Health Sciences

UNIVERSITY OF Southampton

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Prostate Cancer UK Continence Management Programme
Development of a new penile compression device
Phase 2: Evaluation of prototype clamps

Appendix 16.

Participant Information Sheet – Phase 2a & 2b.

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You are being invited to take part in a research study to evaluate prototype penile compression devices (clamp). Before you decide whether or not you wish to be included in this study it is important for you to fully understand why the research is being done and what it will involve. Please take the time to read the following information and ask us if there is anything you are unclear about. We will phone you in a few days to answer your questions. You may wish to contact us on the telephone number at the end of this information sheet.

This project is part of a larger project funded by Prostate Cancer UK and the Movember Foundation.

What is the purpose of this study?

10-15% of men who have had treatment for prostate cancer experience long-term urinary incontinence and most will use absorbent pads to contain their leakage. Alternative devices are available, including clamps. These devices are suitable for some men but they aren't widely used and little is known about how well they work. A recent study suggested that the Cunningham clamp (Figure 1) has the potential to be useful in preventing urinary leakage when worn for short periods of around 1-2 hours, especially during vigorous activities (such as swimming, dancing or walking). However, it was found to be uncomfortable and men could only wear it for short periods. Most men reported that they would like an improved clamp to use as well as other devices and pads.

In Phase 1 of this study we evaluated a number of penile clamps. None were found by men to be more acceptable than the Cunningham clamp. In Phase 2, we will evaluate several prototype clamps which have been developed by the engineers and nurses working with men who use clamps. We want to test the clamps for effectiveness and acceptability to men. If at the end of this study we have developed a clamp which is found to be significantly better than existing clamps, we intend to make it commercially available.

What are penile compression devices or clamps?

A clamp is a type of urinary continence device designed specifically for men. Clamps are available in a wide variety of designs (some examples are shown in figure 1-3). The clamp is applied to the central portion of the penis (the shaft) and is designed to prevent leakage by closing off the urethra (the drainage channel within the penis through which urine passes from the bladder). Based on the research available, it is recommended that all clamps should be released at least every 2 hours to allow urine to drain from the bladder and to ensure good blood circulation is maintained. They are designed to be used during the daytime only, and are not suitable for use during the night because of the need to release them regularly. There is no need for any other products to be used with these devices, although most men choose to use them in conjunction with a pad for extra security.

Examples of penile clamp designs

Figure 1: Bard Cunningham

Figure 2: Weisner

Figure 3: Dribblestop

Why have I been invited?

We are looking for men who:

- have had treatment for prostate cancer
- have urinary incontinence
- use continence products 3 months or more after treatment for prostate cancer.
- have experience of using a clamp
- have participated in the first phase of our study
- do not have a latex allergy (some of the clamps or equipment may contain Latex)

What will it involve?

Phase 2a. Focus Groups

You will be invited to attend focus groups held in the Southampton area. At the meeting, you will be asked to handle some prototype clamps and give your opinion about them. The focus groups are small (up to six men). It is difficult to say how many meetings might be required but it would not be more than six. When developing prototype products there may be several attempts to get the product right and we would wish to consult you at each

stage. These meetings will be audio recorded, and the tapes transcribed for analysis. Anonymised quotes may be used in reports or in other material related to the study.

If a prototype is considered by the group to be a promising design you would be asked to try the clamp for up to 30 minutes. You would wear a pad at the same time and do a series of simple exercise e.g. walking up and down some stairs to test if the clamp prevents leakage. This might be repeated with up to four clamps.

Phase 2b. Laboratory testing

You would be invited to come to Southampton General Hospital for laboratory testing. We need to find out more about how the clamps affect blood flow in the penis and if they are likely to irritate or damage the penile skin. While you are wearing a clamp, we would measure:

a. **Blood flow to the penis** – using a laser Doppler machine. The machine is placed above the penis with no skin contact and will assess penile blood flow.

b. **Pressure between the surface of the clamp and the penis (interface pressure)** - A small pressure monitoring device will be placed between the clamp and your penis.

c. **Irritation / inflammation of the skin** – using small strips of tape (Sebutape®) applied to the underside of your penis.

d. **Irritation** your urine will be tested for cytokines (indicating an inflammatory response). A dipstick test of the urine will check for the presence of blood cells. Please note, the presence of either cytokines or red blood cells in your urine could indicate cancer. If we find either of these we will tell you and we will write to your GP to inform them.

Tests a-c will be repeated at various points before you put the clamp on, while you are wearing it and after the clamp has been removed. We would also record your height, weight and current medication. We have done these tests with men previously and they have found the process to be acceptable.

You will be invited to visit the clinic at Southampton General Hospital. **You will either be asked to take part in intermittent testing which will involve testing two clamps on one day only. Or continuous testing which will test two clamps on separate days.** These two days need not be consecutive**.** - The research nurse will accompany you at these visits and carry out the measurements.

All activities will take place at Southampton General Hospital. We will reimburse you for your travel when attending SGH or any alternative venue, for meetings or laboratory tests. This includes travel by bus, 2nd class rail, parking or taxi fares (with receipts), and travel by car @45p/mile) up to £50 per visit).We will provide you with appropriate refreshments.

Giving your consent

If you are willing to take part in the study we will ask you to sign a consent form to say that you have read this document and agree to take part. We will also ask for your consent to

contact your GP and Urologist to tell him/her that you are going to take part in the study (if you do not wish us to inform your GP or Urologist you can still take part). We will give you a copy of the consent form to keep for your records.

Will there be any benefits from taking part in the study?

You will have the opportunity to try some clamps that you may not have come across before. You will be able to directly influence the design of a new, improved clamp. You may gain satisfaction from helping to advance medical knowledge for men with urinary incontinence and prostate cancer. You will get to meet other men in the focus groups who are in similar circumstances to yourself.

What if something goes wrong?

Every care will be taken to ensure your safety during the course of the study. The University of Southampton is the sponsor for the study and is responsible for the way it is run. Insurance arrangements provided by the manufacturer and the sponsor are in place in the unlikely event that something goes wrong and you are harmed as a result of taking part in the research study. Please contact the Research and Governance Office, Building 37 Room 4079, Southampton University, SO171BJ. E-mail Rgoinfo@soton.ac.uk
If for some reason you have any other complaints you may use your local community NHS complaints procedure.

What happens with the information I give the researchers?

All information (data) will be treated confidentially and not revealed to other parties. At the beginning of the study you will be given a 'participant code' which is then used on all documents relating to your participation in the study. This code will contain your initials and a number but your name will not be written on any forms. Any information that you give us will be kept anonymous.

With your approval, data collected for this study might be shared with other academic researchers who seek permission from us for other studies that are unknown at this time. Any data shared with other researchers will not include your name or other personal identifying information. Biological samples will be destroyed after analysis.

In study reports and publications we may use direct quotes from you. We will ensure that it is not possible to identify you from these quotes. Data obtained from the study will be published in a report for the funder and a summary will be available for men who take part. During the study we shall be available by telephone to answer any queries you may have.

Confidentiality

This study is intended to produce a new clamp suitable for commercialisation – that is for sale to the public. The design of the new clamp is confidential. Therefore, you are respectfully asked not to share information about any aspect of the new clamp with others outside the research team. As you may be testing the clamp at home, it is understood that members of your family may become aware of the new clamp design. Please explain the

need for confidentiality to them. As a research participant, it will not be possible for you to benefit financially in any way if commercialisation of the product is successful.

Do I have to take part?

No, you do not have to agree to take part in this study if you do not want to. If you do decide to enter, you may withdraw at any time, without having to give a reason. You may wish to only take part in certain parts of the study and the research nurse will be happy to discuss this with you.

Please note, your participation in this study will in no way affect your supply of pads or other products. Your community nurses will not know that you are taking part unless you choose to tell them. We will inform your GP and urologist that you are taking part but only with your permission. If you do not give this permission you are still able to take part.

An ethics committee reviews all proposals for evaluations and research involving human subjects before they can proceed. This study has been reviewed by the Hampshire B Research Ethics Committee. The information you give (although not your name) might have to be disclosed to research auditors (professional people who check the work of research departments). All research auditors work within strict confidentiality regulations and the information you give will remain confidential.

If you would like to discuss any aspects of this study with a member of the research team, please contact:

Mandy Fader (Principal Investigator) or Jackie Broadbridge (Research Nurse)
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Thank you.

To independently discuss this study please contact:
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