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Behavioural activation for promoting well-being in mild dementia: feasibility and outcomes of a pilot randomised controlled trial

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Abstract

Engaging in meaningful and enjoyable activities is an important contributor to well-being and maintaining good quality of life. There is a paucity of randomised controlled trials of interventions supporting people with mild dementia to engage in meaningful and purposeful activity. The aim of this study was to assess whether Behavioural Activation (BA) is an acceptable psychological intervention for people with mild dementia and whether a large scale trial is feasible.

Participants were randomly assigned to BA (n = 42) or treatment as usual (TAU) (n = 21). BA aimed at increasing engagement in enjoyable and meaningful activity, and preventing low mood. Follow-up was at 3 and 6 months. Assessors were blind to treatment allocation (trial registration number: ISRCTN75503960).

Retention rate was above 80% at both assessment time points. Treatment acceptability and credibility were high. Depressive symptoms remained unchanged in both groups. There was evidence of improvement associated with BA for every day function (-3.92, 95% Confidence Interval (CI) -6.87 to -0.97), and engagement in meaningful and enjoyable activity (5.08, 95% CI 0.99 to 9.16) post-treatment (3 months) in comparison to TAU. Both carer-rated patient health-related quality of life (0.16, 95% CI 0.04 to 0.28) and physical health (11.31, 95% CI 2.03 to 20.59) showed evidence of improvement at 3 months. Improvements in meaningful and enjoyable activity were maintained at 6 months.

BA for people with mild dementia is feasible and acceptable and may be associated with clinically significant changes in function and quality of life. A full scale randomised controlled trial of clinical effectiveness is now needed.

Key words: behavioural activation, behavioural therapy; randomised controlled trial; dementia; activity scheduling; low mood; pleasant events; feasibility; acceptability.

Given the rapidly growing prevalence and socio-economic costs associated with dementia, developing innovative interventions to improve treatment outcomes and promote well-being for people with dementia is currently an important priority worldwide [1, 2]. In the UK, recent National Institute of Health and Clinical Excellence (NICE) guidelines recommend access to psychological treatments for people with dementia but highlight that further research is needed to assess which psychological interventions are most effective for each stage of the condition [3]. Psychological interventions have been associated with small but statistically significant improvements in depression and anxiety [4], but the evidence base remains small, and the various approaches used, combined with diverse patient groups and settings [5], limit conclusions about which psychological treatment components may be more effective.

Behavioural activation (BA) has recently gained increasing research interest as a psychological intervention that aims to engage individuals with positive reinforcement and improve mood [6, 7]. BA's strength is that it is easy to teach even by non-specialists, and is highly acceptable to providers and patients across settings and cultures [8]. The fundamental rationale behind BA is the importance of value-driven and meaningful activities, supporting individuals to identify and engage in activities that are reinforcing and consistent with their long-term goals [8, 9]. This is particularly important for people living with dementia, which often experience disengagement from every day rewarding activities and opportunities for community participation [10]. As a result, people with dementia can have limited access to meaningful and purposeful activity, which stems partly due to loss of skills, but also due to lack of confidence, and stigma associated with the disease [11].

Recent consensus studies highlight that maintaining a high sense of purpose in life and remaining socially integrated is an important psychological need for people with dementia and should be a core outcome for future community-based interventions [10]. Increasing access to effective and cost-effective interventions supporting people with dementia maintain their activity levels is important within the context of the progressive nature of the disease, which may hinder individuals from maintaining purposeful activity [12, 13].

In this study we report on the feasibility and acceptability of a BA intervention developed after extensive consultations and piloting with people with mild dementia and their families [14]. The primary aim was to test the feasibility and acceptability of activity scheduling as a psychological intervention for people with mild dementia and assess whether a pragmatic trial would be feasible. A secondary aim was to evaluate suitability of outcome measures for a main trial and any evidence of change beyond post-treatment to inform the design of a full-scale randomised controlled clinical trial (RCT). We hypothesised that BA would be feasible if there was evidence of: a) a recruitment rate comparable to BA studies of older people; b) high retention and c) high adherence and credibility ratings of the intervention.

Methods

Design and setting

The trial was an individual based single blind pilot RCT of BA versus treatment as usual (TAU). We recruited through National Health Service (NHS) secondary care services by receiving referrals from memory clinics and community mental health teams. The London – Camberwell St Giles Research Ethics Committee approved the study (REC

16/LO/0540). Written informed consent was obtained from all people with dementia and their carers, and decision-making capacity to consent was regularly monitored.

Participants

Participants were recruited if they met the following criteria: 1) had a diagnosis of mild dementia of any type (defined by a Mini Mental State Examination Score – (MMSE) of ≥ 18 [15]; 2) were living in the community; and 3) had a family carer who was available to participate in the research and support the person in the intervention. Participants were excluded if (1) they were deemed by their clinical team to be at risk of self-harm (excluding neglect) or a risk to others; (2) experienced difficulties communicating in English, or (3) were already taking part in another intervention study. After trial commencement, a large proportion of participants did not meet criteria of having received a diagnosis in the last 6 months; therefore this eligibility criterion was revised.

Randomisation and masking

Randomisation was undertaken via an on-line randomisation system stratified by site provided by internet-based sealed envelope codes, based on random permuted blocks of sizes of three and six to allow a 2:1 allocation to BA and TAU, performed by one of the therapists. All assessors were blind to treatment allocation. All data were collected in participants' homes.

Statistical methods

The heuristic sample size for feasibility studies is 30 per group [16]. Given that the primary aim of this study was to examine feasibility, the study was not powered to detect effectiveness, but to provide data to inform the sample size calculation for a full trial [17].

We analysed feasibility outcomes, which included number of clinician referrals, number of participants recruited and randomised and retention rates for both outcome time points. We considered the main trial and intervention feasible if > 75% of participants completed the intervention and outcome measures. If this rate was found to be lower between 65 and 70% then adjustments would need to be considered. We decided a priori that a 75% acceptability of BA measured by a) number of people completing the intervention and b) number of sessions attended would indicate that the intervention was acceptable. Intervention acceptability included percentage of BA sessions completed, and credibility ratings completed via self-report separately by people with dementia and family carers. Data on outcomes proposed for the main trial were analysed using the intention-to-treat principle. We used linear regression to model outcomes at 3 and 6 months, and reported 95% Confidence Intervals (CIs) of the adjusted effect (controlling for baseline scores of each outcome). All analyses were carried out using SPSS Statistics 24 for Windows.

Intervention and control conditions

The development of the intervention was informed by a systematic review of effectiveness of BA in older people [5], consultations with people with dementia and their carers, piloting and further refinement in line with Medical Research Council guidelines [18]. It was pretested in 15 dyads to be adapted to people with a diagnosis of mild dementia and for informing BA materials, activities content, key fidelity parameters and training of therapists. Based on qualitative feedback, several adaptations were made which included: 1) identification of important values and current activities in the first session, 2) emphasis on the person's current activities providing positive reinforcement 3) tailoring the intervention to individual patient and carer needs. The final content of the

adapted intervention differed from BA interventions in older people without dementia in terms of: an emphasis on living well with dementia despite experiencing memory difficulties; a focus on activities the person engages regularly; and guidance for therapists based on specific patient and carer-engagement scenarios.

The adapted intervention, **S**TAYing well and active - schedulINg meaninGful and enjoyAble aCTIvities to promote Vitality and wEll-being in mild dementia (STAYING ACTIVE), was an eight (1 hour) session manualised individual intervention, delivered weekly at home by trained graduate psychologists supervised fortnightly by a clinical psychologist. The intervention comprised psychoeducation to BA, identifying enjoyable and meaningful activities based on personal interests and life values, generating goals, and practising relaxation breathing exercises to manage worry and anxiety in everyday life. Family carers were introduced to the key principles of BA, and supported the person with dementia in identifying and scheduling activities. All participants were given access to a diary and a booklet with physical activity and relaxation exercises. Participants in the control group received TAU, which varied and may have changed over time. In general, services offered to the TAU group were also available to those in the active treatment condition.

Clinical outcomes evaluated for suitability for a main trial

Depressive symptoms were measured by the Cornell Scale for Depression in Dementia (CSDD) [19], rating depression across five domains. The CSDD is administered as an interview, using information provided by both the person with dementia and proxies. The CSDD has established validity and specificity for depression in people with dementia [20]. Activities of daily living were measured using the Bristol

Activities of Daily Living Scale (BADLS) [21], developed as a functional informant assessment scale for people living with dementia in the community. The BADLS rates 20 basic and instrumental activities across several domains of daily life, and has good inter- and intra-observer reproducibility and sensitivity to change over time [22]. We measured engagement with meaningful and enjoyable activity using a scale specifically developed for the purpose of this study. The Meaningful and Enjoyable Activities Scale (MEAS), comprises 20 items of carer-rated activity participation for the person with dementia across several domains such as creative activities, physical exercise, socialising, and community involvement. The MEAS uses the following response options: 0 (*Never*), 1 (*once a month*), 2 (*2 to 3 times a month*), 3 (*1 to 2 times weekly*), 4 (*almost daily*), and showed good reliability and validity (Cronbach's alpha = 0.79).

Self-rated and carer-rated dementia-specific quality of life for the person with dementia – was measured using the DEMQOL and DEMQOL-proxy [23], which have established validity measuring five domains of quality of life in dementia [24]. Generic self and carer-rated quality of life for people with dementia was measured using the European Quality of Life-5 Dimensions (EQ-5D) [25]. We used the three-level response version, which has acceptable reliability and validity for both self and carer ratings [26].

Neuropsychiatric symptoms were measured by the Neuropsychiatric Inventory (NPI) [27], assessing a total of 12 symptoms as rated by the carer. The NPI has established validity and reliability and assesses both frequency and severity of each symptom [28].

Carers' mental and physical health was assessed with the Short Form questionaire-12 items (SF-12) [29]; expressed as two meta-scores. Depression and anxiety were measured using the Hospital Anxiety and Depression Scale (HADS) [30], completed as a self-report

instrument. Health-related quality of life for carers was measured with the EQ-5D [25]. We used a modified version of the Credibility and Expectancy Questionnaire (CEQ) [31] to measure patient and carer satisfaction with the intervention.

Results

Feasibility of recruitment and retention to the study

Figure 1 (CONSORT diagram) shows participant flow through the study. We were able to recruit the required number of participants within the given timeframe, which was 10 months (October 2018-July 2019). Approximately one in three referrals were recruited to the study; indicative of a recruitment rate of 34% (63/187). There were a total of 182 referrals, assessed for eligibility, of which 27% (49) did not meet inclusion criteria, 19% (34) were unavailable due to moderate-to-severe physical illness and/or hospitalisation, 13% (22) declined participation to the study, 6% (11) declined participation in research in general, and 1.6% (3) no longer lived in the local area. The final sample was 63 participant-caregiver dyads randomised to BA (n = 42) or TAU (n = 21).

Retention rates were 84% at both the 3- and 6-month assessments. Nine participants withdrew from the trial at first follow-up. Two dyads were not able to complete the first follow-up assessment but were assessed at second follow-up. Another two dyads withdrew from the trial at second follow-up. In the 6- months assessment for two dyads only patient data were available (due to carer unavailability) (see Figure1 CONSORT flow chart). Retention did not differ by condition at 3- (p = 0.41) or 6-months (p = 0.56). There was evidence that those who withdrew from the study had lower rates of both self and carer-rated quality of life at baseline as measured by the DEMQOL (self ratings: p <

0.01; carer ratings: p = 0.02) and EQ5D (self ratings: p < 0.01; carer ratings p = 0.26), and their carers were younger (p = 0.01).

Sample characteristics

Table 1 shows demographic characteristics of the sample. There were 35 (56%) females and 28 (44%) males aged between 59 to 94. Median time since diagnosis was 12.5 months (IQR 4-21). Average MMSE was 24 for both groups. Acetylcholinesterase inhibitor (AchEI) prescription rates were higher in the BA group compared to TAU. Carers were mostly family members of the person with dementia, with a mean age of 68 years. Table 2 shows baseline summary statistics for all measures by randomised condition. Baseline summary scores were similar between the two groups, indicative of high levels of activities of daily living, engagement in meaningful activity and quality of life. Scores on the CSDD were low on average, and balanced across treatment arms, with the majority of participants identified as not having depression [32]. A total of 28 adverse events occurred; of which one was a death; 15 in the BA group and 13 in the TAU group; none of which were assessed as being related to the trial.

Feasibility, adherence and credibility of BA

Out of the 42 people with dementia randomised to receive BA, 5 dyads did not receive the intervention (see CONSORT Flow diagram). Of the remaining 37, 30 dyads completed all 8 sessions, and 7 dyads 7 sessions. Treatment credibility (range 1 low to 9 high) was high for people with dementia at both the start (session 1- Mean = 7.18, SD = 1.32); and end of treatment (session 7- Mean = 7.63, SD = 1.10). Carer ratings were slightly lower but overall moderately to highly credible at both the beginning (Mean = 6.92, SD = 1.30) and end of sessions (Mean = 7.59, SD = 1.18). Treatment expectancy

(range 0% low to 100% high) was moderate to high increasing from start to end of treatment for both people with dementia (session 1: Mean = 65.81, SD = 24.65; session 7: Mean = 80.00, SD = 18.26; $t(30)= 24.40$; $p < 0.001$), and carers (session 1: Mean = 55.20, SD = 22.01; session 7: Mean = 67.33, SD = 21.72; $t(29)= 16.55$; $p < 0.001$). There were no adverse events associated with the intervention.

Main clinical outcomes at 3 months

Depressive symptoms, activities of daily living, and meaningful activity

Follow-up scores were compared between the intervention and control group using regression models to provide estimates of the effect of STAYING ACTIVE with 95% CIs adjusted for baseline scores. There was no evidence of differences for symptoms of depression between the two groups as measured by the CSDD (-0.29, 95% CI -2.09 to 1.51). There was evidence of improvement in activities of daily living measured by the BADLS, which favoured BA after adjusting for baseline scores (-3.92, 95% CI -6.87 to -0.97) (see Table 3) indicating higher levels of every-day function. Meaningful and enjoyable activity measured by the MEAS increased in the BA group after adjusting for baseline levels (5.08, 95% CI 0.99 to 9.16).

Neuropsychiatric symptoms, self and carer-rated patient quality of life, and carer outcomes

There were no evidence of change on neuropsychiatric symptoms (-1.13, 95% CI -6.58 to 4.32), self-rated quality of life for the person with dementia measured by the DEMQOL (2.05, 95% CI -2.45 to 6.55), EQ-5D (0.09, 95% CI -0.06 to 0.24) and EQ5D VAS (-5.04, 95% CI -16.88 to 6.60) or carer-rated patient quality of life as measured by the DEMQOL (3.96, 95% CI -0.88 to 8.80). There was evidence of improvement on

carer-rated quality of life measured by the EQ-5D (0.16, 95% CI 0.04 to 0.28) and EQ5D VAS ratings (11.31, 95% CI 2.03 to 20.59), with higher ratings for the BA group compared to TAU. There was no evidence of differences on outcome measures for carers (see Table 3). Based on Cohen criteria [33] the observed effects are moderate (see Table 3).

Outcomes at 6 months

Depressive symptoms, activities of daily living, and meaningful activity

As with post-treatment, there was no evidence of change in depression between groups (-0.34, 95% CI -2.91 to 2.22) at long-term follow-up. There were no differences on activities of daily living at 6 months (-1.10, 95% CI -4.71 to 2.52) but the advantage of higher engagement with meaningful and enjoyable activity was maintained long-term for people with dementia engaging in BA (4.89, 95% CI 0.49 to 9.11).

Neuropsychiatric symptoms, self and carer-rated patient quality of life, and carer outcomes

At 6 months, there were no differences on neuropsychiatric symptoms, and self-rated quality of life. Carer-rated quality of life for the person with dementia measured by the DEMQOL showed no evidence of change, however carer ratings of patient quality of life measured by the EQ-5D showed evidence of improvement, an effect that fell a little short of statistical significance (0.11, 95% CI 0.00 to 0.22). There were no other differences observed.

Discussion

This is the first community-based study assessing feasibility and acceptability of BA for people with mild dementia. Our study shows that interventions that support people

with dementia to maintain and engage in meaningful and purposeful activity are feasible and acceptable psychological treatments that merit further evaluation. Our study provides further support for the use of psychological interventions adapted to meet the needs of people with dementia in line with recent clinical guidelines [3]. There was good adherence to the intervention, and high credibility ratings indicating that BA interventions have face validity for people with dementia and their family carers. Levels of attrition and outcome loss were low, similar to other BA trials [5].

Feasibility and acceptability of BA

In order to test our main objectives we piloted BA to examine whether this would be a feasible and acceptable intervention for people with a diagnosis of mild dementia. We used a theoretically driven and structured approach of BA that was adapted to people living with a diagnosis of dementia and were able to demonstrate high credibility ratings, adherence to sessions and high participant retention. We were able to collect outcomes at both 3 and 6 months and participants accepted randomisation to the study. Overall our recruitment rate was comparable to BA studies in the general population, in older people and psychological trials in dementia [4, 5, 8]. Around 11% of participants did not complete the intervention which is a common finding in both psychotherapy trials and routine practice. Successful engagement in any treatment is important because it means that people with dementia are more likely to receive the full intervention.

Clinical outcomes for main trial

Our preliminary results show that BA interventions may impact on many areas of health-related quality of life and every day function for people with dementia. Participants randomised to receive BA were able to maintain their levels of function

compared to the TAU group. Quality of life for the person with dementia as rated by carers followed a similar pattern of improvement at 3 months. Carer-rated patient physical health also improved. BA was associated with increased participation in meaningful and enjoyable activities compared to TAU, an effect that showed evidence indicative of improvement beyond post-treatment. Although our study was not powered to detect effects our findings indicative of improvement in activities of daily living are in line with previous meta-analysis and longitudinal studies [5, 34], highlighting that engaging in meaningful activity is an important outcome in late life regardless of level of cognitive impairment [10].

Strengths and limitations

An important strength of our pilot study was that we were able to investigate retention and any potential improvement with BA long-term, beyond post-treatment. Our findings were overall in the expected direction, and are in line with evidence that BA may be associated with medium to large effects, being observed in relatively few sessions [35]. The reported changes compare favorably with effects of pharmacological treatments on function and activities of daily living for people with dementia which tend to be small [36].

However our study has several limitations. Our small sample size increases the imprecision of any effects, hence conclusions about the effectiveness of the intervention are not warranted. Our pilot study can therefore only provide data that support further research and evaluation of BA via a large scale fully-powered clinical trial. Self-reported outcomes for people with dementia did not show evidence of change; it will be important for future research to examine which parameters of the intervention may influence self-

ratings. Levels of depressive symptoms as measured by the CSDD remained unchanged between the two groups, therefore any potential change in this outcome remains uncertain. However, people with dementia were not selected on the basis of depressive symptoms and the average score and interquartile range (IQR) on the scale indicate that very few participants had scores indicative of probable or definite depression. Alternatively, the CSDD may not be appropriate to capture the profile of depressive symptoms or psychological distress of people who experience mild dementia.

The development and feasibility data of our intervention are based on people who are generally very active and do not experience significant co-morbidity; our findings therefore may not be generalizable to all people with dementia especially those with significant comorbidity, physical impairment or poor mobility. We were unable to recruit people with dementia that had no regular carer and people experiencing significant communication difficulties, including marked hearing or vision loss. We relied on carers to provide ratings of activities of daily living, depression and engagement in activities, rather than collecting data from people with dementia, which is an important limitation of our study.

Implications for research and practice

Our research aimed to address an important gap in the provision and evidence base of psychological treatments for people with dementia [3]. Future research should investigate which mechanisms associated with BA interventions may maintain functional independence; for example the intervention may target general inactivity, social withdrawal or limited environmental stimulation, often referred to as ‘excess disability’ in dementia. Based on previous literature we estimate that between-group differences of 4

points in every-day function could be clinically significant. There were no serious adverse events associated with the intervention, suggesting that BA does not carry any notable risk to participants. We found evidence that depression as measured by the CSDD may not be sensitive to change in a future large-scale trial. Careful consideration of outcomes therefore is required alongside future research to test which instruments are more likely to be sensitive to change.

We were able to demonstrate that it is possible to train non-specialist professionals to deliver BA, indicating that this may be a cost-effective intervention, which is brief, and can be delivered by a range of professionals, increasing treatment accessibility to people with dementia [35]. Future studies should assess fidelity of intervention by non-specialists compared to skilled professionals. Further research is required to evaluate whether BA is an effective and potentially valuable approach in enabling people with dementia maintain and/or re-establish active lives. A strength of BA may be its focus on increasing value-driven activities in the patient's life, which is considered an important outcome by people with dementia, closely aligned to the ethos of memory clinics and current policy on Living well with dementia [37, 38]. Our results suggest that interventions that focus on activity scheduling and promoting meaningful activity in people with dementia could be a front-line early psychological intervention if effectiveness is confirmed.

Conclusion

Behavioral activation adapted to meets the needs of people with a diagnosis of mild dementia, is an acceptable and feasible psychological intervention, and should be considered for further evaluation in a large-scale clinical trial. Detecting change in

everyday functioning is clinically meaningful and may be an important outcome of clinical trials for people with mild dementia.

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Data availability

The full dataset can be requested by the corresponding author, Dr Vasiliki Orgeta, Division of Psychiatry, Faculty of Brain Sciences, University College London, 6th Floor, Maple House, 149 Tottenham Court Road, London W1T 7NF, UK. Email: v.ogreta@ucl.ac.uk. The full protocol can be accessed here: https://bmjopen.bmj.com/content/8/2/e021074.

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Conflict of interest statement

Dr Vasiliki Orgeta is the lead author of the Cochrane review on psychological treatments and received a personal senior fellowship award to undertake this work. There are no other known conflicts of interest. All other co-authors report no conflict of interest.

Ethics and Contribution Statement

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. All procedures involving human patients were approved by the London Camberwell St Giles Research Ethics Committee (16/LO/0540). All authors have contributed to the work undertaken.

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Table 1: Participant demographics for the full sample and separately by study arm

	All participants n = 63	BA (n= 42)	TAU (n= 21)
Participants			
Age (years) – mean (SD)	80.4 (7.6)	80.4 (8.3)	80.4 (6.2)
Female	35 (56%)	22 (52%)	13 (62%)
Education			
School leaver	30 (48%)	19 (45%)	11 (52%)
Higher/further education	16 (25%)	12 (29%)	4 (19%)
Higher/postgraduate education	17 (27%)	11 (26%)	6 (29%)
Ethnicity			
White British/Irish	44 (70%)	28 (67%)	16 (76%)
Other White/Other Mixed	9 (14%)	6 (14%)	3 (14%)
Black Caribbean/Other Black	7 (11%)	6 (14%)	1 (5%)
Indian/Other Asian	3 (5%)	2 (5%)	1 (5%)
Marital status			
Married/cohabiting	45 (72%)	30 (71%)	15 (71%)
Widowed	14 (22%)	8 (19%)	6 (29%)
Divorced/separated/single	4 (6%)	4 (10%)	
Living status			
With carer	50 (80%)	33 (79%)	17 (81%)
Alone	9 (14%)	5 (12%)	4 (19%)
Other family	4 (6%)	4 (9%)	
MMSE – mean (SD)	24.5 (3.6)	24.5 (3.6)	24.4 (3.6)
Months living with diagnosis	13.8 (10.6)	15.0 (11.3)	11.5 (8.8)
Diagnosis			
Alzheimer's disease	41 (65%)	27 (64%)	14 (66%)
Vascular dementia	10 (16%)	6 (14%)	4 (19%)
Mixed dementia	9 (14%)	7 (17%)	2 (10%)
Other dementia diagnosis	3 (5%)	2 (5%)	1 (5%)
Taking AchEI	41 (65%)	32 (76%)	9 (43%)
Taking antidepressants	13 (21%)	8 (19%)	5 (24%)
Carers			
Age (years) – mean (SD)	68.2 (13.3)	68.0 (14.5)	68.5 (11.0)
Female	39 (62%)	26 (62%)	13 (62%)
Education			
School leaver	15 (24%)	10 (24%)	5 (24%)
Higher/further education	22 (35%)	16 (38%)	6 (28%)
Higher/postgraduate education	26 (41%)	16 (38%)	10 (48%)
Ethnicity			
White British/Irish	41 (65%)	27 (64%)	14 (67%)
Other White/Other Mixed	11 (17%)	8 (19%)	3 (14%)
Black Caribbean/Other Black	5 (8%)	5 (12%)	-
Indian/Other Asian/Chinese	6 (10%)	2 (5%)	4 (19%)
Marital status			

Married/cohabiting	50 (79%)	33 (79%)	17 (81%)
Widowed	1 (2%)	-	1 (5%)
Divorced/separated/single	12 (19%)	9 (21%)	3 (14%)
Relationship to participant			
Spouse/partner	42 (67%)	29 (69%)	13 (62%)
Child/Child in law	19 (30%)	12 (29%)	7 (33%)
Friend	2 (3%)	1 (2%)	1 (5%)

Note: All statistics are counts (n) and percentages (%) unless otherwise specified.

Table 2: Baseline summary statistics overall and by study arm

Measure	All participants n = 63 Mean (SD)	Median (IQR)	BA n = 42 Mean (SD)	Median (IQR)	TAU n = 21 Mean (SD)	Median (IQR)
BADLS	12.35 (9.12)	12.00 (4.00 – 19.00)	11.98 (9.24)	11.00 (3.00 – 19.00)	13.10 (9.05)	12.00 (5.50 – 19.00)
MEAS	39.07 (12.25)	37.00 (31.00 – 46.50)	40.08 (12.71)	41.00 (31.25 – 47.75)	37.14 (11.39)	34.00 (30.00 – 41.50)
CSDD	7.25 (5.66)	6.00 (3.00 – 10.00)	7.57 (5.56)	6.00 (3.00 – 12.25)	6.62 (5.93)	4.00 (2.50 - 9.50)
NPI (Total)	12.34 (12.29)	8.00 (2.00 – 20.50)	13.32 (12.96)	10.00 (2.50 – 23.50)	10.43 (10.91)	7.00 (2.00 – 17.50)
DEMQOL Self	90.50 (16.20)	95.00 (82.00 – 102.00)	88.28 (18.22)	92.00 (79.00 – 102.00)	94.62 (10.80)	96.00 (87.50 – 103.00)
DEMQOL Proxy	97.47 (16.11)	101.00 (85.00 – 111.00)	95.74 (17.71)	101.00 (80.00 – 112.00)	100.85 (12.12)	101.00 (93.50 – 110.50)
EQ5D Self	0.71 (0.30)	0.80 (0.62 – 1.00)	0.68 (0.33)	0.79 (0.59 – 1.00)	0.77 (0.20)	0.80 (0.64 – 0.92)
EQ5D Proxy	0.52 (0.32)	0.62 (0.19 – 0.73)	0.52 (0.30)	0.60 (0.20 – 0.70)	0.52 (0.35)	0.69 (0.15 – 0.81)
EQ5D VAS Self	70.67 (19.37)	70.00 (55.00 – 85.00)	69.62 (20.55)	70.00 (53.75 – 86.25)	72.76 (17.03)	70.00 (56.50 – 82.50)
EQ5D VAS Proxy	60.44 (18.30)	60.00 (50.00 – 71.00)	61.19 (16.90)	60.00 (50.00 – 71.25)	58.95 (21.19)	65.00 (47.50 – 71.00)
Carers						
SF-12 PC	45.78 (9.92)	48.65 (38.90 – 54.49)	45.80 (9.17)	48.33 (38.80 – 54.09)	45.73 (11.66)	49.53 (39.29 – 55.33)
SF-12 MC	43.72 (11.97)	44.18 (36.91 – 54.31)	42.78 (12.40)	43.27 (36.67 – 53.45)	45.45 (11.21)	45.85 (37.69 – 56.69)
HADS Depression	4.71 (3.92)	4.00 (2.00 – 7.00)	5.00 (4.19)	4.00 (2.00 – 7.25)	4.14 (3.35)	3.00 (2.00 – 6.50)
HADS Anxiety	6.74 (4.68)	6.00 (3.00 – 9.00)	7.00 (4.90)	6.00 (3.00 – 9.50)	6.24 (4.29)	7.00 (2.00 – 9.00)
HADS Total	11.45 (8.27)	10.00 (4.75 – 16.00)	12.00 (8.78)	10.00 (5.50 – 16.50)	10.38 (7.26)	10.00 (4.00 – 16.00)
EQ-5D	0.75 (0.26)	0.80 (0.69 – 1.00)	0.76 (0.24)	0.80 (0.69 – 1.00)	0.72 (0.30)	0.80 (0.60 – 1.00)
EQ-5D VAS	75.79 (14.87)	78.00 (70.00 – 90.00)	76.29 (13.58)	75.00 (70.00 – 90.00)	74.81 (17.50)	80.00 (62.50 – 87.50)
NPI Carer distress	8.32 (8.07)	6.00 (2.00 – 14.00)	8.93 (8.58)	6.00 (2.50 – 14.50)	7.14 (7.00)	5.00 (1.50 – 11.50)

Note: BADLS – Bristol Activities of Daily Living; MEAS – Meaningful and Enjoyable Activities in Dementia Scale; CSDD - Cornell Scale for Depression in Dementia; NPI - Neuropsychiatric Inventory; DEMQOL – Dementia Quality of Life; EQ-5D – European Quality of Life-5 Dimensions; SF-12 – Short Form- 12 Health Survey; HADS - Hospital and Anxiety Depression Scale.

Table 3: Unadjusted and adjusted Means, SDs, and adjusted treatment effect at 3 months

Outcomes at 3 months	Unadjusted Means and SDs	n	Unadjusted Means and SDs	n	Adjusted Means and SDs	n	Adjusted Means and SDs	n	Adjusted effect	p value	Effect size (d) and 95% CI
	BA		**TAU**		**BA**		**TAU**				
Patients											
BADLS	10.61 (10.01)	36	16.18 (9.57)	17	11.14 (5.11)	36	15.06 (5.12)	17	-3.92 (-6.87 to -0.97)	0.0120	-0.77 (-1.35 to -0.16)
MEAS	44.50 (11.79)	36	37.53 (11.40)	17	44.18 (7.21)	36	39.10 (7.02)	17	5.08 (0.99 to 9.16)	0.0194	0.71 (0.11 to 1.29)
CSDD	5.75 (4.00)	36	5.35 (4.81)	17	5.53 (3.11)	36	5.82 (3.12)	17	-0.29 (-2.09 to 1.51)	0.7527	-0.09 (-0.67 to 0.49)
NPI (Total)	10.71 (11.52)	36	10.12 (12.17)	17	10.15 (9.53)	36	11.28 (9.42)	17	-1.13 (-6.58 to 4.32)	0.6876	0.12 (-0.69 to 0.46)
DEMQOL Self	89.48 (16.13)	36	94.70 (12.36)	17	92.36 (8.06)	36	90.31 (7.67)	17	2.05 (-2.45 to 6.55)	0.3843	0.26 (-0.32 to 0.83)
DEMQOL Proxy	102.11 (12.58)	36	101.23 (12.38)	17	103.03 (8.44)	36	99.07 (8.36)	17	3.96 (-0.88 to 8.80)	0.1161	0.47 (-0.12 to 1.05)
EQ5D Self	0.71 (0.29)	36	0.65 (0.33)	17	0.72 (0.27)	36	0.63 (0.27)	17	0.09 (-0.06 to 0.24)	0.2563	0.33 (-0.25 to 0.91)
EQ5D Proxy	0.64 (0.24)	36	0.47 (0.34)	17	0.63 (0.20)	36	0.47 (0.21)	17	0.16 (0.04 to 0.28)	0.0101	0.79 (0.18 to 1.37)
EQ5D VAS Self	67.20 (20.11)	36	74.06 (19.85)	17	67.77 (19.90)	36	72.81 (20.32)	17	-5.04 (-16.68 to 6.60)	0.3965	-0.25 (-0.83 to 0.33)
EQ5D VAS Proxy	66.08 (18.81)	36	53.88 (17.05)	17	65.80 (16.09)	36	54.49 (16.09)	17	11.31 (2.03 to 20.59)	0.0206	0.70 (0.10 to 1.28)
Carers											
SF-12 PC	46.55 (11.11)	34	44.38 (12.29)	15	46.59 (8.60)	34	44.28 (8.61)	16	2.31 (-2.91 to 7.53)	0.3906	0.27 (-0.33 to 0.86)
SF-12 MC	43.14 (10.89)	35	47.08 (10.33)	15	44.09 (7.09)	35	43.99 (6.85)	15	0.10 (-4.09 to 4.29)	0.9634	0.01 (-0.59 to 0.62)
HADS Depression	5.47 (4.22)	36	3.71 (2.69)	17	5.12 (2.02)	36	4.46 (2.03)	17	0.66 (-0.51 to 1.83)	0.2733	0.33 (-0.26 to 0.90)
HADS Anxiety	6.28 (4.61)	36	5.24 (3.42)	17	5.88 (2.32)	36	6.09 (2.32)	17	-0.21 (-1.55 to 1.13)	0.7595	-0.09 (-0.67 to 0.49)
HADS Total	11.75 (8.21)	36	8.94 (5.61)	17	10.97 (3.41)	36	10.59 (3.43)	17	0.38 (-1.59 to 2.35)	0.7068	0.11 (-0.77 to 0.39)
EQ-5D	0.72 (0.26)	36	0.73 (0.36)	17	0.71 (0.21)	36	0.75 (0.21)	17	-0.04 (-0.16 to 0.08)	0.5180	-0.19 (-0.79 to 0.37)
EQ-5D VAS	73.49 (13.76)	35	76.41 (15.26)	17	73.22 (11.40)	35	76.95 (11.41)	17	-3.73 (-10.34 to 2.88)	0.2738	-0.33 (-0.90 to 0.26)
NPI Carer distress	5.91 (6.75)	33	5.65 (6.69)	17	5.60 (5.81)	33	6.25 (5.82)	17	-0.65 (-4.05 to 2.75)	0.7096	-0.11 (-0.70 to 0.48)

Note: BADLS – Bristol Activities of Daily Living; MEAS – Meaningful and Enjoyable Activities in Dementia Scale; CSDD - Cornell Scale for Depression in Dementia; NPI - Neuropsychiatric Inventory; DEMQOL – Dementia Quality of Life; EQ-5D – European Quality of Life-5 Dimensions; SF-12 – Short Form- 12 Health Survey; HADS - Hospital and Anxiety Depression Scale.

Table 4: Unadjusted and adjusted Means, SDs, and adjusted treatment effect at 6 months

Outcomes at 6 months	Unadjusted Means and SDs	n	Unadjusted Means and SDs	n	Adjusted Means and SDs	n	Adjusted Means and SDs	n	Adjusted effect	p value	Effect size (d) and 95% CI
	BA		**TAU**		**BA**		**TAU**				
Patients											
BADLS	13.21 (11.36)	33	15.67 (8.68)	18	13.69 (6.29)	33	14.79 (6.30)	18	-1.10 (-4.72 to 2.52)	0.5536	-0.17 (-0.75 to 0.40)
MEAS	42.54 (10.95)	33	35.67 (10.65)	18	41.75 (7.68)	33	36.95 (7.47)	18	4.80 (0.49 to 9.11)	0.0354	0.63 (0.03 to 1.21)
CSDD	8.36 (5.66)	33	7.33 (6.09)	18	7.88 (4.46)	33	8.22 (4.48)	18	-0.34 (-2.91 to 2.23)	0.7960	-0.08 (-0.65 to 0.50)
NPI (Total)	13.15 (13.44)	33	12.28 (16.46)	18	11.78 (12.40)	33	14.12 (12.27)	18	-2.40 (-9.47 to 4.67)	0.5107	-0.19 (-0.76 to 0.39)
DEMQOL Self	86.09 (19.18)	34	93.22 (12.52)	18	89.22 (8.99)	34	87.30 (9.10)	18	1.92 (-3.26 to 7.10)	0.4691	0.21 (-0.36 to 0.78)
DEMQOL Proxy	95.09 (16.09)	33	102.00 (11.52)	18	96.58 (10.75)	33	99.27 (10.82)	18	-2.69 (-8.89 to 3.51)	0.3984	-0.25 (-0.82 to 0.33)
EQ5D Self	0.60 (0.36)	34	0.57 (0.36)	18	0.62 (0.26)	34	0.54 (0.26)	18	0.08 (-0.07 to 0.23)	0.3010	0.31 (-0.27 to 0.88)
EQ5D Proxy	0.60 (0.27)	33	0.48 (0.37)	18	0.60 (0.19)	33	0.49 (0.19)	18	0.11 (0.00 to 0.22)	0.0539	0.58 (-0.01 to 1.15)
EQ5D VAS Self	65.41 (18.08)	34	73.61 (20.35)	18	66.31 (17.86)	34	71.91 (17.95)	18	-5.60 (-15.84 to 4.64)	0.2881	-0.31 (-0.88 to 0.27)
EQ5D VAS Proxy	66.47 (14.10)	33	61.28 (20.57)	18	66.85 (16.97)	33	60.60 (16.79)	18	6.25 (-3.43 to 15.93)	0.2131	0.37 (-0.21 to 0.94)
Carers											
SF-12 PC	48.37 (9.03)	33	47.60 (10.45)	18	48.30 (7.05)	33	47.74 (7.05)	18	0.56 (-3.49 to 4.61)	0.7874	0.08 (-0.50 to 0.65)
SF-12 MC	42.20 (11.51)	33	46.83 (8.18)	15	42.05 (6.21)	33	44.35 (5.96)	15	-2.30 (-5.99 to 1.39)	0.2349	-0.39 (-0.99 to 0.24)
HADS Depression	5.50 (4.13)	33	4.28 (3.41)	18	5.09 (2.75)	33	5.00 (2.73)	18	0.09 (-1.48 to 1.66)	0.9115	0.03 (-0.54 to 0.61)
HADS Anxiety	6.91 (5.15)	33	5.11 (3.71)	18	6.40 (2.70)	33	6.01 (2.67)	18	0.39 (-1.15 to 1.93)	0.6228	0.15 (-0.43 to 0.72)
HADS Total	12.41 (8.72)	33	9.39 (6.70)	18	11.44 (4.62)	33	11.11 (4.58)	18	0.33 (-2.31 to 2.97)	0.8079	0.07 (-0.50 to 0.65)
EQ-5D	0.81 (0.14)	33	0.79 (0.19)	18	0.80 (0.11)	33	0.81 (0.12)	18	-0.01 (-0.08 to 0.06)	0.7732	-0.09 (-0.65 to 0.49)
EQ-5D VAS	73.50 (14.71)	33	77.22 (16.73)	18	73.15 (14.25)	33	77.84 (14.04)	18	-4.69 (-12.79 to 3.41)	0.2643	-0.33 (-0.90 to 0.25)
NPI Carer distress	7.75 (7.67)	33	6.94 (7.21)	18	7.12 (6.26)	33	7.95 (6.49)	18	-0.83 (-4.51 to 2.85)	0.6571	-0.13 (-0.70 to 0.45)

Note: BADLS – Bristol Activities of Daily Living; MEAS – Meaningful and Enjoyable Activities in Dementia Scale; CSDD - Cornell Scale for Depression in Dementia; NPI - Neuropsychiatric Inventory; DEMQOL – Dementia Quality of Life; EQ-5D – European Quality of Life-5 Dimensions; SF-12 – Short Form- 12 Health Survey; HADS - Hospital and Anxiety Depression Scale.