

Pilot Controlled Trial of Mindfulness Meditation and Education for Dementia Caregivers

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Abstract

Objectives: The objectives of this study were to evaluate whether a mindfulness meditation intervention may be effective in caregivers of close relatives with dementia and to help refine the protocol for future larger trials.

Design: The design was a pilot randomized trial to evaluate the effectiveness of a mindfulness meditation intervention adapted from the Mindfulness-Based Cognitive Therapy program in relation to two comparison groups: an education class based on Powerful Tools for Caregivers serving as an active control group and a respite-only group serving as a pragmatic control.

Settings/location: This study was conducted at the Oregon Health & Science University, Portland, OR.

Subjects: The subjects were community-dwelling caregivers aged 45–85 years of close relatives with dementia.

Interventions: The two active interventions lasted 7 weeks, and consisted of one 90-minute session per week along with at-home implementation of knowledge learned. The respite-only condition provided the same duration of respite care that was needed for the active interventions.

Outcome measures: Subjects were assessed prior to randomization and again after completing classes at 8 weeks. The primary outcome measure was a self-rated measure of caregiver stress, the Revised Memory and Behavior Problems Checklist (RMBPC). Secondary outcome measures included mood, fatigue, self-efficacy, mindfulness, salivary cortisol, cytokines, and cognitive function. We also evaluated self-rated stress in the subjects' own environment, expectancy of improvement, and credibility of the interventions.

Results: There were 31 caregivers randomized and 28 completers. There was a significant effect on RMBPC by group covarying for baseline RMBPC, with both active interventions showing improvement compared with the respite-only group. Most of the secondary outcome measures were not significantly affected by the interventions. There was an intervention effect on the caregiver self-efficacy measure and on cognitive measures. Although mindfulness was not impacted by the intervention, there were significant correlations between mindfulness and self-rated mood and stress scores.

Conclusions: Both mindfulness and education interventions decreased the self-rated caregiver stress compared to the respite-only control.

Introduction

ALZHEIMER'S DISEASE (AD) and related dementias affect 5 million Americans and over 50% are cared for at home by family members or friends.¹ Caregivers of persons with dementia experience a higher incidence of depression, greater self-rated stress, and more physical symptoms, as well as take more medications and have more hospitalizations than non-caregivers.^{2–5} It is assumed that these relationships are me-

diated through the long-term effects of stress on the human body.

In an attempt to remediate the negative effects of stress on caregivers, there have been many studies with various psychosocial interventions. In meta-analyses, the effect sizes are modest and some individual studies have even produced negative findings, although there is an overall significant effect size of 0.31 on caregiver distress for psychosocial interventions.^{6–8} Interventions in these meta-analyses did not

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include well-controlled trials of isolated mind-body therapies such as meditation.

Clinically, there has been an attempt to modify individuals' stress responses with mind-body therapies.^{9,10} Relaxation techniques are the most commonly used complementary and alternative medicine, with 30% of respondents in a national survey reporting they used relaxation techniques in the past year.¹¹ However, the evidence of efficacy is limited,¹² in part related to the use of only no-treatment controls or only very active controls.

This study was designed to help optimize the clinical trial design for a planned larger study. Interventions for the caregivers and the logistics of implementation and assessment in the nonblinded trial needed to be optimized. We used mindfulness meditation, more specifically a program adapted from Mindfulness-Based Cognitive Therapy (MBCT)¹³ for the caregivers, as the mind-body trial intervention. To assess the effect of the adapted MBCT, we compared self-rated and physiologic markers of stress between the MBCT treatment group, an education/social control, and a respite-only control.

Materials and Methods

Subjects

Subjects were relatively healthy adults 45–85 years old caring for a close family member with progressive dementia. Subjects were required to be providing at least 12 hours per week of assistance for the person with dementia (PWD). The exclusion criteria were established primarily to ensure there were no underlying conditions that would limit the benefit of the intervention, impair or cause excessive fluctuations in outcome measures, or increase the likelihood of subjects dropping out of the study. Exclusion criteria for the subjects included the following: unstable medical conditions; cognitive dysfunction with a score of less than 25 on the Modified Telephone Interview for Cognitive Status¹⁴; medications that were not stable for at least 2 months; significant visual impairment (corrected binocular visual acuity worse than 20/50); and previous experience with similar types of stress-reduction classes. To maximize the likelihood that subjects would benefit from the intervention, they also had to have a high enough baseline stress level (i.e., Perceived Stress Scale [PSS]¹⁵) greater than 9. The PWD needed to have a progressive dementia, but there were no specific exclusion criteria for the PWD. The protocol was approved by the Oregon Health & Science University Institutional Review Board, and all subjects agreed prior to the beginning of the study to be randomized into one of three groups, with commitment to attend the classes.

Interventions

The three groups consisted of one active intervention adapted from MBCT, one active intervention dementia education class adapted from Powerful Tools for Caregivers (PTC),¹⁶ and a respite-only intervention. We chose a 7-week time period for the intervention since it is close to the usual duration of the two active interventions. It is a length of time during which little change in the PWD's condition and reasonably high adherence (class attendance) by the caregivers could be expected. Ninety (90) minutes was chosen as the

class length. While this class duration is less than the usual for MBCT interventions, it was considered the best compromise to maximize adherence with the intervention, since separating dementia caregivers from the PWD for more than 2 hours may represent too large a burden. Additionally, it was considered important to match the duration of the classes in the two active intervention groups. The two active interventions were also matched for time for social support discussion time and for home assignments. During the class sessions for the active interventions, respite care for the PWD for 3 hours to include transportation time to class was provided if necessary as part of the research project. Some PWD's were only mildly impaired, so that some participants had been routinely leaving the PWD at home by themselves for several hours. The respite-only group was also provided with 3 hours of respite care. In order to maintain a class format for the active interventions, we enrolled participants in batches to have 2 class sessions per year.

First class for active intervention arms. The first session was held for participants randomized to both the MBCT and PTC groups; group assignment was concealed from the participant until after the class was completed. The session consisted of an overview of dementia, including diagnostic issues, description of brain changes, current understanding of disease process, current medical treatments, course of the disease, and legal issues. This part of the lecture was adapted from the current Alzheimer's Association curriculum.¹⁷ This combined first class was intended to ensure that both active interventions included similar education regarding planning to complete the weekly assignments for the classes using an action plan. An action plan was defined as an agreement to complete one or more specific activities in the week following a given class, including consideration of how to accomplish the goal. The class leaders described steps in developing an action plan, demonstrated the process through role-play, and then coached participants in developing practice action plans. Participants in the meditation intervention used the action plan concept to support completing the home meditation practice and other assignments. Participants in the educational intervention completed an action plan for accomplishing a specific self-selected goal for the week following each class.

Mindfulness meditation. The meditation intervention was based on Mindfulness-Based Stress Reduction (MBSR)¹⁸ and MBCT.¹³ It was adapted by the investigators to meet the multiple and unpredictable time demands facing the caregivers. The objectives of the intervention were to (1) help participants understand their personal reactions to stress, (2) teach skills that provide means to modify stress reactions, and (3) promote self-care and feelings of competence and mastery. The intervention was directed by a clinical psychologist (JBL) trained in MBSR and MBCT and was provided over the course of 6 weekly 90-minute group sessions. Each MBCT session included three components: (1) didactic instruction and discussion concerning stress, relaxation, meditation, and mind-body interaction; (2) instruction and practice in meditation and other mindfulness exercises, both in session and in daily at-home practice; and (3) group discussion and problem-solving regarding successes and difficulties in practicing the exercises and applying the principles

in daily life. Subjects were very strongly encouraged to do some home practice every day. In addition, care was given to discuss other strategies for learning and practicing mindfulness skills because of the time-demanding care of a demented family member. Meditation instruction included seated meditation, beginning with awareness of breathing and later expanding the focus to include awareness of body sensations and cognitive and emotional experience. Informal exercises such as mindful movement and mindful participation in daily activities were aimed at generalizing mindfulness beyond the formal meditation exercises. Mindful awareness was encouraged during routine daily activities such as washing dishes. Participants also practiced a brief meditative exercise, adapted from the 3-Minute Breathing Space of MBCT¹³ as a coping strategy. This exercise involved a three-step process of mindfully attending to a troubling situation and their responses to it, shifting the focus of attention to the breath, and then returning attention to the troubling situation in a calmer and less reactive mood.

Participants were provided written material and recorded audio instructions pertinent to each week's content for at-home practice. All in-session exercises and homework were debriefed in dyads and whole-group discussion.

Education. The education group consisted of 6 weekly lectures co-taught by teachers trained in PTC and who adapted this 6-week intervention from the PTC program. This 6-week program followed the same first-week joint class described above with MBCT. In the classes, caregivers developed a wealth of self-care tools to reduce personal stress, change negative self-talk, communicate their needs to family members and health care and service providers, communicate more effectively in challenging situations, and make tough caregiving decisions (e.g., when a family member can no longer live alone, drive safely, or manage money). Caregivers also received a 300-page book, *The Caregiver Helpbook*, developed specifically for the class. PTC is modeled after the highly successful Chronic Disease Self-Management Program.^{19,20} The class was adapted to address the needs and concerns of family caregivers. Subjects completed weekly assignments consisting of daily reading from *The Caregiver Helpbook* and carrying out of action plans generated by the subject (e.g., do the crossword puzzle 3 times that week or meet a friend for coffee). There was no overt teaching of mind-body-based techniques geared toward the caregiver. Nondidactic, social interaction time was limited to 15 minutes. The patient for whom the participant is caring for was provided with respite care during the classes.

Respite-only. The third group of caregivers was provided with respite care once per week for 7 weeks for 3 hours. This nonclass group did not attend the first class in part to ensure it was a true pragmatic control and to help ensure there was not too much ongoing disappointment related to not having the social interaction. The time for the 3-hour respite care during the week was chosen by the caregiver. This group also was eligible to participate in either the adapted MBCT or PTC class during the next session.

Assessments

In the screening visit, we obtained information related to inclusion/exclusion criteria, consisting of a medical history

of the caregiver, an activities of daily living/independent activities of daily living questionnaire for the PWD,²¹ and screened the caregiver for cognitive dysfunction with the Modified Telephone Interview for Cognitive Status.¹⁴ The full outcome assessments were then completed within 3 weeks before the class start date and within 3 weeks after the last class.

The primary outcome measure was caregiver perceived stress evaluated with the widely used Revised Memory and Behavior Problems Checklist (RMBPC) that was developed for dementia studies.²² It has two components: one is a scale of the frequency of the problem behavior, and the other is the Reaction rating (i.e., how much the problem behavior has bothered or upset the caregiver). Although we administered the Frequency and Reaction components of the RMBPC, the problem behaviors themselves were not the primary outcome measure of this study, just the distress it produced in the caregiver. The RMBPC is a 24-item questionnaire with five responses, 0–4, with a reliable total score.²²

There were a number of exploratory secondary measures. Caregiver stress was also assessed using the Caregiver Appraisal Tool.²³ The PSS¹⁵ was used as an additional measure of stress since it has been widely used, allowing results of this study to be related more directly to other conditions. Depressed mood was assessed by the Center for Epidemiologic Studies Depression Scale (CESD).²⁴ Energy and fatigue was assessed using the SF-36 question 9 subscore.²⁵ Self-efficacy was used as an outcome measure because of prior reports of sense of control being significantly affected by meditation.^{26,27} We used the General Perceived Self-Efficacy Scale²⁸ and a more specific caregiver self-efficacy obtained by adding a confidence question to the RMBPC for each of the problem behaviors.²⁹ Other self-rated measures included the Pittsburgh Sleep Quality Index, the Epworth Sleep Questionnaire, and a Global Impression of Change scale (that was completed at the follow-up visit only). In addition, at both study visits, subjects reported the PWD's behavior problems using the Neuropsychiatric Inventory,³⁰ since the behavior of the PWD may be impacted by the caregiver's stress level and coping ability. Coping strategies were assessed with the Coping Responses Inventory.³¹

Expectancy. We assessed expectancy of improvement from each of the three interventions using a standardized, six-question, expectancy/credibility scale³² and a visual analog scale.

Mindfulness. We used two brief measures of mindfulness to explore whether mindfulness is a mediating factor for improvement with the intervention. We used a measure of attention to the current moment, the Mindful Attention Awareness Scale (MAAS) and a measure of being nonjudgmental adapted from factor five (FFNJ), from a factor analytic study of several mindfulness scales.³³

Experience-based sampling. A hand-held digital personal digital assistant device was used to implement at-home experience-based sampling³⁴ on the 2 assessment days (at baseline and 8 weeks). At five semirandom time points during wakeful hours on 1 day, subjects were asked to rate on a scale of 1–6 their perceived stress, ability to cope with the current situation, focus on the current situation,

perceived fatigue, and the demand level of the current situation. Additionally, all subjects were asked to answer these same questions while in the lab.

Cognitive measures. Several cognitive assessments were performed to determine whether possible improvements in stress with the interventions are associated with improvement in cognitive functions sometimes affected by stress. Cognitive testing included a 10-word list learning task from the widely used Alzheimer's Disease Assessment Scale-cognitive subscale,³⁵ the Stroop Color and Word Test,³⁶ and an Attentional Network Test (ANT).³⁷ The ANT was shortened to include only cued/noncued and congruent/incongruent conditions. The incongruent-congruent reaction time (RT) difference (conflict score) and noncued-cued difference (alerting score) were used as the summary outcome measures. The Stroop interference measure was calculated as a difference between the time in seconds to complete color-naming trial and time to complete word-reading trial.

Physiologic measures. Salivary cortisol was obtained 3 times during the assessment day, within 5 minutes after awakening, 30 minutes later before eating, and at bedtime, approximately 10–11 PM. Analyses were performed as we have done previously³⁸ using enzyme-linked immunoassays (ELISA) (Salimetrics, State College, PA). Interleukin-6 and tumor necrosis factor- α were measured using ELISA (R and D Systems, Minneapolis, MN) and high-sensitivity C-reactive protein was determined by solid-phase, competitive chemiluminescent assay system (Siemens Medical Solutions Diagnostics, Los Angeles, CA). All measurements were performed in duplicate.

Adherence. Adherence was assessed by class attendance and with a biweekly diary logbook where participants recorded daily practice in the MBCT group and action plan in the PTC group. Classes were weekly, but all participants received a phone call every 2 weeks between visits 1 and 2 to ensure there were no logistical problems affecting subjects' continued participation and to assess any significant health changes.

Randomization. A dynamic randomization approach³⁹ was used to balance the distribution of four baseline characteristics. These were characteristics known to impact caregiver stress (gender, age, and relationship to PWD) and

the baseline measure of the primary outcome measure (caregiver stress score at baseline). For age, activities of daily living score, and caregiver stress score, the median in the first cohort of subjects was used to define the split for dynamic randomization. Randomization was performed following the baseline visit 1 using the dynamic randomization program concealing assignment during the outcome assessment from the blinded research assistant assessors. For maintenance of a class format, the participants were randomized in three batches maintaining similar numbers in each group for each batch. Two researchers in the lab were unblinded to the assigned group, but all the outcome assessments were done by the blinded research assistants. The non-blinded research personnel were the primary contact persons with the research subjects and reminded subjects during appointment scheduling for the outcome assessments to not mention their assignment group to the research assistant performing the outcome assessments.

Analysis

The primary analysis compared the completers from the three groups using analysis of covariance (ANCOVA). The primary outcome measure was the RMBPC Reaction score shortly after completing the intervention (visit 2). The other outcomes were similarly analyzed. The main covariate was the outcome measure at baseline visit 1 (just prior to the intervention). Age was a covariate for the cognitive measures. If the measures for the dependent side of the ANCOVA models were not normally distributed, especially if there was significant skewness, one or more transformations (the natural logarithm, square root, or the rank transformation, in order) were used. For the secondary measures in this pilot study, no adjustments for the exploratory multiple comparisons were used.

Results

There were 31 randomized subjects (Table 1, demographics) and only 4 dropouts. We were able to carry out assessments, randomization, and class scheduling while maintaining blinding. Subjects had no significant differences in expectancies and credibility to the two active interventions. Participant attendance rates at classes were also similar (education 0.85 ± 0.08 ; meditation 0.88 ± 0.05).

The primary outcome measure, the RMBPC reaction score after the intervention, was different among the three groups,

TABLE 1. PATIENT CHARACTERISTICS

Variable	Meditation	Education	Respite-only
Age	62.50 \pm 11.607	67.09 \pm 8.360	63.80 \pm 7.927
Number randomized (no. female)	10 (8)	11 (8)	10 (9)
Ethnicity (no.)			
White	8	10	10
African American	1	0	0
Asian	1	1	0
Relationship to PWD (no.)			
Spouse	7	8	8
Child	3	3	2
Completers (no.)	8	11	9

Values are mean \pm standard deviation.

PWD, person with dementia.

TABLE 2. VISITS 1 AND 2 PRIMARY AND SECONDARY OUTCOME MEASURES

	<i>Meditation</i>		<i>Education</i>		<i>Respite</i>		<i>p value</i>
	<i>Visit 1</i>	<i>Visit 2</i>	<i>Visit 1</i>	<i>Visit 2</i>	<i>Visit 1</i>	<i>Visit 2</i>	
Primary outcome							
RMBPC reaction*	27.1 ± 12.9	24.8 ± 12.9	28.1 ± 11.1	21.6 ± 5.8	24.8 ± 23.6	26.4 ± 23.7	0.030
Secondary outcomes							
RMBPC confidence*	28.8 ± 17.6	34.1 ± 17.4	36.7 ± 23.2	30.1 ± 14.3	30.3 ± 18.9	26.6 ± 22.3	0.026
PSS	18.5 ± 8.5	17.8 ± 6.0	18.6 ± 7.5	20.5 ± 5.7	17.33 ± 4.9	17.8 ± 4.7	0.332
CESD	15.8 ± 7.7	12.5 ± 10.9	16.9 ± 10.0	15.2 ± 7.8	14.5 ± 7.7	15.3 ± 7.4	0.705
SF-36 Fatigue	11.4 ± 3.2	9.3 ± 3.9	10.1 ± 5.2	9.5 ± 4.6	9.4 ± 3.8	9.8 ± 3.3	0.287
Mindfulness MAAS	4.4 ± 0.7	4.1 ± 0.7	4.2 ± 0.9	4.2 ± 1.0	4.0 ± 0.5	3.7 ± 0.8	0.950
Mindfulness FFNJ	21.2 ± 6.5	21.7 ± 7.2	22.1 ± 4.4	22.4 ± 7.0	22.1 ± 3.7	23.1 ± 3.1	0.286
GPSE	30.6 ± 4.4	31.4 ± 4.6	30.7 ± 5.4	30.9 ± 4.6	30.2 ± 5.1	31.4 ± 5.1	0.761
PSQI	8.7 ± 3.4	9.0 ± 2.7	8.0 ± 2.7	8.0 ± 4.1	9.5 ± 3.7	9.3 ± 4.0	0.711
ESS	4.7 ± 2.8	4.8 ± 1.6	6.6 ± 4.8	6.1 ± 4.4	7.1 ± 4.7	8.0 ± 5.0	0.859
NPI total	15.4 ± 5.2	19.3 ± 6.3	14.6 ± 8.2	14.0 ± 6.2	12.9 ± 5.8	11.0 ± 6.2	0.848
Caregiver appraisal ^T	89.1 ± 14.7	88.5 ± 15.0	91.2 ± 17.2	88.7 ± 12.0	89.7 ± 11.2	90.4 ± 14.2	0.086
CRI approach	49.9 ± 11.3	51.2 ± 12.9	38.7 ± 10.1	45.2 ± 9.6	43.6 ± 16.5	43.3 ± 15.1	0.200
CRI avoidance	27.5 ± 13.8	28.9 ± 10.3	27.0 ± 6.0	25.6 ± 5.4	30.2 ± 13.0	25.6 ± 9.4	0.710
Cortisol bedtime	3.4 ± 5.1	2.1 ± 4.4	0.2 ± 0.3	0.1 ± 0.0	0.4 ± 0.6	0.2 ± 0.2	0.209
Cortisol awake	3.6 ± 4.0	3.0 ± 3.9	1.5 ± 0.4	0.8 ± 0.4	0.8 ± 0.4	0.8 ± 0.4	0.615
Cortisol 30 min	4.0 ± 4.6	2.7 ± 4.1	1.0 ± 0.6	0.8 ± 0.6	1.2 ± 0.9	0.7 ± 0.4	0.175
IL-6	2.2 ± 1.2	2.0 ± 1.2	3.0 ± 1.9	3.3 ± 3.0	1.5 ± 1.3	2.8 ± 4.0	0.922
TNF-α	1.1 ± 0.4	1.0 ± 0.5	1.2 ± 0.5	1.3 ± 0.7	1.2 ± 0.9	1.1 ± 0.6	0.880
hsCRP	4.3 ± 4.0	2.4 ± 2.6	4.6 ± 5.3	4.7 ± 4.2	3.1 ± 4.1	2.0 ± 1.9	0.891
Stroop interference*	124.9 ± 71.9	105.7 ± 56.3	152.6 ± 35.1	121.8 ± 31.6	121.4 ± 49.7	126.0 ± 81.4	0.038
ANT conflict	144.1 ± 84.1	163.5 ± 70.2	127.4 ± 70.7	124.8 ± 58.9	159.9 ± 62.9	111.8 ± 42.3	0.141
ANT alerting*	28.1 ± 46.3	60.5 ± 18.2	54.5 ± 63.2	64.1 ± 36.8	33.8 ± 27.3	39.6 ± 31.0	0.045
Word List immediate	7.2 ± 1.0	7.1 ± 1.4	6.8 ± 1.3	7.4 ± 1.5	7.7 ± 1.2	8.2 ± 1.0	0.489
Word List delayed	6.6 ± 1.7	7.6 ± 1.9	6.4 ± 1.9	7.6 ± 2.0	7.7 ± 2.1	7.9 ± 1.8	0.988
Expectancy	66.5 ± 19.6	–	66.4 ± 22.7	–	51.8 ± 25.3	–	0.988
Credibility	7.3 ± 1.5	–	7.3 ± 1.6	–	6.5 ± 1.8	–	0.902

Values are mean ± standard deviation.

* $p < 0.05$, ^T $= 0.10 > p > 0.05$.

RMBPC, Revised Memory and Behavior Problems Checklist; PSS, Perceived Stress Scale; CESD, Center for Epidemiologic Studies Depression Scale; MAAS, Mindful Attention Awareness Scale; FFNJ, measure of being nonjudgmental adapted from factor five; GPSE, General Perceived Self-Efficacy; PSQI, Pittsburgh Sleep Quality Index; ESS, Epworth Sleepiness Scale; NPI, Neuropsychiatric Inventory; CRI, Coping Responses Inventory; IL-6, interleukin-6; TNF-α, tumor necrosis-α; hsCRP, high-sensitivity C-reactive protein; ANT, Attentional Network Test.

$p = 0.030$ (Table 2). Pairwise comparisons revealed that post-intervention average RMBPC reaction scores for subjects in the respite-only group were greater than those for subjects in the meditation group, $p = 0.041$, and education group, $p = 0.027$. There were no differences between the meditation and education groups on the RMBPC reaction scores after the intervention, $p = 0.839$ (Table 2). There were no correlations between expectancy or credibility of the group subjects were assigned to and their improvement in the RMBPC ($ps > 0.40$).

Secondary outcome measures (Table 2)

RMBPC confidence scores (a measure of caregiver self-efficacy) after the intervention were different among the three groups, $p = 0.026$. Pairwise comparisons revealed that postintervention average RMBPC confidence score for subjects in the respite-only group was lower than the score for subjects in the meditation group, $p = 0.010$, and there was a difference between meditation and education groups on the RMBPC confidence scores after the intervention, $p = 0.036$.

Stroop interference scores were different among the groups, $p = 0.038$. There were group differences for the ANT

median RTs for cue congruent trials, $p = 0.032$. Pairwise comparisons showed that after the intervention, median RTs for cue congruent trials for subjects in the respite-only group were greater than those for subjects in the education group, $p = 0.010$ but not the meditation group, $p = 0.109$. The alerting score was also different between groups, $p = 0.045$. Simple contrasts showed that after the intervention, the ANT alerting score for subjects in the respite-only group was lower than the score for subjects in the education group, $p = 0.019$ and meditation group, $p = 0.053$. There were no differences among the intervention conditions on any other self-report, cognitive performance variable, or cytokine measures ($ps > 0.05$).

Mindfulness

There was no effect of the intervention on the mindfulness measures ($ps > 0.05$). PSS scores at baseline and outcome were inversely related to Mindfulness MAAS and Mindfulness FFNJ scores (Table 3). Additionally, mindfulness MAAS and FFNJ scores at both time points were correlated with CESD scores (all $ps < 0.05$). As expected, PSS at both

TABLE 3. CORRELATIONS AMONG VARIABLES AT BASELINE VISIT (V1) AND OUTCOME VISIT (V2)

Measure	1	2	3	4	5	6	7	8	9	10	11	12
1. RMBPC reaction V1	–	0.669**	0.381*	0.440*	0.358*	0.360 ^T	–0.262	–0.238	–0.112	–0.368 ^T	0.195	0.180
2. RMBPC reaction V2	–	–	0.233	0.251	0.206	0.232 ^T	–0.042	–0.159	–0.148	–0.210	0.059	0.334
3. PSS V1	–	–	–	0.496**	0.817**	0.519**	–0.583**	–0.391*	–0.637**	–0.745**	0.267	0.388
4. PSS V2	–	–	–	–	0.554**	0.712**	–0.384*	–0.326	–0.216	–0.364 ^T	0.139	0.168
5. CESD V1	–	–	–	–	–	0.590**	–0.688**	–0.530**	–0.421*	–0.739**	0.036	0.172
6. CESD V2	–	–	–	–	–	–	–0.481*	–0.469*	0.011	–0.502*	–0.219	–0.517*
7. Mindfulness MAAS V1	–	–	–	–	–	–	–	0.769**	0.368 ^T	0.647**	0.208	0.026
8. Mindfulness MAAS V2	–	–	–	–	–	–	–	–	0.027	0.529*	0.435 ^T	0.201
9. Mindfulness FFNJ V1	–	–	–	–	–	–	–	–	–	0.438*	–0.183	–0.284
10. Mindfulness FFNJ V2	–	–	–	–	–	–	–	–	–	–	–0.331	–0.315
11. Cortisol V1 (mean)	–	–	–	–	–	–	–	–	–	–	–	–0.187
12. Cortisol V2 (mean)	–	–	–	–	–	–	–	–	–	–	–	–

RMBPC, Revised Memory and Behavior Problems Checklist; PSS, Perceived Stress Scale; CESD, Center for Epidemiologic Studies Depression Scale; MAAS, Mindful Attention Awareness Scale; FFNJ, measure of being nonjudgmental adapted from factor five.

** $p < 0.01$, * $p < 0.05$, ^T $= 0.10 > p > 0.05$.

time points was highly correlated with CESD scores at both time points, as expected (all $p < 0.01$).

Discussion

This pilot trial of mindfulness meditation in dementia caregivers demonstrated a high completion rate and reasonable adherence to the intervention program. Blinding of the assessors was maintained, and there was a comparable expectancy of improvement from and credibility of both the active interventions. There was a significant effect of the interventions, with both active interventions producing improvements in the primary outcome measure, RMBPC reaction score, relative to the pragmatic, respite-only control group. Some of the negative studies of psychosocial interventions for caregivers or for mind-body interventions in general may be due to the outcome measures not being well-matched to the potential benefits of the interventions. We specifically selected caregiver self-perceived stress as the primary outcome measure because it is most likely to be sensitive to a mind-body intervention. One of the secondary outcome measures demonstrating benefit from the intervention was caregiver self-efficacy that was also generated from the RMBPC.

Most secondary outcome measures did not reveal significant effects of the intervention. However, there was a suggestive effect of the intervention on two of our cognitive measures that were utilized because of their sensitivity to executive dysfunction secondary to stress and depression, even cognitive dysfunction related to caregiving.⁴⁰ There was no effect on salivary cortisol or self-reported sleep even though we and others have previously observed dementia caregiving to negatively impact these measures.^{38,41}

Mindfulness, which was thought to be an intermediate marker for this relationship between cognitive function and stress, was not impacted by the intervention even though mindfulness did correlate with the stress and depression scales. The fact that mindfulness measures correlated with depression and perceived stress even before any interventions suggest that the mindfulness measures reflect some baseline quality that relates to depression and stress without specific mindfulness training.

The results of self-rated stress assessment in caregivers are dependent on whether it is done in the clinical research setting or at home. A pilot study using hand-held digital devices revealed that caregivers reported disproportionately more stress in the home setting compared to healthy controls who reported more stress in the clinical research laboratory.⁴² Therefore, when designing future caregiver stress reduction studies, it will be very important to be sensitive to this difference.

Based on our prior mind-body work,^{43,44} we designed the pilot trial of mindfulness meditation with two control arms. There was an active intervention arm to control for some important aspects of the intervention (e.g., socialization, home practice, and nonspecific benefits of education). There was also a pragmatic control group in which participants received respite care, since respite is advocated by health care providers and is easier and less expensive to obtain than a mindfulness meditation or education class. Also, either active intervention required some respite in addition to the intervention. Without the respite-only control, there would have been no clear benefit to mindfulness meditation because the education arm that was beneficially active was similarly effective to the mindfulness meditation arm. Future trials with two similar control arms may be able to minimize the cost relative to loss of power for comparison to the active control by randomizing in a 2:2:1 ratio such that the pragmatic control arm receives only one fifth the total subjects rather than one third. Future mind-body intervention studies will need to include appropriate control arms to the question being asked, but efficacy studies should strongly consider two control arms.

Some subjects are likely do better in particular interventions than others. Although this study was not powered to explore individual predictors and effect modifiers of intervention response, it will be a useful research direction. The class format is likely to be beneficial because of the social interaction and support, but it also makes intervention results more difficult to interpret. Class dynamics are not easily controlled, and variables in our study such as age and whether the caregiver was a spouse or an adult child impacted the dynamics. Additionally, the necessity of a class schedule prevents rolling admissions of participants. Although public health recommendations would be better

served by using a class (from the economics as well as potential benefit), research studies may consider one-on-one training sessions.

As with other studies, this and other results will need to be confirmed and extended by future research. Generalizing the results will also require recruitment of more underrepresented minorities that, in the case of caregivers, includes men. A more flexible training session schedule as described above helps with recruitment because of the severe time constraints of the caregivers. Although it is extremely difficult to compare home practice between the meditation and education arms, better measures of adherence to the mindfulness meditation home practice would be useful also.

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