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PROTOCOL

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Smarthealth technology study protocol to improve relationships between older adults with dementia and family caregivers

Karen M. Rose[1] | Kristina Coop Gordon[2] | Emma C. Schlegel[1] | Matthew Mccall[2] | Ye Gao[3] | Meiyi Ma[3] | Katherine A. Lenger[2] | Eunjung Ko[1] | Kathy D. Wright[1,4] | Hongning Wang[3] | John Stankovic[3]

[1]College of Nursing, The Ohio State University, Columbus, OH, USA

[2]Department of Psychology, University of Tennessee-Knoxville, Knoxville, TN, USA

[3]School of Engineering and Applied Science, Computer Science, University of Virginia, Charlottesville, VA, USA

[4]Discovery Themes-Prevention and Treatment of Chronic Brain Injury Institute, The Ohio State University, Columbus, OH, USA

Correspondence
Karen M. Rose, College of Nursing, The Ohio State University, 1585 Neil Avenue, Columbus, OH 43210, USA.

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Abstract

Aim: The aim of this study is to develop a Smarthealth system of monitoring, modelling, and interactive recommendation solutions (for caregivers) for in-home dementia patient care that focuses on caregiver–patient relationships.

Design: This descriptive study employs a single-group, non-randomized trial to examine functionality, effectiveness, feasibility, and acceptability of the novel Smarthealth system.

Methods: Thirty persons with Alzheimer's Disease or related dementia and their family caregivers (N = 30 dyads) will receive and install Smarthealth technology in their home. There will be a 1-month observation phase for collecting baseline mood states and a 2-month implementation phase when caregivers will receive stress management techniques for each detected, negative mood state. Caregivers will report technique implementation and usefulness, sent via Ecological Momentary Assessment system to the study-provided smartphone. Caregivers will provide daily, self-reported mood and health ratings. Instruments measuring caregiver assessment of disruptive behaviours and their effect on caregivers; caregiver depressive symptoms, anxiety and stress; caregiver strain; and family functioning will be completed at baseline and 3 months. The study received funding in 2018 and ethics board approval in 2019.

Discussion: This study will develop and test novel in-home technology to improve family caregiving relationships. Results from this study will help develop and improve the Smarthealth recommendation system and determine its usefulness, feasibility, and acceptability for persons with dementia and their family caregiver.

Impact: The Smarthealth technology discussed will provide in-home stress reduction resources at a time when older adults may be experiencing increasingly high rates of isolation and anxiety and caregiver dyads may be experiencing high levels of relationship strain.

Trial Registration: This study was registered with Clinical Trials.gov (Identifier NCT04536701).

KEYWORDS
Alzheimer's Disease, caregivers, caregiving, dementia, mindfulness, nursing, stress, technology

1 | INTRODUCTION

More than three quarters of persons with Alzheimer's disease or a related dementia (ADRD) are cared for in their homes (Alzheimer's Association, 2016). Informal caregivers, often family members, bear a large burden of in-home care for persons with ADRD and many of these family caregivers experience higher levels of stress associated with poorer health outcomes for both the caregiver and the person with ADRD, often resulting in higher rates of institutionalization (Stall et al., 2019). Smarthealth technologies allow researchers to meet caregivers and persons with ADRD in their home environment and provide stress-management resources in real time. The goal of the current study is to develop a monitoring, modelling, and interactive recommendation solution for in-home dementia patient care to detect caregiver–patient relationship strain and provide mindfulness-based stress management tools. This study will use a novel Smarthealth acoustic monitoring technology and online learning recommendation system to identify mood states and provide mindfulness-based stress management tools (e.g., taking a time out, performing deep breathing exercises, performing a mindful body scan, and engaging loved ones in pleasurable activities) to family caregivers.

2 | BACKGROUND

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 behaviours and emotions is elicited. While family caregivers report many positive aspects of their caregiving experience (Yu et al., 2018), caregivers also report anxiety and depression and many forego their own health needs as the demands of being a family caregiver are sustained over many years (Schulz et al., 2006; Schulz & Martire, 2004). Behavioural responses to stress, as exhibited through problematic behaviours in persons with ADRD, have been linked to higher levels of caregiver stress (Davis et al., 1997; Sink et al., 2006). Now, amid a historic pandemic (Cucinotta & Vanelli, 2020; Ghebreyesus, 2020), stressors experienced by family caregivers have been compounded by increasing isolation, anxiety, and suicidal ideation (Czeisler et al., 2020) and lack of community-based services, such as adult day care, as a result of the pandemic and the mandate for social distancing to prevent spread of COVID-19.

2.1 | Smarthealth technologies

In-home monitoring systems, a form of Smarthealth technologies (Becker et al., 2008; Helal et al., 2005; Intille et al., 2005; Kientz et al., 2008; Ko et al., 2010; Papangelis et al., 2011; Rantz et al., 2012; Skubic et al., 2009), have been recently developed as a solution to facilitate in-home dementia family care. These systems have the potential to reduce the dependence on outside, paid personnel for in-home care and enable real-time monitoring with low cost. Current systems developed for in-home monitoring systems focus more on tracking patients' behaviour, but one important factor in in-home monitoring—the relational dynamics between the person with ADRD and caregivers—is understudied.

Pre-existing family characteristics can be either protective or aggravating for the caregiver's experience of providing care (Fisher & Lieberman, 1996; Kriegsman et al., 1994). Caregivers who report lower family functioning also report greater strain and feelings of burden (Heru & Ryan, 2006; Heru et al., 2004). Family qualities that increase caregiver's sense of strain include unresolved problems (Teusink & Mahier, 1984), decreased intimacy (Morris et al., 1988), and higher criticism of the patient (Gilhooly & Whittick, 1989). On the other hand, families who develop more adaptive skills, such as mutual acceptance and seeing the person as separate from the illness, report less strain (Mannion, 1996). Thus, the "stress process model" (Lawrence et al., 1998) of family relationships suggests that the quality of the relationship between the caregiver and patient can modify the effects of the illness so that a good relationship can ameliorate and a distressed relationship can exacerbate the stressful effects of the patient's illness (Heru & Ryan, 2006). It appears that caregiving relationships characterized by poor communication, impaired problem-solving skills, and low affective involvement creates caregiver burden; thus, these deficits are important targets for improvement (Heru et al., 2004).

2.1.1 | Acoustic monitoring and mood state recognition

Many attempts have been made to detect a speaker's mood via audio using machine learning (Altun & Polat, 2007; Barros & Wermter, 2016; Danisman & Alpkocak, 2008; Noroozi et al., 2017). These solutions use audio clips that are trained on published datasets of emotional speech by actors (Cao et al., 2014; Dupuis & Pichora-Fuller, 2010; Haq & Jackson, 2011; S. Lee et al., 2005; Livingstone & Russo, 2018). The clips are collected from laboratories or studios with high-end acoustic equipment to ensure the highest quality of the voice. Despite achieving high accuracy when tested, most of the techniques are not suited to be deployed in homes of caregiver–patient dyads because the testing does not consider realistic complications. In particular, voice samples in homes are subject to reverberation, background noise, and deamplification.

Apart from these complications, another major challenge is getting samples of all possible human emotions to train a machine

learning model, which is impossible. The datasets on which many of the techniques are developed consist of only a subset of the common emotions, such as happiness, anger, neutrality, sadness, disgust, fear, and calmness. In real deployments, it is necessary to account for how other emotions affect the accuracy of detecting the ones of interest.

Our acoustic monitoring and mood state recognition address these challenges. The realistic issues are addressed in our solution by subjecting the original samples from the datasets (Cao et al., 2014; Dupuis & Pichora-Fuller, 2010; Haq & Jackson, 2011; S. Lee et al., 2005; Livingstone & Russo, 2018) to a process of sound deterioration to emulate reverberation, noise, and deamplification. Copies of the original samples are retained and combined with the modified samples in the training, ensuring that the model has knowledge of both pristine, high-quality audio samples and audio samples influenced by the effects of reverberation, background noise, and deamplification. As a result, our model, a convolutional neural network (CNN) classifier detects happiness, anger, neutrality, sadness, and is suitable for deployment in home environments.

To handle the issue that other emotions not of interest might exist, we will employ the technique of out-of-distribution (OOD) detection (Lee et al., 2018). This technique recognizes audio samples that do not resemble the training samples and prevents them from being classified, under the assumption that the representation of, for example, fearful speech, which is not of interest differs significantly from the representations of happiness, anger, neutrality, and sadness which are of interest. Consequently, when a model trained on a subset of emotions encounter samples that do not belong to any of the classes in the training data, the OOD technique rejects the samples.

2.1.2 | Intelligent recommender system

The use context of in-home monitoring systems is dynamic; to increase the utility of a system's generated recommendations and the end users' acceptance of the recommendations, it is important that the system models the context (e.g., whether the caregiver is in a good mood or high stress level and whether he/she has taken the system's previous recommendations). Therefore, we take a holistic view of a caregiver's interaction history with the system and all available observations about his/her current behaviours to decide the next optimal action for recommendation, via a contextual bandit algorithm (Li, Chu, Langford, & Schapire, 2010).

2.2 | Incorporation of stakeholder needs

Focus groups were conducted with family caregivers of ADRD patients to assess attitudes towards an in-home vocal monitoring system. Support groups for ADRD family caregivers were contacted and three support groups agreed to participate. Nine caregivers shared their experiences with caregiving-related stress and provided input on the monitoring system. Notable themes included difficulty in relationships with their care recipients, a desire to receive encouraging words from the system and privacy concerns.

Caregivers disclosed that loved ones' dementia-related behaviours can produce strain in their relationship with the care recipient. Describing feelings of exasperation about repetitive behaviour, one participant said, "It's the same five questions … it's constant, it is all day long and that's my struggle." Participants acknowledged difficulty implementing self-regulation strategies during frustrating interactions, which reinforces the potential utility of the proposed system.

Several caregivers expressed a desire for the system to deliver encouraging words and not only reminders of self-regulation strategies. One caregiver expressed she would prefer, "…some kind of reminder of, 'Hey, you're doing okay,' rather than, 'Do this.' It's sort of like you're handling this very well." Another caregiver said, "[Encouragement] would be helpful to me, because I'm so down on everything I'm doing, thinking I'm doing everything wrong." These insights inspired the development of new tools within the recommendation system to address the issue of guilt around caregiver self-care and to provide a source of encouragement alongside tips and tricks to employ.

Finally, various caregivers spoke differently about whether a monitoring system would create privacy concerns. Some caregivers expressed significant concerns, saying, "It's too invasive!" and, "I don't know how to address the problem of feeling like you're under surveillance." Other caregivers did not hesitate to embrace the idea: "And you know, you've got that front doorbell thing now, you've got Alexa, there's so many things. What's another?" These remarks indicated that recruitment materials should clearly describe all measures being taken to protect participants' privacy throughout the study. Privacy-related discomfort may be a significant barrier for some prospective participants and therefore the proposed system might not be an optimal solution for all caregivers.

Evidence supporting the presence of caregiving burden identified gaps in stress reduction programming for caregivers of persons with dementia, improvements in technologies that can allow in-home delivery of such programs, and participant insights about acceptability of technologies derived from focus groups with family caregivers have all contributed to the development of this study's research questions. To address these identified gaps and advancements, this study will develop and deploy a Smarthealth system using acoustic monitoring and intelligent recommendations to improve positive caregiver emotional regulation and caregiving relationships. We aim to answer the following research questions: (1) With what level of functionality and accuracy can we identify patient–caregiver conflict/mood states and deliver appropriate mindfulness-based stress management techniques using an in-home acoustic monitoring and intelligent recommendation system? (2) How effective are mindfulness-based stress management techniques and encouraging words, delivered via an in-home Smarthealth system, at reducing

caregiver strain, stress, loneliness, depressive symptoms, and anxiety; and improving the caregiving relationship and caregiver self-rated health?

3 | METHODS

3.1 | Aims

The aims of this study are to (1) develop and deploy a functional, in-home Smarthealth acoustic monitoring and intelligent recommendation system to identify patient–caregiver conflict and provide stress management techniques in real time; (2) determine the feasibility and acceptability of this system with a population of persons with dementia and their family caregiver and identify areas for system modification and improvement; and (3) measure system efficacy to reduce caregiver strain, stress, loneliness, depressive symptoms, and anxiety and improve caregiving relationships and caregiver emotional health.

3.2 | Study design

The 3-month, single group, descriptive, feasibility study includes 1 month of baseline data collection on caregiver–patient relationship functioning and participant mood states. Subsequently, researchers will test the effectiveness of the mood state recognition and intelligent mindfulness-based recommendation system in reducing caregiver stress levels over a 3-month period. Monitoring emotional reactivity between patient and caregiver could signal when problematic interactions might be occurring. Just-in-time or even predictive recommendations in those moments could improve these interactions and reduce strain on caregivers.

3.3 | Sample

The study sample will be drawn from eligible patients receiving treatment from a memory clinic at a university academic hospital system in the Midwest. Inclusion criteria for persons with dementia include: 1) Females or males; 2) age 60–90 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. The inclusion criteria for family caregivers are as follows: 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 (Burgio et al., 2003). Exclusion criteria for persons with dementia include: 1) presence of acute illness; 2) alcohol abuse or dependence within the past 2 years (DSM-IV criteria); or 3) history of significant psychiatric illness (e.g., schizophrenia).

3.4 | Data collection

3.4.1 | Equipment and procedures

Enrolled participants will identify one or more common rooms in their home for placement and installation of the laptop computer(s), microphone(s), and network router (See Figure 1 for set-up details). Study personnel will encourage placement in a room or rooms where frequent interactions between persons with dementia and the family caregiver occur. Participants will be given a smartphone to receive stress management tips and send survey feedback to the study team and intelligent recommender system. Participants will complete questionnaires at baseline and after the 3-month monitoring period. Additionally, participants will complete an acceptability and feasibility interview at the conclusion of the study. Participants are expected to engage in four study visits lasting approximately 30–90 min. On completion of screening, enrolment, and the verbal consenting process via telephone, participants will schedule an initial study visit. A list of activities for each study visit is provided below:

1. Visit 1: Obtain written informed consent; collect baseline study data; install the acoustic monitor (microphone(s)) and accompanying laptop computer(s) in the participant's home; provide study smartphone to participants for receiving recommendations and providing feedback to the study team through daily and weekly surveys; provide written and verbal instructions on the use of the acoustic monitoring and the smartphone; establish an emergency plan formulated with the family caregiver to further reinforce that the study is not a substitute for seeking medical care for themselves or for their loved one with ADRD in the event of an emergency
2. Visit 2 (Between 2 weeks and 1 month)): provide training on mindfulness-based stress management tools, provide training on use of the study smartphone to receive stress management recommendations, and respond to all follow-up surveys
3. Visit 3: Reinforce all aspects of the study protocol to ensure caregiver understanding of study procedures.
4. Visit 4 (End of Month 3): Collect end of study measures, collect all study equipment, conduct feasibility, and acceptability interviews with participants.
5. Participants will receive a modest financial incentive for completion of study visits.

3.4.2 | Measures

Demographic data will be collected at baseline. Cognitive status of the person with ADRD will be measured by the Modified Mini-Mental State test (Teng & Chui, 1987) and the Self-administered Gerocognitive Examination (Scharre et al., 2010). To measure caregiver mood and emotional reactivity at baseline and 3 months, we will use the Depression

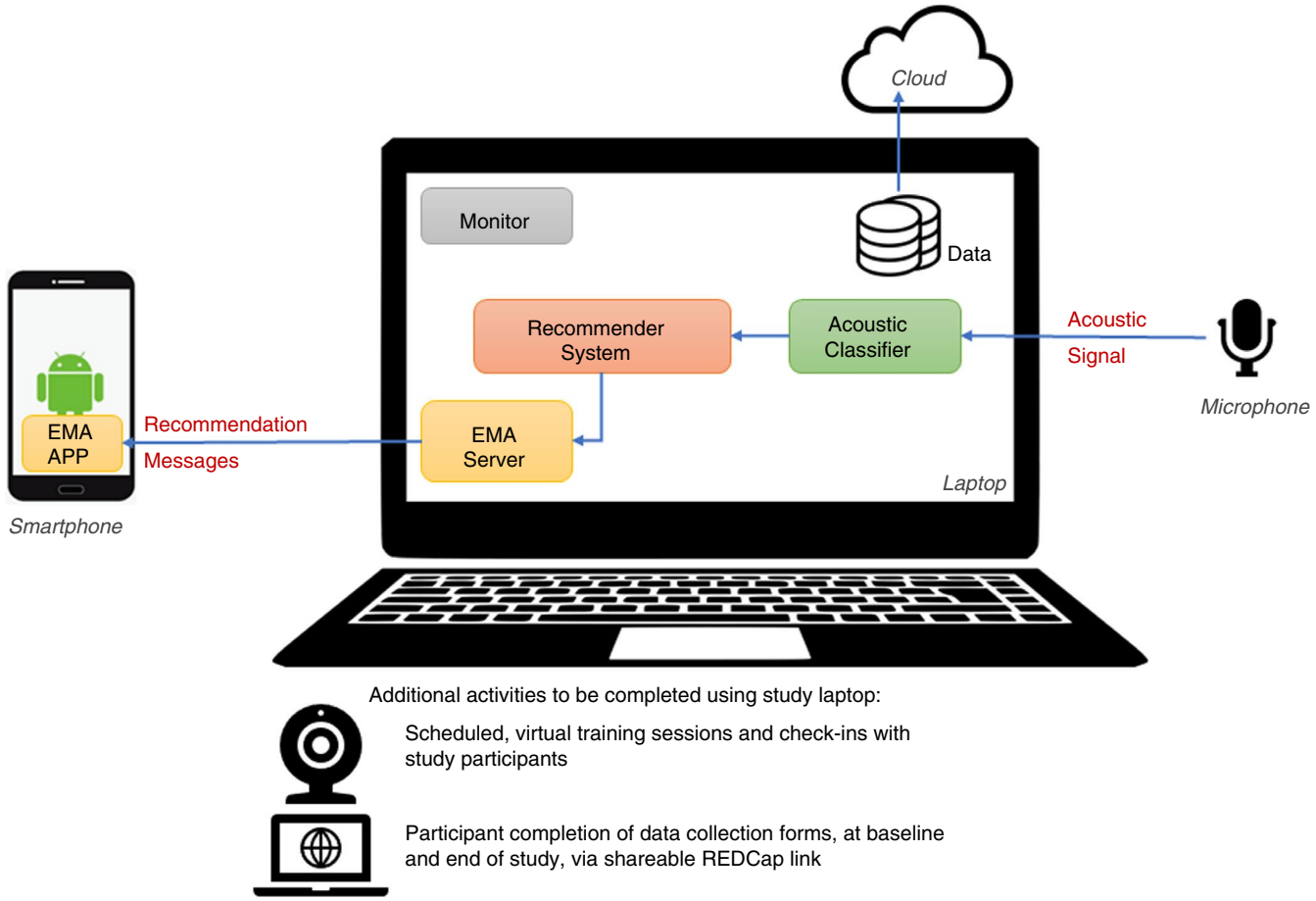

FIGURE 1 Study equipment function and procedural use. This figure provides an overview of smarthealth technology system. EMA, ecological momentary assessment [Colour figure can be viewed at wileyonlinelibrary.com]

Anxiety Stress Scale (DASS; Parkitny & McAuley, 2010), the Revised Memory and Behavior Problems Checklist (Teri et al., 1992), and the Caregiver Strain Index (Thornton & Travis, 2003).

Participants will also respond to questions posed via an Ecological Momentary Assessment system. During month 1 of baseline data collection, when the system identifies a mood state (happy, calm, neutral, sad, angry), a binary yes or no question will be sent to the study smartphone. The question will indicate a mood state that has been detected and ask whether the system correctly identified the participant's mood at that time. For the entire 3-month study period, caregivers will also respond to a series of Likert scales each evening. These Likert scales will ask the caregiver to rate their stress, loneliness, physical health, and emotional health on a scale from 0 to 10. During the 2-month recommendation period, caregivers will also respond to questions regarding implementation of and effectiveness of the recommended stress management technique 30–60 min after receipt of a recommendation.

3.4.3 | Stress management recommendations and encouraging words

To deliver the stress management recommendations and encouraging words, we will use an Ecological Momentary Assessment (EMA) system that was developed at University of Southern California (University of Southern California, 2020). The EMA will be installed on a workstation deployed in the patient homes, which connects the acoustic monitoring system, the rule-based recommendation system, and an EMA app on a smartphone to send recommendation messages to caregivers.

Encouraging words will be delivered each morning during the 2-month recommendation period. These messages will include a prompt to reflect on the positive aspects of caregiving and provide reminders in the form of encouraging words. The positive aspects of caregiving are based on Yu et al.'s (2018) work and are categorized into five categories—general encouragement, sense of personal accomplishment and gratification, feelings of mutuality in a dyadic relationship, increase in family cohesion and functionality, and sense of personal growth and purpose in life. Inclusion of encouraging words is the direct result of feedback provided by caregivers during focus groups.

Stress management recommendations will be sent throughout the day when a negative mood state is detected by the acoustic monitoring system. Caregivers are expected to implement the recommendation within 30–60 min of receiving the EMA message. Thirty to 60 min after the caregiver receives the recommendation message, the EMA system will send a survey question to collect caregiver

feedback on the effectiveness of the recommendation, such as "On a scale from 1–10 how helpful was the stress management tip?" This feedback is sent to the recommendation system to estimate the effectiveness of each generated recommendations, with a goal to keep improving effectiveness for future recommendations.

We will provide family caregivers with an instructional handout and brief training on four stress management techniques: (1) emotion regulation and (2) time-out techniques (Epstein & Baucom, 2002; Gordon et al., 2018), as well as (3) brief mindfulness training (Lenger, 2020) and (4) environment modification techniques to increase emotional acceptance (Khaddouma et al., 2017), before the deployment of the system. Strategies will also be reinforced throughout the study period. Caregivers will also be referred to the UCLA Mindful Awareness Center to practice these exercises. Randomized control trials indicate that brief psychoeducation on mindfulness and self-guided practice using online exercises significantly reduce depression and anxiety (Cavanagh et al., 2013, 2018) and a brief intervention involving training in mindfulness and ecological momentary assessment strategies, which is similar to this project's methodology, significantly increased mindfulness skills (Ruscio et al., 2016). These techniques will be adapted over time based on monitored data from the system and what we learn from our deployments.

The first category of recommendations, breathing awareness, is an effective and brief strategy to reduce physiological and emotional arousal both in non-clinical and clinical populations (Barlow, 2014; Lloyd et al., 2000). The second category, a brief time-out from the interaction has been demonstrated in multiple studies on dyadic interactions to be effective in ameliorating problematic exchanges and reducing emotional reactivity (Epstein & Baucom, 2002; Gordon et al., 2018). The third category, a brief mindfulness exercise, focuses on non-judgment and acceptance. Mindfulness strategies have been shown to reduce stress in caregiver populations (Lindsay et al., 2018; Slatyer et al., 2018), be an effective technique in reducing emotional dysregulation in dyadic conflict (Khaddouma et al., 2017), and reduce emotional reactivity and improve communication in more general studies (Jones & Hansen, 2015; Khaddouma & Gordon, 2018; Lenger et al., 2017; Lindsay et al., 2018; Steffen & Larson, 2015).

The fourth category—aligned with the "Savvy Caregiver" program—is based on recommendations to modify the environment and engage persons with dementia in a pleasurable activity. The "Savvy Caregiver" program is a product of our study consultant, Dr. Kenneth Hepburn (Hepburn et al., 2006, 2007; Ostwald et al., 1999), and based on addressing unmet needs and on aligning caregiver expectations with the abilities of the person with ADRD. Caregivers will be provided information regarding the need to address potentially unmet basic care the recipient needs, such as toileting and hunger, and will be asked to identify three or four 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 tailored to the particular interests of the participants. Individualized, social activities are found to be efficacious and cost-effective in redirecting a person with ADRD and to decreasing disruptive behaviours (Gitlin et al., 2010; Hulme et al., 2010; Yaffe & Hoang, 2013).

3.5 | Ethical considerations

Institutional Review Board approval (IRB#2019B0406) was received for this study protocol and the study was listed on ClinicalTrials.gov (Identifier NCT04536701).

3.6 | Data analysis

Descriptive statistics will be used to identify changes in levels of caregiver depression, anxiety, and stress; caregiver strain; and family functioning at baseline and post-intervention. Repeated measures of caregiver stress, loneliness, and physical and emotional health will be analysed for longitudinal changes over the course of the study period. Data from daily surveys about recommendation implementation and effectiveness and a structured qualitative interview with study participants at the end of the 3-month period will be analysed to determine feasibility and acceptability of the Smarthealth system and stress management techniques.

3.7 | Validity and reliability

Trained graduate research assistants will train study participants on use of the Smarthealth system and each of the four mindfulness-based stress management techniques using a standardized training manual to ensure intervention fidelity. The training manual was developed by experts in mindfulness-based therapy techniques and reviewed for diverse cultural inclusivity and competency. The study team will also engage in periodic review of study procedures and re-training (as needed) with study participants over the course of the study. Study instruments have confirmed reliability, validity, and sensitivity (Parkitny & McAuley, 2010; Scharre et al., 2010; Teng & Chui, 1987; Teri et al., 1992; Thornton & Travis, 2003).

4 | DISCUSSION

The strain of keeping a family member with ADRD safe at home can create a significant and costly burden on caregivers. The relationship quality between the family caregiver and the person with ADRD is an integral characteristic that may influence the course of maintaining a loved one with dementia in their home environment. Although difficult family interactions can increase caregiving stress and burden, careful moment-to-moment study of such interactions and their impact on caregiver functioning has yet to be examined.

One healthcare challenge is to better understand how these daily interactions affect mood and stress and to understand what kinds

of responses can ameliorate these problems as they are occurring. Current efforts to reduce caregiver anxiety and burden tend to be long and resource heavy, thus researchers are calling for briefer and more portable stress and mood management strategies that could be integrated into existing primary care services and more likely to be used by recipients (Brown et al., 2016; Shepardson, Funderburk, & Weisberg, 2016). The proposed solution is to employ in-home technologies (smart phones, microphones, machine learning, and textual feedback) to monitor, model, and then suggest (adaptive) recommendations for the caregivers.

Development of the study protocol occurred through leverage of interdisciplinary expertise and problem solving in the fields of gerontologic nursing, relationship psychology and counselling, and computer science engineering. The three disciplinary perspectives created a novel protocol that addresses urgent needs of the ADRD caregiving population at a time when in-home programming may be becoming the preferred mode of delivery for caregiver support.

4.1 | Modifications related to COVID-19

Protocol refinement coincided with the start of the Coronavirus Disease 2019 (COVID-19) pandemic (Cucinotta & Vanelli, 2020) that reduced researchers' abilities to safely conduct in-person research activities. Thus, important considerations for the implementation of post-pandemic research and programming for older adults were considered. In response to COVID-19, previously planned home visits were converted into virtual meetings with participants. As such, the option to perform participant training and data collection via Zoom video call or telephone was included in the study design 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 decrease the need for study personnel to enter participant homes. The consenting process will occur using 'contact-free' techniques via telephone or Zoom and the research team will obtain either verbal, written – delivered with study equipment –, or virtual consent via REDCap (Harris et al., 2009, 2019).

In response to the COVID-19 pandemic, further infection prevention and control measures have been implemented to protect the health and well-being of the participant population. Efforts have been made to limit in-person contact with participants. Visits 1 through 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 study personnel. These additional precautions will continue until widespread vaccination and immunization of the general public has occurred. When in-person contact is unavoidable research personnel will adhere to current Centers for Disease Control and university-approved procedures for contact during research activities. Efforts to provide in-home services for caregivers have become increasingly important during COVID-19. Protocol modifications will allow the study team to offer these services virtually. These modifications may increase scalability of the study methods for widespread implementation and uptake of the study at a time when the study population is at an increased risk for social isolation, stress, and relationship strain. Furthermore, the decision to convert into virtual study activities will allow our research team to reach a vulnerable population at a time of increased isolation and provide tools to reduce stress and caregiver strain at a time of high anxiety and fear.

4.2 | Limitations

This study has several limitations in terms of attrition and the study procedure. First, the study population may be limited because of difficulty in using the technological devices and potential invasion of privacy issues. In addition, caregivers participating in this study may experience burden as a result of the need to keep the study phone with them throughout the day. These possibilities may cause an increase in the drop-out rate among eligible dementia caregivers in this study.

To reduce these concerns, we intend to provide participants with detailed training and training manuals about device set-up and use. Efforts to protect their privacy have been incorporated, including letting participants choose where study equipment will be placed in their home and opting to collect audio data only. Based on feedback from study participants, the study team may also provide a belt clip for the study phone in an attempt to reduce participant burden. The mindfulness-based intervention provided by the Smarthealth system will help improve dementia caregivers' emotional distress and presents little to no harm, therefore there is little potential of attrition bias related to the stress management intervention. Recruitment will be performed at a single clinical site; limiting the study sample to individuals who are current patients of the clinic. The participant pool may not necessarily represent a broader population, such as those with limited access to university-level care, which may limit generalizability of study findings.

This study will have no comparator group, which may limit our ability to quantify and compare the effects of the Smarthealth system delivery and the mindfulness-based stress management training provided at the beginning of the study. To address this potential limitation, we have incorporated 1 month of baseline data collection to measure caregiver stress, loneliness, and physical and emotional health prior the caregivers receiving training on mindfulness-based stress management techniques. Another limitation is that current emotion classification data does not allow for system training of every possible human emotion. Although this novel technology has established state-of-the-art algorithms that can identify and categorize certain caregiver emotions, they are not able to detect certain complex feelings, such as despair or shamefulness. Therefore, additional development of emotion recognition technology is still needed.

Biological measures, such as salivary cortisol level, are not measured in this study. Although self-reported scales used in this study are validated and reliable, the importance of biological measures

in examining stress cannot be excluded. Therefore, future studies should use both biological and self-reported outcome measures.

Moreover, the COVID-19 pandemic necessitated multiple significant changes to study procedures to convert from in-person to virtual delivery, which may affect this study population of older adults more so than potentially less technologically naive populations. These unanticipated changes may make it more difficult to maintain consistent communication with participants, ensure the Smarthealth system is installed correctly, and provide participant training.

5 | CONCLUSION

Family caregivers of persons with ADRD experience adverse health outcomes related to caregiver burden and increased stress. This study aims to develop and implement in-home smarthealth technology that will provide real-time conflict and stress management via delivery of mindfulness-based stress management techniques. Findings from this study will provide valuable feasibility data for this novel Smarthealth technology and will provide insight on the potential ability of continuous stress management to reduce caregiver stress and loneliness and improve health outcomes. Data from this study will support future research on long-term, caregiver health outcomes. This novel study will provide meaningful findings related to the role of in-home Smarthealth technology in reducing caregiver stress and provide a crucial tool for caregivers during a pandemic that has isolated individuals and increased caregiver strain and stress.

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CONFLICTS OF INTEREST

The Author(s) declare(s) that there is no conflict of interest.

The study protocol was approved by the Ohio State University Social and Behavioral Human Subjects Committee (IRB#2019B0406). This study was registered with Clinical Trials.gov (Identifier NCT04536701).

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ORCID

Karen M. Rose https://orcid.org/0000-0001-7382-3671
Kristina Coop Gordon https://orcid.org/0000-0002-1543-2098
Emma C. Schlegel https://orcid.org/0000-0002-0242-6561
Matthew Mccall https://orcid.org/0000-0001-7810-8263
Ye Gao https://orcid.org/0000-0003-3979-8710
Meiyi Ma https://orcid.org/0000-0001-6916-8774
Katherine A. Lenger https://orcid.org/0000-0002-5115-1349
Eunjung Ko https://orcid.org/0000-0002-1898-0639
Kathy D. Wright https://orcid.org/0000-0001-7346-1981
Hongning Wang https://orcid.org/0000-0002-6524-9195
John Stankovic https://orcid.org/0000-0001-7307-9395

REFERENCES

Altun, H., & Polat, G. (2007). New frameworks to boost feature selection algorithms in emotion detection for improved human-computer interaction. *International Symposium on Brain, Vision and Artificial Intelligence*, 533–541, https://doi.org/10.1007/978-3-540-75555-5_51

Alzheimer's Association. (2016). 2016 Alzheimer's disease facts and figures. *Alzheimer's & Dementia*, *12*(4), 459–509. https://doi.org/10.1016/j.jalz.2016.03.001

Barlow, D. H. (2014). *Clinical handbook of psychological disorders: A step-by-step treatment manual*. Guilford publications.

Barros, P., & Wermter, S. (2016). Developing crossmodal expression recognition based on a deep neural model. *Adaptive Behavior*, *24*(5), 373–396. https://doi.org/10.1177/1059712316664017

Becker, E., Xu, Y., Ledford, S., & Makedon, F. (2008). A wireless sensor network architecture and its application in an assistive environment. *Proceedings of the 1st International Conference on PErvasive Technologies Related to Assistive Environments*, 1–7. https://doi.org/10.1145/1389586.1389616

Brown, K. W., Coogle, C. L., & Wegelin, J. (2016). A pilot randomized controlled trial of mindfulness-based stress reduction for caregivers of family members with dementia. *Aging & Mental Health*, *20*(11), 1157–1166. https://doi.org/10.1080/13607863.2015.1065790

Burgio, L., Stevens, A., Guy, D., Roth, D. L., & Haley, W. E. (2003). Impact of two psychosocial interventions on White and African American family caregivers of individuals with dementia. *The Gerontologist*, *43*(4), 568–579. https://doi.org/10.1093/geront/43.4.568

Cao, H., Cooper, D. G., Keutmann, M. K., Gur, R. C., Nenkova, A., & Verma, R. (2014). CREMA-D: Crowd-sourced emotional multimodal actors dataset. *IEEE Transactions on Affective Computing*, *5*(4), 377–390. https://doi.org/10.1109/TAFFC.2014.2336244

Cavanagh, K., Churchard, A., O'Hanlon, P., Mundy, T., Votolato, P., Jones, F., Gu, J., & Strauss, C. (2018). A randomised controlled trial of a brief online mindfulness-based intervention in a non-clinical population: Replication and extension. *Mindfulness*, *9*(4), 1191–1205. https://doi.org/10.1007/s12671-017-0856-1

Cavanagh, K., Strauss, C., Cicconi, F., Griffiths, N., Wyper, A., & Jones, F. (2013). A randomised controlled trial of a brief online mindfulness-based intervention. *Behaviour Research and Therapy*, *51*(9), 573–578. https://doi.org/10.1016/j.brat.2013.06.003

Cucinotta, D., & Vanelli, M. (2020). WHO declares COVID-19 a pandemic. *Acta Bio-Medica: Atenei Parmensis*, *91*(1), 157–160. https://doi.org/10.23750/abm.v91i1.9397

Czeisler, M. É., Lane, R. I., Petrosky, E., Wiley, J. F., Christensen, A., Njai, R., Weaver, M. D., Robbins, R., Facer-Childs, E. R., Barger, L. K., Czeisler, C. A., Howard, M. E., & Rajaratnam, S. M. W. (2020). Mental health, substance use and suicidal ideation during the COVID-19 pandemic—United States, June 24–30, 2020. *MMWR. Morbidity and Mortality Weekly Report*, *69*(32), 1049–1057. https://doi.org/10.15585/mmwr.mm6932a1

Danisman, T., & Alpkocak, A. (2008). Emotion classification of audio signals using ensemble of support vector machines. In E. André, L. Dybkjær, W. Minker, H. Neumann, R. Pieraccini, & M. Weber (Eds.), *Perception in Multimodal Dialogue Systems* (pp. 205–216). Springer. https://doi.org/10.1007/978-3-540-69369-7_23

Davis, L. L., Buckwalter, K., & Burgio, L. D. (1997). Measuring problem behaviors in dementia: Developing a methodological agenda. *Advances in Nursing Science*, *20*(1), 40–55. https://doi.org/10.1097/00012272-199709000-00007

Dupuis, K., & Pichora-Fuller, M. K. (2010). *Toronto emotional speech set (TESS)*. University of Toronto, Psychology Department.

Epstein, N. B., & Baucom, D. H. (2002). *Enhanced cognitive-behavioral therapy for couples: A contextual approach*. American Psychological Association. https://doi.org/10.1037/10481-000

Fisher, L., & Lieberman, M. A. (1996). The effects of family context on adult offspring of patients with Alzheimer's disease: A longitudinal study. *Journal of Family Psychology*, *10*(2), 180–191. https://doi.org/10.1037/0893-3200.10.2.180

Ghebreyesus, T. A. (2020). *WHO Director-General's opening remarks at the media briefing on COVID-19—11 March 2020*. World Health Organization. https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020

Gilhooly, M. L., & Whittick, J. E. (1989). Expressed emotion in caregivers of the dementing elderly. *British Journal of Medical Psychology*, *62*(3), 265–272. https://doi.org/10.1111/j.2044-8341.1989.tb02835.x

Gitlin, L. N., Hodgson, N., Jutkowitz, E., & Pizzi, L. (2010). The cost-effectiveness of a nonpharmacologic intervention for individuals with dementia and family caregivers: The tailored activity program. *The American Journal of Geriatric Psychiatry*, *18*(6), 510–519. https://doi.org/10.1097/JGP.0b013e3181c37d13

Gordon, K. C., Roberson, P. N., Hughes, J. A., Khaddouma, A. M., Swamy, G. K., Noonan, D., Gonzalez, A. M., Fish, L., & Pollak, K. I. (2018). The effects of a couples-based health behavior intervention during pregnancy on Latino couples' dyadic satisfaction postpartum. *Family Process*, *57*(3), 629–648. https://doi.org/10.1111/famp.12354

Haq, S., & Jackson, P. J. (2011). Multimodal emotion recognition. In *Machine audition: Principles, algorithms and systems* (pp. 398–423). IGI Global. https://doi.org/10.4018/978-1-61520-919-4.ch017

Harris, P. A., Taylor, R., Minor, B. L., Elliott, V., Fernandez, M., O'Neal, L., McLeod, L., Delacqua, G., Delacqua, F., Kirby, J., & Duda, S. N. (2019). The REDCap consortium: Building an international community of software platform partners. *Journal of Biomedical Informatics*, *95*, 103208. https://doi.org/10.1016/j.jbi.2019.103208

Harris, P. A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., & Conde, J. G. (2009). Research electronic data capture (REDCap)—A metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics*, *42*(2), 377–381. https://doi.org/10.1016/j.jbi.2008.08.010

Helal, S., Mann, W., El-Zabadani, H., King, J., Kaddoura, Y., & Jansen, E. (2005). The gator tech smart house: A programmable pervasive space. *Computer*, *38*(3), 50–60. https://doi.org/10.1109/MC.2005.107

Hepburn, K. W., Lewis, M., Kirk, L. N., Narayan, S., Center, B., Bremer, K. L., & Tornatore, J. (2006). Partners in caregiving: A psychoeducation program affecting dementia family caregivers' distress and caregiving outlook. *Clinical Gerontologist*, *29*(1), 53–69. https://doi.org/10.1300/J018v29n01_05

Hepburn, K., Lewis, M., Tornatore, J., Sherman, C. W., & Bremer, K. L. (2007). The Savvy Caregiver program: The demonstrated effectiveness of a transportable dementia caregiver psychoeducation program. *Journal of Gerontological Nursing*, *33*(3), 30–36. https://doi.org/10.3928/00989134-20070301-06

Heru, A. M., & Ryan, C. E. (2006). Family functioning in the caregivers of patients with dementia: One-year follow—up. *Bulletin of the Menninger Clinic*, *70*(3), 222–231. https://doi.org/10.1521/bumc.2006.70.3.222

Heru, A. M., Ryan, C. E., & Iqbal, A. (2004). Family functioning in the caregivers of patients with dementia. *International Journal of Geriatric Psychiatry*, *19*(6), 533–537. https://doi.org/10.1002/gps.1119

Hulme, C., Wright, J., Crocker, T., Oluboyede, Y., & House, A. (2010). Non-pharmacological approaches for dementia that informal carers might try or access: A systematic review. *International Journal of Geriatric Psychiatry*, *25*(7), 756–763. https://doi.org/10.1002/gps.2429

Intille, S. S., Larson, K., Beaudin, J. S., Nawyn, J., Tapia, E. M., & Kaushik, P. (2005). A living laboratory for the design and evaluation of ubiquitous computing technologies. *CHI '05 Extended Abstracts on Human Factors in Computing Systems*, 1941–1944. https://doi.org/10.1145/1056808.1057062

Jones, S. M., & Hansen, W. (2015). The impact of mindfulness on supportive communication skills: Three exploratory studies. *Mindfulness*, *6*(5), 1115–1128. https://doi.org/10.1007/s12671-014-0362-7

Khaddouma, A., & Gordon, K. C. (2018). Mindfulness and young adult dating relationship stability: A longitudinal path analysis. *Mindfulness*, *9*(5), 1529–1542. https://doi.org/10.1007/s12671-018-0901-8

Khaddouma, A., Gordon, K. C., & Strand, E. B. (2017). Mindful Mates: A pilot study of the relational effects of mindfulness-based stress reduction on participants and their partners. *Family Process*, *56*(3), 636–651. https://doi.org/10.1111/famp.12226

Kientz, J. A., Patel, S. N., Jones, B., Price, E., Mynatt, E. D., & Abowd, G. D. (2008). The Georgia Tech aware home. *CHI '08 Extended Abstracts on Human Factors in Computing Systems*, 3675–3680. https://doi.org/10.1145/1358628.1358911

Ko, J., Lu, C., Srivastava, M. B., Stankovic, J. A., Terzis, A., & Welsh, M. (2010). Wireless sensor networks for healthcare. *Proceedings of the IEEE*, *98*(11), 1947–1960. https://doi.org/10.1109/JPROC.2010.2065210

Kriegsman, D. M. W., Penninx, B. W. J. H., & van Eijk, J. T. M. (1994). Chronic disease in the elderly and its impact on the family: A review of the literature. *Family Systems Medicine*, *12*(3), 249–267. https://doi.org/10.1037/h0089395

Lawrence, R. H., Tennstedt, S. L., & Assmann, S. F. (1998). Quality of the caregiver–care recipient relationship: Does it offset negative consequences of caregiving for family caregivers? *Psychology and Aging*, *13*(1), 150. https://doi.org/10.1037/0882-7974.13.1.150

Lee, K., Lee, K., Lee, H., & Shin, J. (2018). A simple unified framework for detecting out-of-distribution samples and adversarial attacks. *Advances in Neural Information Processing Systems*, 7167–7177.

Lee, S., Yildirim, S., Kazemzadeh, A., & Narayanan, S. (2005). An articulatory study of emotional speech production. *Ninth European Conference on Speech Communication and Technology*.

Lenger, K. A. (2020). *Is mindfulness only for the fortunate? The development and dissemination of a brief home-based mindfulness intervention to economic minority couples* [Unpublished doctoral dissertation]. University of Tennessee, Knoxville.

Lenger, K. A., Gordon, C. L., & Nguyen, S. P. (2017). Intra-individual and cross-partner associations between the five facets of mindfulness and relationship satisfaction. *Mindfulness*, *8*(1), 171–180. https://doi.org/10.1007/s12671-016-0590-0

Li, L., Chu, W., Langford, J., & Schapire, R. E. (2010). A contextual-bandit approach to personalized news article recommendation. *Proceedings of the 19th International Conference on World Wide Web*, 661–670. https://doi.org/10.1145/1772690.1772758

Lindsay, E. K., Young, S., Smyth, J. M., Brown, K. W., & Creswell, J. D. (2018). Acceptance lowers stress reactivity: Dismantling mindfulness training in a randomized controlled trial. *Psychoneuroendocrinology*, *87*, 63–73. https://doi.org/10.1016/j.psyneuen.2017.09.015

Livingstone, S. R., & Russo, F. A. (2018). The ryerson audio-visual database of emotional speech and song (RAVDESS): A dynamic,

multimodal set of facial and vocal expressions in North American English. *PLoS One*, *13*(5), e0196391. https://doi.org/10.1371/journal.pone.0196391

Lloyd, S. M., Watson, M., Oaker, G., Sacks, N., Querci della Rovere, U., & Gui, G. (2000). Understanding the experience of prophylactic bilateral mastectomy: A qualitative study of ten women. *Psycho-Oncology*, *9*(6), 473–485. https://doi.org/10.1002/1099-1611(200011/12)9:6%3C473:AID-PON490%3E3.0.CO;2-T

Mannion, E. (1996). Resilience and burden in spouses of people with mental illness. *Psychiatric Rehabilitation Journal*, *20*(2), 13. https://doi.org/10.1037/h0095389

Morris, R. G., Morris, L. W., & Britton, P. G. (1988). Factors affecting the emotional wellbeing of the caregivers of dementia sufferers. *The British Journal of Psychiatry*, *153*(2), 147–156. https://doi.org/10.1192/bjp.153.2.147

Noroozi, F., Marjanovic, M., Njegus, A., Escalera, S., & Anbarjafari, G. (2017). Audio-visual emotion recognition in video clips. *IEEE Transactions on Affective Computing*, *10*(1), 60–75. https://doi.org/10.1109/TAFFC.2017.2713783

Ostwald, S. K., Hepburn, K. W., Caron, W., Burns, T., & Mantell, R. (1999). Reducing caregiver burden: A randomized psychoeducational intervention for caregivers of persons with dementia. *The Gerontologist*, *39*(3), 299–309. https://doi.org/10.1093/geront/39.3.299

Papangelis, A., Galatas, G., & Makedon, F. (2011). A recommender system for assistive environments. *Proceedings of the 4th International Conference on PErvasive Technologies Related to Assistive Environments*, 1–4. https://doi.org/10.1145/2141622.2141630

Parkitny, L., & McAuley, J. (2010). The depression anxiety stress scale (DASS). *Journal of Physiotherapy*, *56*(3), 204. https://doi.org/10.1016/s1836-9553(10)70030-8

Rantz, M. J., Skubic, M., Koopman, R. J., Alexander, G. L., Phillips, L., Musterman, K., Back, J., Aud, M. A., Galambos, C., Guevara, R. D., & Miller, S. J. (2012). Automated technology to speed recognition of signs of illness in older adults. *Journal of Gerontological Nursing*, *38*(4), 18–23. https://doi.org/10.3928/00989134-20120307-01

Ruscio, A. C., Muench, C., Brede, E., MacIntyre, J., & Waters, A. J. (2016). Administration and assessment of brief mindfulness practice in the field: A feasibility study using ecological momentary assessment. *Mindfulness*, *7*(4), 988–999. https://doi.org/10.1007/s12671-016-0538-4

Scharre, D. W., Chang, S.-I., Murden, R. A., Lamb, J., Beversdorf, D. Q., Kataki, M., Nagaraja, H. N., & Bornstein, R. A. (2010). Self-administered Gerocognitive Examination (SAGE): A brief cognitive assessment instrument for mild cognitive impairment (MCI) and early dementia. *Alzheimer Disease and Associated Disorders*, *24*(1), 64–71. https://doi.org/10.1097/WAD.0b013e3181b03277

Schulz, R., Boerner, K., Shear, K., Zhang, S., & Gitlin, L. N. (2006). Predictors of complicated grief among dementia caregivers: A prospective study of bereavement. *The American Journal of Geriatric Psychiatry*, *14*(8), 650–658. https://doi.org/10.1097/01.JGP.0000203178.44894.db

Schulz, R., & Martire, L. M. (2004). Family caregiving of persons with dementia: Prevalence, health effects and support strategies. *The American Journal of Geriatric Psychiatry*, *12*(3), 240–249. https://doi.org/10.1097/00019442-200405000-00002

Shepardson, R. L., Funderburk, J. S., & Weisberg, R. B. (2016). Adapting evidence-based, cognitive-behavioral interventions for anxiety for use with adults in integrated primary care settings. *Families, Systems, & Health*, *34*(2), 114–127. https://doi.org/10.1037/fsh0000175

Sink, K. M., Covinsky, K. E., Barnes, D. E., Newcomer, R. J., & Yaffe, K. (2006). Caregiver characteristics are associated with neuropsychiatric symptoms of dementia. *Journal of the American Geriatrics Society*, *54*(5), 796–803. https://doi.org/10.1111/j.1532-5415.2006.00697.x

Skubic, M., Alexander, G., Popescu, M., Rantz, M., & Keller, J. (2009). A smart home application to eldercare: Current status and lessons learned. *Technology and Health Care*, *17*(3), 183–201. https://doi.org/10.3233/THC-2009-0551

Slatyer, S., Craigie, M., Heritage, B., Davis, S., & Rees, C. (2018). Evaluating the effectiveness of a brief mindful self-care and resiliency (MSCR) intervention for nurses: A controlled trial. *Mindfulness*, *9*(2), 534–546. https://doi.org/10.1007/s12671-017-0795-x

Stall, N. M., Kim, S. J., Hardacre, K. A., Shah, P. S., Straus, S. E., Bronskill, S. E., Lix, L. M., Bell, C. M., & Rochon, P. A. (2019). Association of informal caregiver distress with health outcomes of community-dwelling dementia care recipients: A systematic review. *Journal of the American Geriatrics Society*, *67*(3), 609–617. https://doi.org/10.1111/jgs.15690

Steffen, P. R., & Larson, M. J. (2015). A brief mindfulness exercise reduces cardiovascular reactivity during a laboratory stressor paradigm. *Mindfulness*, *6*(4), 803–811. https://doi.org/10.1007/s12671-014-0320-4

Teng, E., & Chui, H. (1987). The modified mini-mental state examination (3MS). *Canadian Journal of Psychiatry*, *41*(2), 114–121.

Teri, L., Truax, P., Logsdon, R., Uomoto, J., Zarit, S., & Vitaliano, P. P. (1992). Assessment of behavioral problems in dementia: The revised memory and behavior problems checklist. *Psychology and Aging*, *7*(4), 622. https://doi.org/10.1037/0882-7974.7.4.622

Teusink, J. P., & Mahier, S. (1984). Helping families cope with Alzheimer's disease. *Psychiatric Services*, *35*(2), 152–156. https://doi.org/10.1176/ps.35.2.152

Thornton, M., & Travis, S. S. (2003). Analysis of the reliability of the modified caregiver strain index. *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences*, *58*(2), S127–S132. https://doi.org/10.1093/geronb/58.2.S127

University of Southern California. (2020). *Welcome to Nubis*. USCDornsife Center for Economic and Social Rsearch. https://cesr.usc.edu/nubis/index.php

Yaffe, K., & Hoang, T. (2013). Nonpharmacologic treatment and prevention strategies for dementia. *Continuum (Minneapolis, Minn.)*, *19*(2 Dementia), 372–381. https://doi.org/10.1212/01.CON.0000429178.14354.67

Yu, D. S. F., Cheng, S.-T., & Wang, J. (2018). Unravelling positive aspects of caregiving in dementia: An integrative review of research literature. *International Journal of Nursing Studies*, *79*, 1–26. https://doi.org/10.1016/j.ijnurstu.2017.10.008

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