Moe-i-teloos: Blended care behandeling voor vermoeidheid na hersenletsel

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- Six weeks of ESM combined with personalized feedback sessions, compared with treatment as usual (TAU), leads to a stronger reduction in fatigue symptoms (primary outcome clinical effectiveness). - This intervention also leads to improvements in…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	Centraal zenuwstelsel vaataandoeningen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21265

Bron
Nationaal Trial Register

Verkorte titel
Moe-i-teloos

Aandoening

- Centraal zenuwstelsel vaataandoeningen

Aandoening

Acquired brain injury, i.c.: stroke and traumatic brain injury

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: Hersenstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Fatigue Severity Scale (FSS)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Fatigue ranks among the most prevalent consequences of brain injury and has been associated with lower quality of life, poorer neurological recovery and a higher risk of mortality. However, effective interventions for fatigue after brain injury are lagging behind. In this project, we will run a trial of a novel intervention for fatigue after mild to moderate brain injury ('Moe-i-teloos'). Moe-i-teloos is a blended care intervention, consisting of a mHealth web application where participants monitor their daily lives, combined with personalized face-to-face of screen-to-screen feedback by a treating health professional. Objective: Examining the clinical and cost-effectiveness of Moe-i-teloos, compared with treatment as usual (TAU), for individuals with stroke or TBI who report fatigue symptoms. Study design: Multicenter two-group parallel single-blind Randomized Controlled Trial (RCT) with baseline (T0), post-treatment (T1), 3-months follow-up (T2) and 6-months follow-up (T3). Study population: 110 participants (18 years or older) who recently experienced a brain injury (stroke or traumatic brain injury) and report fatigue symptoms. Intervention: 6-week treatment program aimed at reducing fatigue symptoms after acquired brain injury. During the intervention, participants monitor their symptoms, behavior and contextual information (e.g., location) in the flow of daily life using a well-validated app PsyMate, which will be installed on their smartphone. At the end of each week, a face-to-face or screen-to-screen feedback session with a therapist is planned. The central aim is to provide personalized insight in everyday functioning, fatigue and related factors, and to put into action behavioral/contextual changes to improve fatigue, other symptoms, and participation.

Doel van het onderzoek

- Six weeks of ESM combined with personalized feedback sessions, compared with treatment as usual (TAU), leads to a stronger reduction in fatigue symptoms (primary outcome clinical effectiveness). - This intervention also leads to improvements in societal participation and personal goals and a reduction in cognitive and emotional complaints (secondary outcomes) - This intervention is a more cost-efficient intervention relative to TAU (primary outcome economic evaluation).

Onderzoeksopzet

Baseline; post-intervention; 3-month follow-up; 6-month follow-up

Onderzoeksproduct en/of interventie

a.Moe-i-teloos intervention: The Moe-i-teloos intervention is a 6-week treatment program aimed at reducing fatigue symptoms after acquired brain injury. During the intervention, study subjects monitor their symptoms, behaviour and contextual information (e.g., location) in the flow of daily life using an app developed at the UM (www.psymate.eu), which will be installed on their smartphone . This app is based on the Experience Sampling Method (ESM). This app has been used and validated in numerous clinical populations, including brain injury patients (Lenaert et al., 2019; Lenaert et al., 2020). At the end of each treatment week, a face-to-face or screen-to-screen feedback session with a therapist is planned. a.1. ESM-protocol: During the intervention period (6 weeks max. to allow flexible planning), patients will collect ESM data for 3 days per week, receiving 10 beep signals on each of those days. This number guarantees detailed insight in diurnal symptom patterns even in the presence of missing data (our feasibility study showed 71% response rate; Lenaert et al., 2019). Beeps are sent between 7:30 and 22:30, with the added instruction to follow habitual sleep-wake rhythm. Beeps are sent with the restriction that they are separated by at least 15 minutes and no more than 270 minutes. A (semi)random beep design is used to prevent anticipatory behavior, which is likely when timing of beeps is known. The 3 ESM days per week will include 2 week days and 1 weekend day. This will be Thursday, Friday, and Saturday, unless agreed upon otherwise by patient and therapist. After each beep signal, a short self-report questionnaire (approximately 2 minutes) will be presented on their smartphone about current fatigue, mood, physical well-being, location, and current activities. Participants have 15 minutes to respond after each beep before the questionnaire is skipped. Statements regarding fatigue (i.e., 'I feel tired'), physical activity (i.e., 'I have been physically active since the last beep'), enjoyment of activity (i.e., 'I enjoy doing this activity'), and perceived effort (i.e., 'this activity is effortful to me') are answered on a 7-point Likert scale. Whenever participants responded two or higher to 'I feel tired', they also received the statements 'I feel mentally tired' and 'I feel physically tired'. Items like Type of activity (i.e., 'what am I doing?') is presented in multiple-choice format (i.e., 'nothing', 'resting', 'working', 'household', 'self-care', 'relaxing', 'travelling', or 'other'). An overview of the items in the app is provided in the attachments to this application. a.2. Feedback sessions In 6 face-to-face or screen-to-screen sessions at the end of each week, feedback is provided by clinicians trained in using the PsyMate web environment. Sessions consist modules focusing on diurnal variation in fatigue and the factors related to this variation (e.g., mood, physical and mental effort, daily activities, social interactions). The central aim is to provide personalized insight in everyday functioning, fatigue and related factors, and to put into action behavioral/contextual changes to improve fatigue, other symptoms, and (eventually) participation. Proposed changes are based on the current evidence about targets for intervention for fatigue (e.g., stress; mood; sleep problems) and on cognitive/behavioral change that may help reduce fatigue or better cope with fatigue. b. Control group Treatment as usual (TAU) for fatigue after brain injury. TAU consists of treatment of fatigue symptoms by an occupational therapy and/or a neuropsychologist. Treatment as usual for fatigue consists of a multidisciplinary rehabilitation/occupational therapy program (e.g.,'Niet Rennen Maar Plannen'). This program takes on average 4-8 weeks, during which patients are seen once or twice each week. However, in practice, substantial differences in treatment exist between patients.

Importantly, the duration of treatment for fatigue will be recorded in detail for all participants. In addition to treatment for fatigue, patients in outpatient rehabilitation receive multidisciplinary co-interventions (e.g., physical rehabilitation). These co-interventions will be allowed in both the intervention and control group.

Contactpersonen

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Stroke or Traumatic Brain Injury; 2. Objectified by a physician/neurologist and/or neuropsychologist; 3. Starting outpatient rehabilitation; 4. Referred for treatment of fatigue;

5. Good comprehension of Dutch; 6. Capable of handling smartphone 7. Willing and be able to give informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. <18 years; 2. Current diagnosis of depression or chronic fatigue syndrome; 3. Currently receiving cancer treatment

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-04-2023
Aantal proefpersonen:	110
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	28-09-2022

Soort:	Eerste indiening
Toetsingscommissie:	METC Academisch Ziekenhuis Maastricht / Universiteit Maastricht Postbus 5800 6202 AZ Maastricht 043 387 6009 secretariaat.metc@mumc.nl

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	NL9522
Ander register	METC azM/UM : METC20-067

Resultaten

Samenvatting resultaten
No publications up to this point