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TOPCAT-P: a pilot study to determine the feasibility of a nurse-led intervention for improving the symptoms of men recovering from prostate cancer

Submission date
12/09/2013

Recruitment status
No longer recruiting

Registration date
20/09/2013

Overall study status
Completed

Last Edited
25/01/2019

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-trial-of-personalised-care-after-treatment-for-prostate-cancer-topcatp

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Additional identifiers

Protocol serial number
TOPCAT-P, version 3.0

Study information

Scientific Title
Trial Of Personalised Care After Treatment - Prostate Cancer: a pilot study

Acronym
TOPCAT-P

Study objectives
Firstly, it is expected that the recruitment rate will be over 50%. Secondly, it is predicted that participant attrition rate will be no more than 50% and the nurse-led intervention will improve patients' symptoms and quality of life, without a significant increase in the overall use of healthcare services.

On 06/05/2015 the following changes were made to the trial record:
1. The overall trial start date was changed from 01/09/2013 to 01/11/2013.
2. The overall trial end date was changed from 31/12/2014 to 31/07/2015.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Academic Ethics Committee, Schools of Healthcare and Medical Sciences, Bangor University, 29/08/2013, ref: 2013/07/02 TOPCAT-PC
2. North Wales Research Ethics Committee (Central & East), 09/09/2013, ref: 13/WA/0291, IRAS project ID: 128390

Study design
Parallel-group single-site randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
Intervention 1: Usual care
Patients receiving the usual care intervention will continue to have their follow-up appointments (at the hospital or local GP practices), and will receive the usual Macmillan Cancer Support information pack. Patients will be asked to complete the study outcome questionnaire once more at the end of the trial (after 9 months) and also to fill in the health service use questionnaire three times during the trial (at 3, 6, and 9 months from the start of the study).

Intervention 2: Nurse-led intervention
Patients in the nurse-led intervention arm will continue to have their follow-up appointments (at the hospital or local GP practices), and will receive the same usual Macmillan Cancer Support information pack and questionnaires as the patients in the usual care arm (see above). The intervention will include an hour of Clinical Nurse Specialist (CNS) assessment, and tailored follow-up appointments as appropriate. The intervention will make use of dynamic personal care plans and encourage self-management (empowering men to help themselves). Specifically, the CNS will provide individualised information, advice and support tailored to each patient's needs, in order to help men improve their symptoms or cope better with symptoms they can't improve. The key components of the CNS intervention are:
1. Understanding the context of the prostate cancer treatment as experienced by the patient, and exploring any needs unmet by the current follow-up care system;
2. Exploring existing symptoms (e.g., incontinence, frequency, bowel problems, sexual dysfunction and fatigue), and the range of physical and emotional concerns regularly experienced by patients (see below);
3. Encouraging self-management and behavioural activation (e.g., setting goals, teaching pelvic floor exercises, bladder retraining techniques, weight loss and exercise management, etc.), including any appropriate further referrals;
4. Discussing on-going concerns (e.g., fear of cancer recurrence, altered body image, thoughts of not being a man, spirituality, financial worries, etc.) and teaching self-motivation techniques.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The primary measure of the pilot trial will be the patient recruitment rate. This will be calculated from the total number of patients contacted with the invitation to take part in the study and the number of patient giving their written consent to taking part in the trial. This is calculated at baseline, before the start of the trial.

Key secondary outcome(s))
1. Patient attrition rate: calculated from the number of patients who will have given their consent to take part in the trial, and the number of patients who have submitted any of the

intervention outcome and health service use measures (see below) taken at the end of the intervention, regardless of their completion rate. This is calculated after follow-up, at the end of the trial.
2. Intervention outcome measures: Two measures will be taken: at baseline and after follow-up (at the end of the trial - at 9 months). The following questionnaires, collated in a single booklet, and consisting exclusively of validated clinical measures will be administered (before and after the 9 months intervention) to assess:
2.1. Prostate cancer specific follow-up symptoms (EPIC-26, Expanded Prostate Cancer Index Composite - 26; Szymanski et al., 2010)
2.2. Confidence in managing own health (Lorig et al., 2001)
2.3. Medical and support needs (Supportive Care Needs Survey - simplified response format; Schofield et al., 2011)
2.4. General health and quality of life (EQ-5D-5L; Brooks, 1996)
2.5. ICECAP-A (Al-Janabi, Keeley, Mitchell, Coast, 2013)
2.6. Psychological wellbeing (Hospital Anxiety and Depression Scale; Zigmond and Snaith, 1983)
3. Health Service Use Measure: This will be taken three times during the trial: at 3, 6, and 9 months (end of the trial). The usage of health and social care services will be measured at 3, 6 and 9 months after the start of the intervention. The purpose-built questionnaire/diary - a client service receipt inventory (CSRI) (Ridyard & Hughes, 2010) will be used to measure, from a societal perspective, frequency and types of contacts with primary and secondary healthcare services and social services. We will also note contacts with voluntary sector services. The CSRI will include information about:
3.1. The number of times the patients had to see a doctor, nurse, or other healthcare professional in relation to his prostate cancer related symptoms.
3.2. The special medication, aids, and adaptations prescribed to patients to help with their prostate cancer related symptoms.
3.3. The number of days patients felt too unwell to participate in their normal activities due to prostate cancer related symptoms.
4. Relevant Medical History Data: Patient diagnosis, cancer stage, treatment, comorbidities and other relevant medical history data will be collected from GP-and hospital-held records with patients' consent. This will be collected after follow-up (at the end of the trial), from patients' medical records.
5. Feedback interviews: The experiences and views of a sub-sample of patients in the intervention group (n=32), the research nurse (CNS-R), and secondary and primary card Clinicians (n=10) in charge of the patients' usual follow-up care will be sought in the feedback interviews. Patients will be randomly selected from those who have given their consent to take part in the feedback process. Interviews will take place after follow-up (at the end of the trial).

Completion date
31/07/2015

Eligibility

Key inclusion criteria
1. Stable, incident prostate cancer patients in BCUHB (defined as being 9-24 months post-diagnosis) in NE Wales
2. Considered fit for taking part in the trial, as assessed by their multi-disciplinary team (MDT)
3. Having undertaken radical curative therapy for prostate cancer (surgery, radiotherapy, or brachytherapy), or being followed up with PSA monitoring and symptom reporting (watchful waiting)
4. All patients will have the ability to give informed consent, as assessed by the MDT

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Men who are in the Active Surveillance group (men who are suitable for active treatment, but choose to be monitored until proof of progression)
2. Men who are clearly in the palliative phase
3. Men who are deemed to be unable to take part in the trial (e.g., severe learning disability)
4. Men who have active symptoms of severe enduring mental health problems, preventing patients from successfully participating in research studies (as assessed by the MDT)
5. Men who do not have capacity to give informed consent

Date of first enrolment
20/01/2014

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
North Wales Centre for Primary Care Research
Wrexham
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Sponsor information

Organisation
Bangor University (UK)

ROR
https://ror.org/006jb1a24

Funder(s)

Funder type
Charity

Funder Name
Macmillan Cancer Support (UK); Ref no: EA/4237574

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?
Results article	results	01/03/2019	25/01/2019	Yes	No
Protocol article	protocol	25/06/2015		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes