# Guided Physical Exercise of Cardiac Patients during Rehabilitation: Adherence and Changes in Physiological Variables

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***Abstract*— A system to provide cardiac patients with the possibility to perform safe and beneficial exercise during their rehabilitation was developed within the EU project Heartcycle. Within the system, algorithms use physiological signals from a wearable device (embedded in a shirt) to guide the patient through the exercise. After having been technically validated, the system was deployed for clinical evaluation with 63 patients in Germany (21), Great Britain (25) and Spain (17). The paper describes the first findings of this evaluation study with respect to: technical feasibility, adherence of the patients to the prescribed exercise protocol, and changes in physiological observables as the patients follow their exercise plan. Technically, the system functioned well, and overall the adherence of those patients that actually started using the system was stable, or even improving, in the vast majority of cases. An increase was especially seen in adherence to the protocol set for the warm-up phase of the exercise. This is an important finding for a group of patients that is known to have declining adherence to rehabilitation recommendations in the long term. The recovery analysis showed that especially the recovery of the heart rate as measured in the first minute after the exercise end showed improvement over time.**

## I. Introduction

Rehabilitation of patients at home is one area in which telemedicine plays an increasing role. Due to its size and costs to society, an important group for providing assistance in rehabilitation is that of CAD (Coronary Artery Disease) patients. Supporting these patients to carry out physical exercise in a safe and beneficial manner after hospitalization enables them to become cardiovascularly fit again, and to maintain this fitness level in the long term. Additionally, telemedicine helps the healthcare professional to monitor the patient's progress and compliance and allow early intervention if necessary. In the context of the EU FP7 project Heartcycle [1], which has as aim to improve compliance and effectiveness in heart failure and coronary artery disease closed-loop management, a system has been built to provide such guided exercise. After technical validation, the system was used in real-life by cardiac patients in Germany, Great Britain and Spain in the period mid-2012 to mid-2013.

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The guided exercise system is based on an overall exercise plan agreed upon by the healthcare professional and the patient. It comprises a schedule, covering weeks or months, of different physical exercises (e.g. cycling or running) at the right intensity that the patient is able and willing to do. Progress in the exercise schedule is followed by the system using recorded physiological signals, and the exercise plan may be updated accordingly. During each exercise session, vital body signs are monitored with a wearable biosignal-interpretation and feedback set-up to ensure that the exercise is done at the right level: beneficial and safe. The system uses many different information processing methods: methods to define and adapt the exercise plan, methods that are used during the actual exercise session, and methods that help to evaluate how the patient has been adhering to the overall plan. In [2] we presented the biosignal processing methods that are central to guidance during the actual exercise, describing their design considerations and validation with test persons. The clinical assessment of the overall system has ended during June 2013: this paper presents the first analysis results.

The goals of the analyses reported in this paper were: to evaluate whether the technical quality in real-life conditions with patients in three different countries was adequate; to analyze the adherence of the patients to the exercise plan they had agreed upon with the clinicians (this was one of the main goals of the Heartcycle project); and to analyze whether we can observe any changes in relevant physiological variables, such as resting heart rate and heart rate recovery features.

## II. Methods

### *A. System description*

The approach to guide the CAD patient to a desired fitness level, and maintain that level, contains many components. Technically, the system includes three main components. Firstly, the professional station (on a PC), designed for healthcare professionals, is used for performing patient management and creating and personalizing physical exercise plans (using intensity, frequency, and duration of exercise as basis). Secondly, the patient station (on a PC) provides the link between the professional station and the portable station (that is used during the exercise) – and it allows for synchronization of exercise plans and upload of monitored exercise data to the professional station. Finally,

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the portable station, which is used for carrying out the actual exercise, includes both sensor components to acquire vital signs as well as a portable device (PDA, mobile phone) to interact with the patient during exercise. Data acquisition is done using an IMAGE sensor (CSEM, Switzerland [3]) that records ECG, respiration, and 3D-acceleration signals. It is fixed to a special shirt (Clothing+, Finland) that positions the sensors correctly on the upper chest. Raw signals are summarized into features and given as output. They include RR-intervals, Heart Rate (HR, fs = 1/5.5 Hz), Breathing Rate (BR, fs = 1/5 Hz), and Activity Level (vector norm of 3-D acceleration signal, AL, fs = 1/2 Hz). Exercise sessions are executed on an MS Windows Mobile based PDA (worn on the upper arm) which obtains physiological data from the IMAGE sensor via Bluetooth and provides real-time feedback to the patient regarding the measured signals, provides instructions for performing the exercise and gives motivational messages. The system has been evaluated in a Phase I trial [4] and found to be suitable for home-based rehabilitation monitoring. The contents of the exercises are agreed upon beforehand between the patient and clinicians, and documented in exercise plans. These have different phases as the patient progresses through rehabilitation, such as initial phase, improvement phase and maintenance phase, each with its own specifics regarding exercise frequency and duration and target heart rates.

During an exercise session, signal processing methods combine the features, and check whether the heart rate stays within the prescribed ranges during the different phases of the session: the warm-up phase, the core exercise phase, and the recovery phase. These algorithms, that combine activity level measured via accelerometers, heart rate, and breathing rate, give feedback in the form of messages to the patient, encouraging him/her to speed up or slow down to exercise at the right intensity level. In case of adverse events, the system may message to stop the exercise altogether. The algorithms have been described in detail in [2].

As the exercise plan aims to keep the heart rate in a beneficial and safe range for a desired time during the exercise, we devised an index that captures how well the patient has adhered to this plan in one number between 0 and 1, the *exercise index*. It uses 3 sub-indices that reflect adherence to the warm-up, core and cool-down phase respectively. For each phase, the sub-index is based on the relative duration that the exercise is done within the target heart rate range. For the core phase sub-index, there is an additional penalty term for times when the heart rate exceeds the target range. The overall exercise index is the weighted average of the 3 sub-indices – the core phase has a weight of 2, the other phases a weight of 1. Thus the adherence to the exercise plan for a session is given by one number: 1 indicating perfect exercise adherence, 0 indicating that the heart rate was never within the suggested limits.

### *B. Data collected*

Data were collected in three countries following a study outline described in [5]. All study sites received approval from the local ethical committee involved. The studies were carried out between mid-2012 and mid-2013. In total we had data of 63 patients (21 German, 25 British and 17 Spanish; 58 males, 5 females) with an average age of 59 years (s.d. 10.5 years), covering a total 512 exercise sessions (116 walking, 348 bicycling and 48 running). The average duration of the exercise rehabilitation was 97 days for the German cases (ranging from 0 days to 207), and 48 days for the British data (range 0 to 97 days). Only one Spanish subject actually used the system, for one session. The data were uploaded from the PDA to the patient station, and subsequently to the professional's station. For our research purposes, the data were, after anonymization, uploaded to an SQL database. Further processing took place in Matlab (The Mathworks, Natick MA). In order to analyze the longer-term effects of rehabilitation we only included patients who did 10 exercise sessions or more – for those analyses we used a limited set of 14 cases (8 German and 6 British). For the Heart rate and recovery analysis we used only patients that had followed through the entire set of phases of the rehabilitation; these were 10 patients.

### *C. Analysis methods*

We used the following methods.

*Signal quality* was analyzed by plotting all patients' data for different sessions as time-series in conjunction with the ranges for the recommended heart rate and annotations of when the algorithms initiated feedback messages. We have also numerical signal quality indices (one used at the start of the session, and one continuously used during the exercise itself) but in this phase we concentrated on visual examination and human pattern recognition to discern possible different artefacts and noise.

*Adherence to the different exercise session phases* was examined by calculating the exercise index and its components for each session and examining how it developed over the months of rehabilitation. To assess whether there was a specific trend, we plotted the adherence index data vs. time and performed linear regression on the data, and tested whether we could reject the null hypothesis that the slope was 0 at a significance level of $p$=0.05.

*Heart rate and Recovery phase analysis*: we studied whether recovery parameters (that reflect physical functioning) have improved at the end of the program as compared to the beginning by using a paired t-test. These variables include: heart rate before the start of the exercise session (HRrest), mean heart rate during the core phase (HR intensity), mean heart rate during the last minute of the core phase (HRlastmin), and the difference between the mean heart rate at the last minute of the exercise and the heart rate at the end of the $1^{st}$, $2^{nd}$ and $3^{rd}$ minute of the recovery phase (denoted as HRR1, HRR2, and HRR3 respectively).

## III. Results

### *A. General observations*

Overall, there was a considerable amount of variation in adherence at the general level; of German subjects 7 out of 21 did not do any session, of the British subjects, 16 out of 25 did not do sessions, and of the Spanish, no less than 16 out of 17 did not do any sessions. There was a clear cluster of people who were actively using the system, and a cluster of people who did not use it (maybe after trying it once). Examining the reasons for this is not part of this paper; these results are currently being evaluated via separate patient outcome questionnaires and will be reported elsewhere.

In total, for the German cases, 316 out of the 374 started sessions (84.5%) were completed, and for the British cases 133 out of 137 (97.1%). The reason for not completing a session can be 'cancelled', when the PDA cancelled the session before its initiation (e.g. due to a technical problem or a medical reason revealed in the pre-exercise questionnaire) or during the exercise (e.g. due to too high HR); or it can be 'aborted' when the patient stopped the session (e.g. due to a technical problem or feeling bad). For the German cases the prevailing reason was 'cancelled' (41 out of the 58 not-completed sessions) and 17 cases were 'aborted'. For the British cases, the only reason not to complete a session was 'aborted'. Of the cancelled sessions, there was one due to 'not feeling well'. For the aborted sessions, one was due to "felt bad, chest pain, mild palpitations'; and two "tired, exhausted, felt bad, severe". Furthermore, 17 sessions were aborted due to technical problems with the sensors or shirt. For the remaining uncompleted sessions "unknown reason" was given as a reason.

### B. *Signal quality*

We plotted all sessions and examined the signals visually. An example is given in Figure 1.

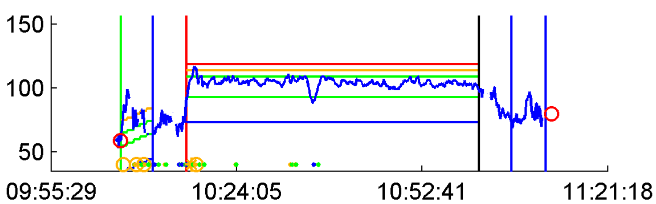


Fig. 1. An example of a bicycling session, with the blue curve indicating the heart rate, and the vertical lines the start of the different phases (warm-up, stretching, core, recovery, end) and the horizontal lines the range of the desired HR (green), in this case 93-109 bpm, and upper (orange and red) and lower (blue) limits. Different feedback messages (marks just above the time-axis) are generated when the HR leaves the desired HR zone.

In general, the quality of the HR signal was good. When we looked at the 512 sessions in total, 30 of them had one or a few short-lasting spikes in the signal (typically at the beginning or end of the recording), which did not hamper functioning of the system or analysis of the signals. HR was fluctuating a lot at certain locations in one session; HR signal was totally missing in 3 sessions. One patient had many sessions with continuous high-frequency 'spiky' fluctuations in the HR (25 out of 53 sessions). As this concerned one patient only, it may have been specific to the exemplar of the sensor/shirt he received. Due Bluetooth connection problems between the IMAGE sensor and the PDA, there were missing data blocks. Median of percentage of missing HR samples during the exercise sessions was 0.78% with the 25th percentile of 0.0% and 75th percentile of 2.23%.

Quality of the BR signal was not as good as the quality of the HR signal. In 29% of the sessions the quality of the BR signal was good. Typically there were single spikes in which the BR dropped suddenly. There were also longer periods of sudden increases, decreases, or fluctuations; sometimes the whole signal was corrupted.

### C. *Adherence to the exercise phases*

Figure 2 shows examples of how the exercise indices of different patients developed during the rehabilitation phase.

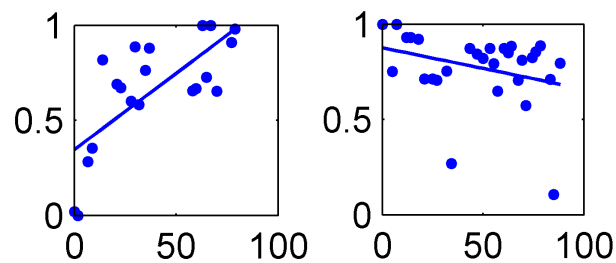


Fig. 2. Two example cases of how the index developed during the rehabilitation for two different patients. X-axis is time in days, y-axis is a component of the exercise index. Left figure shows adherence to the warm-up phase, right figure shows adherence to the core phase. Dots are individual sessions, lines are first-order regressions. The warm-up example shows a patient who starts out too fast during exercise sessions at the beginning of his rehabilitation (adherence is low at the beginning, but improves quickly), the core-phase example shows someone who reasonably well follows the exercise plan, with slight (but not significant) decrease over time.

With the slope of the regression lines as an indication of a significant trend in adherence, we get the results for significant changes as presented in Table I.

TABLE I
SUMMARY OF CHANGES IN ADHERENCE TO THE EXERCISE PLAN

| | increase | decrease | no change |
|---|---|---|---|
| warm-up | 8 | 0 | 6 |
| core | 1 | 2 | 11 |
| cool-down | 6 | 0 | 8 |
| overall index | 6 | 0 | 8 |

Summary of the number of cases with respect to significant changes in adherence throughout the rehabilitation as measured with the different components of the exercise index.

### D. *Heart rate and Recovery phase analysis*

The results of paired testing the differences between the values of physiological variables measured at the beginning vs. the end of the rehabilitation exercise program are given in Table II.

TABLE II
DIFFERENCES BETWEEN THE START AND END OF THE PROGRAM

| *feature* | p | Median at start | Median at end |
|---|---|---|---|
| HR rest | 0.39 | 69.5 | 68.0 |
| HR intensity | 0.09 | 89.5 | 93.2 |
| **HRR1** | **0.02** | **1.5** | **7.7** |
| HRR2 | 0.07 | 5.0 | 7.8 |
| HRR3 | 0.16 | 7.0 | 10.1 |
| HRlastmin | 0.29 | 82.8 | 89.6 |

Indication of which variables showed significant differences between the start and end of the followed exercise-based rehabilitation. A value of $p<0.05$ indicates rejection of the null-hypothesis that there is no difference based on the paired t-test. In the calculations, 2 patients were excluded because they did not complete the entire care plan, so here N=12.

From Table II we can see that the Heart Rate Recovery as measured over 1 minute was significantly improved; for the other measures, the improvements did not reach significance. An example case of how the variables change over time during the program is given in Figure 3. It has to be noted that limited post-exercise heart rate recovery, assessed in stress test protocols where typically a higher maximum heart rate is reached before recovery, has been associated with poor prognosis and a threshold of 12bpm is often employed, with HRR1 than that considered as normal [6]. Therefore an increase in HRR1 could be seen as an encouraging (although not conclusive) finding about the system's added value.

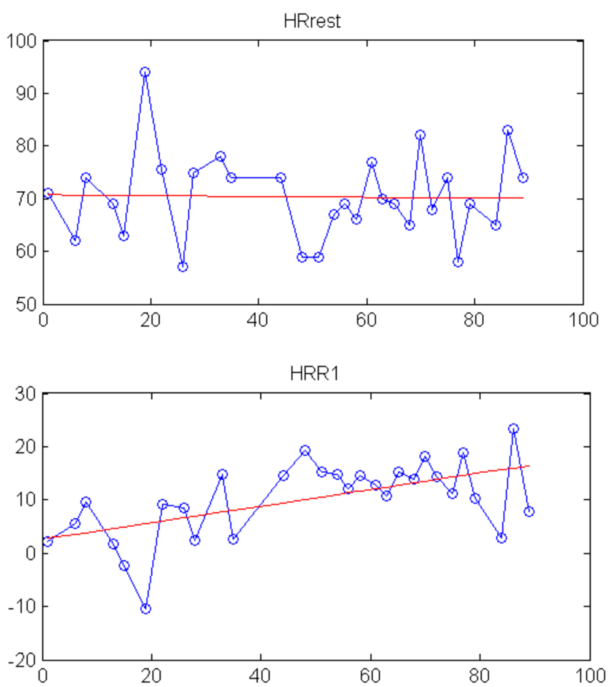


Fig. 3. Example of a patient whose resting heart rate stays stable (top) and whose 1-minute recovery rate (bottom) improved significantly over time.

## IV. Discussion

This paper presents the first results of a study on the feasibility and effects of a guided-exercise based rehabilitation program for cardiac patients. More context of the data collection will become available in the coming months (and can be presented at the conference). This is especially relevant for the outcome questionnaires (that can give information about why certain patients did not use the system as expected), and also about the use of medication (that can influence especially the resting heart rate). Both issues are complex and multi-factorial, and need interpretation.

Overall we can say that the system has functioned in a technically satisfactory manner. Also, the adherence has in most cases stayed stable, or even clearly improved (such as in the adherence to the warm-up phase). This is an especially important result, since declining adherence over time is one of the main problems in rehabilitation of cardiac patients, and, indeed, one of the main motivations of carrying out the Heartcycle project. Also, it can be seen that, for some physiological variables that measure functional capacity, there is improvement over time with prolonged exercise.

## V. Conclusions

The guided exercise system provides a technically functioning system that provides cardiac patients with the possibility to perform safe and beneficial exercise. The initial results showed improved recovery functionality as measured in the 1-minute recovery rate, and an overall positive adherence development.

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