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Instrumented Treadmill for Gait Analysis

An Academic Research Study for a MD(RES)

Research Patient Information Sheet

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Invitation

You are being invited to take part in an educational research study for a MD(RES). 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 us if there is anything that is not

clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Our primary intention is to develop a tool to help us analyze function and malfunction of the hip and knee joint. The information produced from this tool will assist to compare surgical interventions, to assess functional outcome and to assess rehabilitation, all with regards to hip and knee disease.

Why have I been chosen?

You are someone who has had problems with a hip or knee. The treadmill will allow us to assess how you are performing prior and subsequent to intervention, and allow us to understand the extent to which the intervention may be or has proved to be successful.

Do I have to take part?

No. It is entirely up to you. If you would like to take part, you will be asked to sign a consent form. Even after you have signed this consent form and agreed to join the study, you are free to withdraw from the study at any time. If you decide not to take part, or withdraw from the study, it will not affect your current or future treatment by this department in any way. At all times we will aim to give you the best possible treatment.

What will happen to me if I take part?

Once you have decided to take part in this research, you will be asked to come to the Biodynamics Laboratory, where a member of our research team will discuss the study

with you and answer any questions you may have. If you are still happy to take part, we will ask you to sign the consent form.

You will be asked to attend 2 or more sessions in the Biodynamics Laboratory, lasting about 1hr each time. (Unless you have had the joint replacement, then it is only once.)

N.B. You will need to bring a pair of comfortable walking shoes during the assessment.

You will be asked to complete some questionnaires that will assess your hip/knee joint function and pain, your physical activity levels and activity aspirations. The questionnaires should take no longer than 15 minutes to complete. You will be required to complete the questionnaires online via JointPro database. As part of your care you may have previously completed the questionnaires online and if so we will then like to ask permission to access and retain this data for the purposes of this research study.

We will place you on a commercially modified treadmill and ask you to carry out several tasks, which include walking on flat ground, and walking both uphill and downhill. We will modify the speed and the slope of the treadmill within the limits of comfort, to assess what you feel comfortable with. We will also ask you to stand on one limb as long as possible.

Optional assessment: Recording electrical activity of muscles and sounds from joints (available at Charing Cross Hospital)

You will be invited to participate in an additional part of the study, which monitors the activity of a number of muscles while performing the gait analysis treadmill testing and the sounds produces by the joints. In order to record the electrical activity from the

muscles (electromyography), small surface stick-on electrodes will be placed on the skin over some of the muscles involved in walking, e.g., leg muscles, thigh muscles, buttock muscles and trunk muscles (back and stomach). In order to record the sound made by joints during the gait analysis treadmill testing, a microphone will be taped to the skin close to the joint in question. Additional data will be collected while you are resting (lying flat) and during passive and active joint flexion and extension. If you choose to consent to the joint sound assessment, you will be required to complete the HOOS/KOOS questionnaire pre-op and post-op at 6 months for patients undergoing surgery. You will also be required to complete a Physical Activity (PA) questionnaire in order to explore the effect of PA level on joint sound production. We will also like to take a video footage using depth cameras. Video footage will be collected from the posterior position (the whole body from the rear) and anteriorly (waist down only). No Identifiable image will be recorded. Please note this is an additional part of the study and you are not required to take part in it as part of the main gait analysis treadmill test.

After consenting to the study, if you have then undergone surgery, we would like to ask you to complete an additional questionnaire retrospectively at your 6 month post-op follow up visit. We will ask you to remember how you felt before your operation and complete the questionnaire accordingly. Please note this is an optional part of the study and you are not required to take part in it as part of the main gait analysis treadmill test.

We will also be requesting for your permission to access and retain any previous imaging data you may have taken as part of your standard of care in relation to this

study. You will be asked to sign a clause in the consent form agreeing to accessing your imaging data and medical notes for the purposes of this research.

What are the side effects, and are there any risks in taking part?

You may find that some of the tasks we ask you to perform cause you some discomfort, pain or feeling a sense of instability. Should this happen, please inform the researcher, and if you need to rest or want to stop, you can do so at any time. We do not want to cause you any pain, but do want to understand the limits of comfortable function for you at this particular time in your journey. The treadmill is fitted with hand rails, harness, "stop" cord, and an emergency stop button for your safety and to prevent any accidents from occurring.

What are the possible benefits of taking part?

There are no clear benefits to you from taking part. However, the information we get from this research might help in the future with management of joint disease. It also might help assess how well a certain intervention worked on an individual. It may also help in the assessment of a patient rehabilitation process. We also expect that you will gain a strong sense of what you can and cannot do, if this was not already apparent to you. If you have not yet had treatment, or if you have already been treated, this may help us all appreciate any limitations you experience.

Will my taking part in this study be kept confidential?

Any information you give us will be kept strictly confidential. If the study is published in a book or scientific journal, no individual will be identified in anyway.

What if something goes wrong?

If you have any complaints, for example, about your treatment by the investigators or the way the study is run, please direct these to the Principal Investigator (Professor Cobb), or the co-investigator (Miss Victoria Manning: v.manning@imperial.ac.uk) or the Trial Co-ordinator (David Egbosimba: d.egbosimba@imperial.ac.uk), who will deal with them accordingly.

Imperial College London holds insurance policies, which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Dr victoria Manning; v.manning@imperial.ac.uk). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

What will happen to the results of the research study?

The results of the study will be analysed by the research team and presented at health care conferences and published in scientific journals. No individual subject will be identified in any report or presentation arising from the research. If you would like to receive the results of the study when completed, we are happy to send it to you

electronically as an email or by royal mail. Please, tick the box in the consent form along with your details if you would like this information.

Who is organising and funding the research?

This research is being part funded by the Engineering and Physical Sciences Research Council (EPSRC) and the Wellcome Trust. The study will be run by a research team based at Imperial College, London.

Will I be paid for taking part in the study?

You will not be paid for your participation in the study, but we will pay for your travel expenses to Charing Cross Hospital. Please keep the receipts for your journey as these will be required for your reimbursement.

Who has reviewed the study?

This study has been submitted to London-Camberwell St Giles Research Ethics Committee.

Contacts for further information:

If you would like to consider this study further before you make your decision, please take your time to do so. You may ask for further information by telephoning 020 331 38832, which has a 24-hour answer phone. The person to speak to is the investigator, Miss Victoria Manning (v.manning@imperial.ac.uk), or the Clinical Trial Co-ordinator, Hardeep Johal (h.johal@imperial.ac.uk). You may also send an email to treadmill@imperial.ac.uk to request further information.

Inclusion:

1) Participants must be safely ambulatory without assistive devices.

2) Participants must be between the ages of 18-90

3) Participants must be able to give written informed consent to study

Exclusion:

1) Participants who suffer from any neurological or musculoskeletal conditions that might make a gait test dangerous.

2) Participants whose cognitive function prevents them from understanding the study

3) Participants who suffer from medical conditions that might be jeopardised by the exercise.