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IMProVE: a pilot study of prostate cancer screening in Yorkshire

Submission date 04/11/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol
Registration date 23/11/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 23/11/2026	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
In the UK, prostate cancer is the second commonest cause of cancer death in men and people with prostates. There is no NHS screening (searching for cancer in those without symptoms) for this cancer. Men considered at risk are offered a prostate specific antigen (PSA) blood test. However, this test is not definitive. Not all patients with prostate cancer have elevated PSA levels and high PSA values may be due to other causes. Screening for prostate cancer using PSA tests improves survival from the cancer but often finds slow growing cancers that do not need treatment. An MRI scan can identify which men have aggressive prostate cancer and which do not but is unaffordable for everyone. Evidence suggests that combining PSA testing with prostate MRI may improve the detection of aggressive prostate cancer while reducing unnecessary diagnosis of slow-growing cancers. This approach should reduce unnecessary detection of people with slow growing cancers, whilst saving many lives. Importantly, our approach is deliverable by the NHS. Before starting a larger trial, which might involve 300,000 people with a prostate, it is necessary to undertake a pilot study to test the study designs and ideas.

Firstly, the pilot will understand views of men from Black and from lower income backgrounds on prostate screening. Secondly, image-based testing will be compared with traditional NHS care in 4,500 people with a prostate. This study will find out how best to invite people who would benefit most. Thirdly, it will work out the most affordable way to screen for this cancer within the NHS.

Who can participate?
Men, or people with a prostate aged 50-69 years (inclusive) who are living at an address in selected locations within Leeds and Sheffield will be invited to take part. People who match the study criteria could also take part by signing up through our study website.

What does the study involve?
Taking part in the study may involve:
1. Clinic appointment for a Prostate Specific Antigen (PSA) blood test: about 30-45 minutes

2. Magnetic Resonance Imaging (MRI) scan or biopsy (if needed): separate appointments, about 1 hour each
3. Surveys: short online questionnaires completed at several time points over 12 months

What are the possible benefits and risks of participating?
Possible benefits:
Participants may not benefit directly however their participation will help improve how prostate cancer is detected in the future.

Possible risks:
Participants may need extra tests or appointments. Waiting for results may feel worrying for some people. Some cancers found may not have caused harm (overdiagnosis).

Where is the study run from?
The University of Sheffield is the sponsor. The Cancer Prevention Trials Unit at Queen Mary University of London is coordinating the study. The Coordinating Investigator is Professor James Catto, Consultant Urological Surgeon, University of Sheffield. The study team are also working with Sheffield Teaching Hospitals NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
April 2027 to June 2028.

Who is funding the study?
Yorkshire Cancer Research, UK.

Who is the main contact?
IMProVE study team at improve@qmul.ac.uk.

Contact information

Type(s)
Public, Scientific

Contact name
None - IMProVE study team

Contact details
Cancer Prevention Trials Unit (CPTU), Queen Mary University of London, 1st Floor Empire House, 67-75 New Road
London
United Kingdom
E1 1HH
-
sth.improve@nhs.net

Type(s)
Principal investigator

Contact name
Prof James Catto

ORCID ID
https://orcid.org/0000-0003-2787-8828

Contact details
Academic Units of Urology and Molecular Oncology, Department of Oncology and Metabolism, University of Sheffield, GU22, G Floor, The Medical School, Beech Hill Road
Sheffield
United Kingdom
S10 2RX
+44 114 215 9002
j.catto@sheffield.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
328102

Central Portfolio Management System (CPMS)
56053

Yorkshire Cancer Research Grant Code
RA\2024\R2\116

Study information

Scientific Title
Prostate cancer screening using a risk adapted PSA/image-based approach: pilot study for a Yorkshire-wide comparison with standard care

Study objectives
1. Determine screening uptake by invitation methods and demographic factors
2. To determine prostate cancers detected by each arm

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/09/2026, West Midlands - South Birmingham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; southbirmingham.rec@hra.nhs.uk), ref: 26/WM/0160

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Diagnostic, Screening

Study type(s)
Diagnostic, Screening

Health condition(s) or problem(s) studied
Malignant neoplasms of male genital organs

Interventions
Participants will be invited to take part in prostate cancer screening as part of the IMProVE study via 1 of 5 invitation routes, selected at random:
1. SMS invitation only
2. SMS invitation + SMS reminder
3. SMS invitation + letter reminder
4. Letter invitation + SMS reminder
5. Letter invitation only
These invitation methods will form a Study Within a Trial (SWAT). A SWAT analysis will be conducted after the first 10,000 invitations to evaluate the effectiveness of each methods, with ineffective methods discontinued.

Participants will be identified by NHS DigiTrials via searches of the Personal Demographics Service (PDS). Searches will be based on predefined postcode sectors within Sheffield and Leeds. A self-referral pathway will also be available to participants outside the main 5 invitation routes.

Consenting participants will be invited to mobile clinic visit in the community, where they will undergo Prostate Specific Antigen (PSA) and optional Polygenic Risk Scoring (PRS) testing. Participants who complete the PSA test will then be randomised into one of two study arms. Randomisation will be conducted by the Central Research Nursing Team using a randomisation electronic Case Report Form (eCRF) hosted in REDCap after valid PSA results are received from the laboratory. The randomisation schedule will be generated and maintained by the Trial Statistician. Randomisation will occur after PSA sampling, but the PSA result will not influence group allocation:
• Image-guided pathway: Participants whose PSA is >1ng/ml will be referred for a bi-parametric MRI (bpMRI) within a Community Diagnostic Centre (CDC). Participants found to have a lesion with a Likert score 4 or 5, will be referred for an image-guided prostate biopsy within a CDC. Based on the biopsy and MRI results, participants will either be discharged, referred for surveillance or referred for radical treatment via their local secondary care provider. Those with a Likert score of 3 will be offered a repeat PSA test at 6 months following their initial PSA result date. Those found to have a PSA density > 0.15nf/ml2 on the repeat PSA, will be referred to their local secondary care provider for a prostate biopsy as per local practice.
• NHS Pathway: Participants whose PSA is above their age-specific threshold will be referred for a multi-parametric MRI (mpMRI) within a CDC. Participants found to have a lesion with a Likert score of 4 or 5, and those with Likert 3 with a PSA density ≥0.15ng/ml2 will be referred for a prostate biopsy within a CDC. Based on the biopsy and MRI results, participants will either be

discharged, referred for surveillance or referred for radical treatment via their local secondary care provider.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Screening uptake by invitation methods and demographic factors measured using study data collection from the electronic Case Report Form (eCRF) system on attendance at screening following invitation, invitation cost by methods, and adherence with referrals (e.g. MRI, prostate biopsy, repeat PSA) at study end

2. Prostate cancers detected by each arm measured using screen-detected prostate cancer, clinical insignificant prostate cancer, clinically significant cancer and clinical stage at diagnosis, at study end

Key secondary outcome(s)
1. Baseline PSA and PRS values measured using PSA blood testing and optional PRS analysis of saliva samples at the baseline mobile clinic visit prior to randomisation

2. MRI findings measured using consultant radiologist-assigned Likert scores from bpMRI or mpMRI scans at following referral for MRI after PSA testing

3. Prostate biopsy findings measured using histopathology reports of biopsy samples, including Gleason Grade Group, maximum cancer core length, number of cores taken and number of cores with cancer, at the time of biopsy

4. Compliance with trial procedures measured using trial records of completion of protocol-specified MRI scans, biopsies and repeat PSA tests at throughout the study pathway until completion of study investigations

5. Compliance with end-of-trial referral measured using active follow-up data on adherence to end-of-trial referral recommendations at 6 months after diagnosis

6. Treatment patterns and outcomes in participants diagnosed with prostate cancer measured using routine NHS records and medical record review, including treatment pattern at diagnosis and active follow-up and treatment outcomes at 6 months post-diagnosis

7. Treatment patterns and outcomes compared with contemporary NHS prostate cancer patterns measured using diagnosis and treatment data, including patient characteristics, disease characteristics and treatments received, at diagnosis and active follow-up

8. Economic impact of screening measured using a health economic model incorporating trial data to estimate cost per quality-adjusted life year (QALY) gained and incremental net benefit over a lifetime horizon at study end

9. Clinical benefits of screening measured using a health economic model incorporating trial data to estimate QALYs gained over a lifetime horizon at study end

10. Lifetime NHS costs associated with screening measured using a health economic model incorporating trial data to estimate total screening, diagnostic and treatment costs and incremental cost per additional participant recruited over a lifetime horizon at study end

11. Clinical benefits of screening measured using a health economic model incorporating trial data to estimate life years gained and the detection of early-stage versus late-stage disease over a lifetime horizon at study end

12. Screening-related harms measured using a health economic model incorporating trial data to estimate false-positive rates and overdiagnosis over a lifetime horizon at study end

Completion date
30/06/2028

Eligibility

Key inclusion criteria
1. Capacity to provide informed consent prior to study entry
2. Men,or people with a prostate aged 50 – 69 years (inclusive) at the time of invitation into the study
3. Living at an address in selected locations within Leeds and Sheffield.
4. Have a phone number*
5. Have an NHS number
5. Residency in the UK for 12 months prior to consent to enter the study

*Participants recruited via NHS DigiTrials will require a mobile telephone number to receive the SMS study invitation.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 Years

Upper age limit
69 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. PSA testing within 12 months prior to invitation into the study
2. Prostate MRI scan within 24 months prior to invitation into the study
3. Prostate biopsy within 36 months prior to invitation into the study
4.Received antibiotics for urinary tract infection within 3 months prior to receiving invitation to the study
5. Current or prior prostate cancer diagnosis
6. Participant has opted out of data use via the National Data Opt-Out or Study Specific Opt-Out

7. A weight ≥ 200kg
8. Eastern Cooperative Oncology Group (ECOG) performance status ≥ 2 due to a severe comorbidity*
9. Known chronic kidney disease with estimated glomerular filtration rate (eGFR – based on the CKD-EPI Equation) of ≤30 mL/min/1.73 m² (CKD stage 4–5), receiving renal replacement therapy including dialysis, or previous kidney transplantation**

*NB – This will be self-reported by participants against the following lay wording “A severe medical condition which means you have difficulty carrying out normal daily activities e.g. able to care for yourself but unable to work or carry out strenuous activities.”

**NB – This will be self-reported by participants against the following lay wording “Have you ever been told by a doctor that you have severe kidney disease or kidney failure, or are you currently under hospital care for kidney failure or disease (for example, seeing a kidney specialist, receiving dialysis, or having had a kidney transplant)?”

Date of first enrolment
01/04/2027

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Northern General Hospital
Herries Road
Sheffield
England
S5 7AU

Study participating centre
St. James's University Hospital
Beckett Street
Leeds
England
LS9 7TF

Sponsor information

Organisation
University of Sheffield

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Government

Funder Name
Yorkshire Cancer Research

Alternative Name(s)
YCR

Funding Body Type
Government organisation

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

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date