Mild traumatic brain injury and Outcomes with VIsual patient Education (MOVIE), a randomised controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26501

Source
NTR

Brief title
MOVIE-trial

Health condition

Mild Traumatic Brain Injury (MTBI)
Licht traumatische Hoofd-/Hersenletsel (LTH)

Sponsors and support

Primary sponsor: Erasmus Medical Center
Medical Centre Haaglanden
Sint Franciscus Vlietland Groep
Westfriesgasthuis
Source(s) of monetary or material Support: De Nederlandse Hersenstichting

Intervention

Outcome measures

Primary outcome

The occurence and severity of post-concussion symptoms measured by the ‘Rivermead Post-Concussion Questionnaire’ at 1 week and 3 months

Secondary outcome

- Return to usual activities (absence of work questionnaire).

- Return visit to the ED/visit to GP/outpatient clinic.

- Understanding of diagnosis by 3 questions about MTBI

- Anxiety and Depression in patients with MTBI according to HADS questionnaire

- Patient satisfaction on a 10-point scale

- Quality of life by Short Form-36 Health Survey (SF-36)

- Costs of intervention and productivity costs (costs of absence from work and reduced productivity while at work)

Study description

Background summary

Rationale: Mild traumatic brain injury (MTBI) is a common diagnosis at the Emergency department (ED). It is estimated that approximately 85,000 patients in the Netherlands suffer from MTBI each year, of whom 12,580 patients are seen at the ED of Dutch hospitals. In the first weeks to months after MTBI 17-78% of patients suffer from post-concussion symptoms. Previous studies indicate that knowledge and understanding of post-concussion symptoms by the patient may reduce incidence and/or severity of such complaints.

Objective: Our main objective is to study the effect of patient information on occurrence and severity of post-concussion symptoms in patients with MTBI.

Study design: A multi-centre prospective study will be conducted in two phases. Phase 1 is measurement of standard care. Phase 2 is a Randomized Controlled Trial (RCT), comparing standard management, with two intervention groups.

Study population: All patients >18 years with MTBI attending the ED may be eligible for inclusion.

Intervention (if applicable): Patients will receive a printed folder (written information) in the first intervention group, and in the second intervention group patients will receive written information and they will be asked to watch a video explaining the course of posttraumatic symptoms.

Main study parameters/endpoints: The primary outcome will be the occurrence and severity of post-concussion symptoms at one week and three months after attending the ED.

Study objective

Our hypothesis is that receiving written and audio-visual patient information will reduce the frequency and severity of post-concussion symptoms in patients with MTBI.

Study design

1 week and 3 months

Intervention

An online video with discharge instructions will be shown, and/or a link to the video will be provided in the leaflet.

Contacts

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Eligibility criteria

Inclusion criteria

Patients attending the ED of the participating centres with MTBI according to the definition of the Dutch institute for healthcare improvement (CBO):

- Every trauma to the head with a Glasgow Coma Scale score at first examination greater than 13,

- Post-traumatic loss of consciousness less than 30 minutes,

- and Post-traumatic amnesia not more than 24 hours

Exclusion criteria

- Intracranial abnormality on CT-scan

- Focal Neurological deficit

- Language barrier

- No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-12-2015
Enrollment:	1152
Type:	Anticipated

Ethics review

Positive opinion Date:	25-10-2015
Application type:	First submission

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
NTR-new	NL5355
NTR-old	NTR5465
Other	Medische Ethische Commissie : MEC-2015-546

Study results