



Proper Understanding of Recurrent Stress Urinary Incontinence Treatment in Women: a randomised controlled trial of endoscopic and surgical treatment

Participant Information Leaflet (2) Recruitment Study and Interview Study

We invite you to take part in additional research within the PURSUIT study

- We are inviting women with recurrent stress urinary incontinence (SUI) who have been asked to take part in the main PURSUIT study to also take part in one or both of these additional research studies (i.e. the 'Recruitment Study' and/or the 'Interview Study').
- Before you decide whether to take part, it is important that you understand what these additional studies are about, why they are 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 ask questions using the contact details below if there are any parts of this information leaflet that you do not understand, or if you would like further information.

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

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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

1 Why have I been invited to take part?

You have been invited to take part in this additional research because you were invited to take part in the main PURSUIT study.

If you agreed to take part in the main PURSUIT study, you may be asked to take part in either the Recruitment Study or the Interview Study, or both (see *PART A* and/or *PART B* for more details).

If you did not want to take part in the main PURSUIT study, we are inviting you to take part in the Recruitment Study only (see *PART A* for more details).

2 Do I have to take part?

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

3 If I take part, can I change my mind and leave the study/studies?

If you do decide to take part, you are free to leave the study/studies at any time without giving a reason. Your medical treatment will not be affected. If you wish to leave the study/studies, please speak to your urologist/urogynaecologist or research nurse.

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.

PART A: RECRUITMENT STUDY

4 Why is the study being done?

The Recruitment Study is being conducted to find out more about how people who have recurrent SUI make decisions about whether to take part in research such as 'PURSUIT'. To find out, we would like to audio-record telephone and face-to-face consultations between patients and healthcare staff when information about PURSUIT is being discussed. By doing this, we can assess how research into different treatments

is discussed. We may also invite some patients to talk to one of our researchers (see *section 5* for more details).

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

• **First discussion(s) about the PURSUIT study: in person or via telephone**

During your first study visit for the main PURSUIT study (this may be during one of your routine clinical appointments) or over the telephone, a member of your local research team or your doctor will ask you some questions, explain the different ways in which recurrent SUI can be treated and tell you about the main PURSUIT Study.

To understand what information is given to you during that discussion, and during any future consultations where the main PURSUIT study is discussed, **we would like your permission to audio-record your conversation(s)**. If you agree, we will ask you to:

- **sign a separate consent form for the Recruitment Study.**

• **Up to 6-months after your first study visit or your first discussion about the PURSUIT study: in person or via telephone**

Some women will also be invited to attend an interview with one of our researchers; we will ask you to indicate if you agree to be interviewed on the Recruitment Study Consent Form.

A researcher from the University of Bristol will contact you. They will talk to you about your experiences since your diagnosis, the discussions with your surgeon and nurse and your views on the main PURSUIT Study.

The interview will be arranged for a time and place convenient to you and may be in person or over the telephone.

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

If you agree to take part in the Recruitment Study, you will help us to improve how treatment options for patients with recurrent SUI, and research are discussed with patients. There should be no risks associated with participating in the Recruitment Study, as this just involves audio-recording discussions that you already have with healthcare

professionals and talking to researchers for interviews. Most people find that this is comforting but some can find it uncomfortable. If this happens, you will be able to stop the consultation or interview at any time, without giving a reason.

7 What about expenses and travel?

No expenses will be incurred by you if you participate in the Recruitment Study as it does not involve any extra visits to your local hospital above your routine clinical appointments or your visit for the main PURSUIT study.

PART B: INTERVIEW STUDY

8 Why is the study being done?

The Interview Study is being conducted to find out what women involved in the PURSUIT study think about recurrent SUI, and their views and experiences of treatments to manage these symptoms. Different treatments have different outcomes and not all women hope for the same thing. We aim to explore these perspectives (see *section 9 for more details*).

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

If you agree to join the main PURSUIT Study, you may also be asked if you are interested in taking part in the Interview Study. We will interview around 40 women for this part of the study. Interviews will be held at a time and location that are convenient for you.

The interviews aim to explore your expectations and preferences for treatments, and your views on the treatment you will be/were given in the main PURSUIT study. We aim to follow you through your treatment and beyond to understand the full experience, therefore we intend to interview you four times. For example, at the following timepoints we will ask you about:

- **Start of the study:** your reasons for seeking treatment, your expectations from treatment and your thoughts on the different treatment options.
- **3- to 6-months following treatment:** your views on your treatment experience and how you have been since your treatment.

- **1-year following treatment:** your longer-term experience since your treatment, such as your current symptoms and how they compare with your expectations, and whether you are satisfied with the outcome of your treatment.
- **3-years following treatment:** your ongoing situation with regard to lower urinary tract symptoms and any impact they have on your quality of life.

These interviews will be recorded, and we will ask you to give verbal consent to take part at the time of the interview.

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

It is anticipated that your involvement in the Interview Study will help us improve the treatment of women with recurrent SUI. The findings will also help the doctors and researchers working on the main PURSUIT Study by showing them what is important about the treatment experience.

Some people find that undergoing interviews helps them talk through their situation and their views and that this is comforting. We will give you a £10 voucher for each interview as a thank you for taking part.

11 What about expenses and travel?

Interviews will be held at a location which is convenient for you so you should not incur any additional costs.

12 What should I do now?

After reading this leaflet, we hope you are interested in taking part in this additional research. If so, please indicate this on the main PURSUIT study consent form.

You can also contact the research nurse if you have any questions about these studies.

If you would like to take part, please also read PART C of this Information Leaflet (*over the page*).

PART C: FURTHER GENERAL INFORMATION about the study and what will happen to your data if you decide to take part?

13 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.

14 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 2030.

15 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.

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.
- 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, you will have the option to take part in future research using your data saved from this study.

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 <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 928 7219 / 0117 928 7277.

18 What will happen to the results of the study?

The overall study 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.

19 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.

20 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 or unwilling to continue taking part in any aspect of the PURSUIT Study, we would withdraw you from it. 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.

21 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>

**THANK YOU FOR TAKING THE TIME TO
READ THIS INFORMATION.
PLEASE KEEP A COPY FOR YOUR
RECORDS.**

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Department of Health Disclaimer: The views and opinions expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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