CRYOS TECHNOLOGIES INC.

Consent form

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NCT05163418

Project title

Validation protocol for foot orthoses for abnormal plantar arch using a new non-invasive clinical imaging system

Project team

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Why do we give you this form?

We invite you to participate in a clinical trial of foot orthotics for flat and hollow feet. The purpose of these orthoses is to help provide support for people with flat or hollow feet. We are looking for 80 participants for this purpose.

Hollow foot" refers to an exaggerated accentuation of the plantar arch, corresponding to an increase in the height of the longitudinal arches of the foot. The "flat foot" refers to the collapse of the arch of the foot, with the disappearance of the internal arch of the foot. The phenomenon is usually accompanied by some degree of pronation or outward twisting of the foot. These two foot pathologies lead to a loss of stability, poor posture and a faulty gait, and are thus at the root of many ailments and injuries.

The information provided is intended to help you understand exactly what is required so that you can decide whether or not to participate in this study. Please read the form carefully and ask any questions you may have before making your decision. Take all the time you need and consult the people you choose if necessary. Your participation should be entirely voluntary. If you decide not to take part in the study, you will not be penalized in any way.

Why are we doing this study?

Cryos Technologies Inc. has new orthotics for people with flat and hollow feet, as well as a new clinical medical imaging system to evaluate the effectiveness of the foot orthotics. The objectives of the project are to validate the effectiveness of both the medical imaging system and the orthotics.

What do you need to do?

Summary of your participation

At the first session, an orthotist will assist you in completing the consent form. Then, we'll start with an assessment of your feet to classify you into one of the 3 study groups (controls, sunken feet or flat feet). This assessment is called the Foot Posture Index 6.

Control participants

You will only need to attend one session. The session will take place on Topmed's premises at Collège Mérici, 755 Grande-Allée West, Quebec City.

The aim of the session is to collect information relevant to the study and to carry out the stationary and walking tests required to acquire biomechanical data. Motion capture and imaging technologies will be used for this purpose. We will complete a questionnaire and then let you go.

Participants with flat or hollow feet

You'll have to try on orthotics that fit your plantar arch. The orthotic must be worn inside the shoe. You will be required to attend five appointments, which will be held at Topmed's offices on the grounds of Collège Mérici, 755 Grande-Allée West, Quebec City.

The purpose of the first session is to gather information relevant to the study and to take the impressions needed to design the orthosis.

At the second session, we'll deliver the orthosis, i.e. try it on and adjust it if necessary. We'll perform the first trials, which involve standing still and walking with the brace on, to enable biomechanical data to be acquired. Motion capture and imaging technologies will be used for this purpose. We will complete a questionnaire and then let you leave with the orthosis.

You will be required to wear the brace daily for a period of twelve (12) months. A logbook will be left with you to record the details of your orthosis wear.

During this 12-month period, three additional sessions will be held: at 2 months, 6 months and 12 months. At these sessions, we will repeat the data acquisition procedure of the second session, and at the last session, we will complete the final questionnaire.

Explanation of your participation

Control participants

An orthotist will perform an ankle joint assessment to gather information on alignment, joint range and stability. Next, we'll take anthropometric data and begin analyzing your posture and gait pattern.

Figure1 : Cryovizion imaging system for posture assessment

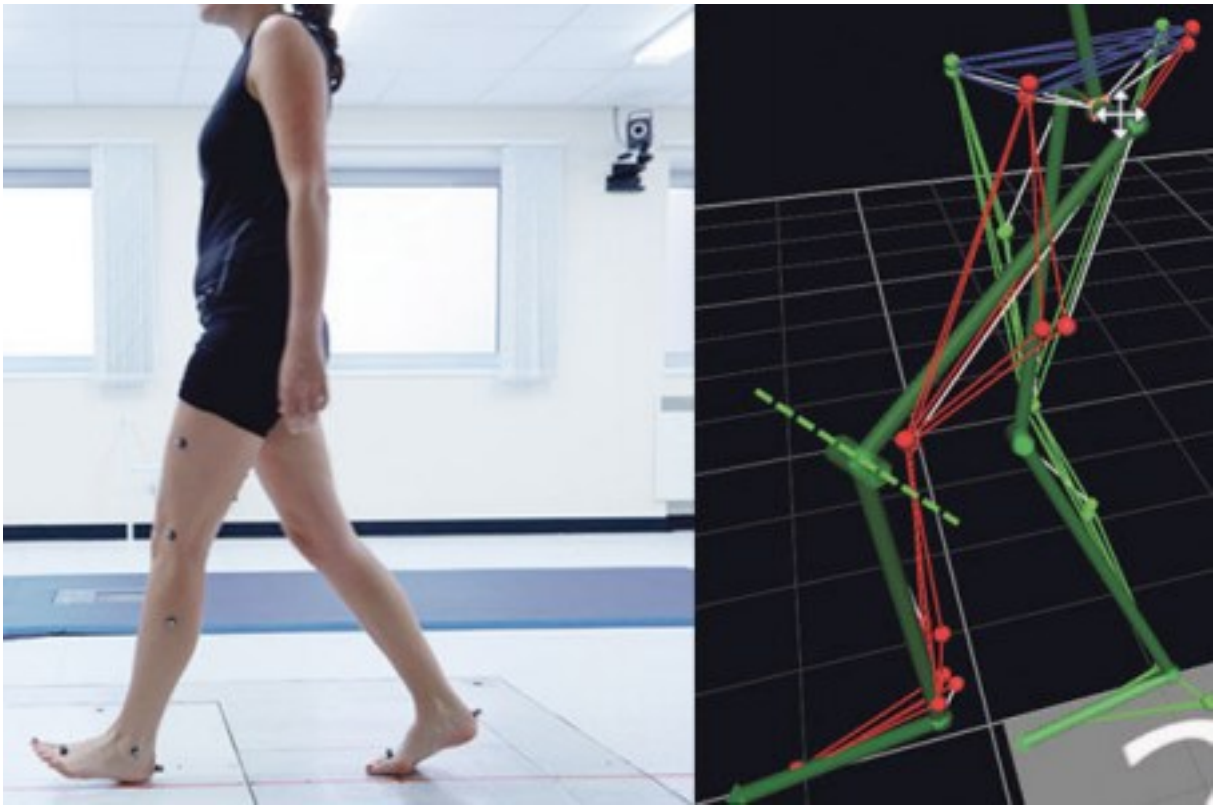

Figure2 : Gait pattern data acquisition with the Vicon system

For postural assessment, we'll be using an imaging system, called Cryovizion, which uses LED light-based technology combined with a soft-tissue reflection enhancement filter and generates a secondary image where color tones on skin surfaces vary according to distance from the camera (Figure1). When taking the image, you'll be asked to stand up straight and dressed in your underwear in different directions. Gait pattern assessment is carried out using a motion capture technology called Vicon (Figure2) which is identical to that used in the film industry. This assessment will be carried out wearing short shorts and a bra for women, and bare-chested for men, so that we can apply markers (small photo reflective beads) to anatomical landmarks on your trunk, pelvis, legs and feet. A peripheral camera system will then capture the position and movement of your legs and feet as you walk down the walkway. We'll repeat this exercise a few times.

This will conclude your participation in this project.

Participants with flat or hollow feet

1st session

At your first appointment, an orthotist will ask you to remove your shoes and socks so that we can measure and record the anthropometric data of your feet. The assessment will be carried out using a measuring tape. He or she will then use a 3D scanner (CryoScan 3D) to create a digital impression of your feet. In addition, the orthotist will perform an ankle joint assessment to gather information on your joint's alignment, range of motion and stability.

This will conclude the first session. We'll plan the next session and you can leave.

2nd session

At a second appointment, an orthotist will ask you to remove your shoes and then position the orthoses in your shoes. If necessary, the orthotist will take the time to make the necessary adjustments to ensure the correct anatomical fit of the orthoses. The orthotist will assist you in completing an initial orthotic assessment questionnaire. Then we'll begin analyzing your posture without and with orthotics, as well as your gait pattern.

Figure3 : Cryovizion imaging system for posture assessment

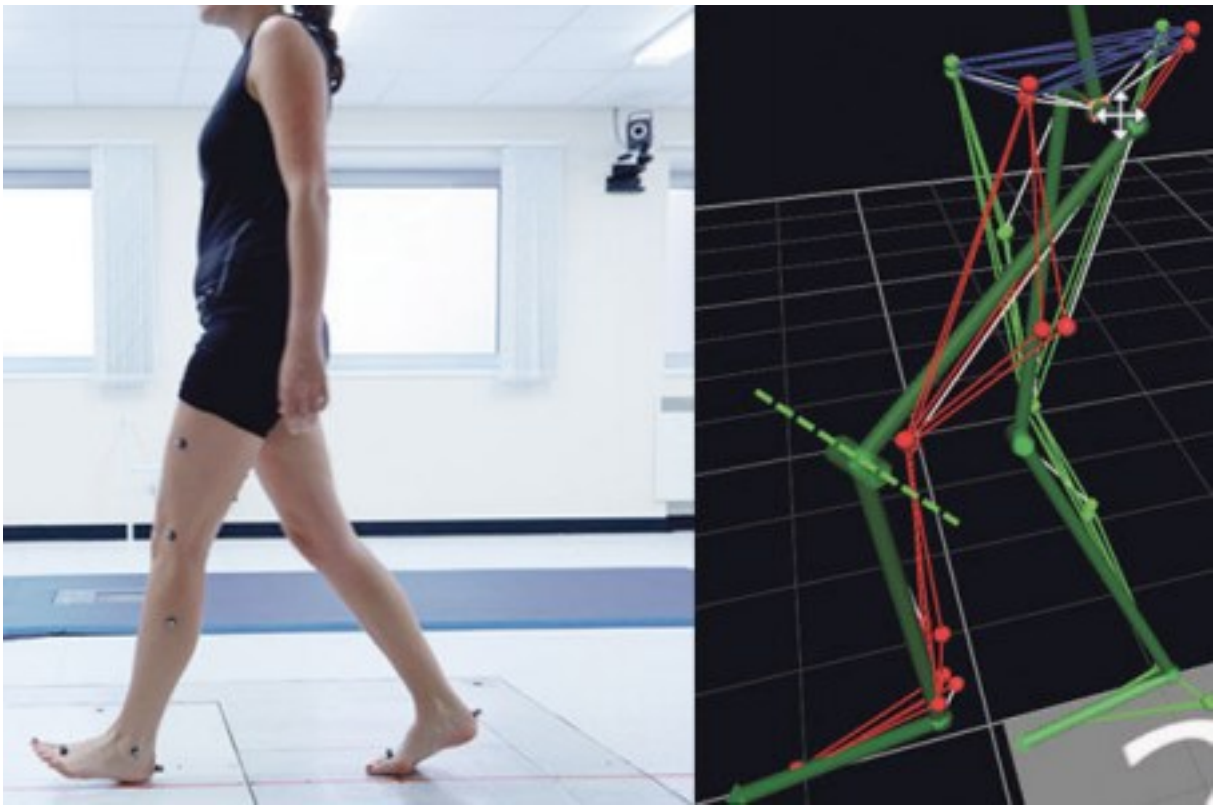

Figure4 : Gait pattern data acquisition with the Vicon system

For postural assessment, we'll be using an imaging system, called Cryovizion, which uses LED light-based technology combined with a soft-tissue reflection enhancement filter and generates a secondary image where color tones on skin surfaces vary according to distance from the camera (Figure3). When taking the image, you will be asked to stand upright and dressed in your underwear in different directions. Gait pattern evaluation is performed using a motion capture technology called Vicon (Figure4), which is identical to that used in the film industry. This assessment will be carried out wearing short shorts and a bra for women, and bare-chested for men, so that we can apply markers (small photo reflective beads) to anatomical landmarks on your trunk, pelvis, legs and feet. A peripheral camera system will then capture the position and movement of your legs and feet as you walk down the walkway. We'll repeat this exercise a few times.

This will conclude the second session. We'll plan the next session and you can leave.

Test phase

Following this session, you will be required to wear the orthoses for a period of 12 months (progressive wear for adaptation). Ideally, the duration of orthotic wear should be the same as the duration of daytime shoe wear. You'll be given a logbook to record the details of daily wear. We can provide you with a printed or digital version at your convenience.

Two weeks after the second appointment, a follow-up phone call lasting about 5 minutes will be made to find out if you have any questions or problems with the orthotics.

3rd session

At the third appointment, you will be invited to take part in the same posture and gait pattern evaluation tests as at the 2nd session.

We'll then plan the next session and you can leave.

4th session

At the fourth appointment, you will be invited to participate in the same posture and gait pattern evaluation tests as at the 2nd session.

We'll then plan the next session and you can leave.

5th session

At the fifth appointment, you will be invited to participate in the same posture and gait pattern evaluation tests as at the 2nd session.

This will conclude your participation in this project.

Probable duration of project stages (questionnaire, data collection, etc.)

Control participants

1st session : 1h to 1h30

Participants with flat or hollow feet

1st session : 1h to 1h30

2nd session : 2h

12-month trial phase

Telephone follow-up 2 weeks after start: 5 minutes

3rd session : 1h30 to 2h

4th session : 1h30 to 2h

5th session : 1h30 to 2h

Possible disadvantages and advantages

Harm: Your rights, interests and well-being will not be harmed. Privacy risks have been minimized.

Risks: An allergic skin reaction (redness) due to wearing the orthoses is a potential harm. The participant should stop wearing the brace, if necessary, and inform the orthotist.

Redness, bruising, corns, scratches and/or pain may occur at pressure points due to improper orthotic fit or placement. Injuries due to appliance breakage are also possible. The participant will have to stop wearing the device until the next adjustment by the orthotist.

Material risk: Wearing orthotics may cause premature wear of socks or shoe insoles.

No potential damage during data capture.

Benefits: There are no immediate benefits to your participation. The advantage of this data collection is that it will provide feedback on the product, which is a benefit to Cryos Technologies Inc.

Informational risks are limited by the conditions mentioned in the "Privacy and confidentiality" section, and by the professional commitment of the project team.

Information requested

We will collect data on your age, weight, height, etc.

You'll be asked if you experience pain in your feet, ankles, knees, hips and back. If the answer is yes, we'll also ask you for details about these pains.

Privacy

As this is a research and development project for an innovative product, you are required to maintain confidentiality so as not to interfere with the company's eventual marketing of the product.

Project sponsor

Natural Sciences and Engineering Research Council of Canada (NSERC)

Cryos Technologies Inc.

Project team remuneration

Members of the project team are remunerated by an NSERC grant and by Cryos Technologies Inc.

Marketing

It is possible that a commercial product may be developed by Cryos Technologies Inc. as a result of this research (see contact details below). If this is the case, you will receive no direct or indirect benefit.

Cryos Technologies Inc.
385 de Salaberry Street
Joliette (Qc) J6E 4G4

Choosing to participate in the project

You have the choice not to participate in this study and/or to participate in future research projects with TOPMED

Privacy and confidentiality

The information collected in the questionnaires, the video captures by the Vicon system, the photos and the biomechanical data collected are confidential and will only be used in the context of this research project, unless otherwise agreed by the participant. All data, notes and computer recordings (including the

Cryovizion system, photos, Vicon motion capture and foot scans) are encrypted on servers. Unless required by law, no information that could directly or indirectly reveal your identity will be released or published without your prior explicit consent.

Data will be kept for a period of five (5) years, then anonymized in a database for retention for a period of ten (10) years for the purpose of reference statistics.

Surnames, first names, telephone numbers and/or e-mail addresses will be collected for communication purposes exclusively related to this project. Participants will not be identified by name in trial documentation. They will be assigned a number, in the order of their recruitment, which will be used to reference the data collected

Data access

All research data will be accessible to the project team. Project sponsors will not have access to research data. Participants will not have access to research data. The Research Ethics Committee, Veritas IRB, will have access to research data for verification in the event of a complaint. Where appropriate, data will be made available to them for viewing only via videoconferencing.

Personal injury compensation, legal rights

By signing the consent form, you do not waive any of your legal rights.

Compensation

Participants with normal feet (controls)

A total compensation of $25.00 is provided for your participation in the complete evaluation protocol.

Participants with flat or hollow feet

A total compensation of $200.00 is provided for your participation in the complete evaluation protocol. This amount will be distributed over the last four sessions: $30 at the 2nd session, $40 at the 3rd session, $50 at the 4th session and $80 at the 5th session. Your legal rights will be maintained. What's more, you'll be able to keep your foot orthotics at the end of your participation, provided you complete all the sessions.

You have the right to change your mind

Your participation should be entirely voluntary. You may refuse to take part in this project now, or you may decide to withdraw at any time, without having to give any reason, and without any penalty. You may notify any member of the project team of your intention verbally or in writing. In the event of your withdrawal, the data collected will be used under the same conditions indicated in this document, unless you request otherwise. Your decision not to participate in this research project or to withdraw will have no consequences.

Do not modify the orthosis

If you feel that the brace needs adjustment, please contact TOPMED. Any deliberate alteration of the orthosis not carried out by the orthotist, i.e. not due to normal wear or incident during wear, will render the participant's data ineligible. In this case, we will be obliged to terminate the validation process and no compensation for participation will be admissible.

New information

In the event of any inconvenience arising from the prototype validation test, you will be promptly notified.

For more information?

Contact :
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E-mail : mlancelot@topmed.ca

Ethics review

This study has been reviewed by the Veritas Independent Review Board (IRB). If you have any questions about your rights as a research participant or about the researcher's responsibilities, you can contact the director of Veritas IRB 24 hours a day, 7 days a week at 514-337-0442 or toll-free at 1-866-384 -4221. An IRB is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of research projects with the rights and welfare of the subject in mind. If you have any comments, complaints or concerns related to the study, you should first contact the study investigator. Please call the IRB if you need to speak to someone independent of the principal investigator and research staff, and/or if the investigator and research staff could not be reached.

Declaration of consent

I, (print name) _____, acknowledge that I have read the form and understand the information provided to me in order to give informed consent. All my questions have been answered to my complete satisfaction. I have had sufficient time to consider my decision whether or not to participate in this study. I understand that my participation in this study is entirely voluntary and that I may decide to withdraw at any time, without penalty.

I voluntarily consent to participate in this study and authorize the TOPMED research team to record my portrait and person on videotape, audiotape or other audiovisual or electronic medium for data collection purposes.

Signature: _____ Date : _____

Member of the research team who interacted with the subject

To the best of my knowledge, the information on this consent form and the information I have provided in response to any questions fairly describes the project. I agree to conduct this study in accordance with all ethical standards applicable to projects involving the participation of human subjects. I undertake to ensure that the subject receives a copy of this consent form.

Name (please print) : _____

Signature: _____ Date : _____

Principal investigator

I undertake to conduct this study in accordance with all ethical standards applicable to projects involving the participation of human subjects.

Name (please print) : _____

Signature: _____ Date : _____