



Research Project: Development of an intelligent robotic knee device to support and monitor rehabilitation therapy for patients with knee osteoarthritis

Participant Information Sheet (Version 3)

This study has been reviewed and given a favourable opinion by University of Leeds Research Ethics Committee on _____, ethics reference _____

You are being invited to take part in the above research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask the research team if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

What is the purpose of the project?

The project is to test and validate a knee device prototype that has been designed to support and monitor the rehabilitation process for patients with knee osteoarthritis and provide scientific evidence for clinicians to evaluate rehabilitation exercises.

Why have I been chosen?

The research aims to test the exoskeleton prototype on both healthy people and those with knee osteoarthritis to evaluate the usability of the prototype, the accuracy and reliability of the monitor function and the muscle support function. To ensure the exoskeleton can meet the needs of different users, participants with different heights, weights and genders will be included during the experimental tests.

What do I have to do? / What will happen to me if I take part?

You will be invited to the Rehabilitation Robotics Lab or Biomechanics Lab at the University of Leeds. You will be asked to wear the exoskeleton which will be attached to the area from the knee to the ankle and the thigh. Also, you might be asked to wear a backpack (part of the exoskeleton device) that contains the motor, pulley, batteries and electrical components. The researcher will help you put on and take off the device if you experience difficulties. You will be asked to wear the prototype to perform different types of rehabilitation exercises

such as walking, cycling, lounging, squatting and straight leg raising in the designated lab space. You might be asked to wear one of the existing assistive devices such as a knee brace or shoe insoles and perform the same exercises as above. The experiment session will not exceed more than 2 hours. The exoskeleton will assist your exercises by providing muscle support to your knee joint.

We will ask you questions about the comfortability of using this device at the end of the experiment. The total time for you to wear the exoskeleton will not exceed 4 hours and you will be able to take regular breaks by taking off the exoskeleton during this period. We will take some photos and videos, specifically focusing on the knee joint.

What are the possible disadvantages and risks of taking part?

The experimental procedure requires you to do some exercises and the exoskeleton will assist you during these exercises. There will be a possibility of feeling uncomfortable around your knee joint, please inform the researcher immediately.

To increase the comfortability and decrease the friction forces between the exoskeleton and your skin, a layer of soft material will be between them. You will be advised to wear long trousers/joggers/leggings during the exercises to avoid direct contact between the skin and the exoskeleton. At the first stage, the pulling force generated from motor to cable will be minimum and the rate of doing these exercises will be slower than normal exercises. The speed will gradually be incremented to meet the same speed of the normal rate of movements.

The exoskeleton has an emergency button to stop its motion and turn off the system in case any risk could happen to you during the experiments.

What are the possible benefits of taking part?

Whilst there are no immediate benefits for those people participating in the project, this work will help the researchers to evaluate and refine the prototype to improve the usability, comfortability and reliability of the exoskeleton. This will speed up the translation of the technology, which will prevent the progression of osteoarthritis and delay the need for surgical treatment such as the total knee replacement; and will also speed up the recovery for patients having undergone a total knee replacement, which will significantly improve the life quality of the ageing population with knee osteoarthritis and reduce cost for the NHS.

Do I have to take part?

It is up to you to decide whether to take part in this research. If you do decide to take part, you will be given this information sheet to keep (and be asked to sign a consent form) and you can still withdraw at any time without it affecting any treatments that you are entitled to in any way. You do not have to give a reason.

Will my taking part in this project be kept confidential? / What will happen to the results of the research project?

Your privacy issues such as the real name will not be obtained in any other form. During the experimental test, participants' height, weight, gender and age will be presented in research without revealing any details that could make you known to others. During the experiment, no privacy or sensitive information (including photos and videos) will be disclosed to the irrelevant people except the researcher himself (and the necessary consultant) who has further knowledge of the participants. In data storage process, participants will be named as pN where p stands for participant and N is a digit. For example, the first participant will be named as p1. The collected data will be stored for 10 years in a trusted university repository (One drive) anonymously. Moreover, the collected data might be discarded before this period if it is not needed more for the project.

The study may be published in the journal, and your data will be fully anonymous without referring back to you to take your permission for publication.

Withdrawing

You have the right to withdraw at any time during the experiment, but once the experiment is completed, the collected data from you is valid and we have the right to store or use it.

Contact for further information

The contact details of researchers:

Name (title, first name, last name)	
Department/ School/ Institute	
Telephone number	
University of Leeds email address	

The contact details of main supervisor:

Name (title, first name, last name)	
Department/ School/ Institute	
Telephone number	
University of Leeds email address	