PATIENT INFORMATION SHEET

1. **Study title**

Single-centre pilot-study to determine the optimal sacral neuromodulation stimulation parameters to treat idiopathic detrusor overactivity and dysfunctional voiding.

2. **Invitation paragraph**

You are being invited to take part in a research study. Before deciding, 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 friends, relatives and your GP if you wish. Ask us if there is anything that is unclear or if you would like more information. Take time to decide whether or not you wish to take part.

Further impartial information about what it means to be part of a research study and your rights as an individual can be obtained in person from the Patients Advisory Liaison Office, situated at the footbridge entrance to the hospital at floor 2. They can be contacted on the telephone via switchboard. Alternatively, you may contact the Trust Research and Development offices via switchboard on 0207 188 7 188 during office hours.

Thank you for reading this.

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

The mechanisms of action for Sacral neuromodulation (SNM) is still not fully understood, in particular, how the same therapy (same surgical procedure and neuromodulator stimulating parameters), can treat two contradictory bladder conditions. Overactive bladder (OAB) which is characterised by increase urinary frequency, urgency and incontinence with associated reduced bladder capacity. In contrast, dysfunctional voiding (DV) is associated with reduced sensation, increased capacity and difficulty emptying the bladder.

It is thought that both diseases (OAB and DV) result from inappropriate activity of the pudendal nerve (PN) which controls the external urethral sphincter. With OAB and DV patients having decreased and increased PN activity respectively. Electrical stimulation of the PN aims to 'normalise' the activity to the urethral sphincter.

Currently, the frequency of stimulation is the same when treating both OAB and VD patients. Whether PN stimulation excites or relaxes the sphincter may be frequency dependant. We propose to assess different stimulation frequencies to determine if we can optimise symptom improvement for each disease.

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4. Why have I been chosen?

Because you have been diagnosed with dysfunctional voiding / High Tone Non-Relaxing Sphincter (HTNRS) during your urodynamics study and you have agreed to undergo a trial of SNM therapy.

5. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to participate you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw from the trial at any time and without giving a reason. This will not affect the standard of care you receive.

6. What will happen to me if I take part?

If you decide to take part in the study, we will use the information already gathered from your medical history.

Usual standard of care include:

- Initial day surgical procedure to place SNM lead near S3 nerves
- Two week trial period to assess change in urological symptoms, this includes bladder diaries and urinary flow tests (non-invasive test measuring volume and speed of urine released from body).
- 2nd surgical procedure to either remove the SNM lead or implant battery depending on whether the trial was a success or failure respectively.

You will be given a home uroflow device to take home. This will allow you to record how often you empty your bladder and how much comes out each time on a mobile application. If you are able to empty your bladder via the urethra (water pipe) without catheters this device can sit in your toilet and record how much you wee and how quickly.

On days 4, 9 and 14 of your SNM trial you will be expected to fill in a questionnaire. On each visit the SNM stimulation frequency will be changed, the order of the frequencies will be decided using a random number generator formula from Microsoft Excel.

7. What do I have to do?

If you decide to take part in this study you will be able to lead your life in the normal way. There are no lifestyle or dietary restrictions and you will still be able to take any medication you normally take.

Train, bus or taxis journeys purchased or car fuel used for making extra trips (above standard of care) to the hospital as required by the study protocol will be reimbursed. A total cost of £200 per participant, per study can be claimed. Receipts must be brought to appointments for reimbursement.

8. What is the drug or procedure that is being tested?

We are testing different stimulation frequencies of the Medtronic InterStim SNM

device.

9. What are the side effects of taking part?

There are no expected side effects with this study. Urodynamic investigations are a low-risk routinely performed test. All usual precautions will be taken in order to minimise patient discomfort and ensure dignity.

10. What are the possible disadvantages and risks of taking part?

You may experience some discomfort when the frequency of SNM stimulation is changed. This will be performed gradually to acclimatise participants.

You may experience discomfort with the additional urodynamics procedure. This will be managed by using local anaesthetic and lubrication when inserting the catheters.

With additional urodynamic investigations there is an increased risk of urine tract infection due to urethral catheterisation (2-4%). This will be managed by advising the patients to drink extra fluids following the procedures.

11. What are the possible benefits of taking part?

Patients will have the benefit of receiving individualised objective data regarding the efficacy of their SNM trial as well as optimal SNM settings. The outcome of this trial could improve SNM therapy for all patients by optimising stimulation parameters for the various indications.

12. What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your Urologist will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your Urologist will make arrangements for your care to continue. If you decide to continue in the study, you will be asked to sign an updated consent form.

Also, on receiving new information your Urologist might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

13. What happens when the research study stops?

As described above the project will only run until you have your second surgical procedure, to either remove SNM lead or implant SNM battery depending on the success of your trial.

You will continue to have routine follow up in the appropriate clinic as part of your standard of care.

The information collected about you may be used to support other research in the future, and may be shared anonymously with other researchers.

14. What if something goes wrong?

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 [Ross Stephens, Ross.Stephens@gstt.nhs.uk]. If you remain unhappy and wish to complain formally, you can do this through the Guy's and St Thomas' Patients Advice and Liaison Service (PALS) on 020 7188 8801, pals@gstt.nhs.uk. The PALS team are based in the main entrance on the ground floor at St Thomas' Hospital and on the ground floor at Guy's Hospital in the Tower Wing.

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

15. **How will we use information about you?**

We will need to use information from your medical records for this research project.

This information will include your:

- *Name*
- *GSTT hospital number*

People will use this information to do the research or to check your records to make sure that the research is being done properly.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

16. **What are your choices about how your information is used?**

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

17. **Where can you find out more about how your information is used?**

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from: www.guysandstthomas.nhs.uk/reseach/patients/use-of-data.aspx
- by asking one of the research team (contact details included below)
- by contacting the Data Protection Officer: (Nick Murphy-O'Kane DPO@gstt.nhs.uk)

In line with clinical trials regulations, research data will be archived and stored in a secure database for 5 years after completion of the study, data will be anonymised and will not include any identifiable information.

18. **What will happen to the results of the research study?**

The results of the study will be published in recognised journals. This will make the results available to all other researchers interested in this field. You will not be identified in any publication.

If you consent to be contacted in the future about the results of this trial, you will receive a summary of the findings by post or email once the trial is over.

19. Who is organising and funding the research?

This study is sponsored by Guy's and St Thomas' NHS Foundation Trust.

. Medtronic the medical device company who produce the InterStim SNM devices are funding the investigator-led study.

20. Who has reviewed the study?

This study has been reviewed by the Brighton & Sussex Research Ethics Committee, the Health Research Authority and Guy's & St Thomas' Research Development Office.

21. Contact for Further Information

You will be given a copy of the information sheet and a signed consent form to keep. You may withdraw from the study at any time without affecting your treatment.

Thank you for taking time to read this information sheet, please do not hesitate to contact us if you have any queries or need any further information.

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