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# Prostate Testing for Cancer and Treatment (ProtecT) Feasibility Study

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|---|---|---|
| **Submission date**<br>20/11/2003 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>20/11/2003 | **Overall study status**<br>Completed | |
| **Last Edited**<br>26/09/2012 | **Condition category**<br>Cancer | |

**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**
HTA 96/20/06

## Study information

**Scientific Title**

**Acronym**

ProtecT

## Study objectives
The overall aim was to evaluate the feasibility of a randomised controlled trial (RCT) of treatments for localised prostate cancer, including:
1. Feasibility of case-finding in the community (including the reliability and psychosocial impact of PSA testing)
2. Determining the most efficient and effective design for a major trial of treatments
3. Randomised trial of recruitment strategies
4. Piloting outcome measures and procedures for the main trial of treatments

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Study design
Multicentre randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Not Specified

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

## Interventions
The study was an RCT of treatment preceded by case-finding in the community, with qualitative research methods integrated at each stage. Men with confirmed localised prostate cancer were asked to consent to randomisation between a nurse or urologist for an information appointment to discuss recruitment to the treatment trial. In the information appointment, the need for a trial was explained in detail, along with the advantages and disadvantages of each treatment, and the recruiter attempted to randomise the patient to the treatment trial or reach a patient-led preference for a treatment. All men, whether randomised or not, were asked to consent to be followed-up, and these formed a pilot for the proposed main trial.

See details of ProtecT main trial on http://www.controlled-trials.com/ISRCTN20141297

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
The primary outcome was the proportion of patients accepting randomisation to the treatment trial. Number of eligible patients randomised by nurses and urologists

### Key secondary outcome(s))
Cost effectiveness of nurses and urologists

### Completion date
31/05/2001

## Eligibility

### Key inclusion criteria
Men aged 50-69 years from specific primary care centres in the three cities were invited to attend a 30-minute prostate check clinic appointment in which they were informed about the study and asked to consent to a prostate specific antigen (PSA) test. Men with a raised PSA (initially ≥3.0 ng/ml if 5059 years; ≥4.0 ng/ml if 6069 years; but changed to ≥3.0 ng/ml for all men after 1 year) were invited for biopsy. Men with confirmed localised prostate cancer were invited to participate in a randomised trial of recruitment strategies.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Male

### Key exclusion criteria
Men considered by the GP to be unfit for any of the potential treatments (ie those terminally ill or with serious co-morbidity).

### Date of first enrolment
01/06/1999

### Date of final enrolment
31/05/2001

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Department of Social Medicine**
Bristol

United Kingdom
BS8 2PR

# Sponsor information

### Organisation
Department of Health (UK)

### ROR
https://ror.org/03sbpja79

# Funder(s)

### Funder type
Government

### Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

# Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 05/10/2002 | | Yes | No |
| Results article | results on patients' perceptions of randomisation and reasons for consent or refusal to participate in the ProtecT study | 01/06/2003 | | Yes | No |
| Results article | results on the effectiveness of nurses and surgeons in recruiting patients | 01/07/2003 | | Yes | No |
| Other publications | HTA monograph | 01/10/2003 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| | Study website | 11/11 | 11/11 | | |

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|---|---|---|---|---|
| Study website | /2025 | /2025 | No | Yes |