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# The usability and effectiveness of connecting technology on physical and psychosocial functioning of cardiovascular disease rehabilitees in usual rehabilitation

**Submission date**
05/12/2016

**Recruitment status**
No longer recruiting

**Registration date**
06/01/2017

**Overall study status**
Completed

**Last Edited**
13/04/2023

**Condition category**
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
Cardiovascular (heart) diseases decrease patients' physical activity and quality of life. Therefore, it is important to develop new rehabilitation methods to promote physical activity or other lifestyle changes. Physical activity and well-being could be promoted, among other means, using technology. The aim of this study is to examine the use of connecting technology in cardiovascular disease rehabilitation. In addition, the aims are to study patients' experiences and the cost-effectiveness of the connecting rehabilitation.

Who can participate?
Cardiovascular disease patients participating in six rehabilitation courses

What does the study involve?
The six rehabilitation courses are randomly allocated into two groups. Patients in the first group receive the usual rehabilitation program. Patients in the second group receive an additional connected technology program, using a Fitbit Charge HR® accelerometer and Movendos m-coach internet application during their rehabilitation. Both groups attend a 12-month rehabilitation course that consists of three five-day inpatient face-to-face rehabilitation periods in the rehabilitation center (at the start of the study, 6 months and 12 months), and in addition, outpatient time (2 x 6 months) between inpatient periods. Physical activity is measured five times with the Fitbit Zip® accelerometer during the rehabilitation and once during follow up. Cardiorespiratory (heart and lung) fitness, weight, height, body mass index, and waist circumference are measured three times during the rehabilitation. Psychosocial functioning and quality of life are assessed with questionnaires three times during the rehabilitation and once during follow up. Focus group interviews are carried out three times during follow up.

What are the possible benefits and risks of participating?
Previous study findings indicate that technology-based rehabilitation may increase motivation and improve communication between healthcare professionals and patients. Patients will

receive more detailed information on their health status and health-related changes. A better understanding of connecting technology will be helpful in developing cardiovascular disease rehabilitation. There are no risks of participation.

Where is the study run from?
Rehabilitation Center Peurunka (Finland)

When is the study starting and how long is it expected to run for?
September 2015 to November 2017

Who is funding the study?
University of Jyväskylä (Finland)

Who is the main contact?
Dr Tuulikki Sjögren
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# Contact information

### Type(s)
Scientific

### Contact name
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
D number 44/26/2015

# Study information

### Scientific Title

The usability and effectiveness of connecting technology on physical activity, physical and psychosocial functioning, participation and quality of life of cardiovascular disease rehabilitees - a cluster randomized trial with six month follow up in usual rehabilitation

## Study objectives
1. Rehabilitation which uses connecting technology is more effective at increasing physical activity, physical and psychosocial functioning and well-being than similar intervention without the use of technology.
2. Rehabilitation which uses connecting technology is more meaningful to a rehabilitee than similar intervention without the use of technology.
3. Rehabilitation which uses connecting technology is more cost-effective at increasing health-related outcomes than similar intervention without the use of technology.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics committee of the Central Finland Health Care District, 06/10/2015, ref: 44/26/2015

## Study design
Parallel cluster randomized trial

## Primary study design
Interventional

## Secondary study design
Cluster randomised trial

## Study setting(s)
Other

## Study type(s)
Treatment

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

## Health condition(s) or problem(s) studied
Coronary artery disease rehabilitation (chronic phase)

## Interventions
The participants consist of 60 volunteer cardiovascular disease rehabilitees from six rehabilitation courses in a 12-month coronary artery disease rehabilitation intervention. Three of the courses are randomized to a usual rehabilitation group and the other three courses use connecting technology (Fitbit Zip® accelerometer and Movendos m-coach internet application) during usual rehabilitation.

12-month usual multidisciplinary rehabilitation consists of three five-day inpatient face-to-face rehabilitation periods in the rehabilitation center (at baseline, 6 months and 12 months) and an outpatient period between inpatient rehabilitation sessions (2 x 6 months). Quantitative data is

collected with physical and psychosocial questionnaires and physical measurements. The effectiveness of the intervention on physical and psychosocial functioning are analyzed using linear mixed models. Cluster-specific methods are justified by the composition of inpatient courses, when groups rather than individuals are randomized. Qualitative data is collected with focus group interviews (baseline, 6 month and 12 months). The qualitative data is analyzed by inductive content analysis.

## Intervention Type
Mixed

## Primary outcome measure
1. Objective physical activity (total physical activity: frequency, duration, intensity and patterns of movement [and different combinations of outcomes]), measured using Fitbit Zip® accelerometer. This study uses five times one-week recall during the intervention (baseline, 3, 6, 9 and 12 months) and once during the follow up period (6 months).
2. Subjective physical activity (vigorous and moderate physical activity and walking [and different combinations of outcomes]), measured using the International Physical Activity Questionnaire (IPAQ) three times during the intervention period (baseline, 6 months and at 12 months) and once during the follow up period (6 months).

## Secondary outcome measures
1. Physical functioning:
1.1. Cardiorespiratory fitness, evaluated using submaximal level of functional capacity by using the 6-minute walking test. Outcome measures are: maximal oxygen uptake, heart rate, walking pace, Borg scale 0-10 (ATS Statements: Guidelines for the Six-Minute Walk Test 2002). Schedule of measurements is three times during intervention period (baseline, 6 months and at 12 months) and once during the follow-up period (6 months).
1.2. Body composition. measured by weight (kg), height (cm), body mass index (BMI) and waist circumference (cm). Schedule of measurements is three times during intervention period (baseline, 6 months and at 12 months) and once during the follow-up period (6 months).
2. Quality of life, measured using The World Health Organization Quality of Life-assessment (WHOQOL-BREF). WHOQOL-BREF domains are physical health, psychological, social relationships, environment (WHOQOL Group 1996, WHOQOL Group 1998, Skevington ym. 2004). Schedule of measurements is three times during the intervention period (baseline, 6 months and at 12 months) and once during the follow-up period (6 months).
3. Adherence to treatment, measured by the times of log-in to the Movendos m-coach internet application and the amount of exercise according to the data that Movendos m-coach software has collected. The data is collected at the end of the 12-month intervention.
4. Technology acceptance, evaluated using a questionnaire (modified by Venkatesh & Bala 2008) with sections “perceived ease of use” and “perceived usefulness”. The data is collected at the end of the 12-month intervention.
5. Cost-effectiveness of connecting technology, evaluated based on the differential between the common benefits and costs. Outcomes are related to direct time-related costs of rehabilitee, rehabilitation employees and management of the rehabilitation center. The main health-related outcomes are related to physical activity and quality of life. Cost-effectiveness is evaluated during the intervention period (12 months) and during the follow-up period (6 months).
6. Expectations and attitudes towards the use of connecting technology in rehabilitation, evaluated by the data from group interviews. Interviews are performed three times during the intervention period (baseline, 6 months and at 12 months) and once during the follow-up period.

### Overall study start date
21/09/2015

### Completion date
30/11/2017

## Eligibility

### Key inclusion criteria
1. Coronary artery disease rehabilitee with basic skills for using internet
2. Adults and elderly, no restrictions in age

### Participant type(s)
Patient

### Age group
Mixed

### Sex
Both

### Target number of participants
N = 60: 6 clusters consisting of 10 persons being at the same rehabilitation course

### Total final enrolment
59

### Key exclusion criteria
Musculoskeletal diseases, cognitive diseases or problems with memory that clearly limit functional capacity

### Date of first enrolment
21/09/2015

### Date of final enrolment
23/05/2016

## Locations

### Countries of recruitment
Finland

### Study participating centre
**Rehabilitation Center Peurunka**
Peurungantie 85
Laukaa
Finland
41340

# Sponsor information

**Organisation**
University of Jyväskylä

**Sponsor details**
c/o Prof Ari Heinonen
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**Sponsor type**
University/education

**Website**
https://www.jyu.fi/en

**ROR**
https://ror.org/05n3dz165

# Funder(s)

**Funder type**
Government

**Funder Name**
Kela

**Alternative Name(s)**
Social Insurance Institution of Finland, Kansaneläkelaitos

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
Finland

# Results and Publications

## Publication and dissemination plan
To be confirmed at a later date

## Intention to publish date
30/11/2018

## Individual participant data (IPD) sharing plan
The research data will be fully owned by the University of Jyväskylä, Faculty of Sport and Health Sciences. The University of Jyväskylä offers research projects protected, backed up storage space. For sensitive data special secure storage services will be provided. During research the data will be accessible only for members of the project team. In order that the data can be reused, de-identified parts of the data will be published using the University's own platforms (JyX, Dataverse).

## IPD sharing plan summary
Stored in repository

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Other publications | Rehabilitees' experiences and attitudes toward technology | 07/02/2019 | | Yes | No |
| Interim results article | Pilot study results | 18/06/2021 | 21/06/2021 | Yes | No |
| Other publications | Biopsychosocial Profiles of Patients With Cardiac Disease in Remote Rehabilitation Processes: Mixed Methods Grounded Theory Approach | 03/11/2021 | 17/02/2023 | Yes | No |
| Other publications | Patients' experiences of the complex trust-building process within digital cardiac rehabilitation | 09/03/2021 | 17/02/2023 | Yes | No |
| Results article | | 12/04/2023 | 13/04/2023 | Yes | No |