PILOT STUDY: WEB-BASED TREATMENT OF SEVERE FATIGUE AMONG ADOLESCENT PATIENTS WITH AN IMMUNE DYSREGULATION DISORDER: A SINGLE-CASE EXPERIMENTAL DESIGN WITH MULTIPLE MEASUREMENTS.

Published: 15-06-2016
Last updated: 17-04-2024

1. To investigate the feasibility of web-based cognitive CBT among severely fatigued adolescent patients with an immune dysregulation disorder, and 2. To estimate intervention effects on reducing fatigue, associated chronic pain and fatigue related...

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

Summary

ID

NL-OMON47565

Source
ToetsingOnline

Brief title
Treatment of severely fatigued adolescents with an IDD

Condition

- Other condition
- Immune disorders NEC

Synonym
Immune dysregulation disorders / (auto)immune diseases

Health condition

Het betreft immuun-dysregulatiestoornissen zoals JIA, JDM, CVID, MCTD, SLE, Syndroom van Sjögren etc

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: -Cognitive Behaviour Therapy (CBT), -Common Variable Immunodeficiency (CVID), -Fatigue, -Juvenile Idiopathic Arthritis (JIA)

Outcome measures

Primary outcome

Fatigue severity, measured with the fatigue severity scale of the CIS-20

questionnaire.

Secondary outcome

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

weeks

2. Physical functioning, measured with the physical functioning scale of the CHQ

3. Pain, measured with the with the VAS scores for pain (with scores ranging

from 0-100 mm)

Study description

Background summary

Chronic severe fatigue is a frequently reported complaint among adolescents
with paediatric immune dysregulation disorders (paediatric rheumatic diseases

and immune deficiencies). Chronic severe fatigue is described as extreme persistent or recurrent fatigue for at least 3 months with a profound, debilitating effect on daily life and should therefore be seen as a clinically relevant symptom. We found that severe fatigue affects 25.1% of adolescents with a paediatric rheumatic disease, thus making fatigue a common problem among this patient population. Importantly, this percentage is significantly higher than in the general population. Furthermore, fatigue among these adolescent patients is associated with a significant decrease in school presence and physical activity. Another important result of our study is the finding that in our subgroup of adolescents with Juvenile Idiopathic Arthritis (JIA), fatigue was not associated independently with disease activity (measured using JADAS-criteria), whereas a significant positive correlation was found between fatigue and pain.
The correlation between fatigue and disabilities among patients suggests that fatigue may be a viable target for therapeutic interventions designed to improve physical functioning and school participation in this patient population. One approach in the treatment of severe fatigue that is promising is cognitive behaviour therapy (CBT). CBT is a highly effective intervention in adolescents with chronic fatigue syndrome (CVS), such as FITNET, a web-based treatment program, but also in adult severely fatigued patients with chronic conditions like Rheumatoid Arthritis or Multiple Sclerosis. The complaint of disabling severe fatigue among paediatric immune dysregulation disorders (with a low and stable disease activity) and chronic fatigue syndrome (CFS) in adolescents share several similarities in physical symptoms, such as the high level of experienced fatigue, pain and chronicity. Functional impairment is a key aspect of both paediatric conditions, thereby affecting most areas of adolescents lives. It is worth noting that even though the abovementioned CBT program was not designed specifically to target pain, both fatigue and pain were reduced in adolescent CFS patients. The proven efficacy of a web-based treatment programme for adolescent patients with CFS (FITNET) might be an excellent opportunity for adjusting this treatment programme for adolescent with disabling fatigue PLUS a paediatric immune dysregulation disorder (FITNET-PLUS).
In this pilot study web-based CBT is applied to severely fatigued adolescent patients with an immune dysregulation disorder to test if CBT will lead to a reduction of fatigue and disabilities.

Study objective

1. To investigate the feasibility of web-based cognitive CBT among severely fatigued adolescent patients with an immune dysregulation disorder, and
2. To estimate intervention effects on reducing fatigue, associated chronic pain and fatigue related disabilities in adolescent patients with an immune dysregulation disorders.

Study design

The research methodology used in the proposed research is a single-case experiment (SCE). SCEs are experimental, and its purpose is to document causal relationships between independent and dependent variables.

Intervention

Participants will receive web-based CBT for fatigue in addition to usual care for their primary disease. The CBT treatment consists of 20 interactive treatment modules, over a period of six months. Trained and licensed (by the Expert Centre of Chronic Fatigue) cognitive behavioural therapists at the Wilhelmina Children*s Hospital will give the CBT. This treatment is already part of routine care for severely fatigued adolescents patients with chronic fatigue syndrome, and adult patients with severe fatigue plus chronic conditions like rheumatic diseases and multiple scleroses. The treatment is adapted to the specific characteristics of adolescent patients with an immune dysregulation disorder.

Study burden and risks

There are no or only minimal risks involved in participating in the CBT intervention. The burden is limited and consists of extra travel time for four face to face sessions with a cognitive behavioural therapist (intake, consultation session, evaluation post intervention and follow-up), completion of questionnaires, wearing an actometer for 12 days before the start of the treatment and doing home-work assignments when the web-based treatment get started. The program will be adapted to the individual situation of the patient. Patients fill out several questionnaires at baseline measurement, in order to determine which topics need to be included in the CBT. During the complete study period (min. 49 to max. 68 weeks) patients will complete a short weekly questionnaire. This short weekly questionnaire will be completed online, within approximately 5-10 minutes. Besides the weekly measures, patients will fill out three longer questionnaires (approximately 30 minutes), three times in total (at baseline, post treatment and follow-up).
There are potential benefits for participants, as CBT had already proved to be a highly effective intervention in reducing fatigue severity and related disabilities among other chronic diseases, disease-free cancer survivors and chronic fatigue syndrome. The intervention may also lead to reducing fatigue severity and increasing social (community) participation among adolescent patients with an immune dysregulation disorder.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age of 11,5 - 18 years old
- Able to speak, read, and write Dutch
- Diagnosed with an immune dysregulation disorder (i.e. JIA, JDM, CVID, MCTD, SLE etc)
- Being severely fatigued for at least 3 months (CIS fatigue * 40)
- Physical functioning subscale (Child Health Questionnaire) score * 85 and/or school absence > 10%
- At least 3 months on stable medication (type and dosage)
- Diagnosed with unexplained fatigue by the general paediatrician

Exclusion criteria

- Suspicion of active disease requiring adaptation of treatment (at the time of inclusion) or a possible visit to the paediatric rheumatologist (during treatment)
- Cognitive impairment, estimated IQ <70
- A somatic cause assessed by the general paediatrician or co-morbid psychiatric disorder

based on questionnaires that can explain fatigue at baseline assessment before the start of CBT
- An anxiety score above 44 on the Spielberger State-Trait Anxiety Inventory for Children (STAIC)
- A depression score above 15 on the Children*s Depression Inventory (CDI)
- Presence of suicidal risk, as assessed by CDI and general paediatrician
- Receiving treatment for a psychiatric disorder at time of inclusion
- No availability of computer with internet access

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-08-2016
Enrollment:	11
Type:	Actual

Ethics review

Approved WMO Date:	15-06-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-11-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	27-02-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-02-2019
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
CCMO	NL56462.041.16