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Management of patients with heart failure with preserved ejection fraction: what do patients and providers need and want?

Submission date
08/06/2020

Recruitment status
No longer recruiting

Registration date
17/06/2020

Overall study status
Completed

Last Edited
05/10/2022

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Heart failure with preserved ejection fraction (HFpEF) accounts for 50% of all cases of heart failure. In the UK 920,000 people are thought to be affected by heart failure and the number of people with HFpEF is thought to be growing due to the increasing prevalence of lifestyle diseases. Researchers previously conducted an interview study with patients and healthcare providers living with or managing HFpEF to try to work out what care patients received with the view to driving improvement. This was especially important as there is low awareness of this type of heart failure and inequality in service provision (e.g. some areas don't take on referrals for HFpEF as they are not funded to do so). This study has now concluded, however, all participants provided consent to be contacted about future linked research. The researchers now plan to undertake a COVID-19-related sub-study with this panel of participants to explore the experiences of this group in these unprecedented times. Due to COVID-19, many patients and providers have experienced changes in the care they receive/provide. The researchers would like to explore the impact of these changes in order to inform an ongoing programme of research (OPTIMISE HFpEF) which aims to design an optimised management pathway for people with HFpEF.

Who can participate?
Patients, carers and healthcare professionals who participated in OPTIMISE HFpEF (https://clinicaltrials.gov/ct2/show/NCT03617848) and who provided consent to be contacted about future research

What does the study involve?
This study involves either participating in an interview with a researcher that will be digitally recorded, or completing and returning a paper-based survey. Both the interview and the survey will ask participants about their experiences of receiving/providing healthcare in the run-up to, during and after the main wave of the COVID-19 pandemic.

What are the possible benefits and risks of participating?
The researchers do not perceive any risks to participating, surveys and interviews will be fully anonymised.

Where is the study run from?
1. University of Cambridge (UK)
2. Keele University (UK)
3. University of Manchester (UK)

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

Who is funding the study?
The Healthcare Improvement Studies Institute (UK)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Protocol serial number
Version 4.0, dated 21/04/2020

Study information

Scientific Title
Management of patients with heart failure with preserved ejection fraction: what do patients and providers need and want? A qualitative and survey-based study

Study objectives
This study aims to understand what patients and providers would like/envision as optimal management of heart failure with preserved ejection fraction (HFpEF). This study is part of a larger programme of research. In April 2020 this study was amended so that the researchers could recall previous participants who provided 'consent to be contacted about future research' in order to understand perspectives since the onset of the COVID-19 pandemic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/05/2020, North East - York Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8091, +44 (0) 207 104 8079; york.rec@hra.nhs.uk), REC ref: 17/NE/0199

Primary study design
Observational

Study design
Observational cross-sectional qualitative and survey study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Heart failure with preserved ejection fraction, impact of COVID-19 (SARS-CoV-2 infection) pandemic on healthcare received and provided

Interventions
Interviews will be performed via telephone or in person, digitally recorded and transcribed verbatim. Semi-structured interview schedules will guide questions. A survey exploring similar

fields will be distributed to those who cannot commit to an interview, the survey employs Likert type scales and free text boxes to capture views, Likert responses will be quantified and free-text answers interrogated thematically. Participation is once only, there will be no follow-up.

Intervention Type
Other

Primary outcome(s)
Perspectives on care provided and received since COVID-19, assessed using interview and survey at a single timepoint (baseline)

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
01/11/2020

Eligibility

Key inclusion criteria
This is a recall study: patients, carers and healthcare professionals who participated in OPTIMISE HFpEF (https://clinicaltrials.gov/ct2/show/NCT03617848) and provided 'consent to be contacted' will be invited to participate

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
50

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
08/06/2020

Date of final enrolment
01/11/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Cambridge
Institute of Public Health
Cambridge Biomedical Campus
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United Kingdom
CB2 0SR

Study participating centre
Keele University
School of Primary, Community and Social Care, Faculty of Medicine and Health Sciences
David Weatherall Building, Room 1.109
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United Kingdom
ST5 5BG

Study participating centre
University of Manchester
Division of Population Health, Health Services Research & Primary Care
Oxford Road
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Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Research organisation

Funder Name
The Healthcare Improvement Studies Institute

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the researchers do not have explicit consent to share the data, even in anonymised format, outwith the research team.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/11/2020	18/05/2021	Yes	No
Results article		05/01/2021	18/05/2021	Yes	No
Protocol article		26/11/2019	05/10/2022	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2	26/07/2018	05/10/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes