Sleep and fatigue following traumatic brain injury.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21103

Source
NTR

Health condition

Traumatic brain injury, sleep, fatigue, biopsychosocial model.
Traumatisch hersenletsel, slaap, vermoeidheid, biopsychosociaal model.

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Subjective sleep quality: score on the Pittsburgh sleep quality index

Subjective fatigue level: score on the fatigue severity index

Secondary outcome

Objective sleep-wake disturbances: Actigraphy data

Objective fatigue levels: Psychomotor vigilance task

Study description

Background summary

Rationale: Moderate to severe traumatic brain injury (TBI) can drastically impact the quality of life 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 problems and fatigue are common symptoms, playing 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 highly distressing symptoms and subsequently these symptoms influence the recovery trajectory. The etiology is still uncertain and no efficacious treatment has been established. The factors underlying development of persistent fatigue and sleep complaints still need to be examined for the moderate to severe TBI spectrum. Assuming a biopsychosocial model of fatigue and sleep complaints after TBI, it is expected that biological, psychological and social factors can all contribute to the complaints, but that the relative contribution of each factor may change over time. Based on results from cross-sectional studies we expect that biological factors may contribute most in the first (3 to 6) months following injury and decline thereafter, whereas the contribution of psychological and social factors may develop more slowly and increase over time, to contribute most after 12 to 18 months. This study will therefore examine the development of sleep complaints and fatigue following moderate to severe TBI and the role biopsychosocial factors play in persistent sleep complaints and fatigue over time. Identifying the factors underlying sleep complaints and fatigue in different phases of recovery post-TBI can give direction and rationale for the development of interventions and treatment of these symptoms.

Objective: Examining the development of fatigue and sleep complaints following moderate to severe TBI and exploring the changes in underlying biological, psychological and social factors across time.
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. The assessments used at each measurement point include subjective questionnaires and cognitive tasks, preceded by 7 nights of actigraphy combined with a sleep diary.

Study population: 137 patients with moderate to severe TBI (21-70 years old) presenting at emergency or neurology department or rehabilitation centre across the Netherlands.

Main study parameters/endpoints: The development of sleep complaints and fatigue following TBI and possible underlying biological (pain, brain damage), psychological (emotional state) and social (support family, participation) factors. Fatigue will be measured by questionnaires and cognitive performance, with the total score on the Fatigue Severity Scale (FSS) as main variable. Sleep problems will be measured by questionnaires and actigraphy, with the total

score on the Pittsburg Sleep Quality Index (PSQI) as main variable.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden and risks associated with participation are considered to be limited. The burden of this study consists of 5 visits and 4 separate weeks of wearing an actiwatch combined with filling out a sleep diary 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.

Study objective

We hypothesize that the associations between biopsychosocial factors and post-TBI sleep complaints and fatigue change over time., i.e., that the associations with biological factors are strongest in the first six months and then decline, whereas the associations with psychological and social factors are initially weak, but slowly increase and become apparent between 12 and 18 months.

Study design

3, 6, 12 and 18 months post traumatic brain injury

Intervention

There are no interventions in this study

Contacts

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Eligibility criteria

Inclusion criteria

- First moderate-severe, closed-head TBI. (Defined as: Glasgow coma scale (GCS) < 13 (75); PTA > 24 hours or trauma related intracranial neuroimaging abnormalities or loss of consciousness (LOC) > 30 min)

- Age 21 – 70.

- 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, meningioma, multiple sclerosis, Huntington’s disease, Parkinson’s disease, meningitis, encephalitis

- History of drug and/or alcohol abuse (addiction or long term abuse, does not include a night of binge drinking)

- Sleep disorders prior to TBI (diagnosed or treated for a sleep disorder)

- 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
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2017
Enrollment:	137
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-04-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50267
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6974
NTR-old	NTR7162
CCMO	NL60332.068.17
OMON	NL-OMON50267

Study results