Improving social cognition and social behaviour in various brain disorders

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Main: To demonstrate the effectiveness of the T-ScEmo treatment for social cognition impairments in neurological patient groups other than TBI (i.e. patients with stroke, subarachnoidal haemorrhage (SAH), brain tumors, multiple sclerosis, cerebral...

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

Summary

ID

NL-OMON50821

Source
ToetsingOnline

Brief title
Improving social cognition in various brain disorders

Condition

- Other condition

Synonym
brain tumors, e.g. stroke, ms, Neurological disorders

Health condition

Neurologische aandoening, waaronder cva, ms, hersentumoren

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Hersenstichting

Intervention

Keyword: brain damage, social behaviour, social cognition, treatment

Outcome measures

Primary outcome

The main study parameter is the difference between T2 (long-term follow-up) and T0 of the score on the Dutch version of the Dysexecutive Questionnaire- Social scales proxy version (DEX-Socproxy; Spikman et al., 2013; Westerhof-Evers, 2017). This is a measure for informant rated social competent behavior. The difference between T2 and T0 should be significantly larger than the difference in the control group to control for test-retest effects. T2 is chosen because we deem it relevant to establish that treatment effects last over time, that is, are still present at follow-up measurement.

Secondary outcome

Secondary endpoints will be improvements on tests for social cognition, questionnaires for social abilities, social participation, quality of life (QoL), mood, relationship quality, goal attainment scaling (GAS), between T0 and T1, and T0 and T2 respectively.

Study description

Background summary

Social cognition involves the abilities to perceive social information,

understand others and respond appropriately, which are underlied by frontal-subcortical brain circuits. Impairments in social cognition are trans-diagnostic: they can be found in various neurological disorders in which these circuits can be affected, such as traumatic brain injury (TBI), stroke, brain tumors and multiple sclerosis. Given the detrimental consequences of impaired social cognition for quality of life and participation of patients, effective treatments are sorely needed. Previously, a treatment for these impairments, called T-ScEmo (Treatment of Social cognition and emotion) was developed at our department and found to be effective in improving social cognition and social behaviour in patients with traumatic brain injury (TBI). For other neurological patient groups with similar problems, who are eligible for rehabilitation treatment, effectiveness still has to be demonstrated, which is the purpose of the present study.

Study objective

Main: To demonstrate the effectiveness of the T-ScEmo treatment for social cognition impairments in neurological patient groups other than TBI (i.e. patients with stroke, subarachnoidal haemorrhage (SAH), brain tumors, multiple sclerosis, cerebral infections) that are eligible for (neuropsychological) rehabilitation treatment. Secondary objective: to determine which patient related factors are of influence on treatment effectiveness.

Study design

A multi-center single blind randomized controlled trial (RCT) in patients with neurological disorders, in a longitudinal repeated measures design (measurements at pre-treatment (T0), post-treatment (T1) and long term follow up (T2)).

Intervention

A neuropsychological rehabilitation treatment (T-ScEmo: treatment of social cognition and emotion) involving training of social information processing and teaching strategies for social cognition and social behavior, consisting of 15 1 hr. *in vivo* sessions (1 or 2 times a week) and 5 e-learn practice sessions. Close others/partners will be involved in a part of the sessions. Control condition: waiting list, to control for test-retest effects.

Study burden and risks

The treatment has no adverse consequences for patients and close-others, and involves no risks. The burden is low and mainly mental, that is, the treatment requires sufficient effort and motivation of patients, to visit the treatment center, follow sessions and perform home-assignments. As it is given by experienced psychologists, these will carefully monitor patients* energetic

status and well being. It is likely that patients in the treatment condition will experience benefits of the treatment. Our experience with the previous T-ScEmo study in patients with TBI was that all patients were able to complete the treatment without negative effects, and the majority reported to have benefitted. For patients in the control condition, the burden is that they will undergo three measurements at similar intervals as the treatment group; the burden of these assessments is low. Moreover, these patients will be offered to receive the treatment in case the study shows that it is effective, which may also be a benefit from participating in the study.

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

Patients should have a neurological disorder (see above); Age between 18 and

75; As prospects may be different for individual patients, patients should be in the chronic stage (> 6 months post acute injuries) or their medical condition should be relatively stable (for those with a slow progressive condition), to be judged by the treating medical or psychological specialist, in order to be able to profit from treatment for a reasonable time period. Also, the presence of a close other is an inclusion criterion

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Serious neurodegenerative or psychiatric conditions (including addiction) interfering with treatment
- Incapacity to act, to be judged by the neuropsychologist and/or neurologist.
- Serious cognitive problems (aphasia, neglect, amnesia, dementia) and/or serious behavioral problems (aggression, apathy) interfering with treatment, to be judged by neuropsychologist.
- Serious (other) medical conditions or physical inability hindering patients to come to the hospital/rehabilitation center,
- Not being available of a close other (life partner, family member, close friend) who can fill out the proxy questionnaires
- Not willing to give permission to send important/unexpected findings to the general practitioner.
- In addition: unexpected progression of disease during the study can be a reason to exclude the patient.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	03-09-2021
Enrollment:	92
Type:	Actual

Ethics review

Approved WMO Date:	27-05-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-02-2024
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	NL75825.042.20