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Treatment of severely fatigued adolescents with an immune dysregulation disorder

Submission date
27/12/2016

Recruitment status
No longer recruiting

Registration date
11/04/2017

Overall study status
Completed

Last Edited
11/04/2017

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Paediatric immune dysregulation disorders (PIDD) are a group of childhood disorders where the immune system does not function properly. This may involve autoimmune rheumatic diseases (where the immune system mistakenly attacks healthy joints) and immune deficiencies (where the immune system's ability to fight infections and disease is compromised or entirely absent). Chronic severe fatigue is a frequently reported complaint amount adolescents with PIDD. It involves extreme, persistent or recurrent fatigue (extreme tiredness) which has lasted for at least three months. It has a profound, debilitating effect on daily life and can lead to a decrease in school attendance and physical activity in those affected. The relationship between fatigue and disabilities among PIDD patients suggests that fatigue may be a viable target for therapeutic interventions designed to improve physical functioning and school participation. One approach in the treatment of severe fatigue that is promising is cognitive behaviour therapy (CBT), a type of talking therapy that aims to change the way people think and behave. The aim of this study is to look at the effectiveness of a web-based CBT treatment programme for adolescent PIDD patients with chronic fatigue at reducing fatigue and disabilities.

Who can participate?
Patients aged between 11 and 18 who have a PIDD and have been suffering from severe fatigue for at least three months.

What does the study involve?
All participants take part in the web-based CBT programme for six months. They are randomly allocated to start receiving the programme at different timepoints. The programme involves 19 interactive modules which include topics such as regulation of sleep-wake pattern; adjustment to a chronic (long-term) disease and managing the uncertainty about disease progression; adjustment to chronic (long-term) pain; reformulation of fatigue related thought patterns; activity regulation and increasing physical activity; and improving social interactions in relation to fatigue. Within a treatment module the participant is asked to keep several journals, answer questions and do several assignments. All answers are sent to the therapist that participants are in weekly email contact with. The main emphasis in the treatment part will be on the setting of goals in behavioural terms to motivate a change in behaviour and accompanying them to normal daily activities including full time education. Patients work toward achieving these goals

throughout the programme. At the start of the study and then every week until four weeks after the programme ends (including the time before they start the programme), participants complete a range of questionnaires about their fatigue, pain and disability levels.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in their fatigue and disability levels. There are no anticipated risks involved with participating in this study.

Where is the study run from?
Wilhelmina Children's Hospital, University Medical Center Utrecht (Netherlands)

When is the study starting and how long is it expected to run for?
August 2016 to January 2018

Who is funding the study?
Univerisity Medical Center Utrecht (Netherlands)

Who is the main contact?
Dr Elise van de Putte
e.vandeputte@umcutrecht.nl

Contact information

Type(s)
Scientific

Contact name
Dr Elise van de Putte

Contact details
Wilhelmina Children's Hospital (part of University Medical Center Utrecht)
Postbox 85090
Utrecht
Netherlands
3508 AB
+31 88 75 545 55
e.vandeputte@umcutrecht.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL56462.041.16

Study information

Scientific Title
Pilot study: web-based treatment of severe fatigue among adolescent patients with an immune dysregulation disorder: a single-case experimental design with multiple measurements

Acronym
FITNET-plus

Study objectives
The main aim of this pilot study is to estimate the feasibility of web-based cognitive behaviour therapy (CBT) for severe disabling fatigue among a limited number of adolescent patients with an immune dysregulation disorder. The secondary aim is to estimate intervention effects of web-based CBT for fatigue, associated pain, and disabilities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Medical Center Utrecht, 02/08/2016, ref: 16-237-M, NL56462.041.16

Study design
Single-centre randomised stepped wedge trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Immune dysregulation disorder

Interventions
All participants will be randomized to receive the web-based cognitive behaviour therapy intervention after 7, 8, 10, 11, 13 (3x), 16, 18 or 24 weeks of randomization (the participants are their own controls during waiting time). The duration of the cognitive behavioural programme is limited to 6 months and the effect will be monitored during the waiting time and the intervention by weekly questionnaires.

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 19 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.

The follow-up duration is four weeks and will be measured by weekly questionnaires and finished by a follow-up assessment.

Intervention Type
Behavioural

Primary outcome measure
Fatigue severity is measured with the fatigue severity scale of the CIS-20 weekly from baseline assessment the end of follow up (four weeks).

Secondary outcome measures
1. School presence is expressed in attended hours / obliged hours * 100% last two weeks measured weekly from baseline assessment the end of follow up (four weeks)
2. Physical functioning is measured with the physical functioning scale of the CHQ weekly from baseline assessment the end of follow up (four weeks)
3. Pain is measured with the with the VAS scores for pain (with scores ranging from 0-100 mm) weekly from baseline assessment the end of follow up (four weeks)

Overall study start date
22/08/2016

Completion date
01/01/2018

Eligibility

Key inclusion criteria
1. Age of 11.5 - 18 years old
2. Able to speak, read, and write Dutch
3. Diagnosed with JIA, JDM or CVID
4. Being severely fatigued for at least 3 months (CIS fatigue ≥ 40)
5. Physical functioning subscale (Child Health Questionnaire) score ≤ 85 and/or school absence > 10%
6. At least 3 months before treatment on stable medication (type and dosage)
7. Diagnosed with unexplained fatigue by the general paediatrician

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Suspicion of active disease requiring adaptation of treatment (at the time of inclusion) or a possible visit to the paediatric rheumatologist (during treatment)
2. Cognitive impairment, estimated IQ <70
3. 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
4. An anxiety score above 44 on the Spielberger State-Trait Anxiety Inventory for Children (STAIC), (average score of Dutch healthy adolescents plus 2 SD)
5. A depression score above 15 on the Children's Depression Inventory (CDI), (average score of Dutch healthy adolescents plus 2 SD)
6. Presence of suicidal risk, as assessed by CDI and general paediatrician
7. Receiving treatment for a psychiatric disorder at time of inclusion
8. No availability of computer with internet access

Date of first enrolment
02/08/2016

Date of final enrolment
01/01/2018

Locations

Countries of recruitment
Netherlands

Study participating centre
Wilhelmina Children's Hospital (part of Univerisity Medical Center Utrecht)
Postbox 85090
Utrecht
Netherlands
3508 AB

Sponsor information

Organisation
University Medical Center Utrecht

Sponsor details

Postbox 85090
Utrecht
Netherlands
3508 AB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Univerisity Medical Center Utrecht

Results and Publications

Publication and dissemination plan
Planned publication is in a high-impact peer reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ms. Linde Nijhof (l.n.nijhof@umcutrecht.nl)

IPD sharing plan summary
Available on request