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Effectiveness of a Treatment for Impairments in Social Cognition and Emotion Regulation (T-ScEmo) After Traumatic Brain Injury: A Randomized Controlled Trial

Herma J. Westerhof-Evers, MSc; Annemarie C. Visser-Keizer, PhD; Luciano Fasotti, PhD; Marleen C. Schönherr, MD, PhD; Martie Vink, MSc; Joukje van der Naalt, MD, PhD; Jacoba M. Spikman, PhD

Objective: To evaluate the effects of a multifaceted Treatment for Social cognition and Emotion regulation (T-ScEmo) in patients with a traumatic brain injury. **Participants:** Sixty-one patients with moderate to severe traumatic brain injury randomly assigned to an experimental T-ScEmo intervention or a Cogniplus control condition. **Interventions:** T-ScEmo is a compensatory strategy training for impairments in emotion recognition, theory of mind, and social behavioral skills. Cogniplus is a computerized cognitive function training. Both interventions were given in 16 to 20 weekly 1-hour sessions. **Main Measures:** Social cognition tests and questionnaires for social behavior (self- and proxy-rated) administered at baseline, immediately posttreatment, and at 3 to 5 months of follow-up. **Results:** Compared with the Cogniplus group, the T-ScEmo group improved significantly on facial affect recognition, theory of mind, proxy-rated empathic behavior, societal participation, and treatment goal attainment, which lasted up to 5 months after treatment. At follow-up, the T-ScEmo group also reported higher quality of life and their life partners rated relationship quality to be higher than the Cogniplus group. **Conclusion:** This study shows that impairments in social cognition can be effectively dealt with by using a comprehensive treatment protocol, leading to improvements in everyday life social functioning. **Key words:** *affect recognition*, *emotion perception*, *social behavior*, *social cognition*, *social skills*, *TBI*, *ToM*

DEFICITS IN SOCIAL COGNITION following moderate to severe traumatic brain injury (TBI) can be disabling and persistent.[1] Social cognition refers to the perception and understanding of social information, including others' emotions and mental states, and it is widely acknowledged that frontal brain networks play a significant role in these abilities.[2,3] Adolphs[3] distinguishes 3 social cognition stages. First, perception of social information, for instance, emotional expressions. Second, social understanding, referring to the ability to mentalize or form a theory of mind (ToM) in order to understand others' thoughts, feelings, and intentions.[4] Third, social behavior, incorporating social skills, in particular, the ability to regulate emotions and behavior. There is increasing evidence that deficits in social cognition underlie social behavioral problems.[5,6] Social-behavioral problems frequently occur, in particular, in patients with moderate to severe TBI[7]; involve inappropriate, indifferent, or disinhibited interpersonal conducts[7,8]; and lead to unemployment,[9] social isolation, and loneliness,[10] thus limiting societal participation.[10,11] Given these detrimental consequences, evidence-based rehabilitation interventions focusing on social cognition with the explicit aim to improve everyday-life social behavior and participation are sorely needed.

To date, only a few treatment studies have been aimed at improving social cognition after TBI, and these

Author Affiliations: *Department of Clinical and Developmental Neuropsychology, University of Groningen, Groningen, the Netherlands (Ms Westerhof-Evers and Ms Spikman); Center for Rehabilitation (Ms Westerhof-Evers and Ms Schönherr) and Department of Neurology (Ms Visser-Keizer, van der Naalt, and Spikman), University of Groningen, University Medical Center, Groningen, the Netherlands; Klimmendaal Rehabilitation Center, Arnhem, the Netherlands (Mr Fasotti); and Reade Rehabilitation Center, Amsterdam, the Netherlands (Ms Vink).*

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Corresponding Author: *Herma J. Westerhof-Evers, MSc, Department of Clinical and Developmental Neuropsychology, University of Groningen, Grote Kruisstraat 2/1, Groningen, 9712 TS, the Netherlands (h.j.evers@rug.nl).*

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studies focused only on single aspects of social cognition. Four studies found significant improvements in emotion recognition following facial affect training.[12–15] However, evidence for generalization to everyday-life social behavior was restricted to one study reporting lower levels of proxy-rated aggression after facial affect treatment,[14] but this finding was not replicated in a larger sample.[15] Furthermore, there is some evidence that ToM was improved following treatment addressing social communication in patients with TBI.[16] A case report suggested that perspective-taking treatment might result in decreased aggression levels.[17] Several studies have been carried out that targeted social skills in patients with TBI. Overall, only modest improvement of social behavior was found.[18–20] Driscoll and colleagues[21] reviewed social cognition treatments and concluded that, in particular, treatment of emotion recognition seems promising. However, the urge of further research due to poor generalization of trained skills to other abilities and everyday-life social functioning was also highlighted.

So far, there is no effective treatment that addresses all the aforementioned aspects of social cognition in conjunction, with the aim to improve everyday-life social behavior. This is important, given the high prevalence of deficits in social cognition following TBI,[22] their potentially devastating effects on everyday-life functioning,[10,23] and the limited effects of treatment on single aspects of social cognition.[21,24] Therefore, we developed a multifaceted treatment protocol (Treatment for Social cognition and Emotion regulation; T-ScEmo), focusing on the improvement of emotion perception, social understanding, and social behavior in conjunction.

The main objective of the present study was to evaluate the effectiveness of this multifaceted T-ScEmo by comparing it with a control treatment, Cogniplus, within a multicenter randomized controlled trial with parallel group design and posttests immediately after treatment and at 3 to 5 months of follow-up. We primarily hypothesized that social cognition in general would significantly improve for patients with TBI in the T-ScEmo condition compared with patients receiving Cogniplus. In particular, we expected that T-ScEmo patients would improve on neuropsychological tests for emotion recognition and ToM as well as on indications of social behavior in everyday life, quality of life, and societal participation, with effects directly after treatment and lasting over time until at least 5 months posttreatment.

METHODS

Design and procedure

This study was designed as a multicenter randomized controlled trial, performed in 3 Dutch rehabilitation or academic institutions, located in Groningen, Beetsterzwaag, and Amsterdam. It was approved by the Medical Review Ethics Committee (METc2011.094) and registered with study ID ISRCTN81350364. Participants gave written informed consent before participation and all data were obtained in compliance with the Helsinki Declaration.

Participants eligible for the study had sustained moderate-severe TBI, classified by a Glasgow Coma Scale score of less than 13, of 30 minutes or more, and/or Post-traumatic amnesia (PTA) duration of 24 hours or more,[25] with a minimal postonset period of 3 months. Age limits were set between 18 and 70 years and participants had to live independently. Furthermore, there had to be a significant other/proxy to fill out proxy questionnaires and participate in the treatment. If available, proxies who were life partners were preferred. In this article, the term life partner is used for persons living together in an intimate relationship either married or unmarried. There were no patients with a life partner who was not willing to participate in this study. If patients had no life partner, they were asked to bring a proxy with whom they had frequent contact in daily life, and when possible, someone who knew the patient from before sustaining the TBI (ie, family member, friend). Patients with TBI had to be referred for rehabilitation with postinjury problems in social functioning, either reported by themselves or observed by significant others. Patients with TBI had to have impairments in social cognition indicated by defective scores on the Facial Expression of Emotion-Stimuli and Tests (FEEST) and/or proxy ratings on the Brock's Adaptive Functioning Questionnaire (BAFQ)-social monitoring/empathy scale[26] score greater than 10, and/or if available, frontal lesions visible on computed tomographic scan/magnetic resonance image indicating higher risk on social behavioral problems.[27] Exclusion criteria were severe cognitive impairment precluding treatment (ie, amnestic syndrome, global aphasia), neurodegenerative or psychiatric illness, or severe behavioral regulation deficits interfering with treatment or threatening the safety of the therapist (eg, physical aggressiveness). We included a group of healthy controls to test whether the performances of patients on social cognition tests and behavioral questionnaires were impaired, since normative data were lacking for several of these measures. The healthy group was recruited from social networks of the researchers and assessed individually; subjects with serious neurological/psychiatric disorders or psychology students were excluded.

Assessments were scheduled at baseline, within 2 weeks after the last training session "posttest-I," and 3 to 5 months after the last session "posttest-II." After baseline assessment, patients were randomly assigned to the T-ScEmo or Cogniplus condition. Cogniplus is a computerized cognitive training program aimed at improving general cognition, in particular, attention, working

memory, and executive functions, all cognitive domains that are frequently impaired in patients with moderate to severe TBI. Cogniplus was primarily included as a control condition for nonspecific treatment effects (eg, attention of therapists, receiving treatment in the context of a clinical environment). Nevertheless, we did not exclude the possibility that eventual improvements in the cognitive functioning brought about by Cogniplus might also result in improved processing of social information and thereby in improved daily life social functioning. Before giving consent, eligible patients were informed that they were given the opportunity to participate in a study comparing 2 treatments that both could have positive effects on social functioning. They were also masked with regard to the expectations of the investigators about the effectiveness of either treatment condition. Balanced assignment (per 4 patients) took place, for which lots were blindly drawn by a coworker not involved in the study. In each condition, patients underwent 16 to 20 sessions of 1 or 2 hours weekly. Research assistants blind to treatment allocation carried out the neuropsychological assessments. Excluded patients were offered rehabilitation care as usual.

Participants

Seventy-four patients were assessed for eligibility, of whom after initial testing 61 were included in the study. Three rehabilitation or academic settings supplied the patients (46, 10, and 5). Figure 1 shows a CONSORT diagram in which the flow after enrolment is displayed. Reasons for not including were as follows: 8 met exclusion criteria, 3 did not meet inclusion criteria regarding social cognition problems, and 2 had logistic problems. After inclusion and randomization, 1 patient declined because of unexpected logistic problems, leaving 60 patients to participate. For all patients, a significant other was available (life partner: $n = 36$, parent: $n = 13$, brother/sister: $n = 3$, son/daughter: $n = 3$, friend: $n = 5$); not having a significant other willing to participate in the study was never a reason for exclusion. The patients with a life partner were equally randomized across the interventions ($n = 36$ in total, $n = 18$ for both arms). In addition, a group of 88 healthy controls was included.

Experimental treatment

The T-ScEmo protocol (see Table 1) is aimed at enhancing emotion perception (module 1), perspective taking and ToM (module 2), followed by basic and goal-directed social behavior (module 3). The T-ScEmo program started by the use of extended psychoeducation larded with daily life examples of social problems, information texts with identifiable fictive situations, and the participation of a proxy. Overall, the main focus of treatment was directed at maintaining and

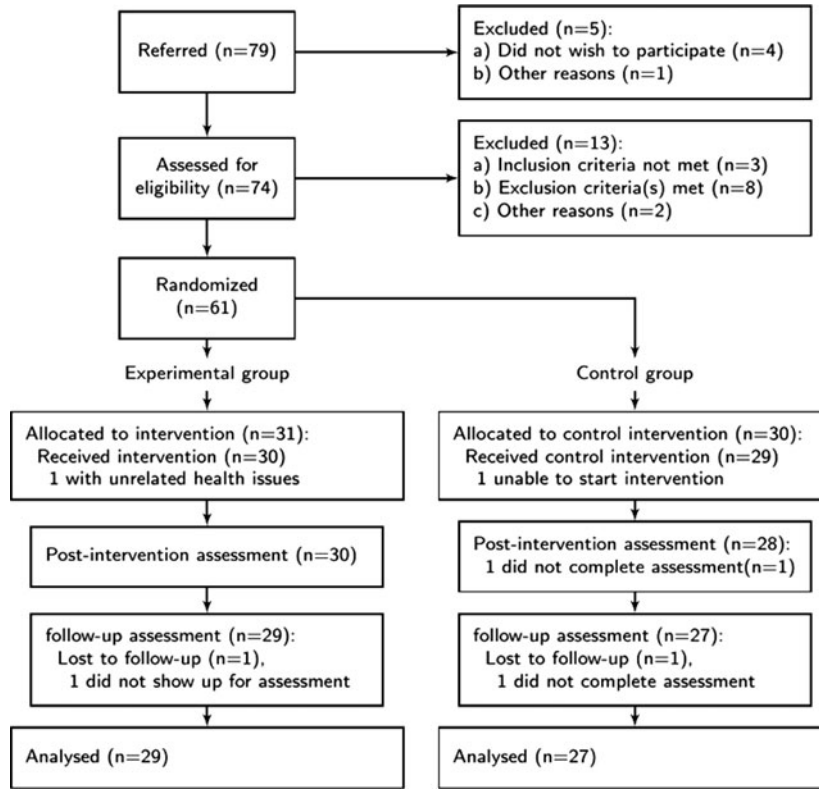

Figure 1. CONSORT diagram of participants' progress through the phases of the trial.

TABLE 1 *Rationale and treatment ingredients of T-ScEmo*

Rationale	Treatment aims	Treatment ingredients
1. Adequate emotion recognition is a basic part of social information processing	Improve emotion recognition	Facial feature processing Mimicry Personal emotional experiences Bodily language
2. Understanding and interpretation of social information precede adequate social behavior	Improve theory of mind and perspective taking	Perspective taking Thoughts—Feelings–Behavior triangle (self, other) Ask others about their thoughts and feelings Attend to feelings of others
3. Correct understanding of social input precedes adequate social behavior, besides that, social behavior and consequences of one's behavior can be addressed directly as well	Improve awareness and inhibition of undesired social behavior Improve socially desired behavior	Basic social skills training: personal space, listening, reflection of feelings (education, role-play) Specific social skills training: registration of behavior, irritability and anger management, coping with conflicts, social reasoning, positive social behavior (role-play, feedback counseling)

improving social relationships. Goal setting and self-monitoring were encouraged. Generalization of what was learned in the treatment to daily life was fostered through homework assignments. Each session included the following elements: an evaluation of the previous session by discussing homework assignments (5-10 minutes), the presentation of new content (45-50 minutes), and a preview of the next session (about 5 minutes). The first 8 to 10 sessions were relatively fixed (modules 1 and 2), followed by module 3 (sessions 11-20) that could be more specifically tailored to individual needs and personal goals. The total treatment consisted of a maximum of 20 individual treatment sessions, offered once or twice a week in a hospital or rehabilitation setting. It was individually given by 6 experienced neuropsychologists, with an average of 18 years of professional experience (range: 8-35 years). They had been given an extensive training in the T-ScEmo protocol application and were monitored and coached during the study through meetings or telephone counseling.

Module 1, Emotion Perception, incorporated the learning of 3 strategies: facial-feature processing, mimicry, and the experience of one's own emotions, which had been successfully incorporated in previous studies evaluating emotion recognition treatment.[13–15] In the current study, we developed a computer-based program with validated static and dynamic Caucasian emotional faces, including basic (ie, happiness, sadness, anger, surprise, fear, disgust) and complex emotions (ie, contempt, embarrassment).

Module 2, Perspective taking and ToM, consisted of psychoeducation, perspective taking, and self-monitoring strategies. In this module, patients learned that different viewpoints can coexist. We used a simplified thoughts-feelings-behavior triangle from cognitive behavioral therapy.[28] Our triangle differed from traditional cognitive behavioral therapy in that it focused solely on explicit communication about thoughts and feelings, instead of attempting to reframe all types of attributions and cognitive distortion. Patients were taught strategies to fill out the thoughts-feelings-behavior scheme (self and other), using hypothetical and real-life personal incidents. Herewith, patients were encouraged to ask significant others about their thoughts and feelings to improve insight and to prevent jumping to conclusions about their motives.

Module 3, Social Behavior, addressed basic social skills (such as turn taking, listening, giving compliments) and specific target social behavior to improve awareness and socially desired behavior (eg, empathy, social reasoning). Also, patients were taught strategies to inhibit inappropriate social behavior (eg, anger management). In this module, proxy attendance was occasionally requested. This significant other played an important role in helping the patient to enhance insight in real-life social conflicts by offering corrective feedback and herewith fostering the generalization of strategies to daily life. In role-plays with both patient and proxy, the perspective of the proxy was discussed, encouraging the reflection of feelings and enhancing empathy and communication of the patient.

Control treatment

Cogniplus is an individually administered computerized attention training comprising various adaptive

exercises aimed at improving aspects of general cognition, in particular, attention, working memory, and executive functions, which might also facilitate everyday-life social functioning.[29] Cogniplus was given by a neuropsychologist in a hospital or rehabilitation setting once or twice a week. The program is largely self-supporting with preprogrammed instructions and monitoring of task performance, but a therapist is continuously available for questions and assistance.

Measures

At baseline, the following neuropsychological tests were administered to control for differences between treatment groups: NART[30] (premorbid intelligence), WAIS-III Digit Span[31] (working memory), and 15-words test[32] (memory and learning). The following tests and questionnaires were administered pre- and posttreatment.

Primary outcome measure

The primary outcome measure was the Dutch short version of The Awareness of Social Inferences Test (TASIT-short),[33] a task measuring recognition of emotions and understanding of others in real-life, dynamic situations, consisting of short films depicting social interactions. The first part comprises 14 film vignettes in which emotional expressions are expressed (happiness, anger, surprise, fear, disgust, sadness, or neutral). The second and third social inferences subtest portray sincere versus contrafactual (ie, lies, sarcasm) interactions. The total score ranges from 0 to 82, with higher scores indicating better performance.

Secondary outcome measures

Secondary outcome measures were tests and questionnaires for social cognition, social behavioral functioning (self- and proxy-rated), societal participation, and quality of life.

Social cognition tests

The FEEST (Sixty faces test)[34] is a test for the recognition of facial affect. Sixty photographs of faces with primary emotions (anger, disgust, fear, happiness, sadness, or surprise) are shown for 3 seconds, 10 of each emotion (0-60 points). The Cartoon test[35] incorporates 12 cartoons displaying humorous situations. Mental state attribution is required to understand the joke. Answers are rated (0 "irrelevant answer" to 3 "adequate perspective taking and understanding") with an overall score ranging from 0 to 36. The shortened version of the Faux Pas (FP)[36] test measures the ability to detect a faux pas in 10 short stories, of which 5 contain a faux pas (0 = "no detection of FP/NFP," 1 = "detection of FP/NFP"). The FP-detection score ranges from 0 to 10 in total.

Attention and executive functioning tests

To investigate possible effects of either treatment on attention or executive functioning, the following tests were administered before and after treatment: Trail Making Test A, TMT B/A,[37] Test of Everyday Attention Lottery,[38] and BADS Zoo-map/Shopping Mall.[39,40]

Behavioral questionnaires

The presence of social behavioral problems in everyday-life was investigated by means of patient and proxy versions of the Dysexecutive Questionnaire–Social scales (DEX-Soc-self, DEX-Soc-proxy). This scale was a sum of the following DEX subscales, corrected for overlapping items: Meta cognition (DEX items 2, 5, 12, 16, 20), Social convention (9, 12, 13, 20), Behavioral emotional self-regulation (3, 7, 8). The items were scored on a 4-point scale (0 = never to 4 = very often, range: 0-80), with higher scores reflecting more problems.[5,39] We also used Brock's Adaptive Functioning Questionnaire-–Social monitoring scale (BAFQ-SM-self, BAFQ-SM-proxy), with items scored on a 5-point scale (1 = almost never to 5 = almost ever, range: 7-35). Finally, we also administered the BAFQ Empathy scale (BAFQ-Emp-self, BAFQ-Emp-proxy, range: 5-25), with higher scores indicating more problems.[26,41]

Other

To measure societal participation, the Role Resumption List (RRL)[42] was administered, which assesses changes in amount and quality of activities compared with premorbid levels in 4 domains (vocational functioning, social interactions with relatives, leisure activities, and mobility), rated on a 5-point scale (0 = no change to 4 = severe loss of independence), with a total score ranging from 0 to 16. Quality of Life after Brain Injury was measured with the QOLIBRI,[43] which incorporates a satisfaction scale, rated on a 5-point scale (1 = not at all to 5 = very much), with a total score ranging from 42 to 210 (higher scores reflecting more satisfaction) and a burden scale (5-point scale, ranging from 13 to 65, higher scores reflecting higher burden) completed by the patient. Goal attainment was measured using Treatment Goal Attainment (TGA[42]). Patients had to determine 3 personal goals to accomplish through treatment, of which the starting level was rated on a 10-point scale (1 = not at all 10 = entirely, range: 3-30) in the first training session. To investigate the quality of the intimate relationships within the subgroup of patients who had a life partner ($n = 36$), patients and their life partners graded their relationship from 1 to

10 on the Relationship Quality Scale (RQS). Also, life partners were asked to grade the treatment result on the Treatment Result Scale (TRS) from 1 to 10 at posttests I and II. At both posttests, all patients were asked to rate treatment satisfaction on a 5-point Treatment Satisfaction Scale,[42] ranging from 1 (not satisfied) to 5 (very satisfied).

Statistical analysis

Before the start of the study, a power analysis was carried out for the primary outcome measure; based on a pilot study ($n = 8$), the effect size could be estimated to find a difference of 2/3 SD between pre- and posttest. The preferred sample size was 80 patients, 40 per group. To test whether both patient groups were matched with regard to age, educational level, sex, injury severity, and time since injury, *t* tests or nonparametric tests for nominal or ordinal variables were used. *T* tests were used to compare participants' test scores at baseline with those of healthy controls, as well as to compare baseline functioning of both patient groups.

Changes between baseline and posttests were analyzed using repeated measures analyses (General Linear Model - Analysis of Variance). First, we analyzed whether scores directly after treatment (posttest-I) differed from baseline for both groups equally (time effect) and whether improvement over time differed between both intervention groups (interaction effect). The same procedure was followed for performances at 3 to 5 months of follow-up (posttest-II). To minimize the possibility of type 1 errors, Bonferroni Holm corrections were applied. Effect sizes were calculated using Cohen *d*. SPSS 23.0 was used to conduct all analyses.

RESULTS

Table 2 shows that at baseline both patient treatment groups were comparable with respect to demographic and injury characteristics. Both groups did not differ

TABLE 2 *Baseline means (and SDs), results of t-tests of demographic variables, social cognition, and behavioral measures*

	T-ScEmo	Cogniplus		All patients	Healthy controls	
	n = 30	*n* = 29	Sign.	*n* = 59	*n* = 88	Sign.
Demographic						
Age, *M* (SD)	43.8 (13)	42.3 (14)	NS	43.2 (13)	43.1 (17)	NS
Education (M/med)	5/5	5/5	NS	5/5	5/5	NS
SD, range	1, 1-7	1, 4-7		1, 1-7	1, 2-7	
Male/female (%)	72/28	93/7	NS	83/17	72/28	NS
Injury severity Moderate/severe (%)	33/67	41/59	NS			
Chronicity in months (M/med)	86/55	109/59	NS			
SD, range	(86, 4-367)	(111, 8-414)				
Estimated IQ, *M* (SD)	98.8 (10)	99.8 (10)	NS			
Cognitive functioning						
WAIS-III Digit Span, *M* (SD)	14.7 (4)	13.8 (4)	NS			
Memory IR, *M* (SD)	40.6 (10)	42.2 (11)	NS			
Memory DR, *M* (SD)	7.8 (4)	8.6 (3)	NS			
TMT—A, *M* (SD)	38.5 (15)	38.8 (18)	NS			
TMT—BA, *M* (SD)	2.0 (1)	2.2 (1)	NS			
TEA lottery, *M* (SD)	9.2 (1)	9.1 (1)	NS			
Zoo-map (BADS), *M* (SD)	11.3 (4)	11.4 (5)	NS			
Social cognition						
TASIT-short, *M* (SD)	63.6 (7)	61.4 (6)	NS	62.5 (7)	66.9 (5)	[a]
FEEST, *M* (SD)	45.0 (8)	42.9 (7)	NS	43.9 (7)	48.2 (5)	[a]
CT, *M* (SD)	16.8 (6)	18.5 (7)	NS	17.6 (7)	24.0 (6)	[a]
FP-Detection, *M* (SD)	8.5 (2)	9.0 (1)	NS	8.7 (1)	9.1 (1)	NS
Behavior						
DEX-proxy, *M* (SD)	35.6 (11)	33.8 (9)	NS	34.7 (10)	15.2 (10)	[a]
DEX-self, *M* (SD)	30.3 (14)	29.0 (12)	NS	29.7 (13)	18.0 (8)	[a]

Abbreviations: Control group, Cogniplus; CT, Happé Cartoons Test; DEX-proxy, Dysexecutive Questionnaire-proxy rated (T-ScEmo: $n = 30$, Cogniplus: $n = 29$, Healthy Controls: $n = 42$); DEX-self, Dysexecutive Questionnaire-self rated; FEEST, facial expressions of emotion stimuli and tests; FP, Faux Pas test; Memory DR, delayed recall; Memory IR, immediate recall; NS, not significant; TASIT-short, The Awareness of Social Inferences Test—shortened; TEA, test of everyday attention; TMT, Trail Making Test; T-ScEmo, Treatment for Social cognition and Emotion regulation; WAIS-III Digit Span, Wechsler Adult Intelligence Scale; Zoo-map (BADS), Behavioral Assessment of the Dysexecutive Syndrome.

[a] $P < .001$.

with regard to measures of social cognition, social behavior, or general cognition. Patients were also well matched to the healthy control group. Patients performed significantly worse on the FEEST, TASIT-short, Cartoon test, but not on the FP-Detection score compared with healthy controls. On the DEX, significantly more behavioral problems were self- and proxy-rated in the patient group.

Effects of treatment

The primary outcome measure, TASIT-short, showed no improvement over time for both treatment groups, both at posttest-I and posttest-II, nor were treatment interaction effects found (see Table 3). Effect sizes were small. However, with regard to the secondary outcome measures, several significant interaction effects were found. With regard to the neuropsychological tests, we found both at posttest-I and posttest-II a significant change over time on the FEEST for both groups, but with a significantly larger improvement for patients in the T-ScEmo condition, showing also large effect sizes indicating substantial group differences. Furthermore, all patients showed significant improvement over time on the Cartoons Test, with again a significant treatment interaction effect indicating more improvement on this ToM measure for the T-ScEmo patients in both posttests, with medium effect sizes. With regard to the other ToM measure, the Faux Pas-Detection score, both groups improved over time, but no treatment interaction effects were found across both posttests, with small effect sizes.

With regard to the social behavioral measures, also significant interaction effects in favor of the T-ScEmo treatment were found for the BAFQ-Emp-proxy at posttest-II, corroborated by a medium effect size. However, for the other BAFQ measures (BAFQ-Emp-self, BAFQ-SM-proxy and self), no significant interaction effects were found. Neither did the DEX-Soc-self and the DEX-Soc-proxy show that T-ScEmo patients improved more, although a decrease of social-behavioral problems was found for both groups over time.

With respect to the other outcome measures, we found that for quality of life, the QOLIBRI-Burden scale showed a significant reduction of burden in the T-ScEmo group, with medium effect sizes. No significant improvements were found on the QOLIBRI-Satisfaction scale (posttest-I and posttest-II). With regard to societal participation, the RRL indicated that all patients had resumed previous roles significantly more after treatment but the T-ScEmo patients to a larger extent, given the significant treatment interaction effects and large effect sizes (posttest-I and posttest-II). With regard to the attainment of goals set before treatment (TGA), a significant interaction effect was also found in favor of the patients in the T-ScEmo condition on both posttests, with a large effect size, although also the Cogniplus patients showed improvement after treatment.

The posttreatment scales Relationship-Quality (RQS) and Treatment-Result (TRS) were intended for life partners only; of the 36 life partners, 30 completed the scales. Patients and life partners in both groups rated the RQS significantly higher than baseline, but life partners of patients in the T-ScEmo condition reported significantly more improvement at posttest-II, corroborated by a large effect size. Life partners ($n = 16$) of T-ScEmo patients rated the TRS significantly higher than life partners ($n = 14$) of Cogniplus patients. Finally, T-ScEmo patients were more satisfied with the treatment results than Cogniplus patients (Treatment Satisfaction Scale).

Table 4 shows the results of repeated measures analyses on measures of attention and executive functioning. Both groups improved on the TMT-A (posttest-I and posttest-II) and TEA lottery (posttest-I), but no interaction effects were found.

DISCUSSION

This study is the first to report on the efficacy of a multifaceted treatment, T-ScEmo, aimed at improving a broad range of deficits in social cognition after TBI, with the final purpose to improve daily life social behavior and societal participation. Social-behavioral problems and social cognition deficits have always been considered difficult-to-treat symptoms after brain injury,[23] but we found that adhering to treatment was feasible for these patients, as there were almost no dropouts. Moreover, our study shows that T-ScEmo is effective in improving aspects of social cognition, namely, facial affect recognition and ToM, as well as proxy-rated empathic behavior, quality of life, quality of the life partner relationship, and societal participation in individuals with moderate to severe TBI. These treatment effects last for at least 5 months posttreatment.

Despite the positive results on several measures, our primary outcome measure (TASIT-short) did not show improvement although at baseline patients were impaired on this measure. Not finding improvement might be related to the fact that we used a revised form of the original TASIT, namely, the shortened Dutch TASIT. In a previous study in which we investigated the psychometrical aspects of this Dutch TASIT-short version, we found that performances of healthy participants were lower when they were administered parallel form-A shortly before form-B, indicating that order of assessment influenced performance.[33] An explanation for this order effect might be that the same actors played different roles in the vignettes of each version. We expected that this carryover effect would fade with a longer time interval between assessments, which was the case

TABLE 3 *Comparison on outcomes for experimental and control group baseline—posttest I-posttest II (T0-T1-T2)*

	T-ScEmo ($n = 30$)			Cogniplus ($n = 29$)			ANOVA T0-T1			ANOVA T0-T2		
	M T0 (SD)	M T1 (SD)	M T2 (SD)	M T0 (SD)	M T1 (SD)	M T2 (SD)	Time	T × G	ES	Time	T × G	ES
Social cognition tests												
TASIT-short	63.1 (7)	64.1 (6)	63.7 (7)	61.4 (6)	62.3 (7)	62.3 (7)	0.31	0.91	0.0	0.28	0.98	0.0
FEEST	45.0 (8)	50.7 (6)	52.2 (5)	43.1 (8)	45.3 (7)	46.4 (7)	<0.01[a]	0.01[a]	0.7	<0.01[a]	<0.01[a]	0.8
CT	16.8 (6)	21.3 (7)	21.9 (7)	18.5 (7)	20 (8)	19.8 (7)	<0.01[a]	0.02[a]	0.6	<0.01[a]	0.02[a]	0.7
FP-Detection	9.0 (1)	9.4 (.8)	9.3 (1)	8.5 (2)	9 (1)	9 (1)	0.01[a]	1.00	0.1	0.02[a]	0.81	0.1
Social behavioral questionnaires												
DEX-Soc-self	19.3 (9)	15.9 (7)	16.5 (9)	17.6 (8)	14.4 (7)	15.2 (8)	<0.01[a]	0.96	0.0	<0.01[a]	0.78	0.1
DEX-Soc-proxy	23.0 (8)	18.0 (9)	19 (9)	21.4 (6)	20 (9)	19.3 (9)	<0.01[a]	0.08	0.5	<0.01[a]	0.42	0.2
BAFQ-SM-self	17.4 (5)	17.5 (4)	16.2 (4)	16.8 (3)	16.4 (3)	17.6 (3)	0.67	0.43	0.2	0.57	0.09	0.5
BAFQ-SM-proxy	18.8 (4)	18.0 (4)	18.1 (4)	20 (5)	19 (5)	19 (5)	0.09	0.86	0.2	0.04[a]	0.98	0.0
BAFQ-EMP-self	12.6 (4)	11.6 (3)	11.2 (3)	12.6 (3)	12 (3)	12 (4)	0.04	0.54	0.1	0.07	0.12	0.4
BAFQ-EMP-proxy	15.7 (4)	13.5 (4)	13.3 (3)	14.7 (4)	14 (4)	14.5 (4)	<0.01[a]	0.16	0.4	<0.01[a]	0.02[a]	0.6
Other												
RRL overall	7.0 (3)	5.9 (3)	5.5 (3)	7.5 (3)	7.5 (3)	7.5 (3)	<0.01[a]	<0.01[a]	0.9	<0.01[a]	<0.01[a]	1.1
QOLIBRI satisfaction	127 (28)	137 (23)	139 (23)	129 (24)	139 (22)	139 (24)	0.10	0.32	0.0	<0.01[a]	0.87	0.0
QOLIBRI burden	22.7 (11)	18.9 (7)	19.3 (12)	19 (9)	19 (8)	23 (13)	0.31	0.18	0.4	0.75	0.04[a]	0.6
RQS-self	5.8 (1)	7.0 (1)	7.2 (1)	6.8 (1)	7.5 (1)	7.1 (2)	<0.01[a]	0.16	0.6	0.01[a]	0.12	0.6
RQS-life partner ($n = 30$)	5.5 (1)	7.1 (1)	7.4 (1)	5.9 (2)	6.8 (1)	6.2 (2)	<0.01[a]	0.18	0.5	<0.01[a]	0.02[a]	0.9
TGA	12.5 (4)	20.1 (3)	20.1 (3)	14.3 (4)	17.9 (4)	18 (4)	<0.01[a]	<0.01[a]	1.2	<0.01[a]	<0.01[a]	1.2
Posttreatment scales		**M T1 (SD)**	**MT2 (SD)**		**MT1 (SD)**	**MT2 (SD)**	**T-Test T1**			**T-Test T2**		
TSS		4.0 (1)	4.0 (1)		3.3 (1)	3.3 (1)	2.3 ($P = .02$)[a]			2.5 ($P = .02$)[a]		
TRS-life partner ($n = 30$)		. . .	7.4 (1)		. . .	5.4 (2)	. . .			3.0 ($P = .01$)[a]		

Abbreviations: ANOVA, analysis of variance; BAFQ-EMP, Brock's Adaptive Functioning Questionnaire—subscale empathy; BAFQ-SM, Brock's Adaptive Functioning Questionnaire—subscale Social monitoring; CT, Happé Cartoons; DEX-Soc; Dysexecutive Questionnaire social scales; FEEST, Facial Expressions of Emotion Stimuli and Tests; FP, Faux Pas; Meta cognition, Social convention, Behavioral emotional self-regulation; QOLIBRI, Quality of Life After Brain Injury; RQS, Relationships Quality Score; RRL, Role Resumption List; TASIT-short, The Awareness of Social Inferences Test—shortened; TGA, Treatment Goal Attainment; TRS, Treatment Result Scale; TSS, Treatment Satisfaction Scale.

[a]Significant *P* value less than Bonferroni Holm corrected a.

TABLE 4 *Comparison on general cognitive measures for experimental condition T-ScEmo and control condition Cogniplus*

	T-ScEmo ($n = 30$)			Cogniplus ($n = 29$)			ANOVA T0-T1		ANOVA T0-T2	
	M (SD)	MT0-T1	MT0-T2	*M* (SD)	MT0-T1	MT0-T2	Time	T × G	Time	T × G
Digit Span	14.7 (3.5)	−0.1	−0.7	13.8 (3.9)	0.4	−0.3	NS	NS	NS	NS
TMT-A	38.5 (14.8)	3.6	5.4	38.8 (17.5)	3.3	4.1	[a]	NS	[a]	NS
TMT-B/A	2.0 (0.6)	−0.1	−0.2	2.2 (0.8)	0.1	0.1	NS	NS	NS	NS
TEA lottery	9.2 (1.3)	−0.4	−0.4	9.2 (0.9)	−0.0	−0.1	[b]	NS	NS	NS

Abbreviations: ANOVA, analysis of variance; NS, not significant; TEA, Test of Everyday Attention; TMT, Trail Making Test.
[a] $P < .05$.
[b] $P < .01$.

in the present study. Nevertheless, we cannot exclude that this may have influenced our results. The reliability of these parallel versions of the Dutch TASIT-short in measuring treatment effects may, therefore, be questionable and further investigation is needed to solve this problem.

Several measures of social cognition did show large effects in favor of the T-ScEmo intervention. As hypothesized, we found a significant improvement in facial affect recognition (FEEST) at both posttests for the T-ScEmo group, compared with the control patient group, which showed only a slight improvement. This difference was corroborated by large effect sizes. Previous studies had already shown the efficacy of 3 separate strategies for facial affect recognition: facial-feature processing, mimicry, and personal emotional experiences.[13–15] In our approach, we combined these 3 strategies in the first module targeting emotion recognition. Apparently, this was an effective therapy ingredient, in combination with the additional emphasis on emotion recognition throughout the treatment. Also, the T-ScEmo group showed a marked improvement compared with the control patients in the ability to develop a ToM (Cartoon test). However, such improvement was not found for another ToM test (FauxPas-Detection). A possible explanation for this lack of effect might be the lower sensitivity of the latter test as it already showed no significant differences between patients and healthy controls at baseline.

In addition to better scores on social cognition tests, we also found improvement in proxy-rated empathic behavior (BAFQ-EMP).[26] This is an important finding, given that empathy is an essential component of interpersonal interactions and of paramount importance for significant others.[44,45] Wells and colleagues,[41] for instance, found that poor empathic behavior rated by TBI survivors and their significant others on the BAFQ was significantly related to a reduction in significant others' quality of life. In addition, these authors found that a lack of empathy was the behavior with most detrimental influence on significant others' life satisfaction compared with other social behavioral problems. Until now, an improvement in empathic behavior has never been found in previous studies on social cognition treatment. Neumann and colleagues,[15] for example, found an improvement in facial affect recognition following a facial feature intervention, but this did not generalize to the ability to empathize or to other social behaviors. Bornhofen and McDonald[13] found an improvement in emotion perception as well, but again no carryover effect to real-life social functioning. In T-ScEmo, empathic behavior was stimulated throughout the 3 modules, in particular, through role-plays, in which a significant other was intensely involved. We deem it likely that this was an effective ingredient of the treatment. Although patients improved their social behavior over time (DEX-Soc), the T-ScEmo group did not improve to a larger extent than the control group. This finding suggests that the rather general DEX-Soc items may be vulnerable for nonspecific treatment effects. However, this conclusion can only be drawn very tentatively. As mentioned in the "Methods" section, we included patients on the basis of their postinjury problems in social functioning. According to normative data,[39] the baseline DEX-self and DEX-proxy reports were about 1 standard deviation higher than a general TBI sample studied 1 year after TBI[46] and about 1.5 standard deviation higher than in patients with posterior lesions.[47] This implies that the current sample is behaviorally challenging,[48] but these patients can still participate and benefit from the T-ScEmo program.

With regard to participation in everyday-life, patients in the T-ScEmo condition had resumed their previous roles (RRL) to a significantly higher extent than patients in the control condition at both posttests. Our hypothesis that improvement in social cognition would positively affect participation was entirely met. Furthermore, T-ScEmo patients were better capable to

accomplish their preset treatment goals (TGA) at posttest I and posttest II. Moreover, patients who received the T-ScEmo intervention reported a significant improvement in quality of life (QOLIBRI), as expressed in decreased levels of perceived burden at the second follow-up, in contrast with the higher burden rates reported by the patients in the control condition. This is an important finding given that quality of life is one of the most important outcome measures in healthcare and rehabilitation.[49] Also, the T-ScEmo intervention improved the quality of partner relationship (RQS) to a significantly higher extent than the Cogniplus control condition, as indicated by life partner reports at posttest II. This finding is far-reaching, given the likelihood of marital breakdown following TBI, with studies reporting rates ranging from 15% to 78%.[50] In addition, life partner relationship quality has been linked to overall health outcomes as well.[51,52]

We conclude that the multifaceted T-ScEmo, addressing social cognition in its entirety, is a successful approach, leading to improvements in a broad range of real-life social skills. According to Ylvisaker et al,[48] it is challenging to teach social skills to persons with TBI, as these subjects may experience difficulties in transferring acquired knowledge to daily life or may lack motivation to change. In our study, it appeared that T-ScEmo patients were capable to apply compensatory strategies after the treatment ends, reflected in delayed interaction effects and for some measures even higher improvements at the second follow-up than at the first posttest (BAFQ-EMP proxy, QOLIBRI, RQS-proxy). Apparently, patients learned to consolidate or even expand the benefits they received from the T-ScEmo program in everyday-life functioning. We consider it important to address all the stages of social cognition within 1 treatment protocol, as these capacities are mutually dependent and jointly strengthen real-life social functioning. In addition to treating all aspects of social cognition, we consider the active participation of a significant other in the treatment of a crucial element of this protocol.

As expected, we did not find differences between both interventions in basic cognitive functioning (eg, attention, memory), as measured with neuropsychological tests. Cogniplus did not improve basic cognitive functions (Digit Span, TMT, TEA), as found in previous studies on the effects of computerized training of cognitive functions.[42] However, patients in the control condition also reported some improvement in levels of societal participation (RRL), empathic behavior (BAFQ-EMP), attainment of treatment goals (TGA), and quality of partner relationship (RQS) but to a much lesser extent than the T-ScEmo patients. This suggests that general, nonspecific effects of treatment were also present. For instance, giving feedback after baseline assessment, knowing that one would participate in a study focusing on social functioning and being treated in a clinical setting might also have yielded positive effects.[53,54] It appeared that all participants appreciated the treatment (Treatment Satisfaction Scale) but the T-ScEmo patients to a significantly higher extent.

The major strengths of this study are its randomized and controlled character, the high level of treatment compliance, the low number of dropout, and the use of a long-term follow-up assessment. Despite these strengths, some limitations have to be mentioned. First, the study included a relatively large number of outcome measures. We deemed this necessary to cover all relevant aspects of social cognition as well as relevant indications of social behavior and societal participation. To minimize the possibility of type 1 errors, we therefore used Bonferroni Holm corrections. Another limitation was that we included fewer patients than was calculated on the basis of the power analysis, which may have contributed to not finding a significant effect on the primary outcome measure, but despite this lower power, the current study still yielded several significant results on important measures. Furthermore, both treatment conditions were comparable in actual contact moments, but the neuropsychologist was more actively involved in the T-ScEmo condition than in the Cogniplus condition. Besides that, significant others were also more actively involved in T-ScEmo. In addition, T-ScEmo patients received homework assignments in contrast to the Cogniplus patients, necessitating them to spend somewhat more time to this treatment. It is possible that these nonspecific differences have added to the overall treatment gain. Although the results of the present study can only be generalized to patients with moderate to severe TBI, we deem it likely that the findings of this study are replicable in other patient groups with acquired brain damage (ie, stroke, brain tumor) affecting prefrontal circuits and resulting into deficits in social cognition. In the present study, we evaluated the overall effects of a multifaceted treatment, but because strategies and techniques applied in T-ScEmo were offered in combination, this impeded the study of the effects of individual treatment ingredients.

In conclusion, this first randomized controlled trial investigating a multifaceted social cognition treatment following TBI has provided evidence for positive effects on long-term emotion recognition, ToM formation, empathic behavior, participation in daily life, quality of partner relationship, and quality of life in general. We consider this combined social cognitive and social behavioral approach a valuable and feasible contribution to the selection of neuropsychological rehabilitation programs available for clinical practice.

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