**Trial:** **Virtual Patient Behavioral Response Training for Family Caregivers**

**ClinicalTrials.gov ID:** **NCT04489303**

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**Investigator:** **Bruno Kajiyama**

**Research Site:**

**Photozig, Inc.**
**NASA Research Park**
**PO Box 128**
**Moffett Field, CA 94035-0128**

## Project Summary

The main cause of behavioral symptoms in patients with Alzheimer's disease (AD) is the deterioration of brain cells which causes a decline in the individual's ability to make sense of the world. Coping with such difficult behaviors is challenging for many caregivers, and it is associated with many distressful situations.

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

The goal of this project is to develop the Virtual Patient Behavioral Response (VPBR) training to improve skills on how to respond to dementia behavioral problems and enhance caregiver coping. We will implement this training in a mobile app (Caring Response App, CRA). The expected benefits include improved psychological health in caregivers and reduced stress related to behavioral disturbances of AD patients.

## 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 Response App (CRA) 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 CRA 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.

- CRA Condition (75 subjects): Participants will receive the Caring Response 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 CRA 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: “CRA will contribute to lower burden of care (RMBPC), alleviate depression (measured by CES-D), and decrease stress (measured by PSS).”

Main Outcome Measures:

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