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Abstract

Conservative treatment for urinary incontinence in Men After Prostate Surgery (MAPS): two parallel randomised controlled trials

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Objective: To determine the clinical effectiveness and cost-effectiveness of active conservative treatment, compared with standard management, in regaining urinary continence at 12 months in men with urinary incontinence at 6 weeks after a radical prostatectomy or a transurethral resection of the prostate (TURP).

Background: Urinary incontinence after radical prostate surgery is common immediately after surgery, although the chance of incontinence is less after TURP than following radical prostatectomy.

Design: Two multicentre, UK, parallel randomised controlled trials (RCTs) comparing active conservative treatment [pelvic floor muscle training (PFMT) delivered by a specialist continence physiotherapist or a specialist continence nurse] with standard management in men after radial prostatectomy and TURP.

Setting: Men having prostate surgery were identified in 34 centres across the UK. If they had urinary incontinence, they were invited to enrol in the RCT.

Participants: Men with urinary incontinence at 6 weeks after prostate surgery were eligible to be randomised if they consented and were able to comply with the intervention.

Interventions: Eligible men were randomised to attend four sessions with a therapist over a 3-month period. The therapists provided standardised PFMT and bladder training for male urinary incontinence and erectile dysfunction. The control group continued with standard management.

Main outcome measures: The primary outcome of clinical effectiveness was urinary incontinence at 12 months after randomisation, and the primary measure of cost-effectiveness was incremental cost per quality-adjusted life-year (QALY). Outcome data were collected by postal questionnaires at 3, 6, 9 and 12 months.

Results: Within the radical group (*n* = 411), 92% of the men in the intervention group attended at least one therapy visit and were more likely than those in the control group to be carrying out any PFMT at 12 months {adjusted risk ratio (RR) 1.30 [95% confidence interval (CI) 1.09 to 1.53]}. The absolute risk difference in urinary incontinence rates at 12 months between the intervention (75.5%) and control (77.4%) groups was –1.9% (95% CI –10% to 6%). NHS costs were higher in the intervention group [£181.02 (95% CI £107 to £255)] but there was no evidence of a difference in societal costs, and QALYs were virtually identical for both groups. Within the TURP group (*n* = 442), over 85% of men in the intervention group attended at least one therapy visit and were more likely to be carrying out any PFMT at 12 months after randomisation [adjusted RR 3.20 (95% CI 2.37 to 4.32)]. The absolute risk difference in urinary incontinence rates at 12 months between the intervention (64.9%) and control (61.5%) groups for the unadjusted intention-to-treat analysis was 3.4% (95% CI –6% to 13%). NHS costs [£209 (95% CI £147 to £271)] and societal costs [£420 (95% CI £54 to £785)] were statistically significantly higher in the intervention group but QALYs were virtually identical.

Conclusions: The provision of one-to-one conservative physical therapy for men with urinary incontinence after prostate surgery is unlikely to be effective or cost-effective compared with standard care that includes the provision of information about conducting PFMT. Future work should include research into the value of different surgical options in controlling urinary incontinence.

Trial registration: Current Controlled Trials ISRCTN87696430.

Funding: This project was funded by the NIHR Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 15, No. 24. See the HTA programme website for further project information.

Contents

List of abbreviations

CEAC	cost-effectiveness acceptability curve
CI	confidence interval
BMI	body mass index
BNI	bladder neck incision
BT	bladder training
EQ-5D	European Quality of Life-5 Dimensions
ICER	incremental cost-effectiveness ratio
ICI-SF	International Consultation on Incontinence Short Form questionnaire
ICI-QoL	International Consultation on Incontinence Quality of Life (score)
ICI-UI	International Consultation on Incontinence Urinary Incontinence (score)
MAPS	Men After Prostate Surgery (trial)
MREC	Multicentre Research Ethics Committee
MUI	mixed urinary incontinence
NICE	National Institute for Health and Clinical Excellence
PFMT	pelvic floor muscle training
PML	postmicturition leakage
QALY	quality-adjusted life-year
RCT	randomised controlled trial
RR	risk ratio
SD	standard deviation
SF-6D	Short Form questionnaire-6 Dimensions
SF-12	Short Form questionnaire-12 items
SUI	stress urinary incontinence
TURP	transurethral resection of the prostate
UI	urinary incontinence
US	urge suppression
UUI	urgency urinary incontinence

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.

Executive summary

Background

Successive Cochrane reviews have shown that, although conservative treatment based on pelvic floor muscle training (PFMT) may be offered to men with urinary incontinence after prostate surgery, there is insufficient evidence to evaluate its effectiveness and cost-effectiveness. Men After Prostate Surgery (MAPS) was a multicentre, UK, randomised controlled trial (RCT), the aim of which was to supply that evidence for men undergoing radical prostatectomy or transurethral resection of the prostate (TURP).

Radical prostatectomy is carried out for men suffering from early prostate cancer. The operation is usually carried out through an open incision in the abdomen, which may damage the urinary bladder sphincter, or its nerve supply, and other pelvic structures. Urinary incontinence occurs in around 90% of men initially but the long-term prognosis varies from 2% to 60%, depending on how incontinence is measured and time after surgery. TURP is carried out using an endoscope through the urethra: the aim is to remove enlarged prostate tissue from the lumen of the urethra. Damage to the distal urinary bladder sphincter or its nerve supply is less common than with radical surgery, and fewer men remain incontinent (an estimated 11% of men wear pads 3 months after surgery).

The two types of surgery were considered in two parallel but separate trials because the rates of incontinence and the chance of regaining continence were expected to differ between the two clinical populations.

Objectives

The following question was addressed, primarily in terms of regaining urinary continence at 12 months after recruitments for both types of surgery: what are the clinical effectiveness and cost-effectiveness of active conservative treatment delivered by a specialist continence physiotherapist or a specialist continence nurse compared with standard management?

The hypothesis tested in each group of men was that active conservative management would result in a difference of 15% between the groups in the proportion of incontinent men at 1 year after recruitment.

Methods

Men having prostate surgery were identified in 34 centres across the UK. Men were invited to receive a screening questionnaire after their operation. Those who reported at screening that they were incontinent were invited to enrol in MAPS.

Inclusion criteria were full informed consent; ability to comply with intervention; and urinary incontinence at 6 weeks after prostate surgery. Incontinence was defined as a 'positive' response to either of two questions in the screening questionnaire: ('how often do you leak urine?' and 'how much urine do you leak?').

Exclusion criteria were formal referral for physiotherapy or teaching of PFMT related to prostate surgery; radiotherapy planned or given during the first 3 months after surgery for men with prostate cancer; resection of prostate as palliation for outflow obstruction in advanced prostate cancer (known as 'channel TURP'); and inability to complete study questionnaires.

Men completed a questionnaire at 6 weeks after surgery and signed a consent form. Baseline information included sociodemographic and clinical characteristics including type of operation. Eligible men were randomised to attending four sessions with a therapist over a period of 3 months (intervention group). The therapists were either specialist continence physiotherapists or specialist continence or urology nurses. All therapists were provided with standardised training in the management of male urinary incontinence and erectile dysfunction. The control group received standard management. Both groups received a lifestyle advice leaflet.

Randomisation was by remote computer allocation using the randomisation service of the Centre for Healthcare Randomised Trials (CHaRT, Health Services Research Unit, University of Aberdeen). Allocation was stratified by type of operation (radical prostatectomy or TURP), and minimised using centre, age and pre-existing urinary incontinence. The process was independent of all clinical collaborators.

The primary clinical effectiveness outcome was urinary incontinence at 12 months after randomisation, and the primary cost-effectiveness outcome was incremental cost per QALY. Outcome data were collected by postal questionnaires at 3, 6, 9 and 12 months. At each time point, men also completed a urinary diary for 3 days. Data collected included: urinary outcomes (presence, frequency and severity of incontinence, effect of incontinence on quality of life, use of pads and catheters, type of incontinence, urinary frequency and nocturia); bowel outcomes (faecal incontinence, constipation, bowel urgency); sexual function (erectile function, ejaculation, change in sexual function); quality of life (EQ-5D and SF-12); use of health services (contact with community, hospital and private staff, use of alternative treatments such as pads, catheters, surgery, drugs or mechanical devices, and their costs); participants' costs (self-purchased health care, costs of accessing health care, cost of time away from usual activities); QALYs derived from responses to the EQ-5D and SF-12; and effect of the intervention in changing health-related behaviour and practice of PFMT and bladder training or urge suppression.

Results

We approached 1158 men having a radical prostatectomy and 5986 having TURP in 34 centres. The response rate for the screening questionnaire was 95% (742/780) of the eligible men in the radical prostatectomy group and 91% (2590/2838) in the TURP group.

Amongst the radical prostatectomy group, of 472 eligible men who returned a questionnaire after surgery, 411 entered the radical prostatectomy RCT: 205 in the intervention group and 206 in the control group. Follow-up rates were high (95% of all men in each arm, 97% and 98% respectively after accounting for withdrawals and deaths).

Ninety-two per cent of the men allocated to the intervention group attended at least one therapy visit. Men in the intervention group were more likely to be carrying out any PFMT at 12 months (67%) than those in the control group (50%, adjusted risk ratio (RR) 1.30, 95% confidence interval (CI) 1.09 to 1.53).

Among the men who had a radical prostatectomy, the difference in urinary incontinence rates at 12 months between the intervention and control groups (148/196, 75.5%, vs 151/195, 77.4%)

was not statistically significant: the absolute risk difference for the unadjusted intention-to-treat analysis was –1.9% (95% CI –10% to 6%), which ruled out the prespecified target difference of 15%. Adjusting for minimisation factors or performing a 'treatment received' analysis did not change these results.

NHS costs were higher in the intervention group (£181, 95% CI £107 to £255), but costs to the NHS and the participant were on average lower (–£588, 95% CI –£1330 to £153). On average, QALYs were virtually identical in both the intervention and the control groups (–0.002, 95% CI –0.027 to 0.023). When the perspective was the NHS there was only a 20% chance that PFMT would be cost-effective. However, from a societal perspective, there was an 80% chance that it would be cost-effective. The findings from the societal perspective were driven by a trend towards more time away from usual activities in the control group. These data are counter-intuitive when considered alongside the rest of the trial data and so should be treated cautiously.

Amongst those who had TURP, of 512 eligible men who returned a questionnaire at 6 weeks after surgery, 442 entered the TURP RCT: 220 in the intervention group and 222 in the control group. Follow-up rates were high (88% and 92% respectively of all men, 97% in both arms after accounting for withdrawals and deaths).

Over 85% of the men allocated to the intervention group attended at least one therapy visit. Men in the intervention group were more likely to be carrying out any PFMT at 12 months after randomisation (65%) than those in the control group (20%, adjusted RR 3.20, 95% CI 2.37 to 4.32).

Following a TURP, the difference between the intervention and control groups in the proportion of men who had urinary incontinence at 12 months (126/194, 64.9% vs 125/203, 61.5%) was not statistically significantly different: the absolute risk difference for the unadjusted intention-to-treat analysis was 3.4% (95% CI –6% to 13%), which rules out the prespecified target difference of 15%. Adjusting for minimisation factors or performing a 'treatment received' analysis did not change these results.

The differences in NHS costs (£209, 95% CI £147 to £271) and NHS and participant costs (£420, 95% CI £54 to £785) were higher in the intervention group. On average, QALYs were virtually identical in the intervention and control groups (–0.00003, 95% CI –0.026 to 0.026). From both a societal and an NHS perspective there was little chance that physical therapy would be considered cost-effective.

Conclusions

The provision of one-to-one conservative physical therapy for men with urinary incontinence after prostate surgery is unlikely to be effective or cost-effective compared with standard care (which includes the provision of information about conducting PFMT).

Implications for research

- Physical therapy of the type used in this trial is not worthwhile, but the continuing burden of incontinence suggests that research into other treatments is worthwhile, for example research on the value of surgery in controlling symptoms. Specifically, an RCT comparing different surgical options for men with severe persistent urinary incontinence is needed.

- MAPS has not tested whether the provision of any PFMT advice is an effective and efficient way of reducing incontinence. Further research into the effectiveness of any other method of delivery of PFMT would be worthwhile.
- Of the men in the radical prostatectomy trial, 80% still had erectile dysfunction at the 12-month follow-up, and over 60% had tried various treatments. As PFMT was of no value to these men, research into effective and efficient treatments for this condition would be worthwhile. Such a study should also include a wider population of men following radical surgery and not just those with urinary incontinence.
- The MAPS data set can be used to improve the quality of further research and to improve other aspects of management. Specifically, MAPS data can be used to further validate the outcome measures for use in future research and clinical settings. The further analysis of the epidemiological data will inform the debate about different methods of prostatectomy and provide prognostic information for counselling men.

Trial registration

This trial is registered as ISRCTN87696430.

Funding

The National Institute for Health Research Health Technology Assessment programme.

Chapter 1

Introduction

In 2003, the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme called for a randomised controlled trial (RCT) to determine the effectiveness and cost-effectiveness of pelvic floor muscle exercises, with and without biofeedback, for men with urinary incontinence at 6 weeks after prostate surgery. This report describes the research that was commissioned.

The Men After Prostate Surgery (MAPS) study was a major multicentre UK trial that aimed to establish whether a structured programme of conservative physical treatment, delivered personally by a trained health professional (therapist), resulted in better urinary and other outcomes compared with standard management with no professionally delivered pelvic floor muscle exercise regimen in men who were incontinent after prostate surgery. Men having (1) transurethral resection of the prostate (TURP) for benign prostatic hypertrophy and (2) radical prostatectomy for prostate cancer were randomised independently in separate trials but using common outcome measures.

Description of the underlying health problem

Urinary incontinence after prostate surgery and effect on well-being

Urinary incontinence is a debilitating condition that can be an iatrogenic consequence of prostate surgery.[1] The effect of urinary incontinence on quality of life can be profound. The economic costs can be personal (such as the need to use pads or devices and the deleterious effect on quality of life) and societal (use of health services and the need for residential or nursing home care). The effect on quality of life of urinary incontinence is greater than that of erectile dysfunction, another possible iatrogenic consequence of prostate surgery.[2]

Continence mechanisms in men

Urinary continence in men is achieved by the interaction of anatomical structures (bladder, urinary sphincter, urethra and the pelvic floor muscles; *Figure 1*) and neurological control. Continence is maintained by contraction of the sphincter and pelvic floor muscles and relaxation of the bladder muscle (detrusor muscle), while controlled, appropriate urination requires the relaxation of the sphincter and pelvic floor muscles at the same time as the bladder muscle contracts. This process is under neurological control. Failure in either muscle or neurological function or both will result in incontinence or urinary retention.

The male urinary sphincter may be divided into two functionally separate units, the proximal sphincter (nearest the bladder, consisting of the bladder neck, prostate and the portion of the urethra that passes through the prostate) and the distal sphincter (further away from the bladder, just below the prostate at the level of the pelvic floor muscles). The pelvic floor muscles contribute to the ability of the distal sphincter to keep the urethra closed.

Radical prostatectomy physically disrupts the integrity of both the muscles and the nerves, thus resulting in urinary incontinence. The proximal sphincter is removed during prostatectomy, and

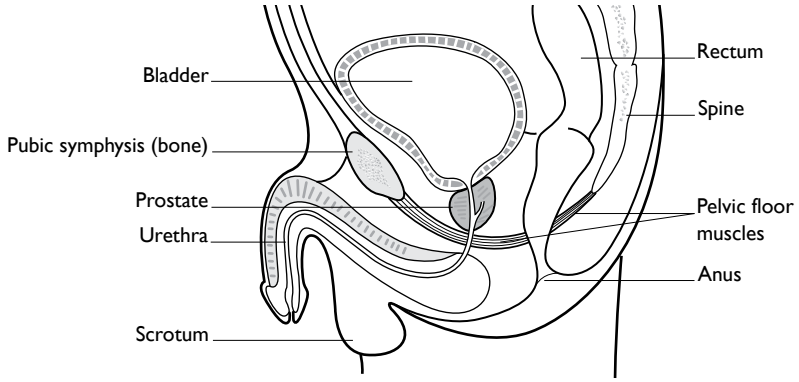

FIGURE 1 Anatomy of the pelvic organs in men (see *Appendix 4.3*).

may also be damaged by radiation to the prostate. After prostatectomy, men achieve continence using the distal sphincter and the pelvic floor muscles that surround it. Thus, following prostatectomy, continence depends on the distal sphincter mechanism, which includes soft tissue supporting structures, the muscles of both the sphincter and the pelvic floor, and their intact innervation (both autonomic via the pelvic nerve and somatic via the pudendal nerve). In addition, the disruption of the nerve supply to the penis can interfere with normal erectile and hence sexual function.

Transurethral surgery for benign prostatic hypertrophy, while theoretically not disrupting the distal sphincter or the nerve supply to the pelvic floor muscles, does remove the proximal urethral sphincter. Such sphincter injury can result in incontinence.

Thus, urinary incontinence can be an iatrogenic outcome of prostate surgery. However, incontinence may also result from bladder dysfunction, which may persist from before surgery or be of new onset. Before surgery, men with benign prostatic hypertrophy have difficulty in emptying their bladders owing to bladder outlet obstruction. This may manifest as the lower urinary tract symptoms of frequency, urgency and urgency urinary incontinence. Detrusor overactivity may be demonstrated by urodynamic studies. While these symptoms are relieved by prostatectomy in over 75% of men,[3,4] residual overactivity or incontinence may be accounted for by a variety of mechanisms, including persistent obstruction (38%), impaired contractility of the bladder detrusor muscle (25%) and sphincter deficiency (8%).[3]

For a detailed description of the continence mechanisms and incontinence resulting from prostatic disease and its treatment see Koelbl *et al.*,[5] pp. 299–308.

Definition of urinary incontinence

The MAPS study has used methods, definitions and units that conform to the standards jointly recommended by the International Continence Society and the International Urogynaecology Association, except where specifically noted.[6] These replace those formerly in use.[7]

Urinary incontinence is defined as the 'complaint of involuntary loss of urine'.[6] This can be subcategorised as follows:

Stress urinary incontinence (SUI) Complaint of involuntary loss of urine on effort or physical exertion (e.g. sporting activities) or on sneezing or coughing.
Urgency urinary incontinence (UUI) Complaint of involuntary loss of urine associated with urgency.
Mixed urinary incontinence (MUI) Complaint of involuntary loss of urine associated with urgency and also with effort or physical exertion or on sneezing or coughing.
Postmicturition leakage Complaint of a further involuntary passage of urine following the completion of micturition.
Urgency Complaint of a sudden compelling desire to pass urine that is difficult to defer.

In the MAPS study these were differentiated according to the men's responses to questionnaires. Men could also categorise their incontinence as 'other' if they were incontinent under other circumstances, but we did not ask for clarification of the type of incontinence.

Incontinence can be further categorised according to the results of urodynamic studies (cystometry). These are:

Urodynamic stress incontinence (USI) Involuntary leakage of urine during filling cystometry, associated with increased abdominal pressure, in the *absence* of a detrusor contraction.
Detrusor overactivity (DO) Involuntary detrusor contractions occurring during filling cystometry. The symptoms of urgency and/or urgency incontinence may or may not occur.

However, we did not require the type of incontinence to be defined using urodynamics in MAPS.

Prevalence and natural history

The prevalence of urinary incontinence after radical prostatectomy is widely reported, ranging from 2% to 60%, albeit at varying times after operation.[8] The wide range in estimates of the incidence of postprostatectomy urinary incontinence may be explained by factors such as differences in populations, type of study, type of operation, definition of incontinence and time of assessment relative to surgery. Estimates of incontinence soon after radical operation are much higher (e.g. 82% in 1013 men[9]). The technique of radical prostatectomy also affects continence rates: the perineal approach,[1] use of laser,[10] preservation of the neurovascular bundle[11] and bladder neck preservation[12] have all been shown to be associated with lower urinary incontinence rates. The incidence also varies according to who measures it: doctors may underestimate urinary incontinence rates by as much as 75%.[13] The incidence of urinary incontinence decreases with time, and seems to plateau at 1 to 2 years after surgery,[14] emphasising the need for long-term follow-up.[8] Other factors sometimes associated with postprostatectomy urinary incontinence include older age, previous TURP, preoperative lower urinary tract symptoms, obesity, clinical stage, race and ethnic differences.[8]

In contrast, the prevalence of urinary incontinence after TURP is less widely reported. Based on a population audit of over 3000 men, an estimated 11% needed to use pads at 3 months after endoscopic resection of the prostate.[15]

Significance in terms of ill health

Extent of problem in the UK

The number of men undergoing surgery for prostate disease is changing: in 2000–1, the number of TURPs in NHS hospitals in England was just under 30,000, while there were about 2000 open excisions of prostate (of which the majority would have been for prostate cancer).[16] By 2008–9, the number of TURPs had fallen to just over 25,000 (of which 2700 were with laser), while over 4000 open operations were performed. Thus, prostate surgery and its sequelae represent a considerable use of health resources and a health burden to men.

Description of standard management

Existing guidelines

For men who have undergone prostate cancer treatment, the current National Institute for Health and Clinical Excellence (NICE) guidelines acknowledge that urinary incontinence has been reported as a result, most especially stress incontinence (which is mentioned as either temporary or permanent). NICE highlights that incontinence may be a problem after brachytherapy and external beam radiotherapy, as well as in those men who have also had a TURP.

NICE guidelines highlight some of the treatments available to men, including physical (pelvic floor muscle re-education, bladder retraining), medical (drug therapy) or surgical (injection of bulking agents, artificial urinary sphincters or perineal sling) interventions, and they give the following recommendations for urinary incontinence management following prostate cancer treatment.[17]

Current recommendations from NICE

- Men experiencing troublesome urinary symptoms before treatment (*of their prostate problem)* should be offered a urological assessment.
- Men undergoing treatment for prostate cancer should be warned of the likely effects of the treatment on their urinary function.
- Health-care professionals should ensure that men with troublesome urinary symptoms after treatment should have access to specialist continence services for assessment, diagnosis and conservative treatment. This may include coping strategies, along with pelvic floor muscle re-education, bladder retraining and pharmacotherapy.
- Health-care professionals should refer men with intractable stress incontinence to a specialist surgeon for consideration of an artificial urinary sphincter.
- The injection of bulking agents into the distal urinary sphincter is not recommended to treat stress incontinence after prostate surgery in men.

No guidelines could be found for the treatment of urinary incontinence associated with either benign prostatic hypertrophy or TURP.

Treatment options

Treatment options for men with urinary incontinence after prostate surgery include:

- containment using continence products, including absorbent products, sheaths, urine drainage bags, mechanical devices such as penile occlusive devices or clamps, and catheters (see Cottenden *et al.*[18] for a comprehensive review)
- conservative options such as advice to modify lifestyle factors and pelvic floor muscle training (PFMT) (see Hay-Smith *et al.*[19] for a comprehensive review)

- surgery using injectable urethral bulking agents, a male sling, an adjustable balloon device or an artificial urinary sphincter or, as a last resort, creation of a catheterisable continent stoma by bladder neck closure or urinary diversion into a rectal reservoir or ileocaecal pouch with a catheterisable stoma (see Herschorn *et al.*[20] for a comprehensive review).

However, few of these options are supported by reliable research evidence.

The decision to test conservative treatment

One of these options, PFMT, was the subject of a Cochrane review first published in 1999.[21] The review found that, although conservative treatment based on PFMT is offered to men with urinary incontinence after either type of prostate surgery, there was insufficient evidence to evaluate its effectiveness, cost-effectiveness and effect on quality of life. In the first version of that review, data from three small trials involving a total of 232 men provided estimates of the effects of PFMT on the chance of having incontinence after radical prostatectomy at 1 year: the relative risk of incontinence, comparing PFMT plus biofeedback versus control, was 0.55 [95% confidence interval (CI) 0.24 to 1.23].[22–24] However, some of the men in two of these trials were not incontinent at baseline, and the trials were all small. Thus, the data did not provide conclusive evidence about whether conservative treatment might reduce incontinence at 1 year after operation.

As a consequence, the NIHR HTA programme commissioned primary research (the MAPS trial) to provide reliable evidence about the effectiveness of PFMT in this population.

In three subsequent updates of the Cochrane review (in 2001, 2004 and 2007), there was still insufficient evidence to guide the practice of providing men with PFMT after prostate surgery. The current (as yet unpublished) update (2011) will have an additional 16 included RCTs, but even after inclusion of data from these trials, no clear conclusions can be drawn.

The questions addressed by this study

The following questions were addressed, primarily in terms of regaining urinary continence at 12 months after recruitment:

1. For men with urinary incontinence 6 weeks after radical prostatectomy, what is the clinical effectiveness and cost-effectiveness of active conservative treatment delivered by a specialist continence physiotherapist or a specialist continence nurse compared with standard management?
2. For men with urinary incontinence 6 weeks after TURP, what is the clinical effectiveness and cost-effectiveness of active conservative treatment delivered by a specialist continence physiotherapist or a specialist continence nurse compared with standard management?

The hypothesis tested in each group of men (in two parallel but separate trials) was that active conservative management would result in a difference of 15% between the groups in the proportion of incontinent men at 1 year after recruitment. The two groups were considered independently because the underlying pathological mechanisms, the rates of incontinence and the chance of regaining continence were expected to be different in the two clinical populations. We recognised that standard management for the control arm in both trials was likely to include non-specialist advice about pelvic floor exercises, including leaflets. Men also had access to any normal care provided locally for men with urinary incontinence, such as pads and advice from continence nurse specialists on continence aids.

Chapter 2

Methods of study

This chapter will describe the methods used to identify and enrol the men in the two trials, and describe the methods of statistical and economic analysis.

Study design and populations

The MAPS study involved men who had urinary incontinence after prostate surgery. Two parallel but separate RCTs were conducted, amongst:

1. men having a radical prostatectomy, usually for prostate cancer
2. men having TURP, usually for benign prostatic hypertrophy.

Approval for this UK study was obtained from the Scottish Multicentre Research Ethics Committee (reference number MREC/04/10/01) and confirmed by each centre's local research ethics committee and research and development department. The study was conducted according to the principles of good practice provided by research governance guidelines.

Local clinical centres

Centres willing to participate in MAPS were identified from a survey of members of the British Association of Urological Surgeons (BAUS), through personal communication [with urological surgeons and with staff from the Radiotherapy and Androgen Deprivation in Combination After Local Surgery (RADICALS) trial] and through the inclusion of the study on the National Cancer Research Network (NCRN). Each centre had a local principal investigator (lead urologist), who co-ordinated the activities of the local recruitment officer(s) and the local therapist(s). All men from all consultants providing prostate surgery in each centre were eligible, but there were some centres that agreed only to the recruitment of men having radical surgery, while others agreed only to the inclusion of those having TURP. Four centres recruited only to the radical prostatectomy trial: three of these sites recruited during the last 6 months of the recruitment period and included only men recruited to the radical prostatectomy trial at the request of the central office, in order to maximise the numbers in that trial. The fourth site had such a large throughput of men having radical prostatectomies that it did not have the capacity to recruit to the TURP trial as well. Seven centres recruited only men having TURP. This was due, in five of these seven, to existing local services for all men having radical surgery that included explicit teaching of PFMT: the staff were reluctant to 'unpick' this element of their service for fear of delivering lower-quality care than before (despite the service not being evidence based). Men were not recruited to the radical prostatectomy trial in the other two sites because of lack of capacity and low numbers of prostate procedures being undertaken locally.

Therapists and training

The therapists could be either specialist continence physiotherapists or nurses with specialist continence or urology training. All therapists received standardised bespoke instruction in the

use of PFMT and bladder training for the conservative treatment of male urinary incontinence and PFMT for erectile dysfunction. Therapists used MAPS study instruction materials and documentation to further ensure standardisation of the intervention (see *Chapter 3*).

Participants

Men were approached at the time of admission for their prostate surgery or at pre-operative assessment clinics. They were initially asked for their consent to receive a screening survey questionnaire sent by post 3 weeks after their operation. Men who indicated in that questionnaire that they were incontinent were invited to participate in the appropriate RCT. Their eligibility was reviewed against the following criteria.

Inclusion criteria

- Urinary incontinence at 6 weeks after prostate surgery (incontinence was defined as a response indicating a loss of urine to either of two questions in the screening questionnaire: 'how often do you leak urine?' and 'how much urine do you leak?'.
- Full informed consent.
- Ability to comply with intervention.

Exclusion criteria

- Formal referral for physiotherapy or teaching PFMT related to prostate surgery.
- Radiotherapy planned or given during the first 3 months after surgery for men with prostate cancer.
- Transurethral/endoscopic resection of prostate carried out as palliation for outflow obstruction in advanced prostate cancer (known as 'channel TURP').
- Inability to complete study questionnaires.

Men with prostate cancer diagnosed at transurethral resection of the prostate

The literature suggested that approximately 15% of men have incidental prostate cancer when the prostatic chips removed at TURP are examined for pathology.[25] Within MAPS, men were still considered eligible for randomisation if the initial management plan did not include formal treatment (a wait and see policy). If the cancer was identified before randomisation, and either radiotherapy or radical prostatectomy was planned within the following 3 months, the man was *not* eligible for the TURP trial. However, men who were not randomised but subsequently readmitted for radical prostatectomy were eligible to be recruited as new participants to the radical prostatectomy group (after signing a new consent form and completing a new screening questionnaire after surgery). If cancer was diagnosed after randomisation, the men remained in the group to which they had been allocated even if radiotherapy or radical prostatectomy was carried out subsequently. These men could still have the MAPS intervention, if the timing of the new treatment allowed, and were followed up as per the MAPS protocol.

Thus, the MAPS study consisted of two stages: stage 1, the screening survey (used to identify eligible men), and stage 2, the two RCTs.

Screening for postoperative urinary incontinence (stage 1, the screening survey)

Potential MAPS participants were identified by recruitment officers in each clinical centre from amongst all men admitted to the urological ward(s) for prostate surgery. A log was kept of

potentially eligible men, categorising reasons if they subsequently became ineligible or did not consent to receive a screening questionnaire. Each man was given a MAPS hospital information sheet (see *Appendix 1.1*) by the recruitment officer, and then, if interested in the study, each man was asked for his consent to be sent the screening questionnaire at 3 weeks after surgery. The hospital patient information sheet, the screening consent form (see *Appendix 2.1*) and the screening questionnaire (see *Appendix 3.1*) all included information about being contacted about further research.

The screening questionnaire was sent to men from the study office in Aberdeen at 3 weeks after the date of operation. A reminder letter with a second copy of the questionnaire was sent after 2 weeks to non-responders. If the returned questionnaire indicated that a man had urinary incontinence, he became eligible for stage 2 of MAPS.

Recruitment to the randomised controlled trial of conservative treatment (stage 2, the randomised controlled trials)

Each man who indicated on his screening questionnaire that he had urinary incontinence was sent an RCT patient information sheet (see *Appendix 1.2*), a baseline questionnaire (see *Appendix 3.2*), a urinary diary (see *Appendix 3.5*) and an RCT consent form (see *Appendix 2.2*) by the study office in Aberdeen. Men who were willing to be contacted by telephone were telephoned around a week later by a dedicated recruitment co-ordinator based at the MAPS study office in Aberdeen. The purpose of this call was to answer the men's questions about the trial, to confirm eligibility and to obtain verbal consent to randomisation. Upon receipt of the signed RCT consent form, men were randomised to the intervention or standard care group. Men who did not respond within 14 days after the initial mailing-out were reminded by post and/or telephone.

Withdrawal

Men were free to withdraw from the study at any point without giving a reason. Verbal consent was obtained from men who initially agreed to enter the trial, but later decided to withdraw, to enable relevant data to be retained or collected through central NHS resources.

Randomisation and allocation to group

When the baseline questionnaire and the consent form were received, the Aberdeen MAPS study office randomised the man to the intervention or standard care group.

Randomisation was by computer allocation using the randomisation service of the Centre for Healthcare Randomised Trials (CHaRT, in the Health Services Research Unit, University of Aberdeen). Allocation was stratified by type of operation (radical prostatectomy or TURP) and minimised using centre, age and pre-existing urinary incontinence. The process was independent of all clinical collaborators.

The study office informed all men of their allocation by post. All groups received a lifestyle advice leaflet (see *Appendix 4.2*). For men allocated to the intervention group, the study office arranged for the local therapist (physiotherapist or continence nurse) to send out the necessary appointments. A letter and GP information sheet were sent to each participant's GP. Copies of the GP's letter and the consent form were sent to the hospital urological consultant for filing in the man's hospital notes.

A flow chart summarising the trial recruitment processes and procedures is shown in *Figure 2*.

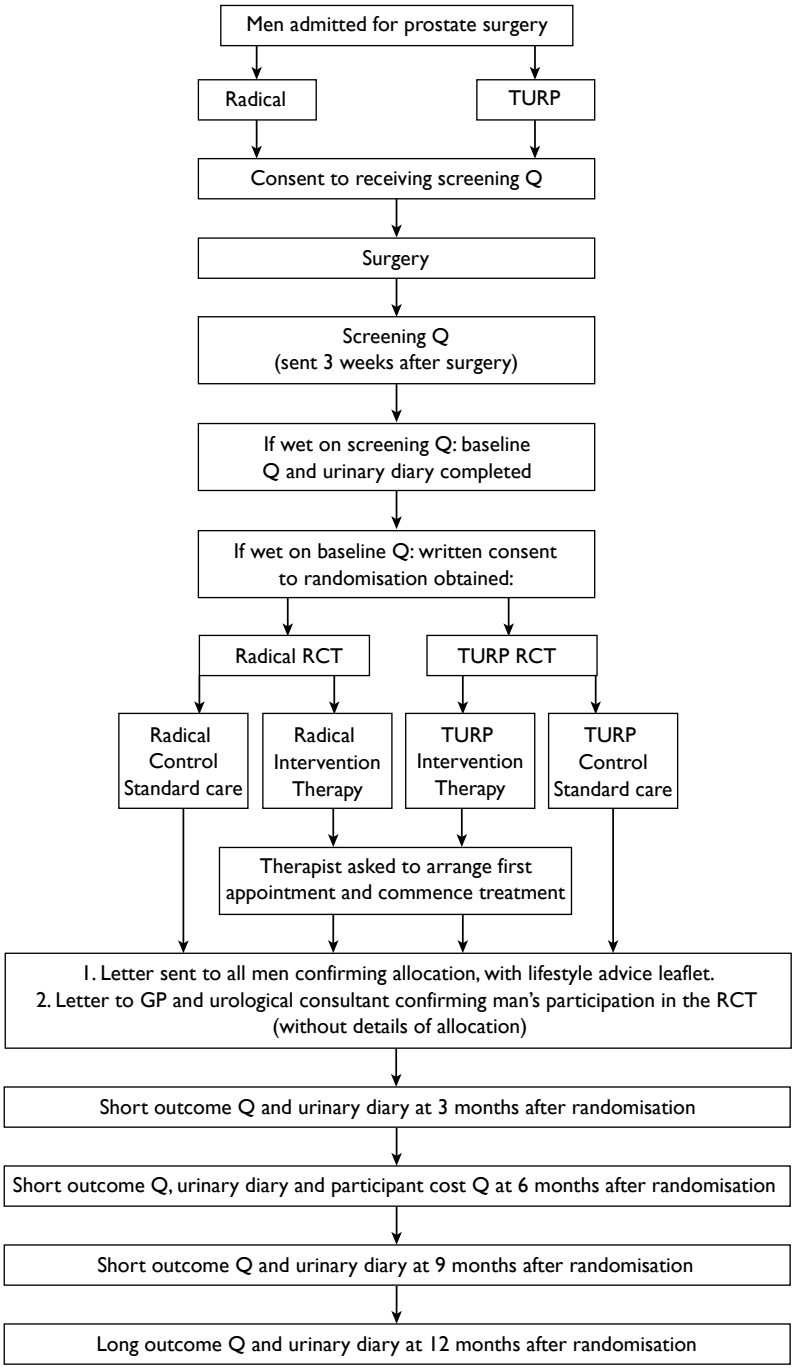

FIGURE 2 Flow chart of the trial recruitment processes and procedures. Q, questionnaire.

Interventions

Intervention arm

The men in the intervention group attended for a MAPS therapist assessment of their symptoms after randomisation (see *Chapters 6* and *11*). The first appointment, for an hour, consisted of assessment and training, including customised goal setting for home practice of exercises. The men then attended a further three appointments, each lasting approximately 45 minutes, at around 2, 6 and 12 weeks after the first appointment. They were taught PFMT, with bladder

training for men with urgency or urge incontinence.[26] This was supplemented by a booklet containing reminder instructions for PFMT and bladder training (see *Pelvic Floor Exercises for Men Taking Part in the MAPS Study; Appendix 4.3*). Men also received the lifestyle advice leaflet sent to the men in the standard care arm (see *Appendix 4.2*).

Biofeedback using digital anal examination was used to teach correct contraction technique and to monitor the strength of contractions. Although biofeedback used for diagnosis or training (repetitive exercising with machine-led feedback on the effectiveness of contractions) was not used routinely in the trial, therapists could use this at their discretion in individual cases. Further details of the intervention are given in *Chapter 3*.

Control arm

Men in the control group received standard care and a booklet containing supportive lifestyle advice only (without reference to PFMT) by post after randomisation (see *Appendix 4.2*). Men did not receive any formal assessment or treatment but were able to access usual care and routine NHS services if they felt they needed help with incontinence. This could include written advice if this was part of routine hospital care (such as leaflets containing instructions on PFMT).

Both arms

Use of NHS services, use of pads and practice of PFMT were documented in both groups using information from questionnaires (see *Appendix 3.4*) and 3-day urinary diaries (see *Appendix 3.5*) issued at baseline and 3, 6, 9 and 12 months after randomisation.

Data collection and processing

Men were recruited between January 2005 and September 2008. Follow-up continued with 3-monthly questionnaires and urinary diaries for 12 months from the date of the last randomisation, at which time the primary end point (incontinent or not) was measured using the International Consultation on Incontinence (ICI) Short Form questionnaire (ICI-SF).[27] Consent was sought to continue follow-up into the future. The men were also asked to consent to be contacted about other relevant research studies.

Questionnaires *(see Appendices 3.1–3.4)*

Men were sent postal questionnaires at baseline and 3, 6, 9 and 12 months. An additional health-care unit cost questionnaire was sent only at 6 months. The short questionnaires at 3 and 9 months contained only brief urinary incontinence, exercise and health-care utilisation questions.

Urinary diaries *(see Appendix 3.5)*

Men were asked to keep diaries at baseline and 3, 6, 9 and 12 months after randomisation, kept for 3 days at each time period.

Data processing

Data from the various sources outlined above were sent to the study office in Aberdeen for processing. Staff in the study office carried out extensive range and consistency checks to enhance the quality and accuracy of the data. Essential missing data were sought from the recruitment officers at the centres, or the men, by post, telephone or email as appropriate.

Outcomes

The primary clinical outcome was subjective report of urinary continence at 12 months.[27]

Incontinence was defined as a response indicating a loss of urine to either of two questions in the screening questionnaire, ICI-SF: 'how often do you leak urine?' and 'how much urine do you leak?'

The primary measure of cost-effectiveness was incremental cost per quality-adjusted life-year (QALY).

Secondary outcome measures were as follows.

Clinical

- Subjective report of continence or improvement of urinary incontinence at 3, 6 and 9 months after randomisation, and improvement at 12 months.
- Number of incontinent episodes in previous week (objective, from diary).
- Use of absorbent pads, penile collecting sheath, bladder catheter or bed/chair pads.
- Number and type of incontinence products used.
- Coexistence, cure or development of urgency or urge incontinence.
- Urinary frequency.
- Nocturia.
- Faecal incontinence (passive or urge).
- Other bowel dysfunction (urgency, constipation, other bowel diseases).
- Sexual function at 12 months (including information about erection, ejaculation, retrograde ejaculation, pain, change in sex life and reason for change).

Quality of life

- Incontinence-specific quality of life outcome measure (10-point scale, ICI-Q).[27]
- General health measures (Short Form questionnaire-12 items, SF-12, and European Quality of Life-5 Dimensions, EQ-5D).

Use of health services for urinary incontinence

- Need for alternative management for incontinence (e.g. surgery, drugs).
- Use of GP, nurse, consultant urologist, physiotherapist.
- Satisfaction with treatment of incontinence after prostate surgery.

Other use of health services

- Visits to GP.
- Visits to practice nurse.

Effects of interventions

- Use of PFMT.
- Lifestyle changes (weight, constipation, lifting, coughing, exercise).

Economic measures

- Patient costs [e.g. self-care (e.g. pads, laundry), travel to health services, sick leave].
- Cost of conservative trial treatment.
- Cost of alternative or additional NHS treatments [e.g. pads, catheters, drugs (e.g. adrenergic agonists, anticholinergics, oral medication for erectile dysfunction), hospital admissions or further surgery].
- Other measures of cost-effectiveness (e.g. incremental cost per additional man continent at 12 months).

Table 1 provides a summary of which study measures and outcomes were collected at each time point in the study.

TABLE 1 Principal study measures and timing of data collection

Study measure	Screening	Baseline	Month 3	Month 6	Month 9	Month 12
Consent/randomisation	✓	✓				
Sociodemographic characteristics	✓					
Operative details	✓					
Clinical characteristics	✓	✓				
Follow-up (outcome) questionnaires			✓	✓	✓	✓
Urinary diaries		✓	✓	✓	✓	✓
Urinary outcomes (primary)	✓	✓	✓	✓	✓	✓
Other urinary outcomes		✓		✓		✓
Health-care utilisation questions		✓	✓	✓	✓	✓
SF-12, EQ-5D		✓		✓		✓
Exercise, including practice of PFMT		✓	✓	✓	✓	✓
Bowel outcomes		✓		✓		✓
Participant cost questionnaire				✓		
Sexual function outcomes						✓
Lifestyle change outcomes						✓
Satisfaction with treatment for incontinence						✓
Further treatment for incontinence						✓

Blinding

As the trial arm to which men were allocated could not be concealed after randomisation had occurred from either the man or the therapist, blinding of participants to intervention was not possible. However, outcome measures were assessed using questionnaires that were processed by MAPS study office staff who were not aware of the randomisation.

The statistician responsible for the final analyses was not the same as the one who performed the interim analyses for the Data Monitoring Committee. All statistical coding and results were agreed before the allocation was revealed.

Sample size

Based on the aim of detecting an absolute difference between intervention and control groups of 15% (30% to 15%) in the number of men who are still incontinent at 12 months, we calculated that we would need 174 men per arm of each trial to give 90% power to detect a significant difference at the 5% level. This would allow detection of a difference of 0.30 of a standard deviation (SD) at 80% power for continuous measures such as quality of life. Should the proportion of men who are incontinent be more than 30%, we would still have 80% power to detect a 15% change from 40% to 25%.

Allowing for a 13% dropout rate after enrolment in the RCT, we planned to recruit 200 men per arm. This would amount to 400 men in each of the two parallel trials, who would come from 615 incontinent men, assuming that 65% agree to join the trial. Based on conservative assumptions of 50% and 5% incontinent at 6 weeks after radical prostatectomy and endoscopic resection of prostate, respectively, and 80% response rates to the screening questionnaire, 1540 and 15,400 men would need to be approached. If a typical centre undertook 30 radical prostatectomies and

300 endoscopic resections of prostate each year, about 26 centres would be required for each trial recruiting over an average of 2 years.

Table 2 shows the number of men whom we estimated we would need to approach and hence the number of 'typical sized' clinical centres that would be required. In summary, we needed to screen around 17,000 men in stage 1 of the study, making conservative assumptions about likely response and participation rates. Based on these figures, a 2-year recruitment period in 26 centres would have been needed.

However, towards the end of planned recruitment (end September 2007), it became apparent that we would fall short of our minimum targets for men randomised. We therefore applied for a 9-month extension to recruitment, based on more accurate estimates of recruitment rates. In consultation with the Data Monitoring Committee and representatives of the HTA programme, recruitment was extended to July 2008 and, as a result, randomisation finished on 23 September 2008. There were no changes to the effective sample size sought (174 in each group at 12-month follow-up).

Statistical methods

Trial analyses

The principal comparisons in each trial were between men allocated to active therapy (up to four visits to a therapist plus the lifestyle advice leaflet) and men allocated to the control group (lifestyle advice leaflet only). The two populations of men (having radical prostatectomy or TURP) were analysed as separate trials. The primary outcome measure (urinary incontinence at 12 months) and secondary outcome measures were analysed using general linear models that adjusted for the minimisation covariates (age and pre-existing urinary incontinence) and, when possible, the baseline measure of the outcome. For the primary outcome only, unadjusted analyses were also reported. All analyses used 95% CIs. For the binary outcomes, a Poisson link function was used to estimate relative risks (instead of estimating odds ratios from a logistic model) and robust standard errors were used to estimate the CIs.[28] For illustrative purposes, the relative risk of the primary outcome was also transformed to a risk difference.

The primary statistical analysis was based on all men as randomised, irrespective of subsequent compliance with the treatment allocated (intention to treat). The intention-to-treat approach gives the least biased estimate of effectiveness of the two interventions. Given that it was likely

TABLE 2 Initial estimate of recruitment numbers and centres needed

Estimate	Radical prostatectomy	TURP
Men needed per arm (minimum)	174	174
Allowing for 13% dropout	200	200
Total men needed in two arms	400	400
Assuming 65% willing to enter RCT, no. of incontinent men needed	615	615
Percentage incontinent at 6 weeks (stage 2)	50%	5%
No. of men needed to reply to survey	1230	12,300
Assuming 80% response to survey, no. needed for survey (stage 1)	1540 (approx.)	15,400 (approx.)
No. of operations per typical centre	30	300
No. of typical centres needed in 2 years	26	26

Approx., approximately.

that some of the participants would not attend the therapy sessions (e.g. because they were continent), a secondary comparison was conducted to estimate the efficacy of the treatment received (i.e. what is the effect if the participants actually received the treatment they were allocated to?). The so-called 'per-protocol' approach for estimating efficacy of treatment, in which compliers with treatment in each group are compared with each other, can have substantial selection bias. A more robust method is to use a latent variable approach.[29] We used the method of adjusted treatment received as described by Nagelkerke *et al.*[30] The method used a two-stage least squares approach, whereby treatment received and the residuals from that model were used as an independent variable in a second model together with the treatment received to estimate the effects on the primary outcome.

Missing items in the health-related outcome measures were treated as per the instructions for that particular measure. No further imputation for missing values was undertaken. The ways in which the data were analysed were prespecified in the statistical analysis plan, which was agreed in advance with the MAPS Trial Steering Committee.

Timing and frequency of analyses

A single principal analysis was carried out at 15 months after the last man was recruited. The Data Monitoring Committee considered confidential interim analyses of data on three occasions during the data collection period (January 2006 – 31 randomised to radical prostatectomy and 48 randomised to TURP; January 2007 – 180 randomised to radical prostatectomy and 200 randomised to TURP; January 2008 – 297 randomised to radical prostatectomy and 364 randomised to TURP). The Data Monitoring Committee did not recommend any amendments to the protocol on any occasion.

Planned secondary subgroup analyses

Subgroup analyses (separately for the two populations) explored the effect on urinary incontinence at 12 months after randomisation of:

1. pre-existing urinary incontinence (before prostate surgery)
2. age (up to 60 years, 61 years and over for radical prostatectomy; up to 70 years, 71 years and over for TURP)
3. body mass index (BMI) (up to 30 kg/m^2, 30–34.9 kg/m^2, 35 kg/m^2 or greater)
4. type of incontinence at trial entry (SUI, UUI, MUI, postmicturition leakage)
5. other morbidity
6. type of therapist (physiotherapist or nurse)
7. centres with and without biofeedback machines.

Stricter levels of statistical significance ($2p < 0.01$) were sought, reflecting the exploratory nature of these analyses.

Ancillary analyses

Screening data

Descriptive statistics were tabulated to describe the derivation of the trial groups from the screening procedures, and included comparison of those who responded versus those who did not respond to the screening.

Therapist data

Descriptive data were tabulated to describe how the therapy intervention was implemented in each of the trials. This included a comparison across therapy visits (one to four) on incontinence, bowel and sexual problems and pelvic floor muscle performance.

Economics methods

Introduction

The economic evaluation was based on a within-trial analysis at 12 months after recruitment for men with urinary incontinence 6 weeks after radical prostatectomy or TURP. The question addressed was: what is the clinical effectiveness and cost-effectiveness of active conservative treatment delivered by a specialist continence physiotherapist or a specialist continence nurse compared with usual management? The perspective of the study was based on a societal viewpoint and included both the costs of the health service provider (the NHS) and those of the patients.

Measurement of resource use

The use of health services as a consequence of being incontinent was recorded prospectively for every participant in the study. Resource utilisation data were collected using questionnaires and urinary diaries. These data were collected using questionnaires sent to the participants at baseline, and 3, 6, 9 and 12 months. Resource utilisation data collected also included the intervention, i.e. the number of visits to the therapists, who were either specialist continence physiotherapists or continence nurse specialists. According to the protocol, PFMT intervention comprised four sessions. Details of the intervention are provided in *Chapter 3*. The first session of PFMT was 1 hour and the other three sessions were approximately 45 minutes each. Each session was conducted in a hospital department. The consumables required per session were gloves, K-Y Jelly, wipes and paper towels. No additional resources were required for the biofeedback as no equipment was used; verbal biofeedback was used to teach the men how to contract their muscles optimally and advise them on improvement from previous appointments.

Primary care and outpatient resource use included visits to the GP as well as to the outpatient department. The number of GP visits and the contact (doctor or nurse) were obtained from the 3-, 9- and 12-month follow-up questionnaires. Number of outpatient visits was obtained from the 3-, 6-, 9- and 12-month follow-up questionnaires. For the length of stay, the number of days the men were admitted was recorded. Other resource use included the number and type of drugs the patients were prescribed for their incontinence problems, the number of pads used and, finally, the number of bed and chair protectors used. The data reported by the patients were used to calculate the average and total resource use per patient.

The information generated from these questionnaires entailed manipulation of the data to perform the comparative analysis. Details of methods used to estimate resource use collected are included in *Table 3*.

Identification of unit costs

As described above, costs focused on the direct health service costs associated with each treatment. Unit cost data were extracted from the literature or from relevant sources such as manufacturers' price lists (*British National Formulary*, BNF)[31] and *NHS Reference Costs*.[32] The year of the cost data is 2008 and the currency is pounds sterling (£).

The costs of the intervention included the cost of PFMT sessions. These comprised the costs of the staff involved, consumables and overheads. The costs of producing the leaflets for the trial were not included in the analysis as all the men in the trial received leaflets. Men in both groups received a booklet containing supportive lifestyle advice (without reference to PFMT) by post after randomisation (see *Appendix 4.2*). Men in the intervention group also received a MAPS pelvic floor exercise leaflet (see *Appendix 4.3*) from the therapist at the first visit. The booklet

TABLE 3 NHS resource use in the last 12 months

Resource	Relevant variables	Source	Reported outcome
Patient management	Physiotherapist 1st visit	DA	Number attending
	Physiotherapist 2nd–4th visit	DA	Number attending
	GP visits	PQ	Number
Primary care	Nurse visits	PQ	Number
	Outpatient visits	PQ	Number
Secondary care	Inpatients days	PQ	Number
	Physiotherapy	PQ	Number
	Medications, e.g. tolterodine tartrate	PQ	Type and number
Other	Pads	PQ	Type and number
	Chair/bed protectors	PQ	Type and number
	Catheters	PQ	Type
	External sheaths	PQ	Type

DA, data abstraction of patient notes; PQ, patient questionnaire.

aimed both to support and to reinforce the anatomy teaching received during MAPS therapy appointments, as well as the exercise programme that had been set. It was therefore assumed that the costs would be the same for both groups. The cost of training that therapists received (1-day course) was included in the intervention costs because it was low and was not likely to impact on the overall costs.

The cost of the follow-up management comprised the cost per visit to both primary (GP and nurse appointments) and secondary (outpatient appointments and number of inpatient days) health-care providers. Unit costs for GP's visits were obtained from the Personal Social Services Research Unit (PSSRU) unit costs of community care.[33] Unit costs for outpatient services were obtained from the *Scottish Health Service Costs* (SHCS) (Information and Statistics Division website[34]) for the primary analysis and the national reference costs in a sensitivity analysis (Department of Health website[35]). The inpatient costs were those of the wards to which the men were admitted.

Other costs considered included containment products. These comprised all the products that participants used, such as absorbent pads, penile collecting sheaths, bladder catheters and bed and chair protectors. The unit costs of these items were taken from the providers of these items or from the NHS suppliers, where available. The unit cost of sheaths is based on a weekly cost of sheaths, estimated assuming that one sheath is used each day, the reusable leg bag is used for 3 days and one night bag is used each night. The unit costs of the catheter were based on the assumption that the catheter was used over a 3-month period, and similar assumptions were made for the leg and night bags. The unit cost of the medications was taken from the BNF,[31] and the cost per patient in terms of medication use was calculated by multiplying the unit cost by each number of units consumed for each patient. The costs considered were those of the drugs, not the prescription charges. *Table 4* provides a summary of the unit costs for the resources used.

The data describing the resource utilisation of participants were combined with estimates of unit costs for each of the areas of management considered. This allowed for estimation of total cost for each participant, as well as the average cost for each area of resource utilisation and average total cost. The results are reported in *Chapters 8* and *13*.

TABLE 4 Average unit costs

Resource use	Unit cost (£)	Notes
Staff costs	67	Based on cost per hour of patient contact for Band 6 of the October–December 2007 NHS staff earnings estimates for qualified nurses[33]
Cost of consumables	0.90	Based on cost of gloves, K-Y Jelly, couch roll, paper towels, wipes for four visits
Medications	Various	Cost based on recommended dosage
GP doctor visit	36	Per surgery consultation lasting 11.7 minutes[33]
GP nurse visit	11	Based on cost per consultation[33]
Physiotherapist visit	31	Based on cost of nurse-led clinic[33]
Outpatient visit	75	Based on cost[34]
Inpatient visit	157	Based on the average cost per day in a urology specialty ward[34]
Pads	0.17	Cost per pad
Chair/bed protector	0.15	Cost per protector
Sheath	8.46	Weekly cost of sheath (condom) catheter, reusable leg bag and disposable night bag
Catheter	2.73	Weekly cost of catheter, reusable leg bag and disposable night bag

Participant costs of urinary incontinence

As the perspective of the study was the NHS and patient, those costs borne by participants and their families were also considered. Participants' resource use was taken as time taken to access services (e.g. attend GP, physiotherapist, outpatient or inpatient appointments), travel costs and the time taken off usual activities owing to poor health. Similar costs were included for spouses, relatives or friends who accompanied them to their appointments. Travel costs to patients and their families were based on actual fares when public transport was used and published mileage rates in the case of those who used their own vehicles (HM Revenue and Customs website[36]). These data were collected through postal questionnaires administered at 12 months.

In the case of patients who would have been engaged in employed work, the value of their time was taken as the gross average full-time wage rate for men (Office for National Statistics website[37]). The value for those who were not in formal employment was based on 57% of the average national rate and 43% for those who may have been involved in leisure activities.[38] The costs of friends/relatives accompanying patients to hospital were estimated in the same way. These unit time costs, measured in terms of their natural and monetary terms, were combined with estimates of number of health-care contacts derived from the health-care utilisation questions. Self-purchased health care included items such as pads bought by the participant, prescription medicines and over-the-counter medications. Information about these was collected through the health-care utilisation questions. Patients' time and travel costs were based on the information collected, and are described in *Table 5*.

Quality of life

Effectiveness within the trial was measured in terms of QALYs and subjective continence at 12 months (assessed using data from the ICI-SF). Quality of life data were collected at baseline and 6 and 12 months. This was generated using generic health status measurement tools, the EQ-5D and SF-12, included in the questionnaires. The EQ-5D measure divides health status into five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Each of these dimensions has three levels, therefore 243 possible health states exist.[39] Responses of the patient EQ-5D questionnaires were transformed using a standard algorithm to produce a health state utility at each time point for each patient. The utility scores obtained at baseline and 6 and 12 months were used to estimate the mean QALY score for each group. The estimation of QALYs took account of the mortality of study participants. Participants who died within the

TABLE 5 Patient and companion resource use and costs

Resource	Resource use	Unit cost
Use of personal car to GP	Distance travelled	Cost per mile/km
Use of personal car to hospital	Distance travelled	Cost per mile/km
Use of public transport to GP	Ticket	Return cost of ticket
Use of public transport hospital	Ticket	Return cost of ticket
Medication purchased	Type and number	Cost of medicines
Loss of earnings	Number of days off work	Daily wage

study follow-up were assigned a zero utility weight from their death until the end of the study follow-up. QALYs before death were estimated using linear extrapolation between the QALY scores at baseline and all available EQ-5D scores up to death.

As described below in the section on the sensitivity analysis, the responses from the SF-12 questionnaire were also used as the basis of QALYs, and were mapped on to the existing Short Form questionnaire-6 Dimensions (SF-6D) measure using the algorithm by Brazier *et al.*[40] to allow utility values to be estimated for each time point. These utility scores were transformed into QALYs using the methods described above to provide an alternative measure of QALYs for each patient.

Incremental cost-effectiveness

Data collected on costs and effects of the interventions were combined to obtain an incremental cost-effectiveness ratio (ICER). This was performed by calculating the mean difference in costs between the interventions and control groups over the difference in effect between the interventions and control groups. This gives us the cost per additional QALY gained for the new interventions relative to standard practice.

The primary analysis was based on the 1-year follow-up of the trial and the outcome was the incremental cost per QALY. This outcome was chosen to reflect a societal decision-making perspective. The results are presented as point estimates of mean incremental costs, proportion of men continent, QALYs and cost per QALY. Measures of variance were based upon bootstrapped estimates of costs, QALYs and incremental cost per QALY. Incremental cost-effectiveness data are presented in terms of cost-effectiveness acceptability curves (CEACs).

Data analysis (economics)

As data were collected over a 1-year period, discounting was not carried out. The numbers of missing data for each variable used in the analyses of cost were quite low, and data that were missing were considered to be missing completely at random. Data reported as mean costs for both cases and controls were derived for each item of resource use and then compared using unpaired *t*-tests and linear regression adjusted for baseline values. As the data were not normally distributed, non-parametric bootstrapping was used to estimate confidence limits around the difference in cost for each area of resource use and total costs.

Sensitivity analysis

With all parameter estimates there are elements of uncertainty owing to the lack of available information. In order to explore the importance of such uncertainties and assumptions, various sensitivity analyses were conducted by varying some of the assumptions or estimates used in the analysis. Two types of sensitivity analyses were performed: one-way sensitivity analysis and threshold analysis.

The base-case analyses in terms of utilities were adjusted for patient outcomes at baseline to account for variability that might be present amongst the intervention groups. An unadjusted analysis was also performed to highlight the importance of this base-case assumption.

There is uncertainty around the QALY estimates as they were derived using one generic instrument, the EQ-5D. There is some debate over whether the dimensions in the EQ-5D are sensitive enough to capture the loss in quality of life for chronic health states of which the worst effects occur during acute episodes. Therefore, the responses from the SF-12 questionnaire were mapped on to the existing SF-6D measure using the algorithm by Brazier *et al.*[40] to allow utility values to be estimated for each time point. These utility scores were then transformed into QALYs using the same methods as used for the EQ-5D scores to provide an alternative measure of QALYs for each patient.

Modelling

Additional information for policy-makers was derived from a simple economic model that considers what difference in continence rates would result in a change in the conclusions about which treatment would be cost-effective. This analysis was performed from the perspective of the NHS.

The data used to populate the model were based on the trial patient data, to inform on the probability of being incontinent at the end of 12 months, and the cost data. The data also included QALYs and costs derived for each participant, based on the group they were allocated to (intervention or control) The model is illustrated in *Figure 3*.

Management of the study

The MAPS study office, working in conjunction with our trials unit, and CHaRT in the Health Services Research Unit, University of Aberdeen, provided support for the clinical centres, randomisation, management of data collection, follow-up, data processing and analysis. The MAPS Project Management Group (grant holders and representatives from the study office) met formally at least monthly during the course of the study to discuss key trial issues.

The study was overseen by an independent Trial Steering Committee with an independent chairman and three other independent members. The remaining members were the grant holders. The Trial Steering Committee met annually on six occasions. An independent Data Monitoring Committee was also established, comprising an independent chairman and three

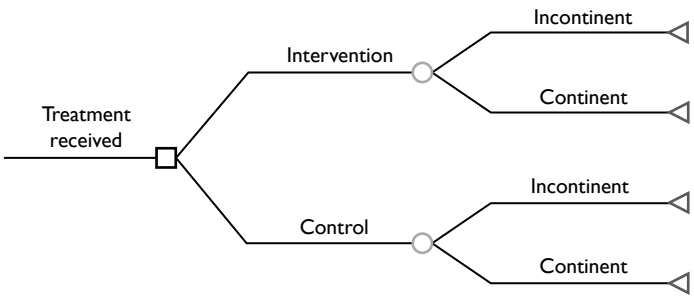

FIGURE 3 Structure of the model used in economic analyses.

TABLE 6 Changes to MAPS study protocol

Change to protocol	Date approved
Nomenclature: the operation types for the two groups of men are referred to as 'radical' and 'TURP'	31 May 2005
Nomenclature: intervention will be delivered by 'therapists' rather than 'physiotherapists'	31 May 2005
Formal referral to a therapist delivering PFMT before or after operation added as a specific exclusion criterion	31 May 2005
Multiple sclerosis or Parkinson's disease no longer a specific exclusion criterion	31 May 2005
Trial Steering Committee concluded that the study should still aim to enrol 25–30 centres as this would allow for sites withdrawing and rates dropping off	30 November 2005
Amendment relating to the diagnosis of unsuspected prostate cancer in men undergoing TURP, and how this would be handled in the MAPS study	30 November 2005
New sponsor: University of Aberdeen	30 November 2007
Revised extension timings	30 November 2007

other independent members, who met on three occasions. The trial statistician supplied, in strict confidence, interim analysis results for their consideration.

The University of Aberdeen assumed the role of sponsor for the study.

Table 6 shows the substantive changes to the MAPS study protocol since its first approval by the MREC: they were approved on the dates shown.

Chapter 3

Intervention design, centres, therapists and therapy

In this chapter, the rationale for the intervention, the methods used to train the therapists in order to standardise the intervention and the types of therapists at each centre are described.

Introduction

The purpose of the MAPS trial was to compare return to continence with or without a structured PFMT programme, delivered by a trained therapist, in men after TURP or radical prostatectomy. Both groups received written information on recovery after surgery. The primary outcome was self-reported urinary incontinence at 12 months after randomisation.

Following radical prostatectomy, some degree of iatrogenic urinary incontinence is a recognised complication in up to 90% of men.[9] Following TURP for benign prostatic hypertrophy, the figure is around 10%.[15]

Some physiotherapists already use PFMT and bladder training (BT) or urge suppression (US) techniques to treat men with urinary incontinence following prostate surgery, despite Cochrane reviews clearly showing that there is currently insufficient evidence to confirm whether or not these are effective.[26,41] Uncertainty also surrounds the most effective PFMT and BT/US protocols for specific clinical indications.

MAPS control protocol

All participants received a lifestyle advice leaflet (see *Appendix 4.2*) (control and intervention groups). Face and content validity were established by review of the literature,[19] with a consumer representative of men who had urinary incontinence, and with health-care professionals. The final copy contained information about moderating fluid intake (avoiding too much or too little), and information on caffeine, cranberry juice, diet and obesity, constipation, general fitness, lifting, smoking, chest problems and urinary tract infections and was based on clinical practice recommendations. The control group had no further contact with the research team, apart from follow-up by questionnaires.

MAPS intervention protocol

In addition to the leaflet described above, all men in the intervention group received a structured PFMT intervention. The protocol was based on one used in a previous trial using PFMT to increase pelvic floor muscle strength for men with erectile dysfunction.[42] The BT/US techniques were based on those typically used in clinical practice for UUI and summarised in a Cochrane review.[43] The advice on fluid intake was based on standard clinical practice.[44]

Constituent elements of the intervention protocol

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 (graded 0–5).[45] An additional grade (6) was added to define a very strong anal squeeze.[46] The new grading system was used to assess separately the strength of both the external anal sphincter and the deeper puborectalis muscle (taken to represent the pelvic floor muscles). The external anal sphincter was assessed at 1–2 cm from the anal meatus, and the puborectalis at 3–4 cm from the anal meatus.

Verbal biofeedback from this examination was 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 timed by counting.

Pelvic floor muscle therapy regimen

PFMT was aimed at improving the strength of the pelvic floor muscles to allow effective contraction during exertion to prevent urinary leakage. PFMT consisted primarily of three maximum-strength contractions with a 10-second break between each one, practised in three positions (lying, sitting and standing) twice daily (see *Appendix 4.3*). 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. In addition, men were taught to carry out a sustained submaximal contraction of the pelvic floor muscles during walking and to perform a strong contraction before and during any event that might cause leakage, such as coughing or rising from sitting ('the knack').[47] Men were advised to eliminate urine remaining in the bulbar urethra by using a strong contraction after urination was finished, in order to prevent postmicturition dribble.[42] Contracting the pelvic floor muscles during sexual activity was also recommended to achieve, maintain or improve erectile strength.

Bladder training/urge suppression

Men with urgency or UUI were taught urge suppression techniques in order to avoid rushing to the toilet when the bladder was starting to contract (see *Appendix 4.3*). Fluid advice, including avoiding or reducing caffeine, was also offered.

Written supplementary guidance

The MAPS PFMT leaflet (see *Appendix 4.3*) aimed both to support and to reinforce the anatomy teaching received during appointments, as well as the exercise programme that had been set. To maximise understanding, careful consideration was given to the language and terminology used in this leaflet, taking into account the sensitive nature of incontinence and erectile dysfunction. The use of medical and anatomical terms was minimised in favour of a plain English approach ('urine leakage' for incontinence).[48]

Drafts of the leaflets were reviewed for face and content validity by lay persons and health-care professionals with knowledge of men's health and continence issues.

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 areas were addressed.

Rationale for performing a digital anal examination

A digital anal examination was undertaken to assess the strength and endurance of, firstly, the external anal sphincter and, secondly, the puborectalis muscles. Wyndaele and Van Eetvelde[49] demonstrated the reproducibility of assessing the puborectalis by anal assessment using grades 0–5. By assessing puborectalis muscle strength, the strength of the surrounding pelvic floor muscles would also be graded. The muscles were graded from 0 to 6, with 0 being 'no flicker or contraction' and 6 being 'very strong, unable to withdraw finger.[42] Repeating the examination at subsequent visits enabled therapists to provide verbal feedback to men that their exercises were effective in building up muscle strength and to monitor progress.

Rationale for asking men to perform pelvic floor exercises in three positions

Pelvic floor muscles support the abdominal contents and prevent urinary leakage. The three positions provided a graded method of increasing the effect of gravity, in order to provide extra muscle work load. The pelvic floor muscles were recruited initially in a lying position, without the effect of gravity. As strengthening occurred, pelvic floor muscles were subject to a higher load by recruiting them in a sitting position, where the downwards descent of the pelvic floor would be partly prevented by the seat of the chair. A greater load would be placed on the pelvic floor during standing, when gravitational forces opposed 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.[24,50–52] It was believed that men needed to be able to tighten their pelvic floor muscles in a number of positions, so that they could recruit them speedily during coughing and sneezing.

Rationale for performing 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. Based on clinical research of quadriceps strengthening using a 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 failed to reach maximum power owing to fatigue.[53] Kegel[54] stated that maximum power was a key element to gaining increased muscle strength. These principles informed the PFMT programme, considering that the maximum power of pelvic floor contraction would be attained using three muscle contractions in each position held for up to 10 seconds. The target was individually adjusted as performance improved.

Rationale for performing the regimen twice a day

Kegel[54] recommended 300–400 pelvic floor muscle contractions a day to treat SUI in women. However, clinical practice has shown that patients find this level of commitment to be too arduous, resulting in attrition and demotivation. The principles of muscle building show that it is the quality of the contraction that is more important than the quantity.[53,55]

The MAPS intervention was therefore designed to provide targets that were achievable in order to motivate men to maintain the regimen within the constraints of the protocol. In a previous trial,[42] 55 men were asked to perform their exercise sets only twice a day. After 3 months, all except one (who had severe back pain) showed a statistically significant increase in pelvic floor muscle strength. We therefore felt that this regimen had a proven ability to increase pelvic floor muscle strength.

Rationale for contracting the muscles as strongly as possible

The pelvic floor muscles consist of two-thirds slow-twitch continually tonic muscle fibres and one-third fast-twitch muscle fibres, which can be speedily recruited when extra support is needed

during activities that increase intra-abdominal pressure.[56] Both fibre types 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 was expected to result in the hypertrophy of muscles and an increase in local blood supply.[53,55]

Rationale for functional use of muscles

Pelvic floor muscles need to be recruited to prevent leakage of urine during activities that increase intra-abdominal pressure. 'The Knack' is the technique, or learned skill, of tightening just before and during these activities.[47] Owing to its significant role in contributing to continence, teaching of 'the Knack' was therefore included as an element in the MAPS intervention.

Reasons for increasing pelvic floor muscle endurance

Slow-twitch muscle fibres fulfil a number of important functions: 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.[57] 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 potentially increasing the use of slow-twitch fibres and hence muscle endurance was achieved.

Rationale for tightening 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.[58] 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.[42] This muscle contraction will then facilitate the evacuation of residual urine from the bulbar urethra. This may restore or develop the reflex postvoid milking mechanism identified by Wille *et al.*[58] and termed the 'urethrocavernosus reflex' by Shafik and El-Sibai.[59] Thus, as an additional strategy to attain continence, participants were taught to perform consciously a pelvic floor muscle contraction immediately after micturition.

Rationale for tightening the pelvic floor muscles during sexual activity

The superficial bulbocavernosus and ischiocavernosus muscles are active during penile erection.[60] 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 prevents blood from escaping through the deep dorsal vein during an erection. One study has shown that pelvic floor exercises can restore erectile function in 40% of men and improve it in a further 36%.[42] As this is another potential benefit of PFMT, it was decided that it would be appropriate to include erectile function in the MAPS intervention materials and be measured as a secondary outcome. However, it is not yet clear whether men will benefit after radical prostatectomy as the amount and degree of nerve damage caused by surgery is likely to be variable. Erectile function was a secondary outcome of the study.

Rationale for choice of urge suppression techniques

A detrusor contraction produces a desire (urge) to empty the bladder. If urgency sensations cannot be overcome, urinary incontinence may occur. The resulting fear of leakage can cause anxiety, breath-holding and descent of the diaphragm, which, coupled with abdominal muscle contraction, can produce early inappropriate micturition. A retrospective study in women has reported that effective urge suppression techniques include keeping calm, sitting down or standing still and waiting 1 minute until the initial urge sensation disappears.[46] PFMT can be

used to strengthen the pelvic floor musculature and, together with urge suppression techniques, can help to restore bladder control.

Rationale for giving fluid, dietary and lifestyle advice

All men received fluid, dietary and relevant lifestyle advice as part of the therapy appointments, supplemented by written information (see *Appendix 4.2*). Advice included information that reducing fluid intake (underdrinking) to avoid leakage may lead to urinary tract infections, constipation and dehydration.[61] Conversely, drinking excessive amounts (in the belief that this is beneficial for health) may have adverse effects such as an increased risk of leakage.[62] However, men experiencing nocturia were advised that avoiding fluids 2 hours before bedtime may be helpful.

Drinks containing caffeine or alcohol may cause increased risk of urgency and men were advised to reduce or avoid them.[61] 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 were highlighted, including the effect of constipation, smoking and obesity.[63] Information on all these elements was included in the MAPS lifestyle advice leaflet (see *Appendix 4.2*).

Rationale for four appointments in 12 weeks

The value of psychological support for men following radical prostatectomy has been stressed in the literature,[52] as has the intrinsic value of therapist contact in order to maintain patient motivation.[64] Within MAPS, therefore, a schedule of four appointments (at baseline, 2 weeks, 6 weeks and 12 weeks) was considered sufficient to monitor postsurgical muscle strength development and maintain motivation but not be too burdensome on patients or costly in terms of resources (chiefly therapist time).

Pelvic floor muscle strength can improve over a 3-month period of PFMT.[42] Men in the study received four appointments and were encouraged to continue their exercise regimen for life, with particular emphasis on functional work (e.g. contracting during activity or counteracting increases in intra-abdominal pressure by use of 'the Knack'). A previous trial by van Kampen *et al.*[24] 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.

Summary of rationale for design of intervention

The MAPS intervention, combining PFMT, BT/US and fluid advice, was evidence based wherever possible. Where evidence was lacking, the intervention was based on expert clinical practice. The rationale underpinning the intervention was published in 2009.[65]

The trial compared the structured PFMT intervention with standard care, in order to add to the current evidence base. This, in turn, should inform practice and treatment decisions for therapists, men with incontinence after prostate surgery, and providers of care.

Training for the therapists

Therapists were either specialist continence physiotherapists or specialist continence nurses. The intervention protocol was standardised by systematically training all the therapists during a bespoke training day programme, and by use of common trial forms for recording assessment

and treatment data. Some therapists were trained on a one-to-one basis if they joined the study late. During the training day, an overview provided information on 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 including:

- assessment and examination of men in a systematic manner
- the diagnosis of SUI, UUI, postmicturition 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 at each visit
- 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 BT/US techniques
- advice about fluid intake and other lifestyle advice corresponding to the leaflet
- the role of PFMT in the treatment of erectile dysfunction
- graded goal-setting for the men in terms of gradually increasing endurance of pelvic floor muscle contractions
- documenting the treatment given at each visit.

Summary of the MAPS intervention

At the baseline assessment visit, the men were taught PFMT. BT/US techniques were included if men described urgency or UUI. The men had reinforcement sessions on three further occasions over 3 months – at around 2 weeks, 6 weeks and 12 weeks after the first appointment. Anal examination was repeated at each visit to document changes in pelvic floor muscle strength, and to provide feedback to the men on their progress.

Pelvic floor muscle training

Men in the intervention group were instructed:

- to carry out three maximum pelvic floor contractions in three positions (lying supine with knees bent and feet on the couch, sitting with knees apart and standing with feet apart) twice per day
- to 'lift' their pelvic floors slightly while walking
- to tighten their pelvic muscles before activities that might cause them to leak, such as coughing
- to tighten after urinating to eliminate the last few drops.

Biofeedback

Biofeedback involved monitoring the strength of a pelvic floor contraction (by digital anal assessment) and verbally relaying the information back to the men in order to confirm that they were performing contractions correctly (lifting up in a cranial direction) and to inform them when they were increasing the strength or duration of their contractions. Therapists were trained to consistently grade the pelvic floor muscle strength and endurance by digital anal assessment at each session. The findings were used to set progressive targets for the men. Treatment was therefore individualised and could be progressively increased for each man.

If it was felt clinically indicated, in addition to digital anal assessment, therapists used machine-mediated biofeedback with an anal biofeedback probe in centres where this was available (see *Table 7*), both for diagnosis and for teaching of correct muscle contraction.

Bladder training/urge suppression

BT/US involved advice to gradually delay urination (by pelvic floor muscle contraction or calming/distracting activities) to teach the bladder to hold increasing volumes of urine. Men were instructed to relax for 1 minute when they first felt an 'urge', then walk calmly to the toilet or delay urination until the next 'urge'.

Written information

All participants received the lifestyle advice booklet (see *Appendix 4.2*), and those in the intervention group also received the pelvic floor exercise booklet (see *Appendix 4.3*).

Ensuring standardisation of intervention

All staff delivering the intervention received exactly the same training in order to ensure consistency of their method of teaching and delivery of the PFMT, BT/US and biofeedback. Both specialist continence physiotherapists and specialist continence nurses were eligible to deliver the intervention, thus increasing the generalisability of the trial.

The therapists recorded their assessments and treatment programmes on standard study forms (see *Appendix 4.1*). Data were stored locally in case notes but collected and analysed centrally (see *Chapters 6* and *11*).

Centres, resources and therapists

Because physiotherapists were not available at every centre, and to increase the generalisability of the intervention to the NHS, we chose to train both specialist continence physiotherapists and specialist continence nurses (as above). There were 17 centres with therapists from a physiotherapy background, and 17 with a nursing background (*Table 7*).

Machine-led biofeedback was available in 13 centres (*Table 7*). Therapists were asked to declare whether they felt that biofeedback would be clinically indicated (whether or not a biofeedback machine was available) and also whether it was actually used. In five centres that had access to a biofeedback machine, and in four without such access, therapists reported that they would like to use one. A biofeedback machine was actually used in 5 of the 13 centres with access, for 17 men after radical surgery and 10 after TURP (*Table 7*).

TABLE 7 Types of therapists at each centre, availability of biofeedback, and use of biofeedback for men in each centre

Centre	Physiotherapist	Specialist continence nurse	Biofeedback available in the centre	Biofeedback clinically indicated[a]	Number of men receiving biofeedback
Aberdeen	No	Yes	No	No	0
Ipswich	Yes	No	Yes	Yes (3R)	2R
Dundee	No	Yes	No	No	0
Stockport	Yes	No	No	Yes (2R, 1T)	0
Tameside	Yes	No	Yes	Yes (3R, 8T)	3R, 4T
Middlesbrough	Yes	No	No	Yes (8R)	0
Falkirk	Yes	No	No	No	0
Newcastle upon Tyne	Yes	No	No	No	1R
Airedale	Yes	No	Yes	Yes (4R)	4R
Reading	No	Yes	No	No	0
Wakefield	Yes	No	Yes	No	0

continued

TABLE 7 Types of therapists at each centre, availability of biofeedback, and use of biofeedback for men in each centre *(continued)*

Centre	Physiotherapist	Specialist continence nurse	Biofeedback available in the centre	Biofeedback clinically indicated[a]	Number of men receiving biofeedback
Ayr	Yes	No	Yes	Yes (1T)	0
Bristol	No	Yes	Yes	Yes (7R, 6T)	7R, 6T
Stevenage	No	Yes	No	No	0
Inverness	No	Yes	No	No	0
Leeds	No	Yes	No	Yes (8R, 6T)	0
Inverclyde	Yes	No	No	No	0
Wolverhampton	Yes	No	No	No	0
Swansea	No	Yes	No	No	0
Sheffield	No	Yes	No	No	0
Ilford	No	Yes	Yes	No	0
Bolton	Yes	No	Yes	No	0
Taunton	No	Yes	No	No	0
Norwich	Yes	No	Yes	No	0
Yeovil	Yes	No	Yes	No	0
Edinburgh	Yes	No	No	Yes (5R, 1T)	0
Dunfermline	Yes	No	Yes	No	0
Cardiff	No	Yes	No	No	0
Macclesfield	No	Yes	No	No	0
Southmead	No	Yes	No	No	0
Crewe	Yes	No	Yes	No	0
Hillingdon	No	Yes	No	No	0
St Mary's, London	No	Yes	Yes	No	0
Hope, Salford	No	Yes	No	No	0

a Numbers in brackets indicate the number of men for whom biofeedback was clinically indicated for men having radical prostatectomy (R) and TURP (T) at each site.

Chapter 4

Centres and recruitment to the two trials

This chapter describes how the two trial groups were identified from the men admitted for radical prostatectomy and TURP at the recruiting hospitals. It reports the baseline comparability of the men in hospital, the response to the screening survey, and the characteristics of the study groups up to the point of entry to the RCTs.

Study recruitment

Men who were having prostate surgery were approached during their hospital stay by recruitment officers in each of the 34 centres. Men were asked to consent to being sent a screening questionnaire at 3 weeks after their surgery. If their response indicated that they were incontinent, they were invited to participate in the RCT of PFMT.

Centre screening and recruitment

Table 8 shows the number of men approached in each centre, and how many were eventually eligible for screening and randomisation. In total, 780 men having radical prostatectomy and 2836 men who had TURP were sent a screening questionnaire, 742 and 2590 responded, and 429 and 442 were eventually randomised. However, 18 of the 'radical' men from one centre were subsequently excluded after randomisation (postrandomisation exclusion) as therapy was not available during some of the period of screening in that centre, leaving 411 randomised to the radical prostatectomy trial.

Reasons for not completing a screening questionnaire

Table 9a describes the reasons given for ineligibility for receiving a screening questionnaire. The most common reasons for ineligibility were that the men were missed (no contact with recruitment officer), they refused, they were unable to give informed consent or they were having radiotherapy or palliative surgery, or that the operation was not carried out or changed to another operation. *Table 9b* shows that the men having TURP who were ineligible for screening were older than those who consented to screening.

Table 10a describes the reasons why men who were eligible for screening (signed consent forms received at the study office in Aberdeen) were in the event not sent a screening questionnaire. The most common reason was that the planned operation was changed or cancelled after the men had signed a consent form. Only men who actually had a radical prostatectomy or TURP were eligible to be screened. *Table 10b* shows that there were no significant differences in age between those who were eligible and screened and those who were eligible and not screened.

TABLE 8 Centres with numbers of men recruited to each trial

	Radical prostatectomy			TURP		
Centre	*n* screened/*N* approached	*n* responded/*N* screened	*n* randomised/*N* responded to screening	*n* screened/*N* approached	*n* responded/*N* screened	*n* randomised/*N* responded to screening
Aberdeen	76/85	74/76	55/74	320/467	302/320	60/302
Ipswich	40/49	39/40	15/39	146/511	138/146	17/138
Dundee	1/1	1/1	1/1	27/37	27/27	4/27
Stockport	70/97	68/70	37/68	191/476	173/191	27/173
Tameside	30/32	26/30	18/26	145/203	125/145	19/125
Glasgow Southern				4/45	3/4	0/3
Middlesbrough	49/60	47/49	36/47			
Falkirk	4/22	4/4	2/4	6/62	6/6	1/6
Newcastle	45/61	42/45	23/42	491/661	448/491	63/448
Airedale	5/15	5/5	2/5	19/109	18/19	3/18
Reading	69/98	68/69	32/68	144/408	131/144	18/131
Wakefield	15/23	15/15	6/15	59/150	57/59	11/57
Ayr				109/225	101/109	17/101
Bristol	26/51	26/26	16/26	110/244	104/110	24/104
Stevenage	0/3			27/108	26/27	8/26
Inverness	38/41	36/38	18/36	108/144	98/108	15/98
Leeds	118/168	113/118	77/113	205/623	180/205	24/180
Inverclyde				20/30	16/20	3/16
Wolverhampton				38/115	36/38	9/36
Swansea	31/36	30/31	15/30	43/63	38/43	6/38
Sheffield	63/67	61/63	27/61	112/143	102/112	22/102
Ilford				20/22	18/20	4/18
Bolton	8/12	6/8	3/6	51/155	43/51	8/43
Taunton	4/5	4/4	2/4	71/82	62/71	14/62
Norwich	12/24	12/12	5/12	18/72	17/18	1/17
Yeovil	1/2	1/1	0/1	40/63	39/40	10/39
Edinburgh	10/81	10/10	6/10	23/220	21/23	4/21
Dunfermline	5/6	5/5	2/5	91/108	82/91	14/82
Cardiff				107/194	97/107	19/97
Macclesfield	0/1			14/45	13/14	1/13
Southmead	29/86	24/29	15/24	44/150	38/44	8/38
Crewe				33/51	31/33	8/31
Hillingdon	1/1	1/1	1/1			
St Mary's, London	28/28	22/28	13/22			
Hope, Salford	2/3	2/2	2/2			
Total (34)	780/1158	742/780	429/742	2836/5986	2590/2836	442/2590

TABLE 9a Number of men admitted for prostate surgery, and numbers eligible for screening survey

	Radical prostatectomy	TURP
Approached	1158	5986
[Consented, *N*]	[804]	[2985]
Not consented	354/1158 (31)	3001/5986 (50)
Reasons for no consent		
No reason given	15 (4)	65 (2)
Refused	75 (21)	601 (20)
Not approached/missed	154 (44)	1078 (36)
Unable to give informed consent	20 (6)	537 (18)
Referred for formal physiotherapy	10 (3)	3 (0)
Radiotherapy planned or palliative surgery	6 (2)	485 (16)
Surgery cancelled or changed (e.g. BNI)	17 (5)	198 (7)
On other trial (e.g. ProtecT)	47 (13)	3 (0)
Unclear/other reason	10 (3)	31 (1)

BNI, bladder neck incision.
n/*N* (%)

TABLE 9b Baseline comparability of men eligible and not eligible for screening survey

	Radical prostatectomy		TURP	
	Eligible	Ineligible	Eligible	Ineligible
Age, years [mean (SD) *n*]	62.5 (5.9) 802	63.1 (6.5) 347	69.9 (8.3) 2972	73.4 (9.1) 2971

TABLE 10a Number of men eligible for screening survey and reasons for not screening some of them

	Radical prostatectomy	TURP
Consented *n*/*N* (%)	804/1158 (69.4)	2985/5986 (49.9)
Consented and screened *n*/*N* (%)	780/804 (97)	2838/2985 (95)
Consented but not screened *n*/*N* (%)	24/804 (3)	147/2985 (5)
Reasons for not screening (*n*)		
No reason given	0 (0)	3 (3)
Refused	0 (0)	11 (8)
Referred for formal physiotherapy	1 (4)	0
Radiotherapy planned or palliative surgery	1 (4)	17 (12)
Surgery cancelled or changed (e.g. BNI)	12 (50)	106 (72)
On other trial (e.g. ProtecT)	0 (0)	1 (1)
Unclear/other reason	10 (42)	11 (6)

TABLE 10b Baseline comparability of men screened and not screened by screening questionnaire

	Radical prostatectomy		TURP	
	Screened	Not screened	Screened	Not screened
Age, years [mean (SD) *n*]	62.4 (6.0) 778	63.5 (5.2) 24	70.0 (8.2) 2825	69.3 (10.0) 147

Recruitment of men to the randomised controlled trial

Each man who indicated on his screening questionnaire that he had urinary incontinence was sent a baseline questionnaire and contacted around a week later by a dedicated recruitment officer based at the MAPS study office in Aberdeen. Eligibility was confirmed and, upon receipt of the signed RCT consent form, men were randomised to the intervention or standard care groups. *Figures 4* and *5* show the flow of the number of patients who were approached to take part in the screening through to randomisation into the radical prostatectomy and TURP trials respectively.

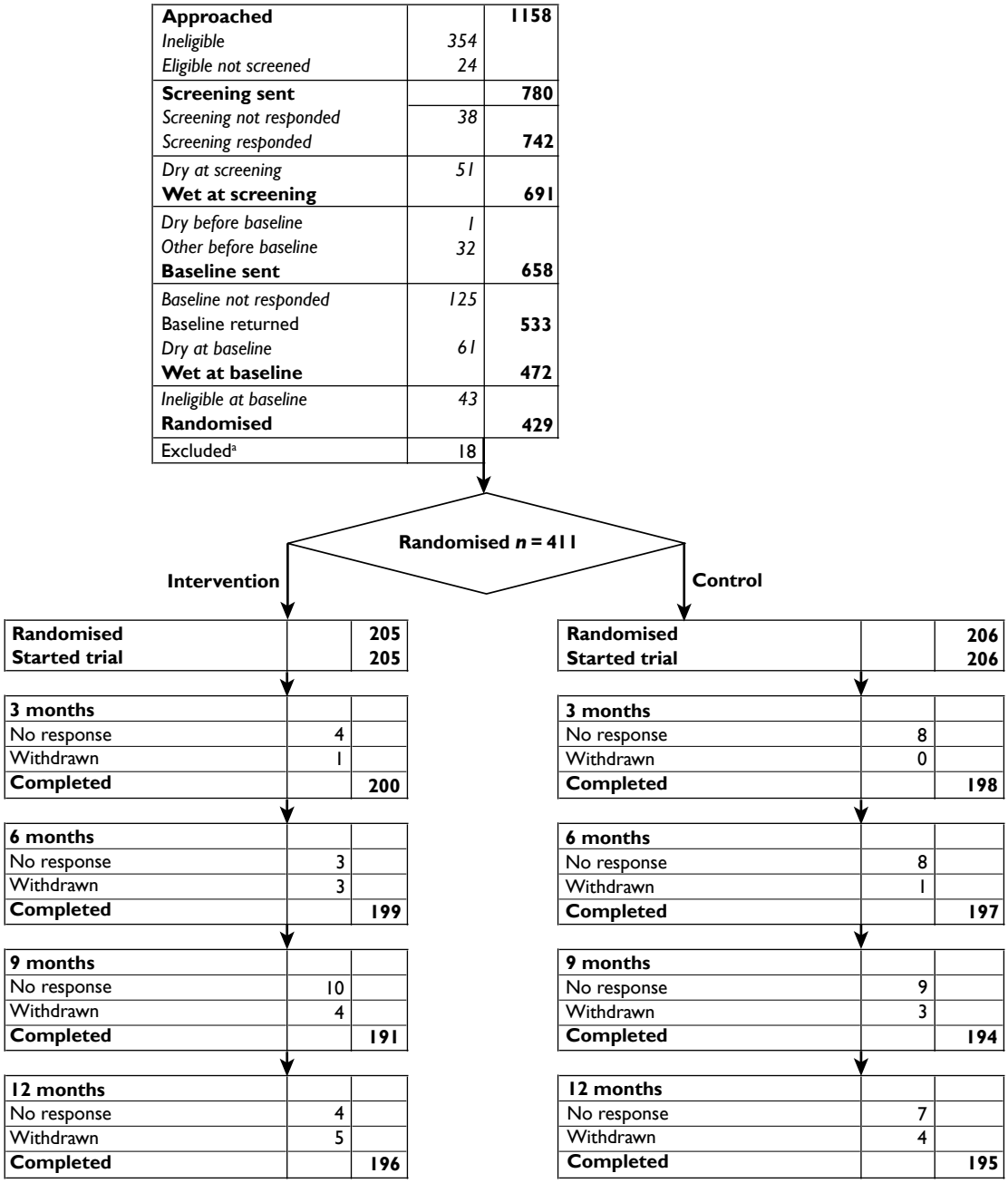

FIGURE 4 Flow chart of men from operation to recruitment to RCT: radical prostatectomy. a, Postrandomisation exclusion: therapy was not available during some of the period of screening in one centre (18 men).

Reasons for screened patients not to be subsequently randomised

Table 11 describes the reasons why screened men were not randomised into the trials. The most common reason was that the men were continent at the screening questionnaire or subsequently continent by the time the baseline questionnaire or telephone recruitment call was conducted.

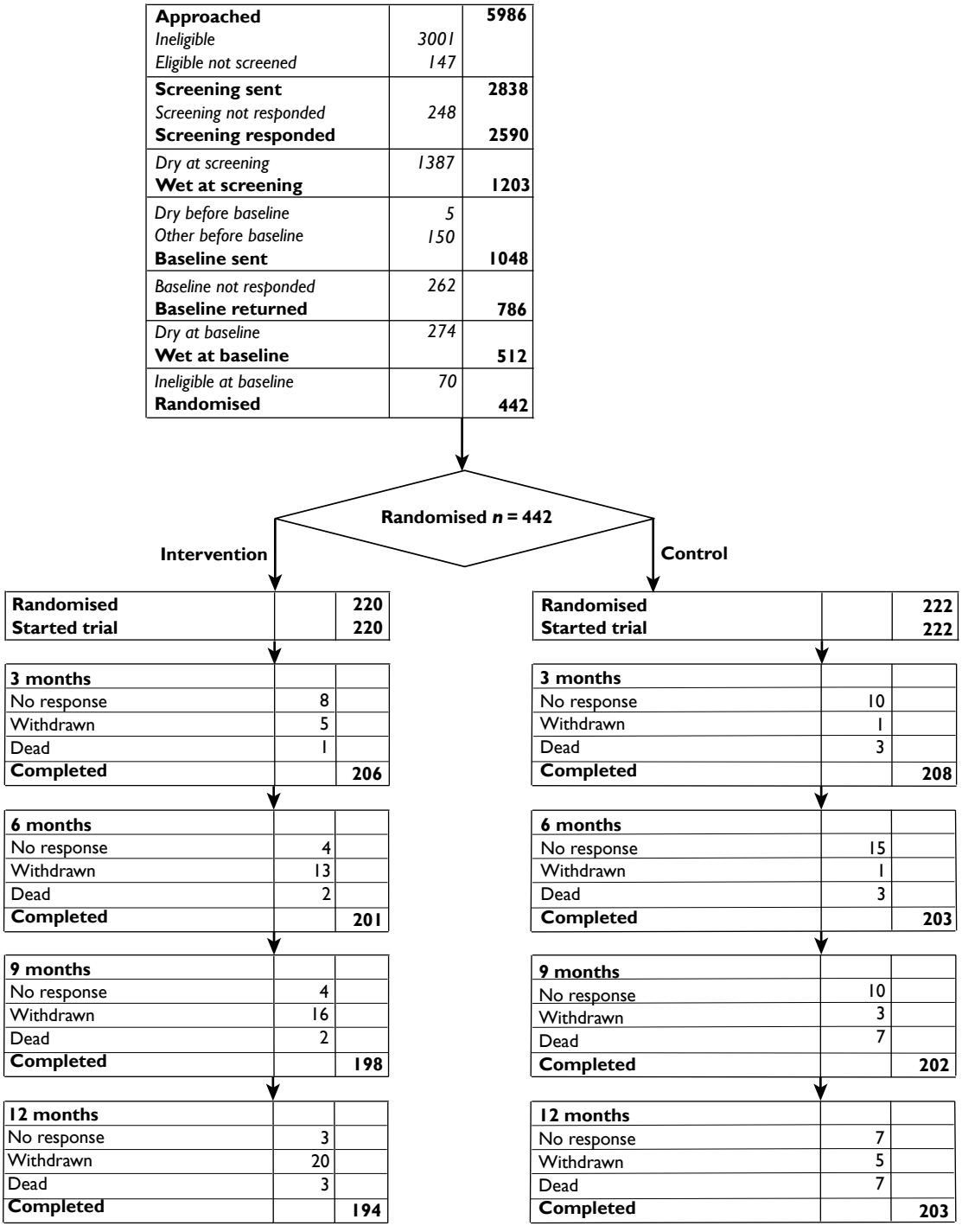

FIGURE 5 Flow chart of men from operation to recruitment to RCT: TURP.

TABLE 11 Reasons why men did not progress during the study, or withdrew before randomisation

	Radical prostatectomy	TURP
Number of men responding at screening but not sent a baseline questionnaire		
Dry at screening	51	1387
Dry before baseline	1	5
Declined further contact	26	122
Referred for PFMT	2	1
Referred for radiotherapy	1	–
Moving away/unable to attend therapy	1	1
Permanently catheterised	–	1
No reason given	2	25
Number of men responding at baseline but not randomised		
Dry before randomisation	61	274
Declined participation in RCT	15	16
Unable/unwilling to travel to therapy appointments	11	32
Dry after baseline	8	18
Attending PFMT training	2	–
Having radiotherapy	5	–
Medical problems	1	4
In another study	1	–
Postrandomisation exclusions		
Therapy not available during some of the period of screening in one centre	18	–

Recruitment rates

The original projections were based on assumptions from the literature that around 50% of men would be wet after a radical prostatectomy, and that 65% of these would be willing to enter an RCT of conservative treatment (see *Table 2*). For the men having TURP, we expected around 5% of men to be wet, and that a similar proportion (65%) would agree to randomisation. The sample size calculation had indicated that we would need to recruit 400 men per trial in order to achieve our prespecified difference, and that 26 centres would be sufficient to achieve this.

In the event, the numbers of men having operations at each centre varied widely (see *Table 8*) but the proportions of men responding, incontinent and willing to enter the RCT were much higher than our assumptions, especially in the TURP group. Despite this, a review of actual accrual rates led us to anticipate a shortfall in recruitment. We therefore prepared revised projections, based on more realistic assumptions and recruitment of extra centres, and were granted a 9-month extension in order to achieve our initial target sample size.

By the end of recruitment, 7144 men had been approached regarding the screening survey in 34 sites, and 853 men from these sites had been randomised. *Figure 6* shows a graphical representation of recruitment against revised targets as agreed for the extension period. The jump in the projected recruitment line after December 2006 reflects the change after implementing the extension. The last men were approached in July 2008 and recruitment to the RCT ended on 23 September 2008.

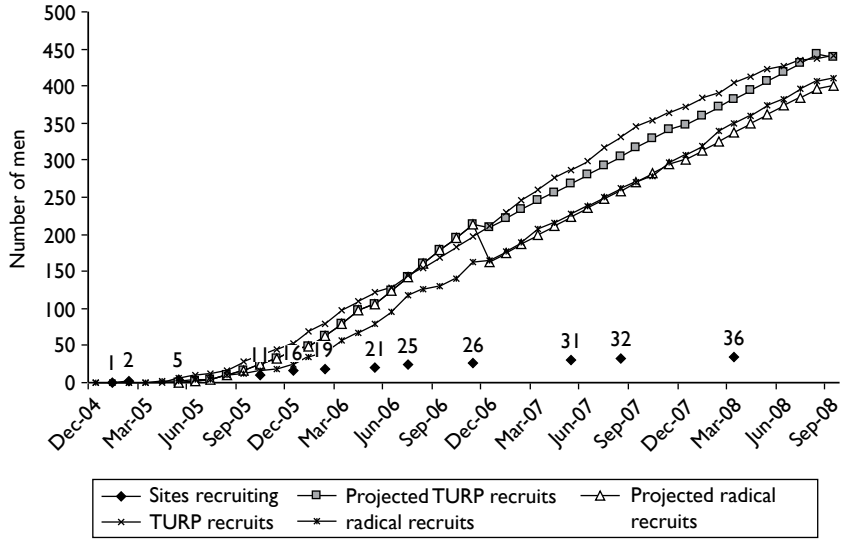

FIGURE 6 Recruitment to MAPS against revised targets agreed for the extension period.

Chapter 5

Radical randomised controlled trial: derivation and description of participants

This chapter describes the men derived from the screening survey in terms of their clinical characteristics and presents the baseline comparability between the randomised groups in the group having radical prostatectomy.

Comparison between those responding and not responding to screening survey

Table 12 shows the comparability at baseline of those responding and not responding to the screening survey in terms of their demographic and clinical characteristics. There were no clinically important differences between the responders and non-responders. The majority of men (around 80%) had a traditional abdominal retropubic prostatectomy, 2% had a perineal approach and just under 20% had a laparoscopic procedure. One or both nerve bundles were spared in just over 60% of operations amongst the responders.

Findings from screening survey

The average time of completion of the screening survey was at around 5 weeks after surgery (mean days since operation 38.1, SD 14.9).

TABLE 12 Screening survey responders and non-responders

Radical prostatectomy	Responder	Non-responder
Number screened [*n*/*N* (%)]	742/780 (95)	38/780 (5)
Age [mean years (SD) *n*]	62.5 (5.9) 740	61.1 (7.4) 38
Weight [mean kg (SD) *n*]	82.8 (12.2) 704	84.2 (12.7) 35
Height (mean cm (SD) *n*]	173.9 (13.1) 664	173.9 (8.4) 34
Current smoker (yes) [*n*/*N* (%)]	81/742 (11)	7/38 (18)
Nights in hospital [mean (SD) *n*]	6.2 (2.9) 687	5.7 (3.2) 33
Type of operation	*N* = *740*	*N* = *38*
Abdominal retropubic prostatectomy [*n*/*N* (%)]	585/740 (79)	31/38 (82)
Perineal radical prostatectomy [*n*/*N* (%)]	15/740 (2)	0
Laparoscopic radical prostatectomy [*n*/*N* (%)]	140/740 (19)	7/38 (18)
Nerve bundle sparing	*N* = *708*	*N* = *36*
One nerve bundle spared [*n*/*N* (%)]	133/708 (19)	10/36 (28)
Both nerve bundles spared [*n*/*N* (%)]	302/708 (43)	9/36 (25)
Neither nerve bundles spared [*n*/*N* (%)]	90/708 (13)	2/36 (6)
Unknown nerve bundle sparing [*n*/*N* (%)]	183/708 (26)	15/36 (42)

Numbers as reported.

Radical prostatectomy can be performed using three main routes: open abdominal, perineal, and laparoscopically. The last two are thought to be associated with less postoperative urinary incontinence and sexual dysfunction.[1,66] In addition, urinary incontinence is thought to be reduced in operations in which it is possible to spare one or both nerve bundles.[11,67,68] The majority of men had a traditional open abdominal prostatectomy, with only a few having a perineal approach ($n = 15$). *Table 13* shows that, at screening, there was little difference in the chance of immediate incontinence according to the route of operation. Nor did the chance of incontinence differ according to the surgeon's ability to spare one or both nerve bundles (*Table 13*). Long-term follow-up will be needed to confirm whether these findings persist. The most common type of incontinence was SUI (76%).

Summary information for progress from screening questionnaire to randomisation

Of 691 men wet at screening, 33 were not eligible to be sent a baseline questionnaire (see *Table 11* for reasons). Of the 658 men sent a baseline questionnaire, 533 (81%) responded, of whom 472 (89%) were still wet and 61 dry. A further 43 were excluded as they were ineligible for randomisation despite still being incontinent (see *Table 11* for reasons). Finally, 429 men were randomised but 18 were excluded after randomisation as there was no therapy available during

TABLE 13 Results of screening survey 3 weeks after operation (responders only, $n = 742$)

Radical prostatectomy	All responders to screening questionnaire ($n = 742$)[a]	Abdominal route ($n = 585$)	Perineal route ($n = 15$)	Laparoscopic route ($n = 140$)
Days since operation [mean (SD) *n*]	38.1 (14.9) 732	33.0 (14.6) 578	30.0 (7.9) 15	34.5 (14.5) 139
Number of men with any urine loss at screening questionnaire [*n*/*N* (%)]	691/742 (93)	543/585 (93)	15/15 (100)	131/140 (94)
Nerve bundle sparing: number of men with any urine loss [*n*/*N* (%)]	658/708 (93)	514/555 (93)	15/15 (100)	128/137 (93)
One nerve bundle spared [*n*/*N* (%)]	126/133 (95)	98/103 (95)	5/5 (100)	23/25 (92)
Both nerve bundles spared [*n*/*N* (%)]	280/302 (93)	212/230 (92)	4/4 (100)	64/68 (94)
Neither spared [*n*/*N* (%)]	87/90 (97)	71/74 (96)	1/1 (100)	15/14 (100)
Unknown sparing [*n*/*N* (%)]	165/183 (90)	133/148 (90)	5/5 (100)	26/29 (90)
ICI-QoL score owing to UI[b] [mean (SD) *n*]	4.6 (5.6) 726	4.4 (3.2) 572	5.1 (3.3) 15	5.5 (3.3) 139
ICI-Q score[c] [mean (SD) *n*]	10.8 (5.6) 740	10.4 (5.5) 585	11.9 (4.7) 15	12.3 (5.8) 140
Number of men with urine loss before surgery [*n*/*N* (%)]	47/740 (6)	45/585 (8)	0	2/140 (1)
Number of men with faecal incontinence after surgery [*n*/*N* (%)]	18/742 (2)	14/585 (2)	1/15 (8)	3/140 (2)
Type of incontinence				
SUI [*n*/*N* (%)]	559/740 (76)	427/585 (73)	14/15 (93)	118/140 (84)
UUI [*n*/*N* (%)]	297/740 (40)	227/585 (39)	9/15 (60)	61/140 (44)
MUI [*n*/*N* (%)]	242/740 (33)	175/585 (30)	9/15 (60)	58/140 (41)
Postmicturition leakage [*n*/*N* (%)]	253/740 (34)	185/585 (32)	7/15 (47)	61/140 (44)
Other incontinence [*n*/*N* (%)]	334/740 (45)	266/585 (45)	6/15 (40)	62/140 (44)

a Type of operation unknown for two participants.
b ICI-QoL score: 0 = none, 10 = maximum (worst) score. Derived from question 3 of the ICIQ-UI Short Form Questionnaire.
c ICI-Q score: 0 = none, 21 = maximum (worst) score. Derived from questions 1–3 of the ICIQ-UI Short Form Questionnaire.

their recruitment period, leaving 411 men properly randomised, 205 in the intervention group and 206 in the control group (see *Figure 4*).

Men who recorded that they were wet at the screening survey were sent a further baseline questionnaire to confirm persistent leakage. Those who were still wet and consented were randomised to intervention or control. The average time to randomisation from the date of surgery was 8 weeks (mean 7.9, SD 2.7).

Comparability on baseline characteristics at trial entry

Table 14 shows that the men in the two randomised groups were comparable at baseline on the clinical and demographic characteristics recorded.

Prior knowledge of pelvic floor exercises

Many men had been counselled before surgery about the possibility of urinary incontinence and sexual dysfunction after surgery.[69] *Table 15* shows that almost all of the men (97% and 99%

TABLE 14 Baseline comparability at trial entry between men in randomised groups

Radical prostatectomy	Intervention ($n=205$)	Control ($n=206$)
Age in years [mean (SD) *n*, (min–max)]	62.4 (5.8) 205, (47–76)	62.3 (5.6) 206, (47–75)
BMI (kg/m^2) [mean (SD) *n*, (min–max)]	25.9 (2.9) 197, (19.4–39.5)	26.3 (3.3) 202, (18.0–36.2)
Type of operation [*n*/*N* (%)][a]	204	205
Abdominal	157/204 (77)	161/205 (79)
Perineal	6/204 (3)	4/205 (2)
Laparoscopic	41/204 (20)	40/205 (20)
TURP before surgery [*n*/*N* (%)]	12/205 (6)	4/201 (2)
Number of men not able to achieve erection before prostate surgery [*n*/*N* (%)]	17/205 (8)	18/202 (9)
Leakage of urine before operation [*n*/*N* (%)]	14/205 (7)	13/206 (6)
ICI-Q score at baseline [mean (SD) *n*][b]	11.2 (4.3) 205	11.5 (4.5) 206
Number of men with severe incontinence at baseline [*n*/*N* (%)][c]	188/205 (92)	189/206 (92)
Urinary frequency at baseline (per day) [mean (SD) *n*]	7.4 (2.9) 187	7.9 (3.7) 192
Nocturia at baseline (per night) [mean (SD) *n*]	2.2 (1.2) 199	2.5 (1.6) 202
Type of incontinence [*n*/*N* (%)]	205	206
SUI	195/205 (95)	195/206 (95)
UUI	135/205 (66)	156/206 (76)
MUI (both)	132/205 (64)	151/206 (73)
Postmicturition leakage	166/205 (81)	170/206 (83)
Other incontinence	72/205 (35)	91/206 (44)
Pad use	180/205 (88)	176/205 (86)
Other health problems	89/204 (44)	94/204 (46)
EQ-5D [mean (SD) *n*]	0.8 (0.2) 200	0.8 (0.2) 206
SF-12 mental [mean (SD) *n*]	50.8 (10.5), 201	49.3 (10.7), 201
SF-12 physical [mean (SD) *n*]	42.7 (9.9), 201	41.8 (10.6), 201

Numbers as reported.
a Information missing in two cases.
b ICI-Q score: 0=none, 21 = maximum (worst) score. Derived from questions 1–3 of the ICIQ-UI Short Form Questionnaire.
c Severe incontinence defined as at least once a day and a moderate or large amount of leakage.

TABLE 15 Number of men with prior knowledge of pelvic floor exercises

Source of information	Intervention	Control
From a doctor	79/195 (41)	72/191 (38)
From a nurse/continence advisor	147/195 (75)	136/191 (71)
From a physiotherapist	21/195 (11)	23/191 (12)
From leaflets or books	127/195 (65)	129/191 (68)
From the internet	22/195 (11)	34/191 (18)
From friends or family	42/195 (22)	43/191 (23)
From another source	2/195 (1)	2/191 (1)
At least one source of information	190/195 (97)	190/191 (99)

Figures are *n*/*N* (%) answering yes. Respondents could cite more than one source of information.

in the two groups) had prior knowledge of pelvic floor exercises for these problems. The most common sources of information were from nurses or continence advisors or from leaflets or books (*Table 15*).

Chapter 6

Radical randomised controlled trial: management received

This chapter describes how the intervention was implemented in the therapy arm of the radical RCT, and the progress of men through the intervention period ($n = 205$). The information in this chapter is derived from the therapy documentation (see *Appendix 4.1*), which was used primarily to guide the therapists while delivering the standardised intervention.

Compliance with therapy

Of the 205 men who were randomised to the intervention, 189 attended at least one visit (92%), and 85% attended every time (*Table 16*). The non-attenders were younger and lighter, but these differences were not clinically important (*Table 17*). Only 5 of the 16 men who did not attend were dry. The other main reason was that, after they were allocated to therapy, five men found it to be inconvenient or impossible to attend appointments, often owing to work commitments (*Table 18*).

TABLE 16 Number of visits attended ($n = 205$)

Radical prostatectomy	First visit	Second visit	Third visit	Fourth visit
Number of men attending [*n* (%)]	189 (92)	186 (91)	177 (86)	175 (85)

TABLE 17 Number of attenders/non-attenders, comparability on age and BMI [mean (SD) *n*]

Radical prostatectomy	Attenders	Non-attenders
Age (years)	62.6 (5.7) 189	59.8 (6.6) 16
BMI (kg/m^2)	26.0 (3.0) 181	25.8 (1.5) 16

TABLE 18 Reasons for non-compliance (not attending any visits at all) ($n = 16$)

Radical prostatectomy	Non-attenders (*n*)
Dry	5
Ill	1
Unable to attend	5
Declined	0
No reason given	5
Total	16

Relationship between type of therapist and outcomes during therapy period

Half of the centres (17) used a physiotherapist to deliver the MAPS intervention, while in the other 17 the therapist had a nursing background (*Table 19*). There was no significant difference in the number of visits men made to physiotherapists or nurse therapists (*Table 19*). During the 3-month intervention period, there were no statistically significant differences in the mean ICI scores (a composite score reflecting urinary incontinence and its effect on quality of life) between therapists (*Table 19*).

Urinary incontinence during therapy period

Incidence of urinary incontinence

The therapists asked the men at each visit to rate their incontinence (in the previous week). This allowed the therapists to monitor the change in reported incontinence. They used the same form of question as the questionnaires, based on the ICI-SF instrument, which were also used to measure the primary outcome. The proportion of men with incontinence fell from 92% to 73%, while the mean ICI score decreased (improved) from around 8 at the start of treatment to around 4 afterwards (*Table 20* and *Figure 7*).

Type of urinary incontinence during therapy period

The distribution of type of incontinence reported by the men did not vary with time across the therapy visits (*Table 21* and *Figure 8*) except that the proportion with stress incontinence alone decreased slightly (from 84% to 72%), and postmicturition leakage also decreased (from 63% to 25%).

TABLE 19 Relationship between type of therapist and attendance rates (mean number of attendances) and effect on ICI composite incontinence score at each visit

Radical prostatectomy	Physiotherapist	Continence nurse	Mean difference (95% CI), *p*-value
Number of attendances	3.7 (1.0) 79, (3.5 to 3.9)	3.4 (1.3) 126, (3.2 to 3.7)	0.26 (–0.06 to 0.59), 0.113
ICI-Q score			
Visit 1	8.3 (4.7) 75, (7.2 to 9.4)	7.6 (4.0) 114, (6.8 to 8.3)	0.71 (–0.55 to 1.98), 0.267
Visit 2	7.1 (4.1) 75, (6.2 to 8.1)	6.6 (4.0) 111, (5.9 to 7.4)	0.54 (–0.65 to 1.74), 0.372
Visit 3	5.7 (4.1) 72, (4.8 to 6.7)	5.5 (3.8) 105, (4.7 to 6.2)	0.26 (–0.94 to 1.45), 0.674
Visit 4	4.6 (3.8) 71, (3.7 to 5.5)	4.1 (3.6) 104, (3.4 to 4.8)	0.49 (–0.64 to 1.61), 0.396

Figures are mean (SD) *n*, (95% CI), unless shown otherwise.
ICI-Q score: 0 = none, 21 = maximum (worst) score. Derived from questions 1–3 of the ICIQ-UI Short Form Questionnaire.

TABLE 20 Number of men incontinent at each time point and mean ICI-Q score at each therapy visit

Radical prostatectomy	Visit 1	Visit 2	Visit 3	Visit 4
Men incontinent [*n*/*N* (%)]	172/187 (92)	165/182 (91)	143/171 (84)	123/169 (73)
ICI-Q score[a] [mean (SD) *n*]	7.9 (4.3) 189	6.8 (4.1) 186	5.6 (3.9) 177	4.3 (3.7) 175

a ICI-Q score: 0 = none, 21 = maximum (worst) score. Derived from questions 1–3 of the ICIQ-UI Short Form Questionnaire.

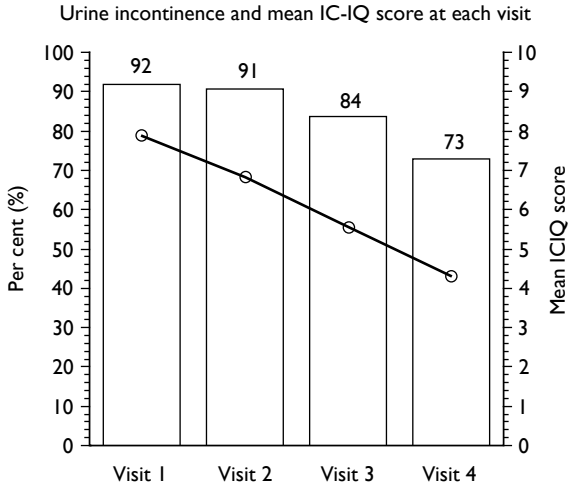

FIGURE 7 Trend analysis of the proportion (%) of men incontinent at each visit: men having had radical prostatectomy. ICI-Q score: 0 = none, 21 = maximum (worst) score. Derived from questions 1–3 of the ICIQ-UI Short Form Questionnaire.

TABLE 21 Type of incontinence at each therapy visit and change over time

Radical prostatectomy	Visit 1	Visit 2	Visit 3	Visit 4
Number of men	189	186	177	175
SUI	152/181 (84)	145/175 (83)	118/162 (73)	110/152 (72)
UUI	35/173 (20)	31/159 (19)	33/154 (21)	22/145 (15)
MUI (both SUI and UUI)	28/182(15)	26/174(15)	24/162(15)	17/155(11)
Postmicturition leakage	113/179 (63)	68/163 (42)	49/157 (31)	36/145 (25)
Other UI	47/162 (29)	35/148 (24)	34/146 (23)	27/135 (20)

Figures are *n*/*N* (%).

Incidence and type of bowel problems during therapy period

Therapists also enquired at each visit about whether the men experienced any bowel dysfunction in the previous week. The proportions of men with three different types of bowel dysfunction (faecal incontinence, faecal urgency and constipation) were low, and did not vary during the therapy period (*Table 22* and *Figure 9*).

Incidence and type of sexual problems during therapy period

The questions relating to sexual problems were those used in routine clinical practice. They were not based on the questions men were asked at 12 months to assess their sexual function and activity [70] (see section G, 12-month questionnaire, *Appendix 3.3*).

The proportion of men with sexual dysfunction ('difficulty gaining or maintaining an erection in the last week') after radical surgery was high (85–90%) and this did not change during the therapy period. The corresponding proportion with premature ejaculation was very low and also did not vary with time (*Table 23* and *Figure 10*).

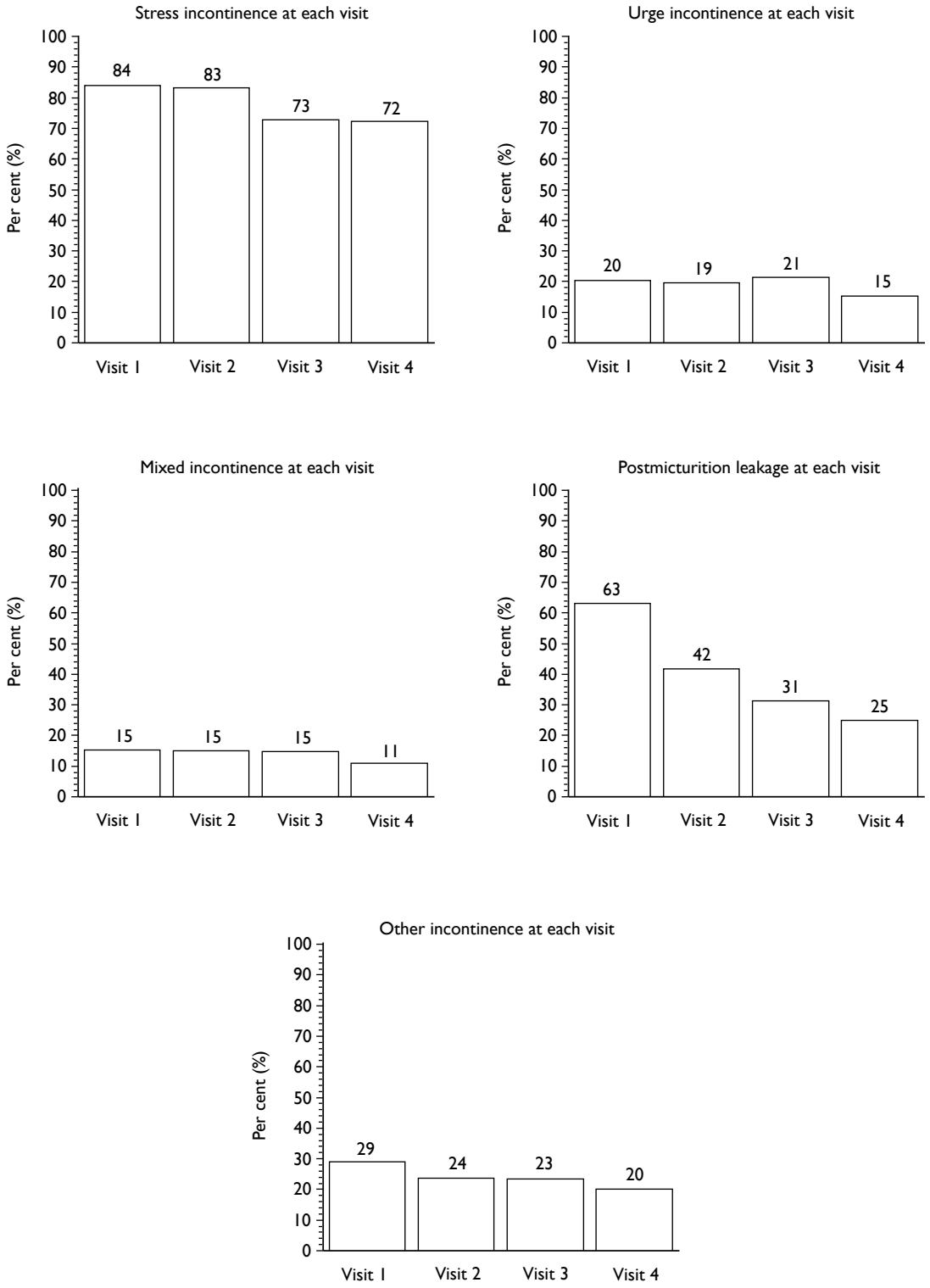

FIGURE 8 Type of incontinence at each visit and change over time: men having had radical prostatectomy.

TABLE 22 Type of bowel problems at each therapy visit and change over time

Radical prostatectomy	Visit 1	Visit 2	Visit 3	Visit 4
Faecal incontinence	4/187 (2)	3/183 (2)	2/172 (1)	2/171 (1)
Faecal urgency	13/187 (7)	11/183 (6)	13/172 (8)	6/171 (4)
Constipation	23/187 (12)	10/181 (5)	11/171 (6)	13/169 (8)

Figures are *n*/*N* (%).

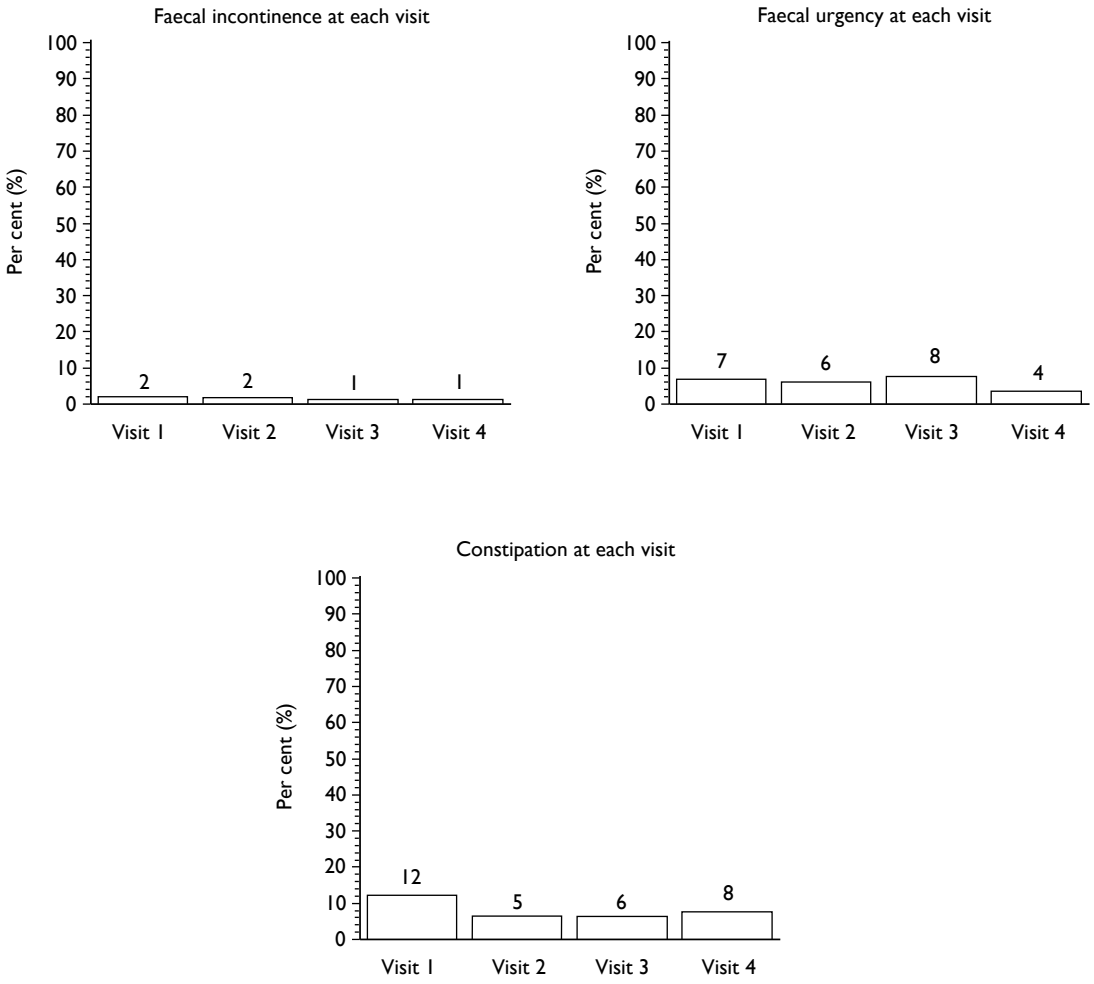

FIGURE 9 Type of bowel problems at each visit and change over time: men having had radical prostatectomy.

Examination of pelvic floor muscle performance during therapy visits

Therapists assessed the strength of the pelvic floor muscle contractions and their endurance (length of time men were able to hold a contraction) at each visit using digital anal assessment (see *Chapter 3*). The external anal sphincter and the internal puborectalis muscle were assessed separately. The internal puborectalis muscle strength was taken to be a measure of pelvic floor muscle strength.

TABLE 23 Type of sexual problems at each therapy visit and change over time

Radical prostatectomy	Visit 1	Visit 2	Visit 3	Visit 4
Difficulty gaining erection	156/176 (89)	153/170 (90)	142/159 (89)	144/161 (89)
Difficulty maintaining erection	148/169 (88)	144/165 (87)	128/148 (86)	145/157 (92)
Premature ejaculation	4/154 (3)	4/150 (3)	4/139 (3)	2/143 (1)

Figures are *n*/*N* (%).

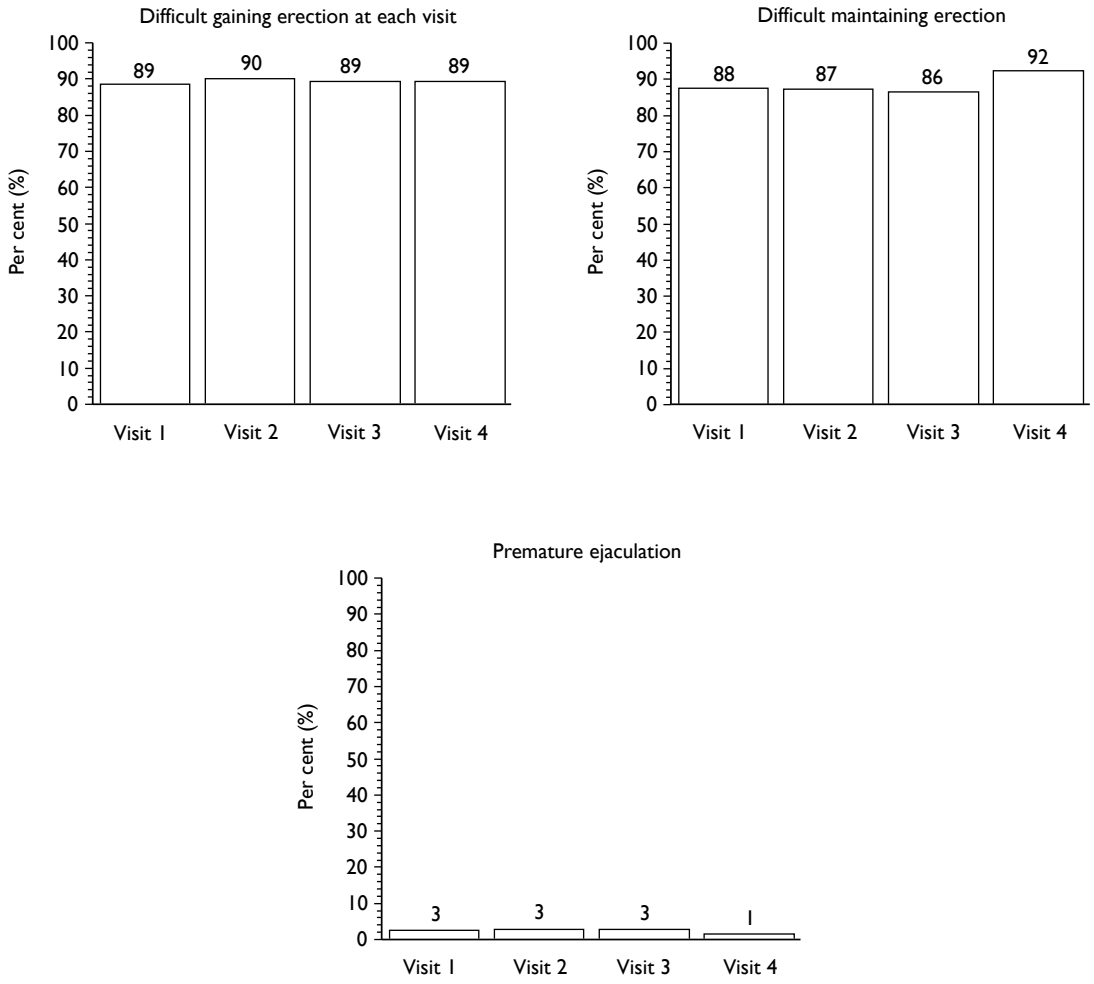

FIGURE 10 Type of sexual problems at each visit and change over time: men having had radical prostatectomy.

For both the sphincter and the puborectalis, both strength and endurance improved during the therapy period (*Table 24* and *Figure 11*). At baseline, only 15% of men had a strength of 5 or more, whereas by the fourth visit around 50% of men were able to contract strongly (5) or very strongly (6), and 85% had good muscle strength (4 or better). The therapists were trained to ask men to hold the pelvic floor muscle contraction for up to 10 seconds during the digital anal examination. This is in line with functional use of these muscles. However, some therapists assessed the maximum length of time for which men could hold a contraction. Of these men, some held the contraction for over 1 minute.

TABLE 24 Ability to contract anal sphincter and puborectalis muscle (pelvic floor) over time

Radical prostatectomy	Visit 1	Visit 2	Visit 3	Visit 4
A: External anal sphincter strength [mean (SD) *n*][a]	3.3 (1.0) 170	3.6 (0.9) 153	4.0 (1.0) 127	4.3 (1.0) 129
0	1/170 (0.5)	0	0	0
1	1/170 (0.5)	2/153 (1)	1/127 (1)	1/129 (1)
2	29/170 (17)	11/153 (7)	9/127 (7)	4/129 (3)
3	71/170 (42)	54/153 (35)	20/127 (16)	17/129 (13)
4	48/170 (28)	62/153 (41)	57/127 (45)	45/129 (35)
5	19/170 (11)	23/153 (15)	38/127 (30)	51/129 (39)
6	1/170 (0.5)	1/153 (1)	2/127 (1)	11/129 (8)
A: External anal sphincter endurance (seconds) [mean (SD) *n*][b]	6.1 (2.7) 170	7.6 (2.8) 153	9.3 (6.0) 127	10.6 (8.4) 129
B: Puborectalis muscle strength [mean (SD) *n*][a]	3.4 (1.0) 169	3.7 (0.9) 153	4.1 (1.0) 126	4.4 (1.0) 128
0	0	0	0	0
1	4/169 (2)	3/153 (2)	2/126 (2)	1/128 (1)
2	24/169 (14)	8/153 (5)	5/126 (4)	3/128 (2)
3	68/169 (40)	43/153 (28)	23/126 (18)	19/128 (15)
4	51/169 (30)	71/153 (46)	48/126 (38)	39/128 (30)
5	22/169 (13)	28/153 (18)	44/126 (35)	52/128 (41)
6	0	0	4/126 (3)	14/128 (11)
B: Puborectalis muscle endurance (seconds) [mean (SD) *n*][b]	6.5 (3.0) 169	7.7 (2.7) 153	9.4 (6.1) 126	10.7 (8.5) 128

Figures are *n*/*N* (%) unless otherwise indicated.

a External anal sphincter and puborectalis muscle strength were measured on a 0–6 modified Oxford scale: 0 = no flicker; 1 = flicker; 2 = weak contraction, no movement; 3 = moderate contraction with movement; 4 = good contraction against resistance; 5 = strong contraction against strong resistance; 6 = maximal contraction, very strong, unable to remove finger.

b Endurance was measured as the duration in seconds for which the man could maintain an anal squeeze contraction.

Examination and functional use of pelvic floor muscles

Therapists examined men at each visit to assess skin damage, skin infection, ability to tighten the anus, perform penile retraction and testicular lift, evidence of leakage on coughing and (for those who did leak) ability to prevent leakage on coughing. Very few men showed evidence of skin damage or infection (data not shown).

Four different aspects of functional use of pelvic floor muscles were assessed (ability to tighten anus; ability to perform penile retraction; leakage on coughing; ability to prevent leakage on coughing). While most men (around 95%) were able to contract well enough to tighten the anal sphincter at least a little from baseline onwards, the proportion able to demonstrate a testicular lift increased slightly with time (from 80% to 90%; *Figure 12*). The proportion who leaked when coughing decreased from about 18% to 9% during the therapy period. Around 80% of these men were able to contract their pelvic floor muscles sufficiently to prevent leakage when coughing at the first visit, and this improved only slightly to around 85% by the fourth visit.

Use of machine-led biofeedback

Biofeedback was available in 13 of 34 MAPS centres, and was used clinically for MAPS men in five of them (see *Table 7*). Therapists would have liked access to this facility in four other centres where biofeedback was not available. Biofeedback can be used in two ways:

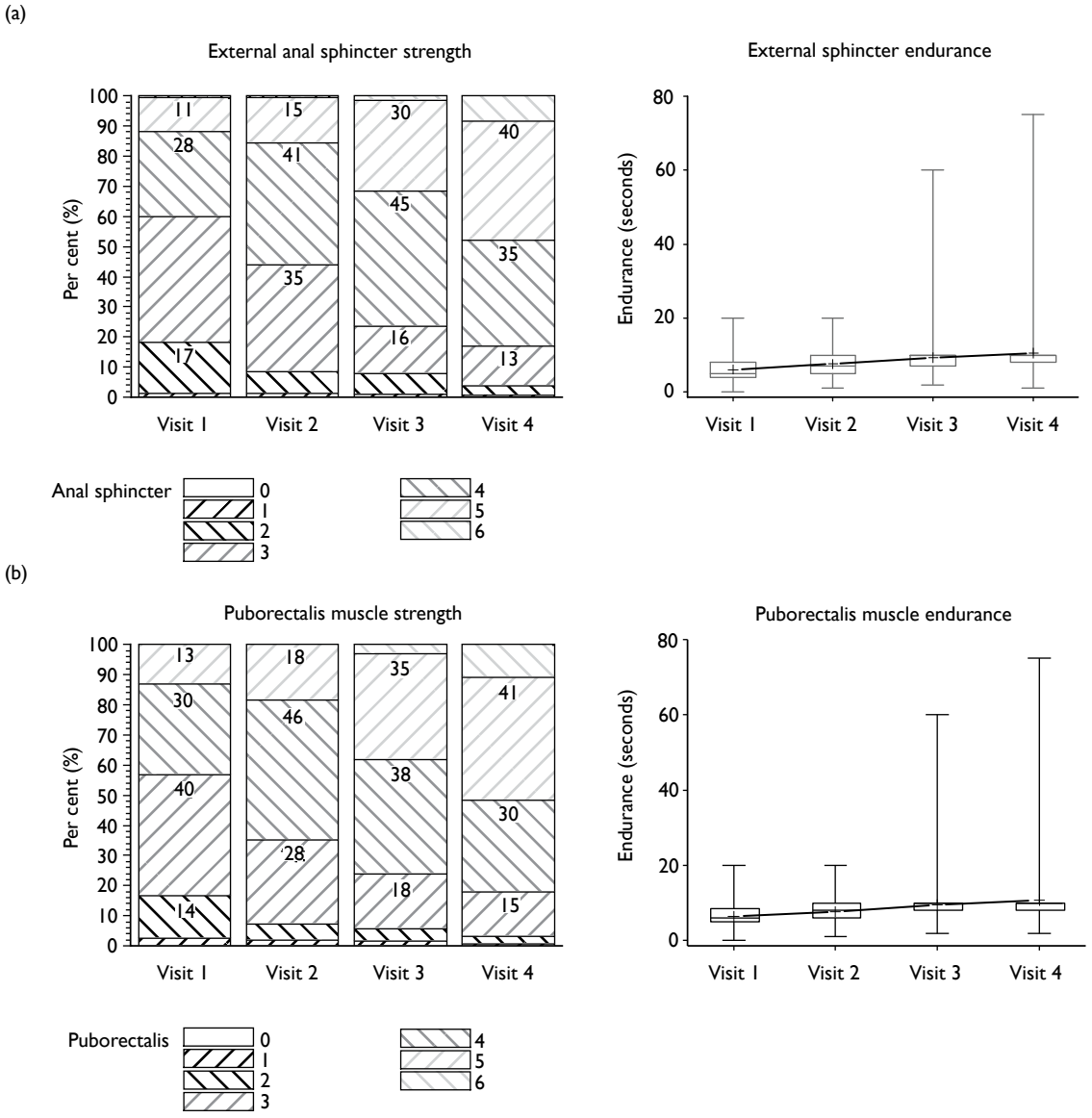

FIGURE 11 Ability to contract anal sphincter and puborectalis muscle (pelvic floor) over time: men having had radical prostatectomy. (a) External anal sphincter strength/endurance. (b) Puborectalis muscle strength/endurance. 0 = No flicker; 1 = flicker; 2 = weak; 3= moderate movement; 4 = good resistance; 5 = strong resistance; 6 = very strong, unable to withdraw finger. Endurance of contraction in seconds: median, minimum, maximum and mean duration.

- to feed back information to men that they are actually performing a correct pelvic floor contraction, and at what strength
- as part of a repetitive training regimen when men are asked to use the machine to enable them to monitor their exercise function for a period of time (such as 20 minutes).

It was unclear which type of biofeedback was practised in the centres where this was available, but therapists from five centres recorded its use in 16 men (see *Table 7*) from the radical prostatectomy group (the number at each time point is shown in *Table 25*). In some cases men may have preferred anal examination using a machine rather than digital examination by the therapist for teaching of correct contractions. As it was most often used on the first visit, this suggests that suggests that biofeedback was used in a diagnostic rather than in a training capacity.

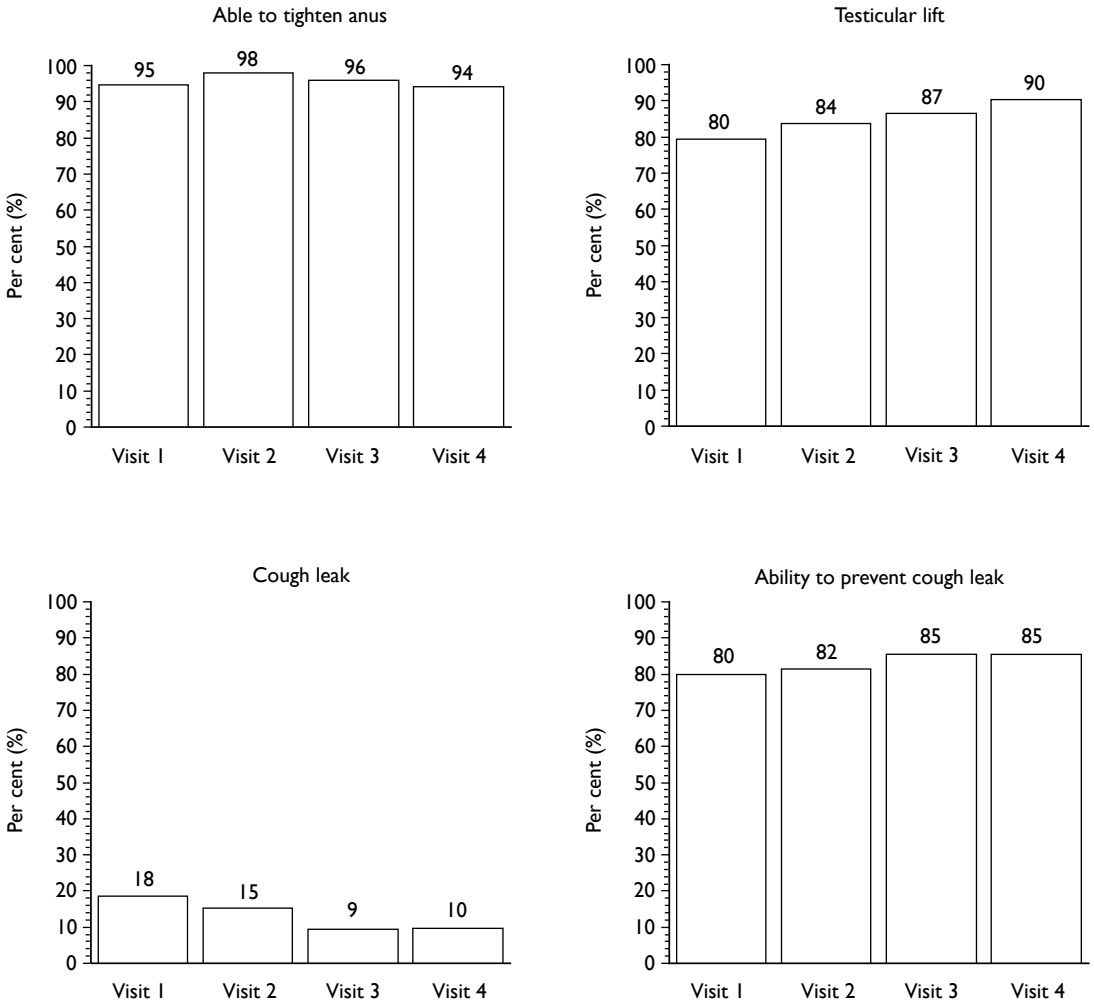

FIGURE 12 Aspects of ability to use pelvic floor muscles at each visit and change over time: men having had radical prostatectomy.

TABLE 25 Use of biofeedback for any men

Radical prostatectomy	Biofeedback indicated	Biofeedback actually implemented
Visit 1	12/123 (10)	8/124 (6)
Visit 2	5/110 (4)	5/110 (4)
Visit 3	5/94 (5)	5/94 (5)
Visit 4	4/106 (4)	4/106 (4)

Figures are *n*/*N* (%).

Chapter 7

Radical randomised controlled trial: outcomes and results

This chapter describes the results of the intervention amongst the men recruited to the radical prostatectomy RCT.

Patient flow

The derivation of the trial study groups and their progress through the trial is summarised in *Figure 13*. This is in the form of a CONSORT (Consolidated Standards of Reporting Trials) flow diagram. In total, 411 participants were recruited to the randomised trial: 205 randomly allocated to the intervention group and 206 to the control group. Nine men had withdrawn from follow-up by 12 months (although some information was available before their withdrawal in some cases). One of these nine, in the intervention group, subsequently died. His death was not attributed to the trial intervention. Sixteen participants (8%) in the intervention group did not attend any therapy sessions and were considered non-compliers with the intervention (see *Chapter 6*).

Response rates

Over 90% of all participants returned completed questionnaires. As shown in *Figure 13*, by the time of each follow-up some participants had formally withdrawn (five from the intervention group and four from the control group; *Table 26*), and so were not sent questionnaires. Of the participants for whom it was appropriate to send a follow-up questionnaire, over 95% returned it at each time point (*Table 27a*).

For return of urinary diaries, the response rate was slightly lower, but still approximately 90% at each time point (*Table 27b*).

TABLE 26 Reasons for withdrawal

	Radical prostatectomy RCT	
Reason	Intervention	Control
Ill	1	1
Dry	1	1
Catheterised permanently	0	0
No reason	2	0
Other	1	2
Total	5	4

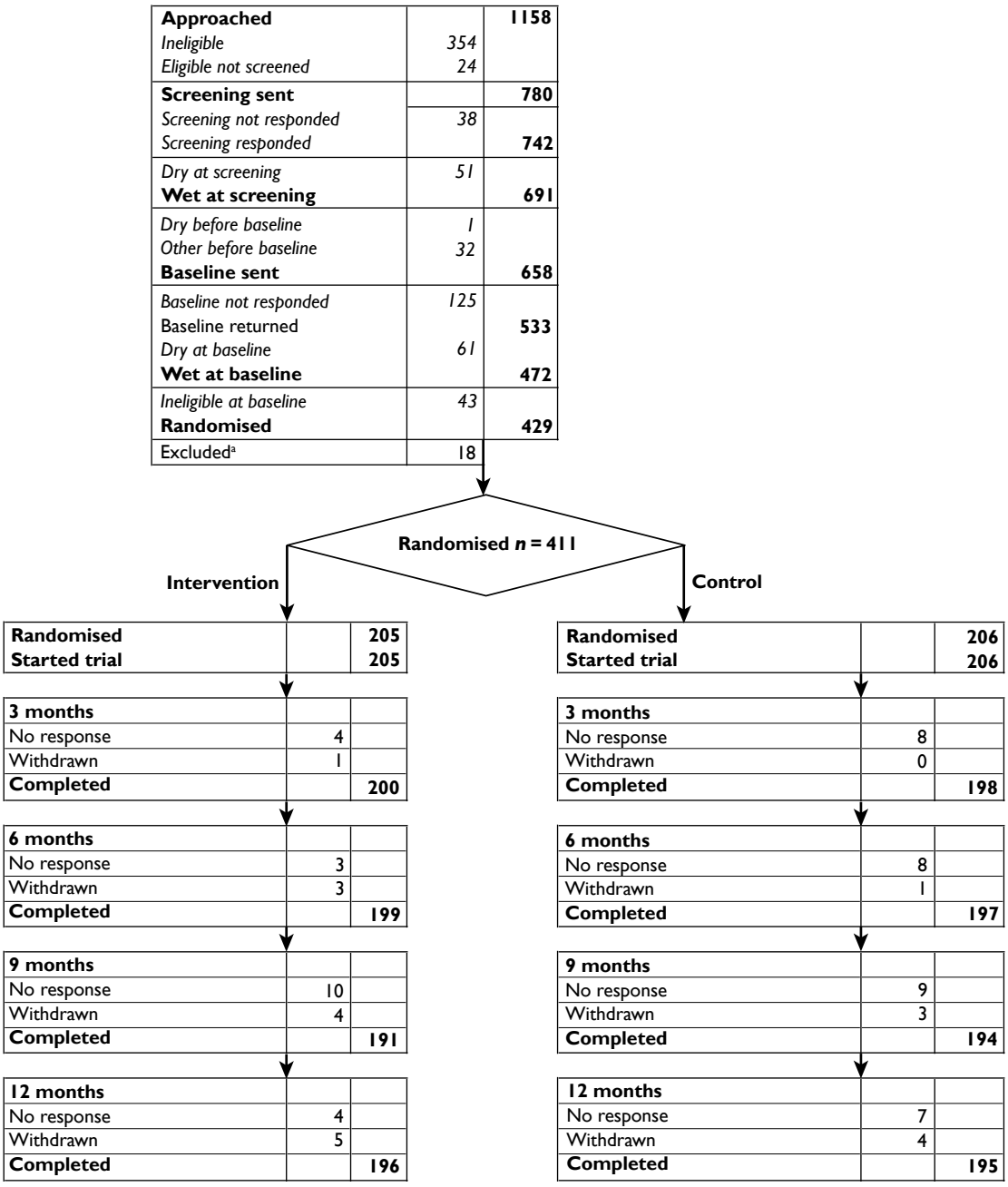

FIGURE 13 Radical CONSORT diagram (men randomised *n* = 411). a, Postrandomisation exclusion: therapy was not available during some of the period of screening in one centre (18 men).

Primary outcome: urinary incontinence at 12 months

The primary outcome was incontinence in men at 12 months after randomisation, measured by a positive response to one of two questions from the ICI-SF questionnaire ('How often do you leak urine' or 'How much urine do you usually leak?'). *Table 28* shows that the difference between the intervention and control groups in urinary incontinence at 12 months (75.5% vs 77.4%) was not statistically significant:

TABLE 27a Patient questionnaire response rates ($n = 205$ in intervention group, 206 in control group)

Radical prostatectomy	Number sent	Number returned (%)	Percentage of all men
Baseline			
Intervention	205	205 (100)	100
Control	206	206 (100)	100
3 months			
Intervention	204	200 (98)	98
Control	206	198 (96)	96
6 months			
Intervention	202	199 (99)	97
Control	205	197 (96)	95
9 months			
Intervention	201	191 (95)	93
Control	203	194 (95)	94
12 months			
Intervention	200	196 (98)	95
Control	202	195 (97)	95

The first returned column is the percentage out of all questionnaires sent (to men continuing in the study); the second is the percentage out of the total number of men randomised to each trial group.

TABLE 27b Urinary diary response rates ($n = 205$ in intervention group, 206 in control group)

Radical prostatectomy	Number sent	Number returned (%)	Percentage of all men
Baseline			
Intervention	205	194 (95)	95
Control	206	199 (97)	97
3 months			
Intervention	204	188 (92)	92
Control	206	187 (91)	91
6 months			
Intervention	202	185 (92)	90
Control	205	182 (89)	88
9 months			
Intervention	201	178 (89)	87
Control	203	181 (89)	88
12 months			
Intervention	200	183 (92)	89
Control	202	181 (90)	88

The first returned column is percentage out of all diaries sent (to men continuing in the study); the second is the percentage out of the total number of men randomised to each trial group.

- either when analysed by intention to treat (all men analysed in the groups to which they were randomised but results as given in the outcome questionnaires without adjustment for missing values)
- or when analysed by 'treatment received', which adjusts the result by a factor related to the men who actually attended a therapist versus those who did not.

TABLE 28 Urinary incontinence at 12 months

Radical prostatectomy	Intervention	Control	RR (95% CI), *p*-value
Urinary incontinence at 12 months [*n*/*N* (%)]	148/196 (75.5)	151/195 (77.4)	Absolute risk difference (95% CI) –1.9% (–10% to 6%)
Intention to treat			
Unadjusted analysis			0.980 (0.879 to 1.094), 0.719
Analysis adjusted for minimisation factors			0.97 (0.87 to 1.09), 0.637
Adjusted treatment received			
Unadjusted analysis			0.979 (0.877 to 1.093), 0.702
Analysis adjusted for minimisation factors			0.977 (0.876 to 1.090), 0.676

The above analyses were then repeated adjusting for the minimisation factors, but this did not alter the findings (*Table 28*). The corresponding risk difference for the unadjusted intention-to-treat analysis was –1.9% (95% CI –10% to 6%), thereby ruling out the likelihood that the trial prespecified difference of 15% in proportion incontinent between intervention and control group could have been missed.

Secondary outcomes

Urinary outcomes

Urinary incontinence was also measured at 3, 6 and 9 months after randomisation together with other urinary outcomes. *Table 29a* describes the various urinary outcomes at each follow-up and *Table 29b* shows the formal statistical testing of the differences at each time point. *Figure 14* is a pictorial representation of the percentage of men incontinent at each follow-up and *Figure 15* shows the change in mean ICI-score over time. The data show that there were no statistically significant differences between the intervention and control groups at any of the time points in terms of urinary incontinence and the other urinary outcomes measured.

Type of incontinence

Table 30 and *Figure 16* show the type of incontinence at baseline, and at 6 and 12 months after randomisation. Men could report more than one type of incontinence. At all time points the majority (70%) of men had (any) stress incontinence: this did not vary much after the first 6 months, and the proportions were not significantly different between the intervention and control groups (see *Table 30* and *Figure 16a*). Around half of the men had urgency or mixed incontinence. The proportions of men with other types of urinary incontinence (urgency, *Figure 16b*; mixed, *Figure 16c*; postmicturition leakage, *Figure 16d*; and other types of incontinence) decreased over the first 6 months, but there was little further improvement, or difference between the groups.

Use of aids or protection for urinary incontinence

Table 31a shows the men's use of aids to protect them from urinary leakage: this did not differ significantly according to the randomised groups at any of the follow-up time points. *Table 31b* presents the statistical analyses of these outcomes. About 40% of the men were still using pads at 12 months to protect themselves from leakage accidents, although in some cases this might have been more of a precaution than because they actually leaked.

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TABLE 29a Urinary outcomes at each 3-month interval: description

	Baseline		3 months		6 months		9 months		12 months	
Radical prostatectomy	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**
Incontinence										
Men with any incontinence [*n*/*N* (%)]	205/205 (100)	206/206 (100)	172/200 (86)	176/198 (89)	158/197 (80)	158/197 (80)	144/191 (75)	157/194 (81)	148/196 (76)	151/195 (77)
Men with severe incontinence[a] [*n*/*N* (%)]	188/205 (92)	189/206 (92)	103/200 (52)	107/198 (54)	81/197 (41)	79/197 (40)	72/191 (38)	84/194 (43)	74/196 (38)	78/195 (40)
ICI-Q score[b]	11.2 (4.3) 205	11.5 (4.5) 206	6.3 (4.2) 198	7.2 (4.9) 198	5.4 (4.2) 197	5.6 (4.6) 197	5.1 (4.2) 186	5.6 (4.6) 194	4.9 (4.1) 196	5.4 (4.5) 195
Frequency of daytime urinary incontinence from diaries	6.9 (8.0) 181	6.9 (8.2) 180	3.3 (3.8) 139	3.9 (4.5) 139	3.3 (5.2) 117	3.5 (4.0) 110	3.1 (4.7) 107	3.3 (3.7) 110	3.0 (3.8) 105	2.9 (3.0) 106
Effect of UI on QoL	4.7 (3.1) 205	5.0 (3.1) 204	2.0 (2.3) 198	2.5 (2.8) 198	1.5 (2.1) 194	1.8 (2.5) 196	1.4 (1.9) 186	1.8 (2.5) 194	1.4 (2.0) 193	1.7 (2.3) 193
Urinary frequency										
Daytime urinary frequency	7.4 (2.9) 187	7.9 (3.7) 192	7.1 (2.4) 187	7.1 (2.7) 188	7.0 (2.2) 183	7.0 (2.3) 189	6.8 (2.1) 187	7.4 (5.1) 185	6.8 (2.1) 184	7.0 (2.8) 183
Daytime urinary frequency from diaries	7.4 (2.6) 182	7.3 (2.6) 190	7.0 (2.0) 182	7.0 (2.5) 177	6.8 (2.1) 174	6.9 (2.9) 169	6.7 (1.9) 172	7.0 (2.1) 166	6.8 (2.6) 175	7.1 (4.1) 171
Nocturia	2.2 (1.2) 199	2.5 (1.6) 202	1.4 (1.1) 191	1.8 (1.2) 191	1.3 (1.0) 183	1.5 (1.0) 194	1.3 (1.4) 185	1.5 (1.3) 186	1.3 (1.0) 180	1.4 (1.0) 185
Nocturia from diaries	2.1 (1.2) 178	2.3 (2.0) 186	1.5 (0.9) 151	1.7 (1.0) 162	1.4 (0.9) 149	1.6 (1.0) 150	1.4 (0.9) 145	1.6 (1.0) 145	1.4 (0.9) 144	1.5 (0.9) 157
Frequency of nocturnal incontinence from diaries	1.4 (1.2) 90	1.6 (1.4) 90	1.1 (0.8) 35	1.6 (1.3) 45	1.1 (0.8) 24	1.1 (1.2) 37	1.1 (0.8) 25	1.2 (1.1) 36	1.4 (0.9) 26	1.6 (1.3) 27

Figures are mean (SD) *n*, unless stated otherwise. Data from men's questionnaires, unless stated otherwise.

a Severe incontinence defined as at least once a day *and* a moderate or large amount of leakage, as defined by the men in questionnaire responses.

b ICI-Q score: 0 = none, 21 = maximum (worst) score. Derived from questions 1–3 of the ICIQ-UI Short Form Questionnaire.

TABLE 29b Urinary outcomes at each 3-month interval: statistical analyses

	Effect size (95% CI), *p*-value			
Radical prostatectomy	**3 months**	**6 months**	**9 months**	**12 months**
Incontinence				
Men incontinent [RR (95% CI), *p*-value]	0.97 (0.90 to 1.04), 0.366	1.00 (0.91 to 1.10), 0.990	0.93 (0.84 to 1.03), 0.174	0.97 (0.87 to 1.09), 0.637
Men with severe incontinence [RR (95% CI), *p*-value][a]	0.95 (0.79 to 1.15), 0.595	1.02 (0.80 to 1.29), 0.875	0.86 (0.67 to 1.09), 0.208	0.93 (0.73 to 1.19), 0.582
ICI-Q score[b]	–0.66 (–1.37 to 0.05), 0.068	–0.15 (–0.86 to 0.55), 0.674	–0.49 (–1.22 to 0.24), 0.188	–0.34 (–1.05 to 0.38), 0.355
Frequency of daytime urinary incontinence from diaries	–0.47 (–1.30 to 0.37), 0.274	–0.09 (–1.03 to 0.85), 0.855	–0.17 (–1.03 to 0.68), 0.690	0.04 (–0.65 to 0.12), 0.919
Effect of UI on QoL	–0.37 (–0.79 to 0.05), 0.086	–0.22 (–0.61 to 0.17), 0.266	–0.24 (–0.63 to 0.15), 0.233	0.14 (–0.51 to 0.24), 0.476
Urinary frequency				
Daytime urinary frequency	0.01 (–0.49 to 0.52), 0.958	0.02 (–0.43 to 0.46), 0.944	–0.61 (–1.44 to 0.22), 0.149	–0.24 (–0.73 to 0.26), 0.346
Daytime urinary frequency from diaries	0.15 (–0.38 to 0.69), 0.577	–0.02 (–0.66 to 0.62), 0.939	–0.11 (–0.42 to 0.65), 0.679	–0.07 (–0.89 to 0.73), 0.861
Nocturia	–0.23 (–0.42 to –0.04), 0.020	–0.09 (–0.25 to 0.07), 0.280	–0.14 (–0.39 to 0.10), 0.248	–0.04 (–0.21 to 0.14), 0.683
Nocturia from diaries	–0.31 (–0.52 to –0.09), 0.005	–0.18 (–0.41 to 0.04), 0.113	–0.13 (–0.35 to 0.10), 0.277	–0.15 (–0.35 to 0.06), 0.167
Frequency of nocturnal incontinence from diaries	–0.18 (–0.44 to 0.07), 0.159	–0.07 (–0.30 to 0.15), 0.516	–0.07 (–0.31 to 0.18), 0.593	–0.05 (–0.27 to 0.16), 0.617

Effect size is mean difference unless indicated as RR (risk ratio) adjusted for age, urinary incontinence before surgery and baseline value.

a Severe incontinence defined as at least once a day *and* a moderate or large amount of leakage, as defined by the men in questionnaire responses.

b ICI-Q score: 0 = none, 21 = maximum (worst) score. Derived from questions 1–3 of the ICIQ-UI Short Form Questionnaire.

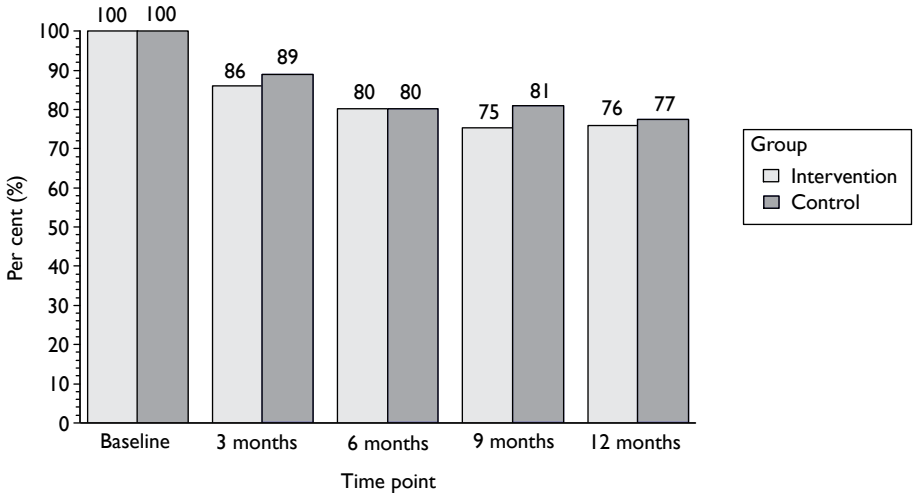

FIGURE 14 Per cent of men incontinent at each time point.

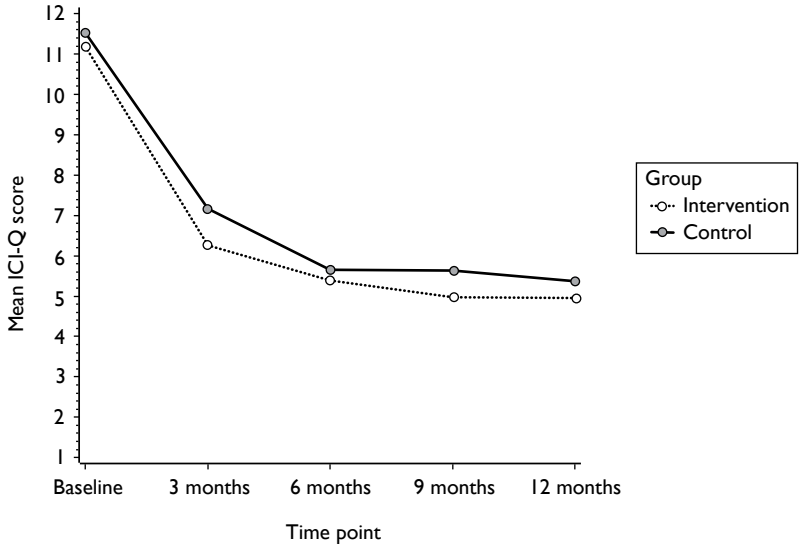

FIGURE 15 Mean ICI-Q score at each time point. ICI-Q score: 0 = none, 21 = maximum (worst) score. Derived from questions 1–3 of the ICIQ-UI Short Form Questionnaire.

TABLE 30 Type of incontinence

	Baseline		6 months			12 months		
Radical prostatectomy	Intervention	Control	Intervention	Control	RR (95% CI), *p*-value	Intervention	Control	RR (95% CI), *p*-value
SUI	195/205 (95)	195/206 (95)	136/197 (69)	135/197 (69)	1.002 (0.88 to 1.14), 0.972	138/196 (70)	128/195 (66)	1.071 (0.94 to 1.22), 0.314
UUI	135/205 (66)	156/206 (76)	58/197 (29)	87/197 (44)	0.735 (0.57 to 0.94), 0.015	61/196 (31)	83/195 (43)	0.782 (0.61 to 1.00), 0.054
Urgency	131/205 (64)	160/206 (78)	76/197 (39)	105/197 (53)	0.827 (0.68 to 1.01), 0.066	80/196 (41)	100/195 (51)	0.879 (0.72 to 1.08), 0.218
MUI (both SUI and UUI)	132/205 (64)	151/206 (73)	55/197 (28)	81/197 (41)	0.752 (0.58 to 0.98), 0.033	59/196 (30)	74/195 (38)	0.843 (0.65 to 1.10), 0.208
Postmicturition leakage	166/205 (81)	170/206 (83)	87/197 (44)	106/197 (54)	0.831 (0.69 to 1.01), 0.059	102/196 (52)	106/195 (54)	0.924 (0.73 to 1.17), 0.512
Other UI	72/205 (35)	91/206 (44)	38/197 (19)	52/197 (26)	0.777 (0.54 to 1.12), 0.181	39/196 (20)	39/195 (20)	1.099 (0.74 to 1.63), 0.640

RR adjusted for age, urinary incontinence before surgery and baseline value.
Figures are *n*/*N* (%), unless stated otherwise.
Note: men could have more than one type of incontinence; hence the numbers are higher than the total number of men.

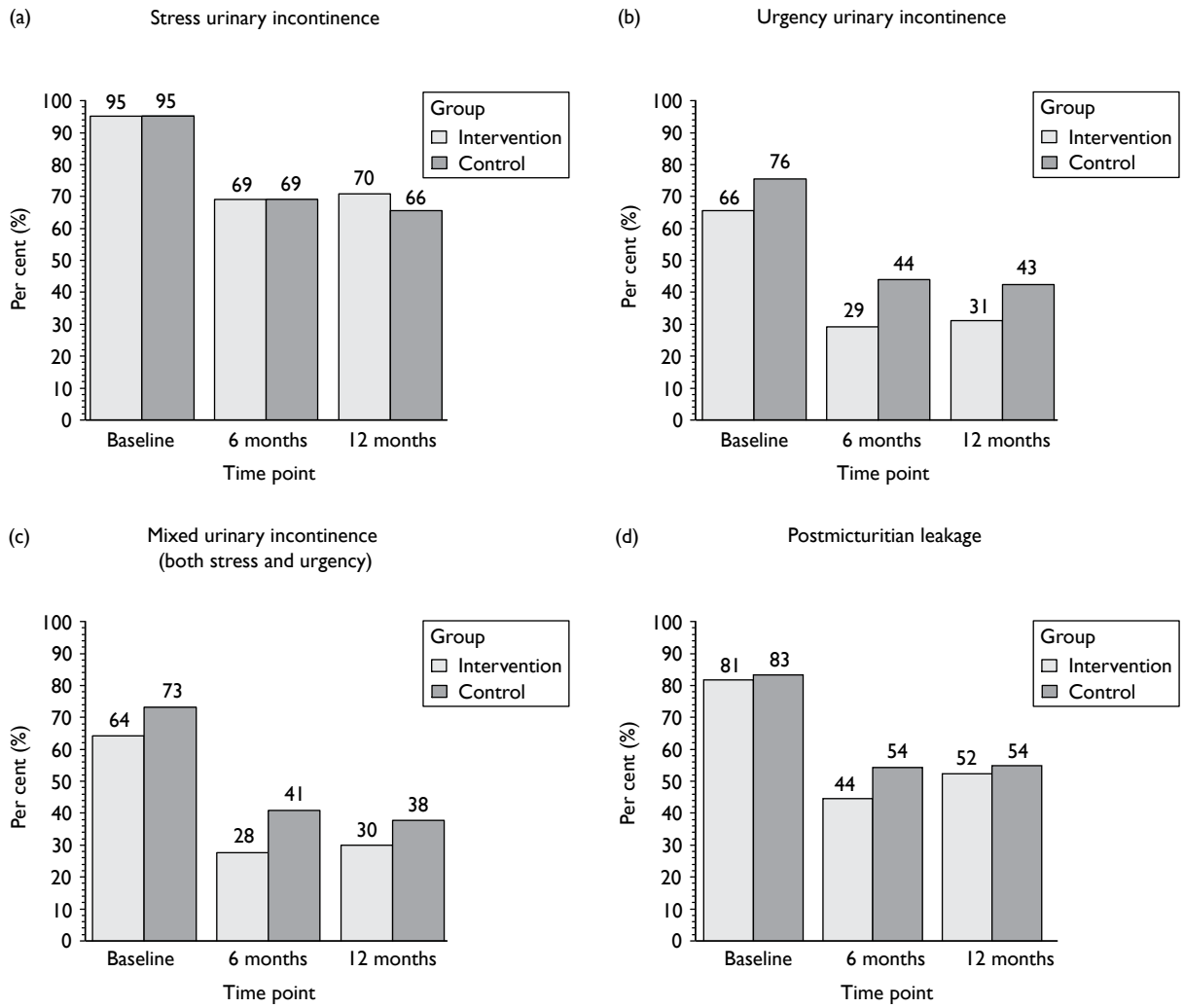

FIGURE 16 Type of incontinence at baseline and at 6 and 12 months after randomisation. Men could report more than one type of incontinence. (a) Stress urinary incontinence. (b) Urgency urinary incontinence. (c) Mixed urinary incontinence (proportion of men reporting both stress and urgency urinary incontinence). (d) Postmicturition leakage (defined as 'urine leaking when urination finished').

Bowel function

In addition to urinary outcomes, men were also asked to describe some aspects of bowel function. Few men (< 10%) had faecal incontinence or constipation by the end of follow-up at 12 months, although rather more reported faecal urgency occasionally or more often. *Table 32* and *Figure 17* show that there were no differences in any aspect of bowel function between the men in the randomised groups.

Sexual function

Table 33 compares the men in the randomised groups in terms of sexual function outcomes. Over 90% of men had normal erectile function before their operation. Although around one-third had an active sex life at 12 months, the majority said that this was less satisfactory than before their operation. There were, however, no differences at 12 months according to the randomised groups in terms of the proportion of men with an active sex life [RR 0.94 (95% CI 0.73 to 1.22); adjusted for age, urinary incontinence before surgery and baseline value, $p = 0.661$] or the proportion of men who rated their sex life as worse after the operation [RR 0.79 (95% CI 0.47 to 1.34); $p = 0.391$].

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TABLE 31a Use of aids or protection for urinary incontinence

	Baseline		3 months		6 months		9 months		12 months	
Radical prostatectomy	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**
Use of any protection	183/205 (89)	181/206 (88)	103/205 (50)	118/206 (57)	76/205 (37)	85/206 (41)	72/205 (35)	74/206 (36)	65/205 (32)	71/206 (34)
Use of body-worn pads (yes)	180/205 (88)	176/205 (86)	101/177 (57)	108/177 (61)	74/161 (46)	83/164 (51)	67/154 (44)	71/156 (46)	63/159 (40)	68/161 (42)
Number of body-worn pads in 24 hours [mean (SD) *n*]	3.1 (2.3) 176	3.4 (2.8) 172	1.8 (1.4) 99	2.3 (1.8) 106	1.6 (1.4) 76	2.2 (1.8) 83	1.6 (0.9) 64	2.2 (1.8) 69	1.6 (1.1) 67	2.0 (1.8) 68
Use of chair or bed pads (yes)	47/201 (23)	54/200 (27)	14/174 (8)	22/175 (13)	11/153 (7)	14/157 (9)	10/154 (6)	12/151 (8)	5/149 (3)	6/155 (4)
Number of chair or bed pads in 24 hours [mean (SD) *n*]	1.4 (1.8) 47	1.4 (1.6) 54	1.1 (0.7) 12	1.1 (1.2) 20	1.0 (0.5) 10	1.5 (2.0) 10	1.1 (0.4) 8	1.1 (1.2) 10	1.0 (0.0) 5	1.4 (1.5) 5
Use of external (sheath) catheter (yes)	17/202 (8)	18/205 (9)	12/197 (6)	18/195 (9)	8/187 (4)	11/189 (6)	12/190 (6)	7/189 (4)	9/189 (5)	5/188 (3)
Use of permanent catheter (yes)	0/205 (0)	0/203 (0)	0/197 (0)	0/196 (0)	0/189 (0)	0/192 (0)	1/190 (1)	0/189 (0)	1/192 (1)	1/191 (1)

Figures are *n*/*N* (%) except where stated otherwise.

TABLE 31b Use of aids or protection for urinary incontinence: statistical analyses

	Effect size (95% CI), *p*-value			
Radical prostatectomy	**3 months**	**6 months**	**9 months**	**12 months**
Use of any protection	0.87 (0.73 to 1.05), 0.139	0.89 (0.70 to 1.13), 0.351	0.97 (0.75 to 1.25), 0.803	0.91 (0.69 to 1.19), 0.489
Use of body-worn pads (yes)	0.912 (0.78 to 1.07), 0.266	0.847 (0.68 to 1.05), 0.132	0.916 (0.72 to 1.16), 0.464	0.858 (0.67 to 1.10), 0.235
Number of body-worn pads in 24 hours [mean difference (95% CI), *p*-value]	–0.40 (–0.77 to –0.02), 0.040	–0.58 (–1.02 to –0.13), 0.012	–0.54 (–0.99 to –0.10), 0.018	–0.45 (–0.94 to 0.05), 0.075
Use of chair or bed pads (yes)	0.651 (0.34 to 1.23), 0.185	0.852 (0.39 to 1.87), 0.690	0.827 (0.37 to 1.83), 0.638	0.911 (0.25 to 3.28), 0.887
Number of chair or bed pads in 24 hours [mean difference (95% CI), *p*-value]		0.04 (–0.83 to 0.91), 0.919		0.01 (–1.60 to 1.63), 0.982
Use of external (sheath) catheter (yes)	0.741 (0.39 to 1.41), 0.360	0.690 (0.26 to 1.81), 0.450	1.720 (0.73 to 4.08), 0.218	1.948 (0.70 to 5.45), 0.204
Use of permanent catheter (yes)	Not estimable	Not estimable	Not estimable	Not estimable

Effect size is RR, unless indicated, as mean difference, adjusted for age, urinary incontinence before surgery and baseline value.

TABLE 32 Type of bowel problems at baseline and 6 and 12 months

	Baseline		6 months			12 months		
Radical prostatectomy	Intervention	Control	Intervention	Control	Effect size (95% CI), *p*-value	Intervention	Control	Effect size (95% CI), *p*-value
Faecal incontinence[a]	6/205 (3)	15/206 (7)	11/190 (6)	14/195 (7)	0.97 (0.41 to 2.29), 0.968	16/193 (8)	11/193 (6)	1.56 (0.74 to 3.29), 0.241
Faecal urgency[a]	76/204 (37)	92/205 (45)	65/190 (34)	80/195 (41)	0.93 (0.73 to 1.18), 0.549	70/193 (36)	86/193 (45)	0.88 (0.70 to 1.10), 0.244
Constipation	31/205 (15)	23/206 (11)	12/189 (6)	16/194 (8)	0.60 (0.29 to 1.23), 0.165	11/193 (6)	14/193 (7)	0.69 (0.28 to 1.58), 0.359
Any bowel dysfunction[b]	97/205 (47)	110/206 (53)	80/190 (42)	94/195 (48)	0.92 (0.75 to 1.13), 0.419	80/193 (42)	98/193 (51)	0.84 (0.69 to 1.03), 0.102

Figures are *n*/*N* (%), unless stated otherwise.
Effect size is RR adjusted for age, urinary incontinence before surgery and baseline value.
a Faecal incontinence and urgency were defined as present when the problem was rated as occurring 'occasionally or more often'.
b Any bowel dysfunction includes faecal urgency, ulcerative colitis, Crohn's disease, irritable bowel syndrome or constipation, but not faecal incontinence.

Table 34 compares the randomised groups in terms of problems with sexual function. There were no significant differences in sexual function outcomes between the intervention and control groups (*Table 34* and *Figure 18*). Only about 20% of the men were able to achieve a normal erection or one with slightly reduced stiffness by 12 months after surgery, and almost all reported a lack of semen or no ejaculation. Of those men, few reported more than slight pain. Around 60% of men used drugs and about 20% used a vacuum device to help with sexual function. Only 20% reported urinary incontinence during intercourse.

Quality of life

General health outcomes were measured using the EQ-5D and SF-12, the latter subdivided into role – mental (SF-12M) and role – physical (SF-12P) scores. The slight increase in the scores over time represents recovery from the operation but there were no differences between the randomised groups at any time point in EQ-5D or SF-12 scores (*Table 35* and *Figure 19*).

Pelvic floor muscle training

All men were asked to report on their practice of carrying out pelvic floor exercises at baseline and 6 and 12 months after randomisation. Initially a high proportion of men (over 80%) reported practising them, of whom around 80% carried them out every day. As this occurred before randomisation, it must reflect the high profile given to PFMT in the standard care of men after radical prostate surgery.

The prevalence of exercising in the control group had fallen by 6 months (to 62%), while men in the therapy group were more likely than controls still to be performing exercises (83%). This difference was maintained at 12 months: a significantly higher proportion of men from the intervention group were carrying out any PFMT at 12 months after randomisation (67%) compared with those in the control group (50%; see *Table 36*). Significantly more were practising for at least 3–4 days each week in the intervention group than in the control group (56% vs 36%). Although men in the intervention group were performing fewer daily contractions by 12 months

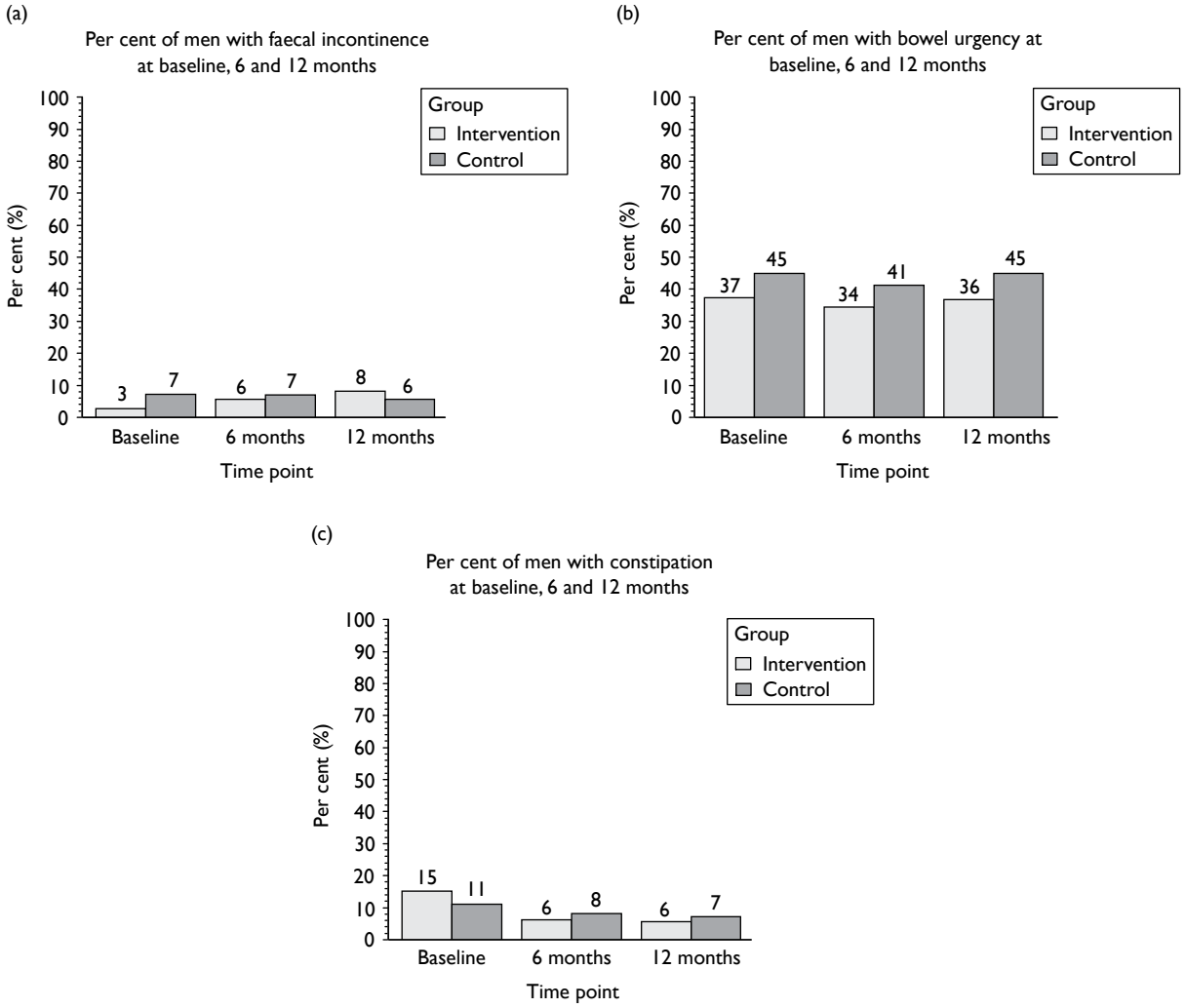

FIGURE 17 Type of bowel problems at baseline and 6 and 12 months.

TABLE 33 Description of sex life variables before and 12 months after prostate surgery

Radical prostatectomy	Intervention	Control
Number of men not able to achieve erection before prostate surgery[a]	17/205 (8)	18/202 (9)
Number of men with active sex life at 12 months	68/184 (37)	73/184 (40)
Reasons for not having an active sex life		
Because of urinary symptoms	13/116 (11)	10/113 (9)
Because of bowel symptoms	0/116	0/111
Because of prostate operation	112/136 (82)	106/132 (80)
Because of medical treatment	1/116 (1)	1/112 (1)
For another reason	27/118 (23)	30/112 (27)
Comparison of sex life with before prostate operation 12 months ago		
Stayed the same	22/163 (13)	24/162 (15)
Better	0/163 (0)	3/162 (2)
Worse	141/163 (87)	135/162 (83)

Figures are *n*/*N* (%), unless otherwise stated.
a This information was collected at baseline but was retrospective, based on men's recall of their sexual function before their operation.

TABLE 34 Type of sexual problems at 12 months after prostate surgery

Radical prostatectomy	Intervention	Control
Difficulty with achieving erection		
Normal stiffness	6/189 (3)	3/190 (2)
Reduced stiffness	29/189 (15)	38/190 (20)
Severely reduced stiffness	49/189 (26)	44/190 (23)
No erection possible	105/189 (56)	105/190 (55)
Bother with erection [mean (SD) *n*][a]	6.0 (3.3) 183	6.5 (3.1) 183
Ejaculation		
Normal quantity of semen	0/187 (0)	1/184 (1)
Reduced quantity of semen	1/187 (1)	2/184 (1)
Significantly reduced quantity of semen	3/187 (2)	3/184 (2)
Ejaculation but without semen	65/187 (35)	69/184 (38)
No ejaculation	118/187 (63)	109/184 (59)
Bother with ejaculation [mean (SD) *n*][a]	3.8 (3.7) 172	4.4 (3.7) 171
Pain or discomfort with ejaculation		
No pain	94/117 (80)	98/124 (79)
Slight pain	14/117 (12)	17/124 (14)
Moderate pain	5/117 (4)	5/124 (4)
Severe pain	4/117 (3)	4/124 (3)
Bother with pain or discomfort [mean (SD) *n*][a]	2.5 (3.4) 49	2.3 (3.1) 55
Number of men using medication for sexual problems	104/186 (56)	110/189 (58)
Number of men using vacuum device for sexual problems	47/185 (25)	39/183 (21)
Number of men using either medication or a vacuum device for sexual problems	116/188 (62)	123/189 (65)
Number of men leaking urine during intercourse	26/135 (19)	30/139 (22)

Figures are *n*/*N* (%) except where stated otherwise.
a Bother scale: 0 = not at all to 10 = a great deal.

FIGURE 18 Quality of erectile function at 12 months after prostate surgery: Radical prostatectomy.

TABLE 35 Quality of life outcomes measured by EQ-5D and SF-12

	Baseline		6 months			12 months		
Radical prostatectomy	Intervention	Control	Intervention	Control	Effect size (95% CI), *p*-value	Intervention	Control	Effect size (95% CI), *p*-value
EQ-5D	0.797 (0.216) 200	0.783 (0.225) 206	0.884 (0.205) 184	0.875 (0.189) 189	0.006 (–0.027 to 0.039) 0.725	0.879 (0.209) 187	0.887 (0.176) 189	–0.013 (–0.047 to 0.021), 0.460
SF-12M	50.8 (10.5) 201	49.3 (10.7) 201	53.6 (8.3) 188	53.2 (8.1) 191	0.4 (–1.3 to 2.1) 0.615	52.9 (9.1) 190	53.6 (7.9) 191	–0.9 (–2.6 to 0.9), 0.321
SF-12P	42.7 (9.9) 201	41.8 (10.6) 201	50.9 (9.4) 188	49.6 (9.9) 191	1.1 (–0.7 to 2.8) 0.246	51.4 (8.3) 190	51.2 (8.4) 191	0.0 (–1.6 to 1.6), 0.967

SF-12M, SF-12 role – mental; SF-12P, SF-12 role – physical.
Figures are mean (SD) *n*, unless stated otherwise.
A higher score on the EQ-5D and the SF-12 represents better health.
Effect size is mean difference adjusted for age, urinary incontinence before surgery and baseline value.

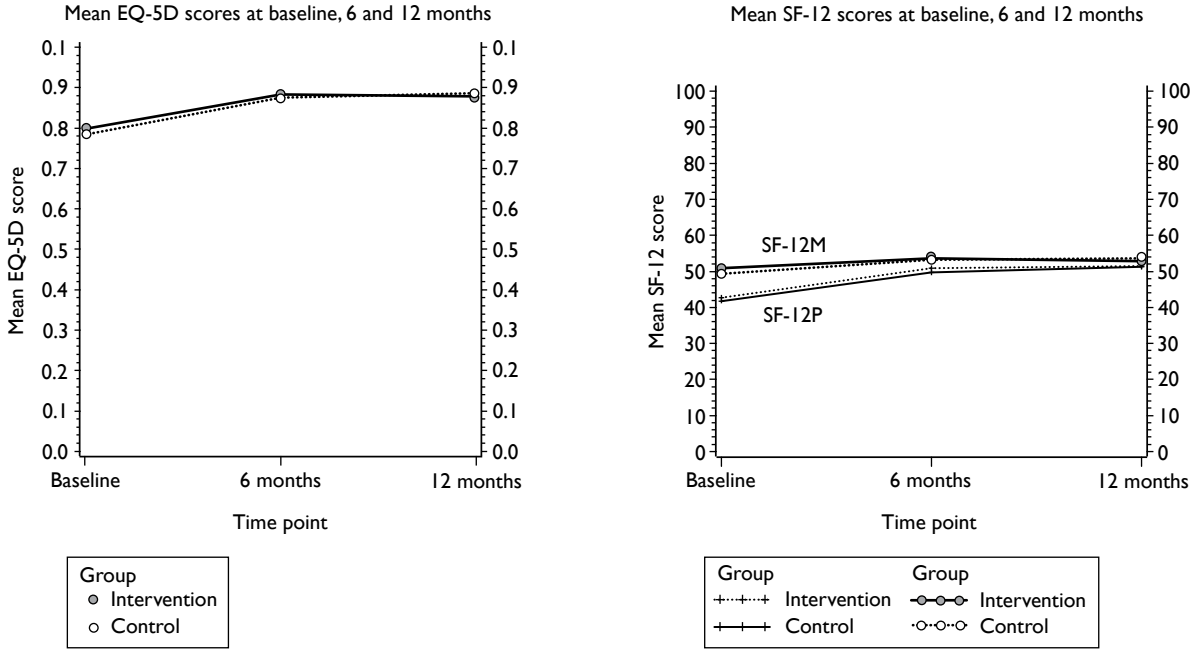

FIGURE 19 Graphical representations of EQ-5D and SF-12 scores over time. SF-12M, SF-12 role – mental; SF-12P, SF-12 role – physical.

than they had previously, the difference between randomised groups at this time point did not reach statistical significance (mean contractions 11.7 intervention vs 19.4 control) (see *Table 36*). This is likely to reflect the taught exercise regimen in the intervention group (aiming for 18 strong contractions every day) compared with recommendations from NICE,[71,72] which are to perform eight contractions three times a day.

TABLE 36 Practice of PFMT at 12 months after randomisation: results from 6- and 12-month questionnaires

	Baseline		6 months			12 months		
Radical prostatectomy	Intervention	Control	Intervention	Control	Effect size (95% CI), *p*-value	Intervention	Control	Effect size (95% CI), *p*-value
Any PFMT in last week								
Yes	176/205 (86)	170/206 (83)	156/188 (83)	117/190 (62)	1.329 (1.17 to 1.51), 0.001	128/191 (67)	95/189 (50)	1.296 (1.09 to 1.53), 0.003
No	22/205 (11)	21/206 (10)	32/188 (17)	70/190 (36)		63/191 (33)	91/189 (48)	
Don't know	7/205 (3)	15/206 (7)	0/188 (0)	3/190 (2)		0/191 (0)	3/189 (2)	
Days carrying out PFMT								
Every day	145/205 (71)	139/206 (67)	96/188 (51)	64/190 (34)		67/192 (35)	51/190 (27)	
5–6 days	8/205 (4)	8/206 (4)	17/188 (9)	10/190 (5)		13/192 (7)	5/190 (3)	
3–4 days	9/205 (4)	16/206 (8)	19/188 (10)	13/190 (7)		26/192 (14)	12/190 (6)	
1–2 days	13/205 (6)	6/206 (3)	20/188 (11)	28/190 (15)		18/192 (9)	28/190 (15)	
None	30/205 (15)	37/206 (18)	36/188 (19)	75/190 (39)		68/192 (35)	94/190 (49)	
Average contractions [mean (SD) *n*; mean difference]			18.2 (29.4) 188	21.1 (45.0) 190	–2.9 (–10.7 to 4.8), 0.457	11.7 (20.0) 192	19.4 (79.2) 189	–7.8 (–19.4 to 3.9), 0.189
Deliberate contractions whilst walking[a]			150/187 (80)	118/184 (64)	1.25 (1.10 to 1.42), 0.001	148/192 (77)	121/186 (65)	1.18 (1.04 to 1.35), 0.011
Deliberate contractions before you do something[a]			128/185 (69)	111/184 (60)	1.15 (0.98 to 1.33), 0.078	134/192 (70)	113/187 (60)	1.16 (1.00 to 1.34), 0.052
Contracting reduces or stops leaking			113/130 (87)	105/125 (84)	1.09 (0.96 to 1.24), 0.197	117/137 (85)	97/126 (77)	1.16 (1.00 to 1.34), 0.046

Figures are *n*/*N* (%), unless indicated otherwise.
Effect size is RR, unless indicated as mean difference, adjusted for age, urinary incontinence before surgery and baseline value.
a Coded as positive if man responded 'sometimes' or more often.

Men in the intervention group were also significantly more likely to perform contractions while walking. Differences between groups in performing a pelvic floor muscle contraction prior to increases in intra-abdominal pressure such as coughing or lifting (also known as 'the Knack') did not quite reach statistical significance (*Table 36*). There were no differences between the groups in terms of 'the Knack' reducing or stopping urinary leakage (although this analysis includes only the men using this technique).

Lifestyle outcomes

Men were also advised, in the lifestyle advice leaflet sent to both groups but reinforced by the therapists in the intervention group, about the benefits of general health strategies such as taking more exercise. There were few differences between the groups in terms of other types of exercise practised (*Table 37*) and no statistically significant difference in the proportion taking general exercise [RR 0.94 (95% CI 0.87 to 1.02); $p = 0.151$].

TABLE 37 Practice of other exercise at 12 months after randomisation: results from 12-month questionnaire

	12 months [*n*/*N* (%)]	
Radical prostatectomy	**Intervention**	**Control**
General exercise (yes)[a]	160/189 (85)	168/188 (89)
Exercise type		
Walking	150/189 (79)	148/188 (78)
Swimming	25/189 (13)	19/188 (10)
Gardening	101/189 (53)	119/188 (63)
Running	9/189 (5)	14/188 (7)
Going to gym	20/189 (11)	20/188 (11)
Other	36/189 (19)	36/188 (19)
Changed exercise since prostate operation		
No changes	142/191 (74)	121/191 (63)
I do less	27/191 (14)	39/191 (20)
I do more	22/191 (12)	31/191 (16)

a Number of men responding 'yes' to question: 'Have you done any general exercise or fitness activity in the last week?'.

Finally, men in both groups were given (via the lifestyle advice leaflet) other general advice on lifestyle changes they could make that might help both with incontinence and with general health. Again, this advice was reinforced by the therapists for men in the intervention group. There were few differences between the groups in terms of changes made to lifestyle factors (*Table 38*).

Prespecified subgroup analyses

Preplanned subgroup analyses were carried out on the primary outcome (urinary incontinence at 12 months) according to factors that we thought would be prognostic. These factors were:

1. pre-existing urinary incontinence (before prostate surgery)
2. age (up to 60 years, 61 years and over)
3. BMI (up to 30 kg/m^2, 30–34.9 kg/m^2, 35 kg/m^2 or greater)
4. type of incontinence at trial entry
   i. SUI
   ii. UUI
   iii. MUI
   iv. postmicturition leakage
5. other morbidity
6. type of therapist (physiotherapist or nurse).

Whilst a subgroup analysis on the use of biofeedback machines was also prespecified, there were insufficient numbers of centres with biofeedback machines to do such an analysis (see *Table 7*).

Figure 20 shows the effect of subgroup analysis on the primary outcome (urinary incontinence at 12 months) according to the prespecified factors. The dotted line reflects the overall main effect of the intervention on incontinence rates. Stricter levels of statistical significance ($2p < 0.01$) were sought (99% CIs), reflecting the exploratory nature of these analyses. There were no apparent clinically relevant differences according to any subgroup and none of the formal tests for statistical interaction effects were significant.

TABLE 38 Compliance with lifestyle advice and changes to lifestyle at 12 months

Radical prostatectomy	Intervention [*n*/*N* (%)]	Control [*n*/*N* (%)]
Weight		
No need to lose weight	75/190 (39)	77/187 (41)
Haven't tried to lose weight	78/190 (41)	73/187 (39)
Extra exercise to lose weight	27/190 (14)	29/187 (16)
Diet to lose weight	12/190 (6)	11/187 (6)
Other ways of losing weight	15/190 (8)	9/187 (5)
Fluid intake		
Number of men making no changes to fluid intake	90/191 (47)	88/192 (46)
Drink more fluids	55/191 (29)	61/192 (32)
Drink more cranberry juice	39/191 (20)	36/192 (19)
Drink fewer caffeinated drinks	49/191 (26)	58/192 (30)
Drink less fluid in evenings	49/191 (26)	59/192 (31)
Other changes to fluid intake	14/191 (7)	18/192 (9)
Diet		
Number of men making no changes to diet or food	130/189 (69)	133/191 (70)
More balanced diet	36/189 (19)	35/191 (18)
More fruit and vegetables	49/189 (26)	53/191 (28)
More fibre	31/189 (16)	35/191 (18)
Less fats or sugars	45/189 (24)	37/191 (19)
Other changes to food intake	7/189 (4)	7/191 (4)
Lifting		
Number of men who reduce lifting	81/193 (42)	76/190 (40)
Smoking		
Number of men who smoked	16/193 (8)	17/189 (9)
Number of men stopping smoking[a]	1/16 (6)	1/17 (6)
Number of men reducing smoking[a]	8/16 (50)	9/17 (53)
Chest or respiratory symptoms		
Number of men who did have chest symptoms	17/188 (9)	19/184 (10)
Taking correct medication[a]	12/17 (71)	6/19 (32)
Consulted GP about medication[a]	6/17 (35)	8/19 (42)
Other changes to reduce respiratory symptoms[a]	0/17 (0)	1/19 (5)

a Responses limited to number of men who did smoke or had chest symptoms respectively.

Satisfaction with treatment for urinary incontinence

Men were asked to score their satisfaction with the treatment they received for urinary incontinence (0 = 'very unsatisfied' to 10 = 'very satisfied') at 12 months after randomisation. Men in the intervention group were significantly more satisfied than those in the control group (see *Appendix 5*, *Table 88*). Thus, the therapy intervention did increase satisfaction rates despite the lack of difference in urinary outcomes.

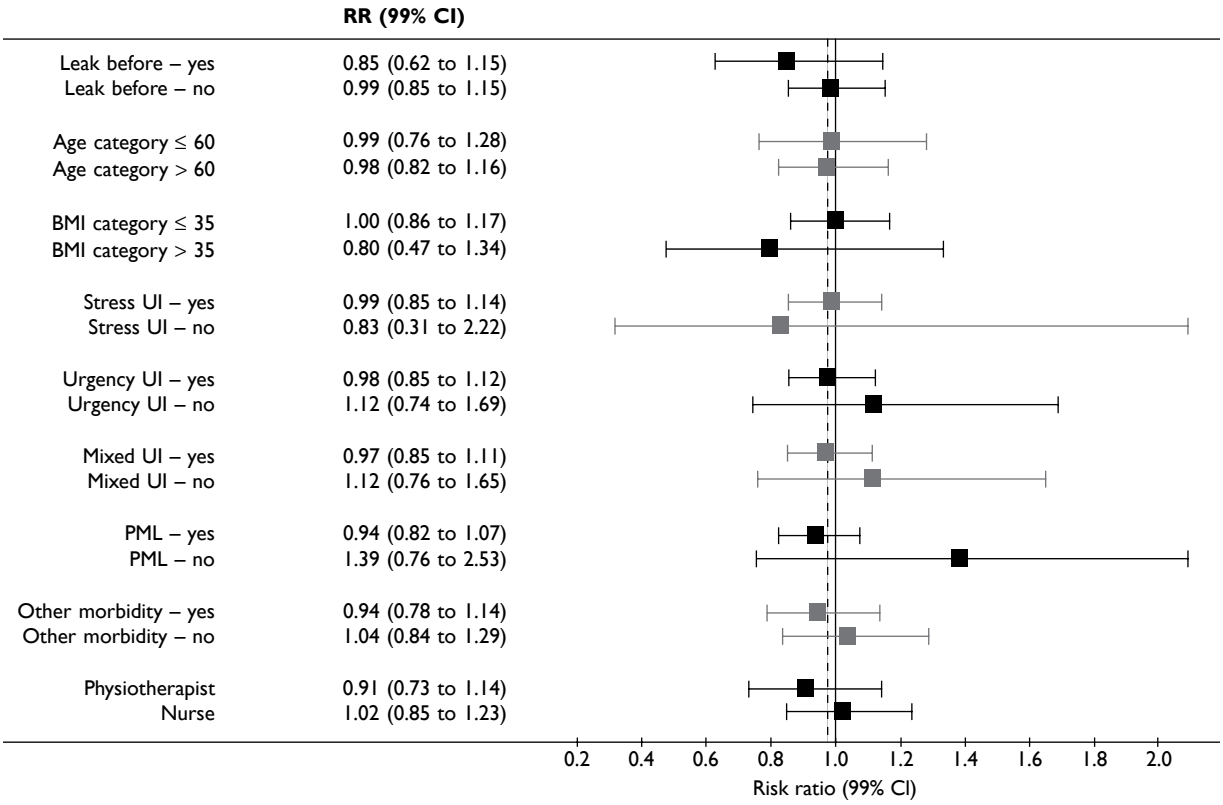

FIGURE 20 Forest plot of subgroup analyses: urinary incontinence at 12 months. PML, postmicturition leakage.

Chapter 8

Resource use and cost-effectiveness in the radical randomised controlled trial

This chapter describes the economic analyses for the radical prostatectomy RCT.

Description of the data available

Table 39 describes the number of men who contributed data for each of the areas of resource use and quality of life at each time point. Fewer data were available at the later data collection time points. For some areas of resource use (for example number of NHS pads at 12 months), only three-quarters of men indicated the quantity used. For other areas, for example hospital physiotherapist visits, nearly 90% of men provided data on the use of that resource even at 12 months. The difference between these two rates cannot be explained by the mode of data collection, as both were collected by participant-completed questionnaire. An alternative explanation might be the limited use of these services by 12 months, which meant that men did not answer the questions because they did not think they were relevant. Other explanations could be advanced, but there is no information to determine what the reasons are for men providing information for some areas of resource use but not for others.

Analysis of resource use and costs

Resource use

Table 40 details the average total resource use for the intervention and subsequent use of health services over the 12-month follow-up period after randomisation. The pattern of resource use was similar across both groups and there were few statistically significant differences between the two groups. In addition to differences in costs of the intervention (incurred only by those randomised to the intervention group), these costs included the use of pads paid for by the NHS, incontinence-related GP doctor and nurse visits, hospital physiotherapist visits and the number of days that participants were off work. The use of resources in each of these areas was higher for the control group, apart from the subsequent number of hospital physiotherapy visits, which was higher for the intervention group. A detailed description of the use of NHS and private provider health services is provided in *Appendix 5*.

Costs

Participant time and travel costs

The average time and costs to participants and their companions (families or carers) of a contact with a GP, an outpatient consultation or an inpatient admission are reported in *Table 41*. These data were combined with the information on number of contacts (e.g. hospital doctor visits) that the trial participants had reported (*Table 40*) to estimate a monetary cost per patient for both intervention and control groups.

TABLE 39 Number of participants providing responses to resource utilisation questions (*n* intervention = 205; *n* control = 206): radical prostatectomy

	Baseline [*n* (%)]		3 months [*n* (%)]		6 months [*n* (%)]		9 months [*n* (%)]		12 months [*n* (%)]	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
NHS-supplied pads	201 (98)	201(98)	174 (85)	175 (85)	157 (77)	162 (79)	151 (74)	154 (75)	158 (77)	157 (76)
Self-supplied pads	197 (96)	196 (95)	170 (83)	169 (82)	152 (74)	156 (76)	148 (72)	150 (73)	153 (75)	147 (71)
NHS-supplied bed/chair protector	196 (96)	194 (94)	171 (83)	173 (84)	151 (74)	153 (74)	152 (74)	149 (72)	149 (73)	154 (75)
Self-supplied bed/chair protector	194 (95)	194 (94)	171 (83)	167 (81)	150 (73)	153 (74)	150 (73)	149 (72)	149 (73)	154 (75)
Catheter	205 (100)	203 (99)	197 (96)	196 (95)	189 (92)	192 (93)	190 (93)	189 (92)	192 (94)	191(93)
Sheath	202 (99)	205 (99)	197 (96)	195 (95)	187 (91)	189 (92)	190 (93)	189 (92)	189 (92)	188 (91)
GP other visit	188 (92)	197 (96)	188 (92)	190 (92)	182 (89)	191 (93)	182 (89)	182 (88)	190 (93)	187 (91)
Nurse incontinent visit	156 (76)	166 (81)	165 (80)	154 (75)	158 (77)	158 (77)	152 (74)	147 (71)	161 (79)	156 (76)
Nurse other visit	194 (95)	183 (89)	189 (92)	188 (91)	180 (88)	184 (89)	180 (88)	186 (90)	187 (91)	188 (91)
Hospital doctor visit	193 (94)	184 (89)	176 (86)	184 (89)	177 (86)	191 (93)	182 (89)	174 (84)	180 (88)	183 (89)
Hospital nurse visit	187 (91)	191 (93)	178 (87)	174 (84)	178 (87)	183 (89)	179 (87)	172 (83)	181 (88)	179 (87)
Hospital physiotherapist visit	191 (93)	191 (93)	184 (90)	175 (85)	172 (84)	180 (87)	179 (87)	168 (82)	177 (86)	179 (87)
Private doctor visit	204 (99)	199 (97)	192 (94)	188 (91)	183 (89)	190 (92)	183 (89)	179 (87)	187 (91)	186 (90)
Private nurse visit	191 (93)	190 (92)	188 (92)	182 (88)	178 (87)	184 (89)	180 (88)	179 (87)	183 (89)	185 (90)
Private physiotherapist visit	199 (97)	195 (95)	190 (93)	185 (90)	180 (88)	184 (89)	182 (89)	180 (87)	176 (86)	178 (86)
Inpatient visit	202 (99)	205 (99)	194 (95)	193 (94)	186 (91)	193 (94)	185 (90)	186 (90)	187 (91)	191 (93)
Days off work	194 (95)	193 (94)	179 (87)	184 (89)	170 (83)	173 (84)	178 (87)	170 (83)	177 (86)	182 (88)

Note: the number of responses available differs from those reported in *Appendix 5* as these values refer to responses not the number of questionnaires returned.

TABLE 40 Mean resource use per patient during 12-month period after randomisation: radical prostatectomy

	Mean (SD)		
Area of resources use	Intervention	Control	Difference (95% CI)[a]
Intervention	3.55 (1.61)	0	3.55
Subsequent resource use			
NHS-supplied pads used[b]	2.46 (3.86)	3.53 (5.71)	–0.90 (–1.74 to –0.07)
NHS-supplied bed/chair protectors used	0.18 (0.64)	0.26 (1.41)	–0.08 (–0.29 to 0.12)
GP doctor incontinence-related visit[b]	0.33 (1.17)	0.63 (1.94)	–0.34 (–0.63 to –0.05)
GP doctor other visit	4.17 (4.03)	4.53 (4.03)	–0.24 (–1.00 to 0.52)
GP nurse incontinence-related visit	0.16 (0.94)	0.37 (1.50)	–0.17 (–0.40 to 0.06)
GP nurse other visit	1.85 (2.21)	2.16 (3.43)	–0.32 (–0.88 to 0.23)
Number of men using catheters	1.17 (1.29)	1.26 (1.29)	–0.09 (–0.34 to 0.16)
Number of men using sheaths	0.20 (0.59)	0.24 (0.61)	–0.03 (–0.14 to 0.08)
Hospital doctor visits	0.44 (1.13)	0.44 (1.14)	–0.01 (–0.23 to 0.21)
Hospital nurse visits[b]	0.62 (1.49)	0.31 (0.88)	0.32 (0.08 to 0.55)
Hospital physiotherapist visits[b]	0.79 (1.44)	0.18 (1.17)	0.62 (0.38 to 0.87)
Inpatient days	0.04 (0.26)	0.06 (0.29)	–0.02 (–0.07 to 0.04)
Number taking incontinence drugs	0.29 (0.85)	0.33 (0.86)	–0.05 (–0.21 to 0.11)
Self-purchased use of health care			
Pads used	1.61 (3.18)	2.37 (4.60)	–0.62 (–1.34 to 0.09)
Bed/chair protector used	0.25 (0.72)	0.48 (2.18)	–0.17 (–0.47 to 0.14)
Private doctor visits	0.13 (0.47)	0.14 (0.53)	–0.02 (–0.12 to 0.07)
Private nurse visits	0.15 (0.53)	0.09 (0.35)	0.07 (–0.02 to 0.15)
Private physiotherapist visits	0.16 (0.60)	0.08 (0.68)	0.07 (–0.05 to 0.19)
Number of days off work[b]	7.62 (24.71)	15.20 (42.93)	–6.54 (–13.08 to –0.01)

Note: the number of days off work refers only to the number of days absent from paid employment after randomisation.
a Differences adjusted for baseline costs.
b Statistically significantly different at 5%.

TABLE 41 Cost to the patient and their companion of a single visit or admission: radical prostatectomy

Resource use	Time or monetary cost	Mean (SD)
Primary care consultation visit	Time spent going to and attending a primary care consultation (hours)	0.67 (0.30)
	Companion's time off work (£)	0.80 (2.40)
	Average cost to participant and companion of a primary care consultation (£)	17.30 (36.75)
Secondary care visit	Time spent attending a secondary care visit (hours)	2.07 (1.51)
	Companion's time off work (£)	9.05 (14.46)
	Average cost to participant and companion of travelling to a secondary care department (£)	36.43 (49.17)
Inpatient visit	Visits to participant during admission (number)	4.04 (5.42)
	Companion's time off work (£)	23.46 (73.12)
	Average cost to participant and companion of travelling to admission (£)	82.78 (136.38)

Estimation of societal costs

Table 42 details the mean cost per participant of the two interventions. The unit cost information in *Tables 4* and *41* was combined with the resource use information reported in *Table 40* to provide estimates of the total cost per participant. For the base-case analysis, based on societal costs, the mean total cost per participant in the intervention group was £1509 (SD £2802) and

TABLE 42 Cost per participant for each area of resource use: radical prostatectomy

Area of resource use	Mean cost [£ (SD)]		Difference (95% CI)[a]
	Intervention	Control	
NHS costs			
Intervention	198.30 (63.89)	0	193.30
Subsequent resource use			
NHS-supplied pads[b]	38.03 (59.71)	54.67 (88.32)	–13.97 (–26.88 to –1.06)
NHS-supplied bed/chair protectors	2.40 (8.74)	3.58 (19.21)	–1.15 (–3.96 to 1.66)
GP doctor incontinence-related visits[b]	11.77 (42.11)	22.54 (69.78)	–12.18 (–22.55 to –1.80)
GP doctor other visit	150.15 (144.90)	163.05 (145.08)	–8.72 (–36.09 to 18.66)
GP nurse incontinence-related visit	1.72 (10.30)	4.11 (16.55)	–1.85 (–4.38 to 0.68)
GP nurse other visit	20.34 (24.29)	23.76 (37.76)	–3.57 (–9.65 to 2.51)
Catheter	0.46 (6.55)	0.23 (3.27)	0.24 (–0.77 to1.24)
Sheath	22.00 (81.06)	21.89 (74.81)	0.73 (–12.33 to 13.80)
Hospital doctor visits	32.93 (84.42)	32.77 (85.22)	–0.72 (–17.19 to 15.75)
Hospital nurse visits[b]	19.20 (46.16)	9.48 (27.19)	9.83 (2.49 to 17.17)
Total hospital physiotherapy visits[b]	24.35 (44.72)	5.57 (36.25)	19.32 (11.79 to 26.85)
Inpatient days	13.80 (46.65)	20.07 (48.83)	–5.67 (–14.73 to 3.39)
Prescribed drugs	28.96 (98.77)	28.20 (86.21)	–2.99 (–19.96 to 13.98)
Total subsequent use cost	358.42 (381.02)	378.99 (399.45)	–17.31 (–89.81 to 55.19)
Total NHS cost	*556.72 (396.07)*	*378.99 (399.45)*	*181.02 (107.06 to 254.97)*
Patient costs			
Self-supplied pads	35.17 (58.52)	49.11 (82.18)	–12.88 (–26.58 to 0.81)
Self-supplied bed/chair protector	0.87 (5.59)	2.85 (21.74)	–1.14 (–4.03 to 1.76)
Private doctor visits	4.02 (44.68)	2.91 (29.49)	0.03 (–7.01 to 7.07)
Private nurse visits	0.00 (0)	0.00 (0)	0
Private physiotherapist visits	0.91 (9.66)	0.30 (4.32)	0.36 (–0.63 to 1.36)
Participant number of days off work[b]	809.19 (2624.53)	1614.14 (4558.83)	–694.77 (–1388.71 to –0.83)
Total patient costs	*832.72 (2628.03)*	*1657.67 (4554.01)*	*–714.57(–1408.16 to –20.97)*
Participant travel and companion travel and time off work costs			
Intervention	132.70 (43.43)	0.00 (0)	
GP doctor incontinence-related visits[b]	5.66 (20.25)	10.84 (33.55)	–5.85 (–10.84 to –0.87)
GP doctor other visit	72.20 (69.67)	78.40 (69.76)	–4.19 (–17.36 to 8.97)
GP nurse incontinence-related visit	2.70 (16.21)	6.47 (26.05)	–2.91 (–6.90 to 1.08)
GP nurse other visit	32.00 (38.22)	37.39 (59.42)	–5.62 (–15.19 to 3.95)
Total GP visits	112.56 (97.54)	133.10 (131.13)	–18.92 (–40.46 to 2.61)
Hospital doctor visits	16.43 (42.12)	16.35 (42.52)	–0.35 (–8.58 to 7.86)
Hospital nurse visits[b]	23.18 (55.72)	11.44 (32.82)	11.89 (3.01 to 20.73)
Hospital physiotherapy visits[b]	29.39 (53.98)	6.72 (43.76)	23.32 (14.23 to 32.41)
Total outpatient visits[b]	201.70 (118.93)	34.51 (81.09)	167.06 (147.36 to 188.77)
For inpatient visits	3.23 (21.44)	4.82 (24.05)	–1.30 (–5.61 to 3.02)
Total participant and companion travel and time off work cost[b]	450.19 (200.28)	172.44 (180.86)	272.74 (225.08 to 320.40)
Total participant and companion cost	*1150.21 (2671.60)*	*1830.11 (4627.01)*	*–567.96 (–1274.10 to 138.15)*
Total societal costs	*1508.63 (2802.37)*	*2209.10 (4835.12)*	*–588.23 (–1329.83 to 153.37)*

a Differences adjusted for baseline costs.
b Statistically significantly different at 5% level.

the mean cost in the control group was £2209 (SD £4835). The trend towards higher costs in the control group, –£588 (95% CI –£1330 to £153), was not statistically significant. The difference in mean societal cost was mainly due to the high number of days taken off work by the participants in the control arm of the trial.

Estimation of NHS costs

In terms of NHS costs incurred after the intervention was delivered, the mean total cost per patient in the intervention group was £358 (SD £381) and the mean cost in the control group was £379 (SD £399). There was, however, no evidence of a statistically significant difference in the cost of subsequent NHS services used. Intervention costs were, as would be expected, greater in the intervention group. Combining information on the cost of the interventions and the cost of subsequent NHS care resulted in a statistically significantly higher total cost per participant in the intervention group. This difference was driven almost entirely by the cost of the PFMT intervention itself.

Quality-adjusted life-years

Table 43 shows the EQ-5D scores for each arm of the trial at baseline and 6 and 12 months. Also reported is the mean difference between arms in EQ-5D score at 6 and 12 months. From these data it was estimated that the mean QALYs were 0.86 (SD 0.16, median 0.796) for the intervention arm and 0.86 (SD 0.19, median 0.796) for the control arm. The mean difference in QALYs after adjusting for minimisation and baseline EQ-5D scores was –0.002 (95% CI –0.027 to 0.023) higher for the intervention group, which was not statistically significant.

Imputation was not performed on missing values in the base-case analysis. Simple plausible extreme value imputation on EQ-5D scores taking the 25th and 75th percentile values indicated that the mean difference in EQ-5D scores did not differ from that reported in *Table 43*.

Estimation of cost-effectiveness

Societal perspective

The cost-effectiveness of the intervention compared with control is dependent on whether the differences in QALYs are considered to be important to people with incontinence. Taking the mean difference in the total societal costs from *Table 42* (–£588) and the mean difference in

TABLE 43 Quality of life measures: radical prostatectomy

	Mean (SD)		Difference (95% CI)
	Intervention	Control	
Baseline EQ-5D	0.80 (0.22)	0.78 (0.23)	
	n=200	*n*=206	
6-month EQ-5D	0.88 (0.21)	0.87 (0.19)	0.009
	n=184	*n*=189	
12-month EQ-5D	0.88 (0.21)	0.89 (0.18)	–0.008
	n=187	*n*=189	
QALYs	0.86 (0.19)	0.86 (0.16)	–0.002
	n=170	*n*=179	(–0.027 to 0.023)[a]

a Difference adjusted for baseline EQ-5D score.

QALYs from *Table 43* (–0.002) it can be seen that the intervention is, on average, more effective and less costly (*Table 44*).

Uncertainty around the estimates of QALYs and costs was derived using 1000 bootstrap simulations. The bootstrap estimates in *Figure 21* indicate that in most of the instances the intervention group had lower costs than the control; however, there was a relatively wide distribution in the difference in QALYs and costs.

At a cost-effectiveness threshold of £20,000 per QALY, the intervention has a likelihood of 89% of being cost-effective, and at a threshold of £30,000 per QALY the intervention is 84% likely to be cost-effective (*Figure 22*). However, these results have to be interpreted cautiously as they are driven almost entirely by differences in time away from usual activities.

NHS perspective

Taking the mean difference in total NHS costs from *Table 42* (£181) and the mean difference in the QALY estimate after adjusting for baseline EQ-5D scores from *Table 43*, the mean incremental cost per QALY is £90,510 (*Table 45*).

As with the societal perspective, bootstrap simulations were undertaken to estimate the uncertainty around the benefit and costs. The bootstrap estimates in *Figure 23* indicate that the intervention group had higher costs than the control. However, there was a relatively wide distribution in the difference in QALYs.

At a cost-effectiveness threshold of £20,000 per QALY, the intervention has a probability of 19% of being cost-effective, and at a threshold of £30,000 per QALY the intervention is 27% more likely to be cost-effective (*Figure 24*). At no point does the probability of being cost-effective reach 50%. This indicates that it is unlikely that PFMT is cost-effective.

Sensitivity analysis

As mentioned in *Chapter 2*, sensitivity analysis is necessary to assess the robustness of the qualitative conclusion and identify areas where research is needed to more precisely estimate the values of those variables to which the result is sensitive. The variables that were considered uncertain in this study related to the costs and QALYs of the different services used.

Incremental cost per quality-adjusted life-year when differences are not adjusted for baseline differences

An unadjusted analysis was performed as a sensitivity analysis to highlight the importance of the assumption that the characteristics of the groups were not the same at baseline. The results of this analysis, from the perspective of the NHS, indicate that at a cost-effectiveness threshold of £20,000 per QALY the intervention has a probability of 45.3% of being cost-effective, and

TABLE 44 Cost-effectiveness results from the societal perspective: radical prostatectomy

Difference in mean NHS costs [mean (95% CI)[a]]	–588.23 (–1329.83 to 153.37)
Difference in QALYs [mean (95% CI)]	–0.002 (–0.027 to 0.023)
ICER (£/QALY)	Organised PFMT is dominant
Probability intervention is cost-effective when threshold is £20,000 per QALY	89.4%
Probability intervention is cost-effective when threshold is £30,000 per QALY	83.7%

a Adjusting for baseline before randomisation.

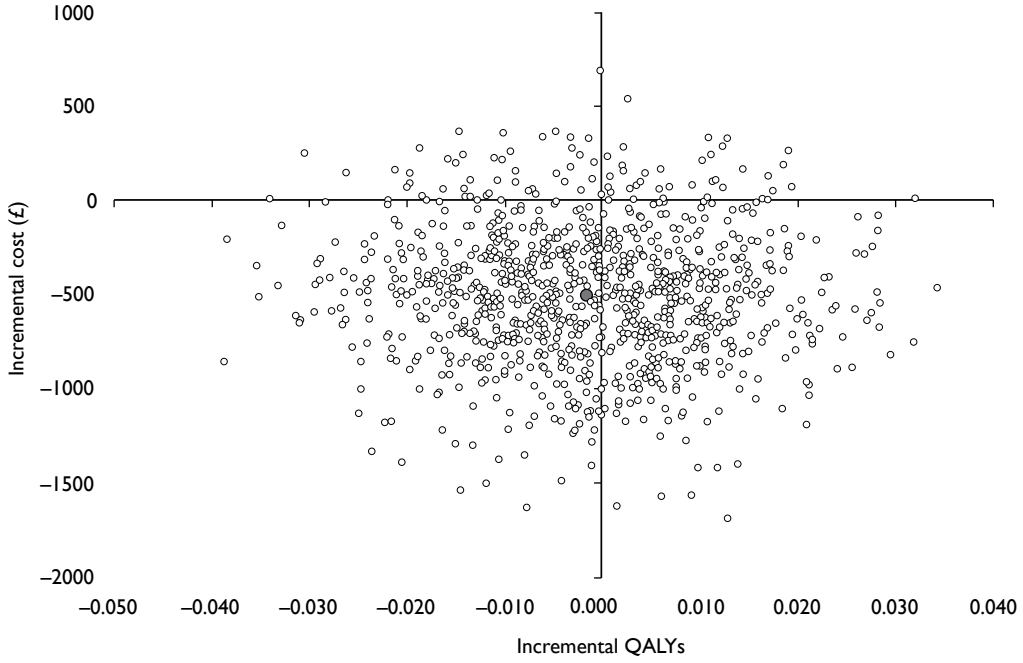

FIGURE 21 Representation of the uncertainty in differential mean costs and QALYs: societal perspective (radical prostatectomy).

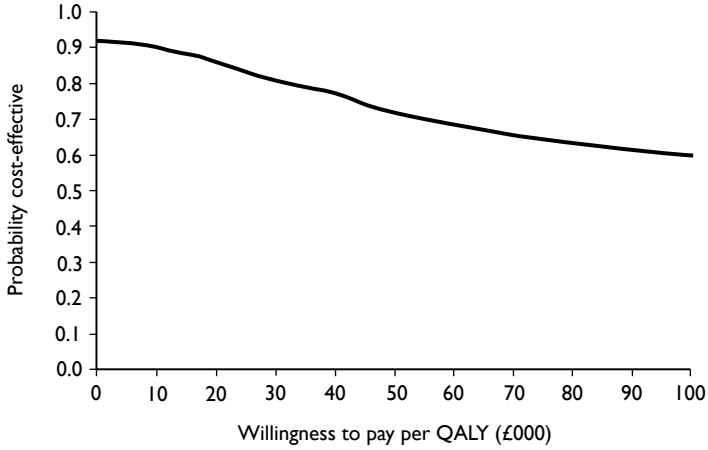

FIGURE 22 Cost-effectiveness acceptability curve for intervention versus control: societal perspective (radical prostatectomy).

TABLE 45 Cost-effectiveness results from the perspective of the NHS: radical prostatectomy

Difference in mean NHS costs [mean (95% CI)]	181.02 (107.06 to 254.97)
Difference in QALYs [mean (95% CI)]	–0.002 (–0.027 to 0.023)
ICER (£/QALY)	90,510
Probability intervention is cost-effective when threshold is £20,000 per QALY	19.2%
Probability intervention is cost-effective when threshold is £30,000 per QALY	27.3%

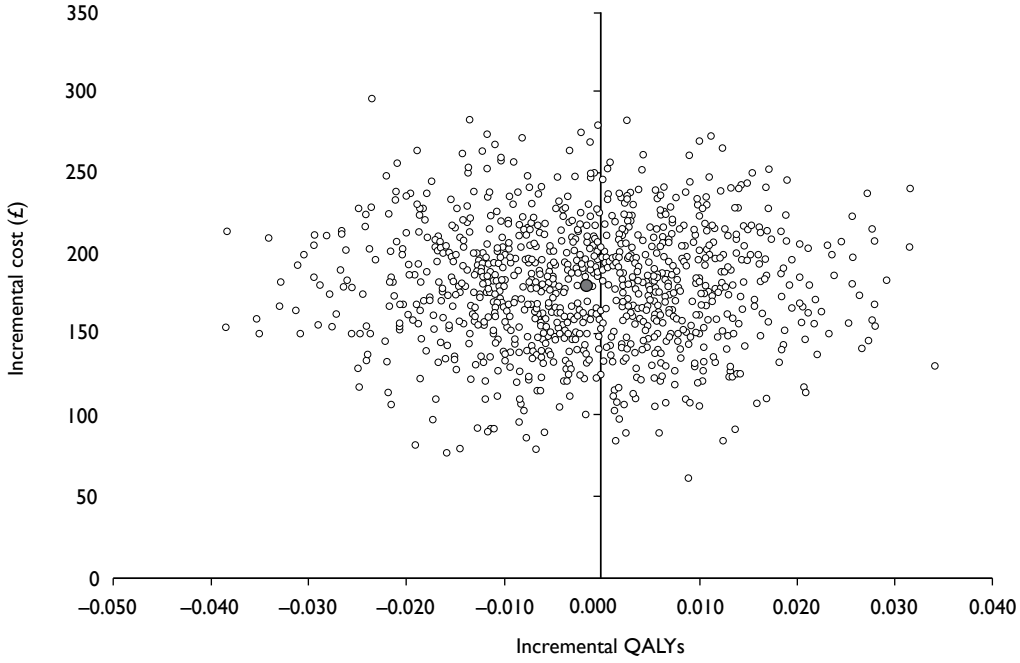

FIGURE 23 Representation of the uncertainty in differential mean costs and QALYs: NHS perspective (radical prostatectomy).

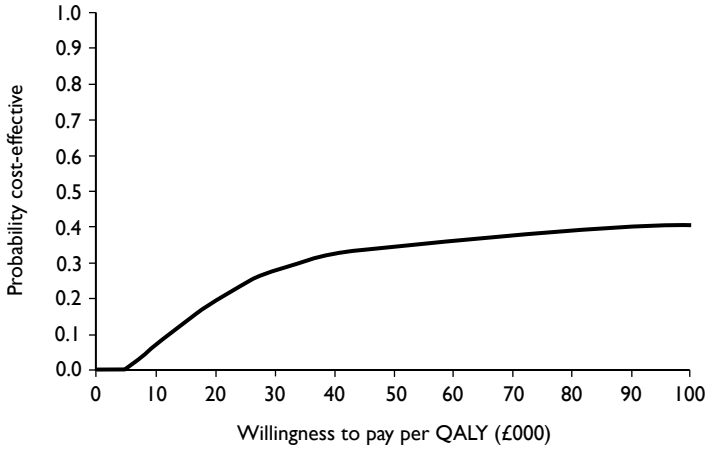

FIGURE 24 Cost-effectiveness acceptability curve for intervention versus control: NHS perspective (radical prostatectomy).

at a threshold of £30,000 per QALY the intervention is 50.2% more likely to be cost-effective (*Figures 25* and *26*).

Basing quality-adjusted life-year estimates on SF-6D values

Table 46 reports the SF-6D scores for each arm of the trial at baseline and 6 and 12 months. These scores were slightly lower than those reported using the EQ-5D. From these data it was estimated that the mean QALYs were 0.80 (SD 0.11, median 0.806) for the intervention arm and 0.79 (SD 0.11, median 0.818) for the control arm. The mean difference in QALYs after adjusting for minimisation and baseline SF-6D scores was 0.005 (95% CI –0.022 to 0.012) higher for the intervention group, which was not statistically significant.

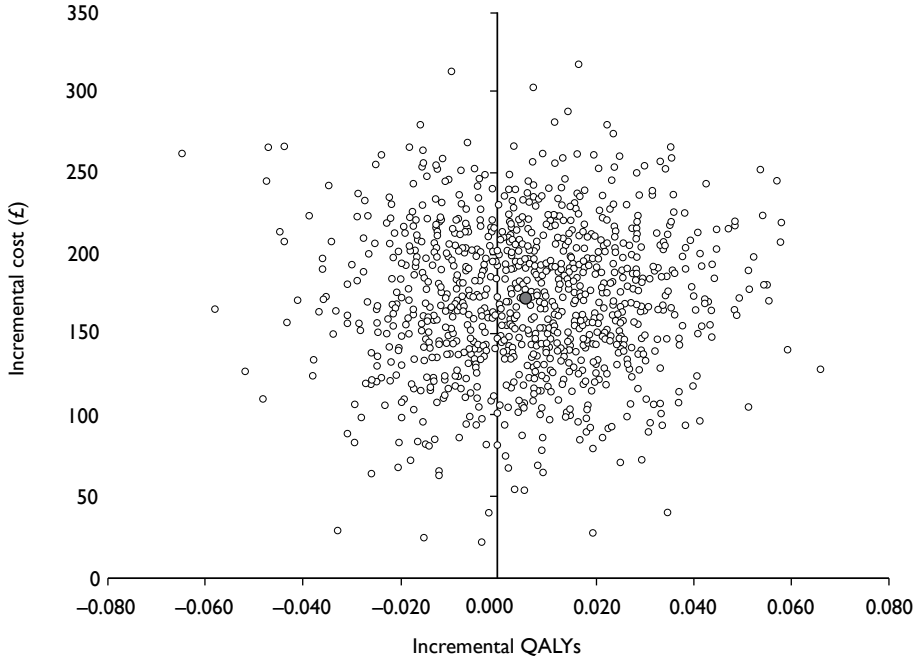

FIGURE 25 Representation of the uncertainty in differential mean costs and QALYs: using unadjusted data (radical prostatectomy).

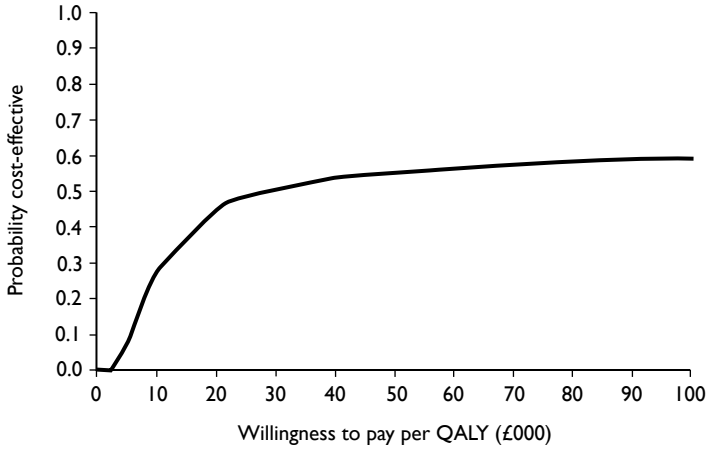

FIGURE 26 Cost-effectiveness acceptability curve for intervention versus control: using unadjusted data (radical prostatectomy).

The results of the analysis using the SF-6D data when estimating incremental cost-effectiveness from the societal perspective were similar to those of the EQ-5D. Taking the mean difference in the total societal costs from *Table 42* (–£588) and the mean difference in QALYs from *Table 46* (–0.005); it can be seen that the intervention is, on average, more effective and less costly (*Table 47*).

At a cost-effectiveness threshold of £20,000 per QALY, the intervention has a likelihood of 85% of being cost-effective, and at a threshold of £30,000 per QALY the intervention is 79.8% likely to be cost-effective (*Figures 27* and *28*). Based on the societal perspective, these estimates indicate that the intervention is likely to be cost-effective. However, as with the base-case analysis, these results

TABLE 46 SF-6D quality of life measures: radical prostatectomy

	Mean (SD)		
	Intervention	Control	Difference (95% CI)[a]
Baseline SF-6D	0.71 (0.12)	0.69 (0.13)	
	n = 201 (98%)	*n* = 200 (97%)	
6-month SF-6D	0.82 (0.14)	0.81 (0.14)	0.012
	n = 188 (92%)	*n* = 189 (92%)	
12-month SF-6D	0.82 (0.13)	0.84 (0.12)	–0.014
	n = 189 (92%)	*n* = 189 (92%)	
QALYs	0.80 (0.11)	0.79 (0.11)	–0.005 (–0.022 to 0.012)
	n = 172 (78%)	*n* = 166 (75%)	

a Differences adjusted for baseline costs.

TABLE 47 Cost-effectiveness results from the societal perspective: radical prostatectomy

Difference in mean NHS costs [mean (95% CI)[a]]	–588.23 (–1329.83 to 153.37)
Differences in QALYs [mean (95% CI)[a]]	–0.005 (–0.022 to 0.012)
ICER (£/QALY)	Organised PFMT is dominant
Probability intervention is cost-effective when threshold is £20,000 per QALY	85.0%
Probability intervention is cost-effective when threshold is £30,000 per QALY	79.8%

a Differences adjusted for baseline costs.

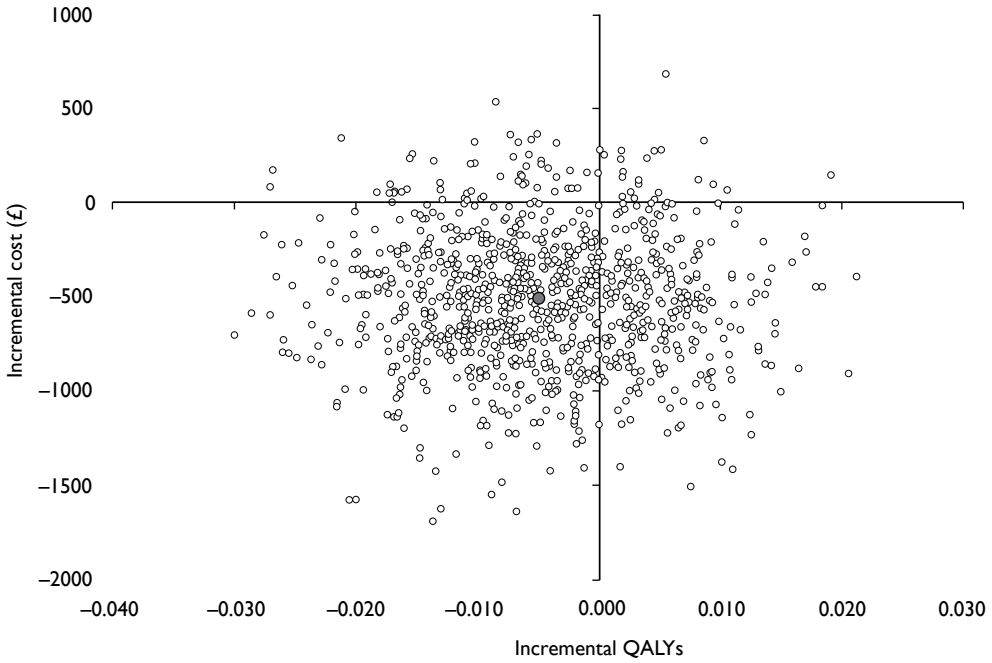

FIGURE 27 Representation of the uncertainty in differential mean costs and QALYs: societal perspective using SF-6D data (radical prostatectomy).

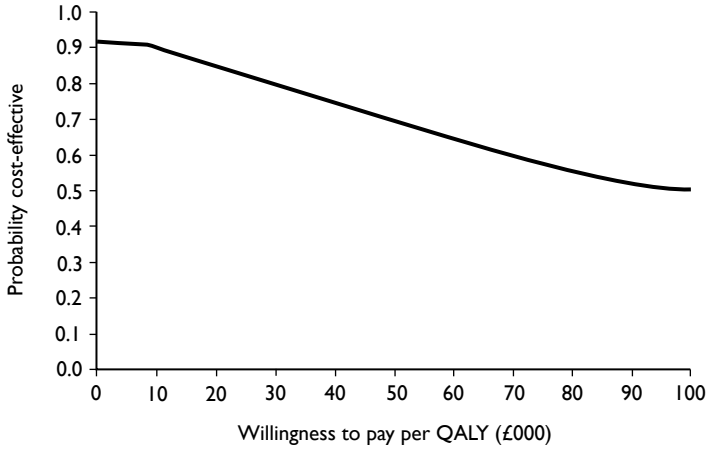

FIGURE 28 Cost-effectiveness acceptability curve for intervention versus control: societal perspective using SF-6D data (radical prostatectomy).

have to be interpreted cautiously as they are driven almost entirely by differences in time away from usual activities for which there is no obvious trial-related explanation.

Taking the mean difference in total NHS costs from *Table 42* and the mean difference in the QALY estimate after adjusting for baseline SF-6D scores from *Table 46*, the mean incremental cost per QALY from the NHS perspective is reduced to £36,204 (*Table 48*).

The probability of the intervention being cost-effective in this analysis was lower than that estimated when using the EQ-5D data. At a cost-effectiveness threshold of £20,000 per QALY the intervention has a probability of 6% of being cost-effective, and at a threshold of £30,000 per QALY the intervention is 11% likely to be cost-effective (*Figures 29* and *30*). At no point does the probability of being cost-effective reach 50%.

Threshold analysis around the cure rates

Further sensitivity analysis was performed by reanalysing the data by patient group for differences in costs and QALYs by continence status. A simple model was used to determine at what reduction in the rate of incontinence in the intervention group compared with the control the physical therapy would be cost-effective. Details of the parameters used in the model are given in *Table 49*.

Figure 31 shows that when the rate of incontinence was reduced below 0.66 in the treatment group (while that of the control group was 0.77), the incremental cost per QALY would reduce to the level that society might be willing to pay. Reductions in the rates of incontinence are consistent with the reported CIs surrounding differences in continence rates. This suggests that, if smaller differences are clinically important, then, should these reductions be achieved, they would be potentially cost-effective.

Conclusions

For men having radical prostatectomy, QALYs were similar in both groups, and the costs of those who received the intervention were higher, but not statistically significantly so, than the costs of those who did not. The costs of the intervention were less than those of the control when the analysis was performed from a societal perspective. However, these results need to be interpreted

TABLE 48 Cost-effectiveness results from the perspective of the NHS: radical prostatectomy

Difference in mean NHS costs [mean (95% CI)[a]]	181.02 (107.06 to 254.97)
Differences in QALYs [mean (95% CI)[a]]	–0.005 (–0.012 to 0.022)
ICER (£/QALY)	36,204
Probability intervention is cost-effective when threshold is £20,000 per QALY	6.0%
Probability intervention is cost-effective when threshold is £30,000 per QALY	11.0%

a Differences adjusted for baseline costs.

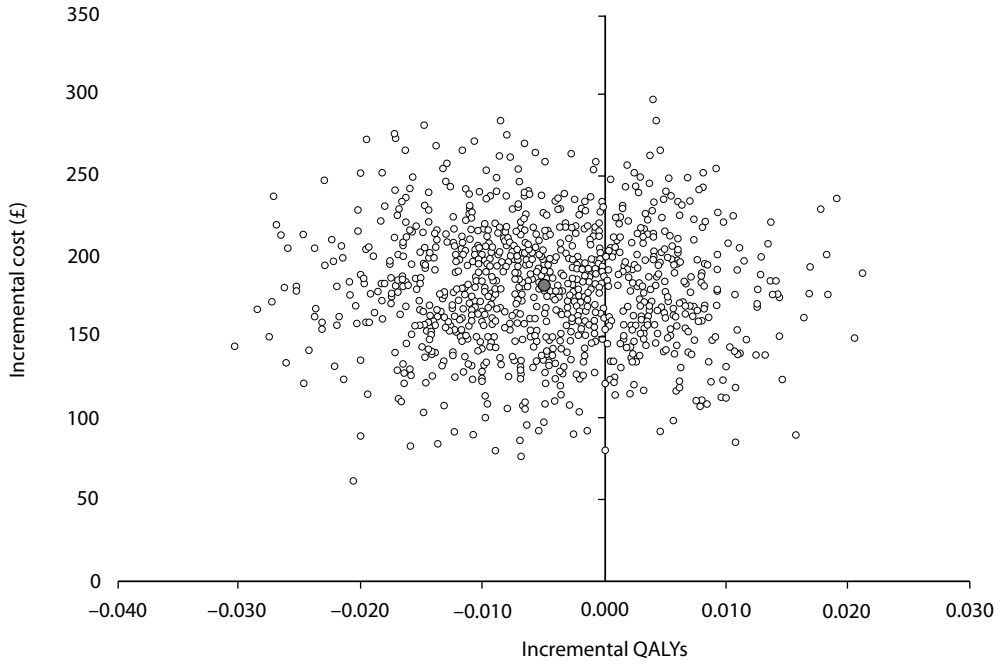

FIGURE 29 Representation of the uncertainty in differential mean costs and QALYs: NHS perspective using SF-6D data (radical prostatectomy).

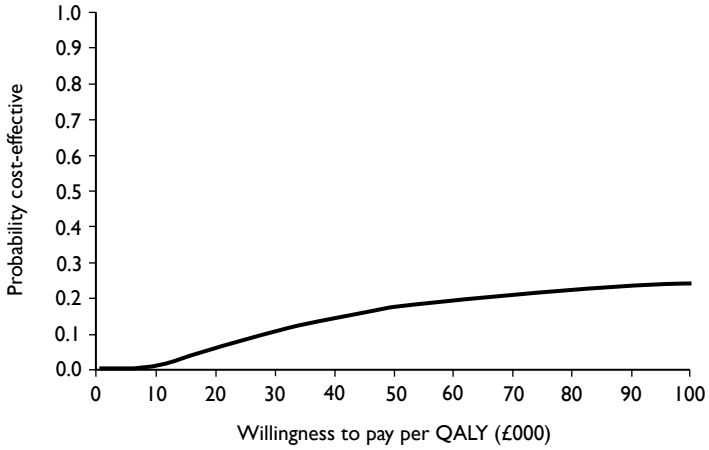

FIGURE 30 Cost-effectiveness acceptability curve for intervention versus control: NHS perspective using SF-6D data (radical prostatectomy).

TABLE 49 Data used in analysis based on random allocation and state of incontinence at 12 months: radical prostatectomy

Parameter	Participants in intervention group who were continent	Participants in intervention group who were incontinent	Participants in control group who were continent	Participants in control group who were incontinent
Cost of intervention (£)	196.34 (223.00) [66.82]	204.56 (223.00) [56.00]	0.00 (0.00) [0.00]	0.00 (0.00) [0.00]
Total subsequent resource use costs (£)	291.17 (239.19) [209.46]	518.59 (365.39) [485.15]	253.63 (214.21) [174.01]	291.17 (239.19) [209.46]
Total NHS costs (£)	487.51 (442.09) [212.57]	723.16 (565.42) [495.26]	253.63 (214.21) [174.01]	291.17 (239.19) [209.46]
QALY	0.92 (0.95) [0.08]	0.84 (0.92) [0.21]	0.91 (0.94) [0.10]	0.84 (0.89) [0.18]
Probability of being continent/ incontinent			0.23	0.77
Relative risk of being incontinent	0.85–1	0.85–1		

Figures are mean (SD) [median].

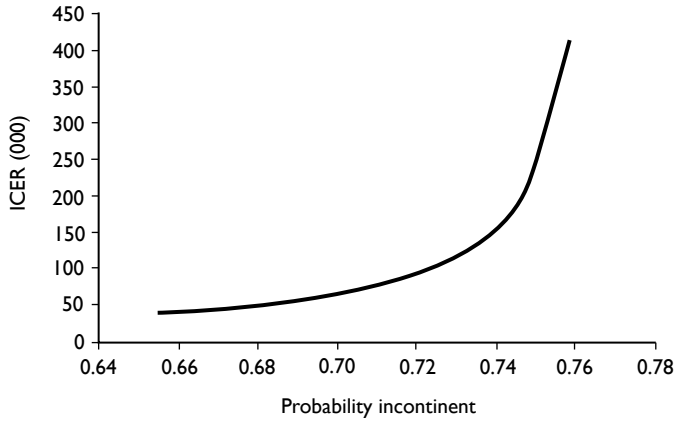

FIGURE 31 Probability that intervention is likely to be cost-effective: radical prostatectomy.

cautiously as they were largely influenced by the number of days that the participants said they were off work. The results of the analysis performed from the NHS perspective had lower costs for the control group, as anticipated. The cost-effectiveness results from a societal perspective favoured the intervention, and those from the NHS perspective favoured the control.

The model-based sensitivity analysis showed that a reduction in continence rates that is consistent with the CIs surrounding the relative risk of incontinence between treatment and control might be cost-effective. A judgement is required whether the smaller differences in incontinence are clinically significant. If they are, then a further judgement is required whether a larger trial would be worthwhile to identify these differences.

Chapter 9

Discussion of results of randomised controlled trial after radical prostatectomy

This chapter summarises the discussions relating to the radical prostatectomy RCT.

Summary of main findings

In the men who had a radical prostatectomy, there were no statistically significant differences in urinary, bowel or sexual function outcomes between the intervention and control groups, despite evidence of extra performance of PFMT and improvement in pelvic floor muscle strength over time in the intervention group. The estimated additional cost to the NHS was on average £181 (95% CI £107 to £255) higher in the intervention group than in the control group.

Recruitment and screening of men in hospital

We approached 1158 men having a radical prostatectomy in NHS hospitals and obtained consent to screen 804 of these men. Of those, 95% returned their screening survey, and over 90% of the responders were incontinent of urine at about 6 weeks after surgery (see *Table 13*). This prevalence was similar to that found by Kao *et al.* (82% in 1013 men).[9] The majority of the men (around 80%) had a traditional open retropubic radical prostatectomy, and around 55% had a procedure in which one or both nerve bundles were spared. Only 6% of the men had urinary incontinence before surgery, and 2% reported faecal incontinence (see *Table 13*). The average age of the men was 62 years.

Recruitment to randomised controlled trial and response rates

Of the 742 men who were incontinent at screening, 411 agreed to be randomised to a controlled trial of conservative treatment (PFMT and lifestyle advice) for urinary incontinence (205 in the intervention group and 206 in the control group). The groups were comparable at baseline on all the epidemiological and clinical characteristics measured (see *Table 14*). Almost all of the men had heard of pelvic floor exercises at some time prior to randomisation (see *Table 15*).

Conduct of the intervention

Compliance (attendance at therapy visits) with the intervention was high, with 92% of the men allocated to the intervention group attending at least one therapy visit and 85% attending all four of them. The most common reasons for not attending were becoming dry and finding it inconvenient to attend.

Association with type of therapist

Half of the centres used physiotherapists as the provider of the intervention, while the rest used nurse therapists (although all therapists received the same standardised training). About 40% of the men attended a physiotherapist while 60% attended a nurse therapist. However, there were no significant differences in the number of visits or the chance of urinary incontinence during the treatment period according to type of therapist (see *Table 19*).

At follow-up, no statistically significant association was demonstrated between the chance of incontinence at 12 months and type of therapist (see *Figure 20*).

Clinical symptoms during the therapy period

During the therapy period, the proportion of men with incontinence fell from 92% to 73% by the fourth visit (see *Table 20* and *Figure 7*). Few men reported bowel problems, and these numbers did not vary much over time (see *Table 22* and *Figure 9*). Around 90% of the men had problems with sexual function and these did not decrease with time (see *Table 23* and *Figure 10*).

Clinical findings during the therapy period

Anal sphincter and pelvic floor muscle contraction strength increased over time in the intervention group: 40% of men rated their strength as good or better at the beginning of the therapy period, rising to 85% by the fourth visit (see *Table 24* and *Figure 11*). However, around 15% still had only moderate or poor contraction strength at the end of the 3-month therapy period.

Machine-led biofeedback was available in only 13 of the 34 MAPS centres (see *Table 7*), and was used clinically in only five centres in 16 men (see *Table 25*). It was not clear whether this was for diagnosis or for repeated use to assist with training. However, almost all men had verbal biofeedback from their therapist following digital anal assessment of muscle contraction, to teach them to perform contractions correctly and to monitor improvement at each successive visit.

Practice of pelvic floor muscle training after end of therapy period

While over 80% of men in both the intervention and the control groups were practising PFMT at baseline (before they were randomised and before the intervention), this fell to 67% in the intervention group and 50% in the control group at the 12-month follow-up.

Findings of the randomised controlled trial

The primary outcome of the RCT was the proportion of men with urinary incontinence at 12 months after randomisation. This was measured using the ICI-SF questionnaire, and was also ascertained at 3, 6 and 9 months after randomisation. In addition, urinary outcomes were obtained from 3-day diaries completed by the men at each of these time points. The response rates were over 95% for the questionnaires and over 80% for the diaries (see *Table 27*).

Urinary outcomes

While the proportion of men with urinary incontinence fell from 100% at baseline to around 75% by 12 months, the majority of the decrease occurred in the first 3 months (to around 87%) with a further fall (to 80%) at 6 months. There was no statistically significant difference in the proportion of men with urinary incontinence between the intervention and control group at 12 months [75.5% vs 77.4%, absolute risk difference –1.9% (95% CI –10% to 6%) (see *Table 28*) or at any other time point (see *Table 29* and *Figure 14*)].

These findings (of no statistically significant differences between the trial groups) were similar for all the urinary outcomes regardless of how (by questionnaire or diary) or when they were measured (see *Table 29*).

Severity of incontinence

If severe incontinence is defined as incontinence at least once a day and a moderate or large amount of leakage, around 40% of the men were still experiencing severe leakage at 12 months (see *Table 29a*) and 40% were also using pads (see *Table 31a*). Using the ICI score as a composite measure of severity and effect on quality of life, the same picture emerged: the majority of the

improvement (decrease) in the score occurred in the first 3 months after randomisation with a further small improvement at 6 months (see *Table 29* and *Figure 15*).

Types of incontinence

The most common type of incontinence was SUI (around 70%; see *Table 30*), while UUI and MUI affected around 40% of men. The prevalence of these and the other types of urinary symptoms was no different between the randomised groups (see *Table 30* and *Figure 16*).

Subgroup analyses

Prespecified subgroup analyses were carried out on the primary outcome (urinary incontinence at 12 months). There were no significant differences between randomised groups in any of the subgroups (see *Figure 20*).

Other clinical outcomes

Men were also asked to report on bowel and sexual problems.

Bowel outcomes

Bowel problems that might be expected to be ameliorated by therapy or lifestyle advice included faecal incontinence, urgency and constipation. Men were also asked about bowel conditions such as ulcerative colitis, Crohn's disease and irritable bowel syndrome. There were no differences at any time point in any aspect of bowel function or disease between the men in the randomised groups (see *Table 32* and *Figure 17*).

Sexual function outcomes

Over 90% of men had normal erectile function before operation. Although around one-third had an active sex life at 12 months, the majority said that this was worse than before their operation (see *Table 33*). There were, however, no differences at 12 months according to the randomised groups in any of the aspects of sexual function measured (see *Tables 33* and *34*). Even at 12 months, 82% of intervention group men and 78% of control group men reported severely reduced or no erectile function (see *Table 34* and *Figure 18*). Neither were there differences between the groups in the proportions of men with an active sex life [RR 0.94 (95% CI 0.73 to 1.22); $p = 0.661$] or the proportions of men whose sex life had become worse after the operation [RR 0.79 (0.47 to 1.34); $p = 0.391$; see *Table 33*].

Over half of the men had used a vacuum device or medication to improve sexual function (see *Table 34*). NICE guidelines[17] suggest that phosphodiesterase type 5 (PDE5) inhibitors could be offered to men who experience loss of erectile function. If PDE5 inhibitors fail or are contraindicated, men could be offered vacuum devices, intraurethral inserts, penile injections or prostheses.

Quality of life outcomes

General health outcomes were measured using the EQ-5D and SF-12 (the latter subdivided into role – mental and role – physical scores). The slight increase in the scores over time can be assumed to represent recovery from operation, but there were no differences between the randomised groups at any time point in EQ-5D or SF-12 scores (see *Table 35* and *Figure 19*).

Knowledge of pelvic floor muscle training in trial groups before intervention

Nearly all of the men in both groups (97% and 99% respectively) had received information about the use of pelvic floor exercises before starting the trial intervention (see *Table 15*). The most common sources were from nurses or continence advisors (over 70%), or from leaflets or books (around 65%; see *Table 15*).

Practice of pelvic floor muscle training in intervention and control groups

It is not surprising, given the prior knowledge of pelvic floor exercises, that over 80% of men in both groups reported carrying out some exercises before randomisation (see *Table 36*). However, by 6 months the men in the intervention group were more likely to be still carrying them out and this difference persisted at the 12-month follow-up (see *Table 36*).

Changes in lifestyle factors

Men in both groups were given written information about lifestyle changes that might improve aspects of both their general health and incontinence. In the intervention group, this advice was reinforced and individualised by the therapists. However, there were no significant differences in the uptake of any aspect of this advice at 12 months after randomisation (see *Tables 37* and *38*).

Economic outcomes

Costs to the NHS

Total costs to the NHS were on average £181 (95% CI £107 to £255) higher in the intervention group than in the control group. This difference was entirely due to the cost of providing the PFMT training in the intervention group. The use of other health services, and hence cost, was, on average, slightly lower in the control group, but this difference was not statistically significant.

Costs to the participants

Costs to the participants related to three broad elements: (i) the cost of private health care; (ii) the cost of accessing NHS care (in terms of time and out-of-pocket expenses); and (iii) the cost of time away from usual activities. On average, the costs of any private health care used were low and there was no evidence of any difference between groups. Similarly, the costs of accessing care other than the intervention were similar for the two groups. However, participants in the control arm appeared, on average, to have more days away from usual activities than participants in the intervention arm [mean difference –6.54 days (95% CI –13.08 days to –0.01 days)]. The mean cost of time away from usual activities was approximately £809 for the intervention group and £1614 for the control group. Given the assumptions made about valuing time away from usual activities, this difference was the key determinant of the differences in average total participant costs. It is not clear why there would be fewer days away from usual activities in the intervention group, given the lack of evidence for any treatment effect. Therefore, as these data are counterintuitive, they should be treated cautiously.

Overall costs to the NHS and participants

On average, the cost to the NHS and participants was £588 [–£1330 to £153] greater in the control group than in the intervention group. Although not statistically significant, the direction of effect was the result of differences in the mean time away from usual activities.

Quality-adjusted life-years

On average, QALYs were virtually identical in both the intervention and the control group [on average, QALYs were 0.002 higher in the intervention group (95% CI –0.027 to 0.023)].

Cost-effectiveness from the perspective of the NHS and participants

Based upon the point estimates of the mean difference in costs and QALYs the intervention is dominant. The point estimates are associated with considerable imprecision, so the probability that the intervention would be considered cost-effective at typical thresholds for society's willingness to pay for a QALY were calculated (see *Figure 22*). This analysis suggested that there was over an 80% chance that organised PFMT training was cost-effective. As noted above, this result was almost entirely driven by the differences in days away from usual activities, and therefore should be treated with caution.

Cost-effectiveness from the perspective of the NHS

When the perspective of the economic evaluation was restricted to the NHS, the point estimate of the incremental cost per QALY was effectively dominated. Furthermore, there was less than a 20% chance that the intervention would be cost-effective should the threshold value for society's willingness to pay for a QALY be £20,000.

Sensitivity analyses

The majority of the sensitivity analyses conducted did not greatly alter the conclusions of the economic evaluation. In one sensitivity analysis, conducted from the perspective of the NHS, the reduction in the rate of incontinence that would make the intervention cost-effective was estimated. The results of this analysis suggested that, should the intervention reduce the rate of incontinence by approximately 10%, then the provision of physical therapy could be cost-effective. This difference is similar to the lower end of the CIs surrounding the risk difference in incontinence rates. However, the trial was of sufficient size to rule out any but a small chance that this difference could exist.

Strengths and weaknesses (specific to the radical prostatectomy randomised controlled trial)

Recruitment

We approached 1158 men who were admitted to hospital for radical prostate surgery in order to identify and recruit our final population of 411 men who entered the RCT. Many of the men approached were ineligible or missed in hospital (354 men; see *Table 9a*) and 24 were subsequently found to be ineligible (see *Table 10a*). This scale of recruitment represented a large burden on the recruitment officers in the centres. However, we felt that this was the most efficient way of identifying our target population, which was men who had urinary incontinence after prostate surgery. Other methods, such as expecting local staff to identify incontinent men and recruit them to the RCT directly, might have been too burdensome and risked missing many men owing to pressure of routine work.

Generalisability of the trial population

Most of the men who agreed, when in hospital, to be screened 3 weeks later returned their screening questionnaire (742/780, 95%; *Table 12*). There were no significant differences in demographic or clinical characteristics when non-responders were compared with responders. Just over half (411/742, 55%) of the men who returned a screening questionnaire were eventually recruited into the RCT. Many of the remainder had become dry [53 (7%) at screening, 61 (8%) at baseline], and a further 125 (17%) were not eligible because they did not return their baseline questionnaire (see *Figure 4* and *Table 11*). Of the 92 not accounted for, 26 (4%) declined further contact, 15 (2%) did not wish to be randomised, and the remainder had a variety of other reasons for not wishing to enter the trial (see *Table 11*). A further 18 (2%) were excluded after randomisation. Thus, our trial population represented 411/472 (87%) of the men who were incontinent and eligible to be randomised, but only 411/780 (53%) of men identified in hospital as having radical prostate surgery.

Response rates

Once randomised, participants were compliant in returning their questionnaires (over 90%) and urinary diaries (over 80%), while the withdrawal rates were very low. There was no evidence of differential dropout from the randomised groups, with outcome data available for 98% (intervention) and 97% (control) of the men continuing at 12 months (see *Table 27a*). This provides some reassurance that the outcome data are representative of the men in the RCT, and that bias from differential attrition was minimal.

Strengths and weaknesses of the economic analyses

The methods of the economic analysis were rigorous and reproducible, and efforts were made to assess the importance of uncertainty surrounding estimates of costs, effects and cost-effectiveness. As the study was not powered to detect differences in economic outcomes, it was anticipated that differences in costs and effects would not reach statistical significance. For this reason, conclusions from the economic evaluation were based upon the consideration of the balance of probabilities.

The conclusions from the economic analysis are sensitive to the perspective taken. When the perspective was the NHS, it was unlikely that the intervention would be cost-effective. When the perspective was widened to the NHS and patients, there was over an 80% chance that the intervention would be cost-effective. The main driver of this difference in the conclusions was the trend towards more time away from usual activities in the control group. It is not clear whether this trend was real or not, given the lack of any meaningful trends in either health or use of health services. Therefore, the conclusion drawn on the basis of the NHS and patient perspective should be treated with caution.

Chapter 10

Transurethral resection of the prostate: derivation and description of participants

This chapter describes the men derived from the screening survey in terms of their clinical characteristics and presents the baseline comparability between the randomised groups in the TURP group.

Comparison between those responding and not responding to the screening survey

Table 50 shows the comparability at baseline of those responding and not responding to the screening survey in terms of their demographic and clinical characteristics. There were no clinically important differences between responders and non-responders. The majority were standard TURPs, but 5% were laser TURPs, 15 were open abdominal procedures and two were transvesical. A further 16 men were all originally admitted for TURP but were subsequently found to need a different procedure. They were not randomised or followed up in MAPS.

Findings from screening survey

The average time of completion of the screening survey was at around 5 weeks after surgery [mean days since operation 34.4 (SD 18.8)]. The majority of the men had a standard TURP, but laser was used for ablation in about 5%: this did not affect the chance of subsequent incontinence. Just under half of the men had urinary incontinence at the time of screening, and the most common type was UUI (*Table 51*).

TABLE 50 Screening survey responders and non-responders

TURP	Responder	Non-responder
Number screened [*n*/*N* (%)]	2590/2836 (91)	246/2836 (9))
Age [mean years (SD) *n*]	69.9 (8.2) 2578	70.6 (9.0) 246
Weight [mean kg (SD) *n*]	81.9 (31.4) 2399	81.5 (15.0) 222
Height [mean cm (SD) *n*]	172.6 (14.0) 2226	171.6 (22.0) 213
Current smoker [*n*/*N* (%)]	285/2590 (11)	44/246 (18)
Nights in hospital [mean (SD) *n*]	3.8 (2.2) 2457	4.2 (2.6) 231
Type of operation[c]	*n* = 2587	*n* = 241
Standard TURP [*n*/*N* (%)][a]	2431/2588 (94.0)	224/246 (93.1)
Laser TURP [*n*/*N* (%)]	140/2588 (5.4)	12/246 (4.9)
No TURP (had other procedure) [*n*/*N* (%)][b]	16/2588 (0.6)	5/246 (2.0)

a Seventeen of the prostatectomies were carried out as open simple retropubic (*n* = 15) or transvesical (*n* = 2) procedures.
b The other procedures included BNI, cystoscopy, cystolithopaxy, circumcision and urethral dilatation. One man had a subcapsular orchidectomy. These men were all originally admitted for TURP but were subsequently found to need the other procedure.
c Data on type of operation missing for 10 men.

TABLE 51 Results of screening survey 3 weeks after operation (responders to screening questionnaire who had TURP only, *N* = 2587)

TURP	All responders to screening questionnaire (*n* = 2587)	Standard TURP (*n* = 2431)	Laser TURP (*n* = 140)	No TURP (*n* = 16)
Days since operation [mean (SD) *n*]	34.4 (18.8) 2518	34.1 (19.1) 2368	32.7 (12.5) 134	34.1 (9.8) 13
Number of men with any urine loss at screening questionnaire	1203/2585 (47)	1129/2433 (46)	66/140 (47)	6/16 (38)
ICI-QoL score due to UI [mean (SD) *n*][a]	1.3 (2.4) 2414	1.3 (2.4) 2269	1.5 (2.7) 129	0.9 (2.0) 16
ICI-Q score [mean (SD) *n*][b]	3.42 (4.7) 2568	3.4 (4.7) 2415	3.7 (4.9) 137	2.6 (3.9) 16
Number of men with urine loss before surgery	883/2588 (36)	839/2432 (37)	38/140 (29)	6/16 (43)
Number of men with faecal incontinence after surgery	112/2585 (4)	105/2433 (4)	7/140 (5)	1/16 (6)
Type of incontinence				
SUI	303/2585 (12)	292/2433 (12)	11/140 (8)	1/16 (6)
UUI	733/2585 (28)	697/2433 (29)	36/140 (26)	1/16 (6)
MUI	135/2585 (5)	131/2433 (5)	5/140 (4)	0
Postmicturition leakage	446/2585 (17)	413/2433 (17)	29/140 (21)	4/16 (25)
Other incontinence	295/2585 (11)	270/2433 (11)	24/140 (17)	1/16 (6)

Figures are *n*/*N* (%), unless stated otherwise.
a ICI-QoL score: 0 = none, 10 = maximum (worst) score. Derived from question 3 of the ICIQ-UI Short Form Questionnaire.
b ICI-Q score: 0 = none, 21 = maximum (worst) score. Derived from questions 1–3 of the ICIQ-UI Short Form Questionnaire.

Summary information for progress from screening questionnaire to randomisation

Of 1203 men wet at screening, 155 were not eligible to be sent a baseline questionnaire (see *Table 11* for reasons). Of the 1048 men sent a baseline questionnaire, 786 (75%) responded, of whom 512 (89%) were still wet and 274 dry. A further 70 were excluded as they were ineligible for randomisation despite still being incontinent (see *Table 11* for reasons). Finally, 442 men were randomised, 220 in the intervention group and 222 in the control group (see *Figure 5*).

Men who recorded that they were wet at the screening survey were sent a further baseline questionnaire to confirm persistent leakage. Those who were still wet and consented were randomised to intervention or control. The average time to randomisation from the date of surgery was 8 weeks (mean 8.4, SD 3.4).

Comparability on baseline characteristics at trial entry

Table 52 shows that the men in the two randomised groups were comparable at baseline on the clinical and demographic characteristics recorded.

Prior knowledge of pelvic floor exercises

Many men had been counselled before surgery about the possibility of urinary incontinence and sexual dysfunction after surgery, although this was less common in the men undergoing TURP than in those undergoing radical surgery.[69] *Table 53* shows that the most common sources of information about pelvic floor exercises were leaflets or books or nurses or continence advisors: around 80% of men had some prior knowledge of pelvic floor exercises for these problems.

TABLE 52 Baseline comparability at trial entry between men in randomised groups

TURP	Intervention ($n=220$)	Control ($n=222$)
Age in years [mean (SD) *n*, (min–max)]	68.2 (7.7) 220, (47–90)	67.9 (8.1) 222, (45–86)
BMI (kg/m^2) [mean (SD) *n*, (min–max)]	27.1 (4.1) 217, (15–48)	27.1 (4.7) 215, (17–44)
Type of operation	220	222
Standard TURP	199/220 (90)	199/222 (90)
Laser TURP	10/220 (5)	15/222 (7)
TURP + other procedure	11/220 (5)	8/222 (4)
TURP before surgery	23/217 (11)	26/218 (12)
Number of men not able to achieve erection before prostate surgery	67/214 (31)	71/215 (33)
Leakage of urine before operation	95/195 (49)	102/205 (50)
ICI-Q score[a] at baseline [mean (SD) *n*, (0–21 max)]	8.6 (4.1) 219	8.7 (4.3) 222
Number of men with severe incontinence at baseline[b]	145/220 (66)	144/222 (65)
Urinary frequency at baseline (per day) [mean (SD) *n*]	8.6 (5.2) 205	7.9 (3.1) 199
Nocturia at baseline (per night) [mean (SD) *n*]	2.7 (1.6) 215	2.5 (1.5) 212
Type of incontinence	220	222
SUI	148/220 (67)	136/222 (61)
UUI	186/220 (85)	183/222 (82)
MUI (both)	129/220 (59)	112/222 (50)
Postmicturition leakage	151/220 (69)	156/222 (70)
Other incontinence	57/220 (26)	44/222 (20)
Pad use	71/220 (32)	70/217 (32)
Other health problems	138/220 (63)	145/222 (65)
EQ-5D [mean (SD) *n*]	0.8 (0.3) 213	0.8 (0.3) 208
SF-12M [mean (SD) *n*]	49.9 (10.4) 216	50.3 (10.4) 212
SF-12P [mean (SD) *n*]	42.7 (11.0) 216	43.2 (11.9) 212

Numbers as reported. Figures are *n*/*N* (%), unless stated otherwise.
a ICI-Q score: 0 = none to 21 = maximum (worst) score.
b Severe incontinence defined as at least once a day *and* a moderate or large amount of leakage.

TABLE 53 Number of men with prior knowledge of pelvic floor exercises

Source of information	Intervention	Control
A doctor	13/106 (12)	13/119 (11)
A nurse/continence advisor	34/106 (32)	40/119 (34)
A physiotherapist	6/106 (6)	5/119 (4)
Leaflets or books	46/106 (43)	54/119 (45)
The internet	2/106 (2)	7/119 (6)
Friends or family	18/106 (17)	16/119 (13)
Another source	10/106 (9)	6/119 (5)
At least one source of information	94/106 (89)	89/119 (75)

Figures are *n*/*N* (%) answering yes. Respondents could cite more than one source of information.

Chapter 11

Transurethral resection of the prostate: management received

This chapter describes how the intervention was implemented in the therapy arm of the TURP RCT, and the progress of men through the intervention period ($n = 220$). The information in this chapter is derived from the therapy documentation (see *Appendix 4.1*), which was used primarily to guide the therapists while delivering the standardised intervention.

Compliance with therapy

Of the 220 men who were randomised to the intervention, 189 attended at least one visit (86%), and 72% attended every time (*Table 54*). The non-attenders were slightly older and lighter, although these differences were not clinically important (*Table 55*). Only 7 of the 31 men who did not attend were dry. The other main reasons were that, after they were allocated to therapy, four men became ill and six men found it to be inconvenient or impossible to attend appointments, often because of work. The remainder simply declined or did not give a specific reason (*Table 56*).

Relationship between type of therapist and outcomes during therapy period

Half of the centres (17) used a physiotherapist to deliver the MAPS intervention, while in the other 17 the therapist had a nursing background (*Table 57*). There was no significant difference in the number of visits men made to physiotherapist or nurse therapists (*Table 57*). During the 3-month intervention period, there were no statistically significant differences in the mean ICI scores (a composite score reflecting urinary incontinence and its effect on quality of life) between therapists (*Table 57*).

TABLE 54 Number of visits attended

TURP	First visit	Second visit	Third visit	Fourth visit
Number of men attending	189 (86%)	173 (79%)	163 (74%)	158 (72%)

TABLE 55 Number of non-attenders/attenders, comparability on age and BMI

TURP	Attenders	Non-attenders
Age [mean years (SD) *n*]	68.0 (7.9) 189	69.2 (6.9) 31
BMI [mean kg/m^2 (SD) *n*]	27.2 (4.1) 187	26.3 (4.5) 30

Urinary incontinence during therapy period

Incidence of urinary incontinence

The therapists asked the men at each visit to rate their incontinence (in the previous week). This allowed the therapists to monitor the change in reported incontinence. They used the same form of question as the questionnaires, based on the ICI-SF instrument, which were also used to measure the primary outcome. During the 3-month intervention period, the proportion of men with incontinence fell from 82% to 52%, while the mean ICI score decreased (improved) from around 6.5 at the start of treatment to 3 afterwards (*Table 58* and *Figure 32*).

Type of urinary incontinence during therapy period

The distribution of type of incontinence reported by the men did not vary with time across the therapy visits, except that the proportion with SUI decreased slightly (from 36% to 21%), the proportion with UUI decreased (from 57% to 20%) and the proportion with postmicturition leakage decreased (from 57% to 33%) (*Figure 33* and *Table 59*).

TABLE 56 Reasons for non-compliance (not attending any visits at all) ($n = 31$)

TURP	Non-attenders (*n*)
Dry	7
Ill	4
Unable to attend	6
Declined	9
No reason given	5
Total	31

TABLE 57 Relationship between type of therapist and attendance rates (mean number of attendances) and effect on incontinence rates (composite ICI score)

TURP	Physiotherapist	Continence nurse	Significance [mean difference (95% CI), *p*-value
Number of attendances	3.1 (1.5) 111, (2.8 to 3.4)	3.1 (1.5) 109, (2.8 to 3.4)	0.02 (–0.4 to 0.4), 0.901
ICI-Q score			
Visit 1	6.7 (4.7) 95, (5.7 to 7.7)	6.4 (3.7) 94, (5.6 to 7.1)	0.3 (–0.9 to 1.5), 0.602
Visit 2	5.0 (3.8) 87, (4.2 to 5.8)	4.5 (3.9) 86, (3.6 to 5.3)	0.5 (–0.7 to 1.7), 0.387
Visit 3	4.3 (3.6) 82, (2.7 to 4.3)	3.8 (3.5) 81, (3.0 to 4.6)	–0.2 (–1.3 to 0.9), 0.691
Visit 4	2.9 (3.9) 81, (2.0 to 3.8)	3.1 (3.3) 77, (2.3 to 3.8)	–0.2 (–1.3 to 1.0), 0.775

Figures are mean (SD) *n*, (95% CI), unless shown otherwise.
ICI-Q score: 0 = none, 21 = maximum (worst) score. Derived from questions 1–3 of the ICIQ-UI Short Form Questionnaire.

TABLE 58 Number of men incontinent at each time point, and mean ICI score at each clinic visit

TURP	Visit 1	Visit 2	Visit 3	Visit 4
Men incontinent [*n*/*N* (%)]	154/188 (82)	118/172 (69)	97/162 (60)	82/157 (52)
ICI-Q score [mean (SD) *n*]	6.5 (4.23) 189	4.8 (3.87) 173	3.7 (3.53) 163	3.0 (3.58) 158

ICI-Q score: 0 = none, 21 = maximum (worst) score. Derived from questions 1–3 of the ICIQ-UI Short Form Questionnaire.

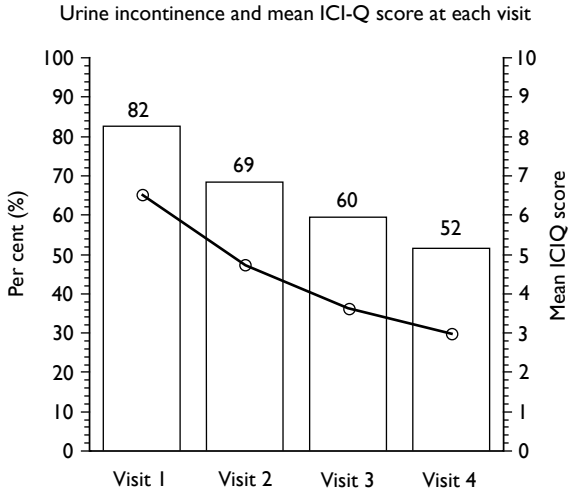

FIGURE 32 Trend analysis of the proportion (%) men incontinent at each visit: TURP. ICI-Q score: 0 = none, 21 = maximum (worst) score. Derived from questions 1–3 of the ICIQ-UI Short Form Questionnaire.

TABLE 59 Type of incontinence at each visit and change over time

TURP	Visit 1	Visit 2	Visit 3	Visit 4
Number of men	189	173	163	158
SUI	59/162 (36)	50/151 (33)	42/146 (29)	28/134 (21)
UUI	95/166 (57)	47/150 (31)	38/144 (26)	27/135 (20)
MUI (both SUI and UUI)	34/170 (20)	15/155(10)	9/148 (6)	5/138 (4)
Postmicturition leakage	97/171 (57)	67/154 (44)	52/144 (36)	45/136 (33)
Other UI	28/146 (19)	22/131 (17)	24/123 (20)	21/127 (17)

Figures are *n*/*N* (%).

Incidence and type of bowel problems during therapy period

Therapists also enquired at each visit about whether the men experienced any bowel dysfunction in the previous week. The proportions of men with three different types of bowel dysfunction (faecal incontinence, faecal urgency and constipation) were low and did not vary during the therapy period (*Table 60* and *Figure 34*).

Incidence and type of sexual problems during therapy period

The questions relating to sexual problems were those used in routine clinical practice. They were not based on the questions men were asked at 12 months to assess their sexual function and activity[70] (see section G, 12-month questionnaire, *Appendix 3.3*).

Just over half of the men reported sexual dysfunction ('difficulty gaining or maintaining an erection in the last week') (52–62%) and this did not change during the therapy period. The corresponding proportion with premature ejaculation was low (around 6%) and also did not vary with time (*Table 61* and *Figure 35*).

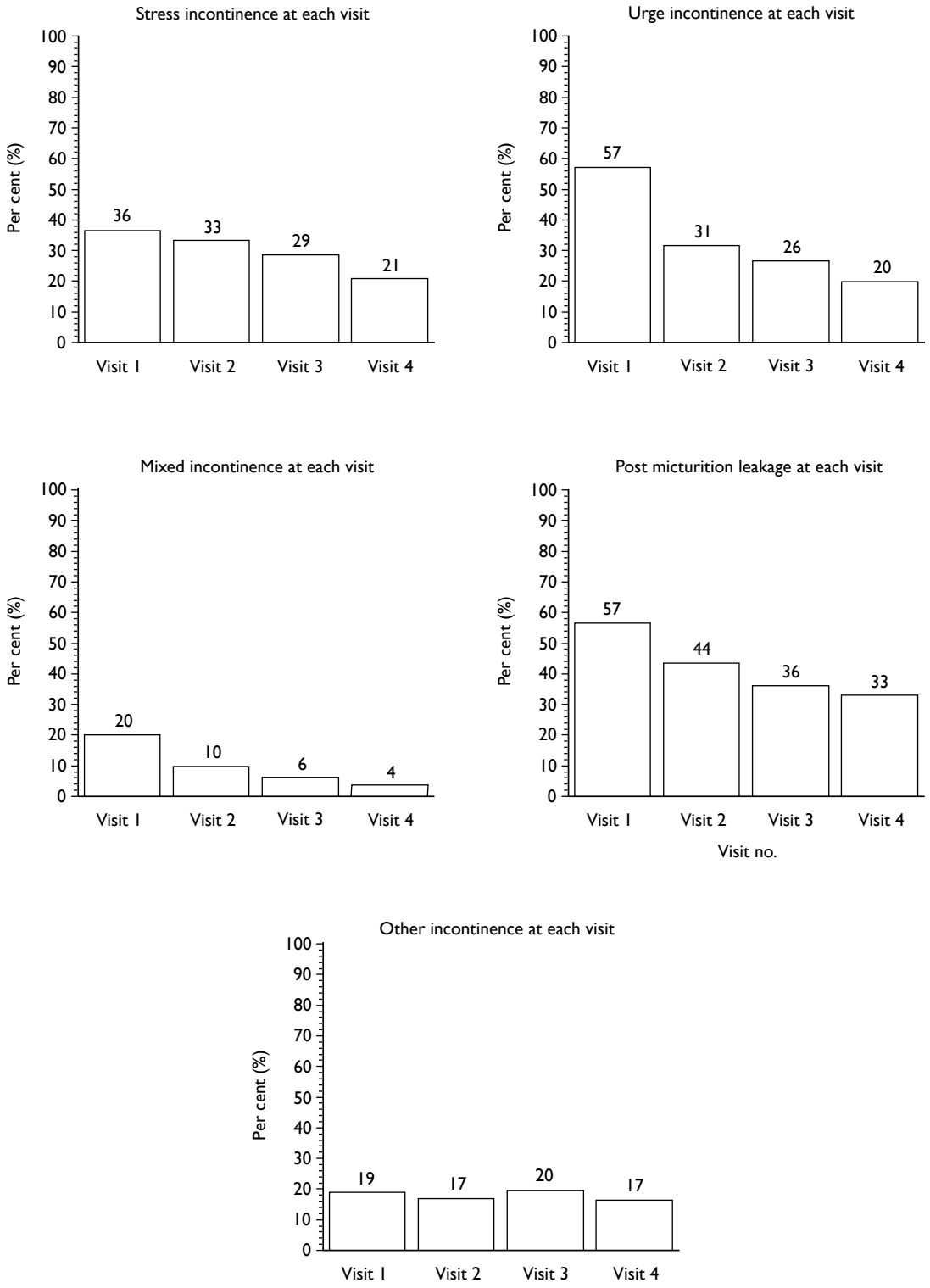

FIGURE 33 Type of incontinence at each visit and change over time: TURP.

TABLE 60 Type of bowel problems at each therapy visit and change over time

TURP	Visit 1	Visit 2	Visit 3	Visit 4
Faecal incontinence	6/184 (3)	3/170 (2)	3/159 (2)	2/156 (1)
Faecal urgency	17/185 (9)	9/170 (5)	7/159 (4)	11/156 (7)
Constipation	30/184 (16)	18/165 (11)	21/156 (13)	10/155 (6)

Figures are *n*/*N* (%).

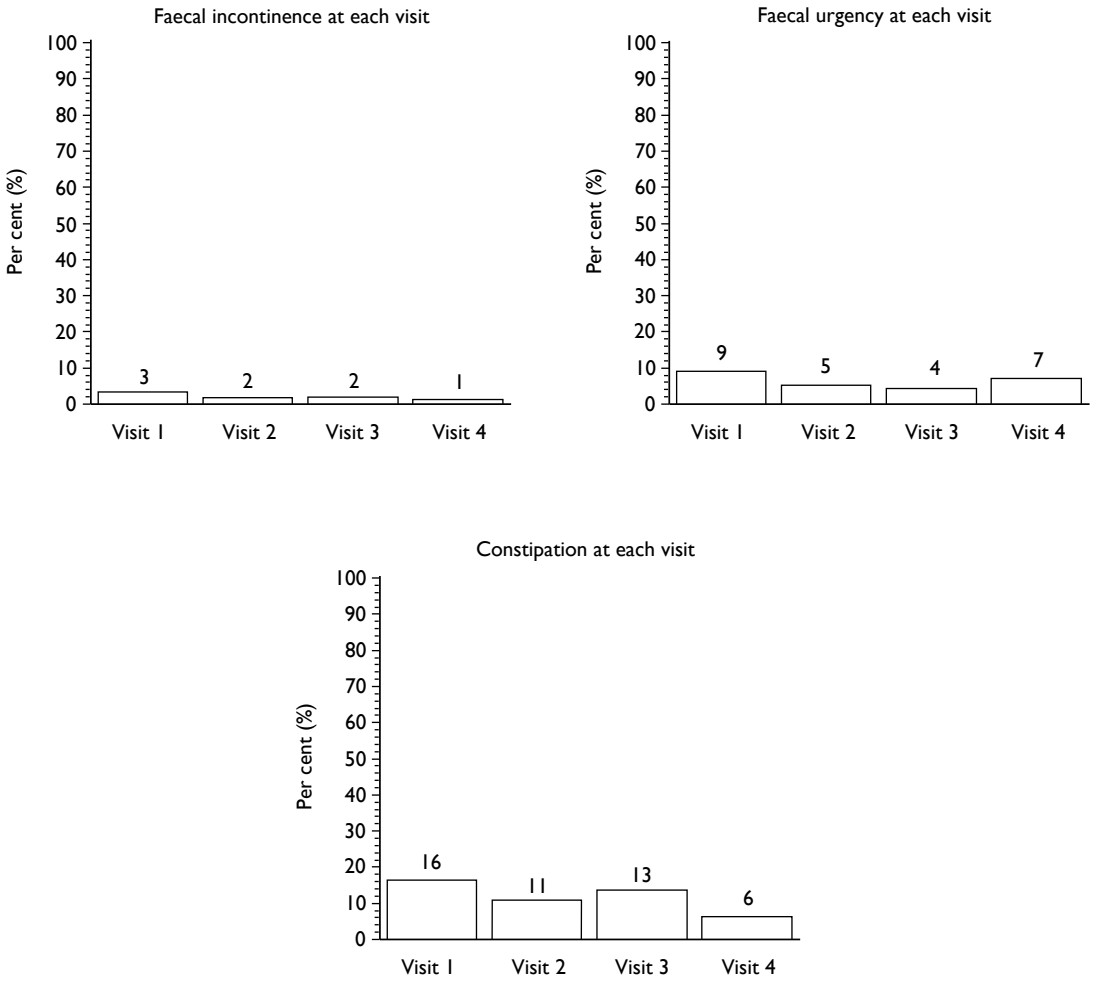

FIGURE 34 Type of bowel problems at each visit and change over time: TURP.

Examination of pelvic floor muscle performance during therapy visits

Therapists assessed the strength of the pelvic floor muscle contractions and their endurance (length of time men were able to hold a contraction) at each visit using digital anal assessment (see *Chapter 3*). The external anal sphincter and the internal puborectalis muscle were assessed separately. The internal puborectalis muscle strength was taken to be a measure of pelvic floor muscle strength.

TABLE 61 Type of sexual problems at each visit and change over time

TURP	Visit 1	Visit 2	Visit 3	Visit 4
Difficulty gaining erection	95/173 (55)	77/149 (52)	79/142 (56)	71/137 (52)
Difficulty maintaining erection	97/168 (58)	86/146 (59)	85/138 (62)	80/134 (60)
Premature ejaculation	8/152 (5)	9/137 (7)	8/130 (6)	7/121 (6)

Figures are *n*/*N* (%).

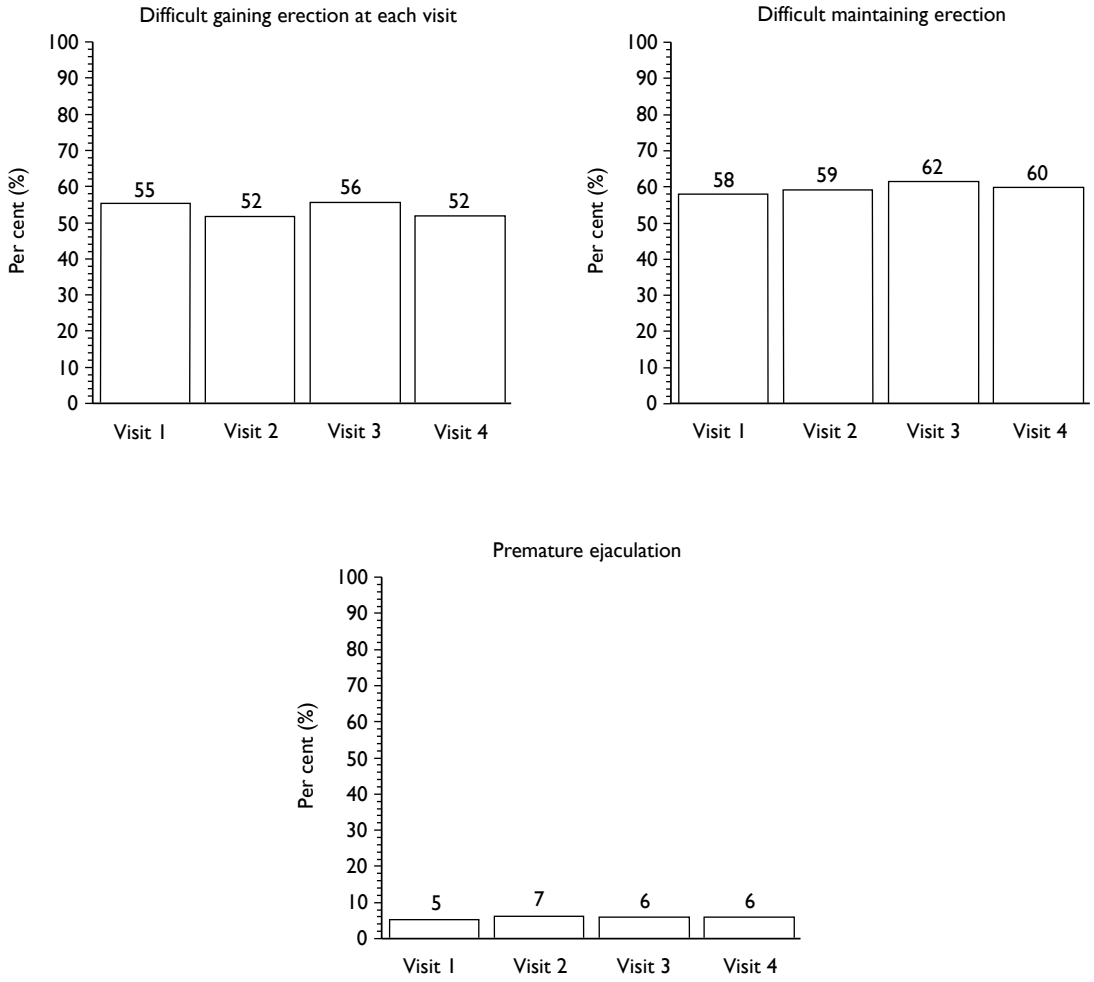

FIGURE 35 Type of sexual problems at each visit and change over time: TURP.

For both the sphincter and the puborectalis, both strength and endurance improved during the therapy period (*Table 62* and *Figure 36*). At baseline, only 4–6% of men had a strength of 5 or more, but by the fourth visit around 35–40% of men were able to contract strongly (5) or very strongly (6), while over 80% had good muscle strength (4 or better). The therapists were trained to ask men to hold the pelvic floor muscle contraction for up to 10 seconds during the digital anal examination. This is in line with functional use of these muscles. However, some therapists assessed the maximum length of time for which men could hold a contraction. Of these men, some held the contraction for over 1 minute.

TABLE 62 Ability to contract anal sphincter and puborectalis muscle (pelvic floor) over time

TURP	Visit 1	Visit 2	Visit 3	Visit 4
A: External anal sphincter strength [mean (SD) *n*][a]	3.1 (0.9), 153	3.5 (0.9), 125	3.9 (0.9), 119	4.2 (1.0), 108
0	1(1)	0	0	0
1	6/153 (3)	1/125 (1)	1/119 (1)	0
2	28/153 (18)	17/125 (14)	7/119 (6)	5/108 (7)
3	63/153 (41)	34/125 (27)	29/119 (24)	16/108 (15)
4	50/153 (33)	59/125 (47)	55/119 (46)	48/108 (44)
5	6/153 (4)	14/125 (11)	24/119 (20)	29/108 (27)
6	0	0	3/119 (2)	10/108 (9)
A: External anal sphincter endurance (seconds) [mean (SD) *n*][b]	6.0 (2.9) 153	7.4 (3.0) 125	8.4 (3.3) 119	10.2 (5.3) 108
B: Puborectalis muscle strength [mean (SD) *n*][a]	3.1 (1.0) 153	3.5 (0.9) 125	3.9 (0.9) 119	4.3 (1.0) 108
0	1/153 (1)	0	0	0
1	8/153 (5)	4/125 (3)	1/119 (1)	1/108 (1)
2	23/153 (15)	13/125 (10)	7/119(6)	4/108 (4)
3	67/153 (44)	42/125 (34)	30/119 (25)	13/108 (12)
4	44/153 (29)	53/125 (42)	52/119 (44)	45/108 (42)
5	8/153 (5)	12/125 (10)	25/119 (21)	37/108 (34)
6	2/153 (1)	1/125 (1)	4/119 (3)	8/108 (7)
B: Puborectalis muscle endurance (seconds) [mean (SD) *n*][b]	6.0 (2.8) 153	7.6 (3.1) 125	8.5 (3.2) 119	10.2 (5.5) 108

Figures are *n*/*N* (%), unless stated otherwise.

a Anal sphincter and puborectalis muscle strength are measured on a 0–6 modified Oxford scale: 0 = no flicker; 1 = flicker; 2 = weak contraction, no movement; 3 = moderate contraction with movement; 4 = good contraction against resistance; 5 = strong contraction against strong resistance; 6 = maximal contraction, very strong, unable to remove finger.

b Endurance is measured as the duration in seconds for which the man can maintain an anal squeeze contraction.

Examination and functional use of pelvic floor muscles

Therapists examined men at each visit to assess skin damage, skin infection, ability to tighten the anus and perform penile retraction and testicular lift, evidence of leakage on coughing and (for those who did leak) ability to prevent leakage on coughing. Very few men showed evidence of skin damage or infection (data not shown).

Four different aspects of functional use of pelvic floor muscles were assessed: ability to tighten anus; ability to perform penile retraction; leakage on coughing; ability to prevent leakage on coughing. While most men (over 95%) were able to contract well enough to tighten the anal sphincter at least a little from baseline onwards, the proportion able to demonstrate a testicular lift increased slightly with time (from 73% to 89%; *Figure 37*). The proportion who leaked when coughing was low (< 5%) and decreased very slightly during the therapy period. Around 77% of these men were able to contract their pelvic floor muscles sufficiently to prevent leakage when coughing at the first visit, and this improved to around 86% by the fourth visit.

Use of machine-led biofeedback

Biofeedback was available in 13 of 34 MAPS centres, and was used clinically for men after TURP in two of them (see *Table 7*). Therapists would have liked access to this facility in four other centres where biofeedback was not available. Biofeedback can be used in two ways:

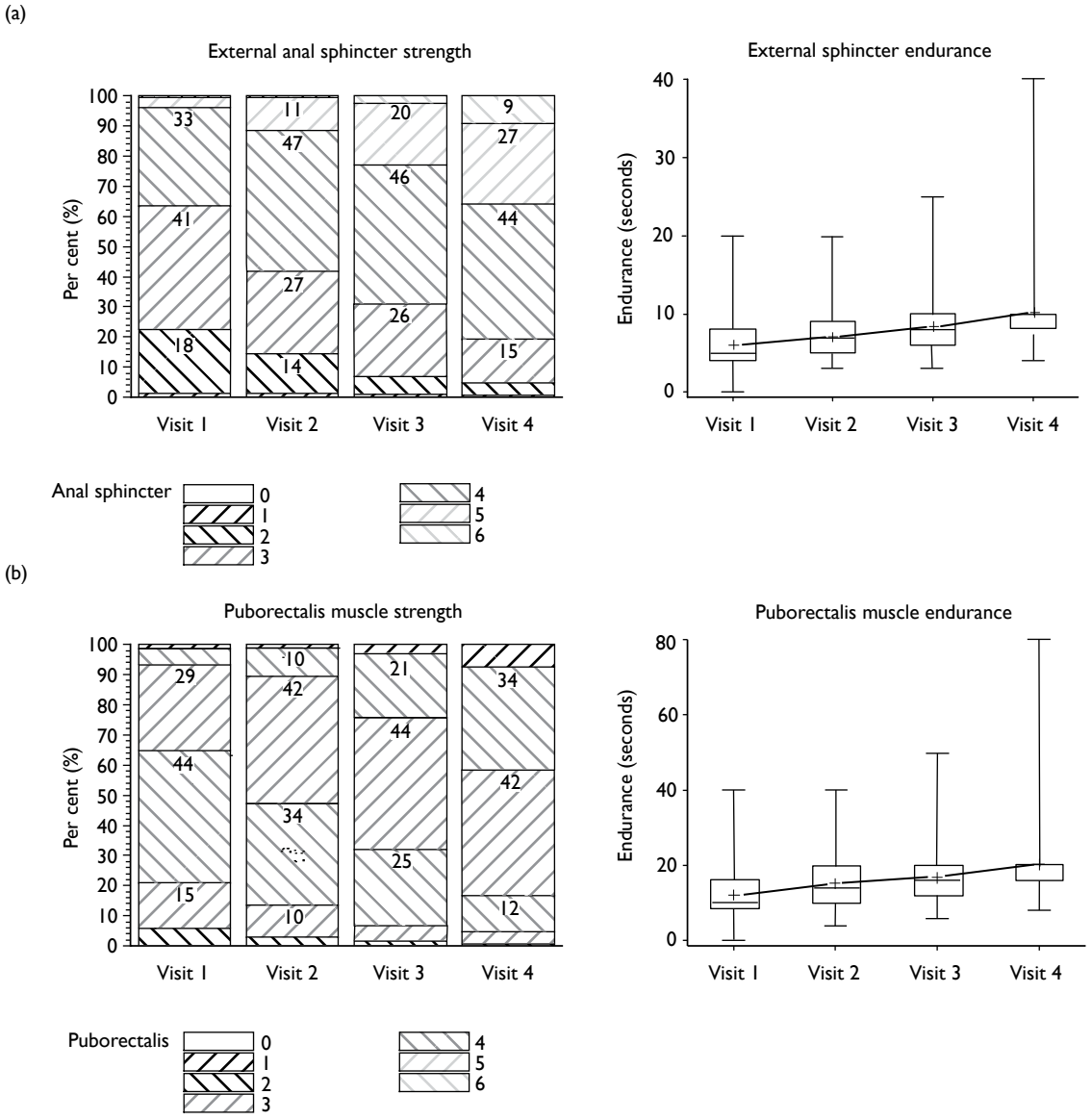

FIGURE 36 Ability to contract anal sphincter and puborectalis muscle (pelvic floor) over time:TURP. (a) External anal sphincter strength/endurance. (b) Puborectalis muscle strength/endurance.

- to feed back information to men that they are actually performing a correct pelvic floor contraction, and at what strength
- as part of a repetitive training regimen when men are asked to use the machine to enable them to monitor their exercise function for a period of time (such as 20 minutes).

It was not clear which type of biofeedback was practised in the centres where it was available, but therapists from two centres recorded its use in 11 men (see *Table 7*) from the TURP group (*Table 63*). In some cases men may have preferred anal examination using a machine rather than digital examination by the therapist for teaching of correct contractions.

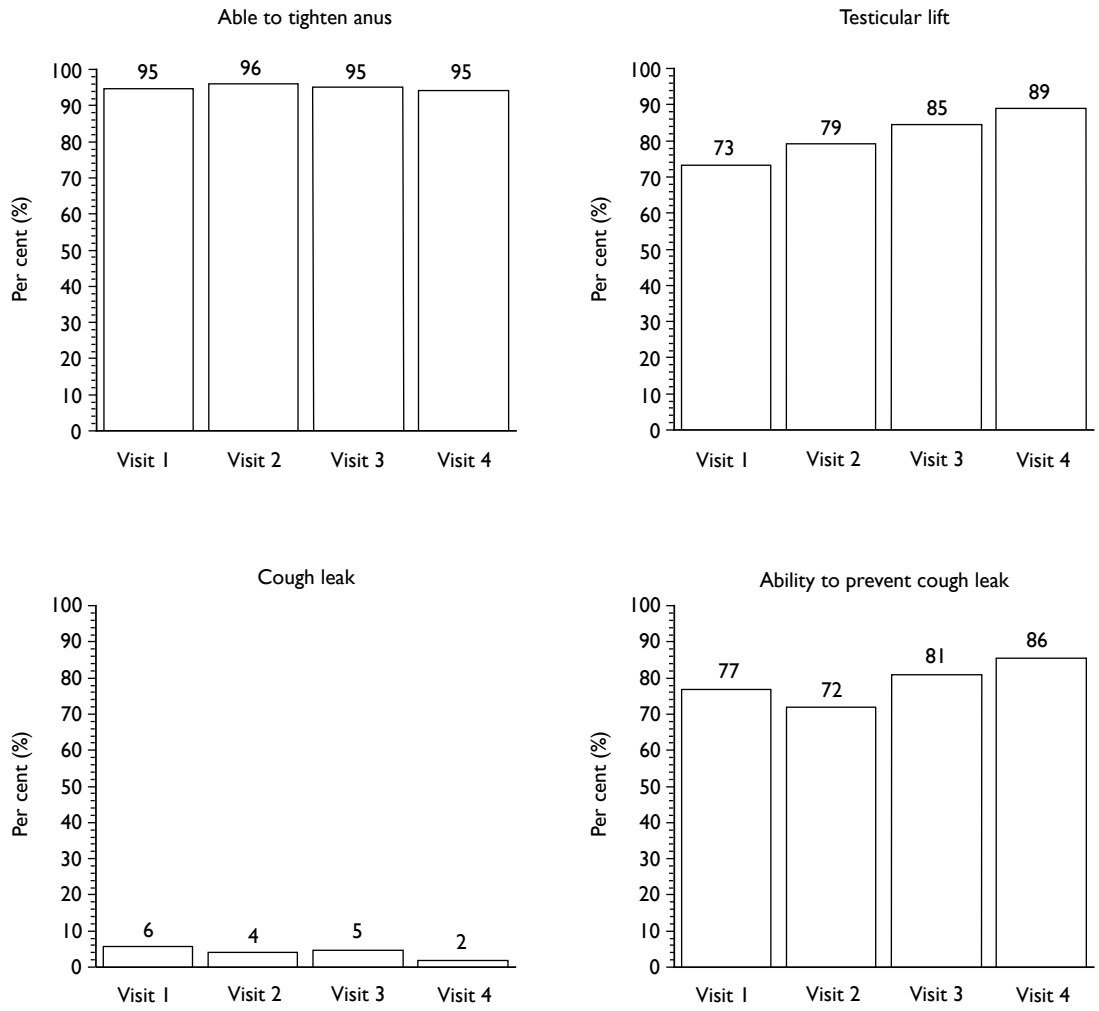

FIGURE 37 Aspects of ability to use pelvic floor muscles at each visit and change over time: TURP.

TABLE 63 Use of biofeedback for any men

TURP	Biofeedback indicated	Biofeedback actually implemented
Visit 1	10/92 (11)	0/90 (0)
Visit 2	7/87 (8)	5/85 (6)
Visit 3	3/81 (4)	3/78 (4)
Visit 4	3/85 (3)	3/85 (3)

Figures are *n*/*N* (%).

Chapter 12

Transurethral resection of the prostate: randomised controlled trial outcomes and results

This chapter describes the results of the intervention amongst the men recruited to the TURP RCT.

Patient flow

The derivation of the trial study groups and their progress through the trial is summarised in *Figure 38*. This is in the form of a CONSORT flow diagram. In total, 442 participants were recruited to the randomised trial: 220 randomly allocated to the intervention group and 222 to the control group. Twenty-five men had withdrawn from follow-up by 12 months (although some information was available prior to the time of their withdrawal in some cases). Ten men, three in the intervention group and seven in the control group, died before 12-month follow-up was reached. These deaths were not attributed to the trial intervention. Thirty-one men (14%) in the intervention group did not attend any therapy sessions and were considered non-compliers with the intervention (see *Chapter 6*) but were retained in their allocated group for the purpose of analysis.

Response rates

Over 90% of all participants returned completed questionnaires. As shown in *Figure 38*, by the time of each follow-up some participants had formally withdrawn or died, and so were not sent questionnaires (*Table 64*). Of the participants for whom it was appropriate to send a follow-up questionnaire, over 90% returned it at each time point (*Table 65a*). For return of urinary diaries, the response rate was slightly less, but still approximately 90% at each time point (*Table 65b*).

TABLE 64 Reasons for withdrawal

	TURP	
Reason	Intervention	Control
Ill	6	2
Dry	6	1
Catheterised permanently	2	0
No reason	2	1
Other	4	1
Total	20	5

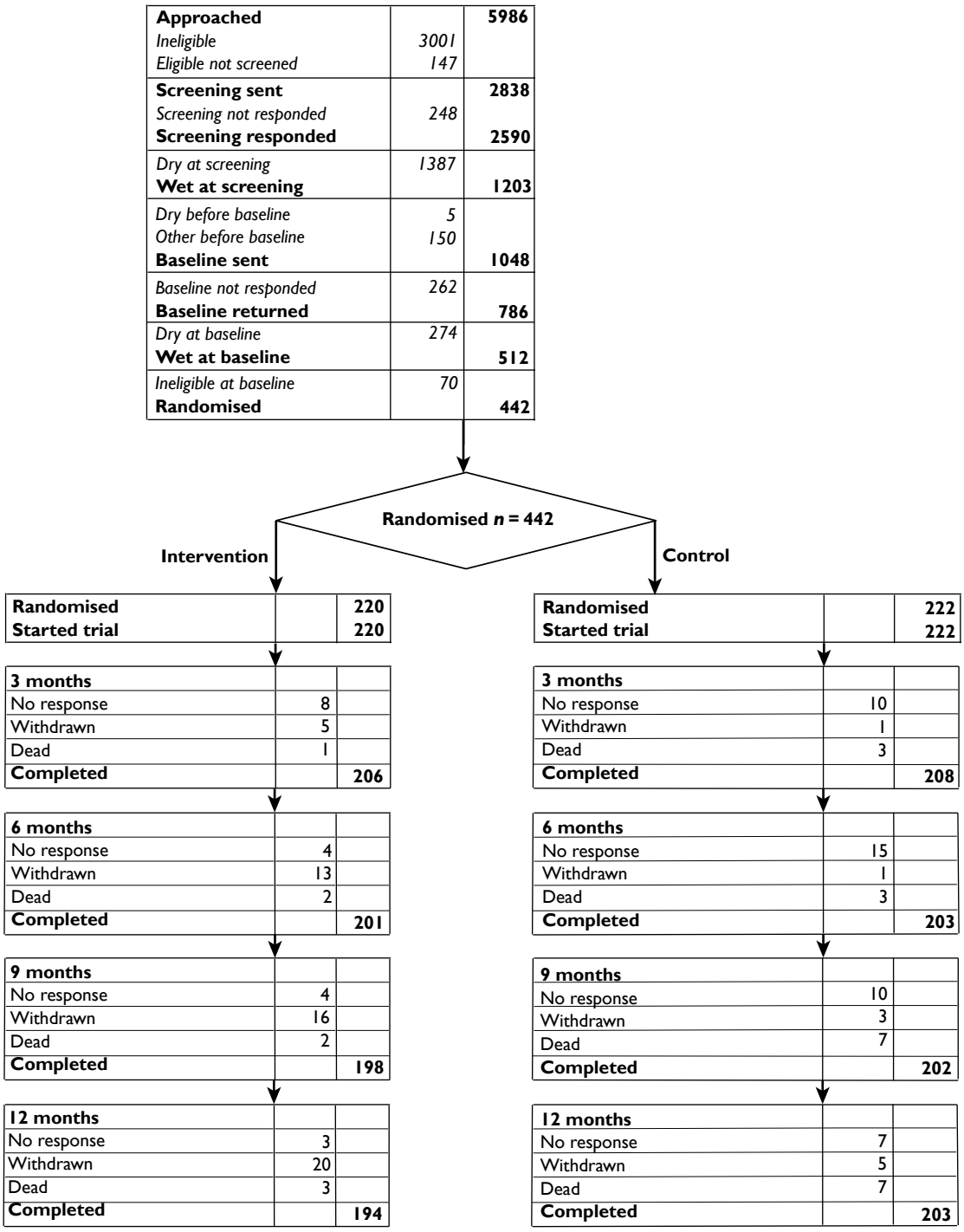

FIGURE 38 TURP CONSORT diagram (men randomised $n = 442$).

Primary outcome: urinary incontinence at 12 months

The primary outcome was incontinence in men at 12 months after randomisation, measured by a positive response to one of two questions from the ICI-SF questionnaire ('How often do you leak urine' or 'How much urine do you usually leak?'). *Table 66* shows that the difference between the intervention and control groups in urinary incontinence at 12 months (64.9% vs 61.6%) was not statistically significant:

TABLE 65a Patient questionnaire response rates ($n = 220$ in intervention group, $n = 222$ in control group)

TURP	Number sent	Number returned (%)	Percentage of all men
Baseline			
Intervention	220	220 (100)	100
Control	222	222 (100)	100
3 months			
Intervention	216	206 (95)	94
Control	220	208 (95)	94
6 months			
Intervention	208	201 (97)	91
Control	219	203 (93)	91
9 months			
Intervention	203	198 (98)	90
Control	215	202 (93)	91
12 months			
Intervention	199	194 (97)	88
Control	211	203 (97)	92

The first returned column above is percentage out of all questionnaires sent (to men continuing in the study); the second is the percentage out of the total number of men randomised to each trial group.

TABLE 65b Urinary diary response rates ($n = 220$ in intervention group, $n = 222$ in control group)

TURP	Number sent	Number returned (%)	Percentage of all men
Baseline			
Intervention	220	207 (94)	94
Control	222	203 (91)	91
3 months			
Intervention	216	183 (85)	83
Control	220	186 (85)	84
6 months			
Intervention	208	184 (88)	84
Control	219	183 (84)	82
9 months			
Intervention	203	177 (87)	80
Control	215	184 (86)	83
12 months			
Intervention	199	176 (88)	80
Control	211	181 (86)	82

The first returned column above is percentage out of all questionnaires sent (to men continuing in the study); the second is the percentage out of the total number of men randomised to each trial group.

- either when analysed by intention to treat (all men analysed in the groups to which they were randomised but results as given in the outcome questionnaires without adjustment for missing values)
- or when analysed by 'treatment received', which adjusts the result by a factor related to the men who actually attended a therapist versus those who did not.

TABLE 66 Urinary incontinence at 12 months

TURP	Intervention	Control	RR (95% CI), *p*-value
Urinary incontinence at 12 months [*n*/*N* (%)]	126/194 (64.9)	125/203 (61.6)	Absolute risk difference 3.4% (95% CI –6% to 13%)
Intention to treat			
Unadjusted analysis			1.055 (0.908 to 1.225), 0.486
Analysis adjusted by minimisation factors			1.057 (0.910 to 1.227), 0.471
Adjusted treatment received			
Unadjusted analysis			1.048 (0.900 to 1.221), 0.546
Analysis adjusted by minimisation factors			1.049 (0.901 to 1.222), 0.538

The above analyses were then repeated adjusting for the minimisation factors, but this did not alter the findings (*Table 66*). The corresponding risk difference for the unadjusted intention-to-treat analysis was 3.4% (95% CI –6% to 13%), thereby ruling out the likelihood that the trial prespecified difference of 15% in the proportion incontinent between intervention and control group could have been missed.

Secondary outcomes

Urinary outcomes

Urinary incontinence was also measured at 3, 6 and 9 months after randomisation, together with other urinary outcomes. *Table 67a* describes the various urinary outcomes at each follow-up, and *Table 67b* shows the formal statistical testing of the differences at each time point. *Figure 39* is a pictorial representation of the percentage of men incontinent at each follow-up, and *Figure 40* shows the change in mean ICI-Q score over time. The data show that there were no statistically significant differences between the intervention and control groups at any of the time points in urinary incontinence and the other urinary outcomes measured.

Type of incontinence

Table 68 and *Figure 41* show the type of incontinence at baseline and at 6 and 12 months after randomisation. Men could report more than one type of incontinence. About two-thirds of men had SUI at baseline, reducing to about one-third over time. More men had urgency and UUI (than stress incontinence) at baseline. The proportions of men with the other types of urinary incontinence (mixed, *Figure 41c*; postmicturition leakage, *Figure 41d*; and other types of incontinence) decreased over time but there was little difference between the groups for any specific type of incontinence.

Use of aids or protection for urinary incontinence

Table 69a shows the men's use of aids to protect them from urinary leakage: this did not vary according to the randomised groups at any of the follow-up time points. *Table 69b* presents the statistical analyses of these outcomes. Just under 20% of the men were still using pads at 12 months to protect themselves from leakage accidents, although in some cases this might have been more of a precaution than because they actually leaked.

Bowel function

In addition to urinary outcomes, men were also asked to describe some aspects of bowel function. Few men (< 20%) had faecal incontinence or constipation occasionally or more often by the end of follow-up at 12 months, although rather more (around 50%) reported faecal urgency.

DOI: 10.3310/hta15240

TABLE 67a Number of men incontinent: mean ICI score and urinary frequency at each 3-month interval

	Baseline		3 months		6 months		9 months		12 months	
TURP	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
Incontinence										
Men incontinent [*n*/*N* (%)]	220/220 (100)	222/222 (100)	142/205 (69)	132/208 (63)	140/199 (70)	129/201 (64)	133/197 (68)	131/202 (65)	126/194 (65)	125/203 (62)
Men with severe incontinence [*n*/*N* (%)][a]	145/220 (66)	144/222 (65)	57/205 (28)	57/208 (27)	53/199 (27)	49/201 (24)	46/197 (23)	45/202 (22)	48/194 (25)	49/203 (24)
ICI-Q score[b]	8.6 (4.1) 219	8.7 (4.3) 222	4.6 (4.0) 201	4.6 (4.8) 203	4.1 (3.7) 199	4.1 (4.3) 201	4.2 (4.0) 193	4.1 (4.3) 198	3.9 (3.7) 194	4.0 (4.3) 203
Frequency of daytime urinary incontinence from diaries	3.01 (3.7) 204	2.7 (3.1) 201	1.31 (2.2) 182	1.4 (2.5) 184	1.1 (2.0) 184	1.4 (2.6) 181	1.2 (2.51) 177	1.31 (2.3) 182	1.4 (2.3) 175	1.2 (2.2) 179
Effect of urinary incontinence on quality of life	3.4 (3.0) 215	3.5 (3.0) 221	1.5 (2.1) 201	1.6 (2.5) 203	1.2 (1.9) 194	1.4 (2.3) 198	1.3 (2.2) 193	1.4 (2.3) 198	1.2 (1.9) 190	1.3 (2.2) 199
Urinary frequency										
Daytime urinary frequency	8.6 (5.2) 205	7.9 (3.1) 199	6.9 (2.8) 186	6.6 (2.5) 177	6.6 (2.1) 186	6.7 (2.2) 181	6.6 (2.3) 182	6.7 (2.3) 183	7.0 (4.3) 177	6.5 (2.1) 178
Daytime urinary frequency from diaries	7.6 (3.8) 204	7.7 (4.8) 201	6.6 (3.9) 182	6.3 (4.0) 184	6.2 (2.6) 184	6.0 (2.1) 181	6.4 (2.3) 177	6.2 (3.0) 182	6.1 (2.6) 175	6.1 (3.3) 179
Nocturia	2.7 (1.6) 215	2.5 (1.5) 212	1.9 (1.5) 193	1.9 (1.4) 192	1.7 (1.1) 185	1.8 (1.2) 185	1.7 (1.2) 174	1.8 (1.5) 188	1.7 (1.4) 177	1.8 (1.6) 181
Nocturia from diaries	2.2 (1.4) 204	2.2 (1.5) 201	1.6 (1.3) 182	1.6 (1.4) 184	1.5 (1.4) 184	1.5 (1.3) 181	1.6 (1.5) 177	1.5 (1.4) 182	1.5 (1.2) 175	1.6 (1.5) 179
Frequency of nocturnal incontinence from diaries	0.8 (1.2) 204	0.7 (1.2) 201	0.3 (0.7) 182	0.4 (1.0) 184	0.3 (0.9) 184	0.3 (0.7) 181	0.3 (0.9) 177	0.4 (0.9) 182	0.4 (0.9) 175	0.4 (0.9) 179

Figures are mean (SD) *n*, unless stated otherwise. Data from men's questionnaires unless stated otherwise.

a Severe incontinence defined as leakage at least once a day *and* a moderate or large amount of leakage, as defined by the men in questionnaire responses.

b ICI-Q score: 0 = none, 21 = maximum (worst) score. Derived from questions 1–3 of the ICIQ-UI Short Form Questionnaire.

TABLE 67b Urinary outcomes at each 3-month interval: statistical analyses

	Effect size (95% CI), *p*-value			
TURP	**3 months**	**6 months**	**9 months**	**12 months**
Incontinence				
Men incontinent [RR (95% CI), *p*-value]	1.09 (0.95 to 1.25), 0.213	1.10 (0.96 to 1.26), 0.184	1.04 (0.91 to 1.20), 0.571	1.06 (0.91 to 1.23), 0.471
Men with severe incontinence [RR (95% CI), *p*-value][a]	1.02 (0.74 to 1.39), 0.925	1.10 (0.78 to 1.53), 0.589	1.05 (0.73 to 1.50), 0.791	1.03 (0.73 to 1.45), 0.884
ICI-Q score[b]	0.03 (–0.74 to 0.81), 0.935	0.01 (–0.72 to 0.74), 0.973	0.09 (–0.68 to 0.85), 0.825	–0.04 (–0.78 to 0.71), 0.925
Frequency of daytime urinary incontinence from diaries	–0.21 (–0.74 to 0.32), 0.441	–0.31 (–0.83 to 0.21), 0.248	–0.06 (–0.64 to 0.52), 0.847	–0.21 (–0.30 to 0.72), 0.421
Effect of urinary incontinence on quality of life	–0.22 (–0.61 to 0.17), 0.273	–0.13 (–0.50 to 0.25), 0.511	–0.08 (–0.47 to 0.31), 0.697	–0.13 (–0.50 to 0.24), 0.499
Urinary frequency				
Daytime urinary frequency	0.11 (–0.42 to 0.64), 0.692	–0.14 (–0.57 to 0.30), 0.530	0.01 (–0.44 to 0.46), 0.960	0.35 (–0.40 to 1.09), 0.362
Daytime urinary frequency from diaries	0.30 (–0.61 to 1.22), 0.518	0.20 (–0.40 to 0.80), 0.510	0.16 (–0.45 to 0.77), 0.608	–0.19 (–0.87 to 0.50), 0.590
Nocturia	–0.08 (–0.33 to 0.17), 0.537	–0.16 (–0.35 to 0.04), 0.110	–0.08 (–0.31 to 0.16), 0.527	–0.05 (–0.30 to 0.20), 0.698
Nocturia from diaries	0.02 (–0.29 to 0.33), 0.911	0.10 (–0.20 to 0.39), 0.518	0.02 (–0.31 to 0.36), 0.886	–0.12 (–0.43 to 0.19), 0.439
Frequency of nocturnal incontinence from diaries	–0.10 (–0.38 to 0.18), 0.472	0.06 (–0.25 to 0.36), 0.717	–0.15 (–0.46 to 0.16), 0.344	0.03 (–0.25 to 0.32), 0.807

Effect size is mean difference unless indicated as RR adjusted for age, urinary incontinence before surgery and baseline value.

a Severe incontinence defined as at least once a day *and* a moderate or large amount of leakage, as defined by the men in questionnaire responses.

b ICI-Q score: 0 = none, 21 = maximum (worst) score. Derived from questions 1–3 of the ICIQ-UI Short Form Questionnaire.

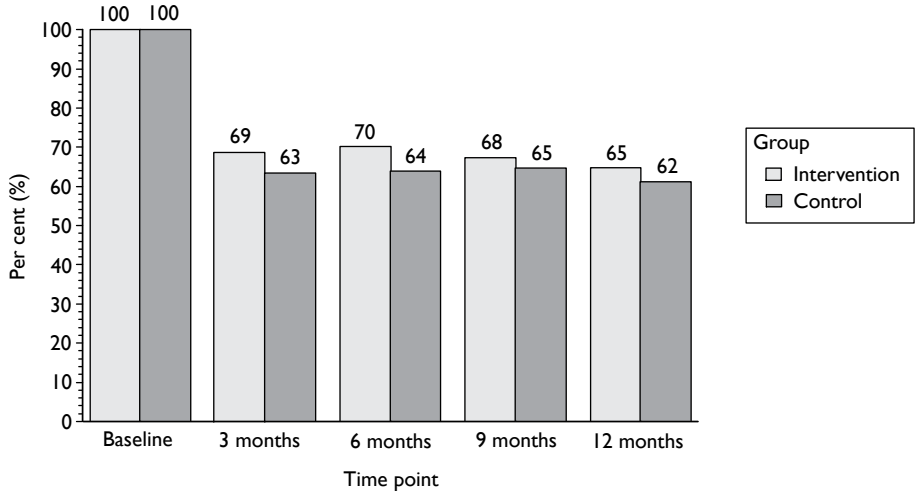

FIGURE 39 Per cent of men incontinent at each time point.

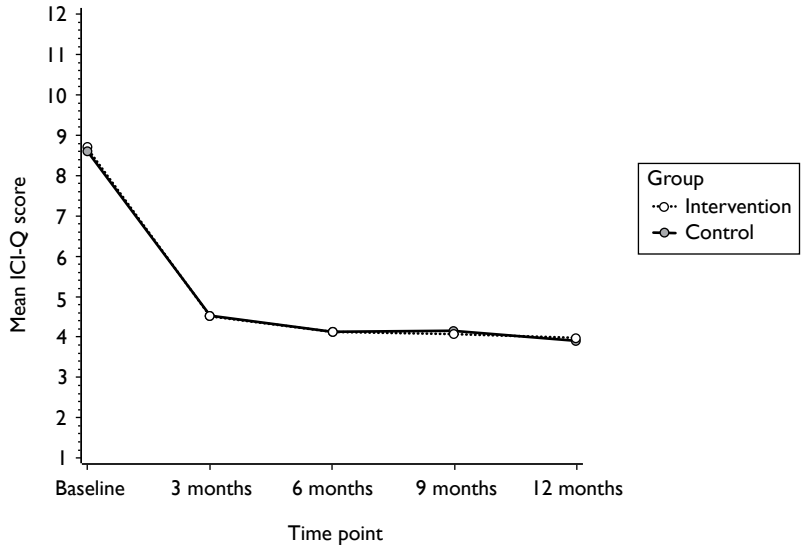

FIGURE 40 Mean ICI-Q score at each time point. ICI-Q score: 0 = none, 21 = maximum (worst) score. Derived from questions 1–3 of the ICIQ-UI Short Form Questionnaire.

Table 70 and *Figure 42* show that there were no differences in any aspect of bowel function between the men in the randomised groups.

Sexual function

Table 71 compares the men in the randomised groups in terms of sexual function outcomes. One-third of men had difficulty with erection before surgery. Although just over one-third had an active sex life at 12 months, about half said that it was the same as before their operation. There were, however, no differences at 12 months according to the randomised groups in terms of the proportion of men with an active sex life [RR 1.04 (95% CI 0.80 to 1.36); adjusted for age, urinary incontinence before surgery and baseline value, $p = 0.768$] or the proportion of men who rated their sex life as worse after the operation [RR 0.99 (0.80 to 1.22), $p = 0.912$].

Table 72 compares the randomised groups in terms of problems with sexual function. There were no significant differences in sexual function outcomes between the intervention and control

TABLE 68 Type of incontinence

	Baseline		6 months			12 months		
TURP	**Intervention**	**Control**	**Intervention**	**Control**	**RR (95% CI), *p*-value**	**Intervention**	**Control**	**RR (95% CI), *p*-value**
SUI	148/220 (67)	136/222 (61)	71/199 (36)	77/201 (38)	0.87 (0.68 to 1.10), 0.246	71/194 (37)	76/203 (37)	0.91 (0.72 to 1.17), 0.477
UUI	186/220 (85)	183/222 (82)	77/199 (39)	80/201 (40)	0.97 (0.76 to 1.22), 0.772	72/194 (37)	82/203 (40)	0.92 (0.72 to 1.17), 0.483
Urgency	198/220 (90)	193/222 (87)	94/199 (47)	97/201 (48)	0.96 (0.79 to 1.18), 0.724	94/194 (48)	94/203 (46)	1.04 (0.85 to 1.27), 0.723
MUI (both SUI and UUI)	129/220 (59)	112/222 (50)	43/199 (22)	59/201 (29)	0.67 (0.48 to 0.92), 0.014	46/194 (24)	58/203 (29)	0.77 (0.56 to 1.06), 0.116
Postmicturition leakage	151/220 (69)	156/222 (70)	90/199 (45)	90/201 (45)	1.04 (0.85 to 1.28), 0.687	92/194 (47)	87/203 (43)	1.13 (0.92 to 1.39), 0.245
Other UI	57/220 (26)	44/222 (20)	22/199 (11)	22/201 (11)	0.93 (0.54 to 1.61), 0.800	18/194 (9)	17/203 (8)	1.04 (0.55 to 1.95), 0.911

Figures are *n*/*N* (%), unless otherwise stated. RR adjusted for age, urinary incontinence before surgery and baseline value.
Note: Men could have more than one type of incontinence; hence the numbers are higher than the total number of men.

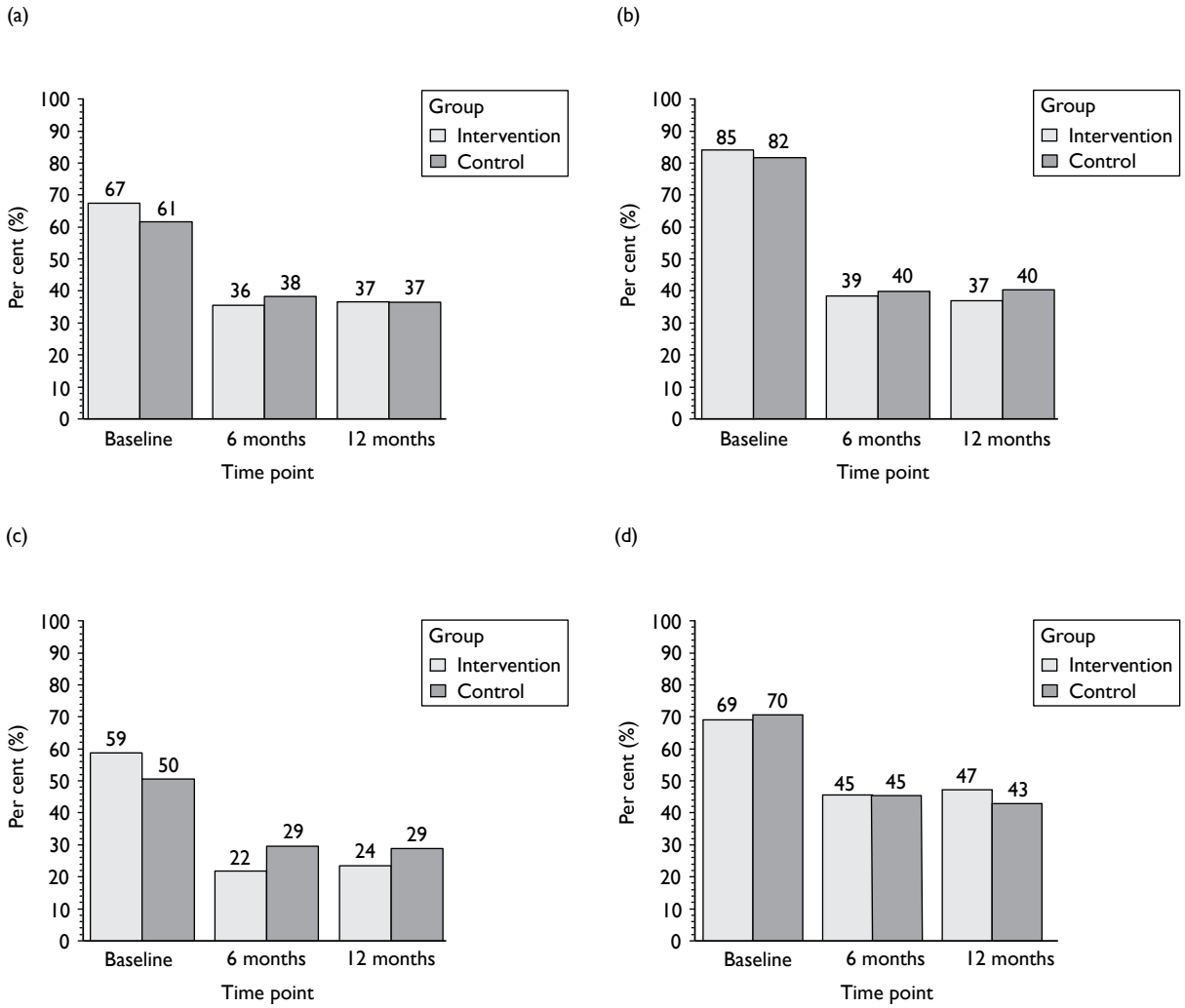

FIGURE 41 Type of incontinence at baseline, and at 6 and 12 months after randomisation: TURP. Men could report more than one type of incontinence. (a) Stress urinary incontinence. (b) Urgency urinary incontinence. (c) Mixed urinary incontinence (proportion of men reporting both stress and urgency urinary incontinence). (d) Postmicturition leakage (defined as 'urine leaking when urination finished').

groups (*Table 72*, *Figure 43*). About half of the men were able to achieve a normal erection or one with slightly reduced stiffness by 12 months after surgery, and almost all reported a reduced quantity of semen or no ejaculation. Of those men, few reported more than slight pain. Around 15% of men used drugs, and about 1% used a vacuum device to help with sexual function. Only 2% reported urinary incontinence during intercourse.

Quality of life

General health outcomes were measured using the EQ-5D and SF-12 (the latter subdivided into role – mental and role – physical scores). The slight increase in the scores over time probably represents recovery from the operation, but there were no differences between the randomised groups at any time point in EQ-5D or SF-12 scores (*Table 73* and *Figure 44*).

Pelvic floor muscle training

All men were asked to report on their practice of carrying out pelvic floor exercises at baseline and 6 and 12 months after randomisation. Initially around 20% of the men reported practising PFMT, of whom around 80% did it every day. The men in the control group continued with

TABLE 69a Use of aids or protection for urinary incontinence

	Baseline		3 months		6 months		9 months		12 months	
TURP	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**
Use of any protection	79/220 (36)	77/222 (35)	51/220 (23)	40/222 (18)	31/220 (14)	26/222 (12)	32/220 (15)	26/222 (12)	28/220 (13)	31/222 (14)
Use of body-worn pads (yes)	71/220 (32)	70/217 (32)	45/153 (29)	30/147 (20)	27/150 (18)	21/145 (14)	25/135 (19)	23/137 (17)	24/146 (16)	24/136 (18)
Number of body-worn pads in 24 hours [mean (SD) *n*]	2.5 (2.1) 69	2.3 (1.3) 67	2.2 (2.0) 41	1.9 (1.4) 29	1.7 (1.5) 31	1.6 (1.3) 24	2.3 (2.3) 24	1.6 (1.0) 22	1.5 (1.4) 28	1.6 (1.3) 26
Use of chair or bed pads (yes)	28/209 (13)	22/214 (10)	12/149 (8)	12/142 (8)	7/143 (5)	8/128 (6)	7/128 (5)	7/132 (5)	8/130 (6)	9/122 (7)
Number of chair or bed pads in 24 hours [mean (SD) *n*]	1.9 (1.5) 25	1.7 (1.2) 20	1.2 (0.8) 10	2.1 (2.3) 11	0.8 (1.0) 9	1.8 (1.6) 8	1.5 (0.6) 4	1.7 (1.6) 7	1.5 (1.0) 4	1.6 (1.3) 9
Use of external (sheath) catheter (yes)	6/219 (3)	3/216 (1)	10/201 (5)	9/199 (5)	6/187 (3)	5/182 (3)	7/186 (4)	5/193 (3)	4/185 (2)	8/192 (4)
Use of permanent catheter (yes)	2/220 (1)	1/218 (0)	2/204 (1)	2/199 (1)	1/187 (1)	0/188 (0)	2/186 (1)	0/194 (0)	1/188 (1)	0/195 (0)

Figures are *n*/*N* (%), unless otherwise stated.

TABLE 69b Use of aids or protection for urinary incontinence: statistical analyses

	Effect size (95% CI), *p*-value			
TURP	**3 months**	**6 months**	**9 months**	**12 months**
Use of any protection	1.27 (0.88 to 1.83), 0.197	1.19 (0.74 to 1.94), 0.475	1.24 (0.76 to 2.00), 0.388	0.91 (0.56 to 1.46), 0.683
Use of body-worn pads (yes)	1.32 (0.93 to 1.88), 0.114	1.03 (0.65 to 1.65), 0.886	1.03 (0.66 to 1.61), 0.903	0.96 (0.61 to 1.51), 0.852
Number of body-worn pads in 24 hours [mean difference (95% CI), *p*-value]	–2.15 (–5.26 to 0.95), 0.144	–0.38 (–1.14 to 0.38), 0.320	–1.57 (–3.45 to 0.31), 0.081	–0.14 (–0.94 to 0.66), 0.724
Use of chair or bed pads (yes)	0.75 (0.36 to 1.56), 0.446	0.70 (0.27 to 1.82), 0.467	0.97 (0.38 to 2.47), 0.943	0.68 (0.29 to 1.59), 0.373
Number of chair or bed pads in 24 hours [mean difference (95% CI), *p*-value]	–2.09 (–5.38 to 1.19), 0.151	0.29 (–2.70 to 3.27), 0.780	0.76 (–6.47 to 7.99), 0.696	2.35 (–28.06 to 32.75), 0.506
Use of external (sheath) catheter (yes)	1.12 (0.46 to 2.74), 0.800	1.50 (0.37 to 6.04), 0.565	1.51 (0.47 to 4.88), 0.491	0.53 (0.17 to 1.68), 0.282
Use of permanent catheter (yes)	1.13 (0.13 to 9.57), 0.912	Not estimable	Not estimable	Not estimable

Effect size is RR unless indicated as mean difference, adjusted for age, urinary incontinence before surgery and baseline value.

TABLE 70 Type of bowel problems at baseline and 6 and 12 months

	Baseline		6 months			12 months		
TURP	Intervention	Control	Intervention	Control	Effect size (95% CI), *p*-value	Intervention	Control	Effect size (95% CI), *p*-value
Faecal incontinence[a]	40/216 (19)	29/218 (13)	35/195 (18)	29/194 (15)	1.13 (0.74 to 1.73), 0.563	40/192 (21)	36/199 (18)	1.06 (0.74 to 1.52), 0.745
Faecal urgency[a]	130/216 (60)	116/218 (53)	96/195 (49)	105/194 (54)	0.86 (0.72 to 1.03), 0.094	107/192 (56)	106/198 (54)	1.00 (0.85 to 1.17), 0.966
Constipation	44/216 (21)	35/218 (16)	29/195 (15)	24/191 (13)	1.03 (0.66 to 1.59), 0.910	32/190 (17)	28/196 (14)	1.03 (0.69 to 1.53), 0.877
Any bowel dysfunction[b]	146/216 (68)	128/218 (59)	113/195 (58)	116/194 (60)	0.91 (0.78 to 1.06), 0.226	121/191 (63)	118/196 (60)	0.97 (0.85 to 1.11), 0.640

Figures are *n*/*N* (%), unless otherwise stated. Effect size is RR adjusted for age, urinary incontinence before surgery and baseline value.

a Faecal incontinence and urgency were defined as present when the problem was rated as occurring 'occasionally or more often'.

b Any bowel dysfunction includes faecal urgency, ulcerative colitis, Crohn's disease, irritable bowel syndrome or constipation but not faecal incontinence.

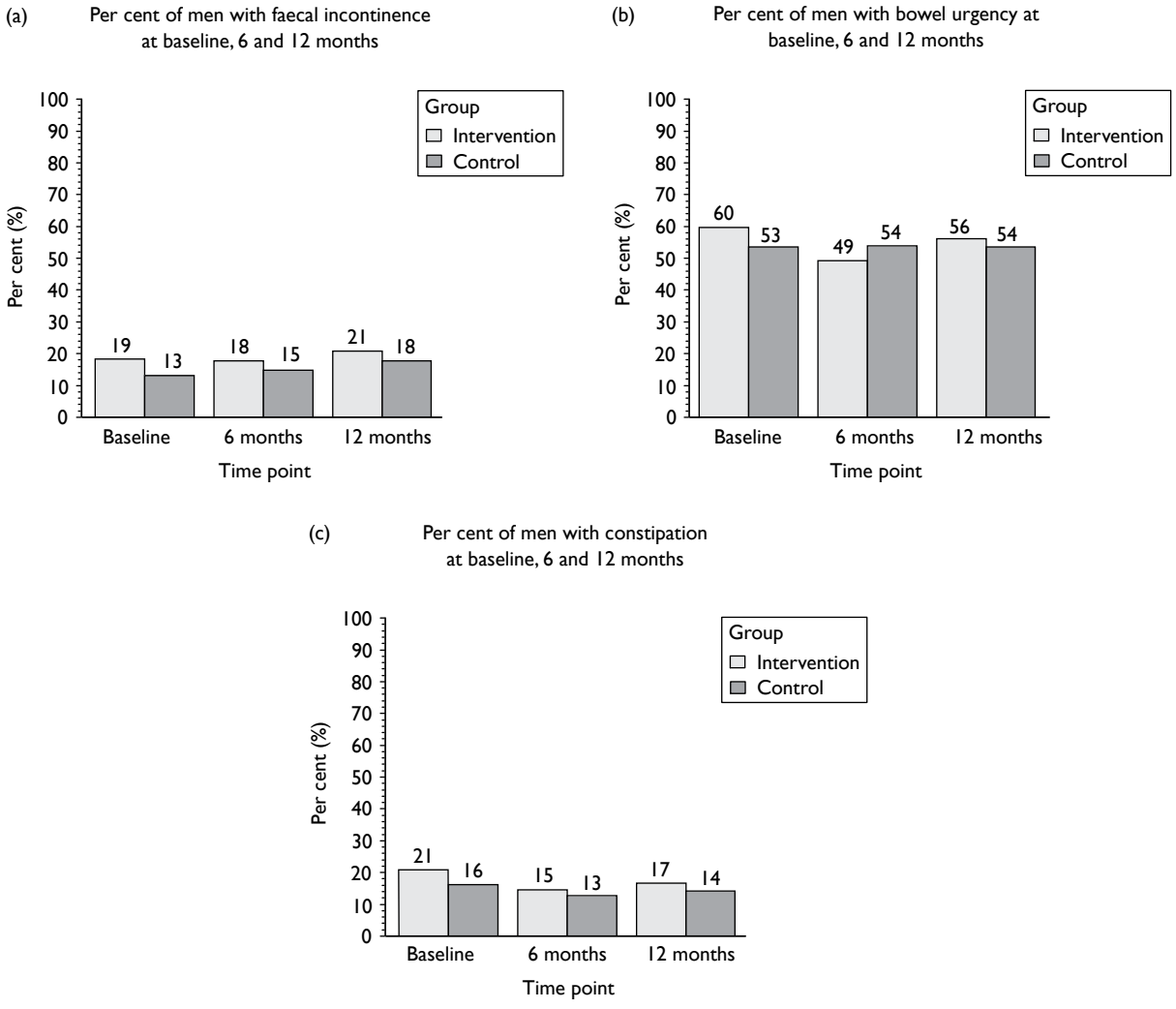

FIGURE 42 Type of bowel problems at baseline and 6 and 12 months: TURP.

TABLE 71 Description of sex life variables before and 12 months after prostate surgery

TURP	Intervention	Control
Number of men not able to achieve erection before prostate surgery[a]	67/214 (31)	71/215 (33)
Number of men with active sex life at 12 months	65/173 (38)	66/184 (36)
Reasons for not having an active sex life at 12 months		
Because of urinary symptoms	7/108 (6)	7/118 (6)
Because of bowel symptoms	3/108 (3)	1/118 (1)
Because of prostate operation	42/113 (37)	38/127 (30)
Because of medical treatment	29/109 (27)	25/119 (21)
For another reason	51/110 (46)	60/123 (49)
Sex life compared now with before prostate operation 12 months ago		
Stayed the same	76/145 (52)	75/145 (52)
Better	3/145 (2)	5/145 (3)
Worse	66/145 (46)	65/145 (45)

Figures are *n*/*N* (%).
a This information was collected at baseline but was retrospective, based on men's recall of their sexual function before operation.

TABLE 72 Type of sexual problems at 12 months after prostate surgery

TURP	Intervention	Control
Difficulty with achieving erection		
Normal stiffness	37/177 (21)	36/178 (20)
Reduced stiffness	48/177 (27)	48/178 (27)
Severely reduced stiffness	40/177 (23)	51/178 (29)
No erection possible	52/177 (29)	43/178 (24)
Bother with erection [mean (SD) *n*][a]	4.2 (3.7) 152	4.6 (3.9) 154
Ejaculation		
Normal quantity of semen	7/174 (4)	5/179 (3)
Reduced quantity of semen	22/174 (13)	27/179 (15)
Significantly reduced quantity of semen	25/174 (14)	27/179 (15)
Ejaculation but without semen	62/174 (36)	54/179 (30)
No ejaculation	58/174 (33)	66/179 (37)
Bother with ejaculation [mean (SD) *n*][a]	3.6 (3.7) 155	3.8 (3.7) 153
Pain or discomfort with ejaculation		
No pain	121/142 (85)	127/150 (85)
Slight pain	15/142 (11)	15/150 (10)
Moderate pain	5/142 (4)	7/150 (5)
Severe pain	1/142 (1)	1/150 (1)
Bother with pain or discomfort [mean (SD) *n*][a]	2.4 (3.6) 54	2.3 (3.4) 68
Number of men using medication for sexual problems	25/177 (14)	20/186 (11)
Number of men using vacuum device for sexual problems	2/175 (1)	2/185 (1)
Number of men using either medication or a vacuum device for sexual problems	26/177 (15)	20/186 (11)
Number of men leaking urine during intercourse	3/135 (2)	3/133 (2)

Figures are *n*/*N* (%), unless otherwise indicated.
a Bother scale: 0 = not at all to 10 = a great deal.

FIGURE 43 Quality of erectile function at 12 months after prostate surgery: TURP.

TABLE 73 Quality of life outcomes measured by EQ-5D and SF-12

	Baseline		6 months			12 months		
TURP	Intervention	Control	Intervention	Control	Effect size (95% CI), *p*-value	Intervention	Control	Effect size (95% CI), *p*-value
EQ-5D	0.752 (0.270) 213	0.781 (0.251) 208	0.800 (0.257) 188	0.826 (0.235) 185	–0.005 (–0.040 to 0.031), 0.789	0.784 (0.249) 177	0.791 (0.266) 189	–0.005 (–0.040 to 0.031), 0.789
SF-12M	49.9 (10.4) 216	50.3 (10.4) 212	51.5 (9.5) 188	51.5 (10.5) 189	–0.039 (–1.708 to 1.630), 0.964	52.6 (9.2) 188	51.7 (10.5) 193	–0.039 (–1.708 to 1.630), 0.964
SF-12P	42.7 (11.0) 216	43.2 (11.9) 212	45.0 (11.6) 188	45.4 (12.6) 189	0.385 (–1.216 to 1.986), 0.636	44.5 (11.1) 188	44.0 (13.3) 193	0.385 (–1.216 to 1.986), 0.636

Figures are mean (SD) *n*, unless stated otherwise.
A higher score on the EQ-5D and the SF-12 represents better health.
Effect size is mean difference adjusted for age, urinary incontinence before surgery and baseline value.

this frequency, while those in the intervention group were more likely to be carrying out PFMT at 6 and 12 months (75% and 65% respectively, *Table 74*). Significantly more, 64%, were practising for 3–4 days or more each week in the intervention group than in the control group at 6 months (14%). Men in the intervention group were also more likely to perform contractions while walking (81% vs 41%) or before a stress situation such as coughing or lifting by performing a pelvic floor muscle contraction before an increase in intra-abdominal pressure, also known as 'the Knack' (40% vs 28%). 'The Knack' was also more likely to reduce or stop urinary leakage in the intervention group (77% vs 62%).

Men in the therapy group were performing more contractions every day (11.5 vs 4.3) by 12 months (*Table 74*). This is likely to reflect the taught exercise regimen in the therapy group (aiming for 18 strong contractions every day). Recommendations from NICE[72] suggest that men should perform eight contractions three times a day (24 per day). The low mean number of

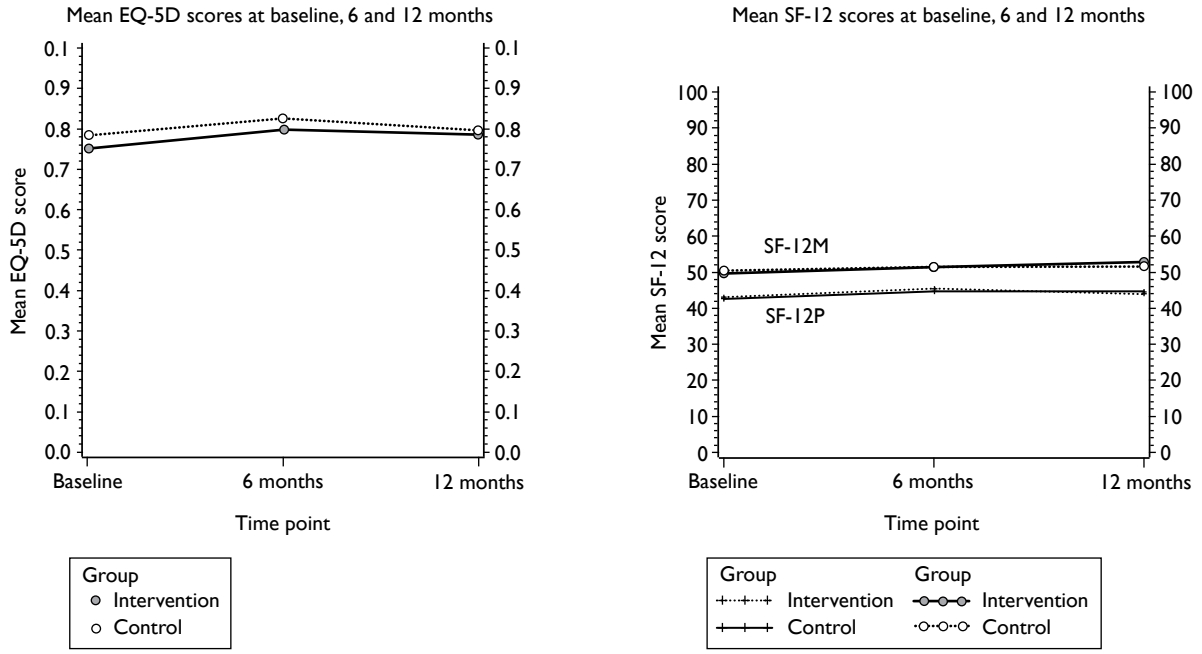

FIGURE 44 Graphical representations of EQ-5D and SF-12 scores over time: TURP. SF-12M, SF-12 role – mental; SF-12P, SF12 role – physical.

contractions reflects the high proportion of men in the control group (80%) not carrying out any exercises at all.

Lifestyle outcomes

Men were also advised, in the lifestyle advice leaflet sent to both groups and reinforced by the therapists in the intervention group, about the benefits of general health strategies such as taking more exercise. There were few differences between the groups in terms of other types of exercise practised (*Table 75*) except that men in the intervention group were more likely to practise walking [RR 1.18 (95% CI 1.02 to 1.35); *p*-value 0.024] or go swimming [RR 2.44 (95% CI 1.19 to 4.98); 0.014].

Finally, men in both groups were given (via the lifestyle advice leaflet) other general advice on lifestyle changes they could make that might help both with incontinence and general health. Again, this advice was reinforced by the therapists for men in the intervention group. There were no significant differences between the groups in terms of changes made to lifestyle factors after TURP (*Table 76*).

Prespecified subgroup analyses

Preplanned subgroup analyses were carried out on the primary outcome (urinary incontinence at 12 months) according to factors that we thought would be prognostic. These factors were:

1. pre-existing urinary incontinence (before prostate surgery)
2. age (up to 70 years, 71 years and over)
3. BMI (up to 30 kg/m^2, 30–34.9 kg/m^2, 35 kg/m^2 or greater)

TABLE 74 Practice of PFMT at 12 months after randomisation: results from 12-month questionnaire

	Baseline		6 months			12 months		
TURP	Intervention	Control	Intervention	Control	Effect size (95% CI), *p*-value	Intervention	Control	Effect size (95% CI), *p*-value
Yes	47/213 (22)	46/220 (21)	146/194 (75)	36/183 (20)	3.93 (2.90 to 5.31), 0.001	122/188 (65)	39/193 (20)	3.20 (2.37 to 4.32), 0.001
No	104/213 (49)	124/220 (56)	44/194 (23)	129/183 (70)		65/188 (35)	133/193 (69)	
Don't know	62/213 (29)	50/220 (23)	4/194 (2)	18/183 (10)		1/188 (1)	21/193 (11)	
Days carrying out PFMT								
Every day	26/213 (12)	28/220 (13)	75/194 (39)	14/183 (8)		51/188 (27)	15/193 (8)	
5–6 days	1/213 (0)	1/220 (0)	17/194 (9)	0/183 (0)		9/188 (5)	4/193 (2)	
3–4 days	12/213 (6)	9/220 (4)	32/194 (16)	11/183 (6)		38/188 (20)	11/193 (6)	
1–2 days	8/213 (4)	8/220 (4)	19/194 (10)	10/183 (5)		20/188 (11)	9/193 (5)	
None	166/213 (78)	174/220 (79)	51/194 (26)	149/183 (81)		70/188 (37)	155/194 (80)	
Average contractions [mean (SD) *n*]			12.4 (19.2) 194	2.7 (10.6) 183	9.6 (6.5 to 12.8), < 0.001	11.5 (22.8) 188	4.3 (16.4) 193	7.1 (3.1 to 11.1), 0.001
Deliberate contractions whilst walking[a]			156/186 (84)	67/163 (41)	2.04 (1.68 to 2.48), <0.001	151/186 (81)	71/175 (41)	1.98 (1.64 to 2.40), < 0.001
Deliberate contractions before doing something[a]			74/179 (41)	35/157 (22)	1.85 (1.32 to 2.60), <0.001	74/183 (40)	48/173 (28)	1.47 (1.09 to 1.98), 0.012
Contracting reduces or stops leaking			77/92 (80)	37/62 (60)	1.32 (1.05 to 1.66), 0.016	79/103 (77)	58/78 (62)	1.24 (1.01 to 1.52), 0.043

Figures are *n*/*N* (%), unless stated otherwise.
Effect size is RR unless indicated as mean difference, adjusted for age, urinary incontinence before surgery and baseline value.
a Coded as positive if man responded 'sometimes' or more often.

TABLE 75 Practice of other exercise at 12 months after randomisation: results from 12-month questionnaire

TURP	Intervention	Control
General exercise (yes)	148/184 (80)	139/192 (72)
Exercise type		
Walking	134/184 (73)	122/192 (62)
Swimming	23/184 (13)	10/192 (5)
Gardening	98/184 (53)	89/192 (45)
Running	6/184 (3)	5/192 (3)
Going to gym	12/184 (7)	10/192 (5)
Other	23/184 (13)	30/192 (16)
Changed exercise		
No	137/190 (72)	142/197 (72)
Less	17/190 (9)	26/197 (13)
More	36/190 (19)	29/197 (15)

Figures are *n*/*N* (%).

TABLE 76 Compliance with lifestyle advice and changes to lifestyle at 12 months

TURP	Intervention	Control
Weight		
No need to lose weight	68/184 (37)	75/192 (39)
Haven't tried to lose weight	67/184 (36)	83/192 (43)
Extra exercise to lose weight	33/184 (18)	19/192 (10)
Diet to lose weight	23/184 (13)	15/192 (8)
Other ways of losing weight	16/184 (9)	11/192 (6)
Fluid intake		
Number of men making no changes to fluid intake	66/189 (35)	86/196 (44)
Drink more fluids	84/189 (44)	85/196 (43)
Drink more cranberry juice	34/189 (18)	36/196 (18)
Drink fewer caffeinated drinks	52/189 (28)	47/196 (24)
Drink less fluid in evenings	67/189 (35)	59/196 (30)
Other changes to fluid intake	9/189 (5)	6/196 (3)
Diet		
Number of men making no changes to diet or food	104/186 (56)	109/193 (56)
More balanced diet	47/186 (25)	41/193 (21)
More fruit and vegetables	67/186 (36)	77/193 (40)
More fibre	44/186 (24)	42/193 (22)
Less fats or sugars	50/186 (27)	56/193 (29)
Other changes to food intake	3/186 (2)	6/193 (3)
Lifting		
Number of men who reduce lifting	90/191 (47)	86/196 (44)
Smoking		
Number of men who smoked	25/186 (13)	23/195 (12)
Number of men stopping smoking[a]	1/25 (4)	1/23 (4)
Number of men reducing smoking[a]	14/25 (56)	11/23 (48)
Chest or respiratory symptoms		
Number of men who did have chest symptoms	50/189 (26)	41/189 (22)
Taking correct medication[a]	36/50 (72)	24/41 (59)
Consulted GP about medication[a]	34/50 (68)	23/41 (56)
Other changes to reduce respiratory symptoms[a]	4/50 (8)	3/41 (7)

Figures are *n*/*N* (%).
a Responses limited to number of men who had chest symptoms.

4. type of incontinence at trial entry
    i. SUI
    ii. UUI
    iii. MUI
    iv. postmicturition leakage
5. other morbidity
6. type of therapist (physiotherapist or nurse).

Whilst a subgroup analysis on the use of biofeedback machines was also prespecified, there were insufficient numbers of centres with biofeedback machines to do so (see *Table 7*).

Figure 45 shows the effect of subgroup analysis on the primary outcome (urinary incontinence at 12 months) according to the prespecified factors. The dotted line reflects the overall main effect

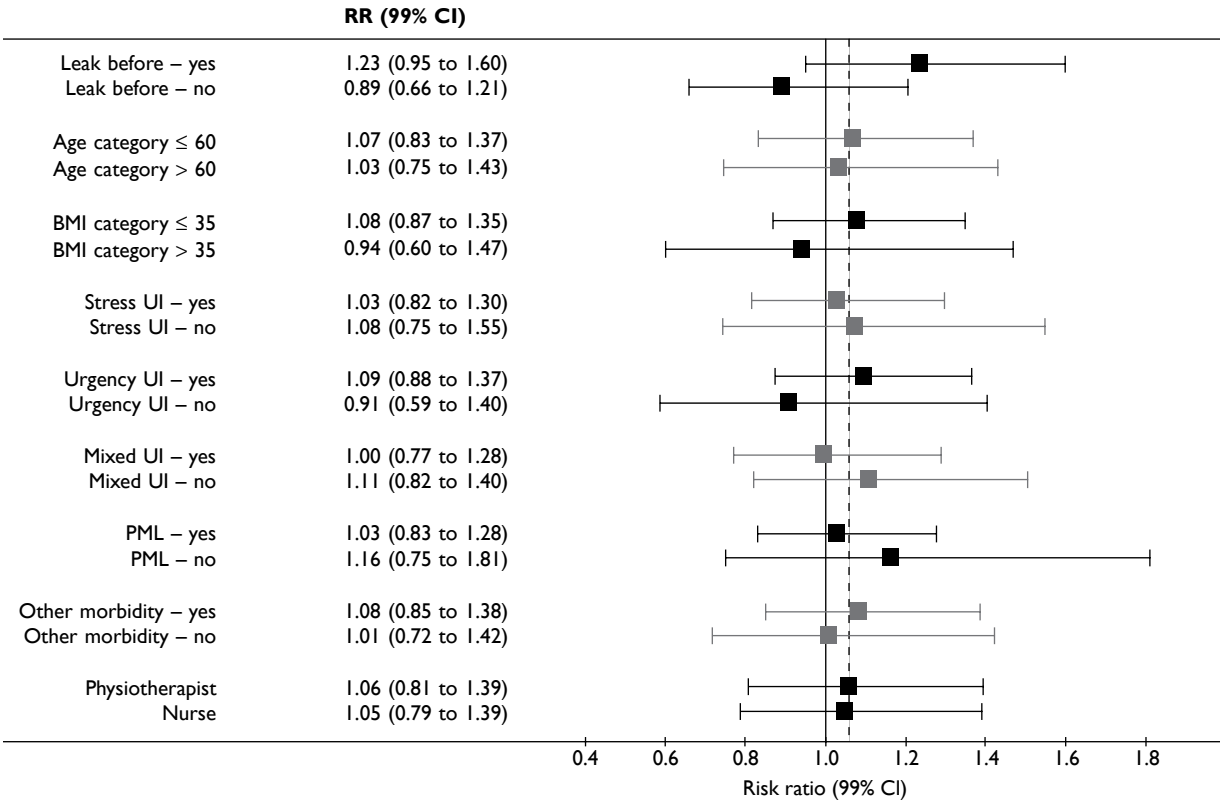

FIGURE 45 Forest plot of subgroup analyses: urinary incontinence at 12 months.

of the intervention on incontinence rates. Stricter levels of statistical significance ($2p < 0.01$) were sought (99% CIs), reflecting the exploratory nature of these analyses. There were no apparent clinically relevant differences according to any subgroup and none of the formal tests for statistical interaction effects was significant.

Satisfaction with treatment for urinary incontinence

Men were asked to score their satisfaction with the treatment they received for urinary incontinence (0 = 'very unsatisfied' to 10 = 'very satisfied') at 12 months after randomisation. Men in the intervention group were significantly more satisfied than those in the control group (see *Appendix 5*, *Table 93*). Thus, the therapy intervention did increase satisfaction rates despite the lack of difference in urinary outcomes.

Chapter 13

Resource use and cost-effectiveness in transurethral resection of the prostate randomised controlled trial

This chapter describes the economic analyses for the TURP RCT.

Description of the data available

Table 77 describes the number of men who contributed data for each of the areas of resource use and quality of life at each time point. Fewer data were available at the later data collection time points. For some areas of resource use (for example number of NHS pads at 12 months), only two-thirds of men indicated the quantity used. For other areas, for example inpatient admissions, 88% of men provided data on use of that resource even at 12 months. The difference between these two rates cannot be explained by the mode of data collection, as both were collected by participant-completed questionnaire. An alternative explanation might include the limited use of these services by 12 months, which meant that participants did not answer the questions because they did not think they were relevant. Other explanations could be advanced but there is no information to determine what the reasons are for men providing information for some areas of resource use but not others.

Analysis of resource use and costs

Resource use

Table 78 details the average resource use for the intervention and subsequent use of health services over the 12-month follow-up period after randomisation. Resource utilisation was slightly higher across most areas in the intervention group than in the control group but the differences were very small and were not statistically significant, apart from nurse and hospital physiotherapy visits and the number of private physiotherapy visits. A detailed description of the use of NHS and private provider health services is provided in *Appendix 5*.

Costs

Participant time and costs

The average time and costs to participants and their companions (families or carers) of a contact either with a primary care service provider or as an outpatient consultation or an inpatient admission are reported in *Table 79*. These data were combined with the information on number of contacts (e.g. hospital doctor visits) that the trial participants had reported (*Table 78*) to estimate a monetary cost per participant for both intervention and control.

Estimation of societal cost

Table 80 details the mean costs per participant of the two interventions. The unit cost information in *Tables 4* and *79* was combined with the resource use information reported in *Table 78* to provide estimates of the total cost per participant. For the base-case analysis based on societal costs the mean total cost per participant in the intervention group was £984 (SD £2626) and the

TABLE 77 Number of participants providing responses to resource utilisation questions (*n* intervention = 220; *n* control = 222): TURP

	Baseline [*n* (%)]		3 months [*n* (%)]		6 months [*n* (%)]		9 months [*n* (%)]		12 months [*n* (%)]	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
NHS-supplied pads	218 (99)	214 (96)	149 (68)	146 (66)	149 (68)	144 (65)	134 (61)	136 (61)	144 (65)	135 (61)
Self-supplied pads	216 (98)	210 (95)	144 (65)	144 (65)	148 (67)	143 (64)	133 (60)	133 (60)	142 (65)	134 (60)
NHS-supplied bed/chair protector	206 (94)	212 (95)	147 (67)	141 (64)	143 (65)	128 (58)	125 (57)	132 (59)	126 (57)	122 (55)
Self-supplied bed/chair protector	205 (93)	212 (95)	143 (65)	140 (63)	142 (65)	128 (58)	124 (56)	132 (59)	125 (57)	121 (55)
Catheter	220 (100)	218 (98)	204 (93)	199 (90)	187 (85)	188 (85)	186 (85)	194 (87)	188 (85)	195 (88)
Sheath	219 (100)	216 (97)	201 (91)	199 (90)	187 (85)	182 (82)	186 (85)	193 (87)	185 (84)	192 (86)
GP incontinent visit	151 (69)	163 (73)	141 (64)	143 (64)	121 (55)	142 (64)	118 (54)	141 (64)	120 (55)	131 (59)
GP other visit	200 (91)	206 (93)	195 (89)	191 (86)	186 (85)	183 (82)	186 (85)	189 (85)	182 (83)	189 (85)
Nurse incontinent visit	189 (86)	195 (88)	162 (74)	157 (71)	141 (64)	145 (65)	136 (62)	148 (67)	137 (62)	149 (67)
Nurse other visit	207 (94)	211 (95)	190 (86)	191 (86)	186 (85)	176 (79)	181 (82)	186 (84)	181 (82)	191 (86)
Hospital doctor visit	203 (92)	204 (92)	170 (77)	190 (86)	173 (79)	183 (82)	181 (82)	187 (84)	176 (80)	178 (80)
Hospital nurse visit	185 (84)	189 (85)	162 (74)	172 (77)	168 (76)	172 (77)	166 (75)	181 (82)	170 (77)	174 (78)
Hospital physiotherapist visit	205 (93)	204 (92)	182 (83)	180 (81)	171 (78)	171 (77)	172 (78)	182 (82)	168 (76)	173 (78)
Private doctor visit	215 (98)	217 (98)	187 (85)	192 (86)	184 (84)	183 (82)	184 (84)	187 (84)	180 (82)	185 (83)
Private nurse visit	191 (87)	193 (87)	181 (82)	182 (82)	179 (81)	174 (78)	178 (81)	184 (83)	176 (80)	178 (80)
Private physiotherapist visit	207 (94)	206 (93)	187 (85)	190 (86)	175 (80)	171 (77)	178 (81)	186 (84)	179 (81)	175 (79)
Inpatient visit	218 (99)	220 (99)	197 (90)	198 (89)	189 (86)	188 (85)	188 (85)	193 (87)	188 (85)	195 (88)
Days off work	206 (94)	204 (92)	185 (84)	192 (86)	183 (83)	179 (81)	176 (80)	179 (81)	183 (83)	186 (84)

Note: the number of responses available differs from those reported in *Appendix 5* as these particular values refer to responses, not the number of questionnaires returned.

TABLE 78 Mean resource use per participant during 12-month period after randomisation: TURP

Area of resource use	Intervention [mean (SD)]	Control [mean (SD)]	Difference (95% CI)[a]
Intervention visits	3.10 (1.51)	0	–3.10
Subsequent resource use			
NHS-supplied pads used	1.09 (3.28)	0.77 (2.33)	0.21 (–0.24 to 0.66)
NHS-supplied bed/chair protectors used	0.14 (0.83)	0.29 (1.54)	–0.18 (–0.40 to 0.04)
GP doctor incontinence-related visits	0.38 (1.32)	0.37 (0.98)	–0.02 (–0.23 to 0.20)
GP doctor other visit	4.25 (4.32)	4.00 (4.04)	0.34 (–0.43 to 1.11)
GP nurse incontinence-related visit	0.20 (1.00)	0.20 (1.15)	0.00 (–0.19 to 0.19)
GP nurse other visit	2.47 (4.00)	2.61 (4.56)	0.01 (–0.75 to 0.76)
Number of men using catheters	0.45 (0.92)	0.34 (0.78)	0.10 (–0.06 to 0.26)
Number of men using sheaths	0.15 (0.52)	0.15 (0.54)	–0.01 (–0.10 to 0.09)
Hospital doctor visits	0.33 (1.48)	0.37 (1.04)	–0.04 (–0.28 to 0.20)
Hospital nurse visits[b]	0.46 (1.33)	0.15 (0.60)	0.31 (0.12 to 0.51)
Hospital physiotherapy visits[b]	0.82 (1.68)	0.06 (0.39)	0.76 (0.53 to 0.99)
Inpatient days	0.06 (0.44)	0.05 (0.35)	0.01 (–0.06 to 0.08)
Number taking incontinence drugs	0.22 (0.66)	0.36 (0.95)	–0.13 (–0.28 to 0.02)
Participant resource use			
Self-supplied pads used	1.10 (3.86)	0.84 (3.58)	0.26 (–0.42 to 0.94)
Self-supplied bed/chair protector used	0.22 (1.51)	0.36 (2.42)	–0.15 (–0.52 to 0.23)
Private doctor visits	0.05 (0.28)	0.10 (0.34)	–0.05 (–0.11 to 0.01)
Private nurse visits	0.10 (0.62)	0.05 (0.27)	0.05 (–0.03 to 0.14)
Private physiotherapist visits[b]	0.26 (0.87)	0.18 (2.29)	0.22 (0.10 to 0.34)
Number of days off work	4.14 (23.32)	1.50 (11.48)	2.63 (–0.58 to 5.84)

Note: the number of days off work refers only to the number of days off paid employment.
a Differences adjusted for baseline costs.
b Statistically significantly different at 5% level.

TABLE 79 Cost to the participant and their companion of a single visit or admission: TURP

Resource use	Time or monetary cost	Mean (SD)
Primary care consultation visit	Time spent going to and attending a primary care consultation (hours)	0.68 (0.29)
	Companion's time off work (£)	1.10 (2.68)
	Average cost to participant and companion of a primary care consultation (£)	11.29 (13.38)
Secondary care visit	Time spent attending a secondary care visit (hours)	1.73 (1.11)
	Companion's time off work (£)	5.81 (9.69)
	Average cost to participant and companion of travelling to a secondary care department (£)	25.25 (25.31)
Inpatient visit	Number of visits to participant during admission	2.10 (4.47)
	Companion's time off work (£)	6.59 (31.69)
	Average cost to participant and companion of admission (£)	30.21 (55.84)

mean cost in the control group was £566 (SD £1285). There was evidence of higher costs in the intervention group: mean difference £420 (95% CI £55 to £785). The difference in mean societal cost was mainly due to the higher number of days taken off work by the participants in the intervention arm of the trial and the cost of the intervention itself.

TABLE 80 Cost per participant for each area of resource use: TURP

Area of resources use	Intervention [mean cost, £ (SD)]	Control [mean cost, £ (SD)]	Difference (95% CI)[a]
NHS costs			
Intervention	174.47 (82.89)	0	174.47
Subsequent resource use			
NHS-supplied pads	16.88 (50.74)	11.85 (35.99)	3.27 (–3.70 to 10.24)
NHS-supplied bed/chair protectors	1.92 (11.32)	3.94 (21.05)	–2.50 (–5.56 to 0.51)
GP doctor incontinence-related visits	13.58 (47.53)	13.46 (35.42)	–0.57 (–8.27 to 7.11)
GP doctor other visit	153.16 (155.65)	143.84 (145.32)	12.13 (–15.53 to 39.79)
GP nurse incontinence-related visit	2.20 (11.01)	2.18 (12.63)	0.12 (–2.12 to 2.14)
GP nurse other visit	27.20 (44.04)	28.74 (50.17)	0.06 (–8.22 to 8.35)
Catheter	1.28 (13.36)	0.42 (4.44)	0.87 (–1.030 to 2.73)
Sheath	13.50 (62.93)	13.38 (55.23)	1.41 (–0.26 to 0.80)
Hospital doctor visits	24.89 (111.12)	27.70 (77.78)	–2.70 (–20.66 to 15.26)
Hospital nurse visits	14.37 (41.19)	4.75 (18.74)	9.67 (3.68 to 15.67)[b]
Hospital physiotherapy visits	25.36 (52.11)	1.82 (12.20)	23.52 (16.45 to 30.59)[b]
Inpatient days	7.15 (47.89)	6.89 (44.15)	0.26 (–8.36 to 8.88)
Prescribed drugs	14.51 (50.33)	24.97 (76.77)	–7.24 (–18.84 to 4..36)
Total subsequent use cost	318.13 (333.42)	284.81 (315.07)	34.43(–25.53 to 94.38)
Total NHS cost	*492.59 (355.95)*	*284.81 (315.07)*	*208.88 (146.69 to 271.07)*[b]
Participant costs			
Self-supplied pads	19.41 (61.51)	11.22 (36.97)	8.22 (–1.17 to 17.60)
Self-supplied bed/chair protector	0.31 (2.42)	3.75 (29.81)	–3.45 (–7.38 to 0.48)
Private doctor visits	0.00 (0.00)	1.35 (15.90)	–1.35 (–3.46 to 0.76)
Private nurse visits	0.00 (0.00)	0.00 (0)	0
Private physiotherapist visits	0.14 (2.09)	4.75 (70.74)	–0.52 (–1.72 to 0.68)
Number of days off work	439.76 (2476.70)	158.82 (1219.55)	279.32 (–61.62 to 620.28)
Total participant costs	*462.30 (2519.18)*	*184.00 (1222.49)*	*277.74 (–68.71 to 624.18)*
Participant travel and companion travel and time off work costs			
Intervention	78.39 (38.18)	0	78.39
GP doctor incontinence-related visits	4.26 (14.90)	4.22 (11.11)	0.18 (–2.59 to 2.23)
GP doctor other visit	48.03 (48.81)	45.11 (45.57)	3.81 (–4.87 to 12.48)
GP nurse incontinence-related visit	2.26 (11.30)	2.24 (12.96)	0.01 (–2.17 to 2.20)
GP nurse other visit	27.92 (45.20)	29.50 (51.49)	0.06 (–8.44 to 8.57)
Total GP travel and time off work	82.47 (85.60)	81.06 (88.75)	2.93 (–12.81 to 18.67)
Hospital doctor visits	8.38 (37.41)	9.33 (26.19)	–0.91 (–6.96 to 5.14)
Hospital nurse visits	11.71 (33.55)	3.87 (15.27)	7.88 (3.00 to 12.76)
Hospital physiotherapy visits	20.66 (42.44)	1.48 (9.94)	19.16 (13.40 to 24.92)[b]
Total outpatient travel and time off work costs	197.52 (118.68)	14.67 (41.33)	13.65 (–4.99 to 32.29)
Total inpatient visits	1.79 (13.27)	1.50 (10.45)	0.29 (–1.94 to 2.52)
Total participant travel and companion travel and time off work costs	360.17 (187.89)	97.23 (104.11)	70.06 (39.73 to 100.39)[b]
Total participant and companion cost	*665.68 (2540.26)*	*281.24 (1224.41)*	*385.11 (35.21 to 35.01)*[b]
Total societal costs	*983.81 (2626.28)*	*566.05 (1284.97)*	*419.50 (53.67 to 785.31)*[b]

a Adjusting for use of health services before randomisation.
b Statistically significant at 5% level.

Estimation of NHS costs

In terms of NHS costs incurred after the intervention was delivered, the mean total cost per patient in the intervention group was £493 (SD £356) and the mean cost in the control group was £285 (SD £315). There was, however, no evidence of a statistically significant difference in the cost of subsequent NHS services used. Intervention costs were, as would be expected, greater in the intervention group. Combining information on the cost of the interventions and the cost of subsequent NHS care resulted in a statistically significantly higher total cost per participant in the intervention group. The mean difference was £209 (95% CI £147 to £271). This difference was driven almost entirely by the cost of the PFMT intervention itself.

Quality-adjusted life-years

Table 81 reports the EQ-5D scores for each arm of the trial at baseline and 6 and 12 months. Also reported is the difference between arms in EQ-5D score at 6 and 12 months. From these data it was estimated that the mean QALYs were 0.78 (SD 0.24, median 0.85) for the intervention arm and 0.82 (SD 0.22, median 0.89) for the control arm. The mean difference in QALYs after adjusting for minimisation and baseline EQ-5D scores was –0.00003 (95% CI –0.026 to 0.026). The mean difference is equivalent to 0.011 days in full health over the 1-year time horizon.

Imputation was not performed on missing values in the base-case analysis. Simple plausible extreme value imputation on EQ-5D scores, taking the 25th and 75th percentile values, suggested that only if it is assumed that all missing values were equal to the 75th percentile range of EQ-5D scores would the mean difference in EQ-5D scores differ from that reported in *Table 81*. However, this mean difference still would not be significantly different.

Estimation of cost-effectiveness

Societal perspective

Taking the mean difference in costs from *Table 80*, and assuming that the mean difference in the QALYs from *Table 81* is 0, then on average the intervention is both more costly and no more effective than the control and hence the intervention is dominated by the control (*Table 82*). Arithmetically, the ICER was 14 million because the difference in QALYs was just negative. However, this has been interpreted as being effectively 0 as the difference was so small as to be meaningless.

One thousand bootstrap simulations were undertaken to estimate the uncertainty around the benefits and costs. At a willingness to pay threshold of £20,000 per QALY the intervention has a probability of 11% of being cost-effective, and at a threshold of £30,000 per QALY the

TABLE 81 Quality of life measures: TURP

	Intervention [mean (SD)]	Control [mean (SD)]	Difference (95% CI)[a]
Baseline EQ-5D	0.75 (0.27)	0.78 (0.25)	
	n=213 (97%)	*n*=208 (94%)	
6-month EQ-5D	0.80 (0.26)	0.83 (0.24)	–0.03
	n=188 (85%)	*n*=185 (83%)	
12-month EQ-5D	0.78 (0.25)	0.79 (0.27)	–0.01
	n=177 (80%)	*n*=189 (85%)	
QALYs	0.78 (0.24)	0.82 (0.22)	–0.00003 (–0.026 to 0.026)
	n=162 (74%)	*n*=163 (73%)	

a Adjusting for baseline EQ-5D before randomisation.

TABLE 82 Cost-effectiveness results from the societal perspective: TURP

Difference in mean costs [mean (95% CI)[a]]	419.50 (53.67 to 785.31)
Difference in QALYs [mean (95% CI)[a]]	–0.00003 (–0.026 to 0.026)
ICER (£/QALY)	Dominated
Probability intervention is cost-effective when threshold is £20,000	11.2%
Probability intervention is cost-effective when threshold is £30,000	17.3%

a Adjusting for baseline before randomisation.

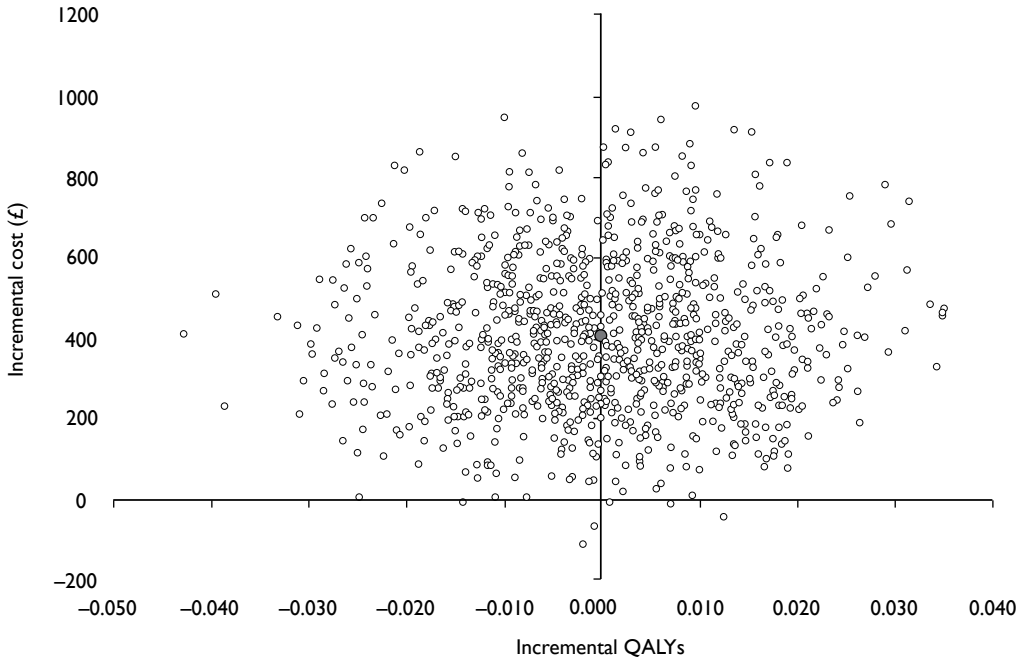

FIGURE 46 Representation of the uncertainty in differential mean costs and QALYs: societal perspective (TURP).

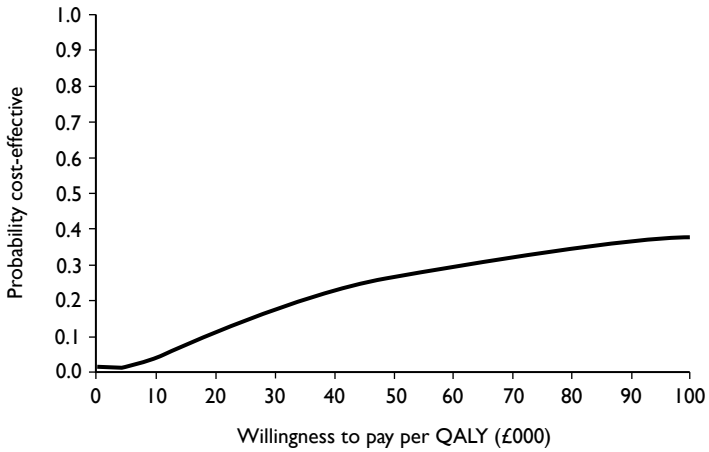

FIGURE 47 Cost-effectiveness acceptability curve for intervention versus control: societal perspective (TURP).

intervention is 17% likely to be cost-effective (*Figures 46* and *47*). At no point does the probability of being cost-effective reach 50%.

NHS perspective

Taking the mean difference in total NHS costs from *Table 80* and assuming that the mean difference in QALYs is effectively zero means that the provision of PFMT is on average both more costly and no more effective than the control and hence dominated (*Table 83*). Arithmetically, the ICER was 6.9 million because the difference in QALYs was just negative. However, this has been interpreted as being effectively 0 as the difference was so small as to be meaningless.

As with the societal perspective, bootstrap simulations were undertaken to estimate the uncertainty around the benefit and costs. The bootstrap estimates in *Figure 48* indicate that the intervention group had higher costs than the control; however, there was a relatively wide distribution in the difference in QALYs.

At a cost-effectiveness threshold of £20,000 per QALY, the intervention has a probability of 20% of being cost-effective and at a threshold of £30,000 per QALY the intervention is 29% likely to be cost-effective (*Figure 49*). At no point does the probability of being cost-effective reach 50%. This indicates that it is unlikely that PFMT is cost-effective.

TABLE 83 Cost-effectiveness results from the perspective of the NHS: TURP

Difference in mean NHS costs [mean (95% CI)[a]]	208.88 (146.69 to 271.07)
Difference in QALYs [mean (95% CI)[a]]	–0.00003 (–0.026 to 0.026)
ICER (£/QALY)	Dominated
Probability intervention is cost-effective when threshold is £20,000 per QALY	20.0%
Probability intervention is cost-effective when threshold is £30,000 per QALY	29.4%

a Adjusting for baseline before randomisation.

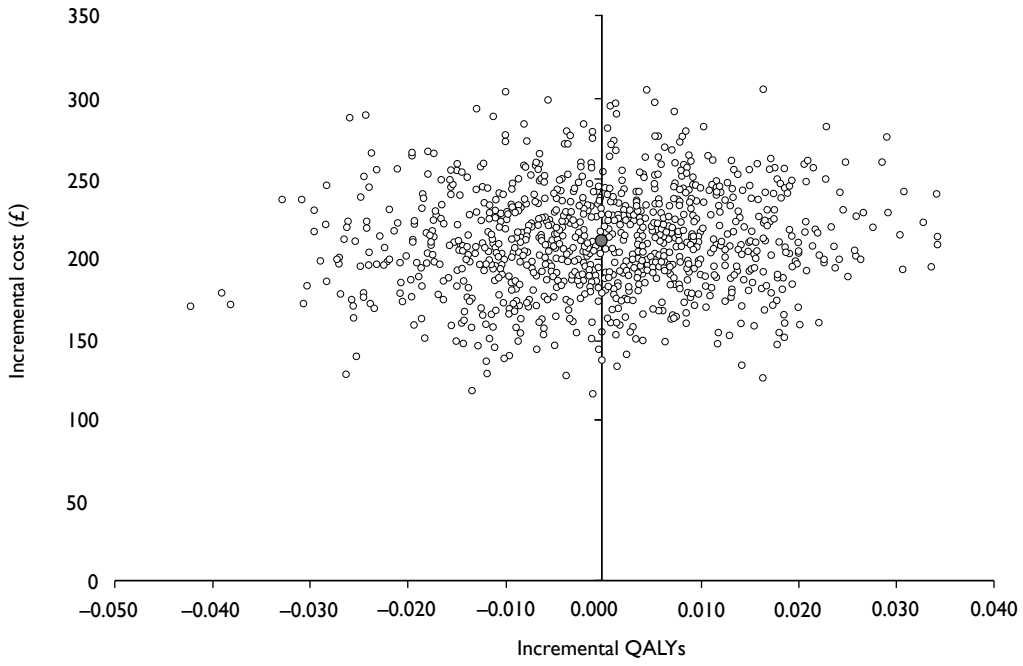

FIGURE 48 Representation of the uncertainty in differential mean costs and QALYs: NHS perspective (TURP).

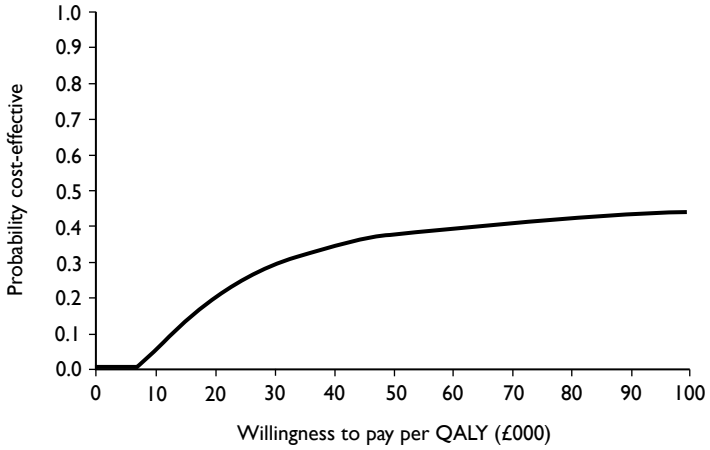

FIGURE 49 Cost-effectiveness acceptability curve for intervention versus control: NHS perspective (TURP).

Sensitivity analysis

As mentioned in *Chapter 2*, sensitivity analysis is necessary to assess the robustness of the qualitative conclusion and identify areas where research is needed to more precisely estimate the values of those variables to which the result is sensitive. The variables that were considered uncertain in this study related to the cost of the different services used.

Incremental cost per quality-adjusted life-year when differences are not adjusted for baseline differences

An unadjusted analysis was performed as a sensitivity analysis to highlight the importance of the assumption that the characteristics of the groups were not the same at baseline. The results of this analysis, from the perspective of the NHS, indicate that at a cost-effectiveness threshold of £20,000 per QALY the intervention has a probability of 41.1% of being cost-effective, and at a threshold of £30,000 per QALY the intervention is 47.4% likely to be cost-effective (*Figures 50* and *51*).

Basing quality-adjusted life-year estimates on SF-6D values

Table 84 reports the SF-6D scores for each arm of the trial at baseline and 6 and 12 months. These scores were slightly lower than those reported using the EQ-5D at the same time points. From these data it was estimated that the mean QALYs were 0.75 (SD 0.13, median 0.800) for the intervention arm and 0.77 (SD 0.15, median 0.783) for the control arm. The mean difference in QALYs, after adjusting for minimisation and baseline EQ-5D scores, was 0.004 (95% CI –0.012 to 0.022) higher for the control group, which was not statistically significant.

The results of the analysis using the SF-6D data when estimating incremental cost-effectiveness from the societal perspective were similar to those of the EQ-5D. Taking the mean difference in the total societal costs from *Table 80* (£420) and the mean QALY difference from *Table 85* (–0.004) it can be seen that the intervention is on average less effective and more costly, indicating that it is dominated.

At a cost-effectiveness threshold of £20,000 per QALY, the intervention has a likelihood of 2% of being cost-effective, and at a threshold of £30,000 per QALY the intervention has only a 4% likelihood of being cost-effective (*Figures 52* and *53*). Based on the societal perspective, these estimates indicate that the intervention is unlikely to be cost-effective.

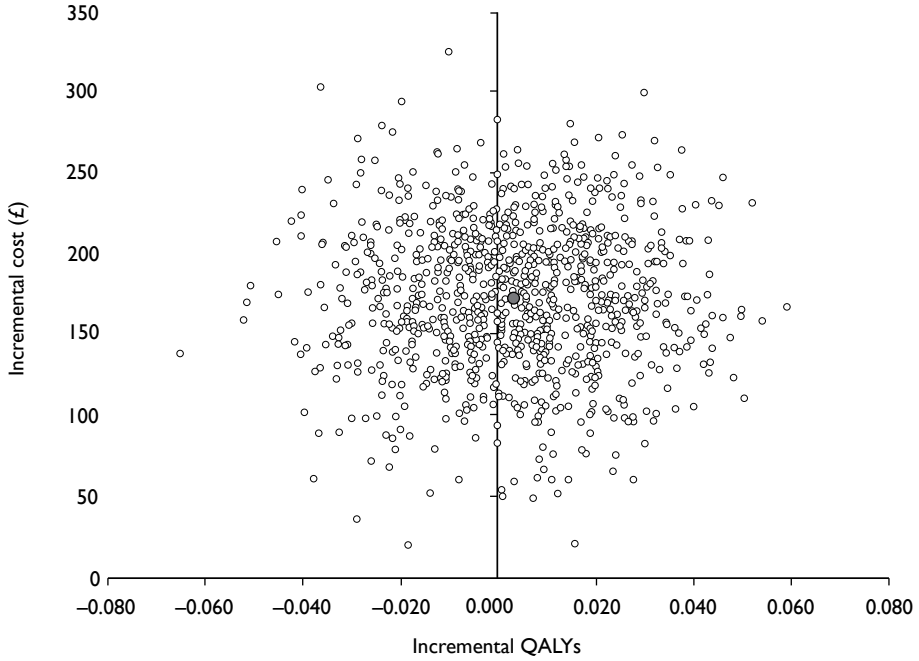

FIGURE 50 Representation of the uncertainty in differential mean costs and QALYs: using unadjusted data (TURP).

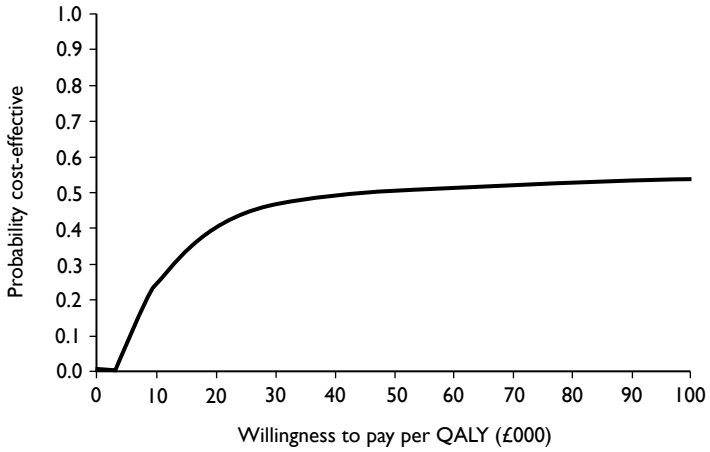

FIGURE 51 Cost-effectiveness acceptability curve for intervention versus control: using unadjusted data (TURP).

TABLE 84 SF-6D quality of life measures: TURP

	Intervention [mean (SD)]	Control [mean (SD)]	Difference (95% CI)[a]
Baseline SF-6D	0.73 (0.14)	0.73 (0.15)	
	n=217 (99%)	*n*=209 (94%)	
6-month SF-6D	0.76 (0.15)	0.77 (0.16)	–0.01
	n=186 (85%)	*n*=187 (84%)	
12-month SF-6D	0.77 (0.15)	0.76 (0.16)	0.01
	n=186 (85%)	*n*=191 (86%)	
QALYs	0.75 (0.13)	0.77 (0.15)	–0.004 (–0.020 to 0.012)
	n=172 (78%)	*n*=166 (75%)	

a Adjusting for baseline EQ-5D before randomisation.

Taking the perspective of the NHS resulted in similar findings (*Table 86*). The probability of the interventions being cost-effective in this analysis was lower than that estimated when using the EQ-5D data. At a cost-effectiveness threshold of £20,000 per QALY the intervention has a probability of 4.2% of being cost-effective, and at a threshold of £30,000 per QALY the intervention has a 9% chance of being cost-effective (*Figures 54* and *55*). At no point does the probability of being cost-effective reach 50%, and it is unlikely that the intervention would be cost-effective.

Threshold analysis around the cure rates

Further sensitivity analysis was performed by reanalysing the data by patient group for differences in costs and QALYs by continence status. A simple model was used to determine at what reduction in the rate of incontinence in the intervention group compared with the control group PFMT might be cost-effective. Details of the parameters used in the model are given in *Table 87*.

The results of the analysis indicate that the intervention was always dominated over the range of reductions in incontinence considered. Hence, it can be concluded that it is unlikely that the intervention could ever be considered cost-effective.

TABLE 85 Cost-effectiveness results from the societal perspective: TURP

Difference in mean NHS costs [mean (95% CI)[a]]	419.50 (53.67 to 785.31)
Differences in QALYs [mean (95% CI)[a]]	–0.004 (–0.020 to 0.012)
ICER (£/QALY)	Dominated
Probability intervention is cost-effective when threshold is £20,000 per QALY	1.9%
Probability intervention is cost-effective when threshold is £30,000 per QALY	3.9%

a Adjusting for baseline before randomisation.

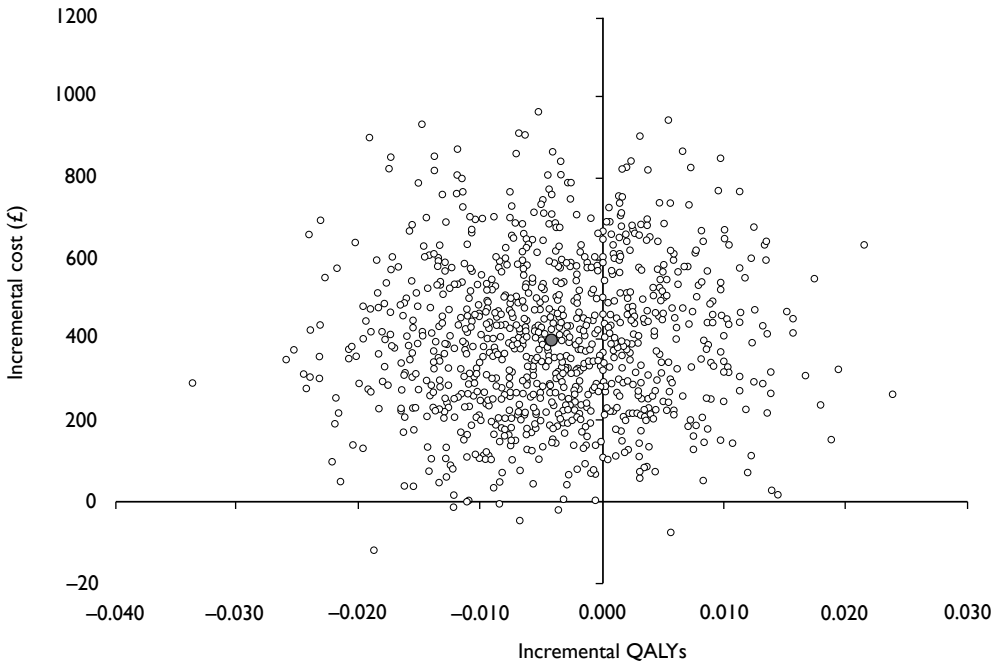

FIGURE 52 Representation of the uncertainty in differential mean costs and QALYs: societal perspective using SF-6D data (TURP).

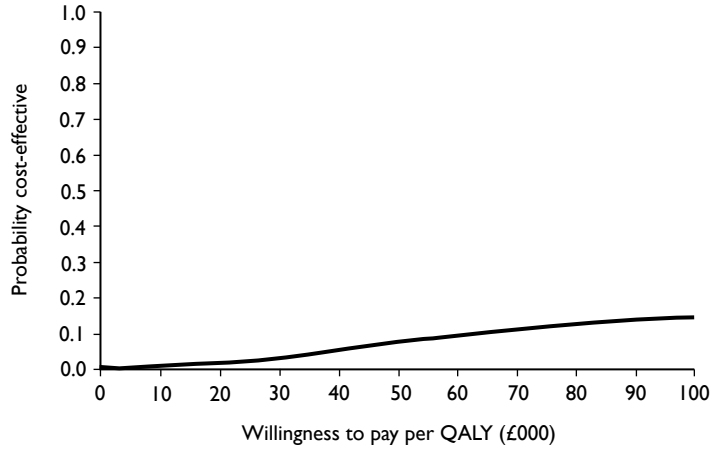

FIGURE 53 Cost-effectiveness acceptability curve for intervention versus control: societal perspective using SF-6D data (TURP).

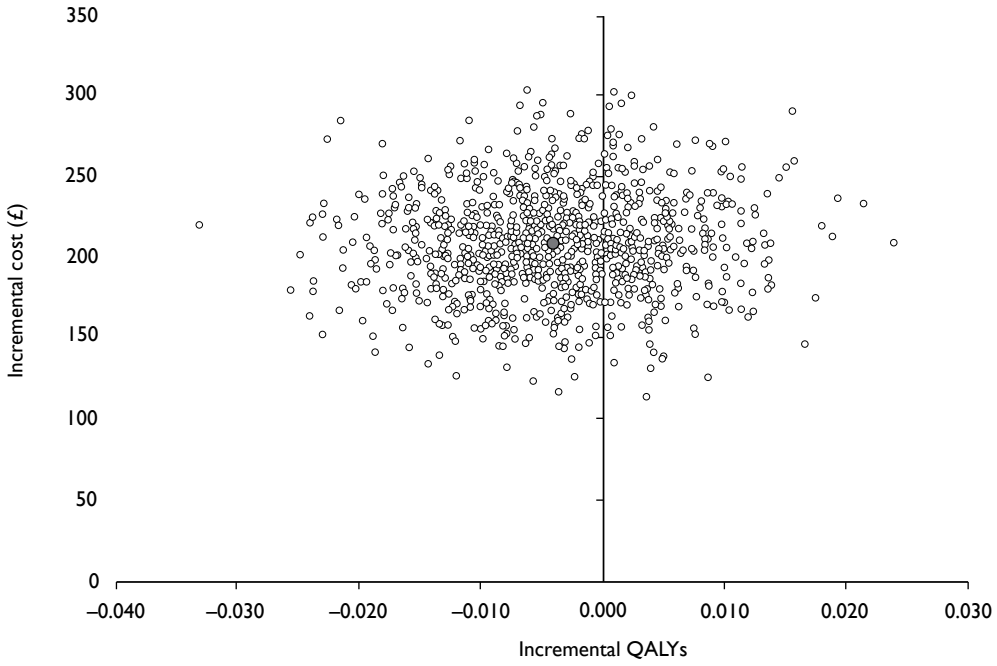

FIGURE 54 Representation of the uncertainty in differential mean costs and QALYs: NHS perspective using SF-6D data (TURP).

TABLE 86 Cost-effectiveness results from the perspective of the NHS: TURP

Difference in mean NHS costs [mean (95% CI)[a]]	181.02 (107.06 to 254.97)
Differences in QALYs [mean (95% CI)[a]]	–0.004 (–0.020 to 0.012)
ICER (£/QALY)	Dominated
Probability intervention is cost-effective when threshold is £20,000 per QALY	4.2%
Probability intervention is cost-effective when threshold is £30,000 per QALY	8.9%

a Adjusting for baseline before randomisation.

Conclusions

For men having TURP QALYs were similar in both groups, and costs for those who received the intervention were higher regardless of whether a societal or an NHS perspective was taken. Therefore, for both perspectives and over the range of sensitivity analyses conducted, it is unlikely that the provision of physical therapy for men who are incontinent after TURP would be cost-effective.

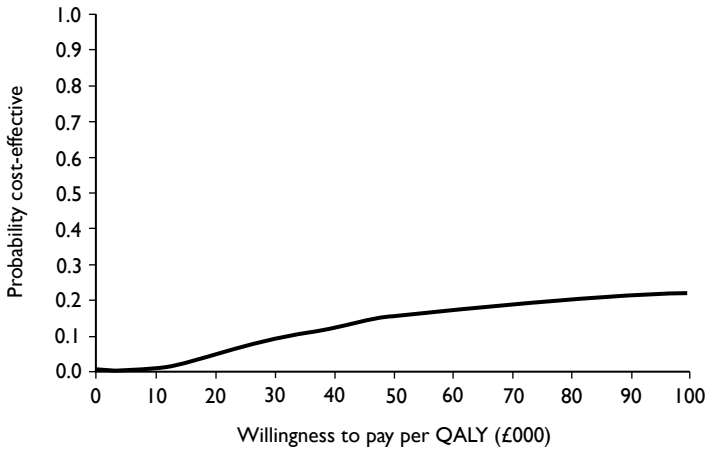

FIGURE 55 Cost-effectiveness acceptability curve for intervention versus control: NHS perspective using SF-6D data (TURP).

TABLE 87 Data used in analysis based on random allocation and state of incontinence at 12 months: TURP

Parameter	Participants in the intervention group who were continent	Participants in the intervention group who were incontinent	Participants in the control group who were continent	Participants in the control group who were incontinent
Cost of intervention (£)	178.81 (223.00) [75.85]	195.07 (223.00) [67.32]	0.00 (0.00) [0.00]	0.00 (0.00) [0.00]
Total subsequent resource use costs (£)	304.69 (223.19) [308.33]	425.02 (351.65) [351.14]	225.67 (141.00) [241.53]	433.08 (334.13) [368.07]
Total NHS costs (£)	483.51 (417.41) [331.26]	620.09 (572.00) [352.32]	225.67 (141.00) [241.53]	433.08 (334.13) [368.07]
QALYs	0.82 (0.87) [0.20]	0.77 (0.85) [0.26]	0.87 (0.95) [0.19]	0.79 (0.84) [0.23]
Probability of being continent/incontinent	0.35	0.65	0.38	0.62
Relative risk of being incontinent	Varied between 0.85 and 1	Varied between 0.85 and 1		

Figures are mean (SD) [median].

Chapter 14

Discussion of results of transurethral resection of the prostate randomised controlled trial

This chapter summarises the discussions relating to the TURP RCT.

Summary of main findings

In the men who had TURP, there were no statistically significant differences in urinary, bowel or sexual function outcomes between men in the intervention and control groups, despite evidence of extra performance of PFMT and improvement in pelvic floor muscle strength over time in the intervention group. The estimated extra cost to the NHS was on average £209 (95% CI £147 to £271) higher in the intervention group than in the controls.

Recruitment and screening of men in hospital

We approached 5986 men having TURP in NHS hospitals and obtained consent to screen 2832 of them. Of those, 91% returned their screening survey, and 46% were incontinent of urine at about 6 weeks after surgery (see *Table 51*). The majority of the men (around 94%) had a standard TURP, and a further 5% had a laser TURP. Around 36% of the men had urinary incontinence before surgery, and 4% reported faecal incontinence (see *Table 51*). The average age of the men was 70 years.

Recruitment to randomised controlled trial and response rates

Of the 1201 men who were incontinent at screening, 442 agreed to be randomised to a controlled trial of conservative treatment (including PFMT and lifestyle advice) for urinary incontinence (220 in the intervention group and 222 in the control group). The groups were comparable at baseline on all the epidemiological and clinical characteristics measured (see *Table 52*). Most men (around 80% in both groups) had heard of pelvic floor exercises at some point before starting the study (see *Table 53*).

Conduct of the intervention

Compliance with the intervention was high, with 86% of the men allocated to the intervention group attending at least one therapy visit and 72% attending all four of them. The most common reasons for not attending were becoming dry or ill, or finding it inconvenient to attend (see *Table 56*).

Association with type of therapist

Half of the centres used physiotherapists as the provider of the intervention, while the rest used nurse therapists (although all therapists received the same standardised training). About half of the men attended a physiotherapist while the other half attended a nurse therapist. However, there were no significant differences in the number of visits or the prevalence of urinary incontinence during the treatment period according to type of therapist (see *Table 57*).

At follow-up, no statistically significant association was demonstrated between the chance of incontinence at 12 months and type of therapist (*Figure 57*).

Clinical symptoms during the therapy period

During the therapy period, the proportion of men with incontinence fell from 82% to 52% by the fourth visit (see *Table 58* and *Figure 32*). Few men reported bowel problems, and these numbers did not vary much over time (see *Table 60* and *Figure 34*), although constipation was more common amongst the men who had a radical prostatectomy (who were around 10 years younger). Around half of the men had problems with sexual function and these did not improve with time (see *Table 61* and *Figure 35*).

Clinical findings during the therapy period

Anal sphincter and pelvic floor muscle contraction strength increased over time in the intervention group: 37% of men had good or better strength at the beginning of the therapy period, rising to 80% by the fourth visit (see *Table 62* and *Figure 36*). However, around 20% still had only moderate or poor contraction strength at the end of the 3-month therapy period.

Machine-led biofeedback was available in only 13 of the 34 MAPS centres, and was only actually used clinically in 10 men from two centres (see *Table 63*). When it was used it was not clear whether it was for diagnosis or for repeated use to assist with training. However, almost all men had verbal biofeedback from their therapist following digital anal assessment of muscle contraction, to teach them to perform contractions correctly and to monitor improvement at each successive visit.

Practice of pelvic floor muscle training after end of the therapy period

While around 20% of men in both the intervention and control groups were practising PFMT at baseline (before they were randomised and before the intervention), this increased to 65% in the intervention group at the 12-month follow-up, but remained at 20% in the control group.

Findings of the randomised controlled trial

The primary outcome of the RCT was the proportion of men with urinary incontinence at 12 months after randomisation. This was measured using the ICI-SF questionnaire, and was also ascertained at 3, 6 and 9 months after randomisation. In addition, urinary outcomes were obtained from 3-day diaries completed by the men at each of these time points. The response rates were almost all over 95% for the questionnaires and over 80% for the diaries (see *Table 65*).

Urinary outcomes

While the proportion of men with urinary incontinence fell from 100% at baseline to around 65% by 12 months, the majority of the decrease occurred in the first 3 months (to around 65%). There was no statistically significant difference between the intervention and control group in the proportion of men with urinary incontinence at 12 months [64.9% vs 61.6%, absolute risk difference 3.4% (95% CI –6% to 13%) at 12 months; see *Table 66*] or at any other time point (see *Table 67* and *Figure 39*).

These findings (of no statistically significant differences between the trial groups) were similar for all the urinary outcomes regardless of how (by questionnaire or diary) or when they were measured (see *Table 67*).

Severity of incontinence

If severe incontinence is defined as leakage at least once a day and a moderate or large amount of leakage, around 25% of the men were still experiencing severe leakage at 12 months

(see *Table 67a*) and around 17% were also using pads at 12 months (see *Table 69a*). Using the ICI score as a composite measure of severity and effect on quality of life, the same picture emerged: the majority of the improvement (decrease) in the score occurred in the first 3 months after randomisation with little further improvement (see *Table 67* and *Figure 40*).

Types of incontinence

The most common type of incontinence was UUI (around 80%, see *Table 68*), while SUI and MUI affected around 60% of men. These and the other types of urinary symptoms were not different in the randomised groups at any time point, although they all decreased in frequency with time (see *Table 68* and *Figure 41*).

Subgroup analyses

Prespecified subgroup analyses were carried out on the primary outcome (urinary incontinence at 12 months). There were no significant differences between randomised groups in any of the subgroups (see *Figure 45*).

Other clinical outcomes

Men were also asked to report on bowel and sexual problems.

Bowel outcomes

Bowel problems that might be expected to be ameliorated by therapy or lifestyle advice included faecal incontinence, urgency and constipation. Men were also asked about bowel conditions such as ulcerative colitis, Crohn's disease and irritable bowel syndrome. There were no differences at any time point in any aspect of bowel function or disease between the men in the randomised groups (see *Table 70* and *Figure 42*).

Sexual function outcomes

Around 70% of men had normal erectile function before operation. Although around one-third had an active sex life at 12 months, about half said that this was much the same as before their operation and just under half said that it was worse than before their operation (see *Table 71*). There were, however, no differences at 12 months, according to the randomised groups in any of the aspects of sexual function measured (see *Tables 71* and *72*). Around a half of the men had severely reduced or no erectile function (see *Table 72*). There were no differences at 12 months according to the randomised groups in terms of the proportion of men with an active sex life [RR 1.04 (95% CI 0.80 to 1.360), $p = 0.768$] or the proportion of men whose sex life had become worse after the operation [RR 0.99 (95% CI 0.80 to 1.22), $p = 0.912$] (see *Table 71*). Around 15% of men had used a vacuum device or medication to improve sexual function (see *Table 72*).

Quality of life outcomes

General health outcomes were measured using the EQ-5D and SF-12 (the latter subdivided into role – mental and role – physical scores). The slight increase in the scores over time can be assumed to represent recovery from operation, but there were no differences between the randomised groups at any time point in EQ-5D or SF-12 scores (see *Table 73* and *Figure 44*).

Knowledge of pelvic floor muscle training in trial groups before intervention

Around four-fifths of the men in both groups had received information about the use of pelvic floor exercises before starting the trial intervention from at least one source (see *Table 53*). The most common sources were nurses or continence advisors (around 30%) or leaflets or books (over 40%, see *Table 53*).

Practice of pelvic floor muscle training in intervention and control groups

It is not surprising, given the level of prior knowledge of pelvic floor exercises, that 20% of men in both groups reported carrying out some exercises before randomisation (see *Table 74*). However, by 6 months the men in the intervention group were more likely to be still carrying them out and this difference persisted at the 12-month follow-up (see *Table 74*).

Changes in lifestyle factors

Men in both groups were given written information about lifestyle changes that might improve aspects of both their general health and incontinence. In the intervention group, this advice was reinforced and individualised by the therapists. However, there were no significant differences in the uptake of any aspect of this advice at 12 months after randomisation (see *Tables 75* and *76*).

Economic outcomes

Costs to the NHS

Total costs to the NHS were on average £209 (95% CI £147 to £271) higher in the intervention group than in the control group. This difference was primarily due to the cost of providing the PFMT training in the intervention group. The use of other health services, and hence cost, was similar between the groups.

Costs to the participants

On average, the costs of any private health care used were low and there was no evidence of any difference between groups. Similarly, the costs of accessing care other than the intervention were similar for the two groups. Participants in the intervention arm had on average more days away from usual activities than participants in the control arm and hence on average a higher cost. However, this difference was not statistically significant.

Overall costs to the NHS and participants

On average, the cost to the NHS and participants was greater in the intervention group than in the control group. This difference was not statistically significant.

Quality-adjusted life-years

On average, QALYs were virtually identical in both the intervention and the control group [mean difference –0.00003 (95% CI –0.026 to 0.026)].

Cost-effectiveness from the perspective of the NHS and participants

Based upon the point estimates of the mean difference in costs and QALYs, the intervention is dominated by the control intervention as it is on average more costly but associated with no more effectiveness. As there was considerable imprecision around the estimates of mean difference in costs and effects, the probability that the intervention would be cost-effective at the typical threshold for society's willingness to pay for a QALY was calculated. This analysis suggested that there was less than an 18% chance that organised PFMT training was cost-effective.

Cost-effectiveness from the perspective of the NHS

When the perspective of the economic evaluation was restricted to the NHS, the intervention was dominated by the control intervention (it was more costly and no more effective). Furthermore, there was only a 20% chance that the intervention would be cost-effective if the threshold value for society's willingness to pay for a QALY were £20,000.

Sensitivity analyses

The majority of the sensitivity analyses conducted did not greatly alter the conclusions of the economic evaluation. However, a sensitivity analysis conducted from the perspective of the NHS

showed that, should the intervention reduce the rate of incontinence by approximately 15%, the provision of physical therapy might be cost-effective.

Strengths and weaknesses (specific to transurethral resection of the prostate randomised controlled trial)

Recruitment

We approached 5986 men who were admitted to hospital for TURP in order to identify and recruit our final population of 442 men who entered the RCT. Many of the men approached were ineligible or missed in hospital (3001 men, see *Table 9a*) and some were subsequently found to be ineligible (149 men; see *Table 10a*). This scale of recruitment represented a large burden on the recruitment officers in the centres. However, we felt that this was the most efficient way of identifying our target population, which was men who had urinary incontinence after prostate surgery. Other methods, such as expecting local staff to identify incontinent men and recruit them to the RCT directly, might have been too burdensome and risked missing many men owing to pressure of routine work.

Generalisability of the trial population

Most of the men who agreed, when in hospital, to be screened 3 weeks later, returned their screening questionnaire (2590/2838, 91%; *Table 50*): although the non-responders were older, more likely to smoke and spent more time in hospital, there were no clinically important differences in demographic or clinical characteristics when compared with responders. Just under one-fifth (442/2590, 17%) of the men who returned a screening questionnaire were eventually recruited into the RCT. Many of the remainder had become dry [1387 (54%) at screening, 274 (11%) at baseline], and a further 262 (10%) were not eligible because they did not return their baseline questionnaire (see *Figure 5* and *Table 11*). Of the 227 (9%) not accounted for, 122 declined further contact, 16 did not wish to be randomised and the remainder had a variety of other reasons for not wishing to enter the trial (see *Table 11*). Thus, our trial population represents 442/512 (86%) of the men who were incontinent and eligible to be randomised, but only 442/2838 (15%) of men identified in hospital as having TURP.

Response rates

Once randomised, our participants were compliant in returning their questionnaires (over 90%) and urinary diaries (over 80%). While the withdrawal rates were slightly higher than from the radical prostatectomy RCT, there was no evidence of differential dropout from the randomised groups, with outcome data available for 97% (intervention) and 97% (control) of the men continuing at 12 months (see *Table 65a*). This provides some reassurance that the outcome data are representative of the men in the RCT, and that bias from differential attrition was minimal.

Strengths and weaknesses of economic analyses

The methods of the economic analysis were rigorous and reproducible, and efforts were made to assess the importance of uncertainty surrounding estimates of costs, effects and cost-effectiveness. As the study was not powered to detect differences in economic outcomes, it was anticipated that differences in costs and effects would not reach statistical significance. For this reason, conclusions from the economic evaluation were based upon the consideration of the balance of probabilities.

Regardless of the perspective taken for the analysis, there was little chance that the intervention would be cost-effective. Furthermore, none of the sensitivity analyses conducted changed the conclusions of this analysis.

Chapter 15

Overview of MAPS study

This chapter draws together the findings generated during the conduct of the MAPS study, discusses its strengths and weaknesses and sets the findings in context with those in the literature.

Summary of findings statement

Urinary incontinence

MAPS has shown that the provision of one-to-one conservative physical therapy for men with urinary incontinence after prostate surgery, either radical prostatectomy or TURP, does not result in better short- or long-term incontinence rates than standard management. The therapy intervention did, however, increase the number of men performing PFMT (compared with the control groups). From the perspective of the NHS, it is unlikely that, for either of the two patient groups considered, provision of one-to-one conservative physical therapy is cost-effective compared with standard care.

Pelvic floor muscle training

It seems that a great deal of information was available to men regarding PFMT in both the control and the intervention groups, for example from routine care in the NHS (from nurses, continence advisors, physiotherapists and doctors), books, leaflets, friends and the internet (*Tables 15* and *53*). It may be that this information was sufficient to allow men to manage their own incontinence. Therefore, this trial has not shown whether PFMT is effective or not; rather, it has shown that one-to-one sessions by a trained therapist are not necessary for instruction in PFMT and other aspects of conservative care such as bladder training and lifestyle advice. There was also no evidence to suggest that an intervention delivered by a trained continence nurse was more or less effective than that delivered by a trained physiotherapist.

Bowel function

Bowel dysfunction was uncommon. There was no evidence from MAPS that PFMT was effective in the treatment of faecal incontinence, constipation or bowel urgency.

Sexual function

There was no evidence from MAPS that PFMT was effective in the treatment of sexual dysfunction. Current NICE guidelines[17] suggest that drugs or mechanical devices should be offered to men, and indeed around 60% of men had tried one or the other of these.

Quality of life

There was no difference between the intervention and control groups in either condition-specific or general measures of quality of life, in either of the clinical groups. The men did, however, show a gradual improvement in quality of life, consistent with a return to health after major surgery.

Prevention of risk of bias

Selection bias at trial entry (generation of allocation sequence, quality of concealment of randomisation process)

The randomisation programme was computer generated and used prespecified minimisation factors that varied according to each participant, which provided protection from selection bias.

Attrition bias (accounting for missing data, withdrawals and deaths)

We accounted for all deaths and men withdrawing from the trial. We did not impute data for them after their withdrawal but did use the information they supplied up to the point of loss of contact. However, the loss to follow-up was low and similar in the randomised groups of both trials.

Performance bias (blinding of participants and care deliverers to allocated group)

Neither the men nor the therapists could be blinded to the intervention, as this would not have been possible.

Detection bias (blinding of outcome assessments)

The majority of the outcomes were obtained using self-reported data from questionnaires posted from the MAPS study office to the men at their homes. The data were entered without the clerks being aware of the randomised allocation.

Strengths and weaknesses

Reliability of findings

One of the main strengths of the MAPS study is the consistency and robustness of the findings. No matter which way we compared the groups, all the different outcome measures concurred in failing to find clinically or statistically significant differences between the randomised groups in the clinical outcomes. Where statistically significant differences in costs were identified, these could be attributed to the cost of providing the intervention rather than the consequences of the intervention.

Trial management

We deliberately chose to minimise the trial processes that needed to occur at local centres, as most of the staff involved were engaged in routine delivery of care in the NHS. Recruitment officers at each site were tasked with approaching men who were admitted for prostate surgery. Rather than ask them to explain the RCT to all men, we chose to ask them only to obtain the men's contact details and consent to receive a postoperative (screening) questionnaire. In this way, staff at the MAPS study office in Aberdeen were able to carry out the administration of the survey and subsequent contact only with men with incontinence in an efficient and standardised manner. This also facilitated follow-up by post and telephone.

If a man was randomised to the intervention group, the MAPS study office contacted the local therapist to ask that an appointment should be set up with the participant in accordance with local conditions.

In this way the burden of participating in research was reduced to a minimum in participating centres. We feel that this contributed to the success of recruitment to both the study and the RCT.

Design and content of pelvic floor muscle training regimen

The design of the PFMT regimen could not be based on evidence as there is no consensus on the most effective types of treatment and frequency of follow-up. The frequency of therapy visits (four in a 3-month period) was chosen to reflect current practice in the NHS. It would potentially have been feasible to roll out this pattern of visits to NHS practice if it had been effective.

The rationale underlying the choice of components is given in *Chapter 3*. The underlying assumption was that any treatment programme would have to be acceptable to men and practical to incorporate into their daily lives without becoming a burden. The emphasis was that men should continue to practise the exercises both during and after the end of the therapy period. The choice of nine strong contractions twice a day is not far removed from the NICE recommendations of eight contractions three times a day.[72]

Standardisation of the therapy intervention

We tried to ensure standardisation in the delivery of the intervention by inviting all therapists to undertake a bespoke training programme. The programme and the intervention were formalised using standardised therapy documentation (see *Appendix 4*), which ensured a consistent content at each visit and between different therapists. The content of the documentation was based on similar documents used in a previous trial of PFMT for women with prolapse, and was also linked to that of the questionnaire (ICI-SF) that was used to obtain urinary outcome data from the men.

Prevalence of help and support services and information for men with urinary incontinence

Men in both groups had access to any standard care that would normally be provided locally for men with urinary incontinence. This would include the service provision of a continence nurse or a community nurse, who would provide continence aids, as well as general advice, which could include verbal instruction and leaflets on PFMT.

We recognised that this advice on PFMT might potentially dilute the measurable effect of our intensive PFMT intervention. Therefore, if a centre was to participate in MAPS, the staff had to agree that they would not provide specific instruction in pelvic floor anatomy, demonstrate PFMT or suggest a daily PFMT exercise regimen. However, they were permitted to provide a PFMT leaflet if this was part of their standard pattern of care. In addition, most men could and did access any care they needed, which included information on pelvic floor exercises from the literature, staff and elsewhere (see *Tables 15* and *53*). It might be that this would be sufficient for men to be able to perform adequate PFMT without the need for specialist advice from a trained therapist.

Effect of prior knowledge of pelvic floor exercises and provision of advice on practice of pelvic floor muscle training

It was clear that almost all of the men having a radical prostatectomy, and 80% of those having a TURP, were aware of the use of PFMT after operation, and they derived this information from a variety of sources (see *Tables 15* and *53*). Before randomisation to the intervention, in the radical RCT, 80% of the men in both the intervention and the control groups were initially performing at least some PFMT at baseline (see *Table 36*), compared with only 20% in each of the TURP groups (see *Table 74*). In the control groups, around 50% of the men in the radical trial were still performing some exercises at 12 months, while the proportion in the TURP trial remained the same as at baseline (20%). This could be regarded as an estimate of the background effect of the provision of PFMT advice outwith a specialist service.

In both trials the proportion of men continuing to do the exercises at 12 months was greater in the intervention group (radical prostatectomy 67%, TURP 65%) than in the control groups (50% and 20% respectively). Therefore, the therapists had succeeded in motivating the men to carry out more exercises. Nevertheless, this did not result in any difference in urinary or other clinical outcomes.

Choice of clinical effectiveness outcome measures

Urinary incontinence

We started from the premise that the outcomes of importance were those that mattered to the men. Clinicians' assessments of patients' outcomes often underestimate the degree of bother perceived by patients, and tend to focus on issues of lesser importance to patients.[73,74] The wide variety of different data collection methods and instruments limits the ability of researchers to compare similar clinical and research data. In the latest iteration of the ICI, Staskin *et al.* devote a chapter to the assessment of 'patient-reported outcomes' and provide grades of recommendation for a wide range of different instruments developed for this purpose.[73]

As a result of an ICI initiative after the first meeting in 1998, an international advisory board was tasked to develop modular ICI questionnaires on each of the clinical issues in incontinence. This was quickly expanded to include wider urinary symptoms, bowel symptoms and vaginal symptoms.[18] The first fruit of this process was the ICI-SF urinary incontinence questionnaire, and we adopted this for our screening questionnaire. We felt that it was short and easy to complete and reliably assessed the aspects of urinary incontinence in which we were interested. This formed the basis for our assessment of male urinary incontinence at each time point.

The questionnaire has now been in use for about 5 years, but when MAPS was starting we felt that we needed another, more 'objective' (though still patient-reported), outcome measure. The most common method was to ask men to complete a urinary diary. In the past, researchers have experienced poor return rates for these diaries, which require participants to record fluid input and, worse, urine output for 3 or 5 days. We decided to reduce the burden of completion of diaries by simplifying it, and indeed obtained return rates of over 80%. There was good concordance between the men's diary records and their questionnaire responses: for example, the two methods of recording daytime urinary frequency and nocturia agreed remarkably (see *Table 29a*).

Another aspect of the ICI-SF questions was the ability to generate a urinary incontinence score, as a composite of the amount of incontinence and the men's assessment of its effect on quality of life. It was also possible to use the 'quality of life' question on its own as a measure of the effect of 'leaking urine on everyday life'. Each separate method of measuring incontinence, however, gave the same general picture: of an improvement in the first 6 months and relatively little change thereafter.

Sexual function outcomes

We addressed this sensitive aspect of male function (symptoms of sexual dysfunction) by using the same outcome measures that were developed and piloted for the ProtecT trial,[70] with permission from the study staff. The ICSmale and ICSsex questionnaires in ProtecT have already been used in related research.[75] Use of common and standardised outcome measures will enable direct comparisons to be made between the outcomes of MAPS and those of ProtecT.

Choice of economic effectiveness outcome measures

Both the EQ-5D and SF-12 are recognised measures for the measurement of health-related quality of life. Furthermore, both can be used to provide utility scores that can be used to estimate QALYs. The EQ-5D was taken as the basis of QALY estimates in the base-case analysis,

as it is the preferred approach of NICE.[17] However, the SF-12 can be converted into similar population-based scores using an algorithm developed by Brazier *et al.*,[40] and this approach was used in a sensitivity analysis. The results of the cost-effectiveness analysis, based upon either the EQ-5D or SF-12 data, are, however, similar.

The perspective adopted for the economic analysis was that of both the NHS and the trial participant. This meant that the costs incurred by the NHS and by participants themselves were combined to produce an overall estimate of cost. While such an approach is not recommended by NICE,[17] this methodological standpoint is contentious and it was felt that a more informed view about the desirability of the intervention would come from the consideration of a wider perspective.

For the TURP trial, the conclusions were sensitive to the choice of perspective (owing to a trend to more days away from usual activities in the control group). The trend towards fewer days away from usual activities following physical therapy was not consistent with the findings about quality of life or use of health services, so should be treated with caution. In the radical prostatectomy trial the conclusions were unaffected by the choice of perspective. A second analysis using an NHS-only perspective was also performed (i.e. only those costs that fell on the NHS were included and those that fell on the participants were excluded). For both trials combining information on the cost of the interventions and the cost of subsequent NHS care resulted in a statistically significantly higher total cost per participant in the intervention group. This difference was driven almost entirely by the cost of the PFMT intervention itself.

Long-term follow-up and potential for further research

When signing the original consent form in hospital, men also consented to being approached about other research in the future. This enabled us to apply to the ethics committee to commence long-term follow-up.

Two-year follow-up is ongoing. This will include information about persistent incontinence, the continuing need for treatment and whether the men have made use of any services (such as pads or surgery). The conclusions of the economic analysis will be reviewed in the light of longer-term follow-up data obtained.

We carried out a short survey to determine the level of provision of services at each site, both by asking the men about the services they used or needed and by asking the staff about what they provided.

Generalisability

Centres

The centres varied widely in size, with our largest centre approaching a total of 118 men having a radical prostatectomy and 661 having a TURP, while in the smallest, one man had a radical prostatectomy and 30 had a TURP.

Some centres, however, did not agree to recruit men from one of the clinical groups. In seven centres, we were able to recruit only men having TURP. This occurred most often because a service was already in place for men after radical surgery that contained specific instruction in PFMT. Centre staff were reluctant to unpick this aspect of their service (which formed part of a larger service addressing other continence needs). In one centre we did not recruit men having TURP because they treated such a large volume of men that recruitment would have been impractical. In a further three centres, which joined MAPS only for the final few months,

we targeted recruitment for the radical prostatectomy group only as we needed to increase our sample size before the study finished.

Therapists

Because of the lack of physiotherapy availability in some centres, we allowed specialist continence or urology nurses to be trained as therapists: they delivered the intervention in about half of the centres and to just over half of the men. This would have increased the generalisability of the trial if the intervention were to be rolled out to the NHS. As specialist physiotherapists are in short supply, it would be possible to train other staff to deliver the PFMT intervention.

Men undergoing prostate surgery

Within each centre, we aimed to explain the research study to all the men admitted during the recruitment period. Owing to unavoidable local factors, such as holidays, some men were missed (154/1158 radical prostatectomies, 1078/5986 TURPs; see *Table 9a*), and a further 20% did not wish to participate in research. Many men also became ineligible when it became apparent that they did not meet the inclusion criteria (for example, almost 500 of the men admitted for TURP were in fact having a palliative 'channel TURP' for advanced local prostate cancer). The 'ineligible' men were older than those who were eligible for screening (see *Table 9b*). Some men were also not screened as, after consenting before operation, they became ineligible because in the event they did not undergo a prostatectomy (24/804 radical prostatectomies, 147/2985 TURPs; see *Table 10a*). Thus, apart from the men who declined participation in screening, we felt that we avoided systematic biases in recruiting our sample, and that we screened a representative sample of the population of eligible men undergoing prostate surgery.

Our trial was aimed at men who were still incontinent at 6 weeks after surgery. A considerable proportion of the men were known to be dry by the time they could have been randomised (113/742 radical prostatectomies, 1661/2590 TURPs) and a further number explicitly declined randomisation, did not return their baseline questionnaire or had another reason why they could not participate (218/742 and 489/2590 respectively). Thus, the men entering the two trials represented 411/742 (55%) of men undergoing radical surgery and 442/2590 (17%) undergoing TURP. These figures compare with our original estimates before the trial started that 50% of the men after radical prostatectomy and 5% after TURP would be randomised.

Timing of the intervention

Nearly all of the improvement in incontinence happened within the first 8 months after surgery for the radical prostatectomies (see *Table 29a* and *Figures 14* and *15*) and 5 months for the TURPs (see *Table 67a* and *Figures 39* and *40*). In retrospect, it might have been better to wait until at least 6 months after surgery before randomising men who were then still incontinent to specialist therapy. This would then have been targeted at men with a persistent problem (avoiding unnecessary treatment of men who recovered spontaneously). The MAPS findings cannot be extrapolated to this group of men, and we know of no evidence to suggest that a delayed intervention would have been more effective. However, it is clear that a substantial proportion of men remain wet with or without specific instruction.

Need for further treatment

At the end of follow-up at 12 months, around 14 months after surgery, a substantial proportion of men were still incontinent. Based on the original populations, 299/742 (40%) in the radical group and 251/2590 (10%) in the TURP group were still incontinent a year after surgery. For men

with severe urinary incontinence (defined as incontinence at least once a day and a moderate or large amount of urine loss), the equivalent figures were radical prostatectomies, 152/742 (20%); and TURPs, 97/2590 (4%). Forty per cent of the men who had radical prostatectomy and 20% of those who had TURP were still using pads.

Although we are still carrying out follow-up at 2 years for these men, it seems likely that this provides a reasonable estimate of the men who are likely to have a continuing problem. We have now shown that four specialised sessions of conservative therapy have not benefited the men and are not likely to be cost-effective, but a considerable number of men are still severely affected by urinary incontinence. It is important to consider what further treatment can be offered to these men.

Need for further research

Surgical treatment for men with persistent urinary incontinence

For some men it may be appropriate to consider a surgical intervention. The options include an artificial sphincter that can be inflated and deflated to permit continence and micturition respectively. More recently, a mesh sling analogous to the minimally invasive slings used in women (such as tension-free vaginal tape and transobturator tape) has been introduced. A new RCT comparing these two options might be an appropriate way of evaluating their relative effectiveness and cost-effectiveness.

While NICE recommends surgery for men with intractable and bothersome SUI,[17] there is no consensus on which surgery is most effective and cost-effective. The recommendation was based on case series evidence only. The MAPS study has shown that, based on the original number of men having prostate surgery, the proportion of men with severe urinary incontinence (defined as incontinence at least once a day and a moderate or large amount) amongst the radical prostatectomy group was 152/742 (20%) and amongst the TURP group 97/2590 (4%).

The type of incontinence in the radical group was mostly SUI, for which surgery might be appropriate. Current management advice from NICE[17] is in favour of the artificial urinary sphincter. This operation has been available for SUI after prostatectomy for several years. Recently, transobturator 'minimally invasive' slings have been marketed for men,[76] extrapolated from their use to treat SUI in women. Published evidence for these male slings is sparse and usually single-centre, uncontrolled case series. Men with SUI are increasingly aware of the sling option and often enquire about it in clinic.

NICE interventional procedure guidance suggests that current evidence (from case series only) on the safety and efficacy of suburethral synthetic sling insertion appears adequate to support the use of this procedure under normal arrangements for consent and audit.[76] However, this suggests that such male sling surgery 'should only be undertaken by units that specialise in the investigation and treatment of postprostatectomy incontinence and that can offer alternative treatments, including the insertion of artificial urinary sphincters'.[76] Adverse effects of male slings were reported, and there was no evidence comparing them with other procedures.

Relative efficacy and adverse effects of the male sling are thus uncertain, and therefore a randomised trial comparing the artificial urinary sphincter with the male sling would be a high priority. Based on a population of 4000 men having radical prostatectomy annually in England, and 20% of those men having severe persistent SUI, up to 800 men per year might be available for a trial. Such a trial should include an economic evaluation.

As artificial urinary sphincter is normally performed only in tertiary centres, only a limited number of urological surgeons would be available to collaborate in such a trial but they would already be treating the majority of eligible men. A collaboration amongst these urologists might feasibly result in a rigorous RCT, which would in turn guide future management of men with persistent and severe urinary incontinence after prostate surgery.

Another possibility that could be tested is the addition of an anti-incontinence procedure such as a sling during the initial radical prostatectomy operation.

Validation of ICI-SF and other outcome measures

A large number of longitudinal data were collected on a variety of measures of urinary, bowel and sexual function outcomes, largely using the instruments developed, or being developed, by the ICI initiative.[27] Quantitative analysis, and work comparing the data with those from the urinary diaries, will allow further validation of these outcome measures for use in future research and clinical settings.

Long-term epidemiology after different types of prostate surgery

The men who agreed to be screened in MAPS also agreed to be contacted in the future about other research related to men's health after prostate surgery. Some valuable epidemiological information was provided in the short term by their responses to the screening survey. We could capitalise on this by carrying out further epidemiological research in this cohort of men. We have detailed information on their clinical characteristics and baseline level of incontinence. This might inform the debate about different methods of prostatectomy and provide valuable prognostic information for counselling men in the future.

In addition, long-term follow-up of the men enrolled in the MAPS RCT would provide useful clinical and epidemiological information about the consequences of urinary incontinence, in particular the need for and use of NHS services, use of products such as pads and catheters, the need for admission to residential or nursing home care and the chance of receiving surgery.

Meaning of the study/relationship to other work in the field

The data from the MAPS study will be added to the Cochrane review in order to supplement the existing body of knowledge. The MAPS trial, however, will more than double the number of existing data on the treatment of men with incontinence after a radical prostatectomy, and provides unique data on men having a TURP.

Chapter 16

Implications for the NHS and further research

Implications for the NHS and patients

Incontinence is a major complication of prostate surgery. It does, however, resolve in a proportion of those initially affected. For those for whom incontinence does not quickly resolve, additional physical therapy for incontinence is unlikely to be effective or cost-effective compared with the current practice of provision of information about PFMT. This suggests that, in centres routinely offering specific PFMT therapy in one-to-one consultations with a trained physiotherapist or continence nurse for all men who are incontinent after prostate surgery, it may be possible to reallocate resources with potentially no loss of benefit.

Incontinence that persists into the longer term represents a considerable continuing burden to both the NHS and the men affected. Further management of these men is necessary.

Unanswered questions and further research

Treatment for men with urinary incontinence after prostate surgery

- Physical therapy of the type used in this trial is not worthwhile, but the continuing burden of incontinence suggests that research into other treatments would be, for example research on the value of surgery in controlling symptoms. Specifically, an RCT comparing different surgical options for men with severe persistent urinary incontinence is needed (see *Chapter 15*).
- While the MAPS study has demonstrated that specific instruction in PFMT from a therapist is not more effective than standard management, nevertheless many men are advised to carry out PFMT and indeed do so. However, MAPS did not test whether any other method of provision of advice about PFMT would be an effective and efficient way of reducing incontinence. If not, this would represent a waste of resources in teaching men or providing leaflets, and a waste of their own time in practising the exercises. Further research into the effectiveness of any other method of delivery of PFMT would be worthwhile.

Treatment for men with erectile dysfunction after prostate surgery

- Of the men in the radical prostatectomy trial, 80% still had erectile dysfunction at the 12-month follow-up, and over 60% had tried various treatments. As PFMT was of no value to these men, research into effective and efficient treatment would be worthwhile. While men who did not also have urinary incontinence were not included in the RCT, it is possible that erectile dysfunction is equally prevalent in that group and might also merit further research and evaluation of treatment.

Validation of ICI-SF and other outcome measures

- The MAPS data set can be used to improve the quality of further research and to improve other aspects of management. The data collected within MAPS can be used to further validate the ICI outcome measures for use in future research and clinical settings. These will

support the work on standardised outcome measures being developed by the ICI initiative.[27] This would include quantitative analysis and work comparing the data with those from the urinary diaries.

Long-term consequences of different types of prostate surgery

- Detailed epidemiological data gathered within MAPS can be analysed and will allow prospective follow-up of the men. This will inform the debate about different methods of prostatectomy and provide valuable prognostic information for counselling men in the future. Issues include the consequences of urinary incontinence, in particular the need for and use of NHS services, use of products such as pads and catheters, the need for admission to residential or nursing home care and the chance of receiving surgery.

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Appendix 1

Patient information sheets

Appendix 1.1 Hospital information sheet for Men After Prostate Surgery: research information leaflet for men having prostate surgery

MAPS

Men After Prostate Surgery

MEN'S HEALTH AFTER PROSTATE SURGERY

RESEARCH INFORMATION LEAFLET
for men having prostate surgery

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

Your Health After Prostate Surgery

Introduction

You are being invited to take part in a research study. This leaflet tells you why the research is being done and what it will involve. We hope you will find this information helpful.

What is the purpose of the study?

We would like to find out more about men's health after prostate surgery. We are undertaking a large study of treatment to see if it will help men who lose control of their urine (urinary incontinence) after prostate surgery. There is not enough evidence to tell us how many men suffer from such incontinence, and if they do, whether simple (non-drug, non-surgery) treatment helps.

We are inviting men to complete a short questionnaire three weeks after their prostate surgery asking them about their health, and especially any experience of urinary incontinence. Later, we may also contact some of the men to ask if they would be interested in helping with further research, for example, into treatment.

Why are you inviting me?

We are inviting you, as we understand that you are about to have, or have just had, prostate surgery.

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. 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.

What will I have to do if I decide to take part?

If you think you might like to take part we will ask you to sign a consent form when you are in hospital and give us your name, address and phone number. This information will be held in a secure database at the MAPS Study Office in Aberdeen. We will send you a short questionnaire in about three weeks. **We would like you to fill this in and return it to us.** You are not obliged to answer every question if you do not want to.

If you do have urinary incontinence we would like to contact you again after you have sent back your questionnaire to find out whether or not you would be interested in helping with further research into treatment for incontinence. Even if you are not incontinent, you might be able to help us with further research. However, you do not have to take part in more research after returning your questionnaire unless you want to at that time.

We are happy to answer any questions you may have before deciding whether you wish to take part in this study. If so, please contact the MAPS Study Office on 01224 551103.

What are the risks and benefits for me if I take part ?
We believe that this study has no risks for your health. Your health care will not be affected. We hope that you will enjoy taking part in the study. You might find it helpful to fill in the questionnaire.

Will the information I give be kept confidential?
Yes. The information will be kept confidential. Your name will not be written on the questionnaire. The information you give us will be kept secure using passwords. Any information will be stored using a Study Identity Number for confidentiality. The information you provide will be seen by the research team only.

In order to increase their usefulness, we hope to link your answers with data related to your health after prostate surgery from your medical NHS records, but again this will be done confidentially and the information will only be available to the research team. When the results of the study are reported, individuals who have taken part will not be identified in any way.

How will the information I provide be used?
The results will help us to understand the best ways to assess whether treatments are helping men with urinary incontinence. We plan to publish the results in a health journal so others can read about and learn from the results of the study.

Who has approved this study?
The Multicentre Research Ethics Committee, your Local Research Ethics Committee and your Consultant Urologist have approved this study.

What do I need to do now if I think I might like to take part?
If you think you might like to take part, please sign the consent form and fill in your contact details. You can return this to the MAPS researcher in hospital.

How do I get in touch with the research team if I want any further information about the study?
If you have any questions about the study please speak to your MAPS hospital researcher or contact the MAPS Study Office on 01224 551103.

Thank you for reading this.

MAPS Study Office
Health Services Research Unit
University of Aberdeen
Polwarth Building, Foresterhill
Aberdeen, AB25 2ZD

Tel: 01224 551103
Fax: 01224 554580
Email: maps@abdn.ac.uk

Version 5 November 2004

Appendix 1.2 Randomised controlled trial patient information sheet: simple treatment for urinary incontinence in Men After Prostate Surgery. Invitation to help with research

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.

MAPS Study Office
Health Services Research Unit
University of Aberdeen
Polwarth Building, Foresterhill
Aberdeen, AB25 2ZD

Tel: 01224 551103
Fax: 01224 554580
Email: maps@abdn.ac.uk

Version 7 February 2005

Appendix 2

Consent forms

Appendix 2.1 Screening consent form: your health after prostate surgery

MAPS Study Number ☐☐☐☐☐☐

MAPS
Men After Prostate Surgery

Consent Form
Your Health After Prostate Surgery

Please tick the boxes, complete, sign and return this form to the researcher or ward staff if you think you might like to take part in the study.

There is no need to sign or return anything if you do not want to take part.

☐ I am willing to receive a short questionnaire after I go home.

☐ I am willing for a researcher to contact me in the future to ask me if I would like to help with further research into men's health after prostate surgery.

☐ I agree that information related to my health after prostate surgery may be collected from my hospital and NHS records.

☐ I agree that this information and my personal details will be held in a secure central database.

Signed .....

Date .....

Date of operation .....

Telephone .....

E-mail .....

Name .....

Address .....

.....

Date of birth .....Hospital number .....

I confirm that I have explained the nature and purpose of the study and the procedures involved to the person named above.

Signature ..... Date .....

This form should be returned to
MAPS Study Office, Health Services Research Unit, University of Aberdeen, Polwarth Building, Foresterhill, Aberdeen, AB25 2ZD

4 Copies: Top copy for Study Office in Aberdeen; 1 for patient;
1 to be filed with hospital notes and 1 for recruitment officer.
The research is funded by the Health Technology Assessment programme of the NHS.
It is being organised by the MAPS Study Office at the Health Services Research Unit, University of Aberdeen.
Hospital Consent Form Version 4 03 11 2004

Appendix 2.2 Randomised controlled trial consent form: simple treatment for urinary incontinence in Men After Prostate Surgery

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

MAPS
Men After Prostate Surgery

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

By signing this form and ticking each box I agree that:

Please tick all boxes

I have:

- been given the Information Sheet about the study (Version 7, February 2005) ☐
- had the opportunity to discuss the study
- received satisfactory answers to questions
- been given enough information about the study ☐

I understand that:

- taking part in the study may not benefit my own health
- I am free to withdraw from the study at any time without having to give a reason
- if I withdraw, this will not affect my care
- information relevant to the MAPS study may be collected from my hospital and NHS records, including Office of National Statistics (ONS) and NHS central registers ☐

I agree to take part in the study ☐

I agree that my family doctor (GP), my hospital Urological Consultant and the person I have nominated as my Best Contact may be told that I am taking part in this study ☐

Your signature (participant).....

Your name in block capitals .....

Date .....

I confirm that I have explained to the person named above, the nature and purpose of the study and the procedures involved

Signature.....

Date .....

Study ID number of participant ☐☐☐☐☐☐

Hospital number of participant ☐☐☐☐☐☐☐☐☐☐

MAPS Study Office, Health Services Research Unit, University of Aberdeen, Polwarth Building, Foresterhill, Aberdeen, AB25 2ZD

Copies: 1 for patient; 1 for researcher in Aberdeen; 1 to be filed with hospital notes.
The research is funded by the Health Technology Assessment programme of the NHS.
It is being organised by the MAPS Study Office at the Health Services Research Unit, University of Aberdeen.
Trial Consent Form Version 7 August 2005

Appendix 3

Questionnaires

Appendix 3.1 MAPS screening questionnaire

Study ID Number ☐☐☐☐☐☐

MAPS
Men After Prostate Surgery

MAPS Screening Questionnaire CONFIDENTIAL

		DAY	MONTH	YEAR
1	**Please write in today's date:**	☐☐	☐☐	☐☐
2	**Please write in your date of birth:**	☐☐	☐☐	☐☐
3	**Please write in the date of your prostate operation:**	☐☐	☐☐	☐☐

Many people leak urine some of the time. We are trying to find out how many people leak urine after prostate surgery, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, in the **LAST WEEK**.

4 How often do you leak urine? *(Cross **one** box only)*

- never ☐
- about once a week or less often ☐
- two or three times a week ☐
- about once a day ☐
- several times a day ☐
- all the time ☐

5 We would like to know how much urine <u>you think</u> leaks. How much urine do you <u>usually</u> leak (whether you wear protection or not)? *(Cross **one** box)*

- none ☐
- a small amount ☐
- a moderate amount ☐
- a large amount ☐

6 Overall, how much does leaking urine interfere with your everyday life?
Please cross a number between 0 (not at all) and 10 (a great deal)

not at all ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 a great deal

7 When does urine leak? *(Please cross **all** that apply to you)*

- never – urine does not leak ☐
- leaks before you can get to the toilet ☐
- leaks when you cough or sneeze ☐
- leaks when you are asleep ☐
- leaks when you are physically active/exercising ☐
- leaks when you have finished urinating and are dressed ☐
- leaks for no obvious reason ☐
- leaks all the time ☐

8 Did you leak urine BEFORE you had your prostate surgery? **Yes** ☐ **No** ☐

PTO

9 Have you lost control of your bowel or leaked bowel motion (stool) at an inappropriate time or place SINCE your prostate operation? **Yes** ☐ **No** ☐

10 Please write here the name of the type of prostate surgery you had if you know it:

.....

THANK YOU

Thank you very much for your time and patience in filling in this questionnaire.

The information you have given us will be extremely useful in helping us carry out research into men's health after prostate surgery. It will be treated with the strictest confidence.

We are planning to carry out further research into men's health after prostate surgery. We would like to contact you again in the future with information about what this might involve. Please could you give us your contact details for this purpose?

My phone number is: .....

My email address is: .....

If you do not have a phone number, we will send everything by post or email.

You will not commit yourself to taking part in any research until you are satisfied that you want to.

If we have sent this questionnaire to the wrong address, please could you give us your correct details in the box below?

Please tick here if you do **NOT** want us to contact you again about any further research ☐

Please send the questionnaire back to us in Aberdeen in the envelope provided.

Thank you again for your help

Appendix 3.2 MAPS baseline questionnaire

Baseline Questionnaire

Study Number | | | | | | |

MAPS

Men After Prostate Surgery

CONFIDENTIAL

MAPS TRIAL

MEN'S HEALTH AFTER PROSTATE SURGERY

Thank you for helping us with our research into urinary incontinence after prostate surgery.
We would be very grateful if you could complete and return this questionnaire.

After you have answered the questions,
we can allocate you to a treatment group.

Version 6 February 2005

Baseline Q

HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting numbers or a tick in the appropriate box or boxes. Please print your answers carefully within the boxes like this:

2	7	OR	M	I	K	E	OR	✓

If you make a mistake, shade out the wrong box completely and tick the correct one like this

e.g. If you ticked often but meant to answer sometimes:

OFTEN	✓	**SOMETIMES**	✓	**NEVER**	

Please try to complete the whole questionnaire.

There are no right or wrong answers.

Sometimes the box you tick tells you to skip forward so that you miss out questions which do not apply to you.

In some questions we would like you to think about different time periods, such as during the last week, during the last 4 weeks or since your prostate operation. Please check the time periods carefully.

Some of the questions ask for answers in your own words, please write these in the boxes provided.

You do not have to answer any question if you do not want to.

Thank you for your help.

SECTION A – URINE SYMPTOMS

When you answer these questions, please think about how you have been in the **LAST WEEK.**

A1 **How often do you leak urine?**
*(Tick **ONE** box only)*

- Never ☐
- About once a week or less often ☐
- Two or three times a week ☐
- About once a day ☐
- Several times a day ☐
- All the time ☐

A2 **We would like to know how much urine <u>you think</u> leaks.**
How much urine do you <u>usually</u> leak (whether you wear protection or not)?
*(Tick **ONE** box only)*

- None ☐
- A small amount ☐
- A moderate amount ☐
- A large amount ☐

A3 **Overall, how much does leaking urine interfere with your everyday life?**
Please choose a number between 0 (not at all) and 10 (a great deal)
*(Tick **ONE** box only)*

Not at all	0	1	2	3	4	5	6	7	8	9	10	A great deal
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

In the following questions (**A4** to **A8**), we would like to find out when you leak urine.
When you answer these questions, please think about how you have been in the **LAST WEEK.**

A4 **Does urine leak when you cough, sneeze, or are physically active or exercising?**
*(Tick **ONE** box only)*

- Never ☐
- About once a week or less often ☐
- Two or three times a week ☐
- About once a day ☐
- Several times a day ☐
- All the time ☐

When you answer these questions, please think about how you have been in the **LAST WEEK.**

A5 **When you feel the need to urinate, do you have to rush urgently to the toilet?**
*(Tick **ONE** box only)*

- Never ☐
- About once a week or less often ☐
- Two or three times a week ☐
- About once a day ☐
- Several times a day ☐
- All the time ☐

A6 **Does urine leak when you have to rush urgently to the toilet?**
*(Tick **ONE** box only)*

- Never ☐
- About once a week or less often ☐
- Two or three times a week ☐
- About once a day ☐
- Several times a day ☐
- All the time ☐

A7 **Does urine leak when you have finished urinating and are dressed?**
*(Tick **ONE** box only)*

- Never ☐
- About once a week or less often ☐
- Two or three times a week ☐
- About once a day ☐
- Several times a day ☐
- All the time ☐

A8 **Does urine leak at times other than shown in your answers to questions A4, A6 or A7?**
*(Tick **ONE** box only)*

Yes ☐ *Go to **A8a*** No ☐ *Go to **A9***

A8a **If you do leak at other times, please give details of when you leak:**

When you answer these questions, please think about how you have been in the **LAST WEEK.**

A9 **Do you wear a pad or other protection because of leaking urine?**
*(Tick **ONE** box only)*

Yes ☐ *Go to **A9a*** No ☐ *Go to **A10***

A9a **If Yes, how many pads do you wear in an average day (24 hours)?**

Enter **TOTAL** number of pads you wear in 24 hours ☐☐

A9b **Of these pads, how many do you pay for yourself?**
If you do not pay for them, please enter zero (0) in the boxes

Enter number of pads **YOU PAY FOR** yourself ☐☐

A10 **Do you use pads or protectors on your chair or bed in case you leak urine?**
*(Tick **ONE** box only)*

Yes ☐ *Go to **A10a*** No ☐ *Go to **A11***

A10a **If Yes, how many chair or bed pads do you use in an average day (24 hours)?**

Enter **TOTAL** number of chair and bed pads you use in 24 hours ☐☐

A10b **Of these chair or bed pads, how many do you pay for yourself?**
If you do not pay for them, please enter zero (0) in the boxes

Enter number of chair and bed pads **YOU PAY FOR** yourself ☐☐

A11 **How often do you usually pass urine during the daytime?**

Enter number of times ☐☐

A12 **How often do you usually have to get up at night to pass urine?**

Enter number of times ☐☐

A13 **Are you using a permanent catheter (inside your bladder) to collect your urine?**

Yes ☐ No ☐

A14 **Do you ever use an external (sheath) catheter to collect your urine?**

Yes ☐ No ☐

SECTION B – CARE YOU HAVE RECEIVED

When you answer these questions, please think about the care you have received **SINCE YOUR PROSTATE OPERATION.**

B1 **Have you seen your family doctor (GP) since your prostate operation?**

Yes ☐ *Go to **B1a*** No ☐ *Go to **B2***

B1a **If Yes, approximately how often have you seen your family doctor (GP) since your prostate operation?**

Enter number of times seen GP **for leaking urine** ☐☐

Enter number of times seen GP **for any other reason** ☐☐

B2 **Have you seen a nurse (from your doctor's practice) since your prostate operation?**

Yes ☐ *Go to **B2a*** No ☐ *Go to **B3***

B2a **If Yes, approximately how many times have you seen a nurse from your doctor's practice since your prostate operation?**

Enter number of times seen nurse **for leaking urine** ☐☐

Enter number of times seen nurse **for any other reason** ☐☐

B3 **Since your prostate operation, have you seen NHS HOSPITAL staff <u>for leaking urine</u>?**

		If yes, enter number of visits
I have seen a hospital doctor **about leaking urine**	Yes ☐ →	Number of visits ☐☐
	No ☐	
I have seen a hospital nurse **about leaking urine**	Yes ☐ →	Number of visits ☐☐
	No ☐	
I have seen a hospital physiotherapist **about leaking urine**	Yes ☐ →	Number of visits ☐☐
	No ☐	

When you answer these questions, please think about the care you have received **SINCE YOUR PROSTATE OPERATION.**

B4 **Since your prostate operation, have you received any PRIVATE TREATMENT (which you had to pay for yourself) for leaking urine?**

If Yes, enter number of visits

I have seen a private doctor **about leaking urine**	Yes ☐	Number of visits	☐☐
	No ☐		
I have seen a private nurse **about leaking urine**	Yes ☐	Number of visits	☐☐
	No ☐		
I have seen a private physiotherapist **about leaking urine**	Yes ☐	Number of visits	☐☐
	No ☐		

B5 **Since your prostate operation, have you been admitted to hospital because of leaking urine?**

Yes ☐ *Go to **B5a*** No ☐ *Go to **B6*** ☐☐

B5a **If you were admitted since your prostate operation, how many nights did you stay in hospital?**

Enter number of nights in hospital ☐☐

B5b **Since your prostate operation, have you had an operation for leaking urine?**

Yes ☐ *Go to **B5c*** No ☐ *Go to **B6***

B5c If Yes, please give the name or type of operation and the date:

B6 **Since your prostate operation, have you taken any medications (from a doctor, or direct from the chemist's) for leaking urine?**

Yes ☐ *Go to **B6a*** No ☐ *Go to **B7***

B6a **If Yes, please give details of medication received since your prostate operation for leaking urine.**
Please give drug names (e.g. detrusitol, duloxetine):

When you answer these questions, please think about the care you have received **SINCE YOUR PROSTATE OPERATION.**

B7 **Have you had any other treatment or advice for leaking urine since your prostate operation (other than the operation you named in B5c or the drugs you listed in B6a)?**

Yes ☐ *Go to **B7a*** No ☐ *Go to **B8***

B7a **If Yes, please give details of other treatment or advice received since your prostate operation for leaking urine:**

B8 **Are you in paid employment?**

Yes ☐ *Go to **B8a*** No ☐ *Go to **Section C***

B8a **If Yes, approximately how many days off sick have you had <u>for any reason since your prostate operation</u>?**

☐☐☐ days

SECTION C – OTHER HEALTH PROBLEMS

C1 **Do you have any health or medical problems** *(such as heart, chest or kidney problems, diabetes, stroke or high blood pressure)* **<u>other than</u> those to do with your prostate operation?**

Yes ☐ No ☐

C2 **Do you take any medications** *(such as drugs or prescriptions from your doctor, or direct from the chemist's)* **<u>for these health problems</u>?**

Yes ☐ No ☐

SECTION D – BOWEL SYMPTOMS

This section is about your bowel symptoms and control of your stool (also called bowel motions or faeces). Many people experience bowel symptoms some of the time. When you answer these questions, please think about how you have been in the **LAST WEEK.**

D1 **How often do you lose control of or leak stool?**
*(Tick **ONE** box only)*

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

D2 **If you do, how much does this bother you?**
Please choose a number between 0 (not at all) and 10 (a great deal)
*(Tick **ONE** box only)*

Not at all ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 A great deal

D3 **When you feel the need to open your bowels, do you have to rush urgently to the toilet?**
*(Tick **ONE** box only)*

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

D4 **When you have to rush urgently, do you ever lose control of or leak stool?**
*(Tick **ONE** box only)*

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

When you answer these questions, please think about how you have been in the **LAST WEEK.**

D5 **Do you ever lose control of or leak stool WITHOUT first feeling that you have to rush urgently?**
*(Tick **ONE** box only)*

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

D6 **If stool leaks, is this usually solid, liquid or both?** *(Tick **ONE** box only)*

- Doesn't leak ☐
- Liquid only ☐
- Solid only ☐
- Liquid and solid ☐

D7 **Are you currently receiving ANY treatment or advice for leaking stool?**

Yes ☐ *Go to **D7a*** No ☐ *Go to **D8***

D7a **If Yes, please give details of treatment or advice received for leaking stool:**

D8 **Did you ever lose control of or leak stool BEFORE your prostate surgery?**

Yes ☐ No ☐

D9 **Do you have any of these other bowel problems?**
*(Tick **ALL** boxes that apply to you)*

- Ulcerative colitis ☐
- Crohn's disease ☐
- Irritable bowel syndrome ☐
- Constipation ☐

When you answer these questions, please think about how you have been in the **LAST WEEK.**

D10 **Are you currently receiving ANY treatment or advice for any of these other bowel problems?**

Yes ☐ *Go to **D10a*** No ☐ *Go to **Section E***

D10a **If Yes, please give details of treatment or advice received for other bowel problems:**

SECTION E – OTHER HEALTH ISSUES

This section is about exercise, weight and other issues to do with your health. When you answer these questions, please think about how you have been in the **LAST WEEK.**

E1 **Have you done any general exercise or fitness activity?**

Yes ☐ *Go to **E2*** No ☐ *Go to **E3***

E2 **If Yes, what sort of exercise have you done?** *(Tick **all** boxes that apply)*

Walking ☐ Swimming ☐

Gardening ☐ Running ☐

Going to the gym ☐ Other *(please give details in E2a)* ☐

E2a **Please give details of other exercise:**

E3 **Have you done any pelvic floor exercises over the last week?**

Yes ☐ *Go to **E4*** No ☐ *Go to **E5*** Don't know what these are ☐ *Go to **E6***

E4 **If Yes, on how many days in the last week did you do pelvic floor exercises?**
*(Tick **ONE** box only)*

Every day ☐

5 to 6 days ☐

3 to 4 days ☐

1 to 2 days ☐

When you answer these questions, please think about how you have been in the **LAST WEEK.**

E5 **How do you know about pelvic floor exercises?** *(Tick **ALL** boxes that apply to you)*

	Yes	No
From a doctor	☐	☐
From a nurse / continence advisor	☐	☐
From a physiotherapist	☐	☐
From leaflets or books	☐	☐
From the internet	☐	☐
From friends or family	☐	☐
From another source *(please give details in **E5a**)*	☐	☐

E5a **If from another source, please give details:**

E6 **Were you able to achieve an erection BEFORE your recent prostate surgery?**

Yes ☐ No ☐

E7 **Have you ever had a prostate operation BEFORE your recent prostate surgery?**

Yes ☐ No ☐

E8 **Please could you enter your weight and height?**
If you are not sure what they are, please give your best guess.
(Please use whichever units you are familiar with)

	Stones	Pounds	**OR**	Kilograms
What is your average weight now?	☐☐	☐☐		☐☐☐

	Feet	Inches	**OR**	Centimetres
What is your height?	☐☐	☐☐		☐☐☐

SECTION F – DESCRIBING YOUR OWN HEALTH TODAY

The next two sections are about your general health.

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

F1 Mobility

- I have no problems in walking about ☐
- I have some problems in walking about ☐
- I am confined to bed ☐

F2 Self-care

- I have no problems with self-care ☐
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

F3 Usual activities *(such as work, study, housework, family or leisure activities)*

- I have no problems with performing my usual activities ☐
- I have some problems with performing my usual activities ☐
- I am unable to perform my usual activities ☐

F4 Pain/discomfort

- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

F5 Anxiety/depression

- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

SECTION G – GENERAL HEALTH SF12 ©

The following questions ask for your views about your health **in the last 4 weeks,** how you feel and how well you are able to do your usual activities.

Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question please give the best answer you can.

G1 **In general, would you say your health is:**
*(Tick **ONE** box only)*

- Excellent ☐
- Very good ☐
- Good ☐
- Fair ☐
- Poor ☐

G2 **During a typical day does your health limit you in moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf? If so, how much?**
*(Tick **ONE** box only)*

- Yes, limited a lot ☐
- Yes, limited a little ☐
- No, not limited at all ☐

G3 **During a typical day does your health limit you in climbing several flights of stairs? If so, how much?**
*(Tick **ONE** box only)*

- Yes, limited a lot ☐
- Yes, limited a little ☐
- No, not limited at all ☐

G4 **During the past 4 weeks, how often have you accomplished less than you would have liked in your work or other regular daily activities as a result of your physical health?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

G5 **During the <u>past 4 weeks,</u> how often have you been limited in performing any kind of work or other regular daily activities as a result of your physical health?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

G6 **During the <u>past 4 weeks,</u> how often have you accomplished less than you would have liked in your work or any other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

G7 **During the <u>past 4 weeks,</u> how often have you done work or other activities less carefully than usual as a result of any emotional problems (such as feeling depressed or anxious)?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

G8 **During the <u>past 4 weeks</u> how much did pain interfere with your normal work (both outside the home and housework)?**
*(Tick **ONE** box only)*

- Not at all ☐
- A little bit ☐
- Moderately ☐
- Quite a bit ☐
- Extremely ☐

G9 **How much during the past 4 weeks have you felt calm and peaceful?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

G10 **How much during the past 4 weeks did you have a lot of energy?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

G11 **How much during the past 4 weeks have you felt downhearted and depressed?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

G12 **During the past 4 weeks how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

Sometimes we lose touch with our participants (for example if they move house). Would you please give us the name and contact details of someone such as a family member or close friend (a 'best contact') who might be able to give us your new address?

This 'best contact' should be someone who does **NOT** live at your own home.

BEST CONTACT

Title *(Mr, Mrs etc)*

Surname

First Names

Address

Postcode

Telephone Number *(including code)*

Relationship to yourself

Please could you let this person know that you have given us their details.

We would also like to tell your GP that you are helping with our MAPS study. Please could you give us his or her contact details

MY GENERAL PRACTITIONER:

Surname

First Name(s) *(if known)*

Address

Postcode

Telephone Number *(including code)*

PTO

Finally:

Date you filled in this questionnaire D D / M M / Y Y Y Y

Your date of birth D D / M M / Y Y Y Y

THANK YOU

Thank you very much for your time and patience in filling in this questionnaire.

The information you have given us will be extremely useful in helping us carry out research into men's health after prostate surgery.

It will be treated with the strictest confidence and kept securely.

Please send the questionnaire back to us in Aberdeen in the envelope provided.

When we receive it, we will contact you to tell you which type of treatment you will receive, and to tell you what to do next.

Please could you confirm your phone number:

Thank you again for your help

If you would like any further information or have any queries about the study, please contact:

The MAPS Study Office in Aberdeen (Tel: 01224 551103)

This study is taking place in centres across the UK but the questionnaires are being processed in Aberdeen at the Health Services Research Unit, Polwarth Building, Foresterhill, ABERDEEN, AB25 2ZD.

Appendix 3.3 MAPS 12-month questionnaire

12 month Questionnaire

Study Number | | | | | | |

MAPS

Men After Prostate Surgery

CONFIDENTIAL

MAPS TRIAL

MEN'S HEALTH AFTER PROSTATE SURGERY

Thank you for helping us with our research into urinary incontinence after prostate surgery.
We would be very grateful if you could complete and return this questionnaire.

Thank you for taking the time to help us with our research.

ISRCTN No:87696430
Version 2 October 2005

12m Q

HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting numbers or a tick in the appropriate box or boxes. Please print your answers carefully within the boxes like this:

2	7	OR	M	I	K	E	OR	✓

If you make a mistake, shade out the wrong box completely and tick the correct one like this

e.g. If you ticked often but meant to answer sometimes:

OFTEN		**SOMETIMES**	✓	**NEVER**	

Please try to complete the whole questionnaire.

There are no right or wrong answers.

Sometimes the box you tick tells you to skip forward so that you miss out questions which do not apply to you.

In some questions we would like you to think about different time periods, such as during the last week, during the last 4 weeks or since your prostate operation. Please check the time periods carefully.

Some of the questions ask for answers in your own words, please write these in the boxes provided.

You do not have to answer any question if you do not want to.

Thank you for your help.

SECTION A – URINE SYMPTOMS

When you answer these questions, please think about how you have been in the **LAST WEEK.**

A1 **How often do you leak urine?**
*(Tick **ONE** box only)*

- Never ☐
- About once a week or less often ☐
- Two or three times a week ☐
- About once a day ☐
- Several times a day ☐
- All the time ☐

A2 **We would like to know how much urine <u>you think</u> leaks.**
How much urine do you <u>usually</u> leak (whether you wear protection or not)?
*(Tick **ONE** box only)*

- None ☐
- A small amount ☐
- A moderate amount ☐
- A large amount ☐

A3 **Overall, how much does leaking urine interfere with your everyday life?**
Please choose a number between 0 (not at all) and 10 (a great deal)
*(Tick **ONE** box only)*

Not at all	0	1	2	3	4	5	6	7	8	9	10	A great deal
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

A4 **If you have not leaked urine in the last week, in which month did you last leak urine?**

(Please enter month and year): **M M** ☐☐ / **Y Y Y Y** ☐☐☐☐

If you do not leak urine now, please go to question **A12**

Otherwise, please go to question **A5**

In the following questions (**A5** to **A9**), we would like to find out when you leak urine.
When you answer these questions, please think about how you have been in the **LAST WEEK.**

A5 **Does urine leak when you cough, sneeze, or are physically active or exercising?**
*(Tick **ONE** box only)*

- Never ☐
- About once a week or less often ☐
- Two or three times a week ☐
- About once a day ☐
- Several times a day ☐
- All the time ☐

A6 **When you feel the need to urinate, do you have to rush urgently to the toilet?**
*(Tick **ONE** box only)*

- Never ☐
- About once a week or less often ☐
- Two or three times a week ☐
- About once a day ☐
- Several times a day ☐
- All the time ☐

A7 **Does urine leak when you have to rush urgently to the toilet?**
*(Tick **ONE** box only)*

- Never ☐
- About once a week or less often ☐
- Two or three times a week ☐
- About once a day ☐
- Several times a day ☐
- All the time ☐

A8 **Does urine leak when you have finished urinating and are dressed?**
*(Tick **ONE** box only)*

- Never ☐
- About once a week or less often ☐
- Two or three times a week ☐
- About once a day ☐
- Several times a day ☐
- All the time ☐

When you answer these questions, please think about how you have been in the **LAST WEEK.**

A9 **Does urine leak at times other than shown in your answers to questions A5, A7 or A8?**
*(Tick **ONE** box only)*

Yes ☐ *Go to **A9a*** No ☐ *Go to **A10***

A9a **If Yes, please give details of when you leak:**

A10 **Do you wear a pad or other protection because of leaking urine?**
*(Tick **ONE** box only)*

Yes ☐ *Go to **A9a*** No ☐ *Go to **A10***

A10a **If Yes, how many pads do you wear in an average day (24 hours)?**

Enter **TOTAL** number of pads you wear in 24 hours ☐☐

A10b **Of these pads, how many do you pay for yourself?**
If you do not pay for them, please enter zero (0) in the boxes

Enter number of pads **YOU PAY FOR** yourself ☐☐

A11 **Do you use pads or protectors on your chair or bed in case you leak urine?**
*(Tick **ONE** box only)*

Yes ☐ *Go to **A11a*** No ☐ *Go to **A12***

A11a **If Yes, how many chair or bed pads do you use in an average day (24 hours)?**

Enter **TOTAL** number of chair and bed pads you use in 24 hours ☐☐

A11b **Of these chair or bed pads, how many do you pay for yourself?**
If you do not pay for them, please enter zero (0) in the boxes

Enter number of chair and bed pads **YOU PAY FOR** yourself ☐☐

A12 **How often do you usually pass urine during the daytime?**

Enter number of times ☐☐

A13 **How often do you usually have to get up at night to pass urine?**

Enter number of times ☐☐

When you answer these questions, please think about how you have been in the **LAST WEEK.**

A14 **Are you using a permanent catheter (inside your bladder) to collect your urine?**

Yes ☐ No ☐

A14 **Do you ever use an external (sheath) catheter to collect your urine?**

Yes ☐ No ☐

SECTION B – CARE YOU HAVE RECEIVED

When you answer these questions, please think about the care you have received **IN THE LAST 3 MONTHS.**

B1 **Have you seen your family doctor (GP) in the last 3 months?**

Yes ☐ *Go to **B1a*** No ☐ *Go to **B2***

B1a **If Yes, approximately how often have you seen your family doctor (GP) in the last 3 months?**

Enter number of times seen GP **for leaking urine** ☐☐

Enter number of times seen GP **for any other reason** ☐☐

B2 **Have you seen a nurse (from your doctor's practice) in the last 3 months?**

Yes ☐ *Go to **B2a*** No ☐ *Go to **B3***

B2a **If Yes, approximately how many times have you seen a nurse from your doctor's practice in the last 3 months?**

Enter number of times seen nurse **for leaking urine** ☐☐

Enter number of times seen nurse **for any other reason** ☐☐

B3 **In the last 3 months, have you seen NHS HOSPITAL staff <u>for leaking urine</u>?**

If yes, enter number of visits

I have seen a hospital doctor **about leaking urine**	Yes ☐ →	Number of visits	☐☐
	No ☐		
I have seen a hospital nurse **about leaking urine**	Yes ☐ →	Number of visits	☐☐
	No ☐		
I have seen a hospital physiotherapist **about leaking urine**	Yes ☐ →	Number of visits	☐☐
	No ☐		

When you answer these questions, please think about the care you have received **IN THE LAST 3 MONTHS.**

B4 **In the last 3 months, have you received any PRIVATE TREATMENT (which you had to pay for yourself) for leaking urine?**

If Yes, enter number of visits

I have seen a private doctor **about leaking urine**	Yes ☐ →	Number of visits	☐☐
	No ☐		
I have seen a private nurse **about leaking urine**	Yes ☐ →	Number of visits	☐☐
	No ☐		
I have seen a private physiotherapist **about leaking urine**	Yes ☐ →	Number of visits	☐☐
	No ☐		

B5 **In the last 3 months, have you been admitted to hospital because of leaking urine?** ☐☐

Yes ☐ *Go to **B5a*** No ☐ *Go to **B6***

B5a **If you were admitted in the last 3 months, how many nights did you stay in hospital?**

Enter number of nights in hospital ☐☐

B5b **In the last 3 months, have you had an operation for leaking urine?**

Yes ☐ *Go to **B5c*** No ☐ *Go to **B6***

B5c **If Yes, please give the name or type of operation and the date:**

B6 **In the last 3 months, have you taken any medications (from a doctor, or direct from the chemist's) for leaking urine?**

Yes ☐ *Go to **B6a*** No ☐ *Go to **B7***

B6a **If Yes, please give details of medication received in the last 3 months for leaking urine.**
Please give drug names (e.g. detrusitol, duloxetine):

When you answer these questions, please think about the care you have received **IN THE LAST 3 MONTHS.**

B7 **Have you had any other treatment or advice for leaking urine in the last 3 months (other than the operation you named in B5c or the drugs you listed in B6a)?**

Yes ☐ *Go to **B7a*** No ☐ *Go to **B8***

B7a **If Yes, please give details of other treatment or advice received in the last 3 months for leaking urine:**

B8 **Are you in paid employment?**

Yes ☐ *Go to **B8a*** No ☐ *Go to **Section C***

B8a **If Yes, approximately how many days off sick have you had <u>for any reason</u> in the last 3 months?**

☐☐☐ days

SECTION C – BOWEL SYMPTOMS

This section is about your bowel symptoms and control of your stool (also called bowel motions or faeces). Many people experience bowel symptoms some of the time. When you answer these questions (**C1** to **C6**), please think about how you have been in the **LAST WEEK.**

C1 **How often do you lose control of or leak stool?**
*(Tick **ONE** box only)*

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

C2 **If you do, how much does this bother you?**
Please choose a number between 0 (not at all) and 10 (a great deal)
*(Tick **ONE** box only)*

Not at all ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 A great deal

When you answer these questions, please think about how you have been in the **LAST WEEK.**

C3 **When you feel the need to open your bowels, do you have to rush urgently to the toilet?**
*(Tick **ONE** box only)*

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

C4 **When you have to rush urgently, do you ever lose control of or leak stool?**
*(Tick **ONE** box only)*

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

C5 **Do you ever lose control of or leak stool WITHOUT first feeling that you have to rush urgently?**
*(Tick **ONE** box only)*

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

C6 **If stool leaks, is this usually solid, liquid or both?**
*(Tick **ONE** box only)*

- Doesn't leak ☐
- Liquid only ☐
- Solid only ☐
- Liquid and solid ☐

C7 **Are you currently receiving ANY treatment or advice for leaking stool?**

Yes ☐ *Go to **C7a*** No ☐ *Go to **C8***

C7a **If Yes, please give details of treatment or advice received for leaking stool:**

C8 **Do you have any of these other bowel problems?**
*(Tick **ALL** boxes that apply to you)*

Ulcerative colitis ☐
Crohn's disease ☐
Irritable bowel syndrome ☐
Constipation ☐

C9 **Are you currently receiving ANY treatment or advice for any of these other bowel problems?**

Yes ☐ *Go to **C9a*** No ☐ *Go to **Section D***

C9a **If Yes, please give details of treatment or advice received for other bowel problems:**

SECTION D – OTHER HEALTH ISSUES

This section is about exercise, weight and other issues to do with your health. When you answer these questions, please think about how you have been in the **LAST WEEK.**

D1 **Have you done any general exercise or fitness activity?**

Yes ☐ *Go to **D2*** No ☐ *Go to **D3***

D2 **If Yes, what sort of exercise have you done?** *(Tick **all** boxes that apply)*

Walking ☐ Swimming ☐ Gardening ☐
Running ☐ Going to the gym ☐ Other *(please give details in D2a)* ☐

D2a **Please give details of other exercise:**

When you answer these questions, please think about how you have been in the **LAST WEEK.**

D3 **Since your prostate operation, have you changed how you exercise?**
*(Tick **ONE** box only)*

- No, I have made no changes ☐
- I take LESS exercise than I did ☐
- I take MORE exercise than I did ☐

D4 **Have you done any pelvic floor exercises over the last week?**

Yes ☐ *Go to **D5*** No ☐ *Go to **D6*** Don't know what these are ☐ *Go to **D9***

D5 **If Yes, on how many days in the last week did you do any pelvic floor exercises?**
*(Tick **ONE** box only)*

- Every day ☐
- 5 to 6 days ☐
- 3 to 4 days ☐
- 1 to 2 days ☐

D5a **On average, how many contractions did you do each day when you did any pelvic floor exercises?**

Enter number of contractions ☐☐☐ Don't Know ☐

D6 **Do you deliberately contract your pelvic floor a little while you are walking about?**
*(Tick **ONE** box only)*

No ☐ Rarely ☐ Sometimes ☐ Often ☐ Always ☐

D7 **Do you deliberately contract your pelvic floor before you do something that would cause you to leak urine? (e.g. cough, sneeze, exercise, lift etc)**
*(Tick **ONE** box only)*

No ☐ Rarely ☐ Sometimes ☐ Often ☐ Always ☐

D8 **If you do, does contracting your pelvic floor stop leakage of urine?**
*(Tick **ONE** box only)*

Yes, completely ☐ Reduces the amount ☐ No ☐

When you answer these questions, please think about how you have been in the **LAST WEEK.**

D9 **Please could you enter your current weight?**
If you are not sure what it is, please give your best guess.
(Please use whichever units you are familiar with)

	Stones	Pounds	**OR**	Kilograms
What is your average weight now?				

D10 **Since your prostate operation (one year ago), have you made any changes to the amount of fluid you drink?** *(Please tick **ALL** that apply)*

I have made no changes ☐ *Go to **D11***

	Yes	**No**
I drink more fluids	☐	☐
I drink more cranberry juice	☐	☐
I take fewer drinks with caffeine	☐	☐
I drink less fluid in the evenings	☐	☐
I have made other changes *(please give details in **D10a**)*	☐	☐

D10a **I have made these other changes to the amount of fluid I drink:** *(please give details)*

D11 **Since your prostate operation, have you made any changes to your diet or the sort of food you eat?** *(Please tick **ALL** that apply)*

I have made no changes ☐ *Go to **D12***

	Yes	**No**
I eat a more balanced diet	☐	☐
I eat more fruit and vegetables	☐	☐
I eat more foods containing fibre eg. wholemeal bread or brown rice	☐	☐
I eat less food containing lots of fat or sugar	☐	☐
I have made other changes *(please give details in **D11a**)*	☐	☐

D11a **I have made these other changes to my diet:** *(please give details)*

When you answer these questions, please think about how you have been in the **LAST WEEK.**

D12 Since your prostate operation, have you tried to lose any weight?

No, I do not need to lose weight ☐ *Go to **D13***

No, I haven't tried to lose weight ☐ *Go to **D13***

	Yes	No
I do extra exercise to help me lose weight	☐	☐
I went on a weight reducing diet	☐	☐
I have tried to lose weight in other ways *(please give details in **D12a**)*	☐	☐

D12a I have tried these other ways of losing weight: *(please give details)*

D13 Since your prostate operation, have you avoided or reduced the amount of heavy lifting you do (e.g. lighter gardening, less heavy shopping or lifting less)?

Yes ☐ No ☐

D14 Do you smoke?

Yes ☐ *Go to **D14b*** No ☐ *Go to **D15***

D14b If Yes, have you changed your smoking habit?
*(Please tick **ALL** that apply)*

No, I have not changed my smoking habit ☐ *Go to **D15***

	Yes	No
I have stopped smoking	☐	☐
I have reduced the amount I smoke	☐	☐

When you answer these questions, please think about how you have been in the **LAST WEEK.**

D15 **Are you affected by any chest / respiratory symptoms (e.g. cough, asthma, bronchitis)?**

Yes ☐ *Go to **D16*** No ☐ *Go to **E1***

D16 **Since your prostate operation, have you tried to reduce your chest / respiratory symptoms?** *(Please tick **ALL** that apply)*

No, I have not tried to reduce my symptoms ☐ *Go to **E1***

	Yes	No
I have made sure that I am taking the correct medication for my condition(s)	☐	☐
I have spoken to my doctor to make sure that that my treatment is up-to-date	☐	☐
I have made other changes *(please give details in **D16a**)*	☐	☐

D16a **I have made other changes to help problems related to my chest symptoms:** *(please give details)*

SECTION E – DESCRIBING YOUR OWN HEALTH TODAY

The next two sections (E and F) are about your general health.

By placing a tick in one box in each group below, please indicate which statements best describe your own health state **TODAY**.

E1 **Mobility**

I have no problems in walking about ☐
I have some problems in walking about ☐
I am confined to bed ☐

E2 **Self-care**

I have no problems with self-care ☐
I have some problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

E3 **Usual activities** *(such as work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ☐
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

By placing a tick in one box in each group below, please indicate which statements best describe your own health state **TODAY**.

E4 Pain/discomfort

- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

E5 Anxiety/depression

- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

SECTION F – GENERAL HEALTH SF12 ©

The following questions ask for your views about your health **in the LAST 4 WEEKS,** how you feel and how well you are able to do your usual activities.

Answer every question by selecting the answer as indicated.
If you are unsure about how to answer a question please give the best answer you can.

F1 In general, would you say your health is:
*(Tick **ONE** box only)*

- Excellent ☐
- Very good ☐
- Good ☐
- Fair ☐
- Poor ☐

F2 During a typical day does your health limit you in moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf? If so, how much?
*(Tick **ONE** box only)*

- Yes, limited a lot ☐
- Yes, limited a little ☐
- No, not limited at all ☐

F3 During a typical day does your health limit you in climbing several flights of stairs? If so, how much?
*(Tick **ONE** box only)*

- Yes, limited a lot ☐
- Yes, limited a little ☐
- No, not limited at all ☐

F4 **During the past 4 weeks, how often have you accomplished less than you would have liked in your work or other regular daily activities as a result of your physical health?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

F5 **During the past 4 weeks, how often have you been limited in performing any kind of work or other regular daily activities as a result of your physical health?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

F6 **During the past 4 weeks, how often have you accomplished less than you would have liked in your work or any other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

F7 **During the past 4 weeks, how often have you done work or other activities less carefully than usual as a result of any emotional problems (such as feeling depressed or anxious)?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

F8 **During the past 4 weeks how much did pain interfere with your normal work (both outside the home and housework)?**
*(Tick **ONE** box only)*

- Not at all ☐
- A little bit ☐
- Moderately ☐
- Quite a bit ☐
- Extremely ☐

F9 **How much during the past 4 weeks have you felt calm and peaceful?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

F10 **How much during the past 4 weeks did you have a lot of energy?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

F11 **How much during the past 4 weeks have you felt downhearted and depressed?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

F12 **During the past 4 weeks how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?**
*(Tick **ONE** box only)*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

SECTION G – SEXUAL MATTERS

We would also like to find out about your sexual function and activity. When you answer these questions, please think about how you have been in the LAST 4 WEEKS.

You do not have to answer any question if you do not want to.

G1 **Do you get erections?** *(Tick **ONE** box only)*

- Yes, with normal stiffness ☐
- Yes, with reduced stiffness ☐
- Yes, with severely reduced stiffness ☐
- No, erection not possible ☐

G1a **If you have a problem with erection, how much does this bother you?**
Please choose a number between 0 (not at all) and 10 (a great deal)
*(Tick **ONE** box only)*

Not at all	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	A great deal

G2 **Do you ejaculate?** *(Tick **ONE** box only)*

- Yes, normal quantity of semen ☐
- Yes, but reduced quantity of semen ☐
- Yes, but significantly reduced quantity of semen ☐
- Yes, but no semen comes out ☐
- No ejaculation ☐

G2a **If you have a problem with ejaculation, how much does this bother you?**
Please choose a number between 0 (not at all) and 10 (a great deal)
*(Tick **ONE** box only)*

Not at all	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	A great deal

When you answer these questions, please think about how you have been in the LAST 4 WEEKS.

G3 **Do you have pain or discomfort during ejaculation?** *(Tick **ONE** box only)*

- ☐ No pain or discomfort
- ☐ Yes, slight pain or discomfort
- ☐ Yes, moderate pain or discomfort
- ☐ Yes, severe pain or discomfort

G3a **If you have pain or discomfort, how much does this bother you?**
Please choose a number between 0 (not at all) and 10 (a great deal)
*(Tick **ONE** box only)*

Not at all	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	A great deal

G4 **Have you taken any medications for sexual problems?**

Yes ☐ No ☐

G5 **Have you used a vacuum device for sexual problems?**

Yes ☐ No ☐

G6 **Do you have an active sex life (with or without a partner)?**

Yes ☐ *Go to **G8*** No ☐ *Go to **G9***

G7 **Do you leak urine during sex?**

Yes ☐ No ☐ Don't Know ☐

G8 **Has your sex life changed compared with before your prostate operation one year ago?**
*(Tick **ONE** box only)*

- ☐ It has stayed the same
- ☐ It is better
- ☐ It is worse

*Now go to **Section H***

When you answer these questions, please think about how you have been, in the LAST 4 WEEKS.)

G9 **If you DO NOT have an active sex life, is this for any of these reasons?**
*(Please tick **ALL** boxes that apply)*

- Because of my urinary symptoms ☐
- Because of my bowel symptoms ☐
- Because of my prostate operation ☐
- Because of medical treatment (e.g. drugs or medication) ☐
- For another reason ☐

SECTION H – FINALLY…

H1 **How satisfied were you with the treatment you received <u>for leaking urine</u> since your prostate operation?**
Please choose a number between 0 (very unsatisfied) and 10 (very satisfied)
*(Tick **ONE** box only)*

Very unsatisfied											Very satisfied
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	

H2 **Do you have any other comments about the MAPS Study, or the care you have received <u>for leaking urine?</u>**

Date you filled in this questionnaire D D / M M / Y Y Y Y

Your date of birth D D / M M / Y Y Y Y

THANK YOU

Thank you very much for your time and patience in filling in this questionnaire.

The information you have given us will be extremely useful in helping us carry out research into men's health after prostate surgery.

It will be treated with the strictest confidence and kept securely.

Please send the questionnaire back to us in Aberdeen in the envelope provided.

Please could you confirm your phone number:

Thank you again for your help

If you would like any further information or have any queries about the study, please contact:

The MAPS Study Office in Aberdeen (Tel: 01224 551103)

This study is taking place in centres across the UK but the questionnaires are being processed in Aberdeen at the Health Services Research Unit, Polwarth Building, Foresterhill, ABERDEEN, AB25 2ZD.

Appendix 3.4 MAPS participants' cost questionnaire

Participant Costs Questionnaire

Study Number | | | | | | |

MAPS

Men After Prostate Surgery

CONFIDENTIAL

MAPS TRIAL

MEN'S HEALTH AFTER PROSTATE SURGERY

Thank you for helping us with our research into urinary incontinence after prostate surgery.
We would be very grateful if you could complete and return this questionnaire.

Thank you for taking the time to help us with our research.

ISRCTN: 87696430
Version 1 February 2005

Participant Costs Questionnaire

This questionnaire will help us to find out how much it costs you to use health services. We wish to ask about your **most recent** admission to hospital, your **most recent** outpatient appointment and your **most recent** appointment with a GP. We wish to know how much money and time were spent by you and any companion in attending these appointments and as a result of any hospital admission you may have had.

It may have been a long time ago and we understand that you are unlikely to remember the exact details. Please just give us your best guess.

If you have a problem in answering any question
please telephone the MAPS Study Office on 01224 551103.

Please return the questionnaire in the enclosed pre-paid envelope.

HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting numbers or a tick in the appropriate box or boxes. Please print your answers carefully within the boxes like this:

2	7	OR	M	I	K	E	OR	✓

If you make a mistake, shade out the wrong box completely and tick the correct one like this

e.g. If you ticked often but meant to answer sometimes:

OFTEN ▒ **SOMETIMES** ✓ **NEVER** ☐

Please try to complete the whole questionnaire.

There are no right or wrong answers.

Sometimes the box you tick tells you to skip forward so that you miss out questions which do not apply to you.

In some questions we would like you to think about different time periods, such as during the last week, during the last 4 weeks or since your prostate operation. Please check the time periods carefully.

Some of the questions ask for answers in your own words, please write these in the boxes provided.

You do not have to answer any question if you do not want to.

Thank you for your help.

SECTION A - YOUR MOST RECENT ADMISSION TO HOSPITAL

If you were NOT admitted to hospital in the last 12 months, please go to **SECTION B**

A1 **How did you travel to hospital?**
If you used more than one form of transport please indicate the way you travelled for the main (longest in terms of distance) part of your journey. Please tick the box that best describes how you travelled.

Bus ☐ Taxi ☐ Ambulance ☐
Train ☐ Hospital car ☐ Private car ☐
Other (please specify) ☐

A2 **If you travelled by bus, train or taxi to hospital, what was the total cost of the (one-way) journey?**
Please write the cost in the box below. Please put zero if you did not travel by bus, train or taxi at all or if you did not pay a fare.

Cost of (one-way) fare (£) ☐☐ - ☐☐ pence

A3 **If you travelled by private car, about how many miles did you travel one-way?**
Please write the number of miles in the box below. Please put zero if you did not travel by private car at all.

Number of miles one-way ☐☐

A4 **If you travelled by private car and you or your companion had to pay a parking fee, how much did this cost?** *Please write the cost in the box below. Please put zero if you did not pay for parking.*

Cost of parking fee (£) ☐☐ - ☐☐ pence

A5 **When you were admitted to the hospital, how long did you spend there?**
Please write the number of days in the box below.

Number of days ☐☐

A6 **What would you otherwise have been doing as your main activity if you had not had to be admitted to hospital?** *Please tick the box that best applies to you.*

Housework ☐ Unemployed ☐ Leisure activities ☐ Childcare ☐
Paid work ☐ Caring for a relative or friend ☐ Voluntary work ☐
Other (please specify) ☐

A7 **When you were admitted to hospital, did anyone come with you?** *Please tick one box only.*

Yes ☐ Go to **A8** No ☐ Go to **Section B**

A8 **Who came with you to the hospital?**
Please tick the box that best describes the main person who accompanied you to the hospital.

Partner/spouse ☐ Paid caregiver ☐ Other relative ☐ Friend ☐

Other (please specify) ☐

A9 **What would your main companion otherwise have been doing as their <u>main</u> activity if they had not gone with you to the hospital?** *Please tick the box that best applies.*

Housework ☐ Unemployed ☐ Leisure activities ☐ Childcare ☐

Paid work ☐ Caring for a relative or friend ☐ Voluntary work ☐

Other (please specify) ☐

A10 **Did your main companion take time off from paid work (or business activity if self-employed)?**
Please tick one box only.

Yes ☐ Go to **A11** No ☐ Go to **Section B**

A11 **Please write the number of hours you companion took off from paid work (or business activity if self-employed) in the box below.** *Please put zero if your main companion did not take time off from paid work (or business) to accompany you to the hospital.*

Number of hours ☐☐

A12 **While you were in hospital, approximately how many times did your main companion come to visit you?**

Number of times ☐☐

SECTION B - YOUR MOST RECENT OUTPATIENT VISIT

If you did not have an outpatient visit in the last 12 months, please go to **Section C**

B1 **How did you travel to the Outpatient Department?**
If you used more than one form of transport please indicate the way you travelled for the main (longest in terms of distance) part of your journey. Please tick the box that best describes how you travelled.

Bus ☐ Taxi ☐ Ambulance ☐

Train ☐ Hospital car ☐ Private car ☐

Other (please specify) ☐

B2 **If you travelled by bus, taxi or train to hospital, what was the total cost of the (one-way) journey?**
Please write the cost in the box below. Please put zero if you did not travel by bus, train or taxi at all or if you did not pay a fare.

Cost of (one-way) fare (£) ☐☐ - ☐☐ pence

B3 **If you travelled by private car, about how many miles did you travel one-way?**
Please write the number of miles in the box below. Please put zero if you did not travel by private car at all.

Number of miles one-way ☐☐☐

B4 **If you travelled by private car and you or your companion had to pay a parking fee, how much did this cost?** *Please write the cost in the box below. Please put zero if you did not pay for parking.*

Cost of parking fee (£) ☐☐ - ☐☐ pence

B5 **When you visited outpatients, how long did it take to travel there?**
Please write the number of hours and minutes in the box below.

Number of hours ☐☐ - ☐☐ minutes

B6 **When you visited outpatients, how long did you spend there?**
Please write the number of hours and minutes in the box below.

Number of hours ☐☐ - ☐☐ minutes

B7 **What would you have otherwise been doing as your <u>main</u> activity if you had not been visiting outpatients?** *Please tick the box that best applies to you.*

Housework ☐ Unemployed ☐ Leisure activities ☐ Childcare ☐
Paid work ☐ Caring for a relative or friend ☐ Voluntary work ☐
Other (please specify) ☐

B8 **When you visited outpatients, did anyone come with you?** *Please tick one box only.*

Yes ☐ Go to **B9** No ☐ Go to **Section C**

B9 **Who came with you to outpatients?**
Please tick the box that best describes the <u>main</u> person who accompanied you to outpatients.

Partner/spouse ☐ Paid caregiver ☐ Other relative ☐ Friend ☐
Other (please specify) ☐

B10 **If your main companion travelled with you by bus or train, approximately how much did they pay (one-way) in fares?** *Please write the approximate cost in the box below. Please put zero if your main companion did not travel by bus or train at all.*

Cost of (one-way) fare (£) ☐☐ - ☐☐ pence

B11 **What would your main companion otherwise have been doing as their <u>main</u> activity if they had not gone with you to outpatients?** *Please tick the box that best applies.*

Housework ☐ Unemployed ☐ Leisure activities ☐ Childcare ☐
Paid work ☐ Caring for a relative or friend ☐ Voluntary work ☐
Other (please specify) ☐

SECTION C - YOUR MOST RECENT GP APPOINTMENT

If you did not visit your GP in the last 12 months, please go to **C12**.

C1 **How did you travel to your GP's surgery?**
If you used more than one form of transport please indicate the way you travelled for the main (longest in terms of distance) part of your journey. Please tick the box that best describes how you travelled.

Walked ☐ Private car ☐ Taxi ☐
Cycled ☐ Bus ☐
Other (please specify) ☐

C2 **If you travelled by bus or taxi, what was the cost of the (one-way) fare?** *Please write the cost in the box below. Please put zero if you did not travel by bus or taxi or if you did not pay a fare.*

Cost of (one-way) fare (£) ☐☐ - ☐☐ pence

C3 **If you travelled by private car, how many miles did you travel one-way?**
Please write the number of miles in the box below. Please put zero if you did not travel by private car at all.

Number of miles one-way ☐☐☐

C4 **If you travelled by private car and you or a companion had to pay a parking fee, how much did this cost?** *Please write the cost in the box below. Please put zero if you did not pay for parking.*

Expenditure on parking fee (£) ☐☐ - ☐☐ pence

C5 **When you visited your GP, how long did it take to travel there?**
Please write the number of minutes in the box below.

Number of minutes ☐☐☐

C6 **When you visited your GP, how long did you spend there?**
Please write the number of minutes in the box below. Please include in your answer the time spent waiting and also the time spent with the doctors and nurses.

Number of minutes ☐☐☐

C7 **What would you otherwise have been doing as your <u>main</u> activity if you had not visited your GP?**
Please tick the box that best applies to you.

Housework ☐ Unemployed ☐ Leisure activities ☐ Childcare ☐
Paid work ☐ Caring for a relative or friend ☐ Voluntary work ☐
Other (please specify) ☐

C8 **When you visited your GP did anyone come with you?** *Please tick one box only.*

Yes ☐ Go to **C9** No ☐ P.T.O. to **back page**

C9 **Who came with you to your GP?**
Please tick the box(es) that best describe the person(s) who accompanied you to your GP's surgery. You may tick more than one box if appropriate.

Partner/spouse ☐ Paid caregiver ☐ Other relative ☐ Friend ☐

Other (please specify) ☐

C10 **If your main companion travelled with you by bus, how much approximately did they pay (one-way) in fares?**
Please write the cost in the box below. Please put zero if your main companion did not travel by bus at all.

Cost of (one-way) fare (£) ☐☐ - ☐☐ pence

C11 **What would your main companion otherwise have been doing as their main activity if they had not gone with you to your GP's surgery?** *Please tick the box that best applies.*

Housework ☐ Unemployed ☐ Leisure activities ☐ Childcare ☐

Paid work ☐ Caring for a relative or friend ☐ Voluntary work ☐

Other (please specify) ☐

C12 **If you wish to provide any further information please do so here.**

THANK YOU

Thank you very much for your time and patience in filling in this questionnaire.

The information you have given us will be extremely useful
in helping us carry out research into men's health after prostate surgery.

It will be treated with the strictest confidence and kept securely.

**Please send the questionnaire back to us in Aberdeen
in the envelope provided.**

Please could you confirm your phone number: | | | | | | | | | | | | | |

Thank you again for your help

If you would like any further information
or have any queries about the study, please contact:

The MAPS Study Office in Aberdeen (Tel: 01224 551103)

This study is taking place in centres across the UK but the questionnaires are being processed in Aberdeen
at the Health Services Research Unit, University of Aberdeen, Foresterhill, ABERDEEN, AB25 2ZD.

Appendix 3.5 MAPS urinary diary

Study Number | | | | | | |

MAPS
Men After Prostate Surgery

Urinary Diary

Please keep this diary to record how your bladder is functioning.

Please could you fill in the diary for the **NEXT 3 DAYS.**

Please mark a cross in the appropriate box for every time you:
- Go to the toilet to pass urine,
- Leak urine (show if it was a small, moderate or large amount),
- Change your pad, clothing or bedding due to leaking urine.

The number of crosses in each box will show how often each event occurred either during the day or after you have gone to bed at night.

For example, if you went to the toilet to pass urine 6 times during the day, but also leaked a moderate amount and changed your pad once; woke twice at night to go to the toilet to pass urine; leaked a small amount at night and changed your pyjamas and bedding, you would enter:

Time		Day 1		Night 1	
Mark with cross each time you go to toilet to pass urine		**X X X X X X**		**X X**	
Mark with cross each time you leak urine (small, moderate or large amount)	**Small**			**X**	
	Moderate	**X**			
	Large				
Mark with cross each time you change pads, clothing or bedding because they are wet	**Pad**	**X**			
	Clothing			**X**	
	Bedding			**X**	

Date today_____

Time		Day 1		Night 1	
Mark with cross each time you go to toilet to pass urine					
Mark with cross each time you leak urine (small, moderate or large amount)	Small				
	Moderate				
	Large				
Mark with cross each time you change pads, clothing or bedding because they are wet	Pad				
	Clothing				
	Bedding				

Date today_____

Time		Day 2		Night 2	
Mark with cross each time you go to toilet to pass urine					
Mark with cross each time you leak urine (small, moderate or large amount)	Small				
	Moderate				
	Large				
Mark with cross each time you change pads, clothing or bedding because they are wet	Pad				
	Clothing				
	Bedding				

Date today_____

Time		Day 3		Night 3	
Mark with cross each time you go to toilet to pass urine					
Mark with cross each time you leak urine (small, moderate or large amount)	**Small**				
	Moderate				
	Large				
Mark with cross each time you change pads, clothing or bedding because they are wet	**Pad**				
	Clothing				
	Bedding				

Thank you very much for filling in this diary.
Please return it in the stamped addressed envelope enclosed, along with your questionnaire, to the MAPS study office.

Version 1 March 2005

Appendix 4

Therapy documentation and participants' advice leaflets

Appendix 4.1 Therapy documentation used during therapy appointments

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Date: | | | | | | | | |

Urinary Incontinence in Men After Prostate Surgery (MAPS)
Assessment at First visit

Unit No: | | | | | | | | | | |

Patient Details

Name | | Date of Birth: | | | | | 1 | 9 | | |

Address | |

Telephone No | | Occupation | |

Hobbies & activities: | |

Consultant | | GP | |

Surgical History

Radical Date: | | | | | | | | |

Previous TURP | Yes | No |

Complications of recent prostate surgery.

Other relevant surgical history

Medical history

	Yes	No		Yes	No
Cystitis / UTI (**Acute**)			Cough /chest problems		
Cystitis / UTI (**Chronic**)			Smoker		
Latex allergy			Neurological disease (please give details)		

Other medical problems (heart, BP, diabetes etc)	*(details)*
Medication / drugs	

Body Mass Measurements *(if blank, please fill in)*

Height | | Metres **OR** | | | Feet | | | Inches

Weight | | Kilograms **OR** | | | Stones | | | Pounds

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Visit No. 1st [X] 2nd [ ] 3rd [ ] 4th [ ] Date: | | | | | | | | |

Name of Therapist

Physiotherapist [ ] Continence Nurse [ ] Other Nurse [ ]

HISTORY

Did urine leak **BEFORE** prostate surgery? Yes [ ] No [ ]

Comments

If Yes, type of incontinence and amount BEFORE prostate surgery

	Yes	No	Small	Moderate	Large	* If other incontinence please give details
Stress incontinence	[ ]	[ ]				
Urgency	[ ]	[ ]				
Urge incontinence	[ ]	[ ]				
Post micturition dribble	[ ]	[ ]				
Incontinence at other times*	[ ]	[ ]				

Urinary incontinence symptoms NOW (in last week)

	Yes	No	If incontinent, amount? Small	Moderate	Large
Any urinary incontinence	[ ]	[ ]			

Frequency of incontinence *(tick **one** box only)*

never [ ] two or three times a week [ ] several times a day [ ]

about once a week or less often [ ] about once a day [ ] all the time [ ]

Overall, how much does leaking urine interfere with everyday life?

Please tick a number between 0 (not at all) and 10 (a great deal)

Not at all [ ] 0 [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ] 7 [ ] 8 [ ] 9 [ ] 10 A great deal

Type of incontinence and amount NOW (in last week)

	Yes	No	Small	Moderate	Large	* If other incontinence please give details
Stress incontinence	[ ]	[ ]				
Urgency	[ ]	[ ]				
Urge incontinence	[ ]	[ ]				
Post micturition dribble	[ ]	[ ]				
Incontinence at other times*	[ ]	[ ]				

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Visit No. 1st [X] 2nd [ ] 3rd [ ] 4th [ ]

Other Symptoms	Yes	No
Sensation when bladder is full?		
Sensation when urine is leaking?		
Use of external sheath catheter		
Use of penile clamp		
Pain passing urine (dysuria)		

Comments

Urinary frequency by day *(enter no. of urinations)*	
Nocturia *(enter no. of times up at night)*	
Number of pads used during day	
Number of pads used at night	

Comments

Use of other aids (eg chair pads, bed pads, mattress protectors etc) *(please give brief details)*

Bowel problems NOW (in last week)	Yes	No		Yes	No
Faecal incontinence			Irritable bowel syndrome		
Faecal urgency			Ulcerative colitis		
Faecal incontinence **WITH** urgency			Crohn's disease		
Faecal incontinence **WITHOUT** urgency			Constipation		

Comments

Sexual problems NOW (in last week)	Yes	No
Difficulty gaining erection now		
Difficulty maintaining erection now		
Premature ejaculation now		
Nocturnal erection now		
Ability to achieve an erection BEFORE prostate surgery		

Comments

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Visit No. 1st [X] 2nd [ ] 3rd [ ] 4th [ ]

EXAMINATION

Informed consent to examination obtained Yes [ ]

Chaperone Accepted [ ]
Declined [ ]

Relationship of chaperone: [ ]

External examination
(in crook lying, i.e. supine, knees bent and separated, feet apart, with paper towel over the pelvis)

	Yes	No
Evidence of skin damage (excoriation/ ulcers) *(penis, perineum, anal area)*		
Evidence of infection of skin		
Able to tighten anus		
Able to perform penile retraction and testicular lift		
Leakage on coughing		
Able to prevent leakage on coughing		

Comments

Dermatomes	**Left**		**Right**	
	Normal	Abnormal	Normal	Abnormal
S 2 Lateral buttocks and thigh, posterior calf and plantar heel				
S 3 upper two-thirds of medial thigh				
S 4 Penis and perineal area				

Comments

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Visit No. 1st [X] 2nd [ ] 3rd [ ] 4th [ ]

Digital anal examination

1. External anal sphincter (insert finger to first joint)

Strength of contraction of external anal sphincter *(tick one only)*

0 (no flicker)	[ ]	3 (moderate movement)	[ ]	6 (very strong, unable to withdraw finger)	[ ]
1 (flicker)	[ ]	4 (good resistance)	[ ]		
2 (weak)	[ ]	5 (strong resistance)	[ ]		

Anal sphincter endurance *(enter number of seconds)* [ ]

	Yes	No
Able to contract anal sphincter quickly	[ ]	[ ]

2. Puborectalis muscle (insert finger to second joint)

Strength of contraction of puborectalis muscle *(tick one only)*

0 (no flicker)	[ ]	3 (moderate movement)	[ ]	6 (very strong, unable to withdraw finger)	[ ]
1 (flicker)	[ ]	4 (good resistance)	[ ]		
2 (weak)	[ ]	5 (strong resistance)	[ ]		

Puborectalis muscle endurance *(enter number of seconds)* [ ]

	Yes	No
Able to contract puborectalis muscle quickly	[ ]	[ ]

If digital anal examination is not performed, please give reason:

Biofeedback

	Yes	No
Biofeedback is available in this centre	[ ]	[ ]
Biofeedback is clinically indicated for this man	[ ]	[ ]
This man has had biofeedback	[ ]	[ ]

If biofeedback is used:

Either: **Anal pressure biofeedback**

Maximum reading in cm H_2O from best of 3 contractions [ ]

Or: **EMG with anuform probe**

Maximum reading in μV from best of 3 contractions [ ]

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Summary of Management

Diagnoses		Yes	No
1	Stress urinary incontinence		
2	Urge urinary incontinence		
3	Post micturition dribble		
4	Faecal incontinence		
5	Erectile dysfunction (unable to gain or maintain erection)		
6	Other diagnoses (please give details)		

Treatment		Yes	No
1	Given and explained PFMT leaflet		
2	Number of seconds ____ agreed with man to hold contraction (also enter in leaflet)		
3	Given (or has got) and explained Lifestyles Advice Leaflet		
4	3 sets of contractions in three positions twice a day		
5	Lift (tighten) pelvic floor muscles before exertion (eg coughing, lifting, rising from sitting)		
6	Lift (tighten) pelvic floor muscles 50% while walking		
7	Lift (tighten) pelvic floor muscles after urinating (to squeeze out last drops)		
8	Lift (tighten) pelvic floor muscles during sexual activity		
9	Urge suppression techniques (bladder training)		
10	Other treatment (please give details)		

Advice

Plan Make appointment in two weeks

Questions for next time
Medication/other treatment for urinary incontinence or sexual problems?

At the end of the session, ask the man if he has any pain anywhere as a result of the examination. If so, document it and if it is severe or it does not resolve advise him to see his GP. Also remind man to keep his travel receipts.

Signed: _____

MAPS No: 1 **RADICAL – Therapy Documentation**

Visit No. 1st ☐ 2nd **X** 3rd ☐ 4th ☐ Date: ☐☐☐☐☐☐☐☐

Name of Therapist ☐

Physiotherapist ☐ Continence Nurse ☐ Other Nurse ☐

HISTORY

Did urine leak **BEFORE** prostate surgery? Yes ☐ No ☐

Comments

If Yes, type of incontinence and amount BEFORE prostate surgery

	Yes	No	Small	Moderate	Large	* If other incontinence please give details
Stress incontinence	☐	☐				
Urgency	☐	☐				
Urge incontinence	☐	☐				
Post micturition dribble	☐	☐				
Incontinence at other times*	☐	☐				

Urinary incontinence symptoms NOW (in last week)

	Yes	No	If incontinent, amount? Small	Moderate	Large
Any urinary incontinence	☐	☐			

Frequency of incontinence *(tick **one** box only)*

never ☐ two or three times a week ☐ several times a day ☐

about once a week or less often ☐ about once a day ☐ all the time ☐

Overall, how much does leaking urine interfere with everyday life?

Please tick a number between 0 (not at all) and 10 (a great deal)

Not at all ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 A great deal

Type of incontinence and amount NOW (in last week)

	Yes	No	Small	Moderate	Large	* If other incontinence please give details
Stress incontinence	☐	☐				
Urgency	☐	☐				
Urge incontinence	☐	☐				
Post micturition dribble	☐	☐				
Incontinence at other times*	☐	☐				

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Visit No. 1st [ ] 2nd [X] 3rd [ ] 4th [ ]

Other Symptoms	Yes	No
Sensation when bladder is full?		
Sensation when urine is leaking?		
Use of external sheath catheter		
Use of penile clamp		
Pain passing urine (dysuria)		

Comments

Urinary frequency by day *(enter no. of urinations)*	
Nocturia *(enter no. of times up at night)*	
Number of pads used during day	
Number of pads used at night	

Comments

Use of other aids (eg chair pads, bed pads, mattress protectors etc) *(please give brief details)*

Bowel problems NOW (in last week)	Yes	No		Yes	No
Faecal incontinence			Irritable bowel syndrome		
Faecal urgency			Ulcerative colitis		
Faecal incontinence **WITH** urgency			Crohn's disease		
Faecal incontinence **WITHOUT** urgency			Constipation		

Comments

Sexual problems NOW (in last week)	Yes	No
Difficulty gaining erection now		
Difficulty maintaining erection now		
Premature ejaculation now		
Nocturnal erection		
Ability to achieve an erection BEFORE prostate surgery		

Comments

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Visit No. 1st [ ] 2nd [X] 3rd [ ] 4th [ ]

EXAMINATION

Informed consent to examination obtained Yes [ ]

Chaperone Accepted [ ]
Declined [ ]

Relationship of chaperone: [ ]

External examination
(in crook lying, i.e. supine, knees bent and separated, feet apart, with paper towel over the pelvis)

	Yes	No
Evidence of skin damage (excoriation/ ulcers) *(penis, perineum, anal area)*		
Evidence of infection of skin		
Able to tighten anus		
Able to perform penile retraction and testicular lift		
Leakage on coughing		
Able to prevent leakage on coughing		

Comments

Dermatomes	**Left**		**Right**	
	Normal	Abnormal	Normal	Abnormal
S 2 Lateral buttocks and thigh, posterior calf and plantar heel				
S 3 upper two-thirds of medial thigh				
S 4 Penis and perineal area				

Comments

MAPS No: [ ][ ]1[ ][ ][ ] **RADICAL – Therapy Documentation**

Visit No. 1st [ ] 2nd [X] 3rd [ ] 4th [ ]

Digital anal examination

1. External anal sphincter (insert finger to first joint)

Strength of contraction of external anal sphincter *(tick one only)*

0 (no flicker)	[ ]	3 (moderate movement)	[ ]	6 (very strong, unable to withdraw finger)	[ ]
1 (flicker)	[ ]	4 (good resistance)	[ ]		
2 (weak)	[ ]	5 (strong resistance)	[ ]		

Anal sphincter endurance *(enter number of seconds)* [ ]

	Yes	No
Able to contract anal sphincter quickly	[ ]	[ ]

2. Puborectalis muscle (insert finger to second joint)

Strength of contraction of puborectalis muscle *(tick one only)*

0 (no flicker)	[ ]	3 (moderate movement)	[ ]	6 (very strong, unable to withdraw finger)	[ ]
1 (flicker)	[ ]	4 (good resistance)	[ ]		
2 (weak)	[ ]	5 (strong resistance)	[ ]		

Puborectalis muscle endurance *(enter number of seconds)* [ ]

	Yes	No
Able to contract puborectalis muscle quickly	[ ]	[ ]

If digital anal examination is not performed, please give reason:

Biofeedback

	Yes	No
Biofeedback is available in this centre	[ ]	[ ]
Biofeedback is clinically indicated for this man	[ ]	[ ]
This man has had biofeedback	[ ]	[ ]

If biofeedback is used:

Either: **Anal pressure biofeedback**

Maximum reading in cm H_2O from best of 3 contractions [ ]

Or: **EMG with anuform probe**

Maximum reading in μV from best of 3 contractions [ ]

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Summary of Management

Diagnoses		Yes	No
1	Stress urinary incontinence		
2	Urge urinary incontinence		
3	Post micturition dribble		
4	Faecal incontinence		
5	Erectile dysfunction (unable to gain or maintain erection)		
6	Other diagnoses (please give details)		

Treatment		Yes	No
1	Given and explained PFMT leaflet		
2	Number of seconds ____ agreed with man to hold contraction (also enter in leaflet)		
3	Given (or has got) and explained Lifestyles Advice Leaflet		
4	3 sets of contractions in three positions twice a day		
5	Lift (tighten) pelvic floor muscles before exertion (eg coughing, lifting, rising from sitting)		
6	Lift (tighten) pelvic floor muscles 50% while walking		
7	Lift (tighten) pelvic floor muscles after urinating (to squeeze out last drops)		
8	Lift (tighten) pelvic floor muscles during sexual activity		
9	Urge suppression techniques (bladder training)		
10	Other treatment (please give details)		

Advice

Plan Make appointment in four weeks

Questions for next time
Medication/other treatment for urinary incontinence or sexual problems?

At the end of the session, ask the man if he has any pain anywhere as a result of the examination. If so, document it and if it is severe or it does not resolve advise him to see his GP. Also remind man to keep his travel receipts.

Signed: _____

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Visit No. 1st ☐ 2nd ☐ 3rd ☒ 4th ☐ Date: | | | | | | | | |

Name of Therapist

Physiotherapist ☐ Continence Nurse ☐ Other Nurse ☐

HISTORY

Did urine leak **BEFORE** prostate surgery? Yes ☐ No ☐

Comments

If Yes, type of incontinence and amount BEFORE prostate surgery

	Yes	No	Small	Moderate	Large	* If other incontinence please give details
Stress incontinence	☐	☐				
Urgency	☐	☐				
Urge incontinence	☐	☐				
Post micturition dribble	☐	☐				
Incontinence at other times*	☐	☐				

Urinary incontinence symptoms NOW (in last week)

	Yes	No	If incontinent, amount? Small	Moderate	Large
Any urinary incontinence	☐	☐			

Frequency of incontinence *(tick **one** box only)*

never ☐ two or three times a week ☐ several times a day ☐

about once a week or less often ☐ about once a day ☐ all the time ☐

Overall, how much does leaking urine interfere with everyday life?

Please tick a number between 0 (not at all) and 10 (a great deal)

Not at all ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 A great deal

Type of incontinence and amount NOW (in last week)

	Yes	No	Small	Moderate	Large	* If other incontinence please give details
Stress incontinence	☐	☐				
Urgency	☐	☐				
Urge incontinence	☐	☐				
Post micturition dribble	☐	☐				
Incontinence at other times*	☐	☐				

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Visit No. 1st [ ] 2nd [ ] 3rd [X] 4th [ ]

Other Symptoms	Yes	No
Sensation when bladder is full?		
Sensation when urine is leaking?		
Use of external sheath catheter		
Use of penile clamp		
Pain passing urine (dysuria)		

Comments

Urinary frequency by day *(enter no. of urinations)*	
Nocturia *(enter no. of times up at night)*	
Number of pads used during day	
Number of pads used at night	

Comments

Use of other aids (eg chair pads, bed pads, mattress protectors etc) *(please give details)*

Bowel problems NOW (in last week)	Yes	No		Yes	No
Faecal incontinence			Irritable bowel syndrome		
Faecal urgency			Ulcerative colitis		
Faecal incontinence **WITH** urgency			Crohn's disease		
Faecal incontinence **WITHOUT** urgency			Constipation		

Comments

Sexual problems NOW (in last week)	Yes	No
Difficulty gaining erection now		
Difficulty maintaining erection now		
Premature ejaculation now		
Nocturnal erection now		
Ability to achieve an erection BEFORE prostate surgery		

Comments

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Visit No. 1st [ ] 2nd [ ] 3rd [X] 4th [ ]

EXAMINATION

Informed consent to examination obtained Yes [ ]

Chaperone Accepted [ ]
Declined [ ]

Relationship of chaperone: [ ]

External examination
(in crook lying, i.e. supine, knees bent and separated, feet apart, with paper towel over the pelvis)

	Yes	No
Evidence of skin damage (excoriation/ ulcers) *(penis, perineum, anal area)*		
Evidence of infection of skin		
Able to tighten anus		
Able to perform penile retraction and testicular lift		
Leakage on coughing		
Able to prevent leakage on coughing		

Comments

Dermatomes	**Left**		**Right**	
	Normal	Abnormal	Normal	Abnormal
S 2 Lateral buttocks and thigh, posterior calf and plantar heel				
S 3 upper two-thirds of medial thigh				
S 4 Penis and perineal area				

Comments

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Visit No. 1st [ ] 2nd [ ] 3rd [X] 4th [ ]

Digital anal examination

1. External anal sphincter (insert finger to first joint)

Strength of contraction of external anal sphincter *(tick one only)*

0 (no flicker)	[ ]	3 (moderate movement)	[ ]	6 (very strong, unable to withdraw finger)	[ ]
1 (flicker)	[ ]	4 (good resistance)	[ ]		
2 (weak)	[ ]	5 (strong resistance)	[ ]		

Anal sphincter endurance *(enter number of seconds)* [ ]

	Yes	No
Able to contract anal sphincter quickly	[ ]	[ ]

2. Puborectalis muscle (insert finger to second joint)

Strength of contraction of puborectalis muscle *(tick one only)*

0 (no flicker)	[ ]	3 (moderate movement)	[ ]	6 (very strong, unable to withdraw finger)	[ ]
1 (flicker)	[ ]	4 (good resistance)	[ ]		
2 (weak)	[ ]	5 (strong resistance)	[ ]		

Puborectalis muscle endurance *(enter number of seconds)* [ ]

	Yes	No
Able to contract puborectalis muscle quickly	[ ]	[ ]

If digital anal examination is not performed, please give reason:

Biofeedback

	Yes	No
Biofeedback is available in this centre	[ ]	[ ]
Biofeedback is clinically indicated for this man	[ ]	[ ]
This man has had biofeedback	[ ]	[ ]

If biofeedback is used:

Either: **Anal pressure biofeedback**

Maximum reading in cm H_2O from best of 3 contractions [ ]

Or: **EMG with anuform probe**

Maximum reading in μV from best of 3 contractions [ ]

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Summary of Management

Diagnoses		Yes	No
1	Stress urinary incontinence		
2	Urge urinary incontinence		
3	Post micturition dribble		
4	Faecal incontinence		
5	Erectile dysfunction (unable to gain or maintain erection)		
6	Other diagnoses (please give details)		

Treatment		Yes	No
1	Given and explained PFMT leaflet		
2	Number of seconds ____ agreed with man to hold contraction (also enter in leaflet)		
3	Given (or has got) and explained Lifestyles Advice Leaflet		
4	3 sets of contractions in three positions twice a day		
5	Lift (tighten) pelvic floor muscles before exertion (eg coughing, lifting, rising from sitting)		
6	Lift (tighten) pelvic floor muscles 50% while walking		
7	Lift (tighten) pelvic floor muscles after urinating (to squeeze out last drops)		
8	Lift (tighten) pelvic floor muscles during sexual activity		
9	Urge suppression techniques (bladder training)		
10	Other treatment (please give details)		

Advice

Plan Make appointment in six weeks

Questions for next time
Medication/other treatment for urinary incontinence or sexual problems?

At the end of the session, ask the man if he has any pain anywhere as a result of the examination. If so, document it and if it is severe or it does not resolve advise him to see his GP. Also remind man to keep his travel receipts.

Signed: _____

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Visit No. 1st [ ] 2nd [ ] 3rd [ ] 4th [X] Date: [ ][ ][ ][ ][ ][ ][ ][ ]

Name of Therapist [ ]

Physiotherapist [ ] Continence Nurse [ ] Other Nurse [ ]

HISTORY

Did urine leak **BEFORE** prostate surgery? Yes [ ] No [ ]

Comments

If Yes, type of incontinence and amount BEFORE prostate surgery

	Yes	No	Small	Moderate	Large	* If other incontinence please give details
Stress incontinence	[ ]	[ ]				
Urgency	[ ]	[ ]				
Urge incontinence	[ ]	[ ]				
Post micturition dribble	[ ]	[ ]				
Incontinence at other times*	[ ]	[ ]				

Urinary incontinence symptoms NOW (in last week)

	Yes	No	If incontinent, amount? Small	Moderate	Large
Any urinary incontinence	[ ]	[ ]			

Frequency of incontinence *(tick **one** box only)*

never [ ] two or three times a week [ ] several times a day [ ]

about once a week or less often [ ] about once a day [ ] all the time [ ]

Overall, how much does leaking urine interfere with everyday life?

Please tick a number between 0 (not at all) and 10 (a great deal)

Not at all [ ]0 [ ]1 [ ]2 [ ]3 [ ]4 [ ]5 [ ]6 [ ]7 [ ]8 [ ]9 [ ]10 A great deal

Type of incontinence and amount NOW (in last week)

	Yes	No	Small	Moderate	Large	* If other incontinence please give details
Stress incontinence	[ ]	[ ]				
Urgency	[ ]	[ ]				
Urge incontinence	[ ]	[ ]				
Post micturition dribble	[ ]	[ ]				
Incontinence at other times*	[ ]	[ ]				

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Visit No. 1st [ ] 2nd [ ] 3rd [ ] 4th [X]

Other Symptoms	Yes	No
Sensation when bladder is full?		
Sensation when urine is leaking?		
Use of external sheath catheter		
Use of penile clamp		
Pain passing urine (dysuria)		

Comments

Urinary frequency by day *(enter no. of urinations)*	
Nocturia *(enter no. of times up at night)*	
Number of pads used during day	
Number of pads used at night	

Comments

Use of other aids (eg chair pads, bed pads, mattress protectors etc) *(please give brief details)*

Bowel problems NOW (in last week)	Yes	No		Yes	No
Faecal incontinence			Irritable bowel syndrome		
Faecal urgency			Ulcerative colitis		
Faecal incontinence **WITH** urgency			Crohn's disease		
Faecal incontinence **WITHOUT** urgency			Constipation		

Comments

Sexual problems NOW (in last week)	Yes	No
Difficulty gaining erection now		
Difficulty maintaining erection now		
Premature ejaculation now		
Nocturnal erection now		
Ability to gain and maintain an erection BEFORE prostate surgery		

Comments

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Visit No. 1st [ ] 2nd [ ] 3rd [ ] 4th [X]

EXAMINATION

Informed consent to examination obtained Yes [ ]

Chaperone Accepted [ ]
Declined [ ]

Relationship of chaperone: [ ]

External examination
(in crook lying, i.e. supine, knees bent and separated, feet apart, with paper towel over the pelvis)

	Yes	No
Evidence of skin damage (excoriation/ ulcers) *(penis, perineum, anal area)*		
Evidence of infection of skin		
Able to tighten anus		
Able to perform penile retraction and testicular lift		
Leakage on coughing		
Able to prevent leakage on coughing		

Comments

Dermatomes	**Left**		**Right**	
	Normal	Abnormal	Normal	Abnormal
S 2 Lateral buttocks and thigh, posterior calf and plantar heel				
S 3 upper two-thirds of medial thigh				
S 4 Penis and perineal area				

Comments

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Visit No. 1st [ ] 2nd [ ] 3rd [ ] 4th [X]

Digital anal examination

1. External anal sphincter (insert finger to first joint)

Strength of contraction of external anal sphincter *(tick one only)*

0 (no flicker) [ ] 3 (moderate movement) [ ] 6 (very strong, unable to withdraw finger) [ ]

1 (flicker) [ ] 4 (good resistance) [ ]

2 (weak) [ ] 5 (strong resistance) [ ]

Anal sphincter endurance *(enter number of seconds)* [ ]

	Yes	No
Able to contract anal sphincter quickly	[ ]	[ ]

2. Puborectalis muscle (insert finger to second joint)

Strength of contraction of puborectalis muscle *(tick one only)*

0 (no flicker) [ ] 3 (moderate movement) [ ] 6 (very strong, unable to withdraw finger) [ ]

1 (flicker) [ ] 4 (good resistance) [ ]

2 (weak) [ ] 5 (strong resistance) [ ]

Puborectalis muscle endurance *(enter number of seconds)* [ ]

	Yes	No
Able to contract puborectalis muscle quickly	[ ]	[ ]

If digital anal examination is not performed, please give reason:

Biofeedback

	Yes	No
Biofeedback is available in this centre	[ ]	[ ]
Biofeedback is clinically indicated for this man	[ ]	[ ]
This man has had biofeedback	[ ]	[ ]

If biofeedback is used:

Either: **Anal pressure biofeedback**

Maximum reading in cm H_2O from best of 3 contractions [ ]

Or: **EMG with anuform probe**

Maximum reading in μV from best of 3 contractions [ ]

MAPS No: | | | 1 | | | | **RADICAL – Therapy Documentation**

Summary of Management

Diagnoses		Yes	No
1	Stress urinary incontinence		
2	Urge urinary incontinence		
3	Post micturition dribble		
4	Faecal incontinence		
5	Erectile dysfunction (unable to gain or maintain erection)		
6	Other diagnoses (please give details)		

Treatment		Yes	No
1	Given and explained PFMT leaflet		
2	Number of seconds ____ agreed with man to hold contraction (also enter in leaflet)		
3	Given (or has got) and explained Lifestyles Advice Leaflet		
4	3 sets of contractions in three positions twice a day		
5	Lift (tighten) pelvic floor muscles before exertion (eg coughing, lifting, rising from sitting)		
6	Lift (tighten) pelvic floor muscles 50% while walking		
7	Lift (tighten) pelvic floor muscles after urinating (to squeeze out last drops)		
8	Lift (tighten) pelvic floor muscles during sexual activity		
9	Urge suppression techniques (bladder training)		
10	Other treatment (please give details)		

Advice

Plan

At the end of the session, ask the man if he has any pain anywhere as a result of the examination. If so, document it and if it is severe or it does not resolve advise him to see his GP. Also remind man to keep his travel receipts.

As this is your patient's last visit, please advise him as follows:

- **Thank him for his help with the MAPS Study**
- **If he needs further treatment please contact the MAPS Study Office**
- **Encourage him to keep doing the exercises for the rest of his life – regularly and forever**

Signed: _____

Appendix 4.2 Lifestyle advice leaflet

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 family and friends if you wish. Do not hesitate to contact us if there is anything you do not understand or if you would like more information.

Lifestyle advice

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 suggestions for 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.

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.

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

Your notes:

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Version 2 February 2005

Appendix 4.3 Pelvic floor exercises for men taking part in the MAPS study

MAPS

Men After Prostate Surgery

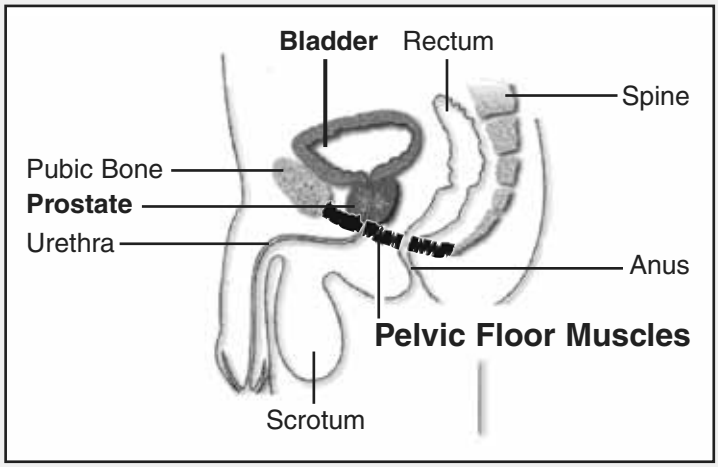
PELVIC FLOOR EXERCISES

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.

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.

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

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

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Appendix 5

Health economics

Resource use tables: radical prostatectomy and transurethral resection of the prostate

TABLE 88 Satisfaction with treatment for urinary incontinence at 12 months after randomisation: radical prostatectomy

	Intervention [mean (SD) *n*]	Control [mean (SD) *n*]	Mean difference (95% CI), *p*-value
Satisfaction score[a]	7.5 (2.7) 175	6.6 (3.3) 158	0.83 (0.19 to 1.48), 0.012

a 0 = 'very unsatisfied' to 10 = 'very satisfied'.

TABLE 89 Use of health services resources in the community: radical prostatectomy

	Baseline		3 months		6 months		9 months		12 months	
Resource	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
Seen GP [*n*/*N* (%)]	118/205 (58)	121/205 (59)	133/200 (67)	141/198 (71)	124/199 (62)	131/197 (66)	103/191 (54)	124/194 (64)	104/196 (53)	103/196 (53)
Number of times for UI	0.61 (0.82) 85	0.56 (0.94) 79	0.13 (0.45) 135	0.36 (0.96) 145	0.17 (0.58) 125	0.21 (0.92) 135	0.17 (0.56) 106	0.20 (0.73) 129	0.10 (0.43) 109	0.28 (1.17) 108
Number of times for other reason	1.28 (0.93) 106	1.35 (0.91) 118	1.89 (1.26) 139	2.14 (1.78) 145	1.90 (1.51) 126	1.75 (1.06) 134	1.69 (1.23) 107	1.74 (1.44) 129	1.73 (1.19) 109	1.60 (1.04) 108
Seen nurse [*n*/*N* (%)]	135/205 (66)	124/203 (61)	77/200 (39)	84/198 (42)	73/199 (37)	78/197 (40)	74/191 (39)	79/194 (41)	70/196 (36)	70/196 (36)
Number of times for UI	1.17 (1.66) 90	1.54 (3.16) 97	0.23 (0.83) 77	0.60 (1.60) 84	0.15 (0.75) 75	0.22 (0.71) 81	0.04 (0.19) 82	0.07 (0.34) 83	0.03 (0.16) 73	0.04 (0.20) 73
Number of times for other reason	2.82 (3.32) 128	2.91 (4.10) 118	1.45 (1.53) 77	1.81 (2.45) 84	1.24 (0.65) 76	1.23 (0.95) 81	1.08 (1.08) 83	1.27 (1.16) 82	1.32 (0.92) 74	1.27 (1.38) 74

Figures are mean (SD) *n*, unless stated otherwise.
Data at each time period cover the previous 3 months.

TABLE 90 Use of health services resources in hospital: radical prostatectomy

	Baseline		3 months		6 months		9 months		12 months	
Resource	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
Seen hospital doctor for UI [*n*/*N* (%)]	25/200 (13)	18/196 (9)	19/200 (10)	25/198 (13)	19/199 (10)	18/197 (9)	14/191 (7)	13/194 (7)	21/196 (11)	14/196 (7)
Number of times	1.36 (0.64) 25	1.50 (1.69) 18	1.24 (0.62) 21	1.38 (0.85) 26	1.21 (0.79) 19	1.17 (0.51) 18	1.00 (0.73) 16	1.29 (0.61) 14	1.29 (0.56) 21	1.29 (0.73) 14
Seen hospital nurse for UI [*n*/*N* (%)]	32/187 (17)	27/191 (14)	32/178 (18)	18/176 (10)	19/178 (11)	15/183 (8)	8/179 (4)	9/172 (5)	12/181 (7)	9/179 (5)
Number of times	1.56 (1.05) 32	2.25 (4.33) 28	2.15 (0.97) 33	1.28 (0.75) 18	1.63 (0.76) 19	1.27 (0.46) 15	1.20 (0.92) 10	1.20 (0.42) 10	1.23 (0.73) 13	1.00 (0.47) 10
Seen hospital physiotherapist for UI [*n*/*N* (%)]	2/191 (1)	3/191 (2)	51/200 (26)	5/198 (3)	15/199 (8)	5/197 (3)	2/191 (1)	3/194 (2)	1/196 (1)	5/196 (3)
Number of times	0.50 (0.58) 4	0.75 (0.50) 4	2.54 (0.85) 52	2.60 (1.52) 5	1.73 (0.96) 15	3.00 (3.39) 5	1.20 (0.92) 10	1.20 (0.42) 10	0.50 (0.71) 2	1.00 (0.63) 6

Figures are mean (SD) *n*, unless stated otherwise.
Data at each time period cover the previous 3 months.

TABLE 91 Use of private health services for management of urinary incontinence: radical prostatectomy

	Baseline		3 months		6 months		9 months		12 months	
Resource	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**
Seen private doctor for UI *n*/*N* (%)	1/204 (0)	0/199 (0)	1/200 (1)	1/198 (1)	2/199 (1)	1/197 (1)	0/191 (0)	1/194 (1)	0/196 (0)	2/196 (1)
Number of times	2.00 (2.00) 1	NR	1.50 (2.12) 2	1.00 (0.0) 1	4.00 (5.66) 2	1.00 (0.0) 1	0.00 (0.0) 1	1.00 (0.0) 1	NR	1.67 (2.08) 3
Seen private nurse for UI *n*/*N* (%)	2/192 (1)	2/190 (1)	0/188 (0)	0/182 (0)	2/180 (1)	2/186 (1)	0/180 (0)	0/179 (0)	0/183 (0)	0/185 (0)
Number of times	1.00 (1.00) 1	1.33 (1.53) 3	NR	0.0 (0.0) 2	0.00 (0.00) 2	0.00 (0.00) 2	0.00 (0.0) 1	NR	NR	0.00 (0.0) 1
Seen private physiotherapist for UI *n*/*N* (%)	1/199 (1)	2/196 (1)	2/200 (1)	2/198 (1)	1/199 (1)	0/197 (0)	0/191 (0)	0/194 (0)	0/196 (0)	0/196 (0)
Number of times	2.00 (2.00) 1	0.50 (0.71) 2	2.00 (2.00) 3	2.00 (2.00) 1	NR	NR	0.00 (0.0) 1	NR	NR	0.00 (0.0) 1

NR, not reported.
Figures are mean (SD) *n*, unless stated otherwise.
Data at each time period cover the previous 3 months.

TABLE 92 Treatment for urinary incontinence: radical prostatectomy

	Baseline		3 months		6 months		9 months		12 months	
Resource	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**
Admitted to hospital for UI	4/202 (2)	6/205 (3)	1/200 (1)	4/198 (2)	4/199 (2)	3/197 (2)	2/191 (1)	2/194 (1)	1/196 (1)	2/196 (1)
Operation for UI	0/127 (0)	1/118 (1)	1/200 (1)	5/198 (3)	3/199 (2)	1/197 (1)	1/191 (1)	1/194 (1)	2/196 (1)	2/196 (1)
Number of nights in hospital [mean (SD) *n*]	2.50 (3.00) 4	2.67 (1.37) 6	1.00 (1.41) 2	1.00 (0.71) 5	0.50 (0.58) 4	1.33 (0.58) 3	0.67 (1.15) 3	1.00 (1.41) 2	1.00 (1.41) 2	0.33 (0.58) 3
Medication or drugs for UI	16/202 (8)	13/203 (6)	14/200 (7)	18/198 (9)	15/199 (8)	18/197 (9)	15/191 (8)	17/194 (9)	16/196 (8)	15/196 (8)
Other treatment or advice for UI	60/202 (30)	57/200 (29)	53/200 (27)	17/198 (9)	22/199 (11)	14/197 (7)	7/191 (4)	11/194 (6)	7/196 (4)	8/196 (4)

Number of men, *n*/*N* (%), unless stated otherwise.
Data at each time period cover the previous 3 months.

TABLE 93 Satisfaction with treatment for urinary incontinence at 12 months after randomisation: TURP

	Intervention [mean (SD) *n*]	Control [mean (SD) *n*]	Mean difference (95% CI), *p*-value
Satisfaction score[a]	7.7 (3.0) 164	6.5 (3.4) 142	1.15 (0.43 to 1.88), 0.002

a 0 = 'very unsatisfied' to 10 = 'very satisfied'.

TABLE 94 Use of health services resources in the community: TURP

	Baseline		3 months		6 months		9 months		12 months	
Resource	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**
Seen GP [*n*/*N* (%)]	131/220 (60)	127/218 (58)	122/206 (59)	119/208 (57)	117/201 (58)	101/203 (50)	109/198 (55)	108/202 (53)	100/194 (52)	108/204 (53)
Number of times for UI	1.23 (1.25) 65	0.88 (1.07) 80	0.26 (0.68) 122	0.35 (0.79) 119	0.20 (0.83) 120	0.27 (0.74) 103	0.10 (0.60) 113	0.05 (0.27) 110	0.16 (0.58) 100	0.07 (0.32) 113
Number of times for other reason	1.47 (1.00) 115	1.67 (1.39) 125	2.11 (1.82) 123	2.07 (1.62) 121	2.07 (1.38) 121	2.00 (1.41) 104	1.97 (1.34) 116	2.02 (1.32) 113	2.18 (1.33) 101	1.99 (1.43) 119
Seen nurse [*n*/*N* (%)]	51/217 (24)	50/219 (23)	66/206 (32)	73/208 (35)	75/201 (37)	68/203 (33)	72/198 (36)	77/202 (38)	75/194 (39)	73/204 (36)
Number of times for UI	1.00 (0.94) 26	0.82 (1.03) 34	0.38 (1.63) 66	0.45 (1.86) 73	0.15 (0.54) 75	0.10 (0.53) 73	0.03 (0.16) 77	0.04 (0.19) 83	0.08 (0.36) 75	0.03 (0.16) 77
Number of times for other reason	1.11 (0.88) 46	1.60 (2.28) 50	1.94 (2.13) 66	1.66 (1.56) 73	1.89 (1.72) 81	1.92 (2.45) 74	1.71 (1.80) 78	2.11 (3.00) 84	1.82 (1.52) 77	2.22 (3.24) 78

Figures are mean (SD) *n*, unless stated otherwise.
Data at each time period cover the previous 3 months.

TABLE 95 Use of health services resources in hospital: TURP

	Baseline		3 months		6 months		9 months		12 months	
Resource	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**
Seen hospital doctor for UI [*n*/*N* (%)]	14/216 (6)	11/215 (5)	23/206 (11)	29/208 (14)	8/201 (4)	18/203 (9)	9/198 (5)	13/202 (6)	8/194 (4)	12/204 (6)
Number of times	1.14 (0.36) 14	2.00 (2.37) 11	1.58 (2.28) 24	1.23 (0.63) 30	1.22 (0.83) 9	1.05 (0.51) 20	1.44 (1.74) 9	1.00 (0.41) 13	1.30 (1.06) 10	0.86 (0.86) 14
Seen hospital nurse for UI [*n*/*N* (%)]	3/185 (2)	8/189 (4)	31/163 (19)	12/173 (7)	9/169 (5)	9/173 (5)	5/169 (3)	3/181 (2)	1/170 (1)	1/174 (1)
Number of times	1.50 (0.58) 4	2.25 (2.76) 8	2.41 (1.05) 34	1.42 (0.79) 12	2.30 (1.95) 10	1.00 (0.77) 11	0.57 (0.53) 7	1.00 (0.82) 4	0.33 (0.58) 3	0.50 (1.00) 4
Seen hospital physiotherapist for UI [*n*/*N* (%)]	1/205 (0)	1/204 (0)	43/206 (21)	3/208 (1)	27/201 (13)	3/203 (1)	4/198 (2)	1/202 (0)	4/194 (2)	1/204 (0)
Number of times	1.00 (0.00) 1	2.00 (0.00) 1	2.53 (0.69) 45	1.33 (0.58) 3	2.11 (1.45) 28	1.00 (1.00) 5	1.80 (2.39) 5	1.00 (1.41) 2	0.83 (0.75) 6	0.50 (1.00) 4

Figures are mean (SD) *n*, unless stated otherwise.
Data at each time period cover the previous 3 months.

TABLE 96 Use of private health services for management of urinary incontinence: TURP

	Baseline		3 months		6 months		9 months		12 months	
Resource	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**
Seen private doctor for UI [*n*/*N* (%)]	0/215 (0)	1/218 (0)	0/206 (0)	1/208 (0)	0/201 (0)	2/203 (1)	0/198 (0)	0/202 (0)	0/194 (0)	0/204 (0)
Number of times	NR	NR	NR	1.00 (0.00) 1	NR	NR	NR	NR	NR	NR
Seen private nurse for UI [*n*/*N* (%)]	0/191 (0)	1/194 (1)	0/181 (0)	0/182 (0)	0/179 (0)	1/175 (1)	0/178 (0)	0/184 (0)	0/176 (0)	0/178 (0)
Number of times	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Seen private physiotherapist for UI [*n*/*N* (%)]	1/207 (0)	1/206 (0)	0/206 (0)	1/208 (0)	1/201 (0)	0/203 (0)	0/198 (0)	1/202 (0)	0/194 (0)	1/204 (0)
Number of times	1.00 (0.00) 1	8.00 (0.00) 1	NR	NR	NR	1.00 (0.00) 1	NR	10.00 (0.00) 1	NR	12.00 (0.00) 1

NR, not reported.
Figures are mean (SD), *n*, unless stated otherwise.
Data at each time period cover the previous 3 months.

TABLE 97 Treatment for urinary incontinence: TURP

	Baseline		3 months		6 months		9 months		12 months	
Resource	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**
Admitted to hospital for UI	6/220 (3)	4/221 (2)	5/206 (2)	5/208 (2)	3/201 (1)	4/203 (2)	0/198 (0)	1/202 (0)	0/194 (0)	1/204 (0)
Operation for UI	2/128 (2)	1/126 (1)	2/206 (1)	6/208 (3)	0/201 (0)	4/203 (2)	0/198 (0)	0/202 (0)	0/194 (0)	2/204 (1)
Number of nights in hospital [mean (SD) *n*]	2.40 (1.52) 5	2.00 (2.38) 7	1.00 (1.73) 5	1.20 (1.30) 5	2.67 (1.53) 3	1.00 (1.22) 5	NR	0.00 (0.00) 4	NR	0.00 (0.00) 2
Medication or drugs for UI	24/217 (11)	25/216 (12)	16/206 (8)	25/208 (12)	14/201 (7)	19/203 (9)	10/198 (5)	18/202 (9)	9/194 (5)	17/204 (8)
Other treatment or advice for UI	10/216 (5)	13/213 (6)	44/206 (21)	13/208 (6)	21/201 (10)	8/203 (4)	3/198 (2)	3/202 (1)	4/194 (2)	6/204 (3)

NR, not reported.
Number of men, *n*/*N* (%), unless stated otherwise.
Data at each time period cover the previous 3 months.

Appendix 6

MAPS study protocol

MAPS STUDY

(Men After Prostate Surgery)

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

PROTOCOL

A UK Collaborative Study funded by the
NHS R&D HTA Programme

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PROTOCOL SUMMARY

QUESTION ADDRESSED	Does conservative (physical) treatment improve urinary incontinence in men who have had prostate surgery?
CONSIDERED FOR ENTRY	Men who have urinary incontinence after prostate surgery, approached initially when inpatients having surgery.
POPULATIONS	1. Radical Prostatectomy (RP) 2. Transurethral Resection of Prostate (TURP)
STUDY ENTRY	Information about all men having prostate surgery collected by recruitment officers in centres, sent to MAPS Study Office. Screening postal questionnaire sent from MAPS Study Office at 3 weeks after surgery. Consent to RCT obtained from incontinent men after written and oral information, and after completing Baseline Questionnaire and Urinary Diary.
INTERVENTIONS	Active group attend four treatment sessions during 3-month period after randomisation (pelvic floor muscle training with biofeedback, bladder training) Control group do not have active treatment Both groups receive Lifestyles Advice Leaflet
OUTCOME ASSESSMENT	Postal questionnaires at 6 and 12 months after randomisation Urinary diaries (incontinent episodes and pad use) and health care utilisation questions at 3, 6, 9 and 12 months
CO-ORDINATION	**Local**: by local lead Urologist and Recruitment Officer. **Central**: by Study Office in Aberdeen (telephone 01224 551103). **Overall**: by the Project Management Group, and overseen by the Steering Committee and the Data Monitoring Committee.
FUNDING	NHS R&D National Coordinating Centre for Health Technology Assessment (NCCHTA).
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MAPS PERSONNEL

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Other Information

International Standard Randomised Controlled Trial Number (ISRCTN)	ISRCTN87696430
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HTA Project Number	03/14/03

Trial Registrations

The NHS HTA Programme website http://www.hta.nhsweb.nhs.uk/projectdata

The CancerHelp UK website: www.cancerhelp.org.uk

INVOLVE www.invo.org.uk

National Cancer Research Network Trials Portfolio: NCRN Trial ID 1459

Current Controlled Trials website: ISRCTN87696430

NIH website: ClinicalTrials.gov Identifier: NCT00237029

CONSERVATIVE TREATMENT FOR URINARY INCONTINENCE IN MEN AFTER PROSTATE SURGERY

Known as MAPS (Men After Prostate Surgery)

Title of trial: Conservative treatment for urinary incontinence in men after prostate surgery (MAPS): multicentre randomised controlled trial of pelvic floor muscle training, biofeedback and bladder training

This protocol describes a major multicentre UK trial to establish whether 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 study is designed to be as simple as possible both for those participating and for those involved in clinical care.

Recruitment officers in each centre will identify and recruit men undergoing prostate surgery and collect descriptive information. Those who are incontinent will be invited to enter a randomised trial of conservative treatment. They will be followed up at 6 and 12 months.

1. THE REASONS FOR THE TRIAL

1.1 The burden of the problem

Prostate surgery is an iatrogenic cause of male urinary incontinence. Urinary incontinence is defined as the complaint of any involuntary leakage of urine.[1] It is a debilitating condition that has a greater effect on quality of life than erectile dysfunction (which is another consequence of prostate surgery).[2] The economic costs include personal (such as need to use pads or devices, and deleterious effect on quality of life) and societal ones (use of health services and need for residential or nursing home care).

Based on a population audit of over 3000 men, an estimated 11% of men needed to use pads at 3 months after endoscopic resection of prostate.[3] The prevalence of urinary incontinence after radical prostatectomy is more widely reported, ranging from 5% to 45%, albeit at varying times after operation.[4] Estimates of incontinence soon after radical operation are much higher (e.g. 82% in 1013 men[5]). We have used estimates of 5% and 50% respectively in calculation of sample sizes (which may be conservative, based on data from a feasibility study).

1.2 The decision to test conservative treatment

A recent Cochrane review has identified that, although conservative treatment based on pelvic floor muscle training may be offered to men with urinary incontinence after either type of prostate surgery, there is insufficient evidence to evaluate its effectiveness, cost-effectiveness and effect on quality of life.[6] Data from three trials involving 232 men provided estimates of the effects of pelvic floor muscle training on the chance of incontinence after radical prostatectomy at 1 year: relative risk (RR) for incontinence, pelvic floor muscle training plus biofeedback versus control, 0.55, 95% CI 0.24 to 1.23.[7–9] However, not all of the men included in the trials were incontinent at baseline, and the trials were all small. Thus the data suggest (but do not provide conclusive evidence) that conservative treatment may reduce incontinence at 1 year after operation.

Data available from these trials suggest that, amongst men incontinent at around 6 weeks after surgery, about 30% will still be incontinent at 1 year. The Cochrane review therefore suggests that this might be reduced to 15%, and this is the basis for the sample size in the proposed trial (70% ‘dry’ increased to 85% ‘dry’).

In one small trial of pelvic floor muscle training started before surgery amongst men having endoscopic resection of prostate, the RR for incontinence at 4 weeks after surgery was 0.31, 95% CI 0.03 to 2.82[10] although again the trial included some men who were not incontinent at baseline. After the first 4 weeks, there were no trial data about expected incontinence rates or effect sizes amongst men having endoscopic resection of prostate.

1.3 The questions which this study will address

The following questions will be addressed, primarily in terms of regaining urinary continence at 12 months after recruitment:

(a) For men with urinary incontinence 6 weeks after radical prostatectomy, what is the clinical and cost-effectiveness of active conservative treatment delivered by a specialist continence physiotherapist or a specialist continence nurse compared with usual management?
(b) For men with urinary incontinence 6 weeks after transurethral resection of prostate, what is the clinical and cost-effectiveness of active conservative treatment delivered by a specialist continence physiotherapist or a specialist continence nurse compared with usual management?

The hypothesis being tested in each group of men (in two parallel but separate trials) is that active conservative management will increase the proportion of continent men by 15% at 1 year after recruitment. The two groups are being considered independently because the rates of incontinence are expected to be different.

2. TRIAL RECRUITMENT AND ALLOCATION

2.1 Men considered for trial entry

The trial will involve men who have urinary incontinence after prostate surgery. Two parallel but separate trials will be conducted, amongst:
(i) men having a radical prostatectomy usually for prostate cancer, and
(ii) men having a transurethral resection of prostate, usually for benign prostatic hypertrophy.

Inclusion criteria:
- Urinary incontinence at 6 weeks after prostate surgery (incontinence defined as a response indicating a loss of urine to either of two questions in the screening questionnaire: ‘how often do you leak urine’ and ‘how much urine do you leak’).
- Informed consent.
- Ability to comply with intervention.

Exclusion criteria:
- Referral for formal therapy (teaching of pelvic floor muscle training) because of prostate surgery.
- Radiotherapy planned or given during the first 3 months after surgery for men with prostate cancer.
- Endoscopic resection of prostate carried out as palliation for outflow obstruction in advanced prostate cancer.
- Inability to complete study questionnaires.

Men with prostate cancer diagnosed at TURP:
Around 15% of men may be found to have incidental prostate cancer when the prostatic chips removed at TURP are examined for pathology. If he is not going to have formal treatment (wait and see policy), he will be eligible for the RCT.

If the cancer is identified before he is randomised and either radiotherapy or radical prostatectomy are planned, he will **not** be eligible for the RCT (TURP group). However, if he is subsequently readmitted for radical prostatectomy, he will be

eligible to be recruited as a new participant to the Radical group. He would sign a new consent form and be sent a new screening questionnaire.

If the cancer is only diagnosed once he has been randomised, even if radiotherapy or radical prostatectomy are planned, he will remain in the group to which he was allocated, and be followed up as normal.

The study consists of two stages: Stage 1 (Section 2.2) concerns the screening survey used to identify eligible men, and Stage 2 (Section 2.3) the randomised controlled trial.

2.2 Screening for postoperative urinary incontinence (Stage 1 of study)

Potential participants will be identified by Recruitment Officers in each clinical centre from amongst all men admitted to the urological ward(s) for prostate surgery. A log will be kept of men meeting the inclusion criteria, describing reasons if they do not agree to receive a screening questionnaire (Appendix 1).

Each man will be given the Hospital Patient Information Sheet by the Recruitment Officer. After reading it and having the opportunity to discuss all aspects of the study, each man will be asked for his consent to be sent the Screening Questionnaire at 3 weeks after surgery. The patient information sheet, the consent form and the questionnaire all refer to the possibility of being contacted about further research if the men are willing. If he agrees, his signed contact details (address, phone number, date of birth, Study Number and Hospital Number) will be sent to the Study Office in Aberdeen (Appendix I).

The questionnaire (Appendix VI) will be sent to men from the Study Office in Aberdeen at 3 weeks after the date of operation (together with a covering letter, Appendix II). A reminder letter will be sent after 2 weeks if there is no response (Appendix II). If the returned questionnaire indicates that a man has urinary incontinence, he will be eligible for Stage 2.

2.3 Recruitment to the RCT of conservative treatment (Stage 2, the trial)

Each man with urinary incontinence will be sent a Patient Information Sheet (PIS, Appendix III) by the Study Office in Aberdeen to inform him about the trial.

- *For men who have a phone*
  The Aberdeen Recruitment Co-ordinator will send the man a Patient Information Sheet (Appendix III*)* by post, with a consent form, Baseline Questionnaire and Urinary Diary. About a week after sending the trial information and documents, she will contact the man by telephone using a Standard Instruction Sheet (Appendix III). She will ask if he has received the Patient Information Sheet, answer any questions or concerns, and ask whether he might be interested in entering the trial. She will explain what would happen in the two groups, that allocation would be randomised and what follow-up is involved. If he agrees orally, he will be asked to complete and return: a Consent Form (Appendix III); a Baseline Questionnaire (Appendix VI); and a Urinary Diary (Appendix VI). Optionally, the man may fill in the Baseline Questionnaire over the phone but written consent is still required before randomisation.
- *For men who do not have a phone:*
  All the documents [the Patient Information Sheet (Appendix III), a Consent Form (Appendix III), a Baseline Questionnaire (Appendix VI) and a Urinary Diary (Appendix VI)] will be sent by mail. The man will be able to ring a helpline (to the Aberdeen Recruitment Officer) if he has any queries. If he decides to enter the trial, he will complete and return the last three documents.

The man would keep the Information Sheet and the bottom (fourth) copy of the consent form (returning the top three to the Study Office in Aberdeen).

If the three documents are not returned by 3 weeks after posting (no phone contact), or 2 weeks after oral consent was given over the phone, men will be sent a postal reminder with duplicate documentation. If they are not returned after another 2 weeks, they will be phoned (if possible) or sent a further reminder letter (if no phone).

Oral Withdrawal Consent will be obtained from men who initially agree to enter the trial but later decide to withdraw to enable us to maintain their existing data and access NHS data.

2.4 Randomisation and allocation to management group

When the baseline documents are received, the Aberdeen MAPS Study Office will randomise the man to active or standard management.

Randomisation will be by computer allocation using the service that already exists at the Health Service Research Unit. Allocation will be stratified by type of operation (radical prostatectomy or transurethral resection of prostate), and minimised using centre, age and pre-existing urinary incontinence.

The Study Office will send out an allocation letter to all men with details of their allocation (Appendix IV) and the Lifestyle Advice Leaflet (Appendix V). If the man is allocated to the Active Group, the Study Office will arrange for the local Therapist (physiotherapist or continence nurse) to send him the necessary appointments (the first, for an hour, as soon as possible, followed by a three-quarter-hour appointment on three occasions at 2, 6 and 12 weeks) (letter to Therapist, Appendix IV).

A letter and GP Information Sheet (Appendix IV) will be sent to the man's GP. A copy of the GP letter and the consent form will be sent to the hospital urological consultant for filing in the man's hospital notes.

3. TRIAL INTERVENTIONS (Appendix V)

3.1 Intervention arm

The men in the intervention group will receive a physiotherapist or continence nurse assessment of their symptoms at about 6 weeks after surgery. They will be taught pelvic floor muscle training, with bladder training for men with urgency or urge incontinence.[11] The men will be taught:

- to carry out three maximum pelvic floor contractions in three positions (standing, sitting and lying down) twice per day;
- to 'lift' their pelvic floors while walking;
- to tighten their pelvic muscles before activities which may cause them to leak, such as coughing;
- and to tighten after urinating to 'squeeze out' any last drops.

Biofeedback involves monitoring the strength of a pelvic floor contraction (by digital anal assessment) and relaying the information back to the men, in order that they know when they are performing contractions correctly and to inform them when they are increasing the strength or duration of their contractions. Therapists may use machine-mediated biofeedback with an anal biofeedback probe at their clinical discretion (if they feel it is clinically indicated) in centres where this is available in addition to digital anal assessment. Bladder training involves gradually delaying urination (by pelvic floor muscle contraction and distracting activities) to teach the bladder to hold increasing volumes of urine.

The men will also receive a booklet describing pelvic floor muscle training (Pelvic Floor Exercise Booklet, Appendix V) in addition to the one giving general lifestyle advice (Lifestyle Advice Booklet, Appendix V). The men will have reinforcement

sessions on three more occasions over 3 months – at around 2 weeks, 6 weeks and 12 weeks after the first appointment.

Ensuring standardisation of intervention
All the staff delivering the intervention will receive training to ensure consistency of their method of teaching and delivery of the pelvic floor muscle training, bladder training and biofeedback. Both specialist continence physiotherapists and continence nurse specialists will be eligible for training, thus extending the generalisability of the trial.

The therapists will record their assessments and treatment programmes on standard study forms (Appendix V). Data from these forms will be collected centrally.

3.2 Control arm
Men in the control group will receive a booklet containing supportive lifestyle advice only (without reference to pelvic floor muscle training) by post after randomisation (Lifestyle Advice Booklet, Appendix V). Men will not receive any formal assessment or treatment but will be able to access usual care and routine NHS services if they feel they need help. This may include written advice if this is part of routine hospital care.

Use of NHS services, use of pads and practice of pelvic floor muscle training will be documented in both groups using information from questionnaires and Urinary Diaries. The lifestyle and pelvic floor muscle training booklets will be customised for each group.

4. SUBSEQUENT ARRANGEMENTS
4.1 Informing key people
Following formal trial entry, the Study Office will contact:
i) The General Practitioner (by letter enclosing an information sheet, with the MAPS phone number in case of queries or notifiable events)
ii) The Hospital Urologist (by copy of letter sent to GP, and copy of consent form for filing in hospital notes)

4.2 Monitoring the men
Men will be contacted by phone, post or email as appropriate. In case of non-return of questionnaires or diaries, or non-attendance at therapy appointments, attempts will be made by staff at the Study Office to trace the men directly using these means or indirectly by contacting the therapist, the GP or the 'Best Contact'.

Notification by GPs
GPs are asked to phone the Study Office if one of the participants moves, becomes too ill to continue or dies, or any other notifiable event or possible adverse effect occurs. Alternatively, staff at the Study Office may contact the GP.

Notification by 'best contact'
If the MAPS Study Office loses touch with a participant (e.g. questionnaires, diaries or phone calls not returned), we will try to establish why via the 'Best Contact'. Men will be asked (in their trial Baseline Questionnaire) to nominate someone, who will be informed (Appendix IV).

Flagging at Office for National Statistics
All men recruited to the RCT will be flagged at the Office for National Statistics for notification of death.

5. DATA COLLECTION AND PROCESSING

Men will be recruited for a median period of 2 years (range 1–3). Follow-up will continue for 15 months from the date of the last operation (allowing 3 months for recruitment and 12 months for follow-up after randomisation). It is not part of this protocol or the current study to follow up the men beyond this time. However, consent will be sought to make this possible in the future.

5.1 **Questionnaires** (Appendix VI)

Men will be sent questionnaires at baseline, 6 and 12 months (Appendix VI). Content will include:

i) Urinary outcome questions [leakage of urine, amount, effect on QOL (http://www.iciq.net/), pad use, catheter use]
ii) Bowel function outcome questions
iii) Sexual function
iv) Health care utilisation questions
v) Exercise, weight and height, including pelvic floor exercises
vi) EQ-5D[12]
vii) SF-12[13]

and additionally at baseline only:

i) Date of operation, type of operation and reason for operation
ii) GP address and phone number
iii) 'Best Contact' at another address for follow-up (not wife or partner)
iv) Other medical problems

and additionally at 6 months only:

i) Health Care Unit Cost Questionnaire

and additionally at 12 months only:

i) Need for further treatment for incontinence
ii) Further treatment for prostate planned?

5.2 **Urinary diaries** (Appendix VI)

Men will be asked to keep diaries at 3, 6, 9 and 12 months, kept for 3 days at each time period. Content will include:

i) Frequency of urination (day and night)
ii) Daily episodes of incontinence, quantity of loss
ii) Daily use of pads, need to change clothing or bedding

and additionally at 3 and 9 months only:

iii) Health care utilisation questions (Appendix VI)

5.3 **ISD Data** (Scotland only)

At 6 months after the last man has been recruited we will run a check for Scottish men only to compare self-reported operations, diagnoses and hospital admissions with centrally collected data to validate a proportion of the data.

5.4 **Data processing**

Data from the various sources outlined above will be sent to the Study Office in Aberdeen for processing. Staff in the Study Office will work closely with local Recruitment Officers to ensure that the data are as complete and accurate as possible. Extensive range and consistency checks will further enhance the quality of the data.

6. ANALYSIS PLANS

6.1 Ground rules for the statistical analysis

The statistical analysis will be based on all men as randomised, irrespective of subsequent compliance with the treatment allocated. The principal comparisons will be:

1. After radical prostatectomy
   i) men allocated to active therapy (four visits to therapist plus Lifestyle Advice Leaflet), compared with
   ii) men allocated to control group (Lifestyle Advice Leaflet only)

2. After transurethral resection of prostate
   i) men allocated to active therapy (four visits to therapist plus Lifestyle Advice Leaflet) , compared with
   ii) men allocated to control group (Lifestyle Advice Leaflet only)

6.2 Measures of outcome

The primary clinical outcome is:

- Subjective report of urinary continence at 12 months (http://www.iciq.net/)

The primary measure of cost-effectiveness is:

- Incremental cost per quality-adjusted life-year

Secondary outcome measures include:

Clinical

- Subjective report of continence or improvement of urinary incontinence at 3, 6 and 9 months after randomisation, and improvement at 12 months
- Number of incontinent episodes in previous week (objective, from diary)
- Duration of incontinence (based on time of resolution relative to time of operation and randomisation)*
- Use of absorbent pads, penile collecting sheath, bladder catheter or bed/chair pads
- Number and type of incontinence products used
- Co-existence, cure or development of urgency or urge incontinence
- Urinary frequency
- Nocturia
- Faecal incontinence (passive or urge)
- Other bowel dysfunction (urgency, constipation, other bowel diseases)
- Sexual function at 12 months (including information about erection, ejaculation, retrograde ejaculation, pain, change in sex life and reason for change)

Quality of life

- Incontinence-specific quality of life outcome measure (10-point scale, ICI questionnaire (http://www.iciq.net/)
- General health measures (SF-12,[13] EQ-5D[12])

Use of health services for urinary incontinence

- Need for alternative management for incontinence (e.g. surgery, drugs)
- Use of GP, nurse, consultant urologist, physiotherapist

Other use of health services

- Visits to GP
- Visits to practice nurse

* We will obtain an estimate from the men who become dry of when they became dry – both by asking them to name the month they were last wet, and for how many months after their operation were they wet, as well as by the change in the 3-monthly diaries, from wet to dry.

Effects of interventions

- Use of PFMT
- Lifestyle changes (weight, constipation, lifting, coughing, exercise)

Economic measures

- Patient costs [e.g. self-care (e.g. pads, laundry), travel to health services, sick leave]
- Cost of conservative trial treatment
- Cost of alternative or additional NHS treatments [e.g. pads, catheters, drugs (e.g. adrenergic agonists, anticholinergics, oral medication for erectile dysfunction), hospital admissions or further surgery]
- Other measures of cost-effectiveness (e.g. incremental cost per additional man continent at 12 months)

The ways in which these data will be analysed are set out in Appendix VII (Dummy Tabulations).

It is anticipated that the data generated by the study, along with other focused data collection sets, may be used as a basis for exploratory or epidemiological research, but these will be described in separate protocols.

6.3 Timing and frequency of analyses

A single principal analysis is anticipated at 15 months after the last man is recruited (at month 48). The Data Monitoring Committee will determine the frequency of confidential interim analyses, but at present these are planned on three occasions during the data collection period (at months 16, 28 and 35).

6.4 Planned secondary subgroup analyses

The two populations of men (having radical prostatectomy or transurethral resection) will be analysed as separate trials as shown above in section 6.1.

Subgroup analyses (separately for the two populations) will explore the effect on urinary incontinence at 12 months after randomisation of:

1. pre-existing urinary incontinence (before prostate surgery)
2. age (up to 70, 71 and over)
3. type of incontinence at trial entry (stress, urge, mixed, other)
4. body mass index up to 30, 30–34.9, 35 or greater
5. centres with and without biofeedback machines
6. type of therapist (physiotherapist or nurse)
7. other morbidity/treatment for other morbidity

Stricter levels of statistical significance ($2p<0.01$) will be sought, reflecting the exploratory nature of these analyses.

All study analyses will be according to a statistical analysis plan that will be agreed in advance by the MAPS Steering Committee.

6.5 Economic analysis

Both trials (radical prostatectomy or transurethral resection of prostate) will include a formal economic evaluation. Resource use and costs will be estimated for every trial participant. Resource-use data collected will include the intervention and the use of primary and secondary NHS services by the men including referral for specialist management. Personal costs to the men (such as use of pads or work/social restrictions) will also be described. Thus the point of view adopted is that of the NHS and the patient.

6.5.1 Collection of data

At each time point of contact during the study (baseline and 3, 6, 9 and 12 months after randomisation), men will provide information about their use of health services

(via the health care utilisation questions, Appendix VI). At baseline, 6 and 12 months, they will complete the SF-12 and EQ-5D. Midway through the trial (at 6 months after randomisation), a questionnaire survey of all men will be used to ascribe costs to typical episodes of such health service use (the Health Care Unit Cost Questionnaire, Appendix VI). The underlying aim is to keep economic data collection as parsimonious as possible to minimise the burden on the men and the effect on response rates.

6.5.2 Participant costs of urinary incontinence

Participant costs will comprise three main elements: self-purchased health care; travel costs for making return visit(s) to NHS health care; and time costs of travelling and attending NHS health care.

- Self-purchased health care is likely to include items such as pads bought by the participant, prescription costs and over-the-counter medications. Information about these will be collected through the health care utilisation questions (see 6.5.1 above).
- Estimation of travel costs requires information from participants about the number of visits to, for example, their GP or physiotherapist (estimated from the health care utilisation questions) and the unit cost of making a return journey to each type of health care provider (from the Participant Unit Cost Questionnaire, Appendix VI).
- The cost of participant time will be estimated in a similar manner. The participant will be asked, in the Participant Unit Cost Questionnaire, how long they spent travelling to and attending their last visit to each type of health care provider. Participants will also be asked what activity they would have been undertaking (e.g. paid work, leisure, housework) had they not attended the health care provider. These data will be presented in their natural units, e.g. hours, and also costed using standard economic conventions, e.g. the Department of Transport estimates for the value of leisure time. These unit time costs, measured in terms of their natural and monetary terms, will then be combined with estimates of number of health care contacts derived from the health care utilisation questions.

6.5.3 Costs of intervention

Health service costs incurred as the consequence of the intervention will be recorded prospectively for every participant in the study. Main areas of costs will be: staffing (four sessions with the therapist), capital costs (buildings and equipment), and consumables (probes for biofeedback, pads).

6.5.4 NHS costs of other health services used

- Consumables (drugs, pads, etc.)
- Staff time (GP, nurse, consultants)
- Outpatient visits
- Hospital admissions (operations, other)

6.5.5 Cost-effectiveness

Effectiveness within the trials will be measured in terms of quality-adjusted life-years (QALYs) and subjective continence at 12 months (assessed using data from the ICI questionnaire). QALYs will be estimated by combining estimated quantity of life, with quality of life derived from the EQ-5D questionnaire (administered at baseline, 6 and 12 months) and UK tariffs. The estimation of QALYs will take account of the mortality of study participants. Participants who die within the study follow-up will be assigned a zero utility weight from their death until the end of the study follow-up. QALYs before death will be estimated using linear extrapolation between the QALY scores at baseline and all available EQ-5D scores up to death. The method of eliciting QALYs described is one commonly adopted in economic evaluation.

The primary analysis is based on the 1-year follow-up of the trial and two outcomes have been specified. These are incremental cost per additional man continent and incremental cost per QALY. The former outcome has been chosen to facilitate understanding of the findings amongst health care professionals while the second measure, the primary economic outcome, has been chosen to reflect a societal decision-making perspective. The results will be presented as point estimates of mean incremental costs, proportion of men continent, QALYs, and cost per man continent or per QALY. Measures of variance for these outcomes are likely to involve bootstrapping estimates of costs, proportion of men continent, QALYs, and incremental cost per additional man continent and per QALY. Incremental cost-effectiveness data will be presented in terms of cost-effectiveness acceptability curves (CEACs).

Other forms of uncertainty, e.g. concerning the unit cost of a resource, will be addressed using standard deterministic sensitivity analysis. The results of the sensitivity analyses will also be presented as CEACs. Further sensitivity analysis will be conducted to consider the effect of differential timing over which treatments may be given. These data are likely to prove useful for the economic model.

6.5.6 Modelling

While the within study results will prove useful it is important to note that incontinence is a chronic condition and the effects of treatment on costs and outcomes may persist into the future. Therefore, assuming that one intervention is not dominant (less costly but more effective at 12 months), additional useful information for policy makers will be derived from an economic model that considers a longer time horizon. In the model, the findings of the trial will be extrapolated to the patient's lifetime. The model will describe the change in levels of incontinence over the patient's lifetime following the start of treatment. The structure of the model will be developed in collaboration with clinicians and trial collaborators, and parameter estimates for costs and utilities will be derived from the trial data.

In order to extrapolate estimates of cost-effectiveness to a longer time horizon (e.g. the participant's lifetime) than that considered by the trial, a modelling exercise will be developed. The model will be populated using individual patient data from the study as well as both published and unpublished evidence in the field. The methods used to assemble additional data will follow recognised methodology, which will vary according to the type of parameter, extent of uncertainty and role within the model. Therefore, comprehensive systematic searching will be limited to those parameters to which the results of the model are likely to be particularly sensitive. The modelling exercise will comply with recent recommendations on good practice for modelling[14] and the results will be presented in terms of incremental cost per continent man and incremental cost per QALY gained.

Estimates of mortality will be based on data from life tables. As the model will be constructed to estimate outcomes both for men with benign disease and for men with prostate cancer, mortality rates will be adjusted, where necessary, using relative risks of mortality for prostate cancer. These data will be obtained from the literature and from an on-going study within the Health Economics Research Unit in Aberdeen that is looking at the cost-effectiveness of screening for prostate cancer.

Outcomes in the model will be expressed in terms of an incremental cost per QALY. Parameter uncertainty will be integrated by the incorporation of probability distributions into the model and involving Monte Carlo simulation. Other forms of uncertainty such as that associated with choices made about the structure of the model, discount rate, etc., will be addressed though sensitivity analysis. The base-case and sensitivity analyses will be presented as CEACs.

7. SAMPLE SIZE AND FEASIBILITY

7.1 Sample size sought

Based on the aim to detect a difference between intervention and control groups of 15% (70% to 85%) in the number of men no longer incontinent, we will need 174 men per arm of the trial to give 90% power to detect a significant difference at the 5% level. This will allow detection of a difference of 0.30 of a standard deviation at 80% power for continuous measures such as quality of life. Should the proportion of men no longer incontinent be less than 70% we shall still have 80% power to detect a 15% change from 60% to 75%.

Table 1 below is an extrapolation to show the number of men who will need to be approached and hence the number of 'typical sized' clinical centres that will be required. Allowing for a 13% dropout rate after enrolment in the RCT, we plan to recruit 200 men per arm. There will thus be 400 men in each of the two parallel trials who would come from 615 incontinent men assuming that 65% agree to join the trial. Based on conservative assumptions of 50% and 5% incontinent at 6 weeks after radical prostatectomy and endoscopic resection of prostate, respectively, and 80% response rates to the screening questionnaire, 1,540 and 15,400 men will need to be approached. If a typical centre undertakes 30 radical prostatectomies and 300 endoscopic resections of prostate each year, about 26 centres will be required for each trial recruiting over an average of 2 years.

In summary, Table 1 shows that we will need to screen around 17,000 men in Stage 1 of the study, making conservative assumptions about likely response and participation rates. Based on these figures, a 2-year recruitment period in 26 centres will be needed.

Table 1 Recruitment numbers needed

	Radical prostatectomy	Transurethral resection
Men needed per arm (minimum)	174	174
Allowing for 13% dropout	200	200
Total men needed in two arms	400	400
Assuming 65% willing to enter RCT, no. incontinent men needed	615	615
% incontinent at 6 weeks (Stage 2)	50%	5%
No. of men needed to reply to survey	1230	12,300
Assuming 80% response to survey, no. needed for survey (Stage 1)	1540 (approx)	15,400 (approx)
No. of operations per typical centre	30	300
No. of typical centres needed in 2 years	26	26

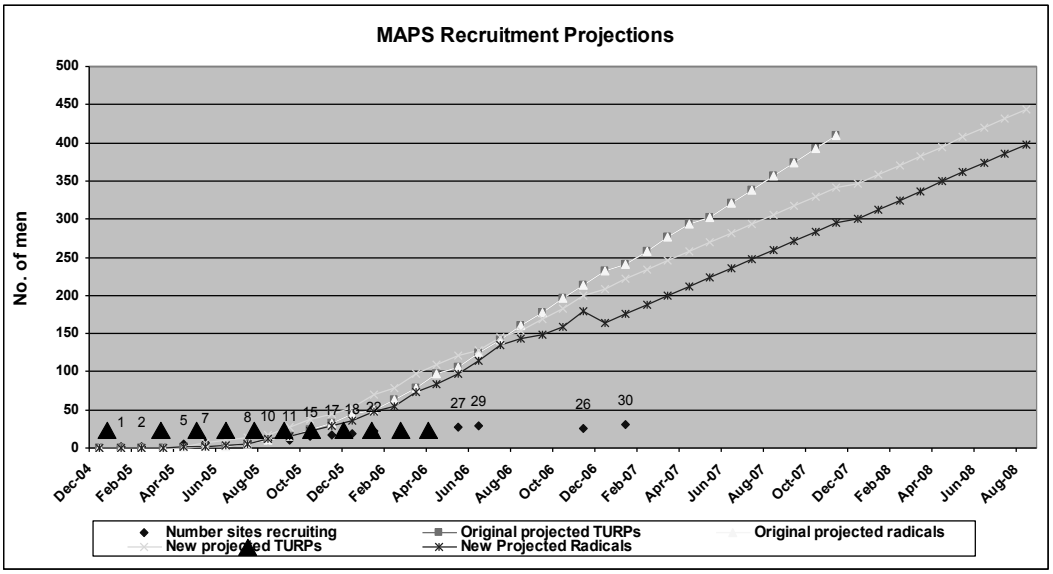
7.2 Recruitment rates

Figure 1 shows the projected recruitment of centres and participants, and projected number of men who would be approached. Three centres will be established relatively early in the project (by 5 months) followed by roll-out to the others over the subsequent 10 months.

The participant recruitment graph in Figure 1 has been modelled to take into account: the phased roll-out to the centres over the first 15 months; that there will be lags between the approach to men when they are in hospital and the despatch of the 'screening' questionnaire and between the despatch of the screening questionnaire and trial recruitment; and that there are likely to be fewer prostatectomies around August and over Christmas (due to holidays). Recruitment continues after the final

screening questionnaires have been sent out because of these 'lags'. The lines for the two trials (radical prostatectomy and endoscopic resection of prostate) are superimposed because their rates of recruitment are expected to be similar.

Figure 1 Projected recruitment chart



In summary, we originally aimed to recruit an average of 8 men to the randomised trial per week over a 2-year period. We estimated that if we had 26 centres, that would have amounted to 30 men per centre in 2 years, half of whom (around 15 in 2 years, or 8 per year) will be randomised to active therapy. In order to achieve this, we estimated that approximately 7 men per centre will need to be screened each week for 2 years. As the recruitment period was extended by 9 months in May 2007 (by the HTA) recruitment targets have altered since these original projections –the graph above therefore now reflects both the original and the extended recruitment periods.

8 ORGANISATION

A detailed plan and timetable of study organisation is given in the Gantt chart (Appendix VIII). In summary, it is as follows – 1–4 months: set up office, assemble team, and establish first centre; 5–15 months: establish study in all 26 centres; 5–36 months: identify and recruit 800 men with urinary incontinence (average 24 months in each centre); 13–48 months: follow up at 6 and 12 months after randomisation; 49–54 months: complete data collection, analysis and dissemination. In the light of the revised recruitment period (the 9-month extension) the Gantt chart has also been revised (Version 6 protocol).

The Gantt chart also shows when we expect the major study events to occur, including recruitment, study progress and meetings. There will be 3-monthly project management meetings, five meetings of the Steering Committee and four of the Data Monitoring Committee. Two meetings are planned for collaborators (including urologists, therapists, local recruitment officers and consumer participants), the first timed to occur when all the sites have been identified and the second when results are available. Four Training Meetings will be held to train the therapists during the course of the first year. Remote training of any other thepaists unable to attend these days will occur as and when applicable.

Based on this chart, the specific, time-related milestones given in Appendix VII will be used to allow close monitoring of progress.

8.1 Local organisation in centres

i) Lead Urologist (Local Principal Investigator)

Each collaborating centre will identify a Lead Urologist who will be the point of contact for that centre. The responsibilities of this person will be to:

- establish the study locally [for example by getting agreement from clinical colleagues; facilitate local research ethics committee approval (LREC); liaise with R&D department; identify and appoint a local Recruitment Officer; and inform all relevant local staff about the study (e.g. secretaries, ward staff)]
- take responsibility for clinical aspects of the study locally (for example if any particular concerns occur)
- notify the Study Office of any unexpected clinical events which might be related to study participation
- provide support and supervision for the local Recruitment Officer
- represent the centre at the collaborators' meeting

ii) Local Recruitment Officer

Each collaborating centre will appoint a local Recruitment Officer to organise the day-to-day recruitment of men to Stage 1 of the study (the Screening Survey). The responsibilities of this person will be to:

- keep regular contact with the local Lead Urologist, with notification of any problem or unexpected development
- maintain regular contact with the Study Office
- keep local staff informed of progress in the study
- contact potential participants by: organising mailing out of the Patient Information Sheet to men being admitted electively for prostate surgery; identifying all eligible men on the ward while they are in hospital for their prostate surgery; explaining the screening study and the potential for participation in a trial if they are incontinent after surgery; explaining what is intended by research access to their NHS data; and describing the possibility of long-term follow-up whether or not they are incontinent
- obtain the men's written consent to being sent a screening questionnaire
- keep a log of whether eligible men are recruited or not (with reasons for non-participation) (Appendix I)
- collect baseline data describing the men (Appendix I), and send these to the Study Office along with the signed consent forms (Appendix I)
- organise and supervise alternative recruiters in case of holiday or absence
- represent the centre at the collaborators' meeting

iii) Therapists and training

Each collaborating centre will identify a Lead Therapist who will be responsible for co-ordinating the active intervention at a local level. (S)he will identify the local therapist who will carry out the intervention, or may assume this role personally. The therapist may be a specialist physiotherapist or continence nurse specialist. The therapist will attend a Training Day (led by Professor Grace Dorey) to ensure consistency of training and intervention in each centre. There will be four Training Days at a range of locations throughout the UK during the setting-up phase of the study.

The therapist will use standard study instruction materials and documentation, which will be provided by the Study Office. The Study Office will also be the first point of contact for the therapist in case of problems, concerns, adverse effects or need for advice.

The responsibilities of the therapist will be to:

- attend a training day to become familiar with the standard method of teaching the men and the standard study documentation
- contact men allocated to the active arm by sending them an initial appointment (for one hour), and repeat three-quarter-hour appointments at 2, 6 and 12 weeks thereafter
- notify the Study Office if men fail to attend: a phone number will be provided for this purpose
- notify the Study Office of any unexpected clinical events which might be related to study participation
- teach all the men pelvic floor muscle training, using digital anal biofeedback to reinforce correct contractions
- use machine biofeedback with an anal probe if, in their opinion, it is clinically indicated (and a machine is available)
- teach bladder training to men who have urge incontinence
- provide other lifestyle advice as appropriate
- record the details of the treatment and response to treatment at each visit using standard study documentation (assessment and treatment forms, Appendix V)
- return the assessment and treatment forms to the Study Office at the end of each man's 3-month treatment period
- support the men in adhering to treatment
- represent the centre at the collaborators' meeting

iv) Other training materials

We hope also to provide an interactive CD-rom instruction and reminder package both to supplement the main Training Day teaching, and in case some therapists cannot attend or if staff changes result in new therapists being appointed.

It may be possible to amend this material for use in training other NHS staff after the trial is finished if the intervention is effective.

8.2 Study co-ordination in Aberdeen

i) The Study Office Team

The Study Office is in the Health Services Research Unit in Aberdeen and provides day-to-day support for the clinical centres. It is responsible for all data collection (such as mailing questionnaires), follow-up, data processing and analysis. It is also responsible for randomisation, despatch of Lifestyle Booklets and communicating with the therapists about men allocated to active treatment. Finally, we intend to produce a yearly MAPS Newsletter for participants and collaborators to inform everyone of progress and maintain enthusiasm.

The MAPS Study Office Team will meet formally at least monthly during the course of the study to ensure smooth running and trouble-shooting.

ii) The Project Management Group

The study is supervised by its Project Management Group. This consists of the grant holders and representatives from the Study Office. Observers may be invited to attend at the discretion of the Project Management Group. We plan to meet every 3 months on average.

iii) The Steering Committee

The study is overseen by an independent Steering Committee. The Chairman is Professor Paul Abrams, with Mrs Jane Dixon and Professor David Torgerson as other independent members appointed by the HTA. The other members are the grant holders. Observers or members of the host university (Aberdeen) and the funders (the HTA) may also attend, as may other members of the Project

Management Group or members of other professional bodies at the invitation of the Chair.

8.3 Research Governance, EU Directives, Data Protection and Sponsorship

i) Research Governance, EU Directive

The trial will be conducted in compliance with the EU Clinical Trials Directive (EU-CTD, 1 May 2004) although it does not come within the scope of the Directive. Other studies associated with the trial will either be conducted in compliance with the EU Clinical Trials Directive (1 May 2004) or in line with local implementation of Research Governance to at least the standard of the Aberdeen University policy on Research Governance (http://www.abdn.ac.uk/iahs/research-governance/index.shtml).

ii) Sponsorship

Before April 2007 the sponsorship for these studies (RCT and observational) was the Department of Health, UK. Their duties as sponsors were co-ordinated through the National Coordinating Centre for Health Technology Assessment (NCCHTA) in Southampton. In April 2007 sponsorship responsibility was transferred from the NCCHTA to the host institution, the University of Aberdeen.

Responsibility for transacting Part 3 of the EU-CTD (study initiation and finance), Part IV (Compliance with Good Clinical Practice) and Part V (Pharmacovigilance) will be delegated to the Chief Investigators, Dr James N'Dow and Dr Cathryn Glazener at Aberdeen University. They will ensure, through the Steering Committee, that adequate systems are in place for monitoring the quality of the study (compliance with GCP) and appropriate expedited and routine reports of adverse effects, to a level appropriate to the risk–benefit assessment of the trials.

iii) Data Protection

All data collected and stored within the study will comply with the Data Protection Act.

8.4 Data and safety monitoring

i) Data Monitoring Committee

A Data Monitoring Committee (DMC) will be established. This will be independent of the study organisers. During the period of recruitment to the study, interim analyses will be supplied, in strict confidence, to the Data Monitoring Committee, together with any other analyses that the committee may request. This may include analyses of data from other comparable trials. In the light of these interim analyses, the Data Monitoring Committee will advise the Steering Committee if, in its view:

a) the active intervention has been proved, beyond reasonable doubt,* to be different from the control (standard management) for all or some types of men, and
b) the evidence on the economic outcomes is sufficient to guide a decision from health care providers regarding recommendation of this service development.

The Steering Committee can then decide whether or not to modify intake to the trial. Unless this happens, however, the Steering Committee, Project Management Group, clinical collaborators and study office staff (except those who supply the confidential analyses) will remain ignorant of the interim results.

The frequency of interim analyses will depend on the judgement of the Chairman of the Committee, in consultation with the Steering Committee. However, we anticipate that there might be three interim analyses and one final analysis.

* Appropriate criteria for proof beyond reasonable doubt cannot be specified precisely. A difference of at least three standard deviations in the interim analysis of a major end point may be needed to justify halting, or modifying, such a study prematurely (Peto R et al., *Br J Cancer* 1976;34:548–612).

The Chairman is Professor Peter Langhorne, with Mrs Julia Brown, Mr Thomas McNicholas and Professor Christine Norton as other independent members, to be appointed after confirmation by the HTA.

ii) Safety concerns

The MAPS trial involves conservative interventions which are well established in clinical practice, although unproven regarding effectiveness for men after prostatectomy. We do not anticipate any adverse effects, but would respond appropriately to any notification.

Collaborators and participants may contact the chairman of the Steering Committee through the Study Office about any concerns they may have about the study. If concerns arise about procedures, participants or clinical or research staff (including risks to staff) these will be relayed to the Chairman of the Data Monitoring Committee.

As the trial arm to which men are allocated cannot be blind after randomisation has occurred, unblinding is not an issue in this trial.

The Multicentre Research Ethics Committee for Scotland has approved the study for the UK (ref MREC/04/10/01). The study will be conducted according to the principles of good practice provided by Research Governance Guidelines.

9. FINANCE

The study is supported by a grant from the NHS R&D National Coordinating Centre for Health Technology Assessment (NCCHTA) (ref 03/14/03).

10. EXPLANATORY STUDIES

The funds provided by the NCCHTA are to conduct the screening survey (Stage 1) and the randomised controlled trial (Stage 2) as described in this protocol. It is recognised, however, that the value of the study will be enhanced by smaller ancillary studies of specific aspects. Plans for some of these are being submitted to other grant funding bodies. Further suggestions would be welcome and should be discussed in advance with the Project Management Group and agreed with the NCCHTA. MREC approval will be sought for any new proposals.

11. INDEMNITY

The Patient Information Sheet provides the following statement regarding indemnity for negligent and non-negligent harm:

> '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.'

In addition, the universities involved with this study hold and maintain a 'no fault' insurance policy. This policy covers all employees of the universities and those working under their direction.

12. PUBLICATION

The success of the study depends entirely on the wholehearted collaboration of a large number of men undergoing prostate surgery, as well as therapists, nurses and doctors. For this reason, chief credit for the study will be given, not to the committees or central organisers, but to all those who have collaborated in the study. The study's publication policy is described in detail in Appendix IX. The results of the study will be reported first to study collaborators. The main report will be drafted by the Project Management Group and circulated to all clinical co-ordinators for comment. The final version will be agreed by the Steering Committee before submission for publication, on behalf of all the MAPS collaborators.

To safeguard the integrity of the main trial, reports of explanatory or satellite studies will not be submitted for publication without prior agreement from the Project Management Group.

We intend to maintain interest in the study by publication of MAPS Newsletters at intervals for participants, staff and collaborators. Once the main report has been published, a lay summary of the findings will be sent in a final MAPS Newsletter to all involved in the trial.

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We look forward to hearing from you.

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