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HeartMan DSS: A decision support system for self-management of congestive heart failure

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ABSTRACT

Congestive heart failure is a chronic medical condition that affects about 2% of the adult population. Even though it cannot be cured, it can be relieved by a proper, long-term, complex and personalized disease management. In this paper we present the HeartMan Decision Support System (DSS), aimed at supporting individual patients in their uptake of well-established clinical guidelines (i.e., both medication and behaviour based) for disease management. The HeartMan DSS is a central component of the wider HeartMan mobile-health platform that employs mobile phones, wristband sensors and a web application for communication with patients, their physicians and caregivers. The DSS itself provides recommendations for (1) managing patient's physical health in terms of exercise, nutrition, medications and self-monitoring, (2) psychological support, and (3) managing environmental parameters. The DSS employs a variety of methods: rule-based decision models and adaptable workflows developed using literature and in collaboration with medical experts, classification models developed by machine learning from data, and optimization algorithms. Taken together, they provide a comprehensive, personalized and user-friendly disease management platform. The system was evaluated in a clinical proof-or-concept trial, involving 56 patients in four hospitals. The results confirmed that the system was successful in improving self-care behaviour, decreased patients' levels of depression and anxiety, and improved the overall predicted 1-year mortality risk.

1. Introduction

Congestive heart failure (CHF) is a chronic medical condition caused by the inability of the heart to pump sufficient blood volume to meet the needs of the body (Heart Failure, 2009). Symptoms include shortness of breath, excessive tiredness and leg swelling. Eventually, blood and other fluids can back up inside the lungs, abdomen, liver and lower body. CHF is a common, chronic, progressive, costly, and potentially fatal condition (McMurray & Pfeffer, 2005). It affects at least 26 million people worldwide and, in developed countries, around 2 % of adults have heart failure, which increases to 6–15 % in the population aged over 65 (Conrad et al., 2018; Johansson et al., 2021; Ponikowski, Voors, Anker, Bueno, & Cleland, 2016; Savarese & Lund, 2017; Seferović et al., 2021).

Presently, there is no cure available for CHF. The only effective treatment is by a proper, long-term disease management that may substantially relieve symptoms, improve survival, prevent hospitalization

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and improve the patients' quality of life (Ponikowski, et al., 2016). Patients have to take various medications, monitor their weight, exercise appropriately, watch their diet, and make other changes to their lifestyle. Therapies and interventions are patient-specific. Many patients, particularly elder ones and those suffering from depression and anxiety, find it difficult to follow the medical advice on their own and on a daily basis (Lainscak, Blue, Clark, Dahlstrom, Dickstein, Ekman, & Jaarsma, 2011). About 50 % of them show signs of cognitive impairment, causing poor self-care management (Falk, Ekman, Anderson, Fu, & Granger, 2013). All this makes CHF management very difficult and calls for a proper support and action (Zannad, 2018).

Disease management in CHF patients is overall unsatisfactory, as indicated by the insufficient uptake of evidence-based clinical practice guidelines (Corotto, McCarey, Adams, Khazanie, & Whellan, 2013; Healy, Ledwidge, Gallagher, Watson, & McDonald, 2019; Lombardi, Ferreira, Carubelli, Anker, Cleland, Dickstein, & Metra, 2020). Medication non-adherence usually ranges from 40 % to 60 %. Compliance with exercise in cardiac patients in general is below 50 %. In CHF patients, an additional barrier is the presence of their physical symptoms. So, despite the evidence on the benefits of exercise for improving the exercise capacity in CHF patients, their participation rates in cardiac rehabilitation programs are disappointingly low at <20 % (Bjarnason-Wehrens, McGee, Zwisler, Piepoli, Benzer, & Schmid, 2010).

Since CHF management is difficult and unsatisfactory in practice, it may benefit from using intelligent tools and systems, aimed at supporting CHF patients carrying out their complicated treatment plans and giving them lifestyle advice. On the one hand, such systems may provide information of what to do in order to combat poor health literacy and cognitive problems. It is known that patients who are actively involved in their own care and treatment, and who adhere to the medication and lifestyle regimen, have better prognosis in terms of improved survival and decreased hospital readmissions (Lainscak, et al., 2011; Toback & Clark, 2017). Their lifestyle should include regular exercise and this demands a specific individualized support. On the other hand, such systems may provide means to increase the patients' motivation and provide psychological support in order to alleviate depression and anxiety problems. A personal health system that enhances the level of patient empowerment and self-control is expected to increase selfefficacy of patients and improve their self-care confidence and management (Goodman, Firouzi, Banya, Lau-Walker, & Cowie, 2013).

HeartMan (http://heartman-project.eu/) is a research project funded by the European Union's Horizon 2020 research and innovation program. The project explored the idea of using mobile health (mHealth) technology (Prescher, Koehler, & Koehler, 2020) to help CHF patients manage their disease A personal mHealth system was developed that provides advice on physical and psychological aspects of disease management adapted to each patient. It does so in a friendly and supportive way using a mobile application connected to a sensing wristband. The system also contains a web application for medical professionals, who can view information collected from the sensing devices and monitor patients' progress and adherence to recommendations. Both applications are connected with the HeartMan Decision Support System (HeartMan DSS for short). This is a central component of the system, aimed at providing:

- recommendations for managing patient's physical health (in terms of exercise, nutrition, medications and self-monitoring);
- psychological support (elements of cognitive behavioural therapy and mindfulness) tailored to improve adherence to clinical advices and changes of behaviours;
- recommendations for managing environmental parameters (temperature and humidity).

All these features are adapted to individual patients and their current situation, which is the main reason for the complexity of this DSS.

In this article, we focus on the HeartMan DSS. After reviewing

related work, we formulate the purpose of and requirements for the DSS, as well as its position within the mHealth environment provided by the HeartMan system. Each DSS component is presented from the methodological and functional viewpoint, and illustrated by examples. Finally, we summarize results of a clinical trial (Baert et al., 2018), which was carried out to evaluate the HeartMan system as a whole and is the subject of another publication. An early design of the HeartMan DSS has been reported by Bohanec, Dovgan, Maslov, Vodopija, Luštrek, and Puddu (2017).

2. Related work

Decision Support Systems (DSSs) are interactive computer-based systems intended to help decision makers utilize data and models to identify and solve problems and make decisions (Power, 2002; Sharda, Delen, Turban, Aronson, & Liang, 2014). DSSs incorporate both data and models, which are designed to assist decision-makers in semi-structured or unstructured tasks. In principle, DSSs do not make decisions on their own, but rather support human judgment by providing appropriate, accurate and timely information, relevant for the problem at hand. This information may include advice about possible courses of action.

DSSs used in medicine are often referred to as Clinical DSSs (CDSSs) (Musen, Middleton, & Greenes, 2014; Sutton et al., 2020). They are aimed at providing clinicians, staff, patients, and other individuals with knowledge and person-specific information, intelligently filtered and presented at appropriate times, to enhance health and health care (Berner, 2009). Typical clinical tasks addressed by CDSSs are (Dinevski, Bele, Sarenac, Rajkovic, & Sustersic, 2011): diagnostic assistance, therapy assessment and consulting, drug dosing and prescribing, test selection, alerts and reminders, information retrieval, image recognition and interpretation, prevention, screening, expert laboratory system, and chronic disease management. CDSSs are often designed as knowledgebased systems, characterized by the use of rules and other types of models, which are made using literature-based, practice-based, or patient-directed evidence (Sutton et al., 2020). Examples of recent CDSSs related to heart diseases include a DSS for heart failure risk prediction, which employs neural network and fuzzy Analytical Hierarchy Process models (Samuel, Asogbon, Sangaiah, Fang, & Li, 2017), a diagnostic system of heart diseases, using fuzzy models (Nazari, Fallah, Kazemipoor, & Salehipour, 2018), a heart arrhythmia diagnosis system, employing metaheuristic optimization (Mazaheri & Khodadadi, 2020), and a coronary heart disease prediction model, using convolutional neural networks (Dutta, Batabyal, Basu, & Acton, 2020). A systematic literature review of heart-disease diagnosis DSSs in presented in Safdar, Zafar, Zafar, and Khan (2018). The rapid growth of CDSSs is playing a key role to gain the continuity of care and a person-centric model, focusing on a knowledge-based approach integrating past and current data of each patient together with statistical evidence.

The modern concept of medical decision support is focused on patient's self-management of health, with the objective to minimize interaction with health professionals and reduce workload and costs to the society. This trend is also increasing the market of mHealth applications ranging from lifestyle/fitness apps for well-being (Rivera et al., 2016) to medical apps for chronic condition managements such as diabetes (Chomutare, Fernandez-Luque, Årsand, & Hartvigsen, 2011), hypertension (Albini et al., 2016), and heart failure (Huang et al., 2014). Despite this success, mobile health interventions still suffer from the lack of trialbased evidence for chronic diseases (Monzo, Schiariti, & Puddu, 2019; Tomlinson, Rotheram-Borus, Swartz, & Tsai, 2013). The main reasons range from legal and societal obstacles, such as inappropriate training for using wearable devices, scepticism of many healthcare professionals, and technical issues related to interface and interactions, which are not always sufficiently simple and intuitive. Furthermore, an important aspect is related to psychological comorbidities of patients. Most patients diagnosed with chronic diseases are affected by anxiety, depression, dysfunctional coping strategies and stress (Loucks, Britton, Howe, Eaton,

& Buka, 2015), which demotivate them to follow medical advice and prescriptions, and interact with applications and sensing technologies (Gracie et al., 2017). To face this problem, such applications, based on DSS, may integrate psychological interventions targeted at behavioural and cognitive changes in order to help patients coping with their chronic disease and lead a fulfilling life, rather than focusing on eliminating the disease (Free et al., 2013). Following this scenario, the HeartMan research project proposes a DSS for the management of CHF focusing on medical interventions delivered by psychological support.

Recently, a systematic review of mobile apps supporting selfmanagement of CHF has been made (Athilingam & Jenkins, 2018). The review was divided in two parts: (1) scientific articles researching mobile interventions for CHF, and (2) commercially available mobile applications for CHF. The review included 18 articles, published between April 2008 and August 2017, and 26 mobile apps, which were evaluated with respect to the quality of the included self-management components and provided user experience. According to the review, most mobile apps are inadequately designed, lack comprehensiveness and do not include all the necessary components for a complete selfmanagement of CHF. Indeed, only two apps, Heart Failure Storylines (HFS, 2020) and HeartMapp (Athilingam et al., 2016), include exercise intervention, which is one of the most important aspects of CHF management. The Heart Failure Storylines app is arguably the most complete mobile app currently available on the market. The app provides medication reminder, symptom tracker, keeps a record of vitals, tracks physical activity and daily mood. However, the provided interventions are insufficiently personalized (except for medication reminders), since the app does not consider patient's psychophysical state, which makes such interventions questionable (Piepoli et al., 2011; Ponikowski, et al., 2016).

In contrast, HeartMapp provides personalized advice, however most of these interventions are basic and do not rely on expert knowledge as foreseen in (Piepoli et al., 2011; Ponikowski, et al., 2016). For example, the section about selecting the optimal training protocol in Piepoli et al. (2011) starts with "Identification of the appropriate and adequate level of training intensity is crucial to obtain the desired benefits while maintaining reasonable control of the related risk. A universal agreement on exercise prescription in CHF does not exist; thus, an individualized approach is recommended, with careful clinical evaluation, including behavioural characteristics, personal goals, and preferences." The HeartMapp physical exercise module encourages the patient to walk three times per week and uses the predicted distance walked during the first six minutes of walking to offer feedback to patients on their performance. In other words, only feedbacks about exercise performances are personalized, while the exercise regime (training intensity, duration, frequency) is common for all patients and is not individualized at all. In addition, HeartMapp was tested in a randomized controlled trial with only 18 participants (intervention group n = 9), making the conclusions statistically uncertain.

The HeartMan system, described hereafter, attempted to advance the state-of-the-art of CHF management applications particularly in two directions: (1) to provide a comprehensive support addressing all the major aspects of CHF management (measurement and monitoring, physical and psychological support, environment management), and, whenever possible, (2) to provide personalized advice in a friendly manner, adapted to each patient. For this purpose, HeartMan employs a variety of decision models and algorithms, developed from data, relevant literature and in collaboration with medical experts.

3. Context and requirements

The overall objective of the HeartMan mHealth system is to help CHF patients manage their disease on their own as much as possible. From the patients' perspective, this is important because good disease management is expected to make them feel better and live longer, and the sense of empowerment may benefit them psychologically. From the perspective of the healthcare system, the HeartMan system can supplement medical professionals who cannot always be at the patients' disposal. Information collected by the system can be used for monitoring the patients' state and progress, for informing informal caregivers about the patient's state and their needs, and used by physicians to make better-informed therapy recommendations. In the long run, this can prevent hospitalizations and reduce expenses.

To achieve this objective, the HeartMan DSS is expected to provide personalised advice to the CHF patient regarding their physical exercise, diet, medication and environment, as well as self-monitoring and psychological support. Accordingly, the HeartMan DSS is composed of three modules that support the following aspects of CHF management:

- 1. Physical health: Physical conditioning by exercise training reduces mortality and hospitalization, and improves exercise tolerance and health-related quality of life. For this purpose, the DSS provides a comprehensive physical exercise program adapted to each patient's physical capacity and psychological profile. CHF patients should also maintain their body weight and take care of their diet, for instance, not eating too much salt or drinking too much fluid. Thus, the DSS addresses nutrition aspects: it assesses the patients' eating behaviour and provides personalised dietary education. The DSS also reminds the patients to take medications and monitor their weight and other parameters.
- 2. Psychological support: To improve compliance with the HeartMan system, the DSS provides structured psychological interventions based on cognitive dissonance a conflict between their desire to be healthy and practicing unhealthy behaviours for a short-term pleasure. This dissonance is exploited by specially designed cognitive behavioural therapy messages to align the patients' actions with their desires. The psychological support is complemented by periodic mindfulness exercises to enhance the patients' awareness of the positive effects of healthy behaviour, and reduce anxiety and depression.
- 3. Environment measurement: Environmental conditions, such as temperature and humidity, may affect the patient's feeling of health. Combining both, the patient's and environmental conditions, the DSS advises the patient how to change the environment to improve their health feeling.

In order to operate, the HeartMan DSS needs to communicate with the patient and physicians, and obtain and process the relevant data. Therefore, the HeartMan DSS is placed in a wider environment of a HeartMan mHealth system (Fig. 1), which serves for:

- obtaining relevant data about the patient's physical (such as weight, blood pressure, heart rate) and psychological profile (such as motivated, anxious, depressed),
- monitoring the current patient's activity (to monitor the exercise progress and trigger appropriate actions, such as messages on a diet),
- monitoring the patient's environment (such as temperature and humidity),
- presenting the system-generated recommendations adapted to the level of expertise and psychological profile of the patient,
- storing, analysing and presenting the collected data in a way suitable for medical professionals (physicians and familiar caregivers), who supervise the patient's disease management,

The main user of the whole system is the CHF patient, who has a dual role: providing medical data to the system and receiving advice produced on this basis by the system. The patient is equipped with a smartphone, a sensing wristband and other devices (such as scales, pillbox, blood-pressure monitor, environmental sensors), which are all used to measure the necessary data.

There is a mobile application that runs on the patient's smartphone and handles the patient's communication with the rest of the system. It

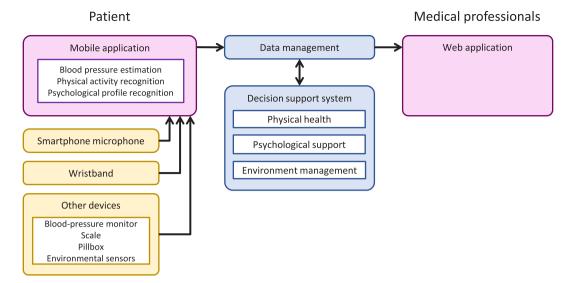


Fig. 1. The HeartMan system overview. The HeartMan DSS is the central component of the system.

is also used to store and interpret information coming from other devices. The wristband continuously measures the heart activity (PPG), sweating, temperature and movement. The smartphone microphone is used to record voice during a weekly interview with an informal caregiver (Section 4.2.1). Other data, such as weight, is entered manually in the application, generally on a daily basis. While manual entry is a small burden for the patient, we decided it was preferable to risking technical difficulties with Bluetooth scales. This information is then interpreted by algorithms for:

- estimating the patients' blood pressure,
- recognizing the patients' physical activity and its intensity,
- recognizing the patients' psychological profile based on surveys, physiological signals and voice analysis.

These algorithms have been mostly developed by means of machine learning. They are not part of the HeartMan DSS and their detailed description is beyond the scope of this paper; the interested reader is referred to (Cvetković, Drobnič, & Luštrek, 2017; Slapničar, Luštrek, & Marinko, 2018).

The collected and interpreted data is sent to the backend completely transparently for the user, whenever Internet connection is available. The backend runs in the cloud and stores the data in the standard HL7 FHIR format (Benson & Grieve, 2016), which enables different information systems to exchange medical data. In the HeartMan system, this data is made available to the web application, which can be used by supervising physicians to monitor the patient's progress and adherence, and accordingly suggest proper disease management measures. This data is also used by the HeartMan DSS, which is presented in the next section.

4. The HeartMan decision support system

The HeartMan DSS is a central component of the HeartMan system (Fig. 1), aimed at providing medical advice to CHF patients. Given data about the patient's current and past physical and psychological state, performed activities and adherence to recommendations, the DSS processes and interprets this data, and on this basis formulates the advice. The advice is formulated in terms of recommendations, adapted to patients who generally have no medical knowledge. No decisions are enforced or made on behalf of the patients. In this way, the HeartMan DSS belongs to the category of cooperative DSS (Turban, Sharda, Delen, King, & Aronson, 2010).

The architecture of the HeartMan DSS is detailed in Fig. 2, which

shows the three constituent modules (Physical health, Psychological support and Environment management) and their internal functional components. Additionally, Fig. 2 shows the main data items that are captured by the sensors and mobile application at the user's side, as well as data items in the database, which is stored and maintained on the server. Arrows show the data flow and indicate which data items are used and/or produced in individual DSS components. These elements are further elaborated in the following sections.

4.1. Physical health advice

Physical Health is a HeartMan DSS module that addresses three physical aspects of CHF management: physical exercises, eating behaviour, and medication intake. Additionally, this module supports self monitoring of patients by keeping time series of their weight, blood pressure and heart rate, calculating basic statistics and displaying them in weekly and monthly charts.

4.1.1. Advice on physical exercise

The HeartMan DSS administers a comprehensive exercise programme (Bohanec, et al., 2017). The exercise module follows the guidelines provided in Piepoli et al. (2011) with minor modifications to accommodate the mobile application. At the beginning, the DSS collects medical information and assesses the patient's physical capacity in order to plan the difficulty level of the exercises. Then, the DSS provides a weekly set of endurance and resistance exercises, which increase in difficulty as the patient becomes fitter. The DSS also guides the patient during each exercise session: it checks whether the patient is ready to start, then provides instructions, and finally asks the patient to evaluate the exercise.

Physical Capacity Assessment. Prior to start using the HeartMan DSS, the patients are requested to perform a cardiopulmonary exercise (cycloergometry) test to assess their physical capacity. Alternatively, when using the system in a supervised setting, patients can perform a 6-minute walking test. On this basis, the physical capacity of each patient is assessed as "low" (<1 W/kg measured by cycloergometry or <300 m walked in 6 min) or "normal" (otherwise). The "low" capacity is assumed for patients who have not performed any tests.

Weekly Exercise Planning. The DSS provides the patient with a combined endurance and resistance exercise programme. Both types follow the same principle described with four parameters: frequency (times per week), intensity, type (endurance or resistance), duration (for endurance exercises), and sets and repetitions per day (for resistance exercises). These parameters are combined with the physical capacity to

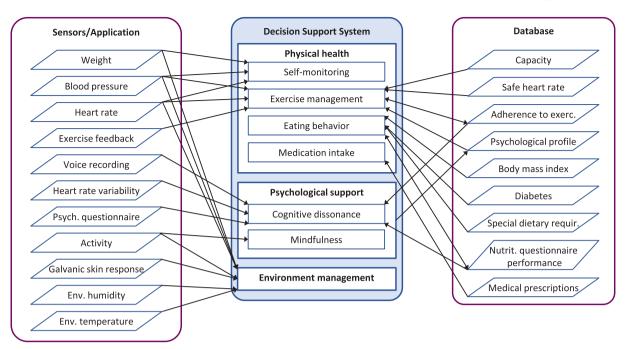


Fig. 2. Modules of the HeartMan DSS and main data items captured by sensors and mobile application at the patient's side and stored in the server database.

make a weekly exercise plan for each patient. For instance, low-capacity patients start with very light 10–15-minute endurance exercises twice per week. According to the patient's progress, these parameters may change with time. In the HeartMan DSS, the progress for endurance exercises is prescribed by three models:

- EnduranceFrequency: a model for suggesting weekly frequency of endurance exercises;
- EnduranceTime: a model for suggesting daily durations of endurance exercises. These increase with time. The increase is more gradual for depressed patients than for the other psychological profiles.
- EnduranceIntensity: a model for suggesting the intensity of exercises and enabling intensive exercises, such as "stairs walking". More intense exercises are allowed if the patient was 80 % adherent in the past, did not report discomfort after the exercise, and did not overshoot the target heart rate for the exercise.

Models for resistance exercises are designed in a similar way, except that the number of repetitions rather than duration are suggested for resistance exercises.

The models are formulated using a qualitative multi-criteria decision analysis method DEX (Bohanec, Rajkovič, Bratko, Zupan, & Žnidaršič, 2013; Trdin & Bohanec, 2018). Here, we illustrate the approach describing the EnduranceFrequency model, whose structure is shown in Fig. 3.

The EnduranceFrequency model is aimed at suggesting the frequency of exercises for the next week, based on the patient's physical capacity, week in the programme, current frequency, and the possible physician's and patient's suggestions for the change. In other words, the model takes into account both the normative (as proposed by a general programme) and actual (as practiced by the patient) frequency, leveraging the patient's and physician's opinion about the suggestion for the subsequent week.

The overall recommendation, which is 2, 3, 4, or 5 times per week, is represented by the root attribute EnduranceFrequency (Fig. 3). The recommendation depends on three sub-criteria:

- 1. Normative: Frequency as suggested according to the default programme. It depends on the patient's physical capacity ("low" or "normal" Category) and the current Week. The progression is defined by decision rules presented in Table 1.
- 2. Current: The frequency of exercises currently carried out by the patient; it can run ahead or behind the Normative plan. In order to make only small and gradual changes to the frequency, Current is compared to Normative and a one-step change at most is suggested in each week.

Table 1

Decision table defining the Normative frequency based on patient's Category and the current Week.

	Category	Week	Normative
1	low	<=4	2x
2	low	5–12	3x
3	normal	<=6	3x
4	low	13–18	4x
5	normal	7–12	4x
6	low	>=19	5x
7	normal	>=13	5x

Attribute	Scale
EnduranceFrequency	2x; 3x; 4x; 5x
Normative	2x; 3x; 4x; 5x
Category	low; normal
Week	1; 2; 3; 4; 5; 6; 7; 8; 9; 10; 11; 12; 13; 14; 15; 16; 17; 18; 19; 20; 21; 22; 23; 24; more
Current	2x; 3x; 4x; 5x
└─Transition	decrease; stay; increase; automatic
-MedicalAssessment	decrease; stay; increase; automatic
PatientsAssessment	decrease; stay; increase; automatic

Fig. 3. Structure of the EnduranceFrequency model.

Table 2

Decision rules for Transition based in the physician's and patient's assessments.

	MedicalAssessment	PatientsAssessment	Transition
1	decrease	*	decrease
2	*	decrease	decrease
3	stay	not decrease	stay
4	not decrease	stay	stay
5	increase	increase or automatic	increase
6	increase or automatic	increase	increase
7	automatic	automatic	automatic

3. Transition is an attribute that captures the patient's wish and the physician's opinion about changing the frequency. The possible values are "decrease", "same", "increase" or "automatic"; the latter is meant to suggest the frequency according to the normal plan, for instance, when neither the patient or physician have given any suggestions. The patient's and physician's suggestions are combined according to decision rules shown in Table 2. The first two rules say that whenever the patient or the physician suggest to decrease the frequency, it should indeed be decreased (the symbol '*' represents any possible value). Rules 3 and 4 suggest keeping the current frequency whenever one of the participants suggests so, unless the other participant suggests "decrease". Rules 5 and 6 define a similar reasoning for "increase". If both participants have no particular suggestions, the "automatic" transition according to the normal plan takes place.

The overall EnduranceFrequency is determined according to the rules shown in Table 3. When Transition is "decrease", "stay" or "increase" (rules 1–3), the Current frequency is decreased by one, left unchanged, or increased by one, respectively; the "min" and "max" are there to keep the result in the 2–5x range. The "automatic" setting increases Current by one only when the Normative programme runs ahead and requires a higher frequency.

Daily Exercise Management. Once a weekly exercise plan has been established, the HeartMan DSS assists the patient in carrying out their daily exercises. This consists of four activities: (1) reminding the patient, (2) pre-exercise checking, (3) exercise monitoring, and (4) post-exercise assessment. Fig. 4 shows a sequence of the HeartMan mobile app screenshots that guide the patient through these stages.

Reminding the patient. Patients can choose the days when they want to exercise (e.g., every Tuesday, Thursday and Sunday). On these particular days, the patients are at some predefined morning time reminded about the daily exercise (Fig. 4, screenshot 1). Another reminder is issued if the exercise has not been completed before a given afternoon time.

Before the exercise. Before the start of each exercise session, the HeartMan DSS checks if all pre-exercise requirements are met, and advises the patients about safety. Fig. 5 shows the decision model.

- 1. Information requirements: The blood pressure should have been measured during the day. If not, the patients are instructed to measure it (Fig. 4, screenshot 2). The pre-exercise heart rate is measured automatically by the wristband; the system makes sure that it is actually worn.
- 2. Subjective requirements: Subjective requirements are checked in a dialogue with the patient, asking about their overall feeling. In the

Table 3

Rules for determining EnduranceFrequency based on Transition, and Current and Normative frequencies.

	Transition	EnduranceFrequency
1	decrease	max(Current – 1, 2x)
2	stay	Current
3	increase	min(Current + 1, 5x)
4	automatic	if Normative > Current then Current + 1 else Current

case of a bad feeling, the patient is instructed to rest until feeling better (Fig. 4, screenshot 3).

3. Physiological requirements: If all the requirements checked to this point are met, patients can start with the exercise, otherwise they are instructed to repeat the measurements after five minutes of rest. If after re-checking the measurements are still not within safe limits, exercise is not allowed and patients are advised to contact their physician or heart failure nurse.

During the exercise. If the exercise is allowed, a list of exercises is shown to the patient, who can then select the preferred exercise (Fig. 4, screenshot 4). After selecting the exercise, a detailed description (textual or graphical) regarding the exercise is provided (Fig. 4, screenshot 5). During the exercise, the heart rate and systolic blood pressure are continuously measured by the wristband. The patients are advised to stop the exercise in case of symptoms or measurements lying outside of prescribed safety margins. If the heart rate is within the safety limits, but too low or too high with respect to the target for the exercise, the patient is advised to increase or decrease the intensity, respectively. The system also advises the patients about the exercise duration and is capable of recognizing a premature ending.

After the exercise. After completing the exercise, the patients can rate their feeling of intensity (very light, light, moderate, intense, very intense) (Fig. 4, screenshot 6). Then the system assesses the exercise based on measurements recorded during the exercise. The system takes into account this information when assessing the adherence to the exercise plan and the patient's improvement. Independent of this, the exercise is shown as completed and the weekly plan is updated.

4.1.2. Advice on patients' eating behaviour

To provide appropriate nutrition interventions, the HeartMan DSS requires the following medical information: the patient's body mass index, whether the patient has diabetes or not, and the prescribed amount of liquid intake. Using this information, the HeartMan DSS creates a personalized questionnaire to be answered by the patient. After the data has been collected, the DSS assesses which topics (about breakfast, lunch, dinner, fat and cholesterol, fluid intake, salt, diabetes and medication) are insufficiently understood by the patient. Finally, the patient receives advice based on these topics.

Nutrition Questionnaire. The questionnaire on nutrition and fluid intake is composed of two parts. The first part aims to educate the patients about healthy nutrition, while the second part assesses the patients' current eating and drinking behaviour.

- Education: Every day of the first week, a topic of education is delivered using a question–answer design. When answered correctly, the patients receive positive reinforcement (e.g. "good job"); when answered incorrectly, an educational statement is delivered immediately on this specific topic.
- Behaviour: This part of the questionnaire takes place in the second week and is additionally divided into two parts: drinking and eating behaviour. First, patients answer the part regarding drinking behaviour to examine how they estimate their fluid intake and register their intake during one day. A typical question is: "How many glasses (200 ml) of water, milk, fruit juice or soda did you drink in total yesterday?" The second part of the questionnaire consists of similar questions about the eating behaviour. The answers provide insights in patients' (mis)perceptions concerning their fluid and food intake, and are used in the next step by the DSS to properly advise the patients on how to modify their diet to make it healthier. The questionnaire has to be answered all at once on Tuesday, Wednesday or Thursday to avoid weekend behaviour.

Advice on Nutrition. Patients receive advice on nutrition 1–3 times per week, depending on the quality of the patients' eating and drinking behaviour as well as on the patients' understanding of healthy nutrition.

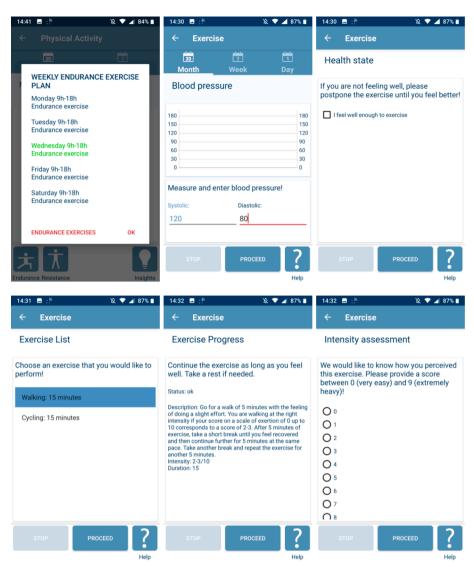


Fig. 4. Screenshots of the HeartMan mobile app guiding the patient through a daily endurance exercise.

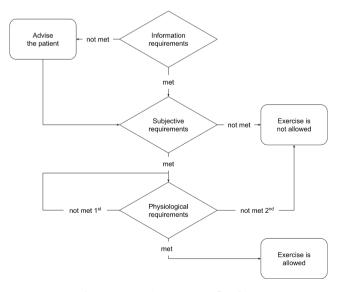


Fig. 5. Pre-exercise assessment flowchart.

Patients with good eating habits, i.e., less misunderstood topics, receive less advice and vice versa. Specifically, the DSS uses questionnaire responses to assess which topics (about breakfast, lunch, dinner, fat and cholesterol, fluid intake, salt, diabetes and medication) are insufficiently understood by the patient. For each topic t_i , i = 1, 2, ..., n, its odds $f(t_i)$ are assessed as the ratio between the number of incorrectly answered questions and the number of all questions about this topic. Then, the probability of the topic $P(t_i)$ is assessed by normalizing the odds:

$$P(t_i) = \frac{f(t_i)}{\sum_{j=1}^{n} f(t_j)}, i = 1, 2, \cdots, n$$

The DSS samples this distribution and chooses one advice that has been incorrectly answered and not yet shown to the patient. Only advice related to misunderstood topics is provided to the patient. Since the questionnaire consists of many questions, advice is not shown immediately after answering the question, but later as daily advice.

Repetition of the Nutrition Questionnaire. The registration of nutrition and fluid intake asks a big commitment from patients. Therefore, the DSS asks the patients to repeat the questionnaire only every three months on a voluntary basis. However, if patients want to see their progress and improvements, they can repeat the questionnaire (or just selected parts) whenever they want.

4.1.3. Advice on medication intake

The HeartMan DSS provides reminders for taking medications and assesses patients' adherence to the medication scheme. Since the HeartMan system cannot monitor the patients' actual medication intake, it acquires medication data with the help of a simple pillbox. The pillbox is normally filled once per week and the patient is occasionally asked about the number of pills remaining in the pillbox.

Reminders. Patients suffering from CHF generally take several types of medications and they often forget to take some (Lainscak, et al., 2011). By using the medical information provided to the HeartMan system, the DSS reminds patients to take the prescribed medication at the right time. Since many patients already have their own methods to cope with this problem, patients (or their caregivers) can select from different reminding options: to be reminded for each medication and each time of intake, only for a specific medication or specific time of intake, or not to be reminded about medication intake at all. After the reminder, the patient may answer that they have taken the medication or request to be reminded later.

Once per week patients additionally receive an optional notification helping them to prepare their medication for the whole week. The HeartMan DSS shows a list with the patient's medications and information about the amount of pills that should be put in the pillbox.

Adherence Assessment. The HeartMan system asks the patient how many pills are left in the pillbox once a week at random and before filling the pillbox. The answers are then used to calculate the patient's adherence to the medication treatment and provided to physicians who can use this information to better assess the patient's status.

4.2. Psychological monitoring and support

The physical health advice module, described above, is additionally supported by a psychological monitoring and support module. The approach is based on Cognitive Behavioural Techniques (CBT) (Jeyanantham, Kotecha, Thanki, Dekker, & Lane, 2017) to promote the pleasant feeling of being able to follow medical prescriptions, increase compliance, and, above all, to gradually learn new everyday habits. The psychological DSS module also manages cognitive dissonance and a weekly set of mindfulness exercises.

4.2.1. Advice structured on psychological status

The HeartMan DSS provides psychological advices based on a structured CBT programme. The DSS collects patient's behavioural and physiological parameters. Once per week, it assesses the patient's psychological status in order to adapt the program of physical exercises and motivate the patient with structured CBT tasks. Each advice provided by the DSS has been structured as a verbal support to the implementation of the patient's behaviour. Specifically, once the advice is received, the patient is supported by other prompts (e.g., images or video tutorial) in order to consolidate the learning of a specific behaviour. When the user executes the health task suggested by the DSS, he/she receives a positive reinforcement message.

Psychological Status Assessment. As explained in section 3, one of the inputs to the DSS is the patients' psychological profile, which is updated weekly during a semi-structured interview between the patient and an informal caregiver. During the call, the HeartMan system uses mobile phone and wristband to collect prosodic features from the speech, heart rate variability and survey in order to assess the patient's psychological status categorized in three main profiles: motivated, anxious and depressed.

• Motivated profile: A motivated user receives a weekly list of activities as foreseen by the standard medical prescriptions. Since it is assumed that the patient is already inclined to perform the exercise from the outset, CBTs (prompt, fading, and reinforcement) are used only to keep the motivation of the user high and to teach, consolidate and maintain a specific behaviour. For this profile, the advices shall highlight the negative and/or positive consequences of the missed and/or implemented behaviour.

- Anxious profile: An anxious user is allowed to select his favourite days of the week, on which he receives only the daily list of activities. This aspect is managed to avoid presenting too many scheduled activities and increase anxiety according to the incubation theory (Eysenck, 1976). For this profile, it is important to structure advices so that they suggest the task to be implemented and mention its positive consequences.
- **Depressed profile:** For such a user it is important to provide the list of all the exercises that will be performed during the week in advance. This gives him the opportunity to choose the days and frequencies of exercises. The CBT used is based on shaping (gradual exposure to stimulation), to propose activities with increasing difficulty, so that the depressed profile develops awareness, confirmed by experience, that the exercises proposed will not have serious consequences on their health. For this profile, the advices are structured providing detailed information on what the patient needs to do to achieve a better physical well-being.

4.2.2. Weekly mental exercise Planning

The DSS schedules a weekly exercise plan based on structured CBT messages and mindfulness exercises. This is supported by two DSS modules, cognitive dissonance module and mindfulness module, described below.

4.2.2.1. Cognitive dissonance module. CBT messages are specific psychological interventions that can fix the issue of cognitive dissonance. The purpose of the DSS is to evaluate the patient's behaviours regarding unhealthy exercise and nutrition habits, and to change them with structured CBT messages. The first step (Fig. 6, left) deals with the assessment of cognitive dissonance comparing scores of self-assessment questionnaires (monitoring Belief) and behavioural data (monitoring Action), such as analytics of weekly physical exercise. In the case of discrepancy between Belief and Action (Fig. 6, right), the DSS sends specific messages to fix the discrepancy of cognitive dissonance. The messages depend on the patient's psychological profile (see an example in Table 4). They are formulated according to Festinger's principles (Festinger, 1957) of "Cognitive Consequences of Force Compliance" for the motivated profile, "Free Choice" for the anxious profile and "Effort Justification" for the depressed profile.

4.2.2.2. Mindfulness module. The mindfulness module is based on experiential audio files, mindful messages and games developed to make the patients more aware of the present moment and to help them seeing their illness in a new light, without allowing fear to consume them and drive unhealthy behaviours. The flow chart in Fig. 7 shows how DSS manages mindfulness exercises.

In general, the DSS schedules a weekly mental plan (as shown in Fig. 8) sending a mindfulness notification to the patient once a day in the morning, considering contextual factors detected by the wristband. In particular, the wearable sensor has to detect if the patient is in a resting or active state. In the first case, the DSS will send the notification of an audio experience or mindful game (an example in Fig. 9). If the patient cannot immediately perform the exercise, it can be postponed to a later time.

If the patient is active, such as walking or eating, the DSS suggests the patient to carry out a mindfulness exercise (see examples in Table 5). If the patient has not done any exercises for one week and this feature is enabled, the DSS informs the informal caregiver. Finally, the patient can choose at any time during a day, independently of the DSS, to do a Mental Support exercise. In this case, he will not receive further mindful notifications from the DSS. If the patient regularly executes mental exercises, the DSS also manages the frequency of mental exercises, reducing the number of notifications ("fading" technique). This

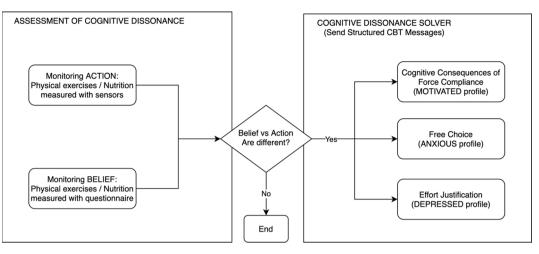


Fig. 6. Cognitive dissonance module of the psychological DSS.

Table 4

Examples of CBT messages about physical exercises for three different psychological profiles.

Psychological profile Motivated	Anxious	Depressed
Cognitive consequences of forced compliance	Free choice	Effort justification
I should perform physical exercise to obtain benefits	Walking for 10 min and watching TV are two ways to relax. Walking	Walking for 10 min will bring benefits similar to
similar to those from medications.	improves your heart health, while TV does not.	those obtained from medication.

approach is designed in order to reduce the subject's dependence of notifications.

Whenever a poor feeling due to environmental conditions is predicted, the DSS informs the patient about the issue and suggests reducing or increasing the temperature, humidity or both.

4.3. Environment management

Environmental conditions may affect the patient's feeling of health. The latter is assessed daily using a predictive model that assesses the patient's feeling of health from current environmental conditions. Environment management in the HeartMan DSS is optional. Unlike the management of physical and mental health in CHF (sections 4.1 and 4.2), for which extensive evidence and medical guidelines are available, there is very little evidence and no guidelines for environment management. This required (and allowed us) to develop something new, but

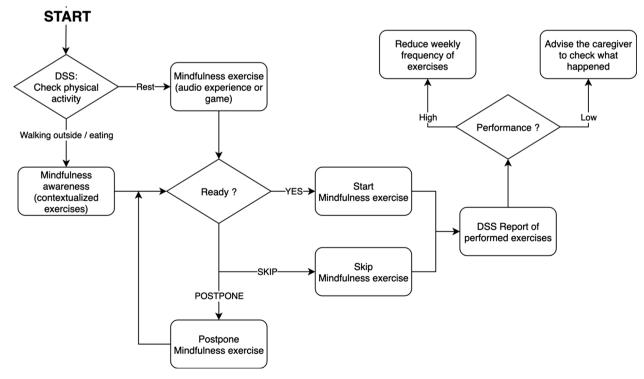


Fig. 7. Flow chart of mindfulness exercises.

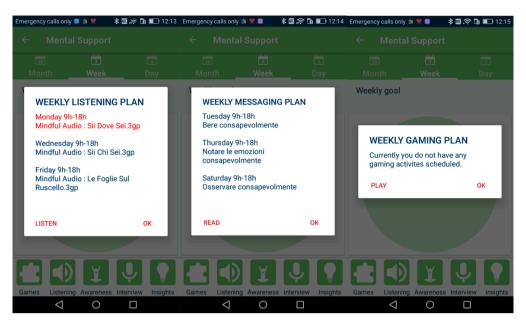


Fig. 8. Screenshots of the HeartMan mobile app with examples of mindfulness weekly schedules.



Fig. 9. Mindful game "Solar System".

Table 5

Examples of Mindful awareness notifications contextualized with activities.

Awareness Messages Mindful breathing	Mindful eating	Mindful walking
Focus on your breath. Breathe in and out slowly. Breathe in through your nose and out through your mouth and let your breath flow in and out of your body.	Find a small piece of food that you like. Look at the food and notice its form and color.Close your eyes, touch it and notice its texture. Smell it and, after, eat it and chew very slowly, noticing its texture and the way it feels in your mouth.	Notice your body as you stand in stillness, Feeling the connection of the body to the ground. Walk mindfully, slowly, and pay attention to the sensations on the soles of your feet. Walk one step at a time.

experimental.

To generate appropriate advice to improve the patient's feeling of health, we took the approach proposed by Vodopija, Mlakar, and Luštrek (2017).

In the first step, we constructed a machine-learning model that can predict the patient's feeling of health from environmental conditions. The prediction is made in terms of one of the two categories: "worse than usual" and "normal or better than usual". For this purpose, data collected in the Chiron project (Cavero Barca, et al., 2014), which conducted a telemonitoring study of CHF patients, has been used. The quantity and quality of the Chiron data allowed us to address only two environmental parameters with sufficient accuracy: temperature and humidity. The model was developed using the Random Forest algorithm and achieved the classification accuracy of 86.6 % using 10-fold cross validation (Vodopija et al., 2017). The Weka implementation of the Random Forest algorithm (Witten et al., 2017) was employed with the default parameter values.

In the second step, we formulated the task of generating advice to improve the patients' feeling of health as an optimization problem: the objective was to change the temperature or humidity by as small an amount as necessary to improve the patient's feeling of health. In this way, the patients would need to make a minimal effort to achieve the desired result. Using the predictive model from the first step, the optimization method suggests whether temperature, humidity or both should be changed and for how much. For this purpose, we used the Classic Differential Evolution algorithm as implemented in the R programming language (Mullen, Ardia, Gil, Windower, & Cline, 2011) with the following settings: 100 individuals and generations, scaling factor 0.8, and crossover probability 0.5. While the predictive model is generated in advance, the optimization is run each time when inappropriate environmental conditions are recognized by the DSS.

5. Evaluation

A proof-of-concept trial was set up to evaluate the effects of the HeartMan intervention on Health-Related Quality-of-Life (HRQoL) and disease management (self-care) as primary endpoints (Baert et al., 2018). A summary of the methods and results of the trial is provided in this section, since more details can be found elsewhere (Clays et al., 2021). The secondary endpoints we targeted were clinical parameters, illness perception, and mental and sexual health. The clinical trial was implemented in two countries: three hospitals were involved in Belgium and one hospital and a local health authority were participating in Italy. In both countries, formal approval was obtained from the ethical committees (Central Ethical Committee of the University Hospital Ghent in Ghent, Belgium and the Central Ethical Committee of Lazio 1 of San Camillo-Forlanini Hospital in Rome, Italy) and from the federal institutions for clinical trials (the Belgian Federal Agency for Medicines and Health Products and the Federal Ministry of Health in Italy). The study was registered at ClinicalTrials.gov (NCT03497871). It is important to note that this trial addressed the HeartMan system as a whole and evaluated the HeartMan DSS only as part of the whole. Given the focus and feasible extent of the study, the trial did not explicitly assess specific functions of the HeartMan DSS.

A randomized-controlled design was used with a 1:2 ratio of control vs. intervention group (Clays et al., 2021). Eligible patients were recruited by the treating cardiologist or general practitioner at the time of regular consultation. After providing informed consent, participants underwent a baseline data collection, containing medical record data registration, questionnaire assessments (using standardized instruments) and some clinical assessments including a 6-minute walking test to assess exercise capacity (Piepoli et al., 2011). Patients were then randomly divided into either the control group receiving the usual care or the intervention condition additionally receiving the HeartMan personal health system which they used in their home setting for a period of 3 to 6 months. During the intervention period a helpdesk was ran by the clinical partners for addressing user problems, while the technical partners addressed the software problems that emerged and improved the system. All outcome measurements were repeated in both intervention and control group at the end of the trial.

The intervention effects could be evaluated in a final sample of 56 patients, i.e., 34 in the intervention and 22 in the control group (Clays et al., 2021). Trial results showed that the HeartMan system was successful in improving self-care behaviour in the intervention group (p < p0.05) and as such resulting in a higher quality of disease management, as measured by the Self-care of Heart Failure Index (Riegel, Lee, Dickson, & Carlson, 2009). No such effect could be observed on HRQoL assessed with the Minnesota Living with Heart Failure Questionnaire (Rector, Francis, & Cohn, 1987). Concerning secondary endpoints, using Heart-Man significantly improved psychological outcomes (p < 0.001), i.e. intervention patients decreased their level of depression (assessed with the Beck Depression Inventory II) (Beck, Steer, & Brown, 1996) and anxiety (assessed with the State Trait Anxiety Inventory Form Y) (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983), and these reductions were even higher in the patients who had used the mental exercise module in the application more intensively. The HeartMan intervention also reduced the experience of sexual problems (p < 0.05) as measured by the Sexual Adjustment Scale (Derogatis, 1986). No effects were shown for illness perception assessed by the brief Illness Perception Questionnaire (Broadbent, Petrie, Main, & Weinman, 2006) and the clinical outcome of exercise capacity. However, additional data available in a subgroup of the trial sample showed significant improvement in left ventricular ejection fraction (p < 0.05) in addition to an improvement in the overall predicted 1-year mortality risk (p < p0.01), i.e., based on the MAGGIC scoring system (Pocock, Ariti, McMurray, Maggioni, & Køber, 2013), in the intervention group.

When assessing the contributions and implications of using the HeartMan system as a whole, it is however important to consider that

different constitutive elements of the system may not be dissociated in terms of individual impacts in relation to the overall results obtained. This is a crucial aspect when comparing other systems to HeartMan in the future or other systems that may have dissimilar components and thus differently impact CHF outcomes or quality of life of involved patients.

6. Conclusion

The HeartMan system as a whole offers a comprehensive and personalised support for the self-management of CHF. The exercise programme is adapted to the patients' physical capacity and psychological profile. The dietary advice depends on the patients' knowledge about appropriate diet and their eating behaviour. The particularly innovative and impactful element is the psychological support: the cognitive behavioural therapy messages are designed to improve adherence to the system's advice, and the mindfulness exercises make the patients more aware of the present moment and help them perceive their illness in a positive way. The HeartMan system has the potential for an important improvement in CHF patients' management of their condition, improving their health and quality of life and reducing healthcare expenses. The results of the first clinical trial already corroborated some of those expectations, indicating: improved self-care behaviour, improved quality of disease management in terms of Self-care of Heart Failure Index, decreased patients' levels of depression and anxiety, reduced experience of sexual problems, and improved the overall predicted 1year mortality risk.

The HeartMan DSS is the core element of the HeartMan system, aimed at managing the patient's physical health, providing psychological support and managing environmental parameters. It contains logic, knowledge and data necessary to generate appropriate, comprehensive, personalized and user-friendly recommendations for the patient. The topics addressed by the HeartMan DSS are diverse, and so are the employed methods:

- Physical exercise is crucial for the successful management of CHF, and a lot of knowledge is already available, although there is no consensus on exercise prescription in CHF. We chose rule-based decision modelling, where the challenges were (1) selecting the relevant knowledge from the literature and eliciting it from medical experts, and (2) formally encoding all the details in the models. Even though the first stage was demanding and time consuming, it resulted in models that have a number of desirable characteristics. They are small, compact, transparent and easy to interpret by a human. The models seamlessly integrate both normative (what is prescribed) and descriptive (what is actually practiced and desired) aspects of physical exercise management.
- Nutrition management requires assessing the patient's eating behaviour and puts emphasis on the patient's education; thus the use of questionnaires and carefully chosen educational messages. The DSS had to translate the patients' answers to advice matching their nutrition knowledge and behaviour. In comparison with pre-existing static approaches, the added value of the HeartMan DSS is in personalization. The treatment of the topic was appreciated by the patients; in semi-structured interviews, patients found the advice about the diet interesting to read, they learned new things about diets and they found it useful.
- Managing medication intake uses an adherence assessment model, which is not difficult per-se, but requires clever workflows for measuring the actual medication intake and generating encouraging reminders to keep the patient going. Medication adherence assessment is a complex problem where one had to weigh the use of invasive methods to assess it accurately against the risk of users' displeasure at being mistrusted. Since our objective was to empower the users, we decided to mostly trust them, although we did use the small "trick" of asking for the number of pills in the pillbox at random

times, when misreporting is more difficult than at the end of the week when the pillbox is supposed to be empty.

- Psychological support is a complex topic in itself. In the DSS, it relies
 particularly on a model for assessing the patient's psychological
 profile and several adaptable workflows. The most critical aspect was
 selecting and designing appropriate psychological techniques for
 supporting the patients in CHF management, but this was closely
 followed by the decision models for deciding what information to
 request from the patients and what interventions to deliver to make
 the psychological support helpful and not overly intrusive.
- For managing environmental parameters in relation with CHF, the knowledge is scarce and little literature is available. This led us to employ the data mining approach: developing a predictive model from data about patients' feeling of health and using it to optimize the humidity and temperature of the environment. The proposed solution is experimental and, due to insufficient data available, limited to just two environmental parameters: temperature and humidity. We did not evaluate it separately from the rest of the system. Nevertheless, this is a novel and potentially powerful methodology worth of further investigation.

Given the diversity of tasks and methods, it was essential to wrap up all these components in a mobile health platform, so as to provide a uniform, user-friendly, safe and useful environment for the main user the CHF patient. In the future, apart from increasing the visibility and adoption of the system, we shall mostly focus on gradual improvement of individual DSS components, based on new evidence and users' feedback. According to the feedback already received in the proof-of-concept trial, a key improvement is increased adaptation to the patients' lifestyle. In addition to methods for recognizing patients' activities, the DSS will be critical for this task, since the decision models will have to handle an extended set of situations, similarly to how it already handles physical activities in psychological support. Environmental management also offers much potential for improvement, for instance by obtaining and using more - and more personalized - data about the patient's feeling of health and integrating the optimization module in a smart-home environment. Given more data, the approach used for environmental management could be extended to other areas of CHF management.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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