# Long-term outcome after mild Traumatic Brain Injury in elderly and its relation with changes in brain network connectivity and cognitive ageing

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Primary objective: To study the relation between cognitive and physical recovery after mTBI in elderly and long-term psychosocial functioning and quality of life. Secondary objective: To study the effect of mTBI in elderly as external stressor on…

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON46718

**Source**
ToetsingOnline

**Brief title**
mTBI in elderly

### Condition

- Other condition

**Synonym**
contusion, mild traumatic brain injury

**Health condition**

traumatisch schedel-hersenletsel

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** brain networks, elderly, mTBI, outcome

## Outcome measures

### Primary outcome

For all patients measures of cognitive and physical functioning, will be taken using questionnaires at several time points. The following time line is considered: T0) baseline, admission to the ED or ward, T1) 1 week, T2) 4-6 weeks, T3) 3 months after injury and T4) 6 months after injury.

For the observational study the main parameter is the outcome determined 3 months after injury using the Glasgow Outcome Scale Extended and WHO scale Quality of Life questionnaires.

### Secondary outcome

As secondary outcome measure the unmet needs are explored together with the level of social participation by questionnaires.

In the Connectivity add-on study acute and longitudinal changes in brain network connectivity will be assessed by multi-channel electroencephalography (EEG) at T0, T2 and T3. Add-on functional magnetic resonance imaging (fMRI) is only performed at T2 for between modality comparison across the whole spectrum of older mTBI patients at this time-point.

# Study description

### Background summary

Traumatic brain injury (TBI) is one of the most important causes of morbidity and mortality in adults. Mild TBI (mTBI) accounts for 85% of cases and 15-20% of those patients suffer from persistent complaints that interfere with resumption of daily activities. The number of elderly sustaining a TBI is increasing due to growing life expectancy and now comprises 20% of all TBI hospital admissions. The majority of TBI in the elderly is caused by a fall and related to high health care costs. Concomitant brain injury is often not reported, although repetitive head injury is related to worsening of symptoms, cognitive decline and dementia. Yet, the effect of mild TBI on cognitive and physical functioning and its relation with long-term psychosocial functioning and quality of life in elderly patients who are more vulnerable to develop persistent complaints in view of age-related cognitive decline has scarcely been investigated.

### Study objective

Primary objective: To study the relation between cognitive and physical recovery after mTBI in elderly and long-term psychosocial functioning and quality of life.
Secondary objective: To study the effect of mTBI in elderly as external stressor on the course of age-related cognitive decline and the development of persistent complaints in relation to acute and long-term brain network connectivity changes.

### Study design

A prospective observational cohort study with an add-on Connectivity study comprising a longitudinal EEG-measurement and an fMRI cross-sectional measurement at first follow-up.

### Study burden and risks

Measurements in this study do not have adverse consequences for those involved, and there are no risks associated with participation, provided the exclusion criteria for fMRI are taken into account. The burden of participation is mainly restricted to the time involved in the measurements. There are no direct benefits for participants.

# Contacts

**Public**
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
**Scientific**
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Patients:
• Glasgow Coma Scale (GCS) scores on admission from 13-15
• having had loss of consciousness and/or posttraumatic amnesia (PTA)
• 60 years or older
• Comprehension of Dutch language (to understand Dutch questionnaires)
Controls:
• age-matched with patients on group level
• comprehension of Dutch language (to understand Dutch questionnaires)
• (corrected) adequate vision
• 6-item CIT score lower than 11 points (unimpaired cognition)

### Exclusion criteria

All participants:
• unavailable for or inability to comply with follow-up
• drug or alcohol addiction
• psychiatric diseases (for which participant was admitted in the past)
• previous TBI (for which participant was admitted in the past)
• fMRI exclusion criteria: claustrophobia, non-MR-compliant implants, metal fragments in eyes, non-removable piercings

## Study design

### Design

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| 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

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 19-11-2018 |
| Enrollment: | 320 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 06-03-2018 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

Approved WMO

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| Date: | 22-03-2019 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# 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 | NL64491.042.17 |