

# Feasibility and practical utility of the revised 9-Item European Heart Failure Self-care Behaviour Scale (EHFScB-9) in the German speaking part of Switzerland: a feasibility study

|  |   |  |
|--|---|--|
| <b>Submission date</b><br>14/09/2011   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>06/10/2011 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>10/02/2016       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Heart failure is one of the most common chronic diseases in Switzerland and represents a major burden to society and for the patient. It is caused by the heart failing to pump enough blood around the body at the right pressure. In dealing with the disease and the symptoms, patients should practice adequate self-care and follow treatment recommendations through behavioral changes. Several studies have shown that improved self-care leads to a better quality of life for patients. The revised European Heart Failure Self-care Behavior Scale (EHFScB-9) is a scientifically proved frequently used questionnaire to assess the self-care behavior of heart failure patients. The questionnaire consists of nine items, which the patient completes on a scale from 1 (I completely agree) to 5 (I strongly disagree with). The individual items can identify in which areas the patient still has need for education. The German-language version of EHFScB-9 is already used in practice, but currently there are no studies testing its practicability in the context of Swiss-German heart failure patients. This study aims to test the practicability and clinical utility of the German version of EHFScB-9 in a health institution in Switzerland.

### Who can participate?

In- and out-patients aged 18 or over at the participating hospital with a diagnosis of heart failure, and for inpatients nurses responsible for the participating patient can take part in this study.

### What does the study involve?

Participants are invited to complete the German version of the questionnaire and have to think aloud while filling in the answers. After that follows a short interview with the sub-investigator with questions about the questionnaire. Staff nurses also have to complete the questionnaire from the perspective of the assigned patient and are asked about the benefit and clinical utility of the questionnaire.

What are the possible benefits and risks of participating?

No adverse effects or risks for are expected.

Where is the study run from?

The study takes place in the outpatient clinic and two inpatients wards of a cardiology department in the North-East of Switzerland.

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

September 2011 to March 2012

Who is funding the study?

Kantonsspital St. Gallen (Switzerland)

Who is the main contact?

1. Verena Cattilaz-Langenauer (vreni.cattilaz@kssg.ch)

2. Dr Virpi Hantikainen (virpi.hantikainen@fhsg.ch)

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Verena Cattilaz

### Contact details

Entwicklung Pflege am Kantonsspital St. Gallen

Spital Rorschach

Heidenerstrasse 11

Rorschach

Switzerland

9400

+41 (0)71 858 34 41

vreni.cattilaz@kssg.ch

## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

Feasibility and practicability of the revised 9-Item European Heart Failure Self-Care Behaviour Scale (EHFScB-9) in the German-speaking Switzerland from the perspective of out- and inpatients and their caring nurses: a cross-sectional concurred mixed-methods feasibility study

### Study objectives

Is the instrument EHFScB-9 practicable from the perspectives of heart failure patients and their nurses in a Swiss-German population?

1. How do patients score their self-care behavior with the EHFScB-9?
2. How understandable, relevant and ethical are the items of the EHFScB-9 from the perspective of patients?
3. What is the relationship between the EHFScB-9 score and the practicability (comprehensibility and feasibility) of inpatient versus outpatient setting?
4. How do nurses evaluate the practical applicability and the benefits of the EHFScB-9?
5. What is the relationship between the patient self-rated self-care behavior and the nurse rated self-care behavior based on the EHFScB-9?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Canton of St. Gallen, Ethics Review Board, 22/08/2011, ref: EKSG 11/080/1b

### **Study design**

Descriptive cross-sectional concurrent mixed-methods single-centre study

### **Primary study design**

Observational

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Diagnosed heart failure patients

### **Interventions**

A concurrent mixed-methods study will be conducted using first a quantitative descriptive part with data collection of heart failure self-care behaviour and secondly a directly subsequent administrated interview.

1. Outpatients and inpatients and their nurses complete the EHFScB-9 independently and are invited after that to commentate the completing process (cognitive debriefing).
2. After that, patients and nurses will be interviewed for the practicability and usefulness of the EHFScB-9.

The estimated duration of study is 20 minutes (complete the questionnaire and interview).  
There is a single data collection.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

1. Practicability of EHFScB-9
2. Patient`s perspective: understandability, relevancy, ethically approved
3. Nurse`s perspective: utility, benefit and incremental effectiveness

### **Key secondary outcome(s)**

**Patient:**

1. Socio-demographic data: age, sex, social support, education
2. Disease related data: disease duration, disease severity, comorbidity, obtained heart failure education
3. Health related self-care behavior: EHFScB-9

**Nursing staff:**

1. Socio-demographic data: age, sex
2. Job-related data: education, degree of employment, years of work experience
3. Estimated patient`s self-care behaviour: EHFScB-9

**Completion date**

31/03/2012

## **Eligibility**

**Key inclusion criteria****Patients:**

1. Diagnosed heart failure New York Heart Association classification (NYHA II-IV)
2. 18 years old
3. Completed informed consent

**Nursing staff:**

1. Nurse responsible for the care of the included patient
2. Works in the department of cardiology
3. Completed informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria****Patients:**

1. Is not capable to speak or understand German
2. Palliative situation
3. Is not capable to complete a scale because of cognitive impairment

**Date of first enrolment**

01/09/2011

**Date of final enrolment**

31/03/2012

## Locations

**Countries of recruitment**

Switzerland

**Study participating centre**

Entwicklung Pflege am Kantonsspital St. Gallen

Rorschach

Switzerland

9400

## Sponsor information

**Organisation**

Kantonsspital St. Gallen (Switzerland)

**ROR**

<https://ror.org/00gpmb873>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Kantonsspital St. Gallen (Switzerland)

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration