HEARTMAN

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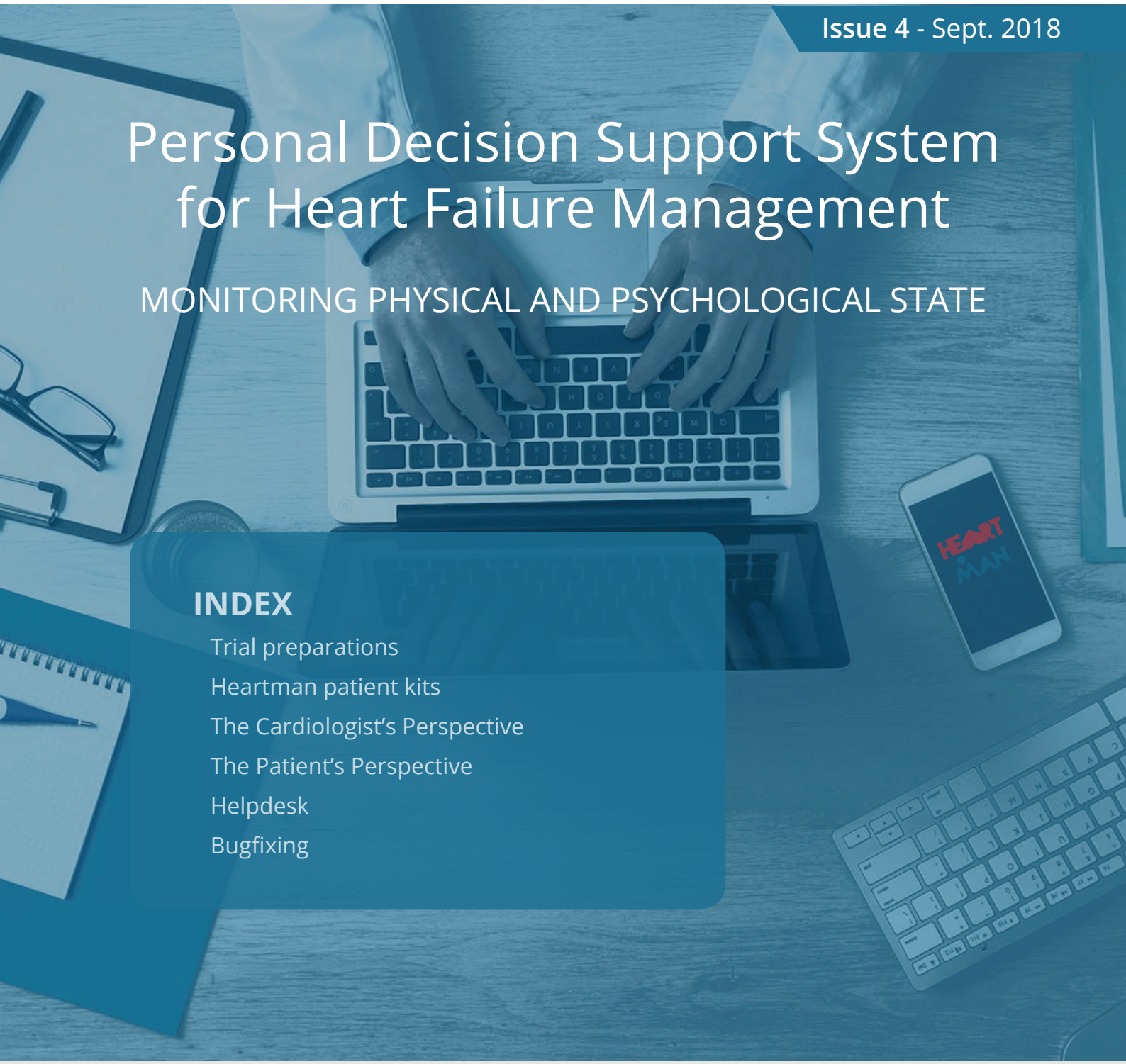
Personal Decision Support System for Heart Failure Management

MONITORING PHYSICAL AND PSYCHOLOGICAL STATE



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Trial Preparation: Finalizing the App, Setting up Servers, Ironing Out Technical Issues

The weeks leading up to the start of the trial have been a period of intense collaboration between different HeartMan project partners. While all the building blocks of the HeartMan technology were available, a period of intense collaboration was necessary to do the final integration work, to iron out some technical issues, test the app and prepare the technology for the first trial patients.

An important step of the trial preparation needed on each of the two sites - in Belgium and Italy - was to set up the servers. Due to the sensitive information the HeartMan system is managing, the setting of the servers is not as simple as deploying the services in the cloud. The servers must be installed and configured inside the hospital facilities following the security restrictions from the IT department. The infrastructure is composed by three virtual machines in order to:

- Receive and send the encrypted data to the HeartMan mobile application.
- Provide the professional caregivers with a Personal Health System web application to manage their patients´ health status using eHealth standards.
- Execute the physical and mental Decision Support Systems to provide patients with personalized weekly exercises.

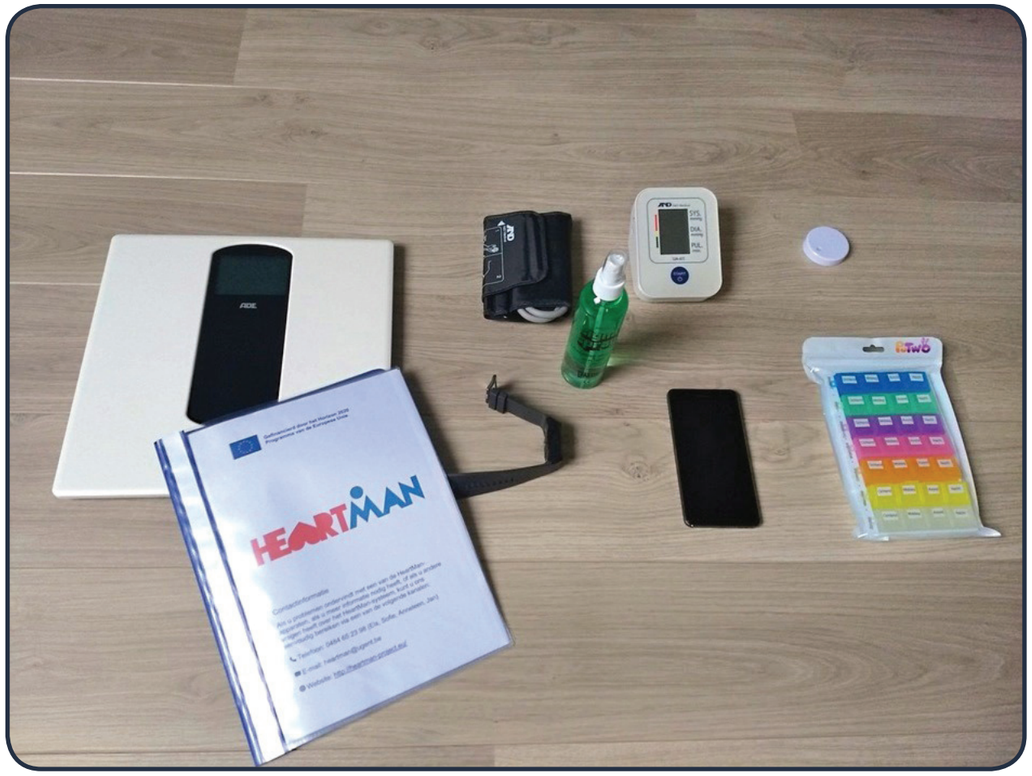
After this finalization period, the first HeartMan trial participant was visited on June 20 by researchers from UGent and KU Leuven, for a trial intake session. All 24 trial participants were visited between June 20 and July 10. The patients' ages ranged from 23 to 76; 19 men and 5 women participated in the trial.

Rome Trial

In Italy, patients are currently being recruited, and the trial in Italy will start in September at Hospital San Camillo de Lellis, in Rieti.

The HeartMan system focuses on four intervention domains: physical exercise, nutrition, mental support, and medication intake. For an accurate monitoring of these four domains, the HeartMan trial participants need to use different pieces of equipment. During the intake visits, this entire HeartMan patient kit was explained to participants:

- First, patients received the central parts of the entire HeartMan system: the smartphone, and the sensing wristband that sends physiological measurements to the smartphone.
- Patients were asked to wear the wristband whenever possible, and especially while they are engaging in physical activity.
- Patients also received a scale and a blood pressure monitor, in order to make sure body weight and blood pressure are monitored accurately.
- Patients are asked to measure their body weight and blood pressure once per day.
- An environmental sensor was included in the HeartMan kit, monitoring the environment temperature and humidity.
- A pill box was provided for monitoring medication adherence.
- Finally, a set of user documentation was provided, consisting of a manual with basic information on the smartphone, and dedicated manuals for the wristband and the HeartMan mobile application.



The Cardiologists' Perspective

In each of the participating centres, training visits were held for cardiologists, heart failure nurses, and study co-ordinators. During these training visits, the HeartMan patient app was demonstrated. In addition, the HeartMan portal website was shown, in which cardiologists and other healthcare professionals can consult the data gathered by the HeartMan patient system.

The Patients' Perspective: Technology Literacy

The intake visits have shown that besides a considerable variety in demographics and health condition, CHF patients also vary considerably in terms of technology literacy. While some patients are confident technology users in their everyday lives, some patients have received their first smartphone during the HeartMan intake visits. This variability in terms of technology literacy has a number of implications.

On a practical level, the length of the intake visits varied considerably based on the prior technology experience of the patients. Patients with a lower technology literacy need more basic explanation than experienced smartphone users. For instance, it was crucial for patients with lower technology literacy to allow them to try the app during the intake visit itself. In that way, patients could build some experience - and confidence – during the intake visit itself.

On the level of the trial itself, a distinction was made between patients with high and low technology literacy. The patients with high literacy received a full explanation about the HeartMan technology, and its functionalities. They were encouraged to navigate through the various functions of the app themselves, and explore the details of the HeartMan app. These patients are the more proactive HeartMan users. The patients with lower technology literacy were asked to primarily react to notifications in the app. Each aspect of the app (nutrition, mental support, medication, and physical activity) has separate notifications associated with them. Therefore, a more 'basic' usage of the HeartMan technology is to react to these notifications, without actively navigating through the app, exploring the details of its functionality. This more basic usage of the HeartMan technology is a more reactive approach.

We consider this segmentation in proactive and reactive users as a basic personalization of technology usage. While the HeartMan technology is personalized based on each patients' individual health condition, the app does not provide personalization of the functionality itself. Given the variation in technology literacy, distinguishing between proactive and reactive use, therefore, provides a basic distinction in how deeply the patients engage with the technology.

Helpdesk

In order to cope with the patients' questions, a HeartMan helpdesk was set up, available on weekdays between 9 am and 5 pm until the end of the trial. After an initial peak of helpdesk calls, the number of calls to the helpdesk number stabilized.

Especially during the first weeks of the Belgian trial, the helpdesk received primarily technical questions, and questions about the app's functionality and usage

Bugfixing

Developing and deploying technology as complex as the HeartMan system is quite a challenge: therefore, some bugs are inevitable. We were of course aware of this from the start, and took several steps to prevent these bugs from affecting the clinical trial too severely.

- The first step is the development process itself, which involves continuous integration and deployment with automatic checks of code quality.
- The second step was rigorous in-house testing, especially by the team of Ghent University who are managing the Belgian clinical trial. Their efforts earned them a best-tester award at the last consortium meeting in Ljubljana.
- The third step is continuous communication with patients, as well as logging of the HeartMan system activity and automatic notifications of anomalous events such as missing data or apparent lack of application usage by patients.

To track bugs and other issues systematically, we use a spreadsheet accessible by all the partners. The spreadsheet contains descriptions of the issues, their priority, current status, responsible partners and other information. We have logged 129 issues so far, and of course solved them (with a few stubborn exceptions we are still dealing with).

ID	Submodule	Description	Priority	Status
71	Nutrition	Replace 'Enquete' into 'Vragenlijst'	Normal	Solved
72	Appointments	reminder before the appointment is not working, it beeps on the moment of the appoint	Normal	Solved
73	Appointments	how does the location link works?	Normal	Solved
74	Psychological	not possible to postpone the exercises for 1h or 4h, reminder is after 1min	High	Solved
75	Psychological	Game "falling circles" (forgot the real name): after finishing the game, I was left with an	Normal	Solved
76	Psychological	Immediately after completing step #75 and returning to the charts by back arrow, I notic	Normal	Solved
77	Physical	Today, after my first entry to Physical Activity, I received the first screen with symptyom	High	Solved
78	Physical	Today is June 1st and I am looking at pretty strange Physical Activity chart values: Mor	Low	Solved
79	Medication	Reported at the telco meeting and exchanged mails with screenshots: Medication JSO	High	Solved
80	Health info	Roughly half of the sensor data shown in the dashboard is missing (interpolated in gray	High	In progress
81	Psychological	the title of the piano keys after the interview is still in English. "agitation" should be tran	Normal	Solved
82		It is not visible on the weekplan if you have completed the exercise or not, so you don't	Normal	Solved
83	Psychological	After turning the app off and starting it again, the notification of my mindfulness exercis	Normal	Solved
84	Psychological	The problem of postponing the exercise remains: it pospones 1 min instead of 1 hour	Normal	Solved
85	Physical	As soon as the the physical exercise (normal BP and HR) is started, the wristband sho	High	Solved
86	Physical	when trying to start the physical exercise, the app indicates "status: wristband not worn	Normal	Solved

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