

Treatment of severely fatigued adolescents with an immune dysregulation disorder

Submission date 27/12/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/04/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/04/2017	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 amongst 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

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 University Medical Center Utrecht)

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3508 AB

Sponsor information**Organisation**

University Medical Center Utrecht

Sponsor details

Postbox 85090
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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