

Cognitive rehabilitation treatment of deficits in emotion, social cognition and regulation of behaviour after traumatic brain injury; development of treatment protocol and pilot study

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To determine the feasibility and the estimation of the effect for the primary study parameter of a cognitive rehabilitation treatment for deficits in social cognition after traumatic brain injury.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32762

Source

ToetsingOnline

Brief title

Treatment of Social Cognition in TBI patients

Condition

- Other condition
- Structural brain disorders

Synonym

behavioural regulation, deficits in social attention, personality changes

Health condition

traumatisch hersenletsel; stoornissen in sociale cognitie

Research involving

Human

Sponsors and support

Primary sponsor: Dr. J.M. Spikman, onderzoeker is zelf de verrichter

Source(s) of monetary or material Support: Hersenstichting Nederland

Intervention

Keyword: cognitive rehabilitation, social cognition, traumatic brain injury (TBI)

Outcome measures

Primary outcome

Improvement of social cognition, that is, a significant difference between pre- and postmeasurement on the The Awareness of Social Inference Test (TASIT, McDonald, 2003).

Secondary outcome

Checklists and questionnaires for social functioning in daily life (KATZ adjustmentscales, (KAS-R, Goran & Fabiano, 1993), Dysexecutive Questionnaire (DEX, Wilson, e.a., 1996), NBAP, Nelson, 1998,, Quality of Life after Brain Injury (QOLIBRI, Von Steinbuchel e.a., 2005). Tests for social cognition (FEEST (Young e.a., 2002), Cartoon Test (Happé e.a. 1999), Faux Pas test (Stone e.a., 1998), Sustained Attention to response Task (SART, Robertson e.a., 1997), Iowa Gambling Task (Bechara e.a., 1994), Emotional Empathy Questionnaire (EEQ, Mehrabian & Epstein, 1972), Read the Mind in the Eyes (Baron-Cohen, e.a., 1997)), for executive functioning (Behavioural Assessment of the Dysexecutive Syndrome (BADS, Wilson et al, 1996)), and an estimation of premorbid IQ by means of the Dutch version of the NART (NLV, Schmand e.a., 1992).

Study description

Background summary

Patients with traumatic brain injury (TBI) can have deficits in social cognition because of damage to orbitofrontal/ventromedial prefrontal brain area's. Social cognition is the ability to perceive social information (i.e. emotional expressions on faces), to integrate this information with general knowledge of social concepts and conventions in order to understand the behaviour or others, and to adapt behaviour to the social situation. Deficits in social cognition manifest themselves as socially inadequate, egocentric, disinhibited or emotionally indifferent behaviour. Such behavior has serious, adverse consequences for the ability of patients to function adequately in daily life situations, that is, to be involved in social relationships with others and to maintain a job. There is much evidence that deficits in social cognition, more than cognitive or physical consequences of brain injury, have a negative influence on the outcome of patients. Until now there were no adequate, multi-faceted treatment possibilities for these patients, although sorely needed. There are some studies in which single aspect treatment of social cognition is described, but the majority of these concern other, neuropsychiatric patient groups. Seldomly treatments are evaluated in the form of an RCT. We developed a treatment protocol in which all three aspects of social cognition (perception, understanding and regulation of social situations) are treated, in which successful elements of other treatments are incorporated and which has the explicit goal to improve social behaviour in daily life.

Study objective

To determine the feasibility and the estimation of the effect for the primary study parameter of a cognitive rehabilitation treatment for deficits in social cognition after traumatic brain injury.

Study design

A pilot study with 8 TBI patients in a repeated measures design (pre- and postmeasurement) on the effect of a cognitive rehabilitation treatment for deficits in social cognition after traumatic brain injury.

Intervention

A cognitive rehabilitation treatment of deficits in social cognition, given by an experienced neuropsychologist, twice a week, 20-24 1hr sessions in total

Study burden and risks

There will be no adverse consequences of the treatment nor risks for the patients involved. The burden is small and mainly psychological, that is, the treatment will be rather intensive and requires patients to be motivated. However, this will be carefully supervised and coached by the psychologist who gives the treatment and who has ample experience with brain injured patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- 1) deficient score on the Neuro Behavioural Affect Profile (NBAP, Nelson, 1998)
- 2) deficient score on the Facial Expression of Emotion Test (FEEST, Young, 2003) AND/OR orbitofrontal/medial frontal damage on MRI

Exclusion criteria

neurodegenerative or psychiatric disorders, lack of self-awareness (indicated by a difference score of 0 on the self-rating version of the NBAP between rating of premorbid and present functioning), severe cognitive comorbidity interfering with the ability to follow treatment (global aphasia, neglect, amnesic syndrome).

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-01-2009

Enrollment: 8

Type: Anticipated

Ethics review

Approved WMO

Application type: First submission

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

CCMO

ID

NL25269.042.08