Cover letter for Protocol:

Official title: Activate For Life: mHealth Intervention To Address Pain And Fatigue In Low-income Older Adults Aging In Place

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Medical University of South Carolina

CAREGIVER CONSENT TO BE A RESEARCH SUBJECT

ACTIVATE FOR LIFE: A NURSE DELIVERED HYBRID TELEHEALTH/mHealth AGING IN PLACE INTERVENTION TO ADDRESS PAIN AND FATIGUE

SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this research study is to see if doing gentle yoga and breathing exercises while following along with instructional videos on a tablet can be helpful with improving the well-being of people who take care of loved ones with Alzheimer's Disease or other dementias.

If you are interested in joining this study, you will be asked to answer a couple of quick screening questions about you and your loved-one. If you are eligible, the study lasts 12 weeks and there are two study visits, one at the beginning and the other at the end. These visits will last about 1 hour each. At each of these visits you will be asked to complete some surveys about you and your loved one, and you will be asked to provide a saliva sample. The surveys can be done over the phone with the researchers or by yourself on the internet, and the researchers will arrange with you to pick-up the saliva samples at a place and time of your choosing. Your saliva samples will be checked for levels of cortisol and sugar, which can show how tired or fatigued you are, and will be destroyed at the end of the study. This test is not a genetic test. You will be given a tablet with the gentle yoga, breathing exercises, and instructional videos on it to use while you are in the study and will be asked to keep a written daily log of when you did these exercises. You will be asked to return the tablet after you have finished with the study.

Participation in this study may improve your overall well-being, but that cannot be guaranteed. The greatest risks of this study include the possibility of physical discomfort, the loss of confidentiality, and that you may find some of questions you are asked to be upsetting. You do not have to participate in this study. You will receive compensated for your time.

If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As the research staff discuss this consent form with you, please ask them to explain any words or information that you do not clearly understand.

The purpose of this research study is to see if doing gentle yoga and breathing exercises while following along with instructional videos on a tablet can be helpful with improving the well-being of people who are 45 years old or older and take care of loved ones with Alzheimer's Disease or other dementias.

You are being asked to participate in this study because you are 45 years or older and have a loved-one with Alzheimer's Disease or other dementias. The investigator in charge of this study is Dr.

Teresa Kelechi, PhD, RN, FAAN, from the Medical University of South Carolina (MUSC) College of Nursing. The study is being done in the greater Charleston tri-county area and 20 people will take part in. A grant from the National Institute of Health (NIH) will sponsor the study. Portions of Dr. Kelechi and her research team's salaries will be paid by this grant.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. You will have the following test to make sure that you are eligible:
   - An eligibility checklist survey ~2 minutes.

2. If you are eligible to join the study, you will then be asked:
   - To complete 11 short surveys over the phone or internet about your general health and overall quality of life ~40 minutes.
   - To complete 2 short surveys over the phone or internet about you loved-one's general health and overall quality of life ~10 minutes.
   - To provide a saliva sample (about a teaspoon) ~5 minutes. These will be picked-up by the researchers at a time and location of your choosing.

3. You will then be given a tablet with the gentle yoga and breathing exercises on it and will be shown how to use it and do both exercises. You will also be given a diary to keep track of how often and how long you do the exercises, which you will be asked to fill out every day while in the 12-week study. You are expected to do at least 30 minutes of yoga and/or breathing exercises a day. All study materials will be delivered to you at home by the researchers.

4. After 12-weeks, you will be asked to do the same surveys you did before and to provide a new saliva samples ~ 55 minutes. You will also be asked to return the tablet that was loaned to you to use while in the study and turn in your exercise diary. You will also be asked some extra questions about how you felt about the study ~5 minutes.

C. DURATION

The active part of the study lasts 12 weeks and there are two study visits. Each visit lasts about 1 hour each. The survey portions of the visits can be done over the phone with the researchers or by yourself over the internet. The researchers will arrange to pick up your saliva sample at a place of your choosing that best suits you

D. RISKS AND DISCOMFORTS

Use of Surveys: Some of the questions the researchers ask about you and your loved-one's health and well-being may make you feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question.

Gentle Yoga and Breathing Exercises: Physical exercise and yoga may cause headache, nausea, fatigue, muscle soreness, dizziness, or shortness of breath. These activities may cause chest pain, chest tightness, or a change in vital signs. If you have difficulty breathing or become dizzy or light

headed or have any unusual feelings while performing these activities, you should immediately stop and go to the nearest emergency department.

Loss of Privacy and Confidentiality: Your privacy is very important to us, and the researchers will make every effort to protect it. However, as with any process that collects personal information about you (such as your name, address, and date of birth) and conducts activities in public settings, there are risks associated for the loss of privacy and confidentiality. Information obtained about you for this study will be kept confidential to the extent allowed by law. Research information that identifies you may be shared with the MUSC Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to conducting research.

E. MEDICAL RECORDS and/or CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Information about your study participation will not be in your MUSC medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFITS

There may be no benefit to you from participating in this study.

G. COSTS

There will be no cost to you as a result of participation in this study. You will be given access to all the materials that are needed to participate in the study. These materials are to be returned at the end of the study to the researchers. If you chose to use your own tablet device, your cellular provider's normal data and usage fees will apply.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $40 if you agree to participate and are enrolled in the study. Additionally, you will receive another $40 after completion of the 12-week visit. You will be paid a total of $80.00 for successful completion of the study. All payments will be made to you in the form of a check that will be mailed to your home. We will ask for your Social Security number to process check payments.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

Your alternative is to not participate in this study. If you choose not to participate in this study, you should talk to your regular physician about physical activities and exercise programs that may be of benefit to you.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

The researchers will share the overall results of this study with you. Your individual research results will not be disclosed.

L. CLINICAL TRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

M. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities.

Please initial by your choice below for paper consents, or scroll down to the bottom of the screen and select your choice electronically:

____Yes, I agree to be contacted.

____No, I do not agree to be contacted.

MUSC
Medical University of South Carolina
Changing What's Possible

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteer's Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Kelechi at (843) 792-4602. I may also contact the Medical University of SC Hospital Medical Director (843) 792-9537 concerning medical treatment. If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should please sign below for paper consents or scroll to the bottom of the screen to provide an electronic signature.

Signature of Person Obtaining Consent Date Signature of Participant Date

MUSC Medical University of South Carolina

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

UNDERSTANDING YOUR PROTECTED HEALTH INFORMATION (PHI)
The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, MUSC Physicians Primary Care, MUSC Health Partners, MUSC Health Alliance, MUSC Strategic Ventures, LLC, and MUSC Strategic Ventures (MSV) Health, Inc.) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." **We collect, receive, or share this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

OUR PLEDGE REGARDING YOUR HEALTH INFORMATION
MUSC is committed to protecting the privacy of health information we create and obtain about you. This Notice tells you about the ways in which we may use and disclose health information about you. It also describes your rights and certain obligations we have regarding the use and disclosure of your health information. We are required by law to: (i) make sure your health information is protected; (ii) give you this Notice describing our legal duties and privacy practices with respect to your health information; and (iii) follow the terms of the Notice that is currently in effect.

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI) –

A. The following uses do NOT require your authorization, except where required by SC law:
1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.
2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.
3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.
4. Business Associates. Your medical information could be disclosed to people or companies outside our Health System who provide services. These companies typically are required to sign special confidentiality agreements before accessing your information. They are also subject to fines by the federal government if they use/disclosure your information in a way that is not allowed by law.
5. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.
6. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.
7. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.
8. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.
9. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement or for continuum of care when in the custody of law enforcement.
10. Military and Veterans. If you are a member of the U.S. or foreign armed forces, we may release your medical information as required by military command authorities.
11. Uses and disclosures about patients who have died. We may provide medical information to coroners, medical examiners and funeral directors so they may carry out their duties.
12. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.
13. Research. We may use and disclosure your medical information for research purposes. Most research projects are subject to Institutional Review Board (IRB) approval. The law allows some research to be done using your medical information without requiring your written approval.
14. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.
15. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.
16. Marketing. We may send you information on the latest treatment, support groups, reunions, and other resources affecting your health.
17. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.
18. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.
19. Disaster Relief Efforts. We may disclose your medical information to an entity assisting in disaster relief efforts so that your family can be notified about your condition.
Note: incidental uses and disclosures of PHI sometimes occur and are not considered to be a violation of your rights. Incidental uses or disclosures are by-products of otherwise permitted uses or disclosures which are limited in nature and cannot be reasonably prevented.

B. You may object to the following uses of PHI:
1. Inpatient hospital directories. Unless you tell us not to, we may include your name, location, general condition and religious affiliation in our patient directory so your family, friends and clergy can visit you and know how you are doing.

2. Information shared with family, friends or others. Unless you tell us not to, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.
3. Health plan. You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:
You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation.
1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.
2. Mental Health Records unless permitted under an exception in section A.
3. Substance Use Disorder Treatment records unless permitted under an exception in section A.
4. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:
A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date**.**
B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI and/or appointment reminders in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.
C. The Right to See and Get Copies of Your PHI. You have the right to inspect and/or receive a copy (an electronic or paper copy) of your medical and billing records or any other of our records used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a cost-based fee. MUSC will act on a request for access or provide a copy usually within 30 days of receipt of the request. We may deny your request in limited circumstances. If you are denied access to your records, you may request that the denial be reviewed by a licensed health care professional. Additionally, we may use and disclose information through our secure patient portal which may allow you to view and communicate with certain health care providers in a secure manner. For more information see our https://mychart.musc.edu/mychart/
D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.
E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record. Notification will be provided within 60 days.
F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 349 / Charleston, SC 29425. The phone number is (843) 792-3881.
G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.
H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers, belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the U.S. Dept. of Health and Human Services, Office for Civil Rights. The address will be provided at your request or by visiting www.hhs.gov/ocr/privacy/hipaa/complaints/.

CHANGES TO THIS NOTICE

We reserve the right to change the terms of this Notice at any time. The changes will apply to all existing PHI we have about you.. This Notice will always contain the effective date and may be reviewed at http://academicdepartments.musc.edu/musc/about/compliance/privacy.html

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003 and was last revised on August 2018.