# PROACTIVE: prostate cancer support intervention for active surveillance

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

## Contact information

## Type(s)

Public

#### Contact name

Dr Sam Watts

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## Type(s)

Scientific

#### Contact name

Dr Sam Watts

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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 followup

#### 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 Southampton United Kingdom SO16 5ST

## Study participating centre University College London Hospitals NHS Trust Foundation

UCH Macmillan Cancer Centre Huntley Street London United Kingdom WC1E 6AG

# Sponsor information

#### Organisation

University of Southampton

#### Sponsor details

Research and Development Office
E Level, Southampton Centre for Biomedical Research
Laboratory and pathology block, mailpoint 138
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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 |                          |              |            | No             | Yes             |
| Other publications    | Intervention development | 09/08/2022   | 10/08/2022 | Yes            | No              |
| Results article       |                          | 11/09/2019   | 06/08/2024 | Yes            | No              |