An adapted mindfulness intervention for people with dementia in care homes:

feasibility pilot study

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Key points:

Group-based mindfulness for people with dementia in care homes was

feasible, although in care homes where there was less managerial support,

staff adherence was compromised.

Results indicate that the intervention may be beneficial for enhancing QoL in

this population, although there is insufficient evidence at this stage to

recommend the intervention to care homes.

Further, larger scale trials are needed to assess the potential of MBIs to

improve QoL, mood and anxiety difficulties in people with dementia.

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Objective

Depression and anxiety are common in dementia. There is a need to develop effective psychosocial interventions. This study sought to develop a group-based adapted mindfulness programme for people with mild to moderate dementia in care homes, and to determine its feasibility and potential benefits.

Methods

A manual for a ten-session intervention was developed. Participants were randomly allocated to the intervention plus treatment as usual (n = 20) or treatment as usual (n = 11). Measures of mood, anxiety, quality of life, cognitive function, stress and mindfulness were administered at baseline and one week post-intervention.

Results

There was a significant improvement in quality of life in the intervention group compared to controls (p = 0.05). There were no significant changes in other outcomes.

Conclusions

The intervention was feasible in terms of recruitment, retention, attrition and acceptability and was associated with significant positive changes in quality of life. A fully powered RCT is required.

Introduction

Anxiety and depression are common in dementia, with prevalence estimates at 8% to 71%, and 10% to 62% respectively (Orgeta et al., 2014). These rates are higher amongst those in care homes and are associated with reduced quality of life (QoL) (Hoe, Hancock, Livingston & Orrell, 2006). Pharmacological approaches have demonstrated limited efficacy, and there is limited evidence supporting a range of psychosocial interventions (Olazaran et al., 2010).

Mindfulness-based interventions (MBIs) promote 'paying attention in a particular way: on purpose, in the present moment and non-judgementally' (Kabat-Zinn, 2003) to enhance emotion regulation. Mindfulness meditation promotes *focused attention* on the breath or body and *open monitoring* of the whole cognitive/affective field. MBIs demonstrate moderate effects in reducing anxiety, depression and stress in clinical and non-clinical populations (Hofmann, Sawyer, Witt & Oh, 2010; Khoury et al., 2013), and mindfulness meditation in healthy adults is associated with improved selective, executive and sustained attention skills (Chiesa, Calati & Seretti, 2011).

Whilst the benefits of MBIs in adult populations are well documented, their application to cognitively impaired and older adult populations is in its infancy. An RCT (*n* = 168) published in Spanish showed that combined mindfulness and 'Kirtan Kriya' meditation slowed cognitive decline in people with mild to moderate dementia (Quintana-Hernandez & Montesdeoca, 2014). Benefits of MBIs on mood, QoL an agitated behaviour have also been noted (Lantz, Buchalter & McBee, 1997; Paller et al., 2015). One of these studies, which consisted of adapted mindfulness-based stress reduction (MBSR) with multi-sensory components, was conducted in a care home context (Lantz et al., 1997). Both these studies were methodologically weak and had

small sample sizes (maximum n = 17). The current study details the development and evaluation of an MBI for people with dementia in care homes.

Methods

The study had two stages, which correspond to the Medical Research Council's guidelines for developing complex interventions (Moore et al., 2014). These were (1) developing a group-based MBI manual and (2) assessing its feasibility and outcomes through a single-blind, randomised controlled pilot study of the mindfulness intervention plus treatment as usual (TAU) versus TAU for people with mild to moderate dementia in care homes. This included an assessment of recruitment and retention, intervention delivery and adherence, acceptability and adverse events. Ethical approval was obtained through the National Research Ethics Service London – Camberwell St Giles Research Ethics Committee (REC; Ref: 14/LO/0581).

Stage 1: manual development

The manual was developed in several phases. (1) The mindfulness practices incorporated were guided by existing protocols for standard group MBIs: MBSR and mindfulness-based cognitive therapy (MBCT) (Kabat-Zinn, 2013; Segal, Williams & Teasdale, 2002); previous MBIs for dementia (Lantz et al., 1997); recommended mindfulness practices for older adults (McBee, 2008) and the sessional structure of cognitive stimulation therapy (Spector et al., 2001). Modification of scripts for the practices and the intervention structure were guided by systematic reviews of MBIs for people with acquired cognitive impairment and older adults (Chan, 2015; Churcher Clarke, 2015). (2) Expert review by 13 multi-disciplinary professionals. (3) Field-testing in a focus group with four people with dementia.

Adaptations from conventional MBIs were made in several areas. (1) *Content of the practices:* There was a concentration on focused attention training, mindful

breathing; simplified and shortened practices; and sensory elements which focused attention on one sense at a time (sound, sight, smell and touch). A mindful warm-up activity was developed to increase engagement and orient participants to the programme. (2) *Intervention structure:* the number and frequency of sessions were increased to enhance learning, and group size was reduced. (3) *Intervention delivery:* there was increased use of modelling with use of simplified language. Guidance and reminders during meditation were frequent to address confusion/monitor distress and physical discomfort. An overview of the content of sessions is provided in Table 1, and the manual is described in detail elsewhere (Chan, 2015; Churcher Clarke, 2015).

Stage 2: Randomised controlled pilot study

Design

A single-blind, multicentre randomised controlled pilot study of the adapted mindfulness programme plus treatment as usual (TAU) versus TAU, for people with mild to moderate dementia in care homes. Given paucity of MBI research in dementia, the estimated medium effect size was determined by drawing on systematic literature reviews on MBIs with cognitively impaired and older adult populations (Chan, 2015; Churcher Clarke, 2015). Sample size to detect a medium effect was calculated using G*Power 3 software, making assumptions of correlation among repeated measures and sphericity of data, with alpha set at 0.05 and power at 0.8. An overall sample size of 34 was identified as necessary to detect significant group differences.

Participants

Inclusion criteria:

 Diagnosis of dementia according to DSM-IV criteria (American Psychiatric Association, 2000);

- Mild to moderate cognitive impairment; scores between 10 and 26 on the Mini
 Mental State Examination (Folstein, Folstein & McHugh, 1975);
- Capacity to consent to participation
- Some ability to communicate verbally;
- Ability to see and hear well enough to participate in the group;
- Ability to maintain some concentration and remain in a 45-60 minute session,
 with minimal challenging behaviour;
- English-speaking.

Participants were excluded if they: (a) had a major physical illness or disability which could impact participation; (b) had a diagnosis of learning disability; (c) were actively practising meditation or yoga, or (d) had a history of brain lesions or major head trauma.

Procedure

Four sites (Care Homes A, B, C and D) participated. Participants gave written, informed consent, with capacity assessed using current guidance from the British Psychological Society. They were then screened for suitability with a full assessment conducted where appropriate.

Assessments were administered one week pre- and one week post-intervention by research assistants who were blind to treatment allocation. Assessments involved interviewing participants and care home staff who knew the participant well. Following baseline assessments, block randomisation was conducted separately at each site, using a computer programme, 'Random Allocation Software' (Saghaei, 2004). Five participants were allocated to receive the intervention, and the remaining number allocated to TAU. This was to ensure that there would be a sufficient number of people to run the intervention group, allowing for drop-out.

One week before intervention, staff were invited to attend a one-hour Mindfulness Taster Session to orient them to the research project and to encourage participation in the upcoming mindfulness programme themselves. It aimed to equip staff to support intervention participants with daily home practice (10-Minute Mindful Breathing practice and/or a briefer, 3-Minute Breathing Space), which was strongly encouraged although not essential.

Measures

Depression was assessed using the Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos, Abrams, Young & Shamoian, 1988). This is a 19-item clinician-administered instrument that uses interviews with PWD and care staff to rate depression in five categories. A score of 8 or more indicates significant depressive symptoms, (Burns, Lawlor & Craig, 2002). Good reliability and validity have been demonstrated.

Anxiety was assessed using the Rating Anxiety in Dementia Scale (RAID) (Shankar, Walker, Frost & Orrell, 1999). This is an 18-item clinician-administered instrument that uses interviews with PWD and care staff to rate anxiety in four categories. A score of 11 or more indicates clinically significant anxiety. It has good inter-rater and test-retest reliability and is sensitive to change.

QoL was assessed using the Quality of Life – Alzheimer's Disease scale (QoL-AD; Logsdon, Gibbons, McCurry, & Teri, 1999). This 13-item self-report is completed by the PWD and their carer. It covers the domains of physical health, energy, mood, friends, fun, self and life as a whole. An overall composite score is derived by combining self-report and proxy scores, with twice as much weight given to self-report. Good reliability and validity have been demonstrated.

Cognitive function was assessed using the Mini Mental State Examination (MMSE; Folstein et al., 1975). The measure covers domains including orientation, attention, short-term memory, language and visual construction. It is a brief measure widely used in clinical practice and research, with satisfactory reliability and validity.

Stress was assessed using the 13-item version of a self-report measure – the Perceived Stress Scale (PSS-13; Cohen et al., 1983). It is designed to capture the extent to which respondents feel overloaded and experience life as unpredictable and uncontrollable. The scale shows good reliability and validity in older adult populations with mild cognitive impairment (Ezzati et al., 2014). As it is not validated in people with dementia, three psychologists specialising in dementia care were consulted to assess face validity, which was deemed acceptable.

Mindfulness was also assessed as a process ability among the intervention group only, using an adapted version of Meditation Breath Attention Scores (MBAS) (Frewen et al., 2008). MBAS is calculated as the sum of the self-reported frequency with which someone can maintain their attention on their breathing as prompted every 3 minutes by a meditation bell, during a sitting meditation of 15 minutes. Good reliability and validity have been demonstrated in non-clinical populations (Frewen et al., 2014). For this study, MBAS was adapted, i.e. prompting was reduced from 3 minutes to 1 minute. Scores were captured five times during a 10-15-minute Mindful Breathing exercise (score range 0-5), in the first, sixth and tenth sessions of the intervention. The adapted version was piloted with people with dementia in a focus group as described above, and deemed feasible.

Adherence to the intervention was assessed in terms of participants' (1) attendance rate; with 80% attendance considered acceptable (Lenze et al. 2014; Wells et al., 2013); (2) engagement in recommended home practice, which was recorded on

log sheets provided to staff. Adherence was also assessed in terms of whether staff (1) attended the Mindfulness Taster Session; (2) were present at the mindfulness programme sessions.

Acceptability was assessed using a brief questionnaire designed for this study and filled in after each session. Participants rated satisfaction with sessions using a 3-point unidirectional Likert scale (from 'not at all satisfied' to 'very satisfied') and also had the opportunity to provide qualitative feedback on aspects experienced as positive and negative.

Intervention and control groups

The adapted mindfulness programme consisted of ten one-hour group sessions, running twice a week for five weeks, in a quiet room at the care home. Groups were facilitated by authors ACC and JC (trainee clinical psychologists who had completed MBSR training, practiced it clinically and were regularly supervised). One researcher took the role of engaging the group in the session plan; the other demonstrated the practices one-to-one with any participants who required additional assistance and maintained observation notes. TAU was defined as whatever was offered within the care home where participants lived.

Statistical methods

Data were analysed using the Statistical Package for the Social Sciences. A 2 x 2 mixed ANOVA was used to analyse the outcome measures (with the exception of MBAS) with group (intervention and control groups) as between subject factor, and the conditions (baseline and post-intervention measures), as within subject factor.

Data from MBAS was analysed using a One-Way Repeated Measures ANOVA, with time (sessions one; six and 10) as the independent variable, and score on this measure

as the dependent variable. Effect sizes were calculated using Pearson's *r*. Data were analysed as allocated, thus all available data, including for those who did not complete the intervention, were analysed.

Results

Participants

Table 2 shows the characteristics of the baseline sample. The majority had moderate dementia and there was high variability in baseline scores of depression and anxiety. There were no significant differences between groups at baseline in terms of cognitive functioning, depression and anxiety.

Recruitment and retention

Figure 1 shows the flow of participants through the trial. A total of 52 prospective participants were assessed for eligibility. Thirty-one participants were recruited and randomised to intervention (n = 20) or control (n = 11) group conditions, and 28 were retained to post-test. In the control group there were three participants who declined to complete post-test measures.

Intervention delivery and adherence

Participants' mean attendance was 8.15 sessions (SD = 2.46, range 1-10). Reasons for non-attendance were being unwell or asleep. Mindfulness taster sessions were delivered to staff in care homes A and C. In the other two homes, the researchers made several unsuccessful attempts to schedule the taster session. In all homes, one or two staff members attended the vast majority of sessions.

Overall, there was a low level of compliance with recorded home practice, however this varied across sites. In one home, no home practice was recorded. In homes where taster sessions were delivered, participants engaged in home practice for

a mean of 0.6 and 5 minutes per day, respectively; in the latter case this was in line with anticipated levels of practice (3-13 minutes per day).

Acceptability

Overall, participants rated that they were satisfied with their experience of the programme. The most highly rated sessions were those containing Mindful Breathing only, as well as those with additional practices of Mindful Listening, the Body Scan and Mindful Movement, which 70% or more participants rating them as 'very satisfied'. Less highly rated were sessions including practices of Mindful Seeing, Smelling and Touch (55% – 68% 'very satisfied'). Of the mindfulness practices, Mindful Breathing (also the most frequent practice) was most often commented on positively, and feedback tended to relate to the experiences of feeling present, as well as relaxed.

Adverse events

No adverse events were recorded.

Clinical outcomes

Exploration of data

On the PSS-13, 15 (54%) participants were missing data on one or more items. Item non-response ranged from a minimum of one item (n = 6) to a maximum of eight items (n = 1). The data for PSS-13 were missing completely at random as indicated by a non-significant Little's (1988) MCAR test ($\chi 2 = 36.44$, df = 35, p = .402). To reduce bias in data analysis where missing data were greater than 10% (Bennett, 2001), the Expectation Maximization (EM) algorithm was used to impute the missing values of those data where there was only one non-response item on PSS-13 at both pre- and post-intervention time points. This resulted in data from 21 participants being included in the analysis for PSS-13.

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All data met assumptions of normality, with the exception of the RAID, where an outlier was detected. This case was retained in the analysis with an adjustment to reduce the impact of their score (Tabachnik & Fidell, 2014). All data met assumptions for homogeneity of variance.

Depression and anxiety

As shown in Table 3, there were no significant changes between groups in terms of depression or anxiety, as assessed by the CSDD and the RAID. Eleven (39%) participants obtained CSDD scores in the clinical range at baseline (9 in the intervention group; 2 controls). At post-test, scores had reduced into the non-clinical range for 3 participants in the intervention group. No other participants in either group moved into, or out of, the clinical range, over the course of the intervention.

Eight (29%) participants obtained RAID scores in the clinical range at baseline (6 in the intervention group; 2 controls). At post-test, scores had reduced into the non-clinical range for 4 intervention group participants. As with the CSDD, no other participants in either group moved into, or out of the clinical range.

Other outcomes

There was a significant and positive difference between groups over time in QoL, as assessed by the QoL-AD (F(1, 26) = 4.36, p = .05), with a medium effect size (r = .48). There were no significant differences between groups over time in cognitive functioning (MMSE) or stress (PSS). Thirteen (65%) intervention group participants provided complete data on their ability to sustain attention towards the breathing process (assessed by MBAS); missing data was due to non-attendance. No significant effects of time were detected. Examination of mean scores (n = 13) show that there was initial improvement in MBAS between session one (mean score =1.62,

SD = 1.61) and session six (mean score = 2.23, SD = 1.42). Between sessions six and 10, scores returned almost to baseline levels (mean score = 1.69, SD = 1.84).

Discussion

Summary of results

This study demonstrated that the adapted mindfulness intervention is feasible in terms of recruitment, retention, attrition and acceptability, for people with mild to moderate dementia, although there were specific aspects which presented challenges. In terms of clinical outcomes, at post-test, there were significant positive differences in QoL between groups, but no significant differences in depression, anxiety, cognitive functioning, stress or mindfulness.

Feasibility

The intervention was acceptable to PWD, as demonstrated by their willingness to participate, their feedback on questionnaires and the absence of any drop-outs from the programme. Participants were able to engage with the content of sessions; Mindful Breathing in particular, as well as the other body-based practices (Body Scan and Mindful Movement) and Mindful Listening, as indicated by their questionnaire feedback and researchers' observation notes. They engaged less consistently with the practices centred on sight, smell and touch, which were not manifest in concrete bodily experience (Michalak et al., 2012). This may be because these required more use of sensory functions known to decline in dementia (Behrman, Chouliaras & Ebmeier, 2014). It is also likely that the more frequent repetition, modelling and instruction of Mindful Breathing supported implicit (and limited, explicit) learning and memory (van Tilborg, Kessels & Hulstijn, 2011), and familiarity in itself may have been therapeutic (Son, Therrien & Whall, 2002).

Where managers were engaged in the project from the outset, staff were more engaged, demonstrated through greater compliance with recorded home practice and utilisation of the opportunity to consult researchers on the intervention. This is consistent with previous research suggesting that engagement and collaboration with managers is essential for the effective implementation of such interventions in care homes (Lawrence et al., 2012).

Outcomes

The observed medium effect size in QoL is consistent with findings in a modified MBSR study of people with traumatic brain injuries (Azulay, Smart, Mott, & Cicerone, 2013) and meta-analytic review of the literature pertaining to adults without cognitive impairments (de Vibe, Bjørndal, Tipton, Hammerstrøm, & Kowalski, 2012). Although improvements in QoL appear relatively robust in this small, heterogeneous sample, non-specific factors such as increased social interaction, rather than the mindfulness training *per se*, cannot be discounted.

An absence of significant changes in depression and anxiety might be explained by the fact that the study did not actively recruit people who met criteria for depression and anxiety at baseline, implying that perhaps there was less scope to change on these outcomes. Low power and substantial variation (including floor effects) within groups may explain lack of significant changes on outcomes other than quality of life.

This was the first study to examine changes in ability to sustain attention towards breathing (as measured by MBAS) in people with dementia, and the measure was found to be feasible. The lack of a significant result may be explained in part by the fact that anticipated levels of home practice were not achieved.

Limitations

In addition to low power, the study was limited by the absence of recording and monitoring of pharmacological treatments, so these could not be discounted as a confounding factor. Further, the fact that the researchers both delivered the intervention and collected acceptability data from participants possibly introduced a social desirability bias. It was not possible to ascertain whether staff were able to continue supporting any of the mindfulness skills once sessions ended. A future phase III trial and phase IV implementation work would need to address this and consider ways of continuing to engage and support ongoing mindfulness work.

Implications for research and practice

This study provides initial evidence that MBIs are feasible for PWD in a care home setting. Given that a sub-group receiving the intervention moved out of the clinical range in both depression and anxiety, future research might aim to recruit depressed and/or anxious people at baseline, with the tentative hypothesis that such individuals may be more receptive to treatment. Future studies should be adequately powered, measure cost-effectiveness and might use an active comparable intervention to ascertain whether any positive effects can likely be attributed to the therapeutic impact of the intervention specifically. Qualitative interviews with participants and staff would be valuable in exploring how the intervention might work, who it might work better for, factors which might prevent implementation, the nature of staff involvement and acceptability amongst staff.

Conclusions

The mindfulness intervention was feasible and led to significant changes in QoL. Before adapted implementation is widely recommended, a fully powered RCT is required to assess its effectiveness and cost-effectiveness.

Conflicts of interest

None

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Table 1

Overview of the Mindfulness Programme

Overview of the Mindfulness Programme							
Session	Session Session Content						
1	 Introduction to the Mindfulness Programme (written and verbal information) Mindful warm-up activity with soft ball Choice of group name and song Mindfulness meditation 1: Mindful Breathing (with MBAS a measure) Group discussion 3-Minute Breathing Space Song Feedback (Participant Rating Form) 						
2 ^b	 Introductions Orientation to the programme and recap of previous session (written and verbal information) Mindful warm-up activity with soft ball Song Mindfulness meditation 1: Mindful Breathing Group discussion Mindfulness meditation 2: Mindful Listening Group discussion 3-Minute Breathing Space (optional) Song Feedback (Participant Rating Form) 						
3	 Mindful Breathing Body Scan						
4	 Mindful Breathing Mindful Movement						
5	 Mindful Breathing Mindful Listening, Seeing, Smelling, Touch ^c 						
6	 Mindful Breathing (with MBAS measure) Body Scan or Mindful Movement^c 						

Table 1 continued

- 7 Mindful Breathing
 - Mindful Listening, Seeing, Smelling, Touch c
- Mindful Breathing
 - Body Scan or Mindful Movement ^c
- 9 Mindful Breathing
 - Listening, Seeing, Smelling, Touch c
- Mindful Breathing (with MBAS measure)
 - Body Scan or Mindful Movement ^c

^a Mindful Breath Attention Scores (Frewen, Evans, Maraj, Dozois & Partridge, 2008).

^b The session structure as shown in session 2 was repeated for the remainder of the programme. The mindfulness practices are indicated in italics.

^c Depending on the capabilities and preferences of the group.

Table 2

Demographic and clinical characteristics of study participants at baseline

Variable	Intervention group (n = 20)	Control group (n = 11)	All participants (n = 31)
Age (years)			
Mean (SD)	81.30 (9.29)	79.36 (9.91)	80.61 (9.40)
Range	61-95	64-93	61-95
MMSE score			
Mean (SD)	15.85 (3.68)	14.45 (4.28)	15.35 (3.89)
Range	10-24	10-21	10-24
Stage of dementia (n) ^a			
Mild	1	2	3
Moderate	19	9	28
Dementia diagnosis (n)			
Not specified	11	6	17
Alzheimer's Disease	4	2	6
Vascular Dementia	3	3	6
Alcohol-related	2		2
Dementia			
Gender			
Male	8	8	16
Female	12	3	15
Ethnicity			
White British	15	9	24
Black Caribbean	4	1	5
White European	1		1
Black African		1	1
Marital status			
Widowed	10	4	14
Married	6	2	8
Single	2	4	6
Not known b	1	1	2
Divorced	1		1
Baseline CSDD			
Mean (SD)	6.80 (4.35)	8.09 (6.06)	7.26 (4.96)
Range	1-15	1-20	1-20
Baseline RAID			
Mean (SD)	8.65 (8.25)	7.64 (4.80)	8.29 (7.14)
Range	1-37	3-19	1-37

^a Stage as defined by MMSE score. The maximum score is 30, with <10 indicating a severe impairment, 10-20 indicating a moderate impairment, and 21-26 indicating a mild impairment (NICE, 2011).

Figure 1. CONSORT diagram.

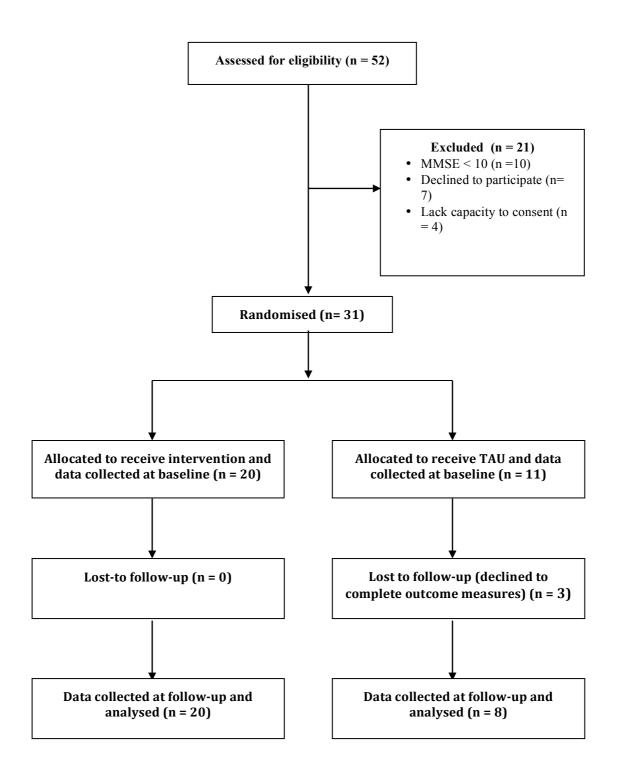


Table 3

Pre/post-intervention changes in outcome measures of mood, anxiety, QoL, cognitive functioning and stress

Junctioning and stress									
Measure	Baseline mean (SD)	Follow-up mean (SD)	Change from baseline	F (1, 26)	p	Effect size <i>r</i>			
CSDD (-)									
Intervention	6.80 (4.35)	5.75 (4.05)	-1.05						
Control	7.88 (6.90)	5.25 (4.62)	-2.63						
ANOVA									
interaction				.03	.87	.03			
RAID (-)									
Intervention	7.80 (5.63)	5.50 (3.94)	-2.30						
Control	8.25 (5.52)	5.88 (5.33)	-2.38						
ANOVA									
interaction				<.01	0.97	.02			
QoL-AD (+)									
Intervention	34.02 (4.24)	36.37 (4.27)	+2.35						
Control	34.58 (4.69)	32.79 (4.44)	-1.79						
ANOVA									
interaction				4.36	.05	.38			
MMSE (+)									
Intervention	15.85 (3.68)	15.25 (4.35)	-0.60						
Control	15.75 (4.27)	13.50 (6.14)	-2.25						
ANOVA									
interaction				1.35	.26	.22			
PSS-13 (-)									
No imputations									
Intervention (n=9)	20.33 (7.12)	23.89 (7.59)	+3.56						
Control (n=4)	22.50 (4.66)	23.50 (4.04)	+1.00						
ANOVA interaction				.23	.64	.14			
With				.23	.04	.14			
imputations									
Intervention	18.07 (8.45)	23.96 (6.20)	+5.89						
(n=13)	(00)								
Control	21.47 (3.95)	25.06 (4.63)	+3.59						
(n=6)									
ANOVA				26	(2	10			
interaction				.26	.62	.12			

^{(+) =} improvement is based on higher test scores

^{(-) =} improvement is based on lower test scores