Consent Form

NCT03576274

Combined Technology Enhanced Home Exercise Program and Other Non-pharmacological Intervention for Cancer Survivors

10/7/2024

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Effect of Combined Home Exercise and Non-Pharmacological Interventions on Cancer Related Fatigue, Physical Function, and Well-Being

Application No.: IRB00154198

Principal Investigator: Nada Lukkahatai
Johns Hopkins School of Nursing
525 North Wolfe Street, Baltimore, MD 21205
Phone: 410-614-5297

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.
- 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.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This research is being done to look at the effect of a home-based exercise program and the combination of the exercise program with a mindfulness-based intervention and acupressure on fatigue and protein levels in the blood of cancer survivors. This study may help us provide better care for cancer survivors who are suffering from chronic fatigue in the future.

People with solid tumor cancer, who have completed treatment, experiencing fatigue and own a smartphone, may join.

How many people will be in this study?

About 110 people are expected to participate in this study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

If after the screening procedure, you can continue to take part in the study, you will be asked to do the following things:

- Install smartphone applications onto your smartphone and respond to a brief survey (less than 1 min survey daily for the duration of the study (12 weeks)
- Wear a step-tracking device (Fitbit) on the non-dominant wrist 24 hours/day. You will be asked to sync the data with the smartphone application daily and take this device off and recharge the battery when taking a shower for the duration of the study (12 weeks)
- Spend 10-15 minutes to complete a questionnaire package online
- Spend 10-15 minutes listening to the online instruction on how to respond to the mobile application questionnaire and how to use the step tracking device
- Your blood will be drawn (approximately 1 tablespoon [15 mL] for a total of 2 blood draws, before starting the program and at the end of the program [week 12])

- If eligible, you will be asked to participate in Magnetic Resonance Spectroscopy (MRS) study. This MRS will create an image of the body using magnetic and radio waves. Similar to a Magnetic Resonance Imaging (MRI) scan, the MRS will create images of the body using a strong magnet and radio waves. There is no radiation involved in an MRS exam. Most MRS scans take about 60 minutes. You will have an MRS before your first exercise program.
    - You may not take part in this study if you have any metal or device in your body which is not compatible with MRS. Examples include certain pacemakers, defibrillators, aneurysm clips, or other implanted electronic or metallic devices, shrapnel, or other metal. If you have a history of metal in your head or eyes, you cannot take part in this study.
    - The MRS machine periodically makes loud banging noises. We will provide earplugs or headphones for you to wear during the MRS exam.

Group Assignment and Study Intervention:

You will be randomly assigned to one of four groups by using an excel program. This is done by chance because no one knows if one study group is better or worse than the others.

You will schedule and meet with a researcher online or by phone and spend 45-60 min to complete the activities based on your assigned group:

- **Group 1**: will meet with the researcher and discuss the previous week's fatigue, and methods to overcome your fatigue problem online and will receive a weekly summary of physical activity and symptoms on the smartphone application
- **Group 2**: will attend an online exercise-training program and monitor your physical activity, symptoms and heart rate and will receive a summary of physical activity and symptoms and activity recommendation weekly on the application
- **Group 3:** will receive online training and written instruction on the acupressure. You will receive a weekly physical activity and symptoms summary and acupressure points recommendation on the application
- **Group 4:** will attend an online training session on the exercise and monitor your heart rate during the exercise and the acupressure instructions. You will receive a weekly of physical activity and symptoms summary, and activity and acupressure points recommendation on the application
- **Group 5**: will attend an online training session on the exercise and monitor your heart rate during the exercise and listen to a 10-15 min audiotape and video for the mindfulness body scan, mindful breathing and mindful movement. You will receive a weekly of physical activity and symptoms summary and new activity and mindfulness techniques recommendation on the application

MRS study

If you agree to take part in this study and meet eligibility criteria for the MRS study, will you allow us to schedule an MRS?

YES ☐ _____
Signature of Participant

NO ☐ _____
Signature of Participant

Request to future contact or additional procedure

If you agree to take part in this study, the researchers would like to ask for your permission to contact you in the future for follow up studies or additional procedures (blood draws or functional MRI).

Will you allow us to contact you in the future for follow-up studies or additional procedures?

YES ☐ _____
Signature of Participant

NO ☐ _____
Signature of Participant

Request to collect blood samples for protein study

Researchers are trying to learn more about cancer-related fatigue. Much of this research is done using samples from your blood. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure this problem. Some of this study may be about genes. These genes carry information about characteristics that are found in you and your relatives. In future studies, we are interested in looking at the way genes affect how the body responds to exercise and treatment.

Will you allow us to collect your blood sample for the protein study?

YES ☐ _____
Signature of Participant

NO ☐ _____
Signature of Participant

The Genetic Information Nondiscrimination Act (GINA) may help protect you from health insurance or health-related employment discrimination based on genetic information.

The law provides that health insurance companies and group health plans

- may not ask for genetic information from this research and
- may not use genetic information when making decision about eligibility or premiums

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law does not apply to other types of insurance (such as life, disability, or long-term care).

Despite the GINA protections and the best efforts of the research team to protect your information, you may still be at risk if information about you were to become known to people outside of this study.

Request to collect and store biospecimens for future research

As part of this research study, we would like to ask you to let us store your biospecimens and health information for future research. This research could include other diseases.
The research may involve research tools such as gene sequencing or the creation of cell lines.

- Gene sequencing of your DNA provides researchers with the code to your genetic material.

- Cell lines are living tissue samples that can be grown in a laboratory. A cell line can provide an unlimited supply of cells in the future without requiring more samples from you. Each cell contains your complete DNA.

The study doctor can provide you with additional information if you have questions. Also, further information about our use of your biospecimens can be found in this consent document under the heading "*What happens to Data and Biospecimens that are collected in the study?"*

Will you allow us to store the biospecimens we collect for this study for use in future research?

YES ☐ _____
Signature of Participant

NO ☐ _____
Signature of Participant

How long will you be in the study?

You will be in this study for 12 weeks.

4. What are the risks or discomforts of the study?

Blood draw
You may experience pain and discomfort during the blood draw. You may also be at risk of bleeding. All blood draws will be performed by a certified phlebotomist or a registered nurse. After the blood draw, your condition will be monitored by a registered nurse (RN).

Exercise Training Sessions:
During the exercise, you may feel light-headed or may be at risk for muscle injury. All of your exercise training sessions will be monitored by an exercise physiologist and a registered nurse to ensure your safety.

Acupuncture (APA):
The acupuncture procedure is considered safe with minimal risks. The most frequently reported side effects were local skin irritation and discomfort, mild tenderness or pain, and dizziness. These events did not last long and were mild, and tolerable. You can remove the tap with the seed when adverse events occur.

Fitbit:
When wearing the Fitbit, you may experience discomfort. The material does not contain latex; however, the clasp is made of surgical grade stainless steel and contains traces of nickel, which may cause a rash. The device can be easily removed if discomfort is experienced. You will be asked to record the time and reason when and why you removed the band.

Exercise program:
You may experience fainting or muscle injury during exercise. We will ask you to walk or exercise at your own pace, wear appropriate clothes (tennis shoes, comfortable clothing) and eat a light snack before exercise.

Mindfulness-based intervention and responding to the questionnaires:
Complications during MBI and responding to the questionnaires are unlikely.

Participation in this study involves the completion of questions asking about the depressive symptoms. Scores from these questions would not be sufficient basis for clinical decisions or diagnosis, contain substantial margins of error, and are not used for diagnostic purposes in this study. This score might hint at problems with depression that some people would want to discuss with an appropriate health professional. Therefore, you will receive your score and a suggestion from a registered nurse to discuss this potential health issue with your primary health care provider.

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Magnetic Resonance Spectroscopy:
While no significant risks have been found from the use of MRS scans, you may be bothered by the noise made by the MRS scanner and by feelings of being closed in (claustrophobia).

Confidentiality:

There is the risk that information about you may become known to people outside this study. A loss of confidentiality may cause psychological discomforts (e.g., embarrassment, guilt, stress, etc.) or social harm. We will protect all of your personal information separately from the information related to the study and study code. A study code will be provided to you and used throughout the study.

Genetic information is unique to you and your family, even without your name or other identifiers. Johns Hopkins follows procedures to prevent people who work with your DNA information from being able to discover it belongs to you. However, new techniques are constantly being developed that may in the future make it easier to re-identify genetic data, so we cannot promise that your genetic information will never be linked to you.

There may be side effects and discomforts that are not yet known.

5. Are there risks related to pregnancy?

This research may hurt an embryo or fetus in ways we do not currently know.

6. Are there benefits to being in the study?

There is no direct benefit to you from being in this study. If you take part in this study, you may help others in the future.

7. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

No.

9. Will you be paid if you join this study?

At the end of the 12 weeks program, you will receive $40 and a Fitbit as an incentive to participate in the study. You will receive an additional $70 if you are eligible and agree to participate in MRS.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

11. Why might we take you out of the study early?

You may be taken out of the study if:

- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is canceled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study, and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone, and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

14. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Nada Lukkahatai at (410) 614-5297. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Principal Investigator Dr. Nada Lukkahatai at (410) 614-5297 during regular office hours.

d. What happens to Data and Biospecimens that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

15. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).