Queen Mary University of London

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# Do you have to rush to the toilet?

Patient Information Sheet

## Invitation to SUBSoNIC Study

We would like to invite you to take part in the **SUBSoNIC** study. The study investigates a surgical treatment for faecal incontinence (FI). Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss with others if you wish. You will have at least a day to decide, but can take as long as you need. You will have the opportunity to go through this information sheet with one of the clinical research team and ask any questions you may have.

## Why is this study needed?

FI is the lack of control over bowel movements including gas, liquid and solid stool and can have many causes. It can have a significant effect on the sufferer's quality of life, including mental and physical health. It can lead to social isolation. The cost of treatment, as well as the cost of days off work must be taken into consideration. Patients are initially offered medication to prevent stool being too soft followed by nurse led treatment such as life style and dietary changes, exercises and bowel retraining. If these treatments don't help then surgery is considered. Traditionally invasive reconstructive surgery or surgery using bulking agents is offered. These procedures do not guarantee success and can cause more problems. As a last resort a stoma can be formed. Over the last 20 years Sacral Neuromodulation (SNM) has been increasingly used and is the least invasive and simplest surgical treatment, which is why it is so often chosen. Studies tell us that SNM is cost effective and produces very few side effects especially compared to other surgical treatments. Now we need more research to work out just how effective it is, and why.

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## Why have I been invited?

This study is taking place in several hospitals in the UK and Europe and is looking for 90 suitable patients. You are being invited because SNM has already been recommended by your doctor, and

- You are aged between 18 and 75
- You have the symptoms of faecal incontinence
- Diet, lifestyle changes and medication have not adequately worked.
- Other treatments like bowel retraining or rectal irrigation have not relieved your symptoms.

## Do I have to take part?

No, it is up to you if you want to take part or not. If you agree to take part you will be asked to sign a consent form. You are free to withdraw at any time without giving a reason. If you decide not to take part, or if you withdraw early from the study, the standard of care you receive will not be affected. Data that has been collected after consent but before you withdraw will be kept.

## What will happen if I agree to take part?

Your participation in the study will last for up to 18months and require up to 10 visits to hospital. Most of the visits are the same as you would normally have if you were not on the trial. However we will ask you to fill out some extra diaries and questionnaires. The details of these visits are outlined below and shown in Figure 1. The study is a randomised trial which means you will be randomly allocated to one of two groups. Both groups will have the SNM surgery. However, patients will undergo stimulation at different times depending on which group they are in. Group 1 will initially have their stimulator set so that they are having stimulation, whilst group 2 will not have any stimulation. After 16 weeks, the groups swap and group 1 will not have any stimulation while group 2 will have stimulation for another 16 weeks. Both groups then have their stimulator set as they would in routine care for the final 26 weeks. You will not know which group you have been allocated to. There is a 50/50 chance of being in each group.

## Are there any restrictions on what I can do?

You will not be able to bath or shower initially after surgery while the wound heals.

### What will I have to do?

- Attend your visits on the scheduled dates
- Complete your diaries and questionnaires.
- Follow the instructions you receive during the visits
- Follow routine postoperative care instructions
- Inform the research staff if you are/or might be pregnant
- Provide information about your medications & adverse/side effects

### Expenses & Payments

If you decide to take part in this study you will be reimbursed for reasonable travel expenses incurred in relation to study visits. You will need to keep travel receipts/tickets for reimbursements.

During the test phase intense physical activity or lifting heavy objects could cause the wires to be displaced so should be avoided. Patients will be unable to drive during this period (up to 1 – 4 weeks).

Once the permanent device is implanted patients are advised to avoid extreme sports. Certain positions like sitting can cause jolting sensations. If you experience any unwanted stimulator effects, such as jolting, you are advised not to drive, operate vehicles or dangerous machinery with the stimulator turned on. You will also not be able to go through full body scanners for example at airports with the stimulator turned on. However, you will be able to turn the stimulator off for these activities, or if you experience any severe effects such as pain or numbness. You will receive more detailed instructions about this from the team if you join the study.

## Study Visits

**Visit 1 Initial Visit:** You will have the chance to discuss the study and then you will be asked to sign a consent form. You will then have your medical history taken and undergo a physical examination. You will then complete some quality of life questionnaires and be given a paper bowel diary to complete at home. You will also be shown how to use an electronic device much like a smart phone, where you can record instances of incontinence as they happen (see Figure 2). The e-diary also measures how far you have travelled from home each day. To respect your privacy, this measures distances travelled and does not record your actual locations (see Figure 3).

**Visit 2 and 3 (surgical visits):** As per routine care for SNM, you will initially have a 2-4 week test period before the more long lasting implant is inserted. Both operations are day procedures, usually carried out under local anaesthetic with sedation. As this is part of routine care you will receive more in-depth written and verbal information during your counselling session for both procedures. For the test period, a temporary wire is inserted in your lower back using x-rays for guidance and attached to the stimulator. If the test period is successful you will once again have wires inserted through the skin of your lower back with the use of x-rays, but this time a battery the size of a match box is inserted (Figure 4).

Figure 2: e-diary event recorder

Figure 3: Plot of distance travelled

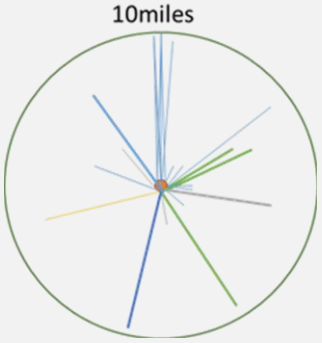
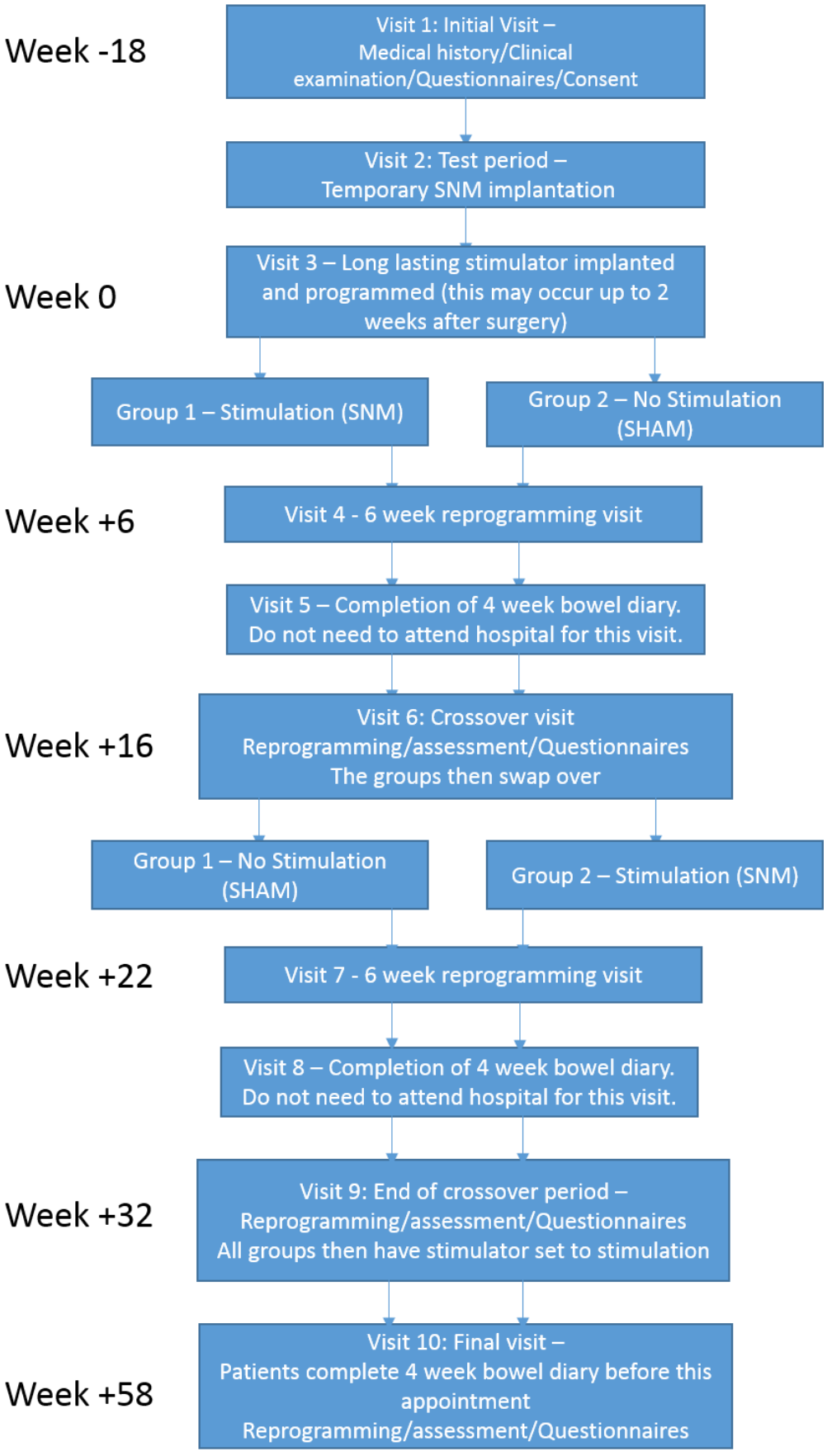
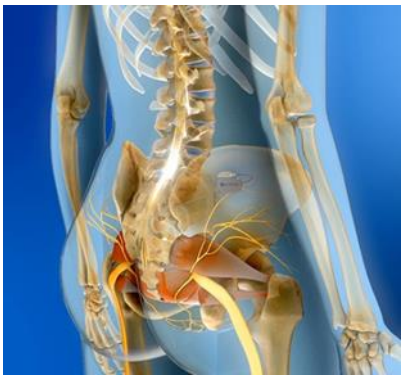



Figure 4: Stimulator

## Figure 1: Participant Flow Chart



During this test period some patients will be asked if they would like to participate in further tests which will help us understand how SNM works.
If you are invited to take part in these studies you will be contacted by our research partners from Aston University, Queen Mary University or Barts Health and given separate information sheets and asked to sign a further consent form. When you have recovered from the surgery the stimulator will be programmed. This will either happen on the same day as your surgery or up to two weeks later (involving another visit). As this is part of routine care this depends on the routine practice of your hospital. The stimulator will be turned up till you feel a fluttering or tingling sensation. It will then be turned down till the feeling just stops. This means that you should not be able to feel anything whether the stimulator is on or off. The stimulator will be set either give stimulation or not, depending on which group you are in. The programmer will be given to you with the settings taped over and you will be given an instruction card explaining what to do in case of an emergency like severe numbness/pain.



**Follow Up Visit 4, 6, 7 and 9**: You will come back for a reprogramming visit. This allows for optimal programming and to see how you are doing. This will be done whether you are receiving stimulation or not. You will also be given questionnaires to fill out and your bowel diary will be reviewed at visits 6 and 9. At visit 9 you will have your stimulator left on for the remainder of the study. You will be given the programmer and shown how to use it.

**Follow Up Visit 5 and 8**: You do not need to come to hospital but you will be asked to complete another 4 week bowel diary which will be sent to you by post or email.

## Surgical Risks

Some of the known but rarely occurring risks of this type of surgery include;

- Bleeding
- Pain
- Wound infection
- Worsening of or new urinary incontinence
- Worsening faecal incontinence
- Jolting or shocking stimulation
- Numbness at neurotransmitter site
- Device problems
- Undesirable sensation

## Research related risks

Some of the questionnaires assessing quality of life may cause some embarrassments or anxiety.

## Potential Benefits

We cannot promise the study will help your FI symptoms. However, the information we get from this study will help inform future treatment options for people with FI.

**Final Visit 10:** This is the final visit for the study. You will be asked to complete a 4 week bowel diary prior to this visit; and the questionnaires during the visit. Any necessary stimulator reprogramming will be carried out and the doctor/nurse will discuss your progress.

## What happens at the end of the study?

If you require further treatment you will return to the care of your consultant in your regular clinic. With your permission, we would like to be able to use the data collected in this study for future research of a similar nature. All future research will require ethical review and approval and your data will remain confidential.

## What will happen with the results?

The results will be published in a medical journal and presented at scientific conferences. The data will be anonymous and you will not be identified in any report or publication. If you would like to see the results, or the publication, please ask your study doctor after the study has ended (results are expected in 2019-2020). The full report will be available on the NIHR website http://www.journalslibrary.nihr.ac.uk/eme

A lay summary of the results will also be provided at www.bowelcancerresearch.org

## Will my information be kept confidential?

The records obtained while you are in this study will remain strictly confidential at all times. The information will be held securely on paper and electronically under the provisions of the 1998 Data Protection Act and EU Data Protection Directive. If you consent to take part in this study, doctors, nurses and other personnel involved in the study may need access to your medical records and test results. Your records will be available to people authorised to work on the study, and by sponsor and regulatory inspectors as far as required by law. Your contact details and data relevant to the study (e.g. name, email address and/or phone number) may be passed to research partners at Queen Mary University of London, Barts Health Trust, or Aston University, but not leave your hospital without your prior consent and will not be transferred outside the EU. You will be allocated a unique trial

### X Ray Risks

You will receive two x-ray fluoroscopy procedures for guiding the placement of the test and permanent SNM implants. You will receive exposure to a small dose of ionising radiation which is part of standard of care. Exposure to ionising radiation carries very small risks of causing cancer in later life, but the dose of radiation involved is low – the same as about 8 months of natural background radiation received in everyday life.

### Female factors

The safety of SNM during pregnancy is not known. Women entering the study may be asked to perform a pregnancy test and use proven methods of contraception. You will not be able to join the study if you are pregnant or trying to get pregnant.

identification number (UTIN). This code will be used so you can't be directly identified on study records, and ensure confidentiality of data reports. By signing the consent form you agree to this access for the current study and any further ethically approved research that may be conducted in relation to it. At the end of the study, confidential data will be made available to collaborators (including Medtronic USA). Study data will be securely archived for a minimum of 20 years. Arrangements for confidential destruction will then be made.

## Who is funding the study?

The research is mainly being funded by the Department of Health through the National Institute for Health Research (NIHR) and Medical Research Council partnership. Some funding will also come from Medtronic, the company that makes the Stimulators and e-diary.

## Who has reviewed the study?

All research is reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights and wellbeing. This study has been reviewed and approved by _____ Research Ethics Committee.

## Who else knows about the study?

After your consent, your GP and any other doctors looking after you will be informed of your involvement.

## What if new information becomes available?

If relevant new information becomes available about the treatments being studied or the way in which we are planning to conduct the study, you will be notified so that you have an opportunity to re-consider your involvement. This is very unlikely to occur but if it does the researcher will discuss this with you and ask you to re-sign a consent form confirming the changes were explained and you have agreed to continue. Alternatively you may withdraw and return to routine care.

## What if I want to stop the treatment or withdraw from the study?

### What if something goes wrong?

We do not expect you to suffer any serious harm or injury as a result of this research. The risks of taking part in the study are considered small on top of the standard surgical risks. The risk of the surgery itself is small. In the event that something does go wrong and you are harmed during the study due to someone's negligence then you may have grounds for legal action against the sponsor but you may have to pay your legal costs.

### Who is the sponsor?

The sponsor is Queen Mary, University of London. They have overall responsibility for this study and provide insurance and indemnity.

Queen Mary University of London

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You may choose to stop treatment or your doctor may decide it is in your best interests e.g. you become pregnant. You may continue to complete the study questionnaires and diaries even if you stop treatment. However, if you decide to withdraw from the study, or anything happens to you during the study and you lose capacity for continued consent, we will not ask you to complete any more diaries and questionnaires. With your permission we will keep the data we have collected so far and will arrange appropriate follow up in your routine clinic.

## Who do I ask if I have questions?

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the procedures involved.

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 you should contact the Patient Advice and Liaison Service (PALS) <insert local PALS or EU equivelant contact here> This completes the information for this study, please refer to the next page for all your local contacts.

## Your local contacts

**Principal Investigator**
Name *add name*
Tel. Number: *add Tel. number*

**Your Research Nurse/Specialist Nurse/** *delete as appropriate*
Name *add name*
Tel. Number: *add Tel. number*

**Research Fellow/Registrar** *delete as appropriate*
Name *add name*
Tel. Number: *add Tel. number*

**Research Coordinator/Assistant** *delete as appropriate*
Name *add name*
Tel. Number: *add Tel. number*

Queen Mary University London

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2 Newark St, London E1 2AT

Chief Investigator: Professor Charles Knowles

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Find us on the Web:

http://www.qmul.ac.uk/pctu/about-us/clinical-strengths-and-studies/our-studies/

http://www.bowelcancerresearch.org/

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