INFORMATION AND CONSENT FORM

Approved in French on May 8th 2024

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NCT06655558

Title of the project :

Clinical effect validation of a knee orthosis

Team

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Why are you receiving this form?

We are inviting you to take part in a clinical trial for a knee orthosis designed for a developing gonarthrosis. This orthosis aims to compensate for biomechanical deficits without reducing comfort, while being easy to equip. We are currently looking for 50 participants.

The information provided aims to help you understand exactly what is being asked so that you can decide whether you want to participate in this study or not. Please read the form carefully and ask any questions before making your decision. Take all the time you need and consult with whomever you choose if necessary. Your participation should be entirely voluntary. You may refuse to take part in this project without having to give any reasons and without any penalty. There will be no infringement on your rights, interests, or well-being.

Why are we doing this study?

The aging population is steadily increasing, partly due to increasing life expectancy. At the same time, chronic diseases, including those affecting the musculoskeletal system (e.g., osteoarthritis), whose prevalence increases with age, limit the daily activities of those affected and thus affect more and more people. Arthrosis is the most common form of these diseases worldwide. According to the l'Institut de la statistique du Québec, nearly one in two Quebecers aged 15 and over is affected by a chronic health problem.

Knee orthosis is one form of treatment that helps patients suffering from knee gonarthrosis. This treatment aims to compensate for certain biomechanical deficits in patients. A variety of joint configurations exists to target specific biomechanical deficits. A constant challenge for companies manufacturing orthoses is transmitting the orthosis's biomechanical effect to the patient. The desired effect requires a change in the forces applied inside the knee, but the orthosis cannot directly transmit forces to the patient's bones due to its external nature to the body. Customization of orthoses is crucial to improve the transmission of the biomechanical effect as well as tolerance to it. O3D Inc. aims to validate the effectiveness of its new custom orthosis for treating knee gonarthrosis symptoms.

If you have any question, do not hesistate to contact the research team:
Phone : (418) 780-1301
email : etudes@topmed.ca

Participants inclusion criterias :

- Suffering from medial gonarthrosis;
- Being between 18 and 75 years old inclusively;
- Receiving a regular model of the O3D orthosis.

Participants exclusion criterias :

- Suffering from tricompartmental gonarthrosis
- Having completed the delivery appointment for a O3D orthosis.

What will you have to do ?

You won't need to travel to participate in the study. You'll be required to fill out two online questionnaires via the secure Lime Survey platform according to the following process:

- The first questionnaire must be completed before beginning to wear the custom orthosis (total duration of approximately 18 minutes). Participants who have already started their treatment will no longer be eligible for the study.
- 8 weeks after receiving your orthosis, a second questionnaire will need to be completed again (duration of approximately 15 minutes).
- Agree to have your anthropometric data measured during your orthothic-assessment session as well as the dates of your appointments communicated to the research team.

Prejudices, risks et possible advantages

Prejudices: There will be no infringement on your rights, interests, or well-being. Risks related to confidentiality have been minimized.
Risks : Informational risks are limited by the conditions mentioned in the "Protection of Personal Information and Confidentiality" section as well as by the professional commitment of the project team.
Avantages : Your participation will not result in any immediate benefits, except for the benefit of providing information to O3D Inc. about the effectiveness of its orthosis.

Requested information
We will collect data related to your health status: age, sex, height, weight, and history of orthosis wear, as well as your symptoms related to your knee gonarthrosis and their effects on your quality of life. You will be required to answer questions about your pain in various daily life situations on two occasions. Several anthropometric measures of your fitted leg acquired during the impression-taking session will be communicated to us. These data will be used in the analyses to explore relationships with treatment effectiveness.

Project sponsor
Natural Sciences and Engineering Reasearch Council of Canada. (NSERC)
O3D Inc.

Commercialization
It is possible that a commercial product may be developed by O3D Inc. as a result of this research (see contact information below). If this is the case, you will not receive any direct or indirect benefit from it.
O3D Inc.
303, 5425 de Bordeaux
Montréal, QC
H2H 2P9
1.888.633.7226

Conflict of interest; real, potential and perceived
The project team members are remunerated through a grant from NSERC, a portion of which comes from O3D Inc.

Choices regarding your participation to the project
You have the choice not to participate in this study and/or to participate in future research projects with TOPMED. You also have the choice to withdraw from this study at any time, without any penalty. The services you receive from O3D Inc. and your orthopedic care clinic will not be affected in any way. If you decide to withdraw your participation, it is important to inform a member of the research team whose contact information is included in this document. All identifying material and the data you have provided will then be retained, unless you request data destruction from a member of the research team. If requested, they will be retained according to the measures described below and which will be applied to all participants. We would

like to thank you for your valuable collaboration in this research. We appreciate the time and attention you dedicate to it.

Mathieu Germain Robitaille, M. Sc. Kinesiologist, research professional, TOPMED
Phone. : (418) 780-1301
email : mgrobitaille@topmed.ca

Protection of Personal Information and Confidentiality
The information collected in the questionnaires will only be used within the scope of the current research project unless otherwise agreed upon by the participant. All questionnaires have been created on the Lime Survey platform. The processed information will be hosted in Canada on encrypted servers (Secure Socket Layer procedure) of the platform that comply with GDPR standards. Unless required by law, no information that could directly or indirectly reveal your identity will be disseminated or published without obtaining your explicit consent beforehand.
The data will be retained for a period of five (5) years, then anonymized in a database for preservation for a duration of ten (10) years for reference statistics.
Participants will not be identified by their name in the documentation of the analyses. Instead, they will be assigned a number relative to the order of their recruitment, which will be used to reference the collected data. The list of codes linking your name to your research record will be kept in the office of the principal investigator (at Collège Mérici, 4th floor), in a locked filing cabinet.

Access to the information
The entire research dataset will be accessible to the project team. The project sponsors will have access to research results from aggregated analyses but will not have access to individual participant results other than the encoded anthropometric data used for orthosis fabrication. Participants will not have access to research data except for their own records upon specific request. The Research Ethics Committee, Veritas IRB, as well as NSERC, will have access to research data for verification in case of complaints. If necessary, data will be made available to them for viewing only through video conferencing.

Compensation for bodily harm, legal rights
By signing the consent form, you do not waive any of your rights, and you do not release the researcher in charge of the research project, the funding agency, or the institution from their civil and professional liability.

Compensation
There will be no compensation.

You have the right to change your mind
Your participation should be entirely voluntary. You can refuse to take part in this project right now, or you can decide to withdraw at any time, without any penalty. You can also end your participation by ceasing to respond to the online questionnaire by closing the Lime Survey web page. You can also communicate your intention

verbally or in writing to any member of the project team. In the event of participant withdrawal, the collected data will be used under the same conditions outlined in this document, unless you request otherwise.

New information

If any inconvenience were to occur because of the data collection, you would be promptly notified.

How to obtain more information ?
Communicate with:
Mathieu Germain Robitaille, M. Sc. Kinesiologist, research professional, TOPMED
Phone : (418) 780-1301
email : mgrobitaille@topmed.ca
Édith Martin, Ph.D., General Manager, TOPMED
Phone : (418) 683-2104
email : emartin@topmed.ca

Review of the ethical aspects of the project
This study has been reviewed by 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 conduct initial and ongoing ethical review of research projects with the participant's rights and well-being in mind. If you have comments, complaints, or concerns related to the study, you should first contact the study investigator. Please call the IRB if you need to speak with someone independent of the principal investigator and research staff, and/or if the investigator and research staff could not be reached.

Consent declaration
I, [_____your name in block letters], acknowledge having read the form and understand the information provided to me so that I can give informed consent. All my questions have been answered to my satisfaction. I have had enough time to reflect on my decision to participate or not in this study. I understand that my participation in this study is entirely voluntary and that I can decide to withdraw at any time, without any penalty.

I voluntarily consent to participate in this study.

Signature : _____ Date : _____