Screened

Enrollment

Screened and assessed for eligibility (n=87 patients)

Excluded (n=68)
- Refusing contact following preliminary information via flyer receival (n=29)
- No heart failure diagnosis (n=24)
- Diagnosis not available (n=4)
- Death (n=2)
- Not eligible (n=9): Home-care withdrawal (n=3), not speaking French/German (n=2), cognitive impairment (n=2), hospitalized (n=1), NYHA I (n=1)

Informed about the study (n=19)

Excluded (n=1)
- Declined to participate (n=1)

Included (n=18)

Screened following inclusion of patients (n=11 caregivers)

Assessed for eligibility (n=11)

Excluded (n=4)
- Declined to participate (n=3)
- Other reasons (n=1 refusal by person with HF)

Included (n=7)

Patients

Caregivers

Patients allocated to intervention (n=18)
- Received allocated intervention (n=17)
- Did not receive allocated intervention (home-care withdrawal) (n=1)

Caregivers allocated to intervention (n=7)
- Received allocated intervention (n=5)
- Did not receive allocated intervention (home-care withdrawal, not present) (n=2)

Follow-Up

Lost to follow-up (n=0)

Discontinued intervention (n=1, intervention perceived not relevant after 2 meetings)

Lost to follow-up (n=0)

Discontinued intervention (n=0)

Analysis

Analysed at T1 (n=18)

Analysed at T2 (n=17), missing data (n=1, not wanting to fill the PROMs)

Analysed at T1 (n=7)

Analysed at T2 (n=6), missing data (n=1, not wanting to fill the PROMs)

SYMPERHEART study. Santos et al. (2023) Pilot and Feasibility Studies. Study flow diagram based on Eldridge, S. M., G. A. Lancaster, M. J. Campbell, L. Thabane, S. Hopewell, C. L. Coleman, and C. M. Bond. 2016. 'Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework', *PloS One*, 11: e0150205.

SYMPERHEART results. Characteristics at baseline

	Persons with HF (n=18) Mean ± SD OR Frequency (%)	**Informal caregivers (n=7)** Mean ± SD OR Frequency (%)
Age (in years)	85.5 ± 7.2	64.7 ± 12.2
Sex		
Women	13 (72.2)	6 (85.7)
Men	5 (27.8)	1 (14.3)
Education		
Less than mandatory school	0 (0.0)	0 (0.0)
Mandatory school	11 (61.1)	2 (28.6)
Secondary education	4 (22.2)	3 (42.9)
Tertiary education	3 (16.7)	2 (28.6)
Living situation		
Living alone	11 (61.1)	0 (0.0)
Living with someone	7 (38.9)	7 (100.0)
Received social support♦		
Yes	18 (100.0)	7 (100.0)
Nature of relationship with the person with HF	/	
Spouse		3 (42.9)
Child		4 (57.1)
Nature of living situation	/	
Living with the person with HF		3 (42.9)
Not living with the person		4 (57.1)
Religion		
Catholic	17 (94.4)	4 (57.1)
Protestant	1 (5.6)	1 (14.3)
Muslim	0 (0.0)	1 (14.3)
Other “no religion anymore”	0 (0.0)	1 (14.3)
Race		
Caucasian	18 (100.0)	7 (100.0)
Time since HF diagnosis		/
< 1 year	2 (11.1)	
≥ 1 year	3 (16.7)	
≥ 5 years	12 (66.7)	
Non-specified	1 (5.6)	
NYHA# functional class		/
NYHA II	11 (61.1)	
NYHA III	7 (38.9)	
NYHA IV	0 (0.0)	
Previous HF hospitalization		/
No	10 (55.6)	
Yes	8 (44.4)	
Yes, 1 hospitalization	7 (38.8)	
Yes, 3 hospitalizations	1 (5.6)	
Comorbidities		/
Cerebrovascular disease	6 (33.3)	
Renal disease	5 (27.8)	
Previous myocardial infarction	5 (27.8)	
	5 (27.8)	

Depressive symptomatology or anxiety *	5 (27.8)	
Cognitive impairment *	2 (11.1)	
Cancer, solid tumor	1 (5.6)	
Diabetes	0 (0)	
Chronic pulmonary disease		
Instruments		
Charlson Comorbidity Index	6.7 ± 2.1	
Patient Health Questionnaire-2ª	0.9 ± 1.2	
Clinical frailty scale¶	4.5 ± 1.1	
Weight scale		/
Having a digital weight scale at home	11 (61.1)	
No digital weight scale at home	7 (38.9)	
Symptom perception confidenceº		
Routinely monitor condition	3.8 ± 0.9	4.0 ± 1.0
Recognize changes in health	3.8 ± 0.9	3.4 ± 1.1

♦ Assessed with the question "*Do you have someone available you can count on*?"; # NYHA New York Heart Association functional class; *any note in medical or healthcare record, ª PHQ-2 score ≥3 suggests clinically significant depression, ¶ frailty if CFS>4, º Assessed with items 33 and 35 of the SCHFI 7.2, 1= not confident, 3= somewhat confident, 5= extremely confident

SYMPERHEART results. Primary outcome measures: intervention feasibility and acceptability

Intervention feasibility		**Intervention acceptability**	
Time needed to recruit participants	112.6 hours	Consent rate in persons with heart failure	37.5%
Time needed to deliver the intervention per participant	177.5 minutes	Consent rate in informal caregivers	63.6%
Eligibility rate in persons with heart failure	55%	Participant retention rate	100%
Eligibility rate in informal caregivers	100%	Persons with heart failure' intervention acceptability (n=17)	3.9 ± 0.6
Intervention fidelity in persons with HF of intervention exposure to body observation & body analysis support	16/18	Informal caregivers' intervention acceptability (n=6)	4.3 ± 0.3
Intervention fidelity in informal caregivers of intervention exposure to body observation & body analysis support	5/7	Nurses' intervention acceptability (n=5)	4.1 ± 0.2
		Persons with heart failure' and informal caregivers' engagement in monitoring dyspnea during 30 days (n=15)	22.2 ± 6.8
		Persons with heart failure' and informal caregivers' engagement in monitoring fatigue during 30 days (n=14)	23.1 ± 6.2
		Persons with heart failure' and informal caregivers' engagement in monitoring weight during 30 days (n=14)	16.7 ± 11.8
		Number of persons with HF who engaged in response to symptoms during 30 days	2

Note. For acceptability scores based on Sekhon et al.2017, p.8 (adapted), responses: 1=completely disagree; 2=disagree ; 3=neutral ; 4=agree ; 5=completely agree. Responses for self-efficacy based on SCHFI 7.2: 1= not confident; 3= somewhat confident; 5= extremely confident.

SYMPERHEART results. Secondary outcome measures: Mean absolute change between pre and post intervention and effect sizes in heart failure (HF) self-care, contribution to HF self-care, health status, symptom burden and caregiver burden

	Persons with HF (n=13-18)	**Informal caregivers (n=6-7)**
HF self-care	Mean ± SD / effect size	Mean ± SD / effect size
Self-care maintenance		
Baseline to post intervention (+30 days)	-0.3 ± 16.1 / -0.01	3.5 ± 12.4 / **0.28***
Baseline to follow-up (+90 days)	-5.9 ± 11.7 / **-0.50** #	7.8 ± 33.5 / **0.23***
Symptom perception		
Baseline to post intervention (+30 days)	3.4 ± 15.4 / **0.22***	10.2 ± 7.4 / **1.37** ¶
Baseline to follow-up (+90 days)	7.6 ± 13.6 / **0.55** #	8.2 ± 16.3 / **0.50** #
Self-care management		
Baseline to post intervention (+30 days)	0.6 ± 16.9 / 0.03	3.1 ± 17.6 / 0.17
Baseline to follow-up (+90 days)	2.9 ± 18.6 / 0.15	8.0 ± 9.1 / **0.87** ¶
Health status, overall		
Baseline to post intervention (+30 days)	-1.3 ± 9.3 / -0.13	
Baseline to follow-up (+90 days)	-1.5 ± 14.2 / -0.10	
Physical limitation		
Baseline to post intervention (+30 days)	-2.3 ± 13.4 /-0.17	
Baseline to follow-up (+90 days)	5.0 ± 26.3 / 0.19	
Symptom frequency		
Baseline to post intervention (+30 days)	-1.7 ± 19.1 / -0.08	
Baseline to follow-up (+90 days)	-1.4 ± 22.2 / -0.06	
Quality of life		
Baseline to post intervention (+30 days)	-2.0 ± 17.2 / -0.11	
Baseline to follow-up (+90 days)	-2.9 ± 15.6 / -0.18	
Social limitation		
Baseline to post intervention (+30 days)	1.7 ± 15.0 / 0.11	
Baseline to follow-up (+90 days)	-8.3 ± 20.4 / **-0.40***	
Symptom burden		
Dyspnea		
Baseline to post intervention (+30 days)	-0.00 ± 0.71 / -0.00	
Baseline to follow-up (+90 days)	0.19 ± 1.00 / 0.19	
Chest discomfort		
Baseline to post intervention (+30 days)	-0.25 ± 1.46 / -0.17	
Baseline to follow-up (+90 days)	0.11 ± 1.55 / 0.07	
Early subtle		
Baseline to post intervention (+30 days)	-0.14 ± 0.77 / -0.18	
Baseline to follow-up (+90 days)	-0.11 ± 0.89 / -0.12	

<u>Edema</u> Baseline to post intervention (+30 days) Baseline to follow-up (+90 days)	-0.12 ± 0.77 / -0.15 0.25 ± 0.76 / **0.32***	
Caregiver burden Baseline to post intervention (+30 days) Baseline to follow-up (+90 days)		2.0 ± 13.5 / 0.14 4.0 ± 9.8 / **0.40***

* small effect size >0.2 # medium effect size >0.5 ¶ large effect size >0.8

Note. Small, medium and large effect sizes are annotated in bold in the table. Other effect sizes were found to be smaller than small effect size.

SYMPERHEART adverse events. There were no adverse events associated with this study.

Santos, G. C., M. Liljeroos, K. Tschann, K. Denhaerynck, J. Wicht, C. Y. Jurgens, R. Hullin, and P. Schafer-Keller. 2023. 'Feasibility, acceptability, and outcome responsiveness of the SYMPERHEART intervention to support symptom perception in persons with heart failure and their informal caregivers: a feasibility quasi-experimental study', *Pilot Feasibility Stud*, 9: 168.