

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/09/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/01/2019	Condition category Cancer	<input type="checkbox"/> 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>

Contact information

Type(s)

Scientific

Contact name

Prof Clare Wilkinson

Contact details

North Wales Centre for Primary Care Research
Gwenfro Units 4-5
Wrexham Technology Park
Wrexham
United Kingdom
LL13 7YP
+44 (0)1978 726651
c.wilkinson@bangor.ac.uk

Type(s)

Scientific

Contact name

Dr Andrei Stanciu

ORCID ID

<http://orcid.org/0000-0001-7492-1898>

Contact details

North Wales Centre for Primary Care Research
Gwenfro Units 4-8
Wrexham Technology Park
Wrexham
United Kingdom
LL13 7YP
+44 (0)1978 726078
a.stanciu@bangor.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please contact Andrei Stanciu: a.stanciu@bangor.ac.uk to request a patient information sheet in Welsh and English

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 measure

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.

Secondary outcome measures

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).

Overall study start date

01/11/2013

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

Age group

Adult

Sex

Male

Target number of participants

120

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

United Kingdom

LL13 7YP

Sponsor information

Organisation

Bangor University (UK)

Sponsor details

North Wales Centre for Primary Care Research

Gwenfro Units 6-7

Wrexham Technology Park

Wrexham

Wales

United Kingdom

LL13 7YP

Sponsor type

University/education

Website

<http://www.bangor.ac.uk/nwcpcr/>

ROR

<https://ror.org/006jb1a24>

Funder(s)

Funder type

Charity

Funder Name

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

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

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	25/06/2015		Yes	No
Results article	results	01/03/2019	25/01/2019	Yes	No
HRA research summary			28/06/2023	No	No