The prevalence and determinants of daily physical activity in heart failure patients: a performance based study.

Published: 02-06-2010
Last updated: 04-05-2024

The main objective of this observational study is to examine DPA in HF patients (NYHA II and III) by means of accelerometry. The secondary objective is to assess the influence of a number of psychosocial determinants (e.g. self-efficacy, intrinsic...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON34681

Source
ToetsingOnline

Brief title
HEART*BEAT project

Condition

- Heart failures

Synonym
compensatio cordis, heart insufficienty

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: accelerometer, daily physical activity, heart failure, psychosocial determinants

Outcome measures

Primary outcome

The main study parameter is the DPA of the participants. DPA is an umbrella-term for total energy expenditure (cal), number of steps, average METS, active energy expenditure (cal), physical activity duration (>=3 METS), time spend on activities at sedentary (up to 3 METS), moderate (3-6 METS), vigorous (6-9 METS) and very vigorous (9 METS and higher) intensity.

Secondary outcome

Scores on the following questionnaires are the secondary study parameters; the Bandura*s Exercise Self-Efficacy Scale, the Self-Regulation Questionnaire-Exercise, the Hospital Anxiety and Depression Scale, the Revised Compliance Questionnaire, the Cardiac Attitudes Index, the Control Attitude Scale, the Minimal Insomnia Symptom Scale and the Berlin Questionnaire.

Study description

Background summary

Heart failure (HF) has worldwide a high prevalence and mortality rate. Daily physical activity (DPA) improves exercise tolerance and other symptoms of HF, slow down the progression of the disease and improves survival rate. Up to now, little is known about the performance based DPA status in HF patients. We hypothesize that most HF patients are sedentary. In addition, we suggest DPA in HF patients is affected by a number of psychosocial determinants like self-efficacy, (intrinsic) motivation and depression.

Study objective

The main objective of this observational study is to examine DPA in HF patients (NYHA II and III) by means of accelerometry. The secondary objective is to assess the influence of a number of psychosocial determinants (e.g. self-efficacy, intrinsic motivation and depression) on DPA.

Study design

A cross-sectional study will be used to examine DPA in HF patients and the effect of a number of psychosocial determinants on DPA. We will include 75 out clinic patients (NYHA II-III). DPA will be measured with the Sensewear Pro3 armband accelerometer (72 hours) and the SQUASH questionnaire. To measure the psychosocial determinants which might be related to DPA, we will use Bandura*s Exercise Self-Efficacy Scale, the Self-Regulation Questionnaire- Exercise, the Hospital Anxiety and Depression Scale, the Revised Heart Failure Compliance Questionnaire, the Minimal Insomnia Symptom Scale and the Berlin Questionnaire, the Cardiac Attitudes Index and the Control Attitude Scale. All questionnaires are valid and reliable.

Study burden and risks

Participation in the HEART*BEAT project is a minimal burden for the patients and there are no disadvantages for the patients. The burden consists of filling in a set of questionnaires and of wearing the Sensewear Armband for three days. There are no risks in participating. There is no direct individually benefit for the participants, but with the results of this study we await to develop a relevant program, additional to usual rehab programs, to enhance DPA in HF patients. This will be beneficial for the quality of life of HF patients.

Contacts

Public
Hanzehogeschool Groningen

Eysssoniusplein 18
9714 CE Groningen
Nederland
Scientific
Hanzehogeschool Groningen

Eysssoniusplein 18
9714 CE Groningen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Heart failure NYHA II-III
• Evidence of structural underlying heart disease
• Unchanged medication >= 4 weeks
• Age >= 18 years
• Able to walk or cycle
• Able to understand and fill in Dutch questionnaires

Exclusion criteria

• Life expectancy < 1 year
• Last six months Percutaneous Coronary Intervention/Coronary Artery Bypass Graft/Heart Transplantation/valvular replacement or planned such an intervention within the next 3 months
• Ventricle tachycardia (VT*s) and atrium fibrillation (AF) during increased physical activity
• Difficult to tune Diabetes Mellitus
• Recent lung embolism (<3 months ago) which is hemodynamic a burden
• Inclusion in another study

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-02-2010
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL30757.042.09