ISRCTN45369814 https://doi.org/10.1186/ISRCTN45369814

Using handheld ultrasound in community centres to help diagnose heart failure earlier

Submission date
18/06/2026

Recruitment status
Recruiting

Registration date
22/06/2026

Overall study status
Ongoing

Last Edited
21/07/2026

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Heart failure is a common condition in which the heart cannot pump blood around the body as effectively as it should. Symptoms can include breathlessness, tiredness and swollen ankles. People with suspected heart failure are usually referred for a specialist heart ultrasound scan (echocardiogram) and assessment. However, long waiting times for these tests can delay diagnosis and treatment, which may lead to worsening symptoms, hospital admission and poorer health outcomes.

New handheld ultrasound devices can be used closer to patients' homes and include artificial intelligence (AI) technology to help analyse the scan images. These devices may allow earlier assessment of people with suspected heart failure. This study aims to evaluate whether an AI-supported handheld heart scan performed by trained non-specialist healthcare practitioners in Community Diagnostic Centres can safely speed up diagnosis and treatment, provide results comparable to standard hospital-based scans, and be acceptable to patients and healthcare staff.

Who can participate?
Adults with symptoms suggestive of heart failure and a raised NT-proBNP blood test who have been referred from primary care for specialist heart failure assessment.

What does the study involve?
Participants will attend a Community Diagnostic Centre where a trained healthcare practitioner will perform a handheld ultrasound scan of the heart using an AI-supported device. Participants will then continue with their usual NHS care, including specialist assessment and standard hospital-based echocardiography where clinically required. Researchers will compare the results of the handheld scan with the standard heart scan and review healthcare records to determine how quickly diagnosis and treatment occur. Participants may also be invited to complete a questionnaire about their experience of the assessment pathway.

What are the possible benefits and risks of participating?
Participants may not receive any direct benefit from taking part. However, the handheld scan may provide information that supports earlier assessment and diagnosis. The findings from this study may help improve future heart failure services and patient care.

The handheld ultrasound scan is non-invasive and does not use radiation. The risks associated with participation are considered low. There is a small possibility of inconvenience from attending appointments or completing questionnaires. Any clinically important findings identified during the study will be managed according to standard NHS practice.

Where is the study run from?
The study is coordinated by the University of Leeds and delivered through participating NHS Community Diagnostic Centres, and Leeds Teaching Hospitals and Barts Health in United Kingdom.

When is the study starting and how long is it expected to run for?
July 2026 to June 2028.

Who is funding the study?
GE Healthcare via British Society of Echocardiography (BSE)

Who is the main contact?
Dr Maria F Paton, m.paton@leeds.ac.uk

Contact information

Type(s)
Scientific, Public

Contact name
Dr Nurul Abdul Samad

ORCID ID
https://orcid.org/0000-0002-1364-8311

Contact details
Leeds Institute of Cardiovascular & Metabolic Medicine, School of Medicine, University of Leeds
Leeds
United Kingdom
LS2 9JT
-
n.h.abdulsamad@leeds.ac.uk

Type(s)
Principal investigator

Contact name
Dr Maria F Paton

ORCID ID
https://orcid.org/0000-0001-8517-4621

Contact details
Leeds Institute of Cardiovascular & Metabolic Medicine, School of Medicine, University of Leeds
Leeds

United Kingdom
LS2 9JT
-
m.paton@leeds.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
364939

Central Portfolio Management System (CPMS)
72155

Study information

Scientific Title
Supporting community AI-enabled non-specialist point-of-care ultrasound for earlier diagnosis and treatment for heart failure

Acronym
Scan-EF

Study objectives
The study aims to evaluate whether an AI-supported handheld heart scan performed by trained non-specialist practitioners in Community Diagnostic Centres can accelerate heart failure diagnosis and treatment compared with standard care pathways, provide measurements comparable to specialist transthoracic echocardiography, and be acceptable to patients and healthcare practitioners.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/06/2026, London - Queen Square Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; no telephone number provided; queensquare.rec@hra.nhs.uk), ref: 26/PR/0495

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment

Single

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Heart failure

Interventions
We will invite adults who have been referred by their primary care to a specialist heart assessment because of symptoms and a raised NTproBNP blood test suggesting possible heart stress. These patients are already waiting for a standard hospital-based specialist heart scan and consultant review as part of usual NHS care following NICE standard diagnostic pathway.

If a patient agrees to take part, they will attend one additional visit for a community-based AI-handheld heart scan at CDC prior to their specialist heart assessment. This visit will last about one hour.

At this appointment:
A member of the research team will explain the study and answer questions.
If the patient wishes to take part, they will sign a consent form.
The research team will collect relevant background information from the patient's medical record (such as age, medical history, current medication, blood test results and referral details).
The patient will then have a handheld ultrasound scan of their heart.
This scan will be performed by a trained healthcare professional.
The device uses AI to help capture images and estimate heart function.
The images will be reviewed and validated by a specialist practitioner (BSE-accredited echocardiographer).
All participants will be asked to complete a patient experience survey at the end of the study visit. The local non-specialist practitioner will be asked to complete a practitioner competency and confidence survey following each participants at the end of study visit.

If the scan shows a possible problem with heart function, the result will be escalated to the specialist heart team. Any decisions about diagnosis or starting treatment will be made by that clinical team as part of standard care.

After this additional community-based AI-handheld heart scan ultrasound, all participants will continue with their standard diagnostic pathway. This includes their hospital-based specialist heart scan and consultant review, whether or not they choose to take part in the study.

There are no additional follow-up visits required for the research. We will collect information from the participant's planned specialist heart scan to compare the results with those obtained from the AI-supported handheld scan. We will also review routine NHS medical records for up to six months after the scan to assess the timing of diagnosis and treatment.

Participants take part in one additional visit only, and their usual NHS care is not delayed or replaced by the study.

Any serious adverse event (SAE) occurring in a research participant, where, in the opinion of the Chief Investigator the event was related to the administration of any of the research procedures will be reported to the Sponsor (governance@ethics@leeds.ac.uk) within one working day of the research team's awareness. SAE will be recorded during the participant's visit, and documented in the electronic healthcare record. Untoward events which occur after the study visit has been completed or are not directly related to the study visit will not be reported. It is anticipated that during this study we will identify important heart muscle weakness, or other abnormal findings on cardiac ultrasound
These findings, and any untoward event which occur as a consequence of new diagnoses /findings (such as hospitalisation) will not be reported to the Sponsor of REC as these are regarded as being part of the patient's usual clinical care.

Intervention Type
Other

Primary outcome(s)
1. Time from initial handheld heart scan assessment to confirmed diagnosis of heart failure measured using review of electronic healthcare records and study case report forms to determine the date of handheld heart scan assessment and the date of confirmed heart failure diagnosis at baseline assessment until confirmed diagnosis of heart failure (up to 6-months after enrolment)

2. Time from initial handheld heart scan assessment to initiation of guideline-directed heart failure treatment measured using review of electronic healthcare records, prescribing records and study case report forms to determine the date of handheld heart scan assessment and the date of first heart failure treatment initiation at baseline assessment until initiation of heart failure treatment (up to 6-months after enrolment)

Key secondary outcome(s)
1. Agreement between AI-derived handheld heart scan measurements and specialist transthoracic echocardiography measurements, including left ventricular ejection fraction and other predefined cardiac parameters measured using comparison of handheld heart scan device outputs with specialist transthoracic echocardiography measurements assessed by Bland–Altman analysis, correlation coefficients and diagnostic agreement measures at baseline assessment

2. Proportion of handheld heart scans that are of sufficient quality for clinical interpretation and AI analysis measured using predefined image quality criteria to determine the proportion of analysable scans at baseline assessment

3. Patient satisfaction with the community-based handheld heart scan pathway measured using the Patient Satisfaction Questionnaire (PSQ18) following completion of the diagnostic pathway

4. Practitioner competency and confidence in performing and interpreting handheld heart scan assessments measured using the Practitioner Competency and Confidence questionnaire (Bull and Dale 2021, STAI-6) at baseline training assessment and study completion

5. Proportion of handheld heart scans identifying clinically actionable cardiac findings requiring further investigation or treatment measured using review of handheld heart scan reports, specialist transthoracic echocardiography reports and clinical records at baseline assessment and completion of the diagnostic pathway

6. Incidence of adverse events related to the handheld heart scan pathway measured using review of participant medical records, adverse event reporting forms and study documentation throughout study participation

7. Resource utilisation and care pathway metrics, including number of appointments, referrals and investigations measured using review of healthcare records, service activity data and study case report forms throughout the diagnostic pathway until completion of follow-up

8. Healthcare resource use and costs associated with the community-based handheld heart scan pathway compared with standard care measured using collection of resource utilisation data from healthcare records, service activity data and study case report forms throughout the diagnostic pathway until completion of follow-up

Completion date
30/06/2028

Eligibility

Key inclusion criteria
1. Adult patients aged >=18 years
2. Patient with suspected for heart failure and referred to specialised heart failure investigation /centre
3. Ability to provide informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients who are unwilling or unable to provide informed consent
2. Patients known to have heart failure or any previous measurement of LVEF <50%

Date of first enrolment
30/07/2026

Date of final enrolment

31/01/2028

Locations

Countries of recruitment
United Kingdom

England

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

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
GE Healthcare Limited

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be available upon reasonable request from the Chief Investigator.

The data that may be shared will include anonymised participant-level study data, study protocol, statistical analysis plan and associated study documentation where appropriate.

Data will become available following publication of the primary study results and will remain available for up to 8 years following study completion, subject to institutional data retention policies.

Access may be granted to researchers whose proposed use of the data has been reviewed and approved by the study team and sponsoring institution. Data will be provided for the purposes of scientific research, secondary analyses, or meta-analyses.

Data requests should be submitted to Dr Maria F Paton (m.paton@leeds.ac.uk). Approved requests will require a data sharing agreement and compliance with applicable data protection regulations.

All shared datasets will be fully anonymised prior to release. No directly identifiable participant information will be shared.

Data sharing is subject to participant consent, ethical approval conditions, UK data protection legislation, and University of Leeds data governance requirements.

IPD sharing plan summary

Available on request