Tired! Recharge and re-engage: a program to treat fatigue for youth with Acquired Brain Injury

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To test the feasibility and preliminary effectiveness of the MOE! program in young people (12-19 years old) with ABI in four rehabilitation centers (Basalt/Merem/Revant/Heliomare) and update the program where needed based on experiences and outcomes...

Ethical review	Approved WMO
Status	Pending
Health condition type	Structural brain disorders
Study type	Observational non invasive

Summary

ID

NL-OMON57313

Source
ToetsingOnline

Brief title
Tired! Recharge and re-engage

Condition

- Structural brain disorders

Synonym
non-traumatic brain injury, Traumatic Brain Injury

Research involving
Human

Sponsors and support

Primary sponsor: Basalt Revalidatie
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Acquired Brain Injury, Fatigue, Pediatrics, Rehabilitation

Outcome measures

Primary outcome

Primary study parameter will be: A blended intervention will be delivered to reduce fatigue. The PedsQL* Multidimensional Fatigue Scale (PedsQL*-MFS) will be used as main endpoint to study fatigue pre- and post-intervention.

Secondary outcome

Secundary parameters for the pilot intervention will be participation, quality of life, compliance, goal achievement and physical fitness.

Parameter (measured by)

Participation (Child and Adolescent Scale of Participation (CASP))

Quality of life (PedsQL Generic Core Scales 4.0 (GCS-4.0))

Compliance, training and daily activity levels (Digital monitoring of the progress with Minddistrict/Physitrack) (and an activity tracker that measures active minutes per hour, steps taken per hour, heartrate variability per hour, burneg calories per hour, VO2max per dag and sleeptime per day/night)

Goal achievement (Questionnaires at the end (achieved yes/no and program satisfaction))

Physical fitness (6 minute walk test and handheld dynamometry)

Goal achievement, feasibility and satisfaction (questionnaires)

Study description

Background summary

Around 75% of the children and adolescents with Acquired Brain Injury (ABI) mention fatigue as one of the most important persistent problems (Norup et al., 2019; Van Markus-Doornbosch et al., 2019; Wilkinson et al, 2018). Fatigue among children and young adults undergoing rehabilitation is significantly higher compared to their healthy peers (Allonsius et al., 2022). Young people mention that they need good treatment for their fatigue, but do not want to go to a rehabilitation center for therapy multiple times a week. Ideally, they want a combination of on-site practice/training (with peers) and digital treatment support at home (Blended Care). A treatment for adults to reduce fatigue exists but is not available for young people between the ages of 12 and 19, nor is it available in a blended care form. Therefore we have adapted the existing intervention for adults in co-creation with young patients with ABI and healthcare professionals and created a blended program for the target group. This blended care fatigue program is called MOE! (Meedoen, Opladen, Energie!).

Study objective

To test the feasibility and preliminary effectiveness of the MOE! program in young people (12-19 years old) with ABI in four rehabilitation centers (Basalt/Merem/Revant/Heliomare) and update the program where needed based on experiences and outcomes.

Study design

This study concerns a prospective intervention study with a pre-post analysis to investigate feasibility and pre-liminary effectiveness.

Intervention

COGRAT is an existing intervention proven effective in reducing fatigue and will be adapted and made blended for the target group (MOE!)**.

Study burden and risks

Participation in this study will cost participants time and they have to wear an activity tracker. However, only patients who would have been treated for their fatigue anyhow will be included, and the new intervention will replace usual care. The benefits for the participants will be that fatigue will possibly be reduced and participation in daily life will improve.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

- Age 12-19 years,
- Must be diagnosed with ABI (traumatic/non-traumatic).
- Physically/cognitively sufficiently capable (assessment by rehabilitation physician),
- Sufficient knowledge of the Dutch language (for completing questionnaires and following online instructions/modules),
- Access to a phone/tablet with internet,
- Able to independently complete digital assignments (cognitive and physical training),
- Able to come to the rehabilitation center for physical meetings.

Exclusion criteria

Limiting psychiatric disorders

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	32
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-02-2025
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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	NL87680.058.24