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Evaluating a new way to provide ultrasound scans in community urology clinics without a specialist sonographer

Submission date
13/10/2026

Recruitment status
Recruiting

Registration date
11/11/2026

Overall study status
Ongoing

Last Edited
11/11/2026

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Ultrasound scans are one of the most common tests requested by NHS doctors, used to check the bladder, prostate and pelvic area. But there are not enough specialist staff trained to do these ultrasounds, so individuals often wait six to twelve weeks or more for an appointment, usually at a hospital. Waiting and travelling are hardest for older people, people with limited mobility, and people living in poorer or more remote areas.

Carrier Tech has developed a portable ultrasound system called CUS (Computed Ultrasound). It is designed so that any trained healthcare staff, rather than a specialist, can perform a scan. With this system, the whole 3D anatomy is imaged and can be reviewed remotely by a specialist. This study aims to find out whether CUS can fit into the normal running of a community urology clinic, and whether patients and staff find it acceptable. If it works well, people could have scans sooner and closer to home.

Who can participate?
Adults aged 18 or over who are attending a community clinic for a urology or prostate problem, and who have been referred for, or would benefit from, a pelvic, prostate or bladder ultrasound. Healthcare assistants, nurses and clinicians who carry out CUS scans or receive CUS reports can also take part by giving feedback.

What does the study involve?
Participants have one extra CUS scan, alongside their normal care. A small amount of gel is put on the lower abdomen and a handheld probe is moved gently over the skin. The scan takes a few minutes. Patients then answer a few questions about themselves and complete a short questionnaire about their experience. Taking part takes no more than 30 minutes, and there is no follow-up. An independent sonographer reviews the images. If the patient also has a standard hospital ultrasound, the two results are compared. Staff taking part complete a usability questionnaire and/or a 30-minute interview about using CUS in the clinic.

The study will measure whether the scans are good enough to be reported, whether patients and staff find CUS acceptable and easy to use, how long it takes to get a result, how quickly staff become competent at using CUS, and whether CUS fits into the clinic's normal routine without adding extra burden. For patients who also have a standard hospital ultrasound, the study will check how well the two results agree.

What are the possible benefits and risks of participating?
There is no direct benefit to participants, but the study will help decide whether scans like this can be offered in community clinics in future. Ultrasound is safe and painless and does not use radiation. Participants may feel light pressure from the probe or find the gel cold. Sometimes a scan shows something unexpected. If this happens, it is passed to the patient's own clinician to follow up in the usual way. Standard care is not changed or delayed.

Where is the study run from?
Carrier Technologies Ltd (UK). The data collection takes place at community urology clinics in England.

When is the study starting and how long is it expected to run for?
September 2026 to August 2027. The study runs for 12 months, and recruitment takes place over about 7 months of that time.

Who is funding the study?
The National Institute for Health and Care Research (NIHR) Invention for Innovation (i4i) FAST programme (UK).

Who is the main contact?
Jade Dougoud, jade@carriertech.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)

374406

Central Portfolio Management System (CPMS)
75006

National Institute for Health and Care Research (NIHR)
521955

Study information

Scientific Title
Evaluating the integration of a guided 3D ultrasound imaging system (CUS) operated by non-specialist staff in a community urology setting

Study objectives
Primary objective
To assess whether a guided 3D ultrasound imaging system (CUS), operated by trained non-specialist staff, can be operationally integrated into routine community urology clinic workflow. Operational integration is evaluated through pre-specified process metrics: scan adequacy rate (benchmark ≥90%), time-to-result, patient acceptability, operator usability, clinic operational feedback, operator competency sign-off rate, and upstream and downstream resource impact.

Secondary objectives
1. To determine the proportion of CUS findings sufficient to inform clinical management without onward imaging referral
2. To assess the landmark clarity of CUS acquisitions
3. To confirm that diagnostic quality is retained in the community setting, through concordance with conventional ultrasound where a standard-of-care scan is available
4. To describe operator workflow efficiency over successive scans, together with uptake, completion, attrition and competency data across operators and sites

The study will also generate input parameters for a subsequent health-economic analysis.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/09/2026, London – Brighton & Sussex Research Ethics Committee (Redman Place, Stratford, London, E20 1JQ, United Kingdom; Not available; brightonandsussex.rec@hra.nhs.uk), ref: 26/PR/1161

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Health services research

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Renal and urogenital imaging

Interventions
This is a multi-site, cross-sectional mixed-methods integrational study. It combines simple counts and measurements (for example, whether a scan taken by a non-specialist is good enough to use, and how long a result takes) with questionnaires and short interviews about people's experience. For participants, the study involves a single visit with no follow-up.

Step 1: Invitation
The clinic team identifies people with a urology or prostate concern who have been referred for, or would benefit from, a bladder, prostate or pelvic ultrasound. They are told about the study in person at their appointment, or by one text message from the clinic with a link to the participant information sheet (PIS).

Depending on site capacity, the study procedures may take place at an existing appointment, or during a separate 30-minute study session, for which travel costs are reimbursed up to £20.

Step 2: Consent
A member of the clinic team explains the study, gives the PIS and answers questions. Consent is given on the day of the study procedures, in person. Taking part is voluntary, and declining does not affect care, which is explicitly stated. Translated materials and online consent are available. Each participant receives a study number, and all data are recorded under it. Study procedures are done in addition to, not instead of, the participant’s usual care.

Step 3: The scan
A trained healthcare staff member from the site with no previous ultrasound experience performs one trans-abdominal CUS (computed ultrasound) scan. This is a non-invasive ultrasound using a handheld probe on the skin, similar to standard ultrasound. The scan takes under five minutes and can be stopped at any time.

Step 4: Questionnaire
After the scan, the participant completes a short questionnaire about their experience of having a community scan, and demographic information is collected (age, sex, ethnicity, height, weight and postcode). This takes under ten minutes.
Participation should add no more than 30 minutes to the visit.

An independent sonographer reviews the images. The report goes back to the clinic under the study number and is passed to the participant’s clinician through the usual results process.

Possible significant findings are reported to the clinician within one working day. Any standard ultrasound goes ahead as planned.

With optional consent, the clinic can share any standard bladder, prostate or pelvic ultrasound images and report from the study period, labelled with the study number only. These are used to compare the two scans.

Participants can withdraw at any time through their clinic.

Staff participants: Clinic staff and operators are invited by the research team to share feedback via questionnaires, the interview, or both. They are approached directly by the researcher, receive a staff PIS and have 72 hours to decide.
Operators rate their confidence after training and during the data collection period. Scan timings are recorded under their study number and are not used to assess individual performance.

The 20-minute semi-structured interview, in person or online, takes place at the end of the data-collection period. It is audio-recorded with consent, and the recording is deleted after transcription.

Intervention Type
Mixed

Primary outcome(s)
1. Scan adequacy measured using the proportion of CUS scans adequate for reporting, rated pass /fail for image quality and completeness by an independent sonographer at review of each scan

2. Time-to-result measured using the interval from CUS scan and clinical appointment to available report, recorded on operational data forms for each scan. Where applicable, it is compared with the participant's conventional ultrasound referral-to-report interval; at review of each scan

3. Patient acceptability measured using a satisfaction and acceptability questionnaire at the single study visit, immediately after the scan

4. Operator usability and confidence measured using a short questionnaire every five days of scanning, and through the the System Usability Scale (SUS) and semi-structured interviews at the end of the data collection period

5. Clinic operational burden, cost and benefits measured using questionnaires and semi-structured interviews with operators, clinicians, and supporting staff at the end of the data collection period

6. Competency sign-off measured using the training length needed to reach sign-off for each operator, and the sign-off rate across operators, recorded in training records at completion of training

7. Resource impact measured using reporting time per CUS scan, onward imaging referral rate, and secondary care appointments avoided or generated. These are taken from clinician questionnaires, clinic activity data, semi-structured interviews and site-agreed estimates, at timepoints across the data collection period

Key secondary outcome(s)
1. Pathway integration measured using the proportion of CUS findings sufficient to inform clinical management without onward imaging referral, assessed at report review for each scan

2. Landmark clarity measured using an ordinal clarity rating by the independent sonographer at review of each scan

3. Concordance between CUS and conventional ultrasound, measured using a randomised paired review by an independent reviewer, at once the standard-of-care ultrasound has been reported, in the subset of participants who have one

4. Workflow efficiency, measured using scan and setup time recorded on operational data forms at each scan. These times are analysed against cumulative scans per operator across the data collection period.

5. Uptake, completion and attrition measured using site enrolment logs and study records at the end of recruitment

Completion date
31/05/2027

Eligibility

Key inclusion criteria
Patient participants:
1. Adults aged 18 or over
2. Seeking clinical care for a urology or prostate concern
3. Referred for a pelvic, prostate, or bladder ultrasound, or would benefit from an ultrasound referral (according to NICE guidelines)
4. Willing and able to give written informed consent

Operator and clinician participants (usability and interview data):
1. Healthcare assistant, nurse or clinician involved in delivering CUS scanning or receiving CUS reports
2. For operators: completion of the study training programme and documented competency sign-off
3. Willing and able to give written informed consent

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex

All

Total final enrolment
0

Key exclusion criteria
Patient participants:
1. Unable to give informed consent
2. Unable to tolerate a transabdominal ultrasound scan
3. Broken or infected skin over the scanning area, or known allergy or sensitivity to water-based ultrasound gel
4. Clinical presentation requiring urgent or emergency imaging, as judged by the treating clinician

Operator and clinician participants:
Unable to give informed consent

Date of first enrolment
11/10/2026

Date of final enrolment
31/05/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Workington Cdc
Central Way
Workington
England
CA14 3GS

Study participating centre
Hillcrest Surgery
337 Uxbridge Road, Acton
London
England
W3 9RA

Study participating centre

Ashburton Surgery
1 Eastern Road
Ashburton
Newton Abbot
England
TQ13 7AP

Study participating centre
Frome Medical Practice
Frome Medical Centre
Enos Way
Frome
England
BA11 2FH

Study participating centre
Seaford Medical Centre
Dane Road
Seaford
England
BN25 1DH

Study participating centre
The Grange Practice
The Montefiore Medical Centre
Dumpton Park Drive
Ramsgate
England
CT11 8AD

Sponsor information

Organisation
Carrier Technologies Limited

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from Jade Dougoud (jade@carriertech.uk).
Type of data: anonymised participant-level quantitative data (scan adequacy and landmark clarity ratings, operational and time-to-result data, questionnaire responses and basic demographics) and de-identified CUS imaging volumes (DICOM/NIfTI). Standard-care ultrasound images and reports transferred for the concordance analysis will not be shared. Interview transcripts will not be shared, to protect the confidentiality of a small and identifiable staff group.
When and for how long: after publication of the main results, for the duration of the study data retention period.
Access criteria: requests from academic or clinical researchers for research or the development of new tests, devices or treatments, subject to review by the Sponsor and a data sharing agreement.
Consent: participants give optional consent for their anonymised data to be used in future research. Only data from participants who gave this consent will be shared.
Anonymisation: data are held against study number only. They become fully anonymous once site enrolment logs are destroyed at the end of the study.
Restrictions: data will be shared only in line with participant consent and UK GDPR.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	24/09/2026	05/11/2026	No	Yes
Participant information sheet	version 1.3	21/10/2026	05/11/2026	No	Yes
	version 1.3				

Protocol file	04/11/2026	05/11/2026	No	No