Developing and Evaluating In-Home Supportive Technology for Dementia Caregivers

Phase IIA

2 SB1 AG059458-04A1

April 12, 2022

Pre-Screening Procedures:

For Phase IIA, participants will be recruited through 1) UCSF Memory and Aging Center, 2) other clinics, and 3) caregiver organizations, such as the Alzheimer's Association (including those contacted by Recruitment Partners, which is a company that specializes in community-level partnerships to identify potential research participants). Recruitment efforts are aimed at the caregivers of individuals with neurodegenerative disease using three types of materials: (a) flyers, (b) a description of the study that was prepared originally for clinicaltrials.gov, and (c) a recruitment video. The video (approximately 2.5-minute) is used to describe this research study and introduce the in-home technology system. This video would be accessible in emails or online links provided by our research team to groups/organizations and caregivers who wish to learn more about the study. Caregiver groups/organizations may elect to embed the video link in newsletters, or show the video to interested caregivers who may qualify to participate. All recruitment materials describe the general nature and goals of the research and provide information about what participation involves and monetary compensation. The Berkeley research team is listed as the source for additional information and addressing questions in all materials.

Initial Encounter:

Potential participants will be caregivers of PWD and will either be contacted via UCSF by Jennifer Merrilees for screening, or recruited via flyer in clinics or other locations where caregivers gather (e.g., dementia support groups). Eligible caregivers will be invited to participate in the study and will schedule an installation with members of the Berkeley Psychophysiology Laboratory. Prior to installation, participants will be sent a link to complete a set of questionnaires. For participants not recruited via UCSF, this will include "Screening Questionnaire: Information about person receiving care", which obtains additional information about the needs of the person receiving care. A member of the UC Berkeley research team listed on this protocol will determine the installation and start date for that participant. For those caregivers recruited by flyers posted in dementia clinics and other locations that current caregivers are likely to visit, we would receive permission for all postings and would comply with any rules that a given clinic or location may have. All interested caregivers recruited via flyers at clinics or other locations, and via online study description would initiate contact with our research team (i.e., we would not ask them to write down any personal information on flyers, or sign up on any forms to be contacted).

Caregivers who complete the IIA study in the control group will be provided with an opportunity at the end of the 9-month study to use a fully-functioning Presence Care system at no cost if they agree to complete questionnaires for an additional 9-month period (completing questionnaires at 12-months, 15-months, and 18-months). These caregivers would be recruited by the UC Berkeley research team just before the completion of their IIA participation. Participation is

completely optional and caregivers who decline participation upon receipt of our group's email will not be penalized in any way.

Consent:
For most participants, we will use Qualtrics to administer the initial screening questionnaire, online consent form (which describes all study procedures involving installation and questionnaires), and all subsequent questionnaires. Online consent requires participants to click on a box stating, "By clicking here, I indicate that I have read the above consent form and agree to take part in the research."

Baseline Outcome Assessment:
Once caregivers complete the screening questionnaire, a member of the Berkeley team will send the caregiver their consent form via a Qualtrics link, along with a link to the first questionnaire administration will be sent for the caregiver. Identical Qualtrics questionnaires will be sent via email to caregivers in both research conditions at baseline, 3 months, 6 months and 9 months. The four sets of questionnaires will be identical, except: a) the baseline questionnaire will also include a contact information form and "Information about person receiving care," and b) the 3-month, 6-month, and 9-month questionnaires will also include questions regarding the usefulness of Presence Care in their homes.

Randomization:
Fifty percent of the caregivers will be randomly assigned to the "experimental in-home technology" condition of Presence Care and the remaining 50 percent of caregivers will be assigned to the "limited control" condition. Randomization of participants in each group will be determined by members (i.e., graduate students listed in this protocol) of the research team and staff members completing the installation will not be aware of which group the caregivers are assigned to. Immediately following the installation, Nicole Concepcion, an employee of People Power, will remotely (i.e., through People Power's online system) activate Presence Care and all sensors for those in the "experimental" condition. Nicole Concepcion will only activate water alerts in the "limited control" group.

Outcome Measures:
All caregivers–regardless of randomized study condition–complete questionnaires on four separate occasions during this study: baseline, 3-months, 6-months, and 9-months. The four outcome measures include are: (a) Zarit Burden Interview-Short Form, a questionnaire measuring caregiver burden (Zarit, Reever, & Bach-Peterson, 1980). 12 items are rated on 0-4 scale. Range: 0-48. No subscales. Higher scores represent worse outcomes; (b) Center for Epidemiological Studies Depression Scale (CES-D), a questionnaire measuring depression (Radloff, 1977). 20 items are rated on a 0-3 scale and summed (range = 0-60). There are no subscales. Higher scores represent worse outcomes. The clinical cut-off is usually set at a score

of 16; (c) Beck Anxiety Inventory (BAI), a questionnaire measuring anxiety (Beck, Epstein, Brown, & Steer, 1988). 20 items are rated on a 0-3 scale and summed (range= 0-60). Higher scores indicate worse outcomes. There are no subscales. A score greater than 36 is considered to be clinically significant; and (d) Satisfaction with Life Scale, a questionnaire measuring overall life satisfaction and well-being (Diener, Emmons, Larsen, & Griffin, 1985). 5 items scored on a 1-7 scale and summed (Range = 5-35). Lower scores indicate worse outcomes. A score of 20 is considered neutral with higher scores considered increasingly more satisfied and lower scores considered increasingly more dissatisfied.

Contact initiated by study staff

Identical Qualtrics questionnaires will be sent via email to caregivers in both research conditions at baseline, 3 months, 6 months and 9 months. The initial questionnaire to be completed prior to installation will be identical to the follow-up questionnaires, except with the addition of a contact information form and "Information about person receiving care", and the 3, 6, and 9 month questionnaires will also have questions regarding the usefulness of Presence Care in their homes. Questions ask about caregivers' health and the ease of use of the equipment. Upon completion of the baseline questionnaire and installation of the Presence Care system, caregivers will be mailed a $100 check. Upon completion of the final questionnaire at 9 months, caregiver participants will be mailed a $75 check to compensate for their time completing questionnaires. A member of the research team will contact the caregivers to determine if they would like the system uninstalled by the research staff members of the Berkeley Psychophysiology Laboratory (in which case a time and date will be determined), or keep any and all sensors, devices, or equipment in their home. For those who choose to keep equipment or devices, they will not be charged any cost and we will end our data collection of any related devices and will not ask that they complete any additional questionnaires regarding their usage of the system, sensors, or equipment (i.e., their participation in this study is complete). Caregivers randomly assigned to the limited control condition will be offered an opportunity to enroll in an additional 9-month study. Those who were originally assigned to a limited "control" group would have all sensor alerts activated. Nicole Concepcion, of People Power, would remotely activate Presence Care features (e.g., alerts for door entry/exit sensors and stove usage) for those originally assigned to Group 1 (i.e., the limited control condition), as necessary. Thus, there would not be a need for additional home visits in order to begin participation. Caregivers in the limited-control condition who opt to continue participation would be asked to complete questionnaires at months 3, 6, and 9 (3 additional questionnaires). Following the completion of this additional 9 month study, caregivers will be mailed a check for $75 to compensate for their time and effort.