MAPS

Men After Prostate Surgery

SIMPLE TREATMENT FOR URINARY INCONTINENCE IN MEN AFTER PROSTATE SURGERY

INVITATION TO HELP WITH RESEARCH

INFORMATION SHEET

Simple treatment for urinary incontinence in men after prostate surgery (MAPS)

1. Title of project

Conservative treatment for men with urinary incontinence after prostate surgery: multicentre randomised controlled trial of pelvic floor muscle training and biofeedback.

2. Invitation

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Do feel free to ask us if there is anything that is not clear or if you would like more information. Take as much time as you need to decide whether or not you wish to take part. You do not have to give a reason if you do not wish to take part.

Thank you for reading this.

3. What is the purpose of the study?

We want to find out if simple (physical and lifestyle) advice and treatment help men with urinary incontinence after prostate surgery. The study will take about 12 months and you will be followed up at 3, 6, 9 and 12 months by being asked to fill in a questionnaire and keep a short diary as explained in Section 7 below.

We have found out that up to 10% of men have urinary incontinence after prostate surgery through the urethra and 50% after abdominal surgery. Although the problem gets better with time, there is hardly any information to show if treatment can also help.

4. Why have I been chosen?

When you kindly returned the questionnaire we sent you after your prostate surgery, your answers showed that you might have this problem and be suitable for our study of treatment. We hope to study up to 800 men with the same problem.

5. Do I have to take part?

No. If you do not want to take part, that is fine. You do not have to give a reason and your health care will not be affected by your decision. You can still have any treatment available locally whether or not you take part.

If you decide to take part but later change your mind, you can withdraw at any time without giving a reason. The information we already have will be stored securely and confidentially, unless you request that we delete it. If you agree, we may still collect NHS information about you (such as from your hospital records), unless you request that we do not. We will specifically seek your consent (or not) to keeping this information if you choose to withdraw.

6. What will happen to me if I take part?

Sometimes because we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer which has no information about the individual (i.e. by chance). Patients in each group then have different treatments and these are compared.

In this study, you will have a 1 in 2 chance of being either in the active treatment group or in the standard treatment group.

If you are in the active treatment group, you will be invited to see a hospital physiotherapist or nurse for advice about diet and exercise, such as pelvic floor muscle training, four times in three months in an outpatient clinic. They will assess you by asking questions and examining you at the first visit, which will last for an hour. The examinations at each visit will include gentle anal (back passage) testing to measure your muscle strength. This could be with a gloved finger and/or using a biofeedback machine with a small sheathed anal probe. In the second, third and fourth visits, which will each last for about three-quarters of an hour, they will find out how you are getting on with following their advice, and may suggest extra ways of helping.

If you are in the standard treatment group you will receive information about lifestyle changes which may help your problem, but otherwise you can continue with your normal activities. You can still have any other treatment available locally if you want it.

In both groups, you are free to consult your GP or anyone else if you feel you need extra help.

7. What do I have to do?

Before you enter the study, we would like you to fill in another questionnaire and sign a consent form. In both groups you will be asked to fill in two more questionnaires, at 6 and 12 months from now. Each questionnaire should take less than half-an-hour to fill in. You do not need to answer every question if you do not want to. Even if you are in the control group, it would be very important to return these questionnaires because otherwise we will not be able to compare the effects of the study treatment with current standard treatment.

We will also ask you to keep a short diary (just for three days) at three monthly intervals (one now before you enter the study, and the others at 3, 6, 9 and 12 months from now). The diary should only take a few minutes a day to complete. There are also two short questionnaires at 3 and 9 months. These are to keep a record of how often you leak urine, and how much you use the health service.

There are no extra outpatient appointments other than the four treatment appointments if you are in the active group.

We may wish to find out in the future how you are after the study has finished, for example by checking your NHS records or by sending you another questionnaire. To make sure we can contact you again, we would be grateful if you could give us details of a person we could contact who would know where you are if you have moved.

8. What is the procedure that is being tested?

Simple (physical exercise and lifestyle) advice and treatment. We do not propose that men in the study will have any operations, drugs or blood tests.

9. What are the alternatives for diagnosis or treatment?

Alternative ways of managing your urinary incontinence include drugs or an operation, but there is also very little information about whether they work. The sorts of treatment available depend on how severe the problem is. However, it is likely that (if they work) simple methods would be recommended in the first instance, depending on the results of this study. That is why we are running this study.

10. What are the side effects of any treatment received when taking part?

Physiotherapists and doctors have been giving simple advice about lifestyle and exercise for many years to individuals but we still do not know how well this works. There are no known side effects. If you do think that you suffer any symptoms, you could report them in your questionnaires.

However, if you are concerned by any aspect of your treatment or health, please do not hesitate to contact the MAPS Study Office on 01224 551103, or your GP, who will know you are in the study. In an emergency please contact your GP or hospital Accident and Emergency Department as usual.

11. What are the possible disadvantages and risks of taking part?

We do not think that there are any possible disadvantages or risks to you.

If you have private medical insurance you should check with the company before agreeing to take part in the study. We do not know of a reason, however, why participation might affect your medical insurance.

12. What are the possible benefits of taking part?

We hope that the treatment you receive will help you. Even if you are in the standard treatment group, you may find that your problems improve. However, this cannot be guaranteed. The information we get from this study will help us to treat men with urinary incontinence better in the future.

13. What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the MAPS Study Office staff will contact you to let you know about the choices available to you. However, we are not aware that any new information is likely to become available before the end of this study.

14. What happens when the research study stops?

If this treatment works, we hope that the NHS will provide it in the future for all men who might benefit. However, this cannot be guaranteed and will depend on local resources. Your GP will be able to refer you for any treatments which are available.

15. What if something goes wrong?

We do not expect any harm to come to you by taking part in this study. However, if you are harmed by taking part in this research project, there are no special compensation arrangements. 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. Regardless of this, 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 mechanisms (which includes professional indemnity insurance) would be available to you.

16. Will my taking part in this study be kept confidential?

If you are willing to take part, we will let your GP and your hospital Urology Consultant know that you have agreed and we will send them information about what this study is about. However, we will not send them any personal or research information about you or your part in the study.

All information which is collected about you during the course of the research will be kept **strictly confidential.** The identification information that you give us will be separated from your answers to the questionnaires and will only be linked using a secret unique study number. We may collect some information from your hospital notes or NHS records about your surgery or use of NHS services, but again this will be confidential to the research team. Any information about you which leaves the hospital or research unit will have your name and address removed so that you cannot be recognised from it.

If we have any questions about your health as a result of you participating in this study, this will be discussed with you in order to find out what you would like to do about it. Any such information would be entirely confidential, however, and would not be given to anyone else (such as your GP) without your express permission.

17. What will happen to the results of the research study?

We shall publish the results of this study in the academic and popular press, and present the information at academic meetings. The information will also be sent to NHS policy makers. However, you will not be identified personally in any report or publication.

18. Who is organising and funding the research?

The research is funded by the Health Technology Assessment programme of the NHS. This study is being organised by staff at the MAPS Study Office at the Health Services Research Unit, University of Aberdeen.

The funds are only available for the expenses necessary for running this study, including the salaries of the researchers and staff employed. No-one will benefit financially from this research.

19. Who has reviewed the study?

This study has been approved by the Multi-centre Research Ethics Committee and your Local Research Ethics Committee. The science has been reviewed and approved by the NHS Health Technology Assessment programme.

If you have any questions or would like any more information, please contact the MAPS Study Office
by phone: 01224 551103
or email: maps@abdn.ac.uk

You should keep this information sheet.

If you agree to enter the study, please sign the enclosed consent form and we will return a copy to you

Thank you very much for reading this information sheet.

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Version 7 February 2005