ISRCTN38893965 https://doi.org/10.1186/ISRCTN38893965

PROACTIVE: prostate cancer support intervention for active surveillance

Submission date 11/06/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/07/2015	**Overall study status** Completed	
Last Edited 06/08/2024	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-a-support-programme-for-men-with-prostate-cancer-pro-active

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
PROstate Cancer Support Intervention for ACTIVE Surveillance: a mixed methods randomized parallel-group exploratory trial

Acronym
PROACTIVE

Study objectives
Primary Hypothesis:
PROACTIVE will reduce anxiety and improve wellbeing compared to Treatment As Usual (TAU).
Secondary Hypotheses:
1. PROACTIVE will improve quality of life compared to TAU.
2. PROACTIVE will reduce the number on AS converting to radical intervention (triggered by anxiety) without a clinical (pathological) indication

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxfordshire Research Ethics Committee, 24/02/2015, ref: 11/SC/0355

Study design
A mixed methods randomized parallel-group exploratory trial to determine the feasibility of delivering PROACTIVE within two NHS prostate cancer clinics

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Men with localised prostate cancer being managed with active surveillance

Interventions
Intervention Group: The intervention group will receive a 6 week psycho-education group based support programme called PROACTIVE. PROACTIVE involves 2 individual interdependent components:
1. Group Sessions
3 group sessions (8-10 men) facilitated by a prostate cancer clinical nurse specialist (CNS). Each session addressing one of 3 themes identified by men on AS as important (Pickles et al., 2007; Hedestig et al., 2008):
1.1.Lack of information
1.2. Uncertainty
1.3. Anxiety and distress
2. Internet Sessions
6 internet sessions run weekly on the LifeGuide platform designed to support and complement the group sessions (lifestyle, relaxation techniques, communication, thoughts and feelings, daily life).

Control Group: The control group for this study will receive routine care. At the completion of the study all individuals randomised to the control group will be offered free and on-going access to the PROACTIVE website.

Intervention Type
Behavioural

Primary outcome measure
1. Hospital Anxiety and Depression Scale (HADS): A validated and reliable 14 item questionnaire that has been used extensively within the field of oncology to assess depression and anxiety
2. Warwick/Edinburgh Mental Wellbeing Scale (WEMWBS): is a validated and reliable measure of mental wellbeing
3. Freiburg Mindfulness Inventory: a valid and reliable 30-item scale that is designed to measure the concept of mindfulness
4. EORTC-QLQ-OV28: A widely used, valid and reliable questionnaire that assesses quality of life specific to ovarian cancer

These will be collected at baselines, 6-weeks (end of intervention) and 6 and 12 months follow-up

Secondary outcome measures
N/A

Overall study start date
01/06/2015

Completion date
01/12/2017

Eligibility

Key inclusion criteria
1. Low or intermediate risk PCa (NICE definition 2014)
2. Willing to participate/provide informed consent
3. Diagnosed at least 2-month prior to entry
4. On AS under 12 months.
5. Have received only 1 MRI
6. Fluent English (questionnaires validated in English)

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
60

Key exclusion criteria
1. Additional cancers
2. Co-morbidities that could significantly impact upon mood
3. Other conflicting research

Date of first enrolment
01/10/2015

Date of final enrolment
01/10/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University of Southampton
Primary Medical Care
Aldermoor Health Centre
Aldermoor Close
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Study participating centre
University College London Hospitals NHS Trust Foundation
UCH Macmillan Cancer Centre
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Sponsor information

Organisation
University of Southampton

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Charity

Funder Name
Prostate Cancer UK

Alternative Name(s)
Prostate Cancer, Prostate Action, ProstateUK, prostatecanceruk

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Findings will be disseminated to the PCa clinical/academic/patient communities through academic and professional publications, liaison with charities (Macmillan, PCUK, PCaSO, etc), press releases and relevant social media. We have a good record of presenting at international urology and cancer conferences (American, British and European Urology Associations, Multidisciplinary Association of Supportive Care in Cancer), national and international academic GP conferences plus conferences attended by health professionals. These form key components of our dissemination strategy. Men affected by PCa will receive information through meetings with relevant charities and short targeted reports for charities and the media. Where requested a written summary of study results will be provided for study participants ensuring they are informed about the results and future research plans.

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results	Intervention development			No	Yes
Other publications		09/08/2022	10/08/2022	Yes	No
Results article		11/09/2019	06/08/2024	Yes	No