35th Annual International Conference of the IEEE EMBS
Osaka, Japan, 3 - 7 July, 2013

HeartCycle: From Insights to Clinically Evaluated ICT Solutions for Telehealth

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Abstract— **HeartCycle is a large European Integrated Project (IP) and develops technologies and services for Telehealth, which is to remotely monitor and manage patients at home and motivate them to be compliant to treatment regimens and to a beneficial lifestyle. Telehealth allows healthcare professionals to better control the progress of the therapy, detect upcoming adverse events early and react in time with personalized care plan adjustments, leading to prevent relapses, stabilizing the patient and avoid costly hospitalizations.**

INTRODUCTION

HeartCycle is developing and evaluating innovations for the next generation of disease management systems for Telehealth and started from an application point of view. We have investigated, and analyzed the needs of patients and professionals for specific disease management solutions. Based on the identified needs, we created specific HeartCycle concepts. These concepts are applications that are tailored to a specific patient group. There are three concepts in HeartCycle

- Guided Exercise (GEx) concept for coronary artery disease (CAD) patients recovering after heart attack
- Heart Failure Management (HFM), a home-based disease management concept for heart failure (HF) patients including health maintenance and medication management
- Assessment procedures for both patients groups including innovative sensor measurements, personalized healthcare processes and risk stratification strategies

This publication concentrates on the description of the final solutions developed for the GEx and HFM concepts and the preparation and execution of the clinical studies. Specific procedures must be completed before the first patient can be enrolled.

It is the intention to provide an overview only. Details on sensors, algorithms and decision support will be presented in related HeartCycle publications. The generation of insights and the development process of HeartCycle systems to arrive at a maturity level allowing clinical studies has already been described in [1][2].

*Research supported by the FP7 program of the European Commission.

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I. THE GUIDED EXERCISE (GEX) CONCEPT

A. The GEx system

The GEx system shown in figure 1 is a closed-loop disease management system intended for the prescription and administration of cardiac rehabilitation therapies based on physical exercise in patients with coronary artery disease.

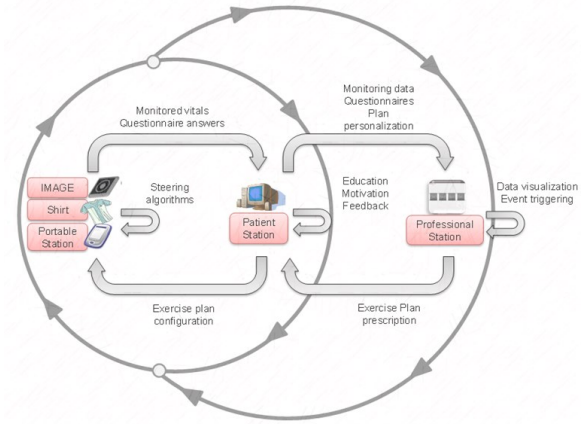


Figure 1: GEx system overview

Medical professionals involved in the cardiac rehabilitation process prescribe physical exercise therapies according to guideline-based trainings plans. The GEx system enhances current cardiac rehabilitation programs by providing patients with a customized training plan, real-time guidance during exercise sessions and personalized motivation and education during the rehabilitation process. Professionals benefit from a follow-up tool that gives offline access to monitored data during sessions and let them adjust prescribed therapies.

During physical activity sessions, the GEx system is monitoring the patient's vital parameters and the exercise intensity allowing to ensure that the patient is exercising according to the training prescription and performing the exercise sessions in a controlled way under the system's surveillance. This way, the benefits from the exercise sessions can be optimized and the patient feels safer.

At the same time, the system provides feedback to patients and delivers educational content tailored to their specific condition and progress through the rehabilitation process. The users' awareness on their condition is measured with the use of specific questionnaires in order to reinforce those areas where the knowledge should be increased.

Finally, the loop is closed by transferring the data monitored during endurance exercise sessions to the medical professional system. This way, professionals can follow the

patient's exertions and perform any optimizations in the rehabilitation plan that might be necessary. The GEx system is built on three main components, as depicted in figure 2.

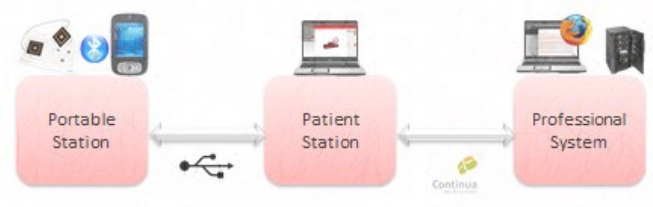


Figure 2: The three components of the GEx system

Professional system: The professional system is the component used for the interaction with medical professionals. Based on client-server architecture, medical professionals are able to access the central server using a standard web browser. This system allows prescription and adaption of physical exercise therapies tailored to each patient and the access to the monitored data during each exercise session.

Patient Station: The Patient Station is the main interface between the patient and the GEx system. It synchronizes exercise plans prescribed by professionals and extracts the monitored data from the portable station. Furthermore, it is used as motivational and educational platform providing content to patients. The content is tailored to their condition based on the analysis of monitored data during the exercise sessions. This analysis uses data processing algorithms where the prescribed exercise plan is compared to the exercise sessions performed by patients and the system is able to create a motivational strategy to help patients achieve the goals in the care plan

Portable Station: This subsystem is depicted in figure 3 and is used by the patient for the training. It includes a wireless sensor (IMAGE sensor) attached to a shirt that senses vital parameters such as ECG, respiration and activity during training and streams them live to a PDA mobile phone which gives feedback and guidance to the patient during the exercise. Algorithms are developed supporting patients during warm-up, exercise and after the training. See figure 4 for an example.

Figure 3: The portable station showing the shirt, the IMAGE sensor and the smart phone (PDA worn on the upper arm) intended for patient guidance during exercising

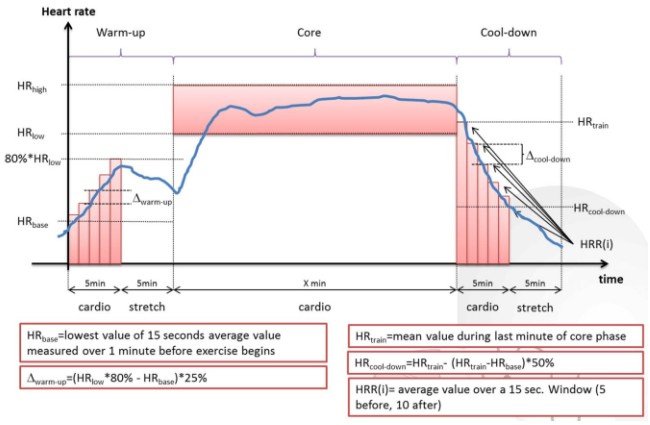


Figure 4: Example of HR algorithm guiding patients during warm-up, exercise and cool-down phases

B. Clinical Study

The GEx system including the sensor, the education platform and coaching program, the algorithms and related decision support have been developed and extensively tested to result at a maturity level allowing using these technologies in clinical studies. Pre-trails have been performed showing the excellent correlation between standard spiroergometry equipment and the GEx measurements of heart rate, breathing rate and detection of arrhythmias [3]. See section III for a description of the approval process. Three clinical sites participating in Heartcycle (Hull in UK, Aachen in Germany and Madrid in Spain) are executing the clinical study. In this open, prospective, randomized study the standard national approach to cardiac rehabilitation is compared to an approach adding the GEx system, which enables training at home supervised with heart monitoring and multimedia feedback

The design of the study is depicted in figure 5.

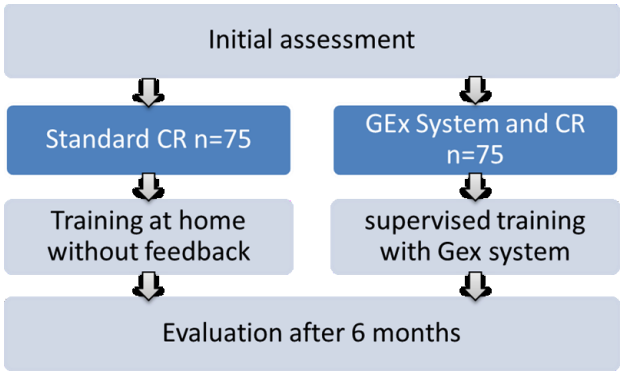


Figure 5: GEx Study design. CR: cardiac rehabilitation. 75 patients are planned for testing the GEx system and 75 patients are foreseen for the control group

The main objectives of this study are:

To evaluate, whether the GEx system can improve physical capacities (measured as $VO2_{peak}$) after a 6 months home-based cardiac rehabilitation therapy compared to national standard for cardiac rehabilitation.

Further (secondary) objectives are to evaluate, whether the use of the GEx system leads to: higher compliance,

higher total exercise time (min) and safety during home training; a reduction of fear and anxiety, of angina pectoris, of serum cholesterol, of LDL and of HbA1c; an increase in physical fitness and reduction of mortality and hospital-stay, improvement of NYHA classification and improvement of blood pressure control. Finally an assessment of the potential socio-economic impact of the GEx system will take place.

The GEx clinical study started in March 2012 and is enrolling patients until the end of February 2013. So far 70 patients participate in the study. The system is working properly without technical problems.

II. B. The Heart Failure Management (HFM) Concept

A. The HeartCycle HFM system

The HeartCycle HFM system is based on Philips existing commercial MOTIVA® disease management system and offers an end-to-end system as illustrated in figure 7. It is an interactive healthcare platform that connects patients with chronic conditions to their healthcare providers via their home television and a broadband internet connection. The system automates disease management activities, and engages patients with personalized daily interactions and education delivered through the home television.

The patients at home are equipped with a number of sensors measuring vital signs to obtain objective measurements about their physical condition, e.g. weight and blood pressure. The vital sign measurements are collected at home and transferred via internet to a management server. In addition subjective measurements such as symptoms are collected from the patients via questionnaires. The questionnaires and all feedback for the patients are presented to the patient via the Personal HeartCycle Health Channel on the patient's TV as depicted in figure 6.

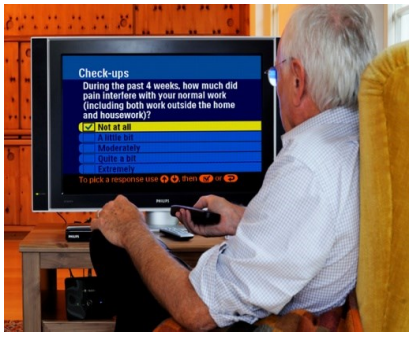


Figure 6: Interaction with the patient via the Personal HeartCycle Health Channel on the patient's TV.

The individual patient measurements and symptoms are evaluated at the management server at the backend to see if they are within the pre-defined limits. If this evaluation shows deviations, an alert is triggered.

As major innovation, the HeartCycle HFM system has been enhanced by medical decision-support tools for patients, supervised by health professionals and supported by safety alerts, which motivate patients to take a more active role in their health management. In addition, as the system ensures a good communication with health professionals, patients feel more secure and less isolated compared to the usual standard of care available to most patients.

The HeartCycle system includes an educational program with information about all medications patients are taking, the importance of diet and exercise and about symptoms and how to manage them [4]. Moreover the HeartCycle system has interactive features that advise patients and health professionals about titration of medications to target doses as prescribed in an expert care plan, identifies reasons why caution in titration is required and helps maintain the patient in a "health maintenance zone" with respect to symptoms, heart rate and rhythm, blood pressure and weight. The health professional remains in control in all decisions about changes in medication.

The system is designed to try and maintain patient well-being and to spot early signs of deterioration. The service is not intended to provide 24 hours/7 days surveillance and is not designed to deal with emergencies.

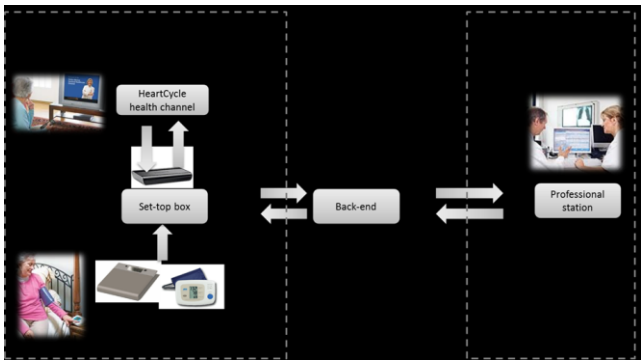


Figure 7: The overview of the overall HeartCycle HFM system

The decision support implemented in medical algorithms is designed such that based on certain medical conditions and values or their changes over time (patients labs, vitals, symptoms, medications and its compliance and compliance to low sodium diet) certain medical actions are requested by the medical professionals. In summary, the algorithms describe:

The analysis of the conditions under which the patient should be assessed, re-assessed or managed by the medical professional

The tasks of the medical professional that are required to be done given a specific set of conditions of a patient, e.g. change medication dose, consider alternative medications, schedule new lab tests, etc.

The tasks required from the patient given the specific set of conditions, e.g. comply with the change in medication dose prescribed by the medical professional, answer the symptoms questioners (i.e., assess your symptoms), take the teaching quiz.

It is the challenging task of the clinical validation to proof the benefit and added value of the HeartCycle innovations in in existing healthcare settings.

B. The HFM Clinical Study

Three clinical HeartCycle sites (Hull in UK, Heidelberg in Germany and Badelona in Spain) are executing the clinical

study which is a set of trials to validate the innovative approaches to telehealth services in chronic heart failure management and consists of four phases (A-D). The main objectives of this study are:

Phase A: The ability of the HFM system to support titration of life-saving medication safely and effectively to target doses [observational]. Phase B: The ability of the system to reduce diuretic doses safely in patients whose symptoms are well controlled and to increase them appropriately in patients in whom symptoms are not well controlled [randomised]. Phase C: How aspects of everyday life alter vital signs [observational but observer blinded]. Phase D: The proportion of time that the system can keep patients in the ideal range for weight, blood pressure and heart rate. [observational].

Further (secondary) objectives are to evaluate the quality-adjusted life-years in program, an assessment of the potential socio-economic impact of the telehealth system, patients' educational attainment on the Dutch Heart Failure Knowledge Scale, and self-care activities with the European Heart Failure Self-care Behaviour scale and an assessment of patients and health professionals views of ease of use and utility of a telehealth system for the different phases and interventions of the trial.

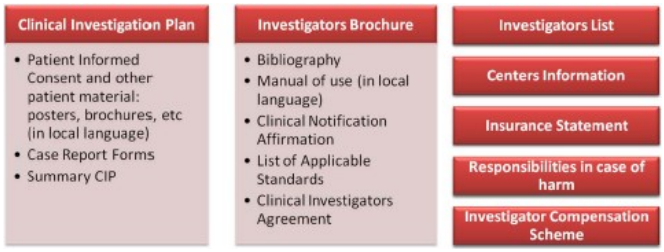
The HFM clinical study started in January 2012 and is enrolling patients until the end of February 2013. So far 103 patients participate in the study. The system is working properly without technical problems.

III. Approvals for Clinical Trials

Specific procedures must be completed before the first patient can be enrolled like obtaining the approvals from Medical Ethical Committee (MEC) and the corresponding local competent authorities (CA) in each country. Furthermore technical training to the medical staff at each clinical site is mandatory.

Both HeartCycle studies are conducted as premarket studies (in accordance with ISO 14155). They comply with the Declaration of Helsinki concerning medical research and are in accordance with the laws and regulations in the countries in which they are conducted. Devices used in this investigation do not bear the CE mark, except for those accessories that can be obtained from the market. Preparing for the pre-market studies is a long and laborious process. Besides providing detailed technical documentation on the developed systems, on applied development processes (especially for software), risk analysis and mitigation documents, on used interfaces also many medical related documents are requested such as clinical study protocol, investigator's brochure and patient information usually in local language. Patient and operator manuals in local language are mandatory as well as proof for existing insurance. All documents need to be stored for at least 10 years. As clinical studies concern patient safety MEC and CA are following an accurate procedure to guarantee all requirements for conducting the study are met. It is usual that there are several iterations about documents and missing information with both authorities. Therefore time for approval can vary between 3 months up to 12 months depending on country and quality of submitted documents. The following picture summarizes some of the required documents:

For Medical Ethical Committee:



For Competent Authority

Figure 8: Examples of required documents submitted to obtain MEC and CA approval

IV. Conclusion

Designing innovative services and technology for Telehealth applications remains a promising solution for improving healthcare delivery to chronic patients. Clinical evaluation of ICT solutions is a prerequisite to get medical endorsement but requires a huge effort in preparation and documentation, a proper understanding of regulations and a good team work with medical professionals and patients.

Acknowledgment

The HeartCycle consortium represented by the authors would like to thank Dr. Erik Skobel for his outstanding support.

References

[1] H.Reiter and N.Maglaveras, 'HeartCycle: Compliance and effectiveness in HF and CAD closed-loop management', EMBC 2009

[2] H.Reiter, HeartCycle: Beyond building demonstrators. A structured approach to develop, implement and validate healthcare innovations in tele-monitoring, EMBC 2010

[3] E. Skobel1, C. Knackstedt, A. Martinez-Romero, B. Scheibe-Schmidt, P. Schauerte, Evaluation of a newly designed shirt-based ECG and breathing sensor for home based training as part of cardiac rehabilitation for coronary artery disease. European Heart Journal (2012) 33 (Abstract Supplement), 662

[4] W. Stut, C. Deighan, W. Armitage, M. Clark, T. Jaarsma
A tailored on-line education and coaching programme to increase compliance of heart failure patients.. 11th Annual Spring Meeting on Cardiovascular Nursing of the ESC 2011 (April 1-2, Brussels)