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PREDICT: Prostate Patient Study

Submission date 20/08/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 31/08/2018	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 20/09/2023	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims
The number of men diagnosed with prostate cancer is rising, in the vast majority of cases the disease has not spread elsewhere (non-metastatic). Here, treatment decisions are complex, with the risks of a cancer diagnosis balanced against potential problems associated with treatment. National guidelines advise that evidence-based decision aids should be used, but no adequate individualised decision aid yet exists. To address the absence of such an important aid 'PREDICT: Prostate' has been developed. This is a decision model and website which provides personalised survival estimates based on an individual's characteristics and those of their cancer. The model allows the risk of dying from cancer to be contextualised against other risks of death and estimates the potential survival benefit from treatment. The aim of this study is to assess the clinical usefulness and potential impact of PREDICT: Prostate amongst patients diagnosed with prostate cancer. The study assesses the impact of the model on treatment decision-making, and on levels of concern, confidence and anxiety amongst newly diagnosed men, and assesses how PREDICT estimates compare to patients' perceptions about survival.

Who can participate?
Men aged 35-80 who are newly diagnosed with primary non-metastatic prostate cancer

What does the study involve?
Participants are randomly allocated to either standard of care (SOC) or to SOC and PREDICT. On the date of their next planned clinical follow-up appointment, participants are invited to attend the hospital slightly earlier for a study meeting. During this meeting, all participants are asked to complete a questionnaire. For those in the SOC and PREDICT group, this questionnaire follows a semi-structured presentation of the PREDICT: Prostate model. Those in the SOC group complete the questionnaire only. The participant's involvement in the study finishes after completion of the questionnaire with no further intervention or involvement required.

What are the possible benefits and risks of participating?
There is no guarantee that participants will benefit from taking part in this study. However, participation may help them decide about their treatment. Participation in this study may enable future refinements to the model and benefit future patients. PREDICT: Prostate is a decision-aid and therefore may influence participants' thinking about their prostate cancer. However, it is designed to inform them in order to help and assist in their decision-making.

Where is the study run from?
Addenbrooke's Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2018 to December 2020

Who is funding the study?
Urology Foundation (UK)

Who is the main contact?
Mr David Thurtle
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
39355

Study information

Scientific Title
Evaluation of a new tool, PREDICT: Prostate, to aid treatment decision-making for men with newly diagnosed non-metastatic prostate cancer

Study objectives
The number of men diagnosed with prostate cancer is rising, in the vast majority of cases the disease has not spread elsewhere (non-metastatic). Here, treatment decisions are complex, with the risks of a cancer diagnosis balanced against potential problems associated with treatment. National guidelines advise that evidence-based decision aids should be used, yet no adequate individualised decision aid yet exists. To address the absence of such an important aid the trialists have developed 'PREDICT: Prostate'. This is a decision model and website which provides personalised survival estimates based on an individual's characteristics and those of their cancer. The model allows the risk of dying from cancer to be contextualised against other risks of death and estimates the potential survival benefit from treatment.

This study seeks to assess the clinical usefulness and potential impact of PREDICT: Prostate amongst patients diagnosed with prostate cancer. The trialists will assess the impact of the model on treatment decision-making, and on levels of concern, confidence and anxiety amongst newly diagnosed men. They will also assess how PREDICT estimates compare to patients' perceptions about survival. They will also seek feedback about the model and its usefulness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/09/2018, REC East of England - Cambridge South (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +442071048104; NRESCommittee.EastofEngland-CambridgeSouth@nhs.net), ref: 18/EE/0254

Study design
Randomised; Both; Design type: Education or Self-Management, Psychological & Behavioural, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
Summary of design:
1. Study introduction and discussion
2. Return for study appointment (prior to next clinical follow up appointment).
2. Consent & randomisation to standard of care (SOC) or intervention (SOC + PREDICT) arm
3. SOC arm complete patient questionnaire
4. Intervention arm go through PREDICT: Prostate with researcher then complete patient questionnaire
5. Active participation concludes following completion of the patient questionnaire

Eligible patients newly diagnosed with PCa will be informed about the study by their diagnosing clinician, specialist nurse or another member of their clinical care team. If interested in the study, potential participants will then be approached in clinic and given information sheets, verbal information about the study and a copy of the consent form. Each will be given the opportunity to ask questions. Verbal consent to be contacted by telephone will be sought. Potential participants will then be contacted and invited to attend a study appointment prior to their next clinical follow-up appointment – where formal written consent will be completed prior to randomisation to one of the two study groups.

During the study appointment, participants will be asked to complete a questionnaire (appendix). For those in the intervention arm, this questionnaire will follow a semi-structured presentation of the PREDICT: Prostate model. Patients on the control arm will simply be asked to complete the questionnaire. These questionnaires assess decisional confidence and anxiety, treatment preferences, and patients' perceptions of risk regarding their disease – using validated scores for each.

For those in the intervention ('SOC+PREDICT') arm, the PREDICT: Prostate model itself will be presented on a computer by an individual researcher trained in the background of the model. They will present the model in a semi-structured manner. First the rationale, goals, and a detailed description of the decision aid will be presented, following the web-pages of the model. The participant's individual details will be entered into the model, then the results explained to participants using positive and negative terms, and expressing uncertainty. For example "out of 100 patients with the same age and disease characteristics as you, 16 are expected to die from prostate cancer in the next 10 years, 10 are expected to die from other causes, and 74 are expected to still be alive. At this moment we cannot say to which group you will belong." Graphs, charts, text, icons and actual numbers will be presented to the participants showing the

estimated outcomes with conservative management and radical treatment – following the design of the website (https://wintoncentre.maths.cam.ac.uk/prostate/#/tool). Adverse effects shown on the website will also be presented, alongside an explanation of where they have been derived from. The researcher will not themselves go into further details on technical aspects and will not offer clinical advice beyond explaining the website itself.

After completing the questionnaire the participants' involvement in the study will cease. All participants will see a clinician in a follow-up appointment as part of their clinical pathway immediately after their study appointment.

Intervention Type
Other

Primary outcome measure
Patient scores on decisional certainty measured by the decisional conflict scale at study appointment

Secondary outcome measures
1. Patient scores on state-anxiety measured on the State-Trait Anxiety Inventory (STAI-Y) at study appointment
2. Reported treatment preference and confidence in their decision on a 0-100 scale measured at study appointment
3. Actual treatment decided upon or received (as recorded in the medical notes) recorded up to 12 months after the study appointment

Overall study start date
01/07/2018

Completion date
30/07/2020

Eligibility

Key inclusion criteria
1. Men newly diagnosed with primary non-metastatic PCa
2. Men for whom either active surveillance or radical treatment (prostatectomy +/- radiotherapy) are felt to be appropriate by the diagnosing clinician
3. Age 35-80 years
4. Able to understand and sign the written Informed Consent Form

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants

Planned Sample Size: 150; UK Sample Size: 150

Total final enrolment
156

Key exclusion criteria
1. Subject is known to have a condition, which affects their ability to see, read or understand the decision aid
2. Subject is known to have any other condition, which in the opinion of the investigator makes the subject unsuitable for study participation
3. The subject is unable to comprehend English. (PREDICT Prostate is only available in English currently)

Date of first enrolment
15/09/2018

Date of final enrolment
25/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Hills Road
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Sponsor information

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Cambridge University Hospitals NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
Urology Foundation

Alternative Name(s)
TUF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Added 15/06/2021:
Abstract presentations accepted for British Association of Urological Surgeons conference June 2021 and European Association of Urology July 2021. Not yet publicly available.

Intention to publish date
31/08/2021

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are/will be available upon request from the study CI: david.thurtle@nhs.net. As per the study protocol, co-investigators or collaborators may be provided with fully-anonymised data when necessary, but will never be provided with any identifiable or potentially identifiable data

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v0	02/07/2018	31/08/2018	No	Yes
Protocol file	version v0	06/07/2018	31/08/2018	No	No
Results article		04/09/2021	08/12/2022	Yes	No
HRA research summary			20/09/2023	No	No