Local Contact Details

PriMUS

Primary care Management of lower Urinary tract Symptoms in men: Development and validation of a diagnostic and decision-making aid.

PriMUS Study Patient Information Sheet

Introduction

You are being invited to take part in a research study. Before deciding if you want to take part, it is important that you understand why the research is being done and what it will involve. Please take the time to read this information sheet carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you feel you need more information. Take as much time as you need to decide if you wish to take part or not.

Thank you for reading this information. If you decide to take part you will be given a copy of both this information sheet and your signed consent form.

The study is being organised by a team from Cardiff University, Centre for Trials Research and Newcastle Upon Tyne Hospitals NHS Foundation Trust together with a local group at local hub name. The research team all have a special interest in medical research, and includes experts in the care of patients with lower urinary tract symptoms. Contact details for some of the researchers are given at the end of this sheet.

This study has been given ethical approval by the Wales Research Ethics Committee (REC) 6. The committee makes sure that the study is conducted ethically and in accordance with the requirements of the Clinical Trials Regulations. Their job is to protect your safety, rights, wellbeing and dignity.

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Background to PriMUS Study

Many men, as they get older, experience problems passing urine. They may need to pass urine more frequently than usual, find their sleep interrupted by having to go to the toilet during the night, notice a change in their flow rate when they urinate or may experience loss of bladder control. These problems are grouped into what we call Lower Urinary Tract Symptoms (LUTS). These symptoms can be unpleasant, can impact on work and social life, and may prompt a visit to a GP for consideration of treatment.

GPs follow well-defined processes when considering signs of serious conditions, but have no easy way of identifying other more less serious but common causes of LUTS, or the best options to relieve symptoms. This means that men are usually referred to hospital for specialist urology tests, and often end up having treatment that could have been given out at an earlier stage by the GP, such as advice about lifestyle measures that may improve symptoms, or medication.

What is the purpose of the PriMUS study?

The aims of the PriMUS study is to create a 'decision aid' to help GPs find the most likely cause of patients' urinary symptoms, so that together they can choose the best treatment. We believe that this will have many benefits such as getting the right treatment sooner, avoiding unnecessary hospital visits, and getting those who need to be seen by a specialist there more quickly.

The decision aid will be a programme on a computer, where the GP will enter patient information and test results. Most of these tests are already done by GPs when a man has urinary symptoms, including a digital rectal examination (where a gloved finger is inserted into the rectum to feel the prostate), symptoms questionnaire and a PSA test (a blood test which may be helpful in ruling out suspected prostate cancer). The programme will then display the most likely cause of symptoms and suggested treatment and management options.

In order to create the decision aid, we need all men taking part in the PriMUS Study to have a test called 'urodynamics', which is the most accurate test to determine the cause of urinary symptoms, and is normally only available to men once they are referred to a specialist by their GP. This is an invasive test where catheters are inserted into the bladder and rectum so that bladder pressure can be measured (described in more detail in a separate information sheet). We can then work out how the less invasive tests above relate to results from urodynamics, so that in the future only the less invasive tests are needed.

Why have I been invited to take part in the PriMUS study?

You have been invited to take part in the PriMUS study, as we understand you have been experiencing Lower Urinary Tract Symptoms (LUTS) and your GP has considered that you might be suitable for this study. There is currently no single effective way to identify and treat the underlying cause of LUTS, so we are inviting patients like you to take part in the PriMUS study to develop a symptom guide, helping to more accurately identify the cause of the LUTS and guide effective treatment. In total, 880 men across the UK, will take part in this study.

Do I have to take part in the PriMUS study?

No, taking part in the PriMUS study is entirely voluntary. It is up to you to decide whether or not you wish to take part. If you decide to take part you will be asked to sign a consent form, but you will still be free to withdraw at any time and without giving a reason. If you decide that you would rather not be in the study, we may ask you why you have decided not to take part, but you don't have to answer this question if you don't want to. Your GP will also be happy to talk through the current standard treatment options and your care will not be affected in any way. Your GP may also stop your involvement in the study if feel that this is in your best interests.

What will happen to me if I take part in the PriMUS study?

Before you take part in this study, you must read this Patient Information Sheet and Consent Form in full. You are encouraged to ask as many questions as you like and should take as long as you need to consider the information provided and consult with your GP, family and friends as you wish. After taking time to consider this information sheet, a member of the research team will contact you by phone. They will discuss the study with you and answer any questions you have. If you are happy to take part, an appointment will be made for you to attend your GP practice, or another one in the area, to meet the researcher.

When you meet, the researcher will explain the study in more detail, check that you understand everything involved in taking part, and answer any further questions. You will be asked to sign a consent form, and you will get a copy to keep.

Not all men with urinary symptoms will be suitable to take part in the study. Men with suspected cancer or serious disease will not be included and will instead be investigated quickly according to national guidelines. If cancer or serious disease is ruled out, they will then become suitable for the study. The researcher will let you know if you are unable to take part and explain what will happen next.

What will happen during the study?

Men who take part in the study will have all of the investigations described below. Some of them will have already been done by your GP as part of your standard care before you joined the study and won't need to be repeated. Any that haven't yet been done will take place at a separate appointment arranged between you and a researcher on a date and time that is suitable for you. Some of the study tests (the Bladder Diary and Home Flowtaker Test) will need to be carried out by you at home. The researcher will provide you with all the necessary equipment and documents for this part.

Medical history	Your age, height and weight, symptom duration, treatment history and any other relevant medical history will be recorded.
Physical examination	An examination of your abdomen and genitals.
Digital rectal examination	A gloved, lubricated finger will be inserted into your back passage so that the prostate can be examined.
Prostate specific antigen blood test	A test to measure the amount of prostate specific antigen in the blood. A raised level may be an indication of prostate cancer, but may also be due to non-cancerous enlargement or inflammation of the prostate.
Symptom score	Two questionnaires which ask about different urinary symptoms, how often you experience them and how severe they are.
Bladder Diary	A chart that you fill in at home for several days by writing down how much urine you pass each time you pass water. You do this by passing urine into a measuring jug rather than your toilet.
Home flowtaker test	You will be provided with a home flowtaker, similar to a weighing scale with jug that you use at home for several days. This measures flow rate, volume and the time that you pass urine. The researcher will give you specific instructions for how to use this at home.
Urodynamics	This is the most invasive test involved in the study and carries a small risk of a bladder infection (more details below), but it also gives the best information about what is causing your urinary symptoms. This is the gold standard test normally only carried out if your GP refers you to a Urology Specialist. We have provided a separate information sheet at the end of this one about urodynamics, **please read this carefully**.

Qualitative Interview Study (One to one feedback interviews)

We also want to know how men feel about taking part in the study and having the tests done. After the tests have been done, a researcher will contact some of the men to see if they would like to take part in a follow-up interview so that they can share their experiences. Not all men will be contacted for an interview, as we only need to speak to around 30 men. The interview should take around 30 minutes, and can be done at a location that is convenient to you, or over the telephone. The researcher will ask you questions about what it was like to take part in the study, and what you thought about the tests. The interviews will be recorded so that we have a record of your feedback. This recording will be made

anonymous and will remain confidential, so your answers will not be fed back to your doctor. Remember, you do not have to take part in the interview if you do not want to.

What other information will you be collecting?

In addition to results from the tests described above, we would like to see how you are doing in the longer term by using routinely collected health data, to find out about any further tests or treatments you have. This is information that your GP and hospital collect when looking after you.

The research team will provide details such as name, NHS number, date of birth, gender and postcode to identify you to NHS Digital in order for those professionals to provide relevant information about your ongoing health. NHS Digital will provide information on how trial participants have used different health services (e.g. how many hospital visits) and for what reasons.

NHS digital will provide data to Cardiff University. No identifiable data will be sent to the database. Instead, a study number will be assigned to each individual and this will be used to join pieces of information together. Data viewed by the research team will not be identifiable. In other words, when we look at your health information, all we will see is a database containing numbers. A Data Manager will use the study number to identify a person and join up the information. We will not know who is who in the database. The data will be held on a secure server and only the research team will have access to it.

What are the alternatives to the PriMUS study?

If you decide not to participate in this study, or your GP feels you are not suitable, an alternative management plan will be made available. Your GP will discuss the alternative options with you before you decide whether or not to take part in this study.

What are the possible disadvantages and risks of taking part?

All men who take part in this study will have a urodynamics test. After the test you may experience a mild stinging sensation when you pass urine for a few hours, or in some cases up to a day or so, but these symptoms usually improve quickly. You may also pass a little blood with the urine the first time you pass water. About 5% (five in a hundred) of patients who have this test get a bladder infection (cystitis) afterwards. If this happens the stinging will get worse and you may feel more unwell. If this occurs you should see your GP as soon as possible, and will probably be treated with a course of antibiotics. There is a small risk, (less than one in a hundred) of urine retention (inability to pass water) following the urodynamics test in men with difficulty emptying their bladders, although this rarely occurs. If you are at all worried you should see your GP as soon as possible.

The PriMUS study may involve one or two more visits to the GP or hospital than might be needed in routine care. Taking part will also mean that the GP, nurse or a researcher may take up a little extra of your time asking certain questions about your symptoms. Being involved in a research study involves a degree of commitment to these visits and additional questions.

What are the possible benefits of taking part?

The main benefit of entering this study means that you will have a very thorough investigation of your urinary symptoms within a few weeks of seeing your GP. This includes a urodynamics test, which is the gold standard test for determining the cause of urinary symptoms and usually takes place once a patient has been referred to hospital. Your symptoms might therefore be suitably managed in a shorter timeframe than usual, as your GP will have all the information they need to make an accurate diagnosis.

Another possible benefit, is that research studies such as this are essential for progress in the treatment of conditions and their symptoms, so taking part will also help inform us about the best way to treat men like you with urinary symptoms in the future.

You will receive a high street shopping voucher to a maximum value of £30, to cover any travel expenses incurred whilst taking part in the study.

What happens when the study stops?

Once the diagnostic tests have been completed, all the results will be considered by a specialist and a management recommendation provided to your GP. At this point your participation in the study will end. You will continue to be managed as before by your GP, which may include referral to specialist care at some point in the future. For a period of approximately up to 6 months we may contact you to ask for an update on your urinary symptoms, to allow us to assess longer term outcomes. A small number of men who take part in this study will be invited to an interview to discuss their experience. If you are invited, you will be provided with a separate information sheet about this.

What will you do with the results of the study?

The results will be published in a detailed report to the National Institute of Health Research who are funding the study. We also hope to publish the results of our study in scientific and medical journals, and present results at medical meetings and conferences. We will never publish any personal details about an individual, or anything that could allow them to be identified. We will be happy to supply a summary copy of the research findings to you once they become available, if requested.

What will happen if I don't want to carry on with the study?

You can leave the study at any time, without giving a reason and this will not affect the standard of care you receive now or in the future. If you decide not to continue the study for any reason, you should discuss this with your GP so that they can make the best arrangements for your continuing care. If you do decide to leave the study you will be asked to help complete a study withdrawal form, indicating to what extent you wish to be withdrawn from the study. We will check whether we can: a) still use the information we have collected about the treatment you were given and your progress up to the time you withdrew, and b) whether you are happy for study organisers to be updated from time to time on how well you are doing.

In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 15 years after which arrangements for confidential destruction will be made.

Will my participation be kept confidential?

If you agree to take part in the PriMUS study, your GP will send information about you, your condition and your progress to the study data centre (Centre for Trials Research) at Cardiff University, separate from your personal information (names, addresses and phone numbers). Only authorised persons on the research team will have access to view identifiable data. However, in some instances authorised persons from regulatory authorities may need to access data for monitoring of the quality of the research. All members of the research team and regulatory bodies are trained in data protection issues and bound by the terms of the Data Protection Act 1998. This information will be put into a computer and analysed by the Centre for Trials Research office staff. All information that is collected about you during the course of the research will be held securely and in strict confidence.

With your consent, we will collect information that is held and maintained by NHS Digital and other UK NHS bodies from your medical records and other health-related records in order for us to follow your health status. This information will be looked at by the research team during the trial but will be treated and kept as strictly confidential.

When the study is complete, the results will be submitted to the National Institute of Health Research who are funding the study. Results will also be presented at conferences and published in scientific journals, but no individual patients will be identified and all results will be completely anonymous. If you would like to obtain a copy of the published results, please ask your GP.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you should ask to speak to your local study team (GP or Nurse) or to the trial organisers who will do their best to answer your questions. The Co-Chief Investigators of the PriMUS study are Professor Adrian Edwards (Cardiff University) and Mr Chris Harding (Newcastle University) who may be contacted via Centre for Trials Research on (Tel: 02922 510475).

- **Complaints:** If you remain unhappy and wish to complain formally you can do this through the NHS complaints procedure. Details can be obtained from your local hospital. For sites in England you may also contact your local Patient Advisory Liaison Office. (Tel……..)
- **Harm:** There are no special compensation arrangements if you are harmed by taking part in this research project. If you are harmed due to negligence, you may complain through your local hospital complaints procedure or you may have grounds for legal action against the trial sponsor (Cardiff University).

Who has organised, reviewed and funded the research and who will be supervising it?

The study is being organised by Centre for Trials Research and is being sponsored by Cardiff University which is, in law, the responsible organisation. The lead individuals responsible for the day to day running of the study, also known as the Co-Chief Investigators, are Professor Adrian Edwards and Mr Chris Harding. The PriMUS study is funded by a grant from the National institute of Health Research (NIHR). The PriMUS study has been reviewed by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Research Ethics Committee (REC) Wales Rec 6 and approved by the R&D department at your local hospital.

Should you have any further questions or require further information about taking part you can contact (during normal working hours):

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7th Floor, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS
Tel: +44 (0)29 22510475 E-mail: **PRIMUS@cardiff.ac.uk**

Please note that this number is only for queries regarding the study; if you have an urgent medical problem please contact your GP in the normal way.