Home-based cardiac rehabilitation: Development and evaluation of a novel intervention with telemonitoring guidance and wearable sensors
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Chapter 6

Effects of home-based training with telemonitoring guidance in low to moderate risk patients entering cardiac rehabilitation:

Short-term results of the FIT@Home study


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Abstract

Background: Home-based exercise training in cardiac rehabilitation (CR) has the potential to improve CR uptake, decrease costs and increase self-management skills. The FIT@Home study evaluates home-based CR with telemonitoring guidance using coaching interventions including strategies for behavioural changes with the aim to maintain adherence to a healthy lifestyle and to improve long-term effects. In this interim analysis we provide short-term results on exercise capacity, quality of life and training adherence of the first 50 patients included in the FIT@Home study.

Design: Randomised Controlled Trial

Method: Low to moderate risk CR patients were randomised to a 12-week home-based training (HT) programme or a 12-week centre-based training (CT) programme. In both groups, training was performed at 70-85% of maximal heart rate (HRmax) for 45-60 minutes, 2-3 times per week. The HT group received three supervised training sessions, before commencing training with a heart rate monitor in their home environment. These patients received individual coaching by telephone weekly, based on training data uploaded on Internet. The CT programme was performed under direct supervision of a physical therapist. Exercise capacity and health-related quality of life were assessed at baseline and at 12 weeks.

Results: CT (n=25) and HT (n=25) both showed a significant improvement in peak VO\(_2\) (10% and 14% respectively) and quality of life after 12 weeks of training, without significant between-group differences. The average training intensity of the HT group was 73.3 ± 3.5% of HRmax. Training adherence was similar between groups.

Conclusion: This analysis shows that HT with telemonitoring guidance has similar short-term effects on exercise capacity and quality of life as CT in CR patients.
**Introduction**

**Background**
Although mortality due to cardiovascular disease is decreasing, it remains one of the leading causes of death worldwide placing a large social and economic burden on society. Recently, total annual costs for cardiovascular disease in the EU were estimated at €196 billion [1]. Cardiac rehabilitation (CR) is a multidisciplinary intervention aiming to accelerate physical and psychosocial recovery and to reduce the risk for future cardiac events. Numerous studies showed that CR can lead to a substantial decrease in morbidity and mortality and is therefore highly recommended in clinical guidelines [2,3]. Exercised training, one of the crucial components of multidisciplinary CR, has proven benefits on exercise capacity, quality of life and mortality [2]. However, despite these benefits, participation and adherence to exercise-based CR is low. Previous studies showed that only 20-30% of all eligible cardiac patients participate in such a programme [4,5]. Especially in younger patients, work and social obligations as well as reluctance to take part in group sessions form important barriers to participate in CR [4,6]. Therefore, there is a need for innovative rehabilitation methods aiming at an increase of CR uptake.

**Home-based CR**
An intervention that has been proposed as an alternative for patients that are unwilling or unable to attend the hospital for supervised CR is home-based exercise training [7–9]. A meta-analysis of 12 studies showed comparable short-term improvement in exercise capacity and mortality rates after home-based as compared to centre-based CR [10]. However, long-term effects of home-based CR are not well established. While most studies report only direct results of CR, others show a decline in exercise capacity after termination of home-based CR [11,12] similar to long-term results of centre-based CR [13,14]. A possible explanation for these disappointing results may be a lack of direct objective feedback on training progression for patients. When patients do receive feedback of their actual training data and are able to monitor their training goals by assessment of training intensity, frequency and duration, they can develop self-management skills for maintaining an active lifestyle. In this way, skills like action planning, problem solving and decision-making can be developed in the early stages of CR, so that self-efficacy for performing independent exercise at home can be improved [15]. Another explanation for the long-term deterioration of exercise capacity in these studies may be that the coaching interventions did not include strategies aimed at behavioural change (e.g. motivational interviewing or cognitive therapy).

The purpose of the FIT@Home study is to investigate the effects of a home-based CR strategy consisting of motivational interviewing in the initial CR phase in combination with on-going objective feedback on training progression in low to moderate risk CR patients. This paper provides short-term results of the FIT@Home strategy on exercise capacity, training adherence and quality of life.
Methods

Study design
We conducted a randomised controlled trial among low to moderate risk patients entering the CR at Máxima Medical Centre Veldhoven in the Netherlands. All patients provided written informed consent before entering the study. The study protocol was approved by the Institutional Review Board of the Máxima Medical Centre Veldhoven in the Netherlands (reference number 1243) and registered at ClinicalTrials.gov with registration number NCT01732419. The protocol is described in detail elsewhere [16].

Population and randomisation
Patients were eligible for participation in the study when they entered CR after hospitalisation for myocardial infarction, unstable angina, or a revascularisation procedure (percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG)). Only patients with a low to moderate risk of future cardiac events according to the Dutch CR guidelines were included [17]. Finally, patients were required to have Internet access and a PC at home. During the CR intake procedure, patients were informed about the study by a specialised nurse practitioner or sport physician. After one week, patients were asked to participate by the coordinating investigator. After written consent, patients were randomly allocated to home-based training (HT) or centre-based training (CT). All treatment modalities other than exercise training (i.e. lifestyle change therapy, relaxation and stress management and/or education) took place as usual at the outpatient clinic.

Exercise protocol
Exercise training in both groups was prescribed according to the current recommendations of the European Society of Cardiology.[18] Both groups participated in a 12-week exercise programme with at least two training sessions per week. Patients were instructed to exercise for 45 to 60 minutes per session at 70-85% of their maximal heart rate. The CT group performed group-based training sessions on a treadmill or cycle ergometer, supervised by physical therapists and exercise specialists. Patients in the HT group received three initial supervised training sessions. During these three sessions, patients received instructions on how to use a wearable heart rate monitor (Garmin Forerunner 70) and how to upload the recorded exercise data to a web application (Garmin Connect) through Internet. The web application was used to review the training data by the patient, the physical therapist and the exercise specialist. During the first sessions, the patients were also familiarized with the training programme (duration, intensity) and their preferred training modality in the home environment was discussed. After three supervised training sessions, patients in the HT group started training in their home environment. They received feedback on training frequency, duration and intensity from the physical therapist once a week via telephone. After 12 weeks, the telephonic feedback was terminated and the patients were advised to continue their training with the heart rate monitor.
Telemonitoring Guidance

To guide behavioural change, we used principles from goal setting theory and motivational interviewing during the home-based intervention. At the start of the rehabilitation programme patients defined personal training goals together with their physical therapist. After three supervised training sessions, patients in the HT group started training at home and received coaching from their therapist through weekly telephone calls. During this phone call the therapist gave feedback on training parameters that were measured during the preceding week, and discussed progress with respect to the personal training goals with the patient. In addition, based on the principles of Motivational Interviewing, they discussed barriers and facilitative factors in adhering to the exercise training protocol. Motivational Interviewing aims at resolving problems and barriers that occur in the process of change by means of activating and providing direction. Both Motivational Interviewing and goal setting appear effective in the enhancement of motivation to maintain behavioural change in various fields [19,20].

Outcomes measures

Exercise capacity was determined at baseline and after 12 weeks, by a maximal exercise test with respiratory gas analysis. Exercise capacity was defined as the average peak oxygen uptake during the final 30 seconds of exercise (peak VO₂). Secondary endpoints were health-related quality of life and training adherence. Health-related quality of life was assessed at baseline and after 12 weeks with a Dutch translation of the MacNew questionnaire [21]. Training adherence was defined as the number of training sessions during the 12-week CR programme either attended at the outpatient clinic (CT group), or performed at home (HT group). Training duration, exercise intensity and exercise time in the prescribed heart rate zone in the HT group were assessed via self-recorded heart rate measurements.

Statistical analysis

Primary endpoints of the FIT@Home study are exercise capacity and physical activity level, assessed at baseline, after 12 weeks and after one year. Besides health-related quality of life and training adherence as described above, other secondary endpoints in the FIT@Home study are patient satisfaction after 12 weeks and cost-effectiveness after one year. Sample size calculations were performed for physical activity levels after one year, based on data from Bonomi et al. [22]. We expect to include 45 patients in each group in the FIT@Home study. For the analysis of short-term results, linear regression analysis was used to assess differences in peak VO₂, quality of life, and training adherence between the two groups. Data were analysed on an intention-to-treat basis and all analyses were performed with the statistical software package R (version 3.0.3) [23].
Table 1: Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Centre-Based</th>
<th>Home-Based</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=25</td>
<td>n=25</td>
</tr>
<tr>
<td>Age (years)</td>
<td>56.1 ± 8.7</td>
<td>60.6 ± 7.5</td>
</tr>
<tr>
<td>Men, n (%)</td>
<td>21 (84%)</td>
<td>22 (88%)</td>
</tr>
<tr>
<td>BMI</td>
<td>27.9 ± 3.7</td>
<td>28.3 ± 3.3</td>
</tr>
</tbody>
</table>

Diagnosis

<table>
<thead>
<tr>
<th></th>
<th>Centre-Based</th>
<th>Home-Based</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACS with PCI, n (%)</td>
<td>10 (40%)</td>
<td>14 (56%)</td>
</tr>
<tr>
<td>ACS without PCI, n (%)</td>
<td>5 (20%)</td>
<td>4 (16%)</td>
</tr>
<tr>
<td>AP with PCI, n (%)</td>
<td>4 (16%)</td>
<td>2 (8%)</td>
</tr>
<tr>
<td>AP without PCI, n (%)</td>
<td>0 (0%)</td>
<td>2 (8%)</td>
</tr>
<tr>
<td>CABG, n (%)</td>
<td>6 (24%)</td>
<td>3 (12%)</td>
</tr>
</tbody>
</table>

Medication

<table>
<thead>
<tr>
<th></th>
<th>Centre-Based</th>
<th>Home-Based</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta-blocker, n (%)</td>
<td>22 (88%)</td>
<td>23 (92%)</td>
</tr>
<tr>
<td>Statines, n (%)</td>
<td>25 (100%)</td>
<td>24 (96%)</td>
</tr>
<tr>
<td>Anti-platelets, n (%)</td>
<td>24 (96%)</td>
<td>25 (100%)</td>
</tr>
<tr>
<td>ACE-i / ARB, n (%)</td>
<td>20 (80%)</td>
<td>16 (64%)</td>
</tr>
</tbody>
</table>

Values are presented as mean (SD) unless stated otherwise.

BMI= body mass index; ACS= acute coronary syndrome; PCI= percutaneous coronary intervention; AP= angina pectoris; CABG= coronary artery bypass graft; ACE-i= angiotensin converting enzyme inhibitors; ARB= angiotensin receptor blockers.

Results

Between March 2013 and March 2014 a total of 55 patients agreed to participate in the study, of which 26 were allocated to the CT group and 29 to the HT group. Of these patients, 34 received a PCI, 10 patients underwent CABG, and 11 patients were only treated with medication during their hospitalisation. One patient in the CT group and one in the HT group were not able to perform an exercise test at 12 weeks, due to co-morbidities. Three patients in the HT group dropped out due to either technical difficulties (n=2) or due to a change in health status (n=1). There were no adverse events in either group. Baseline characteristics of the remaining 50 patients are described in Table 1.
**Table 2: Effect of the FIT@Home intervention at 12 weeks**

<table>
<thead>
<tr>
<th></th>
<th>Centre-based (CT)</th>
<th>Home-based (HT)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 25</td>
<td>n = 25</td>
<td></td>
</tr>
<tr>
<td><strong>Baseline</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peak VO(_2) (ml/min/kg)</td>
<td>23.7 ± 6.4</td>
<td>26.1 ± 7.6**</td>
<td>0.401</td>
</tr>
<tr>
<td>Maximal workload (Watt)</td>
<td>179.6 ± 53.9</td>
<td>202.4 ± 68.2***</td>
<td>0.546</td>
</tr>
<tr>
<td>HRmax (beats/min)</td>
<td>142.2 ± 19.8</td>
<td>147.2 ± 25.3</td>
<td>0.512</td>
</tr>
<tr>
<td>RER at peak VO(_2)</td>
<td>1.3 ± 0.1</td>
<td>1.2 ± 0.1</td>
<td>0.482</td>
</tr>
<tr>
<td>Quality of Life</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical scale</td>
<td>5.0 ± 0.8</td>
<td>5.7 ± 0.8**</td>
<td>0.163</td>
</tr>
<tr>
<td>Emotional scale</td>
<td>5.1 ± 1.0</td>
<td>5.6 ± 0.9*</td>
<td>0.880</td>
</tr>
<tr>
<td>Social scale</td>
<td>5.5 ± 0.8</td>
<td>6.1 ± 0.7***</td>
<td>0.257</td>
</tr>
<tr>
<td>Total score</td>
<td>5.2 ± 0.8</td>
<td>5.8 ± 0.7**</td>
<td>0.498</td>
</tr>
<tr>
<td>Training data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency (sessions)</td>
<td>20.5 ± 4.5</td>
<td>24.0 ± 7.2</td>
<td>0.049</td>
</tr>
<tr>
<td>Duration (min/session)</td>
<td>60 ± 0.0</td>
<td>60.7 ± 16.1</td>
<td>0.690</td>
</tr>
<tr>
<td>Zone (min/session)</td>
<td>41.8 ± 10.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intensity (% HRmax)</td>
<td>73.2 ± 3.5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Values are presented as mean (SD) unless stated otherwise.

Peak VO\(_2\)= peak oxygen uptake; RER= respiratory exchange ratio; HRmax maximal heart rate

Significant change from baseline: *P<0.05, **P<0.01, ***P<0.001

**Exercise data**

Table 2 shows the outcome measures assessed at baseline and after 12 weeks. Peak VO\(_2\) improved significantly in both groups, while no significant between-groups difference was observed (p=0.40). In addition, maximal workload improved significantly in both groups while maximal heart rate remained unchanged.
Training data
On average, patients in the CT group attended 20.5 supervised training sessions (adherence: 86%, range: 6-25), while the HT group performed an average of 24.0 training sessions in 12 weeks (adherence: 100%, range: 13-41). Patients in the HT group exercised 61 minutes per training session, of which they exercised 42 minutes in the prescribed exercise intensity zone (70-85% of maximal heart rate). In the CT group a regular 60-minute training session consisted of a warming up and cooling own phase and two 20-minute bouts on a treadmill or cycle ergometer.

Quality of life
Health-related quality of life improved significantly in both groups, without any between-group differences (Table 2). The improvement was present in all subscales of the quality of life questionnaire.

Discussion
The short-term results of the present study demonstrate two important findings. First, home-based exercise training with telemonitoring guidance results in similar improvement of exercise capacity and health-related quality of life compared to an intensive regular centre-based training. Second, training frequency, exercise duration and training intensity in the home-based training group was comparable with training adherence of the supervised centre-based training. This implicates that patients are able to independently execute a 12-week training programme in their home environment when they receive adequate coaching and objective feedback.

Although previous studies on home-based CR training using objective variables to set training intensity showed favourable effects, improvements in peak VO₂ were somewhat lower than in our study (8%-10% versus 14%) [9,24]. This may be explained by a lack of feedback on training progression for patients. Aamot et al. [9] instructed home-based CR patients to use a heart rate monitor during exercise training, but these data were not used for coaching during the CR period. In the study of Oerkild et al. [24] patients received home-visits during the CR, but patients had no insight in their training data. Yet, the ability for patients to monitor progression of an intervention has been shown to increase motivation and self-management skills, and may therefore result in superior improvements in exercise capacity and physical activity levels [25]. As patients in the FIT@Home study are enabled to continue to use the heart rate monitor and software application after the initial CR phase, we expect that the favourable short-term results can be sustained on the long-term.

A limitation of this study is that the intervention may not be suitable for all patients, as it requires basic computer and Internet skills to install and use the software platform. Yet, in the present study only two patients were not able to independently work with the software. Furthermore,
the average age of the study participants was comparable to that of other studies investigating effects of supervised CR [2,10], suggesting that the applicability of this intervention is not limited to younger patients only. The prescribed training intensity for HT patients was calculated from the maximal heart rate assessed during the exercise test at baseline. However, changes in the prescribed beta-blocker dosage affects heart rate considerably. Although changes in medication during the CR occurred only rarely (twice), we did not perform an additional exercise test for these cases. Instead, exercise intensity was adjusted based on previous training experience, similar training data and the rate of perceived exertion assessed by the Borg scale.[26] Therefore, we expect this has little impact on the presented results.

In conclusion, the results of this study show that home-based CR with telemonitoring guidance can be an effective alternative for regular centre-based CR. In addition, implementation of this strategy may lead to an increase in CR participation. Furthermore, early development of self-management skills by home-based CR with objective feedback for patients may increase long-term results of CR. Therefore, a long-term (cost-) effectiveness analyse will be performed on all FIT@Home data.

Conflicts of interest
The FIT@Home study is executed in collaboration with Philips Research; the heart rate monitors used during home-based training were provided by Philips Research.

Acknowledgements
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References


