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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21360

Source
NTR

Brief title
Cardiac RehApp

Health condition

Coronary heart diseases

Sponsors and support

Primary sponsor: Eurstars-Eureka
Source(s) of monetary or material Support: Eurstars-Eureka

Intervention

Outcome measures

Primary outcome

Time spent moderate to vigorous intensity activities (min/week)

Secondary outcome

Total sitting time (min/week), physical fitness (VO2max), handgrip strength, CV risk profile, quality of life and, cardiac anxiety scores.

Study description

Background summary

Rationale:
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 inactive behavior can be adding a home-based personalized training component to the CR program, resulting in a combination of center-based exercise training and home-based exercise training. Furthermore, prolongation of center-based CR (6 weeks of exercise training in usual care) with home-based personalized CR (daily exercise instructions) could increase its effect on habitual physical activity levels. The availability of mobile health (mHealth) interventions, such as smartphone applications, allows researchers and clinicians to explore the health benefits of home-based CR on cardiovascular risk factors and clinical outcomes.

Objective:
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.
Study design: An 18-week randomized controlled trial with 4 arms will be performed:
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

Study population:
We will recruit 132 adult individuals diagnosed with coronary artery disease(CAD) who are referred to CR. Patients must be older than 18 years of age, and being able to operate a smartphone with the Virtual Training application.

Intervention:
A (mHealth) application (i.e. Virtual Training) will be used to prescribe personalized exercise training in addition to the usual center-based CR program and/or as an extension of CR.

Main study parameters/endpoints: The primary outcome will be habitual physical activity levels expressed in time spent moderate to vigorous intensity activities (min/week). Secondary outcome parameters include total sitting time (min/week), physical fitness (VO2max), handgrip strength, CV risk profile, quality of life, and cardiac anxiety scores. Tertiary outcomes include incidence of hospital admissions, cardiovascular morbidity, and mortality during 5 years of follow-up.

Study objective

-The combination of center-based CR and a home-based exercise training program will lead to a greater increase in physical activity levels compared to standard care.

-Continuation of home-based exercise during a three-month follow-up will lead to an increase in habitual physical activity level compared to standard care.

Study design

Both primary and secondary outcomes are measured three times:
1. Visit 1 (baseline measurements) is scheduled along the CR orientation visit (start CR)
2. Visit 2 (post-rehab measurements) will be scheduled after the last session of the center-based CR program.
3. The third and final visit (follow-up measurements) will be scheduled 12-weeks after completion of the CR.

Primary outcome:
Physical activity patterns will be objectively measured three times with a validated accelerometer (ActivPAL micro, PAL technologies, Glasgow, United Kingdom). The ActivPAL will be worn three times: prior to the start of CR, at the end of CR and after three months follow-up.

Secondary outcome
• Physical fitness between the four groups at post-CR and after follow-up measured with a submaximal exercise test (Astrand-rhyming cycle ergometer test)
• Handgrip strength assessed with a hydraulic, analogue hand dynamometer (Jamar, Jackson, MI, USA)
• Quality of life questionnaire (HeartQoL)
• Cardiac anxiety (Cardiac Anxiety Questionnaire).
• Laboratory values (lipid spectrum, cardiac biomarkers) obtained by venepuncture

Intervention

A (mHealth) application will be used to prescribe personalized exercise training in addition to the usual center-based CR program and/or as an extension of CR.

Contacts

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Eligibility criteria

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 perform exercise during the rehabilitation program.
-Subjects who have severe orthopaedic problems that restrict 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)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2020
Enrollment:	132
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-12-2020
Application type:	First submission

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
NTR-new	NL9156
Other	CCMO Regio Arnhem-Nijmegen : METC 2019-6045

Study results