**Participant Information Sheet 2**

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| Project title: | **A wearable incontinence management system** |
| Principal investigator (PI): | **Kia Nazarpour** |
| Researcher(s): | **Srinjoy Mitra, Wei Ju, Lynda Webb, Sadeque Reza Khan** |
| PI contact details: | **Kianoush.nazarpour@ed.ac.uk** |

This study was certified according to the Informatics Research Ethics Process, RT number **2021/83413**. Please take time to read the following information carefully. You should keep this page for your records.

**Who are the researchers?**

The team are members of Edinburgh Neuroprosthetics Laboratory. Kia Nazarpour is Principal Investigator. Srinjoy Mitra, Lynda Webb, and Sadeque Reza Khan are senior researchers within the team. They may be accompanied by PhD students, e.g. Wei Ju, while conducting this project.

**What is the purpose of the study?**

We work to develop a wearable system, e.g. a sock, to enhance the efficacy of clinical practice in the management incontinence. You are being asked to take part in a research study to help in understanding the wearability and efficacy of the proposed system.

**Do I have to take part?**

No – participation in this study is entirely up to you. You may decide to stop being a part of the research study at any time without explanation. You have the right to ask that any data you have supplied to that point be withdrawn or destroyed. You have the right to refuse to answer or respond to any question that is asked of you. You have the right to have your questions about the procedures answered (unless answering these questions would interfere with the study’s outcome). If you have any questions as a result of reading this information sheet, you should ask the researcher before the study begins. You will have the option of taking part in the longer or shorter experiments.

**What will happen if I decide to take part?**

We will ask you to wear the proposed system, e.g. a sock, and give us feedback about various factors, e.g. comfort, weight, etc. Upon the initial feedback, we may use a technique called non-invasive electrical stimulation to send tiny pulses to your leg and we ask you to report your sensation. We may also measure the electrical activity of your muscles, the so-called the electromyographic signals, from your leg/foot. In some experiments, we may also monitor the movement of your leg/foot with a video stream or with a sensor. These are well-known, safe and clinically certified techniques and are widely used in both academia and the NHS. However the overall system that we use is a research device, that is it is not approved as a medical device. Given that the stimulation thresholds are well below the maximum allowed ranges, and we have incorporated further protection circuits, we believe that the risks associated with our research device is minimal. The results of this experiment will constitute further evidence for us to take this device forward for clinical tests.

The experimental protocol will be as the following:

After skin preparation, e.g. wiping off any dirt from the skin with clinical level (NHS-approved) wipes, you wear a sock and embedded electronic sensors will be placed on your skin to stimulate currents or measure the activity of your muscles. Sensors will usually be placed by an experimental operator; however, you will also have the option to place them yourself. Once sensors are placed, a brief calibration routine will be performed. We may increase the stimulation current to induce a very small twitch in your foot. This level of stimulation is significantly below the pain threshold, i.e. you will not feel any pain.

In various stages of the trial, you may be asked for your opinions on the sock. Your views may be used to provide contextual information for our research. If we quote you in any research output, it will be anonymous so it cannot be traced back to you.

**Time Commitment**

Between different experimental sessions, there will be rest period of up to 30 minutes during which you can relax. The sensors may remain attached to you during the break. Therefore, we may ask that your body movement will have to be under the supervision of the research team. If the experiment takes more than 90 minutes, we will provide light refreshment, e.g. fruits, biscuits and tea/coffee. In the case of long recording sessions, buffet lunch will be provided. Please see the Participants’ Rights section for more details.

Depending on the study question, you may be asked to return to the laboratory, up to five time, to repeat the same experiment. Before you sign up in study, you will know whether it is a one-day or a multi-day study.

**Are there any risks associated with taking part?**

There are no risks associated with participation. All equipment and systems have been tested for safety. The experimental protocol is safe.

If recommended by the UK and/or Scottish Government or The University of Edinburgh Health and Safety guidelines, if required, all experimental operators will be wearing personal protection equipment (PPE). You will also be given the option of wearing such equipment. If required, social distancing measures will be maintained when contact is not necessary. The laboratory space will be clean. Any surfaces you may come into contact with will have been cleaned prior to the experiment.

**What will happen to the results of this study?**

The results of this study may be summarised in published articles, reports and presentations. Quotes or key findings will be anonymised. With your consent, information can also be used for future research. Your experimental data will be anonymised and archived on a public data repository as per the requirement of the funding agency.

**Data protection and confidentiality.**

The data we collect do not contain any personal information about you except your initials for data management and your age for statistical analysis purposes. If you would like your data to be completely anonymised you must inform us as soon as possible, preferably before signing this document. No one will link the data you provided to the identifying information you supply.

Your data will be processed in accordance with Data Protection Law. All information collected about you will be kept strictly confidential. Your data will be referred to by a unique code, e.g. participant number. Your data will only be viewed by the research team.

All electronic data will be stored on a password-protected encrypted computer, on the School of Informatics’ secure file servers and all paper records will be stored in a locked filing cabinet in the PI’s office. Your consent information will be kept separately from your responses in order to minimise risk.

**What are my data protection rights?**

The University of Edinburgh is a Data Controller for the information you provide. You have the right to access information held about you. Your right of access can be exercised in accordance Data Protection Law. You also have other rights including rights of correction, erasure and objection. For more details, including the right to lodge a complaint with the Information Commissioner’s Office, please visit [www.ico.org.uk](http://www.ico.org.uk). Questions, comments and requests about your personal data can also be sent to the University Data Protection Officer at [dpo@ed.ac.uk](mailto:dpo@ed.ac.uk).

**Who can I contact?**

Kia Nazarpour will be glad to answer your questions about this study at any time. You may contact him at [kianoush.nazarpour@ed.ac.uk](mailto:kianoush.nazarpour@ed.ac.uk).If you want to find out about the final results of this study, you can contact Dr Nazarpour directly. If you wish to make a complaint about the study, please contact [inf-ethics@inf.ed.ac.uk](mailto:inf-ethics@inf.ed.ac.uk). When you contact, please provide the study title and detail the nature of your complaint.

**Signature**

By signing below, you are agreeing that:

* you have read and understood the Participant Information Sheet 1,
* questions about your participation in this study have been answered satisfactorily,
* you are aware of the potential risks (if any), and
* you are taking part in this research study voluntarily (without coercion).

Participant’s Name (Printed)\*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant’s signature\*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\**Participants wishing to preserve some degree of anonymity may use their initials.*