UPFRONT - Prospective cohort study on early identification and treatment of adaptive deficits in mild to moderate traumatic brain injury - the impact of frontal network dysfunction for longterm outcome.

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Objectives of the study: Project 1 - To assess early adaptive deficits in a multicentre cohort of mild to moderate TBI patients and their relation to outcome. Project 2 - Early intervention study of Cognitive Behavioural Therapy (CBT) to assess...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37031

Source
ToetsingOnline

Brief title
Adaptive deficits in TBI patients (UPFRONT-study)

Condition

- Other condition
- Cognitive and attention disorders and disturbances

Synonym
adaptive deficit, behavioral regulation

Health condition

traumatisch hersenletsel

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Hersenstichting

Intervention

Keyword: adaptive deficits, frontal dysfunction, traumatic brain injury (TBI), treatment

Outcome measures

Primary outcome

For the intervention study the primary outcome measure is level of resumption

of work or study 12 months, measured with the RTW subscale of the RRL (Van den

Burg & van Zomeren, 1985).

Secondary outcome

-Working status defined as total days off work at 12 months

-GOS-E, determined by an experienced neurologist at 12 months

-Differential Outcome Scale (DOS, van der Naalt, 2000), determined at 12 months

-Role resumption (RRL; Rolhervattingslijst, Spikman et al, 2010)

Study description

Background summary

Rationale: Traumatic brain injury (TBI) may have profound impact on functional outcome. The majority of patients sustain a mild to moderate injury (85-90%). A subgroup of these patients (20-25%) experiences persistent cognitive complaints interfering with resumption of work. Six months after injury 30-40% of patients

has not resumed previous work. Lost work productivity is considered the largest component of TBI related costs. Often explanatory structural brain damage is not demonstrated by imaging techniques despite these impairments. The actual mechanism may be more complex as specific premorbid patient characteristics are also relevant. Illness perception and coping style are decisive for the development of postconcussive complaints and related to unfavourable outcome. Given the long-term consequences it is mandatory to predict which patients will develop persistent cognitive complaints.

The aim of this study is to unravel the role of adaptive deficits for outcome of mild to moderate TBI. A prospective clinical cohort multicentre study is combined with a Randomized Controlled Trial of cognitive behavioural therapy. Simultaneously an imaging study applying functional and structural MRI-studies will be performed to assess the contribution of pre-existent or brain-injury related changes to the frontal network dysfunction.

Study objective

Objectives of the study:
Project 1 - To assess early adaptive deficits in a multicentre cohort of mild to moderate TBI patients and their relation to outcome.

Project 2 - Early intervention study of Cognitive Behavioural Therapy (CBT) to assess whether early CBT reduces cognitive complaints and improves coping style with a positive effect on outcome defined as return to of work.

Project 3 - To determine the relation between adaptive deficits and frontal network dysfunction in TBI patients assessed by the application of functional (fMRI) and structural (DTI) imaging.

Study design

Study design: A prospective longitudinal multicenter cohort study, comprising a single blind randomised placebo-controlled trial (RCT), in mild to moderate TBI patients in four hospitals spanning major regions in the Netherlands, i.e. the UMCG (Groningen), the VU Medical Center (Amsterdam), St. Elisabeth Hospital (Tilburg), MST Enschede.

Study population: Mild to moderate TBI patients (GCS 9-15), age >15 yrs, comprehension of Dutch language, admitted to the emergency department of the participating Trauma Centres.
A selection of patients will be included in the intervention study and MRI-studies for which separately informed consent will be asked. The fMRI-studies will only be done in the NeuroImaging Center (Groningen) due to specialized expertise in this centre.

Intervention

The Cognitive Behavioral Therapy (CBT) is aimed at improving coping skills and diminishing ineffective thoughts and catastrophizing illness perception related to the TBI comprising an intervention group and an control intervention.

For details see page 20 of the research protocol.

Study burden and risks

Measurements and treatment in this study do not have adverse consequences for those involved, and there are no risks or burden associated with participation. The mental burden will be minimal; patients have to fill in questionnaires at 4 occasions in a one-year period. For a subgroup, involvement might be more intensive, with a treatment of 5 sessions and/or fMRI measurements. This will be counseled carefully by the professionals (psychologist, neurologist) involved.

Contacts

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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

Patients with mild to moderate TBI who are admitted to the emergency department of one of the participating hospitals. All patients admitted within the one-year inclusion period will be asked to participate in the follow up study.
Inclusion criteria:
Project 1 - GCS scores on admission from 9-15 with loss of consciousness or Posttraumatic Amnesia. Age >15 years. Comprehension of Dutch language.
Project 2 - Same as for study 1, but age range between 18-65 years. At least 3 complaints determined with a questionnaire 2 weeks postinjury comprising minimally one complaint in the cognitive domain and minimally one in the emotional/social domain (based on the actual incidence of PCS).
Project 3 - age range between 18-65 years.

Exclusion criteria

Inability to follow-up, drug or alcohol abuse, psychiatric co-morbidity, previous TBI, language barriers prohibiting understanding and completion of questionnaires.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2013
Enrollment:	2200
Type:	Actual

Ethics review

Approved WMO Date:	20-11-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-05-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-10-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-07-2019
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	NL41188.042.12