Randomized clinical trial for an extended cardiac rehabilitation program using telemonitoring

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To assess whether an extension of the cardiac rehabilitation program with telemonitoring guidance results in better long term effects on physical and mental outcomes than a regular follow-up period after traditional cardiac rehabilitation.

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

Summary

ID

NL-OMON41024

Source
ToetsingOnline

Brief title
TeleCaRe study

Condition

- Myocardial disorders

Synonym
cardiovascular disease, heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Diagram B.V.

Intervention

Keyword: cardiac rehabilitation, telemonitoring

Outcome measures

Primary outcome

Main study parameter/endpoint is physical fitness defined by peak oxygen uptake obtained from an incremental maximal cycle ergometer exercise test at 12 months.

Secondary outcome

o Physical fitness (peak oxygen uptake obtained from maximal incremental cycle ergometer exercise test) at baseline and 6 months.

o Cardiac structure and function (cardiac dimensions, systolic and diastolic function parameters, valve disorders) at baseline and 12 months.

o General health (quality of life (KVL-H), physical functioning (IPAQ-long version), emotional functioning (PHQ-9, HADS), social functioning (MPSS) at baseline, 6 months and 12 months.

o Traditional risk factors (i.e. cholesterol, lipid profile, HbA1C, blood pressure, and body characteristics) at baseline, 6 months and 12 months.

o Compliance (use of the smartphone in the intervention group for at least half an hour at 5 five days per week during the first 6 months of the study)

o Care consumption ((days) admission, outpatient clinic visits, GP visits, interventions, radiology, nuclear and lab testing) collected throughout the study period.

o Major Adverse Cardiovascular Events (cardiovascular (CV) mortality, all-cause mortality, near sudden cardiac death, acute coronary syndrome, CV

intervention/surgery, CV hospital admission, CV Emergency visits) collected

throughout the study period.

Study description

Background summary

Cardiovascular diseases (CVDs) are the leading cause of death and a major cause of disability and loss of productivity in adults worldwide. In the Netherlands, the substantial burden of CVD is further exemplified by an estimated 45% increase of the number of patients with CVD from 2007-2025. Compliance to physical activity after cardiac rehabilitation, which is generally limited to 12 weeks at most, is found to be relatively low and less than half of the patients continue their physical training after initial rehabilitation. In addition to this, it has been shown that 44% of patients that underwent the standard cardiac rehabilitation program in the Netherlands required rehospitalization within five years.
The problem of low compliance to physical training after regular cardiac rehabilitation is often caused by the transition from a supervised to an unsupervised environment. In order to achieve long term effects on physical fitness and activity, patients need more guidance in this transition phase. On the short term, programs with telehealth interventions seem to be effective in improving self-management skills and provide an effective risk factor reduction and secondary prevention. However, long term effectiveness of telehealth interventions are still not known.

Study objective

To assess whether an extension of the cardiac rehabilitation program with telemonitoring guidance results in better long term effects on physical and mental outcomes than a regular follow-up period after traditional cardiac rehabilitation.

Study design

Randomized clinical trial

Intervention

The intervention of the study starts when patients finish their initial cardiac rehabilitation program. Patients participating in the extended cardiac rehabilitation program with telemonitoring will undergo 6 months of telemonitoring guidance and in addition another 6 months without

telemonitoring. The telemonitoring group will receive instructions before they start training with a heart rate monitor in their home environment. Patients are instructed to perform a moderate exercise 5 days per week for at least half an hour.

Study burden and risks

Noninvasive cardiac testing procedures in this study are not related to any potential risk for the participant. Maximal cycling tests will be performed at the hospital under supervision of highly qualified personnel.
A possible complication of venipuncture is a hematoma, which is induced in ~5% of all cases. To prevent complications, an experienced professional will perform the blood withdrawal and sufficient pressure will be provided after withdrawal of the needle. As patients are included in the study after participation in the standard cardiac rehabilitation program we expect no potential risk for them to exercise in their home environment.

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 participating in cardiac rehabilitation (minimal attendance of 80% in physical program)
- Signed written informed consent
- One of the following criteria:
o Patients with an acute coronary syndrome, including myocardial infarction (MI) within 3 months
prior to start cardiac rehabilitation program
o Patients that underwent a percutaneous coronary intervention (PCI) within 3 months prior to
prior to start cardiac rehabilitation program
o Patients that received coronary artery bypass grafting (CABG) within 3 months prior to start cardiac rehabilitation program

Exclusion criteria

- Contraindication to cardiac rehabilitation
- Mental impairment leading to inability to cooperate
- Severe impaired ability to exercise
- Signs of cardiac ischemia and/or a positive exercise testing on cardiac ischemia
- Insufficient knowledge of the Dutch language
- No access, availability or insufficient knowledge of a computer with internet
- Implanted cardiac device (pacemaker, ICD)

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-09-2014
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	02-06-2014
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL48475.075.14