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Effectiveness of a comprehensive telerehabilitation program for the heart

Submission date	Recruitment status	[_] Prospectively registered
10/01/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/01/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/02/2023	Circulatory System	

Plain English summary of protocol

Background and study aims
Rehabilitation using the internet (telerehabilitation) has been proposed as an addition or alternative to standard cardiac rehabilitation (CR) to address the low use of standard CR programmes. The aim of this study is to test whether the addition of an internet cardiac telerehabilitation program to standard care improves long-term physical fitness in patients with heart disease.

Who can participate?
Men and women aged between 18 and 80 with heart disease (heart failure and diseases of the blood vessels supplying the heart muscle)

What does the study involve?
Half the patients receive standard CR and half receive standard CR and an internet telerehabilitation program (composed of physical activity monitoring and dietary, smoking cessation and activity coaching).

What are the possible benefits and risks of participating?
The possible benefits are an increase in physical fitness, improvements in risk factors that cause heart disease and reduction in the number of rehospitalisations. There are almost no risks.

Where is the study run from?
Three hospitals in Belgium: Jessa Hospital, Ziekenhuis Oost-Limburg and St Fransiscus Hospital

When is the study starting and how long is it expected to run for?
February 2013 to February 2015

Who is funding the study?
Flanders Care (Belgium) and Fonds Wetenschappelijk Onderzoek (Belgium)

Who is the main contact?
Prof. Paul Dendale

Contact information

Type(s)
Scientific

Contact name
Dr Ines Frederix

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Long-term effectiveness of a comprehensive cardiac telerehabilitation program (Telerehab III): a randomised controlled trial

Acronym
Telerehab III

Study objectives
Addition of an internet-based cardiac telerehabilitation program to usual care improves long-term physical fitness in cardiac patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of Ziekenhuis Oost-Limburg/Hasselt University/Jessa, 14/12/2012, ref: 12/085L

Study design
Multicentre randomised controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Coronary artery disease and heart failure

Interventions
1. Patients in the intervention group were provided with an internet-based telerehabilitation program in addition to conventional centre-based cardiac rehabilitation. The telerehabilitation program was composed of physical activity telemonitoring (Yorbody accelerometer) and dietary, smoking cessation and activity telecoaching.
2. Study nurse led training was given to patients within 7 days after randomisation. They were provided with some background and general information about the study design, content and main hypotheses of Telerehab III. Patients were taught how to install the telerehabilitation program on their computer and use the motion sensor. This presentation was followed by a 1 hour practical training session in which patients were familiarised with the accelerometer and associated webpage. They were instructed on how to install the program at home; if they had questions and/or technical difficulties, they were provided with technical support.
3. Patients receiving the intervention were prescribed literature on patient-specific exercise training protocols, based on maximal cardiopulmonary exercise test and calculated body-mass index (BMI) at the start of the study. Patients with a high aerobic capacity (defined as peak oxygen consumption [VO2] of at least 80% predicted) were prescribed with exercise training at an intensity of at least 100 steps per minute, for at least three times per week and a minimum session of 30 minutes. The instructed volume of steps was set at 10000–12000 per day for patients with a BMI greater than 30 kg/m2 and 8000–10000 per day for patients with a BMI of less 30 kg/m2. Patients with a low aerobic capacity (defined as VO2 peak of less than 80% predicted) were allowed to choose the intensity of exercise sessions. The instructed volume of steps was again set at 10000–12000 steps per day for patients with a BMI of greater than 30 kg /m2 and 8000–10000 steps per day for patients with a BMI of less than 30 kg/m2.
4. Patients were instructed to wear the motion sensor during the whole study, except while bathing or sleeping. They uploaded data at least every 2 weeks to a secure webpage with an USB-connection because of the accelerometer's storage capacity of 14 days. The webpage displayed uploaded physical activities, enabling patients to self-monitor these data. Based on the uploaded data, a semi-automatic telecoaching system provided patients with weekly feedback through e-mail or short message service (SMS) or both. The feedback was intended to encourage patients to achieve the goals as predefined in the patient-specific exercise training protocols.
5. Intervention patients were provided with weekly dietary advice, sent by email or SMS or both, according to the patients' preferences. The dietary telecoaching program included a module for

diabetes mellitus, arterial hypertension, obesity and healthy diet. Cardiovascular risk factor profiling at the start of the study determined which module(s) were prescribed for each patient. Key to the diabetes mellitus module was the restriction of fast carbohydrates, energy rich nutrition and ethanol containing beverages. The arterial hypertension and obesity modules focused on salt restriction and energy intake reduction, respectively. Healthy diet included recommendations based on the food triangle.
6. Patients in the control group received the conventional centre-based cardiac rehabilitation program; including 45 pluridisciplinary rehabilitation sessions focusing on healthy diet, psychosocial wellbeing, behavioural change, risk factor modification and exercise training. They were instructed to wear the accelerometer at the start of the study, after 6 weeks and at the end of the study for comparison purposes only. The sensors were taped, making it impossible to see the registered physical activity data. The study nurses at the respective hospitals uploaded the data; patients were not given any access to the webpage with uploaded data. The control patients did not receive any physical activity, smoking cessation or dietary telecoaching by email or SMS.

Intervention Type
Other

Primary outcome measure
Peak oxygen consumption (VO2 peak) at maximal cardiopulmonary exercise testing; measured at baseline, 6 weeks and 6-month follow-up

Secondary outcome measures
1. Daily physical activity: defined as the total number of daily low intensity and high intensity steps and registered during the whole study by accelerometry data (measured continuously with an accelerometer)
2. Cardiovascular risk factor control: body weight, blood pressure, blood lipids, glucose and glycated haemoglobin measured at baseline and 6-month follow-up
3. HeartQol: quality of life score measured at baseline, 6 weeks and 6-month follow-up
4. International Physical Activity Questionnaire: physical activity score measured at baseline, 6 weeks and 6 months
5. EQ-5D score measured at 6 weeks and 6 months
6. Days lost due to cardiovascular rehospitalisation from the start to the end of the study
7. Days lost due to hospitalisation for any reason from the start to the end of the study
8. Time to first cardiovascular rehospitalisation from the start to the end of the study
9. Time to first hospitalisation for any reason from the start to the end of the study

Overall study start date
01/02/2013

Completion date
01/02/2015

Eligibility

Key inclusion criteria
1. Coronary artery disease treated conservatively with percutaneous coronary intervention or coronary artery bypass graft
2. Chronic heart failure (CHF) with reduced ejection fraction (EF)
3. CHF and preserved EF

4. Current active rehabilitation in one of the recruiting centres
5. Patients with a personal computer with an internet connection
6. Age >18 and <80
7. Familiarity with the Dutch language
6. Patients who provided informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
140

Total final enrolment
140

Key exclusion criteria
1. Orthopaedic or neurological condition or both, restricting the patient's ability to actively engage in exercise training sessions
2. Impairment preventing the use of the telerehabilitation equipment or attendance at follow-up visits (terminal disease, dementia and cognitive impairment)
3. Simultaneous participation in another clinical trial
4. CHF New York Heart Association class IV
5. History of ventricular fibrillation, exertional sustained ventricular tachycardia or supraventricular tachycardia within the previous 6 months

Date of first enrolment
25/02/2013

Date of final enrolment
25/08/2014

Locations

Countries of recruitment
Belgium

Study participating centre
Jessa Hospital
Stadsomvaart 11
3500 Hasselt

Hasselt
Belgium
3500

Study participating centre
Ziekenhuis Oost-Limburg
Schiepse Bos 6
3600 Genk
Genk
Belgium
3600

Study participating centre
St Franciscus Hospital
Pastoor Paquayaan 129
3550 Heusden-Zolder
Heusden-Zolder
Belgium
3550

Sponsor information

Organisation
Flanders Care

Sponsor details
Koning Albert II-laan 35 bus 30
B-1030 Brussel
Brussel
Belgium
1030

Sponsor type
Government

ROR
https://ror.org/04qxsrb28

Funder(s)

Funder type

Government

Funder Name
Fonds Wetenschappelijk Onderzoek

Alternative Name(s)
Research Foundation Flanders, Flemish Research Foundation, FWO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Belgium

Funder Name
Yorbody

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/05/2015		Yes	No
Results article	results	01/11/2017		Yes	No
Results article		23/07/2015	09/02/2023	Yes	No