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Optimising standards of care of heart failure in general practice the OSCAR-HF pilot study protocol

Miek Smeets[a], Bert Aertgeerts[a], Wilfried Mullens[d,e], Joris Penders[c,d], Jan Vercammen[e], Stefan Janssens[b] and Bert Vaes[a,f]

[a]Department of Public Health and Primary Care, KU Leuven (KUL), Leuven, Belgium; [b]Department of Cardiovascular Diseases, Universitair Ziekenhuis Gasthuisberg, KU Leuven (KUL), Leuven, Belgium; [c]Department of Clinical Biology, Ziekenhuis Oost-Limburg (ZOL), Genk, Belgium; [d]Faculty of Medicine and Life Sciences, Biomedical Research Institute, Hasselt University, Diepenbeek, Belgium; [e]Department of Cardiology, Ziekenhuis Oost-Limburg (ZOL), Genk, Belgium; [f]Institute of Health and Society, Université Catholique de Louvain (UCL), Brussels, Belgium

ABSTRACT

Background: Heart failure (HF) imposes a burden for patients and health economics. General practitioners (GPs) are confronted with the broadest range of HF management. Although guidelines exist, they are not fully implemented in the Belgian health care system.

Methods: We will conduct a non-randomised, non-controlled prospective observational trial (six months follow-up) to implement a multifaceted intervention in Belgian general practice to support GPs in the implementation of evidence-based HF guidelines. The multifaceted intervention consists of an audit and feedback method to detect previously unrecognised patients with HF and to increase awareness for proactive HF management, an NT-proBNP point-of-care test to improve detection and adequate diagnosis of patients with HF and a specialist HF nurse to assist GPs in the education of patients, optimisation of treatment and follow-up after hospitalisation. All patients aged 40 years and older with a confirmed diagnosis of HF by their GP based on the clinical audit are eligible for participation. The main objective of this pilot study is to evaluate the feasibility of this multifaceted intervention and the evolution of predefined quality indicators. We will measure the impact on HF diagnosis, medication optimisation, multidisciplinary follow-up and patients' quality of life after six months. Additionally, the experiences of GPs and investigators will be studied.

Conclusions: Heart failure is an important health problem in which GPs play a key role. Therefore, we will evaluate the feasibility of a multifaceted intervention to optimise diagnosis as well as implement the guideline recommended therapies in patients with HF in general practice.

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Introduction

Heart failure (HF) is a prevalent disease associated with high morbidity and mortality and a strong impact on quality of life [1–3]. In addition to its epidemiological and clinical impacts, HF also has an important economic impact [4]. In Belgium, 1–2% of the total health budget is spent on HF, largely because of frequent hospitalisations [4,5]. General practitioners (GPs) play a key role in HF management. Patients present themselves with the first HF symptoms and signs in general practice [3,6]. These symptoms and signs need to be recognised by the GPs in a timely manner to assure a referral for echocardiography for confirmation of the HF diagnosis. Additionally, HF patients are often older patients with multiple comorbidities [7,8]. Therefore, primary follow-up of these patients is done by GPs.

However, despite the availability of guidelines for optimal HF care, GP HF care is suboptimal. First, HF is both under- and over-diagnosed [9–11]. Additionally, the majority of HF patients are already in NYHA stage 3 or 4 at the time of diagnosis [3]. Second, patients with HF with reduced ejection fraction (HFrEF) are undertreated [1,6,7]. Third, a 'seamless' system of care, integrating both community and hospital care, has been shown to reduce HF hospitalisation and mortality in patients discharged from the hospital [1,12,13]; however, this system is not yet implemented in

CONTACT Miek Smeets miek.smeets@kuleuven.be Department of Public Health and Primary Care, KU Leuven (KUL), Kapucijnenvoer 33, blok j bus 7001, 3000 Leuven, Belgium

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Belgium. Efforts have been made in the last decade to improve HF management in primary care, and they have shown clear progress in the adaptation of evidence-based treatment [14]; however, barriers for optimal management still remain [15].

To overcome these barriers and optimise care for HF patients in general practice, a multifaceted intervention was developed to support GPs in the implementation of evidence-based HF guidelines [1,16]. First, audit and feedback will be used to identify possible HF patients who were previously unrecognised by the GPs and will provide GPs with a summary of their clinical performance in HF care [17]. Second, each practice will be offered an N-terminal-pro-brain natriuretic peptide (NT-proBNP) point-of-care (POC) test. Up until now, the use of natriuretic peptides is not reimbursed in Belgium. However, in the last decade, the amount of evidence supporting their use for the diagnosis of HF has been enormous, and they have gained a central place in the diagnostic algorithms of international and national guidelines on HF [1,18–20]. Additionally, the diagnostic performance of NT-proBNP was good, irrespective of the setting, and NT-proBNP POC tests have been shown to improve diagnostic accuracy in primary care [21–23]. Third, specialist HF nurses will be introduced in general practice to assist the GPs in HF care. Up until now, specialist HF nurses have been limited to the hospital setting in Belgium. The education of patients, with a special emphasis on adherence and self-care, is considered a key component of each HF management programme [1,16]. The GPs acknowledged the importance of education but experienced a lack of time, and they regarded the education as a task to delegate to the HF nurses. Furthermore, HF nurses will be available for advice about diagnosis and treatment (medication review/up titration of medication) and will support a seamless transition of care from the hospital to general practice, with a special emphasis on patients who were recently discharged from the hospital [12,13,24,25]. High-quality studies on the effectiveness of case management by HF nurses in the community are lacking [26], although a smaller study by Agvall et al. [27] showed that a primary care HF nurse intervention had a positive effect on hospital admittances. Access to echocardiography, in terms of distance and availability, does not pose a problem in Belgium [6]. However, closer collaboration with local cardiologists will be promoted and facilitated [1].

This intervention aims at better outcomes and better processes at a lower cost [28]. To achieve this, it is important to distinguish between HF patients who do not need extra care, patients who need disease management and patients who need case management [28]. Therefore, the continuation of the intervention will be organised by the GP, in collaboration with the HF nurse and the patients themselves, in the light of tailored, patient-centred, needs-based care [16,28].

In conclusion, a multifaceted intervention will be implemented in Belgian general practice to optimise the standards of care for HF patients. In the first stage, this intervention will be tested in a non-randomised, non-controlled pilot trial to evaluate the feasibility and proportion of newly detected, adequately diagnosed, treated and followed HF patients as outcomes. In a later stage, our experiences in this pilot study will be used to develop a disease management programme for HF patients that will be tested on a larger scale in a cluster-randomized controlled trial to evaluate its effect on hospitalisations and mortality.

Methods

Design

This study has a prospective observational design with a six-month follow-up period (Table 1: Study Timeline). Patient enrolment started on the 1st of December 2016 and will last until the 31st of May 2017. The SPIRIT recommendations for reporting protocols of clinical trials were followed [29].

Participants

Study setting and eligibility criteria

The physicians who are eligible to participate are all GPs using Medidoc®, CareConnect® or Health One® as an electronic health record (EHR). Physicians will be included if the following criteria are met:

1. The physician has integrated Medidoc®, CareConnect® or Health One® in the consultations.
2. The physician uses the functionality of e-prescribing within the electronic medical health system so that chronic medications can be identified from the electronic medical records.
3. The physician agrees to participate in the study.

For this pilot study, recruitment will occur in three local peer review groups located in Bilzen (Limburg, Belgium), where the project will be introduced. Additionally, the same amount of practices will be recruited in Leuven (Vlaams-Brabant, Belgium).

Table 1. Study timeline.

	Study period				
Time point	Identification of patients with HF T-8W	Enrolment of patients with HF T-4W	Study meetings with GPs T-1W	Study course T0-T6M	Close-out T7M
Identification of patients with HF					
Audit	x				
Confirmation by GP	x				
Enrolment					
First study visit					
Informed consent		x			
MLWH-Q		x			
Grip Strength		x			
Basic education		x			
Patient's need?		x			
Study meetings with GPs					
Feedback meeting			x		
POC test instructions			x		
Study interventions					
NT-proBNP POCT				x	
Support by HF nurse				x	
Study assessments					
Evolution of Q indicators					x
GPs' experiences					x
Patients' QoL					x

HF: heart failure; GP: general practitioner; W:, week(s); M: month(s); MLWHF-Q: Minnesota Living With Heart Failure Questionnaire; Q: quality; POC: point-of-care; QoL: quality of life.

The recruitment of practices took place between June 2016 and November 2016.

Participating patients (Figure 1)

Heart failure patients are included if:

1. They are 40 years of age or older.
2. They have their electronic medical records ('globaal medisch dossier') registered with one of the participating GPs.
3. Their GPs confirmed the diagnosis of HF based on a list of patients retrieved by a clinical audit.

Patients can be included during the study if:

1. They are 40 years of age or older.
2. They give their informed consent to participate in the study.

Ethics

Before the study start, we will present the participating physicians with an informed consent that outlines the intervention and the purpose of the trial (Supplemental file 1). Additionally, all the identified patients with HF will be visited by the HF nurse before the start of the study. On that occasion, the HF nurse will inform all the patients with HF about the study outline and purpose and will ask for their informed consent (Supplemental file 2.1–2.2). Participation in the study will be indicated in the electronic medical file of each patient, which is visible to their GPs. Furthermore, patients who are eligible for an NT-proBNP POC test will be informed by their GP about the study outline and purpose and will be asked informed consent (Supplemental file 4). However, informed consent cannot be sought for all the patients on a practice level (hospitalisations/mortality). Therefore, information about the study intervention and the purpose of the trial will be presented on a poster in each practice, and it will be visible to all patients, who can opt-out if they object to study participation (Figure 1).

Education of GPs

All the GPs will be offered access to an e-learning course containing six modules on all aspects related to HF management. The e-learning course was specifically designed for GPs by the department of Public Health and Primary Care (KU Leuven, Leuven), and it is case-based and interactive. It is accessible through a secured e-learning platform (Sofia).

Interventions

A multifaceted intervention comprised of audit and feedback, an NT-proBNP POC test and the assistance of an HF nurse in GP practice will be implemented.

Optimizing the identification of HF patients

The included HF patients represent the HF population, as recognised by the GPs. However, the validity of a

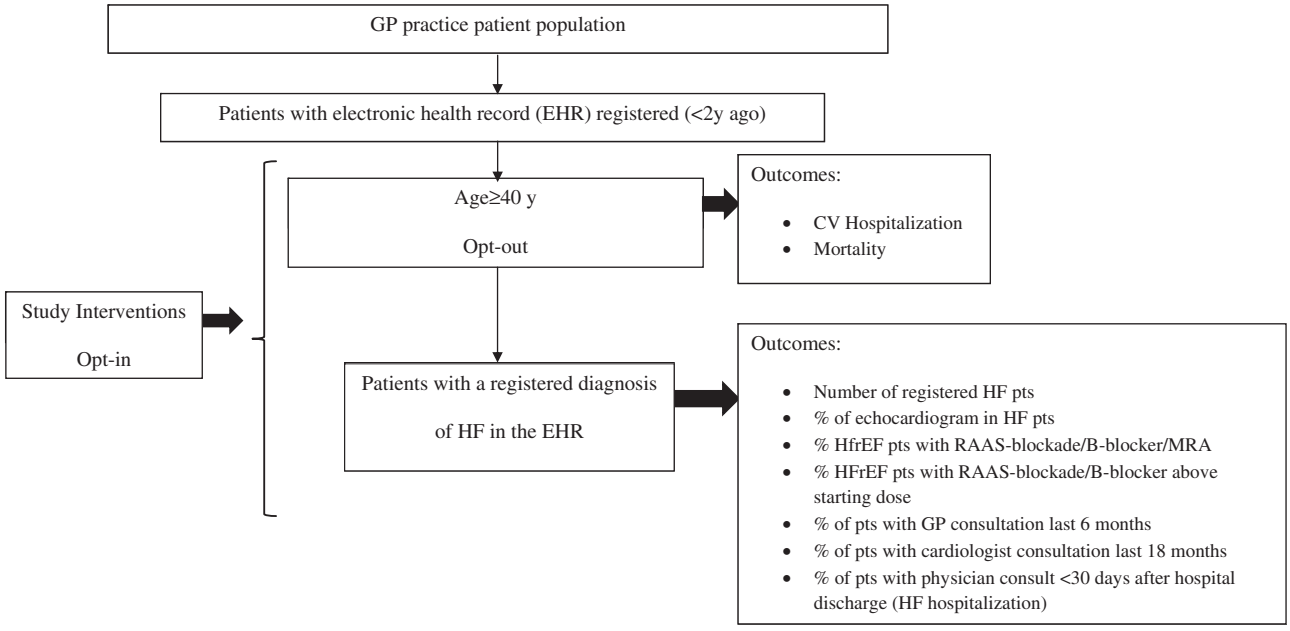

Figure 1. Study flowchart.

GP's HF diagnosis has been questioned [9,10,30,31]. Therefore, this trial aims to optimise the detection of HF patients who were previously unrecognised by their GP and to promote objectified HF diagnoses.

Audit and feedback

A basic audit search on a registered (coded and/or free text) diagnosis of HF will be done in all practices (Supplemental file 4: Queries used for basic audit). However, on top of this basic audit, an extended automated search in the EHR will be done to identify additional HF patients, as we hypothesise that HF diagnoses are often not adequately registered in the EHR. This search includes coded or free text diagnoses of risk factors for HF, HF symptoms and signs and HF medication in different combinations (Supplemental file 5: Queries used for extended audit). The list of all possible HF patients will be presented to the treating physicians, and they will be asked to indicate which patients have HF, no HF or possible HF, according to their judgment. The physicians will be educated about HF diagnosis through the e-learning course and a prior educational session. Registered diagnoses in the EHR will be adapted based on this process. The principal investigator (PI) (MS) will determine, based on the information retrieved from the EHR (e.g. echocardiography results), if the HF diagnosis is objectified (European Society of Cardiology definition of HF [1]). GPs will be encouraged to objectify non-objectified HF diagnoses by a notification in the EHR. Quality indicators of HF management (Supplemental file 6) will be collected for these HF patients [32]. A feedback meeting will be organised in each practice at the beginning of the study, in the presence of the HF nurse, to reflect on their current practice with the GPs and to agree on targets and measures to organise care proactively. A written report will be handed over, informing each practice about their performance on the predefined quality indicators and how this performance relates to the average performance in Belgian/international general practices [14,32] (Supplemental file 6–7). All practices will be asked to specify targets based on these results and to indicate how these targets could be reached. After six months, a basic audit (search for a coded/free text diagnosis of HF) will be repeated, quality indicators will be re-measured and a new feedback meeting will be organised to evaluate improvement and reflect on the experiences of the participating GPs.

NT-proBNP POC test

An NT-proBNP POC test (Cobas h232, Roche Diagnostics Switzerland) will be offered to each intervention practice. This POC assay uses 150 μL of heparinised venous whole blood for its analysis. The stated analytical range is 60–3000 ng/L. The total analysis time is 12 min. Previous research has shown that the results of the Cobas h232 were reliable and the device was easy to use [33]. To ensure its correct use, all GPs must follow a course that teaches them about the value of natriuretic peptides in HF diagnosis, the interpretation of test results and the use of the device. However, the GPs are free to use the test at their own discretion. Every GP must perform one test in order to

become a certified user and receive a personal code. An instrumental quality check (IQC) of the device will be done weekly by the GPs. The Cobas h232 will be connected with the Cobas IT1000 system, recording every result of the POC device itself. A POC coordinator who is attached to the clinical laboratory of the hospital in Genk, Limburg, Belgium (ZOL) will be appointed. This coordinator acts as a point of contact and will supervise the qualitative use of the POC device.

Optimising the management of HF patients

Specialist HF nurses who are currently working in the cardiology department of the hospital (ZOL, Genk and UZ Leuven, Leuven) will be introduced in general practice to assist GPs in the implementation of evidence-based HF management and to promote a seamless transition of care between the hospital and primary care. Before the study start, all identified HF patients will be invited to consult with the HF nurse or will be visited at home. On this occasion, the HF nurse will fill in the Minnesota Living With Heart Failure Questionnaire (MLHF-Q) with the patients to gain the first insights on the patients' disease burden (Supplemental file 8). During the study course, the GPs will be offered the possibility to ask for advice on the treatment of HF patients through a case note review or through a referral to the HF nurse. Additionally, the GPs will be asked to alert the HF nurse by email when a patient is discharged from the hospital after an HF hospitalisation. The HF nurse will first contact these patients by telephone and assess the patients' knowledge on self-management strategies and the risk factors for rehospitalisation. The intensity of further follow-up will be decided based on the patient's and the GP's need. Early physician follow-up after discharge (<30 days) will be promoted [24,34].

Objectives

The objective of this pilot study is to assess the feasibility of a multifaceted intervention to optimise the care of HF patients in Belgian general practice. It is not a primary objective to study the effectiveness of the intervention on the defined outcomes, since the follow-up time might be too short; however, the evolution in quality will be evaluated. Specific research questions are as follows:

1. Do GPs use the NT-proBNP POC test, and how does the test influence practice?
2. Do GPs use the assistance of the HF nurse, and how does this assistance influence practice?
3. Does this multifaceted intervention improve the quality of care for HF patients in primary care?
4. Does this multifaceted intervention improve the quality of life for HF patients in primary care?
5. Is this intervention/data collection method feasible? How do participating GPs and investigators experience the interventions?

Outcomes

Measurements at baseline and after six months of follow-up

Baseline demographic data on patient age, gender, cardiovascular comorbidities (hypertension, ischaemic heart disease, valvular heart disease, atrial fibrillation, cerebrovascular disease, peripheral arterial disease), non-cardiovascular comorbidities (diabetes, depression, chronic obstructive pulmonary disease, dementia, cancer, thyroid disease), the last two blood pressure measurements, last two creatinine measurements, the last two values of the estimated glomular filtration rate (eGFR), the last two values of the total cholesterol/low density lipoprotein (LDL) and high density lipoprotein (HDL) and the last weight and height, last date of GP consultation, involvement of cardiologist (yes/no), last date of cardiologist appointment, echocardiography (yes/no), last date of echocardiography report, ejection fraction (EF), diastolic dysfunction (yes/no), clinically relevant valvular dysfunction (yes/no), left ventricular hypertrophy (yes/no), left atrial enlargement (yes/no), device (yes/no + type of device) and HF treatment with dosage (diuretics, angiotensin-receptor inhibitors [ACE-I], angiotensin-receptor antagonists [ARB], B-blockers, mineralocorticoid receptor antagonists [MRA], digoxin) will be collected. Additionally, the number of chronic medications and the number of chronic comorbidities will be collected. Furthermore, the MLHF-Q (Supplemental file 8) will be collected to evaluate the patients' quality of life, and grip strength (only at baseline) will be recorded as a predictor of functional decline, disability and mortality [35]. At baseline, HF hospitalisation during the last three years will be registered based on the discharge letters in the EHR. All hospitalisations and mortality will be collected at the practice level during the study course. Data on physician age, gender, years of experience and practice organisation (group/single-handed/number of practitioners/EHR) will be requested as well.

Outcomes. The number of identified (registered) HF patients after six months and the number of registered HF patients referred to a cardiologist with echocardiography will be evaluated as outcomes. Additionally, the proportion of HFrEF patients who are treated with RAAS-blockade, B-blockers and/or MRAs will be evaluated. For RAAS-blockade and B-blocker treatment, the proportion of HFrEF patients treated with a dose higher than the starting dose and the proportion of HFrEF patients treated with target doses will be evaluated. Additionally, the evolution in patient quality of life, as measured by the MLHF-Q, will be studied. Furthermore, the number of patients per practice that are hospitalised (HF, cardiovascular, non-cardiovascular hospitalisation) and the number of patients per practice who die during the study course will be counted as outcomes. Moreover, the number of stable HF patients who consulted their GP at least once in the last six months and the number of patients referred to a cardiologist in the last 18 months will be recorded. Finally, physician contact (GP, cardiologist, HF nurse) within the first 30 days after discharge (HF hospitalisation) will be evaluated as an outcome.

Process evaluation

In the process evaluation, the actual use of the interventions, as well as the users' and investigators' perceptions about the feasibility of the interventions, will be measured. The number of times the NT-proBNP POC device is used will be evaluated. Additionally, the indications (diagnosis, follow-up of treatment and prognosis) and impact of its use (referral/no referral) will be revised. Furthermore, a log of the HF nurse interventions and their indications (education, diagnosis, treatment and transition of care) will be kept, and the impact of the HF nurse advice will be evaluated. In the feedback meeting after six months, participating GPs will be asked to share their experiences about the interventions and suggest improvements. Moreover, the steering committee of the trial will reflect on the feasibility from an investigator's point of view after this pilot study.

Data collection

Patient level

Outcomes: All data will be extracted from the EHR of the GP for all patients who satisfy the eligibility criteria. The data will be extracted at baseline and after 6 months. Demographic data can be extracted with an automated search; the other data will need to be collected by a manual chart review. Additionally, all identified HF patients will be visited by the HF nurse at baseline and after six months and will be asked to fill out the MLHF-Q. At this occasion (only at baseline), grip strength will be measured in the dominant hand using a JAMAR® Plus digital hand-held dynamometer. Three attempts at maximal squeeze will be recorded.

Process evaluation: The GPs will be asked to fill out a study registration form about the indication and results of their NT-proBNP POC test use (Supplemental file 9), their referrals to the HF nurse (Supplemental file 10), and how their referrals influenced their decision-making. The HF nurse will keep a log of all the actions.

Experiences of GPs and investigators: The feedback meeting at six months will be organised as a focus group interview in each GP practice to gain more insight into the experiences of the participating physicians and investigators. The meetings will be audiotaped and transcribed. Any harm as a result of the trial will be explicitly collected and reported.

Practice level: The impact of the intervention on hospitalisations and mortality cannot be studied in this pilot trial; however, in a later stage, this would be the outcome in the larger cluster-randomized trial. Therefore, the feasibility of collecting data on hospitalisations and mortality will be tested. These outcomes will be measured at the practice level in all patients aged 40 years or older who are enlisted in one of the participating GP practices (Figure 1). The GPs will be asked to register the date of death and cause of death in the EHR of all patients who die during the study course. A list of hospitalised patients of each participating GP will be collected in all the surrounding hospitals (ZOL Genk, AZ Vesalius, Jessa Hasselt, UZ Leuven, Heilig Hart Leuven) and given to the GPs. The cause of hospitalisation will be deduced from the discharge letter in the EHR by the GP in a standardised manner (trained by PI). The anonymized data will be given to the PI.

Data management

Data collection and data entries will be done by the PI and an assisting data manager. All patient data will be coded and anonymized. All other authors will have full access to the coded data (including the statistical reports and tables) in the study and will be able to take responsibility for the integrity of the data and the accuracy of the data analysis.

Data analysis

Descriptive statistics will be provided regarding the baseline variables of the HF patients and the GPs/general practices. The outcomes measured before and after the study intervention will be compared with a chi-squared test. The experiences of the participating GPs and investigators will be qualitatively analysed using thematic analysis as a method.

Discussion

Heart failure imposes a burden for patients and health economics. Although guidelines exist, they are not fully implemented in the Belgian health care system. GPs are confronted with the broadest range of HF management. Therefore, strategies to bring evidence into practice are needed [15]. However, the results of community HF management programmes are mixed, partly because the GP's HF patients represent a lower risk HF population [26,36,37]. Therefore, the strength of our intervention lies in facilitating GPs by providing evidence-based, multidisciplinary care in a flexible, patient-centred, needs-based manner, keeping cost- and resource-effectiveness in mind. Additionally, all aspects of the intervention could be implemented in the future on a larger scale. Furthermore, acceptance and adherence to the intervention might be larger since it is developed by GPs, for GPs.

A possible shortcoming of studying HF patients who were appointed by GPs based on a list of patients that was generated through a clinical audit is the lack of validity of a GP's HF diagnosis [9,10,30,31]. However, these patients represent the HF population as recognised and treated by their GP in usual care. To compensate for the HF patients who are potentially missed, hospitalisations and mortality will be measured on a practice level. Additionally, in order to minimise the burden of the trial on the participating GPs, data will be collected from the patients' EHR. This strategy implies risks for the quality of data collection, as it depends on the quality of the GPs' registration. Therefore, an important outcome of this pilot trial is to evaluate the feasibility of data collection. Furthermore, we will not be able to deduce which aspect of the intervention will be the most effective. However, the value of each separate intervention has been proven before, and it has been suggested that HF management programmes should target different components of HF care [1,38].

In conclusion, HF is an important health problem in which GPs play a key role.

Therefore, we will evaluate the feasibility of a multifaceted intervention to optimise the standards of care for HF patients in general practice.

Ethics approval and consent to participate

Ethics committee approval for this study was obtained from the University Hospitals Leuven Ethics Committee in November 2016 (B322201630391). All patients will be asked informed consent. Any important protocol changes will be communicated to all relevant parties.

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Disclosure statement

No potential conflict of interest was reported by the authors.

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ORCID

Miek Smeets http://orcid.org/0000-0001-7725-4429

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