

Partnership in prostate cancer care

Submission date 19/12/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/01/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/09/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-using-an-online-assessment-tool-for-prostate-cancer-icare-p>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32774

Study information

Scientific Title

Partnership in Prostate Cancer Care: the feasibility of an integrated system to improve patient outcomes and experience (the ICARE-P Study)

Acronym

ICARE-P

Study objectives

The aim of this study is to assess the feasibility of carrying out a future trial to compare a new model of integrated care for prostate cancer patients with standard care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Yorkshire and the Humber – South Yorkshire NRES, 04/08/2016, ref: 206153

Study design

Non-randomised; Interventional; Design type: Process of Care, Education or Self-Management, Complex Intervention, Management of Care

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Specialty: Primary Care, Primary sub-specialty: Cancer; UKCRC code/ Disease: Cancer/ Malignant neoplasms of urinary tract

Interventions

Intervention group: Intervention practices are recruited on the basis of their being willing to send practice nurses for Macmillan Cancer follow up training and the additional prostate specific training delivered by members of the project team.

Patients will be invited to complete the CHAT-P holistic needs assessment online either alone, with family, friends, peer supporter, or a member of the research team, as is their preference. Links are provided within CHAT-P to sources of advice and information depending on the needs identified. Following completion of the first of 3 HNAs the patient will be directed to make an appointment with the Practice Nurse to discuss any issues of concern identified and personalise the automated Care Plan. The nurse will discuss current concerns which may be physical issues arising from prostate cancer treatment, emotional or social issues, or concerns related to aspects of care. The nurse will discuss aspects of lifestyle and self-management with the patient

and where relevant help patients set realistic goals. Where indicated, the nurse will advise the patient regarding further sources of support and advice on specific issues. The nurse will highlight matters of clinical concern to the secondary care team or the GP as necessary. The HNA will be recompleted at intervals specified in our study timeline. All intervention group participants will complete the HNA at least three times during the 8/9-month study period, and hence may have at least three planned follow-up appointments with the Practice Nurse.

Control group: Control practices include any practices within the same CCG who would agree to recruit men with prostate cancer to complete the outcome measures.

Participating patients will receive usual care for the duration of the study and will complete study outcome measures at baseline and at 8/9 months.

Intervention Type

Other

Phase

Phase II

Primary outcome measure

Feasibility is assessed through recording the the percentage of eligible men recruited and the percentage of men who complete the Holistic Needs assessments at baseline, 6 and 9 months

Secondary outcome measures

1. Cancer survivors' supportive care needs will be assessed using the cancer survivors unmet needs survey (CASUN) at baseline, 6 and 9 months
2. Quality of life will be measured using the EORTC QLQ-C30 at baseline and 9 months
3. Quality adjusted life years will be measured using the EQ-5D-5L at baseline and 9 months
4. Mental wellbeing will be measured using the Warwick and Edinburgh Mental Well-being scale (WEMWBS) at baseline and 9 months
5. Prostate specific concerns will be measured using EPIC at baseline and 9 months
6. Participant engagement in their healthcare will be measured using the Patient Activation measure (PAM) at baseline 3 and 9 months

Overall study start date

01/09/2015

Completion date

30/11/2017

Eligibility

Key inclusion criteria

1. Confirmed diagnosis of prostate cancer and are at any stage of the care pathway
2. Under any treatment regime
3. Diagnosed and/or treated at University Hospitals Birmingham (UHB) or are currently undergoing treatment at UHB
4. Able to read written and comprehend spoken English and complete outcome measures
5. Judged by their GP to have the capacity to participate
6. Aged 18 years or over
7. Able and willing to give informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

Planned Sample Size: 200; UK Sample Size: 200

Key exclusion criteria

1. Aged under 18 years
2. Unable to give informed consent or complete outcome measures
3. Living in a care setting, suffering from severe mental health problems or unable to communicate in English

Date of first enrolment

02/02/2017

Date of final enrolment

28/02/2017

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**Woodland Road Surgery**

Woodland Road

Northfield

Birmingham

United Kingdom

B31 2HZ

Study participating centre**Maypole Health Centre**

10 Sladepool Farm Road

Birmingham
United Kingdom
B14 5DJ

Study participating centre

Ash Tree Surgery

1536 Pershore Road
Stirchley
Birmingham
United Kingdom
B30 2NW

Study participating centre

Kings Norton Surgery

66 Redditch Road
Birmingham
United Kingdom
B38 8QS

Study participating centre

West Heath Medical Centre

West Heath Medical Centre
194-196 West Heath Road
Birmingham
United Kingdom
B31 3HB

Study participating centre

Riverbrook Medical Centre

3 River Brook Drive
Birmingham
United Kingdom
B30 2SH

Study participating centre

The Wand Medical Centre

15 Frank Street
Highgate
Birmingham
United Kingdom
B12 0UF

Study participating centre
Sparkbrook Community and Health Centre
34 Grantham Road
Sparkbrook
Birmingham
United Kingdom
B11 1LU

Study participating centre
St George's Surgery
119 School Road
Moseley
Birmingham
United Kingdom
B13 9TX

Study participating centre
Greet Medical Practice
50 Percy Road
Birmingham
United Kingdom
B11 3ND

Study participating centre
Fernley Medical Centre
560 Stratford Road
Birmingham
United Kingdom
B11 4AN

Study participating centre
The Balaji Surgery
2 Blackford Road
Sparkhill
Birmingham
United Kingdom
B11 3SH

Study participating centre
Bournville surgery
41B Sycamore Road
Birmingham
United Kingdom
B30 2AA

Sponsor information

Organisation
NHS Birmingham South and Central CCG

Sponsor details
Bartholomew House
142 Hagley Road
Birmingham
England
United Kingdom
B16 9PA

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Planned submission of a protocol paper to the Journal of Medical Internet Research. Further publications in high impact factor Digital Health and Oncology/Urology journals are planned for submission during 2018 following completion of the study in November 2017.

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes
Participant information sheet	version V1.3	23/08/2016	09/01/2017	No	Yes
Results article	results	28/07/2017		Yes	No