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A pilot randomised controlled trial of a nurse-led psychoeducational intervention delivered in primary care to prostate cancer survivors (PROSPECTIV)

Submission date
26/06/2012

Recruitment status
No longer recruiting

Registration date
26/06/2012

Overall study status
Completed

Last Edited
04/10/2018

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-quality-life-follow-up-men-prostate-cancer-prospectiv

Contact information

Type(s)
Scientific

Contact name
Prof Eila Watson

Contact details
School of Health Care and Social Care
Oxford Brookes University
Jack Straws Lane Marston
Oxford
United Kingdom
OX3 0FL
-
ewatson@brookes.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12425

Study information

Scientific Title
A pilot randomised controlled trial of a nurse-led psychoeducational intervention delivered in primary care to prostate cancer survivors (PROSPECTIV)

Study objectives
Previous studies have shown that men with prostate cancer can experience a range of problems following treatment, including incontinence of urine, sexual problems, anxiety and depression. These are often not adequately addressed. In this pilot trial men with ongoing problems who are 9-24 months beyond diagnosis will be offered a nurse appointment in a GP surgery, where the nurse will offer advice and support on the best way to deal with these problems. This may involve giving information on how to improve symptoms (eg specific exercises for incontinence), or how to cope better with symptoms that can't be improved. Where appropriate, the nurse will refer the man to the GP (eg for prescription of drug treatment for erection difficulties), or to a specialist /other support service if the problem is more complex. Men will be offered additional nurse follow-up appointments to monitor progress and provide further advice and support, on an individual needs basis. A routine telephone follow-up appointment will take place at six months for all men. Our overall aim is to find out if this nurse-led intervention is more effective than current care in improving men's quality of life, unmet needs and satisfaction with care. Men recruited to the study will complete a questionnaire (Phase 1) which will identify those with ongoing problems. Those who consent will be randomly allocated either to the nurse intervention or to the current care group (Phase 2). Follow-up questionnaires will be given after 9 months and comparisons made between groups to make preliminary estimates of how effective the intervention is. The information from this pilot study will be essential for designing a larger trial which would definitively answer our research question.

Ethics approval required
Old ethics approval format

Ethics approval(s)
12/SC/0373

Study design
Both; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Randomly allocated either to the nurse intervention or to the current care group

Nurse intervention: The intervention will provide tailored advice and support to men on dealing with any prostate related problems they have. The intervention will be delivered by a trained research nurse, based in primary care, who will offer an initial face to face appointment (approximately 30-45 minutes) to men. The intervention will aim to
1. Elicit the man's understanding of his illness
2. Assess the key problem(s)
3. Ensure optimal treatment is offered

Intervention Type
Other

Phase
Phase I

Primary outcome measure
A follow-up questionnaire administered at 9 months will measure outcomes and costs

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2012

Completion date
01/10/2013

Eligibility

Key inclusion criteria
1. 9- 24 months post-diagnosis of prostate cancer
2. Men who have stable disease defined as having the followingm Prostate-specific antigen (PSA) values (most recent):
2.1. Surgical patients: 0.4ng/ml or less
2.2. Radiotherapy patients: 0.4ng/ml or less if nadir (0.2 or less) is reached, or PSA continuing to fall if nadir not reached
3. Hormone therapy patients: 10ng/ml or less

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
Planned Sample Size: 500; UK Sample Size: 500

Key exclusion criteria
1. < 9 or >24 months post-diagnosis
2. Unstable patients
3. Unable to understand/speak English

Date of first enrolment
01/10/2012

Date of final enrolment
01/10/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Brookes University
Oxford
United Kingdom
OX3 0FL

Sponsor information

Organisation
Oxford Brookes University (UK)

Sponsor details
Jack Straws Lane Marston
Oxford
England
United Kingdom
OX3 0FL

Sponsor type
University/education

ROR
https://ror.org/04v2twj65

Funder(s)

Funder type
Charity

Funder Name
Prostate Cancer Charity (UK)

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?
Protocol article	protocol	22/05/2014		Yes	No
Results article	results	01/02/2018		Yes	No