Official Title: **Using Mobile Technology to Reduce Stress in Caregivers of Persons with Dementia. A Scalable Solution to A Growing Problem**
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1. Background and Significance

Approximately 43.5 million caregivers provided unpaid care in 2015, and the numbers are increasing.[1] Nearly half of caregivers attend to an older adult with Alzheimer's Disease or Related Dementia (ADRD).[2] Caregivers are described as "hidden patients"[3,4] because they are at risk for negative health outcomes, but are underrecognized and undertreated. Approximately 40% ADRD caregivers report stress that is negatively impacting their health and quality of life[3,5] . Caregiver stress (also known as caregiver stress syndrome) is defined as the strain or load borne by a person who cares for a chronically ill, disabled, or elderly family member.[6] This subjective stress is consistently depicted as the strongest predictor of negative outcomes for both the caregivers themselves and for those who they care for[7–9]. Not surprising, emotional distress and sleep problems are common; 37% caregivers of dementia patients develop a depressive disorder; 67% an anxiety disorder[10] ; 63% have sleep difficulties[11–14]. Studies over the past 15 years have shown that these sleep disturbance [11,15,16] are due to worries and concerns, and are independent of sleep interruptions due to caregiver responsibilities. Approximately 42-55% of caregivers are actively looking for feasible and effective stress management interventions[1].

Mindfulness Based Interventions (MBIs) are efficacious non-pharmacologic interventions that can decrease caregiver stress. A large body of research shows that the practice of mindfulness meditation is associated with decreased stress[17,18], improved emotional functioning[19,20] and improved sleep[21,22] in a variety of individuals. Seven recent systematic reviews have summarized the existing literature supporting the effectiveness of a variety of mindfulness-based programs in reducing caregiver stress and improving emotional functioning and sleep in caregiver populations, including ADRD caregivers[17,18,22–29]. Practicing meditation has been associated with increase in mindfulness, where individuals are able to face challenging situations by observing, describing, acting with awareness, nonjudgmentally and non-reactively. The mindfulness state has biological correlates (e.g., increases in autonomic nervous system activity, reducing heart rate, and blood pressure[30,31]), cognitive correlates (e.g., increases in self-awareness, improvements in the capacity to determine what is paid attention to, decrease in ruminative thoughts linked to sleep dysfunction), and emotional correlates (e.g., an improved ability to regulate emotions[32]), leading to a reduction in perception of stress, emotional distress (i.e., anxiety and depression[33]) and sleep difficulties, as well as increased ability to prioritize and manage self-care and caregiving tasks.

Although mindfulness-based interventions have established benefits in decreasing caregiver stress, improving emotional function and sleep quality, and caregivers are interested in learning mindfulness training in order to manage stress[34], uptake is limited in four major ways. First, meditation has typically been delivered through in person visits[35], and this is not feasible for caregivers[12]. Second, even when delivery of meditation interventions is virtual programs still require attendance to a specific weekly schedule, which is challenging for many caregivers with unpredictable schedules guided by their caregiving responsibilities. Third, traditional programs are comprehensive and time-intensive (90- minute sessions, 8-12 weeks long) and many caregivers are unable to commit. Fourth, traditional programs require trained providers, and are often costly and not covered by insurance. Finally, the positive effects of mindfulness meditation are predicated on adherence to practice, which is traditionally challenging. A mobile meditation

app with embedded behavioral components (e.g., reminders, tracking) may facilitate adherence and sustained health benefits. A recent systematic review[36] of mobile apps for ADRD caregivers identified 18 unique apps with only 8 accessible for review. Of these 8, 7 did not have a theoretical framework for content development, and none had been trialed or evidence based. None of these apps were mindfulness based.

Smartphone health-related apps have attracted considerable interest from patients as a means of promoting self-management and for better health outcomes[37]. Approximately 81% of caregivers own a smartphone, regularly use mobile apps[38], and are interested in using technology to meet their health care needs[12]. Older adults, who represent a sizable proportion of caregivers, are the highest rising consumers of mobile app technology[39], despite anecdotal reports of resistance to technology in this population. In qualitative content analyses, caregivers themselves noted interest in using mobile apps for stress management and health information[40] including to learn mindfulness meditation for stress management[41–44]. This study will set the stage for a subsequent R01 where we will fill a gap in knowledge related to the efficacy of delivering mindfulness meditation to stressed ADRD caregivers utilizing a commercially available smartphone app with embedded behavioral components to aid sustained practice.

Healthy Minds Program (HMP; manufactured by Healthy Minds Innovations) is a free meditation app available for download from the Apple App store and Google Play Store. The ground-breaking Healthy Minds Program uses neuroscience, contemplative traditions, and skill-based learning methods to help users develop the skills for a healthy mind. Translating pioneering neuroscience into tools for everyday life, the unique framework guides users through the four pillars of the science of training the mind: 1) awareness; 2) connection; 3) insight; 4) purpose.

The app "Wellness App" (WA; manufactured by Apparent Loc, LLC and available for download from the Apple app store only for study participants) will be used as in the time-, dose-, and attention-matched control condition. This app has been previously shown to be an acceptable and appropriate active control to compare to a mobile mindfulness app.

Although mindfulness apps like HMP and healthy lifestyle podcasts have proliferated over the past decade and some are covered by insurance, little is known about their feasibility and efficacy for dementia caregivers. Without clear evidence for feasibility and efficacy, routine implementation within the care of ADRD caregivers is not ethical or appropriate.

The guiding hypothesis of this proposal is that delivering evidence-based mindfulness skills through Healthy Minds has the potential to effectively and efficiently decrease stress and improve emotional functioning for all stressed caregivers, regardless of the type of patient they care for. Support for this hypothesis would allow for routine implementation of Healthy Minds within the care of caregivers to prevent or decrease caregiver stress with tremendous and cost-effective benefits to patients, caregivers and society as a whole.

2. Specific Aims and Objectives

The current study has the following specific aims:

1) Establish the feasibility (markers of acceptability and demand) of HMP and WA in ADRD caregivers with elevated stress (per PSS-4) using evidence based benchmarks[45,46].

Hypothesis 1: Eighty caregivers will be recruited in six months
Hypothesis 2: At least 70% of caregivers will have scores higher than the midpoint on the Client Satisfaction Scale
Hypothesis 3: At least 70% of caregivers will have scores higher than the midpoint on weekly measures of usefulness of daily meditations/components in both HMP/WA groups
Hypothesis 4: At least 70% of caregivers will have scores higher than the midpoint on the Credibility and Expectancy Scale in both HMP/WA groups
Hypothesis 5: At least 70% of caregivers who participate in the 12 weeks of HMP or WA will complete at least 75% of weekly prescribed minutes
Hypothesis 6: At least 70% of caregivers will use at least one of the behavioral components for more than 50% of the length of the intervention
Hypothesis 7: Overall dropout will be no more than 30%

2) Demonstrate proof of concept that HMP can sustainably decrease stress, distress, sleep dysfunction and mindfulness when compared to WA.

Hypothesis 1: Participation in HM will be associated with greater decrease in caregiver stress (primary quantitative outcome), emotional distress (depression and anxiety), sleep dysfunction and mindfulness (secondary quantitative outcomes) compared to WA, and improvement will be sustained through the follow up.

3. General Description of Study Design

The study design is a two-group, single-blind proof of concept randomized controlled trial with baseline, post-intervention (12 weeks from baseline), and follow-up (3 months) assessments. Caregivers will be blinded and randomized to one of two groups: 1) 10-12 minutes per day of Healthy Minds meditation (HMP group) or 2) 10-12 minutes per day of healthy living podcasts Wellness App (WA control group), both delivered via a smartphone app. Participants will be randomly assigned to a group after baseline assessments and consent. Randomization will be stratified by gender with varying block sizes. Research personnel who assign participants to a group will not be the same as those who enroll participants or download and clean data. Group status will be entered separately so that research personnel downloading data will remain blind to treatment assignment.

4. Subject Selection

All subjects will be volunteers and will self-select to participate. We will use various strategies to advertise our study to potential volunteers using trusted caregiver organizations, social media platforms, and community partners. Specifically:

- Our IRB approved ad will be emailed as part of a weekly newsletter that reaches approximately 20,000 individuals, through a collaboration with the National Alliance of Caregiving Research. Approximately 66% of these care for an individual with ADRD. The National Alliance of Caregiver Research subscribers are a good representation of the USA general caregiver population (See letter of support).
- We will email our flyer to caregivers that participated in other dementia caregiver studies and indicated interest in being contacted for additional dementia caregiver research opportunities.
- We will post our ad on caregiver specific groups and discussion boards on Facebook, and we will distribute the ad through other social media methods (e.g., Twitter, Instagram). Social media methods will include IRB approved flyers as well as pre-recorded ads. As per standard advertising practice, pre-recorded ads will be delivered by trusted community partners via social media platforms. All scripts will be IRB approved and the study team will review content prior to posting. Community partners will receive a $1,000 payment for each ad they post.

Of note, community partners and partner organizations will have no direct contact with any potential volunteer. *Partners will also have no access to any participant information*. They will only be used to post advertisements. All social media and emailed ads will direct potential participants to our public REDCap link where they can complete our online screener. Study staff perform all subsequent steps including answering questions, screening, consent, and enrollment.

Interested caregivers will use the link on the flyer/social media ad to fill out the online eligibility questionnaire via REDCap or email the RA who will email the link to the online eligibility questionnaire via REDCap and schedule a phone call to answer questions as needed. Ineligible participants will receive a message on REDCap notifying them of their ineligibility status and links to resources for stress management (Educational Handout on stress for caregivers) including HMP as a resource. Eligible participants will receive an email notifying them they are likely eligible and will be scheduled for an intake appointment. During this appointment an RA will finalize eligibility with the Portable Mental Status Questionnaire (PMSQ) for participants over the age of 65. Interested and eligible participants will be consented and enrolled by the RA. Caregivers that turn out to be ineligible will receive the resource sheet.

Eligible participants must meet the following inclusion criteria:

1) Age 18 or older
2) English fluency and literacy
3) Meeting criteria for being a caregiver[2] (e.g., family or friend of a care recipient who provides unpaid care)
4) Perceived Stress Scale (4 items) version >= 6
5) Willing to be randomized
6) Care recipient must be rated >1 on the Functional Assessment Scale (FAST)

One or more of the following exclusion criteria will render a participant ineligible:

1) Any planned change in psychotropic pharmacologic treatment for the duration of the study

2) Use of any consumer-based mindfulness meditation app for more than 60 min/month in the past 6 months.
3) Current participation in a meditation program (e.g., mindfulness-based stress reduction, mindfulness-based cognitive therapy, etc.).
4) No major illness known to worsen dramatically or require surgery in the next 20 weeks (study duration)
5) Active treatment for cancer (chemotherapy, radiation)
6) Imminent placement of care recipient in a nursing home or with another caregiver (within 4 months).
7) Involvement in another clinical trial for caregivers.
8) For participants age 65 and over: Short Portable Mental Status questionnaire PMSQ: >= or = 4 errors[59]

These criteria were informed by prior mindfulness-based intervention studies with dementia caregivers as well as a prior study in caregivers funded by NIH (NCT00177489).

We will aim to recruit a sample of heterogeneous caregivers that is representative of the general USA caregiving population (National Alliance for Caregivers; caregiver.org). Within USA, the majority of caregivers (75% are females). As such, we anticipate that most participants will be women, and we will stratify randomization by gender.

The National Alliance for Caregiving reported the following racial and ethnic distribution for caregivers within the USA. With regard to ethnicity, 21% caregivers are Hispanic and 79% Non-Hispanic. With regard to race, caregivers self identify as: 62% White, 13% Black/African American, 17% Others, and 6% Asian. Since we will be primarily recruiting from the National Alliance of Caregiving, we anticipate that our sample will follow the distribution of the larger USA caregiver population. We will carefully keep track of the gender, race and ethnicity of our sample and, if necessary, directly target recruitment to underrepresented groups in order to ensure generalizability of findings.

5. Subject Enrollment

Interested caregivers will use the link on the flyer/social media ad to fill out the online eligibility questionnaire via REDCap, or will email the research assistant who will provide detail on the study, and email participants a REDCap screening questionnaire. Ineligible caregivers will receive a message at the end of the screening REDCap notifying them of their ineligibility, as well as a resource sheet for caregivers. Eligible participants will be scheduled to participate in a 20-minute phone call to finalize eligibility with the PMSQ (for those over the age of 65) and further discuss study commitment, consent, and answer any questions. Caregivers that turn out to be ineligible will receive the resource sheet via email. Interested and eligible caregivers will electronically sign the consent form in REDCap once all questions have been answered. The RA will keep track of all caregivers who decide not to participate or are excluded, and will report these numbers within our manuscripts.

The consent form will explicitly state that study participation is voluntary, and that participants may refuse to answer any questions that make them uncomfortable and may discontinue participation at any time. In addition, participants will be assured that withdrawal from the study will not compromise their medical care in any way. Participants will also have the option to receive text messages with survey invitations and reminders to listen to content in their assigned app. The text messages with survey invitations will be sent via Twilio, a third party, Partners-approved, web service that integrates with REDCap to send survey invitations over SMS text messaging. The text messages with reminders only will be sent via EZ text, a third party, Partners-approved web service to send SMS text messages.

After informed consent is reviewed and signed the RA will email the baseline questionnaires via REDCap secure data collection system.

Once baseline questionnaires are complete the participant will be randomized. Randomization will be stratified by gender and programmed into REDCap. The RA will email the participant their HMP or WA login credentials depending on group assignment.

6. STUDY PROCEDURES

Our ads will instruct interested caregivers to complete the screening REDCap or email the RA. The RA will answer questions as needed and email the REDCap screening questionnaire. Eligible participants (see criteria above) will be notified they are likely eligible, and subsequently complete a phone intake to finalize eligibility and enrollment procedures. Interested and eligible participants will be consented and enrolled by the RA during the scheduled phone intake. Ineligible caregivers will be notified at the end of the screening REDCap and will receive access to a resource sheet.

After enrollment, caregivers will be randomized to one of two groups: 1) 10-12 minutes per day of Healthy Minds Program meditation (HMP group) or 2) 10-12 minutes per day of healthy living podcasts on the Wellness App (WA control group), both delivered via a smartphone app. Caregivers will be blinded to intervention vs control. Randomization will be stratified by gender and programmed into REDCap.

HMP is a mindfulness meditation mobile application. For 12 weeks participants in HMP will be asked to complete a minimum of 10 minutes per day of meditation, using a specific prescription for weeks 1-4. During weeks 1-4 participants will complete HMP's standard introductory foundations course which provides users with a basic understanding of the four key pillars of HMP: Awareness, Connection, Insight, and Purpose. Participants are also taught how to meditate during the foundations course. During weeks 5-12 they will have full access to the app. Participants can choose to repeat meditations from the foundations course, listen to new meditations that dive further into the four pillars (Awareness, Connection, Insight, and Purpose) or listen to single meditations on topics like "Stress and Overwhelm" or "Relationships". In addition to the meditations, the app includes optional lessons that provide listeners with every-day applications for the meditations, as well as scientific context.

The control condition WA is time-, dose-, and attention-matched to HMP. Similar to the intervention, participants in the WA group will listen to a minimum of 10 minutes per day of a healthy living education podcast (including topics such as "Nutrients in a healthy diet" or "How do I cook nutritious means?") delivered via the mobile app Wellness App for the 12 weeks. Participants will have a set prescription of podcasts for weeks 1-4. After Week 5, participants will have access to the entire library of podcasts on the app until Week 12 (similar to the prescription of the Healthy Minds meditation sessions).

Measures will be collected at baseline (pre-randomization), post-intervention (12-weeks) and at 2-month follow-up (20 weeks; estimated assessment time= 30 minutes). In addition, participants will complete brief weekly measures (time=5 minutes/week). HMP and WA will also automatically collect data on demand (e.g., amount of time practicing, use of behavioral components such as reminders, schedulings, etc). Data collection and management will be conducted with Research Electronic Data Capture (REDCap), an MGH-supported secure web-based survey tool. HMP engineers will manage the automated HMP data collection and WA engineers will manage the WA data collection which will be merged with the RedCAP file for main analyses

Measures:

Administered at Baseline Only:

- Demographics
- The Credibility and Expectancy Questionnaire (CEQ)

Administered at Baseline, Post-Intervention, and Follow-up:

- Perceived Stress Scale 10
- Hospital Depression and Anxiety Scale (HADS)
- PROMIS Sleep Disturbance Short Form 8a
- Applied Mindfulness Process Scale (AMPS)
- The Healthy Minds Index V2.4
- Caregiver Reaction Scale
- Thermometers

Administered Post-Intervention Only:

- Modified Patient Global Impression of Change (MPGI)
- Client Satisfaction Questionnaire (CSQ-3)
- Perception of daily meditation
    - "Do you think that the amount of daily prescribed app content was: too little, just enough, or too much?"
- Perception of emails/text messages
    - "Do you think that the amount of emails/texts you received was: too little, just enough, or too much?"
- Perceptions of prompts/contacts in situations of low adherence
    - "Do you think that the amount of prompts you received when you struggled with your practice was: too little, just enough, or too much?"
- Open ended perception question

    - Do you have any feedback about your experience in this program that you would like to share?
- Push notification usage questions

Administered Follow-Up Only:
- Caregiving Situation Question

Administered Weekly Only:
- HMP data (objective measure)
    - Automatically collected via user statistics
- WA app data (objective measure).
    - Automatically collected via user statistics
- Emails, text messages, phone calls tailored to ADRD caregivers

Administered Weekly and at Baseline, Post-Intervention, and Follow-Up
- Thermometers (stress, distress, sleep quality, mindfulness)

7. Risks and Discomforts

It is unlikely that participants will incur any risk for physical harm as a result of study participation.

Participants may feel uncomfortable completing various psychological questionnaires.

Both the Healthy Minds Program app and Wellness app will passively collect data on user statistics. Both apps collect usage information such as the content used, screens or features accessed, duration of use and other similar types of usage information. This is in place of typical weekly logs to reduce burden on participants. No identifiable information will be collected. We will assign participants study email addresses to log into the app so they do not need to use their personal email address. These apps do not collect any other identifying information (such as full name, birthdate, medical or governmental IDs, etc.). However, as in any research study, especially those with electronic data collection, there is a small risk that confidentiality may be breached; all efforts to minimize this risk will be taken, as outlined above.

In the unlikely event that participants will become suicidal during the duration of the study, the research assistant will contact the PI and appropriate clinical intervention will be executed.

<u>Meditation-related risks:</u> There are no more than minimal risks to participation in this study. Meditation may cause study participants to feel emotions more intensely on a temporary bases (during practice) as the practice of meditation teaches participants to become more mindful of their thoughts, feelings, and emotions. Participants will learn through the instruction materials that this increase is temporary and is associated with an actual decrease in symptoms over time, due to habituation.

8. Benefits

Participants may not benefit from the study directly. However, knowledge from this research study may benefit others by enhancing our understanding of the role of psychosocial skills-based interventions in treating future patents and caregivers Participants may benefit from the numerous evidence-based advantages associated with engaging in meditation. Caregivers may experience reduced caregiving burden, emotional distress and sleep dysfunction as well as increased quality of life. Caregivers may be able to better regulate their emotions, have less ruminating thoughts, and provide higher quality care to their loved ones.

9. Statistical Analysis

Aim 1: We will utilize Bowen and colleagues' 13 standards for feasibility studies and components of the Behavioral Change Consortium's Treatment Fidelity model[46]. Specifically, we will assess acceptability and demand of the intervention. We will assess acceptability measures – including ability to recruit, satisfaction with the HMP / WA conditions, credibility that HMP /WA would be helpful, and perceived appropriateness and usefulness of the daily meditations and app components – via: (a) the number of participants who provide informed consent as compared to the number of participants that are determined eligible for the study, (b) a weekly satisfaction question; and (c) a satisfaction survey at post intervention. Additionally, we will ask participants in the HMP condition questions about intent to continue using HMP after the intervention. Exact one sided 95% confidence bounds will be calculated for each proportion to evaluate satisfaction of each of the feasibility benchmarks. To examine the acceptability of using HMP or WA for ≥10 mins/day over the 12-week study period, we will calculate the proportion of eligible participants who provide informed consent. We will also explore the range and average satisfaction and use of HMP /WA and its components, including the frequency of responses regarding barriers and facilitators. To assess demand, we will calculate summary statistics regarding completion, time spent, and components used throughout the intervention. When possible, we will examine associations between use of app components (e.g., reminders) and use of the apps (e.g., completion rate, time spent on app), as well as weekly scores on caregiver stress, distress, mindfulness and sleep. Depending on the nature of the estimate or comparison exact binomial tests, Fischer's exact tests, t-tests, or correlations may be used to summarize data and test for statistical significance. HMP and WA user data will be collected automatically from users.

Aim 2: We will estimate between-group differences in change from baseline to 12 weeks and 3 months as a proof of concept. Variance components and effect sizes will be estimated for each outcome. In feasibility studies, observing relative improvement in the intervention arm allows us to demonstrate proof of concept that the intervention shows promise in the intended population[45]. The study is not powered for stringent inferential testing of efficacy (two-tailed $p < 0.05$) unless we observe an overwhelming benefit from the HMP program. We will use variance estimates from repeated-measures analysis of data on PSS to guide the design and power calculations for a future trial testing efficacy[47,48]. We will compute effect sizes of change in these scores. Results will be used with caution in guiding future work. Benchmark: Proofs of concept will be demonstrated if decrease in caregiver stress (PSS-10) in the intervention group from baseline to post-test is greater than in the educational control (between group test of superiority; small to

moderate effect sizes favoring HMP). We chose this benchmark because PSS-10 will be the primary outcome in the future R01.

10. Monitoring and Quality Assurance

Participant Confidentiality. All study materials will identify participants only by study ID, visit number, and visit date. The study research assistant will be trained in procedures to protect study participant confidentiality. The research team will report to the data safety and monitoring committee with details of any participant confidentiality breach and corresponding plans for corrective action.

Data Validity and Security. The research team will develop standard operating procedures for data collection, data management, and quality control. Dr. Vranceanu will oversee all procedures related to secure data collection and management. Data activities will be conducted using (Research Electronic Data Capture (REDCap), a software and workflow tool for research data collection and management, with assistance from Partners HealthCare Research Computing, Enterprise Research Infrastructure & Services (ERIS) group. REDCap provides secure web-based applications with an intuitive user interface data and real time validation rules. Data will be stored on password protected computers that will be stored in secure locations at all times. Paper data files (with coded subject identification) will be stored in a locked filing cabinet. Only research staff will have access to these data locations.

Data Quality. Per study year, the data safety and monitoring committee will receive a data quality report including a summary of (1) participant enrollment and retention, (2) participant adherence with visits, and (3) data completeness and quality. The committee will use this report to evaluate study capacity for valid analysis.

If the research team identifies an adverse, we will follow the steps below under the assistance of the ISM (Independent Safety Monitor):

Serious Adverse Events. Any event that meets the Food and Drug Administration (FDA) definition of a serious adverse event or that is deemed by the research team or ISM to impose significant hazard, contraindication, side effect, or precaution, will involve expedited review. Serious adverse events are any fatal event, immediately life-threatening event, permanently or substantially disabling event, event requiring or prolonging inpatient hospitalization, or any congenital anomaly. Given that this study is a randomized trial comparing a mindfulness meditation intervention delivered via a mobile app (HMP) with an attention control podcast (WA), we do not anticipate any study-related events meeting this definition. The study population is comprised of caregivers who screen in for stress. All Serious Adverse Events (SAEs) will be reported to the ISM by the PI via secure e-mail within 2 days. The ISM will review the information and determine the extent to which the event was relevant to the study procedures. Reporting to the IRB will be done within 5 working days (7 calendar days); reporting to National Institute of Aging (NIA) (including responses of the ISM and the IRB) will be done within 7 days. For any unlikely study related adverse events the PI will follow the IRB and NIA recommendations to prevent re-occurrence, with a case by case plan, under the

assistance of the ISM and study team.

Non-Serious Adverse Events. Per study year and at study completion, the ISM will receive from the Multiple Principle Investigators (MPIs) a summary of unlikely and non-serious adverse (e.g., transient increase in distress) events per randomized group, including number and types of events, severity, time point, and determination of whether the events were study related.

Other Safety-Related Reports. Per study year, the ISM will receive from the MPIs an un-blinded report of study retention and reasons for attrition per randomized group.

Study Stopping Rules. Give low risk associated with this study, we have not identified a stopping rule. However, during the study period, if the ISM deems that participant risk outweighs participant benefit, the committee may choose to recommend study termination.

Email communication with subjects will be conducted using encryption, i.e.,: The "Send Secure" function. We will also discourage subjects from communicating about medical issues by non-secure email

Data from this study will be stored for seven years after the study is completed, at which time all paper data files will be shredded, and computer files will be deleted.

11. Privacy and Confidentiality

- ☒ Study procedures will be conducted in a private setting
- ☒ Only data and/or specimens necessary for the conduct of the study will be collected
- ☒ Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)
- ☐ Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)
- ☒ Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol
- ☒ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)
- ☒ All electronic communication with participants will comply with Mass General Brigham secure communication policies
- ☒ Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research
- ☒ All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens
- ☒ The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research

☐ Additional privacy and/or confidentiality protections

12. References

1. National Alliance for Caregiving. Caregiving in the U.S. 2015. Accessed December 24, 2018. https://www.caregiving.org/caregiving2015/

2. Alzheimer's Disease Facts and Figures. Alzheimer's Disease and Dementia. Accessed June 17, 2022. https://www.alz.org/alzheimers-dementia/facts-figures

3. Sörensen S, Conwell Y. Issues in Dementia Caregiving: Effects on Mental and Physical Health, Intervention Strategies, and Research Needs. *The American Journal of Geriatric Psychiatry*. 2011;19(6):491-496. doi:10.1097/JGP.0b013e31821c0e6e

4. Roche V, Palmer BF. The Hidden Patient: Addressing the Caregiver. *The American Journal of the Medical Sciences*. 2009;337(3):199-204. doi:10.1097/MAJ.0b013e31818b114d

5. Brodaty H, Donkin M. Family caregivers of people with dementia. *Dialogues in Clinical Neuroscience*. 2009;11(2):217-228. doi:10.31887/DCNS.2009.11.2/hbrodaty

6. Caregiver burden | definition of caregiver burden by Medical dictionary. Accessed June 17, 2022. https://medical-dictionary.thefreedictionary.com/caregiver+burden

7. Chiao CY, Wu HS, Hsiao CY. Caregiver burden for informal caregivers of patients with dementia: A systematic review: Caregiver burden for informal caregivers. *Int Nurs Rev*. 2015;62(3):340-350. doi:10.1111/inr.12194

8. Landfeldt E, Edström J, Buccella F, Kirschner J, Lochmüller H. Duchenne muscular dystrophy and caregiver burden: a systematic review. *Dev Med Child Neurol*. 2018;60(10):987-996. doi:10.1111/dmcn.13934

9. de Wit J, Bakker LA, van Groenestijn AC, et al. Caregiver burden in amyotrophic lateral sclerosis: A systematic review. *Palliat Med*. 2018;32(1):231-245. doi:10.1177/0269216317709965

10. Joling KJ, van Marwijk HWJ, Veldhuijzen AE, et al. The Two-Year Incidence of Depression and Anxiety Disorders in Spousal Caregivers of Persons with Dementia: Who is at the Greatest Risk? *The American Journal of Geriatric Psychiatry*. 2015;23(3):293-303. doi:10.1016/j.jagp.2014.05.005

11. McCurry SM, Song Y, Martin JL. Sleep in caregivers: what we know and what we need to learn. *Current Opinion in Psychiatry*. 2015;28(6):497-503. doi:10.1097/YCO.0000000000000205

12. National Alliance for Caregiving & Evercare. *Evercare Study of Caregivers in Decline*.; 2006. https://www.caregiving.org/wp-content/uploads/2020/05/Caregivers-in-Decline-Study-FINAL-lowres.pdf

13. Shaffer KM, Garland SN, Mao JJ, Applebaum AJ. Insomnia among cancer caregivers: A proposal for tailored cognitive behavioral therapy. *Journal of Psychotherapy Integration*. 2018;28(3):275-291. doi:10.1037/int0000105

14. Northouse L, Williams A leila, Given B, McCorkle R. Psychosocial Care for Family Caregivers of Patients With Cancer. *JCO*. 2012;30(11):1227-1234. doi:10.1200/JCO.2011.39.5798

15. Pruchno RA, Potashnik SL. Caregiving Spouses Physical and Mental Health in Perspective. *Journal of the American Geriatrics Society*. 1989;37(8):697-705. doi:10.1111/j.1532-5415.1989.tb02230.x

16. Wilcox S, King AC. Sleep Complaints in Older Women Who Are Family Caregivers. *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences*. 1999;54B(3):P189-P198. doi:10.1093/geronb/54B.3.P189

17. Whitebird RR, Kreitzer M, Crain AL, Lewis BA, Hanson LR, Enstad CJ. Mindfulness-Based Stress Reduction for Family Caregivers: A Randomized Controlled Trial. *The Gerontologist*. 2013;53(4):676-686. doi:10.1093/geront/gns126

18. Hou RJ, Wong SYS, Yip BHK, et al. The Effects of Mindfulness-Based Stress Reduction Program on the Mental Health of Family Caregivers: A Randomized Controlled Trial. *Psychother Psychosom*. 2014;83(1):45-53. doi:10.1159/000353278

19. Lavretsky H, Epel ES, Siddarth P, et al. A pilot study of yogic meditation for family dementia caregivers with depressive symptoms: effects on mental health, cognition, and telomerase activity: Yogic meditation for stress reduction in dementia caregivers. *Int J Geriatr Psychiatry*. 2013;28(1):57-65. doi:10.1002/gps.3790

20. Oken BS, Fonareva I, Haas M, et al. Pilot Controlled Trial of Mindfulness Meditation and Education for Dementia Caregivers. *The Journal of Alternative and Complementary Medicine*. 2010;16(10):1031-1038. doi:10.1089/acm.2009.0733

21. Paller KA, Creery JD, Florczak SM, et al. Benefits of Mindfulness Training for Patients With Progressive Cognitive Decline and Their Caregivers. *Am J Alzheimers Dis Other Demen*. 2015;30(3):257-267. doi:10.1177/1533317514545377

22. Winbush NY, Gross CR, Kreitzer MJ. The Effects of Mindfulness-Based Stress Reduction on Sleep Disturbance: A Systematic Review. *EXPLORE*. 2007;3(6):585-591. doi:10.1016/j.explore.2007.08.003

23. Li G, Yuan H, Zhang W. The Effects of Mindfulness-Based Stress Reduction for Family Caregivers: Systematic Review. *Archives of Psychiatric Nursing*. 2016;30(2):292-299. doi:10.1016/j.apnu.2015.08.014

24. Piersol CV, Canton K, Connor SE, Giller I, Lipman S, Sager S. Effectiveness of Interventions for Caregivers of People With Alzheimer's Disease and Related Major Neurocognitive Disorders: A Systematic Review. *The American Journal of Occupational Therapy*. 2017;71(5):7105180020p1-7105180020p10. doi:10.5014/ajot.2017.027581

25. Chen KW, Berger CC, Manheimer E, et al. MEDITATIVE THERAPIES FOR REDUCING ANXIETY: A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS: Review: Meditative Therapies for Reducing Anxiety. *Depress Anxiety*. 2012;29(7):545-562. doi:10.1002/da.21964

26. Jaffray L, Bridgman H, Stephens M, Skinner T. Evaluating the effects of mindfulness-based interventions for informal palliative caregivers: A systematic literature review. *Palliat Med*. 2016;30(2):117-131. doi:10.1177/0269216315600331

27. Hurley RVC, Patterson TG, Cooley SJ. Meditation-based interventions for family caregivers of people with dementia: a review of the empirical literature. *Aging & Mental Health*. 2014;18(3):281-288. doi:10.1080/13607863.2013.837145

28. Kor PPK, Chien WT, Liu JYW, Lai CKY. Mindfulness-Based Intervention for Stress Reduction of Family Caregivers of People with Dementia: A Systematic Review and Meta-Analysis. *Mindfulness*. 2018;9(1):7-22. doi:10.1007/s12671-017-0751-9

29. Parkinson B, Lawrence M, Mcelhinney E, Booth J. Mindfulness for people with long-term conditions and their family caregivers: a systematic review. *Complementary Therapies in Clinical Practice*. 2019;34:76-86. doi:10.1016/j.ctcp.2018.10.019

30. Carlson LE, Speca M, Faris P, Patel KD. One year pre–post intervention follow-up of psychological, immune, endocrine and blood pressure outcomes of mindfulness-based stress reduction (MBSR) in breast and prostate cancer outpatients. *Brain, Behavior, and Immunity*. 2007;21(8):1038-1049. doi:10.1016/j.bbi.2007.04.002

31. Tang YY, Ma Y, Fan Y, et al. Central and autonomic nervous system interaction is altered by short-term meditation. *Proc Natl Acad Sci USA*. 2009;106(22):8865-8870. doi:10.1073/pnas.0904031106

32. Hölzel BK, Lazar SW, Gard T, Schuman-Olivier Z, Vago DR, Ott U. How Does Mindfulness Meditation Work? Proposing Mechanisms of Action From a Conceptual and Neural Perspective. *Perspect Psychol Sci*. 2011;6(6):537-559. doi:10.1177/1745691611419671

33. Hofmann SG, Sawyer AT, Witt AA, Oh D. The effect of mindfulness-based therapy on anxiety and depression: A meta-analytic review. *Journal of Consulting and Clinical Psychology*. 2010;78(2):169-183. doi:10.1037/a0018555

34. Liu Z, Chen Q lin, Sun Y ying. Mindfulness training for psychological stress in family caregivers of persons with dementia: a systematic review and meta-analysis of randomized controlled trials. *Clin Interv Aging*. 2017;12:1521-1529. doi:10.2147/CIA.S146213

35. Ott MJ, Norris RL, Bauer-Wu SM. Mindfulness Meditation for Oncology Patients: A Discussion and Critical Review. *Integr Cancer Ther*. 2006;5(2):98-108. doi:10.1177/1534735406288083

36. Wozney L, Freitas de Souza LM, Kervin E, Queluz F, McGrath PJ, Keefe J. Commercially Available Mobile Apps for Caregivers of People With Alzheimer Disease or Other Related Dementias: Systematic Search. *JMIR Aging*. 2018;1(2):e12274. doi:10.2196/12274

37. Scott IA, Scuffham P, Gupta D, Harch TM, Borchi J, Richards B. Going digital: a narrative overview of the effects, quality and utility of mobile apps in chronic disease self-management. *Aust Health Review*. 2020;44(1):62. doi:10.1071/AH18064

38. Analysis LB AARP Research & Strategic. Health and Caregiving among the 50+: Ownership, Use and Interest in Mo... AARP. Accessed June 17, 2022. https://www.aarp.org/technology/innovations/info-01-2011/health-caregiving-mobile-technology.html

39. Weigelt D. *50+ Facts and Fiction: Mature Consumers Online.* Immersion Active Accessed January 3, 2019. https://www.immersionactive.com/resources/50-consumers-online

40. Grossman MR, Zak DK, Zelinski EM. Mobile Apps for Caregivers of Older Adults: Quantitative Content Analysis. *JMIR Mhealth Uhealth*. 2018;6(7):e162. doi:10.2196/mhealth.9345

41. Fuller-Tyszkiewicz M, Richardson B, Little K, et al. Efficacy of a Smartphone App Intervention for Reducing Caregiver Stress: Randomized Controlled Trial. *JMIR Mental Health*. 2020;7(7):e17541. doi:10.2196/17541

42. Sikder AT, Yang FC, Schafer R, Dowling GA, Traeger L, Jain FA. Mentalizing Imagery Therapy Mobile App to Enhance the Mood of Family Dementia Caregivers: Feasibility and Limited Efficacy Testing. *JMIR Aging*. 2019;2(1):e12850. doi:10.2196/12850

43. Rathnayake S, Moyle W, Jones C, Calleja P. Co-design of an mHealth application for family caregivers of people with dementia to address functional disability care needs. *Informatics for Health and Social Care*. 2021;46(1):1-17. doi:10.1080/17538157.2020.1793347

44. Davis B, Nies M, Shehab M, Shenk D. Developing a pilot e-mobile app for dementia caregiver support: Lessons learned | OJNI. *Online Journal of Nursing Informatics*. 2014;18.

45. Bowen DJ, Kreuter M, Spring B, et al. How We Design Feasibility Studies. *American Journal of Preventive Medicine*. 2009;36(5):452-457. doi:10.1016/j.amepre.2009.02.002

46. Resnick B, Inguito P, Orwig D, et al. Treatment Fidelity in Behavior Change Research: A Case Example. *Nursing Research*. 2005;54(2):139-143.

47. Rounsaville BJ, Carroll KM, Onken LS. A stage model of behavioral therapies research: Getting started and moving on from stage I. *Clinical Psychology: Science and Practice*. 2001;8(2):133-142. doi:10.1093/clipsy.8.2.133

48. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice: Design and analysis of pilot studies. *Journal of Evaluation in Clinical Practice*. 2004;10(2):307-312. doi:10.1111/j..2002.384.doc.x

APPENDIX A
Data Monitoring Committee / Data and Safety Monitoring Board Appendix

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- *To be completed for studies monitored by Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) if a full DMC/DSMB charter is not available at the time of initial IRB review.*
- *DMC/DSMB Charter and/or Roster can be submitted to the IRB later via Amendment, though these are not required.*

A Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) will be convened for safety monitoring of this research study. The following characteristics describe the DMC/DSMB convened for this study (Check all that apply):

☒ The DMC/DSMB is independent from the study team and study sponsor.

☒ A process has been implemented to ensure absence of conflicts of interest by DMC/DSMB members.

☐ The DMC/DSMB has the authority to intervene on study progress in the event of safety concerns, e.g., to suspend or terminate a study if new safety concerns have been identified or need to be investigated.

☒ Describe number and types of (i.e., qualifications of) members:

We will have 3 DSMB members. We will identify committee members who (1) are independent of our study team with respect to financial or career development interests, and (2) have experience with human subjects protection, biostatistics, and behavioral randomized controlled trials.

☒ Describe planned frequency of meetings:

DSMB will receive semi-annual reports and will meet once prior to initiating the study and then once per study year.

- ☐ DMC/DSMB reports with no findings (i.e., “continue without modifications”) will be submitted to the IRB at the time of Continuing Review.

- ☐ DMC/DSMB reports with findings/modifications required will be submitted promptly (within 5 business days/7 calendar days of becoming aware) to the IRB as an Other Event.