Effects of homebased training with telemonitoring guidance in low to moderate risk patients entering cardiac rehabilitation

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON41640

Source
ToetsingOnline

Brief title
FIT@Home

Condition

- Myocardial disorders

Synonym
acute coronary syndrome, Revascularization

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Exercise Therapy, Myocardial Infarction, Rehabilitation, Telemonitoring

Outcome measures

Primary outcome

Change in physical activity: The physical activity level is assessed by physical activity energy expenditure (PAEE). To calculate PAEE, accelerometrydata (counts/min) will be time-aligned with HR data (bts/min). A previously validated branched equation model will be applied to the data to calculate PAEE (Mj/day).

Change in physical fitness: Physical fitness will be assessed by peak oxygen uptake, determined by maximal exercise testing with respiratory gas analysis.

Secondary outcome

Training adherence

Health-related quality of life

Patient Satisfaction

Cost-effectiviness

Study description

Background summary

Physical training has beneficial effects on exercise capacity, cardiac function, quality of life and mortality in patients with acute cardiovascular syndrome or after cardiac surgery and is therefore one of the main aspects of cardiac rehabilitation. However, adherence to this therapy is low and effects

tempt to decrease directly after the treatment period.

Study objective

The objective of the present study is to investigate whether home-based exercise training with telemonitoring guidance results in improved long-term physical fitness and higher activity levels than regular centre-based exercise training in patients after an ACS or revascularization procedure with a low to moderate risk of further events. Furthermore, both training strategies will be compared with respect to training adherence (during the first 12 weeks), health-related quality of life, patient satisfaction and their relative cost-effectiveness. In a systematic review and meta-analysis published in 2010, home-based training was shown to be equally effective as centre-based training in low-to-moderate risk CR patients.However, the included studies did not apply telemonitoring guidance and in most studies training data could not be reviewed and used to instruct and motivate patients. We hypothesize that telemonitoring guidance using objective training data during the initial rehabilitation period will increase motivation and self-efficacy for independent exercise in CR patients on the longer term (i.e. 1 year after the index event/intervention), eventually resulting in a superior increase in physical fitness and physical activity levels as compared to a traditional centre-based CR program. From a cost perspective, we expect that the investments in monitoring devices and ICT services are compensated for by lower direct medical costs in the home-based training group due to fewer supervised exercise training sessions.

Study design

This study is designed as a monocentre randomized controlled trial among low to moderate risk post- ACS and -revascularization patients at Máxima Medical Centre, a large non-university teaching hospital. All patients referred for CR at Máxima Medical Centre are evaluated at the outpatient clinic first. During this intake procedure, the contents of the CR program is determined based on an individual needs assessment. All patients with an indication for exercise training meeting in and exclusion criteria are asked to participate and receive verbal and written patient information about the study at the end of the intake procedure. All other treatment modalities take place at the hospital as usual (e.g. education therapy, lifestyle change therapy, and/or relaxation and stress management training). After 1 week patients are contacted by the coordinating investigator. If they consent to participate, they are asked to complete and sign the informed consent form. During the first week of the study, all included patients undergo baseline measurements, consisting of maximal exercise testing with respiratory gas analysis on a cycle ergometer and assessment of the physical activity level by continuous accelerometry and heart rate measurement during a 5-day period. Subsequently patients will be randomized in a 1:1 ratio using sealed envelopes. One group will be allocated to home-based training (HT) with telemonitoring guidance (n=45), the other group to a common

12-week centre-based program (CT, n=45). Due to the nature of the intervention, it is not possible to blind either patients or their caregivers to allocation.
In both groups patients receive further instructions during the first session at the department of physical therapy. Maximal exercise testing with gas analysis and continuous physical activity assessment will be repeated after the training period of 12 weeks, and again after 1 year.
A subgroup of 20 patients will also participate in a sub study: modelling of energy expenditure in cardiac rehabilitation patients. This study aims to develop a model which can be used to assess Physical Activity Energy Expenditure reliably in cardiac rehabilitation patients by using heart rate and accelerometry data. These patients will undergo mobile oxygen uptake measurements with simultaneous heart rate and accelerometry assessment at rest and during several activities of low-to-moderate intensity.
A subgroup of 20 patients will participate in a second sub study: exit interviews with FIT@Home participants. Ten patients from each group will be interviewed after the last their last measurement of physical fitness. Each interview will take approximately 45 minutes and is performed to identify the strengths and weaknesses of the research protocol.

Intervention

In the intervention, the first three training sessions of cardiac rehabilitation will be performed in the hospital under direct supervision of a physical therapist. During these sessions they will be familiarized with training duration and intensity and they will be instructed on how to use the wearable HR monitoring device in order to achieve their personal training targets. In addition, patients are asked about their preferred training modality in their home environment (e.g. cycling, walking/running, workout at health club), and, if needed, given advice on how to implement this. Patients are instructed to wear the HR monitoring device during training sessions and to upload their recorded HR data to an online platform (Garmin Connect). Garmin Connect can be used by patients to review their training data graphically and to relate these to their personal goals (training duration and frequency targets as well as HR target zones are entered in advance through the Garmin Connect Dashboard). Training data are also accessed through Garmin Connect by an exercise specialist (ES), a physical therapist specialized in CR, on a weekly basis. During the training program, the ES will contact subjects by telephone every week, providing feedback on training frequency, duration and % of training within the HR target zone. Patients are also informed on the possibility to exchange training data with other participants or family/friends either through the Garmin Connect Dashboard or through a connection of their Garmin account with social media (Facebook, LinkedIn, Twitter, Google). For privacy reasons, access to their training data is only possible with their explicit permission. Also the ES will no longer have access to the training data after the training period. Patients themselves however have the possibility, and are encouraged to continue using their Garmin account. To obtain insight in the subjective experiences of data sharing, a sample of

patients will be interviewed after the training period on their data exchange behavior.

Study burden and risks

The present study will focus on cardiac patients entering outpatient CR after an ACS or a revascularization procedure with a low to moderate risk of further events. As the intervention comprises home-based training during the early rehabilitation period, high risk patients will not be included (e.g. patients with symptomatic heart failure, complex congenital heart disease, severe depression, arrhythmia*s or co-morbidity).

Exercise training performed by post-ACS and revascularization patients, classified as low to moderate risk, is considered to be safe. In order to reduce potential risks of exercise training all patients perform a maximal cardiopulmonary exercise test at baseline, excluding patients with myocardial ischaemia and ventricular arrhythmias during exercise. The first three training sessions will be under supervision of trained physiotherapist in a clinical setting. During those three meetings they will be counselled regarding training modality, the heart rate sensor and safety. Patients can contact the rehabilitation centre or general practitioner if they experience any symptoms during exercise. If preferred, patients can always stop with the home-based intervention and the study protocol and resume regular supervised rehabilitation without consequences.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients with an ACS (including non ST and ST elevation myocardial infarction and unstable angina) or a cardiac revascularization procedure (PCI or CABG) entering outpatient CR at Máxima Medical Centre.
- Indication for exercise training according to the Dutch clinical algorithm for assessment of patient needs in cardiac rehabilitation.
- Internet access and PC at home (i.e. >90% of the Dutch households)

Exclusion criteria

- High risk according to the Dutch CR practice guideline
- Systolic heart failure (left ventricular ejection fraction < 40%):
- New York Heart Association class III-IV (i.e. breathlessness during light exercise or at rest)
- Severe arrhythmia
- Implantable Cardioverter-Defibrilator (ICD) implantation
- Chronic angina or silent ischemia
- Comorbidity impairing exercise capacity (eg. COPD, diabetes mellitus, peripheral vascular disease and orthopedic or neurological conditions)
- Severe psychological/cognitive impairments

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-01-2013
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	30-11-2012
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	25-09-2013
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	06-02-2015
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01732419
CCMO	NL41551.015.12

Study results

Date completed:	01-06-2016
Results posted:	04-11-2016
Actual enrolment:	90

Summary results
Trial is onging in other countries

First publication
26-10-2016