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SYMPERHEART. Supporting symptom perception in persons living with heart failure

Submission date
26/01/2021

Recruitment status
No longer recruiting

Registration date
04/02/2021

Overall study status
Completed

Last Edited
21/11/2023

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 means that the heart is unable to pump blood around the body properly. It usually occurs because the heart has become too weak or stiff.
Symptom perception in heart failure (HF) has recently been identified as crucial for effective self-care. It is related to patient and health-system outcomes. This study aims to test feasibility, acceptability and outcomes responsiveness of an evidence-informed intervention supporting symptom perception. This will provide information for a subsequent study testing how well the SYMPERHEART intervention works on persons living with HF and their informal caregivers.

Who can participate?
This feasibility study will concern 30 adult persons with symptomatic heart failure, speaking French or German, being followed by home-based care; as well as their informal caregivers, that will be exposed to the SYMPERHEART intervention. The study will also concern six nurses from home-based care trained to deliver the intervention at the persons with HF's home. This study will be conducted in Western Switzerland in the canton of Fribourg.

What does the study involve?
After written informed consent has been obtained, baseline data including socio-demographic and clinical variables, as well as symptom perception factors will be collected by the research nurse during a visit at the patient's home. Also, patient-reported outcomes (PRO) will be collected in patients and informal caregivers (respectively HF self-care and symptom perception, perception of HF symptom burden, health status in patients; as well as caregivers' contribution to HF self-care and caregivers' burden) before the intervention exposure, at the end of intervention exposure and two months later. Clinical outcomes will be collected prospectively for three months after participant' inclusion.
In case participants experience difficulty to fill the questionnaire alone, the research nurse will help the participant in reading/filling in or responding to the questionnaire.
The intervention called SYMPERHEART will combine activities supporting body observation (i.e. symptom monitoring using graphs) and body analysis (i.e. symptom recognition and interpretation using guided reflection) thereby involving informal caregivers in these processes. Its duration will last one month with three face-to-face interactions delivered during this period, provided at home by home-care nurses. Each interaction will last about one hour. All face-to-face

interactions will be provided individually for each patient, accompanied by his/her informal caregiver, based on data collected at baseline.

What are the possible benefits and risks of participating?
The study will be conducted according to the Helsinki Declaration; the ethical commission has approved the study and informed consent from patients and caregivers will be obtained. We consider being included in this study as involving a minimal risk, which has been confirmed by the ethical commission. All participants will benefit from the usual medical and nursing care independent from study participation. Participant burden for participating in the study is anticipated to be low and principally related to time to participate (estimated at three hours over a one-month period) as well as time to fill the questionnaire (i.e., 70 and 62 items, representing about 45 and 30 minutes for persons with heart failure and informal caregivers, respectively), and necessitating no additional journey of the participants living with HF given that intervention will be delivered at home. On contrary, several potential benefits are anticipated for the study participants, thanks to having a time dedicated to an intervention targeting their HF self-care that considers their symptom perception and delivered by trained nurses. Participants will be supported in HF symptom monitoring, recognition and interpretation that intends to increase HF self-care and related outcomes and to avoid a delay in seeking care or hospitalization due to HF exacerbation. Also, participants' data will include PRO that are recognized to allow patient-centered care. Risks will be identified for each participants' health on low adherence to medication and risk of caregiver burden that will be shared with healthcare professionals from usual care to follow-up.

Where is the study run from?
The SYMPERHEART study is being run by the School of Health Sciences, HES-SO University of Applied Sciences and Arts Western Switzerland.

When is the study starting and how long is it expected to run for?
February 2020 to March 2022.

Who is funding the study?
1. School of Health Sciences, HES-SO University of Applied Sciences and Arts Western Switzerland
2. Service d'aide et de soins à domicile de la Sarine (SASDS)

Who is the main contact?
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Scientific

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Additional identifiers

Protocol serial number
2020-01820

Study information

Scientific Title
SYMPERHEART. An intervention to support SYMptom PERception in persons living with HEART failure and their informal caregiver: a feasibility study

Acronym
SYMPERHEART

Study objectives
Research questions are formulated as follows:
1. To what extent is the SYMPERHEART intervention feasible?
1.1. How much time is needed to recruit participants and to deliver the intervention?
1.2. How many eligible participants do we identify each week/month?
1.3. To what extend do the nurses deliver the intervention as described in the study manual?
2. Is the SYMPERHEART intervention acceptable for HF persons and caregivers, including informal caregivers and nurses?

2.1. How many eligible participants, including informal caregivers, do consent to participate each month? And what are the reasons for non-participation?
2.2. How many participants are retained and how many participants stop prematurely and for what reasons?
2.3. How do participants (i.e., HF persons, informal caregivers and nurses) rate the SYMPERHEART intervention's acceptability?
2.4. To what extend do HF persons and informal caregivers engage in the SYMPERHEART monitoring activities and in response to symptoms?
3. What is the magnitude of change of outcomes as a response to the SYMPERHEART intervention in HF persons?
3.1. What is the extent of HF self-care and symptom perception; perception of HF symptom burden; and health status responsiveness of symptom perception support?
3.2. How many HF events occur during the SYMPERHEART intervention?
4. What is the magnitude of change of outcomes as a response to the SYMPERHEART intervention in informal caregivers?
4.1. What is the extent of informal caregivers' contribution to HF self-care; and informal caregivers' burden responsiveness of symptom perception support?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/10/2020, Cantonal Council of Ethics for Human Research (Av. De Chailly 23, CH-1012 Lausanne; +41 21 316 18 30; secretariat.CER@vd.ch), ref: 2020-0182; amendment approved on 06/01/2021

Primary study design
Interventional

Study design
Feasibility trial using a repeated measures quasi-experimental pre-post design

Study type(s)
Other

Health condition(s) or problem(s) studied
Chronic heart failure

Interventions
SYMPERHEART is an evidence-based intervention that targets heart failure symptom perception. The intervention combines body observation (i.e. symptom monitoring on paper graphs based on symptom clusters identification, instruction about self-care management and symptom response in case of symptom exacerbation) and body analysis (i.e. situation awareness and guided reflection) thereby involving informal caregivers in these processes.

Its duration will last 1 month with three face-to-face interactions delivered during this period, provided at home by home-care nurses previously trained by modules related to the intervention. Each interaction will last about one hour and will be individualized based on data collected at baseline. All face-to-face interactions will be provided individually for each patient, accompanied by his/her informal caregiver with intervention components delivered to both participants together.

Follow-up will be done at the end of intervention exposure and after 2 months.

Intervention Type
Behavioural

Primary outcome(s)
1. Intervention feasibility measured by :
1.1. Time needed to recruit participants and to deliver the intervention measured using excel files to report time dedicated to this work throughout the study
1.2. Number of eligible participants identified each week and month measured using Redcap® platform that allows to store data on a dedicated secured server and reported on the study flow diagram each month and at the end of the study
1.3. Extend of intervention delivered as described in the study manual (intervention fidelity) measured using fidelity checklists filled by the nurses after each face-to-face interaction with the participants
2. Intervention acceptability measured by:
2.1. Number of eligible participants, including informal caregivers, consenting to participate each week/month, and reasons for non-participation measured using Redcap® platform that allows to store data on a dedicated secured server and reported on the study flow diagram each month and at the end of the study
2.2. Number of participants retained during the 3-month study period; number of participants stopping prematurely and reason for stopping, where available measured using Redcap® platform that allows to store data on a dedicated secured server and reported on the study flow diagram each month and at the end of the study
2.3. SYMPERHEART intervention's acceptability for participants (i.e., HF persons, informal caregivers and nurses delivering the intervention) measured using the Treatment Acceptability and Preferences (TAP) measure adapted for the SYMPERHEART study at 30 days for HF persons and informal caregivers and at the end of the study for nurses
2.4. Extent of HF persons and informal caregivers' responsiveness in the SYMPERHEART monitoring activities and in response to symptoms measured using paper graphs
2.4.1. by the rate of engagement in symptom and weight monitoring daily based on paper graph documentation at 30 days
2.4.2. by the rate of response to weight gain or weight loss of more than 2 kg in 1 to 3 days documented on the paper graph at 30 days

Key secondary outcome(s)
1. PRO in persons living with HF
1.1. HF self-care measured using the Self-Care of HF Index (SCHFI) v.7.2 at baseline, 30 days and 90 days
1.2. Perception of HF symptom burden measured using the Heart Failure Somatic Perception Scale (HFSPS) v.3 at baseline, 30 days and 90 days
1.3. Health status measured using the Kansas City Cardiomyopathy questionnaire KCCQ-12 at baseline, 30 days and 90 days

2. PRO in informal caregivers
2.1. Caregivers' contribution to HF self-care will be measured with the Caregiver Contribution to Self-care of HF Index CC-SCHFI v.2 at baseline, 30 days and 90 days
2.2. Caregivers' burden will be measured with the Zarit Burden Interview at baseline, 30 days and 90 days

3. Clinical outcomes
3.1. Mortality measured using number of deaths occurring during the 90 days after participant enrollment reported in the health records or reported in Serious Advent Event form by the general practitioner
3.2. Hospitalization reason measured using number of hospitalization due to cardiac decompensation and number of hospitalization due to other reason during the 90 days after participant enrollment reported in the health records or reported in Serious Advent Event form by the general practitioner
3.3. Hospitalization length of stay measured using data of admission and date of discharge in case of hospitalization during the 90 days after participant enrollment reported in the health records or reported in Serious Advent Event form by the general practitioner

Completion date
31/03/2022

Eligibility

Key inclusion criteria
Patient participants:
1. HF adults ≥18 years old
2. Confirmed HF diagnostic
3. NYHA class II-IV
4. Speaking French or German
5. Being followed by home-based care
6. Providing written informed consent to participate

Informal caregiver:
1. Adult ≥18 years old
2. Identified by the participating HF patient as an informal caregiver
3. Either living with the patient, or having at least weekly contact
4. Speaking French or German
5. Providing written informed consent to participate.

Nurse sample:
1. Registered/diploma nurses delivering the intervention
2. Fluent in French or German
3. Designated by the home care nurse manager

Participant type(s)
Patient, Health professional, Carer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
32

Key exclusion criteria
Patient participants:
1. Suffering from immediately life threatening or terminal illness
2. Being already enrolled in an interventional study supporting heart failure self-care
3. Clinical instability necessitating a hospitalization
4. Subject to cognitive impairment that would preclude written informed consent

Informal caregiver:
1. Subject to cognitive impairment that would preclude written informed consent
2. Suffering from immediately life threatening or terminal illness
3. Refusal by the HF person to involve an informal caregiver in the study

Nurse sample:
1. Not having attended to the preparation sessions of the intervention

Date of first enrolment
11/01/2021

Date of final enrolment
16/11/2021

Locations

Countries of recruitment
Switzerland

Study participating centre
Service d'aide et de soins à domicile de la Sarine (SASDS)
Route de St-Nicolas-de-Flüe 2
Fribourg
Switzerland
CH-1700

Sponsor information

Organisation
HES-SO Fribourg

ROR

https://ror.org/02kkwkt79

Funder(s)

Funder type
University/education

Funder Name
Haute école Spécialisée de Suisse Occidentale

Alternative Name(s)
University of Applied Sciences Western Switzerland, Fachhochschule Westschweiz, HES-SO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Switzerland

Funder Name
Service d'aide et de soins à domicile de la Sarine (SASDS)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from Petra Schäfer (Petra.Schaefer-Keller@hefr.ch). This will concern the individual de-identified participant data including socio-demographic and clinical variables, as well as data about primary and secondary outcomes. The data will become available after article publication (planned in summer 2022) and for 10 years, by any researcher providing a methodologically proposal and after approval by Petra Schäfer and Gabrielle Santos, to be used for secondary analyses or meta analyses. The data will concern those participants that have accepted to share their data for raw data by signing the informed consent form specific to raw data. The dataset will be anonymized, thus not containing any participant name, nor date of birth.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article		04/10/2023	05/10/2023	Yes	No
Protocol article		27/07/2021	19/10/2021	Yes	No
Basic results	version 23	21/11/2023	21/11/2023	No	No
Participant information sheet	version V3	17/12/2020	01/03/2021	No	Yes
Participant information sheet	version V2	27/08/2020	01/03/2021	No	Yes
Participant information sheet	version V2	27/08/2020	01/03/2021	No	Yes
Participant information sheet	version V3	17/12/2020	01/03/2021	No	Yes