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Conservative treatment for urinary incontinence in men after prostate surgery

Submission date	Recruitment status	[X] Prospectively registered
09/07/2004	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/07/2004	Completed	[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

Study website
https://www.charttrials.abdn.ac.uk/maps/

Contact information

Type(s)
Scientific

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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.charttrials.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
-
Aberdeen
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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