

**P**roper **U**nderstandingof **R**ecurrent **S**tress **U**rinary **I**ncontinence **T**reatment in Women: a randomised controlled trial of endoscopic and surgical treatment

**Participant Information Leaflet (1)**

**We invite you to take part in a research study**

* Before you decide to take part, it is important that you understand what the study is about, why it is being done and what will be involved.
* Please take time to read the following information.
* Feel free to talk to family members or others if you wish.
* Please contact us using the details below if there are any parts of this information leaflet that you do not understand, or if you would like further information.

**Important things that you need to know**

* We are inviting women with recurrent stress urinary incontinence (SUI), who have already had an operation for it, to take part in a research study.
* We want to find out whether endoscopic bulking injections or surgery are more effective for treating recurrent SUI.
* Women who take part will be allocated to one of those treatments; endoscopic bulking injections or surgery.
* We will find out which is better by asking you to complete study questionnaires for 3 years.
* If you take part, you can leave the study at any time.

***Please note:*** *for the purpose of this information leaflet, any reference to ‘we’ means the sponsor and not the local site (hospital).*

**Contact details:**

**Name:** <INSERT Name of Local Research Nurse>, **Tel:** <INSERT Local hospital phone number>

**Address:** <Insert Local hospital address>

**Email:** pursuit-trial@bristol.ac.uk

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# PART A: Why is the study being done and what will happen if you take part.

# Why is the study being done?

We do not know whether endoscopic bulking injections or surgery is the best treatment for recurrent SUI in women who have had an operation for it already. The PURSUIT study will help us to find out which treatment is better for improving your symptoms and quality of life. We will also look at side effects and monitor your symptoms for three years.

# Why have I been invited to take part?

Your urologist or urogynaecologist has found that you have recurrent SUI following an earlier operation for leaking urine, which is now bothering you again. You are looking for further assessment and are willing to consider additional treatment. The medical tests that you have had show that this study may be suitable for you, so we would like to invite you to take part.

# What is involved in the study?

In the PURSUIT study we are trying to find out the best way to treat women who have recurrent SUI by comparing two routine treatments: endoscopic bulking injections or surgery. If you take part, you will receive either an endoscopic bulking injection(s) or a surgical operation to help treat your recurrent SUI (see next section for details on those treatments).

We also plan to audio-record consultations where the PURSUIT study is discussed and interview some women to see how research is explained (PURSUIT Recruitment Study). We will also interview some women to understand how they manage after their treatment (PURSUIT Interview Study). Separate information will be provided if you are invited to take part in these additional studies.

## 3.1 What standard NHS treatments for recurrent SUI in women are currently available?

There are several treatments to treat recurrent SUI.

**(i) ENDOSCOPIC PROCEDURE:**

* **Bulking injections**: a synthetic bulking material is injected in or around the urethra (the tube which takes urine from your bladder to the outside), to improve the seal in the urethra. No incisions are made. The surgeon will place a cystoscope in the natural opening of your urethra to see where to place the injections. The injections are done through the cystoscope under appropriate anaesthetic.

An endoscopic (bulking injection) procedure is generally done as a day case procedure and 1-2 days are required for recovery. Sometimes you may need repeat injections if your symptoms do not fully resolve, or they start to return. Repeat injections may happen anytime.

**(ii) SURGICAL OPERATIONS:**

*(Your surgeon will tell you which ones are available for you at your hospital.)*

All surgical operations are done with general anaesthetic (i.e. you will be sleeping during the procedure). The surgical operations may depend on what has caused your SUI, which your medical tests will show. Your doctor will inform you which options are suitable and discuss them in detail.

Possible surgeries (procedures) include:

* **Autologous fascial sling procedure**: the surgeon uses a strip of your own tissue (taken from the supportive tissue on the front of your abdominal muscles) to gently squeeze the urethra. An incision will be made to take the strip of tissue and another incision will be made in the front of the vagina to position the tissue.
* **Colposuspension**: the surgeon uses stitches to hold the front of the vagina to the back of the pubic bone so that the front of the vagina supports the urethra. This operation can be done through a small incision or by using a medical telescope (called a laparoscope).
* **Midurethral (mesh) tape** **procedures**: the surgeon uses a polypropylene medical mesh tape to support the urethra. A small incision will be made in the front of the vagina so that the tape can be positioned.

***Please note:*** *there are specific rules from the NHS which regulate the use of mesh in vaginal surgery, including midurethral tapes. The rules relevant at the time will be used for anyone wishing to consider this type of surgery.*

* **Artificial urinary sphincter (AUS)**: the surgeon places a cuff around the urethra and a pressure “balloon” in the pelvis. The pressure in the balloon means the cuff gently squeezes the urethra. For you to pass urine when you want to, the pressure in the cuff can be released using a control switch. The switch will sit under the skin to one side of the entrance to your vagina (in one of the labia). An incision will be made to place the cuff, balloon and control switch.

All surgical operations generally require a 1 to 3-day hospital stay and 4 to 6 weeks for a full recovery. You may need to be taught extra techniques, such as intermittent self-catheterisation, which will be discussed with you if relevant.

## 3.2 What treatment will I receive if I take part?

If you take part in the PURSUIT study you will be treated with either an endoscopic bulking injection or a surgical operation, both of which are standard treatments for recurrent SUI. As nobody knows which is best, the type of procedure you have will be allocated through a process called randomisation (i.e. neither you, your clinician, nor the research team choose the treatment).

You will have an equal chance of having an endoscopic bulking injection or a surgical procedure. It is important that you only agree to take part if you are prepared to accept either of the treatment types – endoscopic bulking injection or surgery.

The team treating you are experienced in both procedures and you will receive the best possible care whichever treatment you have. They will also provide further information on all procedures (including all surgical options), together with the pros and cons of each.

**To recap:**

* If you are allocated to the **Endoscopic Group,** you will be offered the endoscopic bulking injection procedure.
* If you are allocated to the **Surgical Group**, you and your doctor will choose which operation you have, depending on the cause of your recurrent SUI, as some of the operations described above may not be appropriate for you or available in your hospital.

# Do I have to take part?

It is your choice whether or not you take part in the PURSUIT study. If you decide not to take part, the treatment and care you receive from your doctors will not be affected in any way.

If you do decide to take part, you are also free to leave the study at any time you wish without giving a reason.

If you have any queries, or if there are any parts of this information leaflet that you do not understand, please contact us using the details on the front page.

# If I decide to take part, what happens next?

The diagram on page 4 illustrates what happens during the study:

**A) First discussion about the PURSUIT study**

A member of the local research team will talk to you either during one of your routine clinical appointments (conducted face-to-face or remotely, e.g. via telephone or video-call), or will contact you separately, to discuss the study in more detail and answer any questions you may have. If you would like to proceed with the study, they will arrange a time for your first study appointment (see ‘B’, below).

**B) First study appointment**

At this appointment (which may be conducted face-to-face or remotely), a member of the local research team will confirm that you are still happy to take part.

You will be asked to:

* **sign a consent form** confirming that you agree to take part in the study;
* **complete a study questionnaire** booklet about your general health, your urinary symptoms and their effect on your everyday life and sex life. The questionnaire should take no more than 30 minutes to complete.
* **Provide some additional information** for the purposes of the study, e.g. contact details, GP information, date of birth.

You will then be informed whether you will be in the “Endoscopic Group” or the “Surgical Group”.

In certain circumstances, it may not be possible to complete all of these study activities during your first study appointment. If this is the case, your research nurse or doctor will arrange a further appointment (face-to-face or remote) to complete the study activities.

We will inform your GP of your participation in the study and let them know which group you have been allocated to.

1. Flow diagram for the PURSUIT study

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***Footnote:*** *At 1 and 3 years after allocation to your study group, we may also collect relevant data about you from electronic databases such as NHS Central Registers or other registries including those managed by NHS Digital (formerly Health and Social Care Information Centre (HSCIC)), Information Services Division Scotland (ISD), Patient Episode Database for Wales (PEDW), o*r *Office for National Statistics (ONS). Please see Section 7 (page 5) for details.*

**C) Treatment visit(s) at your local hospital**

You will be invited to attend your local hospitalto **receive your treatment** (either endoscopic bulking injection or chosen surgery). The clinical team will prepare you for your treatment as they would during normal NHS care. A member of the local research team will also record some other study information from you and/or your hospital notes.

The surgeons who will carry out the treatments in this study perform them regularly. You will receive the usual NHS treatment and aftercare at your hospital (e.g. medical tests, procedures, and follow up appointments).

*Please note: you may need to attend a pre-operative assessment clinic before your main treatment visit. Your clinical team will advise on local procedures.*

1. **Questionnaire booklet to complete at home: 6 months after allocation to your study group (randomisation)**

You will be asked to **complete a study questionnaire** about your general health and any healthcare you have used in the last 6 months due to your urinary problems. The questionnaire should take no more than 20 minutes to complete and can be done either by post (we will provide a pre-paid envelope), online, or via telephone.

1. **Questionnaire booklets to complete at home: 1, 2 & 3 years after allocation to your study group (randomisation)**

At 1, 2 and 3 years after allocation to your study group, you will be invited to complete a study questionnaire booklet. Each booklet can be completed either by post (we will provide a pre-paid envelope), online, or via telephone.

At 1 year, the booklet will include questions about

your general health, whether or not your symptoms have improved since your treatment, your urinary symptoms and their effect on your everyday life and sex life, and about any healthcare you have used in the last 6 months due to your urinary problems. The questionnaire should take no more than 40 minutes to complete.

At 2 and 3 years, the questionnaire booklets will besimilar to the one you completed at 1 year. These should take no more than 30 minutes each to complete.

At 3 years, once you have returned your questionnaire booklet, your direct involvement in the study will be complete. You will return to the usual care of your urologist/urogynaecologist.

# What other information will be collected about me during the study?

If you agree to take part in the PURSUIT study, we will also collect some data about you from information resources such as NHS Central Registers or other registries including those managed by NHS Digital (formerly Health and Social Care Information Centre (HSCIC)), Information Services Division Scotland (ISD), Patient Episode Database for Wales (PEDW), or Office for National Statistics (ONS). These public bodies collect information from all hospitals on behalf of the Government. This information is routinely collected by the NHS whenever you have hospital treatment.

If you take part in the study, we will send information that identifies you, such as full name, gender, NHS number, postcode, date of birth, and study number to the relevant body above.

If they have records about your hospital admission/ attendance, and/or date and cause of death, they will send this information back to us with your identifiable information (study number).

This data will be collected at 1 and 3 years after allocation to your study group. This data will be securely sent to either of the information resources (registries) identified above, and returned securely to the University of Bristol where it will be analysed by the University of Bristol research team working on the study.

# What are the possible risks and benefits of taking part?

There should be no additional risk to routine NHS practice of the endoscopic bulking injections or surgical operations, and neither are new or experimental. You will have the same risks as anyone having treatment for recurrent SUI. This includes the possibility that your symptoms may not improve as much as you would like. Your doctor will explain the risks and benefits of each procedure, and they will provide relevant hospital leaflets.

Some people favour being part of research studies because of the close contact with research staff and the opportunity to share their opinions and experiences of their condition and treatments.

As a thank you for taking part, we will offer you a £10 voucher for completing your questionnaire at 1 year and another £10 voucher when you complete your questionnaire at 3 years.

# What about expenses and travel?

We will provide you with prepaid envelopes to return study questionnaires.

We can offer to cover some travel expenses if you have to attend your local hospital for a study-specific appointment.

# If I take part, can I change my mind and leave the study?

If you do decide to take part, you are also free to leave any part of the study at any time without giving a reason. Your medical treatment will not be affected. If you wish to leave the study, please let your research nurse know; see contact details on front page.

If you do decide you no longer wish to take part, any information we have collected up until the point you leave will be retained and used in our analysis of the trial results. We would continue to collect data from your hospital / medical records (central registries) unless you request otherwise.

# What should I do now?

After reading this leaflet, we hope you are interested in taking part. You can contact the research nurse if you have any questions.

If you would like to take part, please also read **PART B** of this Information Leaflet.

# PART B: Further general information about the study and what will happen to your data if you decide to take part

# How many women will take part and for how long?

We aim to include 250 women in the study.

The study started in April 2019 and we anticipate it will run for 6 years until 2025 when we will publish the overall results of the study as soon as possible thereafter.

# Who funded this study, who is the sponsor, and who is the lead organisation for it?

The study is being funded by the National Institute of Health Research (NIHR) (reference 17/95/03). The research is being carried out by a group of experienced doctors and researchers at each of the hospitals involved in the study and the University of Bristol. This study is sponsored by North Bristol NHS Trust (UK), and the Bristol Randomised Trials Collaboration, as part of the Bristol Trials Centre (UK), are responsible for managing the study.

# Will the information I provide be kept confidential?

Yes. Your data will be stored and used in compliance with the relevant, current data protection laws; Data Protection Act 2018 and General Data Protection Regulation (GDPR).

We will be using information from you and/or your medical records in order to undertake this study and North Bristol NHS Trust and the University of Bristol will act as joint data controllers for this study. This means that we are both responsible for looking after your information and using it properly. Personal information such as your name, email address and phone number will be stored on a secure database with the central research team (University of Bristol). The University of Bristol, on behalf of North Bristol NHS Trust (Sponsor) will keep identifiable information about you for at least 5 years after the study has finished/ until at least 2030.

# How will we use information about you?

We will need to use information from you and/or from your medical records for this research project. This information will include your:

* Initials
* NHS number
* Name
* Gender
* Date of birth
* Contact details (for example: postcode, telephone number, email address)

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.

# 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.
* If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records and/or your hospital. If you do not want this to happen, tell us and we will stop.
* 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.
* If you agree to take part in this study, the information collected about you will be used to support other research in the future and may be shared anonymously with other researchers.
* If you agree to take part in this study, you will have the option of taking part in longer-term follow up beyond the end of this study, and the option to be contacted about taking part in other research.

# 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 https://pursuit.blogs.bristol.ac.uk/how-we-use-information-from-patients/
* at the University of Bristol website, www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/
* at North Bristol NHS Trust website, www.nbt.nhs.uk/research-innovation/our-research/patient-information-health-care-research
* by asking one of the research team (see contact details on front page)
* by sending an email to pursuit-trial@bristol.ac.uk, or
* by ringing us on 0117 9287219.

# What will happen to the results of the study?

The results will be published in medical journals, presented at conferences with other healthcare professionals and specialists, reported on open access databases and open platform research registries. Results will also be available on the study website at https://pursuit.blogs.bristol.ac.uk/. No one will be able to identify you from any of the study reports.

# Who has reviewed this study?

This study has been reviewed by the Health Research Authority and South West - Frenchay Research Ethics Committee who have provided approval for this study to be conducted in the NHS.

# What if there’s a problem?

If you have a concern regarding your care as a patient, please discuss this with your urologist/ urogynaecologist.

If you become unable to continue taking part in the PURSUIT Study, we would withdraw you from it. We would retain, confidentially, the relevant information that we had already collected about you, for the purposes of the study only. Your medical treatment will continue as usual with your hospital team and GP.

In the unlikely event that something does go wrong, and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone’s negligence, then you may have grounds for a legal action for compensation against North Bristol NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

# Who do I contact if I have concerns?

If you have any questions about the study, or any aspect of your treatment or health whilst on the study, please ask to speak to your PURSUIT study research nurse or surgeon <INSERT name, address, email address, telephone numbers including the 24 hour emergency contact number>. Alternatively, you can contact the Trial Manager (email: pursuit-trial@bristol.ac.uk; phone: 0117 9287219).

The Patient Advice and Liaison Service (PALS) /Advice & Complaints Team (ACT) [delete as appropriate] should be contacted for any complaints. Your local PALS/ACT [delete as appropriate] is:<INSERT local details>

<INSERT local details>

<INSERT local details>

**THANK YOU FOR TAKING THE TIME**

**TO READ THIS INFORMATION.**

**PLEASE KEEP A COPY FOR YOUR RECORDS.**