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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
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/10/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/05/2012	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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2509 AE
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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