

BMJ Open SYMPERHEART: an intervention to support symptom perception in persons with heart failure and their informal caregiver: a feasibility quasi-experimental study protocol

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ABSTRACT

Introduction Symptom perception in heart failure (HF) has been identified as crucial for effective self-care, and is related to patient and health system outcomes. There is uncertainty regarding the feasibility and acceptability of symptom perception support and doubts regarding how to include informal caregivers. This study aims to test the feasibility, acceptability and outcome responsiveness of an intervention supporting symptom perception in persons with HF and their informal caregiver.

Methods and analysis A feasibility study with a quasi-experimental pretest and post-test single group design is conducted. The convenience sample consists of 30 persons with HF, their informal caregivers and six nurses. SYMPERHEART is an evidence-informed intervention that targets symptom perception by educational and support components. Feasibility is measured by time-to-recruit; time-to-deliver; eligibility rate; intervention delivery fidelity rate. Acceptability is measured by rate of consent, retention rate, treatment acceptability and the engagement in the intervention components. Outcome responsiveness includes: HF self-care (via the Self-care of Heart Failure Index V.7.2); perception of HF symptom burden (via the Heart Failure Somatic Perception Scale V.3); health status (via the Kansas City Cardiomyopathy Questionnaire-12); caregivers' contribution to HF self-care (via the Caregiver Contribution to Self-Care of Heart Failure Index 2); caregivers' burden (via the Zarit Burden Interview). Clinical outcomes include HF events, hospitalisation reason and length of hospital stay. Descriptive statistics will be used to report feasibility, acceptability, patient-reported outcomes (PRO) and clinical outcomes. PRO and caregiver-reported outcome responsiveness will be reported with mean absolute change and effect sizes.

Ethics and dissemination The study is conducted according to the Declaration of Helsinki. The Human Research Ethics Committee of the Canton of Vaud, Switzerland, has approved the study. Written informed consent from persons with HF and informal caregivers are obtained. Results will be published via peer reviewed and professional journals, and further disseminated via congresses.

Trial registration number ISRCTN18151041.

Strengths and limitations of this study

- A strength lies in the detailed description of the methods, which will allow others to reproduce the study design.
- The study is based on the Medical Research Council Framework for the development and evaluation of complex interventions in health and will inform a subsequent trial on the intervention feasibility and acceptability in persons with heart failure, their informal caregivers and nurses delivering the intervention in a real-world setting.
- Internal validity is ensured by the use of valid and reliable instruments to collect data on outcome responsiveness as well as feasibility and acceptability measures.
- Limitations are related to the design of this pre-test and post-test study, without a control group, between-group effects cannot be assessed.
- Further research will be needed to evaluate the effectiveness of the intervention.

INTRODUCTION

The importance of heart failure self-care

Heart failure (HF) is a major health concern^{1,2} related to poor quality of life,³ frequent hospitalisation and high mortality.^{4,5} HF self-care is recognised as an important contributor to improved outcomes in terms of reduced myocardial stress,⁶ reduced systemic inflammation⁶ and event-free survival.^{7,8} While HF self-care support is recommended within modern treatment approaches including multidisciplinary management programs,⁹ HF self-care remains suboptimal worldwide⁹ as in the Swiss context.^{10,11} HF self-care is composed of three constructs occurring in sequence: self-care maintenance, symptom perception and self-care management.¹² Importantly, symptom perception followed by symptom response has been described as



reducing the need for healthcare services and improving survival.⁷ Symptom perception has been defined as a process to detect physical sensations and interpret their meaning.¹² Symptom perception is composed of two complementary parts: body observing and body analysing.¹³ It involves body listening, monitoring signs, then recognising, interpreting and labelling symptoms.¹²

The role of symptom perception in patient outcomes

Studies evaluating symptom perception have been associated with mixed results¹⁴ and symptom perception outcomes have been reported¹⁴ such as improved general and physical health,¹⁵ reduced mortality,^{16–19} fewer HF decompensation events,²⁰ decreased hospitalisation or emergency visits,^{21 22} decreased length of stay and costs,²³ better weight monitoring,²⁴ symptom recognition²⁵ and self-care management,^{26 27} less healthcare utilisation⁷ and shorter delays to seek care.^{28 29}

Symptom perception remains an issue for persons with HF.¹³ In a recent literature review, symptom perception was described as challenging in terms of detecting physical sensations as well as interpreting the meaning of signs and symptoms.¹³ Negative consequences were escalating symptoms and delayed help seeking, leading to emergency situations or hospitalisation.¹³ Symptom perception facilitators and barriers have been reported.¹³ Prior HF hospitalisation, HF self-care maintenance, confidence in symptom perception and social support have been found to positively influence symptom perception.¹³ Further, uncertainty about illness has been reported as a symptom perception facilitator,¹³ that is, higher illness uncertainty was associated with more attention to somatic changes.³⁰ HF-related knowledge deficits, symptom clusters (ie, the experience of several concurrent symptoms)³¹ and lack of tools/materials (eg, patients without a scale for weight monitoring)³² negatively influence symptom perception.¹³ One instrument, the 29-item Self-Care of HF Index (SCHFI) V.7.2 containing the 11-item Symptom Perception subscale, was found to measure symptom perception.¹⁵

Combining body observation, body analysis and informal caregivers' involvement to support symptom perception

Body observation (ie, body listening, symptom monitoring) and body analysis (ie, symptom recognition, interpretation and labelling) are crucial elements to combine to support symptom perception. According to a literature review,¹⁴ seven interventions^{33–39} targeting symptom perception in pilot studies have shown promising results in terms of clinical improvement of HF self-care,^{33 34} decreased symptom intensity,³⁵ number of symptoms³⁶ and perceived distress³³ as well as better health-related quality of life.^{35 36} Another study⁴⁰ focusing on symptom perception and symptom response pilot-tested the efficacy of a similar training programme and reported greater absolute change compared with controls for self-care maintenance and confidence.⁴⁰ Importantly, some interventions focused only on symptom monitoring^{35 37} or only

on symptom recognition.³⁹ Other interventions^{33 34 36 38 40} including components related both to body observing and body analysing have been recommended to be further tested.¹⁴ Monitoring symptoms,⁴¹ integrating symptom monitoring into daily routines,^{41 42} understanding bodily sensations related with HF⁴³ and learning based on past experience^{42 44} are recommended components for symptom perception support interventions according to systematic reviews.^{41–44} Additionally, body listening and learning based on experience appear to be crucial in body analysing,⁴⁵ which precedes symptom response,^{7 12} and should therefore be added to support symptom perception.

Informal caregivers need to be included in symptom perception support as they play a crucial role in HF symptom monitoring and recognition^{14 46} and contribute to HF self-care.⁴⁷ They have been lacking in HF symptom perception research so far. It has been suggested to involve them in future interventions^{42 43} as they may improve self-care in older, frail and cognitively impaired persons with HF.² Importantly, informal caregivers have specific needs related to symptom perception during all HF phases of illness in terms of symptom monitoring, recognition and management.⁴⁶ Both positive and negative outcomes should be assessed in caregivers to fully evaluate the effect of involvement in HF symptom perception interventions.⁴⁷ Given the reciprocal relation between illness and family,⁴⁸ and because HF can induce a burden on caregivers,⁴⁹ attention should be given to limiting that burden when including caregivers in symptom perception interventions. Nevertheless, no interventional study involving informal caregivers has reported harm to patients or caregivers⁴⁶ and caregiver contribution to self-care maintenance and management did not predict burden on caregivers,⁵⁰ suggesting benefits for both patients and caregivers.

The need to pilot-test an intervention supporting symptom perception

According to the Medical Research Council framework for complex interventions research methods,⁵¹ a complex intervention should be pilot tested for feasibility and acceptability before being evaluated for effectiveness.^{51 52} This pilot testing aims to promote the adoption of a suitable intervention in a specific context, and to anticipate failures in the intervention that would impede its implementation.⁵² In the feasibility or piloting testing phase, uncertainties are addressed regarding methods, intervention delivery and acceptability (eg, intervention fidelity, magnitude of effect), as well as regarding procedures (eg, recruitment, attrition rates, sample size determination) that are specific to an intervention and a particular context.⁵² Given the number and difficulty of different behaviours required by the persons delivering and receiving the intervention,⁵¹ supporting symptom perception is considered a complex intervention.

The literature on symptom perception is mostly descriptive²⁹ and there is a lack of fully powered interventional

studies with appropriate designs to assess the effectiveness of symptom perception support.¹⁴ Except for one randomised controlled trial,^{33 40} studies^{34–39} were quasi-experimental with a pretest and post-test single group or to assess feasibility. Nevertheless, this evidence is sufficient to inform an intervention. Few studies have tested the combination of support for body observing and body analysing. None of them have included informal caregivers, so there is no published knowledge on the feasibility or acceptability of including them, nor on their potential influence on the outcome of an intervention. Before further studying of symptom perception intervention effectiveness, it is first necessary to test an intervention for its feasibility in a given setting.

Study aims

The overall aim of the study is to test the feasibility, acceptability and outcomes responsiveness of the SYMPERHEART intervention supporting SYMptom PERception in HEART failure (SYMPERHEART).

The primary objective is to test the feasibility and acceptability of the SYMPERHEART intervention. The secondary objective is to test outcome responsiveness of

the SYMPERHEART intervention in persons with HF and their informal caregivers.

METHODS AND ANALYSIS

Study design

The study is a feasibility study over a 3-month period with one group exposed to an intervention supporting symptom perception (SYMPERHEART), with a quasi-experimental pretest and post-test design with repeated measures at baseline, and after one and 3 months (ie, over a 3-month study period).

Intervention

The SYMPERHEART intervention (figure 1) was designed based on the situation-specific theory of HF self-care^{12 53} and recent literature reviews^{13 14} and aims to support symptom perception in persons with HF. SYMPERHEART is an evidence-informed intervention that targets symptom perception using both an educational and support component on body observing and body analysing in persons with HF and their informal caregivers. Its duration is 1 month⁴⁰ with three

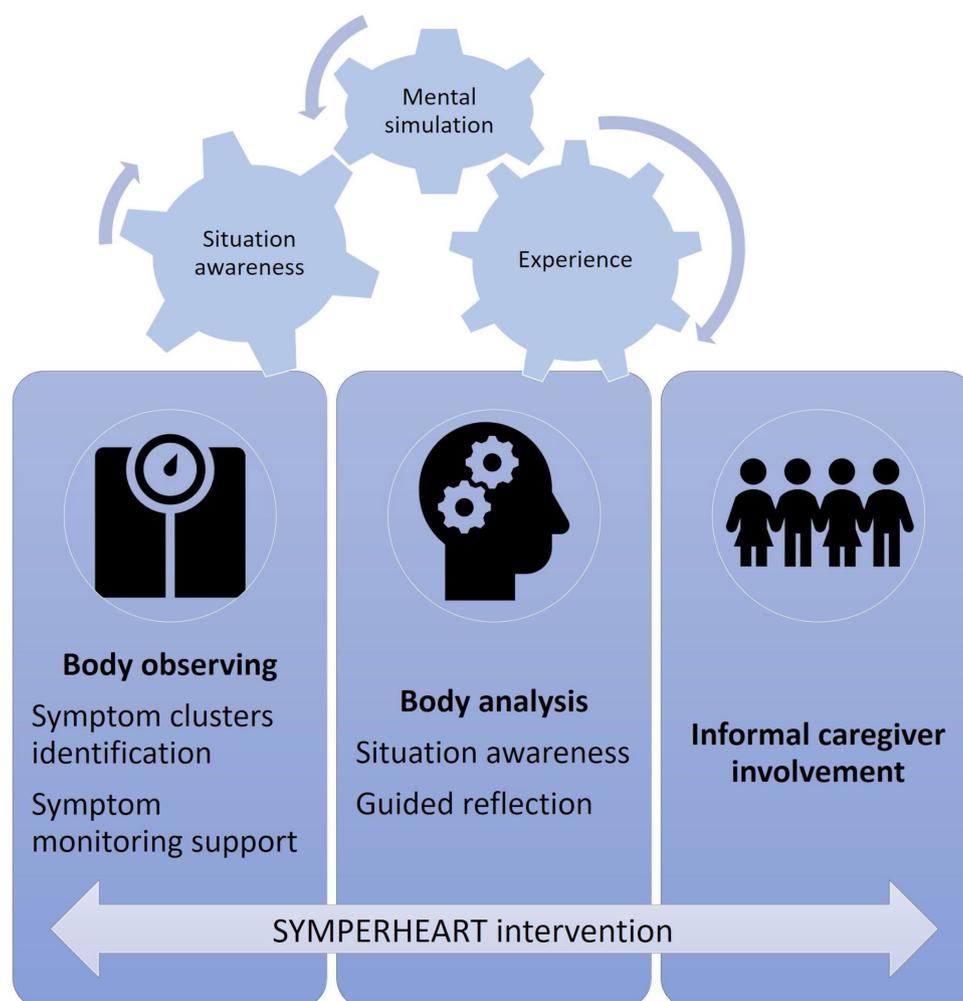


Figure 1 The SYMPERHEART intervention combining body observing, body analysis and informal caregiver involvement to support symptom perception in heart failure. Symptom perception as a naturalistic decision making process.¹²

face-to-face interactions delivered during this period, at home by homecare nurses. Nurses are previously trained in modules related to the intervention and supported to deliver it consistently. Among the nurses delivering the intervention, median years of being a registered nurse and of professional experience in homecare are, respectively, 10 (IQR=9) and 4 years (IQR=6). Each interaction lasts about 1 hour. All face-to-face interactions are provided individually for each person with HF, in the presence of, as far as possible, his/her informal caregiver with intervention components delivered to both participants together.

Prerequisites to symptom perception support

► The nurse informs him/herself about the situation.

The nurse assesses the person's symptom perception barriers and facilitators, self-care levels and symptom clusters as assessed via sociodemographic and clinical variables, HF self-care (SCHFI V.7.2; Caregiver Contribution to SCHFI, CC-SCHFI 2) and perception of HF symptom burden (Heart Failure Somatic Perception Scale, HFSPS V.3). The nurse reads the person's homecare record and informs him/herself about the main concerns related to HF.

► HF self-care maintenance support and information provision.

Self-care behaviours of maintenance, symptom perception and management are often built on each other, in the sense that maintenance is often mastered before symptom perception.¹² Thus, based on SCHFI V.7.2 and CC-SCHFI 2 baseline data, the nurse discusses the results of self-care maintenance with the person. The nurse highlights good self-care behaviours, helps reinforce self-care maintenance activities already mastered and seeks to identify self-care maintenance behaviours that are currently rather low. The nurse links the persons' main concerns related with HF with self-care maintenance (eg, the will to remain as autonomous as possible and the benefits of physical activity), and suggests maintenance behaviours in need of improvement from a professional point of view. The person is provided the HF booklet of the Swiss Heart Foundation⁵⁴ and a focus is made on discussing behaviours to maintain physiological stability. During this discussion, specific attention is paid to communicate to increase confidence.

Intervention components to support body observation

► Symptom cluster identification.

Symptom perception can be hampered by comorbidities,⁵⁵ which have been shown to influence the detection of symptoms and make it difficult to discriminate HF symptoms from those of the comorbidities.^{13 56} Identifying individual symptom clusters can help attribute symptoms to HF⁴⁰ and the results of the HFSPS V.3 are discussed with the person. His/her three most severe symptoms are identified for daily self-monitoring to guide HF symptom recognition.

► Symptom monitoring support.

Paper graphs⁴⁰ for daily symptom monitoring are provided to persons. Persons are instructed to carry out daily monitoring for the severity of their three most severe symptoms after usual exercise (such as having a shower). If dyspnoea is not one of the three most severe symptoms, it is added to the symptoms to monitor. The person is instructed to monitor weight and oedema daily as described in the HF booklet.⁵⁴ Informed by the HF symptom perception subscale (SCHFI V.7.2), the nurse discusses symptom monitoring behaviours and discusses how they might become embedded in the person's daily routines. Persons without a digital weighing scale at home are provided with one. A weight monitoring graph is individualised for each person, that is, baseline weight is documented on the graph, and upper and lower control limits in relation to weight gain or loss are discussed according an increase or loss of 2 kg over 3 days compared with the person's baseline weight.⁵

The importance of responding to symptoms is discussed. Persons are informed when and how to respond to symptoms when experiencing any of the following alarm signs: weight gain or loss ≥ 2 kg in 3 days, sudden shortness of breath, strong cough during the night and orthopnea, dizziness, sudden leg and abdomen swelling, chest pain, sudden palpitations as described in the HF booklet.⁵⁴

Intervention components to support body analysis

► Situation awareness about HF symptoms.

Given the home environment, HF symptoms are not triggered as previously reported.⁴⁰ Instead, person recall is used to remember a particular symptom experience (eg, remembering having had shortness of breath after a shower or after physical exercise). In case symptoms are not remembered, the person walks in the presence of the nurse in his/her home environment, in order to help to recall the experience of shortness of breath.

► Symptom recognition and interpretation using guided reflection.

Symptom recognition and interpretation are supported through open-ended questions (table 1) in line with experiential learning⁵⁷ using guided reflection.³⁴ First, the nurse asks the person to remember a situation when she/he experienced HF symptom exacerbation and guides the person to describe the experience, with reflective observation questions. Then, the nurse supports abstract conceptualisation and helps to interpret HF symptoms from the person's narrative. The nurse ends with the question preparing active experimentation and informs on self-care management activities² and on how to respond to a possible HF symptom exacerbation when alarm signs are detected based on the HF booklet.⁵⁴ At each meeting, the nurse uses these same questions related to symptoms experienced since the previous meeting. Informed by symptom perception and to support confidence in symptom perception,^{12 13 58} the nurse supports related activities already performed. The nurse promotes self-efficacy by providing feedback on each step.⁵⁹

Table 1 Guided reflection questions^{34 57}

Reflective observation questions	First instructions: remember if you have already experienced that kind of symptom exacerbation (eg, relating to a prior HF hospitalisation)
	Describe what happened? What did you do first? And then? What happened at the end?
	What was good and bad about the situation?
Questions supporting abstract conceptualisation	What sense can you make of the situation? What were you thinking at the time? What else could you have done?
Question preparing active experimentation	If the situation arises again, what would you do?

HF, heart failure.

Intervention components involving informal caregivers

The intervention components for informal caregivers are similar to those delivered to persons with HF and are embedded in each step conducted with the person. Thus, intervention components involving informal caregivers are delivered together with the components for the person with HF.

► Prerequisites to symptom perception support.

Each informal caregiver is asked to participate in every meeting, as far as possible. First, the informal caregiver is asked if she/he sees a role for him/herself relating to the person's HF ('What kind of role do you see for yourself in that situation?'). The informal caregiver is asked what kind of role she/he could imagine having to support symptom perception in his/her close relative ('How do you/could you monitor, detect, recognize and/or interpret HF symptoms together?'). The informal caregiver is informed about the key role she/he can have to support body observation and analysis in his/her relative, for example, in participating in weight and symptom monitoring activities and in supporting HF symptom recognition and interpretation of weight gain or swelling. Also, in the presence of the informal caregiver, the nurse asks the person how the informal caregiver could help him/her. Informal caregivers are informed about www.heartfailurematters.org web site containing specific support for informal caregivers.

► Informal caregivers' involvement in body observation.

Informal caregivers are involved to support symptom perception activities related to body observation. They are instructed about daily self-monitoring, with information about which HF symptoms should be monitored, how and how they should be reported on graphs that are provided. Each informal caregiver is asked to contribute the symptoms observed in the person, and is encouraged to review these symptoms with the person.

► Informal caregivers' involvement in body analysis

Informal caregivers are involved to support symptom perception activities related to body analysis. During the interview using guided reflection, the nurse also uses guided reflection with the informal caregiver to support experiential learning, based on previous observations

made by the informal caregiver, and using the same questions as those used for the persons with HF (table 1).

Coordination with usual care

During the delivery of the intervention, nurses take notes to document their intervention. These notes are added to the homecare record to inform the healthcare professionals. Importantly, when the person with HF is recruited, their general practitioner (GP) is informed in writing of the person's enrolment in the study. The GP receives information about HF self-care capabilities, HF symptom burden based on baseline data collection, and estimated risks to person health based on baseline data and clinical judgement. The GP is asked to carry out serious adverse event (SAE) reporting during the study period.

Sample and setting

Three convenience samples, respectively of 30 persons with HF, their informal caregivers and six nurses delivering the SYMPERHEART intervention, compose the study sample (table 2). The recommendations about sample size vary between N=10–60 in pilot studies.^{60–62} We aim to include 30 persons with HF and 20–30 informal caregivers to address the study's aims. Inclusion of persons with HF is done independently from informal caregiver participation.

This feasibility study is conducted in a rural region of Western Switzerland, in collaboration with one home-based service providing primary care. There, more than 2200 persons with any type of disease receive home-based care, and more than 1500 of them are aged >65 years old.⁶³

Recruitment procedures

Persons with HF are identified by the nurse coordinator (JW) at the home-based care service using a list of inclusion and exclusion criteria. The nurse coordinator or the nurses involved in the study provide brief information about the study existence to an eligible person (by providing a study leaflet) with the aim of obtaining permission to transfer the person's contact information to the research nurse. The research nurse (GCS) contacts

Table 2 Participants inclusion criteria

	Inclusion criteria	Exclusion criteria
Persons with HF	<ul style="list-style-type: none"> ▶ Adults ≥18 years old ▶ Confirmed HF diagnostic ▶ NYHA class II–IV ▶ Speaking French or German ▶ Receiving home-based care and living at home ▶ Providing written informed consent to participate 	<ul style="list-style-type: none"> ▶ Suffering from immediately life threatening or terminal illness. ▶ Clinical instability requiring hospitalisation. ▶ Already enrolled in an interventional study supporting HF self-care ▶ Subject to cognitive impairment that would preclude written informed consent.
Informal caregivers	<ul style="list-style-type: none"> ▶ Adults ≥18 years old. ▶ Identified by the participating HF person as an informal caregiver. ▶ Living with the person with HF or having at least weekly contact. ▶ Speaking French or German. ▶ Providing written informed consent to participate. 	<ul style="list-style-type: none"> ▶ Cognitive impairment that would preclude written informed consent. ▶ Suffering from immediately life threatening or terminal illness. ▶ Refusal by the person with HF to involve an informal caregiver in the study.
Nurses	<ul style="list-style-type: none"> ▶ Registered/diploma nurses delivering the intervention. ▶ Working in the study setting's homecare site. ▶ Fluent in French or German. ▶ Being designated by the homecare nurse manager. 	<ul style="list-style-type: none"> ▶ Not having attended to the preparation sessions of the intervention.

HF, heart failure; NYHA, New York Heart Association functional class.

the person per telephone to make an appointment at the person's home, then confirms eligibility, provides full study information, answers questions, collects informed consent and then baseline data. The person with HF identifies an informal caregiver that is contacted by the research nurse with information on the study, and that supplies informed consent. Nurses are recruited by the home-based service managers.

Variables and measures

Primary outcome

Feasibility and acceptability are the primary outcomes of the study. Feasibility is measured by: time-to-recruit; time-to-deliver the intervention; eligibility rate and intervention delivery fidelity rate (measured via a 15-point fidelity checklist filled by the nurse at each interaction). Acceptability is measured by: consent rate; retention rate; treatment acceptability (measured with the Treatment Acceptability and Preferences measure⁶⁴ adapted for the SYMPERHEART study including a space to add comments about the acceptability of the intervention); persons with HF and informal caregivers' engagement in the SYMPERHEART intervention (measured by the rate of engagement in symptom and daily weight monitoring based on paper graph documentation; as well as by the rate of response to weight gain or weight loss of more than 2 kg in 1–3 days documented on the paper graph). Additionally, intervention feasibility and acceptability will be explored via exit interviews with the nurses, regarding what did and did not work regarding the delivery of the intervention.

Secondary outcomes

Patient-reported outcomes (PRO) and clinical outcomes are secondary outcomes of the study. PRO in persons

with HF are the following: HF self-care and symptom perception measured with the SCHFI V.7.2^{15 65}; perception of HF symptom burden measured with the HFSPS V.3⁶⁶; as well as health status measured with the Kansas City Cardiomyopathy Questionnaire short version-12.⁶⁷ Clinical outcomes are HF events (ie, number of HF hospitalisations due to decompensation; number of deaths occurring during the 3 months study period); and length of stay in case of HF hospitalisation. Informal caregiver-reported outcomes are caregivers' contribution to HF self-care measured with the CC-SCHFI 2⁶⁸ and caregivers' burden measured with the Zarit Burden Interview.⁶⁹ Both CC-SCHFI 2, SCHFI V.7.2 and HFSPS V.3 have been translated from English to French and German (for Switzerland) according to state-of the art recommendations for linguistic validation of PROs.⁷⁰

Other variables

For persons with HF

Sociodemographic variables: age, sex, level of education, living alone or with someone, received social support, religion, race. Clinical variables: date of HF diagnosis, severity of HF via the New York Heart Association functional class, previous HF hospitalisation, comorbid conditions measured via the Charlson Comorbidity Index,⁷¹ cognitive impairment as recorded in homecare records, depressive symptomatology and screening via the Patient Health Questionnaire-2.⁷² Other variables: confidence in symptom perception, via two items of the Self-care confidence subscale⁷³ and having a digital scale at home.

For informal caregivers

Age, sex, education level, living situation, received social support, nature of relationship with the person with HF, nature of living situation with the person, religion, race.

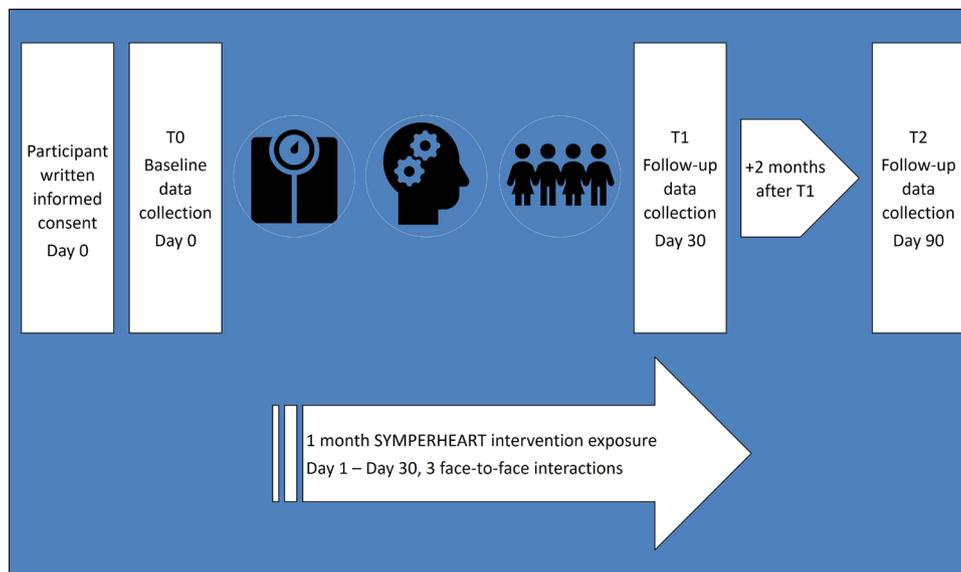


Figure 2 Graph of the study period. Each person and caregiver are enrolled for 3 months from the day of study enrolment until the last follow-up (+90 days). They are exposed to the SYMPERHEART intervention during 1 month following enrolment.

Also, caregiver self-efficacy related to symptom monitoring and recognition is collected with two items of the Caregiver Self-efficacy in Contribution to Self-care Scale.⁷³

For nurses

Age, sex, professional experience, professional experience in home care.

Data collection

Data collection points (figure 2) are at research enrolment (baseline), at the end of the 1-month intervention (T1), and 2 months later (T2). Sociodemographic and clinical data regarding persons with HF are retrieved from homecare records and recorded in a case report form by the research nurse at study enrolment. Interviews are conducted to collect variables not retrievable in the homecare records. PRO and caregiver-reported outcomes are collected at T0, T1 and T2 through participant self-report via paper questionnaires, including treatment acceptability at T1. Persons are asked to send a copy of the pressure-sensitive paper monitoring graph at T1. In case of no response or if baseline data suggest that help is needed to fill in the questionnaire, the research nurse contacts the participants to help complete the questionnaire. HF events and SAE are collected by the research nurse via homecare records, prospectively for the 3-month study period and through SAE forms. At the end of the intervention, we collect variables from nurses (table 3).

Analysis

Descriptive statistics will be used to describe the sample with measures as appropriate of frequency or central tendency (mean, SD or median, IQR if not normally distributed), ordinal (median, IQR) and nominal variables (mode, percentages) as appropriate.

To describe intervention feasibility, the total time necessary for recruitment and delivery to all participants will be reported, as well as the total number of persons eligible. The intervention delivery fidelity rate will be described with the proportion of each intervention component based on fidelity checklist, as well as an overall percentage of intervention components delivered to each participant.

To describe intervention acceptability, consenting rate and retention rate will be reported. Treatment acceptability will be reported with median and IQR for each item of the treatment acceptability measure. The engagement of persons with HF and informal caregivers in symptom and daily weight monitoring will be reported.

Intervention feasibility and acceptability will be determined based on the description of each of the elements above. No cut-off for feasibility and acceptability will be defined beforehand.

The SYMPERHEART outcome responsiveness for persons with HF will be described as the mean absolute change between preintervention and postintervention (baseline and T1; baseline and T2) for HF self-care (mean absolute change for self-care maintenance, symptom perception and management), mean absolute change in symptom burden and mean absolute change for health status. Effect sizes will be estimated using Cohen's d or correlation coefficients⁷⁴ for HF self-care, symptom burden as well as health status. For each of the PRO, a power analysis with an assumed alpha=0.05 and beta=0.80 will estimate the necessary sample size for a further effectiveness study. For clinical outcomes, the total number of HF events will be reported, as well as length of stay for HF hospitalisation.

The SYMPERHEART outcome responsiveness for informal caregivers will be described as the mean absolute change between pre and post intervention (baseline and T1; baseline and T2) for caregiver contribution



Table 3 Variables and time of measurement

Variables	Persons with HF				Informal caregivers			Nurses	
	Baseline (day 0)	T1 (day 30)	T2 (day 90)	End of the study	Baseline (day 0)	T1 (day 30)	T2 (day 90)	End of the study	
Sociodemographic data	x				x			x	
Clinical data	x								
HF self-care	x	x	x						
Symptom burden	x	x	x						
Health status	x	x	x						
Clinical outcomes	x	x	x						
Caregivers' contribution to HF self-care					x	x	x		
Caregivers' burden					x	x	x		
Treatment acceptability		x			x	x	x	x	

HF, heart failure.

of self-care of HF and caregiver burden. Effect sizes will be estimated using the same calculations as described above.

The SPSS V.23 (IBM SPSS Statistics) will be used for analysis, as well as SAS V.9.4 (SAS institute).

Ethics and dissemination

Ethical approval has been obtained from the Human Research Ethics Committee of the Canton of Vaud, Switzerland, on 7 October 2020 (ref. 2020–01820). The study is conducted according to the Declaration of Helsinki. Written informed consent is obtained from persons with HF and informal caregivers; oral informed consent is obtained from homecare nurses.

We consider being included in this study as involving a minimal risk; this viewpoint has been confirmed by the aforementioned Ethics Committee. All persons with HF benefit from usual medical and nursing care independently from their participation in the study. During the intervention and data collection, adequate protective measures are taken in line with the COVID-19 pandemic situation. Given that persons with symptomatic HF are a vulnerable population regarding COVID-19,⁷⁵ and given that technology-based interventions are not always feasible for older citizens,⁷⁶ we consider the risk of face-to-face interactions with persons with HF under use of adequate protective measures to be balanced⁷⁷ with regard to the urgent need to support symptom perception in persons with HF.

Results will be published in peer-reviewed journals as well as professional journals. They will also be made known through local conferences and research seminars, national and international scientific congresses, and through direct and indirect contacts with clinicians, public health managers and other healthcare professionals. Results will be integrated into nursing education.

Patient and public involvement

Patients were not involved in developing the study. However, they are asked to assess the acceptability of the intervention via the adapted Treatment Acceptability and Preferences measure.

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