Translating a Dementia Caregiver Intervention Into a Mobile Application

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SPECIFIC AIMS

The overall goal of this development project is to combine elements of two interventions into a mobile health (mHealth) App for informal dementia caregivers. Caring for a person with dementia is a highly stressful activity and is associated with negative physical and mental health consequences, including increased risk of depression and worse reported health-related quality of life (1). There is currently no effective disease-modifying treatment for Alzheimer's disease (AD) and related dementias, and 70% of persons with AD are cared for by family members or other informal caregivers (2). There is a pressing need for strategies to care for both the increasing population of dementia patients and their family caregivers. Psychosocial interventions (particularly multicomponent interventions) for dementia caregivers are successful in reducing depression, stress, and burden associated with caregiving and delaying nursing home placement (3-6). Although over 200 dementia caregiver interventions have been found efficacious in randomized trials, less than 3% of interventions have been empirically tested in translational studies (7). As a result, family caregivers do not receive intervention strategies shown to be most effective. The few translational studies that exist demonstrate that complex trials from randomized interventions can be adapted for community implementation and tend to obtain similar results seen in RCTs (8,9). One method for widespread dissemination and scalability of an intervention is technology-based approaches, such as mHealth Apps.

Our research group developed the Family Intervention: Telephone Tracking Caregiver (FITT-C), which is an entirely telephone-delivered psychosocial intervention (R21MH062561). A full-scale efficacy study (R01NR010559; [10]) showed that compared to a supportive intervention, the FITT-C reduced caregiver depressive symptoms and their reactions to patient memory and behavior problems. A secondary analysis revealed that FITT-C caregivers had lower healthcare utilization and greater community resource use compared to support caregivers (11). Our team also conducted an RCT of a mind-body intervention (i.e., yoga, meditation) in individuals with depressive symptoms (R01NR012005; [12]), which showed reduced depressive symptoms at 6-month follow-up compared to a health education program. The proposed study will combine and translate each of these interventions into a mHealth App (CARE-Well [Caregiver Assessment, Resources, and Education]). A strength of the proposed project is merging these complementary interventions to provide caregivers with a range of empirically-supported opportunities for psychoeducation, stress management, and problem solving.

Aim 1: Develop and preliminarily test a mHealth tablet App for dementia caregivers incorporating important elements of FITT-C and a mind-body (yoga, meditation) intervention.

- Collaborate with a computer/biomedical engineering team with an expertise in mHealth technologies to integrate key components of both interventions and develop a beta version of the App for initial testing.
- Conduct a month-long open trial of the App in 10 dementia caregivers and elicit feedback about the App using qualitative interviews.

Aim 2: Conduct a feasibility trial of the newly-developed CARE-Well App in 40 dementia caregivers to establish acceptability and feasibility of the intervention, study procedures, and outcome measures.

The current proposal aligns well with NIH priorities as outlined in PAR-18-179, including development of novel interventions to meet needs of caregivers and leveraging technology to support caregivers in the home. The recent 2015 Alzheimer's Disease Summit recommended initiating programs that bring together cross-disciplinary expertise to develop more personalized technologies to serve the diverse populations of aging adults with and without AD and their caregivers. The overarching goal of this application is to develop a highly transportable and scalable intervention for dementia caregivers that can be tested in a future clinical trial.

RESEARCH STRATEGY

SIGNIFICANCE

AD currently affects 5.7 million people in the U.S. (2). There is currently no effective disease modifying treatment for AD, and most pharmaceutical trials for the disease failed, suggesting that we are still far from an effective treatment. Dementia caregivers are the main support source for these individuals, with over 70% of individuals with AD cared for by family members or other informal caregivers (2). Dementia caregivers are at heightened risk for depression, anxiety, stress, and other negative health consequences (1, 13-14). It is therefore important to develop interventions for this high-risk group. Psychosocial interventions for dementia caregivers are successful in reducing depression, stress, and burden associated with caregiving and delaying nursing home placement (3, 5, 10). In addition, there is evidence that multicomponent interventions are most efficacious compared to single-focused approaches in treating the negative effects of caregiving and delaying institutionalization of the care recipient (3,5). Individual and tailored interventions for caregivers are also more effective than group and one-size-fits-all models (15).

Although over 200 dementia caregiver interventions have been found efficacious in randomized trials, less than 3% of interventions have been empirically tested in translational studies (7). As a result, family caregivers do not receive intervention strategies shown to be most effective. Barriers to implementation of multicomponent interventions (even those delivered by telephone) include high cost, personnel time, and limited accessibility. Caregivers also encounter numerous barriers related to in-person programs and support groups, such as limited transportation, time pressures of caregiving, inability to find care for the recipient, lack of knowledge of services, reluctance, or stigma associated with seeking support. Consequently, dementia caregivers tend to underutilize community support services and other resources (16).

MHealth Apps are a particularly promising strategy to meet caregivers' needs that are accessible during convenient times. Mobile and web-based interventions show promise in specific skill building for dementia caregivers (17), lessening burden in cancer caregivers (18) and reducing depressive symptoms in adults with mental illness (19). Many of these studies are plagued by methodological limitations, involving inadequate controls, lack of blinding, and limited descriptions of methods (20). **The proposed project aims to address these limitations by developing and translating an evidence-based, multi-component intervention into a mHealth App that has the potential to increase dementia caregivers' access to support and care.**

Conceptual Framework. The FITT-C intervention is based on a combination of theoretical models, including psychosocial transitions (21), transactional stress and coping (22), and the McMaster Model of Family Functioning (23). These models propose that dementia caregiving consists of stress-inducing events that result in an appraisal process by the caregiver to identify whether resources are available to cope with the events. Caregiver burden can be viewed as a situation in which subjective and objective demands exceed subjective and objective coping and resources, and persisting burden becomes a stressor that results in feelings of depression and helplessness. The focus of the intervention is on increasing caregiver coping through active problem-solving skill development and promoting positive changes within the family system. As such, the FITT-C intervention directly targets caregiver appraisal and coping, and has shown reductions in burden, depression, and reactions to memory and behavior problems in dementia caregivers (10). The framework underlying the mind-body intervention involves multiple components (physical activity/postures, breathing exercises, and meditation) that target depressive symptoms and may decrease rumination. Yoga and meditation are efficacious in reducing depression (12), reducing anxiety (24) and may amplify the FITT-C intervention by providing additional stress management techniques for relaxation and mindfulness that can be applied in daily life. The negative effects of dementia caregiving are broad and complex and may be best addressed by a multipronged approach, such as

increasing coping skills and reducing stress, depression, burden, reactions to behavioral problems, and rumination/worry.

INNOVATION

The current project represents the first study to develop a combined psychosocial and mind-body intervention based on evidence-based programs that show reduction in the negative consequences of dementia caregiving and depression and rumination. The project will create and test a multicomponent, mHealth App rather than a specific educational or skill building approach. The design of the App will allow for: 1) tailoring and personalizing the intervention based on caregiver assessment; 2) using conceptual frameworks of the interventions in developing the App, 3) including current dementia caregivers in the process of refining and adapting the intervention; and 4) developing a cross-disciplinary collaboration between computer engineers and clinical researchers. Given the widespread availability of mobile devices, the intervention has the potential for efficient dissemination into the community following demonstration of efficacy.

APPROACH

Overview. This project will translate the FITT-C and mind-body interventions into a mHealth App through a collaboration between clinical and computer engineering scientists. In Aim 1, we will develop the mHealth App and use participatory research methods to modify the App. In Aim 2, we will conduct a feasibility study in 40 dementia caregivers to establish acceptability and feasibility of the intervention, study procedures, and outcome measures. If the aims are achieved, we will have a fully-developed mHealth App and established feasibility for procedures to conduct a full-scale RCT. Another goal of this project is to demonstrate viability of translating in-person interventions into mHealth Apps. The proposed study includes Stage 1a (intervention modification) and Stage 1b (feasibility and pilot testing the App).

Preliminary Studies. The PI (Tremont) developed the Family Intervention: Telephone Tracking intervention (R21MH062561; [6]) and demonstrated efficacy of the intervention (R01NR010559; [10]), showing that compared to a supportive intervention, the FITT-C reduced caregiver depressive symptoms and their reactions to patient memory and behavior problems. A recent secondary analysis showed that the FITT-C reduced ER visits and hospital stays among caregivers and increased the use of community resources compared to a supportive intervention (11). We have a detailed treatment manual that includes sample dialogue, intervention strategies, and strategies for management common behavioral problems in dementia that will available for use in the current study. The PI and other members of our research group also developed a mind-body intervention that we tested in a randomized clinical trial in 122 individuals with depressive symptoms who were taking antidepressant medications (R01NR012005; [12]). Results showed that the 10-week intervention reduced depressive symptoms at 6-month follow-up compared to a healthy living educational program. As part of developing this project, we started a collaboration with the computer/biomedical engineering group from the University of Rhode Island (URI; led by Dr. Kunal Mankodiya serving as a Co-I in this proposal). Mankodiya's team has developed and deployed a number of mHealth technologies with medical and psychiatric patients including SPARK (25), EchoWear (26-28), Android EAR (29-31), and Face Emotion Monitoring (32,33). **Overall, our multidisciplinary research team is uniquely positioned to conduct this study.**

Aim 1 Approach. We will work closely with computer engineering scientists at URI to translate the caregiver and mind-body interventions into a mobile App. We will then beta test the App in 10 dementia caregivers for one month. Specific recommendations from these caregivers will be obtained via individual qualitative interviews and questionnaires measuring technical issues and content use. Based on this information, the App will be expanded, modified, and translated to be a more effective and user-friendly tool. The research team will meet weekly

over *nine months* to review progress and provide input about content and functionality of the App. For both interventions, we have detailed treatment manuals that will be used to identify specific content.

Phase 1. Translation of intervention. In this step (6 months), we will work with Co-I Mankodiya to design the App and add intervention content. In preliminary discussions, we have identified equipment needed for the study and developed a preliminary outline of the App components (see below and Figure 1).

Technical issues. The mHealth App will be designed for the android platform. We chose this platform because of simplicity in implementation and time and financial limitations of the current award. Future projects will allow for development for other platforms including iOS (iPad or iPhone). In addition, we chose to provide all participants in the study with android tablets to standardize operating procedures and minimize troubleshooting of multiple personal devices. We will restrict participants' access within the tablet to the CARE-Well, Gmail, and Zoom Apps only. Future projects will incorporate personal devices to increase accessibility and applicability of the intervention. All App data will be stored on participants' tablet devices but will not include any personal or health information. At completion of each study phase, data will be downloaded into a password-protected database for analysis. The message forum (described below) will involve a Google group that is embedded in the App. Mankodiya's team at URI will provide technical support for participants and will develop troubleshooting procedures but will not have access to personal or health information. Our partner will also develop an orientation training and video about how to use the App.

Intervention Description. The overall intent of the CARE-Well mobile App is to replicate the content and strategies in the telephone-based FITT-C intervention and to integrate the mindfulness and meditation exercises with FITT-C components (see Table 1). Caregivers will be encouraged to use the App at least four times per week. Caregivers will be prompted to complete an in-App, weekly assessment of key areas (i.e., family functioning, health, mood, social support, and care recipient behavior problems) that will allow for tailoring of intervention components. As caregivers complete recommended components, they will receive rewards within the App. Reminders will be used to increase accountability for tasks assigned and for recommended readings. Embedded in the App will be an online caregiver community (Google group), in which caregivers can anonymously post and respond to messages under a username that is in no way connected to personal Gmail accounts. The research team will recommend against posting any personal or identifying information; however, it is ultimately up to the participant to decide whether or not they want to post more personal information. The Google group will be monitored by the research team who may also provide comments, corrections, and links to helpful material. Allowing caregivers to respond to each other will provide social support and identify content that could be added to the App. Other App components will include:

- *Psychoeducation* – general education about dementia and caregiving; educational components about family functioning, healthy living strategies, managing mood, and seeking social support
- *Community Resources* – listing and links to community supports
- *Daily positive messages* including some that focus on positive aspects of caregiving
- *Managing behavior problems* in care recipient –as part of the FITT-C, we developed a common behavior problem guide that includes recommended strategies to manage behaviors. We will use this guide to develop an interactive problem-solving approach.
- *Stress management exercises* – based on the mind-body intervention video/audio segments of breathing practices, guided meditation/relaxation exercises, simple yoga poses, and mindfulness themes
- *Setting a task directive* – based on caregiver assessments, certain tasks related to social support and family functioning will be recommended.

- *Bibliotherapy* – caregivers will be linked to important brochures and informational materials relevant to problem areas

Table 1. Crosswalk between FITT-C Telephone Intervention, Mind-Body Intervention, and CARE-Well App

FITT-C & Mind Body Key Areas	**CARE-Well Components**
Mood	Daily positive messages;
Health	Health Tips; reminders to attend to their own nutrition, medical care, sleep, exercise; bibliotherapy
Social Support	Message forum; links to community resources; task directives to attend support groups and other activities
Family Functioning	Task directives to involve family in care; educational materials
Care Recipient Behavior Problems	Interactive problem-solving guide; message forum
Yoga	Audio/video (AV) segments – Neck and Shoulder rolls, Yoga Nidra (relaxation)
Breathing	AV segments: Prayer breath, alternate nostril breathing
Meditation	AV segments: Guided meditation
Mindfulness	Education about mindfulness exercises throughout the day, mindful eating, listening to music, walking meditation

Phase 2. Beta Testing and Modification of the CARE-Well App. In this step (3 months), we will recruit 10 dementia caregivers to use the App for one month and then elicit feedback to modify and adapt the intervention. We will use purposive sampling to select diverse caregivers across sex, relationship type (spouse, adult child, other), race/ethnicity, and severity of dementia in care recipient. Otherwise, recruitment will be based on inclusion/exclusion criteria outlined in Aim 2. Participants will be recruited from multiple sources, including the Rhode Island Hospital (RIH) Alzheimer's and Memory Disorders Center (two full-time neurologists seeing only aging and dementia cases; 728 new cases and 1,352 follow-ups annually), RIH Neuropsychology Program (6 full-time adult clinicians seeing about 50% older adult referrals; approximately 200 new dementia cases annually), and community advertising (including the Alzheimer's Association, RI Chapter). Our research team has used these strategies previously to recruit almost 300 dementia caregivers for two intervention studies. Participants will be delivered a package that includes: one android tablet; two copies of the consent form and one prepaid postage envelope to return the signed consent form (if electronic consent form is for some reason inaccessible or unable to be completed for other reasons). A member of the study team will review the consent form (whether paper or electronic) with participants during a Zoom video call on the tablet. They will be instructed to sign and initial the form and send it back to the study team either via REDCap or in the prepaid postage envelope so that a member of the study team can sign it and send a signed copy back to them. Participants will be instructed to keep the unsigned copy in their records as a reference. Once a participant completes the consent process during the initial Zoom call, they will be given a de-identified Gmail username and password for the computer tablet/ App and will be shown how to operate the device and use the App. After one month of use, they will complete and participate in in-depth, semi-structured interviews with two interviewers (clinical researcher and computer engineer). Interviewers will assure participants of privacy and emphasize confidentiality. Interviews will last approximately 30 minutes. Each interview will take place in a private location, will be digitally recorded with audio and video (via Zoom), and transcribed using NVivo software (QSR International, 2018). The interviews will follow a standard discussion guide, include probes to explore and seek clarification, and will address the participants' experience with technical aspects of the App and content (see appendix for sample questions). We will also have quantitative data about frequency of App and component use. The PI along with Dr. Uebelacker will conduct the qualitative data analysis by identifying themes that can help with modifications

of the user interface and content. We plan one month for modifications prior to beginning the feasibility study.

Aim 2 Approach. In this aim, we will conduct a feasibility trial, in which 40 dementia caregivers will be randomized to receive a computer tablet preloaded with the CARE-well App or preloaded with internet links relevant to dementia and caregiving. Electronic outcome measures (detailed below) administered via REDCap secure web platform will be assessed at baseline and end of intervention (3 months) during each study visit. To measure sustainability of the App, the first 10 caregivers from each group will be offered the tablets for an additional month to monitor usage of the App outside the formal trial. The goal of this aim is to determine feasibility of the intervention, study procedures, and outcome measures.

Participants & Recruitment. Informal caregivers of individuals (aged 18 and older) who are formally diagnosed with mild-moderate Alzheimer's disease or related dementia (e.g., Lewy body dementia, frontotemporal dementia) documented by a neurologist, psychiatrist, or geriatrician will be screened for study eligibility (diagnoses will be confirmed via a release of information signed by the care recipient). Care recipients must be living in the community, not in nursing homes or assisted living facilities. Care recipients cannot have another serious, active medical illness besides dementia. Caregivers will be recruited from the RIH Alzheimer's and Memory Disorders Center and RIH Neuropsychology Program by communication between the patients' clinicians and their caregivers. In this way, we will obtain consent to contact the caregiver. In addition, we will provide letters to clinic patients that will invite their caregivers to participate in the study. Community advertising will also be implemented. We will recruit for 11 months (Month 11-Month 21) and will need to recruit about 3-4 caregivers per month. **In the past FITT-C trial, we had a recruitment rate of 4.7 caregivers per month.**

Inclusion/Exclusion Criteria. Inclusion criteria include: 1). adequate English-speaking and reading skills; 2). provide at least 4 hours of supervision per day for the care recipient (either directly or by telephone); 3). live in the community (either with the care recipient or without); 4). have provided supervision/assistance for at least six months prior to enrollment and have no plans for to place the care recipient in long term care or to end their role as caregiver within six months of study enrollment; 5). report some degree of distress associated with caregiving, which will be assessed through endorsement of two of nine negative experiences associated with caregiving (feeling overwhelmed or stressed, sad mood/depression, anger/frustration, loss of contact with family and friends, conflict in family or family stress, neglecting own health, demands or pressures from caregiving, exhaustion/fatigue, not taking care of their own needs or other responsibilities); and 6) access to WIFI at home. Exclusion criteria include: 1). major acute medical illness; 2). severe mental illness (e.g., bipolar, schizophrenia); or 3). diagnosed cognitive impairment.

Procedure & Interventions. After screening and consenting, caregivers will complete an electronic baseline assessment (described below) and will be randomly assigned to receive a computer tablet that has the newly developed CARE-Well App or internet links relevant to dementia caregiving for 3 months. We will provide the caregivers with written information about expectations for the App use at orientation and they will be encouraged to use the website links daily. Computer engineers and/or a research assistant will provide IT support for caregivers in both groups. To minimize face-to-face contact during the COVID-19 pandemic, caregivers will remain at home to complete the second and final study 'visit,' which entails completing follow-up assessments within two weeks of intervention completion. Once follow-up assessments are complete, participants will be instructed to send the computer tablet back to RIH using a prepaid package given to them during their initial study visit. Due to time limitations of the current award, the first 10 caregivers in each group will be offered to keep the tablets and continue to use the App or internet links for an additional month to estimate intervention sustainability.

Outcomes and Analyses. The primary goal of this project is to demonstrate feasibility of the CARE-Well App and study procedures to support a future trial. As such, the study is not

powered to determine efficacy, but rather to determine 1) whether a future trial will be successfully conducted; and 2) whether an in-person caregiver intervention can be reasonably adapted into a mobile App. We will focus on the following (benchmarks in parentheses):

- Identify the best recruitment sites and methods (% who enrolled from each source and % contacts received from each recruitment method)
- Determine participant willingness to be randomized (% who decline participation because of randomization)
- Establish study enrollment rate and retention (latter variable examined by group)
- Determine adherence to intervention (% of participants who use the App or internet links at least once per day)
- Calculate timing of assessments and completion rates (% of assessments completed within two weeks of study enrollment and intervention completion)
- Determine interest in continuation of tablet/App use (along with frequency of use) after formal trial in a subset of caregivers (10 from each group) as an estimate of sustainability
- Collect ratings of satisfaction with technology and content (% satisfied or very satisfied)

To establish feasibility for a future trial, we will collect standard dementia caregiving outcome measures at baseline and following the intervention via REDCap secure web platform. We have used these measures extensively in our previous work. These will include demographic characteristics (sex, age, education, race and ethnicity, characteristics of the caregiver (e.g., relationship to recipient, length of caregiving), and care recipient characteristics (e.g., dementia type and severity). We also will collect the following: 1). *Depression:* Center for Epidemiologic Studies Depression Scale, a 20-item self-report inventory (34); 2) *Caregiver burden*: Zarit Burden Interview, a 22-item self-report measure that examines subjective feelings related to the negative impact of caregiving on physical, emotional, financial, and social functioning (35). 3) *Caregiver reaction to problem behaviors*: Revised Memory and Behavior Problem Checklist (36); 4). *Desire to institutionalize*: Desire to Institutionalize Scale (37): six-item scale to assess caregiver planning for long-term placement of the care recipient; 5). *Healthcare resource utilization:* Resource Utilization in Dementia - Lite Version (38); a measure on sexually disinhibited behaviors observed in the care recipient (39).

Future Trial: Any challenges, recommendations from participants, and innovative solutions that emerge through the proposed project will assure the CARE-Well App will be well-developed and ready for testing in future trials. The next step will be a fully-powered efficacy study in a large sample of dementia caregivers. We will also examine the effect of CARE-Well on specific outcome measures (including behavioral change outcomes) as described above, examine moderators (mechanisms) of treatment (e.g., App usage, component analysis, caregiver characteristics), and compare the effect sizes of CARE-Well to the FITT-C telephone intervention. In the next stage of the intervention, we will examine sustainability of CARE-Well through monitoring usage and feedback from study participants. Given the widespread availability of mobile technology and internet access, we anticipate efficiently moving from efficacy to dissemination. We hope to disseminate the intervention on a community-level, where specific facilities or agencies can tailor the intervention as needed and post specific content in the message forums. Our future trial will combine Stage II (pure efficacy) and Stage III (community efficacy) components. In particular, we will examine the effect of study/setting (memory clinic, agency, community) on effectiveness and utilization of the App.

Potential Problems and Alternative Strategies

App development time. Although we plan on App development in 6 months, we may encounter issues that slow the process. If so, we will adjust the timeline and engage in early recruitment for both beta testing and the feasibility trial.
Recruitment and attrition. Although our team has extensive experience recruiting dementia caregivers, we may encounter barriers to recruitment. If so, we will use community advertising or other methods. In addition, we will recruit an initial cohort while working on Aim 1, so we have a group ready to use the App as soon as the feasibility trial begins.
App use. If we encounter low App or internet links use, we will increase reminders to participants. Older adults (who will likely comprise 50% of our sample) are increasingly using touchscreen devices (40) and accept and use tablet technology (41), suggesting that this would not be a confounding factor to the proposed App.

Protection of Human Subjects

All research contained in this proposal will be approved by the Rhode Island Hospital IRB before initiation. Written informed consent will be obtained for all participants.

1. Risks to Human Subjects

a. Human Subjects Involvement, Characteristics, and Design
We will enroll a total of 50 caregivers of persons with dementia. Specific inclusion and exclusion criteria are detailed below. In Aim 1 of the study, 10 participants will participate in a one month use of the CARE-Well application, In Aim 2, 40 participants will be randomly assigned to receive 3 months of either the CARE-Well application or internet links in a feasibility study. They will be enrolled in the study for 3 months. This project will be a collaboration between Rhode Island Hospital and the University of Rhode Island (URI). Investigators at URI will engage in building the application and will participate in qualitative interviews as part of Aim1.

Inclusion/Exclusion Criteria. Inclusion criteria include: 1). adequate English-speaking and reading skills; 2). provide at least one hour of supervision per day for the care recipient (either directly or by telephone); 3). live in the community (either with the care recipient or without); 4). have provided supervision/assistance for at least six months prior to enrollment and have no plans for to place the care recipient in long term care or to end their role as caregiver within six months of study enrollment; 5). report some degree of distress associated with caregiving, which will be assessed through endorsement of two of nine negative experiences associated with caregiving (e.g., feeling overwhelmed, sad mood, frustration, loss of family/friend contact, family conflict, etc.); and 6) access to wifi at home. Exclusion criteria include: 1). major acute medical illness; 2). severe mental illness (e.g., bipolar, schizophrenia; or 3). diagnosed cognitive impairment.

b. Study Procedures, Materials, and Potential Risks
Ten participants will be given an android tablet and asked to use a mobile application at least four times per week for one month. They will then participate in a qualitative interview in which they will be queried about technical and content aspects of the application. Participants in Aim 1 will be compensated $50.00 in the form of a check

request at time of completion. As part of Aim 2, 40 participants will be complete baseline assessments and be randomly assigned to the CARE-Well application or internet educational links. They will be encouraged to use the application or links at least four times per week. Data will be collected via paper-pencil assessments from participants at two timepoints (Baseline and End-of-Treatment). The assessment measures will address mood, burden, reactions to behavior problems, health-related quality of life, sexual disinhibition in the care recipient, and desire to institutionalize the care recipient. The data from participants' in-App weekly assessments of key areas will be programmed (using a computer algorithm) to generate personalized recommendations and references to relevant resources within the App. This data will not include any personal or health information and will not be extracted from the App. Participants in Aim 2 will be compensated $50 at study completion in the form of a check request. Any hard copies of data will be stored in locked file cabinets in a locked office. Electronic data storage will be in a password-protected database.

There are no serious risks associated with participating in this study. Participants will undergo testing with standardized questionnaires and measures. They may feel slightly frustrated, fatigued, or bored when completing these tests. Because we will assess depression, there is a possibility that participants will report severe depression and/or suicidality. In addition, they are providing care for persons with dementia and we may uncover neglect or abuse.

2. Adequacy of Protection Against Risks
Confidentiality will be protected in the following ways: (1) participants' names will not be included on the App, data sheets, or in the computerized database, (2) all data will be kept in a locked file cabinet in a locked office, and (3) the computer database will be password protected and only accessible by the researchers.

a. *Informed Consent and Assent*

We will follow standardized procedures for obtaining informed consent. Consent will be obtained at a face-to-face visit at the Neuropsychology Program office at Rhode Island Hospital. Consent will be obtained by one of the investigators or trained research staff. We will fully explain the study procedures, risks, benefits, and alternatives to all subjects. They will be informed that they can refuse to participate or withdraw from the study at any time, and that this will have no effect on any treatment or care they receive at our facility.

b. *. Protections Against Risk*

If potential participants report severe depressive symptoms or suicidality, we will refer them to the Acute Psychiatry Service at Rhode Island Hospital. The PI is a licensed clinical psychologist and has the skills to assess the suicidal risk and to make an appropriate referral. If there is evidence of elderly abuse or neglect, we will contact the Rhode Island Department of Elderly Affairs to report the concern.

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c. *Vulnerable Subjects, if relevant to your study*

Not relevant

3. Potential Benefits of the Proposed Research to Research Participants and Others

The potential benefit of developing a mobile health intervention to improve negative effects of dementia caregiving appears to outweigh the risks of the current study. Individuals in the beta test of the application may experience benefits from education and other strategies offered by the application. Caregivers in both groups of the feasibility study may benefit from educational materials and learn about dementia, caregiving strategies, and stress management. Those randomized to the mobile health application may benefit from techniques to manage the negative effects of caregiving and development of coping skills. Participants will receive interventions free of charge.

4. Importance of the Knowledge to be Gained

Results of this study will help to develop an interactive, multicomponent mobile application for dementia caregivers. We will also collect data to inform a future large randomized trial to study the efficacy of the newly developed application. As such, the minimal risks to subjects in the current study seem reasonable given the knowledge to be gained.

Bibliography & References Cited

1. Brodaty, H., & Donkin, M. (2009). Family caregivers of people with dementia. Dialogues in clinical neuroscience, 11(2), 217.
2. Alzheimer's Association. (2018). 2018 Alzheimer's Disease Facts and Figures. Alzheimer' s & Dementia, 14, 367-429.
3. Belle, S. H., Burgio, L., Burns, R., Coon, D., Czaja, S. J., Gallagher-Thompson, D., ... & Martindale-Adams, J. (2006). Enhancing the quality of life of dementia caregivers from different ethnic or racial groups: a randomized, controlled trial. Annals of internal medicine, 145(10), 727-738.
4. Dickinson, C., Dow, J., Gibson, G., Hayes, L., Robalino, S., & Robinson, L. (2017). Psychosocial intervention for carers of people with dementia: What components are most effective and when? A systematic review of systematic reviews. International psychogeriatrics, 29(1), 31-43.
5. Mittelman, M. S., Haley, W. E., Clay, O. J., & Roth, D. L. (2006). Improving caregiver well-being delays nursing home placement of patients with Alzheimer disease. Neurology, 67(9), 1592-1599.
6. Tremont, G., Duncan Davis, J., Bishop, D. S., & Fortinsky, R. H. (2008). Telephone-delivered psychosocial intervention reduces burden in dementia caregivers. Dementia, 7(4), 503-520.
7. Gitlin, L. N., Marx, K., Stanley, I. H., & Hodgson, N. (2015). Translating evidence-based dementia caregiving interventions into practice: State-of-the-science and next steps. The Gerontologist, 55(2), 210-226.
8. Burgio, L. D., Collins, I. B., Schmid, B., Wharton, T., McCallum, D., & DeCoster, J. (2009). Translating the REACH caregiver intervention for use by area agency on aging personnel: The REACH OUT program. The Gerontologist, 49(1), 103-116.
9. Nichols, L. O., Martindale-Adams, J., Burns, R., Graney, M. J., & Zuber, J. (2011). Translation of a dementia caregiver support program in a health care system—REACH VA. Archives of Internal Medicine, 171(4), 353-359.
10. Tremont, G., Davis, J. D., Papandonatos, G. D., Ott, B. R., Fortinsky, R. H., Gozalo, P., ... & Bishop, D. S. (2015). Psychosocial telephone intervention for dementia caregivers: A randomized, controlled trial. Alzheimer's & Dementia, 11(5), 541-548.
11. Tremont, G., Davis, J. D., Ott, B. R., Galioto, R., Crook, C., Papandonatos, G. D., ... & Bishop, D. S. (2017). Randomized Trial of the Family Intervention: Telephone Tracking—Caregiver for Dementia Caregivers: Use of Community and Healthcare Resources. Journal of the American Geriatrics Society, 65(5), 924-930.
12. Uebelacker, L. A., Tremont, G., Gillette, L. T., Epstein-Lubow, G., Strong, D. R., Abrantes, A. M., & Miller, I. W. (2017). Adjunctive yoga v. health education for persistent major depression: a randomized controlled trial. Psychological medicine, 47(12), 2130-2142.
13. Schulz, R., & Martire, L. M. (2004). Family caregiving of persons with dementia: prevalence, health effects, and support strategies. The American journal of geriatric psychiatry, 12(3), 240-249.
14. Vitaliano, P. P., Zhang, J., & Scanlan, J. M. (2003). Is caregiving hazardous to one's physical health? A meta-analysis. Psychological bulletin, 129(6), 946.
15. Sörensen, S., Pinquart, M., & Duberstein, P. (2002). How effective are interventions with caregivers? An updated meta-analysis. The gerontologist, 42(3), 356-372.

16. Robinson, K. M., Buckwalter, K. C., & Reed, D. (2005). Predictors of use of services among dementia caregivers. Western Journal of Nursing Research, 27(2), 126-140.
17. Farran, C. J., Zurawski, P., Inventor, B. R., Urbanic, J., & Paun, O. (2017). An evidence-based technological caregiver skillbuilding intervention for dementia family caregivers: pilot study. Alzheimer's & Dementia: The Journal of the Alzheimer's Association, 13(7), P836-P837.
18. DuBenske, L. L., Gustafson, D. H., Namkoong, K., Hawkins, R. P., Atwood, A. K., Brown, R. L., ... & Govindan, R. (2014). CHESS improves cancer caregivers' burden and mood: Results of an eHealth RCT. Health Psychology, 33(10), 1261.
19. Firth, J., Torous, J., Nicholas, J., Carney, R., Pratap, A., Rosenbaum, S., & Sarris, J. (2017). The efficacy of smartphone-based mental health interventions for depressive symptoms: a meta-analysis of randomized controlled trials. World Psychiatry, 16(3), 287-298.
20. Egan, K. J., Pinto-Bruno, Á. C., Bighelli, I., Berg-Weger, M., van Straten, A., Albanese, E., & Pot, A. M. (2018). Online training and support programs designed to improve mental health and reduce burden among caregivers of people with dementia: a systematic review. Journal of the American Medical Directors Association.
21. Tyhurst, J. S. (1957). The role of transition states—including disasters—in mental illness. In Symposium on preventive and social psychiatry (pp. 149-169). Walter Reed Army Institute of Research Washington, DC.
22. Lazarus, R. S. (1986). Folkman. S.(1984) Stress, Appraisal, and Coping. New York: Springer.
23. Ryan, C. E., Epstein, N. B., Keitner, G. I., Miller, I. W., & Bishop, D. S. (2012). Evaluating and treating families: The McMaster approach. Routledge.
24. Li, A. W., & Goldsmith, C. A. (2012). The effects of yoga on anxiety and stress. Altern Med Rev, 17(1), 21-35.
25. Sharma, Vinod, Kunal Mankodiya, Fernando De La Torre, Ada Zhang, Neal Ryan, Thanh GN Ton, Rajeev Gandhi, and Samay Jain. "SPARK: personalized Parkinson disease interventions through synergy between a smartphone and a smartwatch." In International Conference of Design, User Experience, and Usability, pp. 103-114. Springer, Cham, 2014.
26. *Harishchandra Dubey, Jon C. Goldberg, Mohammadreza Abtahi*, Leslie Mahler, and Kunal Mankodiya. 2015. EchoWear: smartwatch technology for voice and speech treatments of patients with Parkinson's disease. In Proceedings of the conference on Wireless Health (WH '15). ACM, New York, NY, USA, Article 15, 8 pages.
DOI:https://doi.org/10.1145/2811780.2811957
27. *Dubey, Harishchandra*, Matthias R. Mehl, and Kunal **Mankodiya**. "Bigear: Inferring the ambient and emotional correlates from smartphone-based acoustic big data." In Connected Health: Applications, Systems and Engineering Technologies (CHASE), 2016 IEEE First International Conference on, pp. 78-83. IEEE, 2016.
28. *Debanjan Borthakur, Harishchandra Dubey, Nicholas Constant,* Leslie Mahler, Kunal Mankodiya. SMART FOG: FOG COMPUTING FRAMEWORK FOR UNSUPERVISED CLUSTERING ANALYTICS IN WEARABLE INTERNET OF THINGS. In the Proceedings of the 2017 fifth IEEE Global Conference on Signal and Information Processing (GlobalSIP), Montreal, Canada
29. *Constant, Matthew*, Leslie Brick, Nicole Nugent, Michael Armey, and Kunal Mankodiya. "Smartwatch-driven multisensory recorder: Design and testing of a smartwatch-based framework to support psychiatric disorders." In MIT Undergraduate Research Technology Conference (URTC), 2016 IEEE, pp. 1-4. IEEE, 2016.
30. Debanjan Borthakur, Harishchandra Dubey, Nicholas Constant, Leslie Mahler, Kunal Mankodiya. SMART FOG: FOG COMPUTING FRAMEWORK FOR UNSUPERVISED CLUSTERING ANALYTICS IN WEARABLE INTERNET OF THINGS. In the Proceedings of the 2017 fifth IEEE Global Conference on Signal and Information Processing (GlobalSIP), Montreal, Canada

31. *Amiri, Amir Mohammad, Mohammadreza Abtahi*, Anna Rabasco, Michael Armey, and Kunal Mankodiya. "Emotional reactivity monitoring using electrodermal activity analysis in individuals with suicidal behaviors." In Medical Information and Communication Technology (ISMICT), 2016 10th International Symposium on, pp. 1-5. IEEE, 2016.
32. Mankodiya, K., Sharma, V., Martins, R., *Pande, I.*, Jain, S., Ryan, N., & Gandhi, R. (2013, December). Understanding User's Emotional Engagement to the Contents on a Smartphone Display: Psychiatric Prospective. In Ubiquitous Intelligence and Computing, 2013 IEEE 10th International Conference on and 10th International Conference on Autonomic and Trusted Computing (UIC/ATC) (pp. 631-637). IEEE.
33. *Mandal, Indrani, Terry Ferguson, Gabriel De Pace*, and Kunal Mankodiya. "An Emotional Expression Monitoring Tool for Facial Videos." In International Conference on Ubiquitous Computing and Ambient Intelligence, pp. 796-807. Springer, Cham, 2017.
34. Radloff, L. S. (1977). The CES-D scale: A self-report depression scale for research in the general population. Applied psychological measurement, 1(3), 385-401.
35. Zarit, S. H., Reever, K. E., & Bach-Peterson, J. (1980). Relatives of the impaired elderly: correlates of feelings of burden. The gerontologist, 20(6), 649-655.
36. Teri, L., Truax, P., Logsdon, R., Uomoto, J., Zarit, S., & Vitaliano, P. P. (1992). Assessment of behavioral problems in dementia: the revised memory and behavior problems checklist. Psychology and aging, 7(4), 622.
37. Morycz, R. K. (1985). Caregiving strain and the desire to institutionalize family members with Alzheimer's disease: Possible predictors and model development. Research on aging, 7(3), 329-361.
38. Wimo, A., & Winblad, B. (2003). Resource utilization in dementia: RUD lite. Brain Aging, 3(1), 47-58.
39. Chapman, K. (2020). Sexual disinhibition measure.
40. Page, T. (2014). Touchscreen mobile devices and older adults: a usability study.
41. Ramprasad, C., Tamariz, L., Garcia-Barcena, J., Nemeth, Z., & Palacio, A. (2017). The Use of Tablet Technology by Older Adults in Health Care Settings—Is It Effective and Satisfying? A Systematic Review and Meta Analysis. Clinical gerontologist, 1-10.