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Self management of urinary symptoms after prostate cancer treatment

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

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 coparison to usual care, at 26 weeks men in the intervetnion 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

Study design
Randomised interventional process of care trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

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

Overall study start date
01/03/2011

Completion date
28/02/2014

Eligibility

Key inclusion criteria
1. Men
2. Have locally contined 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 syptopms 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

Age group
Adult

Sex
Male

Target number of participants
Planned Sample Size: 96; UK Sample Size: 96

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
England

United Kingdom

Study participating centre
University of Surrey
Guildford
United Kingdom
GU2 7TE

Sponsor information

Organisation
University of Surrey (UK)

Sponsor details
Faculty of Health and Medical Science
Guildford
England
United Kingdom
GU2 7XH

Sponsor type
University/education

Website
http://www.surrey.ac.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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