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Depression in patients with heart failure

Submission date 04/09/2022	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 07/03/2023	**Overall study status** Ongoing	
Last Edited 18/06/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims

Many people in the North East and North Cumbria in England (UK) have heart failure, some of whom will also suffer with depression. Having both conditions is particularly challenging. It means you are more likely to have a worse quality of life, feel more fatigued and more likely to need hospital treatment for your heart failure. It also increases the chances of poor outcomes, such as heart transplant or death. It is much harder to diagnose depression in people with heart failure, so you may be less likely to access specialist mental health support. Also, the usual treatments for depression (talking therapies and medication) do not appear to be helpful in patients with heart failure.

The autonomic nervous system controls the unconscious activity in our body. It has an important role in regulating heart rate. Normally there is variation to the heart rate: sometimes the heart beats a little faster and sometimes a little slower. We call this 'heart rate variability' and it is a sign of a healthy heart. Heart rate variability is often reduced in heart failure and in depression. Therefore, we wonder if dysregulation of the autonomic nervous system is an important link between heart disease and mood, leading to worse outcomes.

Who can participate?

Adults over 18 years, with heart failure.

What does the study involve?

We want to learn more about depression in people with heart failure. We will interview people with heart failure and collect information about their mood, fatigue, quality of life and autonomic nervous system function. Many people with heart failure have implanted heart monitors. They allow us to measure their heart rates, and we will use these data to study heart rate variability – this will be an indicator of autonomic nervous system function. A single blood test will be taken to understand how well the heart is functioning, so that we can correlate heart disease severity with our findings.

What are the possible benefits and risks of participating?

Participants will not have any direct benefit from participating in our study. However, the results of our study might one day help improve the way we identify and treat depression in people with heart failure. We hope that this will help patients and families in this situation to improve their quality of life. If you choose to participate, you will be a fundamental part of making things better.

Apart from asking participants some questions and taking a blood test, we are not doing anything to them that wouldn't normally happen. Because of this, we are not expecting any side-effects to develop. As a result of getting a blood sample collected, participants might experience pain, bruising, light-headedness and on rare occasions, infection. We will help them get assistance if that happens. The usual NHS indemnity scheme will apply to all activities of this study.

We will talk about sensitive topics such a low mood and depression. The person who will interview the participants is a psychiatrist, a medical doctor who is specially trained to do this. We will do our very best to be sensitive in our approach. Participants might still find it distressing and will offer help if that is the case. If we do find that participants have depression and if they feel that they don't have enough help for this, we can help them get in touch with their GP. We will not give them any treatment for depression as part of the study, but we can tell them how to get help.

There will be no changes to the heart failure treatment as a part of this study. If participants feel that they need any extra help, we can help them speak to the doctors and nurses at Newcastle Hospitals who look after their hearts.

Where is the study run from?
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2020 to June 2026

Who is funding the study?
Newcastle upon Tyne Hospitals Charity and Join Research Executive Scientific Committee Research Grant (UK)

Who is the main contact?
Dr Alan Bagnall, alan.bagnall@nhs.net

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
312832

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 312832

Study information

Scientific Title
Quality of life, fatigue and autonomic dysfunction in patients with heart failure: association with symptoms of low mood and depression.

Study objectives
Autonomic nervous system (ANS) dysregulation may underpin the link between depression, fatigue and poor quality of life in comorbid heart failure (HF). This would help explain why so many people with heart failure also have depression, why it has such an impact on their quality of life and why depression in heart failure patients is so difficult to treat.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/11/2022, Newcastle North Tyneside 1 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 2071048255; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 22/NE/0209.

Study design
Observational cross-sectional

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Adult patients with heart failure and cardiac implantable electronic devices (CIED)

Interventions

We will interview people with heart failure and collect information about their mood, fatigue, quality of life and autonomic nervous system function. Many people with heart failure have implanted heart monitors. They allow us to measure their heart rates, and we will use these data to study heart rate variability – this will be an indicator of autonomic nervous system function. A single blood test will be taken to understand how well the heart is functioning, so that we can correlate heart disease severity with our findings.

Intervention Type
Other

Primary outcome(s)
Measured at a single time point:
1. Beck Depression Inventory II (BDI-II) to asses mood.
2. The Quick Inventory of Depressive Symptomatology - Self-report (QIDS-SR) to assess mood.
3. Structured interview, informed by the Mini-International Neuropsychiatric Interview (MINI), to obtain descriptive data about mood.

Key secondary outcome(s))
Measured at a single time point:
1. 5-level EuroQol 5D version (EQ-5D-5L) scale for quality of life.
2. 21-item Minnesota Living with Heart Failure (MLHF) questionnaire for quality of life in people with heart failure.
3. Multi-dimension Fatigue Inventory (MFI) to assess fatigue.
4. Composite Autonomic Symptom Scale-31 (COMPASS-31) to assess symptoms of autonomic function.
5. THINC-it cognitive screening tool for cognition.
6. Blood sample to test for N- terminal pro-brain natriuretic peptide (NT-proBNP) level, to estimate heart function.
7. Heart rate data will be downloaded from participants' cardiac implantable electronic device.
8. Information from patients' clinical records: Data will collected on: Demographics, including age, sex, gender identity, sexuality, ethnicity, marital status and occupation; Previous physical health and mental health diagnosis; Current medication and medication taken over the previous year, including doses.

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. ≥ 18 years of age.
2. Open to the heart failure clinics at the Freeman Hospital or Royal Victoria Infirmary (RVI), NuTH.
3. Diagnosis of heart failure with reduced ejection fraction (HFrEF) - severe left ventricle systolic dysfunction (LVSD) with ejection fraction (EF) < 35%.
4. Cardiac implantable electronic device (CIED) in place.
5. Able to provide written informed consent.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Previous diagnosis of bipolar affective disorder, psychotic disorder or personality disorder.
2. Previous diagnosis of dementia.
3. Previous diagnosis of primary neurological injury (eg, anoxic injury, stroke or traumatic brain injury) or disorder (eg, Parkinson’s disease).
4. Myocardial infarction (MI) within the previous 3 months.
5. Not fluent in English.

Date of first enrolment
01/02/2023

Date of final enrolment
31/01/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
Newcastle upon Tyne Hospitals Charity and Join Research Executive Scientific Committee Research Grant

Results and Publications

Individual participant data (IPD) sharing plan
All data will be stored for up to 5 years after the last data is collected. Data will be available to other researchers on reasonable request, made to the study PI (Dr Alan Bagnall) via email (alan.bagnall@nhs.net).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 5.0	02/12/2022	22/12/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 7.0	02/12/2022	22/12/2022	No	No