# Efficacy of web-based cognitive behavioural treatment for adolescents with the Chronic Fatigue Syndrome

Submission date Recruitment status Prospectively registered 06/07/2007 No longer recruiting [ ] Protocol Statistical analysis plan Registration date Overall study status 29/10/2007 Completed [X] Results [ ] Individual participant data Last Edited Condition category 08/05/2012 Nervous System Diseases

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Elise Van de Putte

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number NCT00893438

Secondary identifying numbers

N/A

# Study information

#### Scientific Title

#### **Acronym**

**FITNET** 

## **Study objectives**

The aim of this study is to determine the efficacy of FITNET (web-based cognitive behavioural treatment) for adolescents with Chronic Fatigue Syndrome (CFS) in The Netherlands. The second goal of the study is to establish predictors of outcome. It is very important to know the characteristics of patients who will benefit from Cognitive Behavioural Treatment (CBT) and who will not. Possible predictors of outcome are: age, depression, anxiety, fatigue of the mother, parental bonding, self-efficacy, body consciousness of child and mother, physical activity (Actometer).

## Ethics approval required

Old ethics approval format

# Ethics approval(s)

METC Utrecht gave approval on the 22nd October 2007 (ref: 07-196/K). First patient was included on 30th January 2008.

# Study design

Randomised controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Not specified

# Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

# Health condition(s) or problem(s) studied

Chronic Fatigue Syndrome

#### **Interventions**

All participants will be randomised to one of the two treatment arms:

- 1. Intervention with web-based cognitive behavioural treatment
- 2. Usual care

The duration of the cognitive behavioural programme is limited to 6 months. The adolescents who have been assigned to the usual care will get the opportunity to attend the programme after these 6 months. The total follow-up time is 12 months after the start of the web-based programme.

The web-based programme is developed for both the adolescents and the parents. The programme consists of two parts, a psycho-educational part and a cognitive behavioural part consisting of 21 treatment modules. The therapist activates one or more treatment modules per week, dependent on the progress of the participant. Within a treatment module the participant will keep several journals, answer questions and do several assignments. All answers are sent to the therapist, with whom a weekly email contact will be realised.

## Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

- 1. School presence
- 2. Severity of fatigue
- 3. Physical functioning as measured by the subscale physical functioning

Efficacy of the web-based programme will be determined after these 6 months. The follow-up measurement at 12 months is meant to define if the result.

## Secondary outcome measures

Self-rated improvement. Efficacy of the web-based programme will be determined after these 6 months. The follow-up measurement at 12 months is meant to define if the result.

# Overall study start date

01/10/2007

#### Completion date

01/10/2010

# Eligibility

#### Key inclusion criteria

Adolescents (12 - 18 years) with Chronic Fatigue Syndrome.

## Participant type(s)

Patient

#### Age group

Child

### Lower age limit

12 Years

## Upper age limit

18 Years

#### Sex

**Not Specified** 

# Target number of participants

140

## Key exclusion criteria

- 1. Score greater than or equal to 44 on the Stait-Trait Anxiety Inventory for Children
- 2. Score greater than or equal to 15 on the Childrens Depression Inventory
- 3. No availability of computer and/or internet
- 4. Risk of suicide
- 5. Mental retardation

#### Date of first enrolment

01/10/2007

### Date of final enrolment

01/10/2010

# Locations

#### Countries of recruitment

Netherlands

# Study participating centre University Medical Center Utrecht

Utrecht Netherlands 3508 AB

# Sponsor information

#### Organisation

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

# Sponsor details

Laan van Nieuw Oost Indië 334 Postbox 93 245 The Hague Netherlands 2509 AE info@zonmw.nl

## Sponsor type

Research organisation

#### **ROR**

https://ror.org/01yaj9a77

# Funder(s)

# Funder type

Research organisation

#### Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/04/2012		Yes	No