Cardiac Rehabilitation Program using Telemonitoring; The effects of an extended program with Telemonitoring guidance versus standard follow-up in patients after Cardiac Rehabilitation

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27912

Source
Nationaal Trial Register

Brief title
TeleCaRe

Health condition

cardiac rehabilitation, hartrevalidatie, telemonitoring, lifestyle change, telehealth

Sponsors and support

Primary sponsor: Isala kliniek Zwolle, Leef en Beweegcentrum
Source(s) of monetary or material Support: Department of Cardiology (Isala - Zwolle)

Intervention

Outcome measures

Primary outcome

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

Study which investigates whether an extended cardiac rehabilitation program with telemonitoring guidance results in a better long term effect on physical and mental outcomes than a regular follow-up period after traditional cardiac rehabilitation. The design used for this study is an open prospective, investigator initiated randomized clinical trial. A total of 120 cardiac patients who almost completed cardiac rehabilitation (after approval cardiologist), will be included in this interventional study and randomly assigned by an algorithm to one of the 2 study groups, i.e. the 6 months telemonitoring follow-up program, or 6 months of regular follow-up after cardiac rehabilitation. Both groups have an additional 6 months of follow-up after the first period without any intervention. Measurements in both groups will be performed at baseline, and after 6, and 12 months during the program

Study objective

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

Testing will be performed at baseline, at 6 and 12 months

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. The duration and intensity (based on the heart rate data) of each training/activity is collected by the smartphone and transferred to a secured website where both patient and researchers/nurses involved in the study can view the results. During the first month patients receive weekly individual coaching and feedback on their results by telephone, in the second month this will be once per two weeks, whereas one monthly call will be held in the last four months (month 3 until 6) of the telemonitoring period. The telephone calls will be performed by a physician or nurse specialized in cardiac rehabilitation. In the second period without telemonitoring (month 7 until 12) patients will receive no coaching or feedback by phone. Subjects participating in the control group will undergo 6 months of regular follow-up after initial cardiac rehabilitation with another 6 months in addition. After the first 6 months patients in the control group have a group meeting held by a nurse specialised in cardiac rehabilitation. During this meeting patients will talk and reflect with one another and receive feedback on their individual Performance of the maximal incremental cycle test and lab results of cardiovascular risk factors. Besides the group meeting, patients in the control group receive no other coaching or feedback during these 12 months.

Contacts

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Eligibility criteria

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)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2014
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	12-06-2014
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	NL4140
NTR-old	NTR4644
Other	CCMO: NL48475.075.14 : METC: 14.0334

Study results