ISRCTN22229432 https://doi.org/10.1186/ISRCTN22229432

The CHART trial – comprehensive assessment for older people with heart failure and frailty

Submission date
29/10/2024

Recruitment status
Recruiting

Registration date
06/11/2024

Overall study status
Ongoing

Last Edited
04/11/2025

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
Frailty is a condition that is common in older age. It develops because as we get older our bodies change and can lose their resilience. This means that older people with frailty can experience sudden, dramatic changes in their wellbeing when they have health problems. Heart failure (HF) is a complex condition where the heart muscle doesn't pump blood as well as it should because it has become too weak or stiff. People with heart failure with preserved ejection fraction (HFpEF) have symptoms of heart failure even though their heart pumps blood well.

Current NHS services are not well developed for people who have multiple health problems. This means people with frailty and HFpEF may not receive the right sort of care they need. Comprehensive Geriatric Assessment (CGA) involves older people as well as their families, carers and healthcare professionals to identify and help manage multiple health problems and prevent new ones arising. Rehabilitation helps people to do what is important to them.

Our research aims to work out if, CGA (including rehabilitation at home) in addition to usual care helps frail older people with HFpEF maintain their ability to carry out everyday activities. This will be compared to people getting usual care alone.

Who can participate?
We aim to recruit 433 people from 17 sites who have HFpEF and frailty, and are aged 65 years or above. Potential participants will be invited to take part from cardiology services and followed-up by a researcher who will confirm eligibility and take consent and complete Baseline assessments.

What does the study involve?
Participants in the study will be randomised to receive either CGA, 12 weeks of home-based rehabilitation, and their usual care or, their usual care only.
We will follow-up participants at 6 and 12 months after they agreed to take part and continue to collect information about them from NHS registries, such as NHS England until 24 months.

What are the possible benefits and risks of participating?
BENEFITS:

Although we don’t know if our new treatment programme helps people with heart failure, you might find it useful to you. You may have more frequent contact with a care team, which you may find helpful. You will also be contributing to important research that may benefit patients in future.
RISKS:
We do not expect there to be many risks to taking part. Agreeing to take part in the study means that if you receive the new treatment programme you will need to attend additional appointments and allow member(s) of the physiotherapy team to visit you at home.
As the treatment involves activities you may experience muscle soreness. The physiotherapy team member will make sure that the exercise is appropriate for you.
You will give up some of your time to complete questionnaires. We will ask you some questions about your health and wellbeing. You don’t have to answer any questions you don’t wish to.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
March 2024 to February 2029

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Hollie Wilkes / CHART Trial Team, ctru-chart@leeds.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
345486

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 55645, NIHR155936

Study information

Scientific Title
Comprehensive geriatric assessment (CGA) to sustain independence for older people living with heart failure with preserved ejection fraction (HFpEF) and frailty: The CHART Trial

Acronym
CHART

Study objectives
To establish whether Comprehensive Geriatric Assessment (CGA) including a 12-week progressive rehabilitation programme (plus usual care) sustains Instrumental Activities of Daily Living IADL at 12 months post-randomisation.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/10/2024, Yorkshire & The Humber - Leeds East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8012; leedseast.rec@hra.nhs.uk), ref: 24/YH/0185

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Older people living with heart failure with preserved ejection fraction and frailty

Interventions
The study is called an individually randomised controlled trial with participants being randomly allocated to the control group (usual care only) or the intervention group (usual care plus comprehensive geriatric assessment and a 12-week home-based rehabilitation programme). The home-based rehabilitation programme will be supported by a trained therapist. We need a control group to help us check that any changes we see are not due to chance.

The study will aim to recruit a total of 433 participants. We will be recruiting the participants from 17 UK hospitals with cardiology services. To ensure the delivery of the study is feasible, we will review participant recruitment rates and the number of participants who have had their CGA assessment as part of an internal pilot. Nine sites will be included in the pilot, and we will assess the progression after nine months of recruitment.

Recruitment will take place from a minimum of 17 sites across three hubs (North West, Yorkshire & Humber, South West). Participants will be identified in three main ways:
1. Prospective identification - participants with HFpEF seen in cardiology services will be identified by site staff.
2. Site staff will screen electronic records and heart failure clinic letters to identify potential participants diagnosed with HFpEF.
3. Identification of participants via the National Institute for Health and Care Research-British Heart Foundation Cardiovascular Partnership national registry.

In all routes of identification, participants will be provided with an invitation to take part in the study, alongside a Summary Study Leaflet. Participants who express an interest will be contacted by a CHART researcher who will explain more about the study and provide them with

a full information sheet. They will also seek verbal consent to collect some information about the potential participant and confirm eligibility. If the study is suitable for the participant, they will be invited to provide written consent and then be randomised onto the study.

Participants will be notified by letter of the outcome of the randomisation. The letter and accompanying leaflet will provide information on the next steps.

Participants allocated to the CHART programme will be approached by a member of the geriatrics team in their local hospital to arrange an appointment for the comprehensive geriatric assessment. At the assessment, they will discuss what is important to the participant and come up with a care plan. There will be at least one more follow-up appointment with this team.

For the home-based therapy part of the CHART programme, a member of the physiotherapy team will contact the participant and arrange a time to visit the participant and introduce them to a programme that aims to improve strength, balance, and movement. Participants will have weekly contact with the member of the therapy team with a mixture of face-to-face appointments in the participant's home and telephone calls.

As part of this study, we will define "usual care" within the study population by asking participants what services they have accessed. Usual care would broadly be summarised as the wide range of care provided in the community, such as GP appointments, hospital appointments, community, and social services.

To help further understand the CHART treatment programme (intervention) and usual care, researchers will be looking at the care appointments participants have and will also be performing interviews with staff and participants in a sample of willing participants. This is called an embedded process evaluation.

Additional data (follow-up) will be collected from all participants at 6 and 12 months following randomisation. The data will be self-reported with participants either completing postal questionnaires or electronic questionnaires. Participants may also complete the questionnaires over the telephone or in their own home with the support of a researcher. Researchers will also have access to participants' health records to check addresses and confirm status before contact points. Researchers collecting follow-up data will be unaware of the participant's allocation (blind) and will be asked to document if they become aware of the participant's allocation during the study.

The study team will also collect health and treatment information about participants held in central NHS databases, via providers such as NHS England. This data will be collected at 6, 12, and 24 months after randomisation.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
To establish whether CGA including a 12-week progressive rehabilitation programme (plus usual care) sustains IADL – measured using the Participant reported Nottingham Extended Activities of Daily Living (NEADL) at 12 months post-randomisation.

Key secondary outcome(s))
1. To establish whether the intervention reduces hospitalisation (all-cause; HF-specific; falls; MACCE) and mortality – measured using Hospital Episodes Statistics (HES) / Civil Registrations data at 6-, 12- and 24-months post-randomisation
2. To establish whether the intervention sustains basic ADL, health-related quality of life and mental health – measured using Participant reported NEADL; Barthel Index; EuroQol 5-dimension health questionnaire (EQ5D-5L); Patient Health Questionnaire (PHQ-8); ICEpop CAPability measure for Older People (ICECAP-O) at baseline, 6- and 12-months post-randomisation
3. To establish whether the intervention improves Days alive and out of hospital – measured using Hospital Episodes Statistics (HES) / Civil Registrations data at 6-, 12- and 24-months post-randomisation
4. To establish whether the intervention reduces home care requirement, new care home placement, and overall health/social care resource – measured using Hospital Episodes Statistics (HES) / Civil Registrations data; participant reported health and social care resource use; researcher review of address at 6- and 12-months post-randomisation

Completion date
14/02/2029

Eligibility

Key inclusion criteria
Current inclusion criteria as of 04/11/2025:

1. Aged ≥65 years
2. Clinical diagnosis of HFpEF*
3. Mild, moderate or severe frailty based on the Clinical Frailty Scale (CFS 5-7)
4. Capacity to provide informed consent (assessed prior to registration)
5. Most recent echocardiogram within the last 2 years and showing LVEF ≥50%
*Diagnosis confirmed by a cardiology specialist. Retrospective identification from clinic letters is a reasonable reference standard as this diagnosis will have been based on guideline standard at the time.

Previous inclusion criteria:

1. Aged >= 65 years
2. Clinical diagnosis of HFpEF*
3. Mild, moderate or severe frailty based on the Clinical Frailty Scale (CFS 5-7)
4. Capacity to provide informed consent (assessed prior to registration)

*Diagnosis confirmed by a cardiology specialist. Retrospective identification from clinic letters is a reasonable reference standard as this diagnosis will have been based on guideline standard at the time. N.B. As per guidelines LVEF of 40-49% should not be considered eligible.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
65 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 28/01/2025:

1. Not frail (as determined by a score on CFS 1-4);
2. Very severe frailty (CFS 8);
3. Terminally ill with an anticipated life expectancy of < 6 months ;
4. Care home resident;
5. Unstable angina*;
6. New York Heart Association (NYHA) class IV HF (assessed after registration by a CHART researcher);
7. Another household member participating in the trial**;
8. Moderate/severe cognitive impairment (Face-to-face Montreal Cognitive Assessment MoCA score of <18 or Blind Montreal Cognitive Assessment MoCA score of <13) (assessed after registration by a CHART researcher)
9. Significant alternative valvular/structural cardiac disease to explain symptoms***;
10. Current hospitalisation or within the last 3 months with decompensated heart failure
11. Referred or receiving CGA and/or exercise-based rehabilitation as part of a clinical service or another research project****.
*A CHART researcher will ask the participant at time of registration whether they have angina and then ask if they have symptoms at rest to determine eligibility.
**A CHART researcher will ask the participant at time of registration whether anyone in their household is also participating in CHART.
***Valve disease exclusions include: severe aortic stenosis, severe aortic regurgitation, severe mitral regurgitation, moderate or severe mitral stenosis. Participants with these exclusions will be screened out prior to initial approach for the study.
**** Patients referred to or currently being seen in community frailty services, outpatient geriatric medicine services or outpatient/community falls prevention services. A CHART researcher will assess through discussion with the potential participant

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Previous exclusion criteria:

1. Not frail (as determined by a score on CFS 1-4);
2. Very severe frailty (CFS 8);
3. Terminally ill (CFS 9);
4. Care home resident;
5. Unstable angina*;
6. New York Heart Association (NYHA) class IV HF (assessed after registration by a CHART researcher);
7. Another household member participating in the trial**;
8. Moderate/severe dementia (Montreal Cognitive Assessment MoCA score < 18) (assessed after

registration by a CHART researcher);
9. Under regular review from geriatric medicine services;
10. Significant alternative valvular/structural cardiac disease to explain symptoms***;
11. Current hospitalisation with decompensated heart failure
12. Receiving or referred for CGA as part of a clinical service or another research project****.

*A CHART researcher will ask the participant at time of registration whether they have angina and then ask if they have symptoms at rest to determine eligibility.
**A CHART researcher will ask the participant at time of registration whether anyone in their household is also participating in CHART.
***Valve disease exclusions include: severe aortic stenosis, severe aortic regurgitation, severe mitrial regurgitation, moderate or severe mitral stenosis. Participants with these exclusions will be screened out prior to initial approach for the study.
****Patients seen in community frailty services, outpatient geriatric services, outpatient clinic-based falls services will be screened out prior to study invitation. CHART researchers will do a further check of involvement in these services prior to randomisation.

Date of first enrolment
07/02/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

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

Study participating centre

Calderdale and Huddersfield NHS Foundation Trust
Trust Headquarters
Acre Street
Lindley
Huddersfield
United Kingdom
HD3 3EA

Study participating centre
Harrogate and District NHS Foundation Trust
Harrogate District Hospital
Lancaster Park Road
Harrogate
United Kingdom
HG2 7SX

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
Mid Yorkshire Teaching NHS Trust
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre

Royal Cornwall Hospitals NHS Trust
Royal Cornwall Hospital
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
Cornwall Partnership NHS Foundation Trust
Carew House
Beacon Technology Park
Dunmere Road
Bodmin
United Kingdom
PL31 2QN

Study participating centre
Torbay and South Devon NHS Foundation Trust
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
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M13 9WL

Study participating centre

Bolton NHS Foundation Trust
The Royal Bolton Hospital
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Individual participant data (IPD) sharing plan
De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.

CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security), and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will

govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.

The CTRU encourages a collaborative approach to data sharing, and believe it is best practice for researchers who generated datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.

The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree suitable requirements for release.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes