

In-Home Technology for Caregivers of People With Dementia and Mild Cognitive  
Impairment: Wearables

Unique Protocol ID: 1247267250000-4

Secondary IDs: 2SB1AG059458-04A1

Identifiers: NCT05159557

Document Date: July 12, 2023

### Pre-Screening Procedures:

Wearable Homes caregivers may be recruited through caregiver organizations (e.g., Alzheimer's Association, clinics (e.g., Nebraska Healthcare), other locations where caregivers gather/visit (e.g., support groups, senior centers), and media (e.g., print, social, digital). We have created a flyer/email script for these organizations to use that describes the research study and introduces the in-home technology, as well as a physical flyer to be posted in physical locations caregivers are likely to frequent. All recruitment materials describe the general nature and goals of the research and provide information about what should be expected if they participate. The Berkeley research team is listed as the source for additional information and addressing questions in all materials.

### Initial Encounter:

Interested caregivers will be directed to an online website to learn more about the study and complete a screening questionnaire to determine eligibility. Caregivers must 1) be fluent/literate in English, 2) reside in the US and live with the person they are providing care for, 3) primarily use a smartphone (iPhone or Android), and 4) have WiFi internet service. Interested caregivers will also give their contact information for enrollment, as well as complete the consent to participate. Once a caregiver has been determined as eligible and enrolled through the website, a member of the Berkeley Psychophysiology Laboratory team will assess the capacity of the PWD to give consent to be in the study as a secondary subject. Once PWD consent is obtained either on their own, or through surrogate consent, caregiver participants will be sent a link to complete a set of questionnaires. Once PWD consent is obtained, People Power will mail the Presence Caregiver system to the caregivers 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.

### 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 consent procedures are complete, caregivers receive a Qualtrics link with their initial questionnaire. 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 the baseline questionnaire will also include a contact information form and "Information about person receiving care."

#### Randomization:

Sixty caregivers will be randomly assigned to the "active in-home technology" condition of the system and the remaining 60 caregivers will be assigned to the "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

Caregivers receive \$75 for completing the installation of the system in their homes and \$25 for each questionnaire they complete (initial questionnaire, 3-months, and 6-months). Qualtrics questionnaires will be sent via email to caregivers in both research conditions at baseline, 3 months, and 6 months. After participation, 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 mail it back with costs covered), or they may choose to keep any sensors, devices, or equipment.

