MBDC-The Mindfulness Based Dementia-Care Study-Protocol

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Summary

Mindfulness refers to a particular type of attention that is focused on the present moment, with non-judgmental awareness and acceptance of that experience, with a general attitude of openness and curiosity. Mindfulness-Based training was designed to enhance the range and use of coping skills, decrease levels of stress, improve mood, and reduce tendencies to react in maladaptive ways [1-3]. We are evaluating a program being conducted at multiple sites, called the Mindfulness Based Dementia-Care (MBDC) in caregivers (CG) for dementia, which combines the traditional mindfulness training approaches with dementia specific education. MBDC is housed by The Presence Care Project non-profit, which offers training to certify MDBC Facilitators.
The overall objective of this study is to evaluate the efficacy of the Mindfulness-Based Dementia Care Program by conducting a prospective, pre-post, observational study with members participating in the MBDC program across multiple sites. Results will be included in a future grant submission for a larger scale research project that will include a control group, as well as objective measures, such as cortisol levels, and blood pressure.

Study aims

Aim 1: Evaluate change in self-reported measures in caregivers participating in Mindfulness Based Dementia-Care (MBDC) program.

Primary Outcome: Change in pre-post stress scores.

Secondary Outcome: Change in pre-post self-reported depressions scores

Exploratory Outcomes:

- Change in pre-post self-reported measures of confidence, self-compassion, sleep, resilience and well-being
- Change in Pre-Follow-up of self-reported measures of stress, depression, confidence, self-compassion, sleep, resilience, well-being

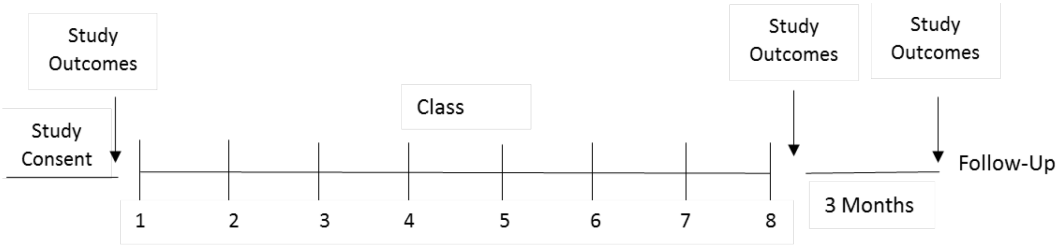
Aim 2: Describe the MBDC program based on participation, instructor and program satisfaction using a post-program survey

Approach

a. *Study design*
We are conducting a prospective pre-post observational study with members of the Mindfulness-Based Dementia Care (MBDC) program.

The MBDC program is an 8-week program designed for family caregivers for those living with dementia. The program is offered typically twice in a year at the HealthPartners Neuroscience center (program brochure attached) and other presence care project sites. Additional sites currently include the University of Michigan, the Ray Dolby Brain Health Center in San Francisco, and through a community offering in Grand Marais, MN. Participants attend a 1-hour orientation session, 2-hour classes each week for 7 weeks,

at-home practice between classes, and a 6-hour retreat. Some of the focuses of the weekly lessons include stress reduction, awareness of breath, grief contemplation, self-compassion, communication, responding to challenges, and mindfulness in everyday life. At the beginning and end of each weekly class, participants are evaluated based on their stress levels during the week prior and immediately after the class. At the end of the 8-week session, participants fill out a survey that includes a program evaluation, an instructor rating, and a self-evaluation of how well they will incorporate what they have learned from the course into their every-day life. Through surveys, the participant's mindfulness and well-being is also evaluated before, immediately after, and 3 months following the 8-week session. The following chart illustrates the timeline for this program, and the table indicates the study measures and at what point on the timeline they are evaluated.



The Program

Mindfulness-Based Dementia Care (MBDC) is an eight-week, group-based program designed for people who care for cognitively impaired individuals.

While not all stress is inherently bad, there are unique stressors experienced in the dementia care exchange that can become mentally, physically, and emotionally overwhelming. A mindfulness practice specifically geared to the care exchange offers invaluable resources and coping practices for responding to these stressors. The Mindfulness-Based Dementia Care program offers a way to establish a practice of mindfulness that is integrated with the day-to-day realities of caring for a loved one with dementia. Such a practice, especially if sustained over time, can help improve the quality of life for both the care partner and the person living with dementia.

MBDC groups typically consist of five to twelve participants. The program consists of seven two-hour sessions and one six-hour Day of Mindfulness. The sessions include formal meditations and informal mindfulness practices, role play, and lectures on dementia-related topics. Participants receive a workbook with literature related to the session topics and journaling prompts. The program also involves practice between classes.

Teaching and practices include formal meditation practices, as well as interventions borrowed from therapeutic modalities, such as Cognitive Behavioral Therapy, and Acceptance and Commitment Therapy. The goal is to reward participants with a transformative experience that may help sustain their wellbeing over the care journey. Though MBDC is not a therapy program, per se, it is quite therapeutic. It is also not a support group, but participants share that they feel very supported by the process, the intimacy of the program, and the new network of fellow dementia caregivers.

b. Population

i. *Inclusion/Exclusion Criteria*

Inclusion criteria:

- Must be ages ≥ 18 years
- Must be able to read and understand English
- Participant of the MBDC Program at any site

ii. Sample size

The MBDC program at a time has only 12-15 participants. We hope to enroll at multiple offerings of the MBDC program. For the study, we plan to contact ~ 60 participants, and enroll ~ 50 in the study. Plan is to enroll through 5 sessions. Depending on the recruitment we may extend beyond the 5 sessions up to a maximum of 7 consecutive sessions. With multiple sites, we will be able to reach this number more quickly and prepare for a grant application to study the MBDC class as an intervention and include a control group.

c. Intervention, treatment

N/A. This is a prospective observational study of the MBDC program.

d. Outcomes/endpoint and other variable definitions, and instruments used

Please see all the surveys and the variables spreadsheet attached. The measures/instruments are defined below.

Primary Outcome: The Perceived Stress Scale (PSS): The Perceived Stress Scale is a widely used measure for stress perception. It measures how often and to what degree situations are characterized as stressful. This measures as been used to evaluate stress associated with chronic disease [9].

Secondary Outcome: Center for Epidemiologic Studies Depression Scale (CES-D): The Center for Epidemiologic Studies Depression Scale measures self-reported symptoms associated with depression. It has been validated for dementia and multiple other diagnoses, and it is sensitive to differences between caregivers and non-caregivers [10].

Exploratory Outcomes:

Self-Compassion: To evaluate self-compassion, participants indicated how often they acted in the manner stated in each of the items on a scare of 1 (almost never) to 5 (almost always). The survey evaluates self-kindness verses self-judgement, common humanity verses isolation, and mindfulness versus over-identification [11].

Zarit Burden Inventory: The Zarit Burden Inventory is an interview that evaluates caregiver burden through a self-report measure. The survey scores are positively correlated with behavior problems in older adults and depression scores of caregivers [12].

The Resilience Scale: The Resilience Scale has been used with people of different ages, education, and socioeconomic backgrounds. It evaluates the individual's stress, anxiety, forgiveness, and health promoting activities [13].

Pittsburgh Sleep Quality Index (PSQI): This is a validated self-report questionnaire that evaluates sleep quality over a 1-month time interval [15]. The measure takes about 5 min to complete.

Five Facet Mindfulness Questionnaire (FFMQ) Mindfulness: This scale evaluates five components, which includes observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience. This measure was developed by Ruth Baer at the University of Kentucky [16].

Likert Scale Stress Rating: Attitudes are measured by asking people to respond to a series of statements, indicating the extent to which they agree with them.

Confidence Survey: A set of questionnaires developed by University of Michigan to understand the confidence of caregiver in their ability to respond to caregiver needs and access to resources (questionnaire # 1, survey).

MBDC Program Evaluation Survey:
Program Evaluation: This survey demonstrates how the participant evaluates the quality and usefulness of the program.

Instructor Rating: The participant evaluates the instructor's ability to give clear expectations, knowledge of the subject matter, and attitude.

Participation in Practice: The participant reports the level of effort that they invested in formal meditation between classes.

e. Statistical analysis plan

Aim 1:

We will describe the patient characteristics using means and standard deviations (for continuous variables) and frequencies (for binary and categorical variables).Mean and standard deviations of scores for each of these validated scales will be calculated.

1. Pre-Post
2. Pre-Follow up

The mean and standard deviation of pre-post and pre-follow-up change in scores within participants will also be calculated. The 3 scores (pre, post and follow up) for each of the scales will be plotted on a histogram and we will describe any trends that we might see over time.

As the primary analysis, we will do paired t-test for change in scores of the PSS. As an exploratory analysis we will do a linear regression model with age and number of classes as covariates.

Aim 2:

We will describe the post-survey measures (evaluation of the program) using means and standard deviations (for continuous variables) and frequencies (for binary and categorical variables) and report qualitatively the themes of the open ended questions.

f. Power analysis or statement of precision

With a sample size of 50, the primary analysis is powered at 80% to detect a mean paired different of -1.8 with an estimated standard deviation of differences of 4.5, based on previous data from mindfulness program. This change is clinically meaningful and seems reasonable given previous research in this area.

g. Strengths and limitations

Strength: Pragmatic way of assessing the mindfulness program

Limitations:

1. Lack of control group in the study.
2. Limited sample size.
3. Observational study.
4. Multiple confounders

Risks and Benefits

There are almost no risks associated with being in this study. The standardized testing may make you uncomfortable because some parts may be too easy and you may feel self-conscious, while some parts of it may be difficult or tiring. The health history survey probes for personal health history information that may be sensitive information.

By being in this study you may or may not receive any direct benefit. You may feel better and more connected with the community.

Data Confidentiality and Privacy

Only research staff on the study will have access to the data. In addition, we also assign study ID for the participants. All the paper based assessment will be kept in a secure location in a locked office. For the web based survey, we will use a secure portal to collect data and the data will be stored on a secure server with password access to the research staff only.

References

1. Baer RA. Mindfulness training as a clinical intervention: A conceptual and empirical review. *Clinical psychology: Science and practice.* 2003;10(2):125-143.
2. Oken BS, Fonareva I, Haas M, et al. Pilot controlled trial of mindfulness meditation and education for dementia caregivers. *J Altern Complement Med.* 2010;16(10):1031-1038.

3. Paller KA, Creery JD, Florczak SM, et al. Benefits of Mindfulness Training for Patients With Progressive Cognitive Decline and Their Caregivers. *American journal of Alzheimer's disease and other dementias.* 2014:1533317514545377.
4. Lavretsky H, Siddarth P, Irwin MR. Improving depression and enhancing resilience in family dementia caregivers: a pilot randomized placebo-controlled trial of escitalopram. *Am J Geriatr Psychiatry.* 2010;18(2):154-162.
5. Ferrara M, Langiano E, Di Brango T, De Vito E, Di Cioccio L, Bauco C. Prevalence of stress, anxiety and depression in with Alzheimer caregivers. *Health Qual Life Outcomes.* 2008;6:93.
6. Whitebird RR, Kreitzer M, Crain AL, Lewis BA, Hanson LR, Enstad CJ. Mindfulness-based stress reduction for family caregivers: a randomized controlled trial. *The Gerontologist.* 2013;53(4):676-686.
7. Brown KW, Coogle CL, Wegelin J. A pilot randomized controlled trial of mindfulness-based stress reduction for caregivers of family members with dementia. *Aging & mental health.* 2015:1-10.
8. Kor PP, Chien WT, Liu JY, Lai CK. Mindfulness-Based Intervention for Stress Reduction of Family Caregivers of People with Dementia: A Systematic Review and Meta-Analysis. *Mindfulness.* 2017:1-16.
9. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *Journal of health and social behavior.* 1983;24(4):385-396.
10. Radloff LS. The CES-D scale a self-report depression scale for research in the general population. *Applied psychological measurement.* 1977;1(3):385-401.
11. Neff KD. The development and validation of a scale to measure self-compassion. *Self and identity.* 2003;2(3):223-250.
12. Zarit SH, Zarit JM. Zarit Caregiving scale. *ZBI.* 1980.
13. Wagnild GM, Young HM. Development and psychometric evaluation of the Resilience Scale. *Journal of nursing measurement.* 1993.
14. Stewart AL, Ware JE, Ware Jr JE. *Measuring functioning and well-being: the medical outcomes study approach.* duke university Press; 1992.
15. Buysse DJ, Reynolds III CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry research.* 1989;28(2):193-213.
16. Baer RA, Smith GT, Lykins E, et al. Construct validity of the five facet mindfulness questionnaire in meditating and nonmeditating samples. *Assessment.* 2008;15(3):329-342.