The effect of cognitive behaviour therapy on central activation failure in Chronic Fatigue Syndrome

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The aim of this study is to determine whether treatment outcome in CBT for CFS is related to Central Activation Failure.

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

Summary

ID

NL-OMON33070

Source
ToetsingOnline

Brief title
Central activation Failure in CFS

Condition

- Other condition

Synonym
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: Central activation, Chronic fatigue syndrome, Cognitive behaviour therapy

Outcome measures

Primary outcome

Slope of Central Activation Failure (CAF) , Muscle Fibre Conduction Velocity

(MFCV) and Maximal Voluntary Force (MVF) during the two-minute MVC before and

after CBT.

Successful therapy, defined as a score on the subscale fatigue of the CIS <35

and a total score on the SIP < 700

Secondary outcome

Slope of the MVF during the two minute MVC before and after CBT. MVF is the

Maximal Voluntary Force (N) of the m. biceps brachii.

Slope of the MFCV during the two minute MVC before and after CBT: MFCV is the

Muscle Fibre Conduction Velocity (m/s) of the nerve to the m. biceps brachii.

(sidebranch n. musculocutaneus)

Study description

Background summary

Chronic fatigue syndrome (CFS) is defined by severe fatigue of at least 6 months duration that substantially interferes with occupational, educational, social and personal activities, is not alleviated by rest, and is accompanied by at least four of eight specific symptoms (Fukuda et al.). Despite ample research into the etiopathology of CFS, physiological processes playing a role

in this disease remain uncertain.
Experienced fatigue has been defined as a difficulty in initiating or sustaining voluntary activities (Chaudhuri et al. 2004). An element of experienced fatigue is physiological fatigue, i.e. a reduction in muscle force during a prolonged muscle contraction (Gandevia 2001).
This loss of force is caused by fatigue in the muscle itself and by a decline in activation of the muscle by the central nervous system. Both can be measured by stimulating a muscle with short electrical pulses during a prolonged contraction. Decline in the force exerted during electrical stimulation is caused by fatigue of the muscle itself, whereas decline in the force exerted without electrical stimulation is caused by a decline in activation of the muscle by the central nervous system. The difference between both represents the failure of the nervous system to activate the muscle and is therefore called Central Activation Failure (CAF).
An earlier study of our department (Schillings et al. 2004) found that in CFS patients, central activation failure was already present at the start of sustained voluntary muscle contraction. This could be caused by changed perception, impaired concentration, reduced effort and physiologically defined changes. As a result, demands on the muscle are lower and peripheral fatigue is decreased.
Cognitive Behaviour Therapy (CBT) is an effective treatment for CFS: it leads to a significant reduction of fatigue and disabilities (Whiting et al. 2001). About 70% of treated patients benefit from this therapy and do no longer meet criteria for CFS (Knoop et al. 2007). It is conceivable that successful CBT leads to a normalization of CAF, while CAF is unaffected by unsuccessful CBT. Therefore we would like to measure central activation during sustained Maximal Voluntary Contraction (MVC) before and after CBT for CFS.

Study objective

The aim of this study is to determine whether treatment outcome in CBT for CFS is related to Central Activation Failure.

Study design

In this observational study, participants will perform a maximal voluntary contraction of the m. Biceps brachii for two minutes. During the MVC, the m. biceps brachii will be stimulated electrically every 15 seconds to measure central activation failure. MFVC will be measured with surface-EMG.These measurements will be done both before and after cognitive therapy.

Study burden and risks

Patients do not have to make extra visits to the study site because measurements will be combined with therapy-related visits. The two measurements will take about 1.5 hour each. Patients do not have to fill in extra

questionnaires, besides those for usual clinical care.
The risk of these measurements are minimal. The electrical stimulation and the MVC itself may be somewhat painful but we think the burden for participants is acceptable. Results of this study may give more insight into the nature of Chronic Fatigue Syndrome and the process through which Cognitive Behaviour Therapy exerts its therapeutic effect.

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

- CDC-criteria for CFS
- starting cognitive behaviour therapy
- female

Exclusion criteria

- self-reported functional limitations of the arm or schoulder

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2009
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	06-07-2009
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	NL27878.091.09