

Informed Consent Form for:

Title: Feasibility of a Soccer-based Adaptation of the Diabetes Prevention Program

NCT Number: NCT03595384

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You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University Consent to be a Research Subject

Title: Feasibility of a Soccer-based Adaptation of the Diabetes Prevention Program

Principal Investigator: Felipe Lobelo, MD, Emory University Rollins School of Public Health, Global Health

Funding Source: Georgia Center for Diabetes Translation Research (NIH center at Emory)

Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in 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.**

Before making your decision:

- Please carefully read this form or have it read 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. By signing this form you will not give up any legal rights.

Study Overview

The purpose of this study is to test whether online diet and behavioral education and playing soccer regularly will improve your health and reduce your diabetes risk. We will be recruiting a total of 40 subjects. The subjects will be Hispanic men between the ages of 35-55 years who could be at risk for diabetes.

Procedures

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 added to a soccer team (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 answer any questions you have about the online education that will be provided. Once you are done with the first 12 weeks of soccer practice you will be invited to play in a local soccer league for another 12 weeks to continue the study.

The study measurements will be done three times: once at the beginning (baseline), once at the end of soccer practice portion (12 weeks), and again after the soccer league (24 weeks). These measurements will include blood pressure, a finger stick to measure HbA1c a test for diabetes, height and weight, and waist circumference. Additional measurements will include physical fitness assessments (aerobic capacity and strength) and questionnaires about your physical and mental health, quality of life, exercise and diet, and at the end we will ask about program satisfaction and injuries. During the soccer sessions/games you will be fitted with a wearable soccer-specific device to measure how much you move and your heart rate. All of these measurements will be done on the soccer field. You will also be asked to wear a Garmin fitness tracker for the duration of the study to measure your steps and activity.

The online education will be a version of the Diabetes Prevention Program and can be completed on your phone or computer with internet access. You will receive reminders by text message to do the online education and the soccer

coach will talk to your soccer team during soccer practice about what you learned and answer any questions you may have about the education material.

Risks and Discomforts

Although this study is designed to have minimal risks to participants, there may be side effects from study participation that are not known at this time. There is minimal risk in this study. Potential risks are related to 1) finger sticks, 2) confidentiality loss 3) Injuries related to soccer practice. 1) Finger stick will be done with a single use device and has minimal risk of discomfort, bruising, or bleeding. There is minimal risk of infection. 2) There is a risk of loss of confidentiality. Efforts will be made to keep all personal information confidential. All data will be stored in locked offices and password-protected computers. Personal identity will be protected in any publication. 3) Exercise can cause muscle soreness, weakness and in some cases muscle strains, ligament sprains and rarely bone fractures can occur. In very rare cases exercise can induce chest pain or a heart attack or other medical emergency. The training program led by the soccer coach is designed to minimize risk of injuries or events by slowly progressing on the practice of soccer using soccer and exercise drills appropriate for your age and level of fitness. Soccer sessions will be led by trained professionals who are able to offer suggestions to limit and prevent these adverse events. They are trained to recognize medical emergencies, will have basic equipment available, and seek emergency care if needed.

New Information

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.

Benefits

Your health may or may not improve during this study. This study is designed to learn more about which methods will benefit people similar to you to improve your diabetes risk and to increase your exercise and physical activity. You also may benefit from the information obtained during the study measurements. The study results may be used to help others in the future.

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.

Compensation

This study will cover the cost of the soccer practice lead by the coach (12 initial weeks) and the soccer league season (last 12 weeks of study). If you complete the whole study and measurements you will be able to keep the Garmin fitness tracker.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include [the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Research Compliance]. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

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

We will do everything we can to keep others from learning about your participation in the research. To further help protect your privacy, the investigators have obtained a Confidentiality Certificate.

What the Certificate of Confidentiality protects:

The National Institutes of Health has given this study a Certificate of Confidentiality. Emory would rely on it to not give out study information that identifies you. For example, if Emory received a subpoena for study records that identify you, we would say no. The Certificate gives Emory legal backup to say no. It covers information about you that could harm your image or finances. It also covers information about you that could harm your chances at a job or getting insurance.

What the Certificate of Confidentiality does not protect:

The Certificate does not prevent you or someone other than you from making disclosing your information. The Certificate also does not prevent Emory from releasing information about you:

- Information to state public health offices about certain infectious diseases
- Information to law officials if child abuse has taken place
- Information Emory gives to prevent immediate harm to you or others
- Information Emory gives to the study sponsor as part of the research

In Case of Injury

If you get ill or injured from being in the study, Emory will help you get medical treatment. Emory and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

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.

Voluntary Participation and Withdrawal from the Study

You have the right to leave a study at any time without penalty. You may refuse to do any procedures you do not feel comfortable with, or answer any questions that you do not wish to answer.

The researchers and funder also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- You get injured;
- or for any other reason.

Contact Information

Contact Felipe Lobelo at [REDACTED]:

- 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 & Authorization

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

Name of Subject

Signature of Subject

Date

Time

Signature of Person Conducting Informed Consent Discussion

Date

Time