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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24643

Source
NTR

Brief title
EU-CaRE RCT

Health condition

Cardiac rehabilitation, eHealth

Sponsors and support

Primary sponsor: Isala Zwolle
Source(s) of monetary or material Support: European Union and Government of Switzerland

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

o Difference in VO2peak between 12 months (T2) and T0

o Difference in VO2peak between T2 and T1

o Traditional risk factors for CVD

o Major Adverse Cardiovascular Events (MACE)

o General health

o Care utilisation

o Costs of care utilisation

o Adherence

o Compliance

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 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.

Study objective

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

Study design

Patients will be monitored at:

T0: baseline

T1: after 6 months

T2: after 12 months

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.

Contacts

Public
Diagram B.V.

Leonie Prins
Dokter Stolteweg 96

Zwolle 8025 AZ
The Netherlands
Tel: +31 (38)4262999
Scientific
Diagram B.V.

Leonie Prins
Dokter Stolteweg 96

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

Eligibility criteria

Inclusion criteria

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)

Exclusion criteria

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)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2015

Enrollment:	238
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion Date:	16-07-2015
Application type:	First submission

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
NTR-new	NL5168
NTR-old	NTR5308
Other	CCMO: NL528862.075.15 : METC: 15.0349

Study results