

Development and evaluation of a patient-reported instrument to monitor oncological and functional outcomes after radical prostatectomy: the true NTH Post Surgery programme

Submission date 06/11/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/11/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/11/2016	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

CTU/2015/182

Study information

Scientific Title

True NTH UK post surgical follow up: development and evaluation of a patient-reported instrument to monitor oncological and functional outcomes after radical prostatectomy

Acronym

True NTH UK Post Surgical Follow up

Study objectives

Prostate cancer is the most common cancer in men in the UK, with over 40,000 new diagnoses every year. The most recent estimates suggest there are over 250,000 men in the UK living with and beyond a diagnosis of prostate cancer, and this has been predicted to increase to 831,000 by 2040. Earlier cancer detection, but also effective treatments, are contributing to these increasing survival rates. Radical prostatectomy is a commonly performed operation to treat localised prostate cancer. The National Cancer Intelligence Network reports that around 10% of men with a new diagnosis of prostate cancer have radical prostatectomy.

However, men who choose radical surgery for prostate cancer can experience side effects, including urine leakage and problems with erections. A recent national UK survey has shown that men want to have greater understanding of, and support for these side effects, both before they choose a treatment, and when they are dealing with side effects after treatment. In particular, in the 2013 survey only 64% of men who had prostate cancer treatment said that they were told about possible future side effects of treatment. One of the difficulties in telling men about the possible side effects after prostate cancer surgery is that these side effects will depend upon the urinary and sexual function that a man has prior to the operation, as well as on the details of the operation itself, which is influenced by the location and aggressiveness of the prostate cancer.

A monitoring instrument (MSK instrument) has been developed in the US and adapted for web-based use ("STAR"). It is used to collect patient-reported outcome measures (PROMs) before and after radical prostatectomy in order to monitor functional recovery in individual men. It has been suggested that men find it helpful to keep track of their progress over time and to compare it to that of men like them, although confirmatory data are awaited. Work in Germany has also demonstrated that this type of monitoring after prostatectomy based on patient-reported information can be used by surgeons to identify and support best practice. In addition, such an instrument could potentially be used as a prognostic tool predicting outcomes after radical prostatectomy. This type of prognostic information may inform men who are deciding whether or not they want to undergo a radical prostatectomy.

The True NTH UK Post Surgical Follow up Programme will focus on using patient reported outcome measures (PROMs) to assess the extent and timeline for recovery of urinary and sexual function after radical surgery for prostate cancer. A new instrument will be developed for radical prostatectomy that can be used with men in the UK to monitor their recovery in the first 12 months after surgery. It is envisaged that the PROMs data will be used in clinical practice to

monitor progress in outcomes for individual patients. The programme will also allow a comparison of results of surgeons and hospitals against appropriate benchmarks for urinary and sexual outcomes after radical prostatectomy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Research Ethics Committee South Central - Hampshire B, 07/09/2015 , ref: 15/SC/0451

Primary study design

Observational

Study design

Observational and cross-sectional study. This is a multi-centre study.

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

Radical prostatectomy

Intervention Type**Primary outcome(s)**

The primary outcome of this study is the new monitoring tool. This study aims to address the following:

1. To develop a new monitoring tool that is suitable for the routine collection of patient reported signs and symptoms, functional status, and health related quality of life before and after radical prostatectomy in the UK
2. To assess to what extent the preoperative results captured with the new monitoring tool can be used – together with other patient characteristics, including comorbidity and disease characteristics – to predict patient reported functional outcomes (e.g. urinary and sexual function) 12 months after radical prostatectomy
3. To determine appropriate 'benchmarks' for urinary and sexual outcomes based on the new monitoring tool against which outcomes of radical prostatectomy surgery can be compared in the UK.
4. To develop a network of radical prostatectomy surgeons who can reflect on the surgical and patient reported outcome data to identify any areas of surgical practice which can be adopted more widely to improve outcomes for men
5. To use the tool to predict patient reported functional outcomes to inform patient led decision making for those men who have a choice of treatment strategies for localized prostate cancer

Key secondary outcome(s)

There are no secondary outcome measures.

Completion date

31/03/2017

Eligibility

Key inclusion criteria

1. A diagnosis of prostate cancer and scheduled to have radical prostatectomy
2. Access to the internet
3. An understanding of the English language sufficient to understand and complete on line CRFs
4. An understanding of the English language sufficient to understand written and verbal information about the trial and consent process
5. Signed informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

Men who are unable to give informed consent.

Date of first enrolment

13/11/2015

Date of final enrolment

31/03/2017

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University College London Hospitals NHS Foundation Trust

250 Euston Road

London

United Kingdom

NW1 2PG

Study participating centre

North Bristol NHS Trust

Frenchay Hospital
Beckspool Road
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United Kingdom
BS16 1JE

Study participating centre**The Newcastle upon Tyne Hospitals NHS Foundation Trust**

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Newcastle upon Tyne, Tyne and Wear
United Kingdom
NE7 7DN

Study participating centre**Cambridge University Hospitals NHS Foundation Trust**

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Hills Road
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CB2 0QQ

Study participating centre**Southampton University Hospitals NHS Trust**

Mailpoint 18
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SO16 6YD

Study participating centre**The Royal Marsden NHS Foundation Trust**

Fulham Road
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United Kingdom
SW3 6JJ

Study participating centre

Guy's And St Thomas' NHS Foundation Trust

Trust Offices

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Study participating centre

University Hospital Birmingham NHS Foundation Trust

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Royal Berkshire Hospital

Craven Road

Reading

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RG1 5AN

Study participating centre

South West London And St George's Mental Health NHS Trust

St George's Hospital

Blackshaw Road

Tooting, London

United Kingdom
SW17 0QT

Sponsor information

Organisation

University College London

ROR

<https://ror.org/02jx3x895>

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No

