PowerMe: Empowering children with mitochondrial disease in dealing with fatigue

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The PowerMe intervention is effective in reducing fatigue severity. The PowerMe intervention improves physical functioning, quality of life and school presence.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27650

Bron
NTR

Verkorte titel
PowerMe study

Aandoening

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

Ondersteuning

Primaire sponsor: Radboud university medical center in Nijmegen.
Overige ondersteuning: Prinses Beatrix Spierfonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

The PowerMe intervention is effective in reducing fatigue severity.

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Data will be made available upon reasonable request

Ethische beoordeling

Positief advies

Datum:	17-12-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7433
NTR-old	NTR7675
Ander register	NL63537.091.18 CMO Arnhem-Nijmegen : 2018-4509

Resultaten

Samenvatting resultaten
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