Unravelling the biopsychosocial factors of fatigue and sleep complaints after traumatic brain injury

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Examining the development of fatigue and sleep complaints following moderate to severe TBI and exploring the underlying causes within a biopsychosocial model. We hypothesize that biological factors are associated with sleep complaints and fatigue in...

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

Summary

ID

NL-OMON50267

Source
ToetsingOnline

Brief title
Sleep and fatigue following TBI

Condition

- Structural brain disorders

Synonym
Brain contusion, Traumatic brain injury

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biopsychosocial model, Fatigue, Sleep, Traumatic brain injury

Outcome measures

Primary outcome

The development of subjective sleep and fatigue complaints following TBI and possible underlying biological (pain, brain damage), psychological (emotional state) and social (support family, participation) factors.

Secondary outcome

The development of objectively measured sleep-wake disturbances and fatigue following TBI and possible underlying biological (pain, brain damage), psychological (emotional state) and social (support family, participation) factors.

Study description

Background summary

Moderate to severe traumatic brain injury (TBI) can drastically impact the quality of life (QOL) and participation of the patient and their family and friends. It is often referred to as a silent epidemic due to lack of public and healthcare awareness. Sleep complaints and fatigue are common symptoms and play a significant role in the disease process and are associated with additional symptoms such as depression, anxiety, and pain. Patients experience sleep-wake disturbances (SWD) and fatigue as one of the most distressing symptoms and subsequently these symptoms influence the recovery trajectory. The etiology is still debated, uncertain and no efficacious treatment has been established. The development over time and the underlying causes of persistent fatigue and sleep complaints still need to be examined for the moderate to severe TBI spectrum. This study will therefore examine the development of sleep and fatigue following moderate to severe TBI and the role biopsychosocial factors play in persistent sleep complaints and fatigue over time. Identifying underlying causes of persistent sleep complaints and fatigue post-TBI can give direction and rationale for the development of interventions and treatment of these

symptoms.

Study objective

Examining the development of fatigue and sleep complaints following moderate to severe TBI and exploring the underlying causes within a biopsychosocial model. We hypothesize that biological factors are associated with sleep complaints and fatigue in the first 3-6 months following injury and that psychological factors are associated with sleep complaints and fatigue over time starting at 6 months. Social factors will start playing a role later in the disease process and are expected to be associated with sleep complaints and fatigue between 12 and 18 months.

Study design

Longitudinal multicentre observational cohort study with 4 measurement points (3, 6, 12 and 18 months post injury). In addition, there is screening visit within the first 6 weeks, if the patient meets the in- and exclusion criteria the study will continue and demographics and pre-injury characteristic will be determined. This screening visit can take place at the home of the participant or if preferred by the participant at Maastricht University or the participating hospital. The 4 measurement points will consist of subjective questionnaires and cognitive tasks and take place at Maastricht University or one of the participating hospitals. In the week prior to these visits the participants will wear a watch-like device (actigraph) and fill in sleep diaries every morning for 1 week. During this week participants can continue normal routines in the natural environment.

Study burden and risks

The burden and risks associated with participation are considered to be limited. The burden of this study consists of 5 visits and filling in a sleep diary during 1 week for four times in the course of 18 months. There is no physical or physiological discomfort associated with participation. Iatrogenic risks of this study are considered negligible due to its observational nature.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- First moderate-severe, closed-head injury TBI
- Age 21 - 80
- Fluent in Dutch
- Informed consent (IC)

Exclusion criteria

- Prior moderate-severe TBI diagnosed by a neurologist
- Mild concussion in the last half year
- Pre-existing neurological disorder or a brain injury with an etiology other than trauma: Stroke, idiopathic epilepsy, brain tumor, multiple sclerosis, Huntington*s disease, Parkinson*s disease, meningitis, encephalitis
- History of drug and/or alcohol abuse abuse (addiction or long term abuse, does not include a night of binge drinking/alcohol intoxication during the accident)
- Sleep disorders prior to TBI (diagnosed or treated for a sleep disorders)
- Chronic fatigue syndrome prior to TBI
- Sleep-wake patterns disturbances or fatigue due to another medical condition than TBI
- Mental disorders for which treatment was necessary (i.e. medication or

psychological/psychiatric treatments; post-injury depression, anxiety disorders no exclusion)
- Pregnancy
- Lacking the ability to complete questionnaires based on clinical judgment (aphasia, severe cognitive impairment).

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-11-2017
Enrollment:	137
Type:	Actual

Ethics review

Approved WMO Date:	05-07-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-10-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-02-2018

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	31-12-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-02-2019
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

ID: 21103
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60332.068.17

Study results

Date completed: 24-05-2024

Summary results
Trial ended prematurely