A personalized mHealth training application to increase physical activity during and after cardiac rehabilitation.

Published: 16-04-2020
Last updated: 10-04-2024

Primary Objective:The aim of the study is to assess the effect of an additional home-based training module during CR and post-CR on physical activity levels among coronary artery disease (CAD) patients.Secondary Objective:The secondary aim of the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON49556

Source
ToetsingOnline

Brief title
Cardiac RehApp

Condition

- Coronary artery disorders

Synonym
Coronary artery disease, coronary heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Eurostars 2020

Intervention

Keyword: Cardiac Rehabilitation, Home-based training, mHealth, Physical activity

Outcome measures

Primary outcome

The main study endpoint is the change in physical activity volume (min/week) between the four groups at post-CR and after follow-up. Physical activity patterns will be objectively measured with a validated activity-monitor (ActivPAL micro, PAL technologies, Glasgow, United Kingdom).

Secondary outcome

Secondary study endpoints are:

* The change in total sitting time (min/week) between the four groups at post-CR and after follow-up.

* Physical fitness between the four groups at post-CR and after follow-up measured with a submaximal exercise test (Astrand-rhyming)

* Handgrip strength

* Quality of life (Quality of life questionnaire - heart)

* Cardiac anxiety (Cardiac Anxiety Questionnaire).

* Laboratory values (lipid spectrum, cardiac biomarkers)

Study description

Background summary

Despite strong recommendations (class 1) and health benefits of cardiac rehabilitation (CR) programs, many patients lapse into a physically inactive lifestyle within months after CR completion. A potential solution to change this unhealthy behavior can be a more intense CR program, including a

combination of center-based exercise training and home-based exercise training. Furthermore, prolongation of center-based CR (6 weeks exercise training in usual care) with home-based CR (daily exercise instructions) could increase its effect on habitual physical activity levels. The availability of mobile-health (mHealth) interventions such as smartphone applications allow researchers and clinicians to explore the health benefits of home-based CR on cardiovascular risk factors and clinical outcomes.

Study objective

Primary Objective:
The aim of the study is to assess the effect of an additional home-based training module during CR and post-CR on physical activity levels among coronary artery disease (CAD) patients.

Secondary Objective:
The secondary aim of the study is to compare the effects of an additional home-based training module during CR and post-CR on total sitting time (min/week), physical fitness (VO2), quality of life, cardiac anxiety score, laboratory values, and cardiovascular risk scores among CAD patients.

Tertiary Objective:
To compare all-cause mortality, cardiovascular mortality, rehospitalisation and recurrence of acute coronary syndromes between groups during 5 years of follow-up.

Study design

In order to provide insight in the effectiveness of a additional home-based training module on the physical activity levels in CAD patients, an 18 week randomized controlled trial with 4 arms will be performed. Participants will will be randomly assigned by an independent researcher to either:
1) CR 6 weeks center-based CR followed by 12 weeks usual care
2) CR+ 6 weeks center-based CR followed by 12 weeks home-based exercise training
3) +CR 6 weeks center-based CR combined with home-based exercise training followed by 12 weeks usual care
4) +CR+ 6 weeks center-based CR combined with home-based exercise training followed by 12 weeks home-based exercise training.

Overview
In the first group (CR), participants will participate in the 6-week center-based CR program (i.e. usual care). After completion of the program, they will follow usual care (no intervention) during the 12 weeks of follow-up.
In the second group (CR+), participants will participate in a 6-week center-based CR program (i.e. usual care). After completion of the center-based

program, participants receive 12 weeks of post-CR home-based training. The third group (+CR) will participate in the 6-week center-based CR program combined with a 6-week home-based training module. After the completion of the 6-week programs, participants will follow usual care (no intervention). The fourth group (+CR+) will participate in the 6-week center-based CR program combined with a 6-week home-based training module. After completion, participants receive 12 weeks of post-CR home-based training.

Intervention

Subjects in group 2(CR+), 3 (+CR) and 4(+CR+) will be asked to perform physical activity in their home situation using a mHealth application called Virtual Training® (introduction video: https://www.youtube.com/watch?v=uhgBoeEMbcI). The application shows the different training programs and provides instructions in the form of both video and text during the exercise. Figure 3 shows an example of the interface of the application

Based on the participants preferences and status, a home-based training program will be drafted by the treating physical therapist. An exercise program will consist of 10-15 bodyweight exercises which patients can perform in their home environment. Exercises are performed in 1-3 sets consisting of either 10-15 repetitions or are timebound (ranging from 30 to 120 seconds). Furthermore, patients can record their walking and biking behaviour using the Virtual Training® application. Subjects will be instructed to try to exercise daily using the Virtual Training® application on a self-chosen moment.

During the center-based rehabilitation period (first 6 week), the intensity of the program of the home-based exercises will be adjusted to the patient*s status and level of physical activity. In the beginning, the exercise program will consist of lighter exercises and longer breaks. Based on the individual participants progression, intensity of exercises and total training program will be increased over 6 weeks. In the 12-week follow-up groups (CR+ and +CR+), intensity and frequency of the program can be adjusted in consultation between the participants and physical therapist.

In the Virtual Training® application, patients can contact their treating physical therapist by sending an in-application text. Questions regarding the training program, exercises, execution or problems can be discussed at any moment.

Study burden and risks

With the results of this study we hope to gain further insight into the potential beneficial effects on physical activity of a center-based CR program plus home-based CR. Risks as the result of participation in this study are minimal. The home-based exercise program is of low to moderate intensity (both

aerobic and strengths exercises) making the possibilities of AE minimal. One potential risk is that patients could experience muscle pain, although this is risk is minimized by personalizing the exercise training part as much as possible, so that participants receive a customized training incentive. Participants in the home-based CR group could potentially benefit from an improvement in their cardiovascular health. There are no notable risks of participating in this study. According to the NFU risk classification guidelines, the present study qualifies as being of *negligible risk* to the participants since there is low likelihood of minor damage, low risks associated with the specific population, low social risks to the participant, and low risk associated with the research set-up and execution.

Contacts

Public
Radboud Universitair Medisch Centrum

Philips van Leydenlaan 15
Nijmegen 6525 EX
NL
Scientific
Radboud Universitair Medisch Centrum

Philips van Leydenlaan 15
Nijmegen 6525 EX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Participants must be older than 18 years of age
* Diagnosed with coronary artery disease (ST-elevation myocardial infarction (STEMI) * non-ST-elevation myocardial infarction (NSTEMI) * UAP (unstable angina pectoris) * stable angina pectoris (AP))
* Being able to operate a smartphone with the Virtual Training application.
* Referred to cardiac rehabilitation
* Able to understand and perform the study procedures.

Exclusion criteria

* Not in the possession of a smartphone, or unable to operate a smartphone for the purpose of the trial (because of vision, hearing, and cognitive or dexterity impairment).
* Have no (mobile) internet access at their place of residence.
* Have contraindications to exercise rehabilitation.
* Subjects who have severe orthopaedic that restricts physical activity.
* Unable to give informed consent
* Language barrier

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-12-2020
Enrollment:	132
Type:	Actual

Ethics review

Approved WMO Date:	16-04-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-06-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL72182.091.19