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14. ABSTRACT

Impairments in social competence are among the most prevalent sequelae after traumatic brain injury (TBI). Without successful social skills a person is often isolated, in conflict with others, and denied access to social and vocational opportunities. The aim of this study is to determine the effectiveness of a manualized group treatment program to improve and maintain social competence for individuals with TBI with identified social skill deficits. The Group Interactive Structured Treatment (GIST) - Social Competence program is a holistic, dual-disciplinary intervention targeting the pervasive interpersonal and communication problems that often interfere with participation at work, home, school and in the community after TBI. All sites completed the Pilot portion of this study during the second year of this project. Experience from the Pilot study resulted in modifications to the RCT protocol which were approved by the HRPO prior to start of the RCT during the second year of this project. During the third and fourth years of this project, 12 "waves" of study intervention were completed across the six sites. All study enrollment, data collection, and data entry is now complete at all sites. We have received a no cost extension to complete data analyses and manuscript.

15. SUBJECT TERMS
Traumatic brain injury, social competence, social skills, intervention

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INTRODUCTION

Background: Impairments in social competence are among the most prevalent sequelae after traumatic brain injury (TBI). Without successful social skills a person is often isolated, in conflict with others, and denied access to social and vocational opportunities. The aim of this study is to determine the effectiveness of a manualized group treatment program to improve and maintain social competence for individuals with TBI with identified social skill deficits. The Group Interactive Structured Treatment (GIST) - Social Competence program is a holistic, dual-disciplinary intervention targeting the pervasive interpersonal and communication problems that often interfere with participation at work, home, school and in the community after TBI.

Aims and Hypotheses: Aim 1: Measure the effectiveness of the GIST intervention with multisite implementation. Hypothesis 1a: Those receiving the GIST will demonstrate significant improvement in social competence, compared to those receiving the alternative treatment, as measured by the Profile of Pragmatic Impairment in Communication (PPIC). Hypothesis 1b: Compared to the alternative intervention, those receiving the GIST will maintain improvement in social competence at 3 months post-intervention, as measured by the PPIC. Hypothesis 1c: Compared to the alternative intervention, those receiving the GIST will demonstrate improvement in additional aspects related to social competence at 3 months post-intervention, as measured by two subscales of the Behaviorally Referenced Rating System of Intermediate Social Skills-Revised, the LaTrobe Communication Questionnaire, the Goal Attainment Scale, the Brief Symptom Inventory-18, and the Post Traumatic Stress Disorder Check List – Civilian version. Hypothesis 1d: Compared to the alternative intervention, those receiving the GIST will demonstrate improvement at 3 months post intervention in quality of life, as measured by the Satisfaction with Life Scale. Aim 2: Identify the potent ingredients associated with the GIST. Hypothesis 2a: Compared to the alternative intervention, those receiving the GIST will demonstrate stronger social self efficacy associated with improved social competence, as measured by the Scale of Perceived Self Efficacy. Hypothesis 2b: For participants in the GIST intervention, higher group cohesion measured by the TFI: Cohesiveness Scale will be associated with improved social competence.

Study Design: This study uses a two-arm, multi-centered randomized controlled clinical trial design to compare the GIST treatment to an alternative treatment, in which participants are presented information from the GIST treatment program without the group process. A total of 192 military, veteran and civilian participants with mild to moderate TBI will be enrolled by six centers. Measures will be collected at baseline, post-treatment, and 3 months post-treatment. Videotapes of participants will be evaluated for social competence by blinded independent raters, and progress on individualized social skills goals will be assessed. Replicable training of group leaders will include a 2 ½ day in-person workshop followed by feedback during a pilot of the intervention and alternative intervention. The fidelity of the intervention will be assessed by independent raters using a standardized instrument to ensure that the intervention is implemented consistently. Results of this study will be disseminated to relevant stakeholders via presentations and publications. By the end of this study, the field will have definitive evidence about the effectiveness of a group social competence intervention for people with TBI.

Military Benefit: The proposed study has a high degree of relevance for returning OIF/OEF soldiers and veterans post-TBI due to the prevalence of social reintegration difficulties in this population. The GIST intervention has the potential to assist our soldiers and veterans in returning to full participation in their families, communities and productive activity.

BODY

OBJECTIVE 1: Establish infrastructure for successful collaboration:

T1: Conduct Steering Committee teleconferences & local Project Site Team meetings:

ONGOING. Monthly teleconferences with all sites; bi-monthly meetings locally all documented by meeting minutes.

T2: Schedule & conduct Steering Committee via web conference:

WEB CONFERENCE not needed at this point as all coordination is occurring via monthly teleconferences.

T3: Schedule study training in Colorado:

COMPLETE.

T4: Monitor budget and study progress monthly:

ONGOING. Due to delays in startup of the RCT, due to slower than expected IRB approvals, need for additional training, and RCT recruitment, the lead site and sub-awardees carried over funds each year and now will do so into the no-cost extension period.

OBJECTIVE II: Finalize study design, project materials, & obtain IRB approval

T1: Finalize study design, measures & interventions:

COMPLETE

T2: Submit IRB/regulatory applications per site:

COMPLETE

T3: Prepare data dictionary/syllabus & project protocols:

COMPLETE

T4: Finalize training agenda and materials:

COMPLETE

T5: Obtain IRB/regulatory approvals at each site:

COMPLETE

OBJECTIVE III: Design, Test, and Implement Data Management System

T1: Design Data Management System:

COMPLETE

T2: Program data dictionary & data entry for all study measures & tracking:

COMPLETE

T3: Test/revise data management system:

COMPLETE

T4: Program data management reports:

COMPLETE.

T5: Conduct 2 data quality site visits to each center:

N/A – this task was removed in March 2013 when it was determined that data quality checks could be coordinated remotely.

OBJECTIVE IV: Train collaborating researchers & group therapists

T1: Train study researchers & therapists

COMPLETE. Initial training for all sites was completed in June of 2012. An additional therapist training was completed with five sites in March 2013, and with the 6th site in June 2013.

T2: Evaluate Training

COMPLETE. An additional training session for therapists after the pilot was completed was added, and ongoing treatment fidelity monitoring was increased.

T3: Training as needed for dropout of group therapists; evaluate training

COMPLETE: Two sites required training of a new therapist during the course of the study.

OBJECTIVE V: Complete pilot of study interventions & assessments

T1: Recruit/consent 8 participants per site – 16 at Craig - total of 56 for 6 sites

COMPLETE. A total of 52 participants were recruited and consented for the Pilot study as follows:

Craig Hospital – 15
Rehab Hospital of Indiana – 7
Hunter Holmes McGuire VA – 8
Palo Alto Health Care System – 7
Rehab Institute of Michigan – 7
University of Washington – 8

T2: Complete baseline testing of pilot participants

COMPLETE. Baseline testing was completed on a total of 52 participants for the Pilot study as follows:

Craig Hospital – 15
Rehab Hospital of Indiana – 7
Hunter Holmes McGuire VA – 8
Palo Alto Health Care System –7
Rehab Institute of Michigan –7
University of Washington – 8

T3: Conduct pilot interventions

COMPLETE.

T4: Complete fidelity checklist, & provide group therapists feedback at weekly calls

COMPLETE

T5: Complete post-treatment testing of pilot participants

COMPLETE. Due to participant drop-out, post treatment testing was completed on a total of 33 out of 52 participants for the Pilot study as follows:

Craig Hospital – 10
Rehab Hospital of Indiana – 5
Hunter Holmes McGuire VA – 3
Palo Alto Health Care System –5
Rehab Institute of Michigan –3
University of Washington – 7

T6: Solicit/integrate feedback from participants, therapists, researchers

COMPLETE. Based on our experience during the Pilot study and on feedback and discussions with the other centers, a number of revisions were made to the original protocol to make the Randomized Controlled Trial a stronger project. All of these changes were submitted to local IRB's and HRPO for approval prior to implementation. These changes included:

1) Added an additional therapist training.

2) Dropped data collection from Significant Others (too difficult to collect, only about 25% of cases in the Pilot study).

3) Added questions about military experience to the demographics form, and added a formal measure for assessing history of TBI.

4) Replaced the Group Cohesion Scale-Revised with a simpler cohesion measure called the TFI: Cohesiveness Scale.

5) Decided not to administer the cohesion scale to the Alternative treatment group because the questions are not appropriate for this intervention which is not group oriented. (This resulted in changing hypothesis 2b which addresses the concept of group cohesion.)

6) Modified and finalized the format for the Alternative treatment.

7) Adjusted the reimbursement/compensation for participation so that individuals get some reimbursement for each session to help offset transportation costs.

T7: Update IRB approvals as needed

COMPLETE. All six sites have local IRB and HRPO approval for the RCT portion of the study.

OBJECTIVE VI: Enroll & randomize participants in study

T1: Identify, recruit & screen potential study participants

COMPLETE. A total of 578 individuals were screened across the 6 study sites. 399 of these did not meet study criteria or chose not to participate. 179 individuals met screening criteria and enrolled in the study.

T2: Consent 16 eligible study participants at each of 6 sites for first wave

COMPLETE. A total of 90 participants have been consented at six sites for Wave 1 as follows:

Craig Hospital – 15
University of Washington – 16
Rehab Hospital of Indiana – 16
Hunter Holmes McGuire VA – 13
Palo Alto Health Care System – 16
Rehab Institute of Michigan – 14

T3: Randomize participants into treatment & alternative treatment

COMPLETE. A total of 90 participants have been randomized at six sites for Wave 1 as follows:

Craig Hospital – 15
University of Washington – 16
Rehab Hospital of Indiana – 16
Hunter Holmes McGuire VA – 13
Palo Alto Health Care System – 16
Rehab Institute of Michigan - 14

T4: Consent 16 eligible study participants at each of 6 sites for 2nd Wave

COMPLETE. (Note that Rehab Institute of Michigan was unable to recruit participants for 2nd Wave. To replace this missing wave of participants, University of Washington recruited additional participants and ran a 3rd Wave. These numbers are included here.)

A total of 89 participants consented for Wave 2/Wave 3 at five sites as follows:

Craig Hospital – 16
University of Washington – 32
Rehab Hospital of Indiana – 13
Hunter Holmes McGuire VA – 14
Palo Alto Health Care System – 14

T5: Randomize Wave 2 participants into treatment & alternative treatment

COMPLETE. A total of 89 participants were randomized for Wave 2/Wave 3 at five sites as follows:

Craig Hospital – 16
University of Washington – 32
Rehab Hospital of Indiana – 13
Hunter Holmes McGuire VA – 14
Palo Alto Health Care System – 14

OBJECTIVE VII: Collect baseline data

T1: Administer initial baseline assessments to study participants

COMPLETE. A total of 179 participants (Waves 1, 2 &3) have completed baseline assessments as follows:

Craig Hospital – 31
University of Washington – 48
Rehab Hospital of Indiana –29
Hunter Holmes McGuire VA – 27
Palo Alto Health Care System – 30
Rehab Institute of Michigan - 14

T2: Enter baseline data into database

COMPLETE: A total of 179 cases of baseline data have been entered into the database as follows:

Craig Hospital – 31
University of Washington – 48
Rehab Hospital of Indiana – 29
Hunter Holmes McGuire VA – 27
Palo Alto Health Care System – 30
Rehab Institute of Michigan - 14

OBJECTIVE VIII: Implement study intervention

T1: Complete 2 waves of treatment group intervention at each site

COMPLETE. Wave 1 of treatment has been completed at all six sites. Wave 2 of treatment has been completed at five sites. Wave 3 of treatment at University of Washington (replacing Rehab Institute of Michigan's Wave 2) has been completed.

T2: Complete 2 waves of alternative intervention at each site

COMPLETE. Wave 1 of alternative treatment has been completed at all six sites. Wave 2 of alternative treatment has been completed at five sites. Wave 3 of alternative treatment at University of Washington (replacing Rehab Institute of Michigan's Wave 2) has been completed.

OBJECTIVE IX: Implement intervention fidelity assessments. *[Note that these tasks were modified slightly from the original SOW and one task was added in order to ensure the crucial component of adherence to study interventions.]*

T1: Complete fidelity ratings for all GIST treatment sessions where fidelity was not met during the Pilot study and provide feedback.

COMPLETE. For Wave 1 of GIST treatment, for sessions where fidelity was not met during the Pilot, 32/37 (86%) of sessions rated met fidelity. Additionally, during Wave 1, there were 5 sessions rated for fidelity because the site had a new therapist – of these, 2/5 (40%) met fidelity. For Wave 2 of GIST treatment, for sessions where fidelity was not met during Wave 1, 9/9 (100%) of session rated met fidelity.

T2: Complete fidelity ratings on 4 random GIST treatment sessions.

ONGOING. For Wave 1 of GIST treatment 19/19 (100%) of randomly rated sessions met fidelity. For Wave 2 of GIST treatment 21/23 (91%) of randomly rated sessions met fidelity.

T3: Complete fidelity ratings on all alternative treatment sessions for Wave 1 and provide feedback.

COMPLETE. For Wave 1, 54/57 (95%) of alternative treatment sessions rated met fidelity. We randomly rated fidelity for Wave 2 of the alternative treatment - 18/18 (100%) of sessions rated met fidelity.

T4: Enter fidelity data into database

COMPLETE

OBJECTIVE X: Collect follow-up study assessments

T1: Administer immediate post-intervention assessments to participants

COMPLETE. A total of 129 post-intervention assessments have been completed as follows:

Craig Hospital – 26
University of Washington – 37
Rehab Hospital of Indiana – 22
Hunter Holmes McGuire VA – 15
Palo Alto Health Care System – 20
Rehab Institute of Michigan - 9

T2: Administer 3-month post-intervention follow-up assessments to participants

COMPLETE. A total of 125 3-month post-intervention assessments have been completed as follows:

Craig Hospital – 25
University of Washington – 35
Rehab Hospital of Indiana – 18
Hunter Holmes McGuire VA – 16
Palo Alto Health Care System – 23
Rehab Institute of Michigan - 8

T3: Enter follow-up data into database

COMPLETE. All 129 cases of post-intervention data have been entered into the database. All 125 cases of 3-month post-intervention data have been entered into the database.

OBJECTIVE XI: Implement PPIC rating system

T1: Train independent PPIC raters & establish reliability

COMPLETE. Training of raters was completed and reliability established in October 2014.

T2: Collate/randomize video tapes from each completed wave of participants

COMPLETE. A total of 423 video files have been randomized for rating (these were randomized in two batches, the first with 211 files; the second with 212 files)

T3: Complete PPIC ratings on all video tapes and enter into database

COMPLETE. PPIC ratings on all 423 video files have been completed and entered into database.

OBJECTIVE XII: Analyze & interpret data

T1: Analyze & interpret baseline data

COMPLETE. Baseline manuscript in preparation.

T2: Analyze & interpret RCT data

ONGOING. RCT analysis in progress.

T3: Analyze & interpret training data

COMPLETE. See fidelity rating information under OBJECTIVE IX above.

OBJECTIVE XIII Transition plan for continuity of development

T1: Give 1 training workshop at a national professional conference or DoD scientific meeting.

DELAYED until RCT analyses are completed

T2: Submit 2 articles for publication

DELAYED. Baseline article in submitted for review. RCT manuscript to be completed by end of no cost extension (January 31, 2016)

T3: Update workbook and training program on current GIST website

DELAYED. Will be completed by end of no cost extension (January 31, 2016).

T4: Conduct a training workshop at a DoD scientific meeting

N/A- task combined with T1.

T5: Collaborate with NIDRR-MSKTC to produce consumer brochure on evidence base for social competence intervention

DELAYED until RCT analyses are completed.

T6: Post study results and brochure for consumers on lead center website.

DELAYED until RCT analyses are completed.

KEY RESEARCH ACCOMPLISHMENTS

- Enrollment is complete:

Final Enrollment Table

SITE	Principal Investigator	HRPO Log Number (Pilot)	# Enrolled (Pilot)	HRPO Log Number (RCT)	# Enrolled (RCT)
Craig Hospital	Cynthia Harrison-Felix, PhD	A-16793.ai	15	A-16793.aii	31
Palo Alto Health Care System	Laura Howe, JD, PhD	A-16793.bi	7	A-16793.bii	30
Rehab Institute of Michigan	Scott Millis, PhD	A-16793.ci	7	A-16793.cii	14
Rehab Hospital of Indiana	Flora Hammond, MD	A-16793.di	7	A-16793.dii	29
University of Washington	Kathleen Bell, MD	A-16793.ei	8	A-16793.eii	48
Hunter Holmes McGuire VA	William Walker, MD	A-16793.fi	8	A-16793.fii	27

- Study intervention is complete.
- Data collection and data entry are complete.
- Baseline data analyses are complete and manuscript has been submitted for publication.
- RCT data analyses are in progress.

REPORTABLE OUTCOMES

Analysis of baseline data is summarized in attached manuscript (Appendix A).

CONCLUSIONS

No conclusions to report as of yet.

REFERENCES

None

APPENDICES

Appendix A

Baseline Manuscript submitted to *Brain Injury* for review.

Title: Characteristics of Adults with Self-Identified Social Competence Problems after Traumatic Brain Injury: a Civilian and Military/Veteran Cohort

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Abstract

Objective: To describe the cognitive, emotional and social competence characteristics of a cohort of civilian and military/veteran adults with self-reported traumatic brain injuries (TBI) who were functioning independently in the community and who reported social competence issues.

Design: Convenience sample enrolled in a clinical trial of a social competence treatment intervention.

Method: One hundred and seventy-nine adults with a history of self-reported TBI and social competence issues were administered measures of neuropsychological functioning, emotional well-being, post-traumatic stress, self-efficacy, and social competence.

Results: Participants showed mild cognitive impairment, mild subjective and objective problems in social competence, low life satisfaction, and high levels of anxiety and depression.

Conclusions: Mildly impaired, independently functioning individuals with TBI report social competence issues that correlate with emotional distress and decreased satisfaction with life.

Introduction

An estimated 3.2 million American civilians are living with disability following hospitalization for traumatic brain injury (TBI) [1]. In the past 15 years, a reported 327,299 United States soldiers were diagnosed with a TBI as well [2]. This high incidence of brain injury in military personnel has increased awareness of TBI and its far reaching effects. Physical, cognitive, emotional, vocational, and social functioning may be affected after TBI. Problems with social competence are common following TBI and often impede social reintegration [3-11]. These impairments may be the result of multiple factors, including the cognitive and personality changes related to the neurological injury, pre-injury social skills, emotional reaction to the injury, and pain [11-14]. The Committee on Gulf War and Health stated that TBI adversely affects social-function outcomes, particularly in the areas of employment and social relationships [15].

The term social competence has been defined to include the cognitive, emotional and communication skills needed to interact successfully, along with the ability to apply those skills in a variety of social situations [5, 16-18]. Social competence also involves having the confidence and initiation to follow through on social interactions [5, 17, 19]. Individuals with TBI may have difficulty with a wide range of social competence skills such as starting, sustaining, and/or ending conversations; staying focused on a social interaction; respecting and setting social boundaries; taking turns; initiating social activities; interacting assertively; resolving conflicts; initiating appropriate topics; and social problem solving. The ability to communicate one's thoughts and needs, to listen to and support others, and to develop social and vocational relationships is critical to being an active member of society [20, 21].

Social competence is essential to success in interpersonal relationships, the work environment, and ultimately to quality of life [13]. Loneliness and social isolation have consistently been cited as a major concern post-TBI [10, 11, 22], and marital breakdown is a common consequence [23, 24]. Impaired social competence has been identified as a significant factor affecting reintegration into the workplace for individuals with TBI [20, 25-27]. Ezrachi et al. [26] found that interpersonal factors, rather than work skills, lead to problems in sustaining employment. In fact, deficits in interpersonal skills have been found to be the most frequent cause of job loss following TBI [25]. Without successful social skills, a person may become isolated, engage in conflicts, and be denied access to social and vocational opportunities. A strong association has been found between mild TBI, PTSD, and other health symptoms in combat veterans, indicating that all of these may play a role in impaired social competence [28]. The purpose of this study was to assess the baseline characteristics of individuals with TBI who were referred or self-referred to a treatment study aimed at improving social competence.

Methods

Data source

This paper reports on the baseline data of a study cohort enrolled in a multi-site randomized clinical trial investigating the effectiveness of a group treatment programme to improve social competence. One hundred seventy- nine individuals, including civilians and individuals with military history, enrolled in the study across six participating centres. This project was funded by the Department of Defense U.S. Army Medical Research and Material Command Congressionally Directed Medical Research Program. All sites received local IRB approval as well as approval from the US Army Medical Research and Material Command Office of Research Protection, Human Research Protection Office.

Recruitment

Craig Hospital in Colorado served as the lead site in this multi-site study. Five other centres specializing in rehabilitation following TBI participated, including Hunter Holmes McGuire Veterans Affairs Medical Center in Virginia, Rehabilitation Hospital of Indiana/Indiana School of Medicine Physical Medicine and Rehabilitation, Rehabilitation Institute of Michigan, University of Washington, and VA Palo Alto Health Care System in California. To solicit participation, each site mailed recruitment flyers to previous and current patients who had sustained a documented TBI and who met the study criteria regarding time since injury. Recruitment materials were also provided to local organizations serving individuals with TBI in each site's community, including state and local Brain Injury Associations; nearby VA centres in Washington, Indiana, Michigan, and Colorado; and TBI outpatient clinics. When possible, recruitment information was posted on websites of area organizations serving individuals with TBI, and in local Brain Injury Association newsletters. Across the six centres, a total of 579 individuals expressed an interest in the study and completed a verbal pre-screen to determine eligibility.

Inclusion criteria

All participants were required to meet the following criteria: (1) history of TBI any time after October 2001 (to ensure inclusion of military individuals who may have sustained TBI during the OEF/OIF conflicts) as evidenced by self-report on the OSU TBI ID screen [29]; (2) at least 6 months post-injury at time of enrollment; (3) at least 18 years of age at time of enrollment; (4) score of Level 1 (Independent) or Level 2 (Overnight Supervision) on the Supervision Rating Scale [30]; (5) score >= 5 on Comprehension and Expression items of the Functional Independence Measure [31]; (6) English speaking; (7) demonstrate some aspect of problematic

social competence by responding 'yes' to at least one of the following 5 screening statements: *I have difficulty taking turns in a conversation; I don't ask questions of the other person or give him or her a chance to talk. I have a hard time maintaining eye contact during a conversation. I feel uncomfortable in many social interactions, and lack confidence in my social skills. I would like to meet new people, but I can't think of any places to go to meet people. I have difficulty controlling my emotions in social interactions; I often become angry, frustrated or giddy.* Because this study cohort was being recruited for an interventional study which required attending 13 weeks of treatment, individuals were excluded if they: (1) were unable to verbally communicate; (2) were unable to attend treatment sessions due to schedule or transportation; (3) were involved in ongoing structured group therapy; or, (4) were participating in another clinical trial.

Measurement

Individuals who met inclusion criteria and provided informed consent were enrolled and completed a two hour, in-person baseline assessment. During this assessment, data was collected regarding injury and demographic characteristics, cognitive functioning, emotional well-being, and social competence skills, as outlined below. Additionally, each participant developed individual social competence goals which are included to further describe participants' specific social competence issues.

Injury and demographic characteristics

Demographic characteristics including, age, gender, race, marital status, education, employment and military involvement were collected by interview with each participant. Additionally, participants were asked to report on their history of TBI using the Ohio State University Traumatic Brain Injury Identification Method (OSU-TBI-ID) [29] structured interview. The

OSU-TBI-ID is a valid and reliable procedure for eliciting a person's lifetime history of TBI and can be used to categorize general severity of reported TBI's [29, 32-34]

Cognitive function

Each participant completed a brief neuropsychological battery to measure cognitive function. This battery included *The Medical Symptom Validity Test (MSVT)* [35], the *Trail Making Test, Forms A and B (TMT)* [36], the *Rey Auditory Verbal Learning Test (RAVLT)* [37] and the Coding and Symbol Search subtests of the *Wechsler Adult Intelligence Scale-III (WAIS-III)* [38].

Emotional well-being

Three measures related to emotional well-being were collected. The *Satisfaction with Life Scale* [39] is a brief (5-item), self-rated measure of global life satisfaction. Scores range from 5 to 35, with higher scores reflecting a greater life satisfaction. This scale has good psychometric properties and has been validated in persons with TBI [40]. The *Post Traumatic Stress Disorder Check List-Civilian Version (PCL-C)* [41] is a widely used and validated [42] 17 item self-report measure to evaluate symptoms of PTSD. Scores range from 17 to 85 with higher scores indicating more PTSD symptomology. The *Brief Symptom Inventory 18 (BSI-18)* [43] is an 18-item self-report inventory developed to screen for psychological distress and psychiatric symptoms. It consists of 18 emotional distress items rated on a 5 point Likert scale which yield a Global Severity Index as well as Somatic, Anxiety, and Depressive Dimension scores. Raw scores for the Global Index and the three Dimension scores were converted to T-scores. The *BSI-18* has been validated with TBI populations [44].

Social competence

To obtain an objective measure of social competence, the *Profile of Pragmatic Impairment in Communication (PPIC)* [45, 46] was used to rate a 10 minute video-recorded conversational

excerpt obtained from each study participant. Conversational excerpts were obtained by sitting each participant in a room with a female research assistant or other hospital staff ('conversational partner') and instructing the two to 'get to know one another'. All conversational partners had undergone training which included general guidelines such as allowing for the normal back and forth of a mutual discussion, and not attempting to correct or compensate for the participants' conversational deficits (i.e. long pauses, rambling on). Conversational partners were not directly associated with the study and the conversation was not scripted. All conversational samples were then rated by two independent TBI clinicians (a Speech Language Pathologist and a Social Worker) who had been trained in the use of the PPIC by two of the study investigators whom had extensive knowledge of the PPIC from previous studies. Training of the PPIC raters concluded when raters achieved at least a 0.75 level of reliability on each of the PPIC summary scores among themselves and their trainers using sample video recordings.

The PPIC is a behavioural rating scale designed to measure social communication impairments following TBI. It includes 84 behaviour items assessing frequency and severity of specific communication impairments that fall into 10 subscales (Logical Content, General Participation, Quantity, Quality, Internal Relation, External Relation, Clarity of Expression, Social Style, Subject Matter, and Aesthetics). Each of these 10 subscales are rated on a scale of 0 to 5 where 0 = normal, and 5 = very severely impaired. Thus, lower scores on the PPIC indicate better functional social communication. For this study, scores on each of the PPIC subscales for each participant were obtained by averaging the two ratings from the two trained raters. As was used in our previous research [47] after personal communication with PPIC author [48], the 10 subscale scores were added together to create one summary score to reflect a more comprehensive index of social competence.

Two subjective assessments of social competence were administered. The *LaTrobe Communication Questionnaire (LCQ)* [49], is a 30-item questionnaire designed to assess self-reported cognitive-communication ability in persons with TBI. Possible scores range from 30 to 120 with higher scores indicating greater communicative impairment. The LCQ has been used in a number of TBI studies [47, 49-51] with Douglas et al. reporting mean scores of 54.94 [49] and 59.70 [51] on the LCQ for persons with severe TBI. The *Scale of Perceived Social Self-Efficacy (PSSE*) [52] is a valid and reliable 25-item self-report questionnaire that measures self-efficacy expectations and beliefs with respect to a wide range of social behaviours. Items are rated on a five-point Likert scale measuring an individual's confidence in their own ability to perform in specific social situations. After personal communication with the authors [53] to approve modification, the PSSE was modified to exclude two items ('Ask someone out on a date' and 'Get a date to a dance that your friends are going to') because they were not applicable to many of the study participants who were in committed relationships. Thus, the total scores on the PSSE ranged from 23 to 115 with higher scores indicating greater perceived social self-efficacy. Use of the PSSE has not been previously reported on in the TBI population.

Individual goals

Each participant worked briefly with study therapists (therapists who were involved in the RCT intervention) to develop three individual social competence goals. Participants were guided to develop goals that were measureable, personally relevant, and realistic; addressing the cognitive, communicative and emotional areas of social competence.

Analysis

SPSS version 21 was used for all statistical analyses. No method of multiple imputation was used to handle missing data as less than 1.5 percent of the data were missing; thus list wise deletion was employed for all analyses. Statistical analyses included baseline descriptive and frequency statistics for demographic, neuropsychological, emotional-behavioural, and social competence characteristics. In addition to descriptive statistics, bivariate correlations were completed for measures encompassing psychological well-being, post-traumatic stress, self-efficacy, and social competence. Analysis of individual goals was completed by two of the authors who reviewed all the goals and placed them into broad descriptive categories.

Results

Demographics

The demographic characteristics of study participants are shown in Table 1. Age of participants ranged from 20 to 83 years with a mean of 45.5. The majority of participants were unmarried, white males. Most participants had more than a high school education and were not working at the time of the study. Of the 30.2% who reported military service, most served in the Army and were deployed in a combat zone; mean duration of service was 9.1 years.

Insert Table 1 here

Brain injury characteristics

Self-reported injury characteristics were obtained using the OSU-TBI-ID; results of which are shown in Table 2. Based on self-report, 83% of participants had history of at least a mild TBI as evidenced by some loss of consciousness (LOC). Sixteen percent had altered mental status making history of TBI possible but uncertain.

Insert Table 2 here

Cognitive functioning

Results from neuropsychological tests shown in Table 3 indicate that participants in this study were functioning in the mild range of cognitive impairment compared to age matched peers (i.e. mean T-scores on most assessments are at or below 40). Also of note and consistent with other TBI studies [54], results from the MSVT indicated that a third (32.7%) of the participants in this study provided responses consistent with poor effort which may imply feigned cognitive impairment or lack of engagement.

Insert Table 3 here

Emotional functioning

Participants in the study reported higher than average depression and anxiety symptoms as evidenced by T-scores greater than 50 on all BSI scales; data on this measure and the other emotional functioning measures are presented in Table 4. These individuals also reported moderately elevated PTSD symptoms on the PCL-C and reported lower than average global life satisfaction (SWLS).

Insert Table 4 here

Social competence

Reported in Table 5 are results of the social competence measures; both the objective and subjective measures revealed impairment in this area. Specifically, the mean PPIC score of nearly 14 suggests that study participants were functioning with mild social communication impairments as objectively rated by independent clinicians (a PPIC score of 0 indicates no social communication impairment). Likewise, study participants subjectively reported having difficulties with social communication (LCQ) as well as reduced confidence (little to moderate confidence) in their ability to perform appropriately in social situations (PSSE).

Insert Table 5 here

Association between social competence and emotional functioning measures

Bivariate correlations are presented in Table 6. Subjective measures of social competence (LCQ and PSSE) correlated with one another in the expected direction. Associations between the emotional functioning and life satisfaction measures with the PSSE and LCQ were weak to moderate. In each instance, greater social impairment was associated with less favorable emotional functioning and decreased life satisfaction. As expected, moderate to strong correlations were found between the PCL-C (measure of PTSD symptomatology) and each BSI subscale. Of all the measures presented in Table 6, the PPIC (objective measure of social competence) correlated only with PSSE.

Insert Table 6 here

Individual social competence goals

The individual goals selected by the participants fell into 10 categories of social competence skills: assertiveness, amount of information, sustained focus, initiating/maintaining/ending conversations, self-centeredness, controlling emotions, boundaries, meeting people/initiating social contact, body language, and speech production. Of these, the categories with the most goals selected were: controlling emotions, starting/maintaining/ending conversations, and meeting people/initiating social contact. The individual goals most frequently chosen were: controlling emotions, taking turns, being assertive, getting to the point, increasing social confidence, and making new friends.

Discussion

This cohort of independently functioning individuals with self-reported TBI and social competence problems had mild cognitive impairment, mild subjective and objective problems in social competence, low life satisfaction, and high levels of anxiety and depression. While much

of the emphasis on treating social competence after TBI has been on moderately to severely impaired individuals [5, 47, 55], the results of this study validate self-perceived problems in a more heterogeneous TBI population.

Participants reported difficulties with social communication on the LCQ, with a mean score of 66.93. This score is notably higher than reported in previous studies using the LCQ to assess adults with severe TBI [49, 51, 56], indicating greater perceived social communication difficulties in this cohort. This may be indicative of greater self-awareness in the independently functioning group of individuals participating in this study, and an acknowledgement that their social competence issues impact their relationships and emotional well-being. Additionally or alternatively, it may indicate greater social engagement with associated opportunities for difficulties to surface. The fact that measures of social competence correlated with emotional functioning also supports an interaction with anxiety and depression levels.

Social competence problems in this more heterogeneous population may be more difficult to assess objectively. While this study population did show overall impairment on the PPIC, participants in our previous study of individuals with moderate to severe TBI [55] were more impaired on this objective measure. The PPIC may not be sensitive enough to capture the more subtle social competence deficits that mildly impaired individuals frequently experience. In fact, the top 10 areas of individual goals selected by participants in this study include two areas not represented in the PPIC: *meeting new friends* and *communicating assertively*. Nonetheless, data from this study on the ten subscales of the PPIC was congruent with our previous study with a moderate to severe cohort. In both studies, the General Participation subscale which observes a person's ability to participate in a conversation in a manner which is organized and sensitive to others' interests was identified as the most problematic. The three

scales that were the least impaired in both studies were the Quality (honest and factual information), Logical Content (coherent language skills) and appropriate Subject Matter.

Individuals in this study also reported symptoms of PTSD but it is unclear whether this level of symptoms indicates a positive PTSD screen. Varying cut-points for a positive screen are found in the literature; a cut-point of 50 is commonly used but others have found that lower cut-points perform better [57]. Walker et al. [58] recommend that cut-points be determined by PTSD prevalence in the population being studied.

The mean self-reported life satisfaction score of 17.54 for this cohort was slightly below the average score of 21 reported for individuals with TBI [59], and well below the general population average of 23.5 [39]. In fact, this population also reported a lower satisfaction with life than found in our previous study of a cohort of moderate to severely impaired TBI participants seeking treatment for social competence issues [55]. This more heterogeneous cross section of individuals with TBI may represent a population which is more aware of the changes that have occurred in life post-TBI.

Conclusion

Social competence difficulties following TBI exist even for individuals functioning independently in the community. Based on results of this study, there is a need for further research to better understand the multiple factors that may contribute to social competence problems in this heterogeneous TBI population. These factors may include self-awareness, anxiety, depression, level of social participation, current roles and responsibilities, and the complexity of the social demands on the individual.

Limitations

One limitation of this study is the use of a self-report instrument to document TBI. Although recently, the OSU-TBI-ID has been recognized as a valuable tool in collecting information regarding TBI history which otherwise may be difficult to obtain [34]; [60], it is not a well-validated proxy for diagnosing mild TBI. Moreover, using the OSU-TBI-ID did not allow for detailed information regarding participants' time post-injury. Another limitation is the lack of information on socio-economic status and family support, both of which often affect social competence, but which was not collected for this study. Future research in this area should consider including this information, along with the family's perspective regarding the individual's social functioning.

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Declaration of interest statement

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Table 1. Participant demographic characteristics

	Subgroup	*n* (%)
Gender	Male	123 (68.7%)
Race	White	123 (69.1%)
	Black	39 (21.9%)
	Hispanic	7 (3.9%)
	Other	9 (5.0%)
Age	20-29	27 (15.2%)
	30-39	28 (15.7%)
	40-49	53 (29.8%)
	50-59	48 (27.0%)
	60 and above	22 (12.4%)
Marital status	Never Married	79 (44.1%)
	Married/Common Law	48 (26.8%)
	Previously Married	52 (29.1%)
Education	Less than high school	18 (10.1%)
	High school diploma	53 (29.6%)
	Associate's or Bachelor's Degree	83 (46.4%)
	Master's or Doctoral Degree	25 (14.0%)
Employment status	Employed	47 (26.4%)
	Unemployed	131 (73.6%)
Military service	No	125 (69.8%)
	Yes	54 (30.2%)

Table 2. Injury characteristics

OSU-TBI-ID Diagnosis	Descriptor	*n* (%)
Possible mild TBI	Altered mental status, no LOC	29 (16.6%)
Mild TBI	LOC less than 30 min	59 (33.7%)
Moderate TBI	LOC between 30 min and 24 hours	25 (14.3%)
Severe TBI	LOC more than 24 hours	57 (32.6%)
Unknown TBI	Unknown duration of LOC	5 (2.9%)

Table 3. Neuropsychological assessment T-scores

Variable	Mean ± SD
WAIS III Coding (n=172)	39.49 ± 10.01
WAIS III Symbol Search (n=172)	43.04 ± 12.03
WAIS III Processing Speed Index (n=171)	40.89 ± 10.81
Trail A Time (n=171)	40.54 ± 13.88
Trail B Time (n=171)	39.98 ± 14.44
RAVLT Learning Total (n=175)	38.08 ± 14.46
RAVLT Immediate Recall (n=173)	39.54 ± 15.20
RAVLT Delayed Recall (n=172)	38.58 ± 15.53

Table 4. Emotional functioning

Variable	Mean ± SD
BSI Somatic T-Score (n=176)	59.15 ± 10.97
BSI Depression T-Score (n=176)	61.27 ± 11.10
BSI Anxiety T-Score (n=176)	58.86 ± 12.71
BSI Global Severity Index T Score (n=176)	61.84 ± 10.92
SWLS (n=177)	17.54 ± 7.70
PCL-C (n=175)	43.98 ± 17.18[1]

[1]Higer score is indicative of greater emotional impairment.

Table 5. Social competence measures

Variable	Mean ± SD
LCQ (n=172)	66.93 ± 13.70[1]
PSSE Modified (n=171)	66.62 ± 21.07
PPIC Summary Score (n=177)	13.98 ± 7.14[1]

[1]Higer score is indicative of greater social impairment.

Table 6. Pearson correlations between emotional and social competence measures

Scale	1	2	3	4	5	6	7
1. BSI Somatic[1]	—						
2. BSI Depression[1]	.564**	—					
3. BSI Anxiety[1]	.707**	.722**	—				
4. LCQ[1]	.489**	.624**	.699**	—			
5. SWLS	-.244**	-.439**	-.354**	-.300**	—		
6. PSSE	-.233**	-.412**	-.409**	-.515**	.370**	—	
7. PCLC[1]	.651**	.693**	.818**	.641**	-.403**	-.393**	—
8. PPIC[1]	.012	.003	.008	-.058	-.024	-.225**	.025

[1]Higher score is indicative of greater social or emotional impairment.

**Correlation is significant at the 0.01 level (2-tailed).