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

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1. To determine the efficacy of web-based CBT for adolescents with CFS;2. To determine which factors contribute to this efficacy;

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30863

Source
ToetsingOnline

Brief title
FITNET

Condition

- Other condition

Synonym
chronic fatigue syndrome

Health condition

chronisch vermoeidheid syndroom

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw programma Chronische Vermoeidheid

Intervention

Keyword: adolescents, Chronic Fatigue Syndrome, cognitive behavioral treatment, efficacy

Outcome measures

Primary outcome

1. School presence, expressed in attended hours / obliged hours * 100%;

2. Subjective fatigue, measured with the subjective fatigue scale of the CIS-20;

3. Physical functioning, measured with the physical functioning scale of the

CHQ and with an actometer.

Secondary outcome

Self-rated improvement, measured using a short questionnaire consisting of 3

items.

Study description

Background summary

Chronic Fatigue Syndrome (CFS) is increasingly recognized as a cause of disability and inactivity in adolescents in the Netherlands. CFS is characterized by unexplained chronic fatigue lasting more than 6 months. Cognitive Behavioral Therapy (CBT) has proven to be effective in two-thirds of these adolescents. CBT availability though is limited and requires special therapeutic skills not always readily available in the region. Furthermore, research on predisposing factors has been insufficient. An alternative to the face-to-face CBT is FITNET, a web-based therapeutic program aimed at adolescents known with CFS, and their parents. This different CBT approach appeals to the modern youth, who grow up with the Internet as their major information source. A web-based program offers the opportunity to lower thresholds for accepting and realization of healthcare. This treatment can be

activated by the patient at any chosen time. The communication between patient and therapist can elapse asynchronously. This web-based program would greatly increase the therapeutic accessibility and commit to the needs and possibilities of modern day adolescents.

Study objective

1. To determine the efficacy of web-based CBT for adolescents with CFS;
2. To determine which factors contribute to this efficacy;

Study design

This research program will determine the efficacy of FITNET for adolescents with CFS in a randomized controlled trial, in which FITNET-intervention is compared with a waiting list condition. After 6 months, the second group will have access to the FITNET program.

Intervention

FITNET is designed by the UMC Utrecht in collaboration with the UMC St. Radboud. FITNET is a web portal accessible to patients and both parents. The program consists of a psycho-educational and a cognitive behavorial treatment (CBT) section. The CBT section consists of 21 modules, accessible upon activation by the therapist. Self-education using comprehensive assignments and personal diaries are the main elements of these modules. The therapist has access to the diaries and views the answers on the assignents. The patient will receive weekly feedback from the therapist. Meanwhile, the parents will follow a parallel program.

Study burden and risks

Burden: 3 times visit to the hospital (total time spent in het hospital 3 x 1/2 hour = 1 1/2 hours) (without the travel time)
Risk: no

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Adolescents (12-18 yr)
Diagnosis CFS according to the CDC-criteria (Fukuda 1994)
Minimal score 40 on the 'Fatigue severity subscale* of the CIS-20
Maximum score 65 on the 'Physical functioning* (Child Health Questionnaire)

Exclusion criteria

Anxiety score >= 44 on the Stait-Trait Anxiety Inventory for Children
Depression score >= 15 on the Children*s Depression Inventory
No availability of computer with Internet possibility
Inadequate control of Dutch language by child or parent
Suicidal risk
Cognitive retardation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-01-2008
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	09-10-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-02-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-11-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-03-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
Other	CCT-NAPN-16700
CCMO	NL18705.041.07