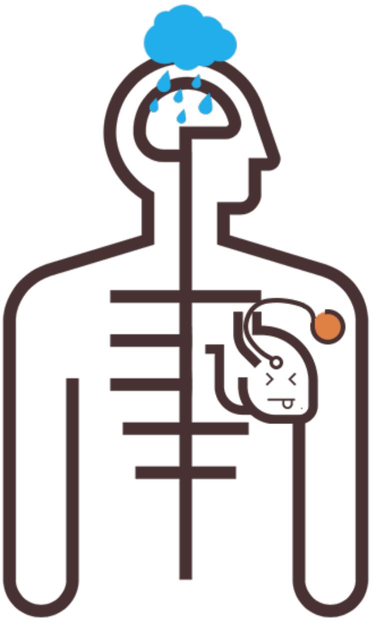
Quality of life, fatigue and autonomic dysfunction in patients with heart failure: association with symptoms of low mood and depression

An observational research study



- Many people in the North East and North Cumbria have **heart failure**, some of whom will also suffer with **symptoms of low mood and depression**

- **Having both heart failure and symptoms of low mood and depression can be very difficult**

- It means you are **more likely to**:

  - Have a **worse quality of life**
  - **Feel more tired**
  - **Need hospital treatment** for your heart failure

We want to:
- Known how common **symptoms of low mood and depression are in people with heart failure in the North East and North Cumbria**.

- **We will:**
- Ask you about your **quality of life**, your levels of **tiredness** and how good your **memory and the way you think** has been.
- Study your **autonomic nervous system function** by downloading **heartbeat data from your defibrillator**. The “autonomic” nervous system controls many things that our bodies do: how fast our heart beats, our breathing, and also how our emotions and mood.
- **Take a single blood test** to understand **how well the heart is working**, so that we can link heart disease severity with the other data we want to get.

How we will use your personal information:
- In this research study we will use information from you, your medical records and your GP, as well as results from a blood test and data from your defibrillator. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.
- Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.
- At the end of the study we will save some of the data in case we need to check it or for future research.
- We will make sure no-one can work out who you are from the reports we write.
- The information pack tells you more about this.

NHS The Newcastle upon Tyne Hospitals NHS Foundation Trust

nectar newcastle cardiovascular trials and research

NHS Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust

NCMD Northern Centre for Mood Disorders

Newcastle University

NEWCASTLE HEALTH INNOVATION PARTNERS

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

Participant information sheet

We would like to invite you to take part in our study of quality of life, fatigue and autonomic dysfunction in patients with heart failure. Before you decide to take part in our study, please take the time to read through this information in full. It is very important that you understand why we are doing this research and what is involved.

You are completely free to decide whether or not to take part in this study. If you choose not to take part, **this will have no effect on your usual treatment**. If you have any questions or something is not clear, please get in touch with us – we'd be happy to answer any of your questions.

1) Symptoms of low mood and depression in patients with heart failure

Many people in the North East and North Cumbria have **heart failure**. Some of whom will also suffer with **symptoms of low mood or depression**. It is normal to feel low, sad or apprehensive from time to time, but sometimes it can become more serious, which is what we are trying to understand better.

Having both heart failure and symptoms of low mood or depression can be very difficult. It means you can have a **worse quality of life, feel tired (fatigued) and means you could need more hospital treatment** for your heart failure. It is also harder to spot when low mood or depression is becoming more serious, which makes it harder to get specialist mental health support when you need it.

2) What is the purpose of this study?

We want to know how common low mood and depression symptoms are in people with heart failure in the North East and North Cumbria. So, we would like to ask you about your **mood** over recent weeks. We would also like to ask you about your **quality of life**, your levels of **tiredness**, and how good your **memory and the way you think has been (**this is sometimes called "cognition"). We would also like to see how well part of your **nervous system is working** (the autonomic part of your nervous system). We can do this by **downloading heart rate data from your defibrillator.** The "autonomic" nervous system controls many things that our bodies do: how fast our heart beats, our breathing, and also how our emotions and mood are. Sometimes this is not working properly in people with heart failure and we need to know more about it.

We want to do this because we wonder if the autonomic nervous system is an important link between heart disease and mood. We think all this might have a very important role in quality of life and levels of tiredness.

Some people taking part in our study might have depression, others won't. **Even if you don't think you are depressed, you can still take part – and we would be very thankful for that.**

A psychiatry doctor who is part of the study team will **interview** you. They will also ask you to complete **questionnaires** about your mood, tiredness, quality of life and autonomic nervous system function. Many people with severe heart failure have **implanted defibrillators (implantable cardioverter-defibrillators, sometimes abbreviated as 'ICDs') which can show how their heart is beating.** We would like to use this "heartbeat" information to study whether changes in your heartbeat are important for mood and the nervous system. We would also like to take **a single blood test,** so we understand how well the heart is working, and link it to the heartbeat information and the information in the questionnaires.

3) Do you need to take part in this study?

No, participation is voluntary. It is completely up to you. Your decision will not affect your health care in any way.

If you choose not to take part in our study, that is absolutely fine. Also, if you choose to take part at the start but then change your mind, that's fine. You don't need to give us any reasons, just tell us you want to stop.

4) How do I give my consent for the study?

If you do choose to take part, we will invite you to **meet with us to discuss the study further** and answer any questions. **We can meet virtually (online, for example using Zoom, or WhatsApp, or over the phone)** to discuss this if that is your preference. Alternatively, we **can also meet with you when you to come to the Freeman Hospital or to the RVI for a routine clinical appointment** – for example, for a review of your defibrillator. We will be able to accommodate whatever works best for you. If you're still happy to go ahead, we will **complete a separate form for informed consent to take part in the study**.

We will **need to get the consent form in writing**. We can do this in several ways, according to what you prefer:
a) **Online**, via a secure form.
b) By returning to the study team a signed paper consent form **via post**.
c) By signing a paper consent form **during the consent visit**.

We will follow Trust rules and document in your clinical notes if we meet with you to discuss the study, and if you chose to take part or not.

5) Why am I being invited?

You are eligible to take part in our study if:

- You are 18 years of age or older.
- You are a patient at the Heart Failure clinics at the Freeman Hospital or RVI.
- You have a diagnosis of heart failure with reduced ejection fraction (HFrEF) – there is severe left ventricle systolic dysfunction, with ejection fraction < 35%.
- You have an implanted defibrillator (an implantable cardioverter-defibrillator, ICD) in place.

To participate in our study, you must **fulfil all the conditions listed above**.

6) Does taking part mean I have depression?

No. We are inviting you to take part because you have been diagnosed with **heart failure and you have an implanted defibrillator**. We expect that some people might have depression, but others won't. We will be able to work this out when we meet you. **If you don't think you are depressed, you can still participate**.

Any information from the study will be kept strictly confidential. If we do think that you have depression when we see you, this would not show up on your GP records, unless you would like some help with it. If you do want some help, we can help to let your GP know. We will never get in touch with your GP without discussing that with you first and **having your permission**.

There are some reasons that mean you would **not** to be able to participate in our study:

- If you have already been diagnosed with bipolar affective disorder, psychotic disorder or personality disorder in the past.
- If you have been given a diagnosis of dementia or Parkinson's disease.
- If you ever had a stroke or a traumatic injury to your brain.
- If you had a myocardial infarction (heart attack) in the last 3 months. If you had a myocardial infarction (heart attack) more than 3 months ago, you can participate.
- If you are not fluent in English.

We can work these things out with you if you are interested in taking part.

7) What is involved in this study?

Our study will be done in **Newcastle**, at the Newcastle upon Tyne Hospitals (NuTH) NHS Foundation Trust.

Heart failure and depression are both quite complex diseases. To understand how much you might be affected by these conditions, with your permission, we will ask you to fill in some questionnaires, interview you, and download data from your clinical files and your defibrillator. We will also take a single blood test from you.

Taking part in our study can be summarised as follows:

1) We will start by meeting with you to discuss the study further, answer any questions and **obtain written informed consent for participation**. We will need to get the consent in writing. However, **we can meet virtually (online, for example using Zoom or WhatsApp, or over the phone)** to discuss this if that is your preference. Alternatively, we can also meet with you when you to come to the Freeman Hospital or to the RVI for a routine clinical appointment – for example, for a review of your defibrillator. We will be able to accommodate whatever works best for you.

2) Next, we will then ask you to fill-in some **questionnaires** about your mood, quality of life, tiredness, and symptoms related to your autonomic nervous system function. **We will ask you to fill them in online if you can**. However, they can also be **filled in on paper. You can do them on your own**, but we can also help if you need it.

   These are the questionnaires we will ask you to fill in:

   a) The **Beck Depression Inventory II**, which helps us diagnose depression.
   b) The **Quick Inventory of Depressive Symptomatology**, which helps us understand how severe the depression might be.
   c) The **5-level EuroQol 5D scale**, which will give us information on your overall health, including your mobility, self-care, usual activities, and pain you might experience.
   d) The **Minnesota Living with Heart Failure questionnaire**, which will give us information on your quality of life, being especially developed for people with heart failure.
   e) The **Multidimensional Fatigue Inventory**, which will give us information on your levels of fatigue.
   f) The **COMPASS-31 questionnaire**, which will give us information about the way your autonomic nervous system is working.

   Each questionnaire takes about 10 minutes to fill-in. We think that it should take you **about 1 hour** to do them all.

3) We will then **meet with you face-to-face** to complete 3 things:

   a) We will have a **meeting with you, focusing on your mood and feelings**, to try and determine if you have a clinical diagnosis of depression. This will basically be a conversation.
   b) Go through a **scale called THINC-it**, which will give us information on your thinking and cognition, or how you use your memory and thoughts while you do some tasks on a tablet computer (iPad). This is designed to feel like a game.

c) Get a **single blood test** – from your arm, like you have had before. We will measure something called N-terminal pro-brain natriuretic peptide (NT-proBNP). This is a good way of measuring how well your heart is working. We will only get one vial, equivalent to less than a tablespoon. The blood sample will be sent to the local hospital laboratory (at the Freeman Hospital or RVI) for analysis and will be destroyed once a result has been confirmed, in line with routine hospital practice.

We expect this visit will take about **1 hour and 30 minutes** in total.

4) After this, an appropriately trained member of the study team will get some **more information about you from your health record**. You don't have to do anything for this part, but it is very important that you understand what information we want to access:

a) An appropriately trained member of the study team will look on your **clinical files on our hospital records** and collect information like:
   - Some demographics details, such as age, sex, gender identity, sexuality, ethnicity, marital status and occupation.
   - Other diseases you might have, the medications you take or might have taken in the past.
   - Your New York Heart Association (NYHA) functional classification, which is a measure of the symptoms you have when exercising.
   - Your Left Ventricular Ejection Fraction (LVEF) and left ventricular dimensions, which were calculated when you had a heart scan ('echo' test) in the past and will give us another measure of how well your heart is working.
   - Our hospital records are linked a regional network called "Health Information Exchange" which will include records from other hospital and your GP. We want to access this for completeness of the information listed above and nothing else.

b) **We would like to download heartbeat data saved in your defibrillator**. Your defibrillator normally saves this data every day as part of how it works. Downloading the data will not impact how your defibrillator works at all. This will give us important information about your heartbeat and will helps us to understand how your autonomic nervous system is working.

8) What happens if you decide to take part in our study?

If you do choose to take part, we will invite you to **meet with a member of the study team to discuss the study further** and answer any questions. If you're still happy to go ahead, we will **complete a separate form for informed consent for participation**.

Then we will ask you to complete the **questionnaires**. **You can complete the questionaries on your own time online**, but we can also give out paper copies and help if you need.

Then, we will arrange for a day that suits you to come to **Newcastle** – to the Freeman Hospital or RVI – to **complete the study interview and take the blood test**. We should be able to do everything in the same day, so that you don't have to come back for extra visits.

And after that there is nothing else you need to do. For the rest of the data we need we just need your consent and we can collect it from your records on the hospital computer systems.

You can also call us at any point if you choose to no longer participate in our study. You won't have to give us any reasons and that's perfectly fine.

9) What happens if we make a diagnosis of depression during the study?

If we make a diagnosis of depression and you would like to have help with that, we can get in touch with your GP. **We will never get in touch with your GP without discussing that with you first and having your permission.** If you don't want to do anything about a possible symptoms of depression, we will respect that. In the unlikely event that the doctor interviewing you feels that you are having a mental health "crisis" (for example, presenting with severe symptoms), he will discuss with you if you would like to be referred to a "mental health crisis team" and if we should inform your GP.

10) How will we use information about you?

We will need to use information from you, from your medical records and from your GP, as well as results from a blood test and data from your defibrillator, for this research project.

This information will include your **NHS number, gender and date of birth**. People will use this information to do the research or to check your records to make sure that the research is being done properly. **People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead**.

We will keep all information about you **safe and secure**.

Once we have finished the study, **we will keep some of the data so we can check the results**. We will write our reports in a way that no-one can work out that you took part in the study.

11) What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. We will follow NuTH Trust guidelines for storage of the data once the study is completed. Personal data will be stored for up to 12 months. All the other pseudonymized data generated by the study will be stored for up to 5 years. This is to there is time for review – in case there are any concerns about the way we ran the study. All paper documentation will be kept in secure locked storage, outside the hospital site.

12) Where can you find out more about how your information is used?

You can find out more about how we use your information:

- By **asking a member of the research team**.
- By visiting the **NHS Health Research Authority website** at: www.hra.nhs.uk/information-about-patients/
- By looking at our **leaflet available at**: www.newcastle-hospitals.nhs.uk/help/privacy/privacy-notice-for-patients/
- By sending an email to the **Sponsor (NuTH) Data Protection Officer** at nuth.dpo@nhs.net or ringing at 0191 223 1474.

13) What are the benefits of taking part?

You 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.

14) Travel expenses

Reasonable travel expenses will be available for the study visits. The study team will manage any payments to reimburse costs to you. You may be asked to provide receipts for your travel. No additional payments will be made for taking part in the study.

15) Can anything bad happen to you?

Apart from asking you some questions and taking a blood test, we are not doing anything to you 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, you might experience pain, bruising, light-headedness and on rare occasions, infection. We will help you get assistance if that happens.

We will talk about sensitive topics such a low mood and depression. The person who will interview you 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. You might still find it distressing and will offer help if that is the case. If we do find that you have depression and if you feel that you don't have enough help for this, we can help you get in touch with your GP. We will not give you any treatment for depression as part of the study, but we can tell you how to get help.

There will be no changes to your heart failure treatment as a part of the study. If you feel that you need any extra help, we can help you speak to the doctors and nurses at the Freeman Hospital and RVI who look after your heart.

The usual NHS indemnity scheme will apply to all activities of this study. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NuTH but you may have to pay your legal costs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service ways of complaining are available to you.

If you prefer to raise your concerns with someone not involved in your care, you can contact the **Patient Advice and Liaison Service (PALS)**. This service is confidential and can be contacted on Freephone: 0800 032 0202

Alternatively, if you wish to make a formal complaint you can contact the **NuTH Patient Relations Department** through any of the details below:

- Telephone: 0191 223 1382
- Email: nuth.patient.relations@nhs.net
- Address: Newcastle Hospitals NHS Foundation Trust, Freeman Hospital, Freeman Road, High Heaton, Newcastle upon Tyne, NE7 7DN

If you would like any more information about risks of participating, please ask a member of our team.

16) Further information

The project team includes professionals from the Newcastle upon Tyne Hospitals (NuTH) NHS Foundation Trust, the Cumbria, Northumberland, Tyne and Wear (CNTW) NHS Foundation Trust, and Newcastle University.

Our study is funded by the NuTH Charity with no industry involvement. The NuTH NHS Foundation Trust Research & Development department is administering the award and sponsoring the research.

Our study protocol was reviewed and approved by independent bodies, which make sure that what we are doing is relevant, safe and ethical. This includes a Research Ethics Committee, which makes sure all participants have their rights protected and are treated with dignity.

If you have any questions or something is not clear, please ask us for more information.

17)Contacts

NECTAR – Newcastle Cardiovascular Trials and Research
Room 122F Education Centre
Freeman Hospital
Newcastle upon Tyne Hospitals NHS Foundation Trust
Newcastle upon Tyne
NE7 7DN

To contact a NECTAR research nurse:

- Telephone: 0191 2137201
- nuth.cardioresearch@nhs.net

Principal Investigator:
Dr Alan Bagnall
alan.bagnall@nhs.net