Implementation and cost-evaluation of a smartphone-based telemonitoring and digital support platform in patients with heart failure: the Bedicare-HF multicentre trial

Study protocol

Version 2 – 11/02/2022

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This is an investigator-initiated study sponsored by Comunicare Solutions SA and the Belgian Working Group of Heart Failure.

Keywords: heart failure, digital support, smartphone, digital health, implementation, remote patient management, telemonitoring

Introduction

Heart failure (HF) is a chronic condition and one of the most challenging issues is to reduce hospital admission and readmission rates for worsening HF. The prevalence of HF is estimated at 1-2% of the total population and ≥10% among people >70 years of age (1). Increasingly, telemonitoring is used as a solution to intervene at the start of an HF decompensation before the patient starts to be symptomatic and to avoid hospitalisation. In recent years, many trials have been published that investigate the utility of telemonitoring in HF in different modalities including invasive monitoring (2,3) and non-invasive monitoring (4).

The most recent large randomised controlled trial (RCT) that demonstrated the efficacy of telemonitoring in HF is the TIM-HF2 trial in which a structured remote patient management intervention reduced the percentage of days lost to unplanned cardiovascular hospital admission and all-cause mortality in patients with New York Heart Association (NYHA) class II-III HF with a hospitalisation within the last 12 months (5).

The utility of smartphone applications for patient care is increasingly being appreciated and in Europe, clear guidelines exist for developers who aim to develop software as a medical device (6). The advantage of using smartphone applications is that little specialised equipment is needed and, if a digital support programme is proven successful, implementation can be widely performed at low cost.

In the current context of the Covid-19 pandemic, HF patients are particularly suffering from the difficulty to meet their cardiologist and HF nurse on a regular basis. Developing the possibility for remote monitoring is a key alternative to avoid re-hospitalization or severe clinical cardiovascular outcome.

We present the design of the Bedicare-HF trial, which aims to take digital support research a step further. It uses an implementation design approach in which a real-life setting will be approximated. The trial aims thus to not only demonstrate the effectiveness of a smartphone-based HF digital support approach but also the feasibility of implementation in a European healthcare context. Also, it aims to evaluate the cost-effectiveness of a smartphone-based digital support approach.

Objectives

The objectives of this study are to demonstrate feasibility, acceptability, adoption, sustainability, and safety of a smartphone-based digital support system in the healthcare system in Belgium and to demonstrate effectiveness, to evaluate the implementation cost of the system, and to demonstrate cost-effectiveness.

Methods

Study design

The study design is a multicentre implementation trial. The conduct of the study is guided by good clinical practice (GCP) in accordance with the Declaration of Helsinki and the laws and regulations applicable in Belgium. Written approval from the Ethics Committees at all involved centres is required and informed consent must be provided by each patient.

Patient recruitment

Eligible patients are consecutive patients that are hospitalised for HF decompensation. The patients will be included in the programme during their hospitalisation or up to one week after hospitalisation. All eligible patients will be offered to participate. At the time of inclusion,

patients must be in New York Heart Association (NYHA) class II, III, or IV with a left ventricular ejection fraction (LVEF) of ≤40%. The inclusion and exclusion criteria are shown in Table 1. A total of 165 patients will be included over 6 month. In total, 11 hospitals (local investigators) in Belgium with an HF clinic employing at least one certified HF nurse will be participating in patient recruitment. Patients are not randomised and will all be participating in the smartphone digital support intervention.
A screening register will be kept including reasons why eligible patients that do not participate are disregarding inclusion. Patients refusing participation will also be asked to complete a quality of life (QOL)-questionnaire at 6 months and 12 months which will be answered online. A total of 165 patients (who do not want to participate) will be asked to answer this questionnaire.
So the app will be made available to 165 patients for home monitoring and another group of 165 patients without an application will be asked to answer quality of life questionnaires.
Patients who agree to use the application can continue to use it after the study, if they wish.

Inclusion criteria	**Exclusion criteria**
Diagnosed with HF – NYHA class II-IV	Acute coronary syndrome
LVEF ≤40%.	High urgent listed for heart transplantation
Hospitalisation due to decompensated HF at the moment of inclusion or up to 1 week prior to inclusion (i.e. discharged ≤1 week prior to inclusion).	Planned revascularisation, TAVI, MitraClip and/or CRT implantation within 3 months after inclusion
Owning a smartphone and able to use an application	Known alcohol or drug abuse
Written informed consent obtained	Terminal renal insufficiency with haemodialysis or peritoneal dialysis
	Impairment or unwillingness to use the digital support equipment (e.g. dementia, impaired self-determination, lacking ability to communicate)
	Existence of any non-cardiac disease reducing life expectancy to less than 1 year
	Age <18 years
	Participation in other treatment studies or remote patient management programmes

Table 1 – Inclusion and exclusion criteria. NYHA: New York Heart Association. LVEF: left ventricular ejection fraction. CRT: cardiac resynchronisation therapy. TAVI: transcatheter aortic valve implantation.

Digital support platform

The digital support intervention uses the Comunicare patient support solution (Figure 1) specifically designed for digital support of HF. The solution consists of a smartphone-based mobile application designed to be used by patients and a web-based dashboard application to be used by the caregivers. The application is a class 1 certified medical device. It includes

different modules for patient education, medication adherence, tracking of vital signs and symptoms, electronic patient-reported outcome (ePRO), appointments, and video consultation.

Patient Education module: a knowledge base has been configured into the application to provide patients with information about HF based on the latest ESC guidelines (1) and the local reimbursement context. The patient information that is provided includes descriptions of the function of the heart, the causes of HF, and advice about how to self-manage and understand HF.

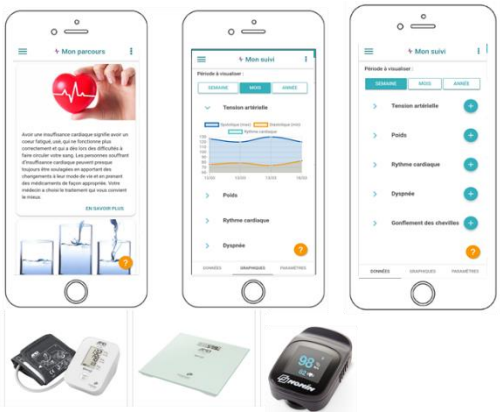
Medication adherence: the application enables patients to maintain a medication list and to configure a reminder system to receive notifications. If medication is not taken an explanation for non-intake can be provided.

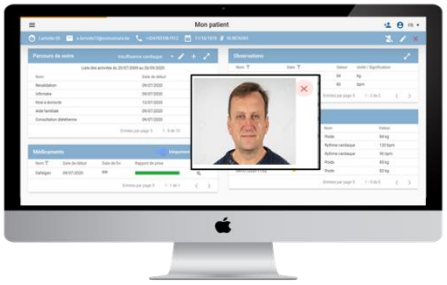
Tracking of vital signs and symptoms: the application enables patients to track and input vital signs and symptoms as recommended by the caregivers. A notification can be configured to remind the moment of measurement. Measured values can be inserted manually or captured directly from validated connected devices (blood pressure monitor, weight scale, activity tracker). Alarm limits can be set, and an alarm will then be triggered as soon as an input breaches the alarm limit. A Bluetooth-compatible blood pressure monitor and weighing scale will be provided at inclusion. If preferred by the patient manual input through their own devices can be performed.

Electronic patient-reported outcome (ePRO): the application enables patients to complete questionnaires about their QOL. A notification can be configured to remind the moment to fill the questionnaires. When available, scoring of the questionnaires is generated in the dashboard for caregivers.

Appointments and video consultation: the application includes an electronic agenda that can be input manually by the patients or automatically synchronized with the hospital system. It also includes a secure video consultation that can be triggered by the caregivers when deemed necessary after reviewing the patient-reported data.

Caregiver dashboard application: this web-based application enables caregivers to administrate the care flow and review all patient-reported data and the alarm generated by the system.

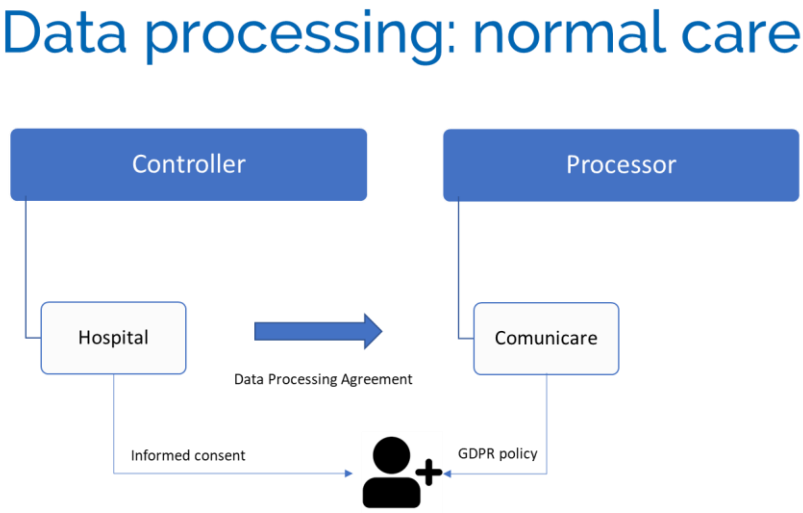




Security and Privacy: the application complies with strict security and privacy-related regulations. All data storages are encrypted on the patients' smartphone and a server located in an ISO-certified data centre located in Belgium, and all information exchanges are highly secured. A General Data Protection Regulation (GDPR)-compliant privacy notice defines how patient personal data is processed and how data protection principles are applied.

According to the General Personal Data Regulation (GPDR), the data controller determines the purposes for which and the means by which personal data is processed and the data processor processes personal data only on behalf of the controller. The duties of the processor towards the controller are specified in a **contract agreement and a Data Processing Agreement (DPA)**.

In the context of a normal usage of the application, the hospital is **data controller** and Comunicare Solutions SA is the **data processor**.

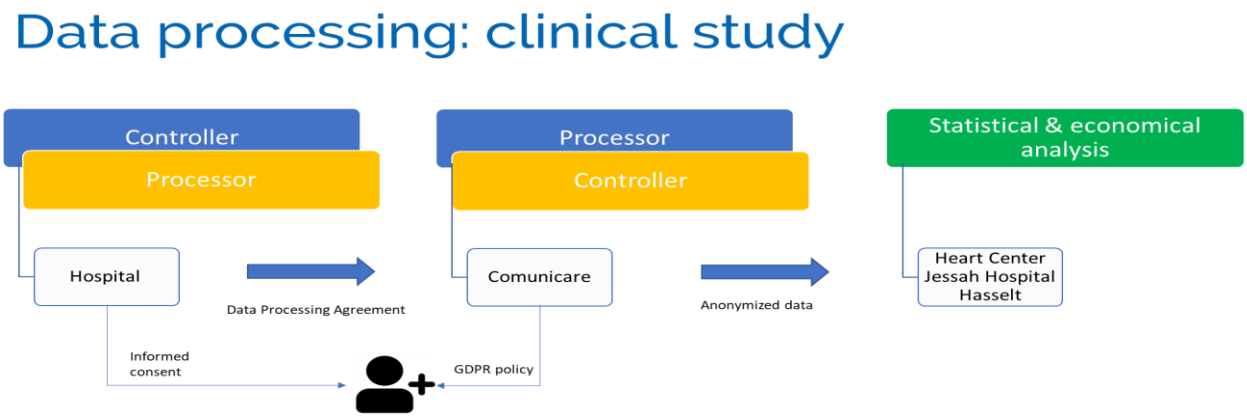


However, in the context of the clinical study, Comunicare Solutions SA is subject to the rights and obligations as "**data controller**" set forth under the GDPR in relation to the processing of personal data for the purpose of conducting the Study in accordance with the Protocol. In that respect Comunicare Solutions SA shall be considered as data controller of all Personal Data processed specifically for Study purposes.

Each participating centre is subject to the rights and obligations as "**data processor**" set forth under the GDPR in relation to the processing of personal data for the purpose of conducting the Study in accordance with the Protocol.

Each participating centre is also subject to the rights and obligations as a separate "**data controller**" set forth under the GDPR in relation to the processing of personal data of its patients for purposes other than conducting the Study. In particular, each participating centre remains data controller of the data contained in the patients' medical records for the purposes of providing medical care to its patients and for academic research purposes.

Comunicare Solutions SA will provide patients with a **GDPR policy**, as required to inform the patient about his/her rights related to their personal data. The hospital will provide the patients with an informed consent document.



Comunicare Solutions SA will provide each participating centre an appropriate number of patient access cards. Each patient access card displays an anonymous user ID and password as well as a scannable QR code. Once the written informed consent form (ICF) is obtained, the study personnel at each participating centre will add the patient to a ICF log (spreadsheet) and attribute a study number to each participant. The hospital study personnel will assign a specific patient access card to the participant and register its code on the ICF log. Data entered into the App and transferred to the sponsor's database will thus be fully anonymized.
The ICF log will allow the hospital study personnel to reconcile data with individual patient identity and should be kept by hospital study personnel in a secured location. Therefore, o nly the medical staff under the responsibility of the investigator in each participating centre will be able to establish a link between the identity of the patient and the data collected throughout the study. The ICF log will not be communicated to the sponsor.
For the statistical analysis, the scientific staff of the Heart Centre Hasselt will only receive and process anonymized data . The generation of anonymous patient code is done via a Universally Unique Identifier (UUID), a 128-bit label generated according to standard methods (https://www.ietf.org/rfc/rfc4122.txt) that guarantee the uniqueness and the non-reversibility. Therefore, the Heart Centre Hasselt will not process any personal data and is therefore not subject to GDPR requirements.

Intervention design

The assessments performed at each visit are displayed in Table 2. At inclusion, laboratory values and echocardiography results of ≤2 weeks prior to inclusion performed as part of routine care will be used.

Smartphone intervention

At inclusion, an account on the smartphone application will be created for the patient and the application will be installed on the patient's smartphone. Instructions on how to use the application will be provided. Patients will be included for 6 months in which they will be asked to use the different modalities of the smartphone application. There will be low-threshold contact with a study nurse if the patient doesn't use or doesn't know how to use the application, as well as when predefined alarm limits are crossed. In case of patients that are

very motivated to participate in the intervention but do not own a smartphone, a smartphone can be provided by the study sponsor for the duration of the study. No costs will be charged to the patient, also in case of loss or damage

Personalised alarm limits that can be predefined include:

- Heart rate: an upper rate will be set to detect possible atrial fibrillation
- Weight gain: ideal weight and alarm weight can be set by the case nurse.
- Blood pressure: hypotension (under normal limits for the specific patient) and extreme hypertension.
- Not using the application, no measurement input by the patient for a predefined time.

After 6 months the inclusion will be ended. If the patient and the care providers deems it necessary for the continuity of care, they may continue using the application after the 6 months period of the study. A new informed consent document should be signed and the application, inside or outside the study, will remain the same. Only the data collected during the 6-month period of the study will be used for the initial data analysis. Further data analysis of the additional data after 6 months may take place in a second stage. 6 months after the end of the study, during a routine appointment (standard of care) of the patient with his cardiologist, he will be asked to answer questions about his well-being again.

Data collection during the trial

Data that will be collected by the smartphone application and the caregiver application for analysis purposes throughout the trial includes parameter measurement (blood pressure, heart rate, weight), medication adherence by using the medication module, and patient-reported outcome questionnaires. In the caregiver dashboard application information on time spent on the caregiver dashboard application and all input (time spent, change in therapy, contacts) by caregivers (nurses, cardiologists, others) will be collected.

Interventions because of the trial

Personalised alarm cut-offs can be programmed by the caregiver team. There is no scheduled study contact on top of the usual care contacts. In case of application alarms being triggered, the patient will be called and the situation will be assessed. If needed, the problem will be discussed with a cardiologist. In emergency situations, the patient will be asked to present to the emergency department.

Monitoring of alarms will not be continuous and will only take place during working hours throughout the working week (Monday to Friday) and patients will be instructed to call their general practitioner, the hospital, or the emergency number in case of problems and not to wait until they are contacted.

End-of-trial assessment

At the end of the trial, the assessments listed in Table 2 will be performed. Cost-related data will be collected: healthcare resource use, hospitalisation time, tests, procedures, and health expenditure. Cost-effectiveness will be calculated using healthcare cost data and work productivity and impairment (WPAI) questionnaire to calculate incremental cost-effectiveness ratio (ICER).

Re-evaluation at 12 months

After the end of the inclusion at 6 months, a re-evaluation of outcome parameters will take place at month 12 to evaluate the continued effect of the intervention after cessation.

	Baseline	**Final visit month 6**
Informed consent and patient information	X	
Medical history: past medical history, symptom control, NYHA classification, smoking behaviour, current medication	X	X
Physical examination including weight, height, blood pressure, heart rate	X	X
Length of initial hospital stay	X	
Registration of medication	X	X
Echocardiography	X	X
12-lead ECG	X	X
Laboratory tests: haemoglobin, haematocrit, leukocytes, thrombocytes, sodium, potassium, creatinine, NT-proBNP	X	X
ePROs: KCCQ-12, EQ5D, HeartQoL, PHQ9, HLS-EU-Q16, EHFScB-9, SUTAQ, WPAI.	X	X
Registration of events: hospitalisation (with the length of stay), emergency department visit, death		X
Cost-evaluation		X

Table 2 – intervention design. ECG: electrocardiogram. ePRO: electronic patient-reported outcome. NT-proBNP: N-terminal prohormone of brain natriuretic peptide. KCCQ-12: Kansas City Cardiomyopathy Questionnaire. EQ5D: EuroQol 5-dimension questionnaire. HeartQol: Health-related quality of life questionnaire. PHQ9: patient health questionnaire-9. HLS-EU-Q16: European Health Literacy Survey Questionnaire. EHFScB-9: European Heart Failure Self-care Behaviour scale revised into a nine-item scale. SUTAQ: Service User Technology Acceptability Questionnaire. WPAI : work productivity and impairment.

Health economic analysis

The costs considered for the cost-effectiveness analysis are direct costs of the smartphone-based digital support intervention and the care utilisation recorded during the inclusion of the trial. The costs for the digital support intervention consist of costs for data management using the application, costs for devices that are provided in selected patients (blood pressure monitor, weighing scale), and personnel costs for inclusion and time spent on follow-up of alarms.

Information on care utilisation will be collected at the end of the trial. Former studies have demonstrated that hospitalisation costs are the key driver of HF-related costs (7,8). This study will thus focus on reduction in length of hospital stay and reduction in rehospitalisations after initial hospitalisation. The 30-day and 90-day rehospitalisation rates will be assessed. All hospital-related costs will be collected from the hospital billing and financial departments. A distinction will be made between scheduled and non-scheduled hospitalisations. Scheduled hospitalisations for elective procedures and scheduled visits with the cardiologist or general practitioner will not be included in the cost-evaluation.

Implementation cost and cost-effectiveness will be assessed in this trial following a pre-post economic model. A historical cohort of all patients hospitalised for HF on a cardiology ward in 2019 in all participating centres will be assessed for comparison. Hospital bills and hospital administrative data based on the international classification of disease (ICD)-codes will be collected. Propensity matching will be applied.

QOL and healthcare-related costs will be collected in selected patients refusing to participate in the smartphone intervention.

Cost reduction between the intervention group, the historical cohort, and the participation refusers will be calculated. Costs and outcomes (utilities) will be compared by calculation of the incremental cost-effectiveness ratio (ICER) (ICER = ($cost_{intervention\ group} - cost_{historical\ cohort}$)/ ($effectiveness_{intervention\ group} - effectiveness_{historical}$ cohort)). The incremental cost represents the difference in total average cost per patient between the intervention group and the historical cohort or the participation refusers. Effectiveness will be calculated by comparing QOL in the intervention group versus the participation refusers.

Study endpoints

The endpoints that will be assessed are summarized in Table 3. As specified before, the objectives of the study are to demonstrate positive implementation measures (e.g. feasibility) as well as to demonstrate cost-effectiveness. Secondary objectives include assessment of clinical impact, based on measurement of clinical endpoints as specified in Table 3. Implementation outcome variables will be assessed using a mixed-method design. Patient and caregiver parameters will be calculated (e.g. time spent using the application). Questionnaires will be used to assess patient variables. Semi-structured interviews in a selection of patients and caregivers will be performed to assess further outcome variables regarding implementation.

Implementation outcome variables	
Feasibility and patient acceptability	SUTAQ, semi-structured interviews.
Caregiver acceptability and burden of care	SUTAQ, semi-structured interviews, daily time spent by case nurses using the platform
Adoption and sustainability	Number and percentage of patients refusing inclusion, of patients continuing application usage after 6 months. Total time-percentage ratio of patients using the application throughout the trial.
Implementation cost	Cost-related data: healthcare resource use, hospital days, tests, procedures, health expenditure. Cost-effectiveness: healthcare cost data, WPAI questionnaire, ICER. Cost of hospital stay at inclusion.
Quality of life, literacy and patient self-care	KCCQ-12, EQ5D, HeartQoL, PHQ9, HLS-EU-Q16, EHFScB-9, SUTAQ.
Clinical outcome measurement	
Combined endpoint	Unplanned CV readmission and all-cause mortality
Individual endpoints	Symptom control (NYHA, KCCQ-12), emergency department visits, length of hospital stay during the trial, unplanned CV readmission, all-cause mortality.

Table 3 - Study endpoints. CV: cardiovascular. SUTAQ: Service User Technology Acceptability Questionnaire. KCCQ-12: Kansas City Cardiomyopathy Questionnaire. EQ5D: EuroQol 5-dimension questionnaire. HeartQol: Health-related quality of life questionnaire. PHQ9: patient health questionnaire-9. HLS-EU-Q16: European Health Literacy Survey Questionnaire. EHFScB-9: European Heart Failure Self-care Behaviour scale revised into a nine-item scale. SUTAQ: Service User Technology Acceptability Questionnaire. WPAI : work productivity and impairment. ICER: incremental cost-effectiveness ratio.

Statistical analysis

Sample size

A total of 165 patients will be included in the study. The sample size is based on comparable implementation trials (9,10). An additional patient group will be included that is not part of the study intervention but will complete questionnaires; this is a non-randomized control group. A minimum of 165 patients will take part in this control group for completion of the study.

Statistical analysis

The primary analyses will be paired Student *t*-tests and Wilcoxon signed-rank tests comparing baseline, 6-month and 12-month values for all patient-level outcomes. Secondary analyses aimed at determining the longitudinal impact of the smartphone digital support programme (i.e., using outcome data from the additional time points), and the correlation of independent variables (e.g., patient characteristics and adherence rates) with outcomes will be analysed using general linear mixed-model procedures. In addition, descriptive statistics will be produced for all variables collected, and subgroup analyses will be performed. All statistical analyses will be performed using the statistical software application SPSS (IBM Corporation, USA).

Descriptive statistics will be produced for the indicators of the implementation outcome to provide an objective measure of implementation success.

Discussion

The Bedicare-HF study is the first study that will investigate implementation of a smartphone-based HF digital support system in a real-life context on the background of European GDPR and medical device regulations.

In recent years, many studies have investigated telemonitoring and digital support of HF in different modalities (2–5) in a RCT setting using strict inclusion and exclusion criteria. Many of these trials had successful results and could prove the superiority of the digital support intervention on their primary endpoints. However, due to the RCT nature, it remains unclear how easily these results will translate into a real-life healthcare context. One trial investigated implementation of a smartphone-based HF digital support intervention and could report a 50% decrease in HF-related hospitalisations (10). However, this trial was conducted in Canada and is thus specific for the Canadian healthcare context.

By its implementation design, the Bedicare-HF study aims to take digital support of HF to the next step towards implementation. A large advantage is that it is an all-comers study, in which all patients meeting the inclusion criteria will be asked to participate, and that information on those who refuse participation will be available for analysis. This information will be of direct use for later implementation in the healthcare setting. An intrinsic limitation is that it is specific to the European and even Belgian healthcare context and that the results about implementation cannot necessarily be generalised to other healthcare systems. Another limitation is that due to the nature of the trial setup, no distinct comparator group is available and a historical cohort will need to be used. However, we believe that the strength of this trial is in its pragmatic design and the value of information not only on trial participants but also on trial non-participants.

A particular challenge to the Bedicare-HF trial will be the European GDPR-context and medical device regulations. The collaboration between a commercial partner and multiple hospitals means that sensitive data will need to be securely exchanged. Overcoming this challenge can directly yield useful information on the implementability of this technology.
In Belgium, there is currently no framework for reimbursement of telemonitoring and digital support of HF, neither non-invasively nor invasively. Recently, a reimbursement framework was approved for reimbursement of medical smartphone applications. If the Bedicare-HF intervention is shown successful, this will have direct implications for reimbursement of HF digital support and telemonitoring in Belgium.
Another important strength of this trial is the emphasis on cost-evaluation and cost-effectiveness analysis which will provide useful information for possible reimbursement. By using semi-structured interviews the study aims to also evaluate important barriers for implementation in patients and physicians.

Conclusion

The Bedicare-HF study will investigate the implementation of a smartphone-supported HF telemonitoring and digital support intervention in a European legislative setting. The design is a multicentre implementation trial. It is an all-comers study in which information on participants but also on non-participants of the study will be collected. This design will allow to take the evaluation of HF digital support a step further and allows to evaluate a low-cost smartphone solution for HF telemonitoring and digital support in a real-life setting. The study will yield important information about the feasibility of implementation in a European healthcare context on a background of European medical device regulation for software. The results of this study will demonstrate if, and how, a smartphone-based digital support system improves the self-care capacities, clinical management, and health outcomes of patients with HF and will yield important information about the implementation of digital support systems into a specific healthcare setting. The results of our study are expected in 2022.

Ethical considerations and additional regulations

The study will be conducted in accordance with the study plan, Good Clinical Practice (GCP) guidelines, and the ethical principles for medical research involving human subjects, set out in the Declaration of the World Medical Association of Helsinki (the Helsinki Declaration). The present study will be submitted to the respective Ethics Committees of participating hospitals for approval. The study may only be started after approval by the respective Ethics Committees.
Any change in the study plan and/or in the study participant information and declaration of consent shall be submitted to the responsible Ethics Committees for approval. All such changes shall be approved by the Ethics Committees before implementation.

Funding

This is an investigator-initiated study sponsored by Comunicare Solutions SA and the Belgian Working Group of Heart Failure.

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Figures and Tables

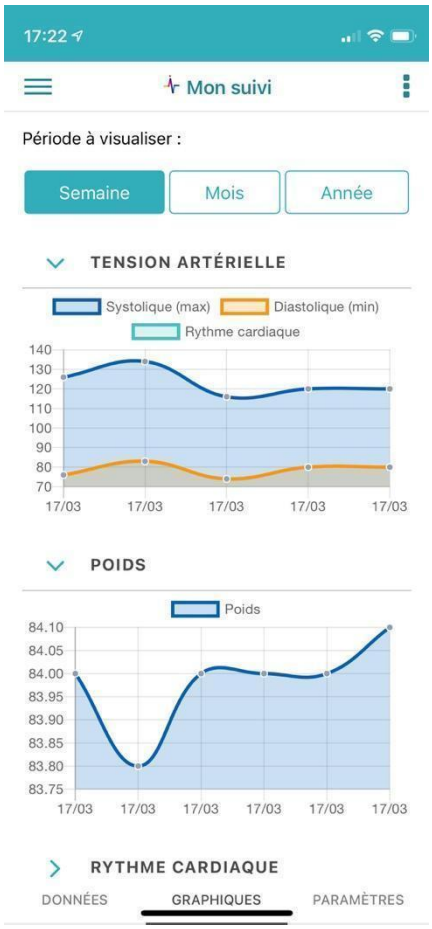

Figure 1 – The Comunicare patient platform. The parameter module is displayed.