

Conservative treatment for urinary incontinence in men after prostate surgery

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| Submission date 09/07/2004 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 12/07/2004 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 26/10/2022 | Condition category Urological and Genital Diseases | <input type="checkbox"/> Individual participant data |

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>

Study website

<https://www.charttrials.abdn.ac.uk/maps/>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00632138

Secondary identifying numbers

HTA 03/14/03

Study information

Scientific Title

Conservative treatment for urinary incontinence in men after prostate surgery (MAPS): multi-centre 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Patient information can be found at <https://www.chartrtrials.abdn.ac.uk/maps/pis.php>

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 measure

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

Secondary outcome measures

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, Euroqol 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)

Overall study start date

01/12/2004

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

Age group

Adult

Sex

Male

Target number of participants

800

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**

Scotland

United Kingdom

Study participating centre

Health Services Research Unit

Aberdeen

United Kingdom

AB25 2ZD

Sponsor information**Organisation**

University of Aberdeen (UK)

Sponsor details

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Aberdeen

Scotland

United Kingdom

AB24 3FX

Sponsor type

University/education

Website

<http://www.abdn.ac.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, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------------|----------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 01/09/2009 | | Yes | No |
| Results article | results | 23/07/2011 | | Yes | No |
| Plain English results | | | 26/10/2022 | No | Yes |

