Randomised Controlled Trial for an e-Health application in EUropean Cardiac Rehabilitation programmes in Elderly; Assessment of the effects on sustainablity and participation level of a mobile telemonitoring guided cardiac rehabilitation programma (mCR) and its cost effectiveness, in elderly patients in Europe

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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...

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

Summary

ID

NL-OMON42642

Source
ToetsingOnline

Brief title
EU-CaRE RCT

Condition

- Myocardial disorders

Synonym
cardiovascular disease, heart disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cardiac rehabilitation, e-health, elderly, telemonitoring

Outcome measures

Primary outcome

Difference in peak oxygen uptake (VO2peak) between the end of CR programme (T1)

and baseline (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)

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

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

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

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

- 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 (T1-T2) are registered and collected by monthly telephone calls.

General health:

- Difference in depression score assessed by: PHQ-9 questionnaire (T1-T0, T2-T0)

- Difference in anxiety score assessed by GAD-7 questionnaire (T1-T0, T2-T0) - Quality of Life: SF-36, difference in Physical Component Summary Score and Mental Component Summary Score (T1-T0, T2-T0)

- Care utilisation as composite endpoint of: (number of) admissions, emergency visits and cardiac interventions (PCI, CABG) (T1-T2)

- 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:

- Number of drop-out or completed CR throughout study period.

Compliance:

- Compliance to usage of the smartphone (percentage of fulfilling the planned exercise sessions with mCR for at least half an hour at 5 five days per week) in the intervention group is determined for the period between baseline and 6 months.

Study description

Background summary

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 (young versus elderly) is limited. 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.

Study objective

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.

Study design

Randomised controlled trial

Intervention

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.

Study burden and risks

Noninvasive cardiac testing procedures in this study are not related to any potential risk for the participant. Maximal ergometer 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 carefully instructed beforehand and individually coached by telephone on their physical progress during the first 6 months of the study we expect no potential risk for them to exercise in their home environment.

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 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

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
- 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)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2015
Enrollment:	48
Type:	Actual

Medical products/devices used

Generic name:	Home activity and physical condition monitor including a heart rate belt (Zephyr HxM) and smartphone
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	03-07-2015
Application type:	First submission
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	NL52862.075.15