

Self management of urinary symptoms after prostate cancer treatment

Submission date 13/03/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 13/03/2012	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 15/08/2024	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/trials-search/a-trial-looking-helping-men-manage-urinary-problems-after-radiotherapy-for-prostate-cancer>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

9433

Study information

Scientific Title

Self-management of urinary symptoms after treatment for prostate cancer: an exploratory randomised controlled trial

Acronym

SMaRT (Self-Management after Radiotherapy Treatment)

Study objectives

This is an exploratory randomised controlled trial to evaluate a self-management intervention for men who have moderate to severe urinary symptoms after radiotherapy treatment for prostate cancer. Participants will be randomised to either the Intervention arm to receive the self-management programme and follow-up as well as usual care or to the Control arm to receive usual care. All participants will be assessed at baseline, at the end of the intervention period and at the end of follow-up. Co-morbidity and demographic data will be collected for all participants. It is hypothesised that in comparison to usual care, at 26 weeks men in the intervention will report significantly less urinary symptoms (measured by the IPSS) (primary outcome) and report significantly better symptom-related quality-of-life (measured by the EORTC 25) and significantly less emotional distress (measured by the EORTC 30) facilitated by improvement in their confidence to cope with the illness and its associated problems (secondary outcome).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Surrey Research Ethics Committee, 10/09/2010, ref: 10/H1109/55

Primary study design

Interventional

Study design

Randomised interventional process of care trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

Supported self-management delivered by a specialist prostate cancer nurse comprising four group sessions and one individual session. The intervention will contain both behavioural and cognitive elements in the form of pelvic floor muscle exercises (supported by biofeedback) and bladder retraining supplemented by patient education, problem solving and goal setting with psycho-social support.

Followed up at 6 months

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

Urinary symptoms measured by the International Prostate Symptom Score (IPSS); Timepoint(s): At two months (end of intervention) and 6 months past baseline

Key secondary outcome(s)

Quality of life measured by the EORTC 25, and emotional distress measured by the EORTC 30 both at 2 and 6 months post baseline.

Completion date

28/02/2014

Eligibility

Key inclusion criteria

1. Men
2. Have locally contained prostate cancer up to stage T3BNO
3. Have received neoadjuvant hormonal therapy
4. Have completed radiotherapy three to four months prior to the intervention
5. Have urinary symptoms and an IPSS score of 8+
6. Have sufficient understanding of written and spoken English

Added 27/01/2014:

7. Brachytherapy patients

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

1. Have a urinary tract infection
2. Have a current psychiatric referral
3. Have a current referral for memory issues
4. Require an interpreter

Date of first enrolment

01/03/2011

Date of final enrolment

28/02/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Surrey

Guildford

United Kingdom

GU2 7TE

Sponsor information**Organisation**

University of Surrey (UK)

ROR

<https://ror.org/00ks66431>

Funder(s)**Funder type**

Charity

Funder Name

Dimbleby Cancer Care

Alternative Name(s)

DCC

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results			15/08/2024	No	Yes