THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Efficacy of an adapted multicomponent physical activity intervention to reduce psychosocial distress in rural adults following cancer diagnosis 2020-1278

Subtitle: Intervention

Study Chair: Scherezade K Mama, DrPH

_____ _____
Participant's Name Medical Record Number or Study ID

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goal of this behavioral research study is to learn if a community-based physical activity program can help to lower the amount of sedentary (physically inactive) time and stress in cancer survivors who are currently undergoing radiation therapy and who live outside of large cities.

There are 2 parts to this study: interviews with cancer survivors and healthcare providers, and the study intervention. **This consent is only for the intervention part.**

This is an investigational study.

Taking part in this study may help you be more active. Future cancer survivors may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including potential expenses and time commitment.

You can read a list of potential risks below in the Possible Risks section of this consent.

Your participation in this study will be over after 14 weeks.

There is no cost for you to take part in this study.

You may choose not to take part in this study.

1. STUDY DETAILS

Baseline Visit (Week 0)

If you agree to take part in the study, the following procedures will be performed at this visit, before you begin the study intervention:

- You will be asked to complete a brief physical health assessment, which will include measuring your heart rate, blood pressure, height and weight. This should take about 15 minutes to complete.
- You will complete computer-based questionnaires about your demographic information (such as your age, race and ethnicity, and education), past medical history, lifestyle habits, social factors, stress, and quality of life. These questionnaires should take about 60 minutes to complete.
- You will be given an activPAL, a small device (roughly 2 inches long and 1 inch wide, about the size of a credit card) that will measure the amount of physical activity you do. The activPAL will be taped to your thigh using a waterproof medical patch, and you will be asked to wear it non-stop for 7 days. You will be given a prepaid envelope to return the activPAL to the research team after you wear it for 7 days.
- You will be given a Fitbit activity monitor that is worn on the wrist (like a watch). You will be asked to wear the Fitbit every day to record the number of steps you take. A study team member will help you set up the Fitbit and answer any questions you may have. When your participation in this study is over, the Fitbit will be yours to keep.

Study Groups

After you have completed your baseline visit and returned your activPAL device, the study team will download your data to confirm you have worn it correctly. Once your data has been verified, you will be randomly assigned (as in the flip of a coin) into 1 of 2 study groups. This is done because no one knows if one study group is better, the same, or worse than the other group. You will have an equal chance of being assigned to either group. A study team member will contact you to let you know which group you are in.

If you are in Group 1, you will attend mind-body sessions focused on stretching, breathing, and relaxation 2 times each week for 8 weeks (2 months) at UT Health East Texas HOPE Cancer Center.

- Stretching, breathing, and guided relaxation sessions will include a 5-minute introduction, 30 minutes of gentle yoga-like stretches, allowing you to stretch comfortably, and 10 minutes of breathing exercises and guided relaxation. You will also be asked to practice your stretching, breathing, and relaxation at home at least 2 more times per week during the 8 weeks (in addition to the sessions at the health center) and write down when you do these (in a paper diary or an electronic format). A research team member will call, text, or email you to remind you to practice at home and ask if you have any questions.
- You will be sent up to 6 text messages every day to encourage you to move more and sit less. The texts will be sent throughout the day during a 12-hour period you specify.

If you are in Group 2, you will be provided educational materials on physical activity and cancer survivorship. This is part of routine care and follow-up for cancer survivors.

Up to 76 total participants will be enrolled in this study, with Up to 56 participants enrolled in the invervention part of the study. All will be enrolled at MD Anderson.

Study Visits at Weeks 4, 8, and 14

At Weeks 4, 8, and 14 after the baseline visit, you will have the following test/procedures:

- You will be asked to complete a brief physical health assessment.
- You will complete computer-based questionnaires about your lifestyle habits, social factors, stress, and quality of life. These questionnaires should take about 60 minutes to complete.
- You will be given another activPAL to wear on your thigh for the next 7 days. You will be given a prepaid envelope to return the device to the research team after you wear it for 7 days.

If you are unable to have an in-person visit due to COVID-19, information will be collected virtually (such as through web-based questionnaires) using videoconference software such as Zoom. You will be mailed the activPAL device and shown how to attach it properly to your leg during a video conferencing session.

Information Collection and Other Information

Information that is collected about you on this study (including your demographic information, questionnaire responses, and activPAL/FitBit data) will be stored in a database at MD Anderson.
Your data will be given a code number. Only the researcher in charge of the database will have access to the code numbers and be able to link the data to you.

You will also be asked to share the names and contact information of 3 family members or friends as additional follow-up contacts, in case the study staff has trouble reaching you. This information will be stored securely in the study database.

2. POSSIBLE RISKS

While in this study, you are at risk for side effects. You should discuss these with the study chair. The known side effects are listed in this form, but they will vary from person to person.

You may have mild discomfort while completing measures of **blood pressure and weight**. You may refuse to complete any of these procedures that may make you feel uncomfortable.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns after completing the questionnaire(s), you are encouraged to contact the study chair. If your questionnaire responses suggest signs of depression, you will be given a list of resources for mental health services. If your responses indicate that you are thinking of committing suicide, you will be contacted by a member of the study team.

If the **activPAL** is lost or stolen, you will not be responsible for the replacement cost, but you should tell the study staff right away. Please note that once you return the activPAL and your study data has been uploaded from it, any of your information that is stored on it will then be deleted. Having the activPAL taped to your thigh may cause mild discomfort or skin irritation.

Mild to moderate **physical activity** may cause sore or pulled muscles, heart problems, physical discomfort, and/or accidental injuries such as falling. You may also experience some physical discomfort such as increased heart rate, sweating, chest pain, shortness of breath, headache, nausea, and/or fatigue.

Although every effort will be made to keep study data safe, there is a potential risk of loss of **confidentiality** or that your **personal health information** could be lost or stolen. Researchers will take appropriate steps to keep your information private. However, there is no guarantee of absolute privacy. Your data will be encrypted and protected on a secure server, and only authorized staff will have access to see your data after you have completed the study. However, despite these security steps, there is a risk this data could be accessed without authorization despite cloud and institutional security.

This study may involve unpredictable risks to the participants.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, you may be contacted in the future to see if you want to take part in other research studies. Even if you agree to future contact at this time, you are free to change your mind and ask to not be contacted at any time.

There will be no cost to you for this optional procedure. You do not have to agree to take part in this optional procedure in order to take part in this study. There are no benefits to you for taking part in the optional procedures. Future patients may benefit from what is learned. You may stop taking part at any time.

Optional Procedure Risks

There are no expected risks to you for this optional procedure.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to be contacted in the future to see if you want to take part in other research studies?

YES **NO**

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or the American Institute for Cancer Research (AICR) for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Unless otherwise stated in this consent form, all of the costs linked with this study, which are not covered by other payers (health maintenance organization [HMO], health insurance company, etc.), will be your responsibility.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

As compensation for your time and effort, you will keep the Fitbit device.

You will also receive a retail gift card after completing each study visit, as follows:

- $20 after completing the baseline visit
- $30 after completing the Week 4 visit

- $40 after completing the Week 8 visit
- $50 after completing the Week 14 visit

You will receive an additional $20 gift card at after each visit once we have received your activPAL device in the mail and checked your data.

Participants may receive up to $220 in gift cards for their time and effort.

Additional Information

4. You may ask the study chair (Dr. Scherezade K. Mama, at 713-563-7546) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the American Institute for Cancer Research, or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

9. This study is sponsored and/or supported by: the American Institute for Cancer Research (AICR).

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and the AICR, and/or shared with other researchers and/or institutions for use in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson may be collecting and using your PHI. For legal, ethical, research, and safety-related reasons, the research team may share your PHI with:
   - The Office for Human Research Protections (OHRP)
   - The IRB and officials of MD Anderson
   - The AICR, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
   - Collaborators at The Pennsylvania State University
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

   Any publications resulting from study data will not contain your name or any other identifying information.

B. Signing this consent and authorization form is optional but you cannot take part in this study if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible according to state and federal law. However, in some situations, health authorities could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer of MD Anderson at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

_____ _____
SIGNATURE OF LAR DATE

_____
PRINTED NAME and RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol 2020-1278.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE
A witness signature is only required for vulnerable adult participants.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT