Trial: **Caring Light for Family Caregivers**

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Project Summary

Every 66 seconds, someone in US develops Alzheimer's Disease, a progressive irreversible neurodegenerative disease, causing distress not only to dementia patients, but also to caregivers (15+ million), who are the hidden patients with high incidence of stress (60%) and depression (30%+).

Due to this significant problem, effective, low-cost, and accessible interventions are needed to help dementia caregivers to deal with the caring demands, heavy emotional toll, life changes, and overwhelming experiences.

A promising delivery mechanism is the smartphone, because: a) smartphone adoption is very high; and b) a large number of Americans nationwide have access to mobile broadband.

Therefore, we propose a unique intervention based on the Coping with Caregiving (CWC) curriculum, mindfulness, self-paced approach, and mobile app delivery, which has not been created before, called Caring Light App (CLA) to enhance caregiver coping skills, reduce stress, and alleviate depression.

Our project will have a high impact because: 1) the blending of CWC and mindfulness is expected to be very effective, based on our preliminary studies and other research results; 2) the proposed program is low-cost; and 3) CLA intervention will be accessible to a large group of caregivers as a mobile app, allowing its broad dissemination to innumerous families struggling with Alzheimer's and related dementia.

By integrating mindfulness practice with the CWC curriculum in a new mobile app, we will create a novel program for caregivers, blending training (coping skills, techniques to deal with dementia, practical tips on difficult behaviors, etc.) with stress reducing strategies (e.g. guided meditation, gentle stretches, and other mindfulness exercises), which is expected to be well accepted and easy to use by caregivers.

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 other dementia.
- Own a smartphone or tablet and have Internet access.
- Minimum age of 18 years old.
- Spend at least 8 hours/week caring for a person with dementia.

Exclusion Criteria:

- Severe psychological or physical illness.
- Inability to read and follow English instructions.
- High level of depressive symptoms.
- 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 Light App (CLA) 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 CLA 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.

- CLA Condition (75 subjects): Participants will receive the Caring Light mobile app containing the coping skills training.

- 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 CLA or the control condition, instructions will be distributed. After 3 months, all subjects will be interviewed for the post-intervention assessment.

Statistical Analysis Plan

Main study hypothesis: “CLA will alleviate depression (measured by CES-D), decrease stress (measured by PSS), and contribute to lower burden of care (RMBPC).

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.
- Burden of care: level of bother or stress due to disruptive behaviors: we will apply the Revised Memory and Behavior Problems Checklist (RMBPC), with 24 items describing possible troublesome behaviors of care receiver and effect (bother and stress) on caregiver.

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 measures (CES-D, PSS, and RMBPC), and comparing the results of CLA with the control condition in order to determine the efficacy of the intervention. We will determine if subjects in CLA had a significant decrease in level of depression, reduced stress, and decreased burden, when compared to the control group. We’ll use univariate ANOVA (analysis of variance) to determine the level of significance for these measures.