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Telerehab II: secondary prevention of cardiovascular disease by means of telerehabilitation.

Submission date	Recruitment status	[_] Prospectively registered
28/02/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/04/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/11/2015	Circulatory System	

Plain English summary of protocol

Background and study aims
Cardiac rehabilitation (CR) is proven to be effective for coronary artery disease patients. However, uptake rates of the conventional CR remain poor. Patients often find it difficult for the conventional in-hospital CR to fit in their weekly time schedule. They sometimes cant attend because of traffic/travel issues. Telerehabilitation could overcome these problems, leading to better physical fitness and health among the cardiac patients. This study explored the effect of a telerehabilitation program on the patient's physical fitness.

Who can participate?
Coronary artery disease (CAD) patients, younger than 80 years old and that posses a personal computer with internet connection, could participate.

What does the study involve?
Participants were randomly allocated to one of two groups: a telerehabilitation group (intervention group) or a conventional cardiac rehabilitation group. In the intervention group, the study involved wearing a motion sensor that recorded the patients daily physical activity. Feedback was also given to the patients in the intervention group.

What are the possible benefits and risks of participating?
There were no risks associated with participating, except for sport injuries (these were only very rarely expected to occur because of the limited intensity of physical activity). The patients were able to benefit from the positive effects of daily exercise.

Where is the study run from?
The study was run from the Jessa Hospital, Hasselt in Belgium.

When is the study starting and how long is it expected to run for?
January 2011 to December 2012.

Who is funding the study?
The Heart Centre in Hasselt (Belgium)

Who is the main contact?
Prof. Dr. Dendale
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Contact information

Type(s)
Scientific

Contact name
Prof Paul Dendale

Contact details
Jessa Hospital
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Belgium
3500

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Telerehab II: a prospective randomised controlled trial that explores the effect on VO2 peak of coronary artery disease patients receiving telerehabilitation, with those receiving conventional cardiac rehabilitation

Acronym
Telerehab II

Study objectives
The hypothesis is that a telerehabilitation program by means of a motion sensor with automated feedback can increase the patient's VO2 peak more, compared to conventional cardiac rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee of Jessa Hospital, 10/12/2010

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Coronary artery disease

Interventions
1. Conventional cardiac rehabilitation.
2. Telerehabilitation will consist of daily recording of the patient's physical activity. These data will be uploaded weekly on a personal computer and sent automatically to the caregivers.The patients will receive weekly new step goals, gradually increasing their daily activity level.The intervention will be carried out during 18 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Change in VO2 peak from baseline (week 1) to week 6 and week 18 of follow-up
2. Change of daily step count from baseline to week 18 of follow-up

Secondary outcome measures
1. Change in HBA1c, lipid profile from baseline to week 18
2. Number and duration of hospitalisation after the start of the study
3. Mortality rate after the start of the study
4. Number of medication changes from baseline to week 18 of follow-up
5. Change in self-reported physical activity (IPAQ-questionnaire) from baseline to week 18 of follow-up

Overall study start date
01/01/2011

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Patients (both male and female) that suffered an uncomplicated acute coronary syndrome (ACS) for which a percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) was performed
2. All included patients possessed a personal computer and internet connection
3. Their age did not exceed 80 years old

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Patients more than 80 years old
2. Patients that have an Implantable Cardioverter Defibrillator (ICD) or pacemaker
3. Patients that suffered from severe arrhythmias
4. Patients that had persistent exertional ischaemia after revascularization therapy.
5. Patients with severe heart failure (NYHA class III and IV)
6. Patients with neurological or orthopaedic disability, limiting their capability to walk and run

Date of first enrolment
01/01/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Belgium

Study participating centre

Jessa Hospital
Hasselt
Belgium
3500

Sponsor information

Organisation
Heart Centre Hasselt vzw (Belgium)

Sponsor details
Begeveldstraat
Bilzen
Belgium
3740

Sponsor type
Hospital/treatment centre

Website
http://www.jessazh.be/

ROR
https://ror.org/03tw90478

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Heart Centre Hasselt vzw (Belgium)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2015		Yes	No