PowerMe: Empowering children with mitochondrial disease in dealing with fatigue

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27650

Source
NTR

Brief title
PowerMe study

Health condition

Mitochondrial disease, ehealth, cognitive behaviour therapy
(Nederlands: mitochondriële ziekte, e-health, cognitieve gedragstherapie)

Sponsors and support

Primary sponsor: Radboud university medical center in Nijmegen.
Source(s) of monetary or material Support: Prinses Beatrix Spierfonds

Intervention

Outcome measures

Primary outcome

Fatigue severity as measured with the Checklist Individual Strength (CIS) subscale fatigue severity (weekly).

Secondary outcome

Fatigue severity measured with the CIS subscale concentration, and the Pediatric Quality of Life Inventory - Multidimensional Fatigue Scale (PedsQL - Fatigue)

Quality of life: Child health questionnaire (CHQ); and weekly questions regarding whether fatigue has interfered with their activities during the week and how much the distress this caused

School presence (attended hours/obliged hours *100); and weekly questions regarding school presence

Physical functioning: CHQ subscale physical functioning

Self-rated improvement: patients indicate whether they feel much better, have the same complaints or have become worse compared with the previous measurement (T0).

Study description

Background summary

Mitochondrial disease is a rare, hereditary disease that can manifest in any age. In over 80% of the patients, the first symptoms start before the age of 18. The disease is very heterogeneous and can affect any tissue and organ. A common and burdensome complaint is fatigue. Therefore, we developed a blended therapy for children and adolescents, which combines face-to-face and online sessions, and a supportive treatment website containing information and assignments. The intervention consists of several cognitive behavioral therapy techniques targeting personally relevant goals related to fatigue. The efficacy of the treatment is evaluated in a multiple baseline single case experiment by the Radboud university medical centre in Nijmegen. Participants will fill out short, weekly questionnaires regarding their fatigue and school presence for 33 weeks. They will be randomly assigned a baseline period of 5-9 weeks before they can start with the PowerMe intervention. In addition questionnaires will be filled out pre- (T0) and post-intervention (T1) measuring fatigue, school presence, quality of life and physical functioning.

Study objective

The PowerMe intervention is effective in reducing fatigue severity.

The PowerMe intervention improves physical functioning, quality of life and school presence.

Study design

Questionnaires measuring both primary and secondary outcomes will be filled out at the start of the study (T0) and after the treatment has ended (T1). Furthermore, the CIS subscale fatigue severity and several items regarding quality of life and school presence will be measured weekly for 33 weeks.

Intervention

The intervention is a blended cognitive behavior therapy targeting fatigue in children and adolescents with mitochondrial disease and severe fatigue complaints. The blended character consists of both face-to-face sessions and online sessions using video calling with a trained psychologist. Furthermore, a website is used as a supportive tool during the treatment. It is a secure treatment environment that contains assignments, information, and an applications for emails and video calling. The intervention will be tailored to the patient, who will work on personal goals. The guideline for treatment length is 16 weeks, but can range from 12-20 weeks within the study. Also, a guideline exists for the amount and type of sessions: 3 sessions face-to-face and 5 sessions online. Again, these can be changed to match the patients needs.

The intervention consist of 7 modules. The patient will only do the modules and assignments relevant to reach his or her goals. Modules will focus on:
1) registration of activities, sleep and possible goals; 2) psycho-education; 3) cognitive techniques; 4) behavioral techniques related to energy management; 5) communication skills; 6) sleeping behavior and 7) relapse prevention. These CBT techniques can be useful in a wide range of possible treatment goals related to fatigue and having a mitochondrial disease.

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Eligibility criteria

Inclusion criteria

- Age between 8 and 18 years

- Able to speak, write, and read Dutch

- Diagnosed with mitochondrial disease (genetically confirmed) OR suspected mitochondrial disease without genetic confirmation

- Being severely fatigued (CIS fatigue higher than or equal to 35)

- Access to a computer with internet connection

- Basic computer skills

- Able to travel to the hospital for the CBT intervention (3 sessions)

Exclusion criteria

- Intellectual disability (developmental age younger than 8 years).

- Primary depression (CDI higher than or equal to 16) or anxiety disorder (SCARED-C higher than or equal to 25)

- No current psychological treatment for fatigue

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2019
Enrollment:	10
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description
Data will be made available upon reasonable request

Ethics review

Positive opinion

Date:	17-12-2018
Application type:	First submission

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
NTR-new	NL7433
NTR-old	NTR7675
Other	NL63537.091.18 CMO Arnhem-Nijmegen : 2018-4509

Study results

Summary results

Klein, I. L., van de Loo, K. F. E., Hoogeboom, T. J., Janssen, M. C. H., Smeitink, J. A. M., van der Veer, E., Verhaak, C.M. & Custers, J. A. E. (2021). Blended cognitive behaviour therapy for children and adolescents with mitochondrial disease targeting fatigue (PowerMe): study protocol for a multiple baseline single case experiment. Trials, 22(1), 1-11. https://doi.org/10.1186/s13063-021-05126-7