DEPARTMENT OF BIOMEDICAl ENGINEERING

University of Strathclyde Engineering

15/05/2019 version 2
IRAS ID: 244306

Participant Information Sheet

Name of department: Biomedical Engineering

Title of the study: Stability and gait analysis of lower limb prosthetic users

Introduction

We wish to invite you to take part in a research study. The study is being organised by the University of Strathclyde. Before you decide, it is important for you to understand why the research is being done and what you would need to do.

Please take time to read the following information carefully. Talk to others about the study if you wish. You are free to choose whether to not to take part. If you decide not to take part this will not affect the care you receive**.**

If you have any questions about this study you may contact a member of the research team using the details at the end of this document.

This information sheet is divided into two parts:

- **Part 1** tells you the purpose of this study and what will happen to you if you take part.
- **Part 2** gives you more detailed information about the study.

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Part 1 – Purpose of the study

What is the purpose of this study?

This research aims to study the stability of prosthetic users whilst walking. This study is a part of a larger PhD study and aims to collect information that will be used for comparison with able bodied walkers who will be recruited in a separate study. This study will focus on measuring the limits of your stability during walking, to learn how your body reacts during walking and to know how balanced your body is. In order to do so, an advanced motion capture system called CAREN will be used as shown in figure 1. This tool uses a sophisticated treadmill which collects data during walking, such as joints angles. Furthermore, the tool uses infrared cameras that can detect the movement of special markers attached to your body allowing to build a 3D model of your body. Using this data with appropriate analysing, the research team can find how balanced your body is and then compare it to other subjects' results.

Figure 1 The CAREN System located at National Centre of Prosthetics and Orthotics, University of Strathclyde. The system is an advanced treadmill with integrated motion capture cameras. Furthermore, for safety the system has a harness that can hold the full body weight to prevent any falling.

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Why have I been invited to take part?

We require unilateral (one-sided) below the knee lower limb prosthetics users to compare their stability when walking with a comparative able bodied population who will be recruited in separate study. To take part you should be able to walk without walking aids; have no visual impairments or neurological deficits affecting the contralateral (other) limb; no current problems with your prosthesis; been a prosthetic user walking with a prosthesis for minimum a year; aged 18 and older. Unfortunately, a subject who is unable to walk, uses walking aids, suffers from motion sickness, skin condition or those who are pregnant will not be able to participate.

Do I have to take part in the study?

No, it is up to you to decide whether or not to take part, since participating in this study is completely voluntary and you may withdraw at any time. Also, even after agreeing to participate in our study, you are still free to withdraw at any time and without giving a reason. However, your anonymised data (i.e. data which do not identify you personally) cannot be withdrawn once they have been included in the study. Participating or not participating in this project will in no way influence your standing or relationship within the University, the charity or NHS Trust.

What will I do in the study?

If you volunteer, you will be invited to attend **a single lab session** at a time of mutual convenience. The session will take place in the CAREN Laboratory CU241a, National Centre for Prosthetics and Orthotics, Curran Building, Department of Biomedical Engineering, University of Strathclyde, 131, St James Rd, Glasgow, G4 0LS.

On arrival at the National Centre, an initial screening session; which will last for approximately 10 minutes; will be carried out in order to determine if you match the study's criteria. A brief introduction about the experiment will be given to you, including what will happen. Any questions that you have will also be answered. If you match the study's criteria and happy to take part in the study, the consent form will be given to obtain your signature.

Secondly, you will be asked to change into appropriate tightly fitted clothing required for accurate marker placement. Lycra shorts may be provided and all participants will be asked to wear a 'snugly fitting' t shirt. Changing facilities are available in the place. Please note only lycra shorts can be provided.

Thirdly, reflective (tracking) markers will be attached to several landmarks, some of which will be on bare skin (e.g. knee joint) and some over the tight-fitting clothes (e.g. pelvic markers) using a low allergen tape (see figure 2). These markers are used in order to capture the subject's movement by the CAREN system which is motion capture system that uses infrared cameras to detect the movement of the attached reflective markers.

You will be walking while wearing your own prosthesis and there will be no changes made.

Following that, you will be assisted onto the motion platform and immediately secured into the safety harness integrated within the CAREN system which can support your full weight and in case of fall, you would not contact the ground. Then, you will walk for around 5 to 6 minutes to become familiar with the system as well as to find the self-selected walking speed.

After that, you will perform 8 trials each one will be for 3 minutes under these conditions:

- One trial with no disturbance (normal walking) with fixed speed.
- Six trials that include treadmill deceleration and treadmill acceleration on each leg with different intensity applied in a random order.
- One Self-pace mode trial in which you control the treadmill speed by slowing down or walking faster.

Breaks and refreshments will be provided between trials but you can take further rest breaks whenever needed. You can also stop the trials at any point.

As you complete the trials, you will be assisted from the motion platform immediately after being unclipped from the harness and the reflective markers will be removed. The appointment is expected to up to 2 hours

There will be video recording upon your approval, please know that any identifiable features in any video recorded will be pixelated, (identifiable features will be blurred), for anonymity.

Figure 2 Participant wearing appropriate clothing with markers being attached

What are the possible benefits of taking part?

There are no direct benefits to you from participation. However, the study will help researchers and prosthetic specialists to learn more about the dynamic and the biomechanical properties of prosthetic users. This information might be taken into account in the future and may inform clinical decision making in choosing which rehabilitation training program would most match individual patient needs.

What are the possible disadvantages and risks of taking part?

Overall, the study is considered to be low risk, the potential risks include;

1. The risk of slipping or falling which is minimized to the lowest by the safety harness integrated within the system which can support your full body weight. Moreover, if this happens the researchers will stop the treadmill immediately. Additionally, one of the research team members will be standing close to you during testing.

2. Testing requires some markers to be attached to the skin with non-allergenic adhesive tape. Very occasionally, this can cause mild skin irritation. This should only be a temporary irritation since the markers will only be in place for a short time and will be very

carefully removed. If you develop a reaction to the tape, the markers will be removed immediately. Removing the reflective markers attached with tape may cause mild discomfort, but these will be removed very carefully, or if you prefer, you can remove them yourself.

3. Motion sickness or fatigue. You will not be active throughout the entire session. Rest breaks are built in between tests while equipment is prepared. Moreover, you will be able to rest as required and refreshments will be provided. You will not be asked to perform any activity which causes distress to you and you will be encouraged to communicate if you are feeling unwell. You can also stop at any time during the trial if you want to.

What happens when the research study stops?

You will continue to receive your standard clinical care. Being involved in the study will not lead to a change in treatment or your standard clinical care.

THIS COMPLETES PART 1 OF THE INFORMATION SHEET

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Part 2 – Further information about the study

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time by speaking to a member of the research team or by writing to us. You do not have to give a reason for not wanting to carry on with the study and the care you receive will not be affected because of your decision.

The data for the study will be written up by a PhD student as part of the degree. If you decide you want to stop being in the study before the data has been analysed it can be removed from the study. If you decide after this point it will not be possible to take your data out of the study.

Participating or not participating in this study will in no way influence your standing or relationship within the University, the charity or NHS.

If the study is stopped for any reason, you will be told why. Your care will not be affected.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to any or all of the researchers who will do their best to answer your questions. Please contact the chief investigator, Dr Anthony McGarry, on 01415485868 or by email to anthony.mcgarry@strath.ac.uk

If you remain unhappy and wish to complain formally, please contact:

Research & Knowledge Exchange Services, University of Strathclyde

50 George street, Graham Hills Building, Glasgow, G1 1QE

Telephone 0141 548 4364

Email to ethics@strath.ac.uk.

The University of Strathclyde has insurance policies that provide cover for any professional negligence of its staff and/or students.

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Will my study data be kept confidential?

All information provided will be treated as confidential information, the identifiable information in the consent forms will be stored in a secured locked cabinet in the Department of Biomedical Engineering and will be only used as instructed in University Data Management Plan. Consent forms will be retained indefinitely and will not be destroyed.

All generated data will be allocated a unique identifiable code (a number to be stored) to make it anonymous. The identified code will be password protected and will be accessible only by the research team of this study. All anonymous data will be stored on the secure university server, Strathcloud, with access only by the named researchers.

Data access and destruction will be in accordance with the University of Strathclyde Data Protection Policy. The anonymization code will be destroyed at the completion of the study (after 13 months).

Furthermore, any identifiable features in any of the recorded videos will be pixelated for anonymity and will be safely destroyed after the final submission of the PhD thesis.

None of your personal details (name, contact details and other identifiable personal information) will be used in any publication related to the study.

The University of Strathclyde is registered with the Information Commissioner's Office who implements the General Data Protection Regulations (GDPR). All personal data on participants will be processed in accordance with the provisions of the GDPR.

What will happen to the results of the study?

The findings will be written up in the form of a report, which will be included in a thesis that forms part of a post-graduate student's PhD. Furthermore, it is also likely that this post-graduate student will write papers based on our findings, and these papers will be published in a professional, peer-reviewed journal.

Who is organising and funding the study?

The research is being organised and funded by the Department of Biomedical Engineering at the University of Strathclyde.

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Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by the East Midlands - Leicester Central Research Ethics Committee; The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS. Telephone: 0207 972 2568

What happens next?

If you are interested and would like to take part in the study, please contact us using the information that is provided at the end of this participant information sheet.

If you have a concern about any aspect of the study that you wish to discuss, you can kindly e-mail or call one of the researchers to get more information about the study and/or to arrange for possible study visit.

It is entirely your choice to decide whether or not to take part in the study. If you are happy to take part and you are considered suitable for participation in the study, the researchers will schedule suitable appointment date and time. A written consent will be requested from you at the start of the trial session.

In the case that you do not wish to be involved in the study, then the investigators of this study would like to take the opportunity to thank you for taking an interest in this research study and reading the information.

If required, the researchers will arrange and pay for travel to collect and take you back home at the end of your visit. Alternatively, if you would like to make your own transport arrangements, you will receive reimbursement of travel costs.

Once the study is over, a summary of the results can be provided to you, if requested, by contacting any of the investigators on the contact details given below.

Researcher contact details:

Thank you for reading this information – please ask any questions if you are unsure about what is written here. If you have any questions about this study you can talk to one of the researchers organising it:

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