Informed Consent Form

Title: A Soccer-based Lifestyle Intervention vs mHealth-based Physical Activity Intervention to Improve Bone Health and Metabolic Health in Prostate Cancer Survivors

NCT Number: NCT04144127

IRB Approval Date: September 7, 2021

EMORY UNIVERSITY | Institutional Review Board
Research Administration

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 20 people who are being studied, at Emory.

Why is this study being done?

This study is being done to answer the question: Does a soccer-based lifestyle program improve bone health in prostate cancer survivors. You are being asked to be in this research study because you are a prostate cancer survivor and therefore at risk for decreased bone density and diseases like heart disease and high blood sugar.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for 3 months (two study visits at Emory and soccer sessions 2 times per week if in the soccer group). The researchers will ask you to do the following: at each Emory study visit you will have a DXA scan to measure your bone health and body fat, a blood test to measure bone health and diabetes, blood pressure, physical fitness tests and questions about physical and mental health, quality of life, exercise and diet. ALL of these tests will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. You will also be given all results and information about how to improve your health.

What are the risks or discomforts I should know about before making a decision?

The study will take time. All studies have some risks. Some risks are small, like being bored or losing time. Some are more serious – for this study, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the “What are the possible risks and discomforts?” section of this document.

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is not to participate.

Costs
You WILL NOT have to pay for any of the study procedures, in particular those that are not covered by your medical insurance.

There is more information in the cost section below.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: A soccer-based lifestyle intervention vs mHealth-based physical activity intervention to improve bone health and metabolic health in prostate cancer survivors

Principal Investigator: R.L. Felipe Lobelo, MD, PhD; Emory University Rollins School of Public Health

Study-Supporter: Winship Cancer Institute

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

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.

What is the purpose of this study?
The purpose of this study is to test the whether a soccer-based lifestyle program improves bone health s. This will involve playing soccer twice a week with diet and behavioral education done by a trained coach. We will be recruiting 20 subjects. The subjects will be men between the ages of 18-79 years who have had prostate cancer.

What will I be asked to do?
You will first be asked to take a short survey about your health and usual physical activity. We will measure your height and weight. We will determine from this information if you are eligible to join the study.

If you are eligible and agree to join the study, you will be join soccer group (as a study participant) with a trained soccer coach that will coach you in soccer and fitness routines for 12 weeks (two 1-hour sessions per week) and lead talks about the diet

and behavior change education and answer any questions you have.

The study tests will be done two times: once at the beginning (baseline), once at the end (12 weeks). You will need to come to the research center at Emory University Hospital. These tests will include blood pressure, height and weight, and waist circumference, a bone scan that measures bone health and body fat. You will have a blood draw to measure blood tests for bone health and a total testosterone if not already in your medical record. Additional tests will include physical fitness tests (aerobic capacity and strength) and questions about your physical and mental health, quality of life, exercise and diet, and at the end, we will ask about how you liked the program and injuries. The soccer group will be fitted with a wearable soccer-specific device to measure how much you move and your heart rate during the soccer sessions. Each group will also be asked to wear a Garmin fitness tracker for the duration of the study to measure your steps and activity.

The online or mobile health education will be a delivered in brochures and text messages during the 6 months. You will receive reminders by text message to do motivate you to make healthy choices.

Who owns my study information and samples?

If you join this study, you will be donating your samples and study information. You will not receive any pay if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study. All personal health information will be entered into a secure online system that protects this information.

What are the possible risks and discomforts?

There may be side effects from the study intervention or procedures that are not known at this time.
The most common risks and discomforts expected in this study are: mild bruising, fainting and infection from blood draw.

The less common risks and discomforts expected in this study are: mild exercise related injuries (12% of sample may experience mild injuries).You will be exposed to additional radiation from x-rays from the DEXA scan. This procedure is not necessary for your medical care and will occur because you participate in this study. The estimated radiation dose that you will receive is equal to or less than the natural environmental radiation the average person receives in the United States annually. The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. The risk for radiation-induced cancer from this study is negligible.

Rare but possible risks include: loss of confidentiality.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. This study is designed to learn more about which methods will benefit people similar to you to improve your bone health and to increase your exercise and physical activity. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will get $_20 gift card for each completed study visit, to pay you for your time and effort and free parking validation. If you do not finish the study, we will pay you for the visits you have completed. You will get $40 total, if you complete all study visits.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. Your doctor can talk to you about your bone health. The study doctor will discuss these with you. You do not have to be in this study to be treated for prostate cancer.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you) may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee your personal data will stay de-identified.

Your data [and specimens] from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your de-identified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

We will use your sample and data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, or a medical test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

We will provide results of the measurements we take during study visits that are readily available like blood pressure and HbA1c.

Medical Record

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

Emory Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory Healthcare medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality

of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: bone health blood tests and any tests from saved blood samples.

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

Emory may choose not to pay for Subject Injury Costs for any subject, no matter if the subject is insured, or how he/she is insured.

If you believe you have become ill or injured from this research, you should contact Dr. Lobelo at telephone number [redacted] You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Neither Emory nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory has not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory, the only exception is if it is proven that, your injury or illness is directly caused by the negligence of an Emory employee. “Negligence” is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under “injury” as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor’s advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done, specifically: Imaging, lab work, surveys.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your “protected health information” or “PHI.” To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the “Privacy Rules.” Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Winship Cancer Institute is the Supporter of the study. The Supporter may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.

- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely

and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Optional Storage of [Data and/or Specimens] for Future Research:

Authorization for This Use of PHI is Required to Participate in Optional Storage of [Data and/or Specimens] for Future Research:
You do not have to authorize the use and disclosure of your PHI for the optional study(ies). If you do not authorize the use and disclosure of your PHI for the optional Storage of [Data and/or Specimens] for Future Research, but you can still be in the main research study.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Felipe Lobelo, MD PhD
[redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization, you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information will not be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

<u>Contact Information</u>
Contact Felipe Lobelo at [redacted]; email:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

Consent and HIPAA Authorization for Optional Study/Studies:
Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study/studies previously described:

Optional Storage of [Data and/or Specimens] for Future Research_____Initials

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study, and any optional studies you initialed above. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Name of Subject

_____ _____
Signature of Subject (18 or older and able to consent) **Date Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____
Signature of Person Conducting Informed Consent Discussion **Date Time**