HEARTMAN

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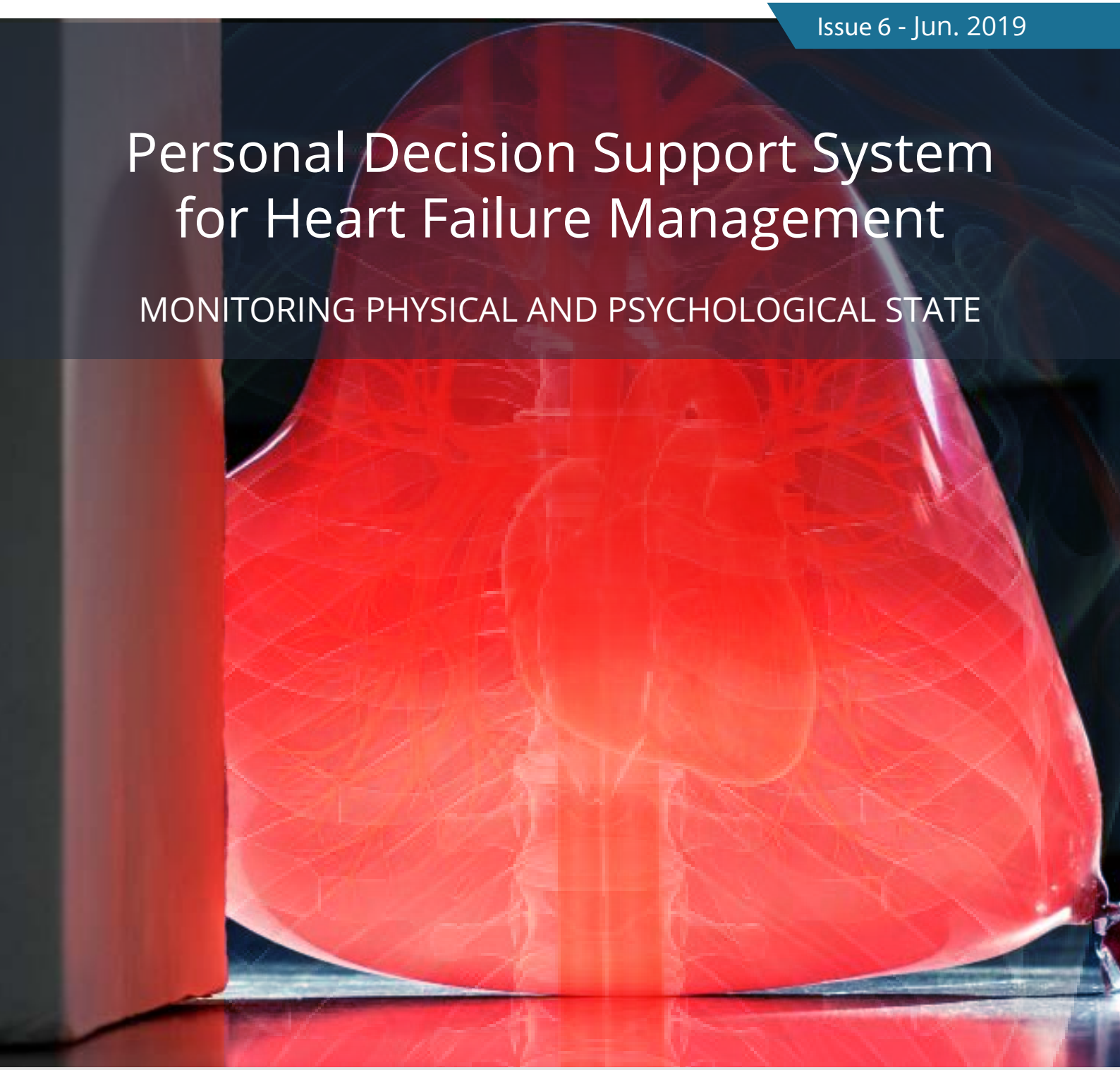


Personal Decision Support System for Heart Failure Management

MONITORING PHYSICAL AND PSYCHOLOGICAL STATE

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement no 689660.

Trial Evaluation Results

HeartMan was designed to be a highly innovative and advanced disease management support system for HF patients, integrating a number of different intervention modalities. The objective of the clinical trial was to evaluate the effects of the HeartMan intervention on HRQoL and disease management (self-care) as primary endpoints. The secondary endpoints we targeted were clinical parameters (including exercise capacity, LVEF and clinical predicted 1-year mortality risk), illness perception, and mental and sexual health. All formal requirements – i.e. approvals from ethical committees and federal institutions for clinical trials – were met before conducting the study.

The HeartMan proof-of-concept trial was implemented in two countries, 3 hospitals were involved in Belgium and 1 hospital and a local health authority were participating in Italy. A randomized-controlled design was used with a 1:2 ratio of control vs. intervention group, meaning there were twice as much patients using the HeartMan intervention than patients acting as reference. 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 and some clinical assessments including a 6 minute walking test. Patients were then randomly divided into either the control group receiving the usual care – i.e. the standard treatment in line with clinical guidelines offered by the cardiologist, general practitioner and HF nurse – or the intervention condition receiving on top of usual care the HeartMan personal health system which they used in their home setting. The intervention was initiated during a home visit by a member of the research team, providing all necessary equipment, technical installation and user instructions. Intervention patients used the HeartMan system during a period of 3 to 6 months, during which a helpdesk was operational for addressing technical difficulties and problems with functionalities. During the intervention a web portal could be consulted by the treating cardiologist or general practitioner for tracking the patient's uptake of the system and some clinical monitoring results. All outcome measurements were repeated in both intervention and control group at the end of the trial.

A sample size of 120 participants (80 intervention and 40 control patients) was targeted. However, due to major challenges in the recruitment process in both countries – strict inclusion and exclusion criteria were adopted and the response rate in eligible patients was low – the actual sample size enrolled at baseline was 69 (39 in Belgium and 30 in Italy). This sample was 80% male and had a mean age of 63 years. The vast majority of participants had a NYHA functional class II and were diagnosed with HF since more than 18 months. 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. Baseline demographic, clinical and other outcome variables were overall well balanced between both groups.

Summing up, the HeartMan system showed to be successful in improving self-care behaviour and as such resulting in a higher quality of disease management, particularly when using the personal health system more intensely. Clinical outcomes were affected by HeartMan, as shown by the improvement in LVEF and decrease in the predicted 1-year mortality risk in the intervention group. Patients who had used HeartMan longer showed a better exercise capacity and lower resting heart rate after the intervention. Using HeartMan significantly improved psychological outcomes, i.e. intervention patients decreased their level of depression and anxiety and these reductions were even higher in the patients who had used the mental exercise in the application more intensively. The HeartMan intervention also reduced the experience of sexual problems and stimulated their interest and expressed need to receive counselling and information about the topic.

In addition to the clinical evaluation, a thorough health economic evaluation was performed based on the observed difference in exercise capacity between the intervention and the control group, as measured by the 6 minute walking test at follow-up. These analyses suggest that the HeartMan tool can be considered cost-effective.

End-Of-Project Conference on Self-Management for Heart Failure

On April 24, the HeartMan consortium organized a conference in Brussels with the central topic: 'Self-Management for Heart Failure'. This conference was organized to mark the end of the project, and spread the results that have been obtained during the project.

During this afternoon, a broad range of topics was addressed, by various speakers from academia, industry, and public policy. The conference was attended by a wide variety of stakeholders, including including clinicians, people from industry, and policy makers.

After a brief introduction by **Tamsin Rose**, the moderator during the afternoon, **Susanne Løgstrup** from the European Heart Network (EHN) kicked off the presentations, talking about the big picture of heart failure, and setting the scene for the rest of the afternoon. She set out the significant burden of cardio-vascular disease, as well as of heart failure. She also informed the audience about the total cost to society of heart failure, concluding that the HeartMan system had the potential to improve patients' health status and quality of life and to contain health care and total cost of heart failure.

Mitja Lustrek, the HeartMan project coordinator, talked about the technical background of the project. He focused on the various elements that are available in the system: sensing devices that generate data, which are used to personalize health advice to the state of the patient, both medically (nutrition, physical activity, medication), and psychologically (mental support).

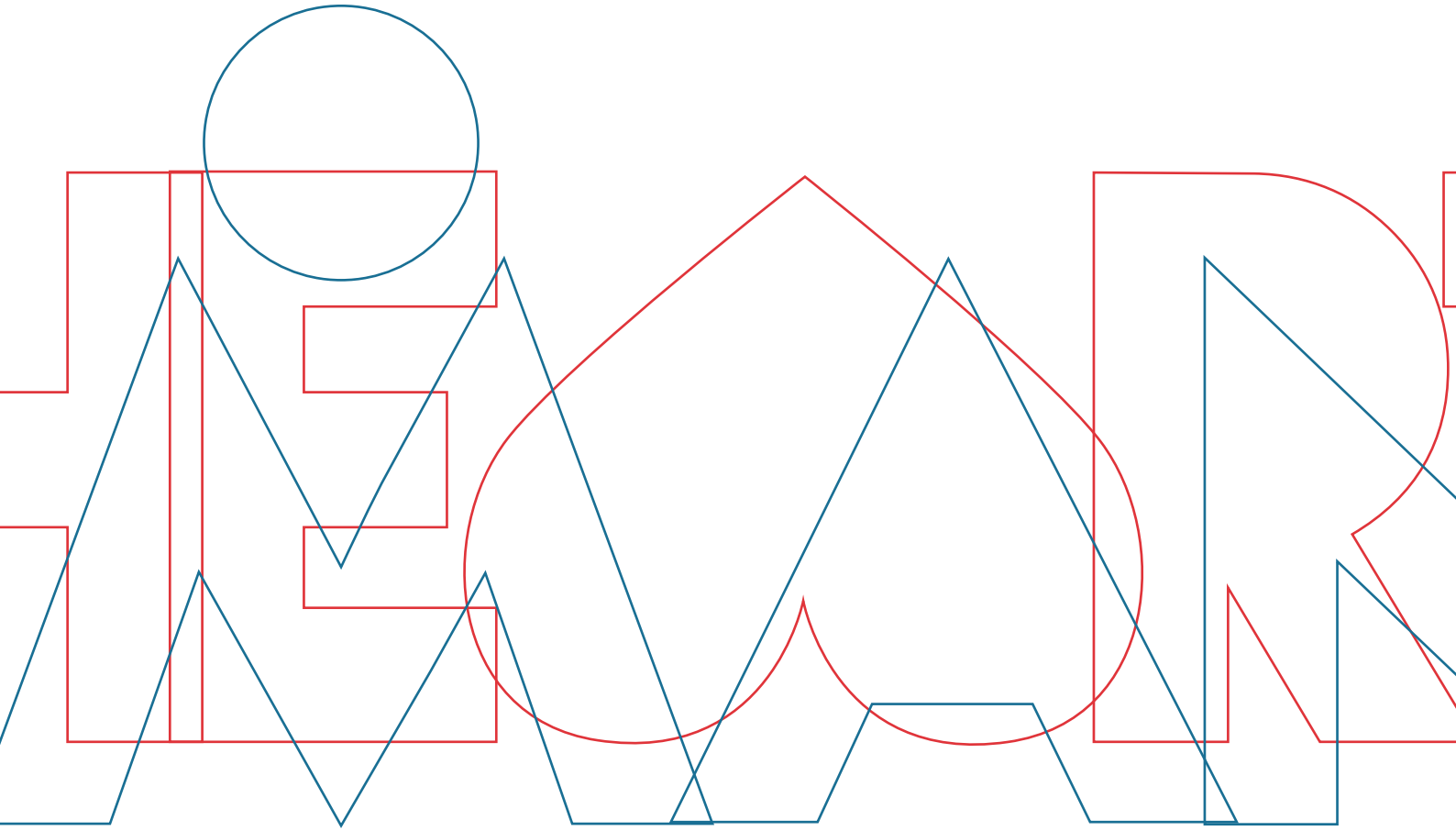
Els Clays, coordinator of HeartMan's clinical trial in Belgium, talked about the outcomes of the trial, focusing mainly on disease management and Health-Related Quality of Life (HRQoL). Preliminary results of the trial show that while it is difficult to obtain statistically significant results for a small sample group, there are clear tendencies that show that illness perception and clinical outcomes of users of the system improve, compared to the control group. After Els's presentation of the clinical results, **Luc De Ram** shared his personal experience with the HeartMan system, as a trial participant. He elaborated on how he adopted the system in his daily life, and how the system motivated him to monitor his disease in a better way, e.g. by measuring his weight and blood pressure on a daily basis.

Petra De Sutter talked about the political aspect at the European level, and developed a political vision. Specifically, she discussed the priorities for digital health at the European, political level, including patient empowerment, regulation of specific issues such as privacy, the potential of digital tools for prevention, and inclusiveness, improving health for all.

Ioana Maria Gligor continued the political perspective, by discussing numerous initiatives taken by the European Commission, including a secure access to and exchange of health data, pooling that health data for research and personalized medicine, and providing digital tools and data for citizen empowerment and person-centered healthcare.

Jure Lampe discussed the valorisation perspective on self-management tools like the HeartMan system. His main message was that while detailed market analysis and business plans have been written, it all comes down to a number of simple questions. These questions include: “what can actually be gained by using a system such as HeartMan?” (i.e., how can the outcomes be quantified, or presented in an understandable way, and how can it improve the patients’ concrete health situation?), and “who will pay for a system like HeartMan” (i.e., in a complex regulatory system including companies, health insurance, and government, how will the costs of such a system be spread?).

Presentations of speakers are available online on HeartMan’s website: http://www.heartman-project.eu/content/heartman-final-event-self-management-heart-failure



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