# Conservative treatment for urinary incontinence in men after prostate surgery

<b>Submission date</b> 09/07/2004	Recruitment status No longer recruiting	[X] Prospectively registered		
		[X] Protocol		
Registration date 12/07/2004	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
26/10/2022	Urological and Genital Diseases			

#### Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-treatment-for-urinary-incontinence-after-prostate-surgery

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

ClinicalTrials.gov (NCT) NCT00632138

Protocol serial number HTA 03/14/03

# Study information

#### Scientific Title

Conservative treatment for urinary incontinence in men after prostate surgery (MAPS): multicentre randomised controlled trial of pelvic floor muscle training and biofeedback

#### Acronym

**MAPS** 

#### **Study objectives**

Randomised controlled trial of conservative treatment for urinary incontinence in men after prostate surgery. 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 one year after recruitment.

#### The questions:

- 1. For men with urinary incontinence six 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?
- 2. For men with urinary incontinence six weeks after endoscopic 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?

Please note that, as of 25/01/2008, the anticipated end date of this trial was updated from 31/05/2009 to 28/02/2010.

Please note that the official scientific title of the trial was added as of 26/01/2009.

## Ethics approval required

Old ethics approval format

# Ethics approval(s)

Multi-centre Research Ethics Committee for Scotland, approved on 11/06/2004 (ref: MREC/04/10/001)

## Study design

Randomised controlled trial

### Primary study design

Interventional

## Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Urinary incontinence

#### **Interventions**

Active Intervention:

Pelvic floor muscle training and lifestyle advice with selective biofeedback (which may be digital or machine-mediated) with or without bladder training. It consists of four visits to a trained therapist who will teach the men the relevant exercises.

Control Intervention: Lifestyle advice only

Added as of 26/01/2009: Total duration of interventions: approximately 3 months

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome(s)

- 1. Primary clinical outcome: subjective report of urinary continence at 12 months
- 2. Primary measure of cost effectiveness: incremental cost per quality-adjusted life year

### Key secondary outcome(s))

Clinical

- 1. Subjective report of continence or improvement of urinary incontinence at six months after randomisation, and improvement at 12 months
- 2. Number of incontinent episodes in previous week (objective, from diary)
- 3. Duration of incontinence (based on time of resolution relative to time of operation and randomisation)
- 4. Use of absorbent pads, penile collecting sheath, bladder catheter or bed/chair pads
- 5. Number and type of incontinence products used
- 6. Co-existence, cure or development of urgency or urge incontinence
- 7. Urinary frequency
- 8. Nocturia
- 9. Faecal incontinence (passive or urge)
- 10. Other bowel dysfunction (urgency, constipation, other bowel diseases)
- 11. Sexual function at 12 months (including information about erection, ejaculation, retrograde ejaculation, pain, change in sex life and reason for change)

#### Quality of life

- 1. Incontinence-specific quality of life outcome measure (10-point scale, International Consultation on Incontinence [ICI] questionnaire, Incontinence Quality of Life [I-QOL] questionnaire)
- 2. General health measures (SF-12® Health Survey, Eurogol EQ-5D)

# Use of health services for urinary incontinence

- 1. Need for alternative management for incontinence (e.g., surgery, drugs)
- 2. Use of GP, nurse, consultant urologist, physiotherapist

#### Other use of health services

- 1. Visits to GP
- 2. Visits to practice nurse

#### Effects of interventions

- 1. Use of pelvic floor muscle training (PFMT)
- 2. Lifestyle changes (weight, constipation, lifting, coughing, exercise)

#### Economic measures

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

#### Completion date

28/02/2010

# **Eligibility**

#### Key inclusion criteria

- 1. Men (no age limits) who have urinary incontinence 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?)
- 2. Informed consent
- 3. Ability to comply with intervention

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Male

#### Total final enrolment

853

#### Key exclusion criteria

- 1. Radiotherapy planned or given during the first three months after surgery for men with prostate cancer
- 2. Endoscopic resection of prostate carried out as palliation for outflow obstruction in advanced prostate cancer
- 3. Multiple sclerosis or Parkinson's disease
- 4. Inability to complete study questionnaires

#### Date of first enrolment

01/12/2004

#### Date of final enrolment

28/02/2010

# Locations

#### Countries of recruitment

**United Kingdom** 

Scotland

Study participating centre
Health Services Research Unit
Aberdeen
United Kingdom
AB25 2ZD

# Sponsor information

## Organisation

University of Aberdeen (UK)

#### **ROR**

https://ror.org/016476m91

# Funder(s)

# Funder type

Government

#### **Funder Name**

Health Technology Assessment Programme

#### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

National government

#### Location

United Kingdom

# **Results and Publications**

# Individual participant data (IPD) sharing plan

Not provided at time of registration

# IPD sharing plan summary

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/07/2011		Yes	No
Protocol article	protocol	01/09/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			26/10/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes