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Feasibility research to determine acceptability and the benefits of nurse consultations in addition to those with physicians to support self-care and care by health care professionals in persons with heart failure

Submission date
06/09/2019

Recruitment status
No longer recruiting

Registration date
04/10/2019

Overall study status
Completed

Last Edited
28/06/2023

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Heart failure is a complex clinical syndrome affecting 1 to 2 percent of the general population, but more than 10% of people aged 70 or more. Despite recent advances in medical treatment, people with heart failure still experience many symptoms, among which breathlessness and fatigue have the highest impact on daily life. Moreover, people with heart failure have frequent hospital admissions, experience impaired quality of life and are subject to poor overall prognoses. To improve their situation, the European Society of Cardiology recommends that people with chronic heart failure receive structured follow-up care. Besides medical care, these recommendations include providing affected persons and their families with self-care education and support, combined with psychosocial support by health care professionals, and easy access to care in case of symptoms.

Studies evaluating such follow-up care programmes have shown that, compared to patients who receive standard care, participants benefit in terms of improved self-care capabilities, heart failure prognosis and overall quality of life. However, as these studies' evaluated programmes and health care settings varied, we currently do not know which programme will work best in our context. Furthermore, in some of the studied programmes, nurses played important roles. For example, they supported participants' self-care and both facilitated and coordinated multi-professional collaborative care. Still, based on the evidence at hand, we currently do not know whether such roles are feasible or appropriate in our context. Thus, we need to conduct a study in our specific context to evaluate a follow-up care programme based on the ESC recommendations.

In preparation for a definitive study to evaluate whether structured follow-up care is beneficial for people with heart failure in our context, we first need to address various uncertainties related to conducting such a study. Therefore, this pilot study, the UTILE study, has two major

objectives: to assess the methodological and procedural uncertainties associated with a definitive study; and to assess the acceptability of the proposed programme within our context from the perspective of people with heart failure, their physicians and their nurses. The findings will help to inform both the procedures and the programme of a definitive study evaluating the benefits of nurse consultations for people with heart failure.

Further, it will fulfil three important qualitative aims. 1) It will determine whether persons with heart failure are likely to participate and stay in a study to investigate the impact of nurse consultations that support self-care and facilitate the delivery of care from other health care professionals. 2) It will help estimate the extent to which nurse consultations are acceptable from the perspective of participating persons with heart failure, their physicians and nurses. And 3) it will measure the impact of nurse consultations on self-care, perceived health, quality of life, hospitalisations, length of hospital stay and mortality in persons with heart failure.

Who can participate?
Adults 18 years of age or older with heart failure who are hospitalised in the HFR Fribourg due to cardiac decompensation or for other reasons but with a history of hospitalisation due to cardiac decompensation during the past six months.

What does the study involve?
Participants are asked to join this study while they are hospitalized in the participating hospital's internal medicine wards. A nurse researcher visits participants in their rooms to obtain data not available from the medical records (e.g., if the person is living alone or with someone). Then, participants are asked to fill in a 41-item questionnaire regarding symptoms and symptom management in daily life. Participants are then randomly allocated to one of two groups. For both groups, a nurse from the cardiology unit provides information on heart failure and on how to manage and respond to symptoms at home. All participants are asked to fill in the same questionnaire with 8 additional questions after twelve weeks. In addition, participants in the second group (the intervention group) receive nurse consultations on a needs-led basis. Participants will have to return to the hospital 1-2 weeks after discharge from the hospital. Further telephone calls and consultations are scheduled, on a needs-led basis, at hospital or at home. At the end of the 12-week study period, a nurse researcher interviews participants in the second group to explore their perceptions of the study's procedures and the helpfulness of the nurse consultation. All participants in both groups receive standard medical care.

What are the possible benefits and risks of participating?
Participation in the study has no influence on standard medical treatment. Nor do we know of any possible adverse secondary effects of the nurse consultation or any other study procedures. A time investment is needed for participation at the start and end of the study to respond to questionnaires. A further time investment is needed to participate in the nurse consultation/s and in the final interview on the acceptability of the nurse consultation/s and other study procedures. The study's results will indicate the feasibility, acceptability and preliminary benefits of the nurse consultation. As the UTILE results are intended to inform the design of a following definitive study, this study will also contribute to that study's value. Based partly on the current study's findings, the definitive study will be designed to evaluate the benefits of a nurse consultation on the self-care, quality of life, hospitalisations, lengths of hospital stay and mortality of persons with heart failure. Participation is cost-free and will lead to no additional costs either for the hospital or for the patients' health insurers.

Where is the study run from?
The UTILE study is being run by the School of Health Sciences, HES-SO University of Applied Science and Arts Western Switzerland – Fribourg (haute école de santé Fribourg) and will take

place at a regional non-university hospital in Western Switzerland (HFR-hôpital cantonal fribourgeois).

When is the study starting and how long is it expected to run for?
The study began in April 2019 and is expected to end in August 2021.

Who is funding the study?
The current sponsors are the Nursing Science Foundation, Novartis, the Swiss Nursing Science Foundation (Stiftung Pflegewissenschaft Schweiz), HES-SO University of applied science and arts Western Switzerland.

Who is the main contact?
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Dr. med. Denis Graf, Cardiologist and medical expert in the study.
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2018-02156

Study information

Scientific Title
Nurse-facilitated multidisciplinary follow-up care in Heart Failure: a pilot randomized controlled trial

Acronym
UTILE

Study objectives
UTILE is a pilot study and no hypothesis will be tested. However, power analyses will be calculated for the null hypothesis that no differences exist between the study groups regarding the following variables: ‘self-care’ (SCHFI), ‘HF-related health status’ (KCCQ), ‘health-related quality of life’ (Euroqol), ‘length of stay’ (LOS), ‘number of readmissions’, ‘all-cause mortality’ and ‘all-cause hospital admissions’.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/01/2019, Cantal Council of Ethics for Human Research (Av. de Chailly 23, CH-1012 Lausanne; +41 21 316 1830; secretariat.CER@vd.ch), ref: 2018-02156.

Study design
The UTILE study will employ a multiple-methods design to address uncertainties associated with an RCT of a nurse-facilitated multidisciplinary follow-up HF care program compared to enhanced usual follow-up care in Western Switzerland. The proposed two-arms, non-blinded pilot RCT includes an embedded concurrent process study using quantitative data on patient recruitment and retention to assess feasibility.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions

The intervention group will receive the nurse-facilitated multidisciplinary follow-up (UTILE) intervention, consisting of seven European Society of Cardiology (ESC) guideline-recommended intervention components (see below), over a three-month follow-up period.

In addition to usual medical and nursing care enhanced by an educational component, the UTILE intervention will cover seven components recommended by the ESC guidelines for multidisciplinary structured follow-up in HF:
1. Patients' symptom monitoring and self-care capabilities support.
2. Early detection of impending decompensation.
3. Optimization of medical and device treatment.
4. Patient education.
5. Psychosocial support for patients and families.
6. Access to care.
7. Multidisciplinary collaboration.

Collaboration between intervention nurses and cardiologists will include case-specific discussions during follow-up. Based on a medical treatment plan for each patient and using patient self-completed web-based symptom experience and self-care capability data, nurses will individualize self-care support. Nurses will also incorporate patients' primary care physicians' perspectives regarding multimorbidity and long-term primary care. The intervention will occur in the cardiology outpatient clinic (or during a home visit if visiting the cardiology outpatient clinic is seen as a barrier – e.g., due to mobility restriction regarding the patient), plus telephone discussions and home visits conducted on a needs-led basis. The first visit will be scheduled one to two weeks post-hospital discharge; additional visits/contacts will be scheduled on a needs-led basis over the 3-months follow-up period.

Participants randomized to the enhanced usual care/control group will receive standard in-hospital treatment and post-discharge follow-up care including follow-up by their general practitioner and/or cardiologist. Additionally, during their inpatient phase or a follow-up meeting, they will receive HF patient education from a cardiology nurse. I.e., as the ESC guidelines suggest, adequate patient education focusing on self-care skills will be provided during one face-to-face encounter. Printed information will consist of Swiss Heart Foundation patient education materials; computerized patient education will consist of access to the Heart Failure Matters webpage (www.heartfailurematters.org) in the appropriate language, as well as access to a related Swiss Heart Foundation app. Knowledge acquisition and development will be facilitated, as appropriate, via teach-back and motivational interviewing communication techniques.

Participants will be 1:1 randomly assigned to either intervention or enhanced usual care (control) group by the Principal Investigator (PI) via the REDCap software's randomization module. The randomization model will be defined using ID and sample size as parameters. The PI will check whether the randomization has resulted in balanced groups before the study begins. After completion of baseline assessment (including outcome variables), participants will be randomized and the assignment of randomized subjects will be noted in REDCap.

Intervention Type
Other

Primary outcome measure
1. The patient recruitment rate (percentage of eligible patients agreeing to participate) will be measured consecutively at each day of recruitment, calculated by the number of patients

screened for eligibility, number of eligible patients, number of eligible patients receiving information to participate in the study, and number of eligible patients agreeing to participate, will be noted by research assistants in the specific screening database (included in REDCap) at the end of each recruitment day.
2. Study nurse time needed for patient recruitment and inclusion into the study will be assessed for each day of recruitment by noting the time (hours, minutes) that the study nurse needs a) to recruit (time for eligibility screening, then to obtain eligibility confirmation from the treating physician) and b) to include the patient (i.e., provide study information to the patient and obtain informed consent, including returning after 24h). This information will be recorded in the specific screening database (included in REDCap) by the research assistants at the end of each recruitment day.
3. Study retention/attrition (percentage of participants remaining in the follow-up vs those who withdraw); fidelity to the intervention components, assessed using a seven-item fidelity check-list with yes/no responses regarding all intervention components, will be noted by the nurses during each consultation and provided to the study nurse; the percentage of patients receiving one visit, additional telephone contacts and/or home visits and the percentage who receive two or more such contacts will be calculated. The duration of each patient visit or telephone consultation will be noted by the nurse at each consultation.

Secondary outcome measures

1. Patient-reported outcomes:
1.1. HF specific self-care is measured via the 22-item Swiss German and French version of the Self-Care of Heart Failure Index, v.6._2 (SCHFI) at baseline and 3-months follow-up.
1.2. HF specific health status and symptom stability is measured via the Swiss German and French version of the 12-item Kansas City Cardiomyopathy Questionnaire (KCCQ), with symptom stability measured via a single item from the KCCQ 23-item version at baseline and 3-months follow-up.
1.3. Health-related quality of life is measured via the French and German version of the 5-item EQ-5D-5L, including a VAS (Euroqol) at baseline and 3-months follow-up.
1.4. Intervention acceptability is measured via the Treatment Acceptability and Preference Questionnaire (the original 5-item TAPQ) adapted for this study resulting in an 8-item questionnaire at 3-months follow-up.
1.5 Patient perspectives (experience of receiving the intervention and their opinions of its value regarding the target outcomes) are determined using semi-structured interviews with each patient between 48 hours and 15 days after what is expected to be his/her final UTILE consultation.
2. Nurse and cardiologist perspectives regarding acceptability are measured using semi-structured one-to-one interviews with involved nurses and cardiologists to explore the nurses' experiences regarding the intervention's delivery, as well as both cardiologists' and nurses' individual perceptions and opinions regarding both UTILE follow-up care quality and their nurse-cardiologist collaboration. These one-to-one interviews will be held late in the trial, i.e., after the 60th participant has completed the follow-up period.
3. The general practitioners' perspectives regarding acceptability are measured using semi-structured one-to-one interviews.
4. All-cause mortality for the three-month intervention period is recorded by the research assistant and as available via patient records or via the patients' general practitioners.
5. All-cause hospital admission and hospital length of stay (LOS) for the 3-month intervention period is recorded by the research assistant for the three-month intervention period and as available via patient records or via the patients' general practitioners.

Overall study start date

01/12/2018

Completion date
12/08/2021

Eligibility

Key inclusion criteria
1. ≥18y of age
2. Diagnosed with HF in NYHA functional classes II-IV
3. Hospitalized in HFR Fribourg internal medicine for decompensated HF or another reason
4. History of hospitalization due to HF decompensation during the previous 6 months
5. Fluent in French or German

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
Current exclusion criteria as of 11/12/2020:

1. Imminently life-threatening illness
2. Short anticipated survival
3. Dementia
4. Complicating serious comorbidity (e.g., untreated psychiatric illness, untreated malignancy)
5. Cognitive impairment that would preclude written informed consent
6. Patients with COVID-19
7. Patients with a positive Sars-CoV2 test result
8. Patients with a positive anamnesis regarding Sars-CoV2 infection while waiting for the test result

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Previous exclusion criteria:

1. Imminently life-threatening illness
2. Short anticipated survival
3. Dementia
4. Complicating serious comorbidity (e.g., untreated psychiatric illness, untreated malignancy)
5. Cognitive impairment that would preclude written informed consent

Date of first enrolment
15/04/2019

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
Switzerland

Study participating centre
Hopital cantonal HFR Fribourg
Route de Bertigny 8
Fribourg
Switzerland
1708

Sponsor information

Organisation
HFR Fribourg

Sponsor details
HFR Fribourg – Hôpital cantonal
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Sponsor type
University/education

Website
https://www.h-fr.ch/

ROR
https://ror.org/00fz8k419

Funder(s)

Funder type
University/education

Funder Name
Nursing Science Foundation, Novartis

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
Stiftung Pflegewissenschaft Schweiz

Results and Publications

Publication and dissemination plan
Presentations of final results in 2021
Article of study results in 2021

Intention to publish date
30/09/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to a likely risk of identifying participants from the coded database as the

study includes a small sample size and homogenous sample, is performed at one single centre, and contains sensitive data such as recurrent hospitalisations.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/06/2023	28/06/2023	Yes	No