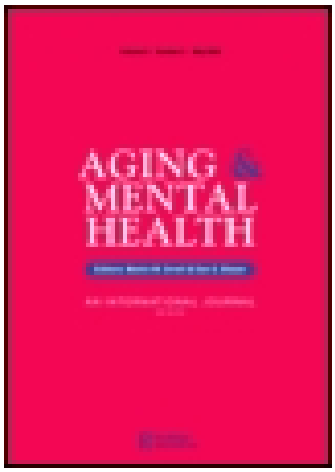

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A pilot randomised controlled trial to compare changes in quality of life for participants with early diagnosis dementia who attend a 'Living Well with Dementia' group compared to waiting-list control

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A pilot randomised controlled trial to compare changes in quality of life for participants with early diagnosis dementia who attend a 'Living Well with Dementia' group compared to waiting-list control

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Objectives: The aim of this paper is to report a pilot study in which participants who had recently received a diagnosis of dementia were randomised to either a 10-week group intervention or a waiting-list control.
Method: Memory clinic staff with limited previous experience of group therapy were trained to lead a 10-week group therapy intervention called 'Living Well with Dementia'. Fifty-eight participants, all of whom had received a diagnosis of Alzheimer's disease, vascular or Lewy body dementia within the previous 18 months, were randomised to receive either the intervention or treatment as usual (waiting-list control). Data collection occurred at baseline, within two weeks after the intervention finished and at 10-week follow-up.
Results: The study met its recruitment targets, with a relatively low attrition rate for the intervention arm. The acceptability of the intervention and research methods was examined qualitatively and will be reported on elsewhere. For the primary outcome, measure of quality of life in Alzheimer's disease (QoL-AD), and secondary outcome, self-esteem, there was some evidence of improvement in the intervention group compared to the control group. There was, also, evidence of a reduction in cognitive functioning in the treatment group compared to the control. Such reported differences should be treated with caution because they are obtained from a pilot and not a definitive study.
Conclusion: This pilot study succeeded in collecting data to inform a future definitive cost effectiveness clinical trial of Living Well with Dementia group therapy.

Keywords: dementia; Alzheimer's disease; group psychotherapy; recovery; psychosocial support system

Introduction

In the UK, government policy makes it clear that people who are affected by dementia should not only receive a timely, ideally early diagnosis, but that they should also be provided with support after this to help them to adapt to the illness. Thus, the recent 'Dementia – State of the Nation' report (Department of Health, 2013) set as a goal that by March 2015, two-thirds of people diagnosed with dementia should 'be supported after diagnosis, to exercise control and choice over their lives and helped to manage their condition so they can live independently for longer'. While the report mentions the importance of peer support, it provides no guidance as to how this support can be provided effectively.

Given the combination of powerful emotional responses to dementia (Aminzadeh, Byszewski, Molnar, & Eisner, 2007; Connell, Boise, Stuckey, Holmes, & Hudson, 2004) and the desire of most people to know about their illness (Elson, 2006; Jha, Tabet, & Orrell, 2001; Ouimet, Dion, Élie, Dendukuri, & Belzile, 2004), it is perhaps unsurprising that psychotherapeutic approaches with people affected by dementia have been consistently reported over the last 20 years. Reports of group therapy interventions, including support groups and a range of psychotherapy interventions are at least as common as descriptions of individual interventions (Cheston, 1998) or couple psychotherapy (Auclair, Epstein, & Mittelman, 2009). This includes small-scale evaluations of group interventions from a wide range of countries, including Denmark (Sørensen, Waldorf, & Waldemar, 2008), Australia (Aarons, 2003), Italy (Fabris, 2006), Japan (Ishizaki et al., 2000) and Germany (Scheuerich & Fellgiebel, 2009; Scheurich, Schanz, Muller, & Fellgiebel, 2008). However, probably the most comprehensive evaluation of group therapy to date comes from the USA. Logsdon et al. (2010) described the results of a randomised controlled trial comparing 96 patient and carer dyads who attended a time-limited early-stage memory loss support group with 46 dyads, who were randomised to a waiting-list control. The intervention was spread across nine sessions, each of which lasted for 90 minutes and combined presentations of educational material to both the persons affected by dementia and their carers (e.g. a video of 'Alzheimer's from the Inside Looking Out', an external speaker giving a medical overview of dementia or an Occupational Therapist talking about daily living skills) and therapeutic discussion of this within separate groups. Significant differences were seen in participant quality of life, depression and family communication.

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Living Well with Dementia group therapy

The group intervention used in this study draws on two areas of work: short-term group psychotherapy and the psycho-educational 'memory matters' courses. Cheston, Jones, and Gilliard (2003) showed significant reduction in levels of depression for 19 people, following a 10-week therapeutic group intervention with the gains being maintained at 10-week follow-up. Cheston and Jones (2009) carried out a feasibility randomised controlled trial (RCT) with participants attending either a 10-week psychotherapy group or an educational group. Again the intervention group showed a reduction in depression during the intervention compared to the educational group. However, the study only reported on eight participants in each arm and allocation to the two conditions was not randomised. Moreover, an observed increase in levels of depression amongst people attending the educational group was attributed to the intervention addressing too many painful issues at too early a point in the therapeutic process. A process analysis of change identified the importance of sharing of experiences around potentially shameful or taboo areas within a containing therapeutic environment (Watkins, Cheston, Jones, & Gilliard, 2006).

'Memory matters' groups were developed by clinicians working in Hampshire in the UK and drew upon a psycho-educational framework (Marshall, 2004; Preston, Bucks, & Marshall, 2005; 2007). They ran for eight weeks and were delivered by nurses and other memory clinic professionals who received training and supervision from clinical psychologists. Informal evaluations of these groups indicated that participants gained in self-efficacy, felt more relaxed about their memory problems and especially valued the chance to meet others who shared their diagnosis. Feedback from participants within these and other similar groups identified two broad categories of helpful events: practical information (including education about dementia and coping strategies), and the reassurance provided by meeting people who are in a similar position.

Methodology

The aim of this paper is to report a pilot study in which participants who had recently received a diagnosis of dementia were randomised to either a 10-week group intervention or a waiting-list control.

Study aims and objectives

This pilot study aimed to collect data about a range of processes, including recruitment rates; the acceptability of the intervention and training procedures (including whether memory clinic staff with little previous experience of therapeutic interventions could deliver the intervention); and estimation of variance of outcomes and loss to follow-up.

Design

The study was a pilot randomised controlled trial using a mixed methods approach. In addition to the collection of quantitative data (reported here), we also incorporated a nested qualitative study that examined issues around acceptability and which drew upon semi-structured interviews with group therapists and participants and their families. This qualitative material will be reported separately.

Participants were randomly allocated to one of two conditions: a group intervention lasting for 10 weekly sessions delivered by nurses from a memory clinic or to a control arm in which participants received usual care before being offered the living well with dementia (LivDem) intervention at the end of the follow-up period. The protocol was registered online (ISRCTN 25079950),[1] and received approval from NRES Ethics Committee South Central – Oxford B.[2]

Participants were recruited from established NHS memory clinics in the South of England using the following criteria:

(1) a diagnosis from a consultant psychiatrist within the memory clinic of either probable Alzheimer's disease according to the NINCDS–ADRDA criteria (McKhann et al., 1984) or probable vascular dementia according to the NINDS–AIREN criteria (Roman et al., 1993) within the previous year;
(2) the participant acknowledged, at least occasionally, that they have a memory problem;
(3) the Modified Mini-Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975) score of at least 18.

Participants were excluded from the study if they had:

(1) a significant pre-morbid history of mental health problems; or
(2) taken part in similar groups.

The initial phases of recruitment suggested that the original inclusion criteria were too restrictive, and permission was sought from sponsors and the ethics committee to extend these to include people affected by dementia with Lewy bodies according to the consensus guidelines (McKeith et al., 1996) and to increase time since diagnosis from 6 to 18 months. In practice, it was also found that memory clinic nurses and others performing the screening also took into consideration patients' overall level of health (including their mental health) before deciding whether or not to approach a potential participant.

Sample size

For pilot studies, sample sizes of between 24 (Julious, 2005) and 50 (Sim & Lewis, 2012) have been recommended. However, others have suggested that 30 participants in each arm of a trial are generally sufficient to allow reliable calculations of statistical power for a future trial (e.g. Browne, 1995; Lancaster, Dodd, & Williamson, 2004). We, therefore, set a recruitment target of 60 participants to be randomised equally into the two arms of the study.

Data collection occurred at three points for both the intervention and the control arms: at baseline two to four weeks before the intervention began (T1); up to two weeks after the intervention finished (T2); and after a 10-week follow-up period (T3). Data collection took place in

participants' homes using a questionnaire-based interview and involved participants and either their carers or someone who knew the person well. Demographic characteristics, health status data and NHS service use data were also recorded.

Randomisation and consent

The study followed the MRC Guidelines for good clinical practice in clinical trials, the Mental Capacity Act (2005) and the principles of EU clinical trials. Memory clinic staff approached suitable potential participants for the study for permission to pass on their contact details. Potential participants and caregivers were then interviewed by either Ann Marshall (AM) or Richard Cheston (RC) to gain informed consent for participation in the research. If necessary, group facilitators made efforts to contact those participants who seemed to have reservations about the intervention and ensured that they continued to be willing to attend the group.

Participants were randomised to either the intervention or control arms of the study once initial data had been collected. Randomisation was made by either AM or RC using an online secure system provided by the Mental Health and Neuroscience Clinical Trials Unit. As there was no evidence linking quality of life amongst people with early-stage dementia to the main demographic variables, stratification was not necessary.

Blinding

It was not possible to blind participants to their treatment, but data was gathered by a researcher [John Spreadbury (JS)] who was independent from the clinical work and blind to which arm a participant had entered.

Intervention

The Living Well with Dementia group intervention incorporated elements of psychotherapy (e.g. a focus on encouraging participants to share feelings associated with dementia such as embarrassment, worry and sadness) and psycho-educational elements, including information about memory loss, dementia and medical treatments. The combination of therapy and educational approaches was identified from process research as being associated with change, and also drew on feedback from over 60 participants in previous groups run by RC and AM. While difficult and potentially threatening aspects of dementia were addressed during group sessions, nevertheless the content of sessions was paced, so that participants were not faced with too great a level of psychological distress at too early a point in the group process. Moreover, unlike the early-stage support groups described by Logsdon et al., (2010) and the psycho-educational groups reported by Cheston and Jones (2009), all sessions were delivered by the same pair of therapists and did not involve outside speakers. The intervention utilised a recovery model of mental health, which emphasises the importance of helping participants to find meaning in life, achieving acceptance of their illness and through this to renew hope. Central to this approach to well-being is the importance of redefining identity, challenging stigma and helping people with dementia to work with their family to take responsibility for living well with their illness (Hill, Roberts, Wildgoose, Perkins, & Hahn, 2010).

The content of the 10 sessions has been standardised into a treatment manual.[3] Seven groups were established, and were led by facilitators who had worked in NHS memory clinics for at least one year and had attended a two-day training course. Three training events were held – two to train staff, who had originally committed to deliver the intervention, and a third 'catch up' training course was also arranged. Training focused on three areas: 'how groups work' which addressed group process issues such as group formation and dynamics; 'how LivDem works' which addressed methods of delivering the content of the sessions; and 'how research works' which provided an overview of the research process, including governance issues such as capacity, consent and data protection. During the intervention, therapists met with either AM or RC at least three times to receive supervision.

Facilitators came from different professional backgrounds (five occupational therapists, four nurses, three support workers, a psychology assistant and a trainee clinical psychologist). The facilitators' experiences of group work prior to participating in the study were varied: all of the occupational therapists were experienced in group work, and a third of the facilitators had also led similar groups to the LivDem intervention before. However, half of the facilitators had no previous experience of working in a group context.

Sessions lasted for 75 minutes and occurred once a week, typically within NHS hospital or community sites. All groups had between five and seven participants (although in one group this was only possible by including two additional participants who met the inclusion criteria for the study, and who wanted to attend the groups, but who did not want to be a participant in the research study). Group participants and their carers attended both the first and the final sessions, with the remaining eight sessions being attended only by participants (see Table 1). Sessions involved a mixture of

Table 1. Structure of Living Well with Dementia intervention.

Week	Attended by	Title of session
1	Participants and carers	Welcome and introductions
2	Participants	Problems and frustrations
3	Participants	Memory aids and strategies
4	Participants	Finding a way through feelings
5	Participants	Coping with stress
6	Participants	Friends and family, health professionals and strangers
7	Participants	What is dementia?
8	Participants	Living as well as you can
9	Participants	Staying active
10	Participants and carers	Bringing it all back together

psycho-educational material (for instance about the causes and treatment of dementia), skills training (e.g. in relaxation) and a psychotherapeutic focus on helping participants to discuss their experiences of dementia – and in particular the emotional impact of the illness. At the end of every session, participants were provided with a handout, describing the main issues that had been covered, and were encouraged to discuss this with their carers between sessions. A DVD of people affected by dementia, talking about different aspects of their illness, and which paralleled the content of the sessions, could also be played during sessions at the discretion of the group facilitators.

Control

A waiting-list control condition was used in which participants received treatment as usual during the length of the trial. Once the study was completed (i.e. after the Time 3 interview), all of the participants in the control arm were contacted by staff working in the memory clinics and were offered the opportunity to take part in a Living Well with Dementia group. All but two participants were able to take this offer up.

Outcome measures

The primary outcome of interest was the participant-rated quality of life in Alzheimer's disease (QoL-AD, Logsdon et al., 1999). The choice of this measure was determined by a combination of three factors: feedback from users and carers identified issues associated with quality of life (such as continuing to be engaged with outside interests and friends) as of crucial importance to them; improvement in quality of life is a central focus of the recovery model; while QoL-AD was identified as the instrument of choice in a pan-European consensus statement on outcome measures for psychosocial interventions in dementia care (Moniz-Cook et al., 2008). Therefore, variance of this outcome measure was of particular interest in informing the sample size of a definitive trial.

However, the variance of secondary outcome measures was also assessed. The secondary outcome measures for mood were the Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos, Abrams, Young, & Shamoian, 1988) for participants, and the General Health Questionnaire (Goldberg & Hillier, 1979) for the spouse/caregiver. Self-esteem was measured using the Rosenberg self-esteem scale (Rosenberg, 1989), with cognitive change over the course of the intervention assessed using the MMSE (Folstein et al., 1975). The MMSE and CSDD are widely used, robust and sensitive to change following psychosocial intervention with people with dementia, while the CSDD is recommended by the INTERDEM consensus group (Moniz-Cook et al., 2008).

Health economic data was collected using a modified version of the Client Services Receipt Inventory or CSRI (Beecham & Knapp, 1992). This is a widely used method of recording the costs associated with mental health interventions and the extent to which we were able to collect data from this population would determine the structure of a future definitive cost effectiveness trial.

Results

The results have been reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) 2010 statement. Figure 1 indicates the flow of participants through the study. Of the 282 people attending memory clinics, 131 did not meet our eligibility criteria, while 72 declined to participate and 19 others were unavailable, for example, they had moved away or were physically unwell. Participant baseline characteristics are outlined in Table 2, and caregiver details are given in Table 3.

Differences between control and intervention arms

All participants were White British, with an average age of 74.6 for the intervention arm and 76.6 years of age for the control condition. In both conditions, the majority of participants lived at home with a spouse or partner. Although there were a higher proportion of women (18) than men (10) in the intervention condition compared to the control condition, this difference was not significant. The most common diagnosis in each arm of the study was probable dementia of the Alzheimer's type, and roughly 70% of participants in each condition (23 of 28 participants in the intervention arm, and 22 of 30 participants in the control condition) were prescribed acetylcholinesterase inhibitors – figures that did not change significantly across the course of the study. Eight participants in the intervention arm were prescribed psychotropic medication at baseline, compared to seven in the control condition. This changed to 10 and 8, respectively, after the intervention, and 10 and 6 at follow-up. Despite randomisation, at baseline the control group scored higher (or better) on most outcomes in comparison with the immediate intervention group.

Recruitment and attrition

The recruitment target of 60 participants was met, although recruitment difficulties around the first group meant that an additional (seventh) group needed to be established. Two participants withdrew from the study between giving consent and taking part in the baseline interview. Three participants withdrew from the intervention arm (two due to physical illness), although data was collected at T2 and T3 from all three. In the control arm, three participants were unavailable or had withdrawn at T2, and although one of these participants was available at follow-up, another four could not be interviewed at T3.

Blinding

At the end of the study but before trial participation was confirmed, JS recorded his guess as to which arm the participant had been in. This was accurate at just above chance level (56.9%), suggesting that blinding for data collection was largely successful.

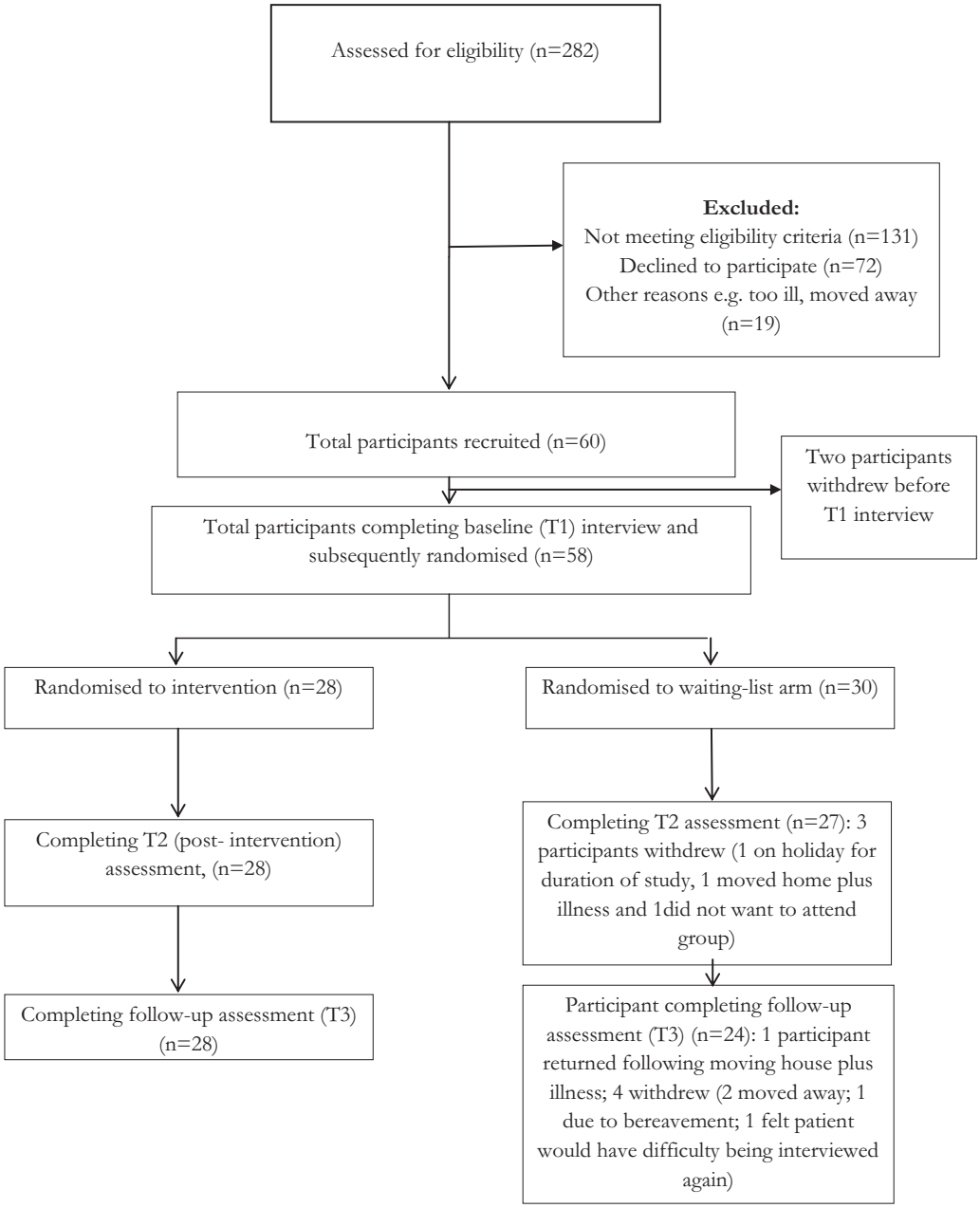

Figure 1. Diagram indicating flow of participants through the study.

Attendance at sessions

The overall attendance rate at sessions was 83%, which compares favourably with other studies.

Treatment fidelity

Fifty-one of the 56 sessions in which carers were not involved were audio-recorded. Treatment fidelity was established by comparing three randomly selected sessions from each group, and analysing facilitator behaviour across four domains: chairing and group management; balancing directive and listening aspects; making sense of dementia; and content. Performance on each domain was rated on a five-point scale, with scores of 3 or above being rated as acceptable. Three sessions from each of the seven groups were rated on four domains, making a total of 84 ratings. Two sessions were rated as falling below the cut-off point of 3 on at least one domain, with one session being rated as less than acceptably compliant on two separate domains (balancing directive intervention and listening, and linking and making sense of dementia). Using these criteria, overall treatment fidelity was high at 96%.

Use of other services

Overall, during the course of the project, patients in the immediate intervention group reported slightly fewer contacts with NHS services (9.81) than patients in the waiting-list control group (10.41). However, during the course of the group intervention, the average contact of

Table 2. Participant baseline demographic and clinical characteristics.

	Immediate intervention ($N = 28$)	Waiting-list control ($N = 30$)
Age		
Mean age (years)	74.6 (7.5)	76.6 (6.4)
Age range (years)	51–88	63–88
Gender		
Male	10 (35.7%)	15 (50%)
Female	18 (64.3%)	15 (50%)
Ethnicity		
White British	28 (100%)	30 (100%)
Marital status		
Single/never married	3 (10.7%)	2 (6.7%)
Married	20 (71.4%)	25 (83.3%)
Living with partner	1 (3.6%)	0 (0%)
Divorced	2 (7.1%)	0 (0%)
Widowed	2 (7.1%)	3 (10%)
Education		
Secondary school	13 (48.1%)	15 (50%)
College or university	14 (51.9%)	15 (50%)
Age at leaving school (years)	15.7 (1.1)	16.1 (1.3)
Living status		
Living with carer	23 (82.1%)	26 (86.7%)
Living alone	5 (17.9%)	4 (13.3%)
Relationship to carer		
Spouse husband	9 (32.1%)	15 (50%)
Spouse wife	12 (42.93%)	9 (30%)
Mother	3 (10.7%)	4 (13.3%)
Son	1 (3.6%)	0 (0%)
Sister	1 (3.6%)	0 (0%)
Friend	1 (3.6%)	2 (6.7%)
Resident	1 (3.6%)	0 (0%)
Dementia diagnosis		
Alzheimer's disease	20 (71.4%)	25 (83.4%)
Vascular dementia	4 (14.3%)	3 (10%)
Mixed dementia	3 (10.8%)	1 (3.3%)
Lewy body dementia (LBD)	1 (3.6%)	1 (3.3%)
Dementia medication		
Donepezil (Aricept)	16 (57.1%)	17 (56.7%)
Rivastigmine (Exelon, Abix)	4 (14.3%)	4 (13.3%)
Galantamine (Reminyl)	1 (3.6%)	2 (6.7%)
Memantine (Ebixa, Axura)	2 (7.1%)	1 (3.3%)
No dementia medication	5 (17.9%)	6 (20%)
Anti-depressant medication		
Yes	11 (39.3%)	10 (33.3%)
No	17 (60.7%)	20 (66.7%)
Contact with health or social care		
Yes	22 (78.6%)	23 (76.7%)
No	6 (21.4%)	7 (23.3%)

participants in the intervention group increased to 4.07, only to fall again to 2.71 by Time 3. By contrast, use of social groups and day care increased for the intervention group at both Time 2 and Time 3, but declined for the waiting-list group.

Table 3. Caregiver baseline demographic characteristics.

	Immediate intervention ($N = 28$)	Waiting-list control ($N = 30$)
Age		
Mean age (years)	70.4 (13.7)	72.2 (10.4)
Age range (years)	40–95	43–89
Gender		
Male	13 (46.4%)	11 (36.7%)
Female	15 (53.6%)	19 (63.3%)
Ethnicity		
White British	27 (96.4%)	29 (96.7%)
Canadian	1 (3.6%)	0 (0%)
Irish	0 (0%)	1 (3.3%)
Marital status		
Married	25 (89.3%)	27 (90%)
Living with partner	1 (3.6%)	1 (3.3%)
Divorced	1 (3.6%)	1 (3.3%)
Widowed	1 (3.6%)	1 (3.3%)
Education		
Secondary school	12 (42.9%)	9 (30%)
College or University	16 (57.1%)	21 (70%)
Age at leaving school (years)	15.7 (1.5)	15.9 (1.1)
Contact with health or social care		
Yes	19 (67.9%)	21 (70%)
No	9 (32.1%)	9 (30%)
Support from friends or family		
Yes	16 (57.1%)	15 (50%)
No	12 (42.9%)	15 (50%)

Data analysis

Data was analysed using IBM SPSS for Statistics (version 21). The variance (standard deviation) was calculated at baseline for all outcome measures. A series of analysis of covariance were carried out on an intention-to-treat basis, comparing primary and secondary outcomes assessed at Time 2 and Time 3 adjusted for baseline (T1) score.

Changes in outcome measures

Table 4 reports the standard deviation of each outcome measure at baseline. This pilot study was not powered to show significant difference in outcomes. We have followed the guidelines of Thabane et al. (2010) and reported the point estimates (mean) of the effect of the intervention and its precision (95% confidence intervals). Thus, Table 4 also details these estimates for the primary and secondary outcomes across the intervention and control arms. In order to adjust for the difference between the control and intervention arms at baseline, we included the baseline measure in analysis of covariance comparing outcomes between the intervention and control groups at Time 2 and Time 3 follow-up assessments. The reported difference should be treated with caution because they are obtained from a pilot study, not a definitive study.

For the primary outcome measure of the participant-rated quality of life (QoL-AD), the improvement in the

Table 4. Means and standard deviations for primary and secondary outcomes by intervention and waiting-list control group.

	Living Well with Dementia group intervention plus treatment as usual			Treatment as usual (waiting-list control)			Adjusted mean differences between intervention and control groups, controlling for baseline score		
	T1: pre-intervention, $n = 28$ mean (standard deviation)	T2: post-intervention, $n = 28$ mean (standard deviation)	T3: follow-up, $n = 28$ mean (standard deviation)	T1: pre-intervention, $n = 30$ mean (standard deviation)	T2: post-intervention, $n = 27$ mean (standard deviation)	T3: follow-up, $n = 24$ mean (standard deviation)	Adjusted difference (95% CI) T1 to T2	Adjusted difference (95% CI) T1 to T3	Baseline (T1) standard deviation ($n = 58$)
Quality of life (QoL-AD) patient rating	34.4 (5.8)	35.4 (7.2)	35.9 (6.3)	37.5 (4.6)	36.3 (6.5)	38.7 (5.8)	+2.12 (−0.17 to 4.42)	+0.30 (−2.09 to 2.69)	5.4
Quality of life (QoL-AD) caregiver rating	31.5 (6.6)	30.3 (7.0)	30.8 (6.7)	33.6 (5.7)	32.5 (6.6)	32.9 (5.2)	−0.50 (−2.90 to 1.88)	−0.31 (−3.09 to 2.47)	6.2
Depression (Cornell rating scale)	7.5 (4.4)	6.7 (4.2)	7.0 (4.6)	5.0 (3.2)	5.0 (4.5)	5.4 (4.0)	+0.11 (−2.02 to 2.25)	+0.29 (−2.08 to 2.67)	4.0
Self-esteem (Rosenberg)	16.9 (3.4)	17.9 (3.2)	18.9 (4.2)	18.5 (2.9)	17.8 (3.2)	18.8 (3.1)	+1.08 (−0.04 to 2.20)	+1.58 (−0.08 to 3.25)	3.2
Cognitive functioning (MMSE)	23.6 (4.3)	22.4 (4.0)	22.5 (4.4)	22.4 (3.7)	22.9 (3.1)	22.4 (2.9)	−1.34 (−2.88 to 0.20)	−0.45 (−2.07 to 1.16)	4.0
Caregiver health (GHQ total)	18.3 (9.3)	18.5 (10.5)	19.2 (12.9)	16.5 (8.6)	17.8 (10.4)	15.8 (8.8)	−0.90 (−4.44 to 2.64)	0.15 (−4.56 to 4.86)	8.9

intervention group compared to the control group observed at Time 2 was 2.12 (95% CI −0.17, 4.42, effect size $d = .46$), although this was reduced to 0.30 at Time 3 follow-up (−2.09, 2.69). The improvement in self-esteem in the intervention group compared to the control group at Time 2 was 1.08 (−0.04, 2.20), which increased to 1.58 at Time 3 follow-up (−0.08, 3.25). There was a reduction in cognitive functioning in the intervention group compared to the control group of 1.34 at Time 2 (−2.88, 0.20), although this deficit had largely disappeared at Time 3 follow-up, −0.45 (−2.07, 1.16).

Participants' mean level of depression, as measured by the Cornell scale, showed a small decrease for participants in the intervention condition between Time 1 and Time 2, while remaining at the same level for those in the control arm. However, these changes disappeared when they were adjusted to account for differences in baseline scores. A score of 7 or above is generally taken to indicate clinically significant levels of depression, and using this, 39% of the participants (11) in the Living Well groups could be identified as depressed at Time 1 compared to 23% (7) in the control arm. In the intervention group, this increased to 42% (12) at Time 2 and fell to 25% (7) at Time 3 follow-up. The rate of depression remained unchanged in the control arm.

Harms

No adverse events were reported during the course of the study.

Conclusions

As a pilot RCT, this study was not powered to provide evidence of effectiveness of the Living Well with Dementia group therapy intervention. Nevertheless, given the importance of identifying support mechanisms for people affected by dementia together with the relative paucity of evidence relating to such interventions, it is important to consider the significance of the findings from the study. There were strong (albeit non-significant) trends towards improvements in both participant-rated quality of life and self-esteem in the Living Well with Dementia condition compared to the control. While at least some of this change was due to a fall in both measures in the control arm between Time 1 and Time 2, similar falls in quality of life scores of the control group were found by Logsdon et al. (2010), who also reported similar improvements for participant-rated quality of life in their intervention group. In contrast to previous research in therapist led groups (e.g. Cheston et al., 2003), there were relatively small decreases in mean levels of depression in the intervention arm before and after the intervention, which disappeared when scores were adjusted for baseline differences. However, the number of participants who were depressed fell at follow-up in the intervention arm, whilst remaining unchanged in the control condition.

The use of resources by the intervention and control groups also showed potentially important differences – during the intervention itself, the average number of contacts with NHS services increased for the intervention group compared to the control condition, possibly indicating that regular contact with nurses and other health care professionals within the memory clinic leads to greater use of services. However, this decreased at follow-up, suggesting the possibility of longer term savings. Similarly, although the number of participants with contact with day care and third sector services was smaller, by the end of the study, the number of participants in the Living Well groups who also used day centres, social clubs and other dementia-related groups had increased from four to seven, while the number of control group participants using these centres had fallen from five to four over the same time period.

Effect size

The largest changes in outcome measure for participants in the intervention arm compared to the control arm were found in participant-rated quality of life and self-esteem. The changes in both measures are encouraging, and are consistent with both the informal feedback that group therapists received from participants and their families, and also with the hypothesised benefits of attending groups. The effect size of $d = .46$ is comparable with that of .44 found by Logsdon et al. (2010).

The overall aim of this pilot study was not to provide a definitive evaluation of the Living Well with Dementia group intervention, but rather to inform a future, more definitive multi-centre trial. In order to do this, we have also collected data about a range of processes.

Recruitment

Recruitment rates between the two NHS trusts involved in the study varied, which was probably due to one trust having an established record of making referrals and being involved in running the groups. However, even in the trust where groups had not been used before, it was still possible to meet the target of establishing three groups.

Attendance at groups and loss to follow-up

Two participants withdrew from the study after giving consent but before being interviewed at baseline. Three participants withdrew from the intervention arm during the course of the study (two due to illness), although data was still collected from these participants under the intention-to-treat principle, while six withdrew from the control arm for a variety of reasons and with knock-on effects on data collection. An attrition rate of less than 10% is better than that achieved by Cheston et al. (2003) and is within acceptable limits for a group intervention lasting for 10 weeks, especially given the often physically frail nature of the population. Similarly, the attendance rate at sessions was relatively high (83%), particularly given participants' difficulties in remembering appointments.

Acceptability

As Figure 1 indicates, of the 132 people who met our eligibility criteria, more than half declined the chance to participate in the project. The main reasons expressed were a reluctance to meet others with dementia, and concerns that the randomisation process meant they might have to wait to participate in a group. In addition, semi-structured interviews were conducted by JS with all therapists and with 18 selected participants depending on whether their outcome scores had clearly benefitted from or deteriorated as a result of being within the groups. This process identified additional outcome measures (e.g. changes in relationship), which may be incorporated into a future study. However, a fuller analysis of these interviews will be reported on separately.

Training staff who lack a background in group intervention

While clinicians working within memory clinics often have an excellent knowledge about working with people who are affected by dementia, they are often less experienced in leading group interventions. The range of staff involved in this project suggests that the intervention can be delivered by staff who have relatively little background in this area. Ratings by therapists given at the end of the two-day training programme by AM and RC were high. Interviews conducted by JS with therapists after they had completed both the intervention and the waiting-list groups suggested that staff were generally extremely positive about providing the groups.

Randomisation

The use of a randomised design differed from normal clinical practice, as it reduced the ability of therapists to control the level of homogeneity of groups. For participants, this increased heterogeneity was often experienced in terms of others in the group having higher levels of disability – a feature that was commented on regularly. As well as being a concern for participants, this may have weakened the therapeutic effects seen in normal clinical practice.

Generalisability

For at least some memory clinics, resource pressures may mean that assessment and diagnosis are prioritised over support and their capacity to provide post-diagnostic support may well be limited. Consequently, other services including primary care and the third sector may become involved in providing interventions including Living Well with Dementia groups.

There is a continuing need to identify effective interventions, which can be widely implemented within health care systems and which focus on facilitating adjustment to a diagnosis. Thus, as we have described above, the UK government aims to provide post-diagnostic support to two-thirds of people diagnosed with dementia by March 2015. Peer support is likely to play an important role in filling the post-diagnostic gap in dementia care. As support groups aimed at people in the early stages of dementia in the USA have been shown to increase quality of life, to improve communication between families and to lower levels of depression (Logsdon et al., 2010), it is appropriate to explore whether similar changes could be found in the UK. This pilot study indicates that a definitive clinical trial of Living Well with Dementia group therapy is warranted.

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Notes

1. http://www.controlled-trials.com/ISRCTN25079950/
2. REC Number 11/SC/0363, approval dated 18 November 2011, protocol amendments accepted on 28 June 2012 and 23 August 2012.
3. Available on request from RC.

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