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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

Submission date
14/09/2011

Recruitment status
No longer recruiting

Registration date
06/10/2011

Overall study status
Completed

Last Edited
10/02/2016

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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?
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Contact information

Type(s)
Scientific

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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 ralted 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

Primary study design
Observational

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

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