Effect of physical activity level on maximal exercise performance in Chronic Fatigue Syndrome

Published: 09-07-2009
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The aim of this study is to compare the aerobic physical capacity of physically inactive CFS patients to relatively active patients and healthy controls.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON33019

Source
ToetsingOnline

Brief title
physical condition in CFS

Condition

- Other condition

Synonym
CFS, chronic fatigue, chronic fatigue syndrome

Health condition

chronisch vermoeidheidssyndroom

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: Activity level, Chronic Fatigue Syndrome, Maximal exercise, Physical activity

Outcome measures

Primary outcome

Maximal oxygen uptake, as achieved during a maximal exercise test

Secondary outcome

Percentage of patients achieving maximal exertion

Study description

Background summary

Patients with Chronic Fatigue Syndrome (CFS) often report an increase in symptoms after physical exercise (Bazelmans et al. 2005). This may lead to avoidance of physical activity, which will result in an even larger symptom increase after physical exercise (Vercoulen et al. 1999). Several studies reported that physical performance was diminished in CFS patients (Montague et al. 1989, Riley et al. 1990, Sargent et al 1997, Sisto et al. 1996, Wallman 2004). This seems to be mainly due to the higher perceived effort, rather than to reduced physical fitness (Sisto et al. 1996, Bazelmans et al. 2001, Wallman et al. 2004). Unfortunately, the physical activity level of patients participating in these studies was not taken into account. The model of reduced activity, leading to reduced physical fitness, leading to symptom increase might only be valid for physically inactive patients.

Study objective

The aim of this study is to compare the aerobic physical capacity of physically inactive CFS patients to relatively active patients and healthy controls.

Study design

Case-control study

Study burden and risks

Only the maximal exercise test itself and lactate measurements are performed especially for this study (1.5h).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- female
- age between 18-50 years
- able to speak, read and write Dutch language ;additional criteria for patients:
- CDC criteria for CFS
- CIS fatigue score of 35 or higher, indicating severe fatigue

- Sickness Impact Profile score of 700 or higher

Exclusion criteria

- cardiac/pulmonary disease
- knee problems
- severe hypertension
- high fever within the last 6 weeks
- unable to undergo maximal exercise testing

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2009
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	09-07-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL26646.091.09