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Research Protocol

Collaborative Research: Learning and Improving Alzheimer's Patient-Caregiver Relationships via Smart Healthcare Technology.

I. Objectives

The purpose of this project is to develop a monitoring, modeling, and interactive recommendation solutions (for caregivers) for in-home dementia patient care that focuses on caregiver-patient relationships. This includes monitoring for mood and stress and analyzing the significance of monitoring those attributes to dementia patient care and subsequent behavior dynamics between the patient and caregiver. In addition, novel and adaptive behavioral suggestions will be provided to family caregivers via text messages on project Smartphones at the right moments aimed to help improve familial interactions related to caregiving, which over time should ameliorate the stressful effects of the patient's illness and reduce strain on caregivers.

The technical solution consists of a core set of statistical learning based techniques for automated generation of specialized modules required by in-home dementia patient care.

There are three main technical components in the solution.

- The first obtains textual content and prosody from voice and uses advanced machine learning techniques to create classification models. This approach not only monitors patients' behavior, but also caregivers', and infers the underlying dynamics of their interactions, such as changes in mood and stress.
- The second is the automated creation of classifiers and inference modules tailored to the particular patients and dementia conditions (such as different stages of dementia).
- The third is an adaptive recommendation system that closes the loop of an in-home behavior monitoring system.

II. Background and Rationale

Over 80% of people with Alzheimer's disease or a related dementia are cared for in their home environments by family members. Family caregivers often report increased anxiety and depression, and many forego their own health needs as the demands of being a family caregiver are sustained over many years. These demands can be stressful and poor preexisting family relationships can exacerbate this burden over time. Behavioral responses to stress, as exhibited through problematic behaviors in persons with ADRD, have been linked to higher levels of caregiver stress. It is also known that poor interactions between patient and caregiver increase the difficulty of providing care: when reactivity is heightened, a stress response ensues and a downward cascade of maladaptive behaviors and emotions is elicited. Monitoring physiological reactivity between patient and caregiver could signal when problematic interactions might occur. Just-in-time or even predictive recommendations in those moments could improve these interactions and reduce strain on caregivers.

To conduct the proposed research, a sensing and recommendation platform is required that can detect mood and stress during interactions between caregivers and patients, and that can issue just-in-time recommendations to caregivers. Our approach is to employ smart phones with microphones and speakers, in-situ microphones, and iPads or laptops to collect affective states from voice and provide recommendations using multiple modalities (text and voice). Smart phones will be used for automated recommendations of mindfulness training provided to the caregivers. This set of equipment will be used to provide the information required by the statistical learning modules as well as for the recommendation generation. A base station, and cloud storage and computation will also be used. All data uploaded to the cloud is encrypted and anonymized by participant ID. The mapping from a person to the participant ID will be kept in a separate secure location to protect security and privacy.

A number of human physiological parameters correlate with mood and respond in the presence of stress, such as voice, skin conductance and pupil diameter. Capturing human voice or speech is generally less obtrusive than capturing other stress sensitive physiological signals, which require on-body sensing equipment and might also introduce safety concerns. As we focus on modeling and improving patient-caregiver relationships, we will build on sensing capability in acoustic events for monitoring patient and caregiver moods, stress and their vocal interactions. As the demands of caregiving for a person with ADRD escalate, many families struggle to maintain healthy relationships with each other, which directly leads to intensified stress on family caregivers. The stress on caregivers, in turn, exacerbates the disease and condition of ADRD patients. Therefore, detecting and modeling stress in caregivers, and providing them with just-in-time training and recommendations becomes crucial. It is a notorious difficult challenge to detect stress from voice, but our approach is to apply novel machine learning techniques that combine multi-instance learning and transfer learning. We have shown these techniques work well for detecting anxiety from voice [25], and propose to now apply this to stress detection.

The end-goals of our research are to provide real-time objective behavior monitoring to reduce in-home patient care cost and to improve the quality of interactions between persons with ADRD and their family caregivers. To achieve the goals, only passively recording what happened for posterior analysis and response is insufficient; real-time recommendation becomes necessary and beneficial to both patients and caregivers. For caregivers, this helps them improve their relation with patient, and may provide them with new insights of how their actions and reactions to their loved one with dementia can either calm or escalate a situation. Furthermore, from a system development perspective, patient's and caregiver's responses to the system's output, e.g., monitoring data, recommendations, become an invaluable source of supervision for us and the back-end automated system to further refine the deployed classifiers and control pipelines.

III. Procedures

A. Research Design

The research design used in this project is a single-group, longitudinal design. All study participants will receive the interventions. Therefore, randomization is not occurring in this project and there is no control group.

This project focuses on building a behavior monitoring and recommendation system for in-home dementia patient care. In the front-end, a flexible sensing and communication platform will support the proposed monitoring, analytics, and recommendation tasks. In the back-end, we focus on multi-modal behavior monitoring with a special emphasis on patient and caregiver vocal events, and the behavior dynamics between them. In particular we focus on detecting mood and stress in a personalized and real-time manner.

To conquer sparsity issue in statistical model training and enable rapid deployment of analytical models, we will develop solutions based on transfer learning [22, 23, 6], such that the labeled instances and learned models can be shared across patients and monitoring scenarios. This further facilitates scalable deployment of our proposed in-home monitoring system.

To fully address these project goals, we will provide caregivers with brief, face-to-face or virtual training on the recommendations that our system will generate for them. These training sessions will take place in-person—in their own home or at the Ohio State University depending on which setting is easiest for them—or via telephone or Zoom call. They will be trained by a graduate research assistant (GRA) who will be supervised by Gordon (via Skype) and Dr. Rose (on site). Recommendations will be personalized to include the caregiver's preferred name (e.g., Jane or Mrs. Smith), as this is found to enhance the efficacy [1]. Although we describe a proposed outline of the training in more detail below, we will engage in a one-month data gathering and baseline assessment phase before we implement this training with caregivers. Information that we gather will be used to refine and better target the training described here before implementation. For example, if we learn that most difficult interactions occur during the dinner hour, we might adapt the training to more specifically focus on behaviors around feeding or eating. Based on the literature regarding problematic caregiver-patient interactions, four types of recommendations will initially be generated when the system indicates that the caregiver-patient might be experiencing high levels of arousal in proximity with each other.

Before we send one of the specific recommendations, we will text the caregiver to insure that the care recipient is safe and is not experiencing acute medical changes. In this text, we will recommend that the caregiver contact the primary care physician (if not urgent) or dialing 911 (if urgent).

The **first** category of reminders would be to take a brief time-out from the interaction, which also has been demonstrated in multiple studies on dyadic interactions to be effective in ameliorating problematic exchanges and reducing emotional reactivity [9, 5, 34].We will use the time-out method described in [9] and the caregiver will again be given training from GRA in this technique.

The **second** category are reminders to practice breathing awareness, which has a long history in the treatment of anxiety and stress, and is an effective and brief strategy to reduce physiological and emotional arousal both in non-clinical and clinical populations [34,35]. The GRA will go over this strategy with the caregiver by explaining the rationale behind this technique using exercises from the UCLA Mindful Awareness research center (see http://marc.ucla.edu/mindful-meditations) and then will practice the breathing skill with the caregiver until they have a good sense of how to do it.

The **third** category of reminders would be to engage in a brief mindfulness exercise that focuses on non-judgment and acceptance. Mindfulness strategies have been shown to reduce stress in caregiver populations [19,27] and more general studies have indicated that mindfulness reduces emotional reactivity and improves communication [19, 16, 27, 17]. Additionally, two RCTs indicate that brief psychoeducation on mindfulness and self-guided practice using online exercises significantly reduce depression and anxiety [30, 29], and a very brief intervention involving training in mindfulness and ecological momentary assessment strategies, which is similar to this project's methodology, significantly increased mindfulness skills [24]. In particular, awareness and acceptance strategies have been shown to be particularly effective in reducing anxiety and stress [19, 30]. The GRA will explain the rationale for this exercise and demonstrate it using transcripts from the UCLA Mindful Awareness research center. Mindfulness has been shown to be an effective technique in reducing emotional dysregulation in dyadic conflict [17]. They will again receive training from the GRA on this exercise and will be referred to the UCLA Mindful Awareness Center website to practice these exercise (or give an audio CD to them if they do not have access to the internet). We will recommend that they practice it daily as much as possible.

The **fourth** category of reminders are strategies that problem solve on how to manage the patients if they are agitated, restless, or are disengaged, which are based on recommendations to modify the environment provided by the "Savvy Caregiver" program. This program is a product of our study consultant, Dr. Kenneth Hepburn [12, 13], and based upon addressing unmet needs and a lowered stress threshold in persons with ADRD. At the first study visit, caregivers will be provided with information regarding the need to address potentially unmet basic care the recipient needs, such as toileting and hunger, and will be asked to identify 3-4 pleasant activities they could engage their loved one with ADRD in if they become agitated, restless, or disengaged. Examples of this include taking a walk, looking at photo albums together, gardening, listening to pleasurable music together, etc. These activities are individualized, based on the interests of the individual persons with ADRD. Caregivers would receive a text recommendation to identify unmet needs or to engage their loved one in one of their pre-identified pleasurable activities to decrease agitation, stress, and to improve mood. Individualized, social activities are found to be efficacious and cost-effective in redirecting a person with ADRD and to decreasing disruptive behaviors [33,11,15]. Caregivers will receive a handouts on all of these five strategies.

B. Sample

The study sample will be drawn from eligible patients receiving treatment either at the Center for Cognitive and Memory Disorders clinic at Ohio State University or at community-based settings. For recruitment from community-based settings, the Center for Clinical and Translational Science (CCTS) will upload a paid advertisement for this study on Facebook and/or Instagram, a social media platform. The advertisement will lead potential participants to the Caregiver Research Study website (https://studysearch.osumc.edu/studies/2837/) and provide detailed information of this research. CCTS will be also affiliated with other organizations and State agencies providing caregiving or ADRD resources; the uploaded post on CCTS Facebook and/or Instagram will be shared with the organizations. The duration of the first social media

advertisement will take two weeks and it may be renewed depending on progress on recruitment. Data from these clinics indicate that several thousand patients with AD and family members have received care and supportive services from these clinics in the past year. We plan to enroll up to **50 participants** with AD and their family caregivers (1 caregiver per participant with AD) during the study to achieve a sample of ***N=30*** dyads as attrition rates of up to 50% are reported in the literature. Given the history of the number of persons with AD who receive care through these clinics, the applicant is confident an adequate sample size can be obtained. At each 3-month interval, recruitment goals will be assessed. Potential study participants (persons with AD and family caregivers) will be given information regarding the proposed study and will be given a consent form to take home and read. Because this is a single-group study design, there is no randomization and no control group.

A member of the study team will follow up with the potential participants to answer any questions that they may have regarding the study via telephone at a mutually agreed upon time. If the potential participants decide to enroll in the study, the study coordinator will make an appointment to visit with the potential participants at their home to gain written, informed consent. At this first visit, the study coordinator will answer any questions that the potential participants have regarding the study. In AD study participants, surrogate assent will be obtained, if needed.

The **inclusion criteria** for this study are as follows. For persons with dementia:

1) Females and males; 2) age 60-99 years; 3) physician documentation of dementia: Alzheimer's disease, vascular, mixed or unspecified type; 4) community-dwelling (living in the home); and 5) fluent in English.

For family caregivers: 1) age 21 years or older; 2) informal, unpaid caregiver who resides with the care recipient; 3) fluent in English; 4) functioning home Wifi; and 5) scoring above a 3 on the Revised Memory and Behavior Problems Checklist, a clinical cut-off point used to determine caregiver stress [24]. And the **exclusion criteria** are that persons with dementia: 1) presence of acute illness as this could lead to delirium; 2) alcohol abuse or dependence within the past 2 years (DSM-IV criteria); 3) history of significant psychiatric illness (e.g., schizophrenia).

C. Measurement/Instrumentation

The specific ***instruments*** we will use in our evaluation include:

1) *San Diego Capacity to Consent form*: In order to determine the capacity for consent, we will use the University Of California San Diego Brief Assessment Of Capacity to Consent (UBACC). This form takes less than 5 minutes to complete and psychometric testing showed that scores greater than 14.5 were 89% sensitive and 100% specific for determining capacity to consent for research [40]

2) *Demographic form/Medical History form*. Demographic form will be used to record participant demographics (e.g., age, gender, ethnicity, time of dementia diagnosis, and months of caregiving experience, caregiving hours per day). Medical history form includes current

medications and co-morbidities. Both are for purpose of describing the study sample. This instrument will be administered at baseline and is completed by the caregiver.

3) *Cognitive status*. The Telephone Interview of Cognitive Status (TICS) will be administered over the phone to determine cognitive status. The instrument has been shown to be clinically relevant and comparable to the Mini-Mental State Examination [30]. Higher scores on the TICS indicate higher cognitive functioning. This instrument will be administered to the subject with ADRD at the screening visit after consent is obtained. AD8 will be administered to ONLY those participants recruited from a community-based setting. This brief measure screens for changes in cognitive function related to dementia as opposed to changes due to normal aging. This scale shows desirable sensitivity (.74-.85) and specificity (.84-.86) [43]. There are eight questions on this scale, and answers to the questions are dichotomous: yes or no. Scoring is measured by calculating the number of items answered as "yes, a change [44]." The Range of scores is from 0 to 8. A score of 2 or greater indicates the individual's cognitive decline is likely dementia related [44]. The AD8 scale will be used in place of physician documentation of ADRD in the community-based setting.

4) *Caregiver assessment of disruptive behaviors and the impact of these behaviors on caregivers*. The Revised Memory and Behavior Problems Checklist (RMBPC) is a 24-item, caregiver-report measure of observable behavioral problems in dementia patients and the caregiver's stress reactions to these behavioral disturbances. The instrument provides a total score and 3 subscale scores for patient behavioral problems (memory-related, depression, and disruptive behaviors) and corresponding scores for caregiver reactions to each of these. Overall scale internal consistency of the instrument is reported as .84 for patient behavior and .90 for caregiver reaction and the instrument has confirmed validity through comparison of instrument scores with measures of depression, cognitive impairment, and caregiver burden [31].

5) *Depressive symptoms, anxiety, and stress:* The DASS is a set of three self-report scales designed to measure the negative emotional states of depression, anxiety and stress. The DASS was constructed not merely as another set of scales to measure conventionally defined emotional states, but to further the process of defining, understanding, and measuring the ubiquitous and clinically significant emotional states usually described as depression, anxiety and stress. As the scales of the DASS have been shown to have high internal consistency and to yield meaningful discriminations in a variety of settings, the scales should meet the needs of both researchers and clinicians who wish to measure current state or change in state over time (e.g., in the course of treatment) on the three dimensions of depression, anxiety and stress [36-38].

6) *Caregiver Strain: Modified Caregiver Strain Index* It is a 13-item self-report measure that examines both subjective and objective elements of caregiver strain. The MCSI showed excellent inter-item and test-retest reliability and was correlated in expected directions with relevant criteria [32]. It has excellent reliability and validity, displays adequate clinical sensitivity, has an established cut-off for determining functional/dysfunctional systems, and has been used successfully on a variety of mental health outcomes [28]. We will use a practice tracking worksheet to assess how much the caregivers practice the exercises over the course of the study.

Patient behavior is affected by caregiver responses, and caregiver responses are in turn influenced by both patient behavior and the historical context of their relationship [10, 14, 18, 7]. Critical and hostile responses on the part of the caregiver are associated with increases in patient dementia symptoms [8]; thus, if we can reduce caregiver's frustration and criticism, we expect this will reduce escalation of negative interactions, reduce caregiver burden and stress over time, and in turn decrease patient stress and physiological reactivity. We will assess the quality of the caregiver-patient relationship and caregiver stress and burden before beginning the study.

7) *Family Assessment Device:* The FAD is a self-report measure that is given as a set of seven subscales of varied length. Each subscale measures a different dimension of family function. Scores for each dimension (problem solving, communication, roles, affective responsiveness, affective involvement, behavior control, and general functioning) are calculated separately as the mean of the items in that subscale. The information obtained through the FAD allows for the elucidation of the structure and organization of the family system, as well as the identification of common patterns of interaction among family members. The FAD is heavily used in research related to the function of family systems, and it has demonstrated excellent validity and reliability in both non-clinical and clinical populations [39].

8) *Caregiver Emotion Regulation and Mindfulness*: The 16-item, Difficulties in Emotion Regulation Scale (DERS-16) will be used to measure caregivers' ability to regulate emotions at baseline and end of study. The scale used is the brief version of a theoretically-driven, valid, and reliable self-report tool used to measure difficulties with emotion regulation. The brief version will be more easily administered with the study population and has been shown to be valid and reliable [41]. Additionally, caregivers will be asked to complete the 39-item Five Facet Mindfulness Questionnaire to measure their capacity for five different domains of mindfulness practice at baseline and end of study. The five facets include non-reactivity to the inner experience, non-judgment of the inner experience, acting with awareness, observing, and describing internal states. The questionnaire has good reliability and validity [42].

D. Detailed study procedures

There are two important research questions this study aims to address: 1) how to generate effective and accurate recommendations; and 2) how to adapt the recommendation generation according to patients' and caregivers' feedback. To the best of our knowledge, no existing in-home health monitoring system provides this capability, instead recommendations are developed in an ad-hoc manner and generated ahead of time and independently of the interaction dynamics. Due to the nature of dementia disease and the consideration of patient safety, we will *only study recommendations for caregivers*. But the technical solutions we examined here are general, and can be applied to other health recommendation scenarios. We should note that we are not replacing medical care; study participants (e.g., caregivers) will be provided information to seek help from their regular healthcare provider or emergency services as needed.

The proposed collaborative research will take place over four years and will follow the outlined timeline:

Year One: In the first year, focus will be on building the front-end monitoring architecture. In-suite sensing and monitoring components will be built and customized for collecting the

participants' vocal and psychological signals. Joint acoustic signal analysis and text mining algorithms will be explored. At this stage of single module development, offline dataset will be used for evaluation purpose. A study consultant, will also assist the study team in developing and pilot-testing a checklist to assess for fidelity of the educational training we deliver to caregiver participants.

Year Two: We will be working on system integration and unit test of the intergraded components in the system. In the meanwhile, from the second half of year two, we will start recruiting patients for our system deployment and evaluation purpose. The PI and research assistant will work with the recruitment clinic to consent and enroll the pilot patients, collect study data, and will be on-call to answer caregiver questions as they may arise. We set "5-7

patients enrolled per month" as our recruitment milestone, and thus it takes about 2 months to recruit 8-10 patients for phase 1 pilot study and about 4 months to recruit 25 patients for phase 2 system evaluation.

Fidelity checks will be performed , and retraining of GRAs will be performed based upon results of fidelity checks. The study team will meet weekly to ensure that recruitment and caregiver trainings are proceeding smoothly and to problem-solve with staff if necessary.

Year Three: According to our evaluation plan, we will start our second phase 4-month pilot evaluation at the beginning of year three (one month for constructing baseline measurement and three months for controlled studies). All personnel will work together to conduct the pilot study and collect feedback from real patients and clinician experts to refine the system design in an iterative way. Fidelity checks will be performed and Re-training of GRAs will be performed by based upon results of fidelity checks.

In particular, we will conduct the patient clinical interviews, and will work with an expert clinical panel to obtain feedback on the system. The caregiver interviews will be analyzed for the specifics of how the recommendation affects the caregiver-care recipient family dynamic. The monitored data, system's automated prediction results will be analyzed, and the system design and implementation revised and updated according to the patients' and clinician experts' feedback. Upon finishing the pilot study, we will start our phase 2 system-level evaluation, which will last 18 months. Note, before we start the phase 2 evaluation, we would have around 2 to 4 months period to adjust to unexpected delays/barriers in algorithm design, system development, or patient recruitment. We will make sure everything is planned and on schedule before we move onto the phase 2 system level evaluation.

Year Four: The second phase of system level evaluation will be undertaken based on the information and lessons learned from phase one. This will include new technical solutions, refined computational models and system deployment designs. All personnel will work together to conduct full system evaluation. We will collaborate with clinicians in the two study sites at Ohio State University Medical Center the in our user study Clinicians, will help us recruit patients for participation and provide feedback on the system development.

Our general plan is that by the end of this project, we will have a deployed practical system for the proposed in-home dementia patient care, and it will be ready for future clinical trial on larger and more diverse populations. All PIs will work very closely with the students on all the research

topics, aiming at regular publications in major conferences/journals. We will provide programming interfaces to the algorithms developed in this project, e.g., activity recognition and joint acoustic signal and text analysis, transfer learning and multi-task learning algorithms, and interactive feedback modeling and recommendation generation, through the developed system.

Study Visits:

Screening: Potential participants will be recruited from the geriatrics/internal medical clinic and the Center for Cognitive and Memory Disorders clinic at The Ohio State University as well as from community-based settings across Ohio state. The community sample will be obtained through Facebook posts by CCTS. The uploaded post on Facebook will be shared with other organizations and State agencies providing caregiving or ADRD resources. Communications made to the community will use the same language as the brochure provided to individuals in the Memory Clinic setting. Following screening for inclusion and exclusion criteria, potential participants will be contacted regarding their interest in the study. A study brochure will be given to the potential participants and, if they are interested in participating, a follow-up telephone call appointment will be made to review the study and to answer any questions the participants may have. If they are interested in participating, an appointment for a home visit or telephone/Zoom call will be scheduled at a mutually-agreed upon time. Prior to visit one participants will provide verbal consent/assent via telephone/Zoom. If participants provide verbal consent they will be asked to sign either an in-person or electronic consent (via REDCap) form at the time of visit one.

Participants will be in the study for up to four months from the time of consent to the time of final study data collection and interview. However, the overall study duration may be longer than the planned duration (4 months), depending on the interview schedule for you.There will be either 4 study visits at your home or 4 telephone or video calls and each will take approximately 30 – 135 minutes.

Visit 1: The study information brochure and the study consent forms will be reviewed in person, via video call, or via telephone with the potential study participants. Written, informed consent will be obtained for both the family caregiver and the persons with dementia. If informed consent is unable to be obtained for the person with dementia based upon their scores on the Capacity to Consent instrument, their surrogate decision-maker will provide informed consent and assent for the person with dementia will be ascertained by the study team member. If willing, participants will be asked to sign for consent electronically using a REDCap link sent via email. In REDCap participants will provide electronic signatures on the consent form indicating they agree to participate in this study. Following the consenting procedure, the acoustic monitor (microphone) and accompanying laptop computer (for transferring the acoustic data to the Cloud for translation processes to occur) will be placed in the participant's home at the location that is amenable to the study participants. We anticipate this will be the kitchen/dining area and the living room areas of the home as many interactions occur in these locations. No acoustic monitoring will occur in any areas of the house that they do not wish to have a microphone placed. A 5-minute audio

recording will be obtained from the caregiver and person with dementia. The recording will be uploaded to the recommender system to generate a person ID for vocal recognition during the study.

The acoustic monitoring will occur for up to 1 month to establish baseline interactions between the family caregiver and the persons with dementia. A Smart Phone will be given to the caregiver for use during the study period for the purpose of receiving recommendations and providing feedback through daily and weekly online surveys. Written and verbal instructions on the use of the acoustic monitoring and the Smart Phone will be provided to study participants. There are no steps that participants need to follow to maintain the equipment, other than keeping the microphone and laptop plugged in to an electric outlet and recharging the Smart Phone. We will also ensure the internet connection via Wifi is enabled.

The following surveys will be administered via paper and pencil forms or RedCap to the family caregiver:

1. DASS
2. DERS-16
3. Five Facet Mindfulness Questionnaire
4. Revised Memory and Behaviors Problem Checklist
5. Modified Caregiver Strain Index
6. Family Assessment Device
7. An emergency plan will be formulated with the family caregiver to further reinforce that our study is not a substitute for their seeking medical care for themselves or for their loved one with dementia.

   For dementia study participants, we will administer these surveys:
   1. AD8 (for participants from community-based settings only)
   2. TICS

During Visit 1, research personnel will prompt the family caregiver to establish an emergency plan. This plan is meant to reinforce use of previously established procedures or create procedures to be used in the event of an emergency. Research personnel will stress that the study equipment is not monitored and is not capable of contacting emergency services and should not be used for such activity. Examples of an emergency plan could include, but are not limited to, notifying a healthcare provider, calling 911, or calling another family member. Caregivers will be reminded periodically to follow the procedures of their emergency plan in the event of any emergency.

We anticipate Visit 1 will take between 90-135 minutes.

Between visits 1 and 2, participants will complete a short survey about their experience deploying the study equipment in their home. The questionnaire will take about five to ten minutes to complete.

Visit 2: Upon completion of the first two weeks to one month of baseline data collection, the trained Graduate Research Assistant will visit the study participants in their homes or set up a

virtual meeting via Zoom or telephone to educate the participants regarding the text messages they will be receiving from the study team when stressful situations are identified. The Graduate Research Assistant will also train caregivers on how to perform mindfulness-based activities. A standardized training guide will be used for all participants by the trained GRAs. During the visit, a principal investigator (PI) may monitor whether the stress management education is delivered as intended (i.e., intervention fidelity check) with no recordings. Retraining of GRAs may be performed based upon the results of fidelity checks. Caregivers will be asked to select personal preferences for messages and helpful reminders they will receive in the text messages that would prompt their understanding of the text messages received from a pre-set list of choices. Additionally, family caregivers will be taught to respond to the daily and weekly feedback surveys regarding their use of the text messages.
Acoustic monitoring and text message recommendations will occur until study end. Trained GRAs will communicate with the family caregiver regarding any difficulties they are encountering with the acoustic monitoring and/or the text message recommendations they are receiving. We will send a text message within an hour after each recommendation is sent to a caregiver for the caregiver to tell us if he/she implemented the recommendation (yes or no) and to provide feedback on how helpful the recommendation was (not helpful at all – very helpful, using a 1-5 star rating). We will send morning text messages that contain a reminder for caregivers to follow their emergency plan in the event of any emergency, a prompt for self-reflection and setting a self-care goal, and encouraging words. We will send evening text messages to follow-up on their self-care goal and inquire about any recommendations that did not receive a response during the day. Additionally, we will text caregivers weekly and will ask them to rate the overall helpfulness of the recommendations (1-5 stars, as above). At each one month interval, participants will receive $50 each, or $100 per dyad, for their time and attention to the study protocol.

We anticipate Visit 2 will take 60 minutes.

Visit 3: The Graduate Research Assistant will visit the caregiver in his/her home or set up a virtual meeting via Zoom or telephone approximately one month after the recommendation system is initiated. Visit 3 will allow the research personnel to reinforce study training—including use of the smartphone, how to respond to text messages, and mindfulness techniques—and troubleshoot any issues that the caregiver may be experiencing.

We anticipate Visit 3 to take 30-45 minutes.

Visit 4: At the completion of the study, a trained GRA will visit the participant's home to collect the end of study measures, pay participants, and collect all study equipment. Additionally, interviews with participants regarding their feedback of the study procedures will be conducted and we will collect feedback via Smart Phones regarding the recommendations and their usability and acceptability. The interview that occurs during the course of the study will be video or audio recorded via Zoom and transcribed verbatim. The interview will take approximately 60 to 90 minutes. During the interview, all the recordings will be saved and retained in REDCap

until they are transcribed. The transcribed interview data will also be saved in REDCap and the recordings from the interview will then be destroyed. The identified information of participants who take part in the interview will be confidential. Caregivers will also have the option to complete end of study surveys and interviews virtually and place the study equipment in a container for the GRA to pick up outside the home. Caregivers will be given a checklist of items to gather and place in the study container.
We anticipate Visit 4 will take 60 to 90 minutes.

COVID-19 Procedures:

As a result of new COVID-19 guidelines and restrictions for in-person gatherings, steps have been taken to allow for virtual participant training, equipment installation, and data collection. Participant training and data collection may occur via Zoom video call or telephone and step-by-step equipment installation guides will be included in packaged study equipment, to be delivered or dropped off at participant homes. These steps remove the need for study personnel to enter participant homes. The consenting process will begin via telephone prior to Visit 1, with participants giving verbal consent over the telephone. The informed consent document will be delivered to participants with study equipment. Participants will provide written informed consent on this document and return to research personnel using "contact-free" techniques.

Personal information will be stored for five years following the completion of the study, per OSU guidelines.

Potential Risks to Human Subjects. The potential risks for this study are minimal but important. Participants may have anxiety and believe their privacy is being invaded from having their daily interactions being monitored. Participants will be reminded that there is no video capture of their activities, so that private activities, such as bathing, toileting, dressing, are not seen. There is a risk that abusive situations may be detected. If this is suspected, the PI (Rose) will be contacted, an assessment would be made and a follow-up plan will be developed that may include contacting a family member, contacting their healthcare provider, going to the Emergency Room, and/or reporting to the Department of Human Services Dependent Adult hotline in the county of residence. The consent form will address this issue. Participants will be reminded that participating in this study does not substitute for or replace their normal healthcare services, and that our project is not intended to be an emergency service of any kind. During the first study visit, caregivers will be asked to outline an emergency plan to reinforce that our project is not an emergency health provider. We will work with the caregiver to write an emergency plan for what they would do if an emergency did occur, such as calling their daughter, going to the Emergency Department, etc. Additionally, caregivers will be given information regarding mental health and caregiving resources available in the county and state of residence.

There is a potential of increased burden for caregivers from completing the surveys. Care has been taken to use instruments that have established, acceptable psychometric properties and are parsimonious. Caregivers will be assured they can stop completing the questionnaires at any time and finish at a later time or not finish at all with no adverse consequences. It has been our experience that caregivers welcome the opportunity to discuss difficulties they face and are eager to find solutions.

Our team will install all acoustic sensors in participants' homes OR participants will follow a detailed installation guide to allow for "contact-free" installation as this is simple and should take less than 60 minutes, which includes validating that the system is working. A research team member will check- in with the subjects each week that they are in the study and go to their homes to troubleshoot as needed. As the acoustic sensors used are not worn there is no risk of electrical interference and there is no risk related to interference with pacemakers, implanted electrical defibrillators, insulin pumps, or other invasive devices. Our team will provide caregiver participants with Smart Phones for use for study purposes only. We will train the caregivers on how to use the phone to receive text messages and to respond to daily and weekly surveys.

Planned procedures to protect against or minimize potential risks. The study will begin only after approval by the Institutional Review Board at participating universities. All investigators and graduate assistants associated with the study will complete required IRB training for the protection of human subjects prior to the beginning of the study. Potential participants will have a full explanation of the study, and those agreeing to participate will sign the consent form and be enrolled in the study. Exclusion criteria have been specified to protect the safety of participants.

Survey data for this study will be stored electronically in the centralized data storage server maintained by the College of Nursing at Ohio State University. Only IRB-approved research team members will have access to the stored data through a secure login. The College of Nursing provides secure file storage for research projects.

At Ohio State University:

- This server runs Windows Server 2012R2 and is only used to host research files. No unnecessary services are running. (No IIS, SQL, MS Office, FTP. Details available upon request.)
- The Windows operating system is kept up to date by weekly, automatic updates from Microsoft.
- The physical server is housed in a secure room within Newton Hall. Only pertinent IT staff and the building coordinator have keys to access this room.
- Electronic access to the research server is restricted to the college LAN or VPN by a Cisco ASA 5510 firewall. Access from the internet without VPN is not allowed.
- Electronic access is further restricted by the on-host Windows Firewall.

- User access is tightly controlled, by request only. New users must be cleared by the College of Nursing Associate Dean for Research.
- Permissions to individual folders and subfolders are managed individually. Users only have access to folders of projects in which they are directly involved. All changes are submitted in writing.
- Permissions are audited annually by IT in collaboration with the folder/study owner.
- The administrator account for the server has a non-standard password and has been disabled.
- All user accounts connecting to the server are domain accounts and are authenticated through a domain controller. Accounts are automatically locked out for 30 minutes after 5 invalid attempts.
- User access and system information is logged and exported to a central event logging server.

Acoustic data will be uploaded and transferred directly to the University of Virginia to Drs. Stankovic and Wang, for their analyses and storage.

At the University of Virginia: The Department of Computer Science provides extensive computing and communications resources in support of its activities at the University of Virginia. The Department provides a shared compute infrastructure of Linux x64 86 (primarily) and Solaris Niagara systems made up of interactive servers and batch scheduled (PBS) compute clusters. The department provides a transparent desktop environment (to match the shared infrastructure) and instructional labs as well. The department employs a systems group to help support this infrastructure and provide project specific IT support and infrastructure development as needed. The department's central storage facility, a Hitachi G200 disk array, is protected by RAID 5, and served by Linux/ZFS servers. It is backed up to the University Data Center every 12 hours. A Fortinet firewall blocks 'ssh' attempts and 'ping' scans from non-UVA subnets. This blocks around 1.2 million attempts per day. The access control policy to the Department's computational services is as follows,

1. The CS Department issues accounts to faculty, students, staff, visitors and research collaborators who are actively working in the department.
2. CS Department accounts are authenticated against a Windows Active Directory server.
3. Login ids are valid for Linux desktops and servers as well as Windows desktops.
4. Special purpose 'project' accounts are created for group use, but these accounts do not permit interactive login.
5. Users who do not have an active, official affiliation with the department must have a faculty sponsor for their account; sponsors will be asked to renew their sponsorship for each account yearly.

6. Graduate students are issued accounts when they matriculate to the university, and are removed when they depart.
7. Undergraduate students are issued accounts via helpdesk requests from a faculty member who is sponsoring the account.
8. System staff accounts are maintained for one month after a staff member has separated from the department; staff accounts are treated in a similar fashion to student accounts; a current faculty member may continue to sponsor the staff account, subject to the annual renewal.
9. Faculty are issued accounts as soon as they have joined the university, and are retained for one month after they separate from the university. If they have an ongoing research or instructional relationship with the department, another faculty member may sponsor their account, subject to annual renewal.
10. The user is notified that their account is scheduled for deletion. They have one month to backup or copy off any data they wish to retain from our systems.
11. Deleted account home directories are not archived.
12. Websites created by faculty or students off the Dept's web page will be removed on the same schedule as that for account deletion.
13. Users receiving new accounts must abide by the Acceptable Use Policy.

Protection of confidentiality. Confidentiality of all participant identifiable information and data will be maintained. Participants will be informed of their rights to privacy and confidentiality on the study consent form. The consent form includes IRB-approved information on the Health Insurance Privacy and Portability Act Protection of Human Subjects (HIPPA) regulations. All participants will be assigned numbers for identification purposes that will be used on all study materials and computer files. Data collected in the study will be de-identified upon study completion and may be used in future research or studies without additional consent.

The participant consent encounter will be conducted using a REDCap-based electronic consent form. The consent form has been developed in REDCap, a secure, web-based, HIPAA-compliant, data collection platform with a user management system allowing project owners to grant and control varying levels of access to data collection instruments and data (e.g. read only, de-identified-only data views) for other users. Potential participants will participate in the consent process by:

Self-initiated access of consent forms on personal portable electronic devices using posted QR codes or web-links on study posters, brochures, or websites. Self-initiated accessing of consent forms may occur at The Ohio State University campus or at home.

For self-initiated consent, contact information will be provided (email and phone) for prospective participants to contact a member of the study team with questions, prior to consent.

Participant signatures will be obtained using a typed name and electronic signature via mouse. Upon completion of the consent encounter, participants will be provided with a copy of the consent document by printing a pdf copy of the consent form.

The recordings from the interview during the study will be saved and retained in REDCap until they are transcribed. The transcribed interview data will also be saved in REDCap and the

recordings from the interview will then be destroyed. The identified information of participants who take part in the interview will be confidential.

Project monitoring. The PIs will have responsibility for verifying the completeness of the collected data and will ensure compliance with all study requirements. The PI (Rose) will verify that a signed informed consent is available for all patients and will check the battery of measures for completeness.

Infection control protocol. Entering and exiting participant homes introduces risk of transmission of infectious processes. Study participants are at increased risk of infection; therefore, the research personnel will take extra precautions to protect against transmission of infectious processes. Efforts have been made to limit in-person contact with participants. Visits 1-4 will be conducted either in-person or virtually and participants will have the option to place study equipment outside their home for retrieval by the GRA.

When in-person contact is unavoidable research personnel will adhere to the following procedures:

Pre-Visit:
Check their temperature prior to leaving the College and/or their home for a visit. Team member temperatures, along with the visit date, shall be documented the study folder. Any team member presenting with a fever will stay home from work and absolutely not be in contact with participants. Clean and sanitize any equipment to be brought in to the home.

Visit:
During the visit, research team members will wear gloves for any physical contact with a participant. Where possible, team members will maximize the distance between them and participants. Hands will be washed before and after visits, and common sense measures such as covering sneezes or coughs will be used.

Post-Visit:
Disinfecting equipment is already standard procedure, but due to heightened risk these cleanings will be documented. We are employing a simple log with the date, participant ID from the visit, and the name of the team member cleaning the equipment.

COVID-19 precautions. Additional precautions will be taken to control the spread of the coronavirus until widespread vaccination of the general public has occurred. In addition to the above infection control measures, the study team will monitor and document any of their own symptoms consistent with coronavirus and will self-quarantine and not conduct any study visits for at least 14 days. Additionally, research personnel will screen study participants prior to scheduling a home visit and determine the need to delay the visit. The following screening tool will be used to determine the need for a delay.

Subject ID (use screening ID if not enrolled yet): _____

Date: _____

Visit Type: _____

Visit Date: _____

1. Have you been out of the country in the last 2 weeks?	
2. Have you had any flu like symptoms in the last week?	
3. If yes to question 2 - What symptoms have you had?	
4. Has you been in contact with anybody who has traveled internationally lately? If so where?	
5. Has anybody in your household traveled internationally lately? If so where?	
6. Have you or anybody in your household traveled within the US lately? If so where?	
7. Have you had a fever?	
8. Have you had chills?	
9. Have you had a cough?	

If a determination has been made that a two week delay is necessary:

May we contact you in two weeks? Yes ☐ No ☐

Staff Name: _____

If a participant answers yes to questions 2+3, 7, 8, or 9 (symptom questions), scheduling visits with the participant will be delayed for at least 14 days per Ohio State's current self-quarantine and monitoring guidelines. If a participant answers yes to any of the travel questions, a holistic, case-by-case risk assessment should be conducted. For now, our lab is recommending a two week delay for the following:

1) Direct contact with an individual diagnosed with COVID-19.
2) Any individual who:
    a. Meets the recommended Ohio State guidelines for self-quarantine (e.g. travel to a level 3 country).
    b. Has had direct contact with an individual meeting the recommended Ohio State guidelines for self-quarantine (e.g. travel to a level 3 country).

Any individual who answers yes to any of the symptom questions above (2+3, 7, 8, 9).

Potential benefits of the proposed research to the subjects and others. The potential benefit of this study is improving home-based dementia care. If the findings from our study support we can sense and report caregiver/care recipient patterns of behavior that may add to stress and mood changes in the dyad, we will have data to support the development and implementation of additional interventions to assist caregivers in providing in-home care. These passive, wireless sensors have the potential to collect valid, reliable data in a more normal environment, home settings, without the need for research assistants to be present. Thus, the science to examine clearly the linkages between caregiver and care recipient behavioral changes will be advanced in significant ways, with the potential to intervene more effectively on these distressing symptoms.

Monetary incentives. As payment for their time and attention to the elements of the study protocol, all families will receive $300 at the completion of the 3-month end of measurement of outcomes, in $100/monthly increments.

Importance of the Knowledge to Be Gained. There may be immediate benefit to the subjects participating in the study, although we do not guarantee this, as family caregivers will be given specific knowledge and helpful reminders to mitigate potentially problematic behaviors regarding care of their loved one with ADRD. If successful, the knowledge gained will be important because of its substantial potential to enhance the treatment of difficult to manage, prevalent, and burdensome care problems of persons with ADRD, increasing their quality of life, reducing caregiver burden, delaying or reducing institutionalization, and decreasing the costs of caring for persons with AD in the future.

E. Internal Validity

The purpose of this study is primarily to establish feasibility and test the model. If we can establish that our system reduces emotional reactivity and that patient and caregiver self-reported and observed outcomes improve over time compared to an individualized baseline period, we will have established justification for a more comprehensive design that will more fully test this system against a credible alternative.

Thus, the caregivers will fill out the measures provided to them and then their interactions with the patients will be monitored for a month to establish a baseline of functioning. We will assess levels of reactivity during caregiver-patient interactions and the time it takes for them to return to their own baseline. At the end of the one-month assessment period, the caregiver will be brought in for training on the recommendations, after which they will receive recommendations when the system detects emotional reactions when the caregiver and patient are with each other. The recommendations will be personalized over time. Effectiveness of the recommendations will be assessed by examining whether the recommendations reduce the frequency and intensity of the negative patient-caregiver interactions and the time required for reactivity to return to baseline in real time, as assessed by information recorded by the monitoring system. Effectiveness also will be assessed by monitoring change in the self-report measures during the baseline period compared to the period in which the caregiver is receiving the recommendations.

At the end of the 3-month period, we will conduct individual interviews with caregiver participants to gather their feedback regarding the recommendations and their suggestions for improvement (e.g., mindfulness and environmental modification training, text messages, timing of messages). The interviews that occur during the course of the study will be video or audio

recorded via Zoom and transcribed verbatim. The data will be summarized and categorized and will inform future work in this area.
The PI will train the GRAs on all aspects of the study protocol. To ensure fidelity of the mindfulness training recommendations, a checklist for assessing the fidelity of delivery of mindfulness/environmental modification caregiver training will be developed.
The PI will conduct GRA training for the mindfulness/environmental modification caregiver training recommendations. The GRAs will need to achieve a minimum of 90% success in the fidelity assessment before they will be able to train caregiver study participants. Retraining of GRAs will be offered to address any deficits. The results of these fidelity checks will be shared with the study team. If fidelity checks fall below 90%, retraining of GRAs will be undertaken by the PI's.
Participant dyads will be compensated $300 at the completion of the 3-month end of measurement of outcomes, in $100/monthly increments; they may opt out at any time in the period of study.

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