

Participation of children and adolescents after mild traumatic brain injury

No registrations found.

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

Summary

ID

NL-OMON28512

Source

NTR

Brief title

Brains Ahead!

Health condition

Consequences of mild traumatic brain injuries in children and adolescents.

Gevolgen van licht traumatisch hersenletsel bij kinderen en adolescenten.

Sponsors and support

Primary sponsor: Primair: Maastricht University

Secundair: Brains Ahead! projectgroep:

C.E. van Heugten - Maastricht University

M.I. Renaud - Maastricht University & Revant Revalidatiecentrum

I.G.L. van de Port - Revant Revalidatiecentrum

S.A.M. Lambregts - Revant Revalidatiecentrum

C.E. Catsman-Berrevoets - Erasmus MC

Source(s) of monetary or material Support: Johanna Kinderfonds

Revalidatiefonds

Intervention

Outcome measures

Primary outcome

Activity and participation, measured with the Child and Adolescent Scale of Participation - Dutch Language Version (parentforms).

Secondary outcome

Participation from children's perspective: Child and Adolescent Scale of Participation (child version) and Children's Assessment of Participation and Enjoyment.

Cognition and behavior - Child Behavior Checklist.

Family functioning - Family Assessment Device.

Fatigue - PedsQL vermoeidheidsschaal.

Quality of life - PedsQL kwaliteit van leven schaal.

Post concussieve symptomen - Health and Behavior Inventory.

Posttraumatische stress symptomen - Schokverwerkingslijst.

Sensory processing - Sensory Profile (short version and AASP).

Study description

Study objective

To examine participation of children and adolescents during the first six months after mild traumatic brain injury and to identify predictors for this outcome. Furthermore, to examine the effect of an early intervention, meant to prevent participation problems at six months post injury, compared to the usual care.

We hypothesize that the early intervention is more effective in preventing long-term problems on activity and participation after mild traumatic brain injury, compared to the usual care.

Study design

Two weeks, three months and six months post injury.

Intervention

Controlgroup receives care as usual consisting of a concise information brochure.

Interventiongroup receives care as usual and casemanagement, consisting of:

- Inventarisation of complaints/problems after the injury;
- Psycho-education;
- Follow-up.

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

Children and adolescents aged 6-18 years.

Diagnosed with mild traumatic brain injury in one of our participating hospitals in the past week.

Exclusion criteria

Limited understanding of the Dutch language.

Reoccurring brain injury or 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)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	06-05-2015
Enrollment:	140
Type:	Anticipated

Ethics review

Positive opinion	
Date:	17-04-2015
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	NL4998
NTR-old	NTR5153
Other	METC Erasmus MC : MEC-2015-047

Study results