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ORIGINAL RESEARCH

Rehabilitation of Social Communication Skills in Patients With Acquired Brain Injury With Intensive and Standard Group Interactive Structured Treatment: A Randomized Controlled Trial

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Abstract

Objective: To determine the efficacy of group interactive structured treatment (standard GIST) for improving social communication difficulties in a wider acquired brain injury (ABI) population compared to a waitlist control (WL). Secondary objectives were to (a) explore GIST across delivery formats by comparing the results to an intensive inpatient version of GIST (intensive GIST) and (b) compare the within-subject results for WL and intensive GIST.

Design: Randomized controlled trial with WL and repeated measures (pre- and posttraining, 3- and 6-month follow-ups).

Setting: Community and rehabilitation hospital.

Participants: Forty-nine persons (27-74 years) with ABI and social communication difficulties (26.5% traumatic brain injury, 44.9% stroke, 28.6% other), minimum 12 months postinjury.

Intervention: Standard GIST (n=24) consisted of 12 weekly outpatient interactive group sessions (2.5 hours/session) and follow-up. Intensive GIST (n=18) consisted of 4 weeks with daily 4-hour inpatient group sessions (2 × 3 d/wk, 2 × 4 d/wk) and follow-up.

Main Outcome Measures: La Trobe Questionnaire, a self-report questionnaire measuring social communication. Secondary measures: Social Communication Skills Questionnaire−Adapted, Goal Attainment Scale, Mind in the Eyes test, and questionnaires addressing mental and cognitive health, self-efficacy, and quality of life.

Results: When comparing the standard GIST and WL results, a trend of improvement was found for the main outcome, La Trobe Questionnaire, and a statistically significant improvement was found for the secondary outcome Social Communication Skills Questionnaire−Adapted. Comparing standard GIST and intensive GIST, improvement in social communication skills after both treatments was detected and maintained at 6-month follow-up. No statistically significant difference was found between groups. Goal attainment was achieved and maintained during follow-up for both standard and intensive GIST.

This is a collaborative study conducted and funded by the Department of Special Needs Education, University of Oslo, Norway, and Sunnaas Rehabilitation Hospital, Norway.

Clinical trial registration number: ClinicalTrials.gov (NCT03636399).

Disclosures: Jody Newman and Lenore Hawley own the copyright for the GIST workbook, *Group Interactive Structured Treatment—GIST: For Social Competence*, and occasionally provide copies of the workbook to clinicians who request it at a cost that covers shipping, handling, and printing.

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Conclusions: Social communication skills were improved after both standard and intensive GIST, indicating that GIST can be delivered across treatment formats and to a wider ABI population.

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Social communication difficulties (SCDs) are some of the most prevalent and persistent problems after acquired brain injury (ABI) representing a barrier to social reintegration.[1-4] SCDs occur when post-ABI impairments (eg, cognitive, communicative, emotional) affect the person's social communication skills (eg, taking others' perspective, making inappropriate statements).[5-7] SCDs can lead to poor social relationships, loneliness/isolation, and difficulty obtaining and maintaining employment.[8] Nevertheless, few studies have investigated the efficacy of SCD treatment after ABI.[1,9]

Prior research suggests that adults with SCDs benefit from a context-sensitive treatment approach, involving individual goal setting, group-based activities with or without an individual component, homework, and feedback.[1] One of the best-validated group interventions that incorporates a context-sensitive approach is group interactive structured treatment (GIST).[1,7,9-13] GIST is based on principles of holistic neurorehabilitation, cognitive-behavioral therapy, and group therapy aiming to improve social competence after ABI.[13] Findings from previous GIST studies showed improved social communication and overall life satisfaction in traumatic brain injury (TBI) populations when delivered in an interactive group format, with results maintained at 6- and 9-month follow-ups.[7,10,11] One study included participants with TBI and concomitant neurologic conditions (eg, stroke, multiple sclerosis), psychiatric conditions, or substance abuse, referred to as TBI-plus.[11] The TBI-plus population showed similar patterns of improvement as the TBI-only population at follow-up, indicating that application to broader patient groups is feasible.[11] Similar results were found when GIST was compared to a noninteractive classroom format using the same curriculum.[10] It thus addresses another research gap: the exploration of GIST's efficacy across different delivery formats and treatment intensities. Inpatient treatment in subacute and chronic phases after ABI has shown promising results,[14,15] and intensive treatment has been associated with better functional communication.[16-19] Based on this, our group conducted a stage I pilot study[20] (n=6) exploring the feasibility of an intensive version of GIST (intensive GIST), with promising results.[5,21] ABI inpatients in the chronic phase were offered the full GIST curriculum and interactive group format delivered in an inpatient setting with daily 4-hour sessions over a period of 4 weeks.

The main purpose of this stage III[20] randomized controlled trial (RCT) was to examine the efficacy of standard GIST in a broader ABI population (including TBI, stroke, etc). Secondary objectives were to:

- compare the standard GIST and intensive GIST protocols
- examine the within-subject results for a waitlist control (WL) and intensive GIST.

Thus, by using an exploratory approach, this study will fill knowledge gaps concerning the application of GIST to a broader ABI population, in addition to SCD treatment dosage and context of treatment. Extended details about the study are presented in the research protocol.[5]

List of abbreviations:

ABI	**acquired brain injury**
BRIEF	**Behavior Rating Inventory for Executive Functions**
CIQ	**Community Integration Questionnaire**
GAS	**goal attainment scaling**
GIST	**group interactive structured treatment**
GPSES	**General Perceived Self-Efficacy Scale**
I-GIST	**intensive GIST**
LCQ	**La Trobe Questionnaire**
MiET	**Mind in the Eyes Test**
PQoL	**Perceived Quality of Life Scale**
RCT	**randomized controlled trial**
SCD	**social communication difficulties**
SCL-10	**Symptom Checklist**
SCSQ-A	**Social Communication Skills Questionnaire−Adapted**
S-GIST	**standard GIST**
TBI	**traumatic brain injury**
WL	**waitlist control**

Methods

Design

This is a 2-armed RCT comparing a standard GIST arm (n=24) to a WL/intensive GIST arm (n=25). A repeated-measures design was applied across 4 time points for standard GIST (pre- and post-intervention and 3- and 6-month follow-ups) and 7 time points for WL/intensive GIST (fig 1). This enabled comparisons between the standard GIST and WL, between the standard GIST and intensive GIST, and within subjects for WL and intensive GIST.

The study was approved by the Regional Committees for Medical and Health Research Ethics Norway (2017/1360), conducted in accordance with the Declaration of Helsinki, reported in accordance with the CONSORT 2010 statement and SPIRIT recommendations, and registered at ClinicalTrials.gov (NCT03636399). See protocol for extended details about the methods.[5]

Setting

This study was conducted at Sunnaas Rehabilitation Hospital in Norway (standard GIST at the outpatient clinic and intensive GIST at an inpatient cognitive rehabilitation unit for patients in subacute and chronic phases).[22]

Recruitment

People with documented ABI and SCD were recruited through health institutions, rehabilitation settings, and arenas where eligible participants in the chronic stage are typically found (fig 1). Participant recruitment occurred from September 2018 through December 2019, resulting in 49 participants.

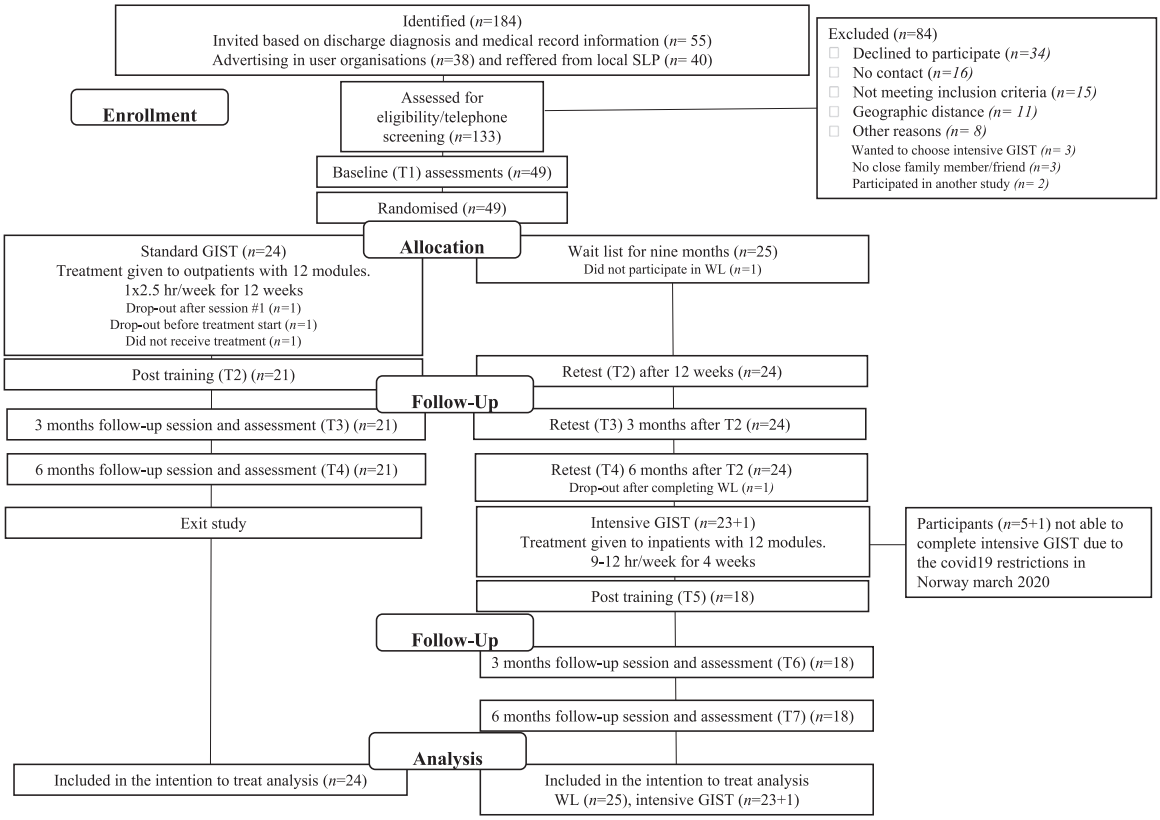


Fig 1 Consort 2010 flow diagram.

Participants

The sample consisted of adults diagnosed with ABI resulting from TBI (26.5%) or nontraumatic brain injuries (eg, stroke [44.9%], brain tumors [16.3%], or other [12.3%]), all at least 12 months postinjury (table 1).

Inclusion and exclusion criteria

Table 2 outlines inclusion and exclusion criteria. Participants were randomly assigned to either standard GIST or WL/intensive GIST (1:1 ratio). Five randomization sequence lists (12 participant numbers combined with 12 random numbers) were created in advance by a researcher not part of the research team using an online list randomizer.[23] Envelopes were sealed and randomly numbered, and the condition was preset to allocate even numbers to standard GIST and odd numbers to WL/intensive GIST. Once a participant was enrolled and assigned a number, the randomization was conducted by a person unrelated to the research group.[5]

Measurement

Primary outcome was the La Trobe Communication Questionnaire (LCQ, total score), Norwegian version.[24,25] This is a 30-item self-report questionnaire assessing communication ability and behaviors rated on a 4-point scale: 1=never/rarely, 2=sometimes, 3=often, and 4=usually/always.

Secondary outcomes included the Social Communication Skills Questionnaire−Adapted (SCSQ-A),[2,26] Goal Attainment Scale (GAS),[7,27] and measures for emotional and cognitive health (Mind in the Eyes test [MiET],[28] Community Integration Questionnaire [CIQ],[29] Behavior Rating Inventory for Executive Functions [BRIEF; self-report],[30] General Perceived Self-Efficacy Scale [GPSES],[31] Perceived Quality of Life Scale [PQoL],[32] Symptom Checklist [SCL-10]).[33] Extended details regarding the outcome measures are provided in Supplementary file 1 (available online only at http://www.archives-pmr.org/). Data from video observations and family/friends will be reported elsewhere.

Because of practical feasibility, the assessors who conducted the assessments after inclusion (T1) were not blinded to group allocation. However, all assessment points (T2-T7) and outcomes were audio-recorded, and test scoring was performed by either the participants (self-report) or a trained research assistant blinded to group allocation to ensure interrater reliability. Participants completed the postintervention self-report measures at home without assessor influence.

Interventions

Arm 1—standard GIST

Arm 1 was a manualized group treatment consisting of 12 modules, plus 1 initial group orientation session, delivered in a weekly outpatient setting over 12 weeks (32.5 contact hours).[13] Key elements of the treatment included introduction to relevant topics, interactive group discussions, individual goal setting, feedback, and social learning.[13] Participants were encouraged to participate in social and family activities during treatment and practice home assignments with a family member/friend to strengthen the

Table 1 Demographics and baseline characteristics of the randomized sample (n=49)

Variable	Standard GIST (n=24)	WL/Intensive GIST(n=25)	*P* Value
Sex (female, %)	12 (50)	12 (48)	.849
Age (M, SD)	47.7 (10.1)	50.5 (13.1)	.305
Education level (%)			.758
High school	13 (59.1)	12 (50)	
<3 Years of higher education	5 (22.7)	8 (33.2)	
>4 Years of higher education	4 (18.2)	4 (16.7)	
Norwegian first language (%)	20 (83.3)	21 (84)	.902
Current work status (%)			.879
Fulltime	1 (4.2)	1 (4)	
Part-time	5 (20.8)	5 (20)	
Vocational rehabilitation	6 (25)	6 (24)	
Disabled	10 (41.7)	11 (44)	
Retired	1 (4.2)	1 (4)	
Other	1 (4.2)	1 (4)	
Type of injury (%)			.471
Traumatic brain injury	9 (37.5)	4 (16)	
Stroke	8 (33.3)	14 (56)	
Anoxic	1 (4.2)	1 (4)	
Tumor	4 (16.7)	4 (16)	
Other	2 (8.3)	2 (8)	
Years since injury (M, SD)	6.6 (5.9)	7.9 (7.7)	.288
Baseline LCQ total (M, SD)	68.6 (12.1)	73.56 (10.2)	.793
Baseline AQ (M, SD)	35.1 (7.3)	33.7 (8.7)	.520
WASI IQ estimate (M, SD)	108.2 (13.7)	105.2 (14.1)	.655
WAIS Digit span (M, SD)	6 (1.6)	5 (1.4)	.909
CVLT-II Learning (M, SD)	47.3 (13.0)	44.6 (9.5)	.084
CVLT-II Long-term (M, SD)	−0.32 (0.90)	−0.29 (0.95)	.850
TMT 4 (M, SD)	8.3 (3.6)	8.6 (3.8)	.697
CWIT 3 (M, SD)	7.9 (4.5)	8.9 (3.8)	.443
CWIT 4 (M, SD)	8.3 (4.2)	8.7 (3.8)	.657

NOTE. The scores for LCQ are presented as reversed raw scores, AQ is presented as raw scores, and WASI, WAIS, CVLT II, TMT, and CWIT are presented with scaled scores.

Abbreviations: AQ, Awareness Questionnaire; CVLT-II, California Verbal Learning Test—second edition; CWIT 3 and 4, Color-Word Interference Test from D-KEFS—Conditions 3 and 4; LCQ, Latrobe Communication Questionnaire; TMT 4, Trial Making Test from D-KEFS—Condition 4; WAIS-IV, Wechsler Adult Intelligence Scale—fourth edition; WASI, Wechsler Abbreviated Scale of Intelligence.

Table 2 Inclusion and exclusion criteria for recruitment

Inclusion Criteria	Exclusion Criteria
TBI or documented nonprogressive acquired brain injuries, a minimum of 12 months postinjury with no upper limit	Major psychiatric disorder or reported ongoing alcohol or substance abuse
Motivation for treatment assessed during interview and expressed directly by answering a direct yes/no question	Concomitant neurologic diseases
One close family member/friend able to participate as a support person during home assignments throughout the treatment	Severe cognitive, sensory, physical, or language impairment affecting the capacity to complete the intervention
Adequate Norwegian language proficiency to participate	Communication difficulties primarily associated with aphasia (as assessed by a speech-language pathologist)
Communication difficulties reported for a minimum 3 questions (ie, often or always) on the LCQ	
A minimum level of intellectual insight into communication difficulties, as assessed with the Awareness Questionnaire (>20 in the discrepancy score)	

generalizability. Two follow-up sessions were conducted after 3 and 6 months.[13]

Arm 2—WL (control)/intensive GIST

After a waiting period (9 months), the WL received intensive GIST. Participants were admitted to inpatient treatment for 4 weeks (44 contact hours; 2 × 3 d/wk, 2 × 4 d/wk) and received the same 12 (+1) modules and interactive group treatment and 3- and 6-month follow-ups as arm 1.[5] The participants had extended leave each weekend to complete home assignments and practice individual goals in real-life social situations with family members/friends. A 1-hour weekly group activity (eg, cooking or garden group, total 4 hours) was added to the schedule and the participants were encouraged to participate in the hospital's social activities (eg, morning walks).

Both treatments were applied to groups of 5-6 participants, with manualized protocols to ensure consistency in intervention delivery (see the protocol[5] and Supplementary files 2 and 3, available online only at http://www.archives-pmr.org/). The intensive GIST week-schedule is presented in Supplementary file 4 (available online only at http://www.archives-pmr.org/).

Therapist training

Two therapists conducted the interventions, a speech-language pathologist (first author) and a clinical social worker, both with extensive experience in post-ABI cognitive rehabilitation and group therapy. The first author received formal GIST training by the GIST developers.[13]

Statistical methods

Sample size

In planning this RCT,[5] a sample size of 60 (30 participants per arm) was in line with previous studies[7,11,34] and considered attainable based on the eligible population in Norway (estimated annual incidence of adult TBI of 12,000 and 15,000 for cerebrovascular accidents).[35,36] However, the a priori calculated sample size was not achieved. Recruitment was challenging (eg, geographic distance, not meeting the inclusion criteria), and only 49 of the 133 participants contacted were included. Twenty-one participants completed the entire standard GIST protocol, 24 completed the WL, and 18 completed intensive GIST. Because of the COVID-19 pandemic, 5+1 participants could not complete the intensive GIST and posttreatment assessments because treatment was canceled after 2 weeks according to the national directives and lockdown (fig 1).

Statistical analysis

All analyses were performed using the Statistical Package for the Social Sciences v28,[a] with $P<.05$ as the significance level. Data analysis followed an intent-to-treat model including all participants enrolled and randomly allocated to the 2 treatment arms.

Demographics and neuropsychological performance variables were described with means and standard deviations (continuous variables) or with counts and percentages (categorical variables). Crude differences between groups were analyzed using *t* tests for continuous variables.

The primary outcome (LCQ total score) was modeled over time for each arm using a generalized linear mixed model for repeated measures to compare results (1) between standard GIST and WL, (2) between standard and intensive GIST, and (3) within subjects between WL and intensive GIST. The models were fitted with unstructured covariance matrices to account for within-subject statistical dependencies. The models included group, time, and Group × Time, and covariates for adjustment included age, sex, and type of injury. All variables were entered as fixed effects.

The secondary outcomes included total mean scores for SCSQ-A, MiET, CIQ, BRIEF, GPSES, PQoL, and SCL-10. Scores were modeled over time using the same mixed modeling strategy presented earlier to compare changes over time and between arms.

Goal attainment was measured only for participants completing the treatments. GAS scores were computed and compared between groups pre- and posttreatment and at 3- and 6-month follow-ups using chi-square tests. The Wilcoxon signed-rank test was used to compare effect from pre- to posttreatment, pretreatment to follow-up, and posttreatment to follow-up.

Results

Descriptive analysis and baseline results

The study sample was 49 participants (standard GIST: n=24; WL/intensive GIST: n=25) aged 27-74 (49% female). See table 1 for baseline characteristics. There were no statistically significant differences between the participants in the 2 arms.

Treatment effects

Standard GIST and WL results

Primary outcome measure analysis (LCQ total, self-report). The LCQ scores changed significantly over time in both the standard GIST and WL groups, and the differences between standard GIST and WL did not reach the level of statistical significance. However, the LCQ scores suggest a trend toward better social communication after standard GIST compared to WL, with moderate effect sizes. Type of injury, sex, and age were not associated with LCQ results (table 3 and fig 2).

Secondary outcome analyses. SCSQ-A (self-report). A statistically significant Group × Time interaction was found for SCSQ-A, with a moderate effect size. That is, the standard GIST group reported significantly better social communication skills over time compared to WL (table 3 and fig 3).

Mental and cognitive health. No statistically significant Group × Time interactions were found for MiET, CIQ, BRIEF, GPSES, PQoL, or SCL-10 measuring mental and cognitive function (see Supplementary file 3 for more details).

Standard GIST and intensive GIST

Primary outcome measure analysis (LCQ total, self-report). No significant differences were found for the LCQ between standard and intensive GIST. However, both groups reported a statistically significant change over time, indicating better social communication skills posttreatment (table 3 and fig 4). Moreover, a statistically significant association was found between type of injury and LCQ (fig 5).

Table 3 Effects of standard GIST (n=24) and WL (n=25) and standard GIST and intensive GIST (n=23) posttreatment and at 3- and 6-month follow-ups

Measure M (95% CI)		Baseline	Posttreatment	3-Month Follow-Up	6-Month Follow-Up	Group *P*	Time *P*	Group × Time *P*	Effect Size *d*
Standard GIST and WL									
LCQ	S-GIST	68.8 (63.2-74.4)	61.9 (56.6-67.2)	61.5 (55.9-67.2)	57.7 (52.4-63.1)	.006	<.001	.073	−0.402
	WL	73.0 (67.4-78.5)	71.4 (66.2-76.6)	71.5 (66.1-76.6)	66.8 (61.6-71.9)				
SCSQ-A	S-GIST	132.7 (125.0-140.5)	142.7 (135.7-149.7)	147.0 (139.2-154.7)	147.3 (137.6-157.1)	.006	<.001	.038	0.335
	WL	128.6 (120.8-136.3)	128.6 (121.6-135.5)	131.7 (124.1-139.2)	133.1 (123.9-142.3)				
Standard GIST and intensive GIST									
LCQ	S-GIST	68.8 (63.3-74.4)	62.1 (56.8-67.3)	61.6 (55.9-67.3)	57.3 (52.7-62.0)	.126	<.001	.238	0.110
	I-GIST	65.6 (60.1-71.2)	57.5 (52.0-63.0)	54.2 (48.4-60.0)	55.1 (50.1-60.2)				
SCSQ-A	S-GIST	131.4 (122.7-140.0)	140.6 (134.7-146.4)	145.0 (137.9-152.1)	145.4 (138.2-152.7)	.301	<.001	.888	0.061
	I-GIST	134.1 (125.6-142.7)	145.8 (139.5-152.1)	150.0 (142.5-157.5)	147.5 (139.6-155.4)				

NOTE. Estimated means from generalized linear mixed models. LCQ is presented as reversed raw scores, and lower scores indicate better social communication skills. SCSQ-A is presented as raw scores, and higher scores indicate better social communication skills. For the WL: Posttreatment=12 weeks from baseline; 3-month follow-up=6 months from baseline; 6-month follow-up=9 months from baseline. Effect size is calculated as ES=mean (X)/(SE. sqrt(n)). Results were analyzed with the intention-to-treat principle including all randomized participants, including 1 participant that received chemotherapy during treatment and 1 participant who had a new stroke during the follow-up period. The results were confirmed by a sensitivity analysis (*P*=.073). Participants completed the study (S-GIST=21; WL=24; I-GIST=18). No missing data were reported for the LCQ. Missing data for SCSQ-A at 3-month follow-up (S-GIST=2; I-GIST=1) and 6-month follow-up (S-GIST=2; I-GIST=2).
Abbreviation: CI, confidence interval.

Secondary outcome analyses. SCSQ-A (self-report). No statistically significant Group × Time interaction was found for the SCSQ-A, indicating no significant difference between standard and intensive GIST results. However, a statistically significant change over time was found for both treatments.

GAS. Immediately posttreatment 97.4%-100% of standard GIST and 94.4%-94.9% of intensive GIST participants showed progress in all 3 social communication goals (GAS scores increased from 2 to 3-5), with maintained progress at 3- and 6-month follow-ups. There were no significant group differences in goal attainment between standard and intensive GIST.

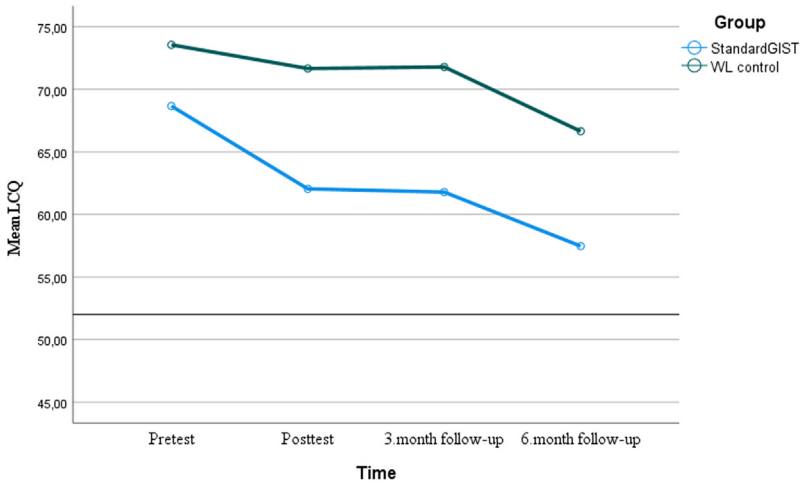
The standard GIST and intensive GIST (goals 1-3) GAS scores for planned comparisons demonstrated a significant change between pre- and posttreatment, and goal attainment was maintained or still increasing at 3- and 6-month follow-ups (table 4). These results indicate that the participants in both groups still experienced positive changes in their social communication skill goals 6 months posttreatment.

Mental and cognitive health. No statistically significant Group × Time interactions were found for MiET, CIQ, BRIEF, GPSES, PQoL, or SCL-10 (Supplementary file 3).

Attendance rate. Three participants dropped out (standard GIST [n=2]; WL [n=1]; fig 1). Most standard GIST participants (n=18) attended 83%-100% of sessions (3 participants attended 66%-75%), and intensive GIST participants (n=15) attended 91%-100% (3 participants attended 75%-83%).

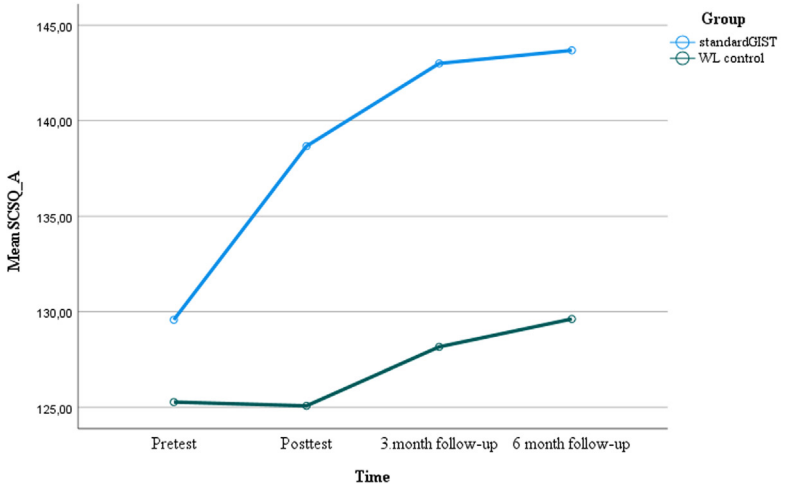
Within-subject results for WL/intensive GIST

Primary outcome measure analysis (LCQ total, self-report). The generalized linear model revealed a statistically significant within-subject change over time (T1-T7) for LCQ. The positive change was



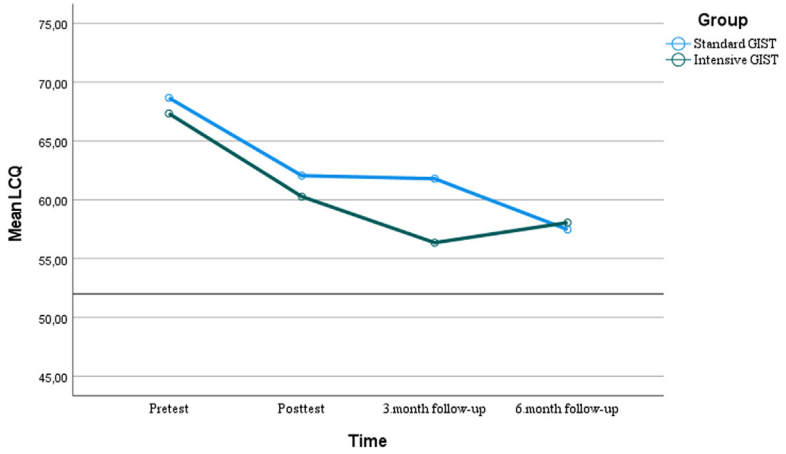
Note. Mean scores for LCQ is presented as reversed raw-scores. Lower scores indicate less reported social communication difficulties. Reference line is set to 52 points for normal population based on average scores for women (=50) and men (=54).20 LCQ=Latrobe Communication Questionnaire. Standard GIST = standard Group Interactive Structured Treatment; WL control= Waitlist control.

Fig 2 LCQ results over time for standard GIST and WL.



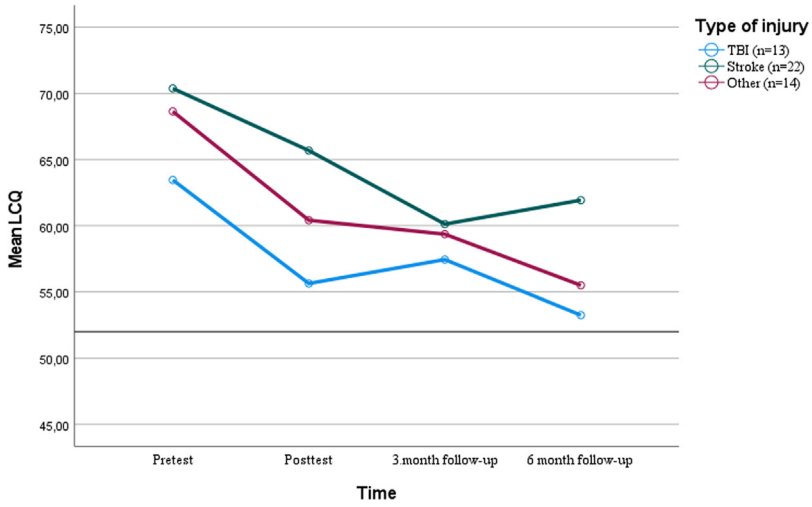
Note. Mean scores for SCSQ_A is presented as raw-scores. Higher scores indicate less reported social communication difficulties. SCSQ_A= Social Communication Skills Questionnaire with additional questions added by Dahlberg et al 2007 to capture all aspects of GIST. Standard GIST= standard Group Interactive Structured Treatment; WL control= Waitlist control

Fig 3 SCSQ.A results over time for standard GIST and WL.



Note. Mean scores for LCQ is presented as reversed raw-scores. Lower scores indicate less reported social communication difficulties. Reference line is set to 52 points for normal population based on average scores for women (=50) and men (=54).20 LCQ=Latrobe Communication Questionnaire. Standard GIST = standard Group Interactive Structured Treatment; Intensive GIST= intensive Group Interactive Structured Treatment

Fig 4 LCQ results over time for standard and intensive GIST.



Note. Mean scores for LCQ is presented as reversed raw-scores. Lower scores indicate less reported social communication difficulties. Reference line is set to 52 points for normal population based on average scores for women (=50) and men (=54).20 LCQ=Latrobe Communication Questionnaire. TBI= Traumatic Brain Injury; Other= Tumor, Anoxic brain injury, Meningitis

Fig 5 LCQ results over time for standard and intensive GIST associated with type of injury.

Table 4 Goal Attainment Scale results

		Assessment points										
		Pre- and Posttreatment			Posttreatment and 3-Month Follow-Up			Posttreatment and 6-Month Follow-Up			Pretreatment and 6-Month Follow-Up		
Measure	GAS	Median	Change	*p*	Median	Change	*P*	Median	Change	*P*	Median	Change	*P*
Goal 1	S-GIST (n=21)	2-3	+21	<.001	3-4	+6, −1, 14	.059	3-4	+9, 12	.003	2-4	+21	<.001
	I-GIST (n=18)	2-4	+16, 2	<.001	4-4	+8, −2, 8	.145	4-4	+11, 6	.021	2-4	+16, 2	<.001
Goal 2	S-GIST (n=21)	2-4	+20, 1	<.001	4-4	+4, −3, 14	.705	4-4	+6, 13	.107	2-4	+20, 1	<.001
	I-GIST (n=18)	2-3	+16, 2	<.001	3-4	+10, −2, 6	.017	3-4	+10, 5	.036	2-4	+16, 1, 1*	<.001
Goal 3	S-GIST (n=19)	2-4	+19	<.001	4-4	+5, −5, 8	1.00	4-4	+10, 5	.166	2-4	+18, 1	<.001
	I-GIST (n=18)	2-3	+15, 2	<.001	3-4	+6, −1, 10	.059	3-4	+7, 10	.035	2-4	+16, 1, 1*	<.001
Goal 4	S-GIST (n=2)	2-3	+1.1	.317	3-3	+1, −1	1.0	3-3	+1, −1		—	+1, 1	—
	I-GIST (n=1)	-	1	—	—	+1	—	—	+1	.655	—	1	—

NOTE. Results were analyzed with the intention to treat principle including all randomized participants, including 1 participant that received chemotherapy during treatment and 1 participant who had a new stroke during the follow-up period. Change shows positive (+), negative (−), and tied ranks between each test point. —Indicates no statistics were computed during analyses.

* Missing from analysis.

Table 5 Overview of the within-subject results for WL/intensive GIST

	Mean (95% CI)						
Measure/ Time Point	WL/Intensive GIST	Pairwise Comparisons From Baseline (T1)	Pairwise Comparisons From Pretreatment (T4)	Time *P*	Pairwise Comparison (Baseline) *P*	Pairwise Comparison (Pretest) *P*	Effect Size *d*
LCQ				<.001			1.153
T1 (n=25)	73.5 (67.1-80.0)						
T2 (n=24)	72.0 (65.3-78.8)	1.5 (−1.5 to 4.5)			.312		
T3 (n=24)	72.1 (65.7-78.6)	1.4 (1.8-4.7)			.381		
T4 (n=24)	67.4 (50.5-74.3)	6.1 (0.37-11.9)			.038		
T5 (n=18)	58.6 (51.1-66.0)	14.9 (8.9-21.0)	8.8 (4.3-13.3)		<.001	<.001	
T6 (n=18)	55.7 (48.9-62.5)	17.8 (11.6-24.0.4)	11.7 (7.9- 15.4)		<.001	<.001	
T7 (n=18)	56.9 (50.6-63.1)	16.6 (10.6-22.7)	10.5 (6.4-14.3)		<.001	<.001	
SCSQ-A				.001			−0.730
T1 (n=25)	127.7 (119-135.8)						
T2 (n=24)	127.8 (120-135.0)	−0.0 (−4.6 to 4.5)			.989		
T3 (n=24)	130.8 (123.5-138.2)	−3.0 (−8.1 to 1.9)			.218		
T4 (n=24)	132.3 (121.7-143.0)	−4.6 (13.4-4.2)			.294		
T5 (n=18)	142.9 (135.6-150.2)	−15.1 (−24.2 to −6.1)	−10.5 (−20.3 to −0.8)		.003	.034	
T6 (n=17)	147.2 (139.9-154.6)	−19.5 (−28.1 to −10.8)	−14.9 (−23.7 to −6.0)		<.001	.002	
T7 (n=16)	146.5 (137.2-155.7)	−18.7 (−29.6 to −7.7)	−14.1 (−25.5 to −2.6)		.003	.018	

NOTE. LCQ is presented as reversed raw scores, and lower scores indicate better social communication skills. SCSQ-A is presented as raw scores, and higher scores indicate better social communication skills. T1=baseline; T2=12 weeks from T1; T3=3 months from T2; T4=6 months from T2/pretreatment test; T5=posttreatment test; T6=3-month follow-up; T7=6-month follow-up. Effect size is calculated as ES=mean (X)/(SE. sqrt(n)). Pairwise comparisons from baseline (T1) compare change from baseline to different time points. Pairwise comparisons from pretest (T4) compare the pretest results to posttest and follow-up.

greater when comparing baseline with post-intensive GIST results (T5-T7) than during WL and when comparing pretreatment (T4) to posttreatment and follow-ups (T5-T7; table 5).

Secondary outcome analyses SCSQ-A (self-report). A statistically significant change over time (T1-T7) was found for SCSQ-A. Pairwise comparisons between baseline and retests during WL (T2-T4) showed no statistically significant change. However, the SCSQ-A showed a statistically significant change after intensive GIST (T5) and at 3- and 6-month follow-ups (T6-T7) when compared to baseline (T1) and pretest (T4).

Mental and cognitive health. A statistically significant change over time was found for MiET, BRIEF, GPSES, PQoL, and SCL-10 (Supplementary file 3).

Discussion

This RCT examined the efficacy of a manualized group treatment, standard GIST, for persons with SCDs in a wider ABI population compared to WL. Overall, our findings demonstrate the potential of GIST to improve social communication in this more varied ABI population. LCQ results indicated that participants receiving standard GIST showed a decrease in self-reported SCD symptoms when compared to WL. Secondary outcome results (SCSQ-A) replicate previous findings suggesting improved social communication skills after standard GIST.[7,11] The SCSQ-A includes additional questions[2,7] to capture all GIST aspects, which could make SCSQ-A more sensitive to measure real-life treatment effects. However, the LCQ has shown good psychometric qualities

in other studies,[10,11,37] and because moderate effect sizes were detected for both LCQ and SCSQ-A, it is possible that sample size limitations affected our results. Future studies with larger sample sizes are warranted.

Population

Our findings suggest beneficial effects after standard and intensive GIST in a broader ABI population. However, the TBI sample reported fewer SCDs on LCQ than the stroke sample, indicating that different injuries might evolve differently posttreatment (fig 5). Factors such as reduced self-awareness, the sensitivity of the LCQ across ABI populations, and/or the small sample size might have affected these results. Despite this, our findings indicate that GIST can be delivered across a wider ABI population. Thus, a further investigation of the efficacy of GIST across ABI populations seems feasible, and further research on active treatment components is warranted.

Delivery format

Our findings indicate that both standard and intensive GIST led to positive effects, with results maintained at 3- and 6-month follow-ups. Goal attainment was either maintained or still increasing at follow-ups for both arms. In this small sample, these results suggest that GIST delivered as an intensive inpatient 4-week treatment could be an equally effective alternative and could provide people with limited social networks an opportunity to practice skills in a social environment. Inpatient delivery of GIST might not be transferable to health care systems where inpatient chronic-phase ABI treatment is not available. Despite this, our findings of efficacy across delivery formats can be seen as a further validation of standard GIST and its treatment components. Our RCT generates further research questions regarding the key treatment components (eg, 12 weeks vs 4 weeks, home environment vs hospital setting, family members'/friends' role). Intensive GIST might also be applicable in earlier phases after ABI (eg, subacute phase) where inpatient treatment might be best suited; for example, in cases where complex rehabilitation is needed.

Waitlist implications

Our findings indicate a positive change over time for WL/intensive GIST. Reported changes in social communication (LCQ, SCSQ-A), self-efficacy (GPSES), and quality of life (PQoL) were much greater for participants after intensive GIST than during WL, indicating a superior effect from active treatment. However, during WL, participants reported a decrease in SCD symptoms between the 6-month (T3) and 9-month (T4) assessments on the LCQ. Participants continued treatment as usual during the WL period, and most did not receive cognitive rehabilitation. General time effects, retest effects, or the effect of assessment meetings with therapists during WL might have affected these results. These interactions might have increased participant awareness of social skills and behaviors, resulting in increased attention to these skills in daily life. Only 1 earlier GIST study used a deferred treatment control but with a considerably reduced waiting period (12 weeks).[7] All participants received treatment in our study, and comparisons were possible because the repeated measures were conducted at the same time points in both groups.

Study limitations

One limitation in this study was that the a priori calculated sample size was not achieved, increasing the risk of type II error. The COVID-19 pandemic affected the data collection and the conducting of 1 intensive GIST group and for 3 of the 6-month follow-up sessions. The national lockdown limited the participants' opportunity to practice social communication skills in a natural social environment during the follow-up periods, which may have influenced the self-report results. Inpatient training is considered more expensive than outpatient training and can be difficult to implement across different health care systems. However, this was a cost-independent study investigating the components and delivery formats of GIST. Although self-report is useful to capture participants' experience of change, several factors (eg, awareness, social desirability bias) may affect the accuracy and validity. Hence, objective measures extending beyond self-report should be explored, including input from significant others.

Conclusions

The results of this small-sample RCT indicate that standard GIST can lead to improved social communication skills in persons with different ABI etiologies. Our findings suggest that GIST can be delivered across different treatment formats, with similar results. This can make treatment more accessible in cases where inpatient treatment is needed (eg, social isolation, acute phases or complex cases). These findings open new research questions regarding the treatment components and delivery of GIST. Future studies should seek to recruit larger samples, increase the understanding of predictors of treatment outcomes, and include objective measurements.

Supplier

a. Statistical Package for the Social Sciences v28. IBM corp.

Keywords

Brain injuries; Rehabilitation; Social interaction; Evidence-based Practice

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