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

Gepubliceerd: 12-06-2014 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27912

Bron
Nationaal Trial Register

Verkorte titel
TeleCaRe

Aandoening

cardiac rehabilitation, hartrevalidatie, telemonitoring, lifestyle change, telehealth

Ondersteuning

Primaire sponsor: Isala kliniek Zwolle, Leef en Beweegcentrum
Overige ondersteuning: Department of Cardiology (Isala - Zwolle)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Physical fitness defined by peak oxygen uptake obtained from an incremental maximal cycle ergometer exercise test at 12 months.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Diagram B.V.

Leonie Prins
Dokter Stolteweg 96

Zwolle 8025 AZ
The Netherlands
Tel: +31 (38)4262999

Wetenschappelijk

Diagram B.V.

Leonie Prins
Dokter Stolteweg 96

Zwolle 8025 AZ
The Netherlands
Tel: +31 (38)4262999

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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)

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2014
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-06-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4140
NTR-old	NTR4644
Ander register	CCMO: NL48475.075.14 : METC: 14.0334

Resultaten