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Effectiveness of a social cognition treatment (T-ScEmo) in patients with moderate to severe traumatic brain injury

Submission date
21/10/2016

Recruitment status
No longer recruiting

Registration date
21/10/2016

Overall study status
Completed

Last Edited
27/11/2020

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Traumatic brain injury (TBI) is an injury to the brain caused by a head injury (trauma to the head). Depending on the part of the brain that is injured, it can cause changes in behaviour, physical abilities or even personality. Patients who have injured the orbitofrontal/ventromedial prefrontal brain areas can develop problems with social cognition. 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. Problems with social cognition often appear as socially inappropriate behaviour, egocentricism (self-centeredness), and uncontrolled or indifferent emotional 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 evidence that these problems can have a negative impact on the outcome of the patient, more so than physical or cognitive (mental processing) problems. In this study, a treatment program which addresses three aspects of social cognition (perception, understanding of and regulation of behaviour) will be tested. The aim of this study is to find out whether this program can lead to improved social functioning in patients with TBI.

Who can participate?
Patients with moderate to severe TBI who are in the long-term recovery stage and have problems with social functioning.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive 20 one-hour sessions of the social cognition treatment program. This involves learning about understanding emotions, perspective, and basic and goal directed social behavior. The main focus of treatment is directed at keeping and improving social relationships. Those in the second group receive 20 one-hour sessions individual computerised attention training which involves completing a range of exercises designed to improve attention. At the start of the study and then two weeks and three to five months after treatment, participants in both groups complete a number of questionnaires and assessments to evaluate their social cognition.

What are the possible benefits and risks of participating?
Participants benefit from receiving information about their social cognition as well as receiving rehabilitation treatment. There are no notable risks involved with participating.

Where is the study run from?
1. University Medical Center Groningen (Netherlands)
2. Reade (Netherlands)
3. Revalidatie Friesland (Netherlands)

When is the study starting and how long is it expected to run for?
April 2010 to December 2016

Who is funding the study?
Dutch Brain Foundation (Netherlands)

Who is the main contact?
1. Mrs Herma Joanne Westerhof-Evers (public)
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2. Professor Jacoba Spikman (scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
METc2011.094

Study information

Scientific Title
The effectiveness of the Treatment op Social cognition and Emotion regulation (T-ScEmo) compared to training of attention (CogniPlus) on social functioning (i.e. social cognition performances, behavioral complaints, participation and quality of life) after moderate to severe traumatic brain injury: a randomized controlled trial

Acronym
T-ScEmo

Study objectives
The primary aim of this study is to evaluate whether an intervention focusing on emotion perception, social understanding and social behavior (T-ScEmo) result in better social functioning, expressed in significant better performances on social cognition tasks, a significant reduction in behavioural complaints and significant improvement of participation and quality of life, compared to a computerized attention training.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethical Committe of the University Medical Center Groningen, 06/05/2011, ref: METc 2011/094

Study design
Multi-center single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Traumatic brain injury in the subacute and chronic phase of recovery, with deficits in social cognition

Interventions
Participants who have given consent to participate are randomly assigned to the experimental condition (Treatment of Social Cognition and Emotion Regulation: T-ScEmo) or the control condition (a training of attention: CogniPlus), for which lots were blindly drawn (two “control” and two “experimental”). After screening in an anamnesis interview a neuropsychological baseline assessment was scheduled.

Experimental intervention: Participants receive 20 1-hour T-ScEmo sessions. The treatment aims to enhance emotion perception,perspective taking and theory of mind ability, and basic and goal directed social behavior. The treatment protocol constitutes an individual approach in which individual goal setting and self-monitoring is emphasized with support of a significant other. Sessions entail psycho-education, strategies to improve emotion perception (i.e. facial-feature processing, mimicry, emotional experiences), strategies to improve perspective taking (following the thoughts-emotion-behavior triangle), strategies and techniques to improve awareness and inhibition of undesired social behavior and improve socially desired behavior. The main focus of treatment is directed at keeping and improving social relationships.

Control condition: Participants receive an individually administered computerized attention training comprising various exercises with an adaptive approach (20 1-hour sessions). The program targets various aspects of attention.

Participants are followed up 2 weeks and 3-5 months after treatment participation.

Intervention Type
Behavioural

Primary outcome measure
Improvement of social cognition (pre- to postmeasurement) on the Awareness of Social Inferences Test (TASIT-short) at baseline, within 2 weeks of the last treatment session and at 3-5 monts follow up.

Secondary outcome measures
1. Facial affect recognition is measured using the Facial Expression of Emotional Stimuli Test (FEEST) at baseline, within 2 weeks of the last treatment session and at 3-5 monts follow up
2. Theory of Mind is measured using the Cartoon Test and Faux Pas test, at baseline, within 2 weeks of the last treatment session and at 3-5 monts follow up
3. Behavioural functioning is measured (participant and significant other ratings) using subscales of the Brock Adaptive Functioning Questionnaire (BAFQ) and the Dysexecutive Questionnaire (DEX) at baseline, within 2 weeks of the last treatment session and at 3-5 monts follow up
4. Treatment goal attainment is measured using the Treatment Goal Attainment (TGA) scale at baseline, within 2 weeks of the last treatment session and at 3-5 monts follow up
5. Participation is measured using the Role Resumption List at baseline, within 2 weeks of the

last treatment session and at 3-5 monts follow up
6. Quality of Life is measured using the QOLIBRI at baseline, within 2 weeks of the last treatment session and at 3-5 monts follow up
7. Quality of the relationship is measured using the Relation-Score at baseline, within 2 weeks of the last treatment session and at 3-5 monts follow up
8. Treatment satisfaction is measured using the Treatment Satisfaction Scale (TSS), within 2 weeks of the last treatment session and at 3-5 monts follow up

Overall study start date
01/04/2010

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Moderate to severe traumatic brain injury
2. Sub-acute or chronic stage of recovery
3. Referred on clinical grounds, that is, being identified as having changes in social functioning, with at least 1 deficit in social cognition tests and/or proxy ratings on the BAFQ-social monitoring and/or empathy scale>10
4. Orbitofrontal/medioprefrontal brain damage demonstrated with MRI
5. Presence of a proxy to fill in questionnaires

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Total final enrolment
61

Key exclusion criteria
1. Neurodegenerative or psychiatric illness
2. Severe cognitive impairment that would preclude treatment (i.e. amnestic syndrome, global aphasia, neglect)
3. Very severe behavioral regulation deficits for which continuous external control was needed and/or physical aggressiveness
4. Severe depression

Date of first enrolment
01/07/2011

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen (UMCG)
Hanzeplein 1
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Netherlands
9700RB

Study participating centre
Reade
Overtoom 283
Amsterdam
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Study participating centre
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Sponsor information

Organisation
Hersenstichting Nederland (Dutch Brain Foundation)

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Sponsor type
Charity

ROR
https://ror.org/04y8met08

Funder(s)

Funder type
Charity

Funder Name
Hersenstichting Nederland (Dutch Brain Foundation)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/03/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2017	27/11/2020	Yes	No