



**Spinal Research Centre and Functional Assessment & Restoration Service (FARS)**  
London Spinal Cord Injuries Centre  
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## **PARTICIPANT INFORMATION SHEET**

### **NEUROMOD: Researching the effect of electrical stimulation on bladder overactivity following Spinal Cord Injury in a home pilot study**

You have been invited to participate in this research because you have a Spinal Cord Injury (SCI) which has led to some bladder dysfunction and you may respond well to neuromodulation for managing this. The aim of this research is to investigate the effectiveness of neuromodulation at improving continence and bladder capacity in day to day life at home.

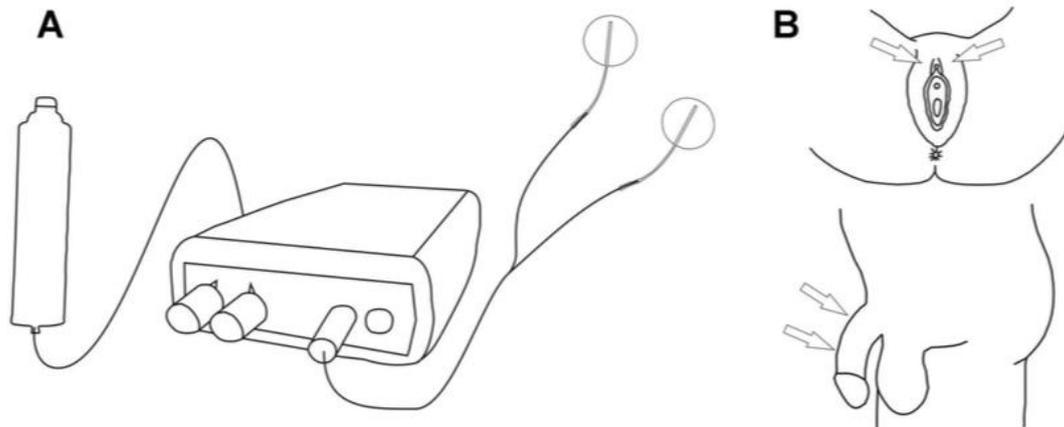
We will describe the study and go through this information sheet, we will then give you time for further consideration and answer any questions you have. Before starting the study we will ask you to sign a consent form to show you understand what will happen and agree to take part. Of course you are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. We will ask your permission to inform your GP that you have taken part.

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

After SCI, signals to and from the brain are disrupted meaning the voluntary signals telling the bladder when and when isn't a convenient time to empty are stopped. Overactivity of the bladder muscle can become a problem, leading to frequent contractions at low volumes. This may result in leaking urine and/or damage to the bladder and kidneys.

We are investigating a new management technique called neuromodulation for its effect on bladder overactivity. Neuromodulation is the alteration of nerve activity, in this case through the delivery of small pulses of electrical stimulation using surface electrodes to the nerves controlling the bladder. We know this can suppress bladder overactivity in controlled conditions, but not whether it is practical for use in everyday life.

In this pilot study we will use small electrodes placed on the penis or clitoris, over the genital nerve, and a portable stimulator controlled by you, through a smartphone app, to find out how effective this technique may be for managing your bladder overactivity at home.



**Fig. 1. A: Stimulation setup. B: Stimulation sites.**

The device being used is a non-commercial modification of a commercial stimulator that is currently used for other purposes, this is a modification that has been made to allow us to use this device for the new purpose being tested in this pilot study. The device you will use will not be available commercially when you complete the study.

### **What will happen to me if I take part?**

If you have not trialled neuromodulation in our research clinic previously you will first need to attend our urodynamics clinic (screening clinic) to test whether neuromodulation can suppress your bladder overactivity. If you have previously trialled neuromodulation we will assess the results and if eligible invite you to participate in the main study outlined below.

### **Screening clinic**

After providing informed consent, we will ask some questions regarding the impact of your injury on your bladder and the level of sensation you have with regard to your bladder function. Then baseline urodynamics, as used in regular clinics for people with SCI, will be done. This involves filling the bladder through a catheter and measuring bladder pressures simultaneously through thin lines placed in the bladder and rectum. This will be repeated, following a short break, and surface stimulation will be applied over the genital nerve as pressure rises, to assess the bladders response. We will repeat this again with stimulation and finally without stimulation. Where stimulation is able to suppress overactivity we will invite you to trial a device at home.

**Location:** RNOH **Time:** 1-2 hours

### **Diary instruction and questionnaires**

We will show how to complete the diary on a smart device with a dedicated app to record a standard bladder diary, including urine output and any leakage, alongside any occurrences of faecal incontinence and a rating of your daily spasticity. We will also ask you to complete some questionnaires regarding your bladder and health.

**Location:** RNOH (same visit) **Time:** 30 minutes

### **Recording a bladder diary at home**

You will use the device in order to record a diary for the next 3 days. This will involve pressing the appropriate buttons regarding what you drink, when you go to the toilet, any leakage that occurs, any faecal incontinence and a rating of your daily spasticity over 3 days.

**Location:** your home **Time:** 3 days

#### **Home use of stimulator with diary**

Following a successful setup session, you will be provided with the portable stimulator to take-home. You will be asked to use this to control unwanted bladder overactivity over the next 3 days and to continue recording a diary in the same app. Sticker electrodes will be worn when the system is in use, you will be provided with enough replacements.

**Location:** your home **Time:** 3 days

#### **Collection of equipment and questionnaires**

We will arrange collection of the equipment and questionnaires from you at your home. A follow-up phone call will be made to arrange this and check in at the end of the study period.

We will reimburse you £50 to cover travel expenses incurred from your visit to Stanmore.

#### **What are the risks involved in the procedures in the study?**

There are some possible risks arising from this study, these are outlined below:

- A small risk of Urinary Tract Infection (UTI) from use of catheters during urodynamics.
- If your injury is above the T6 level then Autonomic Dysreflexia is a risk. This is a condition where a stimulus below the level of your injury causes a dangerous rise in blood pressure, it has not been reported to happen due to stimulation in previous studies however remains a risk. Stimulation will be stopped if symptoms occur. We will monitor your blood pressure at regular intervals when trialling stimulation in the clinic.
- Skin irritation from electrodes is a small risk, in this case stimulation should be stopped and the electrodes removed.

#### **Will there be any benefit to me?**

If you agree to take part, this study would help patients with spinal cord injury in the following ways:

- Improve our understanding of electrical stimulations' capacity to treat bladder overactivity and how best to apply it. This will contribute to improving current bladder management and treatment options.
- A positive outcome for this study could lead to a new treatment for the improvement of continence in the SCI population.

Unfortunately, we are unable to provide you with a device for use after the study period.

#### **What happens when the research study stops?**

When the study ends, you will no longer be able to continue using the system. We're still working, through trials such as this, to establish an effective method of delivering the technique before seeking to include it in clinical options.

**What do I need to do to take part?**

If you would like to participate, please get in touch with a member of the team on the details below, or return the expression of interest form enclosed. We will talk on the phone to answer any questions and confirm your eligibility, then we will book you an initial appointment.

**Will all the information be kept confidential?**

Everyone in the project will respect your confidentiality. All information which is collected about you during the course of the research will be kept strictly confidential. Data collected will be anonymised so that you will not be identified. The anonymised study results may be published in scientific journals.

**What if something goes wrong?**

If you have any concern about any aspect of the study you should speak to the researchers who will do their best to answer your questions.

Should issues arise outside of working hours you should contact the London Spinal Cord Injury Centre desk on **0208 909 5588** who will contact a member of our team.

In the event that something does go wrong and you are harmed during the research and this is due to negligence then you may have grounds for a legal action for compensation against Royal National Orthopaedic Hospital NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

**What should I do if I have a complaint?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this contacting the Patient Advice and Liaison Service via [pals@rnoh.nhs.uk](mailto:pals@rnoh.nhs.uk) or 020 8909 5439/5717.

**Who has reviewed and funded the study?**

The INSPIRE National Scientific Committee has approved this project for funding and London-Stanmore Research Ethics Committee has given approval for this study to take place. The study is funded by INSPIRE Foundation charity.

*If you have any further questions regarding this investigation please contact:*

**Dr Sarah Knight or Sean Doherty  
at the Royal National Orthopaedic Hospital  
0203 947 0606 or [sean.doherty.15@ucl.ac.uk](mailto:sean.doherty.15@ucl.ac.uk)**