Participation of children and youth after mild traumatic brain injury.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON45113

Source
ToetsingOnline

Brief title
Participation after brain injury

Condition

- Neurological disorders NEC

Synonym
Comtusio Cerebri/ Brain Contusion

Research involving
Human

Sponsors and support

Primary sponsor: Maastricht University - Faculty of Psychology and Neuroscience
Source(s) of monetary or material Support: Johanna Kinderfonds en Revalidatiefonds

Intervention

Keyword: Children, Mild Traumatic Brain Injury, Participation, Youth

Outcome measures

Primary outcome

The primary study parameters for both the cohort study and the RCT are (both parent and youth version of) the Child and Adolescent Scale of Participation - Dutch Language Version (CASP-DLV) and the Dutch translation of the Children's Assessment of Participation and Enjoyment (CAPE). With these questionnaires the level of daily activity and participation is measured.

Secondary outcome

The following secundary parameters for both the cohort and for the RCT are:

- Pediatric Questionnaire - Quality of Life Scale and the Multidimensional Fatigue Scale (PedsQL), provides insight into the quality of life and level of fatigue.

- Sensory Profile - short version (SP-NL) and Adolescent / Adult Sensory Profile (AASP-NL), provides insight into sensory information processing.

- Health and Behavior Intventory (HBI), provides insight into cognitive, somatic (eg pain), emotional and behavioral functioning.

- Impact of Event (SVL), provides insight into possible posttraumatic stress reactions.

- Registration form (RF), herein demographic (eg. age, gender, education) and injury-related (eg. nature of injury, GCS, PTA duration) are recorded.

Study description

Background summary

Traumatic brain injury is the leading cause of acquired brain injury among children and youth. Approximately 14,000 children and youth under the age of 24 years are diagnosed annually with traumatic brain injury in the Netherlands. About 80% of this group is diganosed with mild traumatic brain injury (LTH). This subgroup is not structurally followed by a practitioner, while an estimated 10-20% of this group still have adverse consequences after six months. In the Netherlands, this accounts for approximately 1,700 children and youth each year. Lack of diagnostics, underestimation and a too late recognition of the often invisible long-term consequences (such as reduced capacity and cognitive problems), often lead unnecessarily to chronic and disruptive consequences for youth and family participation, such as problems at school and in social relations. The consequences are a major expense for the Dutch society. Early detection of problems in this group and early intervention could potentially prevent the long-term consequences.

Study objective

The aim of this study is to examine the daily level of activities and participation after LTH in children and adolescents (6-18 years) and to identify possible predictors. In addition, experimental research is done in a subgroup to measure the effect of an early intervention, which contains monitoring, psycho-education and case management, meant to prevent the consequences of brain injury on daily activities and participation, compared to regular care.

Study design

Multicenter prospective longitudinal cohort study with a nested randomized clinical trial in a subset of participants in the cohort study, in which the effectiveness of an early intervention compared with usual care is measured. There will be three measurement points for the participants: within 2 weeks after injury, three months after injury and six months after injury.

Intervention

The intervention is offered by a rehabilitation professional, with at least HBO skill level and experience of working with children with aquired brain injury (eg. A paramedic or nurse). Participants in the RCT assigned to the intervention group receive the intervention in addition to the usual care. Participants in the RCT assigned to the control group only receive the usual care. The intervention consists of 1) monitoring, 2) psyco-education, and 3)

case management.

Study burden and risks

Patients are not at risk. It involves questionnaire administration. Child/adolescent and his/her parents are (in the private, secure home) assisted by the researcher during the administration of the questionnaires. It is known that a part of this population (children and youth with mild traumatic brain injury) suffers from complaints. It is unknown which of these children are at risk for complaints and how these complaints can be prevented. This justifies the conduct of this study.

Contacts

Public
Maastricht University - Faculty of Psychology and Neuroscience

Universiteitssingel 40
Maastricht 6229 ER
NL
Scientific
Maastricht University - Faculty of Psychology and Neuroscience

Universiteitssingel 40
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Elderly (65 years and older)

Inclusion criteria

- Children and Youth aged 6-18
- Diagnosed with mild traumatic brain injury (according to criteria ACRM en WHO collaborating centre for neurotrauma, Task Force (Kristman, 2014) in our participating hospitals

Exclusion criteria

- Lack of dutch language
- Recurrent braindamage of central neurological disease during the follow-up period

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-05-2015
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	13-04-2015
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-08-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-01-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-04-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-10-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL51968.078.14