ISRCTN69158864 https://doi.org/10.1186/ISRCTN69158864

The effect of Exercise on Prescription (EoP) on activity levels in heart patients after a completed period of training in outpatient setting

Submission date 29/11/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 19/12/2011	**Overall study status** Completed	
Last Edited 27/05/2025	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Staffan Eriksson

Contact details
-
Nyköping
Sweden
SE-61185
-
staffan.eriksson@umu.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
The effect of Exercise on Prescription (EoP) on activity levels in coronary artery disease patients after a completed a period of training in outpatient setting: a randomised controlled trial

Acronym
EoP

Study objectives
Primary hypothesis:
Information given as Exercise on Prescription (EoP) after a completed period of training in a coronary rehabilitation outpatients setting, including motivational interviewing, gives a larger proportion of individuals that reach an activity level equivalent to 1200 Metabolic Equivalent Task (MET) per week or more compared to orally given advice to be physically active.

Secondary hypotheses:
1. Information given as EoP after a completed period of training in a coronary rehabilitation outpatient setting, including motivational interviewing, gives a higher energy expenditure per week compared to orally given advice to be physically active.
2. Information given as EoP after a completed period of training in a coronary rehabilitation outpatient setting, including motivational interviewing, gives a higher energy expenditure per week by way of moderate intensity exercise (4-8 MET) compared to orally given advice to be physically active.
3. Information given as EoP after a completed period of training in a coronary rehabilitation outpatient setting, including motivational interviewing, gives a higher energy expenditure per week by way of high intensity exercise (≥8 MET) compared to orally given advice to be physically active.
4. Information given as EoP after a completed period of training in a coronary rehabilitation outpatient setting, including motivational interviewing, gives a higher exercise capacity as measured by a submaximal bicycle exercise test compared to orally given advice to be physically active.

On 12/01/2015 the overall trial end date was changed from 31/12/2014 to 31/12/2017.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board, Stockholm, Sweden, 07/10/2011, ref: 2011/1226-31/2

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

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
Prior to study start all of the participants participate in the standard heart rehabilitation group for outpatients diagnosed with coronary artery disease at the Hospital of Nyköping. This standard heart rehabilitation is comprised of strength and fitness training up to three times per week and three months, in line with the Swedish guidelines for heart rehabilitation. In addition to the guidelines group relaxation is also performed two of three sessions each week. On the final session of the standard heart rehabilitation group, all participants will be advised to continue to be physically active, with specific emphasis placed on the importance of fitness training. After termination of the standard heart rehabilitation group participants will be randomly allocated to either an EoP-group or a control group. The control group will receive only the information mentioned above that all participants receive.

After completing the standard heart rehabilitation period outlined above, the EoP-group will meet a physiotherapist for a motivational interview (MI) and an exercise prescription. Two months after this meeting a follow up by telephone will be done. The EoP physiotherapist does not work in the heart rehabilitation team and is not involved in the standard heart rehabilitation group. The prescription can be for any form of exercise, but must last for thirty minutes or more of physical activity daily, and also include fitness training three times a week and strength training twice a week. The strength and fitness training can be combined in the same session. The training intensity for fitness training should be 12-15/20 on the Borg's RPE-scale for 20-40 minutes, depending on the intensity, with higher intensity requiring shorter training duration. The training intensity of strength training should be between 11-13/20 on the Borg's RPE-scale in the trained muscle. Strength training should be comprised of 1-3 sets of 12-15 repetitions of 8-10 different exercises.

Intervention Type
Behavioural

Primary outcome measure
International Physical Activity Questionnaire, short form measured at baseline and after 4 months

Secondary outcome measures
Submaximal bicycle exercise test measured at baseline and after 4 months

Overall study start date

01/12/2010

Completion date
22/12/2021

Eligibility

Key inclusion criteria
Current inclusion criteria as of 17/04/2012:
1. Age 75 years or less
2. Coronary artery disease
3. Completion of a minimum of eight weeks, with a mean of at least one day per week, of group training for outpatients

Previous inclusion criteria:
1. Age 70 years or less
2. Coronary artery disease
3. Completion of a minimum of eight weeks, with a mean of at least one day per week, of group training for outpatients

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Chronic obstructive lung-disease, according to medical records
2. Heart failure, according to medical records
3. Submaximal bicycle exercise test or survey administered by different physiotherapists at baseline an after the intervention period

Date of first enrolment
21/12/2011

Date of final enrolment
22/12/2021

Locations

Countries of recruitment
Sweden

Study participating centre
Sjukgymnastiken
Nyköping
Sweden
SE-61185

Sponsor information

Organisation
Uppsala University (Sweden)

Sponsor details
Centre for Clinical Research Sörmland
Kungsgatan 41
Eskilstuna
Sweden
SE-63188

Sponsor type
University/education

Website
http://www.uu.se/en/

ROR
https://ror.org/048a87296

Funder(s)

Funder type
University/education

Funder Name
Centre for Clinical Research Sörmland, Uppsala University (Sweden)

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal with the intent to publish around one year after the overall trial end date.

Intention to publish date

31/12/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available because the researchers have promised confidentiality in the information letter to the participants. Specifically, they have stated that only the researchers conducting the study will be able to view the data at an individual level and that only group-level data will be displayed to individuals outside of the research group. This statement has also been approved by the Ethical Review Board in Stockholm.

IPD sharing plan summary

Not expected to be made available