

# The impact of heart failure on exercise-induced cardiac fatigue: an explorative study

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Primary objective: To compare the impact of a single day of prolonged walking exercise on cardiac function and biomarker responses between heart failure patients and their age- and sex-matched controls. Secondary objective: To compare the impact of 1...

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

## Summary

### ID

NL-OMON41066

### Source

ToetsingOnline

### Brief title

Cardiac fatigue in heart failure patients

### Condition

- Heart failures

### Synonym

cardiovascular diseases, Heart failure

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Cardiac fatigue, Endurance exercise, Heart failure, Walking

## Outcome measures

### Primary outcome

Left ventricular ejection fraction, E/E\* ratio and global longitudinal strain, RV fractional area change, E/E\* ratio and global longitudinal strain are the primary outcome parameters in this study.

### Secondary outcome

Cardiac biomarkers (high-sensitivity cardiac troponin, NT-proBNP, Galectin 3 and ST2) and pulse wave velocity will be included as secondary outcome parameters

## Study description

### Background summary

Walking represents moderate-intensity exercise which can be performed for several hours. This makes (prolonged) walking exercise an effective strategy to improve physical fitness and to attenuate the development / progression of cardiovascular diseases. Previous studies indicated that a physical active lifestyle can improve longevity and reduce the risk for future cardiovascular events in various clinical populations. Accordingly, walking exercise is frequently prescribed by physicians, resulting in the participation of patients with cardiovascular diseases (e.g. heart failure, myocardial infarction, coronary artery disease, etc.) in walking events like the Nijmegen Four Days Marches.

Prolonged exercise is known to cause an acute, but transient, impairment in cardiac function in healthy young populations. Previous studies reported reductions in ejection fraction and systolic/diastolic dysfunction following endurance exercise, which is referred to as \*cardiac fatigue\*. Whether these exercise-induced responses are also present in heart failure patients, who demonstrate an a priori impaired cardiac function, is currently unknown.

## Study objective

Primary objective: To compare the impact of a single day of prolonged walking exercise on cardiac function and biomarker responses between heart failure patients and their age- and sex-matched controls.

Secondary objective: To compare the impact of 1-day versus multiple days of prolonged walking exercise on cardiac function and biomarker responses in heart failure patients and age- and sex-matched controls.

## Study design

An observational study in which the cardiac function will be examined before and immediately after the 1st and 3rd day of the Nijmegen Four Days Marches in 20 participants. Blood samples for cardiac biomarker analysis will be obtained at baseline, and after day 1, 2, 3 and 4 of the Nijmegen Four Days Marches.

## Study burden and risks

Walking is not associated with serious health risks. Actually, regular physical activity such as walking exercise protects against cardiovascular disease/risk. Furthermore, our primary outcome measures relate to non-invasive measurement of cardiac function. Our secondary outcome measures will be determined from a venous blood sample (i.e. cardiac biomarkers). This procedure is associated with a minor risk for haemorrhage (5%).

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Heart failure group

- Participant of the Nijmegen 4-Day Marches 2014
- $\geq 18$  years
- Mentally able/allowed to give informed consent
- Patients diagnosed with systolic heart failure (including an ejection fraction  $< 50\%$  on current medication)
- NYHA class I + II; Control group
- Participant of the Nijmegen 4-Day Marches 2014
- $\geq 18$  years
- Mentally able/allowed to give informed consent

### Exclusion criteria

Heart failure group

- NYHA class III + IV
- Ejection fraction  $< 25\%$ ; Control group
- Subjects diagnosed with the following cardiovascular diseases:
  - o Congenital heart disease
  - o Myocardial infarction
  - o Cerebrovascular incident
  - o Cerebral infarction

## Study design

## Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Prevention

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2014
Enrollment:	20
Type:	Actual

## Ethics review

Approved WMO	
Date:	04-06-2014
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

## 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**

CCMO

**ID**

NL48730.072.14

## Study results

Date completed: 31-12-2015

Actual enrolment: 20