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

No registrations found.

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

Summary

ID

NL-OMON23825

Source
Nationaal Trial Register

Brief title
SmartCare-CAD

Health condition

coronary artery disease, stable angina, acute coronary syndrome, unstable angina, non ST-segment elevation myocardial infarction (NSTEMI), ST-segment elevation myocardial infarction (STEMI), myocardial revascularisation, percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG), cost effectiveness, physical activity, telemonitoring, telerehabilitation, cardiac rehabilitation.
Dutch: coronarialijden, stabiele angina pectoris, instabiele angina pectoris, acuut coronair syndroom, revascularisatie, kosteneffectiviteit, hartrevalidatie, telerevalidatie.

Sponsors and support

Primary sponsor: Máxima Medisch Centrum
Source(s) of monetary or material Support: European Union

Intervention

Outcome measures

Primary outcome

Change in physical activity level (physical activity energy expenditure, PAEE).

Secondary outcome

- Change in physical activity level (PAEE, 3 months)

- Maximal workload achieved

- Body Mass Index

- Blood pressure

- Health related quality of life

- Anxiety and depression

- Cost effectiveness analysis

- Impact of telehealth care

- Patient empowerment

Study description

Background summary

Despite its proven effectiveness, cardiac rehabilitation (CR) is still vastly underutilized mainly due to patient-related factors such as 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 integration of care among different 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.
Our objective is 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). 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 rehabilitation and treatment goals and other information. Patients are able to grant access to relevant pre-specified caregivers to these data. 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. The primary endpoint is the change in physical activity level (physical activity energy expenditure, PAEE) from baseline to 12 months. Secondary endpoints include 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 and patient empowerment.

Study objective

Multidisciplinary 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 cardiac rehabilitation in patients with coronary artery disease (CAD).

Study design

PRIMARY OUTCOME (PAEE): at 12 months. To calculate PAEE, accelerometry data (counts/min) will be time-aligned with HR data (bts/min) and re-sampled into 15-sec epochs. Consequently, a previously validated branched equation model will be applied to the data to calculate PAEE (Mj/day).

SECONDARY OUTCOMES:

- Change in physical activity level (PAEE, see above) at 3 months

- Maximal workload achieved at a symptom limited exercise test performed on a cycle ergometer: change from baseline at 3 and 12 months

- Body Mass Index: change from baseline at 3 and 12 months

- Blood pressure: change from baseline at 3 and 12 months

- Health related quality of life using KvL and SF-12: change from baseline at 3 and 12 months

- Anxiety/depression, using GAD-7 and PHQ: change from baseline at 3 and 12 months

- Cost effectiveness using iPCQ, iMCQ, iVICQ (and EQ-5D, ACIC): measurements at 3, 6, 9 and 12 months

- Impact of telehealth care using eCCIS: at 6 months

- Patient empowerment using PAM: at 6 months.

Intervention

Usual care:

Centre based cardiac rehabilitation (CR), consisting of one or more of the following treatments: exercise training, an information program, a relaxation program, psycho-educative prevention program and/or individual treatment by a psychologist or dietician. Exercise training sessions are performed under direct supervision of a physical therapist specialized in CR.

Intervention:

The core component of the study intervention is a secured and personalized patient-centred web-based ICT platform. This platform enables patients to register, evaluate and adjust rehabilitation goals, training goals and medication and to upload and inspect exercise training and daily physical activity data (as measured by a heart rate monitor and accelerometer). Besides this, it is possible to perform video consulting with physical therapists. Patients are able to grant access to relevant pre-specified caregivers to these data.
After three supervised in-hospital training sessions, patients are given the opportunity to continue exercise training at home, based on prescriptions from their physical therapist. They will upload training and physical activity data at least once a week. During a weekly video consult between the physical therapist and the patient, both exercise training and physical activity targets will be evaluated and adjusted if needed. During these consultations, motivational interviewing is applied. If the patient chooses to continue exercise training at the hospital, only physical activity will be monitored at home. During the training sessions at the hospital, exercise and physical activity targets will be evaluated and adjusted if needed. After finishing the exercise training program, updated exercise and physical activity targets will be recorded in the ICT platform. Every four weeks, the coordinating investigator will evaluate the exercise training and physical activity data and will schedule a video consult if targets are not met.

Contacts

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Eligibility criteria

Inclusion criteria

- Age 18 or over

- Referral for cardiac rehabilitation due to stable angina pectoris, acute coronary syndrome (with or without ST-segment elevation) or after coronary revascularization, i.e. (primary or elective) percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG)

- Indication for exercise training as a part of outpatient cardiac rehabilitation, based on the individual needs assessment from the guidelines on outpatient cardiac rehabilitation of the Dutch Society of Cardiology

- Internet access at home.

Exclusion criteria

- Ventricular arrhythmia or myocardial ischemia during low to moderate exercise intensity as assessed by symptom limited exercise testing at baseline

- Heart failure NYHA class IV

- Severe comorbidity precluding exercise training (e.g. orthopaedic or neurological conditions).

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2015
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-04-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45170
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5001

Register	ID
NTR-old	NTR5156
CCMO	NL51367.015.14
OMON	NL-OMON45170

Study results