Titre	Nurse-facilitated multidisciplinary Heart Failure follow-up care (UTILE): a pilot randomized controlled trial
Acronyme	UTILE
Statut (dates début-fin)	15.05.2018 au 30.11.2020
Requérant-e principal-e (site)	• Petra Schäfer-Keller, PhD RN (University of Applied Science Western Switzerland: Hochschule für Gesundheit, Freiburg, Haute école de Santé Fribourg - HEdS-FR, http://www.heds-fr.ch/)
Co-requérant-e-s	• Dr med. Denis Graf, médecin responsable de l'étude, cardiologue rattaché (HFR Fribourg, Hôpital cantonal, Fribourg, www.h-fr.ch)
Collaborateur-trice(s)	• Josepha Girard (University of Applied Science Western Switzerland: http://www.heds-fr.ch/) • Marie-Elise Verga (University of Applied Science Western Switzerland http://www.heds-fr.ch/)
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Résumé	**Background:** For patients with chronic heart failure (CHF), structured follow-up with multidisciplinary care management programs have shown positive effects on mortality, morbidity and quality of life. However, the content and structure of multi-component programs vary between studies and health care settings. Therefore, for each target regions and healthcare setting, a fully powered randomized controlled trial (RCT) is required to evaluate the effectiveness of an intervention employing these components. First, though, it is necessary to address the methodological and procedural uncertainties associated with such a trial, as well as the proposed intervention's acceptability within the target context. **Aim:** to test the feasibility and provide information to inform the design of a fully powered randomized controlled trial (RCT) investigating the effectiveness of nurse-facilitated multidisciplinary HF follow-up care for adults with HF in Switzerland. The pilot RCT's two major objectives are: (1) to obtain enough information on recruitment and retention in relation to the intervention's effect size either to design a fully-powered clinical trial or to declare such a trial infeasible; and (2) to explore patients', nurses' and doctors' acceptance of the intervention and procedures in order to inform a UTILE clinical protocol for a proposed RCT. **Methodology:** Design: the UTILE study will employ a multi-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 pilot RCT includes an embedded concurrent process study using quantitative data on patient recruitment and retention to assess feasibility. Outcome data regarding the UTILE program's effects on self-care capabilities will inform sample size calculation for a definitive trial. Interviews will explore patients' impressions of the trial methods and procedures and of the overall UTILE intervention. Along with nurses delivering the interventions, cardiologists and primary care physicians will be asked first for their thoughts on the intervention, then for interprofessional collaboration. Sample and setting: 60 adult individuals with HF (NYHA II-IV) will be recruited during hospitalization for decompensated HF. Randomization: Participants will be 1:1 randomly assigned to either intervention or enhanced usual care (control)

	group. Control group (CG): CG patients will receive usual care enhanced by an education component. Intervention group (IG): Nurse-facilitated multidisciplinary follow-up will cover seven components of the European Society of Cardiology (ESC) guidelines for the multidisciplinary structured follow-up in HF: 1) patients' symptom monitoring and self-care capabilities; 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; and 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 multi-morbidity and long-term primary care. The intervention will occur mainly in the cardiology outpatient clinic, 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. Procedures: Quantitative patient self-care capability, health-status and health-related QOL data will be collected at baseline (pre-randomization) and after three months. The pilot trial and qualitative interviews will be conducted concurrently. The study will be submitted for ethical approval and written informed consent obtained from patients at baseline. Study results will reflect both quantitative and qualitative data, which will be analyzed separately. **Potential significance:** This study's combination of quantitative and qualitative results will inform the design of a fully powered RCT of a nurse-facilitated multidisciplinary HF follow-up care model's effectiveness. With mortality rates increasing and physicians' time for communication with patients and informal caregivers severely limited, enhanced involvement of nurses trained in multidisciplinary HF programs, using ESC guideline recommended cutting-edge non-pharmacological, non-device/non-surgical treatment, while optimizing treatment and interprofessional collaboration–has a strong potential to improve outcomes for patients living with HF.
Partenaire(s) de terrain / académique	
Contact	• Petra.Schaefer-Keller@hefr.ch • +41 26 429 60 37
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