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Social Competence Treatment after Traumatic Brain Injury: A Multicenter, Randomized, Controlled Trial of Interactive Group Treatment versus Non-Interactive Treatment

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ABSTRACT

Objective: To evaluate the effectiveness of a replicable group treatment program for improving social competence after traumatic brain injury (TBI). **Design:** Multicenter randomized controlled trial comparing two methods of conducting a social competency skills program, an interactive group format versus a classroom lecture. **Setting:** Community and Veteran rehabilitation centers. **Participants:** 179 civilian, military, and veteran adults with TBI and social competence difficulties, at least 6 months post-injury. **Experimental Intervention:** Thirteen weekly group interactive sessions (1.5 hours) with structured and facilitated group interactions to improve social competence. **Alternative (Control) Intervention:** Thirteen traditional classroom sessions using the same curriculum with brief supplemental individual sessions but without structured group interaction. **Primary Outcome Measure:** Profile of Pragmatic Impairment in Communication (PPIC), an objective behavioral rating of social communication impairments following TBI. **Secondary Outcomes:** LaTrobe Communication Questionnaire (LCQ), Goal Attainment Scale (GAS), Satisfaction with Life Scale (SWLS), Post-Traumatic Stress Disorder Checklist – (PCL-C), Brief Symptom Inventory 18 (BSI-18), Scale of Perceived Social Self Efficacy (PSSE). **Results:** Social competence goals (GAS) were achieved and maintained for most participants regardless of treatment method. Significant improvements in the primary outcome (PPIC) and two of the secondary outcomes (LCQ and BSI) were seen immediately post-treatment and at 3 months post-treatment in the AT arm only, however these improvements

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24 were not significantly different between the GIST and AT arms. Similar trends were observed
25 for PSSE and PCL-C. **Conclusions:** Social competence skills improved for persons with TBI in both
26 treatment conditions. The group interactive format was not found to be a superior method of
27 treatment delivery in this study.

28 Key Words: Social skills, brain injuries, treatment

29 Abbreviations:

30 AT Alternative Treatment

31 BSI-18 Brief Symptom Inventory 18

32 GAS Goal Attainment Scaling

33 GIST Group Interactive Structured Treatment

34 LCQ LaTrobe Communication Questionnaire

35 OSU-TBI-ID Ohio State University Traumatic Brain Injury Identification

36 PCL – C Post Traumatic Stress Disorder Check List-Civilian Version

37 PPIC Profile of Pragmatic Impairment in Communication

38 PSSE Scale of Perceived Social Self-Efficacy

39 PTSD Post Traumatic Stress Disorder

40 RAVLT Rey Auditory Verbal Learning Test

41 SCSQ Social Communication Skills Questionnaire

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42 SWLS Satisfaction with Life Scale

43 TBI Traumatic Brain Injury

44 TMT Trail Making Test

45 VA Veteran's Affairs

46

47 Social competence encompasses the cognitive, emotional, and communication skills needed to
48 interact successfully, as well as knowing how to apply those skills in a variety of social
49 situations.[1-3] Impairments in social competence and interpersonal skills are among the most
50 prevalent and persistent sequelae after traumatic brain injury (TBI) and often present a major
51 barrier to an individual returning to a satisfying and productive life.[4] Difficulties with social
52 competence may arise due to a combination of factors including the extent of the neurological
53 injury, pre-injury social functioning, psychological reaction to the injury, social context, family
54 dynamics, co-existing pain, and fatigue. Regardless of the etiology, persisting social competence
55 issues after TBI may present a major obstacle to community reintegration.

56 Social competence impairments may occur across a wide range of areas, including starting or
57 ending conversations; staying focused on a social interaction; maintaining social boundaries;
58 taking turns; initiating social interactions; and resolving conflicts. Deficits in interpersonal skills
59 have been found to be the most frequent cause of job loss for individuals post-TBI [5]. Eyrachi
60 *et al.* [6] found that interpersonal factors, rather than work skills, lead to the most problems in
61 sustaining employment. Wehman and colleagues report that individuals with severe TBI, who

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62 worked in positions that required numerous social interactions, had more difficulty obtaining
63 and maintaining jobs[7]. Loneliness and social isolation have also been commonly cited post-
64 TBI[8] [9, 10]. Individuals with TBI commonly have difficulty adapting their social skills to new
65 social situations.[11] Problems with social perception, and misunderstanding the intentions,
66 inferences, and emotions of conversation partners are also often reported.[12] In general,
67 social interactions with individuals with TBI have been characterized as effortful and
68 unrewarding [11].

69 Historically, impairments in social skills have been addressed in group treatment, incorporating
70 group feedback, practice and interaction.[13-15] Social skills treatment after TBI often
71 emphasizes enhancing specific social, behavioral and communication skills and adapting those
72 skills in various social contexts, as well as increasing social self-awareness, self-efficacy and
73 confidence.

74 Published research regarding social skills and TBI specific to the military population is limited.
75 The recent and ongoing military conflicts have resulted in increased difficulties with adjusting to
76 post-deployment life among veterans and service members. [16] Military personnel with TBI
77 who seek treatment for social skills problems report a lack of interest in others, difficulty
78 resolving interpersonal conflicts, and difficulty interacting with family members[3]. In addition,
79 Hoge and colleagues found that 44% of soldiers with mild TBI (MTBI) and associated loss of
80 consciousness also met criteria for post-traumatic stress disorder (PTSD)[17]. Hoge, *et al.* also
81 noted a strong association between MTBI, PTSD, and other health symptoms in combat
82 veterans. These comorbid mental health problems may further impact social functioning within
83 the military TBI population.

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84 Currently, there is no gold standard of treatment for social competence problems after TBI and
85 few evidence-based social competence TBI treatment programs.[18, 19] Group Interactive
86 Structured Treatment (GIST) is a structured cognitive behavioral group intervention addressing
87 social competence after TBI.[3] GIST was developed by two of the investigators (Lenore Hawley
88 and Jody Newman), as a cross-disciplinary, replicable intervention addressing the underlying
89 cognitive, communicative, and emotional impairments impeding social competence after
90 TBI.[3] The intervention combines a psycho-educational curriculum with an interactive group
91 format, emphasizing group feedback and social learning.

92 GIST was found to be efficacious for individuals with social competency impairment following
93 TBI in a previous single-site study.[20] The objective of the current study was to compare the
94 interactive GIST treatment[3] with an alternative non-interactive treatment through a multi-site
95 study with a diverse sample of civilians and veterans with TBI. Specifically, the study aims were
96 to 1) measure the effectiveness of the GIST intervention with multisite implementation, 2)
97 Explore the potent ingredients associated with the GIST intervention.

98 METHODS**99 DESIGN**

100 This was a two-arm, multi-center, randomized-controlled clinical trial. This study was approved
101 by the Institutional Review Board at each study site. A computer generated block
102 randomization sequence was used to randomize to either the experimental treatment (GIST) or
103 alternative treatment (AT) in waves of 16 participants at each study center, with each center

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104 enrolling one to three waves. The outcome data collectors at each site remained blind to study
105 assignment throughout the study.

106 **SETTING**

107 This study was performed at six TBI rehabilitation centers: Craig Hospital; Hunter Holmes
108 McGuire Veterans Affairs Medical Center; University of Washington; Rehabilitation Institute of
109 Michigan; Rehabilitation Hospital of Indiana; and the VA Palo Alto Health Care System.

110 **RECRUITMENT**

111 Recruitment materials were provided to previous and current patients, local organizations
112 serving individuals with TBI, including state and local brain injury organizations; nearby
113 Veteran's Affairs (VA) centers or veteran organizations; and nearby TBI outpatient clinics.
114 Recruitment took place between August 2012 and August 2014.

115 **INCLUSION/EXCLUSION CRITERIA**

116 Study inclusion criteria were: history of TBI after October 2001 per the Ohio State University
117 Traumatic Brain Injury Identification (OSU-TBI-ID) tool [21]; ≥ 6 months post-injury at
118 enrollment; injury must have occurred after October 2001; ≥ 18 years old at enrollment;
119 Independent or Overnight Supervision on the Supervision Rating Scale [22]; ≥ 5 (Supervision) on
120 Comprehension and Expression items of FIMTM [23]; English speaking; demonstrates
121 problematic social competence on at least one of five screening statements. Participants were
122 asked to report their history of TBI using the OSU-TBI-ID [21] structured interview. The OSU-TBI-
123 ID is a valid and reliable procedure for eliciting a person's lifetime history of TBI and can be used
124 to categorize severity of self-reported TBI's [21, 24-26]. Further description of type and severity

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125 of injury was not captured. Individuals were excluded if they were: unable to verbally
126 communicate; unable to consistently attend treatment sessions; involved in ongoing structured
127 group therapy; or, participating in another intervention trial.

MEASUREMENT

128
129 Enrolled individuals completed a baseline assessment including demographic, injury and
130 cognitive functioning data (Trail Making Test-TMT Part B [27], Rey Auditory Verbal Learning
131 Test-RAVLT [28]), and assessments of social competence skills and emotional well-being as
132 outlined below. Several weeks into treatment participants developed individual social
133 competence goals using the Goal Attainment Scaling (GAS)[29, 30]. At the end of treatment,
134 and at three months post-treatment, participants completed assessments of social competence
135 and emotional well-being.

Social Competence

137 The primary outcome measure was a summary score of the Profile of Pragmatic Impairment in
138 Communication (PPIC) [31, 32], an objective, behavioral rating of social communication
139 impairments following TBI. The PPIC has been found to have excellent reliability, convergent
140 validity and discriminant validity in most scales.[33] The PPIC was rated by two blinded trained
141 evaluators (a speech-language pathologist and a social worker) using 10-minute video-recorded
142 conversations of study participants with an unfamiliar conversational partner(site employees
143 not involved in the study and blinded to intervention randomization) at each assessment point.
144 Prior to rating the excerpts, raters were trained (using sample video tapes) by two of the study

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145 authors with extensive knowledge of the PPIC until they achieved at least a 0.75 level of
146 reliability on each of the PPIC summary scores among themselves and the trainers.
147 Each PPIC rater assessed each conversational excerpt for this study independently and
148 remained blind to the scoring of the other PPIC rater. An average of the two raters' scores was
149 used for each of the 10 PPIC subscales for each conversational excerpt. As was used in previous
150 research [34], after personal communication with PPIC author [35], the 10 PPIC subscale scores
151 were then added together to create one PPIC summary score to reflect a more comprehensive
152 index of social competence for each conversational excerpt.

153 The 84 behavior items assess frequency and severity of specific communication impairments
154 that fall into 10 subscales (Logical Content, General Participation, Quantity, Quality, Internal
155 Relation, External Relation, Clarity of Expression, Social Style, Subject Matter, and Aesthetics).
156 Each subscale is rated on a Likert-scale of 0 (normal) to 5 (very severely impaired), with lower
157 scores indicating better functional social communication. Videos were randomized, and an
158 average of the two raters' scores was used for each PPIC subscale. The 10 PPIC subscale scores
159 were summed to create a PPIC total score reflecting a comprehensive index of social
160 competence.

161 Self-report assessments of social competence were: the LaTrobe Communication Questionnaire
162 (LCQ),[36] a 30-item self-report measure of cognitive-communication ability in persons with
163 TBI, with scores ranging from 30 to 120, and higher scores indicating greater communicative
164 impairment; the Scale of Perceived Social Self-Efficacy (PSSE),[37] a 25-item self-report five-
165 point Likert scale of self-efficacy expectations and beliefs regarding social behaviors; the PSSE
166 was modified to exclude two not applicable items, thus total scores ranged from 23 to 115, with

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167 higher scores indicating greater perceived social self-efficacy. The GAS, a functional outcome
168 measure, (based on a five-point scale, with higher scores indicating greater goal attainment)
169 was used to measure change on individual social competence goals.

170 ***Emotional Well-Being***

171 Measures included: the Satisfaction with Life Scale (SWLS),[38] a Likert-scale measure of global
172 life satisfaction, with raw scores ranging from 5 to 35, and higher scores reflecting greater life
173 satisfaction; the Post Traumatic Stress Disorder Check List-Civilian Version (PCL-C),[39] a Likert-
174 scale measure to evaluate symptoms of Post Traumatic Stress Disorder (PTSD), with raw scores
175 ranging from 17 to 85, and higher scores indicating more PTSD symptomology; and the Brief
176 Symptom Inventory 18 (BSI-18)[40] which measures psychological distress and psychiatric
177 symptoms on three dimensions using T-scores (Somatization, Anxiety, and Depression), and
178 provides an overall measure of psychological distress (Global Severity Index).

179 **INTERVENTION**

180 GIST is a 13-week program combining a psychoeducational curriculum with an interactive group
181 format, emphasizing group feedback and social learning. Each group consisted of six to eight
182 participants and two therapists. Topics covered include self-assessment, goal setting, starting
183 conversations, conversation strategies, feedback, assertiveness, social problem solving, positive
184 self-talk, social boundaries, and conflict resolution. Session 6 is a group community outing with
185 the therapists to practice goals. The GIST framework parallels Ben-Yishay's Holistic
186 Neuropsychological Rehabilitation Model for TBI, [41] which emphasizes the integration of
187 cognitive remediation with psychotherapeutic interventions in a structured hierarchical

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188 approach. GIST sessions occur in a group setting, without supplemental individual sessions.
189 During each 90 minute group session, key concepts from the previous session are reviewed, a
190 new topic is discussed, strategies and skills are practiced interactively, and real-life social
191 problems are addressed. Therapists encourage the group to interact, share experiences, and
192 give and receive feedback. Each structured treatment topic is presented and discussed within
193 the interactive group conversation.

194 Group members receive the GIST workbook which includes weekly topics and homework,
195 promoting generalization.. Generalization is specifically targeted through the use of homework,
196 family involvement, use of real-life problem solving, practice in the community, and actual
197 (non-contrived) social interactions during the group sessions. The GIST intervention is
198 described in greater detail elsewhere.[3, 42] Treatment dose was defined as the percentage of
199 sessions attended, regardless of the specific sessions attended.

ALTERNATIVE INTERVENTION

201 The AT consisted of the GIST curriculum presented in 12 weekly classroom sessions via a power-
202 point/audio presentation. One therapist was in the room to provide clarification and answer
203 general questions about the power-point. Each group consisted of six to eight participants and
204 one therapist in the room. GIST treatment activities involving group feedback and interaction
205 were completed individually in AT as pen and paper tasks. Rather than attending a group outing
206 in Session 6, each participant was asked to go on an individual outing (alone, with family, or a
207 friend). Group interaction in the AT was not facilitated but was permitted if it occurred
208 spontaneously. Participants also met individually with a study therapists for 10 minutes each

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209 week for goal setting and monitoring. The fundamental difference from the experimental
210 treatment was the absence of clinician facilitated group dynamics in shaping behavior.

211 **THERAPIST TRAINING**

212 Two therapists per site facilitated the interventions, a speech-language pathologist with adult
213 TBI experience and a licensed psychotherapist (a clinical social worker or psychologist) with
214 adult TBI and group therapy experience. Two in-person, interactive therapist trainings were
215 provided by the GIST developers [43-45]. One was held prior to the study pilot (overview of
216 therapist study role and the GIST intervention), and the second occurred prior to the main
217 study (AT and review of the goal setting process).

218 **TREATMENT FIDELITY**

219 An intervention checklist was developed prior to study onset and each session of both
220 treatment conditions was audio-taped to allow assessment of fidelity. The fidelity checklist
221 included both content items to be covered for each session, and specific therapist behaviors,
222 such as giving a prompt to participants to give feedback to others, or encouraging sharing of
223 real-life social skills situations or problems. Feedback was provided to study therapists for
224 sessions not meeting fidelity. Four sessions from each center were observed. Each session had
225 two content items. Raters scored each item exhibited within a session by at least one group
226 therapist. Fidelity was met for the four rated sessions when the pair of group therapists
227 covered seven of the eight content items over the course of the 13 week group. If this
228 occurred, the group therapists were considered to be successfully implementing the content of
229 the program. In addition, ten group process behaviors were observed in four randomized

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230 sessions. Eight out of the ten behaviors were required in a single session by at least one of the
231 therapists to have met fidelity for the therapist behavior component.

232
233 During the pilot phase, audiotapes from every session at each site were reviewed and feedback
234 was provided to the therapists, through weekly phone conference calls between the therapist
235 pair and the GIST developers. Pilot fidelity was found to be suboptimal for all study sites, with
236 only 17-75% of sessions reaching fidelity. During the intervention phase, fidelity was again
237 assessed for those sessions where fidelity had not been met during the pilot phase, and for an
238 additional four random sessions for each treatment group. If fidelity was not met for a session,
239 a phone conference took place between the therapists and GIST developers to provide
240 feedback. This fidelity monitoring allowed for the assessment of whether the treatment was
241 delivered as intended.

242
243 There was substantial improvement in fidelity during the intervention phase for all centers
244 (wave 1: 60-100%, wave 2: 75-100%, wave 3: 100%). Two of the six centers had 100% fidelity
245 during all waves, and an additional two centers had 100% fidelity during at least one wave.

246 STATISTICAL METHODS**247 *Sample Size and Power Analysis***

248 The *a priori* sample size estimation/power analysis (using PASS 2008) indicated a group sample
249 size of 96 (total $n = 192$) would attain a level of power slightly above 80% in detecting an effect
250 size of 0.5 (equivalent to detecting a 4-unit difference in the PPIC between treatment arms,
251 assuming a standard deviation of 8), at a significance level of $\alpha = 0.05$.

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252 ***Statistical Analysis***

253 All statistical analyses were performed using SAS v.9.4[46]. The mean PPIC total score was
254 modeled over time for each arm using a mixed-effects model with fixed effects for treatment,
255 time, and the treatment by time interaction along with a random center effect to account for
256 center to center variation. Although the random center effect accounted for a small (non-
257 significant) percentage of the variations in the outcome (PPIC and secondary outcomes) it was
258 always retained in the models as this is considered standard practice in multi-center studies. A
259 compound symmetry variance-covariance structure was assumed to account for the
260 correlations in the repeated measures over time as it consistently demonstrated significantly
261 better fit than other correlation structures. Changes over time, within and between the
262 treatment arms, were estimated and tested using a Bonferroni correction of $\alpha = 0.05/9 =$
263 0.0056 . Covariates considered for adjustment were selected a priori and include age, gender,
264 level of education, military status, treatment dose, Trails B (T-scores), RAVLT (Delayed Recall T-
265 score), and baseline PSSE, LCQ, BSI (T-scores), SWLS, and PCL. The effects of each covariate on
266 PPIC scores were tested and included in the model for adjustment if significant ($\alpha = 0.05$). The
267 relationship between the covariates and outcomes were quantified with mean differences for
268 nominal covariates and slopes for continuous covariates.

269 The percentage of participants who (a) showed some progress on at least one goal (GAS = 3-5)
270 and (b) achieving at least one goal (GAS = 4-5) was computed and compared between the GIST
271 and AT arms at post-treatment and at 3 months post treatment using chi-square tests.

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272 The mean responses (LCQ, BSI, PCL, SWLS, and PSSE) were each modeled over time using the
273 same mixed-effects modeling strategy as described for PPIC to determine if changes in the
274 responses over time differed between the arms.

275 **RESULTS**

276 **DESCRIPTION OF SAMPLE**

277 Across the six centers, 579 individuals expressed an interest and completed an eligibility screen,
278 of which 179 consented participants met the inclusion criteria and entered randomization
279 (Figure 1 – CONSORT DIAGRAM). The demographic and baseline characteristics by treatment
280 arm are summarized in Table 1. There were not significant differences in these characteristics
281 between arms.

283 **PRIMARY ANALYSIS**

284 **CHANGES IN PPIC OVER TIME**

285 The mixed-effects model for total PPIC scores included fixed effects for treatment, time, and
286 the treatment by time interaction as well as a random center effect. The model also adjusted
287 for the effects of gender, level of education, Trails B, RAVLT, and baseline PSSE on PPIC scores.

288 The estimated mean PPIC scores from this model are summarized by treatment arm and time in
289 Table 2 and plotted in Figure 2.

290 Overall, there was no significant treatment arm by time interaction ($p = 0.2076$), thus the
291 changes over time in total PPIC scores did not differ significantly between the treatment arms.

292 The estimated changes for each arm and comparisons in the changes between the arms are

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293 summarized in Table 3. Although the between group interaction effect was not significant,
294 further secondary analyses were performed to assess for change in PPIC scores between
295 specific time-points and within each arm (Bonferroni $\alpha = 0.0056$). From baseline to post-
296 treatment, there were nominal (i.e., non-significant) improvements in total PPIC scores for the
297 GIST arm (decrease = 1.79) and significant improvements in the AT arm (decrease = 2.66); the
298 improvements did not differ significantly between arms ($p = 0.4113$). There were nominal
299 worsening in total PPIC scores from post-treatment to 3 months post-treatment observed in
300 both arms (GIST increase = 1.18, AT increase = 0.11); the worsening did not differ significantly
301 between arms ($p = 0.3494$). From baseline to 3 months post-treatment, PPIC scores in the GIST
302 arm nominally improved by 0.61, while PPIC scores in the AT arm significantly improved by
303 2.54; the improvements did not differ significantly between the arms ($p = 0.0766$).

304 The mixed-effects model also indicated there were a significant effects of gender ($p = 0.0045$)
305 and level of education ($p = 0.0275$) on PPIC scores and that there were significant negative
306 relationships between total PPIC scores and RAVLT ($p = 0.0092$), Trails B ($p = 0.0156$), and PSSE
307 ($p = 0.0121$). In particular, greater social competence was associated with female gender,
308 having at least a high school level of education, greater memory, greater cognitive
309 speed/flexibility, and greater perceived self-efficacy. Table 4 summarizes the relationship
310 between these covariates and PPIC scores in more detail.

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311

SECONDARY ANALYSES

312 *Goal Attainment Scale*

313 Immediately post-treatment, 98.5% of GIST and 98.1% of AT participants showed some
314 progress on goals (GAS scores went from 2 to 3-5). Eighty percent of GIST and 82.7% of AT
315 participants achieved at least one goal (GAS scores 4-5). At three months post-treatment,
316 95.3% of GIST and 100% of AT participants showed some progress on goals, 77.4% of GIST and
317 86.0% of AT participants achieved at least one goal. There were not significant group
318 differences in goal attainment between the arms.

319 *Changes in LCQ, BSI, PCL, SWLS, and PSSE over Time*

320 Results from the mixed-effects models for BSI, PCL, SWLS, and PSSE are summarized in Tables 2
321 – 4 and plotted in Figure 2. There was no evidence of significant treatment arm by time
322 interaction effects for any of these measures (LCQ: $p = 0.2898$, BSI: $p = 0.2408$, PCL: $p = 0.1796$,
323 SWLS: $p = 0.9854$, and PSSE: $p = 0.4677$); thus changes in each outcome measure over time did
324 not differ between the treatment arms. Post-hoc comparisons adjusting for multiple
325 comparisons indicated that while the AT arm tended to show nominally better improvement in
326 outcomes over time than the GIST arm, the gains were not significantly different between the
327 treatment arms.

328 **Discussion**

329 The purpose of this study was to test the effectiveness of a manualized social competence
330 group treatment across multiple sites for individuals with chronic TBI living in the community.
331 We hypothesized that this interactive group treatment would be superior to the same content

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332 presented through a non-interactive classroom style video presentation with additional brief
333 individual sessions.

334 After controlling for multiple comparisons, significant improvements in the primary outcome
335 (PPIC) and the two of the secondary outcomes (LCQ and BSI) were seen immediately post-
336 treatment and at 3 months post-treatment in the AT arm only, however these improvements
337 were not significantly different between the treatment arms. Similar trends were observed for
338 PSSE and PCL, except the improvements in PSSE through follow-up were significant in both
339 arms and the improvements in PCL were not maintained through follow-up for either arm.

340 Neither arm showed significant improvements in SWLS over time after controlling for multiple
341 comparisons, although positive trends were noted in both groups.

342 Participants in both treatment conditions met or exceeded their self-selected functional social
343 competence goals. PPIC, LCQ, BSI, PCL scores tended to stay the same or get worse from post-
344 treatment to 3-months post-treatment, potentially indicating the need for booster sessions,
345 whereas SWLS and PSSE scores continued to improve, perhaps showing a delayed efficacy
346 effect. Given the chronicity of these participants, any positive change on these measures may
347 be clinically meaningful. The study suggests a benefit from the GIST curriculum presented
348 through both the interactive group GIST program and the lecture format which included
349 supplemental individual sessions.

350 The lack of significant improvement in the GIST arm on the primary outcome contradicts the
351 findings of the prior GIST efficacy clinical trial; however, there were several differences
352 between these studies. A key component of group therapy is group composition, with clinical
353 groups formed based on participant needs and characteristics.[14] Participants in the prior

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354 study were more homogeneous in severity of injury, all having a history of moderate to severe
355 TBI. The current study randomized a wider range of participants, including mild, moderate, and
356 severe injuries, with various levels of physical impairment, as well as veterans and civilians.

357 In the prior study, each of the 10 PPIC subscale scores were analyzed as opposed to using a sum
358 total score of the 10 PPIC subscales. In addition, the PPIC may not identify the full range of
359 social skills impairments in this more heterogeneous group. In the previous study, the Social
360 Communication Skills Questionnaire (SCSQ)[47] was adapted to capture the spectrum of
361 behaviors addressed by the GIST program that might not be observed through the PPIC. The
362 current study included the LaTrobe Communication Skills Questionnaire due to its wider use
363 within this population.

364 The prior study involved a wait-list control condition, while the current study included an AT of
365 the GIST curriculum presented in a power-point lecture. While the AT participants did not have
366 facilitated social interaction, they did share this experience together and may have had
367 unmeasured social support in addition to educational presentation of material. In addition, AT
368 participants also received brief individual treatment sessions.

369 In the prior study, the intervention was provided by the GIST developers, who have years of
370 experience as group therapists and as co-therapists. Group therapist experience has been
371 found to influence therapist/group member dynamics in group therapy.[48] Group therapy is a
372 complex skill-based modality, usually involving significant training and supervision. The GIST
373 intervention is intended to be implemented flexibly, using the clinical experience and judgment
374 of the co-therapists to meet the needs of each group and individual. This level of clinical
375 judgment and adaptation of GIST may require more extensive clinician training than was

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376 provided in this study. It is important to note that the curriculum content provided in the
377 current study resulted in improved goal attainment and scores in both groups. Improvements in
378 personally meaningful, functional goals were found even though those goal behaviors may not
379 have been captured on the ten minute video sample used for the standardized PPIC
380 assessment. The self-selected GAS goals were a focus in both interventions, through individual
381 sessions during the AT and within the group in the GIST treatment.

382 Limitations

383 With the exception of the primary measure, the study relied upon self-report measures. The
384 wide range of participants in this study (mild, moderate, severe, veteran and military) presents
385 a challenge in terms of defining the study sample. The OSU-TBI-ID, a self-report measure, was
386 used to capture history and severity of TBI. Another limitation is that the objective primary
387 measure may not have captured the broad range of social skills addressed in the treatment
388 such as social confidence, increased social activity, or interactions with family. It is possible that
389 the AT was too similar to the treatment condition, using the same curriculum and goal-setting.
390 Additionally, it is possible that the treatment was not fully exported to the study therapists,
391 although efforts were made through training, fidelity checks, and ongoing support. Although
392 group interaction was not intended in the AT, those individuals had the opportunity to interact,
393 share experiences, and develop relationships. In addition, participants may have taken part in
394 other treatment groups and been more likely to spontaneously engage in group interaction.
395 The attendance rates in both groups were low (69% GIST and 61% AT) but not unexpected
396 given the nature of group treatment. This could decrease the precision and lower the power to

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397 detect clinically important effects.[49] The specific sessions missed by participant were not
398 analyzed in terms of effect on the overall outcome of the participant.

399 **Conclusions**

400 The group interactive format was not found to be a superior method of treatment delivery in
401 this study. However, social competence improved for a heterogeneous group of individuals
402 with chronic TBI in both intervention conditions involving the GIST curriculum. Future research
403 could address a response to treatment analysis to determine which individuals may respond
404 best to this type of treatment, as well as development of assessment tools to capture a wider
405 range of social competence behaviors and skills. The results of this study suggest further
406 investigation of best methods for training multidisciplinary therapists in the complex skills
407 required for group process interventions.

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Table 1: Demographic and Baseline Characteristics

	GIST (N = 90)		Alternative (N = 89)		p-value
	Mean	SD	Mean	SD	
Age	44.74	14.52	46.44	12.05	0.3970
WAIS-III	41.75	11.23	40.03	10.35	0.2997
Trails B	41.34	15.33	38.59	13.42	0.2121
RAVLT	40.22	14.83	36.98	16.10	0.1710
Baseline PPIC	13.78	6.61	14.11	12.05	0.7612
Baseline LCQ	66.90	12.96	66.95	14.44	0.9811
Baseline BSI	62.16	10.05	61.51	11.78	0.6952
Baseline PCL	44.07	16.47	43.89	17.96	0.9442
Baseline SWLS	17.28	7.12	17.79	8.26	0.6654
Baseline PSSE	67.79	20.78	65.47	21.41	0.4726
Dose	69%		61%		0.0960
	<i>N</i>	%	<i>N</i>	%	<i>p</i> -value
Sex					0.7856
Male	61	67.8	62	69.7	
Female	29	32.2	27	30.0	
Race					0.4575
White	60	66.7	63	70.8	
Black	19	21.1	20	22.5	
Other	11	12.2	6	6.7	
Marital Status					0.2765
Never Married	40	44.4	39	43.8	

Married	28	31.1	20	22.5	
Other	22	24.4	30	33.7	
Education Level					0.9043
< High School	9	10.0	9	10.1	
High School/GED	28	31.1	25	28.1	
> High School	53	58.9	55	61.8	
Current					0.2340
Employment					
Employed	27	30.3	20	22.5	
Unemployed	62	69.7	69	77.5	
Military Status					0.4836
Civilian	65	72.2	60	67.4	
Military	25	27.8	29	32.6	
OSU					0.6430
Mild TBI LOC -	11	12.8	18	20.2	
Mild TBI LOC +	31	36.0	28	31.5	
Moderate TBI	14	16.3	11	12.4	
Severe TBI	27	31.4	30	33.7	
Unknown TBI	3	3.5	2	2.2	
MSVT II					0.7045
Valid	56	65.9	59	68.6	
Invalid	29	34.1	27	31.4	

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Table 2: Estimated Mean Response Scores by Group and Time

Treatment	Time	LS Mean	SE	95% CI
PPIC: Functional Social Communication				
GIST	Baseline	13.86	0.91	(12.02, 15.70)
	Post-Treatment	12.07	0.98	(10.10, 14.04)
	3 Months Post-Treatment	13.25	0.98	(11.27, 15.24)
Alternative	Baseline	13.51	0.90	(11.69, 15.33)
	Post-Treatment	10.85	0.97	(8.90, 12.81)
	3 Months Post-Treatment	10.96	1.00	(8.96, 13.0)
LCQ: Communicative Impairment				
GIST	Baseline	66.42	1.01	(64.44, 68.40)
	Post-Treatment	62.79	1.12	(60.59, 64.99)
	3 Months Post-Treatment	63.20	1.12	(61.00, 65.40)
Alternative	Baseline	66.94	0.99	(64.44, 64.99)
	Post-Treatment	60.69	1.19	(58.36, 63.02)
	3 Months Post-Treatment	61.80	1.18	(59.50, 64.09)
BSI: Psychological Distress				
GIST	Baseline	61.83	0.85	(60.08, 63.58)
	Post-Treatment	60.57	0.94	(58.66, 62.47)
	3 Months Post-Treatment	60.95	0.96	(59.02, 62.88)
Alternative	Baseline	61.11	0.83	(59.41, 62.82)
	Post-Treatment	57.85	0.96	(55.92, 59.79)
	3 Months Post-Treatment	58.31	0.97	(56.35, 60.26)
PCL: PTSD Symptomology				
GIST	Baseline	44.42	1.61	(40.87, 47.96)

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	Post-Treatment	43.03	1.71	(39.37, 46.70)
	3 Months Post-Treatment	43.15	1.75	(39.43, 46.87)
Alternative	Baseline	44.67	1.60	(41.14, 48.20)
	Post-Treatment	39.90	1.74	(36.20, 43.60)
	3 Months Post-Treatment	41.21	1.73	(37.51, 44.91)
SWLS: Life Satisfaction				
GIST	Baseline	17.02	0.81	(15.30, 18.73)
	Post-Treatment	18.15	0.86	(16.35, 19.94)
	3 Months Post-Treatment	18.84	0.87	(17.04, 20.64)
Alternative	Baseline	17.13	0.80	(15.45, 18.81)
	Post-Treatment	18.18	0.88	(16.37, 20.89)
	3 Months Post-Treatment	19.06	0.89	(17.23, 20.89)
PSSE: Perceived Self-Efficacy				
GIST	Baseline	68.17	2.05	(63.86, 72.47)
	Post-Treatment	72.05	2.38	(67.15, 76.96)
	3 Months Post-Treatment	74.75	2.37	(69.88, 79.63)
Alternative	Baseline	66.16	2.01	(61.93, 70.39)
	Post-Treatment	73.38	2.46	(68.36, 78.40)
	3 Months Post-Treatment	73.32	2.42	(68.37, 78.26)

LS = Least Squares; SE = Standard Error; CI = Confidence Interval

Table 3: Estimated Changes in Response Measures over Time by Group and Comparisons in the Changes between the Groups

		LS Mean	SE	95% CI	p-value	
Changes in PPIC over Time						
Baseline – Post	GIST	1.79	0.74	(0.32, 3.25)	0.0169	*
	Alternative	2.66	0.75	(1.18, 4.13)	0.0005	†
	GIST – Alternative	-0.87	1.06	(-2.95, 1.21)	0.4113	
Post – 3 Months Post	GIST	-1.18	0.80	(-2.75, 0.39)	0.1409	
	Alternative	-0.11	0.81	(-1.71, 1.48)	0.8896	
	GIST – Alternative	-1.07	1.14	(-3.31, 1.18)	0.3494	
Baseline – 3 Months Post	GIST	0.61	0.76	(-0.88, 2.10)	0.4232	
	Alternative	2.54	0.78	(1.00, 4.08)	0.0013	†
	GIST – Alternative	-1.94	1.09	(-4.08, 0.21)	0.0766	
Changes in LCQ over Time						
Baseline – Post	GIST	3.63	1.21	(1.24, 6.02)	0.0030	*
	Alternative	6.25	1.27	(3.76, 8.74)	<0.0001	†
	GIST – Alternative	-2.62	1.75	(-6.07, 0.83)	0.1361	
Post – 3 Months Post	GIST	-0.41	1.27	(-2.91, 2.09)	0.7475	
	Alternative	-1.11	1.35	(-3.78, 1.55)	0.4124	
	GIST – Alternative	0.75	1.86	(-2.95, 4.36)	0.7053	
Baseline – 3 Months Post	GIST	3.22	1.21	(0.83, 5.61)	0.0084	*
	Alternative	5.14	1.24	(2.69, 7.59)	<0.0001	†
	GIST – Alternative	-1.92	1.74	(-5.34, 1.50)	0.2709	
Changes in BSI over Time						
Baseline – Post	GIST	1.26	0.95	(-0.61, 3.13)	0.1859	

	Alternative	3.26	0.97	(1.35, 5.17)	0.0009	†
	GIST – Alternative	-2.00	1.36	(-4.67, 0.67)	0.1423	
Post – 3 Months Post	GIST	-0.38	1.01	(-2.36, 1.60)	0.7049	
	Alternative	-0.45	1.04	(-2.50, 1.59)	0.6637	
	GIST – Alternative	0.07	1.45	(-2.78, 2.92)	0.9612	
Baseline – 3 Months Post	GIST	0.88	0.97	(-1.02, 2.78)	0.3639	
	IST	2.81	0.98	(0.87, 4.74)	0.0046	†
	GIST – IST	-1.93	1.38	(-4.64, 0.79)	0.1632	
Changes in PCL over Time						
Baseline – Post	GIST	1.38	1.31	(-1.19, 3.95)	0.2913	
	Alternative	4.77	1.35	(2.11, 7.43)	0.0005	†
	GIST – Alternative	-3.39	1.87	(-7.06, 0.29)	0.0709	
Post – 3 Months Post	GIST	-0.11	1.42	(-2.92, 2.69)	0.9366	
	Alternative	-1.31	1.43	(-4.12, 1.50)	0.3588	
	GIST – Alternative	1.20	2.02	(-2.77, 5.17)	0.5529	
Baseline – 3 Months Post	GIST	1.27	1.36	(-1.42, 3.96)	0.3537	
	Alternative	3.46	1.34	(0.82, 6.10)	0.0105	*
	GIST – Alternative	-2.19	1.90	(-5.94, 1.56)	0.2515	
Changes in SWLS over Time						
Baseline – Post	GIST	-1.13	0.70	(-2.51, 0.25)	0.1089	
	Alternative	-1.05	0.73	(-2.49, 0.39)	0.1526	
	GIST – Alternative	-0.08	1.01	(-2.08, 1.91)	0.9353	
Post – 3 Months Post	GIST	-0.70	0.73	(-2.14, 0.74)	0.3412	
	Alternative	-0.88	0.77	(-2.40, 0.64)	0.2563	
	GIST – Alternative	0.18	1.07	(-1.92, 2.28)	0.8643	
Baseline – 3 Months Post	GIST	-1.83	0.71	(-3.23, -0.43)	0.0107	*

	Alternative	-1.93	0.74	(-3.39, -0.47)	0.0097	*
	GIST – Alternative	0.10	1.03	(-1.92, 2.12)	0.9226	
Changes in PSSE over Time						
Baseline – Post	GIST	-3.89	2.25	(-8.34, 0.57)	0.0869	
	Alternative	-7.22	2.34	(-11.86, -2.59)	0.0025	†
	GIST – Alternative	3.34	3.25	(-3.09, 9.77)	0.3066	
Post – 3 Months Post	GIST	-2.70	1.79	(-6.24, 0.84)	0.1335	
	Alternative	0.06	1.87	(-3.64, 3.77)	0.9733	
	GIST – Alternative	-2.76	2.59	(-7.89, 2.36)	0.2877	
Baseline – 3 Months Post	GIST	-6.59	2.22	(-10.98, -2.19)	0.0036	†
	Alternative	-7.16	2.28	(-11.66, -2.65)	0.0021	†
	GIST – Alternative	0.57	3.18	(-5.72, 6.87)	0.8572	

LS = Least Squares; SE = Standard Error; CI = Confidence Interval

* = Statistically significant without adjusting for multiple comparisons ($\alpha = 0.05$)

† = Statistically significant after adjusting for multiple comparisons ($\alpha = 0.05/9 = 0.0056$)

Table 4: Relationship between Covariates and Response Measures

Result	Relationship to PPIC	SE	95% CI
Females had greater social competence than males.	Females had lower PPIC scores than males by 2.844 units.	0.986	(0.895, 4.793)
Participants with at least a High School level of education had greater social competence than those with less than a High School level of education	High School level had lower PPIC than less than High School level by 3.625 units.	1.757	(0.149, 7.101)
	More than High School level had lower PPIC than less than High School level by 4.464 units.	1.655	(1.189, 7.734)
Greater memory was associated with greater social competence.	A one unit increase in RAVLT scores was associated with a 0.065 unit decrease in PPIC scores.	0.030	(0.005, 0.125)
Greater cognitive speed/flexibility (less cognitive impairment) was associated with greater social competence.	A one unit increase in Trails B scores was associated with a 0.092 unit decrease in PPIC scores.	0.033	(0.026, 0.157)
Greater perceived self-efficacy was associated with greater social competence.	A one unit increase in baseline PSSE scores was associated with a 0.064 unit decrease in PPIC scores.	0.022	(0.020, 0.108)
Result	Relationship to LCQ	SE	95% CI
Greater perceived self-efficacy was associated with less communicative impairment.	A one unit increase in baseline PSSE scores was associated with a 0.113 unit decrease in LCQ scores.	0.030	(0.053, 0.172)
Greater psychological distress was associated with greater communicative impairment.	A one unit increase in baseline BSI scores was associated with a 0.462 unit increase in LCQ scores.	0.087	(0.290, 0.663)

Greater PTSD symptomology was associated with greater communicative impairment.	A one unit increase in baseline PCL scores was associated with a 0.217 unit increase in LCQ scores.	0.055	(0.108, 0.327)
Result	Relationship to BSI	SE	95% CI
Greater life satisfaction was associated with less psychological distress.	A one unit increase in baseline SWLS was associated with a 0.141 unit decrease in BSI scores.	0.067	(0.009, 0.274)
Greater PTSD symptomology was associated with greater psychological distress.	A one unit increase in baseline PCL was associated with a 0.359 unit increase in BSI scores.	0.038	(0.284, 0.435)
Greater communicative impairment was associated with greater psychological distress.	A one unit increase in baseline LCQ was associated with a 0.188 unit increase in BSI scores.	0.046	(0.098, 0.278)
Result	Relationship to PCL	SE	95% CI
Adequate effort was associated with less PTSD symptomology.	Those who scored invalid on MSVT II had higher PCL scores by 4.116 than those who scored valid.	1.598	(0.962, 7.271)
More treatment (dose) was associated with less PTSD symptomology.	A one unit increase in dose was associated with a 7.803 unit decrease in PCL scores.	2.422	(3.027, 7.271)
Greater psychological distress was associated with greater PTSD symptomology.	A one unit increase in baseline BSI scores was associated with a 0.959 unit increase in PCL scores.	0.090	(0.781, 1.138)
Greater communicative impairment was associated with greater PTSD symptomology.	A one unit increase in baseline LCQ scores was associated with a 0.202 unit increase in PCL scores.	0.073	(0.057, 0.347)
Result	Relationship to SWLS	SE	95% CI

Adequate effort was associated with greater life satisfaction.	Those who scored invalid on MSVT II had lower SWLS scores by 2.810 than those who scored valid.	1.092	(0.653, 4.968)
Greater psychological distress was associated with less life satisfaction.	A one unit increase in baseline BSI scores was associated with a 0.213 unit decrease in SWLS scores.	0.049	(0.115, 0.310)
Greater perceived self-efficacy was associated with greater life satisfaction.	A one unit increase in baseline PSSE scores was associated with a 0.095 unit increase in SWLS scores.	0.026	(0.044, 0.146)
Result	Relationship to PSSE	SE	95% CI
Greater communicative impairment was associated with less perceived self-efficacy.	A one unit increase in baseline LCQ scores was associated with a 0.649 unit decrease in PSSE scores.	0.095	(0.462, 0.837)
Greater functional social competence was associated with greater perceived self-efficacy.	A one unit decrease in baseline PPIC scores was associated with a 0.723 unit increase in PSSE scores.	0.170	(0.388, 1.058)
Greater life satisfaction was associated with greater perceived self-efficacy.	A one unit increase in baseline SWLS scores was associated with a 0.563 unit increase in PSSE scores.	0.160	(0.247, 0.879)

Figure 1 - Consort Diagram

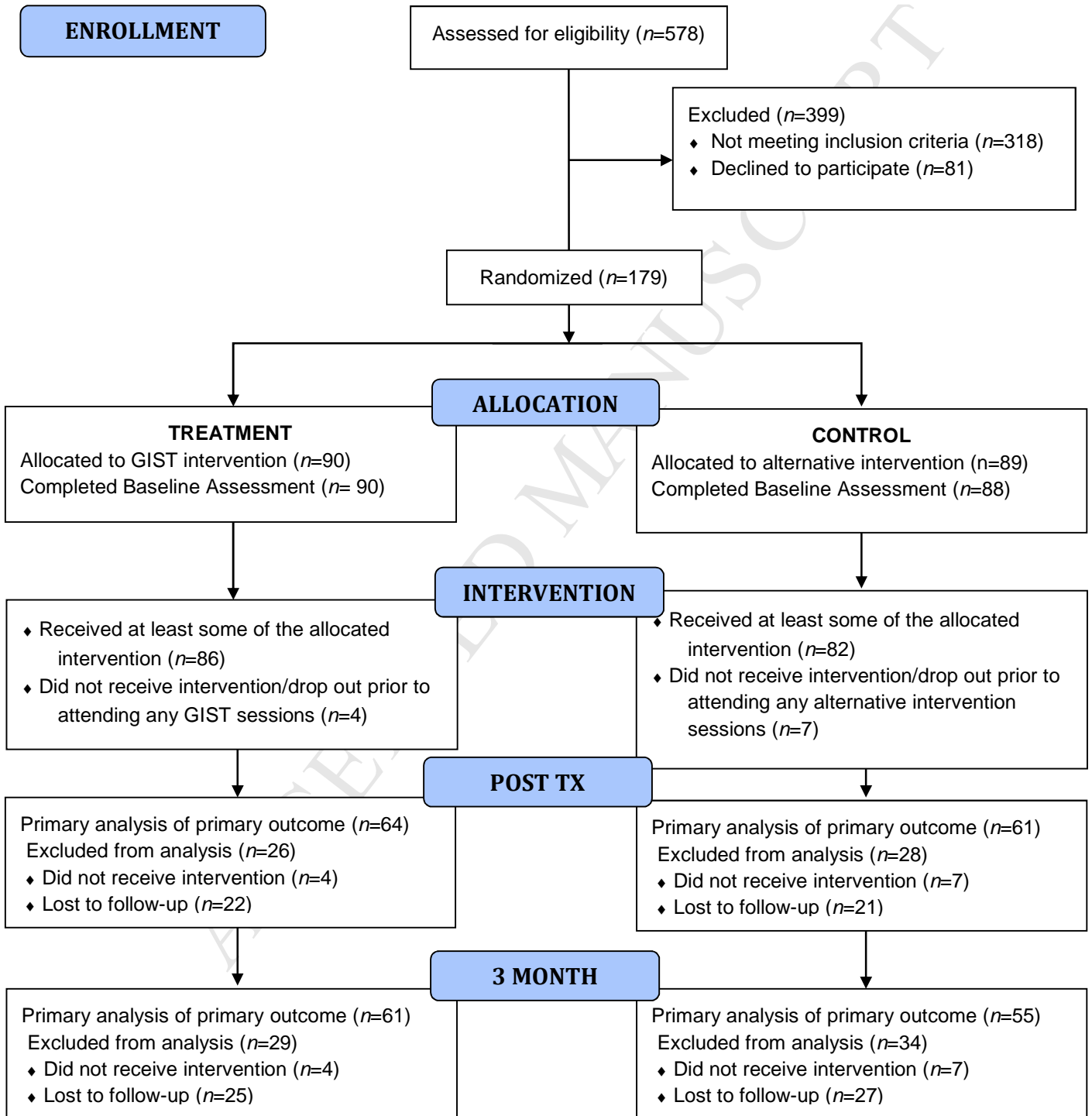
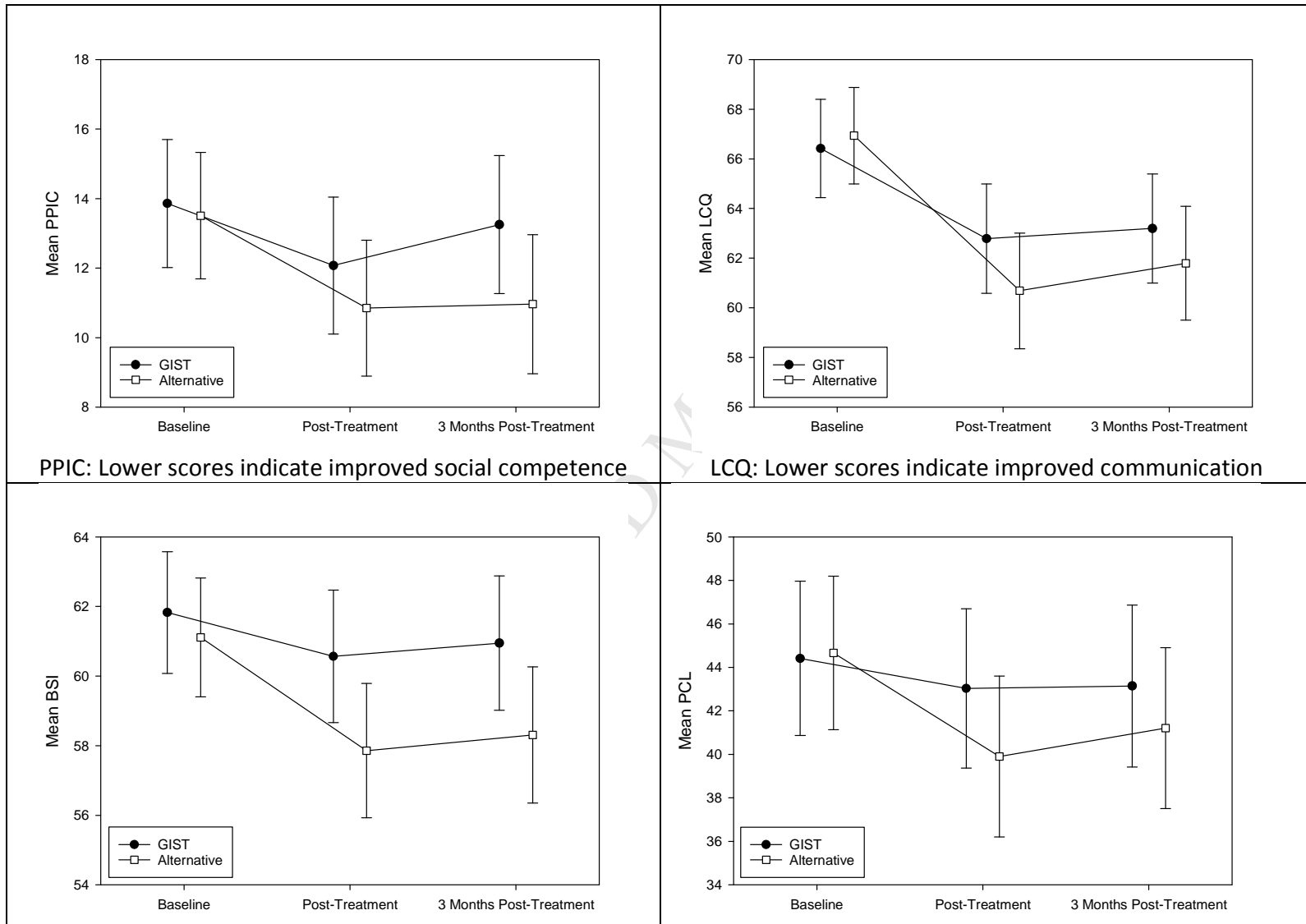
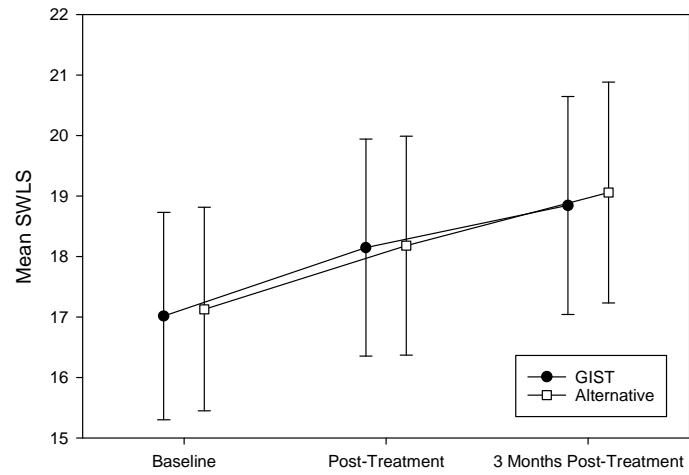


Figure 2: Mean Response Variables over Time by Group with 95% Confidence Intervals

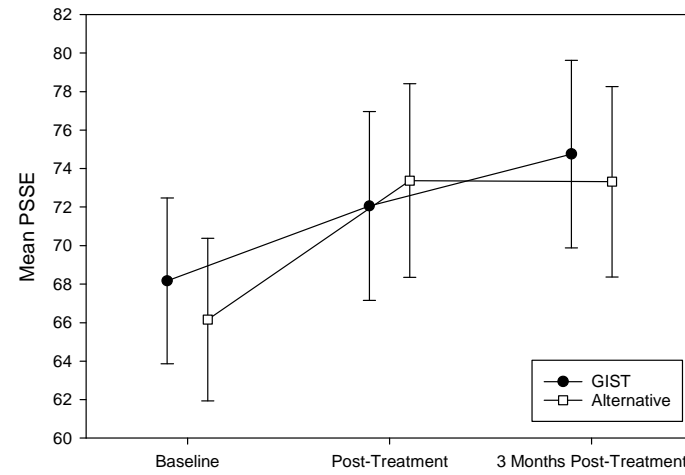


BSI: Lower scores indicate improved psychological distress



SWLS: Higher scores indicate improved life satisfaction

PCL: Lower scores indicate reduced PTSD symptomology



PSSE: Higher scores indicate improved self-efficacy