Cognitive rehabilitation treatment of deficits in emotion, social cognition and regulation of behaviour after traumatic brain injury; evaluation of effect using a randomized controlled trial (RCT)

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To investigate the treatment effect of the protocol Treatment of deficits in Emotion, Social Cognition and behaviour regulation (T-ScEMO) after traumatic brain injury.

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

Summary

ID

NL-OMON38197

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 de 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: Hersenstiching Nederland

Intervention

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

Outcome measures

Primary outcome

Inprovement of social cognition, that is, a significant improvement pre- to postmeasurement on the Awareness of Social Inference Test (TASIT, Mc Donald et al., 2003).

Secondary outcome

Questionnaires and checklist for social functioning in daily life (patient):

* Balanced Emotional Empathy Scale (BEES, Mehrabian,2000),

* Berkeley Expressivity Questionnaire (BEQ, Gross & John, 1997),

* Brock Adaptive Functioning Questionnaire (BAFQ, Dywan & Segalowitz, 1996),

* Dysexecutive Questionnaire (DEX, Wilson, e.a., 1996),

* Quality of Life after Brain Injury (QOLIBRI, Von Steinbuchel e.a., 2005),

* Self Efficacy for Symptom Management (SEsx, Cicerone, 2008),

* Treatment Goal Attainment (TGA, Spikman et al. 2010),

* Utrechtse Copinglijst (UCL, Schreurs & van de Willige, 1988).

Questionnaires and checklist for social functioning in daily life (psychologist, psychological assistant, proxy):

* Brock Adaptive Functioning Questionnaire (BAFQ, Dywan & Segalowitz, 1996),

* Dysexecutive Questionnaire (DEX, Wilson, e.a., 1996),

* Rolhervattingslijst (RLL, Spikman et al., 2010),

* Proxy questionnaire (developed for this study, 2011).

Tests voor social cognition

* Facial Expression of Emotional Stimuli Test (FEEST (Young e.a., 2002),

* Cartoon Test (Happé e.a. 1999),

* Faux Pas test (Stone e.a., 1998),

* Iowa Gambling Task (IGT, Bechara e.a., 1994).

Cognitive functions:

* Premorbid IQ (Nederlandse Leestest voor Volwassenen, NLV, Schmand e.a.,

1992).

* Executive functioning (Zoomap, Behavioural Assessment of the Dysexecutive

Syndrome (BADS, Wilson et al, 1996)),

* Memory

-15 woordentest (15 woordentest, Deelman, Brouwer, van

Zomeren en Saan, 1980)

- WAIS Digit Span (WAIS Digit Span, Wechsler Adult

Intelligence Scale-III, Wechsler, 1997)

* Attention:

-Test of Everyday Attention (TEA, Robertson et al, 1994)

-Stroop Kleur Woord test (Stroop, 1935)

-Trailmaking test (TMT, Reitan, 1958)

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 expression of faces), to interpret this information of others and to adapt behaviour to the social situation. Deficits in social cognition manifest themselves as socially inadequate behaviour, egocentrical, disinhibited er emotionally indifferent behaviour. Such behaviour has serious, adverse consequences for the ability of patients to maintain social relationships with others, to maintain a job and function in society. There is much evidence that these deficits, more than the fysical or cognitive consequences of brain injury, have a negative influence on the outcome of patients. Until now there are no adequate, multi-faceted treatment possibilities for these patients, although sorely needed. There are some studies which focus on aspects of social cognition, mostly in neuropsychiatric patient groups. Seldomly are these treatments evaluated in the form of an RCT, however. We developed a treatment protocol which addresses all three aspects of social cognition (perception, understanding of and regulation of behaviour), based on succesful elements of other existing treatments.

Study objective

To investigate the treatment effect of the protocol Treatment of deficits in Emotion, Social Cognition and behaviour regulation (T-ScEMO) after traumatic brain injury.

Study design

A RCT in which the effectiveness of the treatment protocol social cognition is compared with the training of attention.

Intervention

A cognitive rehabilitation treatment of deficits in social cognition, or a training of attention, given by an experienced neuropsychologist, twice a week, 20 sessions of 1 hour each.

Study burden and risks

There will be no adverse consequences of the treatment a no risk for the patients involved. The burden is small and mainly psychological, that is, the treatment will be intensive and requires the 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 Brock Adaptive Functioning Questionnaire (BAFQ, Dywan & Segalowitz, 1996)
2) Deficient score on the Facial Expression of Emotion Test (FEEST, Young, 2003) AND/OR
3) orbitofrontal/mediofrontal damage on MRI

Exclusion criteria

Neurodegenerative or psychiatric disorders, lack of self-awareness, severe cognitive comorbidity interfering the ability to follow a treatment (global aphasia, neglect, amnestic symdrome), there is no proxy who can fill in the questionnaires. See page 15 and 16 of the protocol

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2011
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	06-07-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-05-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO Date:	26-06-2012
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	NL36391.042.11