

# Brain Power: Functioning after traumatic brain injury (TBI) in children and youth

Published: 19-12-2012

Last updated: 18-07-2024

To establish the incidence and consequences (impairments op body functions, limitations in participation) of traumatic brain injury in children and youth in a region of The Netherlands as well as the incidence of the same symptoms in a group of...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON37723

### Source

ToetsingOnline

### Brief title

Brain Power

### Condition

- Other condition
- Bone and joint injuries
- Neurological disorders NEC

### Synonym

concussion, head injury

### Health condition

traumatisch schedel/hersenletsel

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Sophia Revalidatie

**Source(s) of monetary or material Support:** Ministerie van OC&W, Sophia Revalidatie; aangevraagd wordt subsidie bij Sophia Fonds; Landsteiner Fonds van MCH

## Intervention

**Keyword:** adolescents, brain injury, fatigue, participation

## Outcome measures

### Primary outcome

The main study parameters are questionnaires assessing body functions (fatigue:

Checklist Individual Strength; headaches, depression and anxiety: YSR/ASR;

sleep disturbances: Holland Sleep Disorder List; level of physical activity:

SQUASH); overall quality of life: TAAQOL/TACQOL and a general questionnaire.

### Secondary outcome

n.a.

## Study description

### Background summary

Traumatic brain injury (TBI) is the leading cause of disability in youths today. The symptoms include impairments in motor skills, cognition, behaviour and social-emotional development. The incidence of these symptoms in youth in The Netherlands is not known. There is a delay in recognition of these symptoms leading to long term insufficient knowledge of the relationship of symptoms to the original injury. The disabilities are broad and often vague. They lead to limitations in activities and participation.

### Study objective

To establish the incidence and consequences (impairments op body functions, limitations in participation) of traumatic brain injury in children and youth in a region of The Netherlands as well as the incidence of the same symptoms in a group of children and youth with an orthopaedic injury and a group of healthy

peers.

## Study design

Cross-sectional, multicenter study.

## Study burden and risks

All participants will fill out questionnaires (paper version or digital/online). The total time to complete the questionnaires should be limited to 45-60 minutes. The benefit for the patient is that through a better understanding of long term consequences of TBI better treatment protocols can be developed. Through a better understanding of the consequences after trauma secondary prevention can be initiated earlier after injury.

## Contacts

### Public

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NL

### Scientific

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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)  
Elderly (65 years and older)

## Inclusion criteria

age: 12-25 years of age. Traumatic brain/head injury 6 to 18 months ago. Orthopedic group: same age; fracture to arm or leg without head injury or requiring surgery in the same period. Third group: healthy peers; TBI patients are asked to select friends/neighbors in same age group to participate.

## Exclusion criteria

Intelligence under 70. Poor Dutch skills. Multiple head injuries in the same period. For all groups: other disorders (congenital, rheumatic, chronic fatigue syndrome).

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2013
Enrollment:	700
Type:	Actual

## Ethics review

Approved WMO

Date: 19-12-2012

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

## 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	NL39839.058.12