

TReatling Urinary symptoms in Men in Primary Healthcare using non-drug and non-surgical interventions

Participant Information Leaflet

We would like to 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 do ask questions using the contact details below if there are any parts of this leaflet you do not understand, or you would like further information on.

Contact details:

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What is the aim of the study?

The TRIUMPH study will test whether a personalised booklet given by a nurse providing advice on men's urinary symptoms (LUTS) improves their symptoms compared to usual care from their GP.

Why is the study being done?

Half of men over 40 years old experience at least one urinary symptom, which can have a significant effect on their daily lives. This study will better inform the care of these men in GP practices.

Why have I been chosen?

You have been identified by your GP as experiencing one or more LUTS within the last few years.

LUTS refer to problems with:

- frequency – the need to pass urine often;
- urgency – the need to pass urine without much warning;
- urge incontinence – urgency resulting in leakage of urine which you cannot control;
- hesitancy – not being able to pass urine immediately;
- poor flow – a decrease in the force of your urinary stream; and
- nocturia – the need to pass urine when you are trying to sleep.

Do I have to take part?

It is your choice whether or not you take part in this study. If you decide not to take part, your treatment will not be affected at any point. If you do decide to take part, you are also free to leave the study at any time you wish without giving a reason. You can also speak to your own GP at any time.

If I decide to take part, what happens next?

If you are interested in taking part, please send the expression of interest form included in this information pack back to the research team in the pre-paid envelope provided.

The Nurse will then contact you to discuss the study in more detail. Please take this opportunity to ask the Nurse any questions you may have.

If you decide to take part in the study after speaking to the Nurse, you will be sent:

- a consent form to sign
- a questionnaire to complete asking you about your urinary symptoms, their effect on your everyday life, and your treatment goals

The questionnaires should take about 30 minutes of your time to complete. You may also be asked to fill out a bladder diary over 3 days. You will need to return the consent form and questionnaires to the study team, using a pre-paid envelope that will be provided.

Your GP practice will then be chosen to either provide all their patients in the study with their **usual care**, or our **personalised booklet**. We aim to recruit **840** men to take part in the study.

What happens next will depend on which group your GP practice is allocated to.

Personalised booklet group

If your GP practice is providing our personalised booklet, you will be asked to visit your GP practice to see the Nurse. The Nurse will contact you to arrange a good time for you to visit after you have returned your questionnaires.

What happens at the appointment?

At the appointment the Nurse will explain what you need to do for the study and answer any questions you have.

The Nurse will have the questionnaires you completed and will talk to you about these. They will then work out what type of urinary symptoms you have, and which ones bother you the most.

You will be given a booklet which the Nurse will go through with you. They will show you which sections will give you the information and advice to help your particular symptoms. The booklet focuses on techniques you can do and changes you can make to your everyday life. The booklet will include pictures to guide you.

How long do I need to follow the Nurse's advice for?

After you have met the Nurse, you will be asked to follow their guidance in the booklet for at least 3 months. You can carry on following the advice for as long as you wish after this. The Nurse will contact you (by email, phone or text) after 1 week, 1 month and 3 months to see how you are getting on.

What happens after that?

At 6 and 12 months after you joined the study, you will be sent similar questionnaires to those you completed at the beginning. These can be sent by email or post, whichever you prefer.

Usual care group

If your GP is in the usual care group, you will continue to receive the care that your GP would normally provide.

At 6 and 12 months after you joined the study, you will be sent similar questionnaires to those you completed at the beginning. These can be sent by email or post, whichever you prefer.

Will I need to do anything else?

If you agree to join the TRIUMPH study, you will be asked if you are interested in taking part in the interview study. If so, you may or may not be invited for interview. Around 40 men will be interviewed. If you are invited, you will receive a separate information sheet about the interviews, and an additional consent form. The interviews aim to explore men's expectations and preferences for treatments, and their views on the treatment given.

How long does the research study last?

Each man who participates in this study will be expected to complete questionnaires over 12 months. After the study has been completed we will write a report about the study which will be published in 2020.

What are the possible benefits of taking part?

If you are in the personalised booklet group, you will receive a booklet to keep with personalised information and advice on your symptoms.

If you are in the usual care group, you will have access to the booklet at the end of the study.

Your symptoms may improve and bother you less. Even if you do not feel any improvement, your taking part will help us to understand what advice and information will help improve LUTS in other men, without having surgery or drugs to help their symptoms.

What are the possible disadvantages of taking part?

We do not anticipate any disadvantages in taking part. However, we do not know how much your symptoms will improve, whichever group you are in. Therefore, your symptoms may not improve as much as you would like.

You will need to spend time completing questionnaires, and if you are in the personalised advice group you will be asked to spend time following the advice given.

Do I receive anything for taking part?

We will offer you a total of £20 in vouchers as a thank you for taking part. We will offer £10 for completing the first set of questionnaires and another £10 when you complete the third set of questionnaires at 12 months.

Will the information I provide be kept confidential?

All information you provide will be kept strictly confidential and will only be used for this study. Data about you will be stored in a way that makes it impossible to identify you, except by our research team.

Data with personal details included will only be kept for up to 12 months after the study has ended. After 12 months these details will be destroyed. The purpose for keeping them for 12 months after the study has finished is to notify you about the results of the study.

Data with all personal details removed will be stored on password-protected computers for 5 years, in accordance with University of Bristol guidelines.

Your personal information will not be written on any reports about the study or to anyone outside of the study team, and no one will be able to identify you.

With your permission, data collected in this trial may be used in future ethically approved studies on the understanding that all information may be shared anonymously with other researchers. It will continue to be kept securely and remain confidential.

Can I stop taking part after I have started?

Taking part is voluntary. If you decide you no longer wish to take part, you are still free to leave the study at any time during the 12 months. You do not have to give a reason and your medical care and legal rights will not be affected.

If you do withdraw from the study we would retain, confidentially, the relevant information we had already collected about you, for the purposes of the study only.

What happens when the study is finished?

Once you have returned your questionnaire at 12 months your part in the study will be complete. You will return to the usual care of your GP.

The overall results of the study will be published in medical journals and shared with other healthcare professionals interested in this area of research at conferences.

Patients who take part will also be sent results of the study via a newsletter.

Who funded this study and who is the lead organisation for this study?

This study is funded by the National Institute of Health Research, which is the research arm of the NHS, and is led and sponsored by the University of Bristol.

Who has reviewed this study?

This study has been reviewed by the Health Research Authority and NHS 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 GP.

If you become unable or unwilling to continue in TRIUMPH, we would withdraw you from the study.

In the unlikely event that something should go wrong, the University has Public Liability insurance in place if needed.

How do I make a complaint?

If you have a concern about any aspect of the study, please contact the Trial Manager who will do their best to answer your questions (phone 0117 92 87275, email triumph-study@bristol.ac.uk). If you remain unhappy with any aspect of the study, please email the sponsor (Red-Office@bris.ac.uk).

If you remain unhappy with the care you receive at your GP practice whilst participating in this study and wish to complain formally, you can contact NHS England either by phone, email or post.

By post to:
NHS England
PO Box 16738
Redditch
B97 9PT

By email to: england.contactus@nhs.net
If you are making a complaint, please state: **'For the attention of the complaints team'** in the subject line.

By telephone: 0300 311 22 33

Please visit their website for further information:

<https://www.england.nhs.uk/contact-us/complaint/complaining-to-nhse/>

Thank you for taking the time to read this information. Please keep a copy for your records.



National Institute for Health Research