

Participant Information Sheet

Research study to find out how conditions of the penis change men's lives

You are invited to take part in a research study about men who have a condition that affects their penis.

This leaflet explains why the study is being done and what you can do to help if you decide to take part. You can show this leaflet to your family or friends and discuss it with them if you wish. If there is anything you are not clear about, or if you would like more information then please ask the lead researcher. He is carrying out the study as part of an academic qualification and his contact details can be found at the end of this leaflet.

Who is carrying out this study?

This study is being carried out by a team of doctors and researchers at Newcastle University. It was designed with the help of the Hypospadias UK Trust. The study is funded by the Royal College of Surgeons of England (<http://www.rcseng.ac.uk>).

Why is this study being done?

Some men are born with conditions, get diseases, or have operations that affect the way the penis works. This can cause a range of different problems but the obvious ones are trouble passing urine and having sex. These issues are embarrassing so men may choose to hide them in ways that interfere with their day-to-day lives. For example, a man who is worried about the way his penis looks might avoid the swimming baths on the off chance he would have to get changed in front of others. Research has shown that men who feel they have problems with their penis delay forming relationships or experience difficulties within relationships.

We would like to achieve two things: 1) find out which are the most important issues to men with a condition that affects their penis; 2) use this information to create a health questionnaire which can measure the impact of those issues on men's everyday lives. We hope that this questionnaire will be useful in future for finding out which treatments for these conditions work best.

Why have you asked me?

Although we are interested in all conditions that affect the way the penis works, we are focusing on two specific ones for the purpose of this study. The first is called hypospadias. This is a birth defect that occurs in about 8 in 1000 males where the hole through which urine and semen leave the body is located on the underside of the head or shaft of the penis rather than at the tip. The second condition is penile cancer, which is usually treated with an operation to remove part or all of the penis. If you have or think you have either of these conditions you can take part in this research project.

What is involved?

To be involved in this study you will need to take part in a one-to-one interview. This interview will be with the lead researcher who is also a doctor specialising in these conditions. It should last no longer than one hour and can take place at a time and place of your choosing. The interviewer can travel to meet you – you do not have to live near Newcastle upon Tyne. The interview can also be done over the telephone or by videoconference (e.g. Skype/Apple FaceTime) if that is what you would prefer.

The interview will be recorded on a digital tape recorder. This is so the interviewer can concentrate on what you are saying rather than writing it down. The recording will be written out later (transcribed) so that it can be looked at by the researchers. Your personal details will be removed from the written out version so that you

cannot be identified by anyone other than the research team.

We are planning to interview up to 30 men in total for this part of the study.

What are the benefits of me taking part?

Some men may find it helpful to talk about the issues they have experienced with the interviewer who is a doctor with a special interest in penis conditions (a urologist).

Do I have to take part?

No. It is up to you to decide. If you don't want to take part it would be useful to know why you decided not to, but you do not have to tell us.

Can I say yes now then change my mind?

Yes. You do not have to go through with the interview if you change your mind about it later.

If I agree to be interviewed what will it be like?

The interviewer will check that you are happy to go ahead. He will ask you to sign a consent form to say that you understand what the study involves. The interview is intended to be relaxed and informal. It will begin with some open-ended questions to guide the conversation, but we're really interested in hearing about the things that are important to you. You won't be pressured to talk about anything you don't want to.

Are there any downsides to taking part?

We understand that penis problems are deeply personal and some men find the subject difficult or upsetting to talk about. The interviewer is trained and experienced in discussing sensitive issues like these. If you feel distressed you can stop the interview at any time. If you do decide to stop the interview we will ask you whether we can use the information you have already given us for our research. If you do not want us to use your interview recording it will be erased.

If you would like professional help to discuss any of the issues raised in the interview, or more general support, we will advise you to see your GP. With your permission we are also able to contact your GP to explain how the issues have been raised. If you are already under the care of a hospital specialist for your penis problem we can help you arrange to see

a clinical psychologist or other healthcare professional to explore ways that may help you cope with distress.

Will I get paid for taking part?

No. There is no payment for taking part in this study. If you decide to travel to meet the interviewer we will reimburse your travel expenses. If the interview is conducted over the telephone we will phone you so that you don't have to pay for the call.

Has anyone checked out this study to see if it is all right?

This study has been looked at and approved by the Wales Research Ethics Committee 4. This committee is responsible for making sure that medical research going on in the area is ethical and fair to people who take part.

Will what I tell you be kept private?

Yes. Only the research team will know who is in this study. We are bound by a code of confidentiality. This means that we must take great care to prevent anyone outside the research team seeing any personal information about you. We may share some of the things that you tell us with other researchers, but this information will be anonymous. We may use some of your quotes in medical reports but these will also be completely anonymous.

What happens now?

If you would like to take part or would like more information please contact:

Lead researcher: Matthew Jackson
3rd Floor William Leech Building
The Medical School
Newcastle University
Newcastle upon Tyne
NE2 4HH
Email: matthew.jackson2@ncl.ac.uk
Phone: 07821 330944

Thank you for thinking about taking part in this research study.