THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

TITLE: A Virtually Delivered Exercise Intervention To Mitigate Cognitive Deficits From Radiotherapy In AYAs With Brain Tumors

SUBTITLE: Virtual Exercise Intervention for AYAs with Brain Tumors program

PROTOCOL NO.: 2022-0152

SPONSOR: MD Anderson Cancer Center

INVESTIGATOR: Keri Schadler, PhD
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United States

STUDY-RELATED PHONE NUMBER(S): 713-792-5410 (office)
713-792-7090 (24 hours)

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

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

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).

If you are reading and signing this form on behalf of a potential participant, please note: Any time the words "you," "your," "I," or "me" appear, it is meant to apply to the potential participant (your child).

STUDY SUMMARY

The goal of this research study is to test a new investigational virtual exercise program for adolescents and young adults (AYAs) with brain tumors who plan to receive cranial radiotherapy. You will have two MRIs regardless of your participation in this research study. Researchers want to learn if the exercise program can help lessen the negative impact of radiotherapy on brain function, such as memory and the ability to process information.

This is an investigational study.

Your mood, fatigue, and overall health may improve while taking part in the virtual exercise program. Future patients 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 any concerns you may have, including potential expenses, risks, and time commitment, with the study team.

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, chest pain, shortness of breath, headache, nausea, and/or fatigue.

You may feel embarrassed to **share your physical activity information** with the certified personal trainer during the video calls.

You should discuss the risks of **questionnaires** with the study chair. Some questions may make you feel upset or uncomfortable. There is a risk of loss of confidentiality. You can also read the list of potential risks below in the Possible Risks section of this consent.

You will take part in your assigned exercise program for 12 weeks.

There will be no cost to you for taking part in this study.

Your alternative is that you may choose not to take part in this study.

1. STUDY DETAILS

Up to 40 participants receiving care at MD Anderson will be enrolled in this study.

Current Visit

If you agree to take part in this study, after you sign this consent form:

- The study team will ask you questions about your demographics (such as age, sex, and so on) and your medical history.
- You will be asked to complete questionnaires about your physical activity, foods you eat, symptoms, and your physical and emotional quality of life. These questionnaires will be completed online and should take between 35 to 60 minutes.

The study team will also give you an ActiGraph, a device worn on the waist that measures physical activity (such as the number of steps you walk each day, how long you spend standing, and how long you spend laying down). You should wear the ActiGraph at least 10 hours a day for 7 days. The study team will also give you a diary to log when you wear the ActiGraph during this period.

Baseline Visit

About 1 week after this visit, you will have a baseline visit. This visit should take about 45-60 minutes. The following tests and procedures will be performed at this visit:

- You will take a cognitive test looking at how well your brain processes information. The test takes about 25-30 minutes. During the cognitive test, you will complete tasks like the following:
  - Select matching symbol for the number
  - Reaction to changes on the screen
  - Find a pathway through a maze
  - Recall activities
  - Recognizing patterns
- The study team will measure your height, weight, and waist circumference.
- You will complete 2 rounds of physical function testing. Both rounds will occur at your home over a video conferencing platform (such as Zoom) about 24-48 hours after the first round. The study team will instruct you on how to complete the tests during the video call. Each round of physical function testing will take about 15 minutes. During the physical function testing, you will:
  - Sit in a chair and stand up to walk a short distance
  - Stand on one leg
  - Sit in a chair and stand up several times
  - Step on and step off a step repeatedly
  - Measure your hand grip strength using a small handheld device which you will squeeze with each hand

You will return the ActiGraph during this visit. The study team will then review the data collected by the ActiGraph. If you have not worn the ActiGraph as instructed and there is not enough data, the study team will ask you to wear the ActiGraph for 7 more days so they can get an accurate understanding of how much physical activity you get in your daily life.

Study Groups

Once you have enough ActiGraph data (at the end of your baseline visit, or after the additional 7-day ActiGraph period), you will be randomly assigned (like the flip of a coin) to either the **standard Fitbit program** or the **virtual exercise program.**

This is done because the researchers do not know if one program is better, the same, or worse than the other. You will have an equal (50/50) chance of being assigned to each group.

The study staff will tell you which program you are in.

Physical Activity Programs

You will take part in your assigned program for **12 weeks**, starting at the beginning of your cranial radiotherapy treatment.

All participants will be given a Fitbit to wear during their participation in this program. You will need to wear the Fitbit at least 5 days per week and for at least 10 hours a day. The Fitbit will collect data about your physical activity, heart rate, and sleep patterns. For your use in this study, the study team will create a Fitbit account that does not identify you by name.

During the program, you will take part in video calls (through the video conferencing platform Zoom) **1 time a week**. Each call will be led by a certified trainer. Each call should take no more than 60 minutes.

Standard Physical Activity Program

If you are assigned to the standard program, you will receive a weekly check in with the trainer in order to discuss any questions or technical issues with the Fitbit.

Virtual Exercise Program

If you are assigned to the Virtual Exercise program, you will receive one-on-one physical activity coaching and participate in exercise training with the trainer during each session.

You will also be added to a private FitBit group with the other virtual exercise program participants. You will be able to track your step count and the step counts of other participants in this private group. You will also be able to chat with other research participants in the private group.

You will also be encouraged to take part in self-paced physical activity at home in between video call sessions. You will be given additional resources about physical activity for you to use during the week in between video calls. You will be provided with a set of resistance tubes and an under-desk stationary elliptical to use for your weekly exercise. The trainer will work with you to create an exercise plan and will revise it each week based on your progress. Exercises will be provided and tracked

through the Physitrack, which is a web-based home exercise programming system that can be accessed on a computer or through an app on your phone.

Study Visits

You will be asked to come to the clinic halfway through the program (Week 6± 2 weeks) and at the end of the program (Week 12± 2 weeks). The following tests and procedures will be performed at the specified visit.

Week 6:

- You will be asked to give feedback on your assigned program.
- You will repeat the questionnaire about physical activity online.
- You will be given the ActiGraph monitor and will be instructed to wear it at least 10 hours a day for 7 days after this visit. The study team will also give you a diary to log when you wear the ActiGraph during this period.
- The study team will provide a mailing envelope for you to mail back the ActiGraph after you have worn the ActiGraph at least 10 hours a day for 7 days.

Week 12:

- The study team will measure your height, weight, and waist circumference in person.
- You will be asked to give feedback on your assigned program.
- You will repeat the questionnaires about physical activity, symptoms, and quality of life.
- You will be given the ActiGraph monitor and will be instructed to wear it at least 10 hours a day for 7 days after this visit.
- You will be asked to come to the clinic and complete the cognitive test like you did at the baseline visit.
- You will be asked to log when you wear the ActiGraph in a diary, like you did earlier in the study. You will also need to return the ActiGraph. You will return the ActiGraph via mail or in-person. The study team will discuss this with you.
- You will complete virtual physical function tests like you did at the baseline visit. We will only do one round of physical function testing at the week 12 visit.

Your participation in this study will be complete after the Week 12 visit.

Return/Replacement of Study Devices

You will need to return the **ActiGraph** in person when you return to complete the Week 12 study visit. If you are unable to return the Actigraph in person, a pre-paid mailing label will be sent to you for your use in mailing the Actigraph back. If it is lost, stolen, or damaged, you will not have to pay for a replacement. Please tell the study team that the ActiGraph is lost, stolen, or damaged, and you will be given a replacement.

You will be allowed to keep the **FitBit** after your participation in this study. If the FitBit is lost, stolen, or damaged during the study, you will not have to pay for a replacement. Please tell the study team that the FitBit is lost, stolen, or damaged, and

you will be loaned a replacement FitBit for the rest of the study. You will need to return the loaner FitBit at the end of the study. The study team will mail you a prepaid envelope after the 12-week follow-up so that you may return it, if needed.

You will need to return the **resistance tubes and under-desk elliptical** in person when you return to complete the Week 12 study visit. Please tell the study team if either of these items are lost, stolen, or damaged, and you will be loaned a replacement for the rest of the study. These items are the property of MD Anderson Cancer Center. If lost, damaged, or stolen, you may be responsible for the cost of the loss or damage of the device. You may responsible if the loss or damage is the result of negligence, an intentional act, or a failure to use reasonable care, safeguards, maintenance, and service.

Other Information

The study team may contact you by phone or email for the following reasons:

- To schedule your clinic visits
- To remind you of an upcoming clinic visit
- To follow up on your questionnaire responses or any side effects
- To schedule the return of the ActiGraph device

2. POSSIBLE RISKS

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

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, chest pain, shortness of breath, headache, nausea, and/or fatigue.

You may feel embarrassed to **share your physical activity information** with the certified personal trainer during the video calls.

You should discuss the risks of **questionnaires** with the study chair. Some questions may make you feel upset or uncomfortable. You may refuse to answer any question. If you have concerns after completing the questionnaire(s), you are encouraged to contact your doctor or the study chair.

Although every effort will be made to keep study data safe, there is a chance that **your personal health information could be lost or stolen**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

The **activity monitors** will be encrypted (protected) to prevent unauthorized viewing of the application data. If you are in the Virtual Exercise Program group, you will be

"friends" with the other study participants in the private FitBit group. You will use fake names in the group to provide an additional layer of security. All information collected by the Fitbit and the ActiGraph will be generic and related to physical activity, heart rate, and sleep patterns – no other health information will be collected on these devices.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks

For female participants only: If you are pregnant, you will not be enrolled in this study. If you become pregnant or suspect that you are pregnant, you must tell the research staff right away.

Getting pregnant will not result in your removal from this study. Physical activity has been shown to have benefits for pregnant women when supervised appropriately. The research team will only remove you from the study if your obstetrician-gynecologist does not provide approval for your continued participation.

OPTIONAL PROCEDURES FOR THE STUDY

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

Optional Procedure #1: If you agree, the study team may contact you by text message to schedule your visits, send reminders, follow up on your questionnaire responses, or schedule the return of the ActiGraph.

Optional Procedure Risks: If your phone is lost or stolen, the text messages from the study team may be viewed by others. In this case, please notify the study team so text messages can be discontinued.

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 allow the study team to contact you by text message for the reasons specified above?

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 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 billed to you.

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

You will receive a maximum of $35 for participating in this study. The total amount you receive will depend on how many study visits you complete. You will receive $10 after you complete the baseline visit, $11 after you complete the 6-week visit, and $14 after you complete the 12-week visit.

Additional Information

4. You may ask the study chair (Dr. Keri Schadler, at 713-792-5410 or 713-792-7090 (24hours)) 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 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.

Future Research

This future research is optional. You can still take part in the main study if you do not want your data used for future research. If you do not want your data used in this way, please tell the study chair and study staff.

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson 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. 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 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 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
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

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
(Adult Participants Only)

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 this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
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

PARENT/GUARDIAN PERMISSION

I have read and understand the description of this research. I have had a chance to discuss the study and ask questions. My questions have been answered. I give permission for my child or ward to take part in this study.

_____ _____
SIGNATURE OF PARENT/GUARDIAN DATE

_____
PRINTED NAME OF PARENT/GUARDIAN

_____ _____
SIGNATURE OF PARENT/GUARDIAN DATE
Signature of Other Parent (Optional, unless required by the IRB.)

_____
PRINTED NAME OF PARENT/GUARDIAN

____The IRB has determined that the signature of both parents is required.

If not obtaining both parental signatures, please indicate reason below:

____Other parent is deceased, unknown, incompetent, or not reasonably available.

____Parent/Guardian signing above has sole legal responsibility for the care and custody of the child.

__X__ The IRB has determined that the signature of both parents is NOT required.

ASSENT OF MINOR

(Entire section must be completed if the participant's intellectual age is at least 7 and less than 18 years. Participants with an intellectual age of 7 - 12 are not required to sign.)

If written assent is not obtained on an age-appropriate participant, check reason why not:

____ 1.) The participant's intellectual age is less than seven.

____ 2.) The participant dissented, but the participant's parent(s)/guardian felt that the intervention(s) or procedure(s) involved in the research hold out the possibility of a direct benefit that is important to the health and/or well being of the participant and is available only in the context of this research study.

____ 3.) Other:_____

I have been told what I will be asked to do in this study.

I have been told that I do not have to be in this study. If I decide not to be in this study, no one will be mad at me. I may quit at any time, but if I do, I may need to take a different treatment.

I have had a chance to talk about the study and ask the study doctor questions. All of my questions have been answered. I agree to be in this study and do what I am asked to do

so long as I want to stay in this study. I agree that the study doctor can put me on this study. By signing this paper, I am not giving up any of my legal rights. I have been given a copy of this document.

_____ _____
SIGNATURE OF MINOR (Age 13-17) DATE

_____
PRINTED NAME OF MINOR

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line.)