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Increasing physical activity levels of heart failure patients

Submission date
12/07/2021

Recruitment status
No longer recruiting

Registration date
19/07/2021

Overall study status
Completed

Last Edited
19/08/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Current plain English summary as of 28/04/2023:

Background and study aims
Heart failure (HF) is a disease where the heart is unable to pump blood as efficiently around the body, and this can lead to breathlessness and fatigue and subsequently poor quality of life. Previous research has demonstrated that cardiac rehabilitation and physical activity can improve HF symptoms, quality of life and level of independence in terms of everyday tasks. However, the number of people with HF who engage in cardiac rehabilitation and regular physical activity is sub-optimal. We have developed an intervention that aims to promote and support long-term habitual physical activity behaviour of people with HF, and to promote uptake of centre and home-based cardiac rehabilitation programmes.

Who can participate?
Participants with heart failure - we will recruit adults aged ≥ 18 years with a confirmed diagnosis of HF (reduced or preserved ejection fraction), who are actively involved in the HF care pathway and have no contraindications to physical activity.
Healthcare professional (HCP) participants - we will recruit HCPs who are directly involved in the care pathway of people with HF, including but not limited to; cardiac nurses, cardiology consultants and physiotherapists.

What does the study involve?
The research involves three phases, phase one and two are completed.
Phase 1 (completed): People with HF participated in interviews to determine the behavioural determinants, barriers, and facilitators to engaging in cardiac rehabilitation and physical activity. HCPs participated in semi-structured interviews to explore their views and experiences of promoting physical activity and cardiac rehabilitation in people with HF.
Phase 2 (completed): Co-design workshops with participants with HF and HCPs were conducted to inform decisions on intervention content, format and mode of delivery. A prototype intervention called 'BeActive-HF' was developed informed by the findings of phase 1 and phase 2 of the research.
Phase 3 (feasibility study): this will determine the acceptability and feasibility of the BeActive-HF intervention with participants (HCPs and people with HF). All patient participants will be

supported to use the intervention materials over a 12-month time period during routine care appointments with a HCP participant. The HCP will receive training on how to deliver the BeActive-HF intervention with the overall aim of increasing everyday physical activity levels of patients and promoting uptake of cardiac rehabilitation. Where possible, the delivery of the intervention to participants with HF will be audio recorded to assess fidelity of delivery. HCPs will be asked to complete the capability, opportunity, motivation, and behaviour self-evaluation questionnaire (COM-B-SEQv1) prior to receiving training and following completion of training, and they will be asked to complete an evaluation form.
Data will be collected from participants with HF at baseline (i.e., the beginning of the study). These include: demographics, quality of life measured by the Minnesota Living with Heart Failure Questionnaire (MLHFQ), physical function assessed by the 10-m Incremental Shuttle Walk Test (ISWT), and physical activity behaviour using the Actigraph GT3X. These measurements will be taken at 6 and 12-month time points. HCP participant demographics will be collected at baseline these will include age, sex, time in role, role description, and any previous training in physical activity promotion. HCP participants and patient participants will be asked to complete a semistructured interview following completion of the intervention to assess acceptability and fidelity of receipt and enactment.

What are the possible benefits and risks of participating?
There is minimal risk to participants electing to take part in this study. HCPs will be given the opportunity to deliver a theory- and evidence-based intervention that was developed based on their preferences. Whilst in receipt of the intervention, people with HF may benefit from improved quality of life and reduced symptomatic burden. Both participant groups will potentially be involved in a process that could positively impact routine practice.

Where is the study run from?
Teesside University (UK)

When is the study starting and how long is it expected to run for?
April 2021 to August 2024

Who is funding the study?
Heart Research UK

Who is the main contact?
Professor Leah Avery, leah.avery@tees.ac.uk

Previous plain English summary:

Background and study aims
Heart failure (HF) is a disease where the heart is unable to pump blood as efficiently around the body, and this can lead to breathlessness and fatigue and subsequently poor quality of life. Previous research has demonstrated that physical activity can improve HF symptoms and improve quality of life and level of independence in terms of everyday tasks. However, the number of patients that engage in regular physical activity is sub-optimal. We aim to develop an intervention to engage patients with HF in physical activity to improve health-related outcomes. The intervention will be evaluated to assess feasibility and acceptability with HF patients and healthcare professionals involved with their care.

Who can participate?
HF patients – we will recruit adults aged ≥ 18 years with a confirmed diagnosis of HF (reduced or preserved), who are actively involved in the HF care pathway and have no contraindications to physical activity.
Healthcare professionals (HCPs) – we will recruit HCPs who are directly involved in the care pathway of HF patients, including but not limited to; cardiac nurses, cardiology consultants and physiotherapists.

What does the study involve?
The planned research involves three phases.
Phase 1: HF patients and HCPs will participate in semi-structured interviews.
Phase 2 involves the development of a prototype intervention, informed by the findings of two systematic reviews, interviews from phase one of the planned research, co-design workshops and drawing on the expertise of the research team and previous literature.
Participants involved in phase one will be invited back to take part in workshops during phase 2 and provide their views on the prototype intervention.
Phase 3 will involve a feasibility study to assess the acceptability of the intervention to HCPs and patients with HF. All patients will receive a 12-week intervention to target an increase in physical activity levels. The intervention will consist of weekly audio recorded telephone calls lasting approximately 10-minutes for 12-weeks. Pre and post-intervention patients will be asked to wear an Actiheart device for physical activity monitoring.

What are the possible benefits and risks of participating?
There is minimal risk to participants electing to take part in this study. HCPs will be given the opportunity to inform the development of an intervention and ensure it addresses their needed and preferences. Whilst in receipt of the intervention, patients may benefit from improved quality of life and reduced symptomatic burden. Both patients and HCPs will potentially be involved in a process that could positively impact routine practice.

Where is the study run from?
Teesside University (UK)

When is the study starting and how long is it expected to run for?
April 2021 to October 2023

Who is funding the study?
Teesside University (UK)

Who is the main contact?
Dr Leah Avery, leah.avery@tees.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
300883

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 300883

Study information

Scientific Title
Development and feasibility testing of a multi-faceted evidence- and theory-informed behavioural intervention 'BeActive-HF' targeting physical activity of adults with heart failure

Acronym
BeActive-HF

Study objectives
Current study hypothesis as of 27/02/2024:
Previous research has demonstrated that cardiac rehabilitation and physical activity can improve HF symptoms such as breathlessness, quality of life and level of independence in terms of everyday tasks. However, the number of people with HF who engage in cardiac rehabilitation and regular physical activity is sub-optimal. Research has highlighted the role of healthcare professionals (HCPs) as motivators and enablers to participants in physical activity interventions; however, very few studies report on the use of training interventions for HCPs to support the delivery of interventions and implement physical activity and cardiac rehabilitation guidelines into practice. Even when they are reported, very few report on their form and content, prohibiting replicability. Moreover, rarely are any training interventions for HCPs evaluated. It is vitally important to determine the active ingredients of training interventions to facilitate faithful delivery and robust evaluations. This study will assess whether the BeActive-HF intervention can be delivered as intended and enable effective translation of research into routine clinical care.

In addition to promoting and supporting long-term habitual physical activity behaviour of adults with HF, and to promote uptake of centre and home-based cardiac rehabilitation programmes.

The primary objectives of this study are:
1. To develop a multi-faceted evidence and theory-informed intervention (BeActive-HF) to promote increased physical activity levels of HF patients and attendance at cardiac rehabilitation.
2. To establish the feasibility and acceptability of the BeActive-HF intervention from the perspective of adults with HF and healthcare professionals involved with their care.
3. Increase habitual physical activity levels of adults with HF and promote referral and uptake of cardiac rehabilitation.

Previous study hypothesis as of 28/04/2023 to 27/02/2024:
Effective management of HF incorporates a multidimensional approach of pharmaceuticals, surgical interventions and lifestyle change that can be achieved at cardiac rehabilitation. Adopting a healthier eating approach and increasing physical activity has proven to be effective in improving quality of life and reducing symptomatic episodes. Home-based interventions have shown promise alongside telephone-based support. Previous research has highlighted the role of HCPs to serve as motivators and enablers to facilitate physical activity interventions, however, very few studies report using training interventions to support delivery of interventions. Where they are reported, very few report the content prohibiting replicability, and rarely are any training interventions evaluated. It is vitally important to determine the active ingredients of training interventions to facilitate faithful delivery and robust evaluations to assess whether the BeActive-HF intervention can be delivered as intended and to enable effective translation of research into routine clinical care.

Previous study hypothesis:
Effective management of heart failure incorporates a multidimensional approach of pharmaceuticals, surgical interventions and lifestyle change. Adopting a healthier eating approach and increasing physical activity has proven to be effective in improving quality of life and reducing symptomatic episodes. Home-based interventions have shown promise alongside telephone based support. Previous research has highlighted the role of healthcare professionals to serve as motivators and enablers to facilitate physical activity interventions, however, very few studies report using training interventions to support delivery of interventions. Where they are reported, very few report the content prohibiting replicability, and rarely are any training interventions evaluated. It is vitally important to determine the active ingredients of training interventions to facilitate faithful delivery and robust evaluations to assess whether interventions can be delivered as intended and to enable effective translation of research into routine clinical care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/10/2021, Research Ethics Committee (REC) Health Research Authority (HRA) (Barlow House, 3rd Floor, HRA, NRES Centre, Manchester, M1 3DZ; +442071048384; contact@hra.nhs.uk), Ethics amendments approved accordingly

Study design

Multicentre interventional feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Other, Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Heart failure patients and healthcare professionals involved in the clinical care pathway of heart failure.

Interventions
Current interventions as of 27/02/2024:
Phase 3: A multi-centre study will be conducted to determine the acceptability and feasibility of the BeActive-HF intervention. The BeActive-HF intervention was developed using the findings from Phase One and Phase Two. The intervention aims to increase habitual physical activity levels and referral and uptake to cardiac rehabilitation. Adults with HF will be supported by an HCP during routine clinical appointments to use the intervention materials over 12 months. All HCPs will receive training on how to deliver the BeActive-HF intervention
from a multi-disciplinary team consisting of health psychologists, a consultant in cardiology, patient educators, an exercise physiologist, and a sport psychologist.

Previous interventions as of 28/04/2023 to 27/02/2024:
The planned research involves three phases.

Phase 1: HF patients and HCPs will participate in semi-structured interviews.

Phase 2 involves the development of a prototype intervention, informed by the findings of two systematic reviews, interviews from phase one of the planned research, co-design workshops and drawing on the expertise of the research team and previous literature.
Participants involved in phase one will be invited back to take part in workshops during phase 2 and provide their views on the prototype intervention. Structured discussions guided by a topic guide will explore opinions and views on the components and content of the intervention. The aim is to determine whether the training component (Facet 1) and patient intervention (Facet 2) is acceptable for use within routine clinical care in the first instance. HCP’s will be asked to review the intervention components and provide feedback on the extent to which they believe it will address their training needs, including the mode in which information and skills components are communicated/delivered. HF patients will be asked their views and opinions on the patient

intervention and if it addresses their information and support needs and whether it adequately incorporates suggestions made during qualitative interviews. Patients will be asked to review the prototype intervention and communicate any immediate barriers or facilitators to using it.

Phase 3 will involve a feasibility study to determine the acceptability and feasibility of the BeActive-HF intervention with participants (HCPs and people with HF). All patient participants will be supported to use the intervention materials over a 12-month time period during routine care appointments with a HCP participant. The HCP will receive training on how to deliver the BeActive-HF intervention with the overall aim of increasing everyday physical activity levels of patients and promoting uptake of cardiac rehabilitation. Where possible, the delivery of the intervention to participants with HF will be audio recorded to assess fidelity of delivery. HCPs will be asked to complete the capability, opportunity, motivation, and behaviour self-evaluation questionnaire (COM-B-SEQv1) prior to receiving training and following completion of training, and they will be asked to complete an evaluation form.
Data will be collected from participants with HF at baseline (i.e., the beginning of the study). These include: demographics, quality of life measured by the Minnesota Living with Heart Failure Questionnaire (MLHFQ), physical function assessed by the 10-m Incremental Shuttle Walk Test (ISWT), and physical activity behaviour using the Actigraph GT3X. These measurements will be taken at 6 and 12-month time points. HCP participant demographics will be collected at baseline these will include age, sex, time in role, role description, and any previous training in physical activity promotion. HCP participants and patient participants will be asked to complete a semistructured interview following completion of the intervention to assess acceptability and fidelity of receipt and enactment.

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Previous interventions:
The planned research involves three phases.
Phase 1: HF patients and HCPs will participate in semi-structured interviews.
Phase 2 involves the development of a prototype intervention, informed by the findings of two systematic reviews, interviews from phase one of the planned research, co-design workshops and drawing on the expertise of the research team and previous literature.
Participants involved in phase one will be invited back to take part in workshops during phase 2 and provide their views on the prototype intervention. Structured discussions guided by a topic guide will explore opinions and views on the components and content of the intervention. The aim is to determine whether the training component (Facet 1) and patient intervention (Facet 2) is acceptable for use within routine clinical care in the first instance. HCP's will be asked to review the intervention components and provide feedback on the extent to which they believe it will address their training needs, including the mode in which information and skills components are communicated/delivered. HF patients will be asked their views and opinions on the patient intervention and if it addresses their information and support needs and whether it adequately incorporates suggestions made during qualitative interviews. Patients will be asked to review the prototype intervention and communicate any immediate barriers or facilitators to using it.
Phase 3 will involve a feasibility study to assess the acceptability of the intervention to HCPs and patients with HF. This is a non-randomised intervention, all patients will receive a 12-week intervention to target an increase in physical activity levels. The intervention will consist of weekly audio recorded telephone calls lasting approximately 10-minutes for 12-weeks. Pre and post-intervention patients will be asked to wear an Actiheart device for physical activity monitoring.

Intervention Type
Behavioural

Primary outcome measure

Current primary outcome measure as of 27/02/2024:
Feasibility data will be collected on the number of HCPs who attend and complete the training, attrition rate and the number of times the intervention was used with adults with HF. Patient adherence will be measured by recording the number and percentage of intervention sessions each patient participant received. Participant (adults with HF and HCPs) retention rates will be measured using the number of participants that are still participating in the study at the end of the study period divided by the number of participants at the start of the study period. The attrition rate will be calculated by dividing 'the number of participants who dropped out' by 'the total number of participants enrolled for the study period'. Reasons for patient attrition will be recorded (i.e. patient chose to drop out, patient death, etc.).

Qualitative data collection: At 8 months post-training, HCPs will be invited to participate in a semi-structured interview to explore their views on the intervention content and experience of delivering the intervention to patients, including issues associated with sustainability of the intervention. During the 8-month post-participation period, semi-structured interviews with adults with HF will explore their views on the form and content of the intervention, including their experience of receiving and enacting the intervention in their daily lives.

Fidelity: All training will be video recorded to enable assessment of fidelity of training delivery in 'real-time'. Fidelity will be assessed via a checklist to determine the intervention components delivered, for example, whether the training facilitators satisfactorily deliver key behaviour change techniques. In addition, where possible, the delivery of the intervention to adults with HF will be audio recorded to assess the fidelity of HCP delivery.

Previous primary outcome measure as of 28/04/2023 to 27/02/2024:
Feasibility will be assessed through HCP attendance and completion of training, and HCP and patient attrition, retention and adherence rates over the study period.
1. Participant retention rates will be measured using the number of participants that are still participating in the study at the end of the study period divided by the number of participants at the start of the study period. Attrition will be calculated using the following formula: (Number of participants that dropped out) ÷ (Number of participants for the study period) * 100.
Qualitative data collection will explore views of patients and HCPs on aspects of the intervention including content; delivery; perceived impact on referral behaviour and physical activity behaviours; HCP perceived sustainability (e.g., could this be sustained in routine care?); and patient sustainability (e.g., would patients be happy to receive this as part of routine care?).
2. Adherence will be measured by recording the number and percentage of intervention sessions each patient participant received.
3. Fidelity of intervention delivery by HCPs will be assessed via audio recordings of intervention delivery to patients (where HCPs and patients provide consent to record a consultation). Where consent is not provided, fidelity will be assessed qualitatively via face-to-face or remotely conducted interviews. Recordings will be analysed and coded by two research team members using a checklist of intervention content. Interview topic guides will include specific questions about intervention delivery.
Fidelity of receipt and enactment of intervention knowledge and skills will be assessed with post-intervention interviews with patients (face-to-face or remotely). This assessment will provide important information about how HF patients used the knowledge and skills acquired out with the clinical setting in the context of their everyday lives, including data on perceived benefits and drawbacks of specific components of the intervention. Findings will inform

optimisation.
4. Referral to cardiac rehabilitation will be assessed by reporting pre- and post-intervention (12-month) data on referral to cardiac rehabilitation from each participating Trust. Where feasible, data will be collected on patient attendance at cardiac rehabilitation. However, in some situations this may not be possible within the timeline (e.g., where there are waiting lists).

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Previous primary outcome measure:
1. Feasibility will be assessed through HCP and patient recruitment, retention and adherence rates:
1.1. HCP and patient recruitment and retention rates will be measured using the number and percentage of participants that were recruited against those who were identified as eligible, and from those who participated the number and percentage of those who remained in the study until last data collection point (attrition will also be recorded for the duration of the intervention – i.e., 12 weeks).
1.2. Adherence will be measured by recording the number and percentage of intervention sessions attended by each patient participant.
2. Fidelity of intervention delivery will be assessed via audio recordings of the intervention being delivered by HCPs to patients and analysed using a checklist of intervention content at the end of the study
3. Fidelity of receipt of the intervention will be assessed with pre- and post-intervention interviews with patients

Secondary outcome measures

Current secondary outcome measure as of 27/02/2024:
Data will be collected from adults with HF at baseline and follow-up periods (6- and 12-months). Data collected will consist of socio-demographics; health-related quality of life (the Minnesota Living with Heart Failure Questionnaire, MLHFQ); and physical activity behaviour (Actigraph GT3X). Device wear time will be recorded, along with the number of active minutes spent in light, moderate and vigorous activity, and steps per day. Adults with HF will be asked to wear the device for eight consecutive days (24-hour monitoring).

HCP participants: Age, sex, time in role, role description, and any previous training in physical activity promotion will be collected from HCPs. The COM-B-SEQv1 will be administered to HCPs before attending training and post-training. A training evaluation form will be provided post-training to explore whether the training met its objectives and was considered useful to HCPs in terms of providing them with the required knowledge and skills to deliver the BeActive-HF intervention during routine clinical care appointments.

Referrals to cardiac rehabilitation: Longitudinal data from each study site will be collected on referrals to, and attendance at cardiac rehabilitation. Monthly referral and attendance to cardiac rehabilitation will be observed from each participating site (NHS Trusts) to assess whether referral and uptake rates to cardiac rehabilitation have increased since the introduction of the BeActive-HF intervention. Where feasible, data on unique patient attendance at cardiac rehabilitation will be collected and analysed using time series methods. The time series results will be triangulated with the findings emerging from the patients' and HCPs' interviews to inform the optimisation of BeActive-HF ahead of a larger-scale follow-up evaluation.

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Previous secondary outcome measures as of 28/04/2023 to 27/02/2024:
Participants with HF: Physical activity levels at baseline, 6-months, and 12-months will be assessed using an Actigraph GT3X monitoring device. We will record device wear time, the number of active minutes, steps, and time spent in light, moderate and vigorous activity. Participants will be asked to wear the device for seven consecutive days (24-hour monitoring). Participants will be asked to perform the 10-m ISWT and MLHFQ at baseline, 6-month, and 12-month data collection time points.

HCP participants: The COM-B-SEQv1 will be administered to HCPs before attending training and post-training. A training evaluation form will be provided post-training to explore whether the training met its objectives and was considered useful top HCPs in terms of providing them with the required knowledge and skills to deliver the BeActive-HF intervention during routine clinical care appointments.

Previous secondary outcome measures:
Physical activity levels pre and post-intervention measured using an Actiheart monitoring device. We will record device wear time, the number of active minutes, and time spent in light, moderate and vigorous activity. Participants will be asked to wear the device for seven consecutive days (24-hour monitoring). The device is strapped to the participants chest using self-adhesive electrocardiogram (ECG) and can be secured with the use of a sports strap. It will be fitted by a member of the research team or a trained healthcare professional. If COVID-19 restrictions do not allow this method of physical activity assessment, then a pedometer will be sent to each participant (to their home address) with instructions on how to wear the device. As such, patients will be asked to provide details of daily step count (i.e., they will be asked to record daily steps using a physical activity diary and report these data during intervention sessions).

Overall study start date
16/04/2021

Completion date
31/08/2024

Eligibility

Key inclusion criteria
Heart failure patients:
1.1. Adults aged ≥18 years
1.2. Confirmed diagnosis of HF (reduced or preserved)
1.3. Actively involved in the HF care pathway and have no contraindications to physical activity

Healthcare professionals:
2.1. HCPs who are directly involved in the care pathway of HF patients, including but not limited to; cardiac nurses, cardiology consultants and physiotherapists.

Participant type(s)
Mixed

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 - Phase one: 40 (20 HF patients; 20 HCPs); Phase 2: same participants as phase one; Phase three 60 (40 HF patients; 20 HCPs)

Total final enrolment
40

Key exclusion criteria
HF patients: contraindications to physical activity as advised by a healthcare professional; receiving an intervention to improve lifestyle such as increasing physical activity levels or increase exercise capacity.

(added 28/04/2023) Healthcare professions: No exclusion criteria

Date of first enrolment
21/06/2021

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
University Hospital of North Tees
Hardwick Road

Hardwick
Stockton-on-Tees
Middlesbrough
United Kingdom
TS19 8PE

Study participating centre
South Tees Hospital NHS Foundation Trust
Marton Road
Middlesbrough
United Kingdom
TS4 3BS

Study participating centre
County Durham and Darlington NHS Foundation Trust
Hollyhurst Road
Darlington
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DL3 6HX

Sponsor information

Organisation
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Sponsor type
University/education

Website
https://www.tees.ac.uk/schools/shls/

ROR

https://ror.org/03z28gk75

Funder(s)

Funder type
Research organisation

Funder Name
Heart Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We intend to publish in a high impact peer reviewed scientific journal.
We intend to disseminate the results at a conference.

Intention to publish date
30/11/2024

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication, Other