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Cardiac Arrest REcovery, Self-management and Support (CARESS) feasibility study

Submission date
11/12/2024

Recruitment status
Recruiting

Registration date
28/01/2025

Overall study status
Ongoing

Last Edited
30/06/2025

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
A cardiac arrest occurs when someone's heart suddenly stops beating. In the UK, around 5,500 people survive their cardiac arrest each year. For most of these people, life is never the same again. Many cardiac arrest survivors have long-term problems with memory, emotions, fatigue, and physical and social difficulties which can reduce their quality of life. People are often anxious about carrying out daily activities. These changes can also be upsetting for family members or friends affected by the arrest ('co-survivors'), particularly if they were present at the time of the arrest. As well as caring for the survivor and the changes in the survivor, this can include processing the trauma of the event, and emotional concern that there will be a repeat event.
However, little is known about how to support survivors and their co-survivors, and they have said that they need more help and support on their recovery journey once they have returned home from the hospital. A new online programme of one-to-one and group education, support, and exercise rehabilitation for cardiac arrest survivors has been developed in collaboration with cardiac arrest survivors and co-survivors. This programme is expected to be provided soon after survivors return home from the hospital. A similar programme of education and support has also been developed for co-survivors. This study aims to test the programmes with up to 30 survivors and 30 co-survivors to see if they can be delivered in the NHS.

Who can participate?
Cardiac arrest survivors and co-survivors aged 18 years old and over

What does the study involve?
CARESS is an early, targeted care pathway. It has two routes: one specific for cardiac arrest survivors, and one for their close family, friends and others ('co-survivors'). CARESS is an exercise and support rehabilitation care pathway. Each route consists of 8 sessions. One session will run per week. Each session will last approximately 1 hour. They will be delivered virtually using video-conferencing software. Survivors will also be able to take part in an exercise programme, too. The CARESS facilitators are experts in providing rehabilitative care to cardiac patients. The components are:
1. Individual assessment: A one-hour, online assessment with a trained CARESS facilitator to holistically assess participant needs, introduce the programme, provide individualised advice and

set goals.
2. Online group support programme: seven online group sessions for up to an hour each, led by a CARESSf facilitator. Each session will focus on different key needs of participants (e.g., fatigue).
3. Online exercise programme (survivors only): Up to 30 minutes of exercise two to three times per week for 6-8 weeks. This will include a weekly supervised live session and two self-directed sessions.

What are the possible benefits and risks of participating?
The CARESS programme has been designed by survivors and co-survivors to address some of the common 'big' issues. Affected participants may access help and support. If parts of this support are not relevant, then taking part may not offer them any direct benefits. However, participants may find the opportunity to speak to others within the care programme helpful. Further, the findings from this study may help people recovering from cardiac arrests, and their co-survivors, in the future.

Taking part in group support sessions may feel sensitive for some people and could be upsetting. Participants will have the support of the group facilitator and peers, and if they need to, they can take a short break. For survivors, exercise may feel a little scary but the live exercise sessions involve light exercise, tailored to them, and delivered by experienced exercise physiologists – these are experts in delivering physical rehabilitation for patients. If any problems or concerns arise, participants can speak to the facilitator who will advise them appropriately.

Where is the study run from?
The study is a collaboration between Warwick University and University Hospitals Coventry and Warwickshire NHS Trust (UHCW). Warwick University is the sponsor of this study, and the CARESS care programme is being delivered by UHCW.

When is the study starting and how long is it expected to run for?
November 2023 to April 2026

Who is funding the study?
National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB) programme

Who is the main contact?
Professor Kirstie Haywood (Chief Investigator), k.l.haywood@warwick.ac.uk

Study website
https://warwick.ac.uk/fac/sci/med/research/hscience/sssh/caress/

Contact information

Type(s)
Scientific

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
339054

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 63599, NIHR Central Commissioning Facility Grant Code: NIHR204049

Study information

Scientific Title
The Cardiac Arrest Recovery Enablement and Self-management Support feasibility (CARESSf) study

Acronym
CARESSf v1.1

Study objectives
Cardiac arrest is characterised by the sudden cessation of heart function. In the UK approximately 5,500 individuals survive their cardiac arrest each year. These survivors often face significant long-term challenges, including memory issues, emotional disturbances, fatigue, and physical difficulties, which collectively diminish their quality of life. Anxiety about daily activities

is common, and these changes can also distress family members and friends ('co-survivors'), especially those present during the arrest, leading to their own long-term emotional difficulties. Currently, there is limited understanding of the optimal support strategies for cardiac arrest survivors and their co-survivors. While some survivors participate in cardiac rehabilitation, these programmes do not adequately address their specific physical and emotional needs, resulting in poor attendance.
This study aims to develop and test the feasibility of a new care programme designed in collaboration with cardiac arrest survivors, their co-survivors, and healthcare professionals. The programme will be piloted with up to 30 survivors and 30 co-survivors following hospital discharge. Feedback will be collected post-programme to refine the intervention. The ultimate goal is to conduct a future study to evaluate whether this new programme enhances the quality of life for cardiac arrest survivors and their co-survivors. The study proposal and ethics application have been developed with input from a public research partner group. Findings will be disseminated through accessible articles, events with clinical and survivor networks, conference presentations, and publications.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/09/2024, North East – Newcastle & North Tyneside 2 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 24/NE/0135

Study design
Non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community, Home, Internet/virtual, Medical and other records, Telephone

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Feasibility of a new care program designed in collaboration with cardiac arrest survivors, co-survivors, and healthcare professionals

Interventions
CARESS intervention delivery: CARESS will be delivered over 8 weeks and consists of three components.
1. One-to-one individual assessment: One-hour, online assessment with a CARESS facilitator

(trained and supported by a health psychologist throughout the study) to holistically assess participant needs, introduce the programme, provide individualised advice and set goals. All participants will be directed to validated and relevant external resources, such as those provided by Sudden Cardiac Arrest UK (https://www.SCAUK.org).

2. Psychosocial group support: Over the week intervention period, participants will attend seven weekly online group sessions each lasting for up to one hour, led by a CARESSf facilitator who will be trained and supported by a health psychologist during the study. Core theoretical principles have been drawn on to inform the psychosocial content, structure, and delivery. These include the biopsychosocial model of behaviour change, Michie's behaviour change wheel and taxonomy, Michie's COM-B model (Capability, Opportunity and Motivation), and psychological theories of self-efficacy (perceived confidence in the ability to engage and implement the strategies learnt), cognitive behaviour-change, and motivational interviewing.

3. Online, supervised, home-based, exercise/support rehabilitation (survivors only): Up to 30 minutes of exercise one to three times per week (two of which will be self-directed /independent) for up to 7 weeks; individualised and progressive multi-modality exercise at a manageable intensity, regulated with breathlessness and/ or perceived exertion scales. Participants will be encouraged to attend the live online group exercise session every week for up to 7 weeks led by a CARESS facilitator, using equipment-free exercise to improve confidence, cardiovascular fitness, strength, balance, and coordination. Where possible, groups will be arranged to allow those of similar age, ability, and gender to exercise together as a group.

Intervention Type
Behavioural

Primary outcome measure
1. Feasibility outcomes: Rates of recruitment and retention across the recruitment window measured using screening logs at baseline, 4 months (16 weeks) and 8 months (32 weeks)
2. Outcomes measurement: acceptability, respondent burden, and completion (missing data) of outcome measures measured using descriptive statistics at baseline and follow-up (11 weeks)
3. Quality of the intervention: assessment of delivery procedures for fidelity with study participants and facilitators measured by reviewing recordings of a subset of delivered sessions assessed post-intervention (9-13 weeks)
4. Process evaluation: of recruiter, participant and facilitator perspectives and experiences of delivery or participant in the study measured using data collected from interviews conducted post-intervention (9-13 weeks)

Secondary outcome measures
Current secondary outcome measures as of 30/06/2025:

1. Physical and mental health summary scoring measured using PROMIS® 29+2 Profile v2.1 (PROPr) at baseline and post-intervention (11 weeks)
2. Mental wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scales (WEMWBS) at baseline and post-intervention (11 weeks).
3. Fatigue measured using the Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F) and PROPr fatigue subscale at baseline and post-intervention (11 weeks).
4. Depression and anxiety measured using the Hospital Anxiety and Depression Scale (HADS) and PROPr depression and anxiety subscales at baseline and post-intervention (11 weeks)
5. PTSD symptom severity measured using the Impact of Events Scale-Revised (IES-R) at baseline and post-intervention (11 weeks).

6. Health utility measured using the EuroQoL 5-dimensions 5-levels (EQ-5D-5L) at baseline and post-intervention (11 weeks).
7. Health and social care resource use measured using the Modular Resource-Use Measure (ModRUM) core, at post-intervention only (11 weeks).
8. Personal resource use questionnaire measured using an internally generated questionnaire, at post-intervention only (11 weeks).

Previous secondary outcome measures:

1. Demographic information (age, gender, socioeconomic factors) measured using a questionnaire, captured at baseline.
2. Physical and mental health summary scoring measured using PROMIS® 29+2 Profile v2.1 (PROPr) at baseline and post-intervention (11 weeks)
3. Mental wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scales (WEMWBS) at baseline and post-intervention (11 weeks).
4. Fatigue measured using the Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F) at baseline and post-intervention (11 weeks).
5. Depression and anxiety measured using the Hospital Anxiety and Depression Scale (HADS) at baseline and post-intervention (11 weeks).
6. PTSD symptom severity measured using the Impact of Events Scale-Revised (IES-R) at baseline and post-intervention (11 weeks).
7. Health utility measured using the EuroQoL 5-dimensions 5-levels (EQ-5D-5L) at baseline and post-intervention (11 weeks).
8. Health and social care resource use measured using the Modular Resource-Use Measure (ModRUM) core, at post-intervention only (11 weeks).
9. Personal resource use questionnaire measured using an internally generated questionnaire, at post-intervention only (11 weeks).

Overall study start date
06/11/2023

Completion date
30/04/2026

Eligibility

Key inclusion criteria
Survivors will be included if they meet the following inclusion criteria:
1. Adult aged 18+ years
2. A cardiac arrest survivor
3. Discharged from the hospital to their usual place of residence within 30 days of their cardiac arrest
4. Recruited before, or within 8 weeks of hospital discharge
5. Proficient in the English language
6. Ability to complete online follow-up and attend online sessions

Key supporters will be included if they meet the following inclusion criteria:
1. Adult aged 18+ years
2. Self-refer into the study or are referred to as a nominated adult family member, friend or

significant other (key supporter) of a cardiac arrest survivor
3. Recruited within 8 weeks of the survivor being discharged from the hospital
4. Proficient in the English language
5. Ability to complete online follow-up and attend online sessions

Participant type(s)
Patient, Service user

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
Survivors will be excluded if they meet any of the following exclusion criteria:
1. Unable to give informed consent
2. Have severe mental health difficulties or cognitive impairment that prevents engagement
3. Are participating in another exercise, psychological support or structured rehabilitation study

Key supporters will be excluded if they meet any of the following exclusion criteria:
1. Unable to give informed consent
2. Have severe mental health difficulties or cognitive impairment that prevents engagement
3. Are participating in another exercise, psychological support, or structured rehabilitation study
4. Key supporters of cardiac arrest victims who do not survive to hospital discharge

Date of first enrolment
20/06/2025

Date of final enrolment
30/11/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road

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United Kingdom
CV2 2DX

Sponsor information

Organisation
University of Warwick

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Sponsor type
Hospital/treatment centre

Website
https://warwick.ac.uk/

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal within a year of the feasibility study end date.

Intention to publish date
30/04/2027

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date