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Official Title:	Learning and Improving Alzheimer's Patient-Caregiver Relationships Via Smart Healthcare Technology
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The Ohio State University Consent to Participate in Research

Study Title:	**Collaborative Research: Learning and Improving Alzheimer's Patient-Caregiver Relationships via Smart Healthcare Technology.**
Principal Investigator:	**Karen Rose, PhD, RN, FGSA, FAAN**
Sponsor:	National Science Foundation (NSF)

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary.

Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form.

Purpose:
This study is about studying how family caregivers and persons with memory loss communicate and if certain ways of handling stress are helpful for family caregivers

Procedures/Tasks:
If you are in this study, you will be asked to complete some surveys and you will have microphones and a computer installed in your home. Through these microphones, we will hear the ways you speak with each other in your home. This recording will take place for up to 4 months while you are participating in the study. We are only interested in identifying the ways that you communicate that may cause family caregivers of persons with memory loss to feel stress. We will provide the family caregiver with a mobile phone. We will use this mobile phone to communicate with family caregivers regarding ways they can decrease their stress. At the beginning of the study, we will provide training to family caregivers about ways they can handle their stress. If we detect that a family caregiver is becoming stressed, we will send a text message through the mobile phone as a reminder of ways the family caregiver can reduce their stress, through taking a time-out, performing deep breathing exercises, or doing other pleasurable activities. Through the mobile phone, family caregivers will provide us with a rating of how well they are managing their stress.

Duration:
You will be in the study for up to four months from the time of consent to the time of final study data collection**.** 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 over the phone or in person with you and written, informed consent will be obtained for both you and your family caregiver. 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 your home at a location that is agreeable to you. A Smart Phone will be given to your caregiver for use during the study period for the purpose of receiving recommendations and providing feedback through daily and weekly online surveys.
Between visit 1 and 2, you will complete a short survey about their experience deploying the study equipment in your home. The questionnaire will take about five to ten minutes to complete.
Visit 2: The research staff will either visit you in your home or speak with you via phone or video call to educate your family caregiver regarding the text messages they will be receiving from the study team when stressful situations are identified. 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, the caregiver 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 the end of the study. Your caregiver will receive a text message within an hour after each recommendation is sent to he/she to tell us if they implemented the recommendation (yes or no) and to provide feedback on how helpful the recommendation was. Additionally, we will text your caregiver weekly and will ask them to rate the overall helpfulness of the recommendations.
Visit 3: The research staff will either visit you in your home or speak with your family caregiver via phone or video call to discuss any issue you are having and review the education provided during the previous visit or call.
Visit 4: At the completion of the study, staff will either visit your home or speak with you via phone or video call to collect the end of study surveys.

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

Risks and Benefits:

Benefits: Throughout the study, family caregivers may become more aware of how they handle stress. At the end of the study, the family caregiver will be given an overview of the ways that they handled stress over the study period. This information may be helpful so that they learn better ways to handle stress in the future.

Risks: You may feel like you are losing your privacy as a result of having microphones in your home. We will only place the microphones in areas of your home where you tell us its okay to do so. We are only hearing your words and we will not see you as no video recording is taking place. The information we receive from the microphones will be transferred via the internet to a secured database located at the University of Virginia.
Although we will have records that will allow your name and identifying information to be associated with your data and recordings, we plan to keep this information confidential.

Confidentiality:

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

This study will use the REDCap software for the electronic collection and management of clinical and research data. This is a secure web-based application that simplifies data collection and handling of protected Personal Health Information.

We will work to make sure that no one sees your survey responses or other online data we collect without approval. But, because we are using the Internet, there is a chance that someone could access your online responses or audio recordings without permission. In some cases, this information could be used to identify you. Your data will be protected with a code to reduce the risk that other people can view the responses.

Will my de-identified information be used or shared for future research?

Yes, it/they may be used or shared with other researchers without your additional informed consent.

Incentives:

For the time and attention you give to participating in the study and completing the study surveys, you will be given $50 three times throughout the study period, for a total of $150.

By law, payments to participants are considered taxable income.

Participant Rights:

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

Contacts and Questions:

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact **Karen Rose, PhD, RN, 614-292-7837** or **Rose.1482@osu.edu**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
	AM/PM
Relationship to the participant	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time