

Title: Mobile Tablet Education to Advance Caregiver Health

NCT #: NCT03417219

March 3, 2014

**2.A.3.g. Study Measures.** *Zarit Burden Interview (ZBI)* [1]. Several versions of the ZBI have been used successfully as outcome measures in interventions for dementia caregivers [2, 3]. *Center for Epidemiological Studies-Depression (CES-D)* [4]. The CES-D is frequently used to assess depression in dementia caregivers and has been shown to be sensitive to changes in caregiver depression post intervention [5]. *Perceived Stress Scale (PSS)* [6]. The PSS has been used successfully to measure perceived stress in dementia caregivers [7]. *Global Deterioration Scale (GDS)* [8]. The GDS is a semi-structured rating of functional status in degenerative dementia. It has been successfully used in prior studies of dementia caregiver intervention with adequate reliability [9]. *Telephone Cognitive Screen (T-CogS)* [10]. The T-CogS is a brief mental status examination designed to be administered over the telephone. Scores on the T-CogS strongly correlate with MMSE scores ( $r = 0.88$ ,  $p < 0.001$ ) [11]. An exclusion cutoff score of  $< 20$  on the T-CogS is chosen to match a MMSE cutoff of  $< 23$  [12]. *Caregiver Interview*. All caregivers will also be administered a structured interview to ascertain information on levels of socialization and pleasurable activity participation.

**2.A.3.h. Data Management.** Integrity of data collection, scoring, and entry/verification will be overseen by the MIRECC Data Analyst/Database Manager and the PI.

**2.A.3.i. Statistical Analyses.** While the proposed project is designed to assess study feasibility, to test the hypotheses outlined in the Specific Aims (Section 2) we will use mixed-effects modeling to fully utilize outcome data measured over time (baseline and follow-up assessments) and to better handle missing outcome information in line with the intention to treat principle. Dr. Jo will serve as a statistical consultant, given her expertise in clinical trial and mixed modeling methodologies.

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