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

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Chapter 8

Summary and general discussion
This thesis focused on the development and evaluation of a novel intervention of home-based exercise training with telemonitoring guidance for low-to-moderate cardiac risk patients entering cardiac rehabilitation. In the first chapters we investigated the opportunities to develop a home-based cardiac rehabilitation intervention, focusing on the determinants of physical fitness improvement and opportunities to accurately assess physical activity levels in the home environment. The two final chapters evaluate the randomised controlled trial that compared the effectiveness and cost-effectiveness of a home-based training intervention plus telemonitoring guidance with conventional centre-based training for low-to-moderate cardiac risk patients entering cardiac rehabilitation.

Summary

In Chapter 02, we performed a systematic review and meta-regression analysis to identify which training characteristics determine the improvement of physical fitness after exercise training in coronary artery patients. After the systematic literature search, a total of 13 randomised controlled trials (representing 693 patients) were included in this study. Patients in the exercise group improved their exercise capacity significantly compared to the non-exercise control group. The meta-regression analysis showed that four training characteristics (i.e. session duration, session frequency, programme length and training intensity) and total energy expenditure were independently related to the improvement in exercise capacity. However, when total energy expenditure was added as covariate, no independent effect of any of the four training characteristics was established. Therefore, we concluded that total energy expenditure was the strongest determinant for improvement in physical fitness after centre-based cardiac rehabilitation. Cardiac rehabilitation programmes should be aimed at high total energy expenditure, without preference for high training intensity, duration, frequency or length.

A similar systematic review and meta-regression analysis for chronic heart failure patients was performed in Chapter 03. A total of 17 randomised controlled trials (representing 2935 patients) were identified and included in the study. Because almost 75% of the included patients were from one study, all analyses were performed with and without this trial. The analyses including the large study showed that total energy expenditure of a training programme was the strongest determinant for improvement in physical fitness. This was confirmed when the large study was excluded in the second analysis. In addition, this second analysis showed that three distinct training characteristics (i.e. session frequency, session duration and training intensity) were independently associated with improvement in exercise capacity when corrected for total energy expenditure. Ranking of the training characteristics demonstrated the largest effect for session frequency and session duration, followed by training intensity and programme length.
In Chapter 04, we developed an energy expenditure prediction model for beta-blocker medicated cardiac rehabilitation patients, based on body movement and heart rate data. Sixteen cardiac rehabilitation patients underwent a resting metabolic rate assessment, a maximal exercise test and a physical activity protocol with daily life activities. Heart rate and body movement data were recorded using wearable devices and energy expenditure was assessed by a portable indirect calorimeter, used as gold standard. The best performance was achieved with a multivariate regression model that included heart rate data, body movement data and subject characteristics (i.e. age, weight, height, gender, physical fitness, beta-blocker dose). In current practice, these data are available at the start of the rehabilitation programme when a symptom-limited exercise test is included in the cardiac rehabilitation intake. Therefore, the prediction model is highly applicable in the clinical setting for monitoring physical activity levels in the home environment.

We described the rationale and design of the FIT@Home trial in Chapter 05. We randomised 90 low-to-moderate cardiac risk patients entering cardiac rehabilitation to three months of either home-based training with telemonitoring guidance or regular centre-based training. After three introductory sessions in the hospital, patients in the home-based group were instructed to train with a heart rate monitor in their home environment. They received individual coaching by telephone once a week, based on the measured heart rate data shared through an Internet portal. Main endpoints were physical fitness and physical activity levels. Secondary endpoints were training adherence, quality of life, patient satisfaction and cost-effectiveness. All endpoints were assessed at baseline, after discharge and at one-year follow-up.

In Chapter 06, we described the short-term results of the first 50 patients participating in the FIT@Home trial. Training frequency, exercise duration and training intensity in the home-based training group were comparable to training adherence of the centre-based training group. In addition, physical fitness and health-related quality of life were similar between groups. Therefore, we concluded that the first patients participating in the FIT@Home trial were able to independently execute a 12-week training programme in their home environment when they received coaching and objective feedback through telemonitoring guidance.

We described the full results of the FIT@Home trial in Chapter 07. The study showed comparable results for home-based exercise training with telemonitoring guidance and centre-based exercise training, with respect to improving physical fitness in low-to-moderate cardiac risk patients entering cardiac rehabilitation. The physical activity levels were unchanged at one-year follow-up in both groups. Whereas health-related quality of life and psychological status were similar in the two groups, patient satisfaction was significantly higher in the home-based cardiac rehabilitation group. The cost-effectiveness analysis showed that home-based training is likely to be more cost-effective than centre-based training. In conclusion, these results indicate that home-based exercise training is a valuable alternative for regular centre-based exercise training for low-to-moderate cardiac risk patients entering cardiac rehabilitation. However, the intervention
did not result in increased physical activity levels, indicating that future studies should include physical activity coaching in the intervention to stimulate an active lifestyle.

**General discussion**

In this thesis we explored opportunities to make cardiac rehabilitation more appealing for cardiac patients, without losing its clinical effectiveness. Home-based training offers exercise-based cardiac rehabilitation for patients who are not able to participate in centre-based cardiac rehabilitation due to work resumption or other logistical challenges, or personal preferences. The home-based training intervention with telemonitoring guidance showed similar clinical effectiveness and favourable cost-effectiveness compared to centre-based cardiac rehabilitation.

In the first part of this thesis we demonstrated that the effectiveness of an exercise programme is mainly determined by the total energy expenditure of the exercise protocol. This implies that if total energy expenditure of a training protocol remains the same, session frequency, session duration, training intensity and length of the training programme can be altered without losing effectiveness. As a result, a training programme can be effectively translated to a patients’ home environment when total energy expenditure of the programme is carefully considered. For instance, if high intensity training is not feasible in the home environment, additional sessions at moderate training intensity can be added to the programme to achieve equally high total energy expenditure. As long as total energy expenditure remains the primary focus, other factors that impact training outcome can be taken into account. Previous studies showed that when patients are able to determine their own training type and location, training adherence improves and the beneficial effects of cardiac rehabilitation are sustained [1,2]. Therefore, we recommend that the training programme be tailored to the preferences of the patient, while taking into account total energy expenditure, to optimise patients’ resulting physical fitness. With this in mind, we designed an exercise-based cardiac rehabilitation programme that is feasible for exercise training in the home environment.

We developed an energy expenditure estimation model to monitor and assess the physical activity levels of cardiac patients in the home environment. This model uses body movement and heart rate data assessed by wearable sensors. The method utilises objectively measured physical activity data rather than subjective self-assessments via questionnaires that were often used in previous studies to assess physical activity behaviour. In the final part of this thesis the estimation model was used to assess physical activity levels before and after cardiac rehabilitation. We concluded that neither the centre-based nor the home-based cardiac rehabilitation programme affected the physical activity behaviour. During the intervention, we used the physical activity data only at the start and end of the programme to monitor physical activity behaviour, and the data was not used during the programme to optimise the intervention.
Previous studies showed that a cardiac rehabilitation programme requires an explicit physical activity intervention to improve physical activity levels [3, 4] and that a programme focused on physical fitness improvement does not automatically result in an improvement in physical activity behaviour [5, 6]. Therefore, we recommend implementing both physical activity monitoring and physical activity coaching in the cardiac rehabilitation programme. In recent exercise-based cardiac rehabilitation guidelines, extra emphasis was put on objective monitoring of physical activity data and implementing coaching and behavioural-change strategies in cardiac rehabilitation to improve and maintain an active lifestyle [7–9]. If physical activity data are included in the telemonitoring guidance using behavioural-change coaching techniques (e.g. motivational interviewing, relapse prevention), then we expect that the programme can induce sustainable changes in physical activity behaviour.

In the second part of this thesis we demonstrated that home-based cardiac rehabilitation with telemonitoring guidance appears to be a cost-effective alternative for centre-based cardiac rehabilitation. Evidence concerning cost-effectiveness of telemonitoring cardiac rehabilitation programmes so far is scarce. In addition, evidence of telemonitoring programmes so far was hard to compare across studies due to the high variation in telemonitoring guidance delivered at home (e.g. exercise manual, telephone support, home-visits) and the cardiac rehabilitation population studied [10, 11]. In addition, some programmes provide additional services after regular cardiac rehabilitation resulting in additional costs [12], while others provide a programme replacing usual care [13]. Finally, economic evaluations often fail to include all relevant healthcare- and societal costs, therefore making it difficult to compare the results across studies [11]. Because cost-effectiveness of an innovative intervention is essential for wide scale implementation, we recommend including high quality cost-effectiveness analyses in future trials studying the effects of novel telemonitoring cardiac rehabilitation interventions.

Moreover, with current budget limits and focus on cost savings in healthcare, cost-effectiveness is a key parameter for policy-makers in the decision to implement novel interventions. A shift in the reimbursement of care is necessary, because telemonitoring interventions change the delivery of care from hospital-based care to care at home. The current reimbursement model, in which healthcare providers get paid for the number of visits (fee-for-service), lacks incentives to implement interventions that reduces those hospital visits. Therefore, a shift towards a pay-for-performance reimbursement model is necessary. If the quality and efficiency of the treatments are linked to the reimbursement for care, healthcare organisations are encouraged to implement novel interventions that improve the quality of care [14].

Unanswered questions and future work
This thesis provides insight into various topics concerning innovative cardiac rehabilitation programmes, however, some questions remain unanswered and new questions have emerged. We showed that energy expenditure is the most important determinant for improvement
in exercise capacity in exercise-based cardiac rehabilitation. However, we did not take the effect of training modality into account. In current literature, there is debate whether interval training should be preferred to continuous training for cardiac patients [15,16]. High intensity interval training has shown to be at least as effective as moderate intensity continuous training, it is safe to perform and often requires less exercise time [15,17]. Therefore, it could be a useful alternative to conventional continuous training. On the other hand, high-intensity interval training is more difficult to perform in the home environment considering that fitness equipment is often not available at home and a high training intensity is harder to reach and control during outdoor walking or biking. Nonetheless, it is important to understand the effect of training modality on physical fitness in the design of a cardiac rehabilitation programme. Therefore, we recommend that future studies comparing training modalities correct for total energy expenditure of the training programmes in their analyses, or perform an isocaloric comparison. Furthermore, as previous studies have shown, there can be a substantial gap between prescribed training protocol and the exercises that were actually performed by the patients, hampering the empirical comparison of different training protocols [18]. Therefore, we recommend reporting both the prescribed protocol and the actually performed training. With the current development in wearable sensors, heart rate monitors are able to track the performed training protocol accurately and are widely available.

The beneficial effects of cardiac rehabilitation often decrease after the transition from supervised centre-based training to independent training at home [19]. We therefore hypothesised that training in the home environment with telemonitoring guidance would result in superior long-term effects compared to centre-based training. However, patients in both groups of the FIT@Home study were able to maintain their physical fitness levels at one-year follow-up. The unexpected favourable results from the centre-based cardiac rehabilitation group could be explained by the content of the programme, and our recruitment and selection process. First, today’s cardiac rehabilitation guidelines are more focused on the maintenance of exercise behaviour than several years ago [7]. Therefore, the professionals involved in the centre-based programme may have concentrated more on the maintenance of exercise behaviour than professionals in previous studies. Second, the nature of our intervention, with its emphasis on technology and individual training, prompted mainly young and motivated patients to participate in our study. It is not surprising that they were able to maintain their long-term physical activity levels, even when they started with centre-based training and had to make the transition to the home environment. We therefore suspect that the difference in long-term effects between the centre-based and home-based participants in our trial is biased towards zero. We recommend future studies to adopt innovative strategies to limit this selection bias. For instance, two additional non-randomised, preference-based trial-arms could be added to the conventional randomised controlled trial study design. Although this has substantial implications for the sample size and costs of the study, a more mixed cardiac rehabilitation population could be included, thus enhancing the external validity of the results [20].
The rapid changes in the technological landscape will allow future studies to incorporate innovations that will improve the quality of cardiac rehabilitation. By fully utilising the potential of digital health and telemonitoring, cardiac rehabilitation can be improved even more than described in this thesis. First, wearable sensors, such as smart-watches and activity-trackers, are becoming more accurate and provide the opportunity to monitor more clinical parameters. In addition, sensors are integrated in consumer-end devices and are released by popular non-healthcare brands. As a result, the user-population increases and the concept of activity tracking is becoming more popular. With this in mind, home-based data gathering will increasingly be accepted by patients and clinicians, and subsequently incorporated in the delivery of care [20]. Second, the data generated by those sensors can be analysed and utilised to optimise feedback and supervision during behavioural-change programmes like cardiac rehabilitation. As our results showed, future studies should use physical activity data in behavioural-change coaching techniques, such as Motivational Interviewing and on-demand relapse-prevention, during telemonitoring guidance to improve physical activity levels. Furthermore, sharing data with relatives and other cardiac rehabilitation patients can induce social support and peer pressure, which can motivate patients during the training programme [21,22]. Thirdly, modern telecommunication methods can improve access to healthcare services and improve guidance during home-based interventions [23]. During our study we provided feedback on the exercise sessions by phone. However, video communication can provide crucial nonverbal information and provide a closer simulation of face-to-face contact than telephone contact. If we can fully exploit the potential of these technological developments in the next years, we can make cardiac rehabilitation more appealing and optimise the quality of care delivered.

**Conclusion**

In this thesis we have developed and evaluated the effectiveness of a home-based training intervention that accommodates the preferences and constraints of patients while retaining the effectiveness of conventional, centre-based cardiac rehabilitation. Our systematic reviews of the literature found that the effectiveness of centre-based programmes is mainly determined by their total energy expenditure. This means that adjustments to programme characteristics can be made freely, without impairing effects on exercise capacity. Provided that energy expenditure as a whole is preserved. Therefore, training programmes can be tailored towards patients’ preferences and translated to the home environment. Furthermore, we conclude that home-based cardiac rehabilitation with telemonitoring guidance is a useful alternative to centre-based cardiac rehabilitation for young and motivated patients with low-to-moderate cardiac risks. Home-based training resulted in similar improvements in physical fitness and health-related quality of life as centre-based training, with a trend towards lower costs. We showed that wearable sensors can accurately assess physical activity levels of beta-blocker medicated cardiac patients. However, physical activity levels did not improve during and after completion of the cardiac
rehabilitation programme, suggesting that some form of physical activity guidance is essential to increase physical activity levels. We believe that our work is an important step towards the development of personalised cardiac rehabilitation, and we encourage future interventions to build upon our lessons learned.
References


