Trial: Mindfulness-based Cognitive Coping for ADRD Caregivers

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Project Summary

Alzheimer's Disease (AD) is a devastating illness for patients, families, and society. Most of the care of AD patients rests on shoulders of informal caregivers, largely untrained to undertake the caregiving role, bearing a high level of distress, and suffering deterioration in physical health and psychological well-being.

There are millions of Americans providing care to AD patients, experiencing high rates of depressive symptoms (30%), stress (59%), associated risks for cardiovascular diseases, and many other adverse health effects. For example, in separate studies, hospitalization and emergency department visits were more likely for dementia caregivers than any other types of caregivers.

The severity of AD caregiving is influenced by several factors, such as intensity of dementia symptoms in AD patients, how challenging distressful situations are perceived by caregivers, and available resources. Although information and programs about Alzheimer's Disease are available to the public, an essential missing tool is how to deal with depressive symptoms in an effective manner, as they are very common and demanding.

In this project we will implement the new Mindfulness-based Cognitive Coping (MCC) intervention, and enable easy access with our mobile app, called Caring Mind App (CMA), providing an effective cost-effective intervention for caregivers to reduce their stress and depressive symptoms. The MCC intervention is built upon the Mindfulness-Based Cognitive Therapy (MBCT), which has been effective to treat individuals with major depressive disorder, with the integration of caregiving coping strategies from our past studies to help caregivers to overcome stressful situations in their caregiver role.

We will finalize the MCC curriculum, develop the complete app, and evaluate its effectiveness in a randomized clinical trial; resulting in a novel intervention that integrates MCC content, an effective training to reduce depressive symptoms and psychological stress, and a mobile app to be deployed to millions of families struggling with Alzheimer's Disease.

Protocol

Overview:

1. Recruit subjects: caregivers of individuals with Alzheimer's Disease or other dementia will be recruited.
2. Randomize subjects: participants will be assigned to the study group or the control group.
3. Collect pre-data: Before intervention, we will collect pre-data to establish the baseline status of participants.
4. Deploy treatments: For both study and control groups, we will send instructions and materials.
5. Collect post-data: We will collect post-treatment data after 3 months.

Research Participants: 150 dementia family caregivers (planned enrollment) will be recruited:

Inclusion Criteria:

- Care for an individual with Alzheimer's Disease or Related Dementia (ADRD).
- Own a smartphone or tablet and have Internet access.
- Minimum age of 18 years old.
- Able to read and speak English.
- Spend at least 8 hours/week caring for a person with dementia.
- Plan to stay in the area for six months.

Exclusion Criteria:

- Severe psychological or physical illness.
- Cognitive impairment or any serious medical problem that interferes with caregiving role.
- Caring for ADRD patient with a life expectancy less than six months.
- Unwillingness to participate in all aspects of the study.

Informed consent will be obtained, and participants will receive a stipend for their participation.

Methods: The effectiveness investigation of the Caring Mind App (CMA) will be implemented with a pre-post randomized trial of 3 months. As it takes 3 months to complete the entire program, post testing will happen about 3 months after pre-testing. The trial will have two levels: the CMA treatment package; and a control condition comprised of existing educational programs, information for caregivers, and other resources. Outcome measures of both groups will be recorded at baseline and after 3 months.

- CMA Condition (75 subjects): Participants will receive the Caring Mind mobile app containing the MCC curriculum.

- Control Condition (75 subjects): Participants will receive a traditional educational/resources program, containing a workbook and online resources.

Procedures: Participants will receive and complete informed consent. After initial assessment, subjects will be randomized to either CMA or the control condition, and instructions will be distributed. After 3 months, all subjects will be interviewed for the post-intervention assessment.

Statistical Analysis Plan

Main study hypothesis: “CMA will alleviate depression (measured by CES-D) and decrease stress (measured by PSS)”.

Main Outcome Measures:

- Depression: level of Depressive Symptoms: their presence and strength will be assessed using the Center for Epidemiological Studies Depression scale (CES-D); This is a 20-item measure that asks about the frequency of depressive symptoms (affective, psychological, and somatic) within the past week.
- Overall Perceived Psychological Stress: the 10-item Perceived Stress Scale (PSS) measures overall appraisals of stress in the past month.

Analysis: Our hypotheses will be tested by analyzing the change scores (subtracting the baseline scores from the value obtained at 3 months) for the outcome measure (CES-D and PSS) and comparing the results of CMA with the control condition in order to determine the efficacy of the intervention. We will determine if subjects in CMA had a significant decrease in level of depression and reduced stress, when compared to the control group. We’ll use univariate ANOVA (analysis of variance) to determine the level of significance for these measures.