To be printed on Trust headed paper

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PATIENT INFORMATION LEAFLET

INVITATION TO TAKE PART

You have been sent or given this leaflet because you may be suitable to take part in a research study. We would like you to take a little time to decide if you wish to take part or not.

It is important that you understand why the research is being done and what taking part will involve. Please read this information leaflet carefully. If you wish, you can discuss it with friends, relatives and your GP. If you plan to talk to your GP you should take this leaflet with you, as they may not have heard about the study.

If the information is not clear or if you would like more information, please ask us. Our contact details are at the end of the leaflet.

WHY AM I BEING INVITED TO TAKE PART?

You are being invited to take part because your bladder problem seems not to have improved since you began treatment and it is possible that surgery might be the next option. Often at this stage your doctor would arrange some more tests before surgery. These tests are what our research is about.

DO I HAVE TO TAKE PART?

No, you do not have to take part. Whether you take part or not is your decision. Not taking part will not affect the standard of care that you receive.

You do not have to decide immediately. You can read this information sheet as many times as you wish and ask as many questions as you need to before you decide whether to take part or not.

If you read the information and decide to take part, tell the doctor or nurse at the hospital. They will tell the appropriate research staff who will discuss the study further with you.

If you decide that you do not want to take part in the study, you do not have to do anything more.

Even if you agree to take part you are still free to change your mind later and you are free to withdraw from the study at any time.

Later in the leaflet there is more information about what happens if you decide to take part or not, or about leaving the study.

WHAT IS THE STUDY ABOUT?

The study will look at how bladder tests are used when decisions are made about treatments for urinary incontinence and whether the "invasive" tests that are often used really help us to make better decisions.

As with most medical problems, there are a number of steps we take when deciding how to treat urinary incontinence. We usually start by asking you about your symptoms in detail and by examining you. Then there may be some simple tests such as urine samples, scans and asking you to record your toilet habits. You may have been through these steps already. Very often we can decide on your treatment by using only these simple measures, but before deciding on surgery, we often use more complex tests. These are given several different names, but you might have heard of bladder function tests, cystometry or urodynamics. These tests involve passing a catheter (a thin tube) into the bladder to measure its activity. We describe these tests as 'invasive urodynamic tests'.

The invasive tests are intended to help your doctor to decide whether an operation is the right thing for you, or whether other non-surgical treatments might be more helpful.. However, these tests take time to do, some women experience discomfort during the tests and some may develop a urinary tract infection (cystitis) afterwards.

Even though invasive tests are used very often before surgery these days, there is actually very little evidence to prove that they really help surgeons to choose the best treatment. Our research aims to find out whether treatment for women who have invasive urodynamic tests is more or less successful than treatment that is selected on the basis of the simpler non-invasive tests alone.

This study is what we call a 'pilot study'. This is the first phase of our research and it will help us to 'test' our plans before continuing with the next phase of the research. This is an important stage that will make sure the research programme as a whole answers the questions it sets out to answer … and so makes best use of taxpayers' money.

WHAT WILL HAPPEN IF I AGREE TO TAKE PART?

You may have received this information sheet before or during your outpatient appointment. If you feel that you have had enough time to think about it and have all your questions answered satisfactorily and are happy to agree to take part at this stage, we can proceed straight away. On the other hand, you may wish to take the leaflet home, read through it at your leisure and discuss it further with others before making a final decision. If this is the case, the study team will telephone you to ask about your decision, and to explain the process further from here.

If you agree to take part you will be asked to sign a Consent Form stating that you are happy to help in the research and that you understand what is involved. You will then be put into one of two groups. The groups are explained in the diagram at the end of this leaflet. All women involved in the study will already have undergone 'clinical assessment'. A doctor or nurse will have talked to you about your symptoms, examined you, and perhaps carried out some basic tests.

The allocation of women to the test groups will be done at random. During your discussions your doctor and you have already decided that either test group would be suitable because we have no evidence that the tests definitely help treatments decisions. One group of women will then go on to have the additional invasive urodynamic tests and the other will not. Your hospital doctor and you will decide what treatment you should have based on the information from whichever tests you have had. In every other respect your care will be no different from the care you would receive if you do not take part in the research.

This sort of 'randomised study' is the best way of comparing two methods of doing things in health care. It is considered 'ethically' good practice to randomly select care processes in this way because there is no evidence to prove that one way of doing things is any better than the other. If evidence existed then we would not need to do this research. In this research randomisation means that any differences in the results of treatment at the end of the study depend on whether or not invasive urodynamic tests were used.

Apart from the decision to use invasive urodynamic tests or not being allocated for you, there will be no difference in the care you receive whether or not you take part in the study. If you end up having surgery, your hospital doctor and you will decide which operation seems most likely to be your best option and your treatment will proceed as normal. If you have other non-surgical treatments, again the choice will be made by your hospital doctor and/or nurse and yourself in discussion.

You will be asked to fill in a number of questionnaires, before treatment and again six months afterwards so we can assess how well your treatment has worked. The questions cover what happens to your urinary symptoms, the effect that these symptoms have on the quality of your life and general health, and the costs of your healthcare.

WHAT WILL HAPPEN IF I DO NOT WANT TO TAKE PART?

If you decide not to take part you do not have to do anything. If the study team calls you, simply tell them your decision. You do not have to give a reason.

If you decide not to take part in the main part of the study, you may choose to help us in a different way. We want to find out a little more about why some women agree to take part and others do not. So if you choose not to take part in the main part of the study you can help us by agreeing to be interviewed at a later date about why you chose not to take part. However, this is also up to you and not taking part in this way will not affect the care you receive.

Even if you agree to take part you are still free to change your mind later and you are free to withdraw from the study at any time. It is important for us to understand **why** women do or do not wish to take part in this study, so you may be asked about your reasons for withdrawing. However, if you do not wish to give a reason you do not have to do so. If you withdraw from the study at any time, this will not affect the care you receive subsequently.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

You can withdraw from the study at any time; all we ask you to do is contact the local research nurse to let us know. Because this is a 'pilot study' helping us to plan future research, it is important for us to understand **why** women do or do not wish to take part, or decide to withdraw. You will therefore be asked your reasons for withdrawing; rest assured that if you do not wish to give a reason you do not have to do so.

If you do want to withdraw from the study you can withdraw completely. Alternatively, even if you don't want to take part in the bladder test part of the study, it would be helpful if you could continue to complete the questionnaires for us; you are however under no obligation to do this. Either way, if you withdraw from the study, your investigation, treatment and follow-up will continue just as though you had never been involved, and it will not affect the standard of care you receive subsequently in any way.

HOW WILL THIS RESEARCH HELP OTHER PATIENTS AND DOCTORS?

The purpose of this pilot study is to collect some initial information on the results of the treatment that women receive, but also how many women do or do not agree to take part, and how many provide all the information that we ask for in the six months after their surgery. This will enable us to calculate how many women we need to ask to take part in the next larger phase of the research. This way of planning research ensures that the best use is made of NHS research funds.

Ultimately we will be able to tell whether invasive urodynamic tests help surgeons and patients to choose the best treatments and therefore make sure that, in the future, treatment for stress urinary incontinence is successful for as many women as possible, by ensuring that surgery is offered in appropriate cases.

ARE THERE RISKS IF I TAKE PART?

On balance, we do not believe that there are disadvantages or risks involved in taking part in the research. The main risks you must take into account are to do with the surgery that will be considered whether you take part or not, and your surgeon will have discussed these with you. Most women who take part in the study will have similar surgery whichever group they are in.

There are some risks with invasive urodynamic tests: research suggests that nearly half of all women feel anxious or embarrassed about the tests; about a quarter experience discomfort during or after the tests and some women may develop a urinary infection afterwards (previous studies suggest this may be between 2% and 10%).

The balance of risk versus benefit comes down to whether or not the tests are effective in helping surgeons to decide whether surgery is necessary, and until we complete this research we do not know this.

ARE THERE BENEFITS IF I JOIN YOUR STUDY?

Whichever treatment you have, it is very likely that your incontinence will be helped because the treatments available are all reasonably effective. The study will have no other benefits for you personally. The information we obtain will allow us to plan the next phase of the research so that we will be able to tell whether invasive urodynamic tests help surgeons to plan patients' care more effectively or not; this will help other women in the future and will help us to ensure that NHS funds are used properly.

WHAT IF YOU GET NEW INFORMATION ABOUT THE TESTS DURING THE STUDY?

The results of the study will only be fully analysed after all patients involved have completed their follow-up questionnaires. As we go along the trial will be overseen by a 'Trial Steering Committee', and the results will be reviewed by a 'Data Monitoring and Ethics Committee' (DMEC). If we get new information about the tests that shows that our research is no longer needed, or tells us that there are any risks or benefits that we are not aware of at present, this will be considered by the DMEC. If it is felt appropriate, your study nurse will tell you about these issues. If they think it is best for you to leave the study, they will tell you why and arrange for your care to continue. Otherwise, they will ask if you want to stay in our study.

You can leave the study without giving any reason, and your research doctor will make sure your care continues. If you decide to stay in our study you will be asked to sign a new consent form.

WHAT IF SOMETHING GOES WRONG?

We do not believe that by taking part in this study there is any greater risk of harm than if you have surgery outside of the study. If any harm occurs while you are taking part in this research project, you will have all the rights and protection that you normally have as a patient. There are no special compensation arrangements for study participants. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it.

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures are available to you. The local study team will be able to tell you who to contact in this situation.

If you have a concern about any aspect of this study, you should ask to speak to the Research Nurse who will answer your questions; their contact details are given at the end of this leaflet.

WILL MY DETAILS BE KEPT CONFIDENTIAL?

Provided that you are happy for us to do so, we will notify your GP that you are taking part in the study; otherwise nobody will find out from us that you have taken part in this study. Information about you will be kept strictly confidential; any details of the study that leave the hospital will have all personal identification removed so nobody will know it is about you.

WHAT WILL HAPPEN TO THE RESULTS OF YOUR STUDY?

The results will be used to plan the next phase of our research and may be presented at medical conferences and published in medical journals. All this published information will be anonymous – you will not be identified in any way.

It may be quite a while before we present any information in this way. If you want to know the results of our study, tell us and we will send them to you as soon as they are ready.

WHO IS ORGANISING AND PAYING FOR THE STUDY?

The study is organised by a team of doctors and researchers in Newcastle, Leicester, Sheffield and Swansea. Mr Paul Hilton is primarily responsible for the study; he is a Consultant Gynaecologist in Newcastle where he works closely on the study with colleagues in the Clinical Trials Unit. Our study is funded by the National Institute for Health Research (NIHR); this is an organisation set up to establish the NHS as an internationally recognised centre of research excellence by conducting leading research focused on the needs of patients and the public.

HAS ANYONE APPROVED YOUR STUDY?

Before the money for the study was agreed the details were reviewed by several committees within NIHR to ensure that it is an important study to do, and is planned in a scientifically valid way. They were helped in that assessment by a number of independent medical experts.

The study has also been considered in detail by a Research Ethics Committee. Research like this cannot proceed without being approved by such a committee, which consists of medical, nursing and research experts and lay people. Approval does not guarantee your safety, but it does mean that the Ethics Committee believes your rights will be respected and that risks have been reduced to a minimum and balanced against possible benefits. The Ethics Committee also checks that you have been given the information you need to make an informed choice about whether or not you want to take part in the research.

WHERE CAN I GO FOR MORE INFORMATION?

You can contact your local study team for more information at the addresses given below; alternatively, you can get in touch with the central trial management team in Newcastle, at the addresses given below:

LOCAL STUDY TEAM FOR YOUR AREA:

RESEARCH NURSE

Enter local contact details

CONSULTANT SURGEON

Enter local contact details

CENTRAL STUDY MANAGEMENT TEAM:

TRIAL MANAGER

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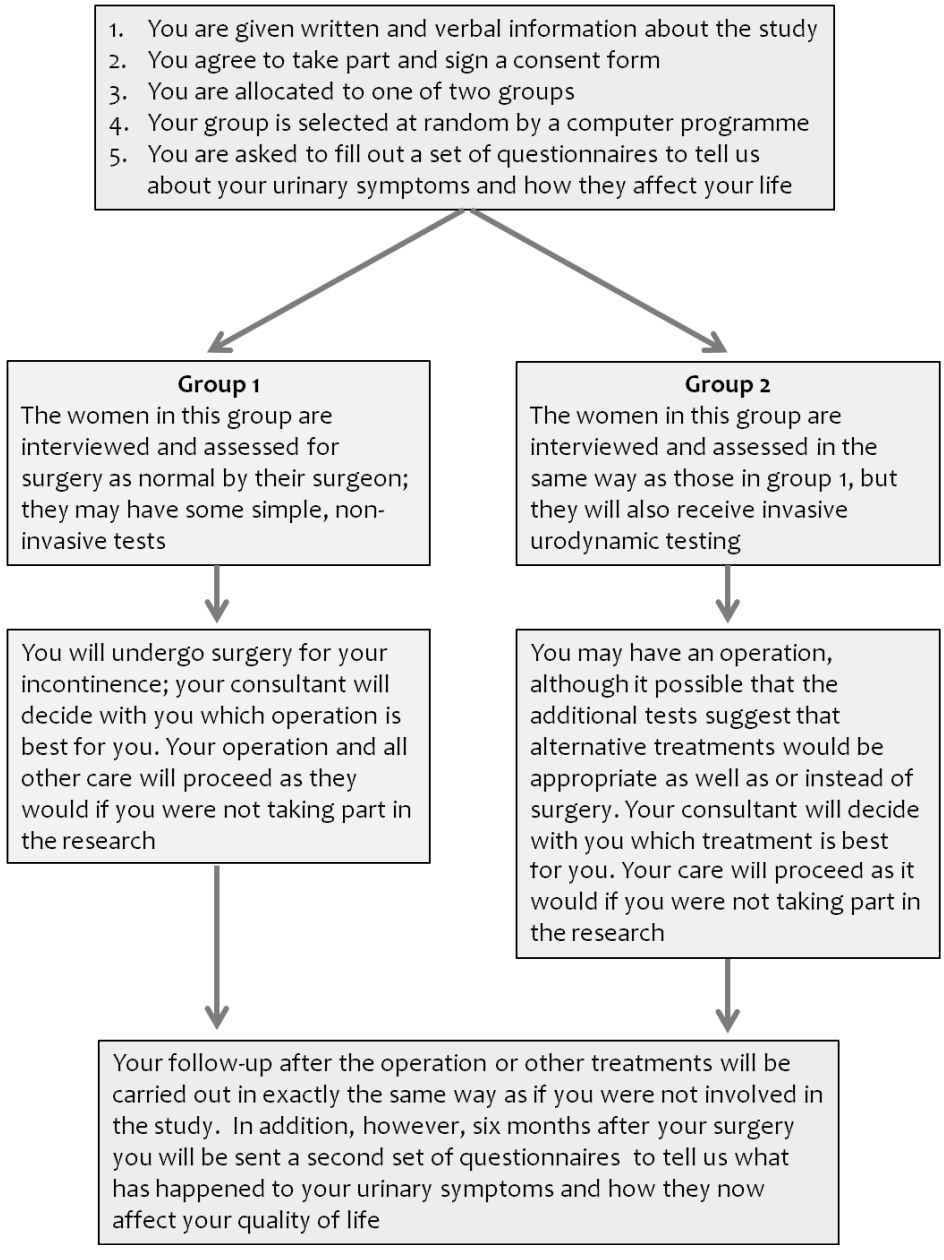
1. You are given written and verbal information about the study
2. You agree to take part and sign a consent form
3. You are allocated to one of two groups
4. Your group is selected at random by a computer programme
5. You are asked to fill out a set of questionnaires to tell us about your urinary symptoms and how they affect your life
Group 1
The women in this group are interviewed and assessed for surgery as normal by their surgeon; they may have some simple, non-invasive tests
Group 2
The women in this group are interviewed and assessed in the same way as those in group 1, but they will also receive invasive urodynamic testing
You will undergo surgery for your incontinence; your consultant will decide with you which operation is best for you. Your operation and all other care will proceed as they would if you were not taking part in the research
You may have an operation, although it possible that the additional tests suggest that alternative treatments would be appropriate as well as or instead of surgery. Your consultant will decide with you which treatment is best for you. Your care will proceed as it would if you were not taking part in the research
Your follow-up after the operation or other treatments will be carried out in exactly the same way as if you were not involved in the study. In addition, however, six months after your surgery you will be sent a second set of questionnaires to tell us what has happened to your urinary symptoms and how they now affect your quality of life