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

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Chapter 1
Introduction and outline of this thesis
In this thesis we explore the opportunities to improve secondary prevention interventions for patients after a cardiac incident. With the current developments in (health-) technology, wearable sensors, eHealth and The Internet of Things, conducting a regular “one-size-fits-all” intervention for patients entering cardiac rehabilitation is out-dated and limits effectiveness. In addition, to control the vast increase in healthcare costs, novel interventions should be tested on cost-effectiveness and subsequently implemented to evolve and sustain healthcare. This thesis describes opportunities to make cardiac rehabilitation more appealing for cardiac patients who are unwilling or unable to participate in centre-based cardiac rehabilitation, without losing its clinical effectiveness.

Introduction

Background

Cardiovascular disease is one of the leading causes of death. Across Europe, cardiovascular disease results in 4.1 million deaths per year and accounted for almost 47% of all deaths in 2014 [1]. Healthcare costs associated with cardiovascular disease in the European Union are estimated to amount for over €100 billion a year, almost 10% of the total healthcare expenses [2]. In the Netherlands, over 600,000 people have currently been diagnosed with coronary artery disease (CAD). Although the prevalence of CAD is decreasing, CAD still represents almost 30% of all deaths [3].

Similar to other chronic diseases, CAD is mainly caused by individual behavioural and lifestyle factors, such as smoking, physical inactivity and an unhealthy diet [4], causing increased blood pressure, raised blood glucose and lipid levels, overweight and obesity. Prevention of CAD and its recurrence (secondary prevention) can be achieved by adopting a healthy lifestyle, consisting of regular physical exercise, a healthy diet, reducing stress levels and smoking cessation [5,6]. Physical exercise has shown to reduce cardiovascular risk factors (e.g. reduced blood pressure, decreased triglyceride levels and increased HDL cholesterol) [7] and has a direct influence on the heart and cardiovascular system. With physical exercise, the myocardial oxygen demand decreases, endothelial function improves and the development of coronary collateral vessels is stimulated [8,9]. Therefore, physical exercise is considered a crucial part of cardiac rehabilitation [6,10]. Cardiac rehabilitation is a multidimensional intervention provided to patients after a cardiac event (myocardial infarction, angina pectoris) or intervention (percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG) and/or pharmacological treatment) [6]. Previous studies have shown that structured exercise-based cardiac rehabilitation programmes reduce mortality, prevent hospital readmission and improve quality of life in patients with CAD in a cost-effective manner [10–12]. Therefore, cardiac rehabilitation is highly recommended in both US and EU guidelines [13,14] and fully reimbursed by the health insurance in the Netherlands.
Barriers in cardiac rehabilitation

Although the beneficial effects of exercise-based cardiac rehabilitation were shown repeatedly, two persistent barriers limit the effectiveness of cardiac rehabilitation. First, participation rates are low, causing eligible patients to miss out on the beneficial effects of cardiac rehabilitation. Second, traditional cardiac rehabilitation programmes tend to focus on short-term physical recovery rather than long-term improvements in physical fitness and activity levels.

A cohort study performed in the Netherlands showed that only 28% of the eligible patients participated in cardiac rehabilitation [15], confirming the results of a European survey that concluded that cardiac rehabilitation services are vastly under-utilised [16]. Although systematic barriers (e.g., lack of referral for cardiac rehabilitation) can partly explain low uptake numbers, practical and personal barriers are also evident [17]. For example, distance and travel time to the outpatient clinic has been shown to negatively affect participation rates. Similarly, a lack of time due to work resumption is a major reason for not participating in cardiac rehabilitation [18]. In addition, personal barriers can be a reason to refrain from cardiac rehabilitation participation, such as reluctance to participate in group-based training, or individual training preferences that deviate from the training provided at the outpatient clinic [18].

Previous studies showed that patients that do participate in cardiac rehabilitation improve their physical fitness, quality of life and initiate an active lifestyle on the short-term but often relapse into old lifestyle habits over time [19,20]. Therefore, the focus during cardiac rehabilitation should be on long-term lifestyle changes. A critical event is the transition from supervised training in the outpatient clinic to individual training in the home environment after cardiac rehabilitation. In traditional cardiac rehabilitation programmes, guidance on integration of exercise training in routine daily life is often not provided and no assistance from healthcare professionals is available when the patient is unable to maintain the lifestyle changes.

Home-based training with telemonitoring guidance

To address the aforementioned barriers, cardiac rehabilitation programmes should be better tailored to patients’ individual needs, constraints and preferences, without losing its clinical effectiveness. A proposed solution is exercise-based cardiac rehabilitation in the home environment. Home-based cardiac rehabilitation does not require journeys to the outpatient clinic, training sessions can be scheduled individually and independently, and cardiac rehabilitation can be combined with work resumption [18,21]. In addition, home-based cardiac rehabilitation provides the opportunity to combine evidence-based behavioural change-strategies with modern wearable sensor techniques in the telemonitoring guidance, during the integration of exercise training in daily routine.

Previous studies have shown that structured home-based cardiac rehabilitation is safe and short-term results of home-based cardiac rehabilitation are similar to the results of centre-based
cardiac rehabilitation [22–25]. However, it is important to note that the interventions described in these studies vary considerably with respect to both the prescribed training protocols and the telemonitoring guidance provided during home-based training. There is no general guideline for home-based training yet, hence training protocols from centre-based cardiac rehabilitation are often translated to the home environment [26]. However, those recommendations cannot be translated directly to home-based training. For instance, fitness equipment used in the outpatient clinic is seldom available at home and high-intensity interval training is difficult to perform during outdoor walking or cycling. Therefore, we should define the characteristics of exercise training that determine the improvement in physical fitness, so we can provide recommendations for designing a feasible and effective home-based training programme for cardiac rehabilitation patients.

Recent advances in sensor technology and ubiquitous connectivity have created opportunities to monitor and guide patients that are exercising in the home environment in real time. Wearable sensors and Internet applications (e.g. heart rate monitors and online dashboards) can provide an accurate insight in training data, which can be used by both the patient and the physical therapist to improve future exercise sessions [27]. Wearable sensors can also be used to monitor physical activity behaviour in the home environment [28]. Although physical inactivity is a major risk factor for cardiovascular disease [29], physical activity levels are rarely monitored during cardiac rehabilitation. Currently, patients are asked about their physical activity behaviour at the start and end of the rehabilitation programme using questionnaires, which often leads to socially desirable responses [30]. With wearable sensors (e.g. accelerometers and/or heart rate monitors) reliable physical activity measurements are obtained and can be used to monitor physical activity levels during cardiac rehabilitation [30,31].

If exercise data and physical activity data are combined with evidence-based behavioural-change coaching techniques during telemonitoring guidance, the intervention has the potential to induce more sustainable results. As such, motivational interviewing, a technique to approach people that are engaged in behavioural change, has shown to improve the success rate of interventions [32]. Feedback on objective training data and insight in training progress enhances a patients’ self-efficacy, the confidence in one’s own ability to execute and complete a task or goal [27]. In addition, independent training in the home environment promotes the development of self-management skills (e.g. action planning, problem solving, decision making), which are required to maintain an active lifestyle after completion of cardiac rehabilitation [33,34]. If those techniques are included in the telemonitoring guidance of home-based cardiac rehabilitation, we expect it can improve long-term benefits of cardiac rehabilitation, and that home-based cardiac rehabilitation is an eligible alternative to centre-based cardiac rehabilitation. However, cost-effectiveness of a novel intervention is essential for wide scale implementation. Unfortunately, cost-effectiveness analyses of home-based cardiac rehabilitation interventions are scarce and the sparse literature is inconclusive due to the high variation in training protocols and telemonitoring guidance in home-based interventions [35–37]. Therefore, a novel intervention like home-based cardiac
rehabilitation requires a comprehensive cost-effectiveness analysis to determine whether the intervention is a valuable alternative to conventional centre-based cardiac rehabilitation.

The aim of this thesis was to develop and evaluate the effectiveness of a home-based training intervention that suits the preferences of a patient entering cardiac rehabilitation, without losing its clinical effectiveness. Therefore, we addressed the following three objectives:

- To identify which characteristics of a training protocol (i.e. training intensity, session frequency, session duration, programme length) determine physical fitness improvement after exercise training in cardiac rehabilitation patients, exploring the best training approach for home-based training.
- To develop a physical activity prediction-model to accurately assess and monitor daily activity behaviour in the home-environment.
- To compare the clinical effectiveness and cost-effectiveness of home-based exercise training including telemonitoring guidance with conventional centre-based exercise training in low-to-moderate cardiac risk patients entering cardiac rehabilitation.

Outline of this thesis

The first part of this thesis focuses on the development of a home-based cardiac rehabilitation intervention. In two systematic literature reviews we study the effect of individual training characteristics on the improvement of physical fitness in coronary artery disease patients (Chapter 02) and chronic heart failure patient (Chapter 03). Although previous literature showed that exercise training in both groups resulted in an improvement in physical fitness, it is unclear to what extent the different training characteristics determine this improvement. We analyse each training programme in terms of session frequency, session duration, training intensity and programme length. In addition, we analyse the effect of the product of those four characteristics, energy expenditure, and study the effect of those characteristics on the improvement of physical fitness. In Chapter 04 we focus on the assessment of physical activity levels of cardiac rehabilitation patients, and develop an energy expenditure prediction model to assess and monitor physical activity levels of patients at home during cardiac rehabilitation. Based on previous methods validated on healthy adults, we combine heart rate and body movement data with patient characteristics to accurately estimate physical activity levels of patients in the home environment. In Chapter 05 we combine the results of the abovementioned chapters and describe the rationale and methodology of the FIT@Home trial, a home-based cardiac rehabilitation intervention with telemonitoring guidance.

In Chapter 06 we describe the interim short-term results of the randomised controlled trial. Data on physical fitness, health-related quality of life and training adherence of the first 25 patients included in the trial are reported. The final results from the FIT@Home trial, both short- and
long-term are described in Chapter 07. In addition to physical fitness and health-related quality of life, also physical activity levels, patient satisfaction and cost-effectiveness of home-based exercise training is compared with centre-based exercise training. The results and the implications of this trial, combined the first chapters of this thesis, are summarised and discussed in Chapter 08.


