Effects of cardiac telerehabilitation in patients with coronary artery disease using a personalized patient-centred ICT platform:
the SmartCare-CAD study

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To investigate whether cardiac telerehabilitation using a personalized patient-centred ICT platform comprising remote monitoring and coaching of physical activity behaviour results in an improved long-term daily physical activity level as compared...

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

Summary

ID

NL-OMON45170

Source
ToetsingOnline

Brief title
SmartCare-CAD study

Condition

- Coronary artery disorders

Synonym
atherosclerosis, myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: EU

Intervention

Keyword: Activity coaching, Cardiac rehabilitation, Self-management, Telemonitoring

Outcome measures

Primary outcome

The primary endpoint is the change in physical activity level (physical

activity energy expenditure, PAEE) from baseline to 12 months.

Secondary outcome

PAEE at 3 months

maximal exercise capacity,

Body Mass Index

blood pressure

health related quality of life

anxiety/depression

health care costs

impact of telehealth care

patient empowerment

Study description

Background summary

Despite its proven effectiveness, cardiac rehabilitation (CR) is still vastly underutilized due to transport difficulties, lack of time, scheduling care of dependents, and reluctance to take part in group-based therapy. Also, physical

fitness and activity levels often decline and relapse into unhealthy behaviours is common after completion of a typical 12-week centre-based CR program due to a lack of development of self-management skills and a lack of communication between caregivers. Therefore, there is an urgent need for innovative rehabilitation methods aiming at an increase of CR uptake and more sustained effects on cardiovascular risk behaviour.

Study objective

To investigate whether cardiac telerehabilitation using a personalized patient-centred ICT platform comprising remote monitoring and coaching of physical activity behaviour results in an improved long-term daily physical activity level as compared to centre based CR in patients with coronary artery disease (CAD).

Study design

Single-centre, randomized controlled trial among 300 patients with CAD entering CR.

Intervention

Patients allocated to the intervention group receive access to a secured personalized patient-centred web-based ICT platform which can be used to register and adjust medication, rehabilitation goals, treatments, measurements (e.g. physical activity, blood pressure, weight) and scheduled appointments with caregivers. In addition, they are offered the possibility to perform exercise training in their home environment with remote monitoring of training and activity data using accelerometry and heart rate assessment. Coaching consists of weekly video consulting by a physical therapist that has access to the ICT platform containing the exercise data. After the initial CR period, exercise data will be reviewed 4-weekly and patients are contacted if adherence to the exercise goals decreases with 50% or more. Furthermore, patients are encouraged to keep using the ICT platform and share information with relevant caregivers.

Study burden and risks

The core component of the study intervention is a secured personalized patient-centred web-based ICT platform. Patients assigned to the intervention group will be offered the possibility to perform part of the training program in their home environment with remote coaching using video consulting. Furthermore, they are enabled to use the ICT platform to keep record of their medication, rehabilitation goals, treatments, relevant measurements and appointments. This information may also be shared with other caregivers. Therefore, the intervention may be beneficial for participants. The risk of the

intervention is considered to be low, as exercise training is performed at home only if the cardiologist approves and if no ischemia and ventricular arrhythmias during low to moderate exercise intensity were observed during symptom limiting exercise testing. Security of data transport is warranted by encryption and signature layers.

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

* Referral for cardiac rehabilitation due to coronary artery disease
* Indication for exercise training as a part of outpatient cardiac rehabilitation
* Personal computer with internet access
* Possession of a mobile phone with SMS-functionality
* Age * 18 years

* Able to speak, read and write Dutch

Exclusion criteria

* Ventricular arrhythmia or myocardial ischemia during low to moderate exercise intensity
* Heart failure NYHA class IV
* Severe comorbidity precluding exercise training

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):	23-05-2016
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	09-01-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	27-01-2016

Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	04-03-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	19-05-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	13-12-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	20-11-2017
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

ID: 23825
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51367.015.14
OMON	NL-OMON23825