

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

Submission date 06/07/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/10/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/05/2012	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00893438

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

Completion date

01/10/2010

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

12 years

Upper age limit

18 years

Sex

Not Specified

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)

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

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