Document Coversheet

Study Title: Improving Person-Environment Fit of Community-Residing Older Adults With Dementia

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KEY INFORMATION FOR PATIENT CONSENT IN:
IMPROVING PERSON-ENVIRONMENT FIT OF COMMUNITY-RESIDING OLDER ADULTS WITH DEMENTIA

We are asking you to choose whether or not to volunteer for a research study exploring behaviors of people with dementia who live at home. We are asking you because you are living with dementia and may be willing to participate in this study. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn about behaviors of dementia in relation to the home environment. The study will involve you and your primary care partner. This study will be conducted remotely using phone calls, email, Zoom video conferencing and mail (Fedex). You will not be required to leave your home beyond normal circumstances for this study. This study has two phases. In Phase 1, your participation will include seven days of activity monitoring, using the Empatica wrist device. This research study will include approximately two hours of your time over the course of one week. For detailed descriptions, refer to the Detailed Consent and Appendix A on page 5. In Phase 2, Your participation in this research will involve one screening visit and eight weeks of educational programs delivered via telehealth including weekly meetings with a member of our research team. Your primary care partner will be asked to implement approaches. We anticipate the project lasting approximately twelve weeks from time of screening at phase 1 visit to the follow up visit. This will include approximately 8 hours of Zoom video conferencing. For detailed descriptions, refer to the Detailed Consent and appendix A on page 5.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. Your willingness to take part, however, may, in the future, help doctors better understand and/or treat others who have dementia.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

This study seeks caregivers of people with dementia who live in their homes within the community, and who do not live in facilities such as nursing homes, personal care homes, or assisted living facilities. A goal of the study of phase 1 is to assess behaviors of the person with dementia within their home environment. You will be asked to wear an activity monitor device for seven consecutive days. Your caregiver will be tracking your observed behaviors with a daily behavior journal. The goal of Phase 2 is to assess a clinical telehealth intervention. Your care partner may complete various new caregiving techniques or home modifications (i.e., dimmed lighting, signage, line of sight access to food and water, etc.) which will be tailored to your needs to live comfortably at home. If you feel as though you are unable or unwilling to engage in interventions included in this study, the dyad will not be included. You may not want to participate if you don't want to use Zoom video conferencing, or if you do not want to participate in the interventions as the patient. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you chose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Elizabeth Rhodus, PhD, OTR/L (PI) of the University of Kentucky, Sanders-Brown Center on Aging at 859-257-5562 or elizabeth.rhodus@uky.edu

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT FOR PATIENT PARTICIPATION:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

This study will involve you and your primary caregiver. If both of you cannot participate in this study, you may not qualify. You may not qualify if you do not live in a rural Kentucky community or if your care partner does not spend approximately 50% of the week with you. You will not qualify if you do not have a diagnosis of Alzheimer's disease as primary type of dementia, are under the age of 60 years or over the age of 99 years, have unstable medical conditions within one month prior to screening visit such as poorly controlled blood pressure, diabetes, current cancer diagnosis, or breathing problems, etc., are wheelchair or bed bound, reside in skilled nursing facility or facility-based care, have caregiver report of physically violent behaviors, recent (within 4 weeks prior to screening) initiation of antipsychotic medication or unpredictable use of such medications, diagnosis of profound or total sensory altering disorders including macular degeneration, legal blindness, total deafness, severe peripheral neuropathy, anosmia, have diagnosis of major depression in past 12 months (DSM-IV criteria), major mental illness such as schizophrenia, bipolar disorder, personality disorders, or recent (in past 12 months) alcohol or substance abuse, or have had a major infection within 4 weeks prior to the Baseline Visit.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at your home. You will not need to come to the center in Lexington, KY. You will be asked to wear an Empatica wrist device during Phase 1. During Phase 2, your caregiver will participate in weekly telehealth visits. Each of those visits will take approximately 1 hour. Additionally, we ask you to participate in daily intervention activities with your caregiver for an 8-week duration. The total amount of time you will be asked to volunteer for this study is approximately 8 hours of Zoom video conferencing throughout the next twelve weeks.

WHAT WILL YOU BE ASKED TO DO?

Phase 1:

The total amount of time you will be asked to volunteer for this study is approximately 2 hours. For this study, you will wear an activity monitor, called Empatica device on your wrist for seven consecutive days. During this time, your caregiver will also complete daily journal entries summarizing your observed behaviors.

Day 1: With assistance from your caregiver, you will don the activity monitor on your wrist.

Day 2-6: Your caregiver will monitor wear of the activity monitor including taking off during bathing and for charging.

Day 7: Following Day 7 wear, with assistance from your caregiver, you will remove the activity monitor for return to the University of Kentucky.

All communications with research team will be recorded either via Zoom or audio recorded while on the phone for research purposes. All video recording/electronic data will be stored for a period of six years after which files will be destroyed using the University of Kentucky's Policy for Reuse and Disposal of Electronic Media. UK Healthcare Policy and Procedure A13-050 states "all electronic media shall be erased (i.e. purged) using data overwriting software that conforms to the requirements stated in NIST SP800-88."

Please see APPENDIX A: Schedule of Events for visualization of this schedule and explanation of assessments.

Phase 2:

You and your care partner will be randomly assigned to complete an 8-week training program in one of two groups: National Institute on Aging Caregiver Education or the Harmony at HOME telehealth program.

The following tasks will be associated with your participation in this study and will take place at your home using Zoom video conferencing. Informed consent will be obtained prior to the following research procedures.

National Institute on Aging Caregiver Education

Visit 1: Study materials will be mailed to your home including a behavior journal and educational materials.

Visit 2-9: You and your care partner will meet weekly via telehealth with a research assistant to discuss caregiver education materials offered by the National Institute on Aging and review behavior tracking.

Visit 10: Four weeks following completion of the program, you will complete a follow up session.

Harmony at HOME telehealth program:

Visit 1: Intervention materials will include items which offer environmental modifications to the home, for example: [redacted]

Visit 2-9: You and your care partner will meet with an occupational therapist to complete intervention training, as well as review the behavior journal and any changes in behaviors or medical issues that arise during the prior week. During these visits, you will be encouraged to participate through discussion of your home environment and responses to the intervention. If at any point you feel uncomfortable, you may step away from the session as the therapist and your care partner continue the session. Throughout the weeks of intervention, your care partner will maintain a behavior journal to document any behavioral symptoms and the situation before and after the presented behavior that you may have for the week. You may also document behaviors as you wish. These visits will last approximately one hour with you and your care partner.

Visit 10: Four weeks following completion of the program, you will complete a follow up session.

Lastly, for both groups, the researcher may contact you to confirm or clarify interpretation of subjective information gained during the Zoom video conferences. The contact may be via phone, email, or a virtual meeting.

Please see APPENDIX B: Schedule of Events for visualization of this schedule and explanation of assessments.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

- Possible discomfort from intervention materials, such as skin irritation, headache, disliking recommendations.
- A risk of sensory overstimulation is present, however, impact of such risks are mild, temporary, and often subside within four hours of intervention.

There is always a chance that any medical treatment, including use of worn activity trackers, can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. If you take part in this study, information learned may help others with caring for people with dementia.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

The costs associated with your participation in this study include your time commitment. All needed materials and technologies will be provided.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Storage of the electronic information/data collected for this study will be provided by University of Kentucky Healthcare Information Technology and will be governed and protected by the enterprise's HIPAA-defined technical, physical, and administrative safeguards for data protection and access control. A protected network share will be the central storage location for the recordings and related project materials that will be collected. Access to this protected share drive will be restricted to study personnel only.

This study will utilize procedures set by the University of Kentucky Telehealth Division. UK has a Business Associate Agreement with Zoom, and uses the HIPAA compliant version of the technology to ensure patient confidentiality is maintained. Telehealth has proven to be a successful modality for clinical encounters for many years, but the COVID 19 pandemic crisis has escalated the use of telehealth at UK. This new direct-to-consumer telehealth service that uses the patient's personal device (home computer, tablet or smartphone) is being used by over 15,000 patients/month.

You should know that in some cases we may have to show your information to other people because it may be required by law. For example, the law may require us to share your information with authorities, if you report information about a child being abused; or if you pose a danger to yourself or someone else.

To ensure the study Is conducted properly, officials of the University of Kentucky and funding sources (Department of Health and Human Services/National Institutes of Health/National Institute on Aging) may look at or copy pertinent portions of records that identify you.

We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained by way of the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of the University of Kentucky.

REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk to you than anticipated,
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may not take part in this study if you are currently involved in another behavior-focused interventional research study. It is important to let the investigator know if you are in another research study. You should discuss this with the investigator before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Elizabeth Rhodus, PhD, OTR/L at 859-257-5562 immediately.

Jordan Clay, MD, is the safety officer for this study and will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm

- will be your responsibility;
- may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances);
- may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study. The behavior journal/workbook and tablet device and charger are property of the University of Kentucky and are required to be returned to Sanders-Brown Center on Aging no later than 14 days following completion of this study. However, all educational and home modification materials which will be mailed to your home will not be collected by the research team following study completion, and materials will belong to your caregiver following completion of the study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Do you give permission for us to contact you about research results or incidental findings that are determined to be important to your health? (Incidental findings are unforeseen findings discovered during the course of the research that may affect your health. For example, reaction to study materials, significant change in functional status during this study, or clinical concerns from the occupational therapist during the study).

☐ Yes ☐ No _____Initials

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to Elizabeth Rhodus, PhD, OTR/L Elizabeth.rhodus@uky.edu 859-257-5562, University of Kentucky, 463 Healthy Kentucky Research Building, 760 Press Ave, Lexington, KY 40536.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to no more than two times per year.

Do you give your permission to be contacted in the future by the PI (Elizabeth Rhodus, PhD, OTR/L) or study staff regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 70 people to do so.

Elizabeth Rhodus, PhD, OTR/L is an Assistant Professor at Sanders-Brown Center on Aging at the University of Kentucky. There may be other people on the research team assisting at different times during the study.

The National Institute for Aging is providing financial support and/or material for this study.

The information that you are providing will no longer belong to you. The research may lead to new clinical or educational knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.

A description of phase 2 will be available on ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information collected in this study. This means that no link or code to your identity will be kept. After all identifiers have been removed, the information may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your de-identified information stored, they will be available indefinitely and cannot be removed due to the inability to identify them.

APPENDIX A: Phase 1 Schedule of Events

Study Activity	1	2-6	7
Visit name *(Approx. length)*	Day 1 15 minutes	Day 2-7 15 minutes	Following Day 7 15 minutes
Don activity monitor to your wrist	X		
Daily monitoring of wear and charging		X	
Removal of activity monitor and preparation for shipping to UK			X

APPENDIX B: Phase 2 Schedule of Events

Visit number	1	2-9	10
Visit name *(Approx. length)*	Baseline +/- 5Days	Tx week 1-6 *1 hour* +/- 3Days	Post-4 week f/u *1 hour* +/- 5Days
Mail study supplies	X		
Weekly check-in with caregiver/patient, review of behavior journal/ compliance		X	X
Adverse events		X	X

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**
- **Appendix A: Phase 1 Schedule of Events**
- **Appendix B: Phase 2 Schedule of Events**

You will receive a copy of this consent form after it has been signed.

_____ **Signature of research subject (patient)** *or, if applicable, *research subject's legal representative*	_____ **Date**
_____ **Printed name of research subject**	
_____ **Printed name of research subject's legal representative*	
**If applicable, please explain Representative's relationship to subject and include a description of representative's authority to act on behalf of subject:* _____ _____	
_____ Printed name of [authorized] person obtaining informed consent	_____ Date