The Journeying through Dementia psychosocial intervention versus usual care study: a single-blind, parallel group, phase 3 trial

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Summary

Background There is an urgent clinical need for evidence-based psychosocial interventions for people with mild dementia. We aimed to determine the clinical benefits and cost-effectiveness of Journeying through Dementia (JtD), an intervention designed to promote wellbeing and independence in people with mild dementia.

Methods We did a single-blind, parallel group, individually randomised, phase 3 trial at 13 National Health Service sites across England. People with mild dementia (Mini-Mental State Examination score of ≥18) who lived in the community were eligible for inclusion. Patients were centrally randomly assigned (1:1) to receive the JtD intervention plus standard care (JtD group) or standard care only (standard care group). Randomisation was stratified by study site. The JtD intervention included 12 group and four one-to-one sessions, delivered in the community at each site. The primary endpoint was Dementia Related Quality of Life (DEMQOL) 8 months after randomisation, assessed according to the intention-to-treat principle. Only outcome assessors were masked to group assignment. A cost-effectiveness analysis reported cost per quality-adjusted life-year (QALY) from a UK NHS and social care perspective. The study is registered with ISRCTN, ISRCTN17993825.

Findings Between Nov 30, 2016, and Aug 31, 2018, 1183 patients were screened for inclusion, of whom 480 (41%) participants were randomly assigned: 241 (50%) to the JtD group and 239 (50%) to the standard care group. Intervention adherence was very good: 165 (68%) of 241 participants in the JtD group attended at least ten of the 16 sessions. Mean DEMQOL scores at 8 months were 93·3 (SD 13·0) for the JtD group and 91·9 (SD 14·6) for the control group. Difference in means was 0·9 (95% CI −1·2 to 3·0; p=0·38) after adjustment for covariates, lower than that identified as clinically meaningful. Incremental cost per QALY ranged from £88 000 to −£205 000, suggesting that JtD was not cost-effective. Unrelated serious adverse events were reported by 40 (17%) patients in the JtD group and 35 (15%) patients in the standard care group.

Interpretation In common with other studies, the JtD intervention was not proven effective. However, this complex trial successfully recruited and retained people with dementia without necessarily involving carers. Additionally, people with dementia were actively involved as participants and study advisers throughout. More research into methods of measuring small, meaningful changes in this population is needed. Questions remain regarding how services can match the complex, diverse, and individual needs of people with mild dementia, and how interventions to meet such needs can be delivered at scale.

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Introduction

The Global Action Plan on Dementia[1] acknowledges the value of providing non-pharmacological (or psychosocial) interventions to people following diagnosis. These interventions are physical, cognitive, or social activities that maintain or improve functioning, interpersonal relationships, and wellbeing in people with dementia.[2] Therefore, non-pharmacological interventions encompass a range of interventions as identified and described in a comprehensive evidence review.[3] The importance of psychosocial interventions for those with mild dementia, including those recently diagnosed, is driven by the knowledge that a cure is unlikely in the near future and for people with dementia to be supported in order to live as well as possible with the condition.[3,4]

The 2015 national audit of UK memory services found that access to post-diagnostic services had increased but that the assistance people received was patchy and inconsistent.[5] At the time of the audit there were very few evidence-based psychosocial interventions for those with mild dementia and people were beginning to articulate their needs.

Research in context

Evidence before this study

People with dementia are being identified and diagnosed earlier and there are consequent demands from this patient group for meaningful, individualised, and non-pharmacological or psychosocial interventions from the point of diagnosis. This need is underscored by national and international policies. A scoping review of evidence of psychosocial interventions for people with mild-to-moderate dementia was done alongside this study. A systematic search strategy was done of national health service evidence (MEDLINE, PsycINFO, CINAHL, Web of Science, and Scopus) for relevant papers from Jan 1, 2000, to 2018 due to poor rates of diagnosis before 2000. The search terms used were (dement* OR Alzheimer*) AND (mild* OR early OR newly OR initial OR "home-based" OR "home based" OR "home-dwelling" OR "home dwelling") AND ("therap*" OR "counselling" OR "training" OR "intervention* "OR "education*" OR "rehabilitation" OR "reminiscence" OR "psycho*2) NOT ("severe "OR "long term" OR "long-term" OR institution* OR "nursing home*" OR "nursing-home*" OR "care home*" OR "care-home*" OR "hospital*") NOT ("drug*" OR "medic*" OR "pharmacologic*"). Additional search terms such as therapies (eg, "art therapy", "cognitive behavioural therapy", and "psychotherapy") and names of specific interventions were not used within this review due to resource limitations. Database searches were complemented by following up results from existing reviews and reference lists of key papers and relevant book chapters. Findings confirmed the need for stage-specific interventions, the value of a classification system for psychosocial interventions, and the need for pragmatic trials to test these interventions. However, when we commenced this study there were very few evidence-based psychosocial interventions for people following diagnosis—in particular for people without carer support. Involvement of patients with dementia in intervention design was scarce.

Added value of this study

The Journeying through Dementia (JtD) randomised trial is one of the largest UK trials of a psychosocial intervention for people with mild dementia. The intervention was co-designed with people with mild dementia and informal carers and can be tailored to meet individual needs. Unlike most psychosocial interventions, people with dementia can take part without accompanying carers. We have shown it is possible to recruit and retain people with dementia as trial participants and to sustain their active involvement as study advisers; we had very good adherence. However, trial results found that the intervention did not improve quality of life at 8 months after randomisation and was unlikely to be cost-effective. One of the secondary outcomes, Diener's Flourishing Scale, did have a significant effect in favour of the intervention.

Implications of all the available evidence

Other large-scale studies of psychosocial interventions for people with mild dementia have reported few clinical benefits and low cost-effectiveness. This study identified the need for reappraisal of methods. Our findings suggest that future randomised trials should use dementia-specific outcome measures of wellbeing and methods that can capture and record small, meaningful changes. We need to consider how to recruit people with dementia from diverse populations. Additionally, we require unobtrusive methods of assessing intervention fidelity. Finally, we must consider the service capacity required to deliver the psychosocial interventions and support that people with mild dementia say that they need.

Service gaps led to the co-creation of the Journeying through Dementia (JtD) intervention, which involved people with dementia informing us of what they considered would be helpful following diagnosis, including potential intervention topics and methods of intervention delivery.[6]

Social cognitive theory[7] underpinned the design of the JtD intervention, thereby including mechanisms to increase self-efficacy and effective problem-solving. It was postulated that these mechanisms would foster positive emotions, relationships, ability to self-manage, retention of functional skills, and wellbeing. The resulting intervention included a mix of facilitated group and one-to-one sessions over 12 weeks (maximum duration considered viable in a national health service [NHS] context). This was found to be acceptable to people with dementia and their carers.[6]

Over time services have become more aware of the needs of people after diagnosis, but the ability to respond to the complexity of needs that individuals can present with is restricted, in particular, how people can be enabled to adapt their lifestyles to living with dementia. The primary aim of the trial was to determine the clinical benefits and cost-effectiveness of the JtD intervention for people with mild dementia.

Methods

Study design and participants

We did a pragmatic single-blind, parallel group, individually randomised, phase 3 trial in 13 NHS Trust sites in England, recruited through the national Clinical Research Network.[8] There were two embedded studies: (1) a qualitative study explored the factors that mediated or moderated the effectiveness of the intervention from the perspectives of a sample of people who took part in or delivered the intervention,[9] and (2) an assessment of fidelity to the manualised training programme and to delivery of the intervention.[10] Facilitators were asked to complete itemised checklists of both group and individual sessions immediately following delivery to record the aspects of the intervention they considered to have been delivered. Attendance registers were also

maintained. Facilitator training sessions and group intervention sessions done in the meeting venue were recorded for fidelity assessment, but for methodological and ethical reasons it was not possible to record delivery of one-to-one sessions or groups held outside the meeting venue.

Eligible patients were in the mild stages of any type of dementia, with a Mini-Mental State Examination (MMSE) score of 18 or above, [11] lived in the community or sheltered accommodation, and were willing to engage in the 12-week intervention. Patients were not eligible if they had moderate or severe dementia (MMSE score <18), did not have dementia, did not have the capacity to consent according to assessment, lived in residential or nursing care, were not able to communicate in English, and were taking part in other pharmacological or psychosocial intervention studies. Informal carers (family or friends) could take part, but only if the person they cared for was recruited and agreed to their participation. Carers had to be older than 18 years, able to communicate in English, and able to give informed consent.

A variety of methods were used to maximise participant recruitment, including identification of potential participants via secondary care (appointments and letters), primary care (mailouts), the UK National Institute for Health Research Joint Dementia Research Database (advertising and searching), service user groups (dementia cafés or other groups), and general promotion (posters and leaflets). After agreeing to take part, individuals were asked to take part in screening to ensure that they met study eligibility criteria. Research staff visited each potential participant at home to complete the MMSE, determine capacity to consent, and ask other questions to determine eligibility. A formal assessment of capacity was not done during the initial home visit, but the researcher needed to be satisfied that the person was able to understand the nature and purpose of the study and the implications of taking part, including random assignment, the need for written consent and their right to withdraw at any point. All researchers were trained in how to make such judgements before the start of recruitment. All people with dementia and informal carers were required to provide written informed consent to take part.

A Data Monitoring and Ethics Committee, Trial Steering Committee, and Trial management group were all established at the outset and met regularly. The Trial Steering Committee included a person with dementia throughout. A patient and public advisory group of people with dementia and informal carers was consulted throughout. The study protocol is available online and was approved by UK Leeds East Research Ethics Committee, on July 1, 2016 (reference number 16/YH/0238). The study was reported according to the extended Consolidated Standards of Reporting Trials Statement.

Randomisation and masking

Participants were randomly assigned (1:1) using a secure, centralised, internet-based interface to receive either the JtD intervention and standard of care (JtD group) or standard care only (standard care group). One of the trial statisticians (EL) generated the assignment sequence using computer-generated random numbers with a block size of four. Assignment was stratified according to site.

Rigorous methods were applied to limit contamination between groups. The risk of sites predicting allocation was minimal because randomisation was done by unmasked, centrally located members of the trial team who directly informed site-based facilitators and participants of allocation.

Outcome assessors—all of whom were researchers who received the same training in how to work optimally with people with dementia—were masked to intervention allocation. All instances of unmasking were recorded and, when practical, a new masked assessor did the subsequent assessments. However, this was not possible in all cases. The study statisticians (EL and SJW) and the health economist (TY) were masked throughout the trial. Contamination between groups was unlikely because similar interventions are rarely provided in the UK as part of usual care for people with mild dementia. Patients were unmasked to group assignment.

Procedures

All recruited participants were assessed face to face in their homes at baseline before random assignment (intended to occur less than two months before intervention delivery) and again at 8 months and 12 months after randomisation.

The JtD group intervention is summarised using the template for intervention description and replication checklist in the appendix (pp 52–53). Consultations with five people with dementia and five carers, recruited through the voluntary sector, underpinned initial development of the JtD intervention.[12] The content of the draft intervention was subsequently explored with approximately 15 people with dementia and ten carers in a service context. The intervention was then refined with an additional ten people with dementia and seven carers during the feasibility study.[6]

See **Online** for appendix

The intervention was designed to promote independence and self-management in people with dementia. It supports individuals to recognise, build upon, and use existing skills, and develop new interests. The content was not designed for carers; the role of carers in the JtD intervention was to support the person with dementia with their involvement. However, carers were engaged alongside people with dementia as study advisers (K Sprange, University of Nottingham, personal communication). The JtD intervention comprised a menu of topics (appendix pp 52–53). However, groups can also identify their own topics to work on. Facilitators were trained to judge the extent of assistance groups

For the **study protocol** see https://bmjopen.bmj.com/content/9/9/e029207

required to identify topics to work on. Intervention delivery was composed of a mix of facilitated group and individual sessions, with individual sessions feeding into group sessions, and group sessions supporting individual sessions.

It was recommended that each intervention group should involve a maximum of 12 people with mild dementia who meet together on a weekly basis for 12 consecutive weeks. All participants commenced their involvement at week one. Each participant received four one-to-one sessions with one of the facilitators approximately every three weeks with the first one to one session being before commencement of the group sessions. As far as possible, the same facilitator should conduct all four one-to-one sessions with a participant. Group sessions were held in an accessible community venue and at least three sessions were held outside the meeting venue to promote putting learning into practice and mastery with support from others. Each group session was designed to have the same structure: first, welcome and sharing of aims; second, information giving (to set the context); third, group discussion of topics to build shared understanding, drawing upon participant strengths; fourth, a practical activity to provide an opportunity for active experimentation, particularly through out-of-venue activities; and finally, a summary of key messages and an opportunity to plan for the next session. Group discussion of each topic selected by the group was followed by facilitated exploration through in-venue practical sessions and didactic information if appropriate. Participants were encouraged to take what they had learnt into community settings and to work on their own challenges with both peer and facilitator support.

The nature and content of the one-to-one sessions were guided by the participant's expressed needs, interests, and aspirations. These sessions involved some discussion and enactment of activities in the home and the community, depending upon the participant's goals. Examples of goals taken forward during the feasibility study[6] included introducing methods to read recipes, maintain a diary, attend a community group, engage in physical activities, and prepare resources to take to a forthcoming group session.

Usual care was recorded at each site and could include pharmacological treatments, such as cholinesterase inhibitors and memantine and medication for other conditions (eg, depression); needs assessment; provision of educational material; and, in some instances, referral to various individual and group sessions and other health and social care services, such as community mental health teams. Usual care could also involve referral to third sector organisations, such as the Alzheimer's Society. Recorded usual care by site is provided in the appendix (p 14).

The per-protocol therapeutic threshold was defined as each participant randomly assigned to receive the intervention attending at least ten of the 16 sessions. Involvement of more sites and additional facilitators to meet the recruitment target necessitated different formats for delivery of facilitator training in the later stages of the trial, but content always followed the manualised format. Further details of support required for implementation of the intervention have been published previously.[13]

Outcomes

The primary outcome was Dementia Related Quality of Life measure (DEMQOL),[14] at 8 months after randomisation. DEMQOL was assessed at baseline, 8 months, and 12 months after randomisation. DEMQOL was designed for self-completion by people with dementia and is a scale from 28 to 112, with higher scores representing higher health-related quality of life. The health economics evaluation was a cost–utility analysis that compared the intervention plus usual care with usual care over a year from the perspective of UK NHS and social care services.

Eight secondary outcome measures were used. We selected instruments to assess the benefits that we aimed to achieve through the JtD intervention. None were dementia-specific because of the absence of instruments to measure capacities, such as independence, resilience, and self-management. Several instruments used in this study had been applied in other studies of psychosocial interventions for people with dementia. The eight secondary outcomes were: (1) health and social care resource use assessed at 8 months to support the cost-effectiveness evaluation; (2) Generalised Self-Efficacy scale,[15] to measure the ability to feel self-efficient and manage day-to-day challenges, assessed at baseline and 8 months; (3) Diener's Flourishing Scale,[16] in which higher scores indicate greater self-efficacy and more psychological resources and strengths, assessed at baseline and 8 months; (4) Self-Management Assessment scale, a measure of perceived ability to self-manage, assessed at baseline and 8 months (appendix p 14); (5) Instrumental activities of daily living, which measures the ability to undertake complex activities of daily living, assessed at baseline, 8 months, and 12 months (appendix p 14); (6) EQ-5D-5L[17] a measure of self-reported health related quality of life based on 5 dimensions, which included a visual analogue scale rating overall health, applied at baseline, 8 months, and 12 months; (7) Patient Health Questionnaire (PHQ-9),[18] which measured severity of depressive symptoms at baseline and 8 months; (8) Generalised Anxiety Disorder-7,[19] which measured severity of symptoms of anxiety at baseline and 8 months.

Recruited informal carers completed the EQ-5D-5L, PHQ-9, and the Sense of Competence Questionnaire (SCQ)[20] for carers of people with dementia, at baseline and 8 months.

For the health economic analysis cost-effectiveness, results were expressed as costs per quality-adjusted

life-years (QALYs) over a 1-year timeframe. No discounting was applied. Intervention costs and costs for individual participants' use of routine health and social care services were estimated. Resource use cost sources are summarised in the appendix (pp 9–13). Costs are presented in the 2018–19 value of British sterling.

Utilities were estimated by applying van Hout and colleagues'[21] mapping algorithm to map EQ-5D-5L utility values to EQ-5D-3L values.[21] A total of 5000 bootstrap replicates were done to allow for uncertainty and bias-corrected bootstrap 95% confidence intervals were estimated. Sensitivity analysis was applied to alternative utility values and to allow for missing data (appendix p 13).

Serious adverse events (eg, resulting in death, threat to life, or requiring hospitalisation), were collected for participants with dementia throughout the study and communicated to the trial manager within 24 h of discovery. Local site investigators assessed whether serious adverse events appeared to be related to the intervention. The trial oversight committees reviewed serious adverse events at regular intervals. The trial sponsor (Sheffield Health and Social Care NHS Foundation Trust) and the NHS Research Ethics Committee were informed of any unexpected and related serious adverse events.

Statistical analysis

The statistical analysis plan was created while the statistician was masked to treatment allocation. There were no major changes after trial commencement.

The sample size was calculated based on a 90% power of detecting a four-point difference (deemed to be clinically meaningful) in the DEMQOL 8 months after randomisation, with a two-sided α of 5%. The trial was individually randomised, but we inflated the sample size to allow for clustering by intervention group. This calculation assumes that the SD of the DEMQOL 8 months after randomisation was 11 and the intra-cluster correlation was 0·03 to account for the effects of group facilitation at site and an average cluster size of eight participants (equivalent to a design effect of 1·21), and that there would be 20% loss to follow-up. This led to a target sample size of 486 participants.

For analysis of the primary outcome, the DEMQOL total score at 8 months after randomisation was compared between the JtD and standard care groups using a mixed-effects linear regression model adjusted for baseline DEMQOL total score and stratification site (fixed effect), allowing for clustering of the outcome by intervention group (random effect). A partly clustered mixed-effects

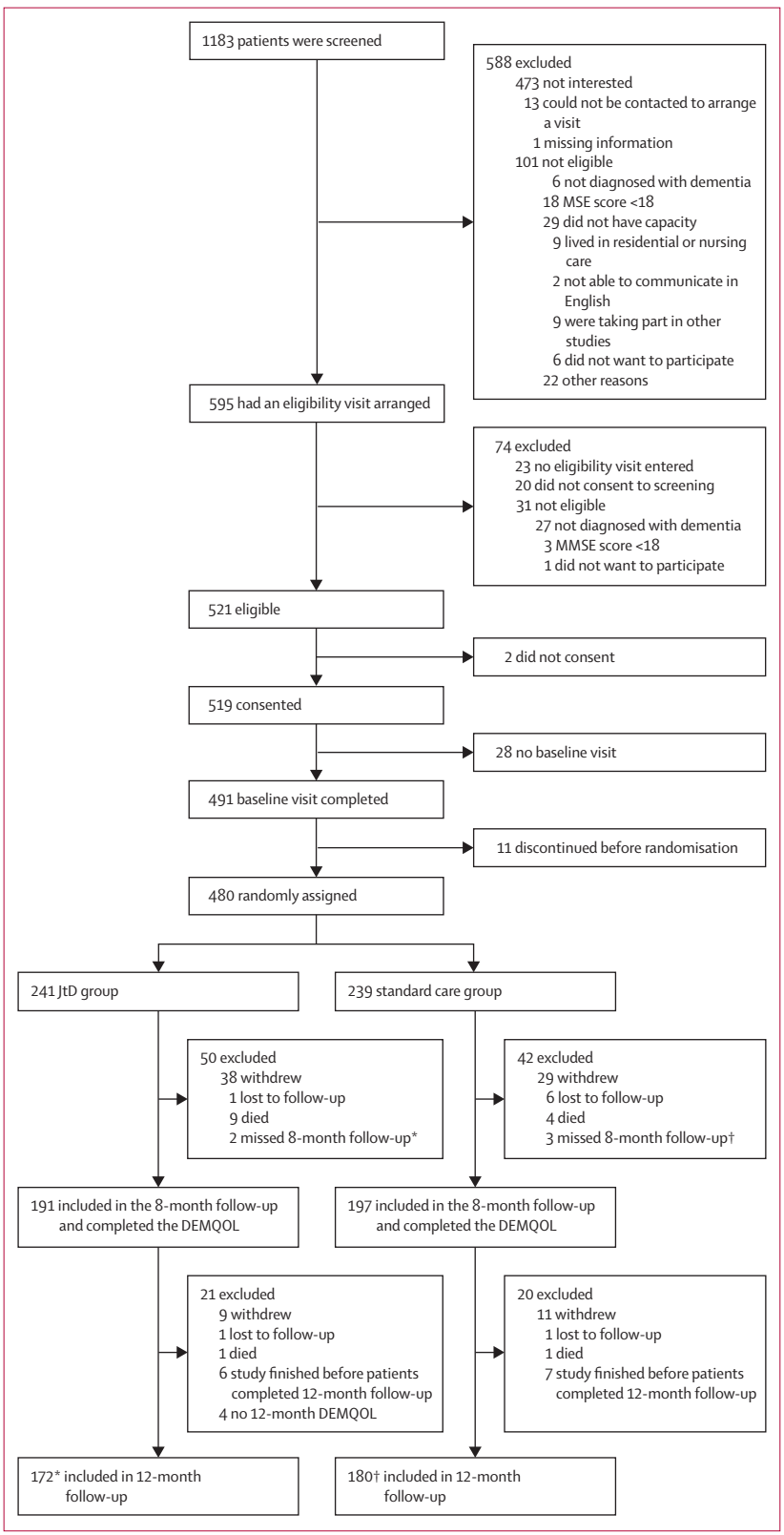

Figure 1: **Flowchart of the Journeying through Dementia Trial.**
DEMQOL=Dementia Related Quality of Life. JtD=Journeying through Dementia. MMSE=Mini-Mental State Examination. *Two participants missed the 8-month follow-up, but completed 12-month DEMQOL follow-up. †Three participants missed the 8-month follow-up, but completed 12-month DEMQOL follow-up.

	JtD group (n=241)	Standard care group (n=239)
Sex		
Male	136 (56%)	143 (60%)
Female	105 (44%)	96 (40%)
Mean age (years)	77 (7·0)	77 (7·7)
Ethnicity		
White	238 (99%)	232 (97%)
Non-White	2 (1%)	7 (3%)
Prefer not to say	1 (<1%)	0
Lives with others		
No	62 (26%)	63 (26%)
Yes	178 (74%)	176 (74%)
Lives with		
Spouse or partner	156 (65%)	157 (66%)
Child or children	15 (6%)	6 (3%)
Both partner and children	5 (2%)	10 (4%)
Other	2 (1%)	3 (1%)
Accommodation type		
Sheltered or retirement housing	27 (11%)	16 (7%)
Own home	207 (86%)	218 (91%)
Friend or relative's home	7 (3%)	3 (1%)
Other	0	2 (1%)
Type of dementia diagnosed		
Alzheimer's disease	142 (59%)	148 (62%)
Vascular dementia	31 (13%)	19 (8%)
Mixed Alzheimer's and vascular dementia	51 (21%)	58 (24%)
Dementia in Parkinsons disease	3 (1%)	3 (1%)
Frontotemporal dementia	5 (2%)	2 (1%)
Lewy body dementia	1 (<1%)	3 (1%)
Unspecified dementia	7 (3%)	5 (2%)
Other	1 (<1%)	1 (<1%)
Years since dementia diagnosis	1·3 (1·5)	1·3 (1·7)
MMSE (total score)	24·5 (3·1)	24·6 (3·2)
DEMQOL (total score)	90·8 (13·0)	90·3 (13·2)
PHQ-9 (total score)	4·2 (4·4)	4·0 (4·4)
GAD-7 (total score)	2·8 (3·6)	2·8 (3·5)
EQ-5D-5L (crosswalk value index)	0·77 (0·21)	0·78 (0·19)
EQ-5D VAS	75·6 (16·7)	73·8 (17·8)
GSE (total score)	30·4 (5·5)	30·9 (5·4)
Diener's Flourishing Scale	45·3 (6·7)	45·6 (7·2)
SMAS	124·6 (20·7)	125·6 (19·5)
IADL (total score)	5·7 (1·8)	5·8 (1·9)

Data are n (%) or mean (SD). DEMQOL=Dementia Related Quality of Life. EQ-5D-5L= European Quality of Life – 5 Dimensions version. EQ-5D VAS=European Quality of Life – 5 visual analogue scale. GAD-7=Generalised Anxiety Disorder Scale. GSE=Generalised Self-Efficacy Scale. IADL= Instrumental Activities of Daily Living. JtD=Journeying through Dementia. MMSE=Mini-Mental State Examination. PHQ-9=9-question Patient Health Questionnaire. SMAS=Self-Management Assessment Scale.

Table 1: **Characteristics of the participants at baseline including baseline measures**

linear regression model with homoscedastic errors was used to model clustering in the JtD group. Degrees of freedom were computed using the Satterthwaite approximation.[22]

Preplanned sensitivity analyses were done on the primary outcome and included imputation of missing data and Complier Average Causal Effect (CACE) modelling, and are displayed alongside the primary analysis results. CACE analysis used treatment allocation (instrumental) and covariates to predict treatment receipt (endogenous), before using this prediction in place of treatment in the primary analysis model.[23] We excluded participants with data collected more than 2 weeks before and more than 10 weeks after eight 8-month follow-up and those who attended less than ten of the 16 possible sessions. The CACE sensitivity analysis aimed to yield estimates of the effects of the JtD intervention for individuals who complied with treatment. Additional details regarding the statistical analysis are provided in the protocol.[8] The statistical analysis plan[24] is provided in the appendix (pp 15–51).

Secondary outcomes were analysed using a mixed-effects regression model, as done for the primary outcome. We did not correct for multiple comparisons in the evaluation of secondary or other outcomes. Thus, such results are exploratory and are reported as point estimates with 95% CIs. Analyses of outcome measures were done on an intention-to-treat (ITT) basis, defined as all participants who underwent randomisation and had valid outcomes. Two preplanned subgroup analyses based on type of dementia (Alzheimer's disease *vs* any vascular dementia *vs* other disease and presence of participating supporter) were undertaken. All statistical analyses were done with Stata (version 15) statistical software. The study is registered with ISRCTN, ISRCTN17993825

Role of the funding source

The study funder reviewed and approved research protocols, but the funder took no part in the collection, analysis, or interpretation of the data; the writing of the report; or the decision to submit this paper for publication.

Results

Between Nov 30, 2016, and Aug 31, 2018, 1183 patients were screened for inclusion, of whom 480 (41%) participants were randomly assigned: 241 (50%) to the JtD group and 239 (50%) to the standard care group (figure 1). At randomisation no site was imbalanced by more than two participants. Baseline characteristics are reported in table 1. 69 facilitators were recruited at the 13 study sites and were trained. 28 interventions were delivered during the study. Intervention adherence was good; 165 (68%) of 241 participants in the JtD group attended at least ten of the 16 available sessions (group and one-to-one), meeting the per-protocol therapeutic threshold.[8]

	JtD group		Standard care group		Adjusted*	
	Patients (n=191)	Mean (SD)	Patients (n=197)	Mean (SD)	Mean difference (95% CI)	p value
8 months						
DEMQOL score	191 (100%)	93·3 (13·0)	197 (100%)	91·9 (14·6)	0·9 (–1·2 to 3·0)	0·38
PHQ-9 (total score)	186 (97%)	3·4 (4·2)	193 (98%)	3·6 (4·8)	–0·3 (–1·1 to 0·5)	0·41
GAD-7 (total score)	185 (97%)	2·4 (3·5)	192 (97%)	2·4 (3·8)	0·1 (–0·5 to 0·7)	0·76
EQ-5D-5L (crosswalk value index)	190 (99%)	0·78 (0·21)	195 (99%)	0·78 (0·22)	0·01 (–0·03 to 0·05)	0·67
EQ-5D VAS	188 (98%)	74·6 (18·3)	193 (98%)	72·1 (18·0)	2·1 (–1·7 to 5·9)	0·28
GSE (total score)	178 (93%)	30·1 (5·5)	185 (94%)	29·5 (5·8)	0·9 (–0·1 to 1·9)	0·066
Diener's Flourishing scale	169 (88%)	46·0 (6·3)	177 (90%)	45·1 (7·1)	1·2 (0·1 to 2·3)	0·028
SMAS	171 (90%)	124·8 (20·2)	176 (89%)	123·7 (18·1)	1·5 (–2·3 to 5·3)	0·45
IADL (total score)	181 (95%)	5·2 (1·8)	190 (96%)	5·2 (1·9)	0·1 (–0·3 to 0·4)	0·75
12 months						
DEMQOL (total score)	172 (90%)	92·3 (14·3)	180 (91%)	91·7 (13·9)	0·4 (–1·6 to 2·5)	0·69
EQ-5D-5L (crosswalk value index)	170 (89%)	0·79 (0·22)	178 (90%)	0·78 (0·22)	0·02 (–0·02 to 0·06)	0·31
EQ-5D VAS	173 (91%)	70·8 (19·1)	177 (90%)	70·9 (19·1)	–0·4 (–4·3 to 3·6)	0·86

Mini-Mental State Examination was measured on a scale from 0 to 30; higher scores indicate better cognitive function; we used the cutoff scores of 21 to 26 for mild dementia to identify the trial population. DEMQOL is measured on a scale from 28 to 112; higher scores represent higher health-related quality of life. PHQ-9 is measured on a scale from 0 to 27; higher scores indicate more severe depressive symptoms. GAD-7 is measured on a scale from 0 to 21; higher scores represent increasing severity of anxiety. EQ-5D-5L score is measured on a scale from –0·224 to 1·00 (full health). EQ-5D VAS is measured on a scale from 0 (worst imaginable health state) to 100 (best imaginable health state). GSE is measured on a scale from 10 to 40; higher scores indicate more self-efficacy. Diener's Flourishing scale is measured from 0 to 56; higher scores represent more psychological resources and strengths. SMAS is measured on a scale from 30 to 175; higher score indicates greater self-management ability. IADL is measured on a scale from 0 to 8; higher scores represent lower level of dependence. DEMQOL=Dementia Related Quality of Life. EQ-5D-5l=European Quality of Life – 5 Dimensions version. EQ-5D VAS=EuroQol-5 Dimension visual analogue scale. GAD-7=Generalised Anxiety Disorder Assessment. GSE=Generalised Self-Efficacy measure. IADL=Instrumental Activities of Daily Living. JtD=Journeying through Dementia. PHQ-9=9-question Patient Health Questionnaire. SMAS=Self-Management Assessment Scale. *Adjusted for baseline DEMQOL score, stratification site and JtD intervention group (random effect – partially clustered model)

Table 2: **Primary and secondary outcomes**

Follow-up was between Oct 1, 2017, and May 31, 2019. Valid primary outcome data were obtained from 388 people with dementia (191 [79%] patients in the JtD group and 197 [82%] patients in the standard care group). ITT analysis found that the mean DEMQOL score at 8 months was 93·3 (SD 13·0) in the JtD group and 91·9 (SD 14·6) in the standard care group, with a difference in means of 0·9 (95% CI –1·2 to 3·0; p=0·38; table 2) after adjustment for covariates. The estimated mean difference was small and the 95% CI did not include the 4-point difference defined as being clinically meaningful. Figure 2 shows the results of sensitivity analyses on the 8-month DEMQOL score, which gave similar results to the primary analysis. At 12 months the mean DEMQOL score was 92·3 (SD 14·3) in the JtD group and 91·7 (SD 13·9) in the standard care group, with a difference in means of 0·4 (–1·6 to 2·5; p=0·69; table 2) after adjustment.

A modest difference was found in psychological wellbeing (Diener's Flourishing scale) in favour of the JtD intervention (1·2 [95% CI 0·1 to 2·3]; p=0·028; table 2). However, due to the large number of outcomes assessed, caution must be taken not to over-interpret one significant finding. Analysis of the other seven outcomes showed no evidence of differences between the groups. Analysis of outcome data also found some evidence of a difference in quality of life of carers who took part in the JtD group compared with the control group (mean difference in EQ-5D-5L crosswalk value index –0·06 [95% CI –0·09 to –0·02], p=0·0020; SCQ –1·4 [–4·3 to 1·5], p=0·34; PHQ-9 0·4 [–0·4 to 1·2], p=0·35) suggesting that the quality of life of carers in the intervention group was slightly lower than that of the control group carers at 8 months. Investigation of prespecified subgroups (participating carer [yes or no]; type of dementia [Alzheimer's disease, vascular dementia, or other]) found no reliable differences between subgroups in the primary outcome (appendix pp 5–6).

Health economics analyses showed that the observed difference in QALYs between the JtD group and the standard care group was small, non-significant, and favoured the standard care group (–0·003 [95% CI –0·044 to 0·038]; table 3). Resource use costs are summarised in the appendix (pp 9–13). The JtD intervention cost an average of £609 more per participant (95% CI 105 to 1179) compared to standard care (table 3). Overall, owing to the small effect size, JtD was more expensive and less effective than standard care, with an incremental cost per QALY of –£202 857 (95 CI –£534 733 to £483 739) suggesting that JtD might not be cost-effective. Sensitivity analyses are reported in the appendix (p 13) and showed that QALY differences remained small and in favour of the control group.

Unrelated serious adverse events were reported by 40 (17%) patients in the JtD group and 35 (15%) patients in the standard care group (appendix pp 6–7).

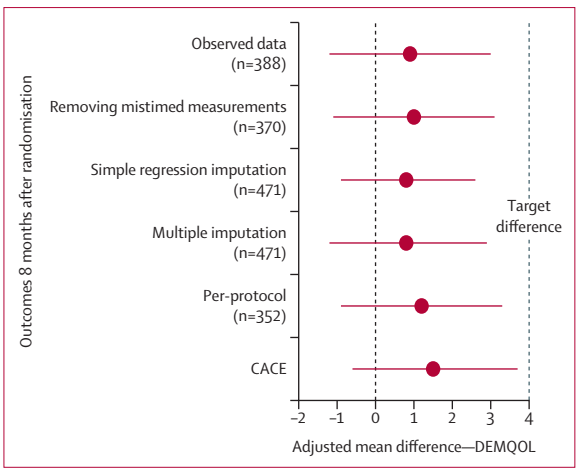

Figure 2: **Forest plot of the mean difference in DEMQOL at 8 months after randomisation for the sensitivity analysis samples with the target difference of 4 points**

Error bars are 95% CI. DEMQOL is measured on a scale from 28 to 112; higher scores represent higher health-related quality of life. A positive mean difference implies the JtD group had the better health-related quality of life. Observed data were adjusted for baseline DEMQOL score, stratification by site and JtD intervention group. Removing of mistimed measurements removed outcome measures taken outside the window of 2 weeks before to 8 weeks after 8-month follow-up was due. Simple regression imputation used sex, age, presence of supporter, type of dementia, and baseline DEMQOL, PHQ-9 and GAD-7 scores as covariates. Multiple imputation used chained equations (regression) based on 100 imputed data sets, with age, sex, stratification by site, presence of supporter, type of dementia, duration of dementia, and baseline DEMQOL, GAD-7, and PHQ-9 score as covariates. The per-protocol population attended at least ten of the 16 possible sessions. CACE used two stage least squares regression with age, sex, presence of supporter, stratification by site, and baseline DEMQOL as covariates and standard errors that allow for intragroup correlation by JtD intervention groups. All other analyses used a mixed-effects regression model, with clustering in the standard care group only. CACE=Complier Average Causal Effect. DEMQOL=Dementia Related Quality of Life. GAD-7=Generalised Anxiety Disorder Scale. JtD=Journeying through Dementia. PHQ-9=9-Question Patient Health Questionnaire.

	JtD group* (95% CI)	Standard care group (95% CI)†	Incremental costs and quality-adjusted life-years (95% CI)	Incremental cost-effectiveness ratio (95% CI)
Quality-Adjusted Life Years	0·774 (0·744 to 0·802)	0·777 (0·748 to 0·803)	−0·003 (−0·044 to 0·038)	..
Overall costs (over 12 months)	£1676 (1367 to 2227)	£1067 (792 to 1484)	£609 (105 to 1179)	−£202 857 (−534 733 to 483 739)

Incremental cost-effectiveness ratio is calculated as incremental costs divided by incremental quality-adjusted life years; a negative difference in incremental quality-adjusted life-years means that the standard care group had, on average, more quality-adjusted life-years; a positive difference in the incremental costs means that, on average, the intervention group incur more resources. 95% CIs are bias-corrected bootstrap intervals. JtD=Journeying through Dementia. *n=166. †n=173.

Table 3: **Mean costs and quality-adjusted life years for main analysis and sensitivity analysis**

Discussion

This study assessed the clinical benefits and cost-effectiveness of the JtD intervention, designed to promote wellbeing and independence in people with mild dementia, and co-designed with members of this population. The main study finding was that the intervention did not show a statistically significant or clinically important improvement in self-reported quality of life compared with standard care. There were indications of improved psychological wellbeing in those who received the intervention, but other secondary outcomes did not show any differences. This finding is echoed in other trials of psychosocial interventions for people with mild dementia published since 2018.[25–27]

Enabling people diagnosed with dementia to live as well as possible with the condition is a global policy imperative, particularly given the absence of a cure.[1,3] However, delivery of interventions to meet the complex needs of patients in the early stages of dementia is new territory for most services. Our fidelity assessment found good fidelity to delivery of the in-venue group aspect of the intervention,[10] but a limitation of the study was that it was not possible to record other essential elements of the intervention for fidelity assessment, namely, delivery of group sessions held in the community or one-to-one sessions. Therefore, questions remain regarding the capacity of services to deliver the range of psychosocial services and support that people with mild dementia identified as being important.

The paucity of existing measures to assess positive changes informed our use of DEMQOL as the primary outcome for this study. Although high, the mean baseline DEMQOL scores we obtained were similar to those obtained in similar studies,[25] and in the original study that developed the instrument.[28] Therefore, we deduce that DEMQOL might not be sufficiently sensitive to detect changes that might be attributed to interventions of this kind and that new approaches are required for measurement of psychosocial outcomes for those with mild dementia.[29] Additionally, most of the secondary outcome measures had not been validated in dementia populations due to an absence of available instruments to measure positive outcomes in people with dementia and might have been insensitive to differences or changes in outcomes over time or in health status. This might explain some of the small differences observed between the treatment groups. Use of the existing instruments, although unavoidable, was a limitation of the trial.

This study has underscored the need for a new focus on what people with dementia are still able to do—rather than deficits—and the need to identify ways of minimising requirement for recall when using measures. The embedded qualitative study[10] identified how participant outcomes were influenced by the dynamic relationships between a participant, their environment, and their resulting activity. It is important to consider how best to capture what people with dementia said was of importance to them during these interviews, such as community connectedness and continued engagement in meaningful activities. The qualitative study also highlighted the importance of subtle outcomes and effects, such as improved confidence through knowledge acquisition, feeling valued and empowered as a still functional member of society, and the benefits gained

from social contacts and friendships. The finding that the intervention was not cost-effective is set against a backdrop of uncertain cost-effectiveness for most, if not all, psychosocial interventions delivered through existing services.[26,30]

Our study has significant strengths. We recruited a seldom heard group in sufficient numbers to reach our target sample size, successfully retained study participants, and delivered a complex intervention across multiple sites. We also meaningfully involved people diagnosed with dementia and carers as research advisers throughout (K Sprange, University of Nottingham, personal communication). However, there were also several limitations. The speed of recruitment required for a trial of this nature can mitigate against targeting those most likely to benefit from the intervention (people with mild dementia with low levels of independence and wellbeing, but also with sufficient cognitive reserve to be able to take forward positive life changes). Facilitators also reported that some participants had a higher level of cognitive impairment than screening suggested.[10] Other factors which might have contributed to the trial outcomes were the limitations of the methods of the fidelity assessment and the absence of dementia-specific outcomes to record individual strengths, such as resilience, self-management, and independence.

The inherent challenges of responding to the complex and diverse range of needs that patients with mild dementia can present with are illustrated by our findings. Steps must now be taken to consider why the findings from this and other large-scale studies of psychosocial interventions for people with mild dementia are reporting similar results[26,27] and how the challenges might be addressed.

Future studies should consider using approaches that promote the inclusion of people with dementia in intervention design and delivery and that reflect the diversity that exists within this heterogenous group. Such approaches include forming productive relationships with people with dementia and their advocates and enhanced training for researchers. Policy changes are also required by funders to acknowledge the additional effort required to successfully do a trial with an underserved group, such as patients with dementia.

Contributors

GAM is the grant holder and wrote the initial version of the paper with assistance from CLC and JW. EL and SJW did the statistical analysis and verified the data. TY did the health economics analysis. CC, KB, KS, EM-C, TD, AL, ET, JB-D, BDT, BJT, and ELY reviewed the manuscript and assisted with data interpretation. All authors contributed to the design and conduct of the trial and to data acquisition. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Declaration of interests

We declare no competing interests.

Data sharing

Requests for anonymised data can be submitted to the corresponding author. Relevant data might be released following consideration by Sheffield Clinical Trials Research Unit in conjunction with study investigators. Criteria for approval include that the researcher must have a valid research protocol and relevant ethics approval. Other documents including the study protocol and statistical analysis plan are available. Data requestors will be asked to sign a contract.

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