The effects of a mobile telemonitoring guided cardiac rehabilitation programme (mCR) versus no cardiac rehabilitation in elderly patients in Europe.

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Null hypothesis: there is no difference in mean change in VO2peak level between the randomised groups.

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

Samenvatting

ID

NL-OMON24643

Bron
NTR

Verkorte titel
EU-CaRE RCT

Aandoening

Cardiac rehabilitation, eHealth

Ondersteuning

Primaire sponsor: Isala Zwolle
Overige ondersteuning: European Union and Government of Switzerland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Difference in peak oxygen uptake (VO2peak) between the end of CR programme (T1) and baseline (T0).

Toelichting onderzoek

Achtergrond van het onderzoek

Cardiovascular diseases (CVDs), such as coronary heart disease and stroke, are one of the four main non-communicable diseases in the world causing over 4 million deaths in Europe each year. Not only mortality rates are high, morbidity of CVD patients is becoming an increasingly important problem. Through enormous improvements in high-technology diagnostic and therapeutic procedures the survival rates from CVD in (Western) Europe have increased substantially. Yet, the recurrence rate of CVD events and consumption of care resulting from CVD, or associated co-morbidities are high and patient numbers are expected to rise the next decades due to an ageing population.
Literature shows that comprehensive cardiac rehabilitation (CR) is highly effective. However, knowledge on the effectiveness of individual CR components and their appropriateness for specific patient groups is limited. This is particularly true for the elderly with CVD, which represent a special population often characterised by physical impairment, comorbidities and reduced mobility. The current approach for CR is often less appropriate for the elderly, as a result of which effectiveness, compliance, participation levels and cost-utility of CR programmes in this group is hampered.

Home-based CR seems to be equally effective as centre-based CR and has the potential to increase the participation rate. In combination with novel e-Health applications (where guidance from distance is enabled), home-based care could overcome barriers to access to CR and therefore be a useful tool for increasing participation. Furthermore it seems that telehealth interventions are effective in improving self-management skills and provide effective risk factor reduction and secondary prevention. However, this is only shown on the short term, long term effectiveness of telehealth interventions is still not known.

Therefore the aim of this study is to investigate whether a mobile telemonitoring guided CR (mCR) as alternative for a regular CR programme is an effective means to increase participation and adherence of elderly in a CR programme, and results in better long term effects than in patients who do not follow the mCR programme. In addition the cost effectiveness of the mCR programme will be analysed.

Doel van het onderzoek

Null hypothesis: there is no difference in mean change in VO2peak level between the randomised groups.

Onderzoeksopzet

Patients will be monitored at:

T0: baseline

T1: after 6 months

T2: after 12 months

Onderzoeksproduct en/of interventie

Patients aged 65 years and older, who are candidate for CR, but nut opting for regular CR are randomised in two study arms: the mCR programme for 6 months or no mCR programme. The mCR programme involves a home-based programme for 6 months in which patients are supplied with a smartphone/application with a data subscription from MobiHealth. Through this application patients are able to measure and register physical activity, heart frequency and intensity (BORG scale) and can monitor progress. Patients are instructed to perform a moderate exercise 5 days per week for at least half an hour. A care professional (typically a CR nurse) also has access to a portal to monitor progress of different patients, advice on rehabilitation approach and stimulate compliance telephone calls. 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 mobile telemonitoring period. In the second period without mobile telemonitoring (month 7 until 12) patients will receive no coaching or feedback by phone. Patients participating in the control group with no mCR programme receive no advice or coaching throughout the study period.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Patients of 65 years or older who are a candidate for CR and non-voluntary to participate in the regular CR programme

- Signed written informed consent

- One of the following criteria:

o Patients with an acute coronary syndrome, including myocardial infarction (MI) and/or revascularisation within 3 months prior to the start of the CR programme

o Patients that underwent a percutaneous coronary intervention (PCI) within 3 months prior to the start of the CR programme

o Patients that received coronary artery bypass grafting (CABG) within 3 months prior to the start of the CR programme
o Patients who were treated surgically or percutaneously for valvular heart disease (including TAVI) within 3 months prior to the start of the CR programme
o Patients with a stable angina with documented significant CAD (defined by standard non-invasive or invasive methods)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Contraindication to CR

- Mental impairment leading to inability to cooperate

- Severe impaired ability to exercise

- Signs of severe cardiac ischemia and/or a positive exercise testing on severe cardiac ischemia

- Insufficient knowledge of the native 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:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2015
Aantal proefpersonen:	238
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	16-07-2015

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	NL5168
NTR-old	NTR5308
Ander register	CCMO: NL528862.075.15 : METC: 15.0349

Resultaten