

This article was originally published in *Physiotherapy* 2009;95(3):199-209
doi:[10.1016/j.physio.2009.03.003](https://doi.org/10.1016/j.physio.2009.03.003) and is available from URL:
<http://www.sciencedirect.com/science/journal/00319406>

Version 18 3 09 FINAL

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Developing a pelvic floor muscle training regimen for use in a trial intervention

Background

Following radical surgery for prostate cancer, some degree of iatrogenic urinary incontinence is a recognised complication in up to 90% of men (Kao et al, 2000). Following transurethral resection of prostate (TURP) for benign prostatic hypertrophy this figure is around 50% (Emberton et al, 1996). Some physiotherapists treat these men with pelvic floor muscle training and urge suppression techniques despite a recent Cochrane review concluding that there is currently not enough evidence to show whether this is effective (Hunter et al, 2007).

In response to the lack of evidence, the NHS Research and Development National Co-ordinating Centre for Health Technology Assessment (NCCHTA) commissioned a trial that would provide definitive data to address this uncertainty. The Men After Prostate Surgery (MAPS) Study is a large, multi-centre randomised controlled trial co-ordinated from the Health Services Research Unit at the University of Aberdeen. MAPS aims to establish whether or not conservative physical treatment, delivered personally by a trained health professional, results in better urinary and other outcomes compared with standard management in men who are incontinent after prostate surgery. The trial includes two arms which will be analysed separately: men who underwent radical

surgery for prostate cancer (Radical) and men who underwent transurethral resection of prostate (TURP) for benign prostatic hypertrophy.

Ethical approval

Ethical approval for the MAPS trial was received from the Multi Research Ethics Committee and all Local Regulatory Ethics Committees.

Methodology

In MAPS, men who were found to have urinary incontinence at about 6 weeks after prostate surgery were invited to be randomised into one of two groups; one received an active physiotherapy intervention from a MAPS trained therapist and the others received standard care. The standard care varied; some centres routinely handed out a patient information leaflet on pelvic floor muscle exercises (PFMT), while some centres provided no information on PFMT. All centres continued with their standard existing post operative continence service such as contact with a continence nurse, or supply of pads.

Participants randomised to the intervention group were given a Pelvic Floor Muscle Training Leaflet (Appendix 1) detailing pelvic floor exercises, methods of suppressing the urge to urinate, and basic fluid advice. They were initially assessed by therapists approximately six weeks after their surgery, and received an individualised training programme. At follow up appointments two, six and twelve weeks later the programme was adjusted depending on progress.

There exists some uncertainty as to the most effective PFMT protocol for specific clinical indications. This paper describes the regimen devised by the MAPS study team for the intervention and the rationale underlying its various elements.

Training for the therapists

Therapists were either in Specialist Continence Physiotherapists or Specialist Urology nurses. The intervention protocol was standardised by systematically training all the therapists in a bespoke Training Day programme, and by use of common trial forms for recording assessment and treatment data. During the Training Day, a background overview discussed the anatomy and physiology of the lower urinary tract, the pelvic floor muscles and the abdominal muscles together with information on how prostate surgery affects normal urine control. Therapists received instruction on the MAPS PFMT protocol; which included:

- assessment and examination of men in a systematic manner
- the diagnosis of stress urinary incontinence, urge urinary incontinence, post-micturition dribble and erectile dysfunction by history
- grading the strength of the pelvic floor muscles during a digital anal examination by evaluating the anal sphincter and also the puborectalis sling
- affirmation that all the pelvic floor muscles (including the transversus abdominis) should tighten during a maximum contraction and that if the contraction was strong, they would see a scrotal lift and the penis moving slightly into the body
- description of the MAPS approved method of teaching PFMT
- instruction in urge suppression techniques
- advice about fluid intake
- the role of pelvic floor muscle training in the treatment of erectile dysfunction

- how to document the treatment given at each visit.

Basis of the Intervention Protocol

The PFMT protocol was based on one used in a previous trial using PFMT to increase pelvic floor muscle strength for men with erectile dysfunction (Dorey et al, 2004a). The urge suppression techniques were based on those typically used in practice in women with urge urinary incontinence (Dorey et al, 2006). The fluid advice was based on that used by senior clinicians in the incontinence field and documented by Stephens (2008).

The Intervention

Assessment of pelvic floor strength

During each therapy appointment pelvic floor muscle contraction strength was evaluated by a digital anal examination using the Oxford Score (Beasley, 1961) modified by Dorey to include grades 0-6 (Dorey, 2006). This new grading system was used to assess the strength of the anal sphincter and puborectalis muscle in men. It includes an extra grade (grade 6) to define a very strong anal squeeze. Verbal feedback from this examination was then used to teach the men how to contract their muscles optimally, and advise them on improvement from previous appointments. At each assessment, the maximum duration of each contraction was noted. Targets were set for the duration of each contraction, up to a maximum of 10 seconds, and revised in successive appointments if progress had been made.

Pelvic floor muscle contraction regimen

The regimen was aimed at improving the strength of the pelvic floor muscles so that they could be used strongly during exertion to prevent urinary leakage. The PFMT regimen consisted primarily of three maximum strength contractions with a 10 second break between each one, practiced in three positions (lying, sitting and standing) twice daily (Appendix 1). In addition to this, men were also taught to carry out sustained submaximal contractions of the pelvic floor muscles during walking and to perform a strong contraction before and during any event which might cause leakage such as coughing or rising from sitting ('the knock') (Miller et al, 1996). Men were advised to eliminate urine left in the bulbar urethra by using a strong contraction after urination was finished and prevent post-micturition dribble (Dorey et al, 2004b). Contracting the pelvic floor muscles during sexual activity was also recommended to maintain or improve erectile strength.

Urge suppression

Men with urgency or urge incontinence were taught urge suppression techniques so that they were able to avoid rushing to the toilet when the bladder was starting to contract (Appendix 1). Fluid advice, including avoiding or reducing caffeine, was also offered. Cranberry juice (taken with meals) was suggested for those men with urinary tract infections.

Written supplementary guidance

The MAPS Pelvic Floor Muscle Training Leaflet (Appendix 1) aimed to both support and reinforce the anatomy teaching received during MAPS therapy appointments, as well as the exercise programme they had been set. Careful consideration was given to the language used in this leaflet. It was appreciated that incontinence and erectile

dysfunction are issues which are seldom discussed, and in such circumstances uncertainty must exist as to how widely certain terms are understood. The use of impersonal language can be alienating. For example, confusion exists between the meanings of “incontinence” and “continence”. The use of medical and anatomical terms was therefore minimised in favour of a plain English approach.

A Lifestyle Advice Leaflet was also produced both for the men receiving the active intervention and for the men in the control group (Appendix II). This contained information about fluid intake, caffeine, diet and obesity, constipation, general fitness, lifting, chest problems and urinary tract infections.

The taboo and embarrassment that affects help-seeking by people affected by incontinence may also affect the quality of self-reporting in research (Buckley, 2006). Therefore the language and layout of each item of study documentation intended for use by the men participating in the research was discussed at length by researchers, clinicians and a patient organisation representative with an academic interest in research. The aim was to ensure that the language used was consistent, clear and familiar.

Understanding strategies selected for the MAPS Intervention

In order to clarify key aspects of the rationale behind elements of the MAPS standardised intervention, the following frequently asked questions have been addressed.

Why do we perform a digital anal examination?

A digital anal examination is undertaken to assess the strength and endurance of the anal sphincter and the puborectalis muscles. These can be graded from 0-6, with 0 being no contraction and 6 being very strong (Dorey, 2004). Wyndaele and Van Eetvelde (1996) demonstrated the reproducibility of assessing puborectalis by anal assessment using grades 0-5. Dorey (1994) demonstrated the need for another grade (grade 6) for men with a very strong squeeze. Repeating the examination at subsequent visits enabled therapists to provide verbal feedback to men that their exercises were effective.

Why do we ask men to perform pelvic floor exercises in three positions?

Men need to be able to use their pelvic floor muscles against gravity to support the abdominal contents and avoid urinary leakage. The pelvic floor muscles may be recruited initially in a lying position, without the effect of gravity. As strengthening occurs, pelvic floor muscles may be subject to a higher load by recruiting them in a sitting position, where the downward descent of the pelvic floor is partly prevented by the seat of the chair. A greater load is placed on the pelvic floor during standing where the gravitational forces oppose the elevation of the pelvic floor during exercise. MAPS adopted this regimen for the intervention supported by evidence from four previously documented trials which found it to be convenient, acceptable and comfortable for patients (Burgio et al, 1989; Paterson et al, 1997; Moore et al, 2008; Van Kampen et al, 2000). Men need to be conversant with tightening their pelvic floor muscles in a number of positions, so that they can recruit them speedily during coughing and sneezing.

Why perform three pelvic floor muscle contractions?

The PFMT programme was aimed at increasing pelvic floor muscle strength in order to counteract increases of abdominal pressure during exertion. Clinical experience has indicated that when strengthening the quadriceps muscle using the progressive resistance machine, repeated computerised readings showed that the first contraction gave the patient the feel of the movement but failed to achieve maximum power. The second contraction attained maximum power whilst the third contraction failed to reach maximum power due to fatigue. DiNubile (1991) stated that maximum power was a key element to gaining increased muscle strength. It was therefore considered in MAPS that the maximum power of contraction would be attained using three muscle contractions in each position held for up to 10 seconds, with the target individually adjusted for each man and as performance improved (Dorey et al, 2004a).

Why perform the regimen twice a day?

Kegel (1951) recommended women to perform 300-400 pelvic floor muscle contractions a day to treat stress urinary incontinence. However, clinical practice has shown that in reality patients find this level of commitment to be too arduous, resulting in many falling short of the expected regimen, becoming demotivated and eventually withdrawing from treatment completely.

The MAPS intervention was aimed at giving men achievable targets. It was hoped that this would enhance adherence to the protocol, by expecting a regimen that these men could physically manage and be motivated to maintain. The principles of muscle building show that it is the quality of the contraction that is more important than the quantity (Guyton, 1986; DiNubile, 1991). In a previous trial (Dorey et al 2004a) 55 men were asked to perform their exercise sets only twice a day. After three months, all of the patients, except one who had severe back pain, showed a significant increase in pelvic floor muscle strength (Intervention group range 51-242cm H₂O, Controls 15-106 H₂O, Mann-Whitney U test = 36.5, P<0.001) (Dorey et al, 2004a). We therefore felt that this regimen had a proven ability to increase pelvic floor muscle strength.

Why contract the muscles as strongly as possible?

The pelvic floor muscles consist of two-thirds slow twitch muscle fibres (which are continually tonic to support the pelvic floor) and one third fast twitch muscle fibres (which can be speedily recruited when extra support is needed during activities which increase intra-abdominal pressure) (Gosling et al, 1981). Both types of fibres are recruited during maximum contraction of the pelvic floor muscles. In order to achieve an increase in muscle bulk, the MAPS intervention used maximum voluntary effort which would result in the hypertrophy of muscles and increase their local blood supply (Guyton 1986; DiNubile, 1991).

Why is functional use of the muscles so important?

Pelvic floor muscles need to be recruited to prevent leakage of urine during all activities which increase intra-abdominal pressure. 'The Knack' is the technique or learned skill of tightening just before and during these activities (Miller et al, 1996). Due to its significant role in maintaining continence, teaching of 'The Knack' was therefore included as an element in the MAPS intervention.

Why increase pelvic floor muscle endurance?

Slow twitch muscles fibres are continually active in order to fulfil a number of important functions such as pelvic floor support, bladder and bowel control, sexual activity, posture and respiration. The upright posture stimulates the pelvic floor reflex which results in contraction of the slow twitch fibres in response to the weight of the abdominal contents

(Gordon and Logue, 1985). In order to meet this demand, the pelvic floor muscles need to have sufficient muscle endurance to prevent urinary leakage. By encouraging the patient to tighten the pelvic floor muscles slightly during walking (as taught in the MAPS intervention), a functional method of increasing muscle endurance may be achieved and urinary leakage prevented.

Why tighten the pelvic floor muscles after urinating?

One of the superficial pelvic floor muscles, the bulbocavernosus muscle, encircles the proximal 50% of the penis and tightens by reflex action at the end of micturition to facilitate emptying of the bulbar portion of the urethra (Wille et al, 2000). Teaching men to contract their pelvic floor muscles strongly after they have completed micturition will result in the recruitment of the bulbocavernosus muscle along with the other pelvic floor muscles (Dorey, 2004b). This muscle contraction will then facilitate the evacuation of residual urine from the bulbar urethra. This may restore or develop the reflex post-void milking mechanism identified by Wille et al (2000) and termed the 'Urethrocavernosus reflex' by Shafik and El-Sibai (2000).

Why tighten the pelvic floor muscles during sexual activity?

The superficial bulbocavernosus and ischiocavernosus muscles are active during penile erection (Claes et al 1996). The bulb of the penis sits on the inferior aspect of the deeper layer of the pelvic floor muscles which form a firm base for the erect penis. The bulbocavernosus muscle, which surrounds the proximal portion of the penis, prevents blood from escaping through the deep dorsal vein during an erection. One study has shown that pelvic floor exercises can cure erectile dysfunction in 40% of men and improve it in a further 36% (Dorey et al, 2004a). As this is another potential benefit of pelvic floor muscle training it was decided that it would be appropriate to highlight this in the MAPS intervention materials. However, it is not yet clear whether men who have had a radical prostatectomy will actually benefit from such an effect (as the amount and degree of nerve damage caused by surgery is likely to be variable). MAPS will monitor erectile function as a secondary outcome of the study.

Why in MAPS do we advise urge suppression techniques?

A slight detrusor contraction can produce a desire (urge) to empty the bladder. Strong urgency sensations can lead to urgency urinary incontinence, if they cannot be overcome. The resulting fear of leakage can cause anxiety, breath-holding and descent of the diaphragm which, coupled with abdominal muscle contraction, can produce early untimely micturition. Pelvic floor muscle training can be used to strengthen the pelvic floor musculature and together with urge suppression techniques can help to restore bladder control. A retrospective study in women has reported that urge suppression techniques include keeping calm, sitting down or standing still and waiting one minute until the initial urge sensation disappears (Dorey, 2006).

Why give fluid, dietary and lifestyle advice?

All men receive fluid, dietary and relevant lifestyle advice as part of the therapy appointments, supplemented by written information (Appendix II). Under-drinking (to avoid leakage) may lead to urinary tract infections, constipation and dehydration (Wilson et al, 2005). Drinking an excessive amount of fluid (in the belief that this is beneficial for health) may have adverse effects such as an increased risk of leakage (Valtin, 2001). MAPS men experiencing nocturia are advised that it may be prudent to avoid drinking fluid for two hours before bedtime.

Drinks containing caffeine or alcohol may cause increased risk of urgency and men are advised to moderate or avoid them (Wilson et al, 2005). Anecdotal evidence has shown that certain foods (e.g. onions, spicy foods and curries) can cause increased gut peristalsis, which may also have an effect on the bladder causing it to be overactive and contractile. Other risk factors for an overactive bladder are highlighted, including the effect of constipation, smoking and obesity (Haidinger et al, 2000).

Why have four appointments in twelve weeks?

The value of psychological support for men following radical prostatectomy has been stressed in the literature (Moore et al, 2008), as has the value of therapist contact in order to maintain patient motivation (Jackson et al 1996). Four appointments (at baseline, two weeks, four weeks and 12 weeks) was considered sufficient to monitor post surgical muscle strength development and maintain motivation but not too burdensome on patients or costly of scarce resources (chiefly therapist time).

In the trial by Dorey et al (2004a) men significantly improved pelvic floor muscle strength over a 3 month period. Even though they received only four appointments they were encouraged to continue their exercise regimen for life, with particular emphasis on functional work (e.g. contracting during activity or by counteracting increases in intra-abdominal pressure by use of 'the knack'). A previous trial by Van Kampen et al (2000) using pelvic floor exercises and functional use of these muscles showed significant reduction in urinary incontinence. at 1, 6, and 12 months after radical prostatectomy, demonstrating that improvement was maintained while men continued to perform their exercises.

Conclusion

The MAPS intervention, combining pelvic floor muscle training, urge suppression and fluid advice, was evidence based wherever possible. Where evidence was lacking, the intervention was based on expert clinical practice. The results of the MAPS trial will compare this intervention with standard care, and in doing so will further enhance the current evidence base. This in turn will inform practice for therapists treating this population of patients with urinary incontinence and those with erectile dysfunction after prostate surgery.

Acknowledgements:

The authors wish to thank the MAPS Study Office Staff (Louise Campbell, Lynne Swan, Diane Collins), the therapists who contributed to the intervention design and the members of the Trial Steering Committee and the Data Monitoring Committee.

This paper is written on behalf of the MAPS Study Group:

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Conflicts of Interest: None

Funding: NIHR Health Technology Assessment Programme Project Number 03/14/03.

Department of Health Disclaimer: The views and opinions expressed therein are those of the Authors and do not necessarily reflect those of the Department Of Health.

Ethical Approval: MREC Edinburgh 04/10/01

Sponsorship: University of Aberdeen

ISRCTN number: ISRCTN87696430

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Appendix 1 wording and content of MAPS pelvic floor training leaflet (an A5 colour leaflet)

Page 1: Covering Page



Men After Prostate Surgery

PELVIC FLOOR MUSCLE EXERCISES

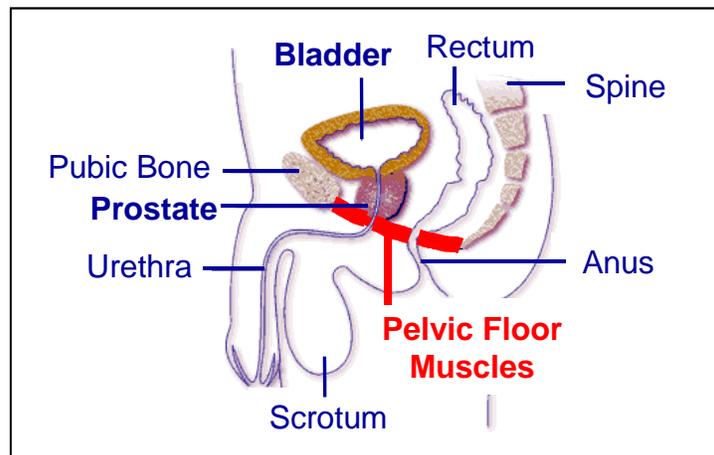
For men taking part in the MAPS study

Please take time to read this information leaflet and discuss it with your therapist if you wish. Do not hesitate to contact us if there is anything you do not understand or if you would like more information.

Page 2:

The Pelvic Floor

The pelvic floor is made up of **muscles** which hold the bladder and bowel in place. The pelvic floor muscles help to stop leaks from the bladder and bowel.



After prostate surgery some men leak urine. Exercises may help. These exercises are called **PELVIC FLOOR EXERCISES**. They may help prevent urine from leaking.

Pelvic floor exercises

Please practise these exercises (numbered 1 to 3) every day

- one set in the morning, and
- one set in the afternoon or evening

1 Lying down

- Lie on your back with your knees bent, and your feet comfortably apart on the bed.
- Tighten (contract) your pelvic floor as if you are trying to stop wind escaping.
- Hold the pelvic floor contraction as **strongly** as you can.
- Try to avoid holding your breath, pulling in your abdomen or tensing your buttocks.

Perform 3 strong contractions lying down. Hold each one for seconds.

Page 3:

2 Sitting

- Sit on a chair with your knees apart.
- Tighten (contract) your pelvic floor as if you are trying to stop wind escaping.
- Hold the pelvic floor contraction as **strongly** as you can.
- Try to avoid holding your breath, pulling in your abdomen or tensing your buttocks.

Perform 3 strong contractions sitting down. Hold each one for seconds.

3 Standing

- Stand with your feet apart. Tighten your pelvic floor **strongly**. You should see the base of your penis move in and your testicles lift.
- Try to avoid holding your breath, pulling in your abdomen or tensing your buttocks.

Perform 3 strong contractions while standing. Hold each one for ... seconds.

During other activities

- **while walking**
Tighten your pelvic floor a little while you are walking.
- **after urinating**
Tighten your pelvic floor **strongly** to 'squeeze out' the last few drops before leaving the toilet.
- **during sexual activity**
Tighten your pelvic floor to help keep the penis firm.

Important tip

Tighten your pelvic floor quickly just before and during activities such as:

- coughing
- sneezing
- lifting
- shouting
- rising from sitting.

Do your exercises regularly to keep your pelvic floor strong

Page 4:

Suppressing the urge

Some men have a sudden strong urge to urinate and feel they have to rush to the toilet. They may leak urine after they feel this urge. Most men can overcome this urge using the following tips.

- 1 Stay CALM** (panic makes things worse)
- 2 Sit down or stand still for ONE MINUTE** until the urge disappears
- 3 THINK** of something to distract your thoughts
- 4 Try NOT to rush to the toilet** when you feel the urge
- 5 Continue normal activity** or visit the toilet once the urge has disappeared

You are trying to train your bladder to hold more urine. Some people find that it helps to drink less caffeine (coffee, cola, tea).

With practice you will overcome the urge...and the need to urinate so often.

Bladder training is a method of controlling the bladder instead of the bladder controlling you

Thank you for reading this

Appendix 2 wording and content of MAPS Lifestyle Advice Leaflet (an A5 colour leaflet)

Page 1: Covering Page



Men After Prostate Surgery

LIFESTYLE ADVICE LEAFLET

For men taking part in the MAPS study

Please take time to read this information leaflet and discuss it with your therapist if you wish. Do not hesitate to contact us if there is anything you do not understand or if you would like more information.

Page 2:

Lifestyle advice leaflet for MAPS

Leaking urine is quite common after prostate surgery but usually gets better with time. It is affected by many sorts of daily activities. This leaflet contains examples of things you

could do for yourself which may help you get better faster. Even small changes may make your urine symptoms better.

What you drink

It is important to drink enough each day. If you do not drink enough, it makes your urine too concentrated. This could make bladder problems worse or cause a urine infection. Try to drink at least six cups or glasses of fluid during the day. Drinking less in the evening may reduce the number of times you urinate at night. Some people find that drinking cranberry juice helps bladder problems. However, if you are taking warfarin you should not drink cranberry juice.

Caffeine

Sometimes bladder problems are made worse by caffeine (for example in coffee, tea and cola drinks). Try reducing your caffeine intake gradually over three weeks. You could drink water, decaffeinated coffee, decaffeinated tea, herb tea, fruit juice or milk instead.

What you eat

Eating a balanced diet is important, including five helpings of fruit or vegetables a day. Being overweight can put extra pressure on the bladder. If you are overweight, think about going on a weight reducing diet. Try to avoid foods that contain lots of fat or sugar.

Page 3:

Constipation

Constipation may make incontinence worse. Straining to empty your bowel may weaken the muscles which hold the bladder closed. You can help prevent constipation by eating some food that contains fibre every day – such as fruit and vegetables, wholemeal bread or brown rice.

Fitness

Try to take regular exercise and keep as active and mobile as you can. Regular exercise can include walking, using the stairs, swimming, cycling or gardening. Drink extra fluids if you exercise a lot. Taking extra exercise may also help you to lose weight if you are overweight.

Heavy lifting

Incorrect or heavy lifting can weaken the muscles which hold the bladder closed. Try to avoid it if you can, or be careful how you lift. If you cannot avoid heavy lifting, try to lift less often or for shorter periods of time. Think about what you could do – can you lift two lighter loads rather than one heavy one?

Chest problems

Coughing can cause you to leak urine by putting extra strain on the muscles which keep the bladder closed. If you smoke or have chest problems, you are more likely to cough or have chest infections. Try to reduce or stop smoking. If you have asthma, bronchitis or hay fever, you should ensure you are taking the correct treatment. You could ask your doctor to make sure that your treatment is up to date.

Page 4:

Urine infections

Sometimes a urine infection can make bladder problems worse.

Symptoms of a urine infection are:

- pain or burning while urinating
- fever or chills
- the urine becomes dark, cloudy, blood-stained or begins to smell, or
- you suddenly start urinating more often than normal for you or in smaller amounts

If you think you might have a urine infection, you should tell your GP, who will test your urine and may give you an antibiotic.

Thank you for reading this.