Developing and Evaluating In-Home Supportive Technology for Dementia Caregivers

Phase IIB

R44AG059458-03

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Pre-Screening Procedures:

For Phase IIB, participants will be recruited through caregiver organizations, such as the Alzheimer's Association. 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-minutes) describes this research study and introduces 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 recruited through online listservs of caregivers. Interested caregivers will be directed to an online website to learn more about the study, and complete a screening questionnaire to determine eligibility. Interested caregivers will also give their contact information for enrollment, as well as complete the consent to participate. Once a caregiver has enrolled through the website and been determined as eligible for the study, a member of the Berkeley Psychophysiology Laboratory team will assess the capacity of the PWD to give consent to be in the study. Once PWD consent is obtained either on their own, or through surrogate consent, participants will be sent a link to complete a set of questionnaires. Once patient consent is obtained, People Power will mail the Presence Caregiver system to the caregivers in the active condition for self-installation. People Power will be available to schedule virtual self-installation sessions if caregivers want by email or phone. Additional technical support for the system is available by email and phone during the course of the study.

Caregivers who complete the IIB study in the control condition will be provided with an opportunity at the end of the 6-month study to receive a fully-functioning Presence Care system at no cost if they agree to complete questionnaires for an additional 6-month period(completing questionnaires at 9-months and 12-months). Participation is completely optional and caregivers who decline participation upon receipt of our group's email will not be penalized in any way.

Consent:

Participants will give consent online through the study website. 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." Individuals receiving care (PWD) are asked to consent to participation as secondary subjects in order for information about them to be used

for research purposes. In order to assess a patient's ability to consent to participation, a member of the research team will conduct a phone conversation with both caregiver and patient. The purpose of this conversation is to provide information about the study (e.g., participation responsibilities, compensation information, etc.) and to assess the PWDs cognitive capacity to consent for themselves using UCLA's "Decision-Making Capacity Assessment Tool." More specifically, a member of the Berkeley research team will determine the PWDs ability to 1) understand relevant study information, 2) ability to appreciate the situation and consequences of the study, 3) ability to rationalize or reason information presented, and 4) ability to make their own decision to participate in the study. If the investigator's evaluation is that the PWD can provide consent (i.e., the answer to questions 8 and 9 on the Assessment Tool are both "yes") the PWD will be asked to complete their own consent form via Qualtrics. If the PWD is judged to have diminished capacity (i.e., the answer to questions 8 or 9 are "no") then the caregiver will be asked to provide surrogate consent if the patient assents. Here, caregivers will be informed to the nature of their decision during the study including patient's participation and decision to participate in certain procedures for the patient in order to ensure that the caregiver will be willing to undertake these on-going responsibilities. In addition, caregivers will be asked to identify a witness who will be willing to provide a bystander signature when they are completing the Self-Certification of Surrogate Decision Maker Form.

Baseline Outcome Assessment:
Once caregivers verbally understand and agree to these responsibilities they will be sent the surrogate consent form for the PWD, the self-certification of surrogate decision maker form, and their own consent form via a Qualtrics link. If the investigator's evaluation is that the PWD can provide consent, the PWD will be asked to complete their own consent form via Qualtrics. Once all forms are completed, 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, and 6 months. The three 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 and 6-month questionnaires will also include questions regarding the usefulness of Presence Care in their homes.

Randomization:
300 caregivers will be randomly assigned to the "active in-home technology" condition of Presence Care and the remaining 100 caregivers will be assigned to the "waiting control" condition. Randomization of participants in each group will be determined by People Power employees after the consent process.

Outcome Measures:
All caregivers–regardless of randomized study condition–complete questionnaires on three separate occasions during this study: baseline, 3-months, 6-months. The four outcome measures

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

After completion of the first questionnaire and successful installation of the system, caregivers randomly assigned to the active condition will be mailed a check of $100. Qualtrics questionnaires will be sent via email to caregivers in both research conditions at baseline, 3 months, and 6 months. Upon completion of the final questionnaire at 6 months, caregiver participants will be mailed a $50 check to compensate for their time completing questionnaires. A member of the research team will contact the caregivers to let them know they are welcome to uninstall and dispose of the system, or they may choose to 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 waiting control condition will be mailed a check for $25 upon completion of the first questionnaire. After completion of the 3 and 6 month questionnaires, caregivers will be mailed a check for $50 and offered an opportunity to enroll in an additional 6-month study. If they enroll, they will be mailed the Presence Care system for them to self-install and have all sensors activated. They will also be asked to complete the questionnaires at 9-months and 12-months. Following the completion of this additional 6-month study, caregivers will be mailed a check for $125 for the 9 and 12 month questionnaires, as well as the installation to compensate for their time and effort.