills and competencies required to facilitate the programme
- the barriers and facilitators to its uptake and continued use
- the effect of the programme on participation and living with the diagnosis
- impact of caring for someone with dementia.

The sampling frame used to identify the purposive sample of people with dementia will be based on a range of characteristics, including sex, age, ethnicity, availability of supporter support, severity of dementia (by MMSE score) and extent of participation. For participating supporters, since these will be largely associated with participants who have agreed to be interviewed we will record and report their relationship to the participant, age, sex and how long they have been in this caring role.

All interviews will be conducted in a convenient location for the participant and audio recorded with consent. All researchers undertaking interviews will be trained to use enhanced methods of communication with people with dementia to ensure that meaningful findings are obtained. For researchers that are blinded, they will undertake interviews at sites other than those they are working in so that blinding is maintained. Transcripts of interviews will undergo respondent validation. For the purposes of reporting, confidentiality will be assured by removing all identifiable or recognizable information and use of pseudonyms in reports.

Facilitators and supervisors

Semi-structured interviews will also be conducted with approximately 20% of all facilitators and supervisors across the sites. A ***facilitator interview schedule*** and ***supervisor interview schedule*** will be developed to cover the following themes:

- what issues promote the effectiveness of intervention facilitation
- the skills and competencies required to facilitate the programme
- the barriers and facilitators to its uptake and continued use
- factors that may mediate or moderate the effectiveness of the intervention

Interviews will take place with a 20% sample of facilitators and supervisors at the end of a cycle of delivery (post completion of a group at approx. week 13). The sample will include a range of sites and different levels of experience delivering the intervention, for example whether they have delivered one or two groups as part of the trial. The interviews will provide feedback on intervention delivery, training needs, consistency in delivery, perceptions of growth into the role (or lack of), participant receipt of the intervention, potential drift, impact on own practice, as well as inviting any other feedback.

Analysis

The same methods of analysis will be applied to all interviews [38]. For the purposes of reporting, confidentiality will be maintained by using unique participant identifiers and removing identifiable or recognisable information. Transcripts will be entered into NVivo and Framework analysis [39] will be used for analysis. This will involve the identification of a thematic framework by two researchers (Fidelity lead and another member of the research team) and an index developed for transcript coding. This will follow the five stages of Framework analysis including familiarization, identifying a thematic framework, indexing, charting, mapping and interpretation. The interview data will be charted using the framework and the resulting data map used to identify explanations and processes underlying the intervention.

People living with dementia will be approached to help validate the qualitative analysis from

the perspective of people with lived experience of dementia. The study team will invite people from University of Bradford Experts by Experience group, and particularly those who are members of our existing Advisory Group, to take part in two workshops over one to three months. Quotation/extracts from the interview data that researchers identify as being representative of the categories identified in their framework analysis will be selected for presentation to group members. Group members will be asked to respond to these quotations/extracts, focusing on a few key questions about them (for example: are there any words or phrases that stand out? Is there anything interesting in what is being said? Are there any similarities or differences in what is being said across quotations/extracts?). There will be a maximum of 12 persons per workshop and this can include carers of the people with dementia. Workshop attendees will receive reimbursement for their time and travel. The workshop outcomes will be used to refine and, if necessary, revisit the qualitative analysis.

Overall qualitative 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 [38]. The qualitative findings will be triangulated with those obtained from the fidelity assessment and quantitative analysis.

4.3 Developing the JtD Intervention

Anonymous information from the individual and group sessions within the intervention, alongside fidelity and qualitative data, will be fed back to the intervention developer in order to further develop the intervention for future use beyond and outside the trial. The group and individual record sheets will be used to understand which topics and activities were used (because the intervention is menu-led) in order to inform the development of the intervention manual. Fidelity and qualitative data will also inform the developer about topics and activities that were useful, or where problems arose, to inform the development of the manual for future use.

5. Selection and withdrawal of participants

5.1 Setting

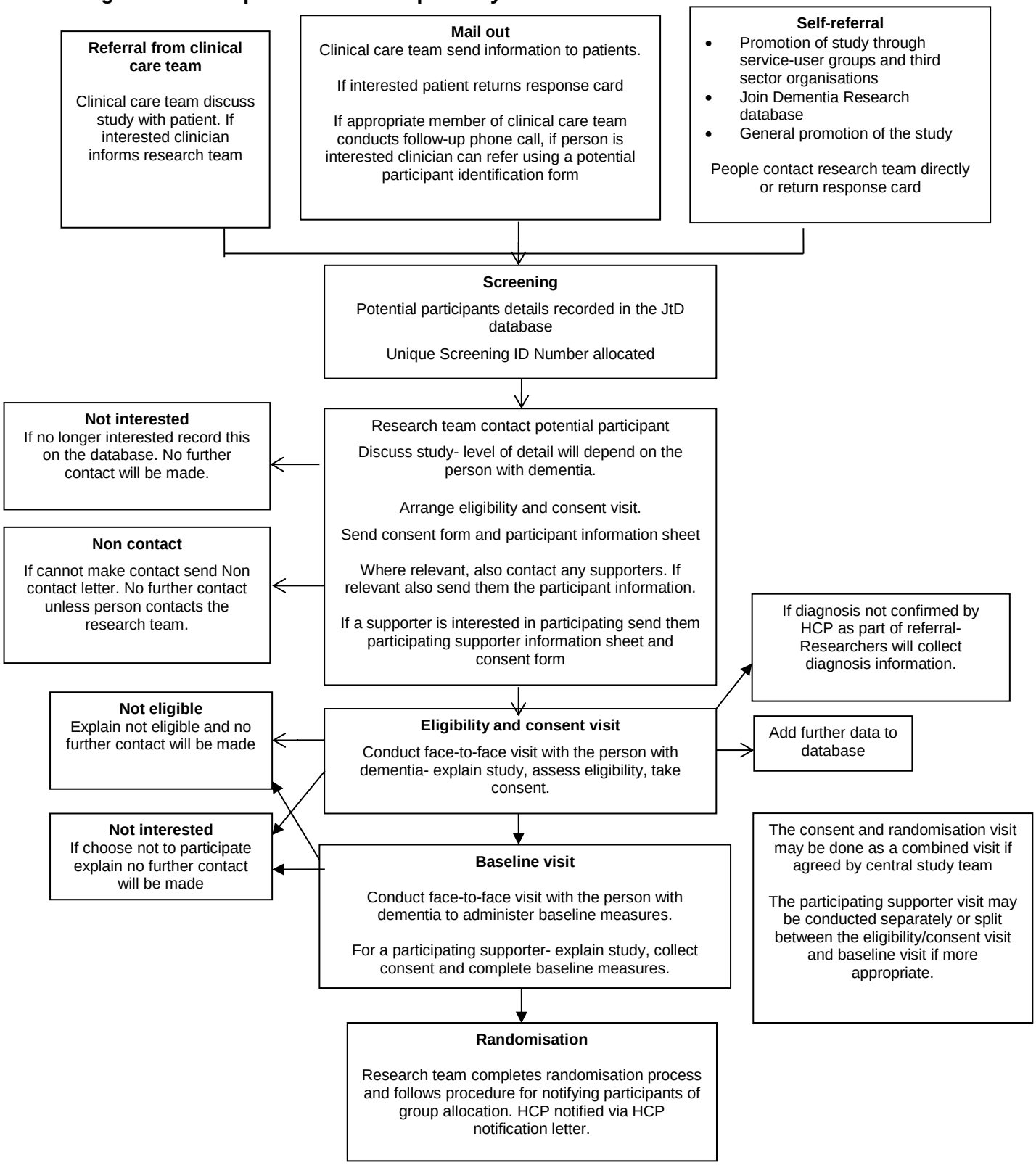
The JtD trial will operate in England within approximately 10 NHS trusts which run specialist dementia services. Additional NHS services may be involved in identifying potential participants for the trial and will operate as PICs. Recruitment will also be conducted through other sources such as third sector organisations e.g. Alzheimer's Society, general publicity and the Join Dementia Research database. The intervention itself will be run in the community and on NHS premises.

5.2 Participant identification

Our previous experience of recruiting people with dementia to trials has demonstrated the challenges that exist. Therefore it will be important to use a range of methods and sources to identify potential participants. Figure 2 details the participant identification and recruitment process. As in each NHS trust, the configuration of treatment and care for people with dementia varies as well as the number of potentially eligible participants seen by services, it

will be necessary to tailor the recruitment methods to the specific nature of each site. For example in some sites, promotion through third sector organisations may not be necessary because greater recruitment may come from NHS memory clinics.

Figure 2: Participant recruitment pathway



NHS Secondary services

Relevant secondary care NHS trusts within the geographical localities of and near Sheffield, Hull and Nottingham will be approached and invited to participate to identify and refer patients. Relevant NHS service staff such as Clinical Studies Officers (CSOs) and clinical and research staff in memory clinics and related service provision including community mental health teams and outreach services will be asked to support the trial. They will all act under arrangements agreed with the responsible NHS trust. Some NHS trusts will be involved in the trial as full sites, whilst others will act as PICs, and only recruit participants.

Referral from clinical care team as part of a dementia related appointment

As part of a dementia related appointment health care professionals (HCPs) and other relevant NHS members of staff at participating NHS sites (be they full sites or PICs) will be asked to explain the trial to patients who may meet the trial eligibility criteria. Verbal information will be supplemented with brief written information which has been specifically designed to take account of the comprehension challenges that dementia can give rise to. If the person with dementia is potentially interested in JtD, they will be asked to give their verbal consent for the member of staff to pass their information to the research team. this will be recorded on their notes (e.g. the patient's electronic record). Depending on the specific arrangements at each trust, a member of staff may complete a ***potential participant identification form.*** This collects information on the person with dementia's diagnosis and their contact details. It will be explained to the person with dementia that a researcher will be contacting them about the trial. The member of staff will inform the relevant member of the research team e.g. the Clinical Studies Officer that the person with dementia is potentially interested in the study. If a potential participant identification form has been completed, this will be returned to the research team by fax, email, or post, or a member of the research team will collect the form from the NHS service. The recruitment process in section 5.4 will then be followed.

On occasions, a representative from JtD may be in attendance at a service; for example at a post diagnostic clinic. In these cases, if a person with dementia has expressed verbal permission to an NHS member of staff about interest in the study, then they can meet with the representative from JtD to discuss the trial in more detail with the person, and to answer any questions they may have.

It is known from previous dementia trials that due to competing priorities, staff may not always remember to promote the JtD trial to potentially relevant patients. Given this, members of the research team will be pro-active in reminding site staff about the trial, such as attending team meetings and visiting clinics.

Mail out by clinical team at participating sites

Appropriate NHS trust staff will conduct searches of patient records to identify patients that may be potentially appropriate for this trial. Identified patients will be mailed out a recruitment pack which will include a ***participant invite letter and response card.*** If someone is interested in the trial, they can return the response card to the research team or contact them directly. It is known that people with dementia can find it challenging to return paperwork; therefore, if appropriate NHS staff will follow up the invite letter with a telephone call to the person with dementia to explain the trial. If a person with dementia expresses an interest in the trial, the NHS staff member will collect verbal consent that they can pass on the contact details of the person with dementia to the research team. They will record this in the patient's notes. On obtaining this verbal consent, the NHS staff member will complete a potential participant identification form and return this to the research team. The recruitment process detailed in Section 5.4 will then be followed.

NHS Primary Care

In some areas, recruitment will also take place through having PICs within primary care. In these cases, similar recruitment methods to those described for NHS secondary services will be used, for example mail-outs.

Join Dementia Research database

The JtD trial will be registered on the Join Dementia Research (JDR) database. This is a NIHR database, where people with dementia who are interested in research can be matched to studies that they may be suitable for. There will be two methods of how people with dementia can enter into the trial. Firstly, they can peruse the JDR to identify the trial and contact the research team themselves. Alternatively participants on the database can give permission for their contact details to be passed onto the research team. In either scenario, once the research team receive the person with dementia's contact details, a researcher will contact the potential participant using the process detailed in Section 5.4.

Service-user groups

Relevant service-user groups such as those convened by the Alzheimer's society will be informed about the trial by direct contact with researchers. Researchers will visit groups and explain the trial. People who are interested in participating will complete a response card. Once the research team receive the person with dementia's contact details, a researcher will contact the potential participants using the process detailed in Section 5.4.

General promotion of the trial

Alongside targeted approaches, the trial will be promoted to people with dementia through more general promotional methods. Posters and flyers about the trial will be put up in locations such as NHS premises and dementia support organisations. The trial will also be promoted through using relevant organisations' newsletters, social media, mailing lists and websites. As part of these promotional methods, the contact details of the research team will be included so that if people are interested they can contact the research team. Once the research team receive the person with dementia's contact details, a researcher will contact potential participants using the process detailed in Section 5.4.

5.3 Eligibility criteria:

Selection of participants will be based on the following inclusion and exclusion criteria:

Person with dementia

Inclusion criteria

1. People diagnosed with dementia for example Alzheimer's disease, vascular dementia or mixed Alzheimer's/vascular dementia.
2. A Mini Mental State Examination (MMSE) Score of 18 or more (taken <2 months pre-consent).
3. Can make informed decisions (assessed by the ***Capacity Assessment Form)***
4. Living in the community or in sheltered accommodation, alone or with others.
5. Are able to converse and communicate in English.
6. Are willing to engage in a 12 week group self-management intervention.

Exclusion criteria

1. People not diagnosed with a form of dementia.
2. Being in more moderate stages of dementia. Measured by having a MMSE score of less than 18
3. Is assessed as lacking capacity (assessed by the Capacity Assessment Form)
4. Living in residential or nursing care.
5. Not able to converse or communicate in English.
6. Is taking part in any other pharmacological or psychosocial intervention studies.

Participating supporter

Inclusion criteria

1. Is aged 18 years or older
2. Is named by the person with dementia as their supporter
3. Are able to converse and communicate in English
4. Has the ability to give informed consent

Exclusion criteria

1. Is under 18 years old.
2. The person with dementia they provide support to is not participating in the trial.
3. Is not able to converse or communicate in English.
4. Is not able to give informed consent.

5.4 Consent process

Upon the research team receiving the details of a potential participant, they will allocate them a unique screening number.

There will be different processes followed depending on whether it is less than 2 months before the commencement of the JtD intervention wave (in which case the consent and baseline visits will be combined) and whether the research team has received a confirmation of diagnosis. However the process will involve the research team having an initial conversation with the person with dementia about the trial (and, where relevant, with their supporter). Following this, there will be a face-face eligibility and consent visit with the person with dementia to explain the trial, assess eligibility and gain informed consent. Following on from this, in the two month period before the JtD intervention begins in the locality, a face-to-face baseline visit will take place with the participant to collect baseline outcome measures. Following this appointment the participant will be randomised. This consent process will be explained in greater detail below.

Initial contact

On receipt of the contact details of a person with dementia, a researcher will attempt to make contact with them within two weeks of receiving a person's details.

The purpose of this initial contact, which will usually be a telephone call, is to organise an eligibility and consent visit and to establish whether a supporter will be involved in the trial. As part of this contact, the researcher will establish whether the person with dementia has someone they would either like to take part in the trial with them as a participating supporter, or have someone who will support their involvement informally in the trial as a supporter.

The researcher will organise an eligibility and consent visit with the person with dementia, at a time and location most appropriate for the person with dementia. Where appropriate, the researcher will also contact the supporter with this information. As part of this contact, the person with dementia and, where relevant, supporters will be asked about receiving a reminder about the visit, and when and how it would be best to do this.

Following the telephone call, a ***baseline visit appointment letter, participant information sheet and participant consent form*** will be posted or emailed to the participant, depending on their preferences. If the person with dementia wishes, this information can also be sent out to the supporter.

It is acknowledged that each person with dementia may have specific communication needs. Therefore whilst this first contact will usually be done via a telephone conversation, if the person with dementia wishes, this communication will be via email or with a supporter. It is important that whilst there are standardised processes that there is also flexibility within the research process because of the specific needs participants may have.

If a participating supporter is to be involved in the trial then they will be telephoned and their involvement explained. They will then be sent a ***participating supporter information sheet*** and ***participating supporter consent form***. It will be explained to the participating supporter that a visit will be organised with them to explain the trial, collect consent and

collect outcome measures. Depending on the preferences of the participating supporter, this visit may be undertaken alongside the visits for the person with dementia or on a separate occasion.

If the research team cannot make contact with the person with dementia, they will send the ***non-contact letter***. This explains that the research team sought to make contact and ask that the person with dementia or their supporter contact the research team if they are still interested in participating.

Eligibility and consent visit- Person with dementia

If required, a member of the research team will contact the person with dementia and/or the relevant supporter to remind them about the visit.

The purpose of the eligibility and consent visit is to:

- Explain the trial
- Assess eligibility
- Obtain consent

The researchers will explain to the person with dementia (and where relevant supporters) about the trial, talking through the participant information sheet. It will be clearly communicated that the visit can be terminated and the researcher arrange another visit if the person needs further time to consider the trial before being assessed for eligibility or consenting.

Initially the researcher will collect written permission to assess eligibility from the person with dementia using the Permission to Screen Form.

They will then assess eligibility using the:

- Eligibility checklist
- Capacity assessment form
- MMSE

If the participant is visually impaired they can still take part in the study, however, the MMSE will be used differently. Questions 17, 18, 19 will not be asked and an adjusted score calculated based on the 27 questions that have been answered, The adjusted score would still have to be 18 (so a minimum non adjusted score of 16 is required) for the person to take part in the study.

If a person is ineligible, the researcher will explain that the trial is not suitable for them and finish the visit. If need be, the researcher will provide signposting about sources of support, for example the Alzheimer's Society. If a person with dementia is eligible, then the researcher will continue the consent visit.

The next stage of the visit will involve collecting informed consent. This includes the person with dementia signing two copies of the consent form, they will keep one copy and the researcher will keep one. The researcher will also collect some information on the

participant's demographics and discuss with the person with dementia if a supporter will help with their participation in the trial and how they would like them to be involved.

If there is longer than 2 months before the next intervention wave, it will be explained to the person with dementia that a member of the research team will be in contact in due course about the next stages of the trial. The person with dementia will be told how long this will approximately be (this will vary depending on how long it will be until the site they are connected to is running the intervention but will be less than 5 months). During that period contact will be maintained, for example sending out study newsletters.

If it is less than 2 months before the next intervention wave begins, and the central research team has agreed to this, then the researcher will also conduct the baseline visit (see below for details).

After the visit, the research team will seek confirmation of diagnosis for those participants they have not yet got this information on (e.g. those that have not had returned a potential participant identification form). The process for collecting this information will vary depending on local arrangements.

Baseline visit- Person with dementia

In addition to the consent visit, a baseline visit will be conducted with the person with dementia to collect their baseline outcome measures. This visit ideally needs to be completed less than 2 months before the commencement of the JtD intervention at their associated site. Consequently this visit may be conducted separately or at the same time as the eligibility and consent visit depending on when a person with dementia is recruited into the trial and the person's specific needs. For details of what the baseline visit entails see Section 6.1.

Baseline visit- Participating supporter

It is anticipated that the baseline visit for the participating supporter will usually be conducted at the same time as the baseline visit for the person with dementia (which may be conducted in two separate sessions depending upon the tolerance of the person). Therefore the participating supporter may provide baseline information at one of these sessions or in a separate visit to the supporter depending upon the preferences of the person with dementia and their nominated supporter. As part of the baseline visit, a researcher will explain the trial, talking through the participating supporter information sheet. The researcher will check the participating supporter's eligibility**.** If the supporter is eligible, the researcher will ask the participating supporter to complete two copies of the participating supporter consent form. The participating supporter will keep one copy of the consent form and the researcher the other copy. The participating supporter will then be asked some demographic questions and will be supported to complete the baseline outcome measures. For details of these see Section 8.

If the person with dementia or the participating supporter are finding the visits too long and/ or challenging, a visit may be terminated before all the processes are covered and another visit organised for as soon as possible to finish collecting the information.

After each visit, the information collected will be entered into the trial database, such as recording whether consent has been taken or reasons for ineligibility.

Informing Health Care Professionals (HCPs) of participation in the trial
Once a person with dementia has consented and been randomised (see Section 6 for details) the participant's GP and if relevant, a HCP at their specialist dementia related service will be notified of their involvement in the trial and which arm they have been randomised to via the ***HCP notification letter***. If a participating supporter has also consented into the trial, their GP will be sent a ***HCP notification letter- Participating supporters' version.*** These letters explain that their patient is participating in the JtD trial and which arm they have been randomised to.

5.5 Consultee Process

Due to the nature of dementia, people may lose capacity during the trial. As part of the recruitment process, a person with dementia will be asked to nominate people who may be able to act as consultees if they lose capacity. If a participant loses capacity, then a member of the research team will contact the consultee to explain the situation, discuss with them about the role and provide them with the consultee information sheet. If they are agreeable they will be asked to complete the consultee declaration form.

5.6 Withdrawal Process

All participants including people with dementia and participating supporters will be free to withdraw from the trial at any time without giving a reason. If a participant does withdraw during the trial period, data already collected prior to withdrawal will be retained and used for the purposes of the study as stated in the participant/participating supporter information sheet. If a person with dementia withdraws, they will not be replaced in the trial. If a participating supporter withdraws, outcome measures will not be collected from another supporter. However, the person with dementia can bring a different supporter along to the intervention.

Person with dementia- Participant choice withdrawal
The person with dementia may drop out of the intervention or withdraw fully from the trial. Participants will be informed that they can withdraw at any time by telling a JtD facilitator or any member of the research team. A withdrawal form will be completed recording whether the person is dropping out of the intervention or withdrawing from the trial and their reasons.

The participant's GP and where relevant, HCP at their specialist dementia service will be informed of the withdrawal through a ***HCP withdrawal notification letter.***

If the person with dementia has a participating supporter in the trial, the person with dementia will be informed that we will be contacting the participating supporter to discuss their involvement in the study.

Person with dementia- Consultee choice withdrawal
Should the person with dementia lose capacity, a consultee can recommend whether they feel the person with dementia should drop out of the intervention or be withdrawn fully from the trial due to a loss of capacity. The consultee will be asked to contact the trial manager regarding this. A withdrawal form will be completed recording the type of withdrawal and reasons why. The participant's GP and, where relevant, a HCP at their specialist dementia service will be informed about the withdrawal through a HCP withdrawal notification letter.

Participating supporter withdrawal due to person with dementia withdrawal
If a person with dementia drops out of the intervention and has a participating supporter, an unblinded member of the research team will contact them to explain that they can no longer participate in the intervention because the person with dementia has chosen to stop attending. The participating supporter will be asked whether they would be willing to continue to provide outcome data. A participating supporter withdrawal form will be completed about their reasons for withdrawal. The participating supporter's GP will be informed about the type of withdrawal using the HCP withdrawal notification letter.

Participating supporter withdrawal- Their choice.
The participating supporter may drop out of the intervention or choose to withdraw from the trial at any point. Participating supporters will be informed that they can withdraw at any time by informing a member of the research team. A participating supporter withdrawal form will be completed detailing reasons for withdrawal. The participating supporter's GP will be informed about their withdrawal through the HCP withdrawal notification letter.

6. Randomisation and enrolment

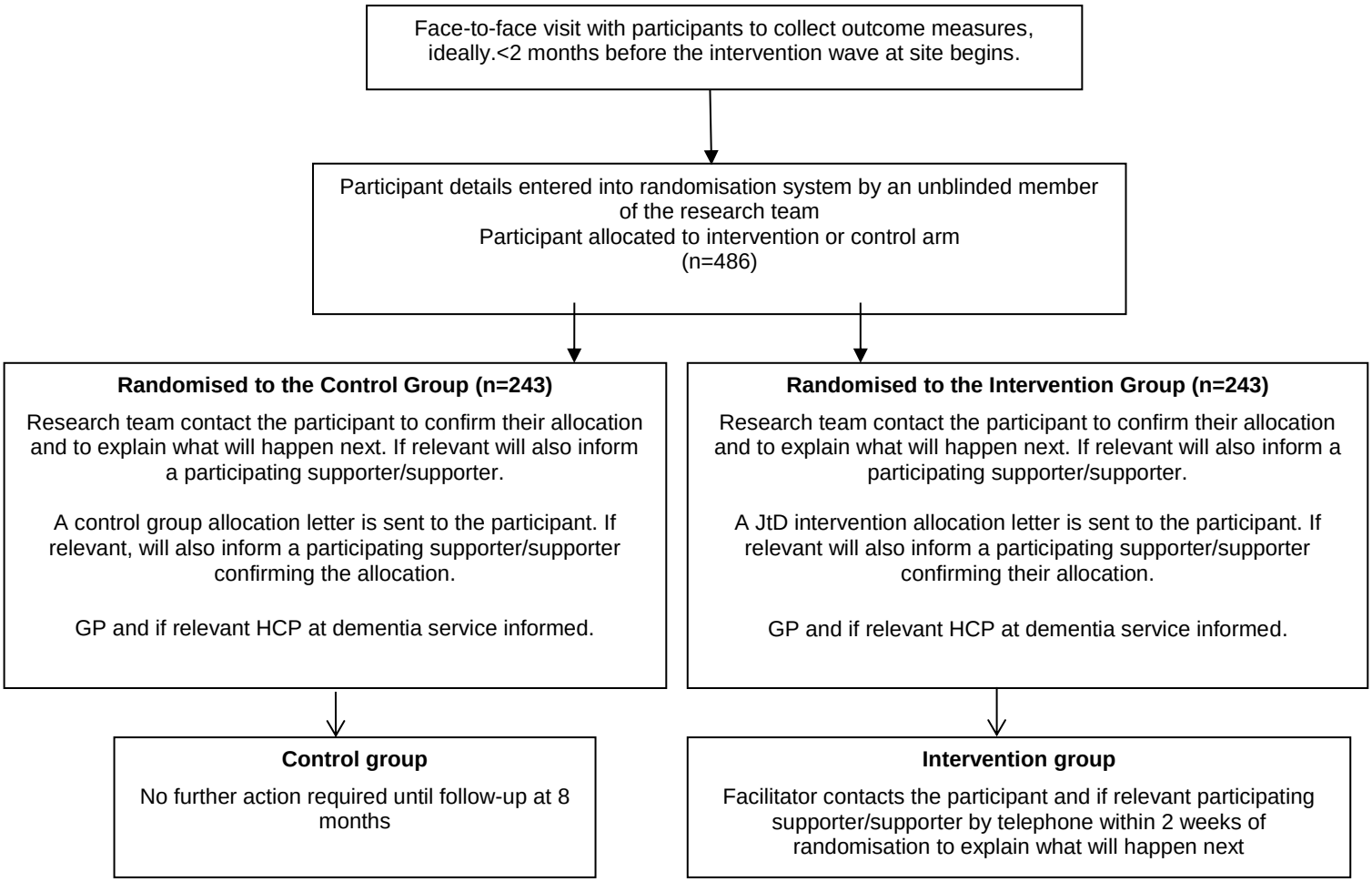
6.1 Randomisation

The CTRU will oversee randomisation. The Sheffield CTRU SOP ST007 will be adhered to. The randomisation schedule will be generated by the CTRU prior to the start ofrecruitment. The randomisation sequence will be computer generated, stratified by delivery site and constrained by a fixed block size will be used to ensure enough participants are allocated evenly to each arm of the trial at each delivery site.

Due to the group nature of the intervention, a process of delayed randomisation will be employed in the JtD trial whereby participants are not randomised at the point of consent, but after the collection of the baseline outcome measures. This must ideally be less than 2 months before the intervention wave at that site begins. In the event of a couple in the same household both consenting to take part in the study the pair will be randomised as a couple

and not separately i.e. to both get the intervention or to both get usual care. Figure 3 details the randomisation process.

Figure 3: Participant randomisation and allocation pathway



To ensure the outcome assessors are blinded to group allocation, an unblinded member of the research team who will not be conducting outcome assessment will enter the participants' details onto a remote web-based randomisation system. Details entered onto the system will include confirmation of signed consent. Participants will then be randomly allocated to either the intervention (n=243) or usual care (n=243) arm of the trial. This outcome will be recorded in the trial database.

Participants randomised to the control (usual care) arm of the trial will be contacted by an unblinded member of the research team. If the person with a dementia has a participating supporter in the trial, they will also be contacted about the group allocation. If the person with dementia wishes, their supporter can also be informed about the allocation. An ***usual care allocation letter*** confirming allocation will be sent (by post or email depending on preferences) to the participant and, if relevant, to the participating supporter and/or supporter to keep as a record.

Participants randomised to the intervention arm of the trial will be contacted by an unblinded member of the research team. It will be explained to participants that an intervention

facilitator will contact them within the next 2 weeks to discuss what will happen next. If the person with dementia has a participating supporter in the trial, they will also be contacted about the group allocation. If the person with dementia wishes, their supporter can also be contacted about the allocation. A ***JtD intervention allocation letter*** confirming allocation will also be sent (by post or email depending on preferences) to the participant and, if relevant to the participating supporter and/or supporter to keep as a record.

When a participant is allocated to the intervention group, an unblinded member of the research team will inform the relevant intervention facilitators so that they can contact them/their supporter within 2 weeks to arrange delivery of the intervention.

7. Trial treatment

7.1 Intervention group – JtD intervention

Participants who are randomised to receive the intervention will receive the JtD intervention in addition to usual care. The intervention is in a manualised format.

The intervention consists of 12 weekly facilitated group sessions with 8-12 participants (all with dementia) over 12 successive weeks (occasionally there may be a week break, for example due to a bank holiday). As part of the intervention each participant also receives four individual sessions with one of the two facilitators to pursue their individual goals. The first individual session takes place before the commencement of the group and introduces the participant to one of the facilitators and enables discussion about their forthcoming involvement. The other three sessions will be spaced out over the course of the group sessions, with the final session likely to be delivered once the group sessions have finished.

The content of the intervention includes (but is not limited to) the following topics:

[a] Ways of thinking about dementia (*What is dementia, effects on everyday life, challenging stereotypes, sharing coping strategies*).
[b] Keeping physically well *(Relationship between physical and mental wellbeing, embedded health activity in everyday life, diet).*
[c] Memory *(strategies to aid memory, impact on everyday life and learn and practice new techniques).*
[d] Keeping mentally well (*relationship between anxiety and memory and dementia and stress*).
[e] Endings (*celebration of achievements and how to move forward*).

There is flexibility within the intervention to select different topics and explore topics in the level of detail dictated by the group. Some groups may spend more time on certain topics. One essential component is enactment of activities, particularly in the community with participants being encouraged to support each other.

Participants are able to invite a supporter (e.g. family member, friend or neighbour) to participate in the group during sessions 1, 6 and 12, and in the individual sessions if the

participant finds this helpful in achieving their goals. This does not have to be the same person each time.

The intervention is facilitated by two relevant NHS staff members. Facilitators need to be experienced with working with people with dementia. Facilitators will usually be someone on an Agenda for Change Band 3-5. Examples of relevant staff include nurses, social workers, occupational therapy assistants, assistant psychologists and support workers. Facilitators do not have to be registered health care professionals. Additional staff will be trained in the intervention to provide cover for annual leave and sickness absence.

Facilitators at each site will initially receive a two day training course from Dr Claire Craig who devised the intervention, or another experienced trainer from the research team. In some cases, for example if the individual is to be a reserve facilitator, or the group to be trained is small, they may receive a shortened course supported by online resources created for this purpose. They will then be supported and supervised within their trust by someone experienced in supervision who has also attended the intervention training. This will usually be a HCP or social care professional who is a Band 7 on the NHS Agenda for Change scale. For example, someone who is a clinical psychologist or occupational therapist. The supervisors will receive supervision from Dr Katherine Berry, a clinical psychologist experienced in the 'train the trainer' model.

7.2 Control group

The control group will receive usual care. In this case, usual care is defined as accessing health and social care, acute and community services, including third sector support and self-help groups as appropriate to meet participants' needs. This may include dementia self-management and education programmes offered by NHS services and third sector organisations. Information will be collected from participating NHS sites about what treatment they offer as usual care.

8. Assessments and procedures

Throughout the trial, the eligibility assessments and collection of outcome measures will be administered as part of face-to-face visits by members of the research team, such as blinded outcome assessors who have received training in collecting outcome measures with people with dementia and their supporters.

A range of outcome measures are being used in the trial. These have been chosen because they measure key components of the JtD intervention.

Mood- A key component of the intervention seeks to improve the mood of people with dementia and their supporters. Therefore the GAD-7 will be used to measure changes in anxiety, the PHQ-9 used to measure changes in depressive symptoms and the DEMQOL used because it is specially designed for people with dementia [40,41,42].

Building relationships and sense of connectedness- The intervention seeks to build relationships and people's sense of connectedness. This will be measured through Diener's flourishing scale and the Self-Management Ability Scale (SMA) [43,44].

Belief life is meaningful despite dementia-The intervention seeks to improve people's quality of life. This will be measured through Diener's flourishing scale, the DEMQOL, SMA and General Self-Efficacy (GSE) scale [42,43,44,45].

Improving skills in IADLs and strategies to maintain cognitive functioning- The intervention seeks to improve participant's IADLs and cognitive functioning. To measure this, the IADL [46] will be used.

As a cost-effectiveness analysis is being undertaken, the EQ-5D-5L [47] and HSCRU will be used to collect information that is required for the cost-effectiveness analysis.

8.1 Baseline collection of outcome measures

Baseline collection of outcome measures- Person with dementia
The baseline collection of outcome measures from a person with dementia will occur as part of a specific baseline visit. If the eligibility and consent visit and baseline visit are being conducted at the same time, then the steps for organising the baseline visit will be superseded by the process of organising an eligibility and consent visit.

Collection of baseline outcome measures will occur in a 2 month period before an intervention begins at a related site. A researcher will contact the relevant person to organise a face-to-face meeting to collect the outcome measures. The baseline visit will be done at a location and time most appropriate to the person with dementia and their supporter. The method of communication to organise the visit and whether it is with the person with dementia or their supporter will depend on the preferences of the person with dementia. As part of the contact, it will be established how and when they may want a reminder about the visit.

A ***confirmation of visit letter*** will be sent out to confirm the details of the visit.

A researcher will attend the visit to collect the outcome measures. If necessary, depending on the needs of the person with dementia, a second visit may be required to finish collecting the outcome measures. If this is the case then a second visit will be organised for as soon as possible.

The following outcome measures will be collected at baseline:

- DEMQOL
- EQ-5D-5L
- PHQ-9
- GAD-7

- GSE
- Diener's Flourishing Scale
- SMA
- IADL

Baseline collection of outcome measures- Participating supporter

The collection of baseline outcome measures for a participating supporter will usually occur as part of the baseline visit with the person with dementia. For details about the process of organising the baseline visit see Section 5. However, a separate visit with the participating supporter may be conducted if this is more appropriate or feasible. As part of the face-to-face baseline visit, a researcher will assist the participating supporter to collect their baseline outcome measures. The following outcome measures will be collected:

- PHQ-9
- EQ-5D-5L
- SCQ

After the visits, a member of the trial team, such as the trial support officer, will input the baseline outcome measures into the trial database.

8.2 8 month post randomisation collection of outcome measures

8 months post randomisation collection of outcome measures- Person with dementia

The primary collection of outcome measures will take place at 8 months post randomisation. The outcome measures will ideally be collected < 2 weeks pre and < 8 weeks post the date they are due. However, in circumstances where this is not possible, attempts will be made to collect the data irrespective of whether it is outside this ideal window.

The 8 month follow-up visit will be done at a location and time preferred by the person with dementia and their supporter. Depending on the needs of the person with dementia, this visit may be arranged either by contacting them or their supporter. As part of this, it will be agreed whether – and how and when – a researcher will contact the participant and/or his or her supporter with a reminder about the visit.

A ***confirmation of visit letter*** will be sent out to confirm the details of the visit.

A blinded outcome assessor will attend the visit to collect the outcome measures. If necessary, depending on the needs and preferences of the person with dementia, a second visit may be required to finish collecting the outcome measures. If this is the case then a second visit will be organised for as soon as possible.

The following outcome measures will be collected from the person with dementia:

- DEMQOL
- EQ-5D-5L
- PHQ-9
- GAD-7
- GSE
- Diener's Flourishing Scale
- SMA
- IADL
- HSCRU questionnaire

Whilst the outcome measures will usually be collected from a participant during a face-to-face visit, in some cases, where this is the only feasible way of collecting this data, we will collect a reduced set of measures (DEMQOL, HSCRU and EQ5D-5L) via the telephone. We will record all instances where these measures are taken on the telephone and be flexible with what elements we ask for, which will be guided by the participant's willingness to answer questions over the phone.

8 months post randomisation collection of outcome measures- Participating supporter

The participating supporter will be contacted to arrange a visit to collect outcome measures from them. If feasible and appropriate this will be done as part of the same visit with the person with dementia. As part of this contact, it will be agreed on how and when a reminder may be done.

A confirmation of visit letter will be sent out to confirm the details of the visit.

A blinded outcome assessor will attend the visit to collect the outcome measures.

The following measures will be collected from the participating supporter:

- PHQ-9
- EQ-5D-5L
- SCQ

The outcome measures will ideally be collected < 2 weeks pre and < 8 weeks post the date they are due. However, in circumstances where this is not possible, attempts will be made to collect the data irrespective of whether it is outside this ideal window.

Whilst the outcome measures will usually be collected from a participating supporter during a face-to-face visit, it is acknowledged that due to their caring responsibilities, participating supporters may not have the time/capacity to receive a face-to-face visit. Therefore as an option, if participating supporters would prefer, follow-up outcome measures for participating supporters can be collected via the telephone.

A member of the research team, for example the trial support officer, will input the outcome measures into the trial database.

8.3 12 months post randomisation visit

Further collection of outcome measures, where possible within project timescales, will take place at 12 months post randomisation from the person with dementia only.

The outcome measures will ideally be collected < 2 weeks pre and < 8 weeks post the date they are due. However in circumstances where this is not possible, attempts will be made to collect the data irrespective of whether it is outside this ideal window.

To arrange the collection of outcome measures, a member of the research team will contact the relevant person to organise a face-to-face visit. The 12 month follow-up visit will be done at a location preferred by the person with dementia and their supporter. Depending on the needs of the person with dementia, the visit will be arranged via the person with dementia or their supporter. As part of this contact, it will be decided how and when a reminder will be carried out. A *co*nfirmation of visit letter will be sent out to confirm the details of the visit.

A blinded outcome assessor will attend the visit to collect the outcome measures. If necessary depending on the needs of the person with dementia, a second visit may be required to finish collecting the outcome measures. If this is the case then a second visit will be organised for as soon as possible.

The following outcome measures will be collected from the person with dementia:

- DEMQOL
- EQ-5D-5L
- HSCRU questionnaire

After the 12 month visit, a member of the research team, such as the trial support officer, will input the outcome measures into the trial database.

Whilst the outcome measures will usually be collected from a participant during a face-to-face visit, in some cases, where this is the only feasible way of collecting this data, we will collect the measures (DEMQOL, HSCRU and EQ5D-5L) via the telephone. We will record all instances where these measures are taken on the telephone and be flexible with what

elements we ask for, which will be guided by the participant's willingness to answer questions over the phone.

The tables below explain what assessments are conducted at what stages of the trial.

Table 2- Assessments for the person with dementia

Assessment	Eligibility and Consent visit*	Baseline visit*	8 months post randomisation visit	12 months post randomisation visit, where possible within project timescales
Baseline demographics	X			
Capacity assessment	X			
Mini Mental State Examination	X			
Eligibility checklist	X			
DEMQOL		X	X	X
EQ-5D-5L		X	X	X
PHQ-9		X	X	
GAD-7		X	X	
GSE		X	X	
Diener's Flourishing Scale		X	X	
SMA		X	X	
IADL		X	X	X
HSCRU			X	X

*The eligibility/consent and baseline visits may be conducted as one visit.

Table 3- Assessments for participating supporter

Assessment	Baseline visit	8 months post randomisation visit
Baseline demographics	X	
Eligibility checklist	X	
PHQ-9	X	X
EQ-5D-5L	X	X
SCQ	X	X

8.4 Intervention attendance

Attendance (or not) at group and individual intervention sessions will be recorded. Non-attendance at session/s will not be recorded as protocol non-compliance. If relevant, course materials from a missed session may be provided by facilitators. A person with dementia will

be classed as receiving the intervention if they attend at least 10 of the sessions (out of a possible 16). This is 62.5% of the intervention.

8.5 Intervention dropout

If a participant decides to drop out of the JtD intervention, this will be recorded on the CRF including their reasons (if known). The participant will be followed-up unless they explicitly also withdraw consent for follow-up of outcome measures (data up to this time will be included in the trial). The reason for withdrawal from the trial will also be recorded (if known). For further information on the withdrawal process please see Section 5.5.

8.6 Lost to follow-up

The person with dementia will be considered 'lost to follow up' if they do not complete the outcome measure data at 12 months post randomisation, when such as visit is possible given the timescales of the Trial. If outcome measures are not collected at 8 months post randomisation and the participant has not formerly withdrawn from the trial, attempts will be made to collect the 12 month post randomisation outcome measures. Participating supporters will be considered 'lost to follow up' if they do not complete the outcome measure data at 8 months post randomisation (as this is the only post randomisation data collection point for participating supporters).

8.7 Study completion

The end of the trial is defined as the date of the last follow-up (including qualitative sub-study where applicable) of the last participant in the trial.

8.8 Safety assessments

There are few anticipated adverse effects of the JtD intervention. There is the potential that discussing dementia, particularly the potential longer-term impact of it, may cause distress. However, it is believed that this risk is outweighed by the potential benefits people with dementia and their supporters may experience through receiving the intervention, namely improved quality of life.

Adverse Events (AEs) are not anticipated as a consequence of the intervention and thus will not be recorded. Serious Adverse Events (SAEs) will be recorded for all participants.

Serious Adverse Event (SAE)

The definition of SAEs is an event that:

(a) results in death
(b) is life-threatening* (subject at immediate risk of death);
(c) requires hospitalisation or prolongation of existing hospitalisation**;
(d) results in persistent or significant disability or incapacity;

(e) consists of a congenital anomaly or birth defect;
(f) is otherwise considered medically significant by the investigator***.

* ‘life-threatening’ in the definition of ‘serious’ refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

**Hospitalisation is defined as an inpatient admission, regardless of length of stay, even if the hospitalisation is a precautionary measure for continued observation. Hospitalisations for a pre-existing condition, including elective procedures that have not worsened, do not constitute an SAE.

***Other important medical events that may not result in death, be life-threatening, or require hospitalisation may be considered a serious adverse event/experience when, based upon appropriate clinical judgment, they may jeopardise the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

If anyone associated with the trial, for example researchers or intervention facilitators become aware of a SAE they need to inform the trial manager or chief investigator using the CTRU reporting system within 24 hours. In their absence, another person will be delegated to assess them.

The trial manager will record all SAEs in the trial master file and on the database. The local principal investigator will assess the SAEs in order to make a judgement as to whether they are unexpected and related. The Sponsor and REC will be informed of any unexpected and related SAEs. SAEs will be reported periodically to the trial’s oversight committees.

In this trial, the term related is defined as resulting from the administration of the JtD intervention or through the collection of trial data, such as the outcome measures or during the qualitative study.

Throughout the trial, the Sheffield CTRU SOP PM004 will be adhered to.

8.9 Risk

The clinical care teams e.g. GPs of both people with dementia and participating supporters remain responsible for all patient level treatment and management decisions, including risk assessments.

Should a participant's cognitive state deteriorate significantly, or risk (such as harm to others or self) arise, the relevant member of the research team will raise the concerns to the person with dementia’s GP or HCP. If any risk is identified (such as harm to others or self) in relation to a participating supporter, a member of the research team will contact their GP.

If any risk related referrals are made, this will be recorded in the database, including information about the reason. The informed HCP can recommend for the person with

dementia or the participating supporter to be withdrawn from the trial if they feel this would be appropriate.

As the PHQ-9 is being used within the trial with both people with dementia and their participating supporter there is the potential of identifying that an individual is at risk of self-harm or suicide. Question 9 asks whether a person has experienced self-harm or suicidal thoughts in the last two weeks. If a person scores either '2' (more than half the days) or '3' (nearly every day) on this question then action will be taken. This will involve notifying their GP or HCP at their dementia service (depending on who is most appropriate) of the person's answers and ask them to use their clinical judgement of the patient to take the action they deem most appropriate.

The results of the PHQ-9 and GAD-7 questionnaires could indicate moderate/severe depression (score on PHQ-9 of/over 15) or moderate/severe anxiety (score on GAD-7 of/over 10) respectively. The local site PI will determine further steps, but if the outcome is severe, the GP or HCP at their dementia service (depending on who is most appropriate) will be informed.

9. Statistics

9.1 Sample Size

The primary outcome for the study is the mean DEMQOL score 8 months post randomisation. If we assume a standard deviation of 11 points for the DEMQOL, a mean difference of 4 or more points is clinically and practically important [26]. The sample size has been calculated to have a 90% power of detecting this 4 point difference (equivalent to a standardised effect size of 0.36) in group mean scores at eight months as being statistically significant at 5% (two sided) level. As the JtD intervention is a facilitator led group intervention, the success of the intervention may depend on the facilitator delivering it so the outcomes of the participants in the same group with the same facilitators may be clustered. With no adjustment for clustering by facilitator the target sample size would be 160 per arm with a total sample size of 320). We have assumed an average cluster size of 8 dementia patients per facilitated group and an intra-cluster correlation (ICC) of 0.03; this will inflate the sample size by a design effect of 1.21; to 194 per group (388 total sample size) with valid primary outcome data. It has been assumed that there will be at least a 20% lost to follow-up. Therefore, given these calculations, the target sample size for the trial is to randomise to 243 participants in each arm (n=486).

9.2 Analysis

As JtD is a pragmatic parallel group randomised trial, with a usual treatment (control) arm, data will be reported and presented according to a revised CONSORT statement [48]. Statistical analysis will be performed on an intention-to-treat-basis. All exploratory tests will be two-tailed with alpha = 0.05. Baseline demographics (e.g. age, gender) and baseline dementia related quality of life (DEMQOL) and other data collected (e.g. EQ-5D-5L, PHQ-9, GAD7, GSE, Diener's Flourishing Scale, SMA and IADL) will be described and summarised overall and for both treatment groups.

The aim will be to establish whether the intervention is beneficial compared with the control group. The primary analysis will compare mean patient reported DEMQOL scores at 8 months post randomisation between the Intervention (JtD) group and Control groups using a mixed effects linear regression model adjusted for DEMQOL baseline score and site and allowing for the clustering of the outcome by the JtD intervention [49,50,51].The trial is a partially nested design with comparison of a group therapy (JtD) with individual therapy with clustering in one arm. Each dementia patient in the control group (unclustered arm) will be treated as a cluster (singleton) of size one. The cluster indicator will be treated as a random effect. A stratification variable used for randomisation (site) will be included as a fixed factor [52]. A partially clustered mixed effects linear regression model with homoscedastic errors as well as a heteroscedasticity mixed effects linear regression model will also be considered to account for potential differential variability of outcomes between the two treatment groups. A 95% confidence interval (CI) for the mean difference in DEMQOL scores between the intervention and control groups will also be calculated together with the associated P-value. A further adjusted analysis may also be performed alongside this baseline DEMQOL and site adjusted analysis depending on the observed degree of imbalance in baseline covariates (which are of potential prognostic importance) again using a mixed effects linear regression model. Additional covariates (of potential prognostic importance) include other baseline variables, such as age, gender, PHQ-9, and GAD-7. In the event that there are more than 10 couples (20 participants) from the same household the primary and secondary analyses will be changed to take into account the hierarchical or clustered nature of the data. A multi level mixed effects model will be used; the random effects will be JtD intervention groups (top level) and couple/singles (lower level). Individual participants who are not part of a couple will be treated as clusters of size one.

Participants will be followed up for up to 12 months post randomisation. Mean DEMQOL scores at 12 months follow-up will be compared again using the mixed effects linear regression model as described for the primary and secondary outcomes from above. A 95% CI for the mean difference in this parameter between the treatment groups will also be calculated.

For the primary outcome, the DEMQOL score at 8 months follow-up, missing data will be imputed through a variety of methods including: regression and multiple imputation as part of a sensitivity analysis.

We will complement the intention to treat (ITT) analysis of the primary outcome with a complier average causal effects analysis (CACE) as a secondary analysis alongside the primary ITT analysis. Compliance will be defined as a binary variable with participants who attend at least 62.5% of their scheduled JtD sessions (both individual and group sessions combined) regarded as being compliant with the JtD therapy.

There are no plans for any formal interim statistical analysis or formal stopping rules in relation to efficacy; the only stopping rules are in relation to recruitment. The trial may be stopped early on safety or other grounds by the TSC, DMEC, funder or Sponsor.

Secondary outcome measures: (8 and 12 months post randomisation)

Secondary outcomes including the EQ-5D-5L, PHQ-9, GAD7, GSE, Diener's Flourishing Scale, SMA and IADL at 8 months post-randomisation will be compared between the intervention and control groups using a mixed effects linear regression model as for the primary outcome. A 95% CI for the mean difference in this parameter between the treatment groups will also be calculated together with the associated P-value. A similar approach will be used to compare secondary outcomes at 12 months post randomisation.

Outcome measures for the participating supporters will be collected at baseline and 8 months. This includes the PHQ-9, EQ-5D-5L and SCQ .They will be compared between the intervention and control groups using a mixed effects linear regression model. The mean difference in outcome with associated 95% CI and P-value will be presented for: a) the baseline (specific to the secondary outcome) and site adjusted analysis and b) adjusted analysis with additional covariates in addition to a).

9.3 Subgroup analysis
A sub group analysis using a mixed effect linear regression model, with the primary outcome (DEMQOL) at 8 months post randomisation as the response will be carried out. We will use an interaction statistical test between the randomised intervention group and subgroup to directly examine the strength of evidence for the treatment difference between the treatment groups (intervention versus control) varying between subgroups. Supporter involvement (yes or no) will be the only a priori defined sub groups to be considered for interaction test. Sub group analysis will be performed regardless of the statistical significance on the overall intervention effect (intervention versus control).

9.4 Serious Adverse events
Information will be collected on serious adverse events through the SAE case report forms. For further information on the definition of SAEs see Section 8.8.

The following summaries will be presented:

- The number and percentages of patients reported as having SAEs in each treatment arm.

The details of these will be described in the SAP.

10. Trial supervision

10.1 Trial Committees

The following committees have been established to oversee the trial.

Trial Steering Committee
The Trial Steering Committee (TSC) will meet approximately every 6 months and is composed of a range of experts, including people with dementia, researchers and clinicians.

Membership of the TSC has been approved by the HTA, who are funding the trial. The TSC has an independent chair: Professor Catherine Hewitt, Deputy Director of York Clinical Trials Unit, University of York. Professor Hewitt is a statistician. For membership details of the TSC please see Page 6. The TSC acts in accordance with the Sheffield CTRU SOP GOV002.

The role of the TSC includes:

- Advise the chief investigator on all aspects of the trial.
- Provide overall supervision of the trial protocol, case report form and statistical analysis.
- Monitor trial progress.
- Review relevant information from other sources related to the trial.
- Consider recommendations of the DMEC
- Review outputs and final reports.
- If necessary, prematurely close the trial.

Data Monitoring and Ethics Group

The Data Monitoring and Ethics Group (DMEC) will meet at least annually and are comprised of a Chair, a statistician and clinical researcher. Membership of the DMEC has been approved by the HTA, who are funding the trial. All members of the DMEC are independent of the trial. The DMEC will be chaired by: Dr Mona Kanaan, Senior Lecturer, University of York, who is a statistician. For membership details of the DMEC please see Page 6. The DMEC acts in accordance with the Sheffield CTRU SOPGOV003.

The role of the DMEC includes:

- Review the trial protocol as per their duties as a DMEC.
- Review the protocol and study materials, pertinent to their duties as the DMEC.
- Monitor patient safety.
- Advise the TSC when it believes the trial protocol should be altered.
- Advise the TSC if they feel the trial should be prematurely closed.

Trial Management Group

The Trial Management Group (TMG) will meet on a monthly basis during the set-up of the trial and then, if appropriate, bimonthly. It will consist of key individuals directly involved in the development and delivery of the trial. This will include the chief investigator, trial manager, collaborators and experts by experience. For membership details of the TMG please see Page 7. The TMG will act in accordance with the Sheffield CTRU SOP GOV001.

The role of the TMG includes:

- Being accountable to the TSC for the implementation of the trial.
- Identify and resolve issues on the intervention and associated research in a timely manner.
- Consider and act on recommendations of the TSC, DMEC and Research Ethics Committee.

10.2 Project management

SHSC will act as sponsor for the trial. They have appointed the University of Sheffield's CTRU to manage the trial on a day-to-day basis. This will include a trial manager, who will co-ordinate the trial and who will be overseen by the Director of the CTRU.

Monitoring will be conducted by the research team in line with the Sheffield CTRU SOP DM009 and in accordance with the trial's monitoring plan.

10.3 Patient and public involvement

Throughout the trial there will be input from people with dementia and people supporting a person with dementia, such as family members. On the TSC there will be a person with dementia. A separate Patient and Public Involvement group consisting of local representatives will meet regularly throughout the course of the trial, and this group will link into the TMG, facilitated by the PPI lead within the study team. The group will be asked to input into the trial in a variety of ways including reviewing recruitment documents, contributing to data analysis and contributing to dissemination. The clinical research assistant and trial manager will be pro-active in facilitating the involvement of people with dementia and supporters in the trial.

11. Data handling and record keeping

11.1 Data handling

Data management will be provided by the University of Sheffield's CTRU who adhere to their own SOPs relating to all aspects of data management including data protection and archiving. A separate data management plan (DMP) will detail data management activities for the study in accordance with Sheffield CTRU SOP DM009.

The CTRU will co-ordinate the data collection and follow-up of trial participants in conjunction with the collaborating universities and participating NHS sites. Researchers employed by the Universities of Sheffield, Hull, Bradford and Nottingham along with authorised staff at participating NHS sites will collect information using the CRF which has been specifically designed for this trial. The CRF will capture information such as the participant outcome measures. Some parts of the CRF will be paper-based and other parts will be electronic.

Data will be entered remotely on to a centralised web-based data capture system (Prospect) by trained and authorised staff connected to the trial. Access to Prospect is controlled by usernames and encrypted passwords.

Prospect provides a full electronic audit trail, as well as validation features which will be used to monitor study data quality, in line with Sheffield CTRU SOPs and the DMP. Where data clarification is required, error reports will be generated detailing queries.

The format and frequency of outputs for analysis will be agreed between the CTRU and the chief investigator. During the trial, paper documents will be retained in a secure location in accordance with Sheffield CTRU SOP PM015.

11.2 Archiving

All source data will be retained and archived for at least 5 years and in accordance with the Sheffield CTRU SOP PM012. Sites and collaborating universities are responsible in conjunction with the CTRU for organising the archiving of their source data in accordance with the agreed process. At the University of Sheffield, Sheffield CTRU SOP PM012 will be adhered to for the retrieving of archived records. Withdrawal of documents from the archive (e.g. archive loans) should be under the control of the named individual who will track and retrieve documents on loan from the archive. The University of Sheffield's Records Management Service has a process to manage this. The storage and archiving of electronic data will be in line with the Sheffield CTRU SOP DM012.

11.3 Confidentiality

Throughout the trial, the confidentiality of participants and their supporters will be maintained. At all times the trial will follow ethical and legal practice. Information about participants will be handled in confidence, except in cases where there is risk of harm to either the participant or others. In these cases, the participant's GP or HCP at their specialist dementia service will be informed. Consent for this will be collected at the start of the trial.

People with dementia participating in the trial may want supporters to be informed and/or take part with them in the trial, and the intervention if allocated to receive it. If this is the case, consent will be collected at the start of the trial to give permission for information relating to the person's participation to be shared with supporters.

Due to the nature of the condition, there is a risk that during the trial, people with dementia may lose the capacity to consent to participate. Consequently, as part of the consent process, people with dementia will be asked to nominate people who could act as a consultee. If the person with dementia loses capacity during the trial, the consultee can suggest that they are withdrawn from the trial if they feel this is in their best interests.

In terms of dissemination outside of the research team, the identity of participants will be protected by the removal of any identifiable data.

12. Data access and quality assurance

12.1 Data access

The sponsor will permit monitoring and audits by the relevant authorities, including the Research Ethics Committee. The investigator will also allow monitoring and audits by these bodies and the sponsor, and they will provide direct access to source data and documents in line with Sheffield CTRU SOPs QA001 and DM009.

The trial will use the CTRU's in-house data management system (Prospect) for the capture and storage of participant data. Prospect stores all data in a PostgreSQL database on virtual servers hosted by Corporate Information and Computing Services (CiCS) at the University of Sheffield. Industry standard techniques are used to provide security, including password authentication and encryption using SSL/TLS. Access to Prospect is controlled by usernames and encrypted passwords, and a comprehensive privilege management feature is used to ensure that users have an appropriate level of access to data required to complete their tasks. This can be used to restrict access to personal identifiable data.

Participant confidentiality will be respected at all times. Patient/participant names and contact details will be collected and entered onto Prospect. Access to these personal details will be restricted to users with appropriate privileges. All other data will be anonymised and will only be identifiable by participant ID number, and no patient identifiable data will be transferred from the database to the statistician or health economist.

12.2 Quality assurance

To oversee the progress of the trial, a Monitoring Protocol (MP) will be developed. This will be in line with GCP and the Sheffield CTRU SOPs DM009 and QA001. The MP will detail the monitoring activities that will be conducted during the course of the trial. The trial will also operate within a series of quality standards and guidelines.

There will also be three oversight committees that will be operation during the trial. These are the TSC, DMEC and TMG. For further details of these see Section 10.

13. Publication

A number of outputs will be produced both during and after the trial, including outputs related to trial delivery and the results. Other stakeholder specific outputs in relevant formats will also be produced for commissioners, health and social care practitioners, user organisations and participants. A website will be established to promote the work of the trial. Any potential outputs will be agreed by the chief investigator.

14. Finance

JtD is funded by the National Institute for Health Research- Health Technology Assessment Programme (project number: 14/140/80) and details have been drawn up in separate agreements.

15. Ethics approval

JtD will be submitted to an NHS Research Ethics Committee (REC) through the Integrated Research Application System (IRAS). The approval letter from the ethics committee will be

received from the CTRU before the initiation of the trial at sites and any participant recruitment.

The trial will be submitted to the Health Research Authority. Through this system NHS research governance approval for each NHS site will be obtained.

Throughout the process of gaining ethics approval, the CTRU SOP: RA003 will be adhered to.

16. Indemnity/Compensation/Insurance

This is an NHS sponsored study. For NHS sponsored research HSG (96) reference no.2 is relevant. If there is negligent harm during the clinical trial when the NHS body owes a duty of care to the person harmed, NHS indemnity will cover NHS staff, medical academic staff with honorary contracts and those conducting the trial. NHS indemnity does not offer no-fault compensation and is unable to agree advance to pay for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.

The University of Sheffield has in place insurance against liabilities for which it may be legally liable and this cover includes such liabilities arising out of the research project.

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