North Bristol NHS
NHS Trust

UPSTREAM

Urodynamics for Prostate Surgery Trial; Randomised Evaluation of Assessment Methods (UPSTREAM) for diagnosis and management of bladder outlet obstruction in men

A study for men who have bothersome urinary symptoms (e.g. difficulty passing urine) and are seeking further treatment, which may include the possibility of surgery.

Participant Information Sheet

We would like to invite you to take part in our research study. Before you decide, it is important to understand why the research is being done and what it will involve. One of our team will go through this information sheet with you and answer any questions you have. This should take about 30-60 minutes. Please ask us if there is anything that is not clear.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the study if you think you are interested in taking part. Please take time to read this information and discuss it with your family, friends or GP if you wish.

Part 1: If you are interested in finding out more

Background

UPSTREAM is a study for men who have urinary symptoms, such as difficulty passing urine. Your doctor has referred you because the symptoms are causing you bother and you are seeking further treatment. As men get older they often experience lower urinary tract symptoms (LUTS) which can affect their quality of life, such as needing to pass urine more frequently or dribbling. These symptoms can be the result of the prostate growing larger and getting in the way of urine flow, which is called 'benign prostatic obstruction' (BPO). BPO is the most common reason for urination problems in men. However, not all men with LUTS have enlarged prostates and for some men symptoms are caused not by the prostate but by a bladder problem, such as weakness of the bladder muscle. There are various possible treatments for men with LUTS, for example prostate surgery. However, choosing the treatment depends on working out what is causing the symptoms. For example, prostate surgery may not be sensible if the prostate is normal, and the cause of the symptoms is actually the bladder.

When assessing men with LUTS, there are two main approaches used in NHS Hospitals. The most commonly used is to do a physical examination and a test called 'uroflowmetry' or 'flow rate testing'. This test measures the flow of the urine stream and how well the bladder has emptied, showing how severe a man's symptoms are. However uroflowmetry cannot work out the cause of the symptoms, whether it is BPO or bladder weakness. So, some Hospitals also do a test called 'urodynamics', which measures how much pressure the bladder generates when the man is passing urine, and this is used to prove whether BPO is present. When the man has completed his assessment tests, he will discuss with his urologist to discuss what the most appropriate treatment is for his symptoms, which may include whether surgery for BPO is appropriate. For those men not having urodynamic tests, proceeding to surgery is based on a presumption that BPO is the cause of the problem, while for the men having urodynamic tests, BPO would be proven.

This study will invite men who have bothersome LUTS to take part. These men will be split into two groups (by chance). Both groups will receive usual care, which includes completing a standard set of assessments used in the NHS, such as questionnaires about your symptoms, a bladder diary, a physical examination and a urinary flow test (uroflowmetry). One group will also go on to have urodynamic testing in addition to usual care. We will then ask these two groups of men about their experiences and follow-up their longer-term health and symptoms.

What is the purpose of the UPSTREAM study?

At present we don't know whether using urodynamics as an additional assessment for men with bothersome LUTS is better overall than assessment without urodynamics. What we want to find out with this study is firstly, to check what the results of treatment are for men being assessed with or without urodynamics. Secondly, we would like to compare the number of men who had surgery for their symptoms, in the two groups. We are also very interested in finding out how the men felt about having the assessment procedures.

This study aims to provide evidence to help doctors and the NHS decide whether urodynamics should be more widely used for the assessment of men with LUTS who are seeking further treatment, such as surgery.

Why have I been invited to take part?

You are being invited to take part in the UPSTREAM trial because you are experiencing bothersome LUTS and are seeking further treatment, which may include the possibility of having surgery for your symptoms.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part 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 at any time and without giving a reason. A decision to withdraw or not to take part will not affect the standard of care you receive now or in the future.

What happens if I want to stop being involved in this study?

At any stage you can decide to withdraw from the study. Your doctor will look after you normally, the same as if the study were not happening at all. Withdrawing from the study will not affect your medical treatment in any way. Throughout the study you are free to consult your own GP at any time. If you wish to withdraw from the study, please contact an UPSTREAM research nurse using the contact details at the end of this information sheet (page 7).

What will happen to me if I take part?

We expect around 800 men to take part in the study. This group will be split into two groups by chance (randomisation). Both groups will receive usual care, which includes completing a standard set of assessments used in the NHS, such as questionnaires about your symptoms, a bladder diary, a physical examination and having their symptoms assessed by uroflowmetry. One of the groups will also go on to have their symptoms assessed by urodynamics as well (i.e. usual care plus urodynamic assessment). All men will then meet up with their urologist, who will refer to the results of the tests to recommend what treatments you might consider. You will be able to choose which treatment you actually receive; in other words, your treatment will not be chosen by chance (at random), and you do not have to accept the urologist's recommendation.

There is a detailed flow-diagram on page 4 which charts possible journeys through the study. The following is a summary of what you will be asked to do if you decide you would like to take part and agree to be randomised to one of the diagnostic assessment groups.

Clinic visits

- Pre-assessment *(all men)*: the doctor or nurse will check your symptoms using uroflowmetry
- Urodynamics visit *(only men in Urodynamics group)*
- Treatment decision *(all men)*: to discuss your results and to decide on the most appropriate treatment, such as whether to have surgery
- 4 months after surgery *(only men who chose to have surgery)*: there will be a clinic visit for another uroflowmetry test
- 18 months visit *(all men)*: the doctor or nurse will check your symptoms using uroflowmetry

So, if you are in the Uroflowmetry (i.e. usual care only) group you may be invited to up to 3 visits to clinic (or 4 if you chose to have surgery), and if you are in the Urodynamics group you may be invited to up to 4 visits to clinic (or 5 if you chose to have surgery). The number of visits may be less, depending on the set-up at your local hospital; your research nurse or urologist, will be able to advise you.

You can reclaim travel and parking expenses if you have to come to the hospital specifically for the purposes of this study (that is for non-routine visits to the hospital).

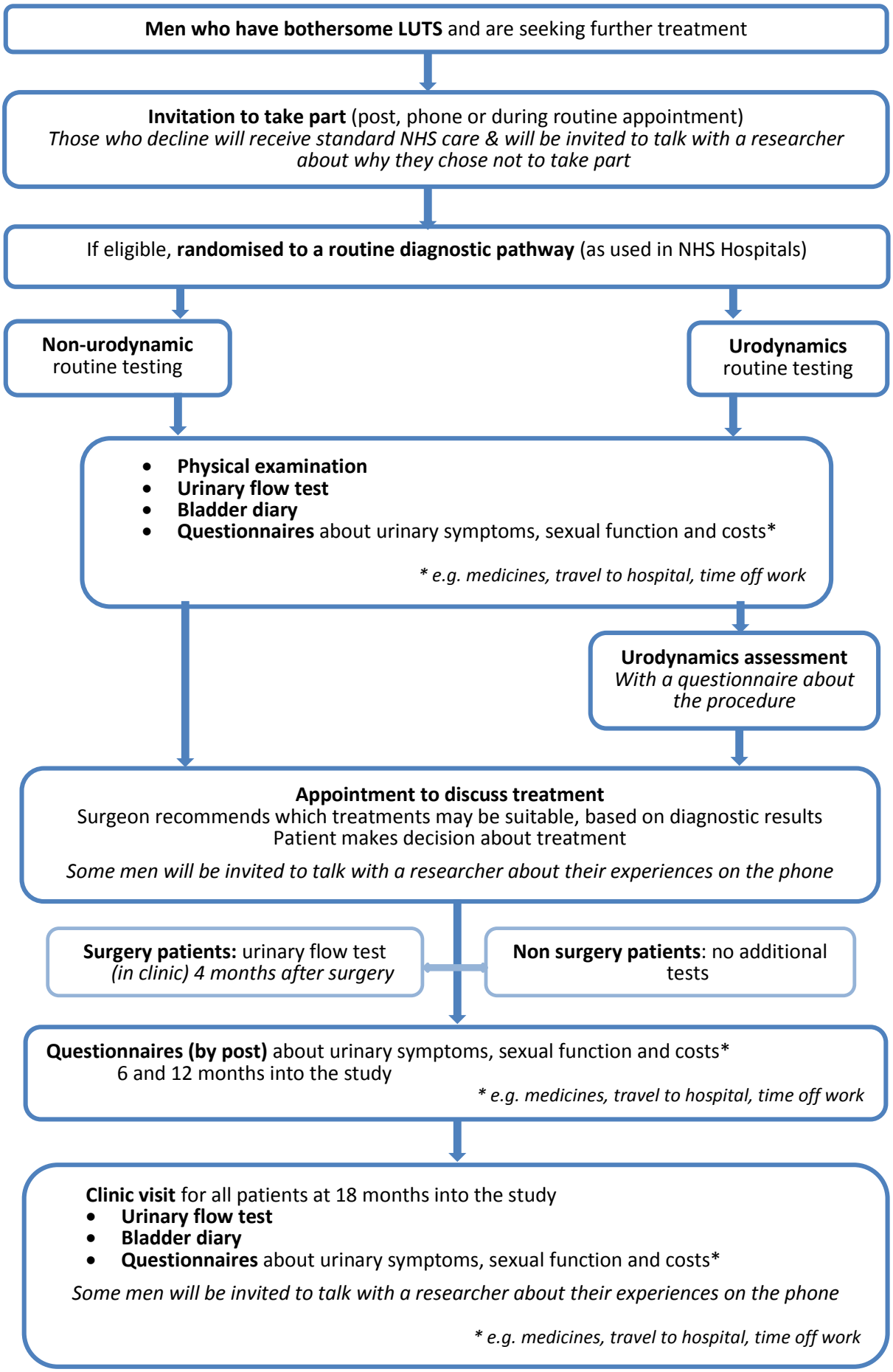
Questionnaires

You will be given questionnaires to complete at these points in the study:

- At Pre-assessment clinic *(all men)*: questionnaire about urinary symptoms, sexual function and costs you might have incurred because of your symptoms
- After the urodynamics assessment *(only men who have the urodynamics assessment)*: a short satisfaction questionnaire about the test
- At 6 and 12 months into the study by post *(all men)*: about urinary symptoms and sexual function and about costs you might have incurred because of your symptoms
- At 18 months clinic visit *(all men)*: about urinary symptoms and sexual function and about costs you might have incurred because of your symptoms

So, if you are in the Uroflowmetry (i.e. usual care) group you will be asked to complete 4 sets of questionnaires (1 each at 0, 6, 12 and 18-months), and if you are in the Urodynamics group you will be asked to complete an additional, short questionnaire following the test. Each set of questionnaires will take 10-25 minutes of your time to complete.

We also plan to interview *up to* 45 patients about their experiences with LUTS and the treatment they have received, however this is an optional part of the study. You can take part in the study but choose not to be invited for an interview. If you agree to being contacted, a researcher will arrange a mutually convenient time and location to discuss the interview and ask for your consent. The interview will take up to one hour.


Men who have bothersome LUTS and are seeking further treatment
Invitation to take part (post, phone or during routine appointment)
Those who decline will receive standard NHS care & will be invited to talk with a researcher about why they chose not to take part
If eligible, **randomised to a routine diagnostic pathway** (as used in NHS Hospitals)
Non-urodynamic routine testing
Urodynamics routine testing
• **Physical examination**
• **Urinary flow test**
• **Bladder diary**
• **Questionnaires** about urinary symptoms, sexual function and costs*
* e.g. medicines, travel to hospital, time off work
Urodynamics assessment
With a questionnaire about the procedure
Appointment to discuss treatment
Surgeon recommends which treatments may be suitable, based on diagnostic results
Patient makes decision about treatment
Some men will be invited to talk with a researcher about their experiences on the phone
Surgery patients: urinary flow test *(in clinic) 4 months after surgery*
Non surgery patients: no additional tests
Questionnaires (by post) about urinary symptoms, sexual function and costs*
6 and 12 months into the study
* e.g. medicines, travel to hospital, time off work
Clinic visit for all patients at 18 months into the study
• **Urinary flow test**
• **Bladder diary**
• **Questionnaires** about urinary symptoms, sexual function and costs*
Some men will be invited to talk with a researcher about their experiences on the phone
* e.g. medicines, travel to hospital, time off work

What are the possible risks and benefits of taking part?

You have been invited to take part in this study because you are experiencing bothersome LUTS and are seeking further treatment, which may include surgery. If you decide to take part in this study you will be randomised by chance into a group that will be assessed by uroflowmetry alone or a group assessed by both uroflowmetry and urodynamics before deciding on the most appropriate treatment, including whether or not to have surgery. Both groups will be assessed with standard clinical pathways used currently in NHS Hospitals.

Those randomised into the Urodynamics group, *may* have to wait 4-6 weeks for the test to be arranged, and an additional visit to the hospital may be needed for the tests to be carried out; travel expenses and parking can be reclaimed for this visit In addition urodynamic testing involves the insertion of catheters and this may expose you to the possibility of side-effects that you would not have been exposed to if you had the uroflowmetry assessment only (these are discussed in more detail in the Assessment Information Sheet [version 3.0, 18/08/2014]) which you will have received along with this sheet).

The benefits of taking part are that you will be providing evidence for future men with bothersome LUTS who may be faced with this decision about diagnostic methods before surgery.

What happens after the trial is over?

After your 18 months hospital appointment you will return to standard NHS care. However we would like to be able to contact you after this, with your permission.

We would like to contact you again to a) check on your long-term health, for example by sending you other questionnaires to add information to what we already know about you, or by checking NHS medical records; and b) to ask you if you would like to take part in other relevant studies. You will not have to reply to any questionnaires or take part in other studies unless you want to at that time.

Part 2: If you are thinking about taking part

How will the information I provide by used?

We hope that 800 men will take part in this study across the UK. Urologists will be informed of the recommendations from the study, so that in future all men can receive the best assessment available before deciding on what treatment to have, including whether or not to have surgery, for their bothersome LUTS.

The results of the study will be published in scientific journals and a short version will also be available to you. No one will be able to identify you from any of the study reports.

Who is doing this study?

This study is being funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme (HTA) (project number 12/140/01). The research is being carried out by a group of experienced doctors and researchers at each of the hospitals involved in this study. They are working in collaboration with researchers at the University of Bristol's Bristol Randomised Trials Collaboration (BRTC), a fully registered Clinical Trials Unit.

Who has approved this study?

South Central Oxford B Research Ethics Committee, your local hospital and your urology consultant have given approval for this study to be carried out. An independent Trial Steering Committee and a Data Monitoring Committee monitor safety and ensure that the study is conducted in accordance with good research practice.

What if there is a problem?

Taking part in this study does not affect your normal legal rights. Whether or not you do take part, you will retain the same legal rights as any other patient in the NHS (which includes professional indemnity insurance for negligence). If you wish to complain about your health care or any aspects of this study, the normal NHS mechanisms will be available to you. We do not expect participation to affect private medical insurance, but please check with your insurers before agreeing to take part in the study.

If you have a concern about any aspect of the study, you should ask to speak with the research team who will do their best to answer your questions (phone 0117 331 3907). If you are still concerned and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your hospital.

If you became unable or unwilling to continue in UPSTREAM, we will withdraw you from the study. We would retain, confidentially and with your consent, the relevant information that we had already collected about you, for the purposes of the study only. However, we will remove your personal data if you prefer.

Will the information I provide be kept confidential?

Yes, all information collected for the study at any time will be stored using a Study Identity Number for confidentiality and will be kept secure using passwords. This includes the questionnaires that may be sent to you in the longer term as mentioned above. The information will only be available to the research team and the NHS or University bodies responsible for maintaining research standards. Your own doctor (GP) and consultant will be informed of your participation in the study.

In order to increase the usefulness of the whole study, we plan to confidentially link your answers with electronic data from your medical NHS records related to your health after your surgery. We will ask you for specific consent to this. Again this information will be kept secure and confidential.

It is a requirement that your records in this research, together with any relevant medical records, can be looked at by monitors from the sponsors, the Research and Development Department of your local hospital or the Regulatory Authorities. Their job is to check that research is properly conducted and the interests of those taking part are adequately protected.

Other researchers may wish to access data from this study in the future: this will not include names, addresses or dates of birth, and it will not be possible to identify participants in any way. If this happens, the consultant leading the study will ensure that the other researchers comply with legal, data protection and ethical guidelines.

How do I get in touch if I want any further information about the study?

If you have any questions about the study, or any aspect of your treatment or health whilst on the study, please speak to your UPSTREAM research nurse or consultant or your own urology consultant or GP. Alternatively you can contact the UPSTREAM Study Office (contact details on the next, and final, page).

Your own UPSTREAM consultant/ research nurse details

(insert sticky label)

Or, you can contact the study team who are organising the research:

Dr Amanda Lewis (Study Manager)

UPSTREAM Study Office

School of Social and Community Medicine,
Canynge Hall, 39 Whatley Road, Bristol, BS8 2PS.

T: 0117 331 3907; Email: upstream-trial@bristol.ac.uk

or

Mr Marcus Drake (Chief Investigator)

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Southmead Hospital, Bristol, BS10 5NB

Thank you for reading this leaflet and considering taking part in UPSTREAM

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