Effectiveness of currently available cardiac rehabilitation programmes from 8 European institutes in elderly patients.

Gepubliceerd: 16-07-2015 Laatst bijgewerkt: 13-12-2022

Null hypothesis: the 8 centres with different cardiac rehabilitation (CR) programmes do not differ from each other with regards to the effectiveness.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21225

Bron
Nationaal Trial Register

Verkorte titel
EU-CaRE observational study

Aandoening

Cardiac rehabilitation

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) are still the leading cause of death in Europe and a major cause of disability and loss of productivity in adults worldwide, this comes down to more than 4 million deaths each year in Europe. The substantial burden of CVD is further exemplified by a huge economic strain. Costs of CVD in the European Union (EU) are estimated at €169 billion annually, with healthcare costs accounting for 54% of the costs.
Literature shows that cardiac rehabilitation (CR) is highly effective, but knowledge on the effectiveness of individual CR components and appropriateness for specific patient groups is limited. With the ageing population and high survival rates from CVD due to improved technologies, there is growing need to a more tailored approach for different patient groups, like the elderly, within cardiac care. CR is currently underused by elderly and the effects of these programmes are underestimated by professionals. This group of people is often characterised by physical impairment, comorbidities and reduced mobility. The current approach of CR is often less appropriate for the elderly, and as a result of which effectiveness, compliance, participation levels and cost-utility of CR programmes is hampered.

Therefore the aim of this observational study is to obtain the evidence base to improve CR programmes regarding sustainable effectiveness, cost-effectiveness and participation level in elderly patients, by comparing 8 currently available CR programmes. The sustainability of CR programmes will be analysed by adding a follow-up period after the end of the regular CR programmes.

Doel van het onderzoek

Null hypothesis: the 8 centres with different cardiac rehabilitation (CR) programmes do not differ from each other with regards to the effectiveness.

Onderzoeksopzet

Patients will be monitored at

T0: start of CR programme

T1: end of CR programme

T2: after 12 months

Onderzoeksproduct en/of interventie

Not applicable.

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 have accepted CR

- Signed written informed consent

- One of the following criteria:

o Patients with an ACS, including MI and/or revascularisation within 3 months prior to the start of the CR programme

o Patients that underwent a PCI within 3 months prior to the start of the CR programme

o Patients that received 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

- Implanted cardiac device (CRT-P, ICD)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2015
Aantal proefpersonen:	1760
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	NL5166
NTR-old	NTR5306
Ander register	CCMO: NL52816.075.15 : METC: 15.0350

Resultaten