

Tied by Tiredness

Published: 31-05-2021

Last updated: 03-03-2024

- 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...

Ethical review	Positive opinion
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON21265

Source

NTR

Brief title

Moe-i-teloos

Condition

- Central nervous system vascular disorders

Health condition

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

Research involving

Human

Sponsors and support

Primary sponsor: Maastricht University

Source(s) of monetary or material Support: Hersenstichting

Intervention

Outcome measures

Primary outcome

Fatigue Severity Scale (FSS)

Secondary outcome

Dutch Multifactor Fatigue Scale (DMFS); Utrecht Scale for Evaluation of Rehabilitation-Participation-restrictions scale (User-P); CheckList Cognition and Emotion (CLCE-24); Hospital Anxiety and Depression Scale (HADS); Attainment of personal goals; Short Form Survey (SF-12); Quality of Life (EQ-5D-5L); Economic evaluation.

Study description

Background summary

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 or 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.

Study objective

- 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).

Study design

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

Intervention

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.

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Eligibility criteria

Age

Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	20-04-2023
Enrollment:	110
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date: 28-09-2022

Application type: First submission

Review commission: METC Academisch Ziekenhuis Maastricht / Universiteit Maastricht

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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	NL9522
Other	METC azM/UM : METC20-067

Study results

Summary results

No publications up to this point