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Exploring the interaction between symptom burden and burden of treatment in patients with chronic heart failure

Submission date
03/12/2018

Recruitment status
No longer recruiting

Registration date
28/02/2019

Overall study status
Completed

Last Edited
18/08/2022

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:
Patients with chronic heart failure have debilitating and progressive symptoms. Key to improving outcomes is engagement with 'self-management' (tasks such as: taking medications, monitoring symptoms, etc.). Patients struggle with these tasks, leading to worsening illness and poorer quality of life. The concept, 'burden of treatment', describes this workload and its impact on patients' lives. It suggests, the balance between the treatment workload and their capability to manage is crucial. If burden of treatment is lessened it may improve self-management and quality of life.

Burden of treatment argues that symptom burden is a separate concept. But, symptoms in heart failure have been linked to changes in physical, cognitive, and emotional function that may make completing the self-management tasks harder. This may also alter their burden of treatment.

SYMPACT aims to examine and explore the interaction between symptoms and burden of treatment in patients with chronic heart failure.

Who can participate?
Adults (> 18 years of age) with chronic heart failure (> 6 months since diagnosis), able and willing to participate, whose health care is based in one of the participating NHS Trusts, will be invited to take part in this study. These individuals must not have had a heart transplant or be receiving end of life care. Their heart failure can be either with preserved ejection fraction or reduced ejection fraction.

What does the study involve?
SYMPACT has two phases. Phase I will invite patients to complete a single survey. They will be asked to share health information and complete three validated questionnaires. This can be completed at a health trust or in their home, it is their choice. The questionnaires capture their experience of symptoms and of managing their heart condition. Patients in Phase I may be

invited to participate in Phase II. Phase II consists of a single conversation, a 'semi-structured interview', where everyone will be asked similar questions. This will invite patients to share more of their experiences and elaborate on their responses from the questionnaires.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in this research study but you will be helping us to better understand your experience of managing your heart condition at home. It may help us find ways to make this experience better for other people in the future. There are no direct risks to taking part in this study

Where is the study run from?
This is multi-centre study. The lead NHS site is the Portsmouth Health Trust. University Hospital of Southampton NHS foundation Trust and Solent NHS are also helping to identify and invite people to take part in this study.

When is the study starting and how long is it expected to run for?
The study opened in Nov 12, 2018 and will remain open to recruitment until May 4, 2020.

Who is funding the study?
This study is sponsored by the University of Southampton. This study is a part of a PhD project being completed as a Clinical Academic Research Fellowship, which is supported by the Wessex Clinical Academic Training Programme.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
40297

Study information

Scientific Title
Exploring the interaction between symptom burden and burden of treatment in patients with chronic heart failure: a sequential explanatory mixed methods study

Acronym
SYMPACT 0.9

Study objectives
Phase I (Quantitative): If a patient with CHF reports a high symptom burden (measured by HFSS) then they will also report a high level of BoT (measured by BoT), additionally this occurrence will also result in a low quality of life (measured by MLHFQ).

Phase II (Qualitative): Study aim: Explore the experiences of living with chronic heart failure and elaborate on their thoughts of any interaction between symptom burden and burden of treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Nottingham 1 Research Ethics Committee, 07/11/2018, ref. 18/EM/0339

Study design
Observational, Cross-sectional

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Heart failure

Interventions
The design chosen for this study allows the researcher to use validated tools to measure both symptoms and burden of treatment in patients with chronic heart failure. However, as the interaction between these two concepts has not been explored before and as the burden of treatment tool was designed for a multi-morbid population these tools alone may not fully demonstrate possible interaction between these concepts. The qualitative phase of the study allows deeper exploration into this interaction. Further it promotes relating the quantitative results to the qualitative work through the use of the interim results to inform the interview question. This will also allow exploration around those results and if they hold meaning for the participants.

This study has two phases:
1. Phase I: Multi-Centre Survey of Symptoms and Burden of Treatment in Chronic Heart Failure
2. Phase II: Semi-Structured Interviews of Symptoms and Burden of Treatment in Chronic Heart Failure

Phase I
Clinical teams will identify possible participants and refer them to the study. Patients with heart failure can also self-identify through the public promotion campaign. Following identification of potential participants they will be either; a) sent an invite letter and patient information leaflet or b) given a patient information leaflet, whichever is most appropriate. They will then be given an appropriate amount of time to read and consider if they wish to participate in the study. If they are happy to take part they will then give their consent by completing the Phase I consent form. They will then be invited to share their health information and complete three validated questionnaires. This can be done independently in their home or within the health care trust, as appropriate and according to the patient's wishes. This then concludes their active participation in Phase I. It is anticipated that it will take participants between 30-90 minutes to complete the questionnaires. Phase I will continue until 18 months, and so will overlap with Phase II.

Phase II
After the interim analyses (9 months or 175 participants); participants from Phase I will be approached (depending on their optional consents and their eligibility criteria) by an invite letter to take part in Phase II. Phase II will consist of a single interview, conducted by the Chief Investigator. The interview will incorporate the interim results and their individual response into the interview schedule. The interview will occur in a safe environment mutually agreed upon by the chief investigator and participant. This could be the patient's home or a health care trust facility. It is anticipated the interview will take between 30-60 minutes but will be guided by the participants.

Timetable
Pending ethical and local approvals recruitment aims to begin Sept 1, 2018. The plan is to conduct the interim analyses of Phase I data after 175 patients have completed Phase I or nine months after recruitment starts, whichever occurs first. Once the interim results are known, Phase II recruitment can begin. Phase II will continue until the end of the recruitment period, 18 months. Phase II will continue until a month after the last eligible patient finished Phase I or when data saturation is reached, which ever happens first. The researchers will take 6-8 months to perform the data analysis, interpretation, integration, and prepare the final report (total duration estimated at 2 years and 3 months).

Data accuracy
Phase I: The chief investigator will not be completing all of the data entry, a portion of it will be performed by trained and delegated individuals. The electronic database will be built to minimize data entry errors. 10% of all data will be checked by an independent individual. These efforts will help to eliminate bias and check for errors. Phase II: The chief investigator will record a reflection after each interview to include in analysis and to check for researcher effects. Further the coding of the interviews will be discussed with the supervisors and 10% of coding checked by another researcher.

Sample Size:
Phase I: The goal is to recruit 350 patients, however if this goal is achieved before the end of months the researchers can continue to recruit patients until the end of 18 months. The goal of 350 patients is thought to be feasible over this time period, based on the Chief Investigators experience as a research nurse in other research studies.

Phase II: The goal is to achieve data saturation across the purpose sample that represents the population in Phase I. This is estimated to be between 16-32 patients but sample size will be guided by data saturation.

Sampling
Phase I: Will be a multi-centre study and seeks to identify patients with heart failure across a wide spectrum of illness severity. This will be achieved through identifying patients in both primary and secondary health care trusts in Hampshire. In addition, the chief investigator has created a public and community campaigns which aim to further broaden the scope of this study.

Phase II: Will be coordinated by the chief investigator and all participants from Phase I who agreed to participate in further studies will be considered. They must have completed their participation within the last 4 weeks, following the interim analysis. They must also meet one of the purposive sampling categories, which will ensure representation across the full Phase I population characteristics.

Public and Patient Involvement (PPI)
The chief investigator has invited the involvement of the Patient Research Ambassador group at the Queen Alexandra Hospital who have chosen to help researchers with PPI activities. The group think this project is worthwhile. They have helped in the writing of the lay summary, the patient invite letter, the patient information leaflets, the recruitment poster and flyer, and the thank-you letter. They have also guided the researcher in designing the study to be as least burdensome as possible. This has resulted in the researcher obtaining the authority (from the author of the tool) to use the shorter version of the Patient Experience of Treatment and Self-care (PETS) questionnaire. They have also offered help in creating the public and community campaigns and have volunteered to help with the promotion of the study once ethical approval is granted. Further, the chief investigator plans to get their help in the dissemination of the results especially in the community and public groups that help in the promotion of the study.

Intervention Type
Other

Primary outcome(s)
1. Symptom Burden is measured using the Heart Failure Symptom Survey (HFSS) at a single time point.
2. Quality of Life is measure using the Minnesota Living with Heart Failure Questionnaire (MLHFQ) at a single time point
3. Burden of Treatment is measure using the Patient Experience of Treatment and Self-care (PETS) questionnaire at a single time point

Key secondary outcome(s))
N/A

Completion date
22/09/2020

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Diagnosis of Heart Failure (preserved and reduced ejection fraction) at least 6 months prior to

consent (supported by any conventional imaging modality).
3. New York Heart Association (NYHA) class II - IV
4. On active treatment for heart failure (minimum of one evidenced based heart failure medication and a diuretic)
5. Life expectancy of at least of 12 months
6. Able and willing to complete study questionnaires
7. Able and willing to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
333

Key exclusion criteria
1. Clinical plan or past occurrence of treatment through heart transplant
2. Severe cognitive concerns, in the opinion of the investigator, which would substantially limit the individual's ability to report on what it is like to live with heart failure and manage the condition

Date of first enrolment
28/11/2018

Date of final enrolment
22/09/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Portsmouth Hospitals NHS Trust
Trust Headquarters,
F Level,

Queen Alexandra Hospital,
Southwick Hill Road,
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
University Hospitals of Southampton NHS Foundation Trust
Southampton General Hospital Level E,
R&D Division D,
Laboratory & Pathology Block,
SCBR - MP138
Southampton
United Kingdom
SO16 6YD

Study participating centre
Solent NHS Trust
Research &Improvement,
1st Floor PEC,
St Mary's Community Health Campus
Portsmouth
United Kingdom
PO3 6AD

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

The datasets generated during and/or analysed during the current study are/will be available upon request from the main study contacts (contact details above). The data will not be made available until after the completion of the main study contacts PhD. Additionally, the Sponsor can also be contacted in regards to the data for 10 years following the completion of the study (contact details above). Requests will be considered individually by all the authors and an appropriate response and release of data (only from participant who consent to their data being shared) will be provided.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results of survey on patient-reported symptoms and burden of treatment	21/04/2022	24/06/2022	Yes	No
Results article	Results of interviews on interaction between symptoms and burden of self-care work	09/08/2022	12/08/2022	Yes	No
Protocol article	protocol	17/09/2020	23/09/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes