Participant Information Sheet

(Control participants)

Title of Project: Smart wearable device (gaitQ) that helps people with long-term conditions affecting movement walk better

Researchers name: Prof. Helen Dawes, Dr Mae Mansoubi, Dr Genevieve Williams, Dr Pavlos Evangelidis

Thank you very much for considering taking part in this. The sponsor of this study is the University of Exeter and therefore any references to 'we' is referring to the sponsor and not just the local site team. We would like to explain to you the reasons for conducting this research and how it would involve you should you decide to take part. Please take time to read the following information carefully and to ask if there is anything that is unclear or if you would like more information.

Purpose of the research:
Approximately one-third of adults experience mobility issues and require rehabilitation. There is a shortage of skilled rehabilitation professionals, which is why we are developing a new device called gaitQ to help. This device is designed to help people with mobility issues, starting with those with Parkinson's disease, and then those with other conditions affecting movement, such as stroke and arthritis.
The purpose of this study is to develop and test gaitQ, a device that helps people with long-term conditions affecting movement walk better, improve their quality of life, and reduce their risk of falls.

Why have I been approached?
We are seeking **30** healthy participants without any long-term conditions affecting their movement as volunteers to help us test and give feedback on the gaitQ device. You have been invited because you are healthy and aged over 18. You should be able to walk on your own with or without walking aids.
Please take time to read the following information carefully. Please discuss it with others. We need you to understand the research and what it will involve before you decide if you want to take part. This information sheet will explain more about what would happen if you took part in this study. If you would like more information or there is anything that is not clear to you, please do contact us. Thanks for your thinking about taking part.

What would I be asked to do if I decide to take part?
Before any visit
You will be given all the necessary information about the study at least 48 hours before the visit. We have outlined what is involved for the study visits below.

Getting ready for the test:
- You will be asked by the researcher to sign the consent form.
- You will fill in questionnaires that asks about you including your age, sex, occupation, medication, past medical conditions, physical activity readiness and physical activity level and about how your condition affects your everyday mobility and functioning.

- We will then set up the equipment and prepare you to get ready. You will be asked to wear a number of pieces of small devices (gaitQ device), which will be taped to your skin. Firstly, some small boxes that measure your muscle activity will be placed on your lower leg and calf muscle. To do this we may need to shave any hair in the small area which they will be attached to and clean the area with alcohol wipes.

- Another small box will be attached to you lower back, which measures accelerations. We will then either place a number of markers on your skin or ask you to put on a black, tight-fitting suit made of trousers and a top, and some shoe covers. To this suit we will attach up to 36 small shiny markers for the motion capture cameras. Lastly, you may be asked to wear a tight-fitting fabric skull cap (as shown in the following photo), that collects information on brain activity put on your head.

Getting used to the testing:

- With the equipment on, we will take you on a tour to show you the equipment and to get familiar with the place. Then we will make sure you get used to the tasks. The tasks will be first with no gaitQ device on, then with gaitQ device on. The tasks will involve siting -to-standing to sitting, walking, and turning, walking while having virtual reality (VR) headset on and balance tasks which we do gentle vibration through the machine you stand on. A virtual reality headset is a device that you wear on your head like a pair of goggles. It has screens inside that display images and videos in 3D, making you feel like you are inside a virtual world and can interact with it as if it were real.

Performing the activities at the VSimulators lab:

- We will now ask you to do the walking and balancing activities in the VSimulators which may be with and without gaitQ device. This should take around 1.5 hours. gaitQ device does gentle vibration on your skin behind your knee or on your leg. Finally, we will ask how difficult it is to do the tests and whether you feel any symptoms like fatigue or pain.

Survey after activities:

- Lastly, we will ask you to fill in a number of questions about how you get on doing activities at home and how you feel. We will ask you to perform some thinking tasks

with a pen and paper. This will take around 1 hour. We may ask you to do some movements to check your movement and coordination.

Once all the equipment is removed the testing will finish. The total duration of the session is approximately 3 hours.

Refreshments will also be given at the start of each study day and made available throughout the study.

What would happen at the end of study?
Your participation in this study ends when you complete the tests.
A summary of the study will be available upon request at the end of the study.

What are the possible benefits of taking part?
There may or may not be a direct benefit from you participating in this study. Some people do derive benefit from sharing or discussing. Your participation, however, will provide us with information on what matters to people with long-term conditions affecting movement.
Involve guidance set by the National Institute for Health Research will be followed when reimbursing you for your participation in the study. We can reimburse you for your travel and time including taxis. Unfortunately, there will be no other compensation for the study.

What are the possible disadvantages and risks of taking part?
The gaitQ device we use for this study have gone through the necessary checks to ensure it is safe to wear, following health and safety regulations set by the British Standards Institution (BSI) standards for medical electrical equipment (BS EN 60601).
There are no risks associated with the gaitQ device, however, if you do feel any discomfort or wish to stop the study at any time during the study, please inform the researcher and we will stop your participation and data collection**.**

What happens to the data collected?
After the study, we will analyse the data collected from you. To do this, your data will be transferred to a secure computer at the University of Exeter and will be pseudo-anonymized. Pseudo-anonymised data refers to data stored using your participant number only, and a separate log is kept linking your participant number to your name. This log is ONLY accessed by named researchers and will not be shared or analysed.
With your consent we may place this anonymised data into a publicly accessible database (e.g. http://www.physionet.org/). By using this approach, it allows the maximal re-use of the research carried out, and greatly enhances the impact of this work on the wider research community for future research.
It means your anonymised data may be used for new analyses, beyond the research planned here. If you do not wish your data to be used in this way you are free to opt-out of this aspect of the study. If you withdraw from this study, there will be no detriment to you. The only difference is that your data will only be analysed by researchers from the University of Exeter, the University of Oxford and gaitQ ltd.

University of Exeter GDPR Data Statement
In 2018 regulatory changes in the way that data is processed came into force, with the EU General Data Protection Regulation 2018 (GDPR) and the Data Protection Act 2018 (DPA 2018). Since the UK left the EU, the key principles of EU GDPR have been adopted in the UK GDPR (a ‘UK-only’ version) and the DPA 2018 still applies.
The University of Exeter terms its lawful basis to process personal data for the purposes of carrying out research as being in the ‘public interest’. The University continues to be transparent about its processing of your personal data and the participant information sheet should provide a clear explanation of how your data will be collected, processed, stored, and

destroyed. If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information can be obtained from the University of Exeter's Data Protection Officer via the web-link;
https://www.exeter.ac.uk/aboutoursite/dataprotection/dpo/
If you have any concerns about how your data is controlled and managed for this study, then please contact the Sponsor Representative: Dr Antony Walsh , Head of Research Governance, Ethics and Compliance (Contact details at the end of the information sheet).

What is the duration of the research?
You will be asked to come in for one visit that takes up to **3 hours**.

Where will the research be conducted?
The research will be conducted at the University of Exeter Medical laboratory at the Vsimulators facility. The VSimulators facility is located on Exeter Science Park. The study researcher (Dr Pavlos Evangelidis: p.evangelidis@exeter.ac.uk, Dr Mae Mansoubi: m.mansoubi@exeter.ac.uk or Professor Helen Dawes: H.dawes@exeter.ac.uk), will send you the detail time and address for your visit ahead of your appointment. Once you are onsite, please notify the researcher when you have arrived, and they will meet and guide you to the lab.

What will happen if I don't want to carry on with the study?
Having read this information sheet you are free to decide that you do not wish to take part.
If you do choose to participate, you are free to change your mind and to withdraw from the study at any time before and during the sessions. No questions will be asked, and it will not affect the care you receive or your legal rights if you chose not to take part.
Your rights to access, to change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

How will my information be kept confidential?
All information collected in this study will be kept strictly confidential and stored either on an encrypted password-protected computer, or in a locked cabinet in a secure office at the University of Exeter, which can only be accessed by the research team. You will be allocated a unique participant number, to ensure your information will be protected and cannot be identified outside of the research team. Any personally identifiable information will be stored separately and securely from information obtained from the research, it will only be kept for a limited time and securely destroyed within 20 years of the end of the study.

Will the outcomes of the research be published?
Yes. The results will be anonymised and will be published in scientific journals and presented at scientific conferences.

Who is organising and funding this study?
This is organised and led by Professor Helen Dawes (University of Exeter) funded by the Department of Health and Social Care through the National Institute for Health Research (NIHR) grant with the University of Exeter as the study Sponsor.

Who has reviewed this study?
This research has been registered with and approved by the Department of Health and Social Care through the National Institute for Health Research (NIHR) and Research Ethics Committee (REC).

Further information and contact details

If you have any questions or concerns at any time, you are free to ask the researcher in your session. Alternatively, for any questions, now or later, you are encouraged to contact the researchers below:

- Prof. Helen Dawes (Chief Investigator)
  University of Exeter, Medical School Building, College of Medicine and Health, St Lukes Campus, Heavitree Road, Exeter, EX12LU/ Tel: +44(0)7866138664/ Email: h.dawes@exeter.ac.uk
- Dr. Maedeh Mansoubi (Senior Research Fellow)
  University of Exeter, Medical School Building, College of Medicine and Health, St Lukes Campus, Heavitree Road, Exeter, EX12LU/ Email: m.mansoubi@exeter.ac.uk
- Dr. Pavlos Evangelidis (Postdoctoral Research Fellow)
  University of Exeter, Medical School Building, College of Medicine and Health, St Lukes Campus, Heavitree Road, Exeter, EX12LU/ Tel: +44(0)7866138722/ Email: p.evangelidis@exeter.ac.uk

Am I Insured?

The University of Exeter will provide insurance for Professional Indemnity and Public Liability with respect to the potential legal liability of the Sponsor for harm to participants arising from the management of the research, design of the research and conduct of the research.

What if something goes wrong?

If there are any issues or complaints regarding this research that you would prefer not to discuss with members of the research team, please contact the Research Ethics and Governance Team's Sponsor Representative:
Dr Antony Walsh - Head of Research Governance, Ethics and Compliance
University of Exeter, Research Ethics and Governance Office, Lafrowda House, St Germans Road Exeter EX4 6TL / Tel: 01392726621 / Email: A.Walsh3@exeter.ac.uk

Thank you for reading the above guidance and information.