The (cost) effectiveness, sustainability and participation levels of current EUropean Cardiac Rehablitation programmes in Elderly: a prospective cohort study

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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...

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

Summary

ID

NL-OMON45028

Source
ToetsingOnline

Brief title
EU-CaRE

Condition

- Myocardial disorders

Synonym
cardiovasculair disease, heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Isala Zwolle
Source(s) of monetary or material Support: Europese Unie en Zwitserse overheid

Intervention

Keyword: cardiac rehabilitation, elderly, Europe, VO2 peak

Outcome measures

Primary outcome

Physical fitness:

- Difference in peak oxygen uptake obtained from an incremental exercise test

(T1-T0)

Secondary outcome

Physical fitness:

- Difference in peak oxygen uptake obtained from an incremental exercise test

(T2-T0)

- Difference in peak oxygen uptake obtained from an incremental exercise test

(T2-T1)

Traditional risk factors:

- Changes in lipid profile (T1-T0, T2-T0, T2-T1)

- Changes in HbA1C (T1-T0, T2-T0, T2-T1)

- Changes in renal function (T1-T0, T2-T0, T2-T1)

- Changes in lean body mass (T1-T0, T2-T0, T2-T1)

- Changes in blood pressure (T1-T0, T2-T0, T2-T1)

- Changes in smoking habit (T2-T0)

Major Adverse Cardiovascular Events (MACE):

- The occurrence of events (cardiovascular (CV) mortality, all-cause mortality, near sudden cardiac death, ACS, CV intervention/surgery, CV hospital admission, CV emergency visits) as composite endpoint (T2-T0) are registered and collected by monthly telephone calls.

General health:

- Difference in depression score assessed by: PHQ-9 questionnaire (T1-T0, T2-T0, T2-T1)
- Difference in anxiety score assessed by GAD-7 questionnaire (T1-T0, T2-T0, T2-T1)
- Quality of Life: SF-36v2, difference in Physical Component Summary Score and Mental Component Summary Score (T1-T0, T2-T0, T2-T1)
- Difference in dietary pattern (reflected by total score and score on individual components) assessed by Mediterranean Diet Score (T1-T0, T2-T0, T2-T1)

- Care utilisation as composite endpoint of: (number of) admissions, emergency visits and cardiac interventions (PCI, CABG) (T2-T0)

- Costs of care utilisation based on activities (clinical admission days, emergency and outpatient clinic visits, GP visits for cardiac (related) complaints or issues, radiology/cardiophysiology/nuclear and laboratory tests, and cardiac interventions) registered at T0, T1 and T2 and collected by monthly

telephone calls with the participants between T1 and T2

Adherence:

- The occurrence of drop-outs (including reason for drop-out) or completed CR

is registered per CR programme throughout the study period.

Compliance:

- Percentage of attended training sessions is registered per CR programme.

Study description

Background summary

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 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 (young versu elderly) is limited. CR is currently underused by elderly (in comparison to the younger population) and the effects of these programmes are underestimated by professionals. 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.

Study objective

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.

Study design

A prospective cohort study

Study burden and risks

Non-invasive cardiac testing procedures in this study are not related to any potential risk for the participant. All procedures are performed routinely at the departments and are part of usual care. Incremental maximal exercise 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 participating in existing CR programmes (based on the current guidelines) we expect no additional risk by joining the study.

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 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 (including Transcatheter Aortic Valve Implantation) within 3 months prior to the start of the CR programme
o Patients with a stable angina with documented significant coronary artery disease (defined by standard non-invasive or invasive methods)

Exclusion criteria

- 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)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2015
Enrollment:	330
Type:	Actual

Ethics review

Approved WMO Date:	03-07-2015
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	04-04-2017
Application type:	Amendment
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	NL52816.075.15