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TITLE: Treatment of Social Competence in Military Veterans, Service Members, and
Civilians with Traumatic Brain Injury

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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. During the second year of this project, all sites completed the Pilot portion of this study. The Pilot study enabled us to accomplish the following: 1) train clinicians involved on this project and give them experience and feedback implementing the GIST treatment; 2) refine the alternative intervention at Craig Hospital; 3) gain experience with the assessment tools for this project; and 4) modify the protocol for the RCT based on the experience during the Pilot. All modifications to the protocol for the RCT have been made and approved by all local IRBs and by the HRPO. Five of the six site began actively recruiting for the RCT during this second year; two sites have begun the first wave of the RCT 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 will be carrying over funds from Year 2 to Year 3.

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:
ONGOING
- T4: Program data management reports:
COMPLETE. Data management reports are run internally at NDSC and each center is given instructions on data fixes.

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
Not applicable at this time as no therapists have dropped out.

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

ONGOING. Five of the six sites have local IRB and HRPO approval for the RCT portion of the study. One site is awaiting local IRB approval for the RCT portion of the study.

OBJECTIVE VI: Enroll & randomize participants in study

T1: Identify, recruit & screen potential study participants

ONGOING. Five sites have IRB approval for RCT portion of study and are actively recruiting.

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

ONGOING. A total of 31 participants have been consented at two sites as follows:

Craig Hospital – 15

University of Washington - 16

T3: Randomize participants into treatment & alternative treatment

ONGOING. A total of 31 participants have been randomized at two sites as follows:

Craig Hospital – 15

University of Washington - 16

OBJECTIVE VII: Collect baseline data

T1: Administer initial baseline assessments to study participants

ONGOING. A total of 31 participants have completed baseline assessments as follows:

Craig Hospital – 15

University of Washington - 16

T2: Enter baseline data into database

ONGOING

OBJECTIVE VIII: Implement study intervention

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

ONGOING. Wave 1 of treatment is underway at two sites

T2: Complete 2 waves of alternative intervention at each site

ONGOING. Wave 1 of alternative treatment is underway at two sites.

OBJECTIVE IX: Implement intervention fidelity assessments

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

ONGOING

T2: Complete fidelity ratings on 4 random GIST treatment sessions

ONGOING

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

ONGOING

T4: Enter fidelity data into database

ONGOING

OBJECTIVE X: Collect follow-up study assessments

T1: Administer immediate post-intervention assessments to participants

DELAYED. Post-intervention assessments scheduled to start in August 2013.

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

DELAYED. 3-month post-intervention assessments scheduled to start November 2013

T3: Enter follow-up data into database

DELAYED. Due to above.

OBJECTIVE XI: Implement PPIC/BRIS rating system

T1: Train independent PPIC/BRIS-R raters & establish reliability

DELAYED. Training of raters to begin March 2014 to coincide with projected completion of all data collection for Wave 1 for all 6 sites.

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

DELAYED. Video files will be randomized when all sites have completed all assessments for Wave 1.

T3: Complete PPIC/BRIS-R ratings on all video tapes and enter into database

NOT YET SCHEDULED TO START

OBJECTIVE XII: Analyze & interpret data

T1: Analyze & interpret baseline data

NOT YET SCHEDULED TO START

T2: Analyze & interpret RCT data

NOT YET SCHEDULED TO START

T3: Analyze & interpret training data

NOT YET SCHEDULED TO START

OBJECTIVE XIII Transition plan for continuity of development

T1: Give 1 or 2 presentations at national professional meetings

NOT YET SCHEDULED TO START

T2: Submit 2 articles for publication

NOT YET SCHEDULED TO START

T3: Update workbook and training program on current GIST website

NOT YET SCHEDULED TO START

T4: Conduct training workshop at a DoD Scientific meeting

NOT YET SCHEDULED TO START

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

NOT YET SCHEDULED TO START

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

NOT YET SCHEDULED TO START

KEY RESEARCH ACCOMPLISHMENTS

No key research accomplishments to report as of yet with the exception of completing many Objectives and Tasks as planned and on time.

REPORTABLE OUTCOMES

No reportable outcomes as of yet.

CONCLUSIONS

No conclusions to report as of yet.

REFERENCES

None

APPENDICES

None