Document Coversheet

Study Title: Environmental Design for Behavioral Regulation in People With Dementia

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	Protocol 10/10/22; ICF 3/18/21
NCT Number:	NCT04555616
IRB Number	61291
Coversheet created:	11/22/22

IRB Approval
10/10/2022
IRB # 61291
IRB2
CLOSED

PROTOCOL TYPE

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Which IRB

◉ Medical ○ NonMedical

Protocol Process Type

○ Exemption
◉ Expedited (Must be risk level 1)
○ Full

IMPORTANT NOTE: You will not be able to change your selections for "Which IRB" and "Protocol Process Type" after saving this section. If you select the wrong IRB or Protocol Process Type, you may need to create a new application.

See below for guidance on these options, or refer to ORI's "Getting Started" page. Please contact the Office of Research Integrity (ORI) at 859-257-9428 with any questions prior to saving your selections.

Which IRB

The **Medical IRB** reviews reviews research from the Colleges of:

- Dentistry
- Health Sciences
- Medicine
- Nursing
- Pharmacy and Health Sciences
- and Public Health.

The **Nonmedical IRB** reviews research from the Colleges of:

- Agriculture
- Arts and Sciences
- Business and Economics
- Communication and Information
- Design; Education
- Fine Arts
- Law
- and Social Work

Note: Studies that involve administration of drugs, testing safety or effectiveness of medical devices, or invasive medical procedures must be reviewed by the **Medical IRB** regardless of the college from which the application originates.

Which Protocol Process Type

Under federal regulations, the IRB can process an application to conduct research involving human subjects in one of three ways:

- by exemption certification
- by expedited review.
- by full review;

The investigator makes the preliminary determination of the type of review for which a study is eligible. Please refer to ORI's "Getting Started" page for more information about which activities are eligible for each type of review.

The revised Common Rule expanded exemption certification category 4 for certain secondary research with identifiable information or biospecimens. The regulations no longer require the information or biospecimens to be existing. For more information see the Exemption Categories Tool.

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EXPEDITED CERTIFICATION

0 unresolved comment(s)

To Be Completed Only If Protocol is to Receive Expedited Review

Applicability

A. Research activities that (1) present no more than *minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
B. The categories in this list apply regardless of the age of subjects, except as noted.
C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
D. The expedited review procedure may not be used for classified research involving human subjects.
E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

**"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.*

Check the appropriate categories that apply to your research project:

☐ Study was originally approved by the full IRB at a convened meeting.

☐ 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

A. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
B. Research on medical devices for which (i) an investigational device exemption application is not required*; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.**

* Study must meet one of the IDE Exempt categories listed on the Device Form Attachment.
** An approved Device used in research according to its approved labeling is considered Exempt from IDE requirements.
NOTE: Select Category 1 for compassionate use medical device applications or individual patient expanded access investigational drug applications for which FDA has waived the requirement for full review.

☐ 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

A. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
B. From other adults and children* considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

NOTE: Intravenous (IV), Port, Central, or any other lines are NOT eligible under this category even if the research involves "minimal risk".

*In Kentucky, "child/children" refers to all individuals less than 18 years of age unless the individual(s) is/are legally emancipated. (See Informed Consent SOP for discussion of "Emancipated Individuals" under Kentucky state law.) Individuals less than 18 years of age who are not emancipated meet the federal definition for "child" (e.g., DHHS, FDA, and U.S. Department of Education). Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." If conducting research outside the state of Kentucky, you are responsible for complying with applicable state law.

☐ 3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

A. Hair and nail clippings in a nondisfiguring manner;
B. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
C. Permanent teeth if routine patient care indicates a need for extraction;
D. Excreta and external secretions (including sweat);
E. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
F. placenta removed at delivery;
G. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
H. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
I. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
J. Sputum collected after saline mist nebulization.

☑ 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

A. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
B. Weighing or testing sensory acuity;
C. Magnetic resonance imaging;
D. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
E. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☑ 5) Research involving materials (data, documents, records, or specimens) that have been or will be collected solely for non-research purposes (such as medical treatment or diagnosis) as well as research involving existing information or specimens that were previously collected for research purposes, provided they were not collected for the currently proposed research. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

☑ 6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☑ 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

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PROJECT INFORMATION

0 unresolved comment(s)

Title of Project: (Use the exact title listed in the grant/contract application, if applicable).
If your research investigates any aspect of COVID-19, please include "COVID19" at the beginning of your Project Title and Short Title

Environmental Design for Behavioral Regulation in People with Dementia

Short Title Description
Please use a few key words to easily identify your study - this text will be displayed in the Dashboard listing for your study.

Environmental design for persons with dementia

Anticipated Ending Date of Research Project: 3/1/2022

Maximum number of human subjects (or records/specimens reviewed) 56

After approval, will the study be open to enrollment of new subjects or new data/specimen collection? ○ Yes ◉ No

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PI CONTACT INFORMATION

0 unresolved comment(s)

Principal Investigator (PI) role for E-IRB access
The PI is the individual holding primary responsibility on the research project with the following permissions on the E-IRB application:

1. Read;
2. write/edit;
3. receive communications; and
4. submit to the IRB (IR, CR, MR, Other Review*).

If research is being submitted to or supported by an extramural funding agency such as NIH, a private foundation or a pharmaceutical/manufacturing company, the PI listed on the grant application or the drug protocol must be listed as PI here.

Please fill in any blank fields with the appropriate contact information (gray shaded fields are not editable). Required fields left blank will be highlighted in pink after you click "Save".

To change home and work addresses, go to myUK and update using the Employee Self Service (ESS) portal. If name has changed, the individual with the name change will need to submit a 'Name Change Form' to the Human Resources Benefits Office for entering into SAP. The new name will need to be associated with the individual's Link Blue ID in SAP before the change is reflected in E-IRB. Contact the HR Benefits Office for additional information.

The Principal Investigator's (PI) contact information is filled in automatically based on who logged in to create the application.

If you are not the Principal Investigator, do NOT add yourself as study personnel.
To change the PI contact information on an application in Researcher edit status:

- click "Change Principal Investigator";
- search for the PI's name using the search feature;
- click "Select" by the name of the Principal Investigator, then "Save Contact Information".

  You will automatically be added as study personnel with editing permissions to continue editing the application.

Change Principal Investigator:

First Name:	Elizabeth	Room# & Bldg:	1030 S. Broadway
Last Name:	Rhodus	Speed Sort#:	40504
Middle Name	Kelly		
Department:	Sanders-Brown Ctr On Aging …	Dept Code:	7H030
PI's Employee/Student ID#:	12060375	Rank:	Postdoctoral scholar
PI's Telephone #:	8592575562	Degree:	PhD
PI's e-mail address:	elizabeth.rhodus@uky.edu	PI's FAX Number:	
PI is R.N. ○ Yes ◉ No		Trained:	Yes
		Date Trained	10/16/2021
		RCR Trained:	Yes

Do you, the PI, have a significant financial interest related to your responsibilities at the University of Kentucky (that requires disclosure per the UK administrative regulation 7:2)?

○ Yes ◉ No

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RISK LEVEL

0 unresolved comment(s)

Indicate which of the categories listed below accurately describes this protocol

- (●) (Risk Level 1) Not greater than minimal risk
- ( ) (Risk Level 2) Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects
- ( ) (Risk Level 3) Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- ( ) (Risk Level 4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

*****For Expedited and Exempt Applications, the research activities must be Risk Level 1 (no more than minimal risk to human subjects).*****

Refer to UK's guidance document on assessing the research risk for additional information.

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SUBJECT DEMOGRAPHICS

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 21 to 95

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Census Regional Analyst Edition, Kentucky Race/Ethnic Table, Kentucky Population Data.
(Please note: The IRB will expect this information to be reported during Continuation Review for Full review applications, FDA-regulated Expedited applications, and Pre-2019 Expedited applications.):

Enter Numbers Only!

Ethnic Origin	#Male	#Female
American Indian/Alaskan Native:		
Asian:		
Black/African American:	10	10
Hispanic/Latino:		
Native Hawaiian/Pacific Islander:		
White/Caucasian:	20	20
Other or Unknown:		

If unknown, please explain why:

Indicate the categories of subjects and controls to be included in the study. You may be required to complete additional forms depending on the subject categories which apply to your research. If the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check populations which the research does not specifically target. For example: a large record review of a diverse population may incidentally include a prisoner or an international citizen, but you should not check those categories if the focus of the study has nothing to do with that status.

Check All That Apply (at least one item must be selected)

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☐ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☑ Impaired Consent Capacity Adults

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook for more information on:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults

Other Resources:

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☐ Pregnant Women/Neonates/Fetal Material ☐ Prisoners ☐ Non-English Speaking ☐ International Citizens ☑ Normal Volunteers ☐ Military Personnel and/or DoD Civilian Employees ☑ Patients ☐ Appalachian Population	• UKMC Residents or House Officers [see requirement of GME] • Non-English Speaking [see also the E-IRB Research Description section on this same topic] • International Citizens [DoD SOP may apply] • Military Personnel and/or DoD Civilian Employees

Assessment of the potential recruitment of subjects with impaired consent capacity (or likelihood):

☐ Check this box if your study does NOT involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). If there is no direct intervention/interaction you will not need to answer the impaired consent capacity questions.

Does this study focus on adult subjects with any conditions that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

◉ Yes ○ No

If Yes and you are not filing for exemption certification, go to "Form T", complete the form, and attach it using the button below.

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

Attach Type	File Name
ImpairedConsent	Form T CLEAN.pdf
ImpairedConsent	Form T HIGHTLIGHTED.pdf

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INFORMED CONSENT/ASSENT PROCESS/WAIVER

0 unresolved comment(s)

For creating your informed consent attachment(s), please download the most up-to-date version listed in "All Templates" under the APPLICATION LINKS menu on the left, and edit to match your research project.

Additional Resources:

- Informed Consent/Assent Website
- Waiver of Consent vs. Waiver of Signatures
- Sample Repository/Registry/Bank Consent Template

Consent/Assent Tips:

- If you have multiple consent documents, be sure to upload each individually (not all in a combined file).
- Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".
- It is very important that only the documents you wish to have approved by the IRB are attached; DELETE OUTDATED FILES -- previously *approved* versions will still be available in Protocol History.
- Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.
  Document Types that do NOT get an IRB approval stamp are:
  - "Highlighted Changes",
  - "Phone Script", and
  - "Sponsor's Sample Consent Form".

How to Get the Section Check Mark

1. You must check the box for at least one of the consent items and/or check mark one of the waivers.
2. If applicable attach each corresponding document(s) **as a PDF**.
3. If you no longer need a consent document approved (e.g., closed to enrollment), or, the consent document submitted does not need a stamp for enrolling subjects (e.g., umbrella study, or sub-study), only select "Stamped Consent Doc(s) Not Needed".
4. After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!

Check All That Apply

- ☐ Informed Consent Form (and/or Parental Permission Form)
- ☐ Assent Form
- ☐ Cover Letter (for survey/questionnaire research)
- ☐ Phone Script
- ☐ Informed Consent/HIPAA Combined Form
- ☐ Debriefing and/or Permission to Use Data Form
- ☐ Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol
- ☑ Stamped Consent Doc(s) Not Needed

Attachments

Attach Type	File Name
CoverLetter	SAAF Invite cover letter.pdf

☑ Request for Waiver of Informed Consent Process

If you are requesting IRB approval to waive the requirement for the informed consent process, or to alter some or all of the elements of informed consent, complete, Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

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SECTION 1.

Check the appropriate item:

☑ I am requesting waiver of the requirement for the informed consent process.

☐ I am requesting alteration of the informed consent process.

If you checked the box for this item, describe which elements of consent will be altered and/or omitted, and justify the alteration.

SECTION 2.

Explain how each condition applies to your research.

a) The research involves no more than minimal risk to the subject.

This research involves no more than minimal risk to participants, as the interactions with participants will be conducted remotely and will not pertain to highly sensitive content, the interventions are non-invasive with little to no risk of harm or serious adverse events and are aimed to promote relaxation and comfort.

b) The rights and welfare of subjects will not be adversely affected.

The rights and welfare of subjects will not be adversely affected as this request is for recruitment purpose to access medical records and all information will be protected following HIPAA guidelines.

c) The research could not practicably be carried out without the requested waiver or alteration.

We would be unable to sufficiently recruit participants without access to medical records prior to recruitment.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

The subjects and LAR's will be informed and consented prior to enrollment of study, but their medical records will be accessed prior to consent.

e) If the research involves using or accessing identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

- Private information/specimens are “identifiable” if the investigator may ascertain the identity of the subject or if identifiers are associated with the information (e.g., medical records). This could be any of the 18 HIPAA identifiers including dates of service.
- If not using identifiable private information or identifiable biospecimens, insert N/A below.

Identifiable private information will be used and accessed prior to informed consent. All information will be protected in accordance to HIPAA rules and regulations. We would be unable to recruit for this study without access to medical records and identifiable private information.

☑ Request for Waiver of Documentation of Informed Consent Process

If you are requesting IRB approval to waive the requirement for signatures on informed consent forms, **your research activities must fit into one of three regulatory options**:

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., a study that involves participants who use illegal drugs).
2. The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (e.g., a cover letter on a survey, or a phone script).
3. The participant (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk to the subject, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select the option below that best fits your study.

*If the IRB approves a waiver of signatures, participants must still be provided oral or written information about the study. To ensure you include required elements in your consent document, use the **Cover Letter Template** as a guide. There is an English and a Spanish version.*

○ **Option 1**

Describe how your study meets these criteria:

a) The only record linking the participant and the research would be the consent document:

b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant (or legally authorized representative) must be asked whether (s)he wants to sign a consent document; if the participant agrees to sign a consent document, only an IRB approved version should be used.

◉ **Option 2**

Describe how your study meets these criteria:

a) The research presents no more than minimal risk to the participant:

Addition of the SAAF online survey does not alter or increase the risk to the participants.

b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

Informed consent regarding continued contact with participations via email communication was obtained during initial consenting of this study. Addition of the SAAF will be accompanied with a cover letter and completion of the assessment will indicate implied consent.

○ **Option 3**

Describe how your study meets these criteria:

a) The subject (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm.

b) The research presents no more than minimal risk to the subject.

c) There is an appropriate alternative mechanism for documenting that informed consent was obtained.

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STUDY PERSONNEL **0 unresolved comment(s)**

Do you have study personnel who will be assisting with the research?
After selecting 'Yes' or 'No' you must click the 'Save Study Personnel Information' button.

◉ Yes ○ No

Manage Study Personnel

Identify other study personnel assisting in research project:

- The individual listed as PI in the 'PI Contact Information' section should NOT be added to this section.
- If the research is required for a University of Kentucky academic program, the faculty advisor is also considered study personnel and should be listed below. ***Residents and students who are PI's are encouraged to designate the faculty advisor or at least one other individual as a contact with an editor role (DP).***
- Role: DP = Editor (individual can view, navigate, and edit the application for any review phase (IR, CR/FR, MR) or 'Other Review", and submit Other Reviews on behalf of the PI.)
- Role: SP = Reader (individual can view and navigate through the currently approved application only.)

To add an individual via the below feature:

- Search for personnel;
- Click "select" by the listing for the person you want to add;
- For each person, specify responsibility in the project, whether authorized to obtain informed consent, AND denote who should receive E-IRB notifications (contact status).

NOTE: Study personnel must complete human subject protection (HSP) and Responsible Conduct of Research (RCR) training before implementing any research procedures. For information about training requirements for study personnel, visit UK's HSP FAQ page, the RCR Getting Started page, or contact ORI at 859-257-9428. If you have documentation of current HSP training other than that acquired through UK CITI, you may submit it to ORI (HSPTrainingSupport@uky.edu) for credit.

Study personnel assisting in research project:

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI
Barber	Justin	Data Collection	SP	Y	N		P	Y	07/16/2020	Y	N	07/29/2020	N
Bardach	Shoshana	Co-Investigator	SP	Y	N		P	Y	08/10/2020	N	N	07/29/2020	N
Brooks	Maranda	Data Collection	SP	Y	N		P	Y	09/14/2020	Y	N	01/26/2021	N
Coy	Beth	Sub-Investigator	SP	Y	N		P	Y	03/19/2021	Y	N	11/04/2020	N
George	Rosmy	Data Collection	SP	N	N		P	Y	06/16/2022	Y	N	10/30/2020	N
Gibson	Allison	Data Collection	SP	Y	N		P	Y	05/26/2020	Y	N	08/17/2020	N
Hamilton	Sara	Data Collection	DP	Y	N		P	Y	08/25/2020	Y	N	03/14/2021	N
Jicha	Gregory	Faculty Advisor	DP	Y	Y		P	Y	12/11/2019	Y	N	09/03/2020	N
Johnson	Julia	Project Assistance/Support	SP	Y	N		P	Y	01/30/2021	Y	N	07/29/2020	N
Kryscio	Richard	Data Analysis/Processing	SP	N	N		P	Y	07/15/2022	Y	N	10/08/2021	N
Lowry	Kimberly	Sub-Investigator	SP	Y	N		P	Y	01/12/2022	Y	N	11/04/2020	N
Nichols	Heather	Project Assistance/Support	DP	Y	N		P	Y	02/16/2021	Y	N	07/29/2020	N
Parsons	Kelly	Project Assistance/Support	SP	Y	N		P	Y	05/03/2020	Y	N	07/29/2020	N
Rowles	Graham	Consultant/Advisor	DP	N	N		P	Y	08/16/2020	Y	N	06/18/2021	N
Seeders	Brent	Project Assistance/Support	SP	N	N		P	N	06/03/2019	Y	N	10/30/2020	N
Shady	Kristine	Data Analysis/Processing	DP	Y	N		S	Y	03/19/2021	Y	N	04/01/2021	N
Thompson	MaryEllen	Consultant/Advisor	SP	N	N		N	Y	03/03/3000		N	08/31/2020	N
Wilcock	Donna	Co-Investigator	SP	Y	N		P	Y	06/29/2022	Y	N	08/17/2020	N

RESEARCH DESCRIPTION

1 unresolved comment(s)

You may attach a sponsor's protocol pages in the "Additional Information" section and refer to them where necessary in the Research Description. However, each prompt that applies to your study should contain at least a summary paragraph.

****!!!PLEASE READ!!!** Known Issue: The below text boxes do not allow symbols, web addresses, or special characters (characters on a standard keyboard should be ok). If something is entered that the text boxes don't allow, user will lose unsaved information.**

Workaround(s):

- **Save your work often to avoid losing data.**
- **Use one of the attachment buttons in this section, or under the Additional Information section to include the information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background: Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of your study. For research involving investigational drugs, describe the previously conducted animal and human studies. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below. For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol. Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference in the applicable E-IRB "Study Drug" or "Study Device" section.

Individuals with Alzheimer's disease and related dementias (ADRD) face numerous changes throughout the course of cognitive decline. Behaviors and psychiatric symptoms of dementia (BPSD) are reported in over 80% of those diagnosed with ADRD and contribute to increased mortality.1-4 Most common BPSD include apathy, depression, agitation, aggression, anxiety, and sleep disorders.5-7 These behaviors are often correlated with increased caregiver burden, placement in institutional care, and decreased quality of life for the caregiver and person with ADRD.8-10 Safe and effective treatment options are limited.2 Innovative intervention approaches for BPSD in persons with ADRD is needed and can be applied immediately.

National and international agencies in ADRD intervention recognize the need for non-pharmacological intervention, including environmental assessment and modification, as first-line treatment for BPSD in ADRD.2 However, lack of frameworks and protocols to guide and apply such intervention severely limit real-world implementation.11 Studies in ADRD research have examined interventions using fragments of the environment, such as physical modifications, caregiver training to improve social contexts, and sensory-based interventions, but there is limited representation in the evidence exploring holistic environmental design combining these aspects for optimal behavioral regulation and performance.12 There is significant need to establish innovative protocols for holistic environmental design as a well-defined first-line intervention for BPSD.

Recent evidence suggests similar behavioral sequelae between autism spectrum disorder (ASD), a neurodevelopmental disorder recognized in early childhood, and ADRD, neurodegenerative conditions at the opposite end of the life spectrum.13-15 The neurological overlap to cause similar behaviors is unknown at this time.16 Yet, interventions including pharmacological and non-pharmacological treatment are being shared between conditions.17,18 ASD is frequently treated with non-pharmacological approaches including environmental modification, sensory-based intervention, caregiver training, behavior therapy, and compensatory training.19,20 Currently, there is minimal evidence exploring non-pharmacological approaches derived from ASD treatment for behavioral management and regulation in those with ADRD.

Environmental design incorporates aspects of well-established ASD interventions including environmental modification, sensory-based intervention, and caregiver training to create ideal physical, social, and sensorial surroundings.12,21 Renowned gerontologists have long recognized behavior as a product of environmental interaction. In 1936, Kurt Lewin defined (B)ehavior as a (f)unction of the (P)erson and (E)nvironment: B = f (P,E).22 Lawton and Nahemow23 developed the Ecological Model of Aging which depicts zones of adaptive behavior when environmental demands are attuned with one's competencies. By incorporating successful facets of interventions for similar ASD behaviors and increasingly recognized non-pharmacological interventions in ADRD care, environmental design protocols will create ideal surroundings for maximal function and adaptive behavioral response.

Maladaptive behaviors and BPSD can sometimes be attributed to environmental incongruence with the individuals' sensory needs, as defined in environmental press theory24,25. Our environment is perceived through our senses. Additional physiological changes associated to aging such as sensory receptor changes and the onset of apathy in dementia6 can lead to internal causes of sensory deprivation26,27. Under-stimulating environments can lead to external sensory deprivation28,29 possibly causing boredom, whereby eliciting maladaptive behaviors. Sensory processing theories, as defined by Dunn30 indicate sensory patterns and needs specific to each individual (Table 1). These sensory needs depict thresholds for optimal function of the nervous system. When paired with environmental stimuli, the result is behavioral expression. If demands of the environment are not compatible with sensory processing abilities, then the individual may not behave optimally. An environmental (physical and social) and behavioral, nonpharmacological approach31,32 may be most effective in promoting ideal sensory experiences whereby decreasing BPSD33. Sensory-based assessment is necessary34 in determining individual sensory needs. The Adult sensory profile is a validated measure in those with dementia30,35.

Current research lacks sensory-based assessment, individualization of intervention, use of protocols, and is plagued with methodological errors creating mixed results36-40. Individual sensory programs, also known as sensory diets, have been shown effective for decreasing agitation in various neurological disorders, but have not been well-established with individual assessment, development and implementation in dementia care20,41,42. Once established, environmental design protocols for ADRD care will likely decrease burdensome BSPD, decrease need for institutional care, and possibly delay mortality while preserving quality of

life.43 The need for well-designed non-pharmacological interventions for BPSD is significant.44 Application of th
described here is driven by clinical observations across the lifespan and can have immediate translation into treatment options for BPSD.

Objectives: List your research objectives. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below.

1. To assess feasibility of environmental design protocols for intervention adherence and behavior change in subjects with moderate to severe dementia.
2. To evaluate sensory processing patterns and preferences of subjects with moderate to severe dementia.
3. To assess behavioral impact of environmental design intervention on functional activity engagement and cognition.

Study Design: Describe the study design (e.g., single/double blind, parallel, crossover, etc.). Indicate whether or not the subjects will receive placebo medication at some point in the research procedures. Also, indicate whether or not the subjects will be randomized in this study. You may reference sponsor's protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below. (Including the study design table from a sponsor's protocol is helpful to IRB members.)

Community-Based Participatory Research: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.

Research Repositories: If the purpose of this submission is to establish a Research Repository (bank, registry) indicate whether the material you plan to collect would or would not be available from a commercial supplier, clinical lab, or established IRB approved research repository. Provide scientific justification for establishment of an additional repository collecting duplicate material. Describe the repository design and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance or the UK Research Registry Guidance.

This study will use a single-blind, placebo controlled, three-arm, parallel-design. Thirty subjects with moderate to severe Alzheimer's disease as primary dementia type (Clinical Dementia Rating Scale score of 2-3) will be randomly assigned to one of three arms: standard care; standard protocol (pre-determined set of environmental design modifications); or personalized protocol (environmental design modification developed with subject based on sensory preference and behavioral needs). Intervention will last 4 weeks. Weekly monitoring for protocol adherence and adverse events will occur throughout study. An follow-up 4 weeks post-intervention will occur. The entire project will be conducted over 10 weeks of participant engagement.

With recent in-person limitations to due COVID-19, as well as the need for increased evidence involving telemedicine, this study will be conducted in accordance with the University of Kentucky Telemedicine regulations and practices. The University of Kentucky has had an active telehealth program since 1995 and has conducted hundreds of thousands of telehealth encounters using interactive videoconference technology in over 25 medical, surgical, mental/behavioral health and therapeutic specialties. UK's videoconference platform is Zoom. UK has a Business Associate Agreement with Zoom, and uses the HIPAA compliant version of the technology to insure 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. The state of Kentucky shutdown of all elective medical services and the inherent fear of patients to come to a healthcare facility mandated that UK Healthcare launch an enterprise-wide telehealth solution to meet the overwhelming demand for acute primary care visits as well as scheduled visits that could not take place while clinics were closed. 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.

Participants will be selected with assistance from Sanders Brown Center on Aging (SBCoA) staff using the University of Kentucky Alzheimer's Center Longitudinal participant database (IRB# 88-0102-F2L [Jicha, PI]). University of Kentucky Alzheimer's Disease Center Clinical Core Leader, Dr. Gregory A. Jicha, has approved access to and use of the University of Kentucky Alzheimer's Disease Center Community Registry database, which is located at the SBCoA Clinic, 1030 S. Broadway, Lexington, KY 40504. The database follows 200-300 volunteers who live in the local community around SBCoA Clinic for longitudinal data collection purposes. Participants with cognitive impairment are primary targets for data tracking for the database. Each participant in the database has corresponding information for primary caregivers, which is also maintained in the database. All cognitively impaired database enrollees and their caregivers have agreed to be contacted by SBCoA associates for invitation to participate in additional research projects. Annual confirmation is obtained by the center to ensure participants continue to permit contact via phone calls or other methods from researchers and staff at SBCoA for notification, explanation, and invitation to additional research opportunities offered by the University of Kentucky.

Patients of the Kentucky Neuroscience Institute with memory impairment may also be contacted for participation of this study. Upon identification of eligible participants, the KNI medical team will determine patient interest to be contacted by study personnel and notify Dr. Rhodus (PI) to follow up with contact to potential participants and/or the study flyer will be mailed or emailed to eligible patients with request to contact study personnel if interested in study participation.

Primary measures:
Feasibility will be assessed by monitoring of protocol adherence and behavior change.
• Caregivers will be responsible for providing treatment protocols throughout duration of treatment window. Adherence to the protocol will be kept and measured using the behavioral journal and intervention adherence log
• Weekly check-ins with the caregivers will provide opportunity to review adherence and reactions to the protocol, as well as assess for adverse reactions, need for modification, or discontinuation. If the investigator finds that the participant is noncompliant, the PI

may remove the participant from further participation in the study.
• Caregiver burden will be measured using the Zarit Caregiver Burden Scale.

Secondary measures:
• Behavior will be assessed using the Vineland Adaptive Behavior Scales (VABS) and the Neuropsychiatric Inventory (NPI) at baseline and post-intervention, and behavior tracking throughout intervention.
• Cognitive measures will include the MOCA and CDR at baseline, post-intervention and follow up
• Heart rate tracking and sleep will be measured using wearable activity tracker (Actigraph) at all times except while charging device.

Sensory processing patterns and functional activity engagement will be assessed for all participants with dementia and used for individualization arm of intervention.
• Sensory processing will be measured using the Adult Sensory Profile (ASP) for all subjects at baseline.
• Functional activity engagement will be measured using the Canadian Occupational Performance Measure (COPM) at baseline and post-intervention.

Control Group: Standard of care for behavioral management and 2-page educational pamphlet describing safety for home environments. At the conclusion of the study, following the four-week follow up visit, participants will be offered a standardized sensory kit (as described below) to use at their discretion.
Standard Environmental Design Protocol: Participants' caregivers will receive standard recommendations for physical environmental modifications, caregiving techniques, and a sensorimotor stimulation kit via mailing from study site. Physical environmental modifications will include declutter living space, reduce background noise, increase natural light, accommodate for accessibility to commode and areas for drinking and eating. Caregiving techniques will include training for calming demeanor (emotional contagion), needs-driven care to decrease onset of behavioral disruption, and accepting and accommodating approach to behavioral disruption. A sensorimotor stimulation kit will be provided to each participants' caregiver for administration three times per day, lasting 30-60 minutes total per day. The stimulation kit will include an item for tactile tool via hands and arms, auditory input via a CD or audio file for music and speakers, olfactory input will be gained through use of scented oils on cotton balls, proprioceptive input will be provided with a 3 pound lap pad, vestibular input will be provided through written instruction of movement (walking, dancing, arm movements if unable to walk unassisted), and visual input via fiberoptic lights and a handheld liquid gel timer.
Individualized Environmental Design Protocol: Participants' caregivers will receive standard recommendations of physical environment modifications and caregiving techniques. Physical environmental modifications will include declutter living space, reduce background noise, increase natural light, accommodate for accessibility to commode and areas for drinking and eating. Caregiving techniques will include training for calming demeanor (emotional contagion), needs-driven care to decrease onset of behavioral disruption, and accepting and accommodating approach to behavioral disruption. Individualized sensory stimulation kids will be developed using subjects' preferred sensory stimuli (as determined by the Adult Sensory Profile assessment) and behavioral concerns identified in the COPM. One target behavior and/or time period of the day will be targeted for improvement. Selection of items included in the individualized sensory kit will be determined based on the attached decision tree and sensory mode plans. The sensory kit will be provided via caregiver administration or supervision two scheduled times (once in the morning and once in the afternoon) per day and one time as needed prior to activity or task associated with behavior concern to promote maintained behavioral regulation and adaptive responses.

Data Analysis: Due to the nature of feasibility of this study, sample size of 30 participants with cognitive impairment (10 per arm) does not fully power the study. Statistical description of behavior change results will be explorative and descriptive in nature. Per-protocol analysis (PPA) will be performed with 75% or more adherence to program as determined from weekly visits and journals. Power analyses for secondary outcome measures cannot be performed as this study is a preliminary investigation of these secondary outcome measures.
Summary statistics will be tabulated for the behavior change, protocol adherence, and adverse events. The frequencies of behavior change, protocol adherence, and adverse events will be compared between participants within same group and between group for differences.
Summary statistics will be tabulated by treatment arm for the baseline, week 4, and week 8 outcome measures of VABS, NPI, and protocol adherence based on behavior journals. The change from baseline to week 4 and follow-up will be calculated for each patient. Descriptive statistics will be examined to see whether levels of each assessment at baseline are normally distributed. If they are, then the mean changes will be compared in each treatment group with the standard of care group by analysis of variance (ANOVA). If they are not normal, then consideration will be given to data transformation.

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Study Population: Describe the characteristics of the subject population, such as anticipated number, age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion. Explain the rationale for the use of special classes such as fetuses, pregnant women, children, institutionalized, adults with impaired consent capacity, prisoners, economically or educationally disadvantaged persons or others who are likely to be vulnerable.

If women or minorities are included, please address how the inclusion of women and members of minority groups and their subpopulations will help you meet your scientific objectives. Exclusion of women or minorities requires clear and compelling rationale that shows inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be excluded routinely from participation in clinical research.

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- The proposed dates of enrollment (beginning and end);
- The proposed sample composition of subjects.

You may reference grant application/sponsor's relevant protocol pages and attach as an appendix using the below attachment button, however, a summary paragraph must be provided in the text box below.

The current study will use participants enrolled in the University of Kentucky Alzheimer's Center Longitudinal Cohort database sponsored by the University of Kentucky SBCoA. Individuals enrolled in this database undergo cognitive testing and are followed clinically by Dr. Greg Jicha at SBCoA. The database contains contact information, demographic information, results of cognitive tests, and caregiver information, along with other information as collected by SBCoA. Upon enrollment to the University of Kentucky Alzheimer's Center Longitudinal Cohort database, participants have agreed to be subjects in research and allow contact from SBCoA for invitations into additional research projects, such as the project explained in this IRB. Diagnosis of dementia creates significant cognitive impairment. All participants with these diagnoses will have cognitive impairment limiting their ability to independently provide informed consent. See section 6 regarding informed consent processes used to maximize participant understanding and participation.
Individuals with moderate to severe dementia with primary type as Alzheimer's disease and caregiver report of behavioral disturbance will be selected. Recruitment will occur continuously based on eligibility status and ADC cohort participation. This selective sampling approach will allow for greatest applicability and homogeneity for this study afforded by the cohort database at SBCoA.
In addition to individuals with dementia, this study will enroll caregivers of the subjects who have dementia. Individuals with dementia and their caregivers will create a participant dyad for data collection means. Enrollment of participant dyads is planned to occur upon IRB approval through May, 2021.

Inclusion Criteria:
Participants must meet all of the following inclusion criteria in order to participate in the study:
1. Men or women aged 21-90, inclusive.
2. Living at home in the community with one primary caregiver.
3. Diagnosis of Alzheimer's disease as primary dementia type of moderate to severe stages (confirmed by Clinical Dementia Rating Scale score of 1.5+)
4. Stable medical condition for one month prior to screening visit
5. Stable medications for 4 weeks prior to screening visit
6. If on psychotropic medication, they are at a point where dosage and treatment are stabilized for the duration of the study
7. Physically acceptable for this study as confirmed by medical history, physical exam, neurological exam and clinical tests completed by MD/APRN/PA
8. Functional sensory abilities with or without aids (hearing, vision, smell, touch, taste)
9. Caregiver report of challenges related to behaviors within 4 weeks of study enrollment
10. Caregiver willing to participant throughout duration of study
11. Caregiver access to and ability to use video technology (Zoom video call)
12. UKADC visit with medical provider within 24 months of study recruitment
13. Not actively participating in physical/occupational therapy for four weeks prior to or throughout duration of study

Exclusion Criteria:
1. Unstable medical conditions for three months prior to screening visit such as poorly controlled blood pressure, diabetes, or breathing problems…etc.
2. Wheelchair or bed bound.
3. Residence in skilled nursing facility or facility-based care.
4. Skin lesions or skin abnormalities throughout upper extremities.
5. Allergies related to lotion or fragrance.
6. Caregiver report of physically violent behaviors.
7. Initiation of antipsychotic medication within 6 weeks prior to screening or unstable use of such medications
8. Diagnosis of profound or total sensory altering disorders including macular degeneration, legal blindness, total deafness, severe peripheral neuropathy, anosmia.
9. 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.
10. Diagnosis or concern of epilepsy.
11. History of invasive cancer within the past two years.
12. Use of any investigational agents within 30 days prior to screening.
13. Major infection within eight weeks prior to the Baseline Visit.
14. Physically unacceptable for this study as confirmed by medical history, physical exam, neurological exam and clinical tests

Dates of Enrollment: Upon IRB approval-May, 2021

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Subject Recruitment Methods & Privacy: Using active voice, describe plans for the identification and recruitment of subjects, including how the population will be identified, and how initial contact will be made with potential subjects by those having legitimate access to the subjects' identity and the subjects' information.

Describe the setting in which an individual will be interacting with an investigator or how and where members of the research team will meet potential participants. If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations as participants in clinical research. Describe steps taken to minimize undue influence in recruiting potential participants.

Please note: Based upon both legal and ethical concerns, the UK IRB does not approve finder's fees or "cold call" procedures made by research staff unknown to the potential participant. The ORI/IRB does not control permission to any UK listserv, mass mailing list, etc. Investigators must secure prior approval for access and use from owners/managers.

For additional details, see topic "Recruitment of Subjects/Advertising" on ORI's IRB Survival Handbook web page and the PI Guide to Identification and Recruitment of Human Subjects for Research.

The University of Kentucky SBCoA will assist in participant identification based on the participant database for the University of Kentucky Alzheimer's Center Longitudinal Cohort. Participants who have a Clinical Dementia Rating Score of 1.5 or above and reside in the community will be targeted for recruitment. Additional referrals will also be requested from SBCoA medical team staff. Of individuals identified, flyers will be mailed or emailed to the LAR on file with SBCoA and primary caregivers will be contacted via flyer and phone call from study personnel staffed at SBCoA. In addition, all patients with memory impairment of the Kentucky Neuroscience Institute (KNI) who are eligible for this study may be recruited for participation for this study. Recruitment from KNI will occur prior to informed consent including a review of medical records to identify additional subjects that are not in the recruitment database. This PHI information will be collected via AEHR UKHC (or EPIC). A waiver of informed consent is requested with this protocol. Information that will be collected prior to informed consent will include identifiable private health information including: Name, email address, phone number, DOB, address, medical history, diagnoses, medications, tests completed at SBCoA or KNI. Upon identification of eligible participants, the KNI medical team will determine patient interest to be contacted by study personnel and notify Dr. Rhodus (PI) to follow up with contact to potential participants and/or the study flyer will be mailed or emailed to eligible patients with request to contact study personnel if interested in study participation.

Explanation of no changes in care or participation at SBCoA and the University of Kentucky will be provided. All forms and data collected will be stored electronically on a secure web application, REDCap, sponsored by the Institute for Pharmaceutical Outcomes and Policy (IPOP) physically located in the new Biological and Pharmaceutical Complex building on University of Kentucky's campus. Video recordings will be captured through Zoom, in accordance with the University of Kentucky Telemedicine office and privacy standards. All material will be stored for six years, at which time the content will be deleted and destroyed. Participant and caregiver confidentiality will be maintained through use of pseudonyms and removal of identifying information. The results of this study will be published. In accordance with UK Alzheimer Disease Center data sharing policies, access to the de-identified, raw data collected will restricted up to a period of 1 year after final data is collected and the primary manuscript is published. After such time, the full dataset will be made available for independent analysis and publication without restriction.

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Advertising: Specify if any advertising will be performed. If yes, please see "IRB Application Instructions - Advertisements" for instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use. For additional details, see topic "Recruitment of Subjects/Advertising" on ORI's IRB Survival Handbook web page for the *PI Guide to Identification and Recruitment of Human Subjects for Research* [D7.0000] document [PDF]. If you will be recruiting subjects via advertising at non-UK owned or operated sites, you should include a copy of written permission from that site to place the advertisement in their facilities.

Note: Print and media advertisements that will be presented to the public also require review by UK Public Relations (PR) to ensure compliance with UK graphic standards, and equal opportunity language. See Advertising Instructions for PR contacts.

Advertisement with Flyer approved, Stamped approval attached.

Attachments

Attach Type	File Name
Advertising	Rhodus_Flyer MP edit STAMPED.pdf

Informed Consent Process: Using active voice, describe the consent/assent procedures to be followed, the cir
which consent will be sought and obtained, the timing of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent, who will seek consent., steps taken to minimize the possibility of coercion or undue influence, the method used for documenting consent, and if applicable who is authorized to provide permission or consent on behalf of the subject. Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Describe provisions for obtaining consent/assent among any relevant special populations such as children (see Children in Research Policy [PDF] for guidance), prisoners (see Summary of Prisoner Regulations [PDF] for guidance), and persons with impaired decisional capacity (see Impaired Consent Capacity Policy [PDF] for guidance). Describe, if applicable, use of specific instruments or techniques to assess and confirm potential subjects' understanding of the nature of the elements of informed consent and/or a description of other written materials that will be provided to participants or legally authorized representatives. If you have a script, please prepare it using the informed consent template as a guide, and submit it on a separate page.

Informed Consent for Research Involving Emancipated Individuals
If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **when preparing the IRB application and prior to submitting the application to the IRB**. Include legal counsel's recommendations (legal counsel's recommendations may be attached in the E-IRB "Additional Information" section as a separate document, if necessary). For a complete definition of emancipated minors, see the section on *Emancipated Individuals* in the Informed Consent SOP [PDF].

Informed Consent for Research Involving Non-English Speaking Subjects
If you are recruiting non-English speaking subjects, the method by which consent is obtained should be in language in which the subject is proficient. Describe the process for obtaining informed consent from prospective subjects in their respective language (or the legally authorized representative's respective language). In order to ensure that individuals are appropriately informed about the study when English is their second-language, describe a plan for evaluating the level of English comprehension, and the threshold for providing a translation, or explain why an evaluation would not be necessary. For additional information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.

Research Repositories
If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the Sample Repository/Registry/Bank Consent Template [PDF]

A waiver of informed consent is included within this proposal, along with access to HIPAA information prior to obtaining informed consent for participation. PHI from KNI medical records will be accessed for recruitment purposes through the AEHR UKHC system. PHI and identifying information will be sought from SBCoA participant charts. PHI accessed will include: Name, DOB, email address, phone number, address, medical history, diagnoses, medications, tests completed, and/or visit notes at Sanders-Brown Center on Aging or the Kentucky Neuroscience Institute.

Given the nature of cognitive impairment associated dementia (see Form T), upmost precaution and protection will be included in the informed consent process. The intent of this study is to conduct research with severely cognitively impaired participant whom may also have communication deficits. Participants have associated dependency on caregivers/LAR for decision making, safety, and activities and/or instrumental activities of daily living. Explanation of the study objectives, informed consent process and confidentiality will be explained to the individuals with cognitive impairment and their caregiver/LAR. If the dyad is willing to participate, informed consent will be sought by:

During pre-screening, it will be determined if the patient has a legally authorized representative/advocate. If so, the consent will be sent to and signed by this person (LAR) and assent will be obtained from the patient. If the patient does not have legally authorized representative and appears oriented (to time, place, person) and is able to verbalize understanding of the study expectations and risks, informed consent will be signed by the patient with patient advocate present.

Informed consent will be collected via several ways. The electronic or hard copy IRB-Stamped informed consents will be emailed/mailed to the person with dementia's legally authorized representative (LAR) or the patient with dementia and their care advocate if LAR is not established (patient consent form), and their identified caregiver (caregiver consent form). An electronic form e-Consent will be emailed to both individuals (LAR and Caregiver) and required for signature using REDCap technology. This form will be signed prior to the screening visit, or after thorough review during the screening visit, along with assent obtained from the person with dementia. The assent form will be discussed and used with the patient via Zoom video conferencing during screening visit. Verbal confirmation of understanding and willingness to participant will be sought. If they are unable to provide verbal communication, non-verbal cues such as head nodding (described in Form T) will be collected. If non-verbal cues are unable to be collected, consent will be deferred entirely to the LAR.

A copy of the consent form will be emailed or mailed to the participants prior to Visit 1. LAR's, participants with dementia, and caregivers will be advised that participation is strictly voluntary, and they can withdraw from the study at any time. Participants will be assured that participation or nonparticipation of this study will have no direct effect on enrollment or participation of SBCoA program and healthcare services.

A waiver of documentation of informed consent will be used for administration of the Situational Assessment of Activity and Function (SAAF) survey. A link will be emailed to caregiver participants with a cover letter explaining the assessment. Participants are not required or obligated to respond to the email or survey and all responses will be deidentified. Completion of the assessment and feedback via email to the study PI regarding participants' experience with the assessment will indicate implied consent.

Research Procedures: Describe the research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project.

For this study, the following step-by-step sequence will be used. Recruitment will occur via discussion with SBCOA medical team (MD/APRN/PA) and Dr. Gregory Jicha of appropriate referrals of heightened cognitive impairment with behavioral disturbance. Additionally, SBCOA records will be reviewed for all eligible cohort participants. These participants will be contacted via SBCOA recruitment team with calling, mailing, and/or emailing eligible participants with an invitation to participate in the current study. Following agreement to participate, SBCoA staff and researcher will coordinate with the participant a date and time for Visit 1 to be completed via a virtual telemedicine platform. All visits within this study will be scheduled at times convenient for the participants using telemedicine Zoom video conferencing. Videos will be recorded and saved on private and secure server hosted by Sanders-Brown Center on Aging Data Management Team.
During the screening visit, a research assistant or PI will review and obtain consent as described above, talk with the LAR and caregiver to determine eligibility status, and record medications. The PI will complete a UKADC or KNI chart review of medical conditions, medications, and symptoms from the prior 24 months if available. Records will be assessed for most recent vital signs (systolic and diastolic blood pressure, pulse, temperature, and respiration), known allergens, chronic medical conditions, recent medical changes, and medications. The PI (OT) or UKADC medical staff (MD/APRN/PA) will conduct a physical and neurological examine via Telemedicine.The physical examination will include skin, head/ears/eyes/nose/throat (HEENT), oral/teeth/gums (history of dental problems/dentures), sensory function, gait/walking ability, and musculoskeletal range of motion of upper extremities. All complete physical and neurological examination data will be entered on the appropriate CRF. Neurological assessment will include of cranial nerves, strength, coordination, symmetry of movements, and movement speed. Verbal assessment of patients' sensory function (including hypersensitivity) with caregiver will occur at the screening. Significant abnormalities consistent with disease processes will be documented.

Once eligibility is confirmed, the research assistant will email a REDCap link to the caregiver for the Zarit Caregiver Burden and the Adult Sensory Profile, Actigraph and charger, and a copy of consent forms to the participant's caregiver. The PI will complete the COPM on visit 1, and provide caregiver and participant with Actigraph wear and care instructions. The VABS will be emailed to the caregiver via a confidential link through Pearson Publishing.
Subjects will be randomized to treatment arms by the statistical team. Participants will be randomized into one of the three groups: control, standard environmental design protocol, individualized environmental design protocol. Recruitment will be ongoing until all groups have 10 participants. In the event of drop out or early termination (causes will be recorded), researchers will recruit for replacement participants so that the study is completed with 30 entire study duration cases.
Visit 2 will consist of baseline assessment. A research assistant or the PI will complete the MOCA, with the participant with dementia. The caregiver will complete the NPI. Following Visit 2, an occupational therapist will be provided results of the COPM and ASP for participants of the individualized treatment arm. A sensory protocol will be developed based on assessment results following predetermined guidelines. All intervention materials for all study participants will be mailed to caregivers within 4 days of Visit 2. Upon receipt of intervention supplies, caregivers will contact the PI or occupational therapist for study initiation. Visit 3 will provide caregiver training for intervention use and initiation of Actigraph use. Adverse events since Visit 2 will be recorded. Visit 3 marks day 1 of intervention implementation. Participants will mail Actigraph back to UKADC in provided pre-paid envelop following week one of intervention.
Visits 4-8 will be scheduled at the end of each week following Visit 3. The PI, occupational therapist, or research assistant will record concurrent medication, and adverse events. With the caregiver, the interviewer will review behaviors observed by the caregiver, the behavior journal, compliance and acceptance of the intervention by the caregiver and the person with dementia. Actigraphs will be mailed from UKADC to participants, and patient will be asked to wear actigraph for last week of intervention window.
Visit 9 will conclude the intervention window at the end of week 4. The PI, occupational therapist, research assistant will record adverse events, concurrent medication, Actigraph, and weekly behavior journals/compliance. The research assistant will conduct the NPI, COPM, VABS with the caregiver and the MOCA with the person with dementia. A member of the SBCoA medical team will conduct a physical and neurological exam. Due to the length of assessments within Visit 7, this session may be split and completed in more than one Zoom conference. The Zarit Caregiver Burden Scale will be emailed or mailed to the caregiver with prepaid envelop for return.
A four-week follow up will be conducted at Visit 10 whereby the research assistant will conduct the NPI, COPM, VABS with the caregiver, and the MOCA with the person with dementia. A member of the SBCoA medical team will conduct a physical and neurological exam. The Zarit Caregiver Burden Scale will be emailed or mailed to the caregiver with prepaid envelop for return.

Schedule of events can be found in attached detailed protocol.
A list of potential items sent in sensory kit is attached here.

Attachments

Attach Type	File Name
ResearchProcedures	Sensation Kit.pdf

Data Collection: List the data or attach a list of the data to be collected about or from each subject (e.g. interview script, survey tool, data collection form for existing data).

If the research includes survey or interview procedures, the questionnaire, interview questions or assessment scales should be included in the application (use attachment button below).

The data collection instrument(s) can be submitted with your application in draft form with the understanding that th
submitted to the IRB for approval prior to use (submit final version to the IRB for review as a modification request if initial IRB approval was issued while the data collection instrument was in draft form).

Note: The IRB approval process does not include a statistical review. Investigators are strongly encouraged to develop data management and analysis plans in consult with a statistician.

Neuropsychiatric Inventory
The NPI-Q will be administered with the caregiver at baseline, week 4, and week 8. The NPI-Q is a commonly used behavior assessment tool for persons with cognitive impairment.[63] This tool was selected in order to best represent behaviors characteristic of cognitive impairment. The assessment includes 12 behavioral and psychiatric domains including delusions, hallucinations, irritability, anxiety, agitation, depressions, dysphoria, apathy, disinhibition, aberrant motor behavior, appetite/eating changes, and night-time behaviors. The care provider rates these behaviors based on severity of the impact on the patient on a scale of 1 (mild), 2 (moderate), or 3 (severe). The care provider also rates distress to themselves caused by each behavior on a scale from 0 (not distressing at all) to 5 (extreme or very distressing). Both behavior severity and caregiver distress will be used in analysis.

Vineland Adaptive Behavior Scale (VABS)
The VABS will be used to assess behavior at baseline, week 4, week 8. The VABS is a standardized, norm-referenced assessment of adaptive behavior for individuals from birth to age of 90 years. Domains of communication, daily living skills, socialization, motor skills, and maladaptive behavior are examined. The assessment is designed for a variety of developmental, intellectual, and cognitive disabilities, including autism spectrum disorder, ADHD, traumatic brain injury, and Alzheimer's disease and related disorders. This assessment has an option specific for telehealth, remote administration. For this study, change in the Adaptive Behavior Composite (ABC) score, as well as domain specific scores of communication, daily living skills, socialization, and motor skills will be used in analysis.

Adult Sensory Profile (ASP)
In order to maximize time consideration, the ASP will be mailed to caregivers following screening with a prepaid return envelope. The ASP is a validated instrument and will yield norm referenced (for age) data regarding sensory processing abilities and will be used in development of individualized protocols, as is typical in occupational therapy clinical practice.[35, 64, 65] The ASP is a 60-item survey and is completed by the participant or their care partner. For this study, care partners will complete the survey. Each item describes a behavior attributed to sensory processing. The behaviors belong to one of four sensory processing patterns (15 items each): low registration, sensation seeking, sensory sensitivity, and sensation avoiding. Participants rate the frequency with which they engage in each behavior or they observe it in the participant, in the case of caregivers responding. The ratings for all items are summed within each sensory processing pattern to obtain summary scores. The summary score of each category is compared to normative data and classified as being 'much less', 'less', 'similar', 'more than' or 'much more' than most people in their age range.

Behavioral Journal
Behavior journals will be kept by caregivers daily during the 4-week intervention. Behavior journals will be used to measure adherence to the treatment protocol using a daily tracking log, prompt care partner reflection of each week's intervention use, and monitor behavioral changes throughout the intervention. Journals will be reviewed weekly with study personnel and returned to investigator at intervention completion on week 4 visit. Analysis will include quantitative

Actigraph Wrist Wearable
The Actigraph wGT3X-BT will be used to collect behavioral and physiological data of sleep, movement, and physical activity. The device will be worn during baseline (1 week), first week of treatment (1 week), and last week of treatment (1 week). The device will be mailed back to UKADC during treatment window for charging and data collection, and mailed to patient prior to last week of treatment. The device will be returned to UKADC via prepaid postage following last week of intervention. The data will be collected off of the device following completion of the 4-week intervention window and stored in ActiLife 6, a private and secure platform for data acquisition from Actigraph. All data will be deidentified and stored in REDCap.

Montreal Cognitive Assessment (MoCA)
The MoCA is a rapid screening instrument for mild cognitive dysfunction. The MoCA assesses different cognitive domains: attention and concentration, memory, language, conceptual thinking, calculations, and orientation. Time to administer the MoCA is approximately 5-10 minutes. The total possible score is 30 points; a score of 18 or above is considered normal.

CDR (Clinical Dementia Rating)
The CDR will be administered to the participant and informant, at screening, week 24 and week 48 and will be administered by a certified tester. During the CDR is a structured interview protocol that assesses a patient's cognitive and functional performance in six areas: memory, orientation, judgment & problem solving, community affairs, home & hobbies, and personal care. Scores in each of these are combined to obtain a composite score ranging from 0 through 3. The CDR can discern very mild impairments, based on informant interview and short task-based participant responses.

Canadian Occupational Performance Measure (COPM)
COPM is a client-centered, standardized, criterion-referenced outcome measure which allows for individualized treatment implementation. The COPM is administered via a semi-structured interview with caregivers at baseline, Week 4, and 8 week follow up. The COPM is a multidisciplinary health assessment that assesses all areas of the participants' occupational performance, including self-care, leisure, and instrumental activities of daily living. Caregivers identify areas of concern or that need improvement, and the top five activities are rated for performance and satisfaction. Caregiver rating of performance and satisfaction of self-identified activities will be used in statistical analysis.

Situational Assessment of Activity and Function (SAAF)
The SAAF is a new assessment created by current study PI (Rhodus) to gain better insights on the situational characteristics that cause behavioral reactions in persons with dementia. The SAAF was developed from initial data collection of the current study. The SAAF is 120 questions to be completed by caregivers of persons with cognitive impairment and will take approximately 15 minutes to complete. Questions are review caregiver perceptions of the activity performance of the person they care for in various activities (i.e., cooking, dressing, community mobility, etc.) The assessment is completed electronically using Redcap survey emailed to caregivers. Use of the SAAF is in this study is to glean initial reactions from caregiver participants regarding their ease of use and to determine time length of administration. The use of the SAAF in this study will be completed using REDCap public survey link. This feature allows individuals to complete the survey, but does not associate a record ID to answers, all responses are anonymous. Data from survey item responses will not be stored, saved, reviewed or analyzed. Caregivers currently enrolled in this study will be asked to voluntarily complete the electronic survey if they would like. It is not required. Participants will be asked to disclose the length of time it took to complete the form and to document any initial perceptions of the ease of use of the form and/or it's perceived applicability.

Attachments

Attach Type	File Name
DataCollection	CDR.pdf
DataCollection	Behavior journal.pdf
DataCollection	COPM.pdf
DataCollection	Form M Sensory.pdf
DataCollection	MoCA-Test-English_7_1.pdf
DataCollection	ZBI-22_AU1.0_eng-USori_ReviewCopy-1.pdf
DataCollection	Vineland-3 Interview (002).pdf
DataCollection	npiq-questionnaire.pdf
DataCollection	SituationalAssessmentOfActivit.pdf

Resources: Describe what resources/facilities are available to perform the research (i.e., staff, space, equipment). Such resources may include a) staffing and personnel, in terms of availability, number, expertise, and experience; b) psychological, social, or medical services, including counseling or social support services that may be required because of research participation; c) psychological, social, or medical monitoring, ancillary care, equipment needed to protect subjects; d) resources for subject communication, such as language translation services, and e) computer or other technological resources, mobile or otherwise, required or created during the conduct of the research. Please note: Some mobile apps may be considered mobile medical devices under FDA regulations (see FDA Guidance). Proximity or availability of other resources should also be taken into consideration, for example, the proximity of an emergency facility for care of subject injury, or availability of psychological support after participation.

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see IRB Application Instructions - Off-Site Research web page); supportive documentation can be attached in the E-IRB "Additional Information" section. Provide a written description of the role of the non-UK site(s) or non-UK personnel who will be participating in your research. The other site may need to complete its own IRB review, or a cooperative review arrangement may need to be established. Contact the Office of Research Integrity at (859) 257-9428 if you have questions about the participation of non-UK sites/personnel.

If the University of Kentucky is the lead site in a multi-site study, or the UK investigator is the lead investigator, describe the plan for managing the reporting of unanticipated problems, noncompliance and submission of protocol modifications and interim results from the non-UK sites.

Resources for this study include research assistants and medical staff at SBCoA. University of Kentucky Telemedicine office will provide technical support needed for secure access to Zoom conferencing. Data will be uploaded and saved to REDCap the day of researcher acquisition following completion. REDCap is a password-protected, secure data management web application in the secure data center run by the Institute for Pharmaceutical Outcomes and Policy (IPOP) physically located in the new Biological and Pharmaceutical Complex building at the University of Kentucky. REDCap will be accessed using password-protected computers issued by the University of Kentucky. Intervention materials will be purchased by SBCoA administrative staff and mailed via UPS shipping to participants' homes.
Dr. MaryEllen Thompson from Eastern Kentucky University, Department of Occupational Science and Occupational Therapy will be included in this study. Her role will be to serve as an occupational therapy consultant if needed during development of individualized sensory protocols, during treatment for consultation for sensory procedures if questions from participants arise and PI is not able to independently address questions, and during data analysis. Dr. Thompson will have access to recorded patient videos. An IRB Authorization Agreement with EKU will be sought.

Potential Risks: Describe any potential risks or likely adverse effects of the drugs, biologics, devices or procedures subjects may encounter while in the study. Please describe any physical, psychological, social, legal or other risks and assess their likelihood and seriousness.

There is minimal risk involved in participation of this study. Potential for minimal risk is associated with possibly sensory system overload associated with interventions. Signs of sensory overload include neurophysiological changes (sweating, dizziness, changes in balance, pallor, pupil dilation, yawning), emotional and behavioral changes (fearful responses, avoidance, irritability, anxiety, angry outbursts, aggression, agitation), and cognitive changes (increased confusion, decreased orientation to time, place, self, etc.), and decreased attention span (more than typical). Monitoring of sensory overload will be monitored by caregivers following training of

intervention techniques. psychosocial stress and burden to the individual with dementia and their caregiver during and the presence of the researcher during observation. Interventions may include topical lotions which may cause skin irritation, rash, or dermatitis. Caregivers will be trained to observe patient for any signs of discomfort, sensory overload, or skin irritation. distress or anxiety. If a participant/caregiver shows signs of distress or anxiety, the researcher will provide the participant/caregiver with a break. If the participant wishes to proceed then another topic may be discussed, if not the interview or observation will be rescheduled for a different date.

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Safety Precautions: Describe the procedures for protecting against or minimizing any potential risks, *including risks of breach of confidentiality or invasion of privacy*. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects. If vulnerable populations other than adults with impaired consent capacity are to be recruited, describe additional safeguards for protecting the subjects' rights and welfare.

The procedures for protecting against and minimizing any potential risks of breach of confidentiality or invasion of privacy during the research will require each individual with dementia, their LAR, and the caregiver to review and sign the consent and confidentiality agreements. All study conduct will occur using procedures outlined and validated by the University of Kentucky Telemedicine office. Contact information for Dr. Greg Jicha (SBCOA Clinical director) and SBCOA social workers will be kept on file and accessible during data collection in the field in case issues or concerns arise during intervention visits. Collected data will be de-identified and all data will be kept in a password-protected computer for a period of six years, then destroyed via deletion of files.

Benefit vs. Risk: Describe potential benefits to the subject(s); include potential benefits to society and/or general knowledge to be gained. Describe why the risks to subjects are reasonable in relation to the anticipated benefit(s) to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If you are using vulnerable subjects (e.g., impaired consent capacity, pregnant women, etc…), justify their inclusion by describing the potential benefits of the research in comparison to the subjects' vulnerability and the risks to them. For information about inclusion of certain vulnerable populations, see the IRB/ORI Standard Operating Procedure for Protection of Vulnerable Subjects [C3.0100] [PDF].

There are no direct benefits to subjects. Risks to participants, both caregivers and those with dementia, are minimal, including possible discomfort with sensory-based intervention implementation.

Available Alternative Treatment(s): Describe alternative treatments and procedures that might be advantageous to the subjects, should they choose not to participate in the study. This should include a discussion of the current standard of care treatment(s).

Not applicable.

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Research Materials, Records and Privacy: Identify the sources of research material obtained from living human subjects. Indicate what information (specimens, records, data, genetic information, etc.) will be recorded and whether use will be made of existing specimens, records or data. Explain why this information is needed to conduct the study.

Return of Research Results or Incidental Findings (if applicable):
If research has the potential to identify individual results or discover incidental findings that could affect the health of a subject, describe plans to assess, manage, and if applicable disclose findings with individual subjects or provide justification for not disclosing. For IRB expectations, refer to the UK IRB "Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings" [PDF].

All materials, except behavior journals, will be in electronic format. Materials will include consent agreements (hard copy mailed to participants), Adult Sensory Profile Questionnaire, Zarit Caregiver Burden Scale, COPM results, VABS results, CDR, NPI, Actigraph, MOCA, video recordings, and electronic case report files including medication, medical and neurological examination results, and adverse events. These forms will be uploaded and saved to REDCap the day of acquisition from participants. Hard copies of behavior journals will be electronically scanned and will be destroyed via shredding following uploading to REDCap. REDCap is a password-protected, secure data management web application in the secure data center run by the Institute for Pharmaceutical Outcomes and Policy (IPOP) physically located in the new Biological and Pharmaceutical Complex building at the University of Kentucky. The files will be stored for a period of six years per UK Policy A13-050. Digital audio recordings and electronic transcription of all interviews will be obtained. These electronic files will also be stored on REDCap. Upon enrollment in the study, subjects will be given pseudonyms to protect confidentiality and de-identify data.

Confidentiality: Specify where the data and/or specimens will be stored and how the researcher will ensure the privacy and confidentiality of both. Please address the following items or indicate if the following has been addressed in a HIPAA or Limited Review form:

- physical security measures (e.g., locked facility, limited access);
- data security (e.g., password-protection, data encryption);
- who will have access to the data/specimens and identifiers;
- safeguards to protect identifiable research information (e.g., coding, links, certificate of confidentiality);

- procedures employed when sharing material or data, (e.g., honest broker if applicable, written agreement with identify, measures to ensure that subject identifiers are not shared with recipients).
- management after the study

Describe whether data/specimens will be maintained indefinitely or destroyed. If maintained, specify whether identifiers will be removed from the maintained information/material. If identifiers will not be removed, provide justification for retaining them. If the data/specimens will be destroyed, describe how and when the data/specimens will be destroyed. For multi-site studies, the PI consults the study sponsor regarding retention requirements, but must maintain records for a minimum of six years after study closure. Also, specify who will access the identified data/specimens, and why they need access. If applicable, describe what measures will be taken to ensure that subject identifiers are not given to the investigator. If applicable, describe procedures for sharing data/specimens with entities not affiliated with UK (If the research is non-sponsored you need a data use agreement to share data/specimens [Transfer Agreements]).

HIPAA/FERPA Minimal Access Standards: The IRB expects researchers to access the minimal amount of identifiers to conduct the study and comply with applicable HIPAA and Family Educational Rights and Privacy Act (FERPA) requirements. If data are going to be collected, transmitted, and/or stored electronically, for appropriate procedures please refer to the guidance document "Confidentiality and Data Security Guidelines for Electronic Data" [PDF].

Cloud storage: For storage of data on cloud services other than UK OneDrive, please verify security settings are sufficient and in accordance with respective departmental, UK Corporate Compliance, and/or UK Information Technology requirements.

Creation of digital data application/program: If a research protocol involves the creation and/or use of a computer program or application, mobile or otherwise, please specify whether the program/application is being developed by a commercial software developer or the research team and provide any relevant information regarding the security and encryption standards used, how data is stored and/or transmitted to the research team, what information about the subjects the program/application will collect, etc. For relevant information to include, see Considerations for Protocol Design Concerning Digital Data [PDF]. The IRB may require software programs created or used for research purposes be examined by a consultant with appropriate Internet technology expertise to ensure subject privacy and data are appropriately protected.

NIH-funded genomic research: The National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data consistent with the informed consent of study participants from which the data was obtained. If you are submitting genomic data to an NIH data repository, describe your NIH data sharing plan.

Management after study: Describe how the collected data/specimens will be managed after the end of the study. Specify whether identifiers will be removed from the maintained information/material. If identifiers will not be removed, provide justification for retaining them and specify what steps will be taken to secure the data/specimens (e.g., maintaining a coded list of identifiers separate from the data/specimens).

If the data/specimens will be destroyed, describe how, when, and why this will be done. Note that destruction of primary data may violate NIH and NSF retention and sharing requirements, journal publication guidance, and University Data-Retention policies. Additionally, primary data may be necessary for other purposes (to validate reproducibility, for data sharing, or for evidence in various investigations). PIs should carefully consider whether the destruction of data is justified.

The investigator is responsible for retaining signed consent and assent documents and IRB research records for at least six years after study closure, as outlined in the Study Closure SOP [PDF]. If the research falls under the authority of the FDA or other regulatory agencies, or a study sponsor is involved, additional requirements may apply.

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Each participant will be assigned a participant number and pseudonym, which will be used to identify the person during data analysis and when managing data. This de-identified human subject data will be stored on REDCap. Records maintained by SBCoA are not UK medical records, and so PHI and PII will not be used. At the conclusion of the study, all individual data will be stripped of identifying information and stored on REDCap, a secure location, for a period of 6 years, after which deletion of electronic files will destroy it. The IRB determined all video recording/electronic data must 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." Confidentiality will be maintained, however, in the case in which abuse or concern of participants' safety, the researcher is required by law to report to authorities.

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Payment: Describe the incentives (e.g., inducements) being offered to subjects for their time during participation in the research study. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms and schedule of payment. (It is IRB policy that provision should be made for providing partial payment to subjects who withdraw before the completion of the research. Monetary payments should be prorated or paid in full.)

No monetary incentive will be provided for participation in this study. Intervention kits will be mailed to participants for all arms of the study. These materials will not be returned to the researcher following study completion and kept by caregiver or patient, decided at their discretion.

Costs to Subjects: Describe any costs for care associated with research (including a breakdown of standard of care procedures versus research procedures), costs of test drugs or devices, and research procedure costs that are the subject's responsibility as a consequence of participating in the research. Describe any offer for reimbursement of costs by the sponsor for research related injury care.

This study requires participant use of personal device with webcam and Zoom video conferencing capability. Costs may be associated with cellular use or internet use while operating Zoom platform for this study.

Data and Safety Monitoring: The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research, or NIH-funded/FDA-regulated clinical investigations.

If you are conducting greater than minimal risk research, or your clinical investigation is NIH-funded/FDA-regulated, describe your Data and Safety Monitoring Plan (DSMP). Click here for additional guidance on developing a Data and Safety Monitoring Plan.

If this is a *non-sponsored investigator-initiated* protocol considered greater than minimal risk research, or your clinical investigation is FDA-regulated, *and* if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, click here for additional guidance for information to include with your IRB application.

If relying on an independent agent or committee for DSMB services, it is the PI's responsibility to establish the services with the agent or committee. Please be reminded that the PI must submit DSMB reports to the IRB via modification or continuing review.

DATA AND SAFETY MONITORING PLAN
The Principle Investigator (PI, Rhodus) and Faculty Advisor (Greg Jicha, MD, PhD) will be responsible for monitoring the data and safety of participants along with their co-investigators.
a. Periodic Review: The PI and faculty advisor will hold bi-weekly meetings for the first two months of enrollment, then monthly for four more months, and quarterly thereafter. The faculty advisor will review all minor AE and SAE reported to date of review. The staff meetings will include the PI, co-investigators, and lay co-workers in charge of assessment. The meetings will include evaluation of all research procedures, fidelity to protocol, discussion of newly enrolled participants, and review of status of all formally enrolled participants including all adverse events. Adverse events will be reviewed to determine if changes in the protocol are indicated. Participant demographics to date, recruitment progress, difficulties encountered during enrollment, an update on data entry, and any other issues or concerns that have arisen since the last research team meeting will also be discussed.
In addition to review of all research procedures and AE/SAE, specific review of risk related to behavioral condition of the patient and related to the intervention will be completed at meetings. Review will assess:
1. Risk to behavioral condition: Weekly checks via Zoom video conferencing of behavioral tracking will occur with PI and participants. If substantial behavioral change is noted by caregiver or patient report, this behavior change will be reviewed with faculty advisor.
2. Risk of Intervention: Weekly checks via Zoom video conferencing with participants will assess adverse events and patient complaint related to the intervention tools. We anticipate the following potential areas of concern:
a. Lotions-minor dermatological reaction
b. Exercise cards-muscle soreness, fall during exercise
c. Snacks-possible choking hazard
d. Actigraph wear-skin irritation at wear site (wrist)
e. Scents of lotion-headache
f. Gel lap pad-strain from lifting 3 pound lap pad.
b. Adverse Events: In compliance with Federal Regulation 21CFR §56.108(b)(1) and 45 CFR 46.103(b)(5), any unanticipated problems, including adverse events that are unexpected and related to the study, will be promptly reported to the University Institutional Review Board (IRB). Events judged as "unexpected" are those not specified in the IRB-approved research protocol or informed consent document.
The Data and Safety Monitoring Plan for the proposed project incorporates the policies on human subject data and safety monitoring specified by the University of Kentucky IRB.
Risk Assessment: Minimal risk. The study procedures and intervention represents minimal risk to study participants as this study intervention is a combined environment-based educational/sensory stimulation and standard-of-care intervention to improve neuropsychiatric behaviors in people with dementia.
The PI and faculty advisor will assess the severity (intensity) of reported AEs according to the NCI CTC. If a participant experiences an event not detailed by the NCI CTC, the following guidelines will be used to analyze severity:
• Mild: symptoms or signs exist and may require treatment, but are transient and easily tolerated.
• Moderate: treatment is required and continued monitoring of event is prescribed to avert participant discomfort.
• Severe: event requires treatment and continued monitoring is prescribed to prevent incapacitating or life threatening effects to the participant's health.
• Life threatening: when the participant is, in the opinion of the Investigator, at immediate risk of death from the event as it occurs, or if the event requires immediate medical treatment and continued monitoring. Note that this definition does not include an event that, had it occurred in a more serious form, might have caused death.
• Fatal: Death resulted from AE.

All adverse events occurring during the study observed by study personnel or reported by the participant (whether or not attributed to study procedures or interventions), will be recorded in the subject electronic record. Medically significant adverse events considered related to the study procedures or interventions by the faculty advisor will be followed until resolved or considered stable. It will be left to the faculty advisor's clinical judgment whether or not an adverse event is of sufficient severity to require the participant's removal from treatment. A participant may also voluntarily withdraw from treatment due to what he or she perceives as an intolerable adverse event. If either of these occur, the participant must undergo a Termination (early discontinuation) visit, and be given appropriate care

under medical supervision until symptoms cease or the condition becomes stable.
In order to adhere to all applicable laws and regulations for reporting an SAE, the PI will formally notify the UK IRB within 24 hours of the study site staff becoming aware of the SAE. Adverse events will be coded according to body system using MedDRA. A final medical review and sign off on all codes by a designated reviewer within the ADCS will ensure accuracy and consistency.
In this study, we do not anticipate moderate, severe, life-threatening or fatal AEs.
c. Plans for Safety Review: A methodical review of all procedures will be an integral part of each research team meeting. This review will include discussion of the protocol to ensure adherence, discussion of procedures to insure confidentiality is maintained and that data are collected with minimal risk for violations of confidentiality. A meeting involving the PI, faculty advisor, co-investigators, and lay coworkers will be called if an unexpected adverse event occurs.
d. Plans for Data Quality: The research design, methods and procedures have been reviewed by all members of the research team, all of whom have indicated their approval of the processes as delineated and believe that this research project will yield quality data that will generate new knowledge. Detailed operationalization of this plan will be done as a team to assure data quality.
e. Reporting Mechanisms: Reporting for this study will include an annual report to the University of Kentucky IRB, with appropriate updates and reports in the event of an adverse event(s). SAEs will be reported to the UK IRB within 24 hours of notification as mandated by this regulatory body.
f. Plans for Modification or Termination of Study: If SAE or frequent AE's beyond mild severity occur in more than 30% of participants, we will review research intervention causes and modify intervention to minimize risk. We will withdrawal patients with AE's above moderate severity if AE is associated with study intervention, as this will indicate risks may exceed potential benefits of this study.

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Subject Complaints: Describe procedures (other than information provided in consent document) for handling subject complaints or requests for information about the research. The procedures should offer a safe, confidential, and reliable channel for current, prospective, or past research subjects (or their designated representative) permitting them to discuss problems, concerns and questions, or obtain information.

Subjects will be provided with the PI's email and phone numbers for contact if concerns or complaints arise. A confidential meeting between the PI and participants will be arranged using Zoom, video call, or telephone call with the subject to address concerns and complaints. Subjects may also speak with SBCoA social workers or Clinic director with concerns. If subjects have any questions or complaints about the research study they may contact staff in the Office of Research Integrity at the University of Kentucky at (859) 257-9428.

Are you recruiting or expect to enroll **Non-English Speaking Subjects or Subjects from a Foreign Culture**? (does not include short form use for incidentally encountered non-English subjects)

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Recruitment and Consent:

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.
When recruiting Non-English-speaking subjects, provide a consent document in the subject's primary language. After saving this section, attach both the English and translated consent documents in the "Informed Consent" section.

Cultural and Language Consultants:

The PI is required to identify someone to serve as the cultural consultant to the IRB.

- This person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted.
- The consultant should not be involved with the study or have any interest in its IRB approval.
- Please include the name, address, telephone number, and email of the person who will act as the cultural consultant for your study.

For more details, see the IRB Application Instructions on Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture.

Local Requirements:

If you will conduct research at an international location, identify and describe:

- relevant local regulations
- data privacy regulations
- applicable laws
- ethics review requirements for human subject protection

Please provide links or sources where possible. If the project has been or will be reviewed by a local ethics review board,

attach a copy in the “Additional Information/Materials” section. You may also consult the current edition of th
Compilation of Human Research Standards

61291
CLOSED

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis**

○ Yes ◉ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "Reporting Requirements for Diseases and Conditions in Kentucky" [PDF].

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online IRB Survival Handbook to download a copy of the "Medical IRB's requirements for Protection of Human Subjects in Research Involving HIV Testing" [D65.0000] [PDF], and visit the Office for Human Research Protections web site for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

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1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?

○ Yes ◉ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the investigator assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor IND regulatory requirements for drug trials [PDF], IDE regulatory requirements for SR device trials [PDF], and abbreviated regulatory requirements for NSR device trials [PDF]. For detailed descriptions see FDA Responsibilities for Device Study Sponsors or FDA Responsibilities for IND Drug Study Sponsor-Investigators.

- Describe the experience/knowledge/training (if any) of the investigator serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if any sponsor obligations have been transferred to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

IRB policy requires mandatory training for all investigators who are also FDA-regulated sponsors (see Sponsor-Investigator FAQs). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the sponsor-investigator completed the mandatory PI-sponsor training prior to this submission?

○ Yes ○ No

If the sponsor-investigator has completed equivalent sponsor-investigator training, submit documentation of the content for the IRB's consideration.

Attachments

61291
CLOSED

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CLOSED

HIPAA

0 unresolved comment(s)

Is HIPAA applicable? ◉ Yes ○ No

(Visit ORI's Health Insurance Portability and Accountability Act (HIPAA) web page to determine if your research falls under the HIPAA Privacy Regulation.)

If yes, check below all that apply and attach the applicable document(s):

☐ HIPAA De-identification Certification Form

☑ HIPAA Waiver of Authorization

Attachments

Attach Type	File Name
Waiver	HIPAA Waiver Approval.61291.pdf
Waiver	Form K Signed 4-1-21.pdf

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CLOSED

STUDY DRUG INFORMATION

0 unresolved comment(s)

The term drug may include:

- FDA approved drugs,
- unapproved use of approved drugs,
- investigational drugs or biologics,
- other compounds or products intended to affect structure or function of the body, and/or
- complementary and alternative medicine products such as dietary supplements, substances generally recognized as safe (GRAS) when used to diagnose, cure mitigate, treat or prevent disease, or clinical studies of e-cigarettes examining a potential therapeutic purpose.

Does this protocol involve a drug including an FDA approved drug; unapproved use of an FDA approved drug; and/or an investigational drug?

○ Yes ◉ No

If yes, complete the questions below. Additional study drug guidance.

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

Note: Inpatient studies are required by Hospital Policy to utilize Investigational Drug Service (IDS) pharmacies (Oncology or Non-Oncology). Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

Indicate where study drug(s) will be housed and managed:

☐ Investigational Drug Service (IDS) UK Hospital

Other Location:

Is the study being conducted under a valid Investigational New Drug (IND) application?

○ Yes ○ No

If Yes, list IND #(s) and complete the following:

IND Submitted/Held by:

Sponsor: ☐		Held By:	
Investigator: ☐		Held By:	
Other: ☐		Held By:	

☐ Checkmark if the study is being conducted under FDA's Expanded Access Program (e.g., Treatment IND) or if this is an Individual Patient Expanded Access IND (FDA Form 3926).

FDA's Expanded Access Program Information for Individual Patient Expanded Access INDs, and attach the following:

- FDA Form 3926;
- FDA expanded access approval or correspondence;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Expanded Access SOP.

61291
CLOSED

Complete and attach the required Study Drug Form.

Attachments

61291
CLOSED

STUDY DEVICE INFORMATION

0 unresolved comment(s)

A DEVICE may be a:

- component, part, accessory;
- assay, reagent, or in-vitro diagnostic device;
- software, digital health, or mobile medical app;
- other instrument if intended to affect the structure or function of the body, diagnose, cure, mitigate, treat or prevent disease; or
- a homemade device developed by an investigator or other non-commercial entity and not approved for marketing by FDA.

For additional information, helpful resources, and definitions, see ORI's Use of Any Device Being Tested in Research web page.

Does this protocol involve testing (collecting safety or efficacy data) of a medical device including an FDA approved device, unapproved use of an approved device, humanitarian use device, and/or an investigational device?

○ Yes ◉ No

[Note: If a marketed device(s) is only being used to elicit or measure a physiologic response or clinical outcome, AND, NO data will be collected on or about the device itself, you may answer “no” above, save and exit this section, (Examples: a chemo drug study uses an MRI to measure tumor growth but does NOT assess how effective the MRI is at making the measurement; an exercise study uses a heart monitor to measure athletic performance but no safety or efficacy information will be collected about the device itself, nor will the data collected be used for comparative purposes against any other similar device).]

If you answered yes above, please complete the following questions.

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

Is the study being conducted under a valid Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE) or Compassionate Use?

○ Yes ○ No

If Yes, complete the following:
IDE or HDE #(s)

IDE/HDE Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Check if this is a Treatment IDE or Compassionate Use under the Food and Drug Administration (FDA) Expanded Access program.

For Individual or Small Group Expanded Access, see FDA's Early Expanded Access Program Information, and attach the following:

- FDA expanded access approval or sponsor’s authorization;
- An independent assessment from an uninvolved physician, if available;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Medical Device SOP.

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CLOSED

Does the intended use of any research device being tested (not clinically observed) in this study meet the regulatory definition of Significant Risk (SR) device?

- Yes. Device(s) as used in this study presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- No. All devices, as used in this study do not present a potential for serious risk to the health, safety, or welfare of subjects/participants.

Complete and attach the required Study Device Form.

Attachments

RESEARCH SITES

0 unresolved comment(s)

To complete this section, ensure the responses are accurate then click "SAVE".

A) Check all the applicable sites listed below at which the research will be conducted. If none apply, you do not need to check any boxes.

UK Sites

- ☐ UK Classroom(s)/Lab(s)
- ☑ UK Clinics in Lexington
- ☐ UK Clinics outside of Lexington
- ☐ UK Healthcare Good Samaritan Hospital
- ☐ UK Hospital

Schools/Education Institutions

- ☐ Fayette Co. School Systems *
- ☐ Other State/Regional School Systems
- ☐ Institutions of Higher Education (other than UK)

***Fayette Co. School systems, as well as other non-UK sites, have additional requirements that must be addressed. See ORI's IRB Application Instructions - Off-site Research web page for details.**

Other Medical Facilities

- ☐ Bluegrass Regional Mental Health Retardation Board
- ☐ Cardinal Hill Hospital
- ☐ Eastern State Hospital
- ☐ Norton Healthcare
- ☐ Nursing Homes
- ☐ Shriner's Children's Hospital
- ☐ Veterans Affairs Medical Center
- ☐ Other Hospitals and Med. Centers

- ☐ Correctional Facilities
- ☐ Home Health Agencies
- ☐ International Sites

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see IRB Application Instructions - Off-Site Research web page), including:

- A letter of support and local context is required from non-UK sites. See *Letters of Support and Local Context* on the IRB Application Instructions - Off-Site Research web page for more information.
- Supportive documentation, including letters of support, can be attached below.
- NOTE: If the non-UK sites or non-UK personnel are engaged in the research, there are additional federal and university requirements which need to be completed for their participation. For instance, the other site(s) may need to complete their own IRB review, or a cooperative review arrangement may need to be established with non-UK

sites.
- Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

List all other non-UK owned/operated locations where the research will be conducted:

Participants' homes; protocol has been reviewed and approved by UK Legal

Attachments

B) Is this a multi-site study for which **you are the lead investigator or UK is the lead site**? ○ Yes ◉ No

If **YES**, you must describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites in the E-IRB "Research Description" section under *Resources*.

If the non-UK sites or non-UK personnel are *engaged* in the research, there are additional federal and university requirements which need to be completed for their participation, such as the establishment of a cooperative IRB review agreement with the non-UK site. Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

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CLOSED

RESEARCH ATTRIBUTES

0 unresolved comment(s)

Indicate the items below that apply to your research. Depending on the items applicable to your research, you may be required to complete additional forms or meet additional requirements. Contact the ORI (859-257-9428) if you have questions about additional requirements.

☐ Not applicable

Check All That Apply

- ☑ Academic Degree/Required Research
- ☑ Aging Research
- ☐ Alcohol Abuse Research
- ☐ Cancer Research
- ☑ Certificate of Confidentiality
- ☐ CCTS-Center for Clinical & Translational Science
- ☑ Clinical Research
- ☑ Clinical Trial
- ☐ Clinical Trial Multicenter(excluding NIH Cooperative Groups)
- ☐ Clinical Trial NIH cooperative groups (i.e., SWOG, RTOG)
- ☐ Clinical Trial Placebo Controlled Trial
- ☑ Clinical Trial UK Only
- ☐ Collection of Biological Specimens
- ☐ Collection of Biological Specimens for Banking
- ☐ Community-Based Participatory Research
- ☐ Data & Safety Monitoring Board
- ☑ Data & Safety Monitoring Plan
- ☐ Deception
- ☐ Drug/Substance Abuse Research
- ☐ Educational/Student Records (e.g., GPA, test scores)
- ☐ Emergency Use (Single Patient)
- ☐ Genetic Research
- ☐ Gene Transfer
- ☐ GWAS (Genome-Wide Association Study) or NIH-funded study generating large scale genomic data
- ☐ International Research
- ☐ Internet Research
- ☐ Planned Emergency Research Involving Waiver of Informed Consent
- ☐ Pluripotent Stem Cell Research
- ☐ Recombinant DNA
- ☐ Survey Research
- ☐ Transplants
- ☐ Use of radioactive material, ionizing radiation, or x-rays [Radiation Safety Committee review required]
- ☐ Vaccine Trials

For additional requirements and information:

- Cancer Research (MCC PRMC)
- Certificate of Confidentiality (look up "Confidentiality/Privacy...")
- CCTS (Center for Clinical and Translational Science)
- Clinical Research (look up "What is the definition of....)
- Clinical Trial
- Collection of Biological Specimens for Banking (look up "Specimen/Tissue Collection...")
- Collection of Biological Specimens (look up "Specimen/Tissue Collection...")
- Community-Based Participatory Research (look up "Community-Engaged...")
- Data & Safety Monitoring Board (DSMB)

  *For Medical IRB: Service Request Form for CCTS DSMB

- Data & Safety Monitoring Plan
- Deception*

  *For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF)
- Genetic Research (look up "Specimen/Tissue Collection...")
- Gene Transfer
- HIV/AIDS Research (look up "Reportable Diseases/Conditions")
- Screening for Reportable Diseases [E2.0000] (PDF)
- International Research (look up "International & Non-English Speaking")
- NIH Genomic Data Sharing (GDS) Policy (PDF)
- Planned Emergency Research Involving Waiver of Informed Consent*

  *For Planned Emergency Research Involving Waiver of Informed Consent, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Use of radioactive material, ionizing radiation or x-rays for research

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CLOSED

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CLOSED

FUNDING/SUPPORT

0 unresolved comment(s)

If the research is being submitted to, supported by, or conducted in cooperation with an external or internal agency or funding program, indicate below all the categories that apply.

☐ Not applicable

Check All That Apply

- ☐ Grant application pending
- ☑ (HHS) Dept. of Health & Human Services
  - ☑ (NIH) National Institutes of Health
  - ☐ (CDC) Centers for Disease Control & Prevention
  - ☐ (HRSA) Health Resources and Services Administration
  - ☐ (SAMHSA) Substance Abuse and Mental Health Services Administration
- ☐ (DoJ) Department of Justice or Bureau of Prisons
- ☐ (DoE) Department of Energy
- ☐ (EPA) Environmental Protection Agency
- ☐ Federal Agencies Other Than Those Listed Here
- ☐ Industry (Other than Pharmaceutical Companies)
- ☐ Internal Grant Program w/ proposal
- ☐ Internal Grant Program w/o proposal
- ☐ National Science Foundation
- ☐ Other Institutions of Higher Education
- ☐ Pharmaceutical Company
- ☐ Private Foundation/Association
- ☐ U.S. Department of Education
- ☐ State

Other:

Click applicable listing(s) for additional requirements and information:

- (HHS) Dept. of Health & Human Services
- (NIH) National Institutes of Health
- (CDC) Centers for Disease Control & Prevention
- (HRSA) Health Resources & Services Administration
- (SAMHSA) Substance Abuse & Mental Health Services Administration
- Industry (Other than Pharmaceutical Companies) [IRB Fee Info]
- National Science Foundation
- (DoEd) U.S. Department of Education
- (DoJ) Department of Justice or Bureau of Prisons
- (DoE) Department of Energy Summary and Department of Energy Identifiable Information Compliance Checklist
- (EPA) Environmental Protection Agency

Specify the funding source and/or cooperating organization(s) (e.g., National Cancer Institute, Ford Foundation, Eli Lilly & Company, South Western Oncology Group, Bureau of Prisons, etc.):

NIH T32 AG057461
NIH/NIA 1 P30 AG028383

Add Related Grants

If applicable, please search for and select the OSPA Account number or Electronic Internal Approval Form (eIAF) # (notif #) associated with this IRB application using the "Add Related Grants" button.
If required by your funding agency, upload your grant using the "Grant/Contract Attachments" button.

Add Related Grants

Grant/Contract Attachments

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The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other
(See DoD SOP and DoD Summary for details)

○ Yes ◉ No

Using the “attachments” button (below), attach applicable materials addressing the specific processes described in the DoD SOP.

DOD SOP Attachments

Additional Certification: (If your project is federally funded, your funding agency may request an Assurance/ Certification/Declaration of Exemption form.) Check the following if needed:

☐ Protection of Human Subjects Assurance/Certification/Declaration of Exemption (Formerly Optional Form – 310)

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OTHER REVIEW COMMITTEES

0 unresolved comment(s)

If you check any of the below committees, additional materials may be required with your application submission.

Does your research fall under the purview of any of the other review committees listed below? [*If yes, check all that apply and attach applicable materials using the attachment button at the bottom of your screen.*]

○ Yes ◉ No

☐ Institutional Biosafety Committee
☐ Radiation Safety Committee
☐ Radioactive Drug Research Committee
☐ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)
☐ Graduate Medical Education Committee (GME)
☐ Office of Medical Education (OME)

Additional Information

- Institutional Biosafety Committee (IBC)--Attach required IBC materials
- Radiation Safety Committee (RSC)-- For applicability, see instructions
- Radioactive Drug Research Committee (RDRC)--information
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)**--Attach MCC PRMC materials, if any, per instructions
- See requirement of Office of Medical Education (OME)
- See requirement of Graduate Medical Education Committee (GME)

Attachments

**** If your study involves cancer research, be sure to select "Cancer Research" in the "Research Attributes" section.** ORI will send your research protocol to the Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC). The MCC PRMC is responsible for determining whether the study meets the National Cancer Institute (NCI) definition of a clinical trial and for issuing documentation to you (the investigator) which confirms either that PRMC approval has been obtained or that PRMC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

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ADDITIONAL INFORMATION/MATERIALS

0 unresolved comment(s)

Do you want specific information inserted into your approval letter? ○ Yes ◉ No

Approval Letter Details:

If you wish to have specific language included in your approval letter (e.g., serial #, internal tracking identifier, etc…), type that language in the box below exactly as it should appear in the letter. The text you enter will automatically appear at the top of all approval letters, identical to how you typed it, until you update it. Don't include instructions or questions to ORI staff as those will appear in your approval letter. **If these details need to be changed for any reason, you are responsible for updating the content of this field.**

Protocol/Product Attachments - For each item checked, please attach the corresponding material.

- ☑ Detailed protocol
- ☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
- ☐ Drug Documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.)
- ☐ Device Documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.)
- ☐ Other Documents

Protocol/Product Attachments

Attach Type	File Name
AddInfoProtocol	Environmental design protocol 10-11-20 highlighted.pdf

NOTE: [Instructions for Dept. of Health & Human Services (DHHS)-approved protocol]

If you have password protected documents, that feature should be disabled prior to uploading to ensure access for IRB review.

Additional Materials:

If you have other materials you would like to include in your application for the IRB's consideration, please attach using the Attachments button below.

To view the materials currently attached to your application, click "All Attachments" on the left menu bar.

Attachments

Attach Type	File Name
AdditionInfoConsiderations	E-IRB comments 9-30.pdf
AdditionInfoConsiderations	Screening comments.pdf
AdditionInfoConsiderations	Minor Revisions 10-30.pdf
AdditionInfoConsiderations	Revisions 11-4-20.pdf
AdditionInfoConsiderations	IAA_Thompson_UK.pdf
AdditionInfoConsiderations	IAA_Thompson_UK and EKU.pdf
AdditionInfoConsiderations	Modification Request 1-26-21.pdf
AdditionInfoConsiderations	Modification Request 3-17-21.pdf
AdditionInfoConsiderations	Modification Request 4-1-21.pdf
AdditionInfoConsiderations	IRB# 61291.email to PI with minor revisions.pdf
AdditionInfoConsiderations	RE_ IRB# 61291.pdf

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SIGNATURES (ASSURANCES)

0 unresolved comment(s)

All IRB applications require additional assurances by a Department Chairperson or equivalent (DA), and when applicable, a Faculty Advisor or equivalent (FA). This signifies the acceptance of certain responsibilities and that the science is meritorious and deserving of conduct in humans. The person assigned as DA *should not* also be listed in the Study Personnel section, and the individual assigned as FA *should* be listed in the Study Personnel section.

For a list of responsibilities reflected by signing the Assurance Statement, refer to "What does the Department Chairperson's Assurance Statement on the IRB application mean?"

Required Signatures:

First Name	Last Name	Role	Department	Date Signed	
Gregory	Jicha	Faculty Advisor	Neurology	08/31/2020 12:06 PM	View/Sign
Linda	Van Eldik	Department Authorization	Department of Neuroscience	08/29/2020 09:20 AM	View/Sign
Elizabeth	Rhodus	Principal Investigator	Sanders-Brown Ctr On Aging	08/17/2020 02:38 PM	View/Sign

Faculty Advisor's Assurance Statement

☑ This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study; to the qualifications of the investigator(s) to conduct the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate.

**If the Principal Investigator is completing this project to meet the requirements of a University of Kentucky academic program, in addition to Department Authorization, the student's faculty advisor should sign the Assurance Statement. The student's faculty advisor is accepting a supervisory role in guiding the student in conducting regulatory compliant research and therefore must be certified in human research protection training throughout the life of the protocol.

Department Authorization

☑ This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study; to the qualifications of the investigator(s) to conduct the project and their time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate. When the principal investigator assumes a sponsor function, the investigator has been notified of the additional regulatory requirements of the sponsor and by signing the principal investigator Assurance Statement, confirms he/she can comply with them.

*If the Principal Investigator is also the Chairperson of the department, the Vice Chairperson or equivalent should complete the "Department Authorization".

**IF APPLICABLE FOR RELIANCE: I attest that the principal investigator has been notified of the regulatory requirements of both the Reviewing and Relying IRBs, according to the information provided in the E-IRB application. The attached Reliance Assurance Statement, signed by the principal investigator, confirms that he/she can comply with both sets of IRB requirements.

Principal Investigator's Assurance Statement

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CLOSED

I understand the University of Kentucky's policies concerning research involving human subjects and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. To accept responsibility for the scientific and ethical conduct of this research study;
3. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent/assent form;
4. To report to the IRB in accord with IRB/IBC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects;
5. To complete, on request by the IRB for Full and Expedited studies, the Continuation/Final Review Forms;
6. To notify the Office of Sponsored Projects Administration (OSPA) and/or the IRB (when applicable) of the development of any financial interest not already disclosed;
7. Each individual listed as study personnel in this application has received the mandatory human research protections education (e.g., CITI);
8. Each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.
9. To recognize and accept additional regulatory responsibilities if serving as both a sponsor and investigator for FDA regulated research.

☑ Furthermore, by checking this box, I also attest that:

- I have appropriate facilities and resources for conducting the study;
- I am aware of and take full responsibility for the accuracy of all materials submitted to the IRB for review;
- If applying for an exemption, I also certify that the only involvement of human subjects in this research study will be in the categories specified in the Protocol Type: Exemption Categories section.
- If applying for an Abbreviated Application (AA) to rely on an external IRB, I understand that certain items above (1, 3, 4, 7-8) may not apply, or may be altered due to external institutional/IRB policies. I document my agreement with the Principal Investigator Reliance Assurance Statement by digitally signing this application.

*You will be able to "sign" your assurance after you have sent your application for signatures (use Submission section). Please notify the personnel required for signing your IRB application after sending for signatures. Once all signatures have been recorded, you will need to return to this section to submit your application to ORI.

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CLOSED

SUBMISSION INFORMATION

2 unresolved comment(s)

Each Section/Subsection in the menu on the left must have a checkmark beside it (except this Submission section) indicating the Section/Subsection has been completed. Otherwise your submission for IRB review and approval cannot be sent to the Office of Research Integrity/IRB.

If applicable, remember to update the Approval Letter Details text box under the Additional Information section

If your materials require review at a convened IRB meeting which you will be asked to attend, it will be scheduled on the next available agenda and you will receive a message to notify you of the date.

If you are making a change to an attachment, you need to delete the attachment, upload a highlighted version that contains the changes (use Document Type of "Highlighted Changes"), and a version that contains the changes without any highlights (use the appropriate Document Type for the item(s)). Do **not** delete approved attachments that are still in use.

Modification Request Information

Select One:

- ◉ This modification does not increase risk to study participants.
- ○ This modification may or will increase risk to study participants.

Is this modification request due to an Unanticipated Problem/Adverse Event, or Protocol Violation?

- ○ Yes ◉ No

In your professional opinion, does this modification involve information that might relate to a subject's willingness to continue to take part in the research?

- ○ Yes ◉ No

If yes, state how the information will be communicated to subjects (i.e., re-consent, send letter, etc.):

For each proposed modification, include a justification.

Example: Jane Doe, MD, is being added as co-investigator because she has expertise with the subjects on this protocol. She has completed human subject protections training, and is authorized to obtain consent.

***** If this modification changes the scope of your activities to include COVID-19 related research, please insert "COVID19" at the start of your Project and Short Titles.*****

Addition of the Situational Assessment of Activity and Function (SAAF) assessment.
The SAAF is a new assessment created by current study PI (Rhodus) to gain better insights on the situational characteristics that cause behavioral reactions in persons with dementia. The SAAF was developed from initial data collection of the current study. The SAAF is 120 questions to be completed by caregivers of persons with cognitive impairment and will take approximately 15 minutes to complete. Questions review caregiver perceptions of the activity performance of the person they care for in various activities (i.e., cooking, dressing, community mobility, etc.) The assessment is completed electronically using Redcap survey emailed to caregivers. Use of the SAAF in this study is to glean initial reactions from caregiver participants regarding their ease of use and to determine time length of administration. The use of the SAAF in this study will be completed using REDCap public survey link. This feature allows individuals to complete the survey, but does not associate a record ID to answers, all responses are anonymous. Data from survey item responses will not be stored, saved, reviewed or analyzed. Caregivers currently enrolled in this study will be asked to voluntarily complete the electronic survey if they would like. It is not required. Participants will be asked to disclose the length of time

it took to complete the form and to document any initial perceptions of the ease of use of the form and/or it's perceived applicability.

Your protocol has been submitted.

IRB Approval
3/18/2021
IRB # 61291
IRB2

KEY INFORMATION FOR PATIENT CONSENT IN:
ENVIRONMENTAL DESIGN FOR BEHAVIORAL REGULATION IN PEOPLE WITH DEMENTIA:

We are asking you to choose whether or not to volunteer for a research study about the impact of the environment on behaviors of people with dementia. We are asking you because you are living with dementia (or are the Legally Authorized Representative, LAR) 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 if environmental strategies aimed to improve behavior are easily implemented by caregivers within the homes of people with dementia via telehealth provision. The study will involve the primary care partner and the person with dementia, referred to in this study as a 'dyad.' This study will be conducted using a telehealth approach with phone calls, Zoom video conferencing, and all materials will be mailed directly to your home. You will not be required to leave your home for the purposes of this study. Your participation in this research will involve one screening visit, three assessment visits, and six weeks of treatment implementation including weekly contact with an occupational therapist. Your primary care partner will be asked to implement approaches to help you feel more relaxed. We anticipate the project lasting approximately twelve weeks from time of screening visit to the follow up visit. This will include approximately 9.5 hours of Zoom video conferencing and 45 hours of at-home intervention throughout the twelve weeks. For detailed descriptions, refer to the Detailed Consent and appendix A on page 8.

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. For a complete description of benefits, refer to the Detailed Consent.

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

This study seeks dyads 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 is to assess applicability of telehealth provision using Zoom video conferencing for assessment, training, and weekly communications. You will need to have access to a computer or smart phone which has the capability of running Zoom video conferencing. You will be asked by your caregiver to participate in various activities (i.e., listen to music, use lotion, etc.). If you feel as though you are unable or unwilling to engage in interventions included in this study, the dyad will not be included. For a complete description of risks, refer to the Detailed Consent. 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.

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 choose 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 a primary caregiver and a person with dementia (patient). If both individuals cannot participate in this study, you may not qualify. The study also uses Zoom video conferencing, and so access to a camera (such as a smartphone, tablet, webcam, etc.) and internet access is required.

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

The research procedures will be conducted at your home via Zoom video conferencing with research staff at Sanders-Brown Center on Aging. You will not need to come to the center, but weekly times for videoconference meeting will be arranged during the study. Reminder calls 24-48 hours prior to each videoconference will be made by telephone with the primary caregiver. Each of those visits will take a 1-2 hours.

Additionally, we ask you to participate in daily treatment activities for a 6-week duration. The total amount of time you will be asked to volunteer for this study is approximately 9.5 hours of Zoom video conferencing. If the dyad is randomized to a treatment group, the patient will engage in 45 hours of at-home intervention throughout the next twelve weeks.

WHAT WILL YOU BE ASKED TO DO?

Each patient/caregiver dyad will be randomized into one of three groups:

-Control group: Will receive standard of care currently received through medical and social services outside of this study. A one-page home safety instructional flyer will be provided to the dyad. All assessments and Zoom video time requirements are listed in Appendix A. At the conclusion of the study, following the four-week follow up visit, participants will be offered a standardized sensory kit (as described below) to use at their discretion.

-Standardized Environmental Design Protocol Group: Caregivers will receive training for physical and social environment setup which may alter interactions and home set up for the patient. Pre-determined sensory kits will be mailed to the patient's home and caregivers will distribute and facilitate use of the tools included on a schedule provided to the caregiver. These supplies may promote relaxation, such as a CD player, a CD, scented lotion, a blanket, exercise cards, hand-held toys, and snacks (pretzels or mints). All assessments and zoom video time requirements are listed in Appendix A.

-Individualized Environmental Design Group: Caregivers will receive training for physical and social environment setup which may alter interactions and home set up for the patient. After baseline assessments, an occupational therapist will create an individualized sensory kit based on the sensory and behavior needs of the patient. These kits will be compiled and mailed to the patients' home, and caregivers will distribute and facilitate use of the tools included on a schedule provided to the caregiver. These supplies may promote relaxation, and include a CD player, a CD, scented lotion, a blanket, exercise cards, hand-held toys, and snacks (pretzels or mints). All assessments and zoom video time requirements are listed in Appendix A.

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

Visit 1: Sanders Brown Center on Aging staff will complete a screening visit to obtain consent to participate in the study. This will take approximately one hour with both the caregiver and patient, and will consist of determining baseline symptoms, the Clinical Dementia Rating (CDR) Scale, physical/neurological examination of the patient over Zoom (approximately 15 minutes with caregiver facilitation).

Visit 2: Baseline data will be collected at Visit 2 consisting of the Montreal Cognitive Assessment (MOCA) (with patient approximately 15 minutes). We anticipate this visit will last 1.5-2 hours with the patient. All intervention materials will be mailed to the patients' homes following visit 2.

Visit 3: Visit 3 marks the first day of the intervention window. Caregivers and patients will have a virtual meeting with research staff to receive training for all intervention materials and initiation of Actigraph use (wearable wrist device) and review adverse events will be reviewed. This visit will last approximately 1 hour with the caregiver and patient.

Visit 4-8: At the end of each week, caregivers and patients will meet with research staff or occupational therapist to review treatment use and concerns With your caregiver, you will be asked to demonstrate intervention use during video conference. These visits will last less than one hour with the caregiver and patient.

Visit 9: At the final week of intervention, patients will engage in a follow-up assessment, will engage in a one-hour session to involve complete assessment including physical/neurological examination (with patient approximately 15 minutes), and MOCA (with patient approximately 15 minutes).

Visit 10: Four weeks following completion of the intervention, participants will complete a follow up session consisting of the same visit 9 assessments except Actigraph data.

Lastly, the researcher may contact the patients 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 A: 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 sensory stimulation, such as smells of lavender or grapefruit.
- A risk of sensory overstimulation is present, however, impact of such risks are mild, temporary, and often subside within four hours of intervention.
- There may be muscle soreness related to mild stretches and exercises within the intervention.

There is always a chance that any research procedure can harm you. The research 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. However, some people have experienced relaxed moods with decreased occurrence of behavioral disruption when participating in similar activities included in this study. If you take part in this study, information learned may help others 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?

Access to Zoom using either internet or cellular data is required. There may be costs to you associated with internet or phone fees. Use of Zoom program does not have added costs.

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.

Included within this study's personnel is Dr. MaryEllen Thompson, OTR/L, faculty from Eastern Kentucky University and registered occupational therapist. She will have access to video recordings and identifiable private information but will be held to the laws and regulations of HIPAA regarding access and knowledge of private information. Her involvement in this study has been approved through the Institutional Review Board at the University of Kentucky and Easter Kentucky University.

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 materials 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 (University of Kentucky's Institutional Review Board/Office of Research Integrity)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. REDCap administrators will have access to identifiable private health information. 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.

To help us protect your privacy, this research has a Certificate of Confidentiality. The researchers can use this Certificate to refuse to disclose information that may identify you to anyone not connected with this study, or in any legal proceedings. The exceptions to this rule are release of information:

- you have requested us to provide, for instance, to your insurance company or doctor;
- to the sponsor (e.g., National Institutes of Health/National Institute of Aging);
- about child or elder abuse, neglect, or harm to yourself or others; and
- about you if it involves a reportable disease.

This policy does not prevent you from releasing information about your own participation in this study.

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 than benefit to you, or
- 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 interventional research study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor 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 Dr. Elizabeth Rhodus at 859-257-5562 immediately.

Dr. Gregory Jicha, the faculty advisor for this study 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. All treatment materials which are mailed to patients will not be collected by the research team following study completion. With the exception of the behavior journal/workbook and Actigraph device and charger which are required to be returned to Sanders-Brown Center on Aging, materials will belong to the study caregivers or patients at their discretion 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 you/your family's 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 Dr. Elizabeth Rhodus, Elizabeth.rhodus@uky.edu 859-257-5562, 1030 S. Broadway, Ste 5, Lexington, Kentucky 40504.

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 *ADDED:* the PI (Elizabeth Rhodus) 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 60 people to do so.

Dr. Elizabeth Rhodus is a postdoctoral fellow and is being guided in this research by Dr. Gregory Jicha. 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 this clinical trial 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.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Demographic information (name, birthdate, email address, address, phone number, primary contact information, University of Kentucky medical identification number, diagnoses, medications, medical history, tests completed at Sanders-Brown Center on Aging or the Kentucky Neuroscience Institute under medical supervision by Dr. Gregory Jicha)
- Medical history within last 5 years, including diagnoses
- UK Healthcare medical identification number
- Kentucky Neuroscience Institute clinical visit notes within last five years

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives (REDCap system administrators);
- National Institutes of Health (NIH); National Institute on Aging (NIA); Department of Health and Human Services (HHS)
- Eastern Kentucky University, Department of Occupational Science and Occupational Therapy Faculty-only Dr. MaryEllen Thompson as occupational therapy consultant, approved by UK IRB/ORI

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information may still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky;
- Current or future payments to the University of Kentucky;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- Send a written letter to: Dr. Elizabeth Rhodus; Elizabeth.rhodus@uky.edu; 859-257-5562, 1030 S. Broadway Ste 5, Lexington, KY 40504 to inform her of your decision.
- Researchers may use and release your health information **already** collected for this research study to study personnel and agencies listed within this form.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

You will not be allowed to review the information collected for this research study until after the study is completed. When the study is over, you may have the right to access the information.

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.

APPENDIX A: Schedule of Events

Visit number	1	2	3	4-8	9	10
Visit name *(Approx. length)*	Screen *1 hour*	Baseline *1 hour*	Initiation *30 min.*	Tx week 1-5 *<1 hour*	Tx week 4 *1 hour*	Post-4 week f/u *1 hour*
	-7 Days	+/- 5Days	+/- 3Days	+/- 3Days	+/- 3days	+/- 5Days
Obtain consent (First task completed prior to any research activity)	X					
CDR (with patient)	X					
Physical/Neuro examination (with patient)	X				X	X
Concurrent meds	X	X		X	X	X
Actigraph activity tracker	*mailed*	X	X	X	X	
MOCA (with patient)		X			X	X
Mail treatment supplies		X				
Treatment training for caregiver/patient			X			
Weekly check-in with caregiver/patient, review of behavior journal/ compliance				X	X	X
Adverse events		X	X	X	X	X

Assessments:

Baseline Symptoms: Caregiver report of behavioral concerns presented by the patient.
Physical/Neurological Examination: A brief assessment of patients' physical and neurological functioning completed over Zoom video conferencing.
Clinical Dementia Rating Scale (CDR): A brief interview with the caregiver and patient regarding current cognitive and functional status.
Montreal Cognitive Assessment (MOCA): A brief cognitive assessment to be completed by the patient, facilitated by the caregiver and SBCoA research over Zoom. This assessment will take approximately 15 minutes.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**
- **Appendix A: 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 and HIPAA authorization	_____ Date

Statistical Analysis

Participants' characteristics were compared among the three arms using analysis of variance (ANOVA) for continuous measures and chi-square tests or Fisher's exact for categorical measures. The analysis of the primary endpoint used a chi-square test to compare the proportion of participants completing at least 75% of the video sessions among the study arms. The analysis of all secondary and exploratory endpoints relied on a modified intention-to-treat (mITT) strategy in which participants were included in the analysis only if the dyad completed at least one video session. For those endpoints, the main analysis tool was ANCOVA in which the mean value of an endpoint at the end of the intervention period was adjusted for baseline and then compared among the study arms. Sensitivity analyses were conducted in which multiple imputation was used for missing responses at the end of the intervention period (regressed on baseline) and in which the list of covariates included age of the person with AD at baseline and gender of the caregiver when appropriate. These sensitivity analyses did not change any of the conclusions drawn from the reported ANCOVA in Table 3 and are not reported here. A further sensitivity analysis included the measurements made at the four-week follow-up and relied on ANCOVA to compare the profile of responses at the end of the intervention and at the four-week follow-up each adjusted for baseline. This analysis did not change the conclusions drawn from Table 3 and is not reported here. All analyses were done using PC-SAS, Version 9.4.