Tied by tiredness: blended care intervention for fatigue in brain disorders

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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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55248

Source
ToetsingOnline

Brief title
Tied by tiredness

Condition

- Other condition
- Central nervous system vascular disorders

Synonym
'brain damage' en 'acquired brain injury (ABI)'

Health condition

langdurige vermoeidheidsklachten na hersenletsel

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Hersenstichting

Intervention

Keyword: Experience Sampling Methodology, Fatigue, mHealth, self-management

Outcome measures

Primary outcome

The main study parameter is the severity of self-reported fatigue symptoms post-treatment (T1), at 3-months follow-up (T2) and 6-months follow-up (T3). Primary outcome measure for the cost effectiveness will be the five-dimensional five-level EuroQol (EQ-5D-5L) and acost-questionnaire specifically designed for this study.

Secondary outcome

Secondary outcome measures are the 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 with the help of visual analoge scale, Dutch Multifactor Fatigue Scale (DMFS), ESM-questions and the SF-12.

Study description

Background summary

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.

Study 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).

Intervention

6 week treatment program aimed at reducing fatigue symptoms after acquired brain injury. During the intervention, participants monitor their symptoms, behaviour and contextual information (e.g., location) in the flow of daily life using a well-validated app developed at the UM, 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 burden and risks

The study is a therapeutic study without risks for the participants. Participant burden consists of filling in questionnaires for a maximum of 4 times over a period of 9 months. Participants in the intervention group will also be asked to monitor their symptoms, mood, behaviour and contextual information during the intervention phase of the study (6 weeks) during 3 days each week. This will result in approximately 20 minutes per day * 3 days per week * 6 weeks = 360 minutes (or 6 hours, or 1 hour per week). This may be experienced as a burden or may make participants more aware of the presence of negative feelings (e.g., depressed mood). This study provides participants with a highly detailed insight in their own symptom patterns and behaviors, which constitute the basis for interventions aimed at reducing fatigue, and improving mood, participation and well-being (i.e., the goal of the Moe-i-teloos intervention). The number of visits to the clinic does not differ from regular treatment (control group).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Stroke or TBI;
2. Objectified by a physician/neurologist (i.e., presence of brain damage; period of loss of consciousness at time of injury) and/or neuropsychologist (i.e., impaired neuropsychological test results following the brain injury).
3. Starting outpatient rehabilitation;
4. Referred for treatment of fatigue and scoring 4 or higher on Fatigue Severity Scale;
5. Good comprehension of Dutch (PsyMate);
6. Capable of handling smartphone
7. Willing and 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 type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-09-2021
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO Date:	25-01-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-09-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

	Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-10-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL74449.068.20