# Patient information sheet: HAARP study

**H**ome **A**ssessment of urinary voiding and storage function before and **A**fter **R**adical **P**rostatectomy for prostate cancer (**IRAS ID:** 242020)

## Invitation

You are being invited to take part in a research study. Before you decide, it is important that you understand why the research is being done and what it will involve. Please take your time to read this information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part. Contact details for the researchers and the patient advice service are given at the end of this document.

## Background

A prostate cancer diagnosis can be a very difficult time of life for you and your loved ones. There is a lot of information to take in at the time of diagnosis, and your understanding is likely to be affected by feelings of shock, fear and upset. Your main thought when considering treatment options is likely to be getting rid of the cancer, and so you may think less about how your decision will affect your life later on.

### Prostate cancer in the UK

Prostate cancer is the most common cancer in men in the UK. In 2014, there were over 40,000 new cases, and the number rises each year. Many of these men are treated by surgery to remove the whole prostate, an operation called a 'radical prostatectomy'. This has a good chance of curing the cancer, but it can cause side effects.

### Radical prostatectomy side effects

Leakage of urine is the most common unwanted side effect of radical prostatectomy. Several large research studies have looked into this and measured how many men have leakage after surgery (ranging between 4% and 69%). Other studies have looked at how the surgery affects urinary symptoms. They found that symptoms such a weak flow rate improved, but that patients felt they passed urine more often after the operation. Although patients have been asked about their

symptoms, the effect on flow rate and the number of times they pass urine has never actually been measured. Doing so has recently become more convenient using a device called Flowtaker.

### Flowtaker

Flowtaker (pictured below) is a device that you can use at home to measure your flow rates and volumes, and how often you pass urine. First the jug must be placed on the sensor, before you pass urine into the jug, which you then empty and rinse. You are asked to use Flowtaker to record as many voids as possible whilst at home over the course of 1 week. Previous studies using the device have shown that it is easy to use.


## What is the purpose of the study?

We aim to measure how radical prostatectomy affects urinary flow rates, volumes and frequencies. We will do this by asking a group of men to use Flowtaker before and at 3 and 12 months after surgery. We will use this information to create an easy to understand leaflet that can be given to patients who are thinking about having a radical prostatectomy. This way they can make a more informed decision about their treatment. We will also measure the link between urinary changes and symptoms and general well-being changes by asking patients to fill out questionnaires.

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

You are scheduled for radical prostatectomy surgery following a diagnosis of prostate cancer. All men who have a radical prostatectomy at this hospital will be invited to take part in this study.

## Do I have to agree to take part?

No, taking part in this study is voluntary. If you would rather not take part, you don't have to tell us why and your care will not be affected. To help us plan future research work, 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.

## What will be involved if I take part?

The first step is for you to provide written consent to take part. As this is a very low risk study, if you are happy to agree to take part today, you can provide written consent and take home the Flowtaker and questionnaires for the first part of the study. If you would rather have more time to consider your involvement, the research team will phone you after at least 48 hours to ask if you wish to take part. If you do, another visit will be arranged for consent and collecting the Flowtaker and questionnaires.

Men who take part in this study will carry out the following activities at three time-points: 1) before your prostate surgery, 2) three months after surgery, and 3) 12 months after surgery:

1. Use the Flowtaker at home for one week, whilst completing a fluid intake diary. You will be given clear, simple instructions on how to use it. The Flowtaker can be collected from the clinic by you, or sent to you by post. Similarly, when you have finished using the Flowtaker, you can bring it back in person or return it by pre-paid post. A new device will be required for each of the three one-week periods.
2. Complete symptoms questionnaires that ask about your urinary function, bowel habits, sexual function, hormones, and general quality of life. These can be completed at home and returned with the Flowtaker.

After the study activities 12 months following your surgery, your involvement in the study will end.

## Are there any risks to taking part in the study?

We believe there are no risks to taking part. It may be a temporary inconvenience to pass urine into the flowmeter instead of your toilet whilst using the Flowtaker.

## What are the benefits to me of taking part in the study?

There is no personal benefit in taking part in this study. The results will not be used to make decisions about your management. The information we collect from this study may help to improve the care of men in a similar situation to you in the future. Travel expenses will be reimbursed for any additional visits to hospital for the purpose of the study.

## Can I change my mind about taking part?

Yes, you can withdraw from the study at any time, without giving a reason, and your care will not be affected. Again, we may ask you why you have decided to withdraw, but you don't have to answer this question if you don't want to.

## Will information about me be kept confidential?

Yes, all members of the research team who collect and review information about you will act in a professional and confidential manner. Data from the study will be stored securely using password-protected computer systems. Identifiable data (your name and contact details) will be kept until 12 months after the study has ended, and then destroyed. It will be stored in a locked filing cabinet in a room on hospital premises which is locked when unoccupied. For quality control reasons, research data might be reviewed by authorised members of staff from the Research and Development department, but this will be completely confidential.

## What will you do with the results of the study?

The results of the study will be written into a report by the researchers. We also hope to publish them in scientific and medical journals, and present them 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 after the end of the study. Please let us know if you would like to receive this.

## Who has organised, reviewed and approved the study?

The study is being run by a team from The Newcastle upon Tyne Hospitals NHS Foundation Trust. The research has been reviewed and approved by the Health Research Authority, a Research Ethics Committee, and our local R&D department.

## What if there is a problem about the study?

If you have any concerns about the study you should speak to the researcher, who will do their best to answer your queries. If you are still concerned you can contact the patient advice service (contact details below). To make a formal complaint you can use the NHS complaints procedure, and details are available from the patient advice service.

If you feel you have been harmed during a research study, and that this is due to someone's negligence, you may have grounds to consider legal action against The Newcastle upon Tyne Hospitals NHS Foundation Trust, but you may have to pay.

## Contact details

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| Lead researcher | Alison Bray<br>Clinical Scientist (pre-registration)<br>Medical Physics<br>Royal Victoria Infirmary<br>Newcastle upon Tyne<br>NE1 4LP<br>0191 2823823<br>abray3@nhs.net |
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