

Title: Mobile Tablet Education to Advance Caregiver Health

NCT #: NCT03417219

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## Study Protocol

### **2.A.3. Research Design and Methods.**

**2.A.3.a. Approach.** To test the feasibility of a group-based education and skill-building rehabilitation (ESBR) intervention in improving dementia caregiver and care recipient outcomes, our proposed trial will consist of 40 family caregivers coping with all-cause dementia who will be randomized to ESBR. Twenty participants will be randomized to receive mobile media ESBR (ESBR-m), and 20 participants will be randomized to receive usual care plus supplemental educational materials on dementia (UC).

The results of this project will determine the efficacy of a low-cost, pragmatic intervention for caregivers of Veterans with all-cause dementia and will be used to build upon prior findings indicating the efficacy of resource-intensive methods to rehabilitate caregivers of Veterans with all-cause dementia.

#### **2.A.3.b. Participants**

<i>Inclusion criteria</i> - Participants must:	<i>Exclusion criteria</i> - Participants will be excluded for:
<ul style="list-style-type: none"><li>• be adults (age <math>\geq 18</math>)</li><li>• report distress associated with being the primary caregiver for a family member with dementia</li><li>• reporting at least 2 of the following 6 items at baseline assessment: felt overwhelmed, felt like they often needed to cry, were angry or frustrated, felt they were cut off from family or friends, reported moderate to high levels of general stress, or felt their health had declined</li><li>• provide at least 7 hours of care (supervision or direct assistance) per week over the past 3 months (other sources of caregiving for the Veteran with dementia can also be utilized; e.g., respite, home health aide, other family members)</li><li>• cohabitate with a Veteran diagnosed with dementia</li><li>• be proficient in spoken and written English</li><li>• be capable of providing informed consent</li></ul>	<ul style="list-style-type: none"><li>• current or lifetime history of any psychiatric disorder with psychotic features</li><li>• prominent suicidal or homicidal ideation</li><li>• having met DSM-IV criteria for drug or alcohol abuse or dependence (except nicotine) within the past six months</li><li>• presence of alcohol intoxication (by breathalyzer) or alcohol withdrawal (by exam) during study recruitment or participation</li><li>• diagnosis of probable or possible dementia</li><li>• a Telephone Cognitive Screen score of <math>&lt; 20</math></li><li>• participation in another caregiver intervention study within the past year</li><li>• lack of access to telephone and internet services in the home</li><li>• illness that would prevent study participation</li><li>• planned transfer of care receiver to another caregiver or nursing home within 6 months</li></ul>

**2.A.3.c. Recruitment.** We aim to recruit 40 participants who meet inclusion/exclusion criteria for the proposed project (ESBR-m:  $n = 20$ ; UC:  $n = 20$ ). Participants will be recruited primarily from the VA Palo Alto Health Care System (VAPAHCS). We anticipate primary referral sources to include: Sierra-Pacific Mental Illness Research Education and Clinical Center (directed by Dr. Yesavage); VAPAHCS Dementia Committee (chaired by Dr. Scanlon, PI); VA Memory Clinic (directed by Dr. Kinoshita); Geriatric Research, Education, and Clinical Center; Stanford/VA Aging Clinical Research Center (directed by Drs. Yesavage and Taylor); Stanford/VA Alzheimer's Research Center (co-directed by Dr. Yesavage); Psychology and Psychiatry Services (Dr. Yesavage is ACOS for Mental Health); and the War Related Illness and Injury Study Center (Dr. Adamson, see support letter, serves as Director of Research). Based on clinical experience in the VA Memory Clinic, we also expect primary care clinics to serve as key referral resources. Dr. John Chardos, Associate Chief of Staff for Ambulatory Care at VAPAHCS, has designated resources to our team to aid with recruitment in Patient Aligned Care Team (PACT; i.e., primary care) clinics. Additional participants will be recruited from the Veteran community via word of mouth, an IRB-approved recruitment flyer, and public and private speaking engagements. These additional recruitment avenues have been highly successful in providing subject pools for prior studies from our group. Given our Center's experience in participant recruitment, participants' response to a pilot of the intervention, and high prevalence (80%) of home broadband internet access in the San Francisco Bay Area (Baldassare, Bonner, Petek, & Shrestha, 2013), we expect ample ability to meet our enrollment goals. In the interest of maintaining recruitment of an adequate number of participants, we will supplement our Veteran sample with non-Veterans, if necessary.

**2.A.3.d. Retention.** We will implement several procedures to enhance recruitment and study retention. First, we will provide remuneration (\$25) for each study event. We will also provide telephone and electronic/mail reminders of upcoming appointments. We will also be flexible in scheduling appointments to accommodate the participant's schedule. Furthermore, we will make a strong effort to "personalize" each participant's

experience. For example, we will send out thank you cards to all participants and will make follow-up telephone calls to express gratitude for participation. We will follow procedures that we have successfully used in our previous research.

**2.A.3.e. Screening Procedures.** Participant screening for eligibility and other data collection will mainly occur during telephone interviews. Should caregivers prefer, face-to-face (in-person) screening/assessment will also be offered. An interview will be conducted with caregivers to determine study eligibility. During this interview, study staff will explain the study, its requirements, and answer any questions the potential participant may have. Upon the potential participant's willingness to be screened, study staff will ensure all inclusion criteria are met and screen the potential participant for all exclusionary criteria. The results of all screening assessments will be reviewed by the PI in consultation with Co-I's. After consensus determination of study eligibility, the Study Coordinator will contact the participant to schedule a Baseline assessment (if eligible), or provide appropriate referral (e.g., VA Caregiver Support Program) and explanation (if not deemed eligible). Both "screen failures" and eligible participants who drop out prior to receiving any intervention will be replaced.

### **2.A.3.f. Procedures Involving Eligible Participants**

#### **2.A.3.f.1. Enrollment, Randomization, and Baseline Assessment**

Enrollment and Randomization. Once participants are deemed eligible, they will be invited by the Study Coordinator to participate in the study, if willing and able to provide informed consent. At this point, the Data Manager will randomize the participant to one of two arms: ESBR-m or UC. For randomization, a modification of the Efron procedure (Efron, 1971) developed by Dr. Helena Kraemer (Kraemer, 1981) will be implemented to assure the two groups are comparable at baseline in terms of dementia subtype. Participants who drop out after receiving any intervention will not be replaced, but their data will be used in mixed-effects analyses.

Baseline Assessment. Trained study staff, blind to the participants' ESBR-m/UC assignment, will administer a baseline assessment including clinicodemographics and measures of caregiver burden, depression, and perceived stress, in addition to care recipient functional status (see Section 2.A.3.g. for a description of outcome measures). Assessment will mainly occur over the telephone to reduce study participation burden. Packets with assessment aids will be sent to the caregiver prior to each assessment. Should caregivers prefer, in-person assessments will also be offered.

Mental Health referrals to Stanford Outpatient Psychiatry Clinics will be offered to all participants who score 16+ on the CES-D, in addition to participants who endorse symptoms of significant clinical concern, as determined by study staff. All participants are also provided information on accessing the VA Caregiver Support Program and the Veterans Crisis Line.

**2.A.3.f.2. Mobile Media Education and Skill-Building Rehabilitation Intervention (ESBR-m).** Our ESBR-m intervention consists of four, 90-minute group ( $\leq 5$  participants) sessions. **These four sessions are supplemented with a booster session one month following the last intervention session.**

While prior studies have reported barriers to engaging dementia caregivers in treatments delivered via the internet, these issues were related to challenges with more complicated tasks performed with personal computers (Hayden, Glynn, Hahn, Randall, & Randolph, 2012) (e.g., entering a chat room, downloading streaming videos). Our novel intervention and our use of customized tablets alleviates many of the technical hurdles faced by previously developed internet interventions. Tablets offer several advantages over traditional computer-delivered interventions including 1) a pared down, user friendly interface; 2) increased access due to relative affordability in comparison to traditional computers; 3) integrated availability of video telehealth service provision; 4) ultimate portability; and 5) ease of delivering prepackaged content and services. Content (e.g., skill-building videos, multimedia relaxation facilitation, challenging behavior tipsheets) will be prepackaged on the tablets and will be available offline, making the tablets a fully portable resource for caregivers.

#### **2.A.3.f.3a. ESBR-m Session 1 – Dementia: what does it mean for me and my family?**

Session 1 objectives are to:

- increase caregiver knowledge about dementia (~20 minutes)
- build caregiving skills (tailored to the needs of each small group) (~40 minutes)
- emphasize the importance of self-care (stress awareness) (~15 minutes)
- introduce the relaxation technique of guided imagery (~15 minutes)

Session 1 is designed to increase the caregiver's knowledge of dementia, its causes, and how disease impacts the brain to create symptoms of dementia. It simplifies the most common causes of dementia into relatable, understandable information (information is adapted to the needs of each group based on care receiver

diagnosis). This session explains common symptoms of dementia syndromes using concrete examples provided both by the leader of the session and caregiver participants.

Targeted skill-building to address care recipient symptoms (and other stressors) elicited from participants is integrated into the session to maximize training in skills pertinent to the group. Discussion is focused around challenging symptoms of dementia experienced by participants and skills to address these symptoms are interwoven into the discussion. Information and skill sheets that focus on specific symptoms and behaviors are prepackaged on the caregiver tablets for easy access.

Caregiver self-care is emphasized through group discussion of the following: stress warning signs, identification of specific stressors, and introduce appropriate use of problem-focused and emotion-focused coping for controllable and uncontrollable aspects of stressors.

The relaxation technique covered in Session 1 is guided imagery, including instruction and practice. Guided imagery audio-visual exercises will be prepackaged on the caregiver tablets. Continued use is encouraged; participants set self-made goals for implementation.

### **2.A.3.f.3b. ESBR-m Session 2 – Dementia: what resources are available to help me and my family?**

Session 2 objectives are to:

- increase caregiver knowledge of dementia resources (~30 minutes)
- build caregiving skills (tailored to the needs of each small group) (~30 minutes)
- emphasize the importance of self-care (sleep hygiene) (~15 minutes)
- introduce the relaxation technique of deep breathing (~15 minutes)

Session 2 is designed to increase the caregiver's knowledge of resources available within VA, the local community, and on a national level. Participants' prior use of dementia resources is discussed and education is provided regarding additional available resources. Resources that are available 24/7 are highlighted (e.g., Veterans Crisis Line; VA Caregiver Support Line). Medical and mental health services are explained (e.g., primary care, psychiatry, neurology), other consultation services are identified (e.g., driver evaluation, respite care), and specialty centers are introduced (e.g., GRECC, PADRECC, academic medical centers). National organizations with missions dedicated to causes of dementia and caregivers are introduced and their services (e.g., support groups) are discussed. Contact information and access to all resources is facilitated through tablet customization. Information is adapted to the needs of each group based on care receiver diagnosis.

Targeted skill-building to address care recipient symptoms (and other stressors) elicited from participants is integrated into the session to maximize training in skills pertinent to the group. Discussion is focused around challenging symptoms skills to address these symptoms are interwoven into the discussion.

Self-care activities from the previous session are briefly discussed and continued self-care is emphasized. Sleep hygiene education and discussion is included due to the fluctuations in sleep (Carter, 2003) most likely due to the demands of care provision and sleep problems (Carter & Chang, 2000; Wilcox & King, 1999) in caregivers. Exercise commensurate with physician approval is also promoted due to its effects on sleep (King, Baumann, O'Sullivan, Wilcox, & Castro, 2002) in addition to its general paucity in caregivers (King & Brassington, 1997).

The relaxation technique covered in Session 2 is deep breathing, including instruction and practice sessions. Continued use (instructional materials prepackaged on caregiver tablets) is encouraged with participants setting self-made goals for implementation.

### **2.A.3.f.3c. ESBR-m Session 3 – Dementia: How can I best communicate with my sources of support?**

Session 3 objectives are to:

- build caregiver communication skills (~50 minutes)
- emphasize the importance of self-care (planned pleasant activities) (~20 minutes)
- introduce the relaxation technique of progressive muscle relaxation (~20 minutes)

Session 3 is designed to enhance the caregiver's ability to communicate with family, friends, and health care providers. Targeted skill-building geared toward effective communication is the focus of this session. Role play is utilized to promote effective communication techniques. Skill-building targeted at improving caregiver/health care provider communication is modeled after the National Institute on Aging publication *Talking with your doctor: a guide for older people* (copies prepackaged on caregiver tablets). Communication tools, preparing for a healthcare appointment, getting information from healthcare providers, and partnering with healthcare providers to make decisions are addressed in detail.

Self-care activities from the previous sessions are briefly discussed and continued self-care is emphasized. This session will specifically focus on planning pleasurable activities.

The relaxation technique covered in Session 3 is progressive muscle relaxation, including instruction and practice sessions. Continued use (instructional materials and audiovisual segments are prepackaged on caregiver tablets) is encouraged with participants setting self-made goals for implementation.

#### **2.A.3.f.3d. ESBR-m Session 4 – Dementia: How can I cope with the stress caused by dementia?**

Session 4 objectives are to:

- build caregiver coping skills (~45 minutes)
- solidify the importance of self-care (review) (~15 minutes)
- review of learned relaxation techniques (~30 minutes)

Session 4 is designed to improve the caregiver's coping skills, specifically targeted to address the challenges of being a dementia caregiver. Ways to manage common symptoms of dementia syndromes using concrete examples, provided both by the leader of the session and caregiver participants, are demonstrated and practiced in role play. The intervention leader will aid participants in reframing cognitive, behavioral, and psychiatric symptoms of dementia as manifestations of damage to the brain.

Targeted skill-building to address care recipient symptoms elicited from participants is integrated into the session to maximize training in skills pertinent to the group. Non-pharmacological interventions for dementia symptom management from previous sessions are reviewed and consolidated.

Self-care activities from the previous sessions are discussed; importance of continued self-care is solidified.

The relaxation techniques covered in Sessions 1-3 are reviewed and consolidated. Continued use post-intervention is encouraged with participants setting ongoing goals for implementation.

**2.A.3.f.3e. ESBR-m Booster Session.** The 90-minute booster session (1-month after the final intervention session) is designed to briefly review dementia knowledge and resources available to dementia patients and their caregivers. Caregiving skills, as they pertain to current stressors, are honed in a manner that is tailored to the small group's needs. The importance of continued self-care is accentuated. Intervention relaxation techniques are revisited and continued use is fostered.

**2.A.3.f.4. Usual Care (plus supplemental educational materials).** Participants randomized to the Usual Care (UC) group will receive supplemental educational materials (e.g., VA Caregiver Support Program; Veterans Crisis Line; National Institute on Aging's "Understanding Memory Loss").

**2.A.3.f.5. Follow-up (at 3-months post-intervention).** Trained study staff, blind to the participants' ESBR-m/UC assignment, will administer follow-up assessments 3 months after the conclusion of the intervention or assignment to usual care. These assessments will mainly occur over the telephone. Packets with assessment aids will be sent to the caregiver prior to each assessment. Should caregivers prefer, in-person assessments will also be offered.

**2.A.3.f.6. Study Conclusion.** Similar to referral procedures implemented throughout the study, at the conclusion of the study all participants will be provided with referrals for services for significant stress, mental health challenges, or cognitive concerns.

## References

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