Neural correlates of chronic fatigue syndrome

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20349

Source
Nationaal Trial Register

Brief title
CFS and the brain

Health condition

chronic fatigue syndrome

Sponsors and support

Primary sponsor: Donders Institute for neuroimaging, Radboud University Nijmegen
Expert Centre for Chronic fatigue, Radboud UMC Nijmegen
Source(s) of monetary or material Support: private funding (anonymous)

Intervention

Outcome measures

Primary outcome

- Blood Oxygenation Level Dependent (BOLD) signal as measured with functional Magnetic Resonance Imaging (fMRI)

- Cerebral tissue properties as measured with Magnetic Resonance Imaging (MRI), Diffusion

Tensor Imaging (DTI) and MR-spectroscopy.

- Behavioural performance on computerized tasks

- Fatigue severity: checklist individual strength (CIS)

Secondary outcome

- Subjective measurements, e.g. self-report questionnaires, visual analogue scales

- NAA concentration as determined by MR-spectroscopy

- Cortisol and cytokine protein concentrations from hair, saliva and blood samples

Study description

Background summary

Chronic fatigue syndrome (CFS) is characterized by profound disabling fatigue with an unknown aetiology. CFS is currently treated with cognitive behavioural therapy (CBT), which has proven to be a successful intervention leading to a reduction in fatigue and disability. Consistent with cognitive behavioural models of CFS, recent clinical research has shown that mainly cognitive factors mediate successful therapy outcome. Accordingly, with support from neuroimaging studies, it has been suggested that central (cognitive) mechanisms play a role in CFS and its treatment. This project aims at identifying the neural correlates of central mechanisms that perpetuate CFS symptoms and underlie the mechanisms of change of CBT. Our hypotheses are derived from a neurobiological hierarchical Bayesian model of medically unexplained symptoms (Edwards et al., 2012) that emphasizes the influence of dysfunctional beliefs on perception. According to this model, somatoform symptoms arise from an inference failure between prior beliefs and sensory evidence. Thus, it is hypothesized that fatigue-related beliefs may bias perception towards experiencing fatigue. This project aims at investigating neural correlates associated with inference processes that are thought to underlie CFS symptoms. In addition, we will assess how these mechanisms change during cognitive behavioural therapy.

Study objective

The primary objectives of this project are:

- Identify neural correlates and behavioural measures that underlie cognitive processes that perpetuate CFS symptoms

- Identify neural mechanisms of change that mediate successful CBT.

Study design

CFS patients will be tested before and after cognitive behavioral therapy or waiting list (6 months apart) and compared with healthy controls.

Intervention

Cognitive behavioural therapy versus waitinglist

Contacts

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Eligibility criteria

Inclusion criteria

• ≥ 18 years ≤ 65 years;

• Women;

• Able to speak read and write Dutch;

• Predominantly right handedness;

• Give written informed consent;

Patients:

• Meet the 1994 US centre for Disease Control and Prevention criteria for Chronic Fatigue

Syndrome (revised
2003)

• Severely fatigued, i.e. scoring ≥ 40 on the subscale fatigue severity of the Checklist Individual Strength (CIS);

• Severely disabled; i.e scoring ≥ 700 in the Sickness Impact Profile r_08 (SIPr08) total score;

Healthy control:

• Scoring ≤ 35 on the subscale fatigue severity of the Checklist Individual Strength (CIS);

Exclusion criteria

• Any injury to the right hand that confounds hand grip performance;

• A maximal voluntary contraction (MVC) that exceeds the maximal dispersion of the hand grip device (>400
Newton)

• (History of) long term use of anti-depressants, anti-anxiety medications, beta-blockers benzodiazepines, psychostimulants
or sleep medication;

• Current major depressive or bipolar disorder

• (History of) Schizophrenia or delusional disorder.

• (History of) Anorexia nervosa or bulimia nervosa

• (History of) alcohol or substance abuse

• Severe obesity (BMI ≥ 40)

• Abnormal hearing or (uncorrected) vision;
MRI Contraindications:

• Irremovable metal objects in or around the body (e.g. braces, pacemaker, metal fragments, hearing devices);

• Claustrophobia;

• (History of) Epilepsy;

• Possible pregnancy or breastfeeding;

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2014
Enrollment:	120
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	09-12-2013
Application type:	First submission

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
NTR-new	NL4122
NTR-old	NTR4311
Other	CCMO Arnhem/Nijmegen : 2013/113
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A