

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

A study protocol for a randomised controlled trial of the clinical and cost-effectiveness of the Journeying through Dementia (JtD) intervention compared to usual care

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-029207
Article Type:	Protocol
Date Submitted by the Author:	18-Jan-2019
Complete List of Authors:	<p>Wright, Jessica; University of Sheffield, Clinical Trials Research Unit Foster, Alexis; University of Sheffield, School of Health and Related Research Cooper, Cindy; The University of Sheffield, Sheffield Clinical Trials Research Unit, School of Health and Related Research Sprange, Kirsty; The University of Nottingham, Nottingham Clinical Trials Research Unit Walters, Stephen; University of Sheffield, SchARR Berry, Katherine; The University of Manchester, School of Psychological Sciences Moniz-Cook , Esme ; The University of Hull, School of Health and Social Work Loban, Amanda; University of Sheffield, School of Health and Related Research Young, Tracey; The University of Sheffield, School of Health and Related Research Craig, Claire; Sheffield Hallam University Denning, Tom; University of Nottingham, Division of Psychiatry & Applied Psychology, School of Medicine Lee, Ellen; University of Sheffield, Clinical Trials Research Unit Beresford-Dent, Julie; University of Bradford, Centre for Applied Dementia Studies Thompson, Benjamin; The University of Sheffield, School of Health and Related Research Young, Emma; The University of Sheffield, School of Health and Related Research Thomas, Benjamin; The University of Sheffield, School of Health and Related Research Mountain, Gail; University of Bradford, Centre for Applied Dementia Studies</p>
Keywords:	Randomised Controlled Trial, Dementia < NEUROLOGY, Research Protocol, Post diagnostic support, Self-management, Well-being

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60



TITLE PAGE**Title**

A study protocol for a randomised controlled trial of the clinical and cost-effectiveness of the Journeying through Dementia (JtD) intervention compared to usual care

Corresponding author

Jessica Wright
Journeying Through Dementia (JtD) Trial,
Sheffield Clinical Trials Research Unit,
SchHARR, The University of Sheffield,
Regent's Court,
30 Regent St, Sheffield S1 4DA
Telephone: 0114 222 4304
Email: Jessica.wright@sheffield.ac.uk

Author Names/Affiliations

Jessica Wright, Sheffield Clinical Trials Research Unit, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Alexis Foster, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Cindy Cooper, Sheffield Clinical Trials Research Unit, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Kirsty Sprange, Nottingham Clinical Trials Research Unit, The University of Nottingham, Nottingham, UK

Stephen Walters, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Katherine Berry, Manchester Institute for Collaborative Research on Ageing, The University of Manchester, Manchester, UK

Esme Moniz-Cook, School of Health and Social Work, The University of Hull, Hull, UK

Amanda Loban, Sheffield Clinical Trials Research Unit, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Tracey Young, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Claire Craig, Art & Design Research Centre, Sheffield Hallam University, Sheffield, UK

Tom Dening, Institute of Mental Health, The University of Nottingham, Nottingham, UK

Ellen Lee, Sheffield Clinical Trials Research Unit, School of Health and Related Research, The University of Sheffield, Sheffield, UK

1
2
3 Julie Beresford-Dent, Centre for Applied Dementia Studies, University of Bradford, Bradford, UK
4

5 Benjamin John Thompson, Sheffield Clinical Trials Research Unit, School of Health and Related
6 Research, The University of Sheffield, Sheffield, UK
7

8 Emma Louise Young, Sheffield Clinical Trials Research Unit, School of Health and Related Research,
9 The University of Sheffield, Sheffield, UK
10

11 Benjamin David Thomas, Sheffield Clinical Trials Research Unit, School of Health and Related
12 Research, The University of Sheffield, Sheffield, UK
13

14 Gail Mountain, Centre for Applied Dementia Studies, University of Bradford, Bradford, UK
15
16

17
18
19 **Word Count: 5709 (excluding references, abstract, tables and figures)**
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

ABSTRACT

Introduction

UK Memory Services are being encouraged to provide post diagnostic treatment to those with dementia but the availability of evidence-based interventions following diagnosis has not kept pace with increase in demand. To address this, Journeying through Dementia (JtD) was developed. A randomised controlled trial (RCT), based on a pilot study, is in progress.

Methods and analysis

The RCT is a pragmatic, two-arm, parallel group trial designed to test the clinical and cost-effectiveness of JtD compared to usual care. Recruitment will be through NHS services, third sector organisations and Join Dementia Research. The sample size is 486 randomised (243 to usual care and 243 to the intervention in addition to usual care). Participants can choose to have a supporter involved. The primary outcome measure for participants is the Dementia Related Quality of Life measure collected at baseline and at follow-up 8 months' post randomisation. Secondary outcome measures will be collected from participants and supporters at those visits. Participants will also be followed-up at 12 months' post randomisation. Embedded qualitative and fidelity sub-studies will be conducted.

Analyses will compare the two arms of the trial on an intention to treat as allocated basis. The primary analyses will compare the mean DEMQOL scores of the participants with dementia at 8 months between the two study arms. A cost-effectiveness analysis will be undertaken of the incremental cost per Quality Adjusted Life Years of the JtD intervention compared with usual care. Qualitative and fidelity sub-studies will be analysed through framework analysis and fidelity assessment tools respectively.

Ethics and dissemination

Research Ethics Committee and Health Research Authority approval have been obtained. A Data Monitoring and Ethics Committee has been constituted. Dissemination will be via publications, conferences, websites and social media. Finalised intervention materials will be offered via open access.

Trial registration number

ISRCTN17993825

STRENGTHS AND LIMITATIONS OF THE STUDY

- People living with dementia were involved in developing the content of the Journeying through Dementia (JtD) intervention and are involved in advising on the study.
- The JtD intervention includes sessions without supporters present, to help develop independence and confidence, and is one of the only interventions that people with dementia can participate in without supporters.
- The JtD study will recruit up to 500 participants and is therefore one of the largest dementia related trials in the UK.
- A qualitative sub-study will explore the mediators and moderators of the intervention.
- Recruitment can be challenging in this population but we plan to try multiple pathways for recruitment including through services, the Join Dementia Research database, promotion and the third sector.

INTRODUCTION

The impact on the economy, for services and for individuals living with dementia and their family carers is larger for dementia than for all other long-term illnesses in people aged 60 and over.[1] Two thirds of people with dementia live in the community, and half of these require some form of support.[2] As a result, dementia research (both for cure and for care) in the NHS and social care is important, and this is reflected in UK health policy.[3] In 2009, the UK Government announced a National Dementia Strategy, which mandated the establishment of memory services and aimed to increase the rates of early diagnosis and improve support for people in the early stages of dementia.[4]

The National Audit of Memory Services (2013) found there had been a fourfold increase in numbers presenting since 2010/11, and in 2013 49.3% were in the early stages of the condition.[5] Earlier diagnosis allows individuals to receive treatment earlier and enables both the individual and memory services to plan more effectively for the future.[6] Memory services have been strongly encouraged to provide post diagnostic treatment and support,[7,8] but the availability of appropriate evidence-based interventions has not kept pace with the increase in demand, in particular for those with early stages of dementia. The lack of appropriate interventions has led to inconsistency between Trusts as to what is being offered to people post diagnosis.

The potential value of psychosocial interventions for people in the early stages of dementia is recognised[9–12] 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 independence and well-being. 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.[11]

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).[13–18] A qualitative study which interviewed people with dementia who attended a self-management programme reported that participants identified the opportunity for peer support as a benefit and felt the programme

1
2
3 could be improved by having more emphasis on maintaining activities and relationships and
4 improving positive wellbeing.[19] The Healthbridge evaluation[20] and the Mental Health
5 Foundation evaluation[21] found evidence that people with dementia and their carers also benefit
6 from receiving group based peer support.
7
8

9 The Journeying through Dementia (JtD) intervention was developed from the Lifestyle Matters
10 programme and a pilot study was conducted to examine the feasibility of a future population-based
11 larger trial of this intervention.[22] The intervention was found to be acceptable to both people with
12 dementia and their supporters. Reported benefits included increased confidence and self-efficacy,
13 engagement in activities and re-engagement with fun and friendships.[22] The intervention is
14 manualised, based on occupational therapy principles, and is designed to support independence and
15 well-being. The intervention incorporates elements of self-management and group-based peer
16 support and has been designed to improve the quality of life for people in the early stages of
17 dementia.
18
19
20

21 The JtD randomised controlled trial (RCT) will test the clinical and cost effectiveness of the JtD
22 intervention. Funding was obtained through the National Institute of Health Research (NIHR) Health
23 Technology Assessment (HTA) theme to conduct the RCT. This paper describes the research protocol
24 for undertaking the RCT which started recruitment in November 2016.
25
26

27 **AIMS AND OBJECTIVES**

28
29 The primary aim of the JtD trial is: to determine the clinical and cost-effectiveness of the JtD
30 intervention for people in the early stages of dementia. To meet this aim, the objectives are to:
31
32

- 33 1. Undertake a pragmatic RCT evaluating the clinical and cost-effectiveness of the JtD
34 intervention.
- 35 2. Conduct fidelity checks regarding the delivery of the JtD intervention.
- 36 3. Undertake an embedded qualitative sub-study to explore the mechanisms that might result
37 in intervention effectiveness
- 38 4. Identify how the intervention might be realistically delivered through services.
- 39 5. Be an exemplar of best practice in involvement of people living with dementia in a large trial.
40
41

42 **METHODS**

43 **Trial design**

44
45 The JtD trial is a pragmatic, two-arm, parallel group, individually randomised RCT. It uses a
46 superiority framework to deliver an intention-to-treat comparison of the JtD intervention with usual
47 care.
48
49

50
51 The trial includes three sub-studies. The first is a health economics evaluation using a cost-
52 effectiveness analysis of the incremental cost per Quality Adjusted Life Year (QALY) of the JtD
53 intervention compared with usual care.
54
55

56 The second sub-study is a fidelity assessment, using an intervention fidelity framework based on that
57 identified by the Behaviour Change Consortium and National Institute for Health and Care Excellence
58 (NICE).[23,24]
59
60

1
2
3 The third sub-study is a qualitative study, in line with Medical Research Council (MRC) guidance on
4 developing and evaluating complex interventions.[25] The qualitative sub-study will involve semi-
5 structured interviews with participants, participating supporters, facilitators and supervisors.
6
7

8 **Randomisation and blinding**

9

10 To minimise bias, allocation will be concealed through the use of a centralised web-based
11 randomisation service. The randomisation sequence will be stratified by delivery site and
12 constrained by a fixed block size to ensure participants are allocated evenly to each arm of the trial
13 at each delivery site. Participants will be randomised in equal numbers to intervention and control
14 arms. An unblind member of the research team who will not be conducting outcome assessments
15 will enter the participants' details into the randomisation system and inform the relevant parties of
16 the outcome.
17
18

19
20 Members of the Trial Steering Committee (TSC), study statisticians, health economists and outcome
21 assessors will be blinded to treatment allocation whilst the trial is ongoing. For practical reasons,
22 some members of the research team will not be blinded, including the Trial Manager and Chief
23 Investigator. Due to the nature of the intervention, participants will not be blinded. If the outcome
24 assessors know (or suspect) they have been unblinded this will be recorded on an unblinding form.
25
26

27 **Participants**

28

29
30 Persons with early-stage dementia will be approached to take part in the trial. A family member,
31 friend or neighbour that provides support to the study participant (referred to as the 'participating
32 supporter') can be approached to take part in the trial, but only if invited to do so by the person with
33 dementia. Participating supporters will automatically be randomised to the same arm as the
34 participant. See Figure 1 for participant flow through the study.
35
36

37 (Insert Figure 1 here)
38

39 **Eligibility criteria**

40

41 Participants will be eligible for the study if they:
42

- 43 1. have a diagnosis of any form of dementia,
- 44 2. have a Mini Mental State Examination (MMSE) score of 18 or more, taken less than 2
45 months' pre-consent,
- 46 3. have capacity to make informed decisions,
- 47 4. are living in the community in their own or sheltered accommodation (those living in
48 residential or nursing care are not eligible),
- 49 5. are willing to attend the JtD intervention,
- 50 6. are able to converse and communicate in English, and
- 51 7. are not taking part in any other pharmacological or psychosocial intervention studies at the
52 time of enrolment.
53
54
55
56

57 Participating supporters will be eligible if they are aged 18 years or over, and are named by the
58 person with dementia as their supporter, the person with dementia wishes them to take part, they
59 can converse and communicate in English, and have the ability to give informed consent.
60

Site selection and participant recruitment

The JtD trial will operate in England within 13 NHS trusts with specialist dementia services. The sites will be selected based on a convenience sample of locations clustered geographically around the north and midlands (for a list of sites, see study ISRCTN webpage[26]).

Previous studies involving persons with dementia have shown that recruiting participants to such studies can be challenging.[27] To ensure sufficient numbers are recruited to the study a number of recruitment pathways will be used: referral from clinical teams; mail-outs to eligible patients via primary or secondary care clinical teams; study promotion via posters etc.; third sector organisations; and the Join Dementia Research database. The research team will contact interested participants who agree to be approached and send further information about the study. A consent and eligibility visit will be arranged if they would like to take part where trained researchers will assess eligibility and request written informed consent.

Intervention

JtD is a manualised intervention consisting of twelve weekly facilitated groups with 8-12 participants with dementia, which take place over successive weeks. Each participant also receives four one-to-one sessions with one of the intervention facilitators, to pursue individual goals. The first one-to-one session takes place before the start of the group intervention, with the remaining three being scheduled during, or shortly after, the 12 weeks and at a location and time agreed with the participant. The group aspect of intervention should be delivered in a community venue.

The content of the JtD intervention is summarised below:

- 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, embedding health activity in everyday life, diet).
- c. Memory (strategies to aid memory, impact on everyday life and learning and practicing new techniques).
- d. Keeping mentally well (relationships between anxiety and memory, and dementia and stress).
- e. Endings (celebration of achievements and how to move forward).

Participants are encouraged to select different topics from the manual and explore them with guidance and suggestions from facilitators. Participants are also able to suggest topics not within the manual. One essential component of the intervention is the enactment of activities, particularly in the community; three of the twelve group meetings should be out of venue activities. Participants are able to invite a supporter to participate in the group aspect of the intervention during sessions 1, 6 and 12, and in the individual sessions if the participant finds this helpful in achieving their goals.

Facilitating staff

The intervention should be facilitated by a minimum of two NHS staff who are experienced with working with people with dementia. Facilitators will normally be someone employed on Agenda for Change Bands 3-5. Facilitators must receive a two-day training course prior to delivering the

1
2
3 intervention. In some cases, for example they are a reserve facilitator, they may receive a shortened
4 course supported by online resources created for this purpose. Facilitators will be supervised by a
5 colleague experienced in supervision who has also attended the facilitator training and is of suitable
6 seniority and experience. The supervisors themselves will be supervised by a member of the central
7 study team who is a Clinical Psychologist and is experienced in the 'train the trainer' method[28].
8
9

10 **Patient and public involvement (PPI)**

11
12
13 People living with dementia were involved in developing the content of JtD[29] and in the feasibility
14 study.[22] The JtD Trial Steering Committee will include a member who is living with dementia.
15 Additionally, an advisory group (experts by experience) will meet at intervals throughout to provide
16 input into study materials used by participants such as information sheets and interview guides. We
17 also plan to involve people living with dementia in some aspects of the qualitative data analysis and
18 in developing and delivering the study dissemination plans.
19
20
21

22 **OUTCOMES**

23
24 The primary outcome is the Dementia Related Quality of Life Measure (DEMQOL)[30,31] at 8
25 months' post randomisation.
26

27 The secondary outcomes are:

- 28 – European Quality of Life - 5 Dimensions (EQ-5D-5L)[32,33]
- 29 – Patient Health Questionnaire-9 (PHQ-9)[34,35]
- 30 – Generalised Anxiety Disorder-7 (GAD-7)[36]
- 31 – General Self-Efficacy Scale (GSE)[37]
- 32 – Diener's Flourishing Scale (DFS)[38]
- 33 – Self-Management Ability Scale (SMAS)[39]
- 34 – Instrumental Activities of Daily Living (IADL)[40]
- 35 – Health and Social Care Resource Use Questionnaire (HSCRU)[22]
- 36 – Sense of Competency Questionnaire (SCQ)[41,42]

37
38 The outcome measures used were selected to measure the following key components of the
39 intervention: mental wellbeing or mood (DEMQOL, PHQ-9, GAD-7); building relationships and a
40 sense of connectedness (DFS, SMAS); belief that life is meaningful despite dementia (DEMQOL, GSE,
41 DFS, SMAS); and Instrumental Activities of Daily Living (IADL) and strategies to maintain cognitive
42 functioning (IADL). Additionally, they also support analysis of the cost-effectiveness of the
43 intervention (DEMQOL, EQ-5D-5L, HSCRU) and the participating supporters' perceptions of
44 competence (SCQ). Dementia specific outcome measures are those recommended for use across
45 Europe.[43] Non dementia specific outcome measures were selected if there was no appropriate
46 dementia specific measure available.
47
48
49
50
51
52

53 **DATA COLLECTION**

54 **Quantitative**

55
56 Data will be collected from all participants living with dementia at eligibility/consent, baseline, 8 and
57 12 months' post randomisation and from participating supporters at baseline and 8 months' post
58
59
60

randomisation (see Table 1). The outcome measures will be interviewer-administered at face-to-face visits by blinded outcome assessors who have received training to deliver the measures to people living with dementia and their supporters. The follow-up outcome measures will be collected 2 weeks pre and 8 weeks post the date they are due. Participant retention will be promoted by regular communication with the participants and supporters through newsletters and Christmas cards.

Table 1 Outcome measures and time-points for collection. * Denotes the primary outcome measure.

Measure	Participant				Participating Supporter	
	Eligibility and Consent visit	Baseline <2 months prior to the intervention start date	8 Months Due < 2 weeks pre and < 8 weeks post randomisation	12 Months Due < 2 weeks pre and < 8 weeks post randomisation if within study timelines	Baseline Due <2 months prior to the intervention	8 Months Due < 2 weeks pre and < 8 weeks post randomisation
Capacity assessment	✓					
Mini Mental State Examination	✓					
Eligibility checklist	✓				✓	
Baseline demographics	✓				✓	
DEMQOL		✓	✓*	✓		
EQ-5D-5L		✓	✓	✓	✓	✓
PHQ-9		✓	✓		✓	✓
GAD-7		✓	✓			
GSE		✓	✓			
DFS		✓	✓			
SMAS		✓	✓			
IADL		✓	✓	✓		
HSCRU			✓	✓		
SCQ					✓	✓

Visits to collect outcome data will be arranged with the participant by a researcher, in some cases a participating supporter will assist with these arrangements. All visits will be conducted at a time and location most suitable for the participant. A second visit may be required to complete the outcome measures if the participant becomes tired, which will be organised as soon as possible after the first. Participating supporters may not have the time or capacity to receive a face-to-face visit and follow-up outcome measures may therefore be collected from them over the telephone. Similarly, in the case that a participant is likely to withdraw, a reduced set of outcome measures may be taken by telephone (including DEMQOL and telephone versions of HSCRU and EQ-5D-5L).

Intervention attendance

Records will be kept of all attendances for each participant randomised to the intervention.

Intervention dropout and study withdrawal

1
2
3 If a participant decides to withdraw either from the intervention or the study, this will be recorded.
4 If the participant solely withdrew from the intervention, they will be followed-up unless they
5 explicitly also withdraw consent for follow-up of outcomes (data up to this time will be included in
6 the trial).
7
8

9 Intervention costings

10
11 Information on the cost of facilitated group and individual sessions will be collected including hire of
12 local community venues, facilitator salaries and travel, refreshments, and other costs such as
13 administration and materials used.
14
15

16 Fidelity assessment

17
18 The fidelity of intervention delivery, as well as of the training and supervision received by facilitators
19 will be assessed according to the intervention protocol and manual. Fidelity checks will adhere to a
20 framework based on that identified by the Behaviour Change Consortium[23] and NICE guidance on
21 behaviour change.[24] The fidelity assessment framework (adapted from Bellg et al, 2004[23]) will
22 assess and monitor for the consistency, facilitator training (in terms of standardised delivery of
23 training and skills acquisition for facilitators), intervention delivery (in terms of standardised delivery
24 between intervention groups) and the receipt of the intervention by intervention group participants.
25
26

27
28 Training delivery and receipt of the facilitator training will be observed and rated by the same two
29 researchers (the lead for fidelity and one other member of the research team) for inter-rater
30 reliability using a bespoke *Training observation checklist*. To assess facilitator adherence to the
31 manualised intervention and participant receipt of the intervention, a purposive selection of group
32 meetings across sites will also be observed using a *Group observation checklist* based on the
33 contents of the intervention and the training to assess each meeting. Each group selected will be
34 observed on two occasions to identify facilitator drift or changes in participant behavior.
35
36

37
38 Frequencies will be used to determine the extent to which the training programme received by
39 facilitators maintained fidelity to what was intended. Comparison of intervention delivery between
40 and across sites will also be conducted to check for consistency. Inter-rater reliability between
41 coders will be determined using the Kappa statistic.[44] Similar methods have been used in previous
42 studies, for example the Lifestyle Matters Trial.[45]
43
44

45 Qualitative sub study

46
47 An embedded qualitative sub-study will explore the mechanisms of the intervention, for example
48 what elements of the intervention appear to support people to improve their self-management and
49 well-being and what promotes good facilitation of the intervention.
50
51

52
53 Individual qualitative semi-structured interviews will be conducted with a purposive sample of
54 approximately 20 participants (approximately 10%) from the fidelity intervention groups and with
55 approximately 12 participating supporters, preferably supporters of participants who are also being
56 interviewed. A participant interview schedule and supporter interview schedule will be developed to
57 cover the following themes:
58
59
60

- Range and nature of issues that influence experiences of taking part in the intervention
- Factors that may mediate or moderate the effectiveness of the intervention
- Perceived skills and competencies required to facilitate the intervention
- The barriers and facilitators to uptake and continued use
- The effect of the intervention upon living with dementia
- The effect of the intervention upon the experiences of supporting someone with dementia

Semi-structured interviews will also be conducted with approximately 20% of all facilitators and supervisors across the sites at the end of their delivery of the intervention. The sample will include a range of sites and facilitators with different levels of experience of delivering the intervention. 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

Researchers undertaking participant and supporter interviews will be trained to use enhanced methods of communication with people with dementia to ensure that meaningful discussion can take place. Transcripts of interviews will undergo respondent validation.

SAMPLE SIZE

The primary outcome for the study is the mean DEMQOL score 8 months post randomisation. Assuming a standard deviation of 11 points for the DEMQOL, a mean difference of 4 or more points is clinically and practically important.[30] 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 intervention with a group component, 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 people with dementia per facilitated group and an intra-cluster correlation 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. Assuming at least a 20% loss to follow-up the target sample size for the trial is to randomise to 243 participants in each arm (n=486).

DATA ANALYSIS

Statistical data analysis

As JtD is a pragmatic parallel group randomised trial, with a usual care (control) arm, data will be reported and presented according to a revised CONSORT statement.[46] Statistical analysis will be performed on an intention-to-treat-basis. All exploratory tests will be two-tailed with alpha = 0.05. Baseline demographics and quality of life data will be described and summarised overall and by treatment group.

1
2
3 The primary analysis will compare mean patient reported DEMQOL scores at 8 months post
4 randomisation between the intervention (JtD) arm and control arms using a mixed effects linear
5 regression model adjusted for DEMQOL baseline score and site and allowing for the clustering of the
6 outcome by the JtD intervention.[47–49] The trial is a partially nested design with comparison of a
7 group therapy (JtD) with individual therapy with clustering in one (intervention) arm. Each person
8 with dementia in the control group (unclustered arm) will be treated as a cluster (singleton) of size
9 one. The cluster indicator will be treated as a random effect. A stratification variable used for
10 randomisation (site) will be included as a fixed factor.[50] A partially clustered mixed effects linear
11 regression model with homoscedastic errors as well as a heteroscedasticity mixed effects linear
12 regression model will also be considered to account for potential differential variability of outcomes
13 between the two treatment groups. A 95% confidence interval (CI) for the mean difference in
14 DEMQOL scores between the intervention and control groups will be calculated together with the
15 associated P-value. A further adjusted analysis may also be performed depending on the observed
16 degree of imbalance in baseline covariates (which are of potential prognostic importance) again
17 using a mixed effects linear regression model. Additional covariates (of potential prognostic
18 importance) include other baseline variables, such as age, gender, PHQ-9, and GAD-7. In the event
19 that there are more than 10 couples (20 participants) from the same household the primary and
20 secondary analyses will be changed to take into account the hierarchical or clustered nature of the
21 data. A multi level mixed effects model will be used; the random effects will be JtD intervention
22 groups (top level) and couple/singles (lower level). Individual participants who are not part of a
23 couple will be treated as clusters of size one.

24
25
26
27
28
29
30
31 Participants will be followed up for up to 12 months post randomisation. Mean DEMQOL scores at
32 12 months follow-up will be compared as described for the primary outcome above.

33
34 For the primary outcome, the DEMQOL score at 8 months follow-up, missing data will be imputed
35 through a variety of methods including: regression and multiple imputation as part of a sensitivity
36 analysis.

37
38
39 We will complement the intention to treat (ITT) analysis of the primary outcome with a complier
40 average causal effects analysis (CACE) as a secondary analysis alongside the primary ITT analysis.
41 Compliance will be defined as a binary variable with participants who attend at least 10 of the 16 JtD
42 sessions (both individual and group sessions combined) regarded as being compliant.

43
44
45 There are no planned interim statistical analyses or formal stopping rules in relation to efficacy.

46 47 Secondary outcome measures

48
49 Secondary outcomes at 8 and 12 months post-randomisation will be compared between the
50 intervention and control groups using a mixed effects linear regression model as for the primary
51 outcome. A 95% CI for the mean difference in this parameter between the treatment groups will
52 also be calculated together with the associated P-value.

53
54
55 Outcome measures for the participating supporters at 8 months will be compared between the
56 intervention and control groups using a mixed effects linear regression model. The mean difference
57 in outcome with associated 95% CI and P-value will be presented for: a) the baseline (specific to the
58
59
60

1
2
3 secondary outcome) and site adjusted analysis and b) adjusted analysis with additional covariates in
4 addition to a).
5

6 Subgroup analysis

7
8 A subgroup analysis using a mixed effect linear regression model, with the primary outcome
9 (DEMQOL) at 8 months post randomisation as the response will be carried out. We will use an
10 interaction statistical test between the randomised intervention group and subgroup to directly
11 examine the strength of evidence for the treatment difference between the treatment groups
12 varying between subgroups. Supporter involvement (yes or no) will be the only a priori defined sub
13 groups to be considered for interaction test.
14
15

16 Qualitative analysis

17
18 Framework analysis[51] will be applied to all interviews.[52] For the purposes of reporting,
19 confidentiality will be maintained by using unique participant identifiers and removing identifiable
20 information. A thematic framework will be agreed by two researchers and an index developed for
21 transcript coding. This will follow the five stages of framework analysis.[51] Findings will be used to
22 identify emergent factors that influence the uptake and impact of the intervention as well as explore
23 potential explanations for the quantitative findings.[52] Further analysis will also be undertaken to
24 triangulate the qualitative data (between facilitator/supervisor and participant/supporter
25 interviews) as well as the fidelity and qualitative data in order to look for between source similarities
26 and divergences. Analysis workshops will be held with persons living with dementia and their
27 supporters to respond to and help validate the qualitative analysis. The workshop outcomes will be
28 used to refine the qualitative analysis.
29
30
31
32
33

34 Health economics evaluation

35
36 A trial based economic evaluation will be undertaken of an intention-to-treat comparison of the
37 costs and outcomes of the two trial arms. A cost-effectiveness analysis will be undertaken of the
38 incremental cost per Quality Adjusted Life Year (QALYs) of the JtD intervention compared with usual
39 care provided through NHS memory services. QALYs will be calculated using the EQ-5D-5L
40 preference-based index administered at baseline, 8 and 12 months. A sensitivity analysis will be
41 undertaken using utility values from the DEMQOL-U, which can be derived from responses to the
42 DEMQOL questionnaire.[30] The total cost of the intervention will be estimated at the individual
43 participant level and will include the costs of providing the intervention and the subsequent
44 consequences for the use of routine health and social care services. The average cost per attendance
45 will be calculated and this estimate will be applied to the actual number of group and individual
46 sessions that each participant attended.
47
48
49
50
51

52 The use of services by trial participants will be collected in detail using a Health and Social Care
53 Resource Use (HSCRU) questionnaire administered at 8 and 12 months post randomisation. Service
54 use will be costed using the most recent National Reference Cost Data and Unit Costs of Health and
55 Social Care.[53,54] Missing data will be dealt with using multiple imputation for EQ-5D-5L, DEMQOL-
56 U and resource use data.[55] A random effects linear regression model, accounting for clustering,
57 will be fitted, the model will include baseline scores for EQ-5D-5L and baseline costs. The central
58
59
60

1
2
3 analysis of mean incremental costs per QALY will be subjected to a full sensitivity analysis of key
4 parameters including the measure used to estimate QALYs and number of participants at the weekly
5 sessions. A full probabilistic sensitivity analysis will be performed to examine the probability of cost-
6 effectiveness of the intervention for the NHS for different levels of costs and QALY gains.[56]
7
8

9 **DATA MANAGEMENT, CONFIDENTIALITY AND SHARING**

10
11 Sheffield Clinical Trials Research Unit (CTRU) will provide data management services. Data will be
12 entered remotely on to a centralised web-based data capture system (Prospect) by university
13 researchers and authorised staff at participating NHS sites. The Case Report Form captures trial data
14 and has been specifically designed for this trial. Access to Prospect is controlled by usernames and
15 encrypted passwords. Prospect provides a full electronic audit trail, as well as validation features
16 which will be used to monitor study data quality. The identity of participants will be protected by the
17 removal of any identifiable data prior to dissemination of information, and no identifiable data will
18 be transferred to the statistician or health economist. All participating NHS Sites will be subject to
19 data monitoring reviews to check data entry, consent and eligibility, amongst other items.
20
21
22

23 **Data sharing**

24
25
26 JtD trial data will be held and available for five years after the end of the trial (November 2019). JtD
27 Trial Data will not be archived in a repository, instead data will be released on a case-by-case basis.
28 We shall make data available to the scientific community with as few restrictions as feasible. Data
29 access requests will be reviewed and authorised by a sub-committee of the Trial Management Group
30 (TMG) during the trial and by the Sheffield CTRU after the trial has ended. Access requests will be
31 considered against pre-determined criteria and data sharing will only take place if this aligns with the
32 consent provided by JtD participants. Data will be anonymised prior to being shared.
33
34
35

36 **ETHICS, GOVERNANCE AND SAFETY**

37 **Ethical issues**

38
39
40 There are two key ethical issues to take into account. The first is the potential need to break
41 confidentiality where there is a risk of harm. We will request consent to contact the participants or
42 supporter's GP or other health professional in situations where researchers are concerned that there
43 might be risk of harm. For example, two outcome measures used on the study may indicate a need
44 to treat anxiety (GAD-7) or depression (PHQ-9) clinically. Additionally, concerns regarding participant
45 safety may also be raised at any stage of the study; e.g. observed deterioration in mental or physical
46 state of participants, safeguarding issues, or of a risk to self or others. We will work alongside local
47 Trust procedures to report any risks appropriately. Local site investigators with clinical backgrounds
48 will be asked to provide advice when appropriate. The responsible healthcare professional or PIs will
49 be able to recommend the withdrawal of the participant if they feel it is appropriate. We will record
50 all actions taken.
51
52
53
54

55
56 The second is the risk that during the trial, people with dementia may lose the capacity to consent to
57 continuing participation. As part of the consent process, people living with dementia will be asked to
58 nominate a person to act as a consultee. If the person with dementia loses capacity during the trial,
59 the consultee will be contacted to give their independent assessment of whether the person has the
60

1
2
3 capacity to continue or not with the study. We will record information about the activation of the
4 consultee pathway on the trial.
5

6 **Governance**

7
8
9 The trial is coordinated by the Sheffield CTRU on behalf of the Sponsor. The sponsor of the trial is
10 Sheffield Health and Social Care Foundation Trust, Fulwood House, Old Fulwood Road, Sheffield, S10
11 3TH. The JtD TMG contains project co-applicants, members of the data management team, the
12 Sponsor, Trial Manager and other representatives, and oversees the operation of the trial and
13 enables communication throughout the Trial, for example to disseminate protocol amendments. An
14 independent Trial Steering Committee (TSC), comprised of an independent statistician, PPI
15 representative and a Senior Clinical Research Associate, provides overall supervision of the trial,
16 advises the CI, oversees protocol modifications, monitors the trial's progress and if necessary closes
17 the trial. An independent Data Monitoring and Ethics Committee (DMEC) comprised of two
18 independent statisticians and an Occupational Therapist Clinical Researcher, reviews the trial
19 protocol, monitors patient safety and advises the TSC if they feel the trial should be prematurely
20 closed.
21
22
23
24

25 **Safety**

26
27
28 A Serious Adverse Event (SAE) reporting system will be used on the Trial. Adverse Events are not
29 anticipated as a consequence of the intervention and will not be monitored. An SAE either:
30

- 31 a) results in death,
- 32 b) is life-threatening (subject at immediate risk of death),
- 33 c) requires hospitalisation or prolongation of existing hospitalisation,
- 34 d) results in persistent or significant disability or incapacity, or
- 35 e) is otherwise considered medically significant by the investigator.
36
37

38 All SAEs will be assessed to see if they are related to the intervention or other trial procedures, and if
39 they are the Sponsor and Research Ethics Committee will be immediately informed. SAEs are
40 periodically reported to the trial's DMEC.
41

42
43 Additionally, we consider safety of the researchers to be extremely important and have developed a
44 lone worker policy.
45

46 **DISSEMINATION**

47
48 The results of this study will be communicated in relevant academic and professional journals,
49 conferences and workshops, and via websites and social media, ensuring reach to all stakeholders
50 (people living with the condition, professionals, commissioners and academics). A short film will be
51 created to illustrate experiences of participation from the perspectives of people living with the
52 condition, and those involved in delivery of the intervention. The manualised intervention will be
53 refined and made available on the website in an open access format.
54
55
56

57 **AUTHOR CONTRIBUTIONS**

1
2
3 AF, GM, CCo, KS, EL, SW, TY, CCr, EMC, AL, TD and KB co-wrote the original Trial Protocol. JW led the
4 development of the Protocol for publication. JBD and KS developed the sections on fidelity and
5 qualitative analysis. JBD developed the section on PPI. BDT adapted the introductory section, BJT the
6 methods section, EY the outcomes section and EL the statistical analysis section. All authors
7 contributed to reviewing and revising the draft versions prior to submission.
8
9

10 **ACKNOWLEDGEMENTS**

11
12 We would like to thank the following people for assisting with the original project application:
13 Martin Orrell, Institute of Mental Health, The University of Nottingham; Daniel Blackburn, Sheffield
14 Institute for Translational Neuroscience, The University of Sheffield; and Diana Papaioannou,
15 Sheffield Clinical Trials Research Unit, School of Health and Related Research, The University of
16 Sheffield.
17
18

19
20 Additionally, we would like to thank Peter Bowie, Old Age Psychiatry, Sheffield Health and Social
21 Care NHS Foundation Trust, Sheffield, for advising on clinical aspects; and Nicholas Bell, Sheffield
22 Health and Social Care NHS Foundation Trust, for acting on behalf of the sponsor and advising on
23 trial procedures.
24
25

26 **FUNDING STATEMENT**

27
28 This study was funded by the NIHR Health Technology Assessment Programme (project number
29 14/140/80). The views expressed are those of the author(s) and not necessarily those of the NHS,
30 the NIHR or the Department of Health.
31
32

33 **COMPETING INTERESTS**

34 All authors, with the exception of those below, declare no competing interests.
35

- 36 - SW, TY, CCo, JW, AF, AL, EL, BJT, BDT, EY as SchARR has contracts and/or research grants
37 with the Department of Health, NIHR, MRC and NICE.
- 38 - SW, CCo and TY are co-applicants or co-investigators on NIHR portfolio grants (NIHR
39 Research Design Service for Yorkshire and Humber; HTA, RfPB, PHR; SDO) and grants from
40 the MRC.
- 41 - SW and TY also receive external examining fees from various UK higher education institutes.
- 42 - SW receives book royalties from publishers including John Wiley and Sons Ltd and Blackwell
43 Publishing.
- 44 - BDT is a Consultant for Arch research in the area of dementia.
45
46
47
48

49 **ETHICS APPROVAL**

50
51 This study was approved by Leeds East Research Ethics Committee, on 01/07/16, reference number
52 16/YH/0238. Health Research Authority approval was provided for the study to commence on
53 25/08/16. The current Protocol version is v7, 5th December 2018.
54
55

56 **REFERENCES**

- 57
58 1 World Health Organisation. The global burden of disease: 2004 update. Geneva: World
59 Health Organisation 2008.
60

- 1
2
3 2 Knapp M, Comas-Herrera A, Somani A, et al. Dementia: international comparisons – summary
4 report to the National Audit Office. London: London School of Economics 2007.
5
- 6 3 Department of Health. Prime Minister’s challenge on dementia 2020. London: Department of
7 Health 2015.
8 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/406076/Dementia_vision.pdf (accessed 26 Sep 2018).
9
10
- 11 4 Department of Health. Living well with dementia : A National Dementia Strategy. London:
12 Department of Health 2009. <https://www.gov.uk/government/publications/living-well-with-dementia-a-national-dementia-strategy> (accessed 26 Sep 2018).
13
14
- 15 5 Hodge AS, Hailey E. English National Memory Clinics Audit Report. London: Royal College of
16 Psychiatrists 2013. [http://www.rcpsych.ac.uk/pdf/English National Memory Clinics Audit
17 Report 2013.pdf](http://www.rcpsych.ac.uk/pdf/English%20National%20Memory%20Clinics%20Audit%20Report%202013.pdf) (accessed 30 Oct 2018).
18
19
- 20 6 Banerjee S, Wittenberg R. Clinical and cost effectiveness of services for early diagnosis and
21 intervention in dementia. *Int J Geriatr Psychiatry* 2009;24:748–54. doi:10.1002/gps.2191
22
- 23 7 Copland E, Hodge S, Clary L, et al. Memory Services National Accreditation Programme
24 (MSNAP): Standards for memory services. London: Royal College of Psychiatrists 2018.
25 https://www.rcpsych.ac.uk/pdf/MSNAP_Standards_6_Edition_2018.pdf (accessed 16 Oct
26 2018).
27
- 28 8 NHS England. Well Pathway for Dementia. Leeds: NHS England 2017.
29 [https://www.england.nhs.uk/mentalhealth/wp-
30 content/uploads/sites/29/2016/03/dementia-well-pathway.pdf](https://www.england.nhs.uk/mentalhealth/wp-content/uploads/sites/29/2016/03/dementia-well-pathway.pdf) (accessed 30 Oct 2018).
31
- 32 9 National Institute for Health and Clinical Excellence (NICE). Donepezil, galantamine,
33 rivastigmine, and memantine for the treatment of Alzheimer’s Disease. London: NICE 2011.
34 [http://www.nice.org.uk/guidance/ta217/resources/guidance-
35 donepezilgalantaminerivastigmineandmemantine-for-the-treatment-of-alzheimers-disease-
36 pdf](http://www.nice.org.uk/guidance/ta217/resources/guidance-donepezilgalantaminerivastigmineandmemantine-for-the-treatment-of-alzheimers-disease-pdf) (accessed 26 Sep 2018).
37
38
- 39 10 Woods B, Aguirre E, Spector AE, et al. Cognitive stimulation to improve cognitive functioning
40 in people with dementia. *Cochrane Database Syst Rev* 2012;15.
41 doi:10.1002/14651858.CD005562.pub2
42
- 43 11 Moniz-Cook E, Vernooij-Dassen M, Woods B, et al. Psychosocial interventions in dementia
44 care research: The INTERDEM manifesto. *Aging Ment Health* 2011;15:283–90.
45 doi:10.1080/13607863.2010.543665
46
- 47 12 McDermott O, Charlesworth G, Hogervorst E, et al. Psychosocial interventions for people with
48 dementia: a synthesis of systematic reviews. *Aging Ment Health* Published Online First:17
49 January 2018. doi:10.1080/13607863.2017.1423031
50
- 51 13 Clare L, Woods RT. Cognitive training and cognitive rehabilitation for people with early-stage
52 Alzheimer’s disease: A review. *Neuropsychol Rehabil* 2004;14:385–401.
53 doi:10.1080/09602010443000074
54
- 55 14 Graff MJL, Vernooij-Dassen MJM, Thijssen M, et al. Community based occupational therapy
56 for patients with dementia and their care givers: randomised controlled trial. *BMJ*
57 2006;333:1196. doi:10.1136/bmj.39001.688843.BE
58
59
- 60 15 Vernooij-Dassen M, Olde Rikkert MG. Personal disease management in dementia care. *Int J*

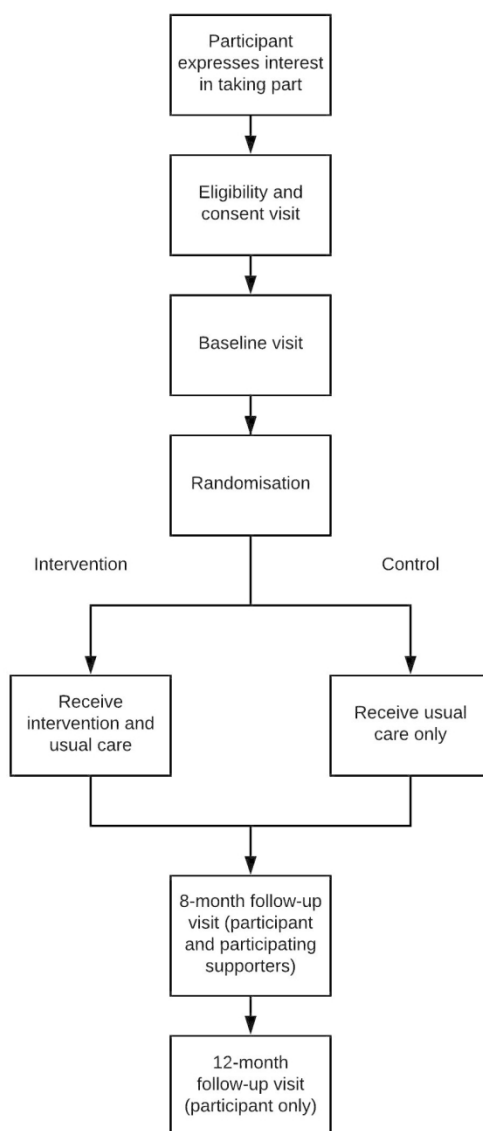
- 1
2
3 *Geriatr Psychiatry* 2004;19:715–7. doi:10.1002/gps.1149
4
- 5 16 Moniz-Cook E, Manthorpe J, eds. *Early Psychosocial Interventions in Dementia*. London:
6 Jessica Kingsley Publishers 2008.
7
- 8 17 Quinn C, Toms G, Anderson D, et al. A review of self-management interventions for people
9 with dementia and mild cognitive impairment. *J Appl Gerontol* 2016;35:1154–88.
10 doi:10.1177/0733464814566852
11
- 12 18 Quinn C, Toms G, Jones C, et al. A pilot randomized controlled trial of a self-management
13 group intervention for people with early-stage dementia (The SMART study). *Int*
14 *Psychogeriatr* 2016;28:787–800. doi:10.1017/S1041610215002094
15
- 16 19 Martin F, Turner A, Wallace LM, et al. Qualitative evaluation of a self-management
17 intervention for people in the early stage of dementia. *Dementia* 2015;14:418–35.
18 doi:10.1177/1471301213498387
19
- 20 20 Clarke CL, Keyes SE, Wilkinson H, et al. *Healthbridge: The National Evaluation of Peer Support*
21 *Networks and Dementia Advisers in Implementation of the National Dementia Strategy for*
22 *England*. London: Department of Health 2013.
23
- 24 21 Chakkalackal L, Kalathil J. *Evaluation report: Peer support groups to facilitate self-help coping*
25 *strategies for people with dementia in extra care housing*. London: Mental Health Foundation
26 2014.
27
- 28 22 Sprange K, Mountain GA, Shortland K, et al. *Journeying through Dementia, a community-*
29 *based self-management intervention for people aged 65 years and over: a feasibility study to*
30 *inform a future trial*. *Pilot Feasibility Stud* 2015;1:42. doi:10.1186/s40814-015-0039-6
31
- 32 23 Bellg AJ, Resnick B, Minicucci DS, et al. *Enhancing treatment fidelity in health behavior*
33 *change studies: Best practices and recommendations from the NIH Behavior Change*
34 *Consortium*. *Health Psychology* 2004;23:443–51. doi:10.1037/0278-6133.23.5.443
35
- 36 24 National Institute for Health and Care Excellence (NIHCE). *Behaviour Change at population,*
37 *community and individual levels*. Public Health Guidance 6. London: NIHCE 2007.
38
- 39 25 Craig P, Dieppe P, Macintyre S, et al. *Developing and evaluating complex interventions: new*
40 *guidance*. London: Medical Research Council 2008.
41 <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC004871> (Accessed 28 Sep
42 2018).
43
- 44 26 ISRCTN Registry. *ISRCTN17993825 Journeying through dementia: exploring the clinical and*
45 *cost-effectiveness of a group self-management intervention for people in the early stages of*
46 *dementia*. 2019. <http://www.isrctn.com/ISRCTN17993825> (accessed 15 Jan 2019).
47
- 48 27 Alzheimer's Disease International. *Participation in dementia trials and studies: Challenges and*
49 *recommendations*. 2014. <https://www.alz.co.uk/sites/default/files/pdfs/dementia-trials.pdf>
50 (accessed 28 Sept 2018).
51
- 52 28 Herschell AD, Kolko DJ, Baumann BL, et al. *The role of therapist training in the*
53 *implementation of psychosocial treatments: A review and critique with recommendations*.
54 *Clin Psychol Rev* 2010;30:448–66. doi:10.1016/j.cpr.2010.02.005
55
- 56 29 Mountain GA, Craig CL. *What should be in a self-management programme for people with*
57 *early dementia?* *Aging Ment Health* 2012;16:576–83. doi:10.1080/13607863.2011.651430
58
59
60

- 1
2
3 30 Mulhern B, Rowen D, Brazier J, et al. Development of DEMQOL-U and DEMQOL-PROXY-U:
4 Generation of preference-based indices from DEMQOL and DEMQOL-PROXY for use in
5 economic evaluation. *Health Technol Assess (Rockv)* 2013;17:1–140. doi:10.3310/hta17050
6
7 31 Smith S, Lamping D, Banerjee S, et al. Measurement of health-related quality of life for
8 people with dementia: development of a new instrument (DEMQOL) and an evaluation of
9 current methodology. *Health Technol Assess (Rockv)* 2005;9:1–93.
10 doi:https://doi.org/10.3310/hta9100
11
12 32 Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-
13 level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–36. doi:10.1007/s11136-011-
14 9903-x
15
16 33 Hounsome N, Orrell M, Edwards RT. EQ-5D as a quality of life measure in people with
17 dementia and their carers: Evidence and key issues. *Value Health* 2011;14:390–9.
18 doi:10.1016/j.jval.2010.08.002
19
20 34 Spitzer RL, Williams JBW, Kroenke K. Test Review: Patient Health Questionnaire-9 (PHQ-9).
21 *Rehabil Couns Bull* 2014;57:246–8. doi:10.1177/0034355213515305
22
23 35 Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a Brief Depression Severity
24 Measure. *J Gen Intern Med* 2001;16:606–13. doi:10.1046/j.1525-1497.2001.016009606.x
25
26 36 Löwe B, Decker O, Müller S, et al. Validation and standardization of the generalized anxiety
27 disorder screener (GAD-7) in the general population. *Medical Care* 2008;46:266–74.
28 doi:10.1097/MLR.0b013e318160d093
29
30 37 Schwarzer R, Jerusalem M. Generalized Self-Efficacy scale. In: Weinman J, Wright S, Johnston
31 M, eds. Measures in health psychology: A user's portfolio. Causal and control beliefs.
32 Windsor: NFER-NELSON 1995: 35–7.
33
34 38 Diener E, Wirtz D, Tov W, et al. New measures of well-being: Flourishing and positive and
35 negative feelings. In: Diener E, ed. Social Indicators Research Series. New York: Springer
36 Science + Business Media 2009: 247–66.
37
38 39 Schuurmans H, Steverink N, Frieswijk N, et al. How to Measure Self-Management Abilities in
39 Older People by Self-report. The Development of the SMAS-30. *Qual Life Res*
40 2005;14(10):2215–2228. Doi: doi:10.1007/s11136-005-8166-9
41
42 40 Lawton MP, Brody EM. Assessment of Older People : Self-Maintaining and Instrumental
43 Activities of Daily Living 1. *Gerontologist* 1969;9:179–86. doi:10.1093/geront/9.3_Part_1.179
44
45 41 Vernooij-Dassen MJFJ, Persoon JMG, Felling AJA. Predictors of sense of competence in
46 caregivers of demented persons. *Soc Sci Med* 1996;43:41–9. doi:10.1016/0277-
47 9536(95)00332-0
48
49 42 Jansen APD, van Hout HPJ, van Marwijk HWJ, et al. Sense of competence questionnaire
50 among informal caregivers of older adults with dementia symptoms: A psychometric
51 evaluation. *Clin Pract Epidemiol Ment Health* 2007;3:1–11. doi:10.1186/1745-0179-3-11
52
53 43 Moniz-Cook E, Vernooij-Dassen M, Woods R, et al. A European consensus on outcome
54 measures for psychosocial intervention research in dementia care. *Aging Ment Heal*
55 2008;1:14–29. doi:10.1080/13607860801919850
56
57 44 McHugh ML. Interrater reliability: the kappa statistic. *Biochem Med (Zagreb)* 2012;22:276–82.
58
59
60

- 1
2
3 doi:10.11613/BM.2012.031
4
5 45 Sprange K., Mountain GA, Brazier J, et al. Lifestyle Matters for maintenance of health and
6 wellbeing in people aged 65 years and over: study protocol for a randomised controlled trial.
7 *Trials* 2013;14:302. doi:10.1186/1745-6215-14-302
8
9 46 Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement : updated guidelines for reporting
10 parallel group randomised trials. *BMJ* 2010;340:332. doi:10.1136/bmj.c332
11
12 47 Baldwin SA, Bauer DJ, Stice E, et al. Evaluating models for partially clustered designs. *Psychol*
13 *Methods* 2011;16:149–65. doi:10.1037/a0023464
14
15 48 Walters SJ. Therapist effects in randomised controlled trials: What to do about them. *J Clin*
16 *Nurs* 2010;19:1102–12. doi:10.1111/j.1365-2702.2009.03067.x
17
18 49 Roberts C, Batistatou E, Roberts SA. Design and analysis of trials with a partially nested design
19 and a binary outcome measure. *Stat Med* 2015;35:1616–36. doi:10.1002/sim.6828
20
21 50 Kahan BC, Morris TP. Improper analysis of trials randomised using stratified blocks or
22 minimisation. *Stat Med* 2012;31:328–40. doi:10.1002/sim.4431
23
24 51 Ritchie J, Spencer L. Qualitative Data Analysis for Applied Policy Research. In: Humberman
25 AM, Miles MB, eds. *The Qualitative Researcher's Companion*. London: SAGE Publications
26 2002: 305–29. doi:10.4135/9781412986274
27
28 52 Cooper C, Ketley D, Livingston G. Systematic review and meta-analysis to estimate potential
29 recruitment to dementia intervention studies. *Int J Geriatr Psychiatry* 2014;29:515–25.
30 doi:10.1002/gps.4034
31
32 53 NHS Improvement. Reference Costs 2017/18. 2018.
33 <https://improvement.nhs.uk/resources/reference-costs/> (accessed 15 Jan 2019).
34
35 54 Curtis L, Burns A. Unit Costs of Health & Social Care 2018. Canterbury: University of Kent
36 2018.
37
38 55 Schafer JL. Multiple imputation: A primer. *Stat Methods Med Res* 1999;8:3–15.
39 doi:10.1191/096228099671525676
40
41 56 Van Hout BA, Al MJ, Gordon GS, et al. Costs, effects and C/E-ratios alongside a clinical trial.
42 *Health Econ* 1994;3:309–19. doi:10.1002/hec.4730030505
43
44

FIGURE LEGENDS

45
46
47 Figure 1: Participant flow through the study
48
49
50
51
52
53
54
55
56
57
58
59
60



45 Figure 1 Participant flow through the study

46 92x190mm (300 x 300 DPI)



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	_____ i _____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_____ 2 _____
	2b	All items from the World Health Organization Trial Registration Data Set	_____ See 2a _____
Protocol version	3	Date and version identifier	_____ 14 _____
Funding	4	Sources and types of financial, material, and other support	_____ 14 _____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_____ i-ii _____
	5b	Name and contact information for the trial sponsor	_____ 13 _____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_____ n/a _____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_____ 13 _____

1 **Introduction**

2

3 Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention _____ 2-3 _____

4

5

6 6b Explanation for choice of comparators _____ 2-3 _____

7

8 Objectives 7 Specific objectives or hypotheses _____ 3 _____

9

10 Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) _____ 3-4 _____

11

12

13

14 **Methods: Participants, interventions, and outcomes**

15

16 Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained _____ 5 _____

17

18

19 Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) _____ 4-5 _____

20

21

22 Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered _____ 5-6 _____

23

24

25 11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) _____ n/a _____

26

27

28 11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) _____ 8-9 _____

29

30

31 11d Relevant concomitant care and interventions that are permitted or prohibited during the trial _____ 6 _____

32

33

34 Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended _____ 6-7 _____

35

36

37

38

39

40 Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) _____ Table 1 and figure 1 _____

41

42

43

44

45

46

1	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	___9___
2				
3				
4	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	___5___
5				

6 **Methods: Assignment of interventions (for controlled trials)**

7 Allocation:

8				
9				
10	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	___4___
11				
12				
13				
14				
15				
16	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	___4___
17				
18				
19				
20	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	___4___
21				
22				
23				
24	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	___4___
25				
26				
27		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	___4___
28				
29				
30				

31 **Methods: Data collection, management, and analysis**

32				
33	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	___6-8___
34				
35				
36				
37				
38				
39		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	___6-7___
40				
41				
42				

1	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	__12
2				
3				
4				
5	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	___9-11_
6				
7				
8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	__11_
9				
10		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	_10-11__
11				
12				
13				
14	Methods: Monitoring			
15				
16	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	___13_____
17				
18				
19				
20				
21				
22		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_____n/a_____
23				
24				
25	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	___12-13__
26				
27				
28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___12_____
29				
30				
31				
32	Ethics and dissemination			
33				
34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	_____14_____
35				
36				
37	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_____13_____
38				
39				
40				
41				
42				

1	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_____5_____
2				
3				
4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	__See supplementary information__
5				
6				
7				
8	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	___12-13_____
9				
10				
11	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_____14_____
12				
13				
14				
15				
16	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_____12_____
17				
18				
19	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_____n/a_____
20				
21				
22	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_____13_____
23				
24				
25				
26				
27		31b	Authorship eligibility guidelines and any intended use of professional writers	_____n/a_____
28				
29		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____12_____
30				
31	Appendices			
32				
33	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	See supplementary materials_____
34				
35				
36				
37	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____n/a_____
38				
39				
40				

1 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.
2 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons
3 [“Attribution-NonCommercial-NoDerivs 3.0 Unported”](#) license.
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

For peer review only

BMJ Open

A study protocol for a randomised controlled trial of the clinical and cost-effectiveness of the Journeying through Dementia (JtD) intervention compared to usual care

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-029207.R1
Article Type:	Protocol
Date Submitted by the Author:	25-Jun-2019
Complete List of Authors:	<p>Wright, Jessica; University of Sheffield, Clinical Trials Research Unit Foster, Alexis; University of Sheffield, School of Health and Related Research Cooper, Cindy; The University of Sheffield, Sheffield Clinical Trials Research Unit, School of Health and Related Research Sprange, Kirsty; The University of Nottingham, Nottingham Clinical Trials Research Unit Walters, Stephen; University of Sheffield, SchARR Berry, Katherine; The University of Manchester, School of Psychological Sciences Moniz-Cook, Esme; The University of Hull, School of Health and Social Work Loban, Amanda; University of Sheffield, School of Health and Related Research Young, Tracey; The University of Sheffield, School of Health and Related Research Craig, Claire; Sheffield Hallam University Denning, Tom; University of Nottingham, Division of Psychiatry & Applied Psychology, School of Medicine Lee, Ellen; University of Sheffield, Clinical Trials Research Unit Beresford-Dent, Julie; University of Bradford, Centre for Applied Dementia Studies Thompson, Benjamin; The University of Sheffield, School of Health and Related Research Young, Emma; The University of Sheffield, School of Health and Related Research Thomas, Benjamin; The University of Sheffield, School of Health and Related Research Mountain, Gail; University of Bradford, Centre for Applied Dementia Studies, Faculty of Health Studies</p>
Primary Subject Heading:	Geriatric medicine
Secondary Subject Heading:	Mental health, Health economics, Qualitative research
Keywords:	Randomised Controlled Trial, Dementia < NEUROLOGY, Research Protocol, Post diagnostic support, Self-management, Well-being

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60



SCHOLARONE™
Manuscripts

TITLE PAGE**Title**

A study protocol for a randomised controlled trial of the clinical and cost-effectiveness of the Journeying through Dementia (JtD) intervention compared to usual care

Corresponding author

Jessica Wright
Journeying Through Dementia (JtD) Trial,
Sheffield Clinical Trials Research Unit,
SchHARR, The University of Sheffield,
Regent's Court,
30 Regent St, Sheffield S1 4DA
Telephone: 0114 222 4304
Email: Jessica.wright@sheffield.ac.uk

Author Names/Affiliations

Jessica Wright, Sheffield Clinical Trials Research Unit, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Alexis Foster, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Cindy Cooper, Sheffield Clinical Trials Research Unit, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Kirsty Sprange, Nottingham Clinical Trials Research Unit, The University of Nottingham, Nottingham, UK

Stephen Walters, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Katherine Berry, Manchester Institute for Collaborative Research on Ageing, The University of Manchester, Manchester, UK

Esme Moniz-Cook, School of Health and Social Work, The University of Hull, Hull, UK

Amanda Loban, Sheffield Clinical Trials Research Unit, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Tracey Young, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Claire Craig, Art & Design Research Centre, Sheffield Hallam University, Sheffield, UK

Tom Dening, Division of Psychiatry & Applied Psychology, School of Medicine, University of Nottingham, Nottingham, UK

Ellen Lee, Sheffield Clinical Trials Research Unit, School of Health and Related Research, The University of Sheffield, Sheffield, UK

1
2
3 Julie Beresford-Dent, Centre for Applied Dementia Studies, University of Bradford, Bradford, UK
4

5 Benjamin John Thompson, Sheffield Clinical Trials Research Unit, School of Health and Related
6 Research, The University of Sheffield, Sheffield, UK
7

8 Emma Louise Young, Sheffield Clinical Trials Research Unit, School of Health and Related Research,
9 The University of Sheffield, Sheffield, UK
10

11 Benjamin David Thomas, Sheffield Clinical Trials Research Unit, School of Health and Related
12 Research, The University of Sheffield, Sheffield, UK
13

14 Gail Mountain, Centre for Applied Dementia Studies, Faculty of Health Studies, University of
15 Bradford, Bradford, UK
16
17

18
19
20
21 **Word Count: 6589 (excluding references, abstract, tables and figures)**
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

ABSTRACT

Introduction

Services are being encouraged to provide post diagnostic treatment to those with dementia but the availability of evidence-based interventions following diagnosis has not kept pace with increase in demand. To address this need, the Journeying through Dementia (JtD) intervention was created. A randomised controlled trial (RCT), based on a pilot study, is in progress.

Methods and analysis

The RCT is a pragmatic, two-arm, parallel group trial designed to test the clinical and cost-effectiveness of JtD compared to usual care. Recruitment will be through NHS services, third sector organisations and Join Dementia Research. The sample size is 486 randomised (243 to usual care and 243 to the intervention usual care). Participants can choose to ask a friend or relative (supporter) to become involved in the study. The primary outcome measure for participants is Dementia Related Quality of Life (DEMQOL), collected at baseline and at 8 months' post randomisation. Secondary outcome measures will be collected from participants and supporters at those visits. Participants will also be followed-up at 12 months' post randomisation with a reduced set of measures. A process evaluation will be conducted through qualitative and fidelity sub-studies.

Analyses will compare the two arms of the trial on an intention to treat as allocated basis. The primary analyses will compare the mean DEMQOL scores of the participants at 8 months between the two study arms. A cost-effectiveness analysis will consider the incremental cost per Quality Adjusted Life Years of the intervention compared with usual care. Qualitative and fidelity sub-studies will be analysed through framework analysis and fidelity assessment tools respectively.

Ethics and dissemination

REC and HRA approval were obtained. A Data Monitoring and Ethics Committee has been constituted. Dissemination will be via publications, conferences and social media. Intervention materials will be made open access.

Trial registration number

ISRCTN17993825

STRENGTHS AND LIMITATIONS OF THE STUDY

- People living with dementia were involved in developing the content of the Journeying through Dementia (JtD) intervention and are involved in advising the study.
- The JtD intervention includes sessions without supporters present, to help develop independence and confidence, and is one of the only interventions that people with dementia can participate in without supporters.
- The JtD study will recruit up to 500 participants and is therefore one of the largest trials of a psychosocial intervention for people with dementia in the UK.
- The potential for unblinding of researchers when arranging or attending follow-up visits is a limitation but this will be monitored and minimized by not sending unblind researchers to visits.
- Recruitment is known to be challenging in this population but we plan to try multiple pathways for recruitment including through services, the Join Dementia Research database, promotion and the third sector.

INTRODUCTION

The impact on the economy, for services and for individuals living with dementia and their family carers is larger for dementia than for all other long-term illnesses in people aged 60 and over.[1] Two thirds of people with dementia live in the community, and half of these require some form of support.[2] As a result, dementia research (both for cure and for care) in the NHS and social care is important, and this is reflected in UK health policy.[3] In 2009, the UK Government announced a National Dementia Strategy, which mandated the establishment of memory services and aimed to increase the rates of early diagnosis and improve support for people in the early stages of dementia.[4]

The National Audit of Memory Services (2013) found there had been a fourfold increase in numbers presenting since 2010/11, and in 2013 49.3% were in the early stages of the condition.[5] Earlier diagnosis allows individuals to receive treatment earlier and enables the individual and memory services to plan more effectively for the future.[6] Memory services have been strongly encouraged to provide post diagnostic treatment and support,[7,8] but the availability of appropriate evidence-based interventions has not kept pace with the increase in demand, in particular for those with early stages of dementia. The lack of appropriate interventions has led to inconsistency between Trusts regarding what is being offered to people post diagnosis.

The potential value of psychosocial interventions for people in the early stages of dementia is recognised[9–12] and is also driven by the knowledge that a cure for dementia is unlikely in the near future. Psychosocial interventions are diverse but a common theme is that they do not involve the use of medication and instead focus on supporting people to overcome challenges and maintain independence and well-being. However, whilst there has been some shift, the use of psychosocial interventions within dementia care has been a neglected area for both research and practice.[11]

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).[13–18] A qualitative study

1
2
3 of people with dementia who attended a self-management programme reported that participants
4 identified the opportunity for peer support as being beneficial and considered that the programme
5 could be improved by greater emphasis being placed upon maintaining activities and relationships
6 and improving positive wellbeing.[19] The Healthbridge evaluation[20] and the Mental Health
7 Foundation evaluation[21] found evidence that people with dementia and their carers can benefit
8 from receiving group based peer support.
9

10
11 The Journeying through Dementia (JtD) intervention was developed from the Lifestyle Matters
12 programme and a pilot study was conducted to examine the feasibility of a future population-based
13 larger trial of this intervention.[22] The intervention was found to be acceptable to both people with
14 dementia and their carers. Reported benefits included increased confidence and self-efficacy,
15 engagement in activities and re-engagement with fun and friendships.[22] The intervention is
16 manualised, based on occupational therapy principles, and is designed to support independence and
17 well-being. The intervention incorporates elements of self-management and group-based peer
18 support and has been designed to improve the quality of life for people in the early stages of
19 dementia.
20
21
22
23

24 The JtD randomised controlled trial (RCT) will test the clinical and cost effectiveness of the JtD
25 intervention. Funding was obtained through the National Institute of Health Research (NIHR) Health
26 Technology Assessment (HTA) theme to conduct the RCT. This paper describes the research protocol
27 for undertaking the RCT which started recruitment in November 2016.
28
29

30 **AIMS AND OBJECTIVES**

31
32 The primary aim of the JtD trial is to determine the clinical and cost-effectiveness of the JtD
33 intervention for people in the early stages of dementia. To meet this aim, the objectives are to:
34

- 35 1. Conduct an internal pilot RCT of the intervention to check the feasibility of rates of
36 recruitment at scale.
- 37 2. Proceed to a full a pragmatic RCT evaluating the clinical and cost-effectiveness of the JtD
38 intervention.
- 39 3. Conduct fidelity checks regarding the delivery of the JtD intervention.
- 40 4. Undertake an embedded qualitative sub-study to explore issues concerned with intervention
41 delivery.
- 42 5. Identify how the intervention might be realistically delivered through services.
43
44
45

46 **METHODS**

47 **Trial design**

48
49 The JtD trial is a pragmatic, two-arm, parallel group, individually randomised RCT. It uses a
50 superiority framework to deliver an intention-to-treat comparison of the JtD intervention with usual
51 care.
52
53

54
55 The trial includes three sub-studies. The first is a health economics evaluation using a cost-
56 effectiveness analysis of the incremental cost per Quality Adjusted Life Year (QALY) of the JtD
57 intervention compared with usual care.
58
59
60

1
2
3 The second sub-study is a fidelity assessment as part of the process evaluation, using an intervention
4 fidelity framework based on that identified by the Behaviour Change Consortium and National
5 Institute for Health and Care Excellence (NICE).[23,24]
6
7

8 The third sub-study is a qualitative study, part of the process evaluation, in line with Medical
9 Research Council (MRC) guidance on developing and evaluating complex interventions.[25] The
10 qualitative sub-study will involve semi-structured interviews with participants, supporters,
11 facilitators and supervisors.
12
13

14 **Randomisation, blinding and bias**

15
16 To minimise bias, allocation will be concealed through the use of a centralised web-based
17 randomisation service. The randomisation sequence will be stratified by delivery site and
18 constrained by a fixed block size to ensure participants are allocated evenly to each arm of the trial
19 at each delivery site. Participants will be randomised in equal numbers to intervention and control
20 arms. An unblind member of the research team who will not be conducting outcome assessments
21 will enter the participants' details into the randomisation system and inform the relevant parties of
22 the outcome.
23
24

25
26 Members of the Trial Steering Committee (TSC), study statisticians, health economists and outcome
27 assessors will be blinded to treatment allocation whilst the trial is ongoing. For practical reasons linked
28 to the provision of a centralised web-based randomisation service and the set-up and delivery of the
29 intervention groups, some members of the research team will not be blinded, including the Trial
30 Manager and Chief Investigator. Due to the nature of the intervention, participants will not be blinded.
31 If the outcome assessors know (or suspect) they have been unblinded this will be recorded on an
32 unblinding form.
33
34
35

36 We protect against facilitator bias where the same facilitators also provide usual care in three ways:
37 (a) usual care is limited and often restricted to cognitive stimulation therapy which would not be
38 readily influenced by training in JtD principles, as it follows a manual with a session-by-session plan
39 already laid out; (b) where usual care was also delivered by intervention facilitators, they were
40 instructed not to deliver JtD wholly or partly as part of usual care; (c) many of the facilitators recruited
41 are not those who would deliver usual care, for example approximately 25% of facilitators are trained
42 research staff. A further form of bias, that caused by cross-contamination of participants between the
43 two study arms, is considered as unlikely as post diagnostic services for people living with dementia
44 are limited and often only involves cognitive stimulation therapy which is unlikely to be concurrent.
45 Extended post diagnostic follow-up is not common so it is unlikely participants would meet at routine
46 appointments.
47
48
49
50

51 **Participants**

52
53
54 Persons with early-stage dementia will be approached to take part in the trial. A family member,
55 friend or neighbour that provides support to the study participant (referred to as the 'supporter')
56 can be approached to take part in the trial, but only if invited to do so by the person with dementia.
57 The study participant can also choose not to invite a supporter to take part in the trial and still take
58
59
60

part. Participating supporters will automatically be randomised to the same arm as the participant. See Figure 1 for participant flow through the study.

(Insert Figure 1 here)

Eligibility criteria

Participants will be eligible for the study if they:

1. have a diagnosis of any form of dementia,
2. have a Mini Mental State Examination (MMSE) score of 18 or more, measured less than 2 months' pre-consent,
3. have capacity to make informed decisions,
4. are living in the community in their own or sheltered accommodation (those living in residential or nursing care are not eligible),
5. are willing to attend the JtD intervention,
6. are able to converse and communicate in English, and
7. are not taking part in any other pharmacological or psychosocial intervention studies at the time of enrolment.

Supporters will be eligible to participate if they are aged 18 years or over, are named by the person with dementia as their supporter, the person with dementia wishes them to take part, they can converse and communicate in English, and have the ability to give informed consent.

Site selection and participant recruitment

The JtD trial will operate in England within 13 NHS trusts with specialist dementia services. The sites will be selected based on a convenience sample of locations clustered geographically around the north and midlands (for a list of sites, see study ISRCTN webpage[26]).

Previous studies involving persons with dementia have shown that recruiting participants to such studies can be challenging.[27] To ensure sufficient numbers are recruited to the study a number of recruitment pathways will be used: referral from clinical teams; mail-outs to eligible patients via primary or secondary care clinical teams; study promotion via posters etc.; third sector organisations; and the Join Dementia Research database. The research team will contact interested participants and send further information about the study. Clinical teams will check with the potential participants that they are willing to be approached by the research team before an approach is made.

To enable potential participants to make a direct approach to the research team, a reply card will be designed which can be completed, sealed and returned to the central research team who will then pass the information on to relevant local site researchers. These reply cards will be distributed with information sheets at events including dementia cafes or posted as part of mail-outs to GPs. Local promotions, for example via posters in clinics or GPs, will include the telephone and email details of local researchers for direct contact to take place.

A consent and eligibility visit will be arranged if an individual would like to take part where trained researchers will assess eligibility and request written informed consent.

Intervention

JtD is a manualised intervention consisting of twelve weekly facilitated groups with 8-12 participants with dementia, which take place over successive weeks. Each participant also receives four one-to-one sessions with one of the intervention facilitators, to pursue individual goals. The first one-to-one session takes place before the start of the group intervention, with the remaining three being scheduled during, the 12 weeks and at locations and times agreed with the participant. The group aspect of intervention should be delivered in a community venue.

The content of the JtD intervention involves:

- 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, embedding health activity in everyday life, diet).
- c. Memory (strategies to aid memory, impact on everyday life and learning and practicing new techniques).
- d. Keeping mentally well (relationships between anxiety and memory, and dementia and stress).
- e. Endings (celebration of achievements and how to move forward).

Participants are encouraged to select different topics from the manualised intervention and explore them with guidance and suggestions from facilitators. Participants are also able to suggest topics not within the manual. One essential component of the intervention is the enactment of activities, particularly in the community; three of the twelve group meetings should be 'out of venue' activities. Participants are able to invite a supporter to participate in the group aspect of the intervention during sessions 1, 6 and 12, and in the individual sessions if the participant finds this helpful in achieving their goals.

The intervention should be facilitated by a minimum of two NHS staff who are experienced with working with people with dementia. Facilitators will normally be someone employed on Agenda for Change Bands 3-5. Facilitators must receive a two-day training course prior to delivering the intervention. In some cases, for example if they are a reserve facilitator, they may receive a shortened course supported by online resources created for this purpose. Facilitators will be supervised by a colleague experienced in supervision who has also attended the facilitator training and is of suitable seniority and experience. The supervisors themselves will be supervised by a member of the central study team who is a Clinical Psychologist and is experienced in the 'train the trainer' method[28].

Patient and public involvement (PPI)

People living with dementia were involved in developing the content of JtD[29] and in the feasibility study.[22] The JtD Trial Steering Committee will include a member who is living with dementia. Additionally, an advisory group of people living with dementia (experts by experience) will meet at intervals throughout to provide input into study materials. We also plan to involve people living with dementia in some aspects of the qualitative data analysis and in creating and delivering the study dissemination plans.

OUTCOMES

Outcomes were identified through a feasibility study which identified appropriate measures and tested their application.[22] The burden of questionnaires was found to be acceptable.

The primary outcome is the Dementia Related Quality of Life (DEMQOL)[30,31] measure at 8 months post randomisation.

The secondary outcomes are:

- European Quality of Life - 5 Dimensions (EQ-5D-5L)[32,33]
- Patient Health Questionnaire-9 (PHQ-9)[34,35]
- Generalised Anxiety Disorder-7 (GAD-7)[36]
- General Self-Efficacy Scale (GSE)[37]
- Diener's Flourishing Scale (DFS)[38]
- Self-Management Ability Scale (SMAS)[39]
- Instrumental Activities of Daily Living (IADL)[40]
- Health and Social Care Resource Use Questionnaire (HSCRU)[22]
- Sense of Competency Questionnaire (SCQ)[41],[42]

See Table 1 (below) for further information on who completes which measures in the study. The outcome measures used were selected to measure the following key components of the intervention: mental wellbeing or mood (DEMQOL, PHQ-9, GAD-7); building relationships and a sense of connectedness (DFS, SMAS); self-management (SMAS); belief that life is meaningful despite dementia (DEMQOL, GSE, DFS, SMAS); and Instrumental Activities of Daily Living (IADL) and strategies to maintain cognitive functioning (IADL). Additionally, they also support analysis of the cost-effectiveness of the intervention (DEMQOL, EQ-5D-5L, HSCRU) and the participating supporters' perceptions of competence (SCQ). Dementia specific outcome measures are those recommended for use across Europe and are selected for self rather than proxy completion.[43] Non dementia specific outcome measures were selected if there was no appropriate dementia specific measure available.

DATA COLLECTION

Quantitative

Data will be collected from all participants living with dementia at eligibility/consent, baseline, 8 and 12 months post randomisation and from consented participating supporters at baseline and 8 months' post randomisation (see Table 1). There is a reduced set of measures linked to the 12 month visit as we require limited further information on quality of life and health and social care resource use at that time-point; the key outcome point is at 8 months. The outcome measures will be interviewer-administered at face-to-face visits by blinded outcome assessors who have received training to deliver the measures to people living with dementia and their supporters. The follow-up outcome measures will be collected 2 weeks pre and 8 weeks post the date they are due. Participant retention will be promoted by regular communication with the participants and supporters through communication including newsletters and Christmas cards.

Table 1 Outcome measures and time-points for collection. * Denotes the primary outcome measure.

Measure	Participant				Participating Supporter	
	Eligibility and Consent visit	Baseline <2 months prior to the intervention start date	8 Months Due < 2 weeks pre and < 8 weeks post randomisation	12 Months Due < 2 weeks pre and < 8 weeks post randomisation if within study timelines	Baseline Due <2 months prior to the intervention	8 Months Due < 2 weeks pre and < 8 weeks post randomisation
Capacity assessment	✓					
Mini Mental State Examination	✓					
Eligibility checklist	✓				✓	
Baseline demographics	✓				✓	
DEMQOL		✓	✓*	✓		
EQ-5D-5L		✓	✓	✓	✓	✓
PHQ-9		✓	✓		✓	✓
GAD-7		✓	✓			
GSE		✓	✓			
DFS		✓	✓			
SMAS		✓	✓			
IADL		✓	✓	✓		
HSCRU			✓	✓		
SCQ					✓	✓

Visits to collect outcome data will be arranged with the participant by a researcher, in some cases a participating supporter will assist with these arrangements. All visits will be conducted at a time and location most suitable for the participant. When we conduct the follow-ups we will prioritise the importance of the measures in case the participant tires. We will offer a second visit if the participant is tired or otherwise unable to complete the assessments, which will be organised as soon as possible after the first. Participating supporters may not have the time or capacity to receive a face-to-face visit and follow-up outcome measures may therefore be collected from them over the telephone. Similarly, if a participant does not want a visit, a reduced set of outcome measures may be taken by telephone (prioritising collection of DEMQOL and telephone versions of HSCRU and EQ-5D-5L).

Intervention attendance

Records will be kept of all attendances for each participant randomised to the intervention.

Intervention dropout and study withdrawal

If a participant decides to withdraw either from the intervention or the study, this will be recorded. If the participant just withdraws from the intervention, they will be followed-up unless they explicitly also withdraw consent for follow-up meetings for collection of outcomes (data up to this time will be included in the trial). If the participant fully withdraws from the study no further data will be collected.

Intervention costings

Information on the cost of facilitated group and individual sessions will be collected including hire of local community venues, facilitator salaries and travel, refreshments, and other costs such as administration and materials used.

SAMPLE SIZE

The primary outcome for the study is the mean DEMQOL score 8 months post randomisation. Assuming a standard deviation of 11 points for the DEMQOL, a mean difference of 4 or more points is clinically and practically important.[30] 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 intervention with a group component, 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 people with dementia per facilitated group and an intra-cluster correlation 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. Assuming at least a 20% loss to follow-up the target sample size for the trial is to randomise to 243 participants in each arm (n=486).

DATA ANALYSIS

Statistical data analysis

As JtD is a pragmatic parallel group randomised trial, with a usual care (control) arm, data will be reported and presented according to a revised CONSORT statement.[44] Statistical analysis will be performed on an intention-to-treat-basis. All exploratory tests will be two-tailed with $\alpha = 0.05$. Baseline demographics and quality of life data will be described and summarised overall and by treatment group.

The primary analysis will compare mean patient reported DEMQOL scores at 8 months post randomisation between the intervention (JtD) arm and control arms 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.[45–47] The trial is a partially nested design with comparison of a group therapy (JtD) with individual therapy with clustering in one (intervention) arm. Each person with dementia 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.[48] 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 be calculated together with the associated P-value. A further adjusted analysis may also be performed 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

1
2
3 that there are more than 10 couples (20 participants) living under the same roof from different
4 households in the study, then the primary and secondary analyses will be changed to take into
5 account the hierarchical or clustered nature of the data. A multi level mixed effects model will be
6 used; the random effects will be JtD intervention groups (top level) and couple/singles (lower level).
7 Individual participants who are not part of a couple will be treated as clusters of size one.
8
9

10 Participants will be followed up for up to 12 months post randomisation. Mean DEMQOL scores at
11 12 months follow-up will be compared as described for the primary outcome above.
12
13

14 For the primary outcome, the DEMQOL score at 8 months follow-up, missing data will be imputed
15 through a variety of methods including: regression and multiple imputation as part of a sensitivity
16 analysis.
17
18

19 We will complement the intention to treat (ITT) analysis of the primary outcome with a complier
20 average causal effects analysis (CACE) as a secondary analysis alongside the primary ITT analysis.
21 Compliance will be defined as a binary variable with participants who attend at least 10 of the 16 JtD
22 sessions (both individual and group sessions combined) regarded as being compliant.
23
24

25 There are no planned interim statistical analyses or formal stopping rules in relation to efficacy.
26
27

28 In terms of missing data, the primary analysis will be performed based on participants with available
29 8 month primary outcome data. Sensitivity analysis on the primary outcome will include multiple
30 imputation using chained equations and regression imputation.
31
32

33 Secondary outcome measures

34 Secondary outcomes at 8 and 12 months post-randomisation will be compared between the
35 intervention and control groups using a mixed effects linear regression model as for the primary
36 outcome. A 95% CI for the mean difference in this parameter between the treatment groups will
37 also be calculated together with the associated P-value.
38
39

40 Outcome measures for the participating supporters at 8 months will be compared between the
41 intervention and control groups using a mixed effects linear regression model. The mean difference
42 in outcome with associated 95% CI and P-value will be presented for: a) the baseline (specific to the
43 secondary outcome) and site adjusted analysis and b) adjusted analysis with additional covariates in
44 addition to a).
45
46

47 Subgroup analysis

48 A subgroup analysis using a mixed effect linear regression model, with the primary outcome
49 (DEMQOL) at 8 months post randomisation as the response will be carried out. We will use an
50 interaction statistical test between the randomised intervention group and subgroup to directly
51 examine the strength of evidence for the treatment difference between the treatment groups
52 varying between subgroups. Supporter involvement (yes or no) will be the only a priori defined sub
53 groups to be considered for interaction test.
54
55
56
57
58

59 HEALTH ECONOMICS EVALUATION

60

1
2
3 A trial based economic evaluation will be undertaken of an intention-to-treat comparison of the
4 costs and outcomes of the two trial arms. A cost-effectiveness analysis will be undertaken of the
5 incremental cost per Quality Adjusted Life Year (QALYs) of the JtD intervention compared with usual
6 care provided through NHS memory services. QALYs will be calculated using the EQ-5D-5L
7 preference-based index administered at baseline, 8 and 12 months. A sensitivity analysis will be
8 undertaken using utility values from the DEMQOL-U, which can be derived from responses to the
9 DEMQOL questionnaire.[30] The total cost of the intervention will be estimated at the individual
10 participant level and will include the costs of providing the intervention and the subsequent
11 consequences for the use of routine health and social care services. The average cost per attendance
12 will be calculated and this estimate will be applied to the actual number of group and individual
13 sessions that each participant attended.

14
15
16
17
18 The use of services by trial participants will be collected in detail using a Health and Social Care
19 Resource Use (HSCRU) questionnaire administered at 8 and 12 months post randomisation. Service
20 use will be costed using the most recent National Reference Cost Data and Unit Costs of Health and
21 Social Care.[49,50] Missing data will be dealt with using multiple imputation for EQ-5D-5L, DEMQOL-
22 U and resource use data.[51] A random effects linear regression model, accounting for clustering,
23 will be fitted, the model will include baseline scores for EQ-5D-5L and baseline costs. The central
24 analysis of mean incremental costs per QALY will be subjected to a full sensitivity analysis of key
25 parameters including the measure used to estimate QALYs and number of participants at the weekly
26 sessions. A full probabilistic sensitivity analysis will be performed to examine the probability of cost-
27 effectiveness of the intervention for the NHS for different levels of costs and QALY gains.[52]

31 **PROCESS EVALUATION**

32
33
34 The process evaluation has been designed to: 1) examine the factors that may influence the fidelity
35 of intervention delivery and 2) explore its perceived impact and acceptability from user and provider
36 perspectives. There are two strands to this, the fidelity assessment and qualitative interviews,
37 explained below.

38 **Fidelity assessment**

39
40
41
42 The fidelity of intervention delivery, as well as of the training and supervision received by facilitators
43 will be assessed on the basis of criteria derived from the intervention protocol and manual. Fidelity
44 checks will adhere to a framework based on that identified by the Behaviour Change Consortium[23]
45 and NICE guidance on behaviour change.[24] The fidelity assessment framework (adapted from Bell
46 et al, 2004[23]) will assess and monitor for the consistency, facilitator training (in terms of
47 standardised delivery of training and skills acquisition for facilitators), intervention delivery (in terms
48 of standardised delivery between intervention groups) and the receipt of the intervention by
49 intervention group participants.

50
51
52
53 Training delivery and receipt of the facilitator training will be observed and rated by the same two
54 researchers (the lead for fidelity and one other member of the research team) for inter-rater
55 reliability using a bespoke *Training observation checklist*. To assess facilitator adherence to the
56 manualised intervention and participant receipt of the intervention, a purposive selection of group
57 meetings across sites will also be observed using a *Group observation checklist* which is based on the
58 contents of the intervention and the training. Each selected group will be observed on two occasions
59
60

1
2
3 to identify facilitator drift or changes in participant behavior.
4

5
6 Frequencies will be used to determine the extent to which the training programme received by
7 facilitators maintained fidelity to what was intended. Data will also be analysed to compare
8 intervention delivery between and across sites to check for consistency. Inter-rater reliability
9 between coders will be determined using the Kappa statistic.[53] Similar methods have been used in
10 previous studies.[54]
11

12 13 **Qualitative interviews** 14

15 An embedded qualitative sub-study will explore the mechanisms of the intervention, for example
16 what elements of the intervention appear to support people to improve their self-management and
17 well-being and what promotes good facilitation of the intervention.
18

19
20 Individual qualitative semi-structured interviews will be conducted with a purposive sample of 20
21 participants (approximately 10%) from the intervention groups observed in the fidelity sub-study
22 and with approximately 12 participating supporters, preferably supporters of participants who are
23 also being interviewed. A participant interview schedule and supporter interview schedule will be
24 developed to cover the following themes:
25

- 26 – Range and nature of issues that influence experiences of taking part in the intervention
- 27 – Factors that may influence the effectiveness, adoption and diffusion of this innovation in the
28 future
- 29 – Perceived skills and competencies required to facilitate the intervention
- 30 – The barriers and facilitators to uptake and continued use
- 31 – The effect of the intervention upon living with dementia
- 32 – The effect of the intervention upon the experiences of supporting someone with dementia
33
34
35
36

37 Semi-structured interviews will also be conducted with approximately 20% of all facilitators and
38 supervisors across the sites upon completion of their delivery of the intervention. The sample will
39 include a range of sites and facilitators with different levels of experience of delivering the
40 intervention. A facilitator interview schedule and supervisor interview schedule will be created to
41 cover the following themes:
42

- 43 – What issues promote the effectiveness of intervention facilitation
- 44 – The skills and competencies required to facilitate the programme
- 45 – The barriers and facilitators to its uptake and continued use
- 46 – Factors that may mediate or moderate the effectiveness of the intervention
47
48
49
50

51 Researchers undertaking participant interviews will be trained to use enhanced methods of
52 communication with people with dementia to try to ensure that meaningful discussion takes place.
53 Transcripts of interviews will undergo respondent validation.
54

55 56 **Qualitative analysis** 57

58 Framework analysis[55] will be applied to all interview data.[56] For the purposes of reporting,
59 confidentiality will be maintained by using unique participant identifiers and removing identifiable
60

1
2
3 information. A thematic framework will be agreed by two researchers and an index developed for
4 transcript coding. This will follow the five stages of framework analysis.[55] Findings will be used to
5 identify emergent factors that influence the uptake and impact of the intervention as well as explore
6 potential explanations for the quantitative findings.[56] Further analysis will also be undertaken to
7 triangulate the qualitative data (between facilitator/supervisor and participant/supporter
8 interviews) as well as the fidelity and qualitative data in order to look for between source similarities
9 and divergences. Analysis workshops will be held with people living with dementia and their
10 supporters to respond to and help validate the initial qualitative analysis. The workshop outcomes
11 will be used to refine the qualitative analysis.
12
13
14
15
16

17 **DATA MANAGEMENT, CONFIDENTIALITY AND SHARING**

18
19 Sheffield Clinical Trials Research Unit (CTRU) will provide data management services. Data will be
20 entered remotely on to a centralised web-based data capture system (Prospect) by university
21 researchers and authorised staff at participating NHS sites. The Case Report Form captures trial data
22 and has been specifically designed for this trial. Access to Prospect is controlled by usernames and
23 encrypted passwords. Prospect provides a full electronic audit trail, as well as validation features
24 which will be used to monitor study data quality. The identity of participants will be protected by the
25 removal of any identifiable data prior to dissemination of information, and no identifiable data will
26 be transferred to the statistician or health economist. All participating NHS Sites will be subject to
27 data monitoring reviews to check data entry, consent and eligibility, amongst other items. The trial
28 follows the UK Health Research Authority guidance on the General Data Protection Regulation[57]
29 and has implemented a privacy policy and transparency information appropriate to people living
30 with dementia.
31
32
33
34

35 **Data sharing**

36
37 JtD trial data will be held and available for five years after the end of the trial (November 2019). JtD
38 Trial Data will not be archived in a repository, instead data will be released on a case-by-case basis.
39 We shall make data available to the scientific community with as few restrictions as feasible. Data
40 access requests will be reviewed and authorised by a sub-committee of the Trial Management Group
41 (TMG) during the trial and by the Sheffield CTRU after the trial has ended. Access requests will be
42 considered against pre-determined criteria and data sharing will only take place if this aligns with the
43 consent provided by JtD participants. Data will be anonymised prior to being shared.
44
45
46
47

48 **ETHICS, GOVERNANCE AND SAFETY**

49 **Ethical issues**

50
51
52 There are two key ethical issues to take into account. The first is the potential need to break
53 confidentiality where there is a risk of harm. We will request consent to contact the participants or
54 supporter's GP or other health professional in situations where researchers are concerned that there
55 might be risk of harm. For example, two outcome measures used on the study may indicate a need
56 to clinically treat anxiety (GAD-7) or depression (PHQ-9). Additionally, concerns regarding participant
57 safety may also be raised at any stage of the study; e.g. observed deterioration in mental or physical
58 state of participants, safeguarding issues, or of a risk to self or others. We will work alongside local
59
60

1
2
3 Trust procedures to report any risks appropriately. Local site investigators with clinical backgrounds
4 will be asked to provide advice when appropriate. The responsible healthcare professional or
5 relevant PI will be able to recommend the withdrawal of the participant if they feel it is appropriate.
6 We will record all actions taken.
7
8

9 The second is the risk that during the trial, people with dementia may lose the capacity to consent to
10 continuing participation. As part of the consent process, people with dementia will be asked to
11 nominate a person to act as a consultee we may contact in the event that they lose capacity during
12 the trial. The consultee will be independent from the study and can be a relative, friend or medical
13 professional. All researchers will be provided with guidance and local training on identifying and
14 dealing with capacity issues identified before or during 8 and 12 month follow-up visits. If at any
15 point the participant indicates they do not wish to continue to take part in the trial, they will be
16 withdrawn. If the person with dementia loses capacity during the trial, but indicates they wish to
17 remain in the study, the consultee will be asked to make a judgement, based on their existing and
18 pre-existing knowledge of the person with dementia, about whether they would want to continue
19 participation or not. If the consultee advises that the participant would wish to be withdrawn, the
20 researchers will withdraw them from the study. If the consultee advises that the participant would
21 wish to stay taking part, even though they lack capacity, every effort will be made to accommodate
22 this, for example by reducing the number of outcome measures, using prompts or other means to
23 help the participant complete the measures. We will record information about the activation of the
24 consultee pathway on the trial.
25
26
27
28
29

30 **Governance**

31
32 The trial is coordinated by the Sheffield CTRU on behalf of the Sponsor. The sponsor of the trial is
33 Sheffield Health and Social Care Foundation Trust, Fulwood House, Old Fulwood Road, Sheffield, S10
34 3TH. The JtD TMG contains project co-applicants, members of the data management team, the
35 Sponsor, Trial Manager and other representatives, and oversees the operation of the trial and
36 enables communication throughout the Trial, for example to disseminate protocol amendments. An
37 independent Trial Steering Committee (TSC), comprised of an independent statistician, PPI
38 representative and a Senior Clinical Research Associate, provides overall supervision of the trial,
39 advises the CI, oversees protocol modifications, monitors the trial's progress and if necessary closes
40 the trial. An independent Data Monitoring and Ethics Committee (DMEC) comprised of two
41 independent statisticians and an Occupational Therapist Clinical Researcher, reviews the trial
42 protocol, monitors patient safety and advises the TSC if they feel the trial should be prematurely
43 closed.
44
45
46
47
48

49 **Safety**

50
51 A Serious Adverse Event (SAE) reporting system will be used on the Trial. Adverse Events are not
52 anticipated as a consequence of the intervention and will not be monitored. An SAE either:
53
54

- 55 a) results in death,
- 56 b) is life-threatening (subject at immediate risk of death),
- 57 c) requires hospitalisation or prolongation of existing hospitalisation,
- 58 d) results in persistent or significant disability or incapacity, or
- 59
- 60

1
2
3 e) is otherwise considered medically significant by the investigator.
4

5 All SAEs will be assessed to see if they are related to the intervention or other trial procedures, and if
6 they are the Sponsor and Research Ethics Committee will be immediately informed. SAEs are
7 periodically reported to the trial's DMEC.
8
9

10 Additionally, we consider safety of the researchers to be extremely important and have developed a
11 lone worker policy. The researcher must complete a form detailing information about any
12 participant visits and their contact information and provide this to a 'buddy' who will ensure the
13 safety of the researcher. The researcher must check in with the buddy before a visit and after a visit
14 finishes or the buddy will follow escalation procedures. Check-lists provide guidance on what to do
15 before and during the visits, for example ensuring phones are fully charged and being prepared to
16 leave in an emergency if there are concerns about safety. A phrase is provided to enable the
17 researcher to report an emergency during the visit. Guidance is provided for general safe travelling,
18 for example to keep to well-lit paths and driveways.
19
20
21

22 **DISSEMINATION**

23
24 The results of this study will be communicated in relevant academic and professional journals,
25 conferences and workshops, and via websites and social media, ensuring reach to all stakeholders
26 (people living with the condition, professionals, commissioners and academics). A short film will be
27 created to illustrate experiences of participation from the perspectives of people living with the
28 condition, and those involved in delivery of the intervention. The manualised intervention will be
29 refined and made available on the website in an open access format and it is anticipated that this
30 may be of interest to both primary care and memory services.
31
32
33

34 **AUTHOR CONTRIBUTIONS**

35
36 GM, AF, CCo, KS, EL, SW, TY, CCr, EMC, AL, TD and KB co-wrote the original Trial Protocol. JW led the
37 development of the Protocol for publication. JBD and KS developed the sections on fidelity and
38 qualitative analysis. JBD developed the section on PPI. BDT adapted the introductory section, BJT the
39 methods section, EY the outcomes section and EL the statistical analysis section. All authors
40 contributed to reviewing and revising the draft versions prior to submission.
41
42
43

44 **ACKNOWLEDGEMENTS**

45
46 We would like to thank the following people for assisting with the original project application:
47 Martin Orrell, Institute of Mental Health, The University of Nottingham; Daniel Blackburn, Sheffield
48 Institute for Translational Neuroscience, The University of Sheffield; and Diana Papaioannou,
49 Sheffield Clinical Trials Research Unit, School of Health and Related Research, The University of
50 Sheffield.
51
52

53 Additionally, we would like to thank Peter Bowie, Old Age Psychiatry, Sheffield Health and Social
54 Care NHS Foundation Trust, Sheffield, for advising on clinical aspects; and Nicholas Bell, Sheffield
55 Health and Social Care NHS Foundation Trust, for acting on behalf of the sponsor and advising on
56 trial procedures.
57
58

59 **FUNDING STATEMENT**

This study was funded by the NIHR Health Technology Assessment Programme (project number 14/140/80). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

COMPETING INTERESTS

All authors, with the exception of those below, declare no competing interests.

- SW, TY, CCo, JW, AF, AL, EL, BJT, BDT, EY as SchARR has contracts and/or research grants with the Department of Health, NIHR, MRC and NICE.
- SW, CCo and TY are co-applicants or co-investigators on NIHR portfolio grants (NIHR Research Design Service for Yorkshire and Humber; HTA, RfPB, PHR; SDO) and grants from the MRC.
- SW and TY also receive external examining fees from various UK higher education institutes.
- SW receives book royalties from publishers including John Wiley and Sons Ltd and Blackwell Publishing.
- BDT is a Consultant for Arch research in the area of dementia.

ETHICS APPROVAL

This study was approved by Leeds East Research Ethics Committee, on 01/07/16, reference number 16/YH/0238. Health Research Authority approval was provided for the study to commence on 25/08/16. The current Protocol version is v7, 5th December 2018.

REFERENCES

- 1 World Health Organisation. The global burden of disease: 2004 update. Geneva: World Health Organisation 2008.
- 2 Knapp M, Comas-Herrera A, Somani A, *et al.* Dementia: international comparisons – summary report to the National Audit Office. London: London School of Economics 2007.
- 3 Department of Health. Prime Minister’s challenge on dementia 2020. London: Department of Health 2015.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/406076/Dementia_vision.pdf (accessed 26 Sep 2018)
- 4 Department of Health. Living well with dementia : A National Dementia Strategy. London: Department of Health 2009. <https://www.gov.uk/government/publications/living-well-with-dementia-a-national-dementia-strategy> (accessed 26 Sep 2018)
- 5 Hodge AS, Hailey E. English National Memory Clinics Audit Report. London: Royal College of Psychiatrists 2013. http://www.rcpsych.ac.uk/pdf/English_National_Memory_Clinics_Audit_Report_2013.pdf (accessed 30 Oct 2018)
- 6 Banerjee S, Wittenberg R. Clinical and cost effectiveness of services for early diagnosis and intervention in dementia. *Int J Geriatr Psychiatry* 2009;24:748–54. doi:10.1002/gps.2191
- 7 Copland E, Hodge S, Clary L, *et al.* Memory Services National Accreditation Programme (MSNAP): Standards for memory services. London: Royal College of Psychiatrists 2018. https://www.rcpsych.ac.uk/pdf/MSNAP_Standards_6_Edition_2018.pdf (accessed 16 Oct 2018)

- 1
2
3 8 NHS England. Well Pathway for Dementia. 2017.
4 [https://www.england.nhs.uk/mentalhealth/wp-](https://www.england.nhs.uk/mentalhealth/wp-content/uploads/sites/29/2016/03/dementia-well-pathway.pdf)
5 [content/uploads/sites/29/2016/03/dementia-well-pathway.pdf](https://www.england.nhs.uk/mentalhealth/wp-content/uploads/sites/29/2016/03/dementia-well-pathway.pdf) (accessed 30 Oct 2018)
6
7 9 National Institute for Health and Clinical Excellence. Donepezil, galantamine, rivastigmine,
8 and memantine for the treatment of Alzheimer's Disease. London: NIHC 2011.
9 [http://www.nice.org.uk/guidance/ta217/resources/guidance-](http://www.nice.org.uk/guidance/ta217/resources/guidance-donepezilgalantaminervastigmineandmemantine-for-the-treatment-of-alzheimers-disease-pdf)
10 [donepezilgalantaminervastigmineandmemantine-for-the-treatment-of-alzheimers-disease-](http://www.nice.org.uk/guidance/ta217/resources/guidance-donepezilgalantaminervastigmineandmemantine-for-the-treatment-of-alzheimers-disease-pdf)
11 [pdf](http://www.nice.org.uk/guidance/ta217/resources/guidance-donepezilgalantaminervastigmineandmemantine-for-the-treatment-of-alzheimers-disease-pdf) (accessed 26 Sep 2018)
12
13 10 Woods B, Aguirre E, Spector AE, *et al.* Cognitive stimulation to improve cognitive functioning
14 in people with dementia. *Cochrane Database Syst Rev* 2012;15.
15 doi:10.1002/14651858.CD005562.pub2
16
17 11 Moniz-Cook E, Vernooij-Dassen M, Woods B, *et al.* Psychosocial interventions in dementia
18 care research: The INTERDEM manifesto. *Aging Ment Health* 2011;15:283–90.
19 doi:10.1080/13607863.2010.543665
20
21 12 McDermott O, Charlesworth G, Hogervorst E, *et al.* Psychosocial interventions for people with
22 dementia: a synthesis of systematic reviews. *Aging Ment Health* Published Online First: 2018.
23 doi:10.1080/13607863.2017.1423031
24
25 13 Clare L, Woods RT. Cognitive training and cognitive rehabilitation for people with early-stage
26 Alzheimer's disease: A review. *Neuropsychol Rehabil* 2004;14:385–401.
27 doi:10.1080/09602010443000074
28
29 14 Graff MJL, Vernooij-Dassen MJM, Thijssen M, *et al.* Community based occupational therapy
30 for patients with dementia and their care givers: randomised controlled trial. *BMJ*
31 2006;333:1196. doi:10.1136/bmj.39001.688843.BE
32
33 15 Vernooij-Dassen M, Olde Rikkert MG. Personal disease management in dementia care. *Int J*
34 *Geriatr Psychiatry* 2004;19:715–7. doi:10.1002/gps.1149
35
36 16 Moniz-Cook E, Manthorpe J, eds. Early Psychosocial Interventions in Dementia. London:
37 Jessica Kingsley Publishers 2008.
38
39 17 Quinn C, Toms G, Anderson D, *et al.* A review of self-management interventions for people
40 with dementia and mild cognitive impairment. *J. Appl. Gerontol.* 2016;35:1154–88.
41 doi:10.1177/0733464814566852
42
43 18 Quinn C, Toms G, Jones C, *et al.* A pilot randomized controlled trial of a self-management
44 group intervention for people with early-stage dementia (The SMART study). *Int*
45 *Psychogeriatr* 2016;28:787–800. doi:10.1017/S1041610215002094
46
47 19 Martin F, Turner A, Wallace LM, *et al.* Qualitative evaluation of a self-management
48 intervention for people in the early stage of dementia. *Dementia* 2015;14:418–35.
49 doi:10.1177/1471301213498387
50
51 20 Clarke CL, Keyes SE, Wilkinson H, *et al.* Healthbridge: The National Evaluation of Peer Support
52 Networks and Dementia Advisers in Implementation of the National Dementia Strategy for
53 England. London: Department of Health 2013.
54
55 21 Chakkalackal L, Kalathil J. Evaluation report: Peer support groups to facilitate self-help coping
56 strategies for people with dementia in extra care housing. London: Mental Health Foundation
57 2014.
58
59
60

- 1
2
3 22 Sprange K, Mountain GA, Shortland K, *et al.* Journeying through Dementia, a community-
4 based self-management intervention for people aged 65 years and over: a feasibility study to
5 inform a future trial. *Pilot Feasibility Stud* 2015;1:42. doi:10.1186/s40814-015-0039-6
6
7 23 Bellg AJ, Resnick B, Minicucci DS, *et al.* Enhancing treatment fidelity in health behavior
8 change studies: Best practices and recommendations from the NIH Behavior Change
9 Consortium. *Health Psychology* 2004;23:443–51. doi:10.1037/0278-6133.23.5.443
10
11 24 National Institute for Health and Care Excellence. Behaviour Change at population,
12 community and individual levels. Public Health Guidance 6. London: NIHCE 2007.
13
14 25 Craig P, Dieppe P, Macintyre S, *et al.* Developing and evaluating complex interventions: new
15 guidance. London: Medical Research Council 2008.
16 <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC004871> (Accessed 28 Sep
17 2018)
18
19 26 ISRCTN Registry. ISRCTN17993825 Journeying through dementia: exploring the clinical and
20 cost-effectiveness of a group self-management intervention for people in the early stages of
21 dementia. 2019. <http://www.isrctn.com/ISRCTN17993825> (accessed 15 Jan 2019)
22
23 27 Alzheimer's Disease International. Participation in dementia trials and studies: Challenges and
24 recommendations. 2014. <https://www.alz.co.uk/sites/default/files/pdfs/dementia-trials.pdf>
25 (accessed 28 Sept 2018)
26
27 28 Herschell AD, Kolko DJ, Baumann BL, *et al.* The role of therapist training in the
28 implementation of psychosocial treatments: A review and critique with recommendations.
29 *Clin Psychol Rev* 2010;30:448–66. doi:10.1016/j.cpr.2010.02.005
30
31 29 Mountain GA, Craig CL. What should be in a self-management programme for people with
32 early dementia? *Aging Ment Health* 2012;16:576–83. doi:10.1080/13607863.2011.651430
33
34 30 Mulhern B, Rowen D, Brazier J, *et al.* Development of DEMQOL-U and DEMQOL-PROXY-U:
35 Generation of preference-based indices from DEMQOL and DEMQOL-PROXY for use in
36 economic evaluation. *Health Technol Assess (Rockv)* 2013;17:1–140. doi:10.3310/hta17050
37
38 31 Smith S, Lamping D, Banerjee S, *et al.* Measurement of health-related quality of life for
39 people with dementia: development of a new instrument (DEMQOL) and an evaluation of
40 current methodology. *Health Technol Assess (Rockv)* 2005;9:1–93.
41 doi:<https://doi.org/10.3310/hta9100>
42
43 32 Herdman M, Gudex C, Lloyd A, *et al.* Development and preliminary testing of the new five-
44 level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–36. doi:10.1007/s11136-011-
45 9903-x
46
47 33 Hounsome N, Orrell M, Edwards RT. EQ-5D as a quality of life measure in people with
48 dementia and their carers: Evidence and key issues. *Value Health* 2011;14:390–9.
49 doi:10.1016/j.jval.2010.08.002
50
51 34 Spitzer RL, Williams JBW, Kroenke K. Test Review: Patient Health Questionnaire-9 (PHQ-9).
52 *Rehabil Couns Bull* 2014;57:246–8. doi:10.1177/0034355213515305
53
54 35 Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a Brief Depression Severity
55 Measure. *J Gen Intern Med* 2001;16:606–13. doi:10.1046/j.1525-1497.2001.016009606.x
56
57 36 Löwe B, Decker O, Müller S, *et al.* Validation and standardization of the generalized anxiety
58
59
60

- 1
2
3 disorder screener (GAD-7) in the general population. *Medical Care* 2008;46:266–74.
4 doi:10.1097/MLR.0b013e318160d093
5
- 6 37 Schwarzer R, Jerusalem M. Generalized Self-Efficacy scale. In: Weinman J, Wright S, Johnston
7 M, eds. *Measures in health psychology: A user's portfolio. Causal and control beliefs.*
8 Windsor: NFER-NELSON 1995. 35–7.
9
- 10 38 Diener E, Wirtz D, Tov W, *et al.* New measures of well-being: Flourishing and positive and
11 negative feelings. In: Diener E, ed. *Social Indicators Research Series.* New York: Springer
12 Science + Business Media 2009. 247–66.
13
- 14 39 De Vries R, Ryan KA, Stanczyk A, *et al.* Public's approach to surrogate consent for dementia
15 research: Cautious pragmatism. *Am J Geriatr Psychiatry* 2013;21:364–72.
16 doi:10.1016/j.jagp.2012.11.010
17
- 18 40 Lawton MP, Brody EM. Assessment of Older People : Self-Maintaining and Instrumental
19 Activities of Daily Living 1. *Gerontologist* 1969;9:179–86. doi:10.1093/geront/9.3_Part_1.179
20
- 21 41 Vernooij-Dassen MJFJ, Persoon JMG, Felling AJA. Predictors of sense of competence in
22 caregivers of demented persons. *Soc Sci Med* 1996;43:41–9. doi:10.1016/0277-
23 9536(95)00332-0
24
- 25 42 Jansen APD, van Hout HPJ, van Marwijk HWJ, *et al.* Sense of competence questionnaire
26 among informal caregivers of older adults with dementia symptoms: A psychometric
27 evaluation. *Clin Pract Epidemiol Ment Health* 2007;3:1–11. doi:10.1186/1745-0179-3-11
28
- 29 43 Moniz-Cook E, Vernooij-Dassen M, Woods R, *et al.* A European consensus on outcome
30 measures for psychosocial intervention research in dementia care. *Aging Ment Heal*
31 2008;1:29. doi:10.1080/13607860801919850
32
- 33 44 Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement : updated guidelines for reporting
34 parallel group randomised trials. *BMJ* 2010;340:332. doi:10.1136/bmj.c332
35
- 36 45 Baldwin SA, Bauer DJ, Stice E, *et al.* Evaluating models for partially clustered designs. *Psychol*
37 *Methods* 2011;16:149–65. doi:10.1037/a0023464
38
- 39 46 Walters SJ. Therapist effects in randomised controlled trials: What to do about them. *J Clin*
40 *Nurs* 2010;19:1102–12. doi:10.1111/j.1365-2702.2009.03067.x
41
- 42 47 Roberts C, Batistatou E, Roberts SA. Design and analysis of trials with a partially nested design
43 and a binary outcome measure. *Stat Med* 2015;35:1616–36. doi:10.1002/sim.6828
44
- 45 48 Kahan BC, Morris TP. Improper analysis of trials randomised using stratified blocks or
46 minimisation. *Stat Med* 2012;31:328–40. doi:10.1002/sim.4431
47
- 48 49 NHS Improvement. Reference Costs 2017/18. 2018.
49 <https://improvement.nhs.uk/resources/reference-costs/> (accessed 15 Jan 2019)
50
- 51 50 Curtis L, Burns A. *Unit Costs of Health & Social Care 2018.* Canterbury: University of Kent
52 2018.
53
- 54 51 Schafer JL. Multiple imputation: A primer. *Stat Methods Med Res* 1999;8:3–15.
55 doi:10.1191/096228099671525676
56
- 57 52 Van Hout BA, Al MJ, Gordon GS, *et al.* Costs, effects and C/E-ratios alongside a clinical trial.
58 *Health Econ* 1994;3:309–19. doi:10.1002/hec.4730030505
59
60

- 1
2
3 53 McHugh ML. Interrater reliability: the kappa statistic. *Biochem Med (Zagreb)* 2012;22:276–82.
4 doi:10.11613/BM.2012.031
5
6 54 Sprange K., Mountain GA, Brazier J, *et al.* Lifestyle Matters for maintenance of health and
7 wellbeing in people aged 65 years and over: study protocol for a randomised controlled trial.
8 *Trials* 2013;14:302. doi:10.1186/1745-6215-14-302
9
10 55 Ritchie J, Spencer L. Qualitative Data Analysis for Applied Policy Research. In: Humberman
11 AM, Miles MB, eds. *The Qualitative Researcher's Companion*. London: SAGE Publications
12 2002. 305–29. doi:10.4135/9781412986274
13
14 56 Cooper C, Ketley D, Livingston G. Systematic review and meta-analysis to estimate potential
15 recruitment to dementia intervention studies. *Int J Geriatr Psychiatry* 2014;29:515–25.
16 doi:10.1002/gps.4034
17
18 57 HRA. GDPR guidance for researchers and study coordinators. London: Health Research
19 Authority (HRA) 2019. [https://www.hra.nhs.uk/planning-and-improving-research/policies-](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/)
20 [standards-legislation/data-protection-and-information-governance/gdpr-guidance/](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/) (accessed
21 18 Jun 2019)
22
23

FIGURE LEGENDS

24
25
26 Figure 1: Participant flow through the study
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

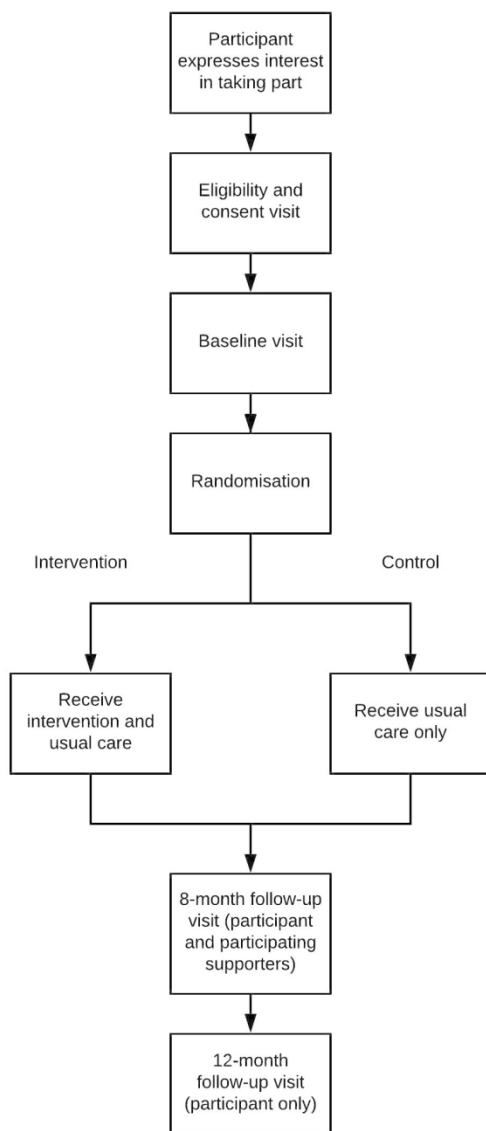


Figure 1 Participant flow through the study

92x190mm (300 x 300 DPI)



STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	_____ i _____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_____ 2 _____
	2b	All items from the World Health Organization Trial Registration Data Set	_____ See 2a _____
Protocol version	3	Date and version identifier	_____ 14 _____
Funding	4	Sources and types of financial, material, and other support	_____ 14 _____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_____ i-ii _____
	5b	Name and contact information for the trial sponsor	_____ 13 _____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_____ n/a _____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_____ 13 _____

1 **Introduction**

2

3 Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention _____ 2-3 _____

4

5

6 6b Explanation for choice of comparators _____ 2-3 _____

7

8 Objectives 7 Specific objectives or hypotheses _____ 3 _____

9

10 Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) _____ 3-4 _____

11

12

13

14 **Methods: Participants, interventions, and outcomes**

15

16 Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained _____ 5 _____

17

18

19 Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) _____ 4-5 _____

20

21

22 Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered _____ 5-6 _____

23

24

25 11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) _____ n/a _____

26

27

28 11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) _____ 8-9 _____

29

30

31 11d Relevant concomitant care and interventions that are permitted or prohibited during the trial _____ 6 _____

32

33

34 Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended _____ 6-7 _____

35

36

37

38

39

40 Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) _____ Table 1 and figure 1 _____

41

42

43

44

45

46

1	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	___9___
2				
3				
4	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	___5___
5				

6 **Methods: Assignment of interventions (for controlled trials)**

7 Allocation:

8				
9				
10	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	___4___
11				
12				
13				
14				
15				
16	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	___4___
17				
18				
19				
20	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	___4___
21				
22				
23				
24	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	___4___
25				
26				
27		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	___4___
28				
29				
30				

31 **Methods: Data collection, management, and analysis**

32				
33	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	___6-8___
34				
35				
36				
37				
38				
39		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	___6-7___
40				
41				
42				

1	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	__12
2				
3				
4				
5	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	___9-11_
6				
7				
8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	__11_
9				
10		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	_10-11__
11				
12				
13				
14	Methods: Monitoring			
15				
16	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	___13_____
17				
18				
19				
20				
21				
22		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_____n/a_____
23				
24				
25	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	___12-13__
26				
27				
28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___12_____
29				
30				
31				
32	Ethics and dissemination			
33				
34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	_____14_____
35				
36				
37	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_____13_____
38				
39				
40				
41				
42				
43				
44				
45				
46				

1	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_____5_____
2				
3				
4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	__See supplementary information__
5				
6				
7				
8	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	___12-13_____
9				
10				
11	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_____14_____
12				
13				
14				
15				
16	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_____12_____
17				
18				
19	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_____n/a_____
20				
21				
22	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_____13_____
23				
24				
25				
26				
27		31b	Authorship eligibility guidelines and any intended use of professional writers	_____n/a_____
28				
29		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____12_____
30				
31	Appendices			
32				
33	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	See supplementary materials_____
34				
35				
36				
37	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____n/a_____
38				
39				
40				

1 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.
2 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons
3 [“Attribution-NonCommercial-NoDerivs 3.0 Unported”](#) license.
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

For peer review only

BMJ Open

A study protocol for a randomised controlled trial assessing the clinical and cost-effectiveness of the Journeying through Dementia (JtD) intervention compared to usual care

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-029207.R2
Article Type:	Protocol
Date Submitted by the Author:	09-Aug-2019
Complete List of Authors:	<p>Wright, Jessica; University of Sheffield, Clinical Trials Research Unit Foster, Alexis; University of Sheffield, School of Health and Related Research Cooper, Cindy; The University of Sheffield, Sheffield Clinical Trials Research Unit, School of Health and Related Research Sprange, Kirsty; The University of Nottingham, Nottingham Clinical Trials Research Unit Walters, Stephen; University of Sheffield, SchARR Berry, Katherine; The University of Manchester, School of Psychological Sciences Moniz-Cook, Esme; The University of Hull, School of Health and Social Work Loban, Amanda; University of Sheffield, School of Health and Related Research Young, Tracey; The University of Sheffield, School of Health and Related Research Craig, Claire; Sheffield Hallam University Denning, Tom; University of Nottingham, Division of Psychiatry & Applied Psychology, School of Medicine Lee, Ellen; University of Sheffield, Clinical Trials Research Unit Beresford-Dent, Julie; University of Bradford, Centre for Applied Dementia Studies Thompson, Benjamin; The University of Sheffield, School of Health and Related Research Young, Emma; The University of Sheffield, School of Health and Related Research Thomas, Benjamin; The University of Sheffield, School of Health and Related Research Mountain, Gail; University of Bradford, Centre for Applied Dementia Studies, Faculty of Health Studies</p>
Primary Subject Heading:	Geriatric medicine
Secondary Subject Heading:	Mental health, Health economics, Qualitative research
Keywords:	Randomised Controlled Trial, Dementia < NEUROLOGY, Research Protocol, Post diagnostic support, Self-management, Well-being

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60



SCHOLARONE™
Manuscripts

TITLE PAGE**Title**

A study protocol for a randomised controlled trial assessing the clinical and cost-effectiveness of the Journeying through Dementia (JtD) intervention compared to usual care

Corresponding author

Jessica Wright
Journeying Through Dementia (JtD) Trial,
Sheffield Clinical Trials Research Unit,
SchHARR, The University of Sheffield,
Regent's Court,
30 Regent St, Sheffield S1 4DA
Telephone: 0114 222 4304
Email: Jessica.wright@sheffield.ac.uk

Author Names/Affiliations

Jessica Wright, Sheffield Clinical Trials Research Unit, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Alexis Foster, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Cindy Cooper, Sheffield Clinical Trials Research Unit, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Kirsty Sprange, Nottingham Clinical Trials Research Unit, The University of Nottingham, Nottingham, UK

Stephen Walters, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Katherine Berry, Manchester Institute for Collaborative Research on Ageing, The University of Manchester, Manchester, UK

Esme Moniz-Cook, School of Health and Social Work, The University of Hull, Hull, UK

Amanda Loban, Sheffield Clinical Trials Research Unit, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Tracey Young, School of Health and Related Research, The University of Sheffield, Sheffield, UK

Claire Craig, Art & Design Research Centre, Sheffield Hallam University, Sheffield, UK

Tom Dening, Division of Psychiatry & Applied Psychology, School of Medicine, University of Nottingham, Nottingham, UK

Ellen Lee, Sheffield Clinical Trials Research Unit, School of Health and Related Research, The University of Sheffield, Sheffield, UK

1
2
3 Julie Beresford-Dent, Centre for Applied Dementia Studies, University of Bradford, Bradford, UK
4

5 Benjamin John Thompson, Sheffield Clinical Trials Research Unit, School of Health and Related
6 Research, The University of Sheffield, Sheffield, UK
7

8 Emma Louise Young, Sheffield Clinical Trials Research Unit, School of Health and Related Research,
9 The University of Sheffield, Sheffield, UK
10

11 Benjamin David Thomas, Sheffield Clinical Trials Research Unit, School of Health and Related
12 Research, The University of Sheffield, Sheffield, UK
13

14 Gail Mountain, Centre for Applied Dementia Studies, Faculty of Health Studies, University of
15 Bradford, Bradford, UK
16
17

18
19
20
21 **Word Count: 6648 (excluding references, abstract, tables and figures)**
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

ABSTRACT

Introduction

Services are being encouraged to provide post diagnostic treatment to those with dementia but the availability of evidence-based interventions following diagnosis has not kept pace with increase in demand. To address this need, the Journeying through Dementia (JtD) intervention was created. A randomised controlled trial (RCT), based on a pilot study, is in progress.

Methods and analysis

The RCT is a pragmatic, two-arm, parallel group trial designed to test the clinical and cost-effectiveness of JtD compared to usual care. Recruitment will be through NHS services, third sector organisations and Join Dementia Research. The sample size is 486 randomised (243 to usual care and 243 to the intervention usual care). Participants can choose to ask a friend or relative (supporter) to become involved in the study. The primary outcome measure for participants is Dementia Related Quality of Life (DEMQOL), collected at baseline and at 8 months' post randomisation. Secondary outcome measures will be collected from participants and supporters at those visits. Participants will also be followed-up at 12 months' post randomisation with a reduced set of measures. A process evaluation will be conducted through qualitative and fidelity sub-studies.

Analyses will compare the two arms of the trial on an intention to treat as allocated basis. The primary analyses will compare the mean DEMQOL scores of the participants at 8 months between the two study arms. A cost-effectiveness analysis will consider the incremental cost per Quality Adjusted Life Years of the intervention compared with usual care. Qualitative and fidelity sub-studies will be analysed through framework analysis and fidelity assessment tools respectively.

Ethics and dissemination

REC and HRA approval were obtained. A Data Monitoring and Ethics Committee has been constituted. Dissemination will be via publications, conferences and social media. Intervention materials will be made open access.

Trial registration number

ISRCTN17993825

STRENGTHS AND LIMITATIONS OF THE STUDY

- People living with dementia were involved in developing the content of the Journeying through Dementia (JtD) intervention and are involved in advising the study.
- The JtD intervention includes sessions without supporters present, to help develop independence and confidence, and is one of the only interventions that people with dementia can participate in without supporters.
- The JtD study will recruit up to 500 participants and is therefore one of the largest trials of a psychosocial intervention for people with dementia in the UK.
- The potential for unblinding of researchers when arranging or attending follow-up visits is a limitation but this will be monitored and minimized by not sending unblind researchers to visits.
- Recruitment is known to be challenging in this population but we plan to try multiple pathways for recruitment including through services, the Join Dementia Research database, promotion and the third sector.

INTRODUCTION

The impact on the economy, for services and for individuals living with dementia and their family carers is larger for dementia than for all other long-term illnesses in people aged 60 and over.[1] Two thirds of people with dementia live in the community, and half of these require some form of support.[2] As a result, dementia research (both for cure and for care) in the NHS and social care is important, and this is reflected in UK health policy.[3] In 2009, the UK Government announced a National Dementia Strategy, which mandated the establishment of memory services and aimed to increase the rates of early diagnosis and improve support for people in the early stages of dementia.[4]

The National Audit of Memory Services (2013) found there had been a fourfold increase in numbers presenting since 2010/11, and in 2013 49.3% were in the early stages of the condition.[5] Earlier diagnosis allows individuals to receive treatment earlier and enables the individual and memory services to plan more effectively for the future.[6] Memory services have been strongly encouraged to provide post diagnostic treatment and support,[7,8] but the availability of appropriate evidence-based interventions has not kept pace with the increase in demand, in particular for those with early stages of dementia. The lack of appropriate interventions has led to inconsistency between Trusts regarding what is being offered to people post diagnosis.

The potential value of psychosocial interventions for people in the early stages of dementia is recognised[9–12] and is also driven by the knowledge that a cure for dementia is unlikely in the near future. Psychosocial interventions are diverse but a common theme is that they do not involve the use of medication and instead focus on supporting people to overcome challenges and maintain independence and well-being. However, whilst there has been some shift, the use of psychosocial interventions within dementia care has been a neglected area for both research and practice.[11]

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).[13–18] A qualitative study

1
2
3 of people with dementia who attended a self-management programme reported that participants
4 identified the opportunity for peer support as being beneficial and considered that the programme
5 could be improved by greater emphasis being placed upon maintaining activities and relationships
6 and improving positive wellbeing.[19] The Healthbridge evaluation[20] and the Mental Health
7 Foundation evaluation[21] found evidence that people with dementia and their carers can benefit
8 from receiving group based peer support.
9

10
11 The Journeying through Dementia (JtD) intervention was developed from the Lifestyle Matters
12 programme and a pilot study was conducted to examine the feasibility of a future population-based
13 larger trial of this intervention.[22] The intervention was found to be acceptable to both people with
14 dementia and their carers. Reported benefits included increased confidence and self-efficacy,
15 engagement in activities and re-engagement with fun and friendships.[22] The intervention is
16 manualised, based on occupational therapy principles, and is designed to support independence and
17 well-being. The intervention incorporates elements of self-management and group-based peer
18 support and has been designed to improve the quality of life for people in the early stages of
19 dementia.
20
21
22
23

24 The JtD randomised controlled trial (RCT) will test the clinical and cost effectiveness of the JtD
25 intervention. Funding was obtained through the National Institute of Health Research (NIHR) Health
26 Technology Assessment (HTA) theme to conduct the RCT. This paper describes the research protocol
27 for undertaking the RCT which started recruitment in November 2016.
28
29

30 **AIMS AND OBJECTIVES**

31
32 The primary aim of the JtD trial is to determine the clinical and cost-effectiveness of the JtD
33 intervention for people in the early stages of dementia. To meet this aim, the objectives are to:
34

- 35 1. Conduct an internal pilot RCT of the intervention to check the feasibility of rates of
36 recruitment at scale.
- 37 2. Proceed to a full a pragmatic RCT evaluating the clinical and cost-effectiveness of the JtD
38 intervention.
- 39 3. Conduct fidelity checks regarding the delivery of the JtD intervention.
- 40 4. Undertake an embedded qualitative sub-study to explore issues concerned with intervention
41 delivery.
- 42 5. Identify how the intervention might be realistically delivered through services.
43
44
45

46 **METHODS**

47 **Trial design**

48
49 The JtD trial is a pragmatic, two-arm, parallel group, individually randomised RCT. It uses a
50 superiority framework to deliver an intention-to-treat comparison of the JtD intervention with usual
51 care.
52
53

54
55 The trial includes three sub-studies. The first is a health economics evaluation using a cost-
56 effectiveness analysis of the incremental cost per Quality Adjusted Life Year (QALY) of the JtD
57 intervention compared with usual care.
58
59
60

1
2
3 The second sub-study is a fidelity assessment as part of the process evaluation, using an intervention
4 fidelity framework based on that identified by the Behaviour Change Consortium and National
5 Institute for Health and Care Excellence (NICE).[23,24]
6
7

8 The third sub-study is a qualitative study, part of the process evaluation, in line with Medical
9 Research Council (MRC) guidance on developing and evaluating complex interventions.[25] The
10 qualitative sub-study will involve semi-structured interviews with participants, supporters,
11 facilitators and supervisors.
12
13

14 **Randomisation, blinding and bias**

15
16 To minimise bias, allocation will be concealed through the use of a centralised web-based
17 randomisation service. The randomisation sequence will be stratified by delivery site and
18 constrained by a fixed block size to ensure participants are allocated evenly to each arm of the trial
19 at each delivery site. Participants will be randomised in equal numbers to intervention and control
20 arms. An unblind member of the research team who will not be conducting outcome assessments
21 will enter the participants' details into the randomisation system and inform the relevant parties of
22 the outcome.
23
24
25

26 Members of the Trial Steering Committee (TSC), study statisticians, health economists and outcome
27 assessors will be blinded to treatment allocation whilst the trial is ongoing. For practical reasons linked
28 to the provision of a centralised web-based randomisation service and the set-up and delivery of the
29 intervention groups, some members of the research team will not be blinded, including the Trial
30 Manager and Chief Investigator. Due to the nature of the intervention, participants will not be blinded.
31 If the outcome assessors know (or suspect) they have been unblinded this will be recorded on an
32 unblinding form.
33
34
35

36 We protect against facilitator bias where the same facilitators also provide usual care in two ways.
37 The first is that usual care is limited and often restricted to NICE recommended cognitive stimulation
38 therapy which would not be readily influenced by training in delivery of JtD, as it follows a detailed
39 and prescriptive session-by-session plan of group exercises which are facilitator-led. Other less
40 common post-diagnostic services include Living Well with Dementia or memory groups, which do
41 contain some features of JtD, but not enactment of learnt skills in the community or the mix of
42 individual and group sessions JtD incorporates. The second way is that a proportion of the facilitators
43 recruited will not deliver usual care, as approximately 25% of facilitators are trained research staff. A
44 further form of bias, that caused by cross-contamination of participants between the two study arms,
45 is considered as unlikely as post diagnostic services for people living with dementia are limited and
46 cognitive stimulation therapy is more likely to be offered later in the dementia trajectory. Extended
47 post diagnostic follow-up is not common so it is unlikely participants from different study arms would
48 meet at routine appointments and discuss involvement.
49
50
51
52
53

54 **Participants**

55
56 Persons with early-stage dementia will be approached to take part in the trial. A family member,
57 friend or neighbour that provides support to the study participant (referred to as the 'supporter')
58 can be approached to take part in the trial, but only if invited to do so by the person with dementia.
59
60

1
2
3 The study participant can also choose not to invite a supporter to take part in the trial and still take
4 part. Participating supporters will automatically be randomised to the same arm as the participant.
5 See Figure 1 for participant flow through the study.
6
7

8 (Insert Figure 1 here)
9

10 **Eligibility criteria**

11
12 Participants will be eligible for the study if they:

- 13 1. have a diagnosis of any form of dementia,
- 14 2. have a Mini Mental State Examination (MMSE) score of 18 or more, measured less than 2
15 months' pre-consent,
- 16 3. have capacity to make informed decisions,
- 17 4. are living in the community in their own or sheltered accommodation (those living in
18 residential or nursing care are not eligible),
- 19 5. are willing to attend the JtD intervention,
- 20 6. are able to converse and communicate in English, and
- 21 7. are not taking part in any other pharmacological or psychosocial intervention studies at the
22 time of enrolment.
23
24
25
26
27

28 Supporters will be eligible to participate if they are aged 18 years or over, are named by the person
29 with dementia as their supporter, the person with dementia wishes them to take part, they can
30 converse and communicate in English, and have the ability to give informed consent.
31
32

33 **Site selection and participant recruitment**

34
35 The JtD trial will operate in England within 13 NHS trusts with specialist dementia services. The sites
36 will be selected based on a convenience sample of locations clustered geographically around the
37 north and midlands (for a list of sites, see study ISRCTN webpage[26]).
38

39
40 Previous studies involving persons with dementia have shown that recruiting participants to such
41 studies can be challenging.[27] To ensure sufficient numbers are recruited to the study a number of
42 recruitment pathways will be used: referral from clinical teams; mail-outs to eligible patients via
43 primary or secondary care clinical teams; study promotion via posters etc.; third sector
44 organisations; and the Join Dementia Research database. The research team will contact interested
45 participants and send further information about the study. Clinical teams will check with the
46 potential participants that they are willing to be approached by the research team before an
47 approach is made.
48
49

50
51 To enable potential participants to make a direct approach to the research team, a reply card will be
52 designed which can be completed, sealed and returned to the central research team who will then
53 pass the information on to relevant local site researchers. These reply cards will be distributed with
54 information sheets at events including dementia cafes or posted as part of mail-outs to GPs. Local
55 promotions, for example via posters in clinics or GPs, will include the telephone and email details of
56 local researchers for direct contact to take place.
57
58
59
60

1
2
3 A consent and eligibility visit will be arranged if an individual would like to take part where trained
4 researchers will assess eligibility and request written informed consent.
5

6 **Intervention**

7
8 JtD is a manualised intervention consisting of twelve weekly facilitated groups with 8-12 participants
9 with dementia, which take place over successive weeks. Each participant also receives four one-to-
10 one sessions with one of the intervention facilitators, to pursue individual goals. The first one-to-one
11 session takes place before the start of the group intervention, with the remaining three being
12 scheduled during the 12 weeks and at locations and times agreed with the participant. The group
13 aspect of intervention should be delivered in a community venue.
14
15

16
17 The content of the JtD intervention involves:
18

- 19 a. Ways of thinking about dementia (what is dementia, effects on everyday life, challenging
20 stereotypes, sharing coping strategies).
- 21 b. Keeping physically well (relationship between physical and mental wellbeing, embedding
22 health activity in everyday life, diet).
- 23 c. Memory (strategies to aid memory, impact on everyday life and learning and practicing new
24 techniques).
- 25 d. Keeping mentally well (relationships between anxiety and memory, and dementia and
26 stress).
- 27 e. Endings (celebration of achievements and how to move forward).
28
29
30
31

32 Participants are encouraged to select different topics from the manualised intervention and explore
33 them with guidance and suggestions from facilitators. Participants are also able to suggest topics not
34 within the manual. One essential component of the intervention is the enactment of activities,
35 particularly in the community; three of the twelve group meetings should be 'out of venue'
36 activities. Participants are able to invite a supporter to participate in the group aspect of the
37 intervention during sessions 1, 6 and 12, and in the individual sessions if the participant finds this
38 helpful in achieving their goals.
39
40

41 The intervention should be facilitated by a minimum of two NHS staff who are experienced with
42 working with people with dementia. Facilitators will normally be someone employed on Agenda for
43 Change Bands 3-5. Facilitators must receive a two-day training course prior to delivering the
44 intervention. In some cases, for example if they are a reserve facilitator, they may receive a
45 shortened course supported by online resources created for this purpose. Facilitators will be
46 supervised by a colleague experienced in supervision who has also attended the facilitator training
47 and is of suitable seniority and experience. The supervisors themselves will be supervised by a
48 member of the central study team who is a Clinical Psychologist and is experienced in the 'train the
49 trainer' method[28].
50
51
52
53

54 **Patient and public involvement (PPI)**

55
56 People living with dementia were involved in developing the content of JtD[29] and in the feasibility
57 study.[22] The JtD Trial Steering Committee will include a member who is living with dementia.
58 Additionally, an advisory group of people living with dementia (experts by experience) will meet at
59
60

1
2
3 intervals throughout to provide input into study materials. We also plan to involve people living with
4 dementia in some aspects of the qualitative data analysis and in creating and delivering the study
5 dissemination plans.
6
7

8 **OUTCOMES**

9
10 Outcomes were identified through a feasibility study which identified appropriate measures and
11 tested their application.[22] The burden of questionnaires was found to be acceptable.
12

13
14 The primary outcome is the Dementia Related Quality of Life (DEMQOL)[30,31] measure at 8 months
15 post randomisation.
16

17 The secondary outcomes are:

- 18 – European Quality of Life - 5 Dimensions (EQ-5D-5L)[32,33]
- 19 – Patient Health Questionnaire-9 (PHQ-9)[34,35]
- 20 – Generalised Anxiety Disorder-7 (GAD-7)[36]
- 21 – General Self-Efficacy Scale (GSE)[37]
- 22 – Diener's Flourishing Scale (DFS)[38]
- 23 – Self-Management Ability Scale (SMAS)[39]
- 24 – Instrumental Activities of Daily Living (IADL)[40]
- 25 – Health and Social Care Resource Use Questionnaire (HSCRU)[22]
- 26 – Sense of Competency Questionnaire (SCQ)[41],[42]

27
28 See Table 1 (below) for further information on who completes which measures in the study. The
29 outcome measures used were selected to measure the following key components of the
30 intervention: mental wellbeing or mood (DEMQOL, PHQ-9, GAD-7); building relationships and a
31 sense of connectedness (DFS, SMAS); self-management (SMAS); belief that life is meaningful despite
32 dementia (DEMQOL, GSE, DFS, SMAS); and Instrumental Activities of Daily Living (IADL) and
33 strategies to maintain cognitive functioning (IADL). Additionally, they also support analysis of the
34 cost-effectiveness of the intervention (DEMQOL, EQ-5D-5L, HSCRU) and the participating supporters'
35 perceptions of competence (SCQ). Dementia specific outcome measures are those recommended
36 for use across Europe and are selected for self rather than proxy completion.[43] Non dementia
37 specific outcome measures were selected if there was no appropriate dementia specific measure
38 available.
39
40
41
42
43
44

45 **DATA COLLECTION**

46 **Quantitative**

47
48 Data will be collected from all participants living with dementia at eligibility/consent, baseline, 8 and
49 12 months post randomisation and from consented participating supporters at baseline and 8
50 months' post randomisation (see Table 1). There is a reduced set of measures linked to the 12
51 month visit as we require limited further information on quality of life and health and social care
52 resource use at that time-point; the key outcome point is at 8 months. The outcome measures will
53 be interviewer-administered at face-to-face visits by blinded outcome assessors who have received
54 training to deliver the measures to people living with dementia and their supporters. The follow-up
55 outcome measures will be collected 2 weeks pre and 8 weeks post the date they are due. Participant
56
57
58
59
60

retention will be promoted by regular communication with the participants and supporters through communication including newsletters and Christmas cards.

Table 1 Outcome measures and time-points for collection. * Denotes the primary outcome measure.

Measure	Participant				Participating Supporter	
	Eligibility and Consent visit	Baseline <2 months prior to the intervention start date	8 Months Due < 2 weeks pre and < 8 weeks post randomisation	12 Months Due < 2 weeks pre and < 8 weeks post randomisation if within study timelines	Baseline Due <2 months prior to the intervention	8 Months Due < 2 weeks pre and < 8 weeks post randomisation
Capacity assessment	✓					
Mini Mental State Examination	✓					
Eligibility checklist	✓				✓	
Baseline demographics	✓				✓	
DEMQOL		✓	✓*	✓		
EQ-5D-5L		✓	✓	✓	✓	✓
PHQ-9		✓	✓		✓	✓
GAD-7		✓	✓			
GSE		✓	✓			
DFS		✓	✓			
SMAS		✓	✓			
IADL		✓	✓	✓		
HSCRU			✓	✓		
SCQ					✓	✓

Visits to collect outcome data will be arranged with the participant by a researcher, in some cases a participating supporter will assist with these arrangements. All visits will be conducted at a time and location most suitable for the participant. When we conduct the follow-ups we will prioritise the importance of the measures in case the participant tires. We will offer a second visit if the participant is tired or otherwise unable to complete the assessments, which will be organised as soon as possible after the first. Participating supporters may not have the time or capacity to receive a face-to-face visit and follow-up outcome measures may therefore be collected from them over the telephone. Similarly, if a participant does not want a visit, a reduced set of outcome measures may be taken by telephone (prioritising collection of DEMQOL and telephone versions of HSCRU and EQ-5D-5L).

Intervention attendance

Records will be kept of all attendances for each participant randomised to the intervention.

Intervention dropout and study withdrawal

1
2
3 If a participant decides to withdraw either from the intervention or the study, this will be recorded.
4 If the participant just withdraws from the intervention, they will be followed-up unless they explicitly
5 also withdraw consent for follow-up meetings for collection of outcomes (data up to this time will be
6 included in the trial). If the participant fully withdraws from the study no further data will be
7 collected.
8
9

10 Intervention costings

11
12 Information on the cost of facilitated group and individual sessions will be collected including hire of
13 local community venues, facilitator salaries and travel, refreshments, and other costs such as
14 administration and materials used.
15
16

17 **SAMPLE SIZE**

18
19 The primary outcome for the study is the mean DEMQOL score 8 months post randomisation.
20 Assuming a standard deviation of 11 points for the DEMQOL, a mean difference of 4 or more points
21 is clinically and practically important.[30] The sample size has been calculated to have a 90% power
22 of detecting this 4 point difference (equivalent to a standardised effect size of 0.36) in group mean
23 scores at eight months as being statistically significant at 5% (two sided) level. As the JtD
24 intervention is a facilitator led intervention with a group component, the outcomes of the
25 participants in the same group with the same facilitators may be clustered. With no adjustment for
26 clustering by facilitator the target sample size would be 160 per arm with a total sample size of 320.
27 We have assumed an average cluster size of 8 people with dementia per facilitated group and an
28 intra-cluster correlation of 0.03; this will inflate the sample size by a design effect of 1.21; to 194 per
29 group (388 total sample size) with valid primary outcome data. Assuming at least a 20% loss to
30 follow-up the target sample size for the trial is to randomise to 243 participants in each arm (n=486).
31
32
33
34
35

36 **DATA ANALYSIS**

37 **Statistical data analysis**

38
39 As JtD is a pragmatic parallel group randomised trial, with a usual care (control) arm, data will be
40 reported and presented according to a revised CONSORT statement.[44] Statistical analysis will be
41 performed on an intention-to-treat-basis. All exploratory tests will be two-tailed with $\alpha = 0.05$.
42 Baseline demographics and quality of life data will be described and summarised overall and by
43 treatment group.
44
45
46

47 The primary analysis will compare mean patient reported DEMQOL scores at 8 months post
48 randomisation between the intervention (JtD) arm and control arms using a mixed effects linear
49 regression model adjusted for DEMQOL baseline score and site and allowing for the clustering of the
50 outcome by the JtD intervention.[45–47] The trial is a partially nested design with comparison of a
51 group therapy (JtD) with individual therapy with clustering in one (intervention) arm. Each person
52 with dementia in the control group (unclustered arm) will be treated as a cluster (singleton) of size
53 one. The cluster indicator will be treated as a random effect. A stratification variable used for
54 randomisation (site) will be included as a fixed factor.[48] A partially clustered mixed effects linear
55 regression model with homoscedastic errors as well as a heteroscedasticity mixed effects linear
56 regression model will also be considered to account for potential differential variability of outcomes
57 between the two treatment groups. A 95% confidence interval (CI) for the mean difference in
58
59
60

1
2
3 DEMQOL scores between the intervention and control groups will be calculated together with the
4 associated P-value. A further adjusted analysis may also be performed depending on the observed
5 degree of imbalance in baseline covariates (which are of potential prognostic importance) again
6 using a mixed effects linear regression model. Additional covariates (of potential prognostic
7 importance) include other baseline variables, such as age, gender, PHQ-9, and GAD-7. In the event
8 that there are more than 10 couples (20 participants) living under the same roof from different
9 households in the study, then the primary and secondary analyses will be changed to take into
10 account the hierarchical or clustered nature of the data. A multi level mixed effects model will be
11 used; the random effects will be JtD intervention groups (top level) and couple/singles (lower level).
12 Individual participants who are not part of a couple will be treated as clusters of size one.
13
14

15
16
17 Participants will be followed up for up to 12 months post randomisation. Mean DEMQOL scores at
18 12 months follow-up will be compared as described for the primary outcome above.
19

20 For the primary outcome, the DEMQOL score at 8 months follow-up, missing data will be imputed
21 through a variety of methods including: regression and multiple imputation as part of a sensitivity
22 analysis.
23

24
25 We will complement the intention to treat (ITT) analysis of the primary outcome with a complier
26 average causal effects analysis (CACE) as a secondary analysis alongside the primary ITT analysis.
27 Compliance will be defined as a binary variable with participants who attend at least 10 of the 16 JtD
28 sessions (both individual and group sessions combined) regarded as being compliant.
29

30
31 There are no planned interim statistical analyses or formal stopping rules in relation to efficacy.
32

33 In terms of missing data, the primary analysis will be performed based on participants with available
34 8 month primary outcome data. Sensitivity analysis on the primary outcome will include multiple
35 imputation using chained equations and regression imputation.
36

37 Secondary outcome measures

38
39
40 Secondary outcomes at 8 and 12 months post-randomisation will be compared between the
41 intervention and control groups using a mixed effects linear regression model as for the primary
42 outcome. A 95% CI for the mean difference in this parameter between the treatment groups will
43 also be calculated together with the associated P-value.
44

45
46 Outcome measures for the participating supporters at 8 months will be compared between the
47 intervention and control groups using a mixed effects linear regression model. The mean difference
48 in outcome with associated 95% CI and P-value will be presented for: a) the baseline (specific to the
49 secondary outcome) and site adjusted analysis and b) adjusted analysis with additional covariates in
50 addition to a).
51

52 Subgroup analysis

53
54
55 A subgroup analysis using a mixed effect linear regression model, with the primary outcome
56 (DEMQOL) at 8 months post randomisation as the response will be carried out. We will use an
57 interaction statistical test between the randomised intervention group and subgroup to directly
58 examine the strength of evidence for the treatment difference between the treatment groups
59
60

1
2
3 varying between subgroups. Supporter involvement (yes or no) will be the only a priori defined sub
4 groups to be considered for interaction test.
5
6
7

8 **HEALTH ECONOMICS EVALUATION**

9
10 A trial based economic evaluation will be undertaken of an intention-to-treat comparison of the
11 costs and outcomes of the two trial arms. A cost-effectiveness analysis will be undertaken of the
12 incremental cost per Quality Adjusted Life Year (QALYs) of the JtD intervention compared with usual
13 care provided through NHS memory services. QALYs will be calculated using the EQ-5D-5L
14 preference-based index administered at baseline, 8 and 12 months. A sensitivity analysis will be
15 undertaken using utility values from the DEMQOL-U, which can be derived from responses to the
16 DEMQOL questionnaire.[30] The total cost of the intervention will be estimated at the individual
17 participant level and will include the costs of providing the intervention and the subsequent
18 consequences for the use of routine health and social care services. The average cost per attendance
19 will be calculated and this estimate will be applied to the actual number of group and individual
20 sessions that each participant attended.
21
22
23
24

25 The use of services by trial participants will be collected in detail using a Health and Social Care
26 Resource Use (HSCRU) questionnaire administered at 8 and 12 months post randomisation. Service
27 use will be costed using the most recent National Reference Cost Data and Unit Costs of Health and
28 Social Care.[49,50] Missing data will be dealt with using multiple imputation for EQ-5D-5L, DEMQOL-
29 U and resource use data.[51] A random effects linear regression model, accounting for clustering,
30 will be fitted, the model will include baseline scores for EQ-5D-5L and baseline costs. The central
31 analysis of mean incremental costs per QALY will be subjected to a full sensitivity analysis of key
32 parameters including the measure used to estimate QALYs and number of participants at the weekly
33 sessions. A full probabilistic sensitivity analysis will be performed to examine the probability of cost-
34 effectiveness of the intervention for the NHS for different levels of costs and QALY gains.[52]
35
36
37
38

39 **PROCESS EVALUATION**

40
41 The process evaluation has been designed to: 1) examine the factors that may influence the fidelity
42 of intervention delivery and 2) explore its perceived impact and acceptability from user and provider
43 perspectives. There are two strands to this, the fidelity assessment and qualitative interviews,
44 explained below.
45
46

47 **Fidelity assessment**

48
49 The fidelity of intervention delivery, as well as of the training and supervision received by facilitators
50 will be assessed on the basis of criteria derived from the intervention protocol and manual. Fidelity
51 checks will adhere to a framework based on that identified by the Behaviour Change Consortium[23]
52 and NICE guidance on behaviour change.[24] The fidelity assessment framework (adapted from Bellg
53 et al, 2004[23]) will assess and monitor for the consistency, facilitator training (in terms of
54 standardised delivery of training and skills acquisition for facilitators), intervention delivery (in terms
55 of standardised delivery between intervention groups) and the receipt of the intervention by
56 intervention group participants.
57
58
59
60

1
2
3 Training delivery and receipt of the facilitator training will be observed and rated by the same two
4 researchers (the lead for fidelity and one other member of the research team) for inter-rater
5 reliability using a bespoke *Training observation checklist*. To assess facilitator adherence to the
6 manualised intervention and participant receipt of the intervention, a purposive selection of group
7 meetings across sites will also be observed using a *Group observation checklist* which is based on the
8 contents of the intervention and the training. Each selected group will be observed on two occasions
9 to identify facilitator drift or changes in participant behavior.
10
11

12
13 Frequencies will be used to determine the extent to which the training programme received by
14 facilitators maintained fidelity to what was intended. Data will also be analysed to compare
15 intervention delivery between and across sites to check for consistency. Inter-rater reliability
16 between coders will be determined using the Kappa statistic.[53] Similar methods have been used in
17 previous studies.[54]
18
19

20 21 **Qualitative interviews**

22
23 An embedded qualitative sub-study will explore the mechanisms of the intervention, for example
24 what elements of the intervention appear to support people to improve their self-management and
25 well-being and what promotes good facilitation of the intervention.
26
27

28 Individual qualitative semi-structured interviews will be conducted with a purposive sample of 20
29 participants (approximately 10%) from the intervention groups observed in the fidelity sub-study
30 and with approximately 12 participating supporters, preferably supporters of participants who are
31 also being interviewed. A participant interview schedule and supporter interview schedule will be
32 developed to cover the following themes:
33
34

- 35 – Range and nature of issues that influence experiences of taking part in the intervention
- 36 – Factors that may influence the effectiveness, adoption and diffusion of this innovation in the
- 37 future
- 38 – Perceived skills and competencies required to facilitate the intervention
- 39 – The barriers and facilitators to uptake and continued use
- 40 – The effect of the intervention upon living with dementia
- 41 – The effect of the intervention upon the experiences of supporting someone with dementia
- 42
- 43
- 44

45 Semi-structured interviews will also be conducted with approximately 20% of all facilitators and
46 supervisors across the sites upon completion of their delivery of the intervention. The sample will
47 include a range of sites and facilitators with different levels of experience of delivering the
48 intervention. A facilitator interview schedule and supervisor interview schedule will be created to
49 cover the following themes:
50
51

- 52 – What issues promote the effectiveness of intervention facilitation
- 53 – The skills and competencies required to facilitate the programme
- 54 – The barriers and facilitators to its uptake and continued use
- 55 – Factors that may mediate or moderate the effectiveness of the intervention
- 56
- 57
- 58

59 Researchers undertaking participant interviews will be trained to use enhanced methods of
60 communication with people with dementia to try to ensure that meaningful discussion takes place.

1
2
3 Transcripts of interviews will undergo respondent validation.
4
5

6 Qualitative analysis 7

8 Framework analysis[55] will be applied to all interview data.[56] For the purposes of reporting,
9 confidentiality will be maintained by using unique participant identifiers and removing identifiable
10 information. A thematic framework will be agreed by two researchers and an index developed for
11 transcript coding. This will follow the five stages of framework analysis.[55] Findings will be used to
12 identify emergent factors that influence the uptake and impact of the intervention as well as explore
13 potential explanations for the quantitative findings.[56] Further analysis will also be undertaken to
14 triangulate the qualitative data (between facilitator/supervisor and participant/supporter
15 interviews) as well as the fidelity and qualitative data in order to look for between source similarities
16 and divergences. Analysis workshops will be held with people living with dementia and their
17 supporters to respond to and help validate the initial qualitative analysis. The workshop outcomes
18 will be used to refine the qualitative analysis.
19
20
21
22
23

24 **DATA MANAGEMENT, CONFIDENTIALITY AND SHARING** 25

26 Sheffield Clinical Trials Research Unit (CTRU) will provide data management services. Data will be
27 entered remotely on to a centralised web-based data capture system (Prospect) by university
28 researchers and authorised staff at participating NHS sites. The Case Report Form captures trial data
29 and has been specifically designed for this trial. Access to Prospect is controlled by usernames and
30 encrypted passwords. Prospect provides a full electronic audit trail, as well as validation features
31 which will be used to monitor study data quality. The identity of participants will be protected by the
32 removal of any identifiable data prior to dissemination of information, and no identifiable data will
33 be transferred to the statistician or health economist. All participating NHS Sites will be subject to
34 data monitoring reviews to check data entry, consent and eligibility, amongst other items. The trial
35 follows the UK Health Research Authority guidance on the General Data Protection Regulation[57]
36 and has implemented a privacy policy and transparency information appropriate to people living
37 with dementia.
38
39
40
41
42

43 **Data sharing** 44

45 JtD trial data will be held and available for five years after the end of the trial (November 2019). JtD
46 Trial Data will not be archived in a repository, instead data will be released on a case-by-case basis.
47 We shall make data available to the scientific community with as few restrictions as feasible. Data
48 access requests will be reviewed and authorised by a sub-committee of the Trial Management Group
49 (TMG) during the trial and by the Sheffield CTRU after the trial has ended. Access requests will be
50 considered against pre-determined criteria and data sharing will only take place if this aligns with the
51 consent provided by JtD participants. Data will be anonymised prior to being shared.
52
53
54

55 **ETHICS, GOVERNANCE AND SAFETY** 56

57 **Ethical issues** 58 59 60

1
2
3 There are two key ethical issues to take into account. The first is the potential need to break
4 confidentiality where there is a risk of harm. We will request consent to contact the participant's or
5 supporter's GP, or other health professional, in situations where researchers are concerned that
6 there might be risk of harm. For example, two outcome measures used on the study may indicate a
7 need to clinically treat anxiety (GAD-7) or depression (PHQ-9). Additionally, concerns regarding
8 participant safety may also be raised at any stage of the study; e.g. observed deterioration in mental
9 or physical state of participants, safeguarding issues, or of a risk to self or others. We will work
10 alongside local Trust procedures to report any risks appropriately. Local site investigators with
11 clinical backgrounds will be asked to provide advice when appropriate. The responsible healthcare
12 professional or relevant PI will be able to recommend the withdrawal of the participant if they feel it
13 is appropriate. We will record all actions taken.
14
15
16
17

18 The second is the risk that during the trial, people with dementia may lose the capacity to consent to
19 continuing participation. As part of the consent process, people with dementia will be asked to
20 nominate a person to act as a consultee we may contact in the event that they lose capacity during
21 the trial. The consultee will be independent from the study and can be a relative, friend or medical
22 professional. All researchers will be provided with guidance and local training on identifying and
23 dealing with capacity issues identified before or during 8 and 12 month follow-up visits. If at any
24 point the participant indicates they do not wish to continue to take part in the trial, they will be
25 withdrawn. If the person with dementia loses capacity during the trial, but indicates they wish to
26 remain in the study, the consultee will be asked to make a judgement, based on their existing and
27 pre-existing knowledge of the person with dementia, about whether they would want to continue
28 participation or not. If the consultee advises that the participant would wish to be withdrawn, the
29 researchers will withdraw them from the study. If the consultee advises that the participant would
30 wish to stay taking part, even though they lack capacity, every effort will be made to accommodate
31 this, for example by reducing the number of outcome measures, or using prompts or other means to
32 help the participant complete the measures. We will record information about the activation of the
33 consultee pathway on the trial.
34
35
36
37
38
39

40 **Governance**

41 The trial is coordinated by the Sheffield CTRU on behalf of the Sponsor. The sponsor of the trial is
42 Sheffield Health and Social Care Foundation Trust, Fulwood House, Old Fulwood Road, Sheffield, S10
43 3TH. The JtD TMG contains project co-applicants, members of the data management team, the
44 Sponsor, Trial Manager and other representatives, and oversees the operation of the trial and
45 enables communication throughout the Trial, for example to disseminate protocol amendments. An
46 independent Trial Steering Committee (TSC), comprised of an independent statistician, PPI
47 representative and a Senior Clinical Research Associate, provides overall supervision of the trial,
48 advises the CI, oversees protocol modifications, monitors the trial's progress and if necessary closes
49 the trial. An independent Data Monitoring and Ethics Committee (DMEC) comprised of two
50 independent statisticians and an Occupational Therapist Clinical Researcher, reviews the trial
51 protocol, monitors patient safety and advises the TSC if they feel the trial should be prematurely
52 closed.
53
54
55
56
57

58 **Safety**

59
60

1
2
3 A Serious Adverse Event (SAE) reporting system will be used on the Trial. Non-serious adverse Events
4 are not anticipated as a consequence of the intervention and will not be monitored. An SAE either:
5

- 6
7 a) results in death,
8 b) is life-threatening (subject at immediate risk of death),
9 c) requires hospitalisation or prolongation of existing hospitalisation,
10 d) results in persistent or significant disability or incapacity, or
11 e) is otherwise considered medically significant by the investigator.
12

13
14 All SAEs will be assessed to see if they are related to the intervention or other trial procedures, and if
15 they are the Sponsor and Research Ethics Committee will be immediately informed. SAEs are
16 periodically reported to the trial's DMEC.
17

18
19 Additionally, we consider safety of the researchers to be extremely important and have developed a
20 lone worker policy. The researcher must complete a form detailing information about any
21 participant visits and their contact information and provide this to a 'buddy' who will ensure the
22 safety of the researcher. The researcher must check in with the buddy before and after a visit
23 finishes or the buddy will follow escalation procedures. Check-lists provide guidance on what to do
24 before and during the visits, for example ensuring phones are fully charged and being prepared to
25 leave in an emergency if there are concerns about safety. A phrase is provided to enable the
26 researcher to report an emergency during the visit. Guidance is provided for general safe travelling,
27 for example to keep to well-lit paths and driveways.
28
29

30 31 **DISSEMINATION**

32
33 The results of this study will be communicated in relevant academic and professional journals,
34 conferences and workshops, and via websites and social media, ensuring reach to all stakeholders
35 (people living with the condition, professionals, commissioners and academics). A short film will be
36 created to illustrate experiences of participation from the perspectives of people living with the
37 condition, and those involved in delivery of the intervention. The manualised intervention will be
38 refined and made available on the website in an open access format and it is anticipated that this
39 may be of interest to both primary care and memory services.
40
41

42 43 **STUDY STATUS**

44
45 At the time of submitting for publication the study was collecting data. At the time of publication the
46 study is approaching database lock.
47

48 49 **AUTHOR CONTRIBUTIONS**

50
51 GM, AF, CCo, KS, EL, SW, TY, CCr, EMC, AL, TD and KB co-wrote the original Trial Protocol. JW led the
52 development of the Protocol for publication. JBD and KS developed the sections on fidelity and
53 qualitative analysis. JBD developed the section on PPI. BDT adapted the introductory section, BJT the
54 methods section, EY the outcomes section and EL the statistical analysis section. All authors
55 contributed to reviewing and revising the draft versions prior to submission.
56
57

58 59 **ACKNOWLEDGEMENTS**

60

We would like to thank the following people for assisting with the original project application: Martin Orrell, Institute of Mental Health, The University of Nottingham; Daniel Blackburn, Sheffield Institute for Translational Neuroscience, The University of Sheffield; and Diana Papaioannou, Sheffield Clinical Trials Research Unit, School of Health and Related Research, The University of Sheffield.

Additionally, we would like to thank Peter Bowie, Old Age Psychiatry, Sheffield Health and Social Care NHS Foundation Trust, Sheffield, for advising on clinical aspects; and Nicholas Bell, Sheffield Health and Social Care NHS Foundation Trust, for acting on behalf of the sponsor and advising on trial procedures.

FUNDING STATEMENT

This study was funded by the NIHR Health Technology Assessment Programme (project number 14/140/80). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

COMPETING INTERESTS

All authors, with the exception of those below, declare no competing interests.

- SW, TY, CCo, JW, AF, AL, EL, BJT, BDT, EY as SchARR has contracts and/or research grants with the Department of Health, NIHR, MRC and NICE.
- SW, CCo and TY are co-applicants or co-investigators on NIHR portfolio grants (NIHR Research Design Service for Yorkshire and Humber; HTA, RfPB, PHR; SDO) and grants from the MRC.
- SW and TY also receive external examining fees from various UK higher education institutes.
- SW receives book royalties from publishers including John Wiley and Sons Ltd and Blackwell Publishing.
- BDT is a Consultant for Arch research in the area of dementia.

ETHICS APPROVAL

This study was approved by Leeds East Research Ethics Committee, on 01/07/16, reference number 16/YH/0238. Health Research Authority approval was provided for the study to commence on 25/08/16. The current Protocol version is v7, 5th December 2018.

REFERENCES

- 1 World Health Organisation. The global burden of disease: 2004 update. Geneva: World Health Organisation 2008.
- 2 Knapp M, Comas-Herrera A, Somani A, *et al*. Dementia: international comparisons – summary report to the National Audit Office. London: London School of Economics 2007.
- 3 Department of Health. Prime Minister’s challenge on dementia 2020. London: Department of Health 2015.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/406076/Dementia_vision.pdf (accessed 26 Sep 2018)

- 1
2
3 4 Department of Health. Living well with dementia : A National Dementia Strategy. London: Department of Health 2009. <https://www.gov.uk/government/publications/living-well-with-dementia-a-national-dementia-strategy> (accessed 26 Sep 2018)
- 7 5 Hodge AS, Hailey E. English National Memory Clinics Audit Report. London: Royal College of Psychiatrists 2013. [http://www.rcpsych.ac.uk/pdf/English National Memory Clinics Audit Report 2013.pdf](http://www.rcpsych.ac.uk/pdf/English%20National%20Memory%20Clinics%20Audit%20Report%202013.pdf) (accessed 30 Oct 2018)
- 11 6 Banerjee S, Wittenberg R. Clinical and cost effectiveness of services for early diagnosis and intervention in dementia. *Int J Geriatr Psychiatry* 2009;24:748–54. doi:10.1002/gps.2191
- 15 7 Copland E, Hodge S, Clary L, *et al*. Memory Services National Accreditation Programme (MSNAP): Standards for memory services. London: Royal College of Psychiatrists 2018. https://www.rcpsych.ac.uk/pdf/MSNAP_Standards_6_Edition_2018.pdf (accessed 16 Oct 2018)
- 21 8 NHS England. Well Pathway for Dementia. 2017. <https://www.england.nhs.uk/mentalhealth/wp-content/uploads/sites/29/2016/03/dementia-well-pathway.pdf> (accessed 30 Oct 2018)
- 25 9 National Institute for Health and Clinical Excellence. Donepezil, galantamine, rivastigmine, and memantine for the treatment of Alzheimer’s Disease. London: NIHC 2011. <http://www.nice.org.uk/guidance/ta217/resources/guidance-donepezilgalantaminerivastigmineandmemantine-for-the-treatment-of-alzheimers-disease-pdf> (accessed 26 Sep 2018)
- 31 10 Woods B, Aguirre E, Spector AE, *et al*. Cognitive stimulation to improve cognitive functioning in people with dementia. *Cochrane Database Syst Rev* 2012;15. doi:10.1002/14651858.CD005562.pub2
- 35 11 Moniz-Cook E, Vernooij-Dassen M, Woods B, *et al*. Psychosocial interventions in dementia care research: The INTERDEM manifesto. *Aging Ment Health* 2011;15:283–90. doi:10.1080/13607863.2010.543665
- 39 12 McDermott O, Charlesworth G, Hogervorst E, *et al*. Psychosocial interventions for people with dementia: a synthesis of systematic reviews. *Aging Ment Health* Published Online First: 2018. doi:10.1080/13607863.2017.1423031
- 43 13 Clare L, Woods RT. Cognitive training and cognitive rehabilitation for people with early-stage Alzheimer’s disease: A review. *Neuropsychol Rehabil* 2004;14:385–401. doi:10.1080/09602010443000074
- 47 14 Graff MJL, Vernooij-Dassen MJM, Thijssen M, *et al*. Community based occupational therapy for patients with dementia and their care givers: randomised controlled trial. *BMJ* 2006;333:1196. doi:10.1136/bmj.39001.688843.BE
- 51 15 Vernooij-Dassen M, Olde Rikkert MG. Personal disease management in dementia care. *Int J Geriatr Psychiatry* 2004;19:715–7. doi:10.1002/gps.1149
- 55 16 Moniz-Cook E, Manthorpe J, eds. Early Psychosocial Interventions in Dementia. London: Jessica Kingsley Publishers 2008.
- 59 17 Quinn C, Toms G, Anderson D, *et al*. A review of self-management interventions for people with dementia and mild cognitive impairment. *J Appl Gerontol*. 2016;35:1154–88. doi:10.1177/0733464814566852

- 1
2
3 18 Quinn C, Toms G, Jones C, *et al.* A pilot randomized controlled trial of a self-management
4 group intervention for people with early-stage dementia (The SMART study). *Int*
5 *Psychogeriatr* 2016;28:787–800. doi:10.1017/S1041610215002094
6
7 19 Martin F, Turner A, Wallace LM, *et al.* Qualitative evaluation of a self-management
8 intervention for people in the early stage of dementia. *Dementia* 2015;14:418–35.
9 doi:10.1177/1471301213498387
10
11 20 Clarke CL, Keyes SE, Wilkinson H, *et al.* Healthbridge: The National Evaluation of Peer Support
12 Networks and Dementia Advisers in Implementation of the National Dementia Strategy for
13 England. London: Department of Health 2013.
14
15 21 Chakkalackal L, Kalathil J. Evaluation report: Peer support groups to facilitate self-help coping
16 strategies for people with dementia in extra care housing. London: Mental Health Foundation
17 2014.
18
19 22 Sprange K, Mountain GA, Shortland K, *et al.* Journeying through Dementia, a community-
20 based self-management intervention for people aged 65 years and over: a feasibility study to
21 inform a future trial. *Pilot Feasibility Stud* 2015;1:42. doi:10.1186/s40814-015-0039-6
22
23 23 Bellg AJ, Resnick B, Minicucci DS, *et al.* Enhancing treatment fidelity in health behavior
24 change studies: Best practices and recommendations from the NIH Behavior Change
25 Consortium. *Health Psychology* 2004;23:443–51. doi:10.1037/0278-6133.23.5.443
26
27 24 National Institute for Health and Care Excellence. Behaviour Change at population,
28 community and individual levels. Public Health Guidance 6. London: NIHC 2007.
29
30 25 Craig P, Dieppe P, Macintyre S, *et al.* Developing and evaluating complex interventions: new
31 guidance. London: Medical Research Council 2008.
32 <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC004871> (Accessed 28 Sep
33 2018)
34
35 26 ISRCTN Registry. ISRCTN17993825 Journeying through dementia: exploring the clinical and
36 cost-effectiveness of a group self-management intervention for people in the early stages of
37 dementia. 2019. <http://www.isrctn.com/ISRCTN17993825> (accessed 15 Jan 2019)
38
39 27 Alzheimer’s Disease International. Participation in dementia trials and studies: Challenges and
40 recommendations. 2014. <https://www.alz.co.uk/sites/default/files/pdfs/dementia-trials.pdf>
41 (accessed 28 Sept 2018)
42
43 28 Herschell AD, Kolko DJ, Baumann BL, *et al.* The role of therapist training in the
44 implementation of psychosocial treatments: A review and critique with recommendations.
45 *Clin Psychol Rev* 2010;30:448–66. doi:10.1016/j.cpr.2010.02.005
46
47 29 Mountain GA, Craig CL. What should be in a self-management programme for people with
48 early dementia? *Aging Ment Health* 2012;16:576–83. doi:10.1080/13607863.2011.651430
49
50 30 Mulhern B, Rowen D, Brazier J, *et al.* Development of DEMQOL-U and DEMQOL-PROXY-U:
51 Generation of preference-based indices from DEMQOL and DEMQOL-PROXY for use in
52 economic evaluation. *Health Technol Assess (Rockv)* 2013;17:1–140. doi:10.3310/hta17050
53
54 31 Smith S, Lamping D, Banerjee S, *et al.* Measurement of health-related quality of life for
55 people with dementia: development of a new instrument (DEMQOL) and an evaluation of
56 current methodology. *Health Technol Assess (Rockv)* 2005;9:1–93.
57 doi:<https://doi.org/10.3310/hta9100>
58
59
60

- 1
2
3 32 Herdman M, Gudex C, Lloyd A, *et al.* Development and preliminary testing of the new five-
4 level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–36. doi:10.1007/s11136-011-
5 9903-x
6
7 33 Hounsome N, Orrell M, Edwards RT. EQ-5D as a quality of life measure in people with
8 dementia and their carers: Evidence and key issues. *Value Health* 2011;14:390–9.
9 doi:10.1016/j.jval.2010.08.002
10
11 34 Spitzer RL, Williams JBW, Kroenke K. Test Review: Patient Health Questionnaire-9 (PHQ-9).
12 *Rehabil Couns Bull* 2014;57:246–8. doi:10.1177/0034355213515305
13
14 35 Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a Brief Depression Severity
15 Measure. *J Gen Intern Med* 2001;16:606–13. doi:10.1046/j.1525-1497.2001.016009606.x
16
17 36 Löwe B, Decker O, Müller S, *et al.* Validation and standardization of the generalized anxiety
18 disorder screener (GAD-7) in the general population. *Medical Care* 2008;46:266–74.
19 doi:10.1097/MLR.0b013e318160d093
20
21 37 Schwarzer R, Jerusalem M. Generalized Self-Efficacy scale. In: Weinman J, Wright S, Johnston
22 M, eds. Measures in health psychology: A user's portfolio. Causal and control beliefs.
23 Windsor: NFER-NELSON 1995. 35–7.
24
25 38 Diener E, Wirtz D, Tov W, *et al.* New measures of well-being: Flourishing and positive and
26 negative feelings. In: Diener E, ed. Social Indicators Research Series. New York: Springer
27 Science + Business Media 2009. 247–66.
28
29 39 De Vries R, Ryan KA, Stanczyk A, *et al.* Public's approach to surrogate consent for dementia
30 research: Cautious pragmatism. *Am J Geriatr Psychiatry* 2013;21:364–72.
31 doi:10.1016/j.jagp.2012.11.010
32
33 40 Lawton MP, Brody EM. Assessment of Older People : Self-Maintaining and Instrumental
34 Activities of Daily Living 1. *Gerontologist* 1969;9:179–86. doi:10.1093/geront/9.3_Part_1.179
35
36 41 Vernooij-Dassen MJFJ, Persoon JMG, Felling AJA. Predictors of sense of competence in
37 caregivers of demented persons. *Soc Sci Med* 1996;43:41–9. doi:10.1016/0277-
38 9536(95)00332-0
39
40 42 Jansen APD, van Hout HPJ, van Marwijk HWJ, *et al.* Sense of competence questionnaire
41 among informal caregivers of older adults with dementia symptoms: A psychometric
42 evaluation. *Clin Pract Epidemiol Ment Health* 2007;3:1–11. doi:10.1186/1745-0179-3-11
43
44 43 Moniz-Cook E, Vernooij-Dassen M, Woods R, *et al.* A European consensus on outcome
45 measures for psychosocial intervention research in dementia care. *Aging Ment Heal*
46 2008;1:29. doi:10.1080/13607860801919850
47
48 44 Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement : updated guidelines for reporting
49 parallel group randomised trials. *BMJ* 2010;340:332. doi:10.1136/bmj.c332
50
51 45 Baldwin SA, Bauer DJ, Stice E, *et al.* Evaluating models for partially clustered designs. *Psychol*
52 *Methods* 2011;16:149–65. doi:10.1037/a0023464
53
54 46 Walters SJ. Therapist effects in randomised controlled trials: What to do about them. *J Clin*
55 *Nurs* 2010;19:1102–12. doi:10.1111/j.1365-2702.2009.03067.x
56
57 47 Roberts C, Batistatou E, Roberts SA. Design and analysis of trials with a partially nested design
58
59
60

- 1
2
3 and a binary outcome measure. *Stat Med* 2015;35:1616–36. doi:10.1002/sim.6828
4
5 48 Kahan BC, Morris TP. Improper analysis of trials randomised using stratified blocks or
6 minimisation. *Stat Med* 2012;31:328–40. doi:10.1002/sim.4431
7
8 49 NHS Improvement. Reference Costs 2017/18. 2018.
9 <https://improvement.nhs.uk/resources/reference-costs/> (accessed 15 Jan 2019)
10
11 50 Curtis L, Burns A. Unit Costs of Health & Social Care 2018. Canterbury: University of Kent
12 2018.
13
14 51 Schafer JL. Multiple imputation: A primer. *Stat Methods Med Res* 1999;8:3–15.
15 doi:10.1191/096228099671525676
16
17 52 Van Hout BA, Al MJ, Gordon GS, *et al.* Costs, effects and C/E-ratios alongside a clinical trial.
18 *Health Econ* 1994;3:309–19. doi:10.1002/hec.4730030505
19
20 53 McHugh ML. Interrater reliability: the kappa statistic. *Biochem Med (Zagreb)* 2012;22:276–82.
21 doi:10.11613/BM.2012.031
22
23 54 Sprange K., Mountain GA, Brazier J, *et al.* Lifestyle Matters for maintenance of health and
24 wellbeing in people aged 65 years and over: study protocol for a randomised controlled trial.
25 *Trials* 2013;14:302. doi:10.1186/1745-6215-14-302
26
27 55 Ritchie J, Spencer L. Qualitative Data Analysis for Applied Policy Research. In: Humberman
28 AM, Miles MB, eds. *The Qualitative Researcher’s Companion*. London: SAGE Publications
29 2002. 305–29. doi:10.4135/9781412986274
30
31 56 Cooper C, Ketley D, Livingston G. Systematic review and meta-analysis to estimate potential
32 recruitment to dementia intervention studies. *Int J Geriatr Psychiatry* 2014;29:515–25.
33 doi:10.1002/gps.4034
34
35 57 HRA. GDPR guidance for researchers and study coordinators. London: Health Research
36 Authority (HRA) 2019. <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/> (accessed
37 18 Jun 2019)
38
39
40

41 FIGURE LEGENDS

42
43 Figure 1: Participant flow through the study
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

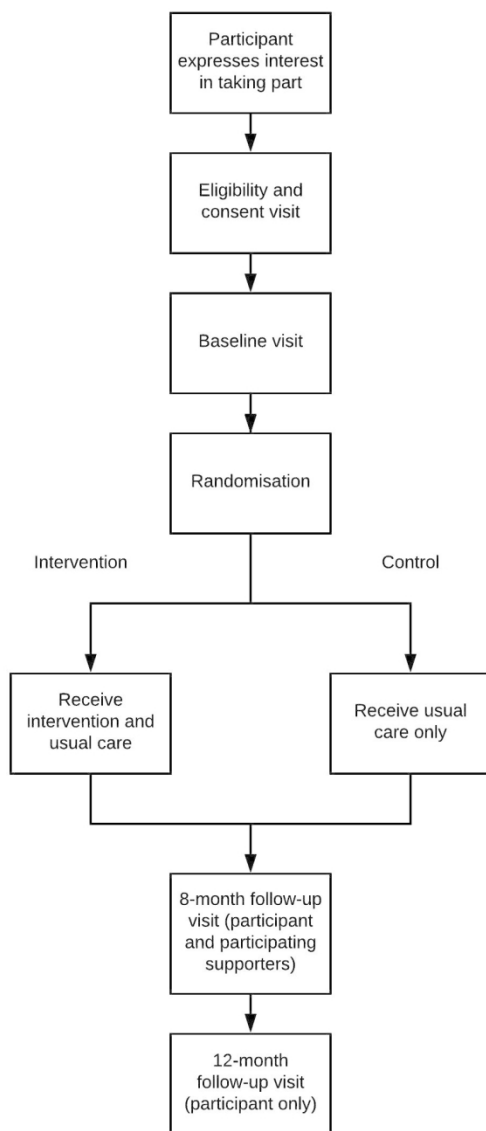


Figure 1 Participant flow through the study

92x190mm (300 x 300 DPI)



STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	_____i_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_____2_____
	2b	All items from the World Health Organization Trial Registration Data Set	____See 2a____
Protocol version	3	Date and version identifier	_____14_____
Funding	4	Sources and types of financial, material, and other support	_____14_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_____i-ii_____
	5b	Name and contact information for the trial sponsor	_____13_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_____n/a_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_____13_____

1 **Introduction**

2

3 Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention _____ 2-3 _____

4

5

6 6b Explanation for choice of comparators _____ 2-3 _____

7

8 Objectives 7 Specific objectives or hypotheses _____ 3 _____

9

10 Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) _____ 3-4 _____

11

12

13

14 **Methods: Participants, interventions, and outcomes**

15

16 Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained _____ 5 _____

17

18

19 Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) _____ 4-5 _____

20

21

22 Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered _____ 5-6 _____

23

24

25 11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) _____ n/a _____

26

27

28 11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) _____ 8-9 _____

29

30

31 11d Relevant concomitant care and interventions that are permitted or prohibited during the trial _____ 6 _____

32

33

34 Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended _____ 6-7 _____

35

36

37

38

39

40 Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) _____ Table 1 and figure 1 _____

41

42

43

44

45

46

1	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	___9___
2				
3				
4	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	___5___
5				

6 **Methods: Assignment of interventions (for controlled trials)**

7 Allocation:

8				
9				
10	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	___4___
11				
12				
13				
14				
15				
16	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	___4___
17				
18				
19				
20	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	___4___
21				
22				
23				
24	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	___4___
25				
26				
27		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	___4___
28				
29				
30				

31 **Methods: Data collection, management, and analysis**

32				
33	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	___6-8___
34				
35				
36				
37				
38				
39		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	___6-7___
40				
41				
42				

1	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	__12
2				
3				
4				
5	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	___9-11_
6				
7				
8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	__11_
9				
10		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	_10-11__
11				
12				
13				
14	Methods: Monitoring			
15				
16	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	___13_____
17				
18				
19				
20				
21				
22		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_____n/a_____
23				
24				
25	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	___12-13__
26				
27				
28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___12_____
29				
30				
31				
32	Ethics and dissemination			
33				
34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	_____14_____
35				
36				
37	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_____13_____
38				
39				
40				
41				
42				

1	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_____5_____
2				
3				
4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	__See supplementary information__
5				
6				
7				
8	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	___12-13___
9				
10				
11	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_____14_____
12				
13				
14				
15				
16	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_____12_____
17				
18				
19	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_____n/a_____
20				
21				
22	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_____13_____
23				
24				
25				
26				
27		31b	Authorship eligibility guidelines and any intended use of professional writers	_____n/a_____
28				
29		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____12_____
30				
31	Appendices			
32				
33	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	See supplementary materials_____
34				
35				
36				
37	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____n/a_____
38				
39				
40				

1 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.
2 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons
3 [“Attribution-NonCommercial-NoDerivs 3.0 Unported”](#) license.
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

For peer review only