The effectiveness of an online exercise program in early cardiac rehabilitation after cardiac surgery

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This study aims to investigate the experiences with and effects of an early online exercise-based CR program among patients after cardiac surgery.

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

Summary

ID

NL-OMON46925

Source
ToetsingOnline

Brief title
E-health in early cardiac rehabilitation

Condition

- Myocardial disorders

Synonym
CABG, heart bypass surgery

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Pioneers in Healthcare Innovatiefonds (UT/MST/ZGT/Menzis)

Intervention

Keyword: cardiac surgery, early cardiac rehabilitation, e-health

Outcome measures

Primary outcome

Primary outcome measue is exercise capacity, measured with the 6 min walktest.

Secondary outcome

Secondary outcomes measures are physical activity, quality of llife,

disability, anxiety, depression and satisfaction with treatment.

Study description

Background summary

Cardiac rehabilitation (CR) has shown to be an effective treatment to reduce mortality and morbidity among cardiac patients who underwent cardiac surgery. Exercise training is a major component of CR. It usually starts in the hospital and continues in an outpatient setting six weeks after discharge from the hospital. In the intervening period patients continue rehabilitation by themselves with the advices they received in the hospital. Research has shown that patients experience this intervening period as stressful. They feel insufficiently supported and are in need of more information and advice. No general consensus exists concerning the best timing of exercise-based CR. Although, there seems to be a positive relation between the timing of the start of an exercise program and physical functioning, no study has compared the effects of early CR with traditional CR (starting at six weeks after hospital discharge). By starting the exercise program in an earlier phase, immediately after discharge from the hospital, patients might start the traditional outpatient CR in a better physical condition and gain better health outcomes.

Study objective

This study aims to investigate the experiences with and effects of an early online exercise-based CR program among patients after cardiac surgery.

Study design

A quasi-experimental study will be conducted comparing patients who completed a

traditional outpatient exercise-based CR program (control group) with patients who completed an early (home-based) online exercise CR program (in the first 6 weeks after discharge from the hospital) as adjuvant to the traditional outpatient exercise-based CR program (intervention group).

To evaluate experiences with the online exercise CR program, in-depth interviews will be conducted with some patients (n=15).

Intervention

Online exercise program which consists of three modules: exercises, monitoring health status and communication (with physical therapist).

Study burden and risks

By starting the exercise program in an earlier phase, we respond to the needs of patients to get more (tailored) support in the first weeks after discharge from the hospital. Furthermore, we expect that patients will start the traditional outpatient CR in better physical condition and gain better health outcomes. From literature we know that there are no indications that early enrollment in exercise-based CR after MI or cardiac surgery is harmful to patients. Moreover, only low to moderate strenuous exercises will be conducted. Exercises will be tailored and the intensity will be build, dependent on the performance and willing of the patient. So, we don*t expect extra risks for the patients, related to participation in this study.

The patient is free to determine when he completes the exercises.There are three measurement points: at baseline (clinical phase) and at the start and end of the traditional outpatient exercise-based CR program. The outcome measures mostly exist of questionnaires, which take maximally 20 minutes at a time to complete. Furthermore the 6 minutes walktest will be conducted. This test will be completed in the hospital. The first and last test are part of usual care. This means that we will ask the patient to visit the hospital for one extra time (for this study). Finally, patients are asked to wear an accelerometer for several weeks (control group: 3x 1 week; intervention group: 1x 6 weeks and 1x 1 week). An accelerometer is a small device that can be worn without hindrance of daily activities.

In-depth interviews will be conducted with some patients in the intervention group (n=15) to evaluate their experiences with the program. This interview is optional / voluntarily, takes maximally 45 minutes of their time and will be conducted at the patients' home or another location according to the patients' preference.

All in all, the burden for the patients seems acceptable and in proportion to

the benefits.

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

- CABG or valve surgery
- Clinically stabile and capable of performing an exercise program (judgement cardiologist)
- Intended to participate in the regular outpatient exercise program
- Access to the internet
- Master of Dutch language (reading and writing)
- Live in adherence area of MST
- Age >18 years

Exclusion criteria

none

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	27-10-2016
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	28-03-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	08-12-2017
Application type:	Amendment

Review commission:	METC Twente (Enschede)
Approved WMO Date:	21-06-2018
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26493
Source: NTR
Title:

In other registers

Register	ID
Other	Aangemeld bij www.trialregister.nl. NTR nummer nog niet bekend.
CCMO	NL59315.044.16
OMON	NL-OMON26493