Document Coversheet

Study Title: Effects of Yoga on Physical and Psychological Outcomes in Older Patients Discharged From Cardiac Rehabilitation: A Pilot Study

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	8/6/2024
NCT Number:	NCT06235658
IRB Number	86669
Coversheet created:	9/8/2025

KEY INFORMATION FOR EFFECTS OF YOGA ON PHYSICAL AND PSYCHOLOGICAL OUTCOMES IN OLDER PATIENTS DISCHARGED FROM CARDIAC REHABILITATION: A PILOT STUDY (PATIENTS)

We are asking you to choose if you want to volunteer for a research study. Our goal is to find out if doing yoga will improve the health of older adults with heart disease. We have a special yoga program for older adults with heart problems who have completed cardiac rehabilitation. We suggest having a study partner for safety during yoga. It is optional, but they can help right away if any health problems happen.

We want you to join our study because you have heart problems and have finished cardiac rehabilitation. If you agree, you will be put by chance into one of two groups: 1) the yoga group or 2) the no-yoga group. If you are in the yoga group, you will do yoga by video calls at home. If you are no-yoga group, we will give you booklets on how to live a healthy life.

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?

The study is about how yoga practice may help improve physical and mental health in older adults with heart problems. By doing this study, we hope to learn about physical and mental benefits of chair yoga. Your participation in this research will last about for 3 months.

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

You can join this study if you want to learn how to be active using yoga practice at home. For more information on the benefits, check the Detailed Consent.

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

Some people may find it hard to do yoga and deep breathing. If you have continued chest pain or shortness of air or other problems that make exercise hard, you might not want to join this study. If your doctor has told you not to exercise, you should not join this study. In this study, we will pick participants for live-video call yoga classes, twice a week for 3 months. Half of the participants will get the video classes, while the other half will not. If you do not want to do yoga, you can choose not to join. If you do not want to participate in yoga with up to 6 other participants (on video), then you should not participate. If you want more information about possible risks, you can read the Detailed Consent form.

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 Geunyeong Cha, Ph.D. student, College of Nursing at University Kentucky, 859-629-0657 (email: gch264@uky.edu) and Debra K. Moser, Professor, PhD, RN College of Nursing at 859-323-6687 (email: dmoser@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:

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

You cannot join this study (1) if you do not finish cardiac rehabilitation (2) you do not have heart problems, or (3) you are younger than 65 years. You also cannot join if (1) you have severe problems with your nerves, like not being able to move, or with your bones, like constant back pain, (2) you have cancer that cannot be cured, or serious memory problems like Alzheimer's disease. This is because yoga might be too hard for you. (3) have a major psychiatric disorder like schizophrenia or bipolar disorder, not including depression (4) you already practice yoga because it might influence your feedback and alter study results and (5) you do not have Wi-Fi at home because a home Wi-Fi connection is needed to get the yoga classes

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

The research procedures will be conducted at the University of Kentucky, College of Nursing, the RICH Heart Program, the research facility located at 2201 Regency Rd, Suite 403, Lexington, KY 40503.

People in both groups will fill out surveys twice, 3 months apart. The first survey will take about 30-40 minutes, and the second one will take 20-30 minutes. You can fill out the surveys at your home or our research office. However, you will need to come 2 times during the study because we will also test your balance and muscle strength. This physical examination test will take 30-40 minutes. We will also ask you to wear an activity watch for 9 days and then return the watch to us. You can mail it back to us in a prepaid package that we will give you or bring it to the research office.

If you are in the yoga group, you will do surveys, physical tests, and yoga for about 26 hours over 3 months. If you are in the no-yoga group, you will do surveys and physical tests for about 2 hours for each time.

WHAT WILL YOU BE ASKED TO DO?

Trained study staff might ask you to join this study. If you want to join the study, trained study staff will talk to you, explain the study, and obtain consent. If you say 'yes' to join the study, you will need to visit us two times. The first visit is when you start, and the next is 3 months later. During these visits, you will come to our offices to finish surveys, balance, and strength testing.

We ask all participants to fill out surveys and do muscle strength, balance, and physical activity checks.
You will fill out surveys when you start and again in 3 months. You will do this online or on paper if you prefer.

We will check your muscle strength when you start and in 3 months. To do this, we will ask you to push hard against the device for 3-5 seconds. The device, called a dynamometer, is a small tool that tells us how strong someone's muscles are. We use it to see if yoga has any effect on muscle strength. We will do this test on the dominant knee, elbow, and hip. We will do this test three times for each place. Each test takes 2 minutes with 1-minute rest in between. It will take a total 8-10 minutes.

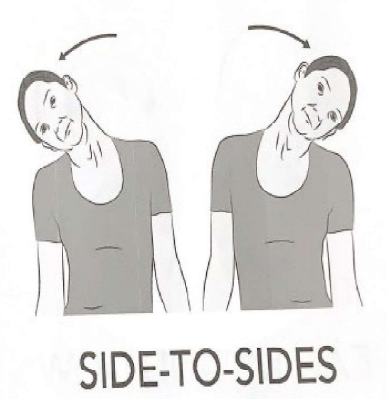
We will check your balance when you start and in 3 months. During the balance test, we will ask you to stand with your hands on your hip for 30 seconds. We will do this test three times. Each test takes 30 seconds with 30 seconds rest in between. It will take a total of 3-5 minutes. You will be with the research staff so there is no chance of falling.

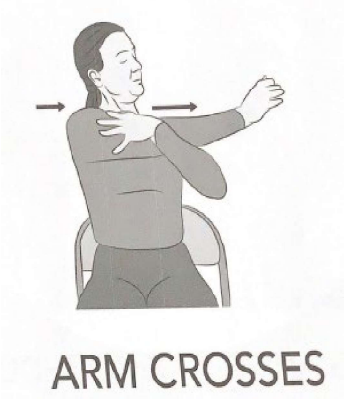
We will check your heart rhythm when you start and in 3 months. You will lie down on your backs for 10 minutes on the exam bed without talking and try to stay still. We will use a small square device to check your heart rate in the middle of your chest.

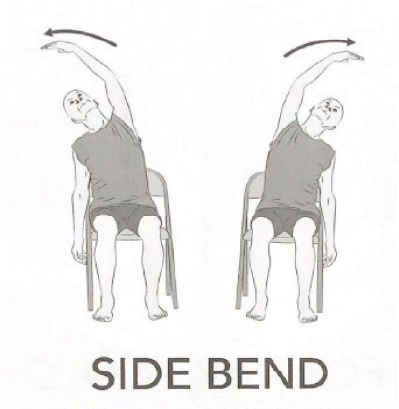
We will also check your physical activity level and sleep quality using a special watch. You will wear this watch at the beginning and about 3 months later. You will wear the watch for 9 days. After 9 days, you will mail the watch back to us in a prepaid, stamped box that we will give you.
If you want to join the optional blood samples, we will take a small amount of your blood. You will be seated, and blood will be drawn by putting a needle into a vein in your arm. We will take about as much as a half spoonful. This will take about five minutes.

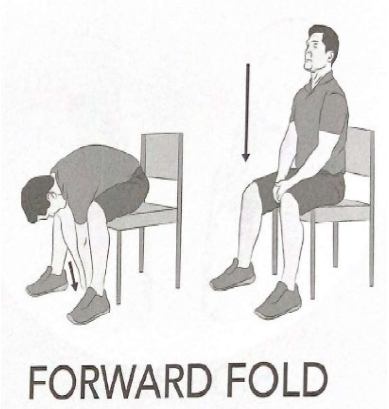
You will be put into one of two groups by chance: the yoga group or no yoga group. You have the option of asking someone who lives with you (like your spouse or friend) to watch you in-person during the online yoga session to help ensure you are safe. Will you go yoga to ensure your safety.

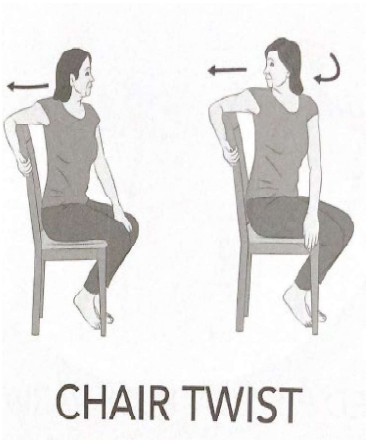
If you're in the yoga group, you will join yoga classes. You will receive yoga blocks, two 1 lb weights, and stretch bands to enhance and ensure safe practice. These classes are live video classes. You do the yoga at home. You need to have an electronic device. If you do not have one, we will lend you an iPad. You will use it for yoga at home. After 3 months, you will need to return it. You will watch a yoga instructor on live video to learn yoga. We will have up to 7 people on the screen at one time. Everyone, including the study team and other participants, can see each other. Names will show at the bottom of each person's screen. If you do not want your real name showing, we will give you a number, and you can change your screen name to that number. Your video and all conversations can be heard by all participants. We ask that you not share any information you hear from other participants with anyone. Before each session, a trained nurse will ask subjects how they have been feeling and if they have had any cardiac symptoms in the last 24 hours. You will do yoga sitting in a chair. You will do yoga two times each week for three months. Each class is about an hour long. The class has three parts: deep breathing (10 minutes), yoga moves (20 – 30 minutes), and relaxing with meditation (10 minutes). The pictures below show examples of chair yoga. We will not ask you to do more than you can do. We will record yoga classes to make sure you do yoga safely. No one will be able to see the recording except the PI, and it requires a password. We will delete all recordings when the study is over. You can also fill out a few extra questions about how you like the yoga.











If you're in the no-yoga group, you will receive the AHA 'Life's Essential 8' booklets but will not join the yoga classes or get an iPad.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

A person is at risk for having a cardiac event based on their medical history.

Filling out these questionnaires is safe and has no known risks. But sometimes, you may feel stressed or bothered by some questions. In our experience with more than 5,000 participants, this feeling rarely happens and does not last long. If any question makes you feel uncomfortable, you can skip it. Talking about mental health

might be hard for some people. A very small number of people feel anxious when answering, but it is rare. If we notice you seem to have a hard time, our staff nurse who specializes in mental health will help you.

Testing your balance and muscle strength might make you a little tired or sore. Our trained staff will keep a close watch on you during these tests and give you breaks when needed.

Yoga can stretch your muscles, which might lead to some soreness or fatigue. But, getting hurt is rare. This is because we've tested our yoga with people who have heart problems. You will also practice yoga while sitting in a chair, which is very safe.

If you agree to participate in the optional blood samples, the needle stick during the blood draw might hurt. There is very small chance that you may experience soreness, bruising, pain, infection, possible fainting, or bleeding from the blood draw. This risk occurs very rarely.

There is always a chance that any medical treatment 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 positive feelings knowing that may help others. Doing yoga might help you learn how to manage your stress better and make you feel better. However, if you take part in this study, information learned may help others with your condition.

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?

It is free to join this research. You will not have to pay for yoga classes.

If you're in the yoga group and don't have a device to access live video, we'll lend you an iPad. But you will need to return it when the study is over. Borrowing the iPad is also free.

The University of Kentucky will not charge your insurance company, Medicare, or Medicaid for the medical tests done for the study. You and/or your insurance company, Medicare, or Medicaid will have to pay for your usual medical care and treatments. These treatments include those you would normally receive. These are costs for important medical care you receive even if you do not join the study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

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

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. You will not be identified in written materials. We will keep your name and personal information private. We will keep private all research records that identify you to the extent allowed by law.

You should know that in some cases we may have to show your information to other people because you may pose a danger to yourself or others.

For example, the law may require or permit us to share your information with:

- a court or agencies, if you have a reportable disease/condition;
- authorities, such as child or adult protective services, if you report information about a child or elder being abused;
- authorities or a mental health professional if you pose a danger to yourself or someone else (e.g., suicidal thoughts).

All information we collect will be stored in locked file cabinets, in a locked room, and in a secure office. All information on computers will be locked with special codes and passwords. When we write about results from the study, we'll write about everyone's information together. But sometimes, we may have to show your information to other people. For example, the University of Kentucky may look at important parts of records that have your name on them. The University of Kentucky wants to make sure the study is carried out correctly and may look at records to make sure that is done.

We will store videos of yoga classes in a special online storage space. The special online storage space meets protection regulations. The recordings will be locked and will need a password to keep them private. Only the PI will see the recordings. The PI will watch videos for only observation purposes. Once we finish the study, we will delete all recordings.

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

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

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.

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.

If you decide to stop the study early, you will be asked to return the activity watch and iPad if you received them.

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 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 Geunyeong Cha, at 859-629-0657 or Debra K. Moser, PhD at 859-323-6687 immediately.

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

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

Everyone in the study will receive a yoga mat. Everyone will receive $70 as a gift card each time you finish data collection. If you finish two data collection sessions, you 'll receive a total of $140. If you agree to join the optional blood samples, you will receive an additional $25 gift card each time. If you are in the yoga group, you will get yoga blocks, small weights (1 lbs), a yoga mat, and stretch bands to help with yoga. These tools make yoga practice safer. With a few exceptions, study payments are considered taxable income reportable to the Internal

Revenue Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

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?

Generally, tests done for research purposes are not meant to provide clinical information. We will not provide you with individual research results.

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

The research staff will contact you in the future with information about participating in additional studies. If so, it will be limited to 1-2 times per year.

Do you give your permission to be contacted in the future by the study staffs in the RICH Heart Program regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?

This PI is guided in this research by Dr. Debra, K. Moser. There may be other people on the research team assisting at different times during the study.

WILL YOUR INFORMATION (OR SPECIMEN SAMPLES) 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 or samples 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 or samples 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 or samples 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:

- Name, age, address, medical record number, phone number, medical history, current medications, and any hospitalizations that have occurred.

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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
- UK HealthCare and their representatives
- UK Health system (EPIC, the electronic medical records) and health systems outside of UK for which you have a patient relationship

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: Geunyeong Cha, University of Kentucky, College of Nursing, and Debra K. Moser, University of Kentucky, College of Nursing, 2201 Regency Rd, Suite 402 Lexington, KY 40503 to inform her of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information have 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.

INFORMED CONSENT SIGNATURES

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

Please indicate if you would like to participate in optional blood samples of this research protocol.

Optional blood samples: Information about Inflammatory and Stress Markers. In the optional blood samples, we collected blood samples to see how yoga affects your inflammatory and stress markers at the start and after 3 months. You will get an extra $25 each time you complete this blood sampling. Whether you choose to join the optional blood samples will not affect your participation in the main research or your medical treatment.

☐ Yes, I would like to participate in the optional blood samples.

☐ No, I would not like to participate in the optional blood samples.

_____ **Signature of research subject**	_____ **Date**
_____ **Printed name of research subject**	
_____ Printed name of [authorized] person obtaining informed consent and HIPAA authorization	_____ Date

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 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.

Modification Request Section

0 unresolved comment(s)

***** 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.*****

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.

Regarding the changes to this study composition, I would like to inform that Dr. Chung will no longer be serving as a co-investigator on this project. Marissa will be joining as another research assistant

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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

Effects of Yoga on Physical and Psychological Outcomes in Older Patients Discharged from Cardiac Rehabilitation: A pilot study

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.

Yoga in older cardiac patients

Anticipated Ending Date of Research Project: 12/31/2024

Maximum number of human subjects (or records/specimens to be reviewed) 40

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

Are you requesting that the UK IRB serve as the lead IRB for a multi-site study, or that the UK IRB to defer review to another IRB? [Click here for "IRB Reliance" help]
○ Yes ◉ No
If "Yes," before completing your IRB application, fill out the Reliance Request Form and submit it to irbreliance@uky.edu.

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:	geunyeong	Room# & Bldg:	751 Rose Street
Last Name:	cha	Speed Sort#:	40536
Middle Name			
Department:	Nursing Instruction - 7E100	Dept Code:	7E100
PI's Employee/Student ID#:	12508683	Rank:	
PI's Telephone #:	8597979266	Degree:	Master of Science in Nursing
PI's e-mail address:	geunyeongcha@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	8/17/2023
		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

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.

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

SUBJECT DEMOGRAPHICS **0 unresolved comment(s)**

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc.) 65 to 99

Study Population:

Describe the characteristics of the subject population, including age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion.

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;
- Justification for the inclusion of vulnerable groups such as children, prisoners, adults with impaired consent capacity, or others who may be vulnerable to coercion or undue influence.

Please consider these resources:
NIH Diversity Policy
FDA Diversity Guidance

Eligible participants will be older patients (aged = 65 years) who: 1) have a history of an acute myocardial infarction within the preceding year, stable angina, cardiac surgery (including heart transplantation, valve surgery, or coronary artery bypass), coronary artery angioplasty or stents, or heart failure (ejection fraction < 35%) diagnosed in the past year; 2) have completed facility-based cardiac rehabilitation program (phase CR-II) within 6 months; 3) are able to read and understand English; 4) have no major comorbidities limiting their ability to participate in a yoga intervention; and 5) reside in Kentucky.
Participants will be excluded if they 1) have incapacitating neurologic, orthopedic, or neoplastic conditions such as stroke paralysis, terminal cancer, or a cognitive disorder because these conditions may limit their ability to participate in a yoga intervention. Neurocognitive conditions like Alzheimer's disease will be excluded based only on medical record reviews.; 2) have pulmonary hypertension, peripheral artery disease, or intermittent claudication; 3) currently practice yoga, and 4) have no home WiFi access.

Eligible study partners are: (1) those who are older than 18 years, and (2) those who can observe patients, with whom they are closely associated, while the patients practice yoga during this study. It's not required for these partners to live with the patients.

Dr. Chung, the advisor to the PI in the proposed study, is conducting a yoga intervention study (IRB # 72684, 2022- 2024) through an expedited application process due to the study's minimal-risk nature. That ongoing study specifically targets outpatients with heart failure in the advanced stages of the condition. This ongoing yoga intervention is a low-intensity yoga program that is thoughtfully designed to accommodate the capacities of each participant. It encompasses deep breathing, exercise, and meditation. Yoga lasts about 20 - 30 minutes and includes low-intensity components, including chair yoga and floor yoga without advanced poses. The ongoing study incorporates the same safety measures outlined above. While the two studies have distinct inclusion and exclusion criteria due to the different study populations, they share a common exclusion criterion: individuals with medical conditions or limitations that could hinder their ability to perform yoga movements are excluded. We have already delivered over 80 yoga sessions for patients with heart failure through videoconference technology, all without the presence or supervision of family members and all without incident.
.
The proposed study falls within the scope of a risk level 1 study, and the following reasons support this classification. First, the proposed yoga intervention features a relatively lower exercise level than the ongoing yoga intervention study (or other yoga interventions listed above) because the proposed yoga program exclusively involves chair yoga and excludes floor yoga. Similarly, advanced yoga poses are not incorporated, mirroring the ongoing study's approach. Second, throughout the ongoing study sessions, we have had no adverse events. This noteworthy outcome underscores the safety of our yoga intervention, especially considering the absence of family supervision during these sessions. Additionally, it is important to note that the ongoing study's participant demographic features a mean age of 59 years.

Attachments

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 at Continuation Review time for Pre-2019 FDA-regulated Expedited review and Full review applications):

Participant Demographics

	Cisgender Man	Cisgender Woman	TGNB/TGE	Unknown/Not Reported
American Indian/Alaskan Native:	0	0	0	0
Asian:	0	0	0	0
Black/African American:	4	4	0	0
Latinx:	0	0	0	0
Native Hawaiian/Pacific Islander:	0	0	0	0
White:	16	16	0	0
American Arab/Middle Eastern/North African:	0	0	0	0

Indigenous People Around the World:	0	0	0	0
More than One Race:	0	0	0	0
Unknown or Not Reported:	0	0	0	0

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
- ☐ Pregnant Women/Neonates/Fetal Material
- ☐ Prisoners
- ☐ Non-English Speaking (translated long or short form)
- ☐ International Citizens
- ☐ Normal Volunteers
- ☐ Military Personnel and/or DoD Civilian Employees
- ☑ Patients
- ☐ Appalachian Population

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook for more information on:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults
- Economically or Educationally Disadvantaged Persons

Other Resources:

- 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

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).
- If another site is serving as the IRB for the project, attach the form as a "Reliance Consent Form" so the document will not receive a UK IRB approval stamp; the reviewing IRB will need to stamp the consent forms.
- 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
  - "Reliance Consent Form",
  - "Sponsor's Sample Consent Form".

How to Get the Section Check Mark

1. You must:

   a) provide a response in the text box below describing how investigators will obtain consent/assent, and
   b) 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 read-only 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 and/or translated short form)
- ☐ Assent Form
- ☐ Cover Letter (for survey/questionnaire research)
- ☐ Phone Script
- ☑ Informed Consent/HIPAA Combined Form
- ☐ Debriefing and/or Permission to Use Data Form
- ☐ Reliance Consent 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
Informed Consent/HIPAA Combined Form	CLEAN CONSENT for patient_10232023.pdf
Informed Consent/HIPAA Combined Form	CLEAN CONSENT for study partner_10232023.pdf
Informed Consent/HIPAA Combined Form	CLEAN CONSENT for patients_10302023.pdf
Informed Consent/HIPAA Combined Form	CLEAN CONSENT for study partners_10302023.pdf

Informed Consent Process:

Using active voice, describe how investigators will obtain consent/assent. Include:

- the circumstances under which consent will be sought and obtained
- the timing of the consent process (including any waiting period between providing information and obtaining consent)
- who will seek consent
- how you will minimize the possibility of coercion or undue influence
- the method used for documenting consent
- if applicable, who is authorized to provide permission or consent on behalf of the subject
- if applicable, specific instruments or techniques to assess and confirm potential subjects' understanding of the information

Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Special considerations may include:

- Obtaining consent/assent for special populations such as children, prisoners, or people with impaired decisional capacity
- *Research Involving Emancipated Individuals*
  If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **prior to submitting this application to the IRB**. Include research legal counsel's recommendations in the "Additional Information" section as a separate document.
- *Research Involving Non-English Speaking Subjects*
  For 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.

E-consent (electronic consent) is the only consent process that will be used. Informed consent will be obtained from potential eligible participants in in-person meetings at the cardiac rehabilitation center or clinics or via Zoom or phone calls by the investigator who has received CITI training and obtaining consent from eligible participants. During an in-person visit, the investigator will explain the study by going through the consent form, allowing the subject time to read the form, and asking any questions. The investigator will then ask the participant what they will do in the study to ensure they understand the consent. The subject will be given a copy of the signed consent form at that time. Ample time will be provided for subjects to ask questions. If during Zoom or telephone, the consent process will be the same, but the subject will receive a copy of the consent from REDCap or an email from us. Patients will then be randomly assigned to one of the groups.
At the beginning of the study, participants are provided with the number of investigators in our instructional materials. They can offer any complaints or concerns to these individuals or the IRB (number included in the consent form). If we learn of any complaints or concerns, they are discussed in our weekly research meeting in an attempt to resolve them. We do not use participant names or ID numbers in these meetings. We work to determine the best course of action to address the

☐ 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).

SECTION 1.

Check the appropriate item:

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

☐ I am requesting an 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.

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

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

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

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.

☐ Request for Waiver of Signatures

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:

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):

○ **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.

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	A C	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI
Angeletti	Brynn	Project Assistance/Support	SP	N	N	BS	P	Y	08/23/2023	Y	N	09/01/2023	N
Biddle	Martha	Co-Investigator	SP	Y	N	Ph.D	P	Y	08/23/2023	Y	N	09/01/2023	N
Frick	Marissa	Project Assistance/Support	SP	Y	N	BS	P	Y	02/07/2023	Y	N	12/06/2023	N
Heebner	Nicholas	Co-Investigator	SP	Y	N	Ph.D	P	Y	07/23/2021	Y	N	09/01/2023	N
McGuire	Patricia	Project Assistance/Support	SP	Y	N		P	Y	09/01/2022	Y	N	09/01/2023	N
Moser	Debra	Faculty Advisor	DP	Y	N	Ph.D	P	Y	04/05/2023	Y	N	10/30/2023	N
Seo	Sue Kyeung	Recruitment	SP	Y	N	BSN	P	Y	12/05/2023	Y	N	09/01/2023	N
Thapa	Ashmita	Project Assistance/Support	SP	Y	N	BS	P	Y	01/28/2022	Y	N	10/30/2023	N
Thompson	Jessica	Co-Investigator	SP	N	N	Ph.D	P	Y	04/19/2023	Y	N	11/16/2023	N
Calvert	Ian	Data Collection	SP	N	N	BS	P	Y	04/24/2023	Y	Y	12/06/2023	N
Chung	Misook	Co-Investigator	SP	N	N	Ph.D	P	Y	10/16/2021	Y	Y	12/06/2023	N
McCallum	Lindsay	Project Assistance/Support	SP	N	N	MS	P	Y	12/23/2021	N	Y	09/01/2023	N
Miller	Jennifer	Co-Investigator	DP	N	N	Ph.D	P	Y	05/22/2023	N	Y	12/06/2023	N

RESEARCH DESCRIPTION

0 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.

Pro Tips:

- **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 supplemental information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background

Include a brief review of existing literature in the area of your research. You should identify gaps in knowledge that should be addressed and explain how your research will address those gaps or contribute to existing knowledge in this area. For interventional research, search PubMed and ClinicalTrials.gov for duplicative ongoing and completed trials with same condition and intervention(s).

Specific Aims.

Engagement in physical activity is crucial for patients after an acute cardiac event (i.e., ST-segment elevation myocardial infarction [STEMI], non-STEMI, percutaneous or surgical revascularization, and unstable angina) who have completed outpatient facility-based cardiac rehabilitation phase II (CR) to prevent recurrent events (1,2). Secondary prevention can only be achieved using comprehensive approaches that include physical activity (3). However, more than half of patients who complete phase II CR reported not maintaining or engaging in physical activity in the home environment (4,5) Due to the nature of aging, which can lead to limited physical mobility and multi-morbidity, older patients (= 60 years) with acute cardiac events have more challenges in promoting their health and engaging in physical activity in a home environment after a CR program (6,7).
Psychological distress in cardiac patients is associated with poor self-care (8,9). At least one out of five of cardiac patients experience psychological distress, such as depressive symptoms and anxiety, after major cardiovascular events (10,11). Psychological distress also negatively interferes with physical health outcomes, and is associated with reduced functional capacity and increased severity of cardiac conditions (12,13). However, most home-based or hybrid (home and facility) CR programs in clinical trials have not addressed psychological distress (14-16). Thus, there is limited knowledge about the impact of the management of psychological distress on physical activity and other outcomes, particularly when such management occurs in the home setting after phase II CR.

Yoga, an increasingly popular exercise modality, consists of the use of stretching and postures (i.e., guided, gentle movements) to enhance physical mobility and balance function, muscle strength, and breathing techniques and meditation to induce relaxation and manage psychological distress (17-19). Yoga has substantial benefits in reducing depressive symptoms and anxiety in cardiac patients (20-22) but there is limited knowledge on whether yoga is beneficial in improving both psychological and physical function in older cardiac patients who have completed the CR program. Additionally, those studies have limited information on whether yoga is beneficial for restoring and improving balance function and muscle strength in old cardiac patients, especially those who need to maintain them through their own self-care after they complete the recommended CR program.

The proposed study will address the knowledge gap about the potential for yoga to improve physical and psychological health outcomes in older cardiac patients. The purpose of this randomized controlled pilot study is to examine the effects of a structured yoga program on physical and psychological health outcomes among cardiac patients over 65 years who have completed a facility-based outpatient phase II CR program. A structured yoga intervention will be delivered for 12 weeks via video conferencing technology, a time and cost-effective delivery modality. Physical outcomes include physical activity, balance function, and muscle strength. Outcomes of physical activity (i.e., time spent in sedentary, light, moderate, and vigorous activity) will be assessed using an ActiGraph watch. Balance function and muscle strength will be assessed through physical examination. Psychological distress (i.e., depressive symptoms and anxiety) will be assessed using the Patient Health Questionnaire-9 and the Beck Anxiety Scale. The immediate short-term intervention effect will be assessed at 3-month follow-up.

Backgrounds.

Individuals with a history of acute cardiac events are more susceptible to recurrent events, and the mortality rate of the second event is up to three times higher than for the first event (23). Despite successful revascularization procedures and pharmacological treatment, the rate of recurrent cardiac events (e.g., recurrent STEMI, non-STEMI, revascularization, unstable angina) and death, remain high within a 1-year period (24) The American Heart Association recommends CR programs that offer multidimensional services with specific core elements, including patient assessment, physical activity counseling, exercise training, diet counseling, and psychosocial management, to achieve lifelong changes in patients who experience any cardiac event (25). Cardiac rehabilitation typically consists of three or four phases of CR, starting in the hospital (phase I), extending to outpatient CR (phase II), and then to phase III/IV, which is home-based self-directed physical activity maintenance (26). During phases I and II, patients are guided to adopt a healthy lifestyle through education about nutrition, medications, risk factors, and exercise with the supervision of healthcare professionals at the hospital and the facility (26). These early phases (I and II) provide positive results for patients' health. Maintaining regular physical activity after discharge from the in-hospital setting is a primary target for patients following any cardiac event to prevent second or recurrent events (1,2). However, the obstacles that most patients face in maintaining a healthy lifestyle happen in their home environment during phase III where there are no healthcare professionals to supervise (4,5).

Older cardiac patients have more barriers to engaging in physical activity at home (phase III). Researchers reported a strong association of lower levels of physical activity with recurrent events, rehospitalization, and mortality in older cardiac patients (27,28). To prevent recurrent cardiac events, North America and Europe, as front-runners in CR research, suggest moderate to vigorous-intensity physical activity for post-event older adults (29). Older cardiac patients (i.e., age = 60 years) generally have limited physical functions and multiple comorbidities (6,7). However, older patients become more fragile or experience rapid physical deconditioning after any cardiac event and generally are unable to participate in anything beyond moderate-intensity exercise (30,31). Thus, older adults have more challenges in maintaining physical activity or sustaining self-care activities, particularly physical activity in a home environment after a CR program (6,32).
Patients who experience major cardiac events commonly experience psychological distress (8,10,11,33). Among psychological distress, depressive symptoms, and anxiety are common as 18-30% of patients who have cardiac events have reported the prevalence of depression (10,33), and up to 28% of patients suffer from anxiety (11,33). Patients with moderate to severe psychological distress were less likely to complete CR sessions and to sustain any level of physical activity.8 However, most CR interventions in phase II do not include the management of psychological distress, even though there is excellent evidence of the improved effectiveness of treating both psychological and physical outcomes (34). In the home environment, cardiac patients have few or limited opportunities to manage psychological distress (35). Given the negative effects of psychological distress on engagement in self-care,8 managing psychological distress is critical in cardiac patients.

Yoga is an appropriate intervention for older adults that addresses physical and psychological outcomes in cardiac patients. Yoga has a positive impact on various medical conditions and has been offered to CR patients as a therapeutic option in phase II CR programs (36-38). Among various types of yoga, a standardized therapeutic yoga (i.e., MediYoga) has been developed by healthcare professionals in Sweden that has been demonstrated to be well-suited to group rehabilitation among cardiac patients (39-41). A strength of this yoga intervention is that the physical postures are easy to follow and consist of gentle stretches specifically designed for cardiac patients; no safety issues have arisen with this yoga intervention (39). Several investigators who used this therapeutic yoga in a variety of patient populations have shown a significant reduction in patient's psychological distress, in addition to improving cardiovascular outcomes (40,41) A few investigators have integrated yoga into the facility-based CR, mostly in Europe and India, and they used different forms of yoga practice and reported inconsistent findings (42-44). Because there are many yoga formats, there is no standardized yoga intervention for older cardiac patients. Yoga is also beneficial in accentuating body alignment through muscle activation patterns and gentle progression and in strengthening muscles (18,19). However, most effects of yoga on balance function and muscle strength have been reported in Parkinson's disease or physical disability (e.g., stroke, post-breast cancer surgery)(45-47), but there is limited information on these effects in older cardiac patients.

We designed the yoga intervention specifically for older cardiac patients. We will examine whether the yoga intervention will be beneficial for patients who are at risk for poor physical function and high psychological distress in older cardiac patients who need to do self-care after they have completed the recommended CR program. The proposed intervention is practical and easy to do in a home or other setting. The successful intervention effect of yoga will advance the knowledge in the field of aging health and secondary cardiovascular prevention.

Research Gap
Older cardiac patients often struggle to sustain their physical activity levels and usually adopt a sedentary lifestyle after completing their cardiac rehabilitation program. While these patients actively engage in physical exercises during the cardiac rehabilitation program (Phase II), the duration of this service is limited, typically ranging from three to six months. Even though these older cardiac patients are inclined to participate in physical activity during Phase II of cardiac rehabilitation, they find it challenging to continue their exercises. This is because many lack access to exercise equipment and knowledge on how to maintain their regimen post-rehabilitation. However, surprisingly, there are no studies focusing on older cardiac patients who have concluded Phase II cardiac rehabilitation. Many cardiac patients are also afraid or anxious about the idea of working out or doing exercises at home without someone there to help or supervise them when they return home (Phase III). Yoga has been recognized for its positive effects on various medical conditions and is introduced as a therapeutic option in Phase II/III cardiac rehabilitation programs. It encompasses not only mild physical activity but also relaxation and breathing exercises. Therefore, gentle yoga may be particularly suitable for older adults who find it challenging to partake in or keep up with the demands of physical activity.

Many older adults with cardiovascular diseases often experience lower self-care levels, particularly physical activity, after completing a facility-based cardiac rehabilitation program. It is known that increased physical activity can potentially counteract declines in vulnerability and improve physical functions such as activity levels, balance, and muscle strength. Therefore, yoga interventions might be an effective strategy for enhancing the functional performance of older patients with cardiovascular diseases. However, when these patients return to their home settings, they often find it challenging to stay active, primarily because they rely heavily on healthcare workers.

Involving a study partner during yoga practices can offer an added layer of safety for older patients by allowing for indirect monitoring. In this study, we will include a study partner whose main role is to observe older patients. To our knowledge, the effectiveness and potential challenges of involving a study partner in a home-based yoga intervention remain unexamined.It is important to understand not just the benefits for the older patients but also the potential implications for the study partners themselves. Therefore, we will describe demographic information about these partners and their relationship to the patients. Furthermore, we will assess their psychological factors, such as depressive symptoms, anxiety, and caregiver burden. This approach aims to provide a comprehensive understanding of the intervention's impact on both older patients and their study partners.

Objectives

List your research objectives. Please include a summary of intended research objectives in the box below.

The specific aims of this study for patients are as follows:
Specific Aim 1: To compare, at 3-month follow-up, the effects of a yoga intervention on physical activity levels (i.e., time spent in sedentary, light, moderate, and vigorous activity), balance function, muscle strength, and psychological distress (i.e., depressive symptoms, anxiety) among older (= 65 years) cardiac patients randomized to an intervention (yoga) or control group.
Hypothesis 1. The intervention group will decrease sedentary time and increase time spent in other activity levels compared to the control group at a 3-month follow-up.
Hypothesis 2. The intervention group will improve physical outcomes (i.e., balance function, muscle strength, sleep quality, short-term heart rate variability, vulnerability, and stress as well as inflammatory indicators) compared to the control group at a 3-month follow-up.
Hypothesis 3. The intervention group will have lower levels of depressive symptoms and anxiety than the control group at a 3-month follow-up.
Hypothesis 4. The intervention group will have higher levels of social support and a higher self-care score than the control group at 3-month follow-up.

Specific Aim 2: To determine the feasibility and acceptability (i.e., recruitment rates, intervention adherence rates, acceptability, and satisfaction) of the modified yoga intervention delivered via video conferencing for older cardiac patients.

The specific aim of this study for study partners is as follows:
Specific Aim 3: To identify the characteristics of study partners and examine psychological distress (i.e., depressive symptoms, anxiety, and caregiver burden) as well as well-being (i.e., social support and quality of life) at baseline and the 3-month follow-up.

Study Design

Describe and explain the study design (e.g., observational, secondary analysis, single/double blind, parallel, crossover, deception, etc.).

- *Clinical Research*: Indicate whether subjects will be randomized and whether subjects will receive any placebo.
- *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.
- *Qualitative research*: Indicate ranges where flexibility is needed, if a fixed interview transcript is not available, describe interview topics including the most sensitive potential questions.
- *Research Repositories*: If the purpose of this submission is to establish a Research Repository (bank, registry) and the material you plan to collect is already available from a commercial supplier, clinical lab, or established IRB approved research repository, provide scientific justification for establishing 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 is a 2-group randomized controlled trial (i.e., yoga intervention versus control group) to determine the effects of a structured yoga intervention on physical activity and psychological outcomes in 40 older adults who have completed phase II CR. Eligible patients will be recruited from UK Gill Heart and Vascular Cardiac Rehabilitation. After eligible patients are randomly assigned to the yoga intervention or control groups, the intervention group will receive 12-weekly yoga sessions via video conferencing. Outcome data will be collected at a 3-month follow-up. In this study, 40 eligible patients will be recruited and randomly assigned to the intervention or control groups by allocating subjects in a 1:1 ratio to either the intervention or control group. Random assignment will be determined from a computer-generated randomization plan.

Yoga intervention group:
Participants in the intervention group will attend two 60-minute yoga sessions per week for 12 weeks. Certified yoga instructors will deliver structured yoga sessions in a group. Each yoga group will have a minimum of 5 participants and a maximum of 7 to ensure the quality of sessions. The PI, who is a certified yoga instructor, worked with other certified yoga instructors to modify an existing MediYoga program to accommodate the needs of older cardiac patients. We will provide written yoga practice materials at the beginning of the intervention on how to do deep breathing, postures, and meditations.
At the first yoga session, we will provide information about how yoga fits into self-care for cardiac patients, as well as the benefits of yoga in cardiac patients. We will then teach and model basic yoga components that include deep breathing, meditation, relaxation, and physical postures. All sessions begin with long, deep breathing practice, where participants will use essential body parts, including the stomach, rib cage, and collarbone, to fully engage in deep breathing that has the effect of increasing parasympathetic tone. After the breathing practice, the yoga instructor will give brief information and demonstration of that session's physical postures, including the effects of each, so that participants can become familiar with the yoga movements they will need to perform. New postures will be introduced in each session. Yoga instructors will modify physical postures on an individual basis as needed to fit individual patients' physical flexibility. Yoga postures will include only low to mild-moderate-intensity poses where the movements are smooth and predictable, which will allow basic muscle training to be combined in a way that maximizes joint operation while avoiding rapid or unexpected movements (49). Following yoga posture practice, the participant will wind down their physical activity with final stretches. Subsequently, the yoga instructor will guide participants to take part in meditation. With the completion of each yoga session, the yoga instructor will encourage participants to share their experiences and feelings about the session.
The PI will communicate on a weekly basis with the yoga instructions about the participants' experiences (via email, phone calls or Zoom meetings) and will work with the instructors monthly to refine each participant's effort based on their performance and their reported responses to the sessions.

Control group:
The control group will not receive yoga but will receive printed or electronic versions of the American Heart Association "Life's Essential 8" at baseline, including information on how to increase and maintain cardiovascular health. They will receive no other intervention from us.

Attachments

Subject Recruitment Methods & Advertising

Describe how the study team will identify and recruit subjects. Please consider the following items and provide additional information as needed so that the IRB can follow each step of the recruitment process.

- How will the study team identify potential participants?
- Who will first contact the potential subjects, and how?
- Will you use advertisements? If so, how will you distribute those?
- How and where will the research team meet with potential participants?
- If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations.
- How you will minimize undue influence in recruitment?
- Attach copies of all recruiting and advertising materials (emails, verbal scripts, flyers, posts, messages, etc.).

For additional information on recruiting and advertising:

- IRB Application Instructions - Advertisements
- PI Guide to Identification and Recruitment of Human Subjects for Research

Using the UKHC EPIC electronic health record (EHR) Best Practice Advisory notifications (BPA) as a tool for research recruitment. Search Criteria: over 65 years of age and who have completed cardiac rehabilitation service. All potential participants over the age of 65 with cardiovascular disease codes associated with the noted conditions/procedures in the UKHC EPIC EHR will have a BPA on their plan tab in EPIC. Patients who have a willingness to visit the research facility for data collection will be included. The BPA will let the healthcare provider (HCP) know that the person they are talking to may be eligible for this yoga study. The HCP will then let the patient know about the study and ask if it is ok to be contacted by our research team. HCPs can ignore the BPA as it is not required documentation, but it will continue to stay on the chart until addressed by someone seeing the patient. They can answer yes: interested, no: not interested, or patients not appropriate for the study, and our research team will receive an EPIC inbox message. Those participants who agree and are interested in further information will be contacted by our research assistant to determine further interest and eligibility. Those who say that they are not interested or for whom the HCP indicates “not appropriate for study participation” will be listed in a “screen out list” so that our recruiters do not approach them a second time regarding the study as they have already declined, and so we may keep track of eligible patients who have declined for our CONSORT diagram.

Older cardiac patients will be referred to this project by physicians and nurse practitioners from multiple recruitment pools: Cardiac rehabilitation and cardiology clinic at the Linda and Jack Gill Heart Institute, University of Kentucky Chandler Medical Center, Good Samaritan and the Chandler Medical Center Hospitals and the associated University of Kentucky Clinics. All study team members have access to EPIC to review health record information. We will review medical records in order to identify potential subjects. In this screening stage, we will collect the name, medical record number, address, telephone number, and comorbidity.
Medical chart review is necessary to determine eligibility and to find potential eligible subjects. Use of that protected health information from the medical chart will not involve more than minimal risk to the privacy of individuals because those protected data will be reviewed by trained nurse researchers who received certificates of CITI and those data will be temporally saved in paper form in the locked file cabinet and will be discarded after we complete the recruitment. Because we will get those protected health information using a structured questionnaire from eligible patients after eligible participants sign the consent form, we will not keep these paper data.
When I visit the cardiac rehabilitation center at UK Health to recruit study participants, I will distribute the flyer to all eligible patients. I will also post the flyer on the bulletin board at the UK Hospital.

Permission to conduct the study will be obtained from the University of Kentucky Institutional Review Board. We will recruit eligible participants who agreed to be contacted for future studies or invite eligible participants in the study using face-to-face invitation letters, emails, and or telephone calls. After potentially eligible participants signed the consent form, they will be invited to the next stage of the study (i.e., baseline assessment, randomization, intervention, follow-up assessment) continuously.

IRB # 86669 Justification of a risk level for the ‘Effects of yoga on physical and psychological outcomes in older patients discharged from cardiac rehabilitation: a pilot study”

The proposed yoga intervention program is designed with safety as a priority. It encompasses gentle stretching exercises, deep breathing techniques, and meditation. The exercise component of this yoga program involves performing movements while seated on a stable chair, avoiding the use of rolling chairs. It is important to note that the chair yoga approach outlined in this study emphasizes simplicity and excludes complex floor or advanced yoga poses. The yoga sessions will be conveniently delivered to the participants' homes via videoconference technology.
It is important for the IRB to note that all patients who will be enrolled in this study have been medically released by their cardiologist for exercise at home or in the community, alone with no monitors, at a far higher level and intensity than that proposed in this yoga study. Once released from phase II cardiac rehab (which is facility-based, supervised exercise), patients are asked to continue exercising at home without supervision and the typical instruction is to engage in moderate to high intensity (vigorous) exercise for 30 minutes or more, most days of the week. This exercise included running, walking, cycling, climbing hills, swimming, playing tennis (and similar games), all of which are at a higher intensity than the yoga that will be used in our study.
Moreover, patients with heart failure are typically as older or older than those who will be enrolled in the proposed study, and they are far more frail, yet, unsupervised exercise is recommended for them, and multiple home-based, unsupervised, telehealth yoga studies have been approved and conducted in heart failure patients and have been found to be safe (Gomes-Neto M, Rodrigues ES Jr, Silva WM Jr, Carvalho VO. Effects of Yoga in Patients with Chronic Heart Failure: A Meta-Analysis. Arq Bras Cardiol. 2014 Nov;103(5):433-439. doi: 10.5935/abc.20140149. Epub 2014 Oct 10. PMID: 25317861; PMCID: PMC4262105; Selman L, McDermott K, Donesky D,

Citron T, Howie-Esquivel J. Appropriateness and acceptability of a Tele-Yoga intervention for people with heart failure and chronic obstructive pulmonary disease: qualitative findings from a controlled pilot study. BMC Complement Altern Med. 2015 Feb 7;15:21. doi: 10.1186/s12906-015-0540-8. PMID: 25887324; PMCID: PMC4324792; Cramer H, Lauche R, Haller H, Dobos G, Michalsen A. A systematic review of yoga for heart disease. Eur J Prev Cardiol. 2015 Mar;22(3):284-95. doi: 10.1177/2047487314523132. Epub 2014 Feb 3. PMID: 24491402; Platz K, Kools S, Howie-Esquivel J. Benefits, Facilitators, and Barriers of Alternative Models of Cardiac Rehabilitation: A QUALITATIVE SYSTEMATIC REVIEW. J Cardiopulm Rehabil Prev. 2023 Mar 1;43(2):83-92. doi: 10.1097/HCR.0000000000000738. Epub 2022 Oct 10. PMID: 36346781.)
In 2023, an investigative group who studies yoga in patients with heart failure, published a paper describing the study (IRB approved) they are conducting currently in patients with heart failure, at home using telehealth as are we (Howie-Esquivel J, Metzger M, Malin SK, Mazimba S, Platz K, Toledo G, Park L. Getting Into Light Exercise (GENTLE-HF) for Patients With Heart Failure: the Design and Methodology of a Live-Video Group Exercise Study. J Card Fail. 2023 Aug;29(8):1175-1183. doi: 10.1016/j.cardfail.2023.03.004. Epub 2023 Mar 21. PMID: 36948269.). Again, it should be noted that the intervention is very similar to ours and the patient population is more frail and as old.

We have implemented a comprehensive set of safety measures in our proposed study to ensure the well-being of participants throughout their yoga sessions:
1. Participant exclusion criteria: To prioritize safety, participants who have medical conditions or limitations that could hinder their ability to perform yoga movements are excluded from the study. Additionally, we included specific exclusion criteria in the proposed study to ensure participants' safety. Patients who have experienced unstable angina, undergone coronary bypass graft within the last 3 months, or suffered an acute myocardial infarction within the past 3 months are not eligible to participate. Similarly, those who have received a biventricular pacemaker less than six weeks prior, have orthopedic limitations impacting stretching, or chronic obstructive pulmonary disease with a forced expiratory volume of less than 1 liter, severe stenotic valvular disease, or have a history of resuscitated sudden cardiac death without receiving an implantable cardioverter defibrillator are also excluded. These stringent exclusion criteria ensure that only those patients least likely to experience any injuries or cardiac events during exercise will be included. To complement these safety measures, we have provided a recent publication that detailed a light exercise with a gentle stretching program based on yoga, delivered through the live-video group (same as a videoconferencing approach in our proposed study) for patients with heart failure. This publication supports the safety of our approach (Howie-Esquivel J, Metzger M, Malin SK, Mazimba S, Platz K, Toledo G, Park L. Getting Into Light Exercise (GENTLE-HF) for Patients With Heart Failure: the Design and Methodology of a Live-Video Group Exercise Study. J Card Fail. 2023 Aug;29(8):1175-1183. doi: 10.1016/j.cardfail.2023.03.004. Epub 2023 Mar 21. PMID: 36948269.)..
2. Furthermore, it is worth noting that standard facility-based cardiac rehabilitation is typically prescribed for 12 weeks for cardiac patients with acute cardiac events. Because the proposed study exclusively involves patients who have successfully completed the standard facility-based cardiac rehabilitation, the chosen timeframe ensures that participants have received the necessary care and support during their early rehabilitation period. This indicates that they are prepared for a home-based cardiac rehabilitation program as part of their recovery journey, without medical supervision.
3. Pre-session Safety Video: Before attending the yoga sessions, participants are required to watch a brief safety video. This video provides an overview of the yoga sessions and imparts crucial safety instructions. It emphasizes the importance of selecting a steady chair (not a rolling one), clearing the area around the chair, and wearing lightweight, comfortable attire. Participants are also advised to recognize their own physical limits to prevent overexertion and injuries.
4. Health assessment by trained yoga instructors: The yoga instructors who will deliver yoga sessions are highly trained to conduct thorough safety assessments of participants before each session. This assessment includes evaluating the participant's overall health status, presence of symptoms, including cardiac symptoms. If, for any reason, a participant does not feel ready to engage in the yoga session, our instructor will have them refrain from participation and seek medical guidance as needed.
5. Guidance during the session: Throughout the yoga session, our yoga instructors provide continuous guidance to participants regarding their physical limits. Participants are reminded not to exceed their capabilities to avoid any potential injuries. Modifications for poses are readily offered to accommodate a variety of fitness levels and limitations, ensuring that everyone can participate safely and comfortably.
6. Providing supportive props: To aid in maintaining proper alignment and support, we supply participants with props such as yoga blocks and straps. Those props are especially beneficial for beginners and those with limited flexibility, helping them achieve poses safely.
7. Hydration emphasis: We also encourage participants to stay adequately hydrated before, during, and after the session to prevent dehydration.

Attachments

Attach Type	File Name
Advertising	Geunyeong_flyer-STAMPED.pdf

Research Procedures

Describe how the research will be conducted.

- What experience will study participants have?
- What will study participants be expected to do?
- How long will the study last?
- Outline the schedule and timing of study procedures.
- Provide visit-by-visit listing of all procedures that will take place.
- Identify all procedures that will be carried out with each group of participants.
- Describe deception and debrief procedures if deception is involved.

Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project. List medications that are explicitly forbidden or permitted during study participation.

Approval of the Institutional Review Board for the study will be obtained from the University of Kentucky Office of Research Integrity. We will then screen eligible patients using electronic medical records and recruit them at the CR centers of the University of Kentucky Healthcare located in Lexington, Kentucky. We will obtain consent, explaining all aspects of the study, so that patients can provide informed consent either on-site or via remote consenting using Zoom or over the phone Eligible participants who signed the consent form will be invited for baseline assessment at our research facility. In our research procedure, we recommend study partners primarily for safety reasons. However, having a study partner is optional. When collecting consent forms from patients, we will also request that their study partners sign a separate consent form, indicating their commitment to observing the patients as they participate in yoga sessions for the duration of the study. We advise having study partners present to ensure immediate assistance in case any medical issue arises during the yoga practice.

At the baseline assessment, participants will be asked to complete survey questionnaires and physical examinations (i.e., balance function, muscle strength, and short-term heart rate variability. The survey includes questions on psychological distress (i.e., depressive symptoms and anxiety) as well as well-being (social support and self-care), and physical symptoms (vulnerability and sleep quality). Participants will be asked to wear an ActiGraph watch for nine days with verbal and written instructions to assess their level of physical activity and sleep quality. All participants will complete all survey questionnaires at baseline assessment using the REDcap platform. Clinical information (e.g., comorbidity, NYHA class, prescribed medications, cognitive functions) will be collected by reviewing medical records by the trained research staff and a questionnaire. If participants agree to participate in optional blood samples, we will proceed with collecting the inflammatory cytokines and stress markers (i.e., IL-6, C-reactive protein, and brain-derived neurotrophic factor) by the blood draw.

Participants will be randomly assigned to either the intervention or control group. The intervention group will be asked to participate twice a week for a 12-week yoga program. Each yoga session is set to last between 40 to 50 minutes and will be conducted via Zoom. We ask study partners to observe patients practicing yoga if the patients are in the yoga group. They don't necessarily need to live with them.
The control group will receive only AHA ‘Life’s Essential 8’ materials without yoga sessions.

For 3-month follow-up, the data collection procedures will be the same as those at the baseline assessment.
Only participants in the intervention group will be asked to complete an additional survey about the satisfaction and acceptability of the intervention. All participants from both groups will be asked to assess their physical functions (i.e., balance function, muscle strengths, short-term heart rate variability), wear the ActiGraph for 9 days again to assess the level of physical activity and sleep quality, and complete follow-up surveys. Each participant will receive a yoga mat one time and a $70 gift card for each data collection period (baseline and the 3-month).

Study partners are also asked to complete several surveys. However, they are not required to visit our research office for the baseline or 3-month assessments, regardless of the group assignment of primary study participants. They can complete the surveys from their homes. If a participant is assigned to the yoga group, we expect their study partner to be seated next to them during the yoga sessions, observing their practice for the entire 12-week duration. For participants in the non-yoga group, there will be no tasks or activities designated for their study partners.

In this study, no deception was involved. Participants will be fully informed of the nature and purpose of the study, which involves a 3-month yoga intervention. They will be made aware of what this intervention includes, what is expected of them, the types of data that will be collected, and how their data will be used. All questions and concerns from participants will be addressed transparently.

Attachments

Data Collection & Research Materials

In this section, please provide the following:

- Describe all sources or methods for obtaining research materials about or from living individuals (such as specimens, records, surveys, interviews, participant observation, etc.), and explain why this information is needed to conduct the study.
- For each source or method described, please list or attach all data to be collected (such as genetic information, interview scripts, survey tools, data collection forms for existing data, etc.).
- If you will conduct a record or chart review, list the beginning and end dates of the records you will view.

We will collect data on physical health (i.e., physical activity intensity, balance function, muscle strength, sleep quality, short-term heart rate variability, vulnerability), and stress as well as inflammatory indicators and psychological health (i.e., depressive symptoms, anxiety, social support, and self-care). All participants, regardless of the randomization, will complete data collection two times at the baseline and 3-month follow-up time.

Physical activity and sleep quality will be measured using the ActiGraph (GT3X Link model), which is the most widely used wearable accelerometer in clinical research. The ActiGraph has been validated to measure the activity level of cardiovascular patients. All participants will be instructed to wear the device for nine days.
Balance function will be measured by using the Inertial Measurement Unit device (IMU; Xsens Technologies, Enschede., the Netherlands). After we attach the IMU sensor to the participant's lower back, participants will be asked to take off their shoes and stand up on the mat with their hands on their hips for 30 seconds. We will measure the balance function 3 times, with 30 seconds of rest between assessments. The total estimated time for the balance function test is 3-5 minutes.
Muscle strength will be measured using the Handheld dynamometry (Lafayette dynamometer, model01165APP; Lafayette Instrument Company, Lafayette, Ind., USA). This device measures the peak force in kilograms for five seconds during muscle contraction on the upper and low extremities and upper arms. We will measure muscle strength three times, with 2 minutes of rest between assessments. It will take a total of 8-10 minutes.
Short-term heart rate variability will be measured by using the Polar H9 heart-rate monitor (Polar Electro OY, Kempele, Finland). Study subjects will be instructed to lay supine for 10 minutes without speaking and to remain still, as much as possible. We will place the Polar H9 heart-rate monitor on the center of the sternum to measure HRV. During HRV data collection, the study subject will also wear the ActiGraph on the waist because the Polar H9 communicates with the actigraph. The HRV data will be transmitted automatically from the HRV monitor to the ActiGraph.
The inflammatory cytokines and stress markers (i.e., IL-6, C-reactive protein, and brain-derived neurotrophic factor) will be collected by obtaining blood samples (6 cc). The trained staff will draw the blood sample at the research facility and the Assay will be run by the UK Clinical Research Center lab using ELISA kits.

Surveys: All participants (patients) will complete the survey questionnaires. It includes depressive symptoms, anxiety, social support, vulnerability, sleep information, self-care, and structured demographics questionnaires. it will take a total of 30-40 minutes to complete the questionnaires.
Depressive symptoms. Depressive symptoms will be measured using the Patient Health Questionnaire-9 (PHQ-9) developed to correspond to symptoms used in the DSMV to diagnose depression. Nine symptoms are rated on a 4-point Likert scale (0 = 'Not at all; 3 = 'Nearly every day'), with possible total scores ranging from 0 to 27 and higher scores indicating higher levels of depressive symptoms.
Anxiety. Anxiety will be measured using the Beck Anxiety Inventory (BAI), which consists of three subscales with 21 items: one to assess physical or physiological symptoms (13 items), one to assess cognitive aspects of anxiety (5 items), and one to assess physical and cognitive connotation (3 items). The responses for the BAI are rated on a 4-point Likert scale (0 = 'Not at all'; 3 = 'Severely, I could barely stand it').
Vulnerability. Vulnerability will be measured using the Vulnerable Elders Survey-13 (VES-13), which is a simple and reliable instrument for the identification and tracking of vulnerable older adults aged 65 years and over. Consisting of 13 items, the VES-13 evaluates age, self-rated health, and functional impairments. It has been proven to predict the risk of mortality and functional decline. The higher the score on the VES-13, the greater the individual's vulnerability and risk of health deterioration.
Social support. Social Support will be measured by the Multidimensional Scale of Perceived Social Support (MSPSS) to examine perceptions of three different sources such as family, friends, and a significant other. The MSPSS encompasses 12 items with three subscales on a 7-point Likert Scale (1 = "Very strongly disagree"; 7 = "Very strongly agree"). Each subscale score has the potential to range from 4 to 28, with higher scores indicating a higher level of perceived social support.
Self-care. Self-care in patients with coronary heart disease will be assessed using the Self-care of Coronary Heart Disease Inventory (SC-CHDI V3). This instrument is specifically designed to evaluate the self-management behaviors and practices of individuals diagnosed with coronary heart disease. The SC-CHDI V3 comprises a series of items spread across multiple subscales, each focusing on a specific domain of self-care, such as symptom recognition, treatment adherence, and lifestyle adjustments. Items are rated on a Likert scale, ranging from 1 (indicating "Rarely or never") to 7 (indicating "Always or consistently"). The total score can vary within a specified range, with higher scores reflecting better self-care practices and behaviors.

Demographic information: We will collect sociodemographic information (i.e., age, gender, ethnicity, marital status, education level, insurance type, and smoking status) using a standardized questionnaire at the baseline assessment.
Clinical data: The trained research staff will collect clinical information on body weight, height, sleep quality, comorbidity, medical history, New York Heart Association (NYHA) classification (if a participant is diagnosed with heart failure), current medications, cognitive function, and any hospitalization. Body weight, Height, Medical history, current medications, and past hospitalization will be collected by electronic medical record review.

The study feasibility assessment:
The study feasibility will be assessed by the recruitment and intervention adherence rates. The recruitment rate (%) will be calculated by dividing the total number of subjects enrolled by approached eligible participants and then multiplying it by 100. The intervention adherence rate will be calculated by dividing the total number of sessions attended by the total number of intervention sessions (i.e., 24) and multiplying that number by 100. The yoga instructor will record the attendance of participants at each session using logs.
The study acceptability and participant satisfaction assessment:
We will use modified versions of the Treatment Acceptability Adherence Scale (TAAS) and The Client Satisfaction Questionnaire (CSQ) to assess the acceptability of the yoga intervention at 3 months follow-up. The TAAS is a 10-item self-report questionnaire designed to evaluate treatment acceptability and adherence. Items are rated on a 7-point Likert-type scale (1 = disagree strongly; 7 = agree strongly). The total score is a sum of seven items, ranging from 10 to 49. The CSQ is an 8-item self-report questionnaire to evaluate participant satisfaction with a specific intervention. Items are rated on a 4-point Likert-type scale (1 = very satisfied; 4= quite

dissatisfied). For both instruments, higher scores indicate higher levels of acceptability of treatment and greater satisfaction.

Surveys: All participants (study partners) will complete the survey questionnaires. It includes depressive symptoms, anxiety, social support, caregiver burden, and structured demographics questionnaires. it will take a total of 20 -30 minutes to complete the questionnaires.
Depressive symptoms. For study partners, depressive symptoms will be measured using the Patient Health Questionnaire-9 (PHQ-9) developed to correspond to symptoms used in the DSMV to diagnose depression. Nine symptoms are rated on a 4-point Likert scale (0 = 'Not at all; 3 = 'Nearly every day'), with possible total scores ranging from 0 to 27 and higher scores indicating higher levels of depressive symptoms.
Anxiety. For study partners, anxiety will be measured using the Beck Anxiety Inventory (BAI), which consists of three subscales with 21 items: one to assess physical or physiological symptoms (13 items), one to assess cognitive aspects of anxiety (5 items), and one to assess physical and cognitive connotation (3 items). The responses for the BAI are rated on a 4-point Likert scale (0 = 'Not at all'; 3 = 'Severely, I could barely stand it').
Social support. For study partners, Social Support will be measured by the Multidimensional Scale of Perceived Social Support (MSPSS) to examine perceptions of three different sources such as family, friends, and a significant other. The MSPSS encompasses 12 items with three subscales on a 7-point Likert Scale (1 = "Very strongly disagree"; 7 = "Very strongly agree"). Each subscale score has the potential to range from 4 to 28, with higher scores indicating a higher level of perceived social support.
Caregiver burden. For study partners, the caregiver burden will be measured by using the short version of the Zarit caregiver Burden Interview (ZBI). The ZBI has 12-items and each item is rated on a 5-point Likert scale from 0 (never) to 4 (always), a higher scores indicating higher caregiver burden. The ZBI is one of the most commonly used measures of caregiving burden, has good reliability, validity, been used widely in cardiovascular diseases, and is correlated with caregiver depressive symptoms in caregivers of patients with cardiovascular diseases.
Quality of life: Quality of life will be measured by using The European Quality of Life-5 Dimensions (EQ-5D) across five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three levels: no problems, some problems, or extreme problems. Choices form a health profile which is converted to an index score using a specific value set. Additionally, an overall health rating is provided on a scale from 0 (worst health) to 100 (best health) via a visual analog scale (EQ VAS).

Attachments

Attach Type	File Name
DataCollection	Table of additional measures of modification_10-23-2023.pdf
DataCollection	additional measures_10-23-2023.pdf

Resources

Describe the availability of the resources and adequacy of the facilities that you will use to perform the research. Such resources may include:

- Staffing and personnel, in terms of availability, number, expertise, and experience;
- Computer or other technological resources, mobile or otherwise, required or created during the conduct of the research;
- Psychological, social, or medical services, including equipment needed to protect subjects, medical monitoring, ancillary care, or counseling or social support services that may be required because of research participation;
- Resources for communication with subjects, such as language translation/interpretation services.

University of Kentucky (UK) College of Nursing
The UK College of Nursing (CON) offers accredited programs leading to the Bachelor of Science in Nursing, Doctor of Philosophy (PhD) in Nursing and Doctor of Nursing Practice programs. The PhD program in Nursing is overseen by the UK Graduate School. The CON is currently ranked 14th nationally in NIH funding among public universities. In 2020, the UK College of Nursing was designated a Center of Excellence by the National League for Nursing. Information and Video conference Technology Support: Information and video conference technology support (i.e., ZOOM) is provided by the UK College of Nursing Information Technology (CONIT) Department and the office of Instructional Design. The HIPAA-compliant version of ZOOM will be used for intervention delivery and meetings of research staff in this proposed study.
Research and Intervention for Cardiovascular Health (RICH) Heart Program
The Research and Intervention for Cardiovascular Health (RICH) Heart Program in the College of Nursing will be utilized to ensure the success of the current project. The RICH Heart Program is nationally and internationally recognized for excellence in self-care research in cardiovascular health. The environment and resources provide ample support, space, equipment, clinical facilities, measurement expertise, clinical trial management, intervention development, database and statistical support, and a ready population of clinically well-characterized adults with cardiovascular disease or at risk of cardiovascular disease development to promptly and efficiently meet target recruitment and retention goals. Led by Dr.Moser (PhD Program director and a dissertation committee member of the PI), the RICH Heart program currently is conducting one PCORI, three NIH-funded R01s, and several other extramurally funded studies focusing on reducing cardiovascular risk factors in rural patients and in Hispanics, promoting cardiopulmonary health promotion, prevention of disease progression and well-being in chronically ill cardiac and pulmonary patients, and also focuses on assisting caregivers of chronically ill patients to better support those for whom they care, and to improve their own physical and mental well-being. The offices of the RICH Heart program faculty, including Ms. Geunyeong Cha (PI, Applicant) and Dr. Moser (Advisor), in this proposed study. The RICH Heart Program has a 5,704 sq. ft space with (1) state-of-the-art computer equipment; (2) a lab for drawing and processing blood and urine for analysis, and multiple point-of-care testing equipment for measurement of a full lipid profile, HgA1c, CRP, BNP, 24-hour urine sodium, inflammatory cytokines; (3) a dedicated computer for Nutrition Data System for Research (NDSR) and two dedicated computers for VioScreen Food FrequencyQuestionnaires to collect diet quality and pattern; (4) data collection packet including more than 50 survey instruments to measures (e.g., self-care, knowledge, quality of life), and objective measures of medication adherence and physical activity. ActiGraph watches, wearable fitness devices, are an emerging technology that allows users to track their daily activity, including steps taken and calories burned. The use of this activity monitor allows

quantification of activity and thus provides an objective indicator of functional status. ActiGraph watch is well-documented reliability and validity and a high degree of subject acceptability. We have more than 150 ActiGraph watches, and platform for downloading that data. The RICH Heart Program will provide the ActiGraph watches to collect physical activity in this study.; (5) The RICH Heart Program has substantial experience delivering interventions to rural and urban participants for last 15 years. Currently, Dr. Moser (Advisor) has 20 iPads to rent to deliver interventions for participants who don't have the devices. The PI will utilize those iPads for the proposed study; (6) three intervention rooms for delivering psychoeducational intervention and counseling; (7) two assessment rooms for data collection; and (8) four conference rooms for video-conference research meetings. Each conference room is equipped with a 65-inches screen monitor and a business conference cam that has advanced technologies of beamforming mic array, 4K ultra HD camera with 5X HD zoom, and full-range speaker system.; (8) The yoga instructor who is part of the study team but not a UK employee is Brynn Angelatti. She has collaborated with our team in the past and has over three years of experience guiding yoga sessions with various populations.

Potential Risks & Benefits

Risks

- Describe any potential risks – including physical, psychological, social, legal, ability to re-identify subjects, or other risks. Assess the seriousness and likelihood of each risk.
- Which risks may affect a subject's willingness to participate in the study?
- Describe likely adverse effects of drugs, biologics, devices or procedures participants may encounter while in the study.
- *Qualitative research* - describe ethical issues that could arise while conducting research in the field and strategies you may use to handle those situations.
- Describe any steps to mitigate these risks.

Benefits

- Describe potential direct benefits to study participants – including diagnostic or therapeutic, physical, psychological or emotional, learning benefits. This cannot include incentives or payments.
- State if there are no direct benefits.
- Describe potential benefits to society and/or general knowledge to be gained.

Describe why potential benefits are reasonable in relation to potential risks. If applicable, justify why risks to vulnerable subjects are reasonable to potential benefits.

There are no known risks associated with filling out these questionnaires and blood sampling. However, you may feel stressed or bothered by the demands placed upon you by answering some of the questions on the study questionnaires. In our experience with more than 5000 participants, this occurs less than 3% of the time and is short-lived. You do not have to answer questions if they cause you undue discomfort. Discussion of psychological health may be upsetting to you. It is possible that you may feel some temporary anxiety while filling out questionnaires, which is experienced less than 1% of the time. Blood sampling may cause minimal bruise or pain, but it is a minimal and common risk related to blood sampling. Should you show signs of distress outside the scope of practice for the person providing education, our staff psychiatric nurse practitioner will be contacted to determine the further need for assessment and or treatment for you based on her scope of practice.
Your privacy and confidentiality will be protected to the fullest extent allowable by law. All recordings, transcripts of recordings, and questionnaire data will be maintained on a password protected server behind the University of Kentucky firewall.
Risks associated with the balance and muscle strength tasks may include fatigue, muscle soreness, falling, or skin irritation from the device sensor. The study investigator will prepare proper skin preparation before test and monitor you closely during the test and provide regular breaks between tests.
Like any exercise, yoga practice may stretch your muscles in general which may cause minimal muscle soreness or fatigue. Injury is rare or minimal because the yoga program has been tested in patients with cardiac problems. The certified yoga instructors and the investigator will monitor and instruct yoga

Available Alternative Opportunities/Treatments

Describe alternative treatments or opportunities that might be available to those who choose not to participate in the study, and which offer the subject equal or greater advantages. If applicable, this should include a discussion of the current standard of care treatment(s).

This study offers participants random assignments into the intervention group usual care group. The only other alternative would be not to participate.

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Records, Privacy, and Confidentiality

Specify where the data and/or specimens will be stored and how the researcher will ensure the privacy and confidentiality of both. Specify who will have access to the data/specimens and why they need access.

Describe how data will be managed after the study is complete:

- If data/specimens will be maintained, specify whether identifiers will be removed from the maintained information/material.

- If identifiers will not be removed, provide justification for retaining them and describe how you will protect confidentiality.
- If the data/specimens will be destroyed, verify that this will not violate retention policies and will adhere to applicable facility requirements.

If this study will use de-identified data from another source, 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 collaborators not affiliated with UK.

For additional considerations:
Return of Research Results or Incidental Research Findings
HIPAA policies
FERPA policies
Procedures for Transfer agreements
Information regarding multi-site studies
NIH Genomic Data Sharing (GDS) Policy
Digital Data

Sources of research material will include both oral and written or digital self-reports from participants (via interviews and questionnaires), the balance and muscle strength from devices (i.e., IMU, Handheld dynamometry), data from the actigraph which measures physical activity levels and the blood specimens. Research data will be obtained at baseline and 3 months after baseline. Research material obtained from participants in this study are used only for research purposes.
We protect patient privacy and confidentiality vigilantly. All physical data are kept in locked file cabinets in a building only accessible by key codes. All virtual data are kept on a UK encrypted server. All computers are accessible only by private passwords. Risks to participants will be minimized by providing clear and complete information regarding the purpose, procedure, risks, and benefits of the study. To minimize potential risk to confidentiality, the following steps will be taken. All participant's data, questionnaires, and yoga session notes will be coded with anonymous identifiers. Master files, which include patient identifiers, will be kept in a locked file cabinet in each research office, with access limited to the PI and project director and appropriate staff. The risk of breach of confidentiality of participants' data will be minimized by ensuring all involved personnel have a full understanding of the Health Insurance Portability and Accountability Act (HIPAA) rules and the protection of privacy guidelines for conducting such reviews through the completion of all IRB-mandated HIPAA training and education, CITI training and Responsible Conduct of Research training. Data-gathering instruments and procedures will be carefully designed to limit access to personal information. We use REDCap to collect data. Password-protected iPads or computers dedicated for this study only will be used to enter data. Each participant will be assigned a unique identification number and all of their records will be marked only with this number. All hard copies of data will be kept in a locked file in the project director's office, separate from the files containing the identification key. To minimize potential risk to confidentiality, the following steps will be taken. All patient data, questionnaires, and therapy notes will be coded with anonymous identifiers. Master files, which include patient identifiers, will be kept in a locked file cabinet in each research office, with access limited to the PI and the advisor. The risk of breach of confidentiality of participants' data will be minimized by ensuring all involved personnel have a full understanding of the Health Insurance Portability and Accountability Act (HIPAA) rules and the protection of privacy guidelines for conducting such reviews through the completion of all IRB-mandated HIPAA training and education. Data-gathering instruments and procedures will be carefully designed to limit access to personal information.
Password protected
iPads or computers dedicated for this study only will be used to enter data. Each participant will be assigned a unique identification number and all of their records will be marked only with this number. All hard copies of data will be kept in a locked file in the project director's office, separate from the files containing the identification key. We will be collect data through audio and video recording of yoga practices, as well as any subsequent discussions related to the intervention. We will use two separate digital recording systems to ensure data capture. We will maintain digital recordings and transcribed materials on a secure server behind the UK firewall. Questionnaire data will be collected via an online link to the REDCap data portal, A HIPAA compliant data repository. Audio-visual data from recordings, including voice and face of participants will not be maintained or stored indefinitely. These electronic files will be destroyed five years after the completion of data analysis. University of Kentucky IT personnel will assist with the complete removal of these files from UK digital storage platforms. Other data and records will be retained for a minimum of 6 years after study closure. Identifiable data will be maintained in a separate file from the data behind the UK firewall on UK data storage and in the UK OnCore management system. Those participants who are not in UK's medical records database will be added as a healthy participant and then included in OnCore. Data will be deleted according to UK policy(s) A13-050 and A05-055.All identifiable information (e.g. name, medical record number, or date of birth) will be removed from the information collected in this study. After all identifiers have been removed, the information collected from the questionnaires and from the audio/video recording transcripts may be used for future research.
To maintain high levels of safety, participants with high risk of cardiovascular diseases or compromised exercise capacity will be asked to provide a release to participate signed by their healthcare provider.
All participants are told that they will be in group sessions that will include other patients. They are told that all participants need to have their videos on and that their names will be displayed if they have written in their name as part of the Zoom set-up. All participants will be visible via Zoom while participating in the yoga practices. They will be told that all conversations are heard by all attendees. They are told that if they have concerns about their confidentiality under these circumstances that they should not participate. Participants are also told that any information revealed in sessions by them or by others is considered private and is not for sharing by them or others.

UK IRB policies state that IRB-related research records must be retained for a minimum of 6 years after study closure. Do you confirm that you will retain all IRB-related records for a minimum of 6 years after study closure?

(•) Yes ( ) No

Payment

Describe the incentives (monetary or other) being offered to subjects for their participation. If monetary compensation is offered, indicate the amount and describe the terms and schedule of payment. Please review this guidance for more information on payments to subjects, including restrictions and expectations.

All patient participants will receive a yoga mat. For each data collection point completed, patient participants will be compensated $70. If they complete two data collection points, the total compensation will be $140. If patient participants agree to participate in the optional blood samples, they will be compensated $25 each.This means that if participants complete data collection for both the original study procedures and the optional blood samples, they will be compensated $95. Completing both time points will result in a total compensation of $190. Additionally, study partners of these patient participants, even without attending, will be compensated $25 for each data collection point their associated patient completes. If patient participants complete two data collection points, their study partners will also receive a total compensation of $50.

Costs to Subjects

Include a list of services and/or tests that will not be paid for by the sponsor and/or the study (e.g., MRI, HIV). Keep in mind that a subject will not know what is "standard" – and thus not covered by the sponsor/study – unless you tell them.

There are no costs to participants in this research. We will lend participants with a digital device (i.e., an iPad) if they are in the yoga session and they need to return the device when the study is over. We will pay the cost of yoga sessions for the study. We will pay the cost of blood sample analysis for the 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, 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, 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.

The proposed pilot study is a clinical trial in which participants are randomized into either Yoga intervention or usual care control groups, and thus requires a data safety and monitoring plan.

a. Periodic Review: We will have weekly staff meetings for the first month of enrollment then bi-weekly thereafter. The staff meeting will include the primary investigator, the advisor, and yoga instructors, The meeting will include an evaluation of all research procedures, fidelity to protocol, discussion of newly enrolled participants, and a status review of all formally enrolled participants, including the occurrence of any adverse events. The PI and advisor will supervise the interventionists (yoga instructors) through regular monthly meetings and random visits to observe the intervention sessions. Adverse events will be immediately reported to the IRB and will be reviewed to determine if changes in the protocol are indicated. Participant demographics to date, recruitment progress, issues 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.

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.

a) Risk Assessment: Minimal risk. This study represents a minimal risk to study participants, as it involves a yoga intervention characterized by low to mild-moderate intensity physical postures. These are designed to prevent physical deconditioning and decrease psychological distress following a facility-based cardiac rehabilitation program.

b) Description of Adverse Event Grading and Anticipated Adverse Events
An adverse event (AE) is defined as any unfavorable and unintended sign, symptom or disease temporarily associated with the use of a medical treatment or procedure, regardless of whether it is considered related to medical treatment or procedure that occurs during the course of the study. Each AE will be scored as follows:
0 =No adverse event or within normal limits
1 =Mild AE – did not require treatment
2 =Moderate AE – resolved with treatment
3 =Severe AE – resulted in inability to carry on normal activities and required professional medical attention, requires or prolongs hospitalization
4 =Life-threatening or disabling AE - results in immediate risk of death and/or results in persistent or significant disability
5= Fatal AE

In this study, we do not anticipate moderate, severe, life-threatening, or fatal AEs.

c. Safety Protocol: A registered nurse trained to monitor for adverse cardiac (or other) symptoms or events will be on every Zoom call with the patients for the entire time that they are on Zoom to monitor the condition of all participants. All participants are always individually visible on Zoom during the entire session.

Before every session, the nurse and the yoga instructor (who may also be a nurse, but who otherwise is trained in basic emergency responses) will ask the participants how they have been feeling and if they have had any cardiac symptoms (e.g., chest pain or discomfort, shortness of breath, fatigue) in the past 24 hours. If they have had symptoms, the nurse will further question the patient to determine if the symptoms are usual or unusual, if they resolved, and what measures were taken to resolve them. If they were unusual or did not resolve, the nurse will have the patient refrain from yoga that day and will ask the patient to call their doctor about the symptoms. If they were symptom-free, or the symptoms were usual and resolved quickly, they will be allowed to do yoga.

During the yoga sessions, both the yoga instructor and the nurse monitor participants for symptoms and will stop the yoga session to question any participant who appears to be having symptoms or who says they are having symptoms. If symptoms resolve quickly, the patient will be asked not to perform further yoga and to ask their physician if they can continue in the yoga program. If medical intervention is needed, the nurse will call EMS to go to the participant's home.

We will also invite one person living with the patient (e.g., spouse, friend, adult child, other relative) if there is one, to join the study by sitting with the patient while they do yoga to help ensure their safety.

d. Plan for Safety Review: A methodical review of all procedures will be an integral part of each research team meeting. This review will include a discussion of the protocol to ensure adherence, a discussion of procedures to ensure confidentiality is maintained and that data are collected with minimal risk for violations of confidentiality. A meeting involving the multi-PIs, co-investigators, and research staffs will be called if an adverse event occurs to determine whether modifications to the protocol are needed.

e. Plan 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. Interim analyses will be performed every 6 months, and a data review meeting with the multi-PIs, Co-Is and project staff will follow.

f. Reporting Mechanisms: Reporting for this study will include an annual report to the IRB and regulatory and sponsoring agencies at a minimum, with appropriate updates and reports in the event of an adverse event(s).
The video recordings of the yoga sessions will be securely stored in a cloud system that is compliant with data protection regulations. The recordings will be encrypted and password-protected to ensure confidentiality. Only the research team will have access to the recordings, and they will be used solely for observation purposes. All recordings will be permanently deleted once the study is concluded, ensuring the privacy and anonymity of the participants.

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Future Use and Sharing of Material (e.g., Data/Specimens/Information)

If the material collected for this study will be used by members of the research team or shared with other researchers for future studies, please address the following:

- list the biological specimens and/or information that will be kept
- briefly describe the types, categories and/or purposes of the future research
- describe any risks of the additional use
- describe privacy/confidentiality protections that will be put into place
- describe the period of time specimens/information may be used
- describe procedures for sharing specimens/information with secondary researchers
- describe the process for, and limitations to, withdrawal of specimens/data

De-identified questionnaire data and biological data results including balance and muscle strength will be stored for potential future study use. no biological specimens will be stored for future study. No link or code to the identities of subjects will be kept by the study team. The data may be combined with data from heart failure patients to examine questions about physical and emotional responses to interventions, cognitive function, and psychological status. There are no risks for additional usage because the data will be completely de-identified. Privacy and confidentiality are protected because the data are completely de-identified. In addition, these data are stored only on encrypted password-protected computers in a locked research building. We will keep this information indefinitely. We may share these data with faculties and students on the RICH Heart team. They are shared by agreement of all PIs upon request by a faculty member or student. We may share data with researchers outside of the University of Kentucky upon their request and agreement by all of the RICH Heart faculties. We ask that all data we share be stored only on encrypted password-protected computers in locked research spaces. We do not store specimens, only data. We have no specimen to withdrawn and data are shared not withdrawn.

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 who is willing 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 agrees to be the cultural consultant for your study.
- ORI staff will facilitate the review process with your consultant. Please do not ask them to review your protocol separately.

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 the International Compilation of Human Research Standards

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

○ 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:

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

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	ori-f10700-form-k-hipaa-waiver-authorization-pdf_05252023.pdf
Waiver	86669_Waiver_917064_updated_08162023.pdf

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.

Complete and attach the required Study Drug Form picking "Study Drug Form" for the document type. Any

applicable drug documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.) should be attached using "Other Drug Documentation" for the document type.

Attachments

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.

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) being tested 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 being tested 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, picking the "Study Device Form" for the document type. Any applicable device documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.) should be attached using "Other Device Documentation" for the document type.

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 (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:

Describe the role of any non-UK site(s) or non-UK personnel who will be participating in your research.

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, describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites:

C) If your research involves collaboration with any sites and/or personnel outside the University of Kentucky, then it is considered multisite research and IRB reliance issues will need to be addressed. This may include national multi-center trials as well local studies involving sites/personnel external to UK. If you would like to request that the University of Kentucky IRB (UK IRB) serve as the lead IRB for your study, or if you would like the UK IRB to defer review to another IRB, please contact the IRBReliance@uky.edu.

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

	For additional requirements and information:
☑ Academic Degree/Required Research	• Cancer Research (MCC PRMC) • Certificate of Confidentiality (look up "Confidentiality/Privacy...") • CCTS (Center for Clinical and Translational Science)
☐ Alcohol/Drug/Substance Abuse Research	• Clinical Research (look up "What is the definition of....)
☐ Biological Specimen Bank Creation (for sharing)	• Clinical Trial
☐ Cancer Research	• Collection of Biological Specimens for Banking (look up "Specimen/Tissue Collection...")
☐ CCTS-Center for Clinical & Translational Science	• Collection of Biological Specimens (look up "Specimen/Tissue Collection...")
☐ Certificate of Confidentiality	• Community-Based Participatory Research (look up "Community-Engaged...")
☐ Clinical Research	• Data & Safety Monitoring Board (DSMB) *For Medical IRB: Service Request Form for CCTS DSMB
☐ Clinical Trial - Phase 1	• Data & Safety Monitoring Plan
☑ Clinical Trial	• Deception* *For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"
☐ Collection of Biological Specimens for internal banking and use (not sharing)	• Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF)
☐ Community-Based Participatory Research	• Genetic Research (look up "Specimen/Tissue Collection...")
☐ Deception	• Gene Transfer
☐ Educational/Student Records (e.g., GPA, test scores)	• HIV/AIDS Research (look up "Reportable Diseases/Conditions")
☐ Emergency Use (Single Patient)	• Screening for Reportable Diseases [E2.0000] (PDF)
☐ Gene Transfer	• International Research (look up "International & Non-English Speaking")
☐ Genetic Research	• NIH Genomic Data Sharing (GDS) Policy (PDF)
☐ GWAS (Genome-Wide Association Study) or NIH Genomic Data Sharing (GDS)	• 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"
☐ Human Cells, Tissues, and Cellular and Tissue Based Products	• Use, storage and disposal of radioactive material and radiation producing devices
☐ Individual Expanded Access or Compassionate Use	
☐ International Research	
☐ Planned Emergency Research Involving Exception from Informed Consent	
☐ Recombinant DNA	
☐ Registry or data repository creation	
☐ Stem Cell Research	
☐ Suicide Ideation or Behavior Research	
☐ Survey Research	
☐ Transplants	
☐ Use, storage and disposal of radioactive material and radiation producing devices	
☐ Vaccine Trials	

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.

- [x] 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.):

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

The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other DoD resources. (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)

Assurance/Certification Attachments

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

Additional Information

- ☐ 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)

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

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.**

Additional Materials:

If you have other materials you would like to include for the IRB's consideration, check all that apply and attach the corresponding documents using the Attachments button below.

☐ Detailed protocol
☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
☑ Other Documents

Protocol/Other Attachments

Attach Type	File Name
Other	Yoga postures.pdf
Other	my_life_check_brochure.pdf
Other	References.pdf
Other	IRB answer_06202023.docx
Other	IRB answer_GC_08152023 dkm.docx
Other	Yoga IRB Form_reliance agreement document.pdf
Other	IRB answer_09262023.pdf
Other	Brynb_HSP training certification.pdf
Other	IRB answers_09072023.pdf
Other	UKY IRB 86669_IIA_Angeletti.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.

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

SIGNATURES (ASSURANCES)

0 unresolved comment(s)

Introduction

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?"

For a detailed illustration of how to complete this section, please review the short online video tutorial "Signatures (Assurance) Section - How to Complete." Otherwise, follow the steps below.

Required Signatures:

First Name	Last Name	Role	Department	Date Signed	
Thomas	Kelly	Department Authorization	Behavioral Science	04/17/2023 08:42 PM	View/Sign
Misook	Chung	Faculty Advisor	Nursing Instruction	04/17/2023 03:49 PM	View/Sign
geunyeong	cha	Principal Investigator	Nursing Instruction	04/17/2023 03:47 PM	View/Sign

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.

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.

Principal Investigator's Assurance Statement

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.

SUBMISSION INFORMATION

0 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.

Your protocol has been submitted.