ORIGINAL ARTICLE

Treatment Efficacy of Social Communication Skills Training After Traumatic Brain Injury: A Randomized Treatment and Deferred Treatment Controlled Trial

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Objective: To evaluate the efficacy of a replicable group treatment program to improve social communication skills after traumatic brain injury (TBI).

Design: Randomized treatment and deferred treatment controlled trial, with follow-up at 3, 6, and 9 months post-treatment.

Setting: Community.

Participants: Volunteer sample of 52 people with TBI who were at least 1 year postinjury, who received rehabilitation, and who had identified social communication deficits.

Intervention: Twelve weekly group sessions (1.5h each) to improve social communication.

Main Outcome Measures: The Profile of Functional Impairment in Communication (PFIC), Social Communication Skills Questionnaire–Adapted (SCSQ-A), Goal Attainment Scale (GAS), Craig Handicap Assessment and Reporting Technique–Short Form social integration and occupation subscales, Community Integration Questionnaire social integration and productivity subscales, and Satisfaction With Life Scale (SWLS).

Results: Independent samples *t* test analysis showed significant treatment effect compared with no treatment on 7 of 10 of the PFIC subscales (*P* range, .024 to <.001) and the SCSQ-A (*P*=.005) after the first 12 weeks of the study. After 12 weeks of treatment for all participants, repeated-measures analysis showed significant improvements from baseline on 9 of 10 PFIC subscales (*P* range, .01−.001), SCSQ-A (*P*≤.001), GAS (*P*≤.001), and SWLS (*P*=.011). At 6-month follow-up, scores were significantly better than baseline on 6 of 10 PFIC scales (*P* range, .01−.001), the SCSQ-A (*P*≤.001), GAS (*P*≤.001), and SWLS (*P*≤.001).

Conclusions: TBI subjects who received social communication skills training had improved communication skills that were maintained on follow-up. Overall life satisfaction for participants was improved.

Key Words: Brain injuries; Rehabilitation; Social interaction.

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SOCIAL COMMUNICATION impairment is among the most pervasive of communication problems in the chronic stage after traumatic brain injury (TBI).[1] Successful social communication skills involve a complex interaction of cognitive abilities, self-monitoring of speech and language skills, awareness of social rules and boundaries, and emotional control. Studies have reported that social communication difficulties contribute to loss of meaningful relationships and/or inability to maintain fulfilling employment, with the end result being social isolation and loneliness.[2,3] Thomsen[4] found that 10 to 15 years after severe head injury, loss of social contact was the most disabling handicap in daily life. This social isolation was accompanied by significant decrease in life satisfaction, which was not correlated with injury severity.[5] Milton et al[6] noted that inappropriate social communications by TBI subjects interfered with social reintegration. Social contacts in work, school, and leisure are decreased after TBI, and areas relating to social competency and adjustment are impaired.[7] Two studies[8,9] found that higher social integration was associated with higher life satisfaction in people with TBI and recommended development of interventions to improve social interactions.

Several studies have compared social communication skills of TBI subjects with normative control groups.[6,10-17] These studies have identified why they often "talk better than they communicate."[6] Subjects with TBI were less appropriate in their use of language and style of speech, involved partners in conversation less often,[10] and took a greater number of "turns" per conversation,[11] which contributed to difficulty in initiating and sustaining a meaningful conversation. Subjects with TBI also needed more direct questions or prompts from their conversational partners in order to extend a conversation, clarify information, and keep their conversations focused and meaningful.[11,15,17] People with TBI were found to be significantly slower in initiating conversation than normative controls, took more time for task completion, and had a disorganized manner of expression, with more difficulty in catching and rectifying their mistakes.[17] TBI subjects also were reported to have difficulty in making socially effective requests that were sensitive to a listener's needs, and had fewer strategies for convincing the listener.[14] Milton[6] identified such problems as decreased social perception, difficulty following the rules of social interaction, disorganized language output, disinhibition, and poor self-monitoring in communication situations when a TBI sub-

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ject attempts to return to work. McDonald and Flanagan[18] noted that TBI subjects have social perception deficits such as difficulty in understanding a conversational partner's emotions, beliefs, intentions, and inferences. Consequently, their conversations are perceived as being less socially rewarding, less interesting, less appropriate, and more effortful, and thus contribute to a breakdown of social relationships.[17]

The literature indicates that the poorer social communication skills of TBI subjects may lead to their decreased participation in social activities and a decrease in satisfaction with their lives. We[19] previously reported the baseline data for the efficacy study we report here. A cohort of 60 TBI patients, their significant others, and their group leaders, each identified specific social communication skills problems of the patient. Group leaders and family members tended to identify more problem areas than did those with TBI. Poorer social communication skills, as rated by the person with TBI at an average of 7 years postinjury, were associated with decreased social integration, productivity, and satisfaction with life.

Treatment of social communication skills deficits has been discussed in regard to other populations. The work of Trower et al[20] in social skills and mental health describes principles of changing social behavior through training, practice, and skill transference for skills acquisition. Training includes identifying the main problems to be addressed and demonstration of the desired behaviors. Practice involves role-playing, feedback through discussion with group leaders and peers, augmented by video- and audiotape review and feedback. Skill transference is encouraged through homework assignments and reports on progress in real situations. Based on skills theory and experimental research in the area of social interaction, this approach, although not specifically developed for TBI subjects, is found in descriptions of social skills training for this population.

Helffenstein and Wechsler[21] compared the effectiveness of interpersonal communication skills training for 16 TBI subjects in a randomized, controlled design. The 8 members of the experimental group underwent 20 hours of treatment with frequent, immediate, and exact visual and auditory videotape feedback from a conversation partner and an objective observer. Specific skills were modeled and then practiced by the subjects during the treatment sessions. Based on significant improvement in 4 of 6 dependent measures, (ratings of anxiety, self-concept, independent observer rating, interpersonal relationship rating), the authors concluded that the treatment improved interpersonal and communication skills in comparison with the no-treatment group. Measures of participant self-perceived change in skills and independent videotape analysis did not show statistical significance. Maintenance of the treatment effect was reported at 1-month follow-up.

Though less rigorous in research design, other studies have reported treatments to be efficacious in improving social communication in TBI subjects. These interventions have included various types of feedback (including video), reinforcement, practice, and self-monitoring.[22-27] Direct corrective feedback is effective in reducing socially inappropriate comments,[28] and video feedback alone is effective in modifying social behavior.[25] Additionally, it has been suggested that videotape feedback can heighten self-awareness and assist in strategy and skill training.[29]

Outcomes related to participation in society have been reported after social skills training. One study[30] found greater frequency of social contact and increased social activity after training. In another study,[31] TBI participants in a comprehensive outpatient program that included both social skills and pragmatic communication groups made significant progress in achieving individual goals, as well as functional improvement in work and independent living, which was maintained at 1-year follow-up.

Group treatment to address social communication makes it possible for participants to practice skills and get feedback from other members of the group.[32] Treatment groups typically target specific communication behaviors with individualized treatment goals, role playing to practice specific skills, feedback through videotape, and skill use in natural environments. Often, family members and others within the community are simultaneously provided with specific suggestions for appropriate feedback, because real world practice with significant others can help generalize newly learned skills. Some researchers[33] advocate training family members to facilitate positive problem-solving in communications and to help with planning social activities, rather than direct social skills training of the TBI subject. In addition, social skills training for these subjects may be most effective a year or more postinjury, as they develop more insight into, and awareness of, their communication problems after their experiences in social interactions.[26,34]

Several studies have reported interventions that address social communication skills in TBI. Some focused primarily on pragmatic language skills, reported with small sample size and efficacy based on pre- and post-testing.[1,23] Ylvisaker et al[29] describe treatment goals for conversational deficits and social skills as a subset of cognitive rehabilitation therapy, and efficacy is not presented. Two studies[31,35] included pragmatic communication and social skills groups as part of a comprehensive program for TBI subjects, but did not identify the specific treatment effects of those groups in overall outcomes, such as independent living or return to work. Wiseman-Hakes et al[26] showed the efficacy of treatment of pragmatic communication skills using pre- and post-measures for 6 adolescents with TBI. Their intervention used a workbook[36] modified for group treatment. Two other workbooks[37,38] designed for treatment of social communication skills in TBI subjects are commercially available. They provide a collection of exercises and activities, but are not designed to be a time-defined group treatment program.

In this study, we used the treatment workbook, *Social Skills and Traumatic Brain Injury: A Workbook for Group Treatment,*[39] that was developed by a speech-language pathologist and a clinical social worker. It is based on their 10 years of experience in facilitating social communication skills in a group setting with TBI subjects. This program is unique in several ways. It targets the broader definition of social skills, uses a group process approach, emphasizes self-assessment and individual goal setting, and encourages generalization through homework and family or friend involvement.

Our objective in this study was to evaluate the efficacy of a specific, replicable group treatment program within a Traumatic Brain Injury Model System of Care center[40] in a randomized controlled trial (RCT) of treatment and deferred treatment. Our specific hypotheses were: (1) social communication skills training in a group setting would improve specific individual pragmatic communication deficits for people with postacute TBI, (2) overall social integration and satisfaction with life would improve through this group training, and (3) these acquired skills would be maintained at 6 months post-treatment.

METHODS

The study was approved by our institutional review board and was funded by the National Institute on Disability and Rehabilitation Research. Eight hundred seventy-nine potential participants, initially identified from a list of former patients of

our rehabilitation center, were recruited by mail. Other rehabilitation and community-based brain injury programs in the same metropolitan area were contacted for potential subjects, which resulted in the recruitment of an additional 3 subjects. Of the 882 people, 134 (15%) expressed interest in participating and were assessed for eligibility.

Based on a screening interview with potential participants and their family or significant others, and a review of their inpatient rehabilitation medical record, people were accepted into the study if they met the following criteria: (1) had a TBI caused by an external mechanical force as evidenced by loss of consciousness due to brain trauma, post-traumatic amnesia (PTA), skull fracture, or objective neurologic findings that could be reasonably attributed to brain injury on physical or mental status examination[41]; (2) were discharged from a TBI rehabilitation program (an indicator of moderate to severe TBI in our facility); (3) were at least 1 year postinjury; (4) were between 18 and 65 years of age; (5) were functioning at or above Rancho Los Amigos Level of Cognitive Functioning VI, based on current interview with participant and family member[42]; (6) had receptive and expressive communication skills functional for group participation (score ≥5 on the comprehension and expression items of the FIM instrument[43] at rehabilitation discharge); (7) demonstrated sufficient recall of day-to-day events for learning in the group setting, based on screening interview with significant other or family member; (8) the participant and/or the significant other indicated some aspect of impairment in social communications skills on the adapted Social Communication Skills Questionnaire (SCSQ-A)[44]; and (9) provided informed consent. Potential participants were excluded if they: (1) reported significant behavioral concerns (eg, low frustration tolerance, behavioral/anger control), medical conditions, or other issues that precluded ongoing group participation in 12 weekly sessions; (2) had a diagnosis of a significant psychiatric or psychologic disorder prior to or after TBI; (3) had a significant history or current alcohol or substance abuse; (4) had a significant motor disorder, precluding ease of speech for group participation, or need for physical assistance in a group setting; or (5) were non-English speaking. All participants lived in the community.

Ultimately, 97 candidates were deemed eligible to participate and 60 were eventually enrolled, representing 62% of the eligible candidates and 7% of those initially recruited. The enrollees' characteristics, as well as a description of their performances on the baseline measures, were reported elsewhere.[19] Participants were paid $20 per evaluation session (a total of 5 sessions) as compensation for the time necessary to complete all study measures and evaluations. The group treatment was provided free.

Recruitment and Randomization

Recruitment began in October 2002 and 4 sets of 14 to 16 participants were entered into the study (total N=60) on a staggered schedule between January 2003 and September 2004; all follow-up data collection was completed by August 2005. After consenting to participate, subjects in each set were then randomized—half into a group that would receive treatment and half into a group in which treatment would be deferred for 3 months. Randomization was done with a computer-generated list prepared by a biostatistician. Although allocation was not concealed, there did not appear to be bias in this process.

Participants

Fifty-two participants were included in the primary analysis of the treatment versus no-treatment effect. Demographic and clinical characteristics of the 52 are reported in table 1. The majority of subjects were considered to have a moderate to severe TBI, based on the Glasgow Coma Scale and PTA. Each subject was asked to identify a significant other, who was in one of the following categories: parent (31%), spouse (27%), friend (17%), other including sibling, child, grandparent, attendant (13%); 12% did not have a significant other. Specific characteristics of the treatment group and the deferred treatment group are also listed in table 1. Sex, age, years postinjury, severity of injury, race, education level, employment status,

Table 1: Baseline Data

Characteristic	All Subjects (N=52)	Treatment (n=26)	Delayed Treatment (n=26)	*P*
Sex (%)*				**.050**
Men	84.60	73.10	96.20	
Women	15.40	26.90	3.80	
Age (y)†				.437
Mean	41.17	42.43	39.91	
Median	39.88	43.54	39.04	
Standard deviation	11.59	11.86	11.40	
Minimum	22.58	24.33	22.58	
Maximum	64.50	64.50	64.17	
Years postinjury†				.466
Mean	9.67	9.18	10.12	
Median	7.17	6.50	10.75	
Standard deviation	5.59	5.89	5.37	
Minimum	2.33	2.75	2.33	
Maximum	22.42	22.42	22.17	
Initial GCS score (%)‡				.609
Severe (3–8)	76.10	72.70	79.20	
Moderate to mild (9–15)	23.90	27.30	20.80	
Duration of PTA (d)§				.413
Mean	63.84	68.78	58.68	
Median	39.00	42.00	35.00	
Standard deviation	73.86	72.83	76.27	
Minimum	3.00	6.00	3.00	
Maximum	365.00	268.00	365.00	
Race (%)†				.701
White	88.50	92.30	84.60	
African American	5.80	3.80	7.70	
Hispanic	5.80	3.80	7.70	
Education level (%)*				>.999
<High school diploma	7.80	7.70	8.00	
High school diploma	9.80	11.50	8.00	
Some college	52.90	50.00	56.00	
≥Bachelor's degree	29.40	30.80	28.00	
Employment status (%)*				.107
Employed/student	23.10	19.20	26.90	
Homemaker/volunteer	25.00	26.90	23.10	
Unemployed	42.30	34.60	50.00	
Retired	9.60	19.20	0.00	
Significant other participation (%)*				.191
Yes	88.50	96.20	80.80	
No	11.50	3.80	19.20	

NOTE: Boldface denotes statistical significance.
Abbreviation: GCS, Glasgow Coma Scale.
*Fisher exact test.
†Independent samples *t* test.
‡Chi-square test.
§Mann-Whitney *U* test.

and significant other participation were examined to identify differences between the 2 groups that could be potential confounders in treatment versus no-treatment comparisons. Significant differences ($P<.05$) were identified with respect to the distribution of men and women across the 2 study groups. Seven women received the treatment intervention, and only 1 woman received the deferred treatment intervention. There were no other significant differences with respect to demographic or clinical characteristics.

In comparing change over time in men and women, only 1 significant sex difference was found among all the outcome measures—women reported more progress on the SCSQ-A ($P=.036$), suggesting that the differential assignment of women to the 2 study groups was not a pervasive bias.

Intervention

After baseline testing, the treatment group met once weekly for 1.5 hours for 12 weeks in a living room-type setting. The group was retested at the conclusion of the intervention, and at 3, 6, and 9 months post-treatment. The deferred treatment (control) group completed the baseline testing, and did not have any alternative intervention for a 12-week period. This group was then retested, after which treatment was initiated (fig 1). No study participants were denied treatment. The deferred treatment group was retested immediately after the intervention and at 3 and 6 months post-treatment. Informal group get-togethers were available to participants at the follow-up assessments (3, 6, 9mo). These sessions were not considered to be part of the treatment program.

The study intervention followed the program described in *Social Skills and Traumatic Brain Injury*[39] and is outlined in appendix 1. Group members were given copies of the workbook and were asked to share it with a family member or significant other. Group size was limited to 8 participants to make possible positive group dynamics and provide ample time for individual participation.

In this intervention, we defined the term *social communication skills* as a combination of pragmatic language skills, social behaviors, and cognitive abilities that are required in successful social interactions and relationships. Social communication skills include: communicating needs and thoughts; listening and understanding others; giving and interpreting nonverbal communication; regulating emotions in social interactions; following social boundaries and rules; working with others to solve tasks; and being assertive.[39]

This curriculum was based on 4 key components. The first was the use of co-group leaders from different clinical backgrounds (ie, social work and speech pathology). This allowed for 2 clinical perspectives, 2 role models, and 2 clinicians collaborating and sharing their expertise. The second component was an emphasis on self-awareness and self-assessment, leading to individual goal setting. A third component was the use of the group process to foster interaction, feedback, problem solving, a social support system, and awareness that one is not alone. The final component was a focus on generalization of skills, addressed through the involvement of family and friends, and weekly assignments completed in the home or community. The first several sessions focused on self-assessment, setting goals, and learning about the skills of a good communicator. In the second session, participants formulated 2 or 3 specific social communication skills goals to be attained during the group process. These goals were then finalized in session 3 and were based on the participant's self-assessment, as well as on input from family and clinician.

Typical examples of goals include cognitive ("I will remain attentive and participate in the conversation for a 15-minute period"); interpersonal ("I will be able to name 3 places to meet new people, and will visit 1 of these places"); language ("I will be able to maintain the topic of conversation for 5 minutes during a group conversation, without jumping to a new topic"); speech ("I will speak slowly enough to be understood at least 90% of the time"); and self-awareness ("I will be able to name my social skill strengths and weaknesses"). These goals were then scaled into 5 steps of achievement.

Middle sessions targeted learning goal-specific strategies, giving and receiving group feedback, and practicing within the

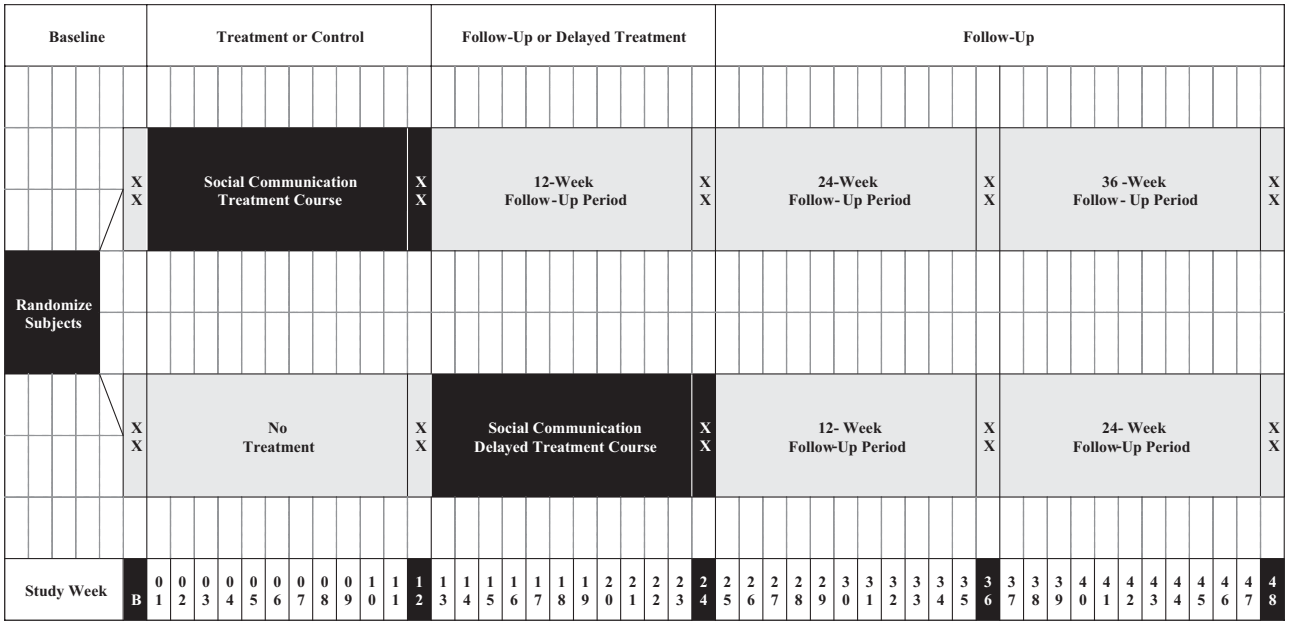

Fig 1. Study design. NOTE. "XX" indicates administration of outcome measurements.

group and at home. Later sessions emphasized generalization of skills and social problem solving. Strategies used throughout the sessions included self-assessment, group feedback, problem solving, practice of new skills, homework, family homework, and video feedback. Generally, sessions followed a consistent format: (1) review of homework, (2) brief introduction of the topic, (3) guided discussion, (4) small group practice, (5) group problem solving and feedback, and (6) homework.

At each session, participants were given time to talk about events in the previous week, time in the middle of the session for an unstructured break, and time at the end to wrap up details and plan for the next meeting. The group went on an outing during 1 session to practice social skills in the community. The final session was a time for review of goals and progress, group closure, and sharing of successes and future recommendations with families. Family members played an important role by giving input into individual goals, providing written feedback as part of homework assignments, and practicing with their group member at home and in the community.

Outcomes

The primary outcome measures included 1 objective and 1 subjective measure of social communication skill, as well as a measure of goal attainment. The secondary outcome measures included 2 assessments of community integration and 1 measure of life satisfaction.

Profile of Functional Impairment in Communication. The Profile of Functional Impairment in Communication (PFIC)[45] is an objective measure of social communication skills designed specifically for use with people with TBI. It includes 10 feature summary scales that assess communication skills on a 6-point scale from normative (0) to very severely impaired (5), with lower scores indicating better performance. These summary scales—logical content; general participation; quantity; quality; internal relation; external relation; clarity of expression; social style; subject matter; and aesthetics—are described in more detail elsewhere.[19,45]

In addition, 84 specific behavior items assess the frequency of communication impairments observed as "not at all," "occasionally," "often," and "almost always/always." We selected this tool because it is based on principles of social communication and the specific impairments associated with TBI, and appears to be comprehensive enough to measure the changes in the varied pragmatic communication skills addressed in treatment. It has good interrater reliability with high concurrent validity.[45] Scoring the PFIC relies on individual interpretation of socially appropriate communication behaviors. Averaging scores of 2 independent raters minimized the effect of any potential bias on the part of a rater, in keeping with the methodology.

In our assessment of this primary objective outcome measure, we used PFIC ratings of 10-minute videotaped conversations at each of the 5 data collection points (see fig 1) with random partners and blinded evaluators. Trained research assistants (all women), blinded to the participant's treatment condition, served as partners in conversations videotaped in the same location as the group sessions. The partners were instructed to engage in conversation and to respond naturally without leading the conversation or compensating for the participant's communication deficits.

The task for the communication dyad was to "get to know each other." Partners were randomized according to a computer-generated list. Each participant had a different partner for each video, and 2 other research assistants who were not conversational partners scored the 5 video conversational samples for each participant in randomized order. Thus, both the conversational partners and the raters were blinded to the treatment or no-treatment condition and to whether the conversation was from baseline, post-treatment, or one of the various follow-up periods.

Social Communication Skills Questionnaire–Adapted. A subjective assessment of social communication, the SCSQ,[44] was developed for social skills group participants with TBI, to establish the participants' level of understanding of social communication and their degree of insight regarding communication behaviors. Additional questions were added to the original instrument to capture all the topics presented in the treatment program, and a scoring system was added to make it suitable for measurement. The adapted tool was completed by the subjects, family members, or significant others to measure perception of improvement in the participant's skills at the 5 data collection points. Details on the adaptation were published elsewhere.[19]

Goal Attainment Scaling. As described for this population by Malec et al,[31,46] Goal Attainment Scaling (GAS) is a flexible system of measuring outcome goals, based on a 5-point scale. Levels of goal attainment are expressed objectively in terms of concrete behaviors that can be observed and recorded. Goals were developed with input from individual participants with assistance from the group leaders, which helped foster self-awareness and the capacity for goal setting through use of a formal, structured process. These goals were scaled into 5 steps so the participant usually fell at the second step, with a chance to achieve 1, 2, or 3 steps toward maximum goal achievement as rated by themselves, the group leaders, and a significant other. This measure is reported to be more sensitive to change than other outcome measures, and correlates moderately with other rehabilitation outcome measures.[46] After setting specific social communication goals in the third week of treatment, goal attainment was evaluated at the end of treatment and at 3-, 6-, and 9-month follow-ups by the TBI subject, significant others, and the group leaders. Samples of the GAS for this study include:

GOAL: I will ask more questions in conversations.
1. I will ask questions in 10% or less of conversations.
2. I will ask questions in 30% of conversations.
3. I will ask questions in 50% of conversations.
4. I will ask questions in 70% of conversations.
5. I will ask questions in 90% or more of conversations.

GOAL: I will interrupt less during a 15-minute conversation.
1. I will interrupt 4 or more times during a 15-minute conversation, with 1 prompt.
2. I will interrupt less than 4 times during a 15-minute conversation.
3. I will interrupt less than 2 times during a 15-minute conversation.
4. I will interrupt only one time during a 15-minute conversation.
5. I will not interrupt during a 15-minute conversation.

GOAL: I will visit new social settings where I could make new friends.
1. I will think of 1 new social setting where I could make new friends.
2. I will think of 3 new social settings where I could make new friends.
3. I will visit a new social setting where I could make new friends.
4. I will visit 2 new social settings where I could make new friends.
5. I will visit 3 new social settings where I could make new friends.

Craig Handicap Assessment and Reporting Technique—Short Form social integration and occupation subscales. The Craig Handicap Assessment and Reporting Technique—Short Form (CHART-SF)[47] is a measure of participation and community integration. The social integration subscale specifically measures living situation, number of contacts with relatives, business associates, friends, and strangers, while the occupation subscale measures hours spent working, in school, active homemaking, home maintenance, volunteer work, recreational activities, and other self-improvement activities. Normative scores were derived from a nondisabled population and Rasch analysis was used to verify CHART's scaling and scoring procedures. Subscale scores range from 0 to 100, with 100 being the highest level of participation.[47] Test-retest reliability for TBI subjects was shown to be good, with intraclass correlation coefficients at .71 (occupation subscale) and .74 (social integration subscale); participant-proxy reliability was moderate (social integration subscale, .49) to good (occupation subscale, .57).[48] This measure was collected at the 5 data collection points from the participant and the significant other.

Community Integration Questionnaire social integration and productivity subscales. The Community Integration Questionnaire (CIQ)[49] is a community integration outcome measure developed for TBI subjects; its social integration and productivity subscales were used for this study. Frequency of such activities as shopping, leisure pursuits, visiting friends or relatives, travel, and one's work, school, or volunteer situation, are scored on a 15-item scale; a higher score indicates greater integration. Test-retest reliability ranged from .83 to .97 with participant-proxy coefficients of .89[50]; concurrent and discriminant validity have been reported.[50,51] The CIQ was collected at the 5 data collection points from the participant and the significant other.

Satisfaction With Life Scale. The Satisfaction With Life Scale (SWLS) is a measure of global life satisfaction developed by Diener et al[52]; this 5-item scale has normative data for people with TBI.[53] The total score ranges from 7 to 35. The SWLS is considered a valid and reliable measure of life satisfaction, a cognitively driven component of subjective well being.[54] This measure was collected at the 5 data collection points from the participant.

Because of the nature of the study, the participants and group leaders were not blinded. While both the conversational partners and the raters of the primary objective outcome measure (PFIC) were fully blinded, most of the other outcome measures did not allow for blinding as they were completed by participants, significant others or family members, and/or group leaders with knowledge of the treatment or deferred treatment condition. The SCSQ-A, CHART-SF, CIQ, and the SWLS paper forms were completed independently by the participants and significant others, and were collected by the study coordinator (who was not involved in the group treatment program, but was not blinded to the treatment condition) at the 5 measurement periods (see fig 1). The GAS forms were independently rated by the group leaders, the participants, and the significant others, and collected by the group leaders.

Sample Size

Power and sample size calculations were performed to evaluate the ability of a given study sample to assess differences. For all sample size calculations, the α level and the probability of falsely rejecting the null hypothesis were set at .05, while power, the probability of correctly rejecting the null hypothesis, was set at .8. Using the measurement schedule in figure 1 and the assumed pattern of improvement, all measurements have a power of .821 for 48 participants completing the entire protocol, with 24 receiving the treatment first, the other 24 receiving delayed treatment. Consequently, 60 subjects were recruited for the study (allowing for dropouts), to meet the 48-participant sample size. The power analysis was reviewed when 52 subjects completed the first 2 data collection points and 47 subjects ultimately completed the study, and it was determined that 47 was adequate to conduct the analysis.

Statistical Methods

All data analyses were performed with SPSS.[55,a] Preliminary analysis examined differences between subjects randomized to the 2 treatment conditions for potential bias. Differences in continuous variables were assessed with independent *t* tests and the Mann-Whitney *U* test when the data were skewed; differences in categorical data were assessed with the Fisher exact test because of small cell sizes.

We analyzed data for all primary and secondary outcomes with 2 different methods. For the first set of analyses, differences were calculated between each outcome measure collected at baseline and 12 weeks later. For the treatment group, the differences represented the amount of change from baseline to the initial post-treatment evaluation. For the deferred treatment group, the differences represented the amount of change from baseline 1 to baseline 2, with no treatment. The differences between baseline and 12-week outcomes for the 2 groups were compared using independent samples *t* tests with a 2-tailed significance level of .05. Analyses of this type are referred to as *treatment versus no-treatment comparisons* in subsequent sections of this article, and they are the primary measure of treatment efficacy.

Treatment versus no-treatment comparisons were done using both a per-protocol and an intent-to-treat (ITT) model. For the per-protocol model, data were restricted to cases without protocol deviations, including only those subjects who completed the intervention without missing more than 2 sessions. For the ITT model, all cases were included. Initial baseline data were carried forward to the 12-week interval for 8 participants who had either dropped out of the intervention or had missed more than 2 treatment sessions (4 participants each in the treatment and deferred treatment groups).

For the second set of analyses, primary and secondary outcome measures collected at baseline, post-treatment, 3 months post-treatment, and 6 months post-treatment were compared using repeated measures general linear modeling (GLM). Baseline measures were selected as the reference category, and *P* values were adjusted for multiple comparisons so a 2-tailed significance level of .017 was designated. Data for all participants were used for the repeated-measures analyses irrespective of treatment allocation. For the deferred treatment group, which had 2 baseline data collection points 3 months apart, the first baseline measure was used. Analyses of this type are referred to as outcome *change over time comparisons* in subsequent sections of this article. These analyses were utilized as a secondary measure of treatment efficacy and were considered a measure of maintenance of the treatment effect. Additionally, maintenance of the treatment effect was analyzed using repeated-measures GLM, comparing the post-treatment score with the scores at 3 and 6 months post-treatment. Again, *P* values were adjusted for multiple comparisons so a 2-tailed significance level of .025 was designated.

We subsequently performed 2 secondary analyses. First, baseline 1 and baseline 2 outcome data for the delayed treatment group were compared utilizing paired samples *t* tests with a 2-tailed significance level of .05. Similar analyses were not

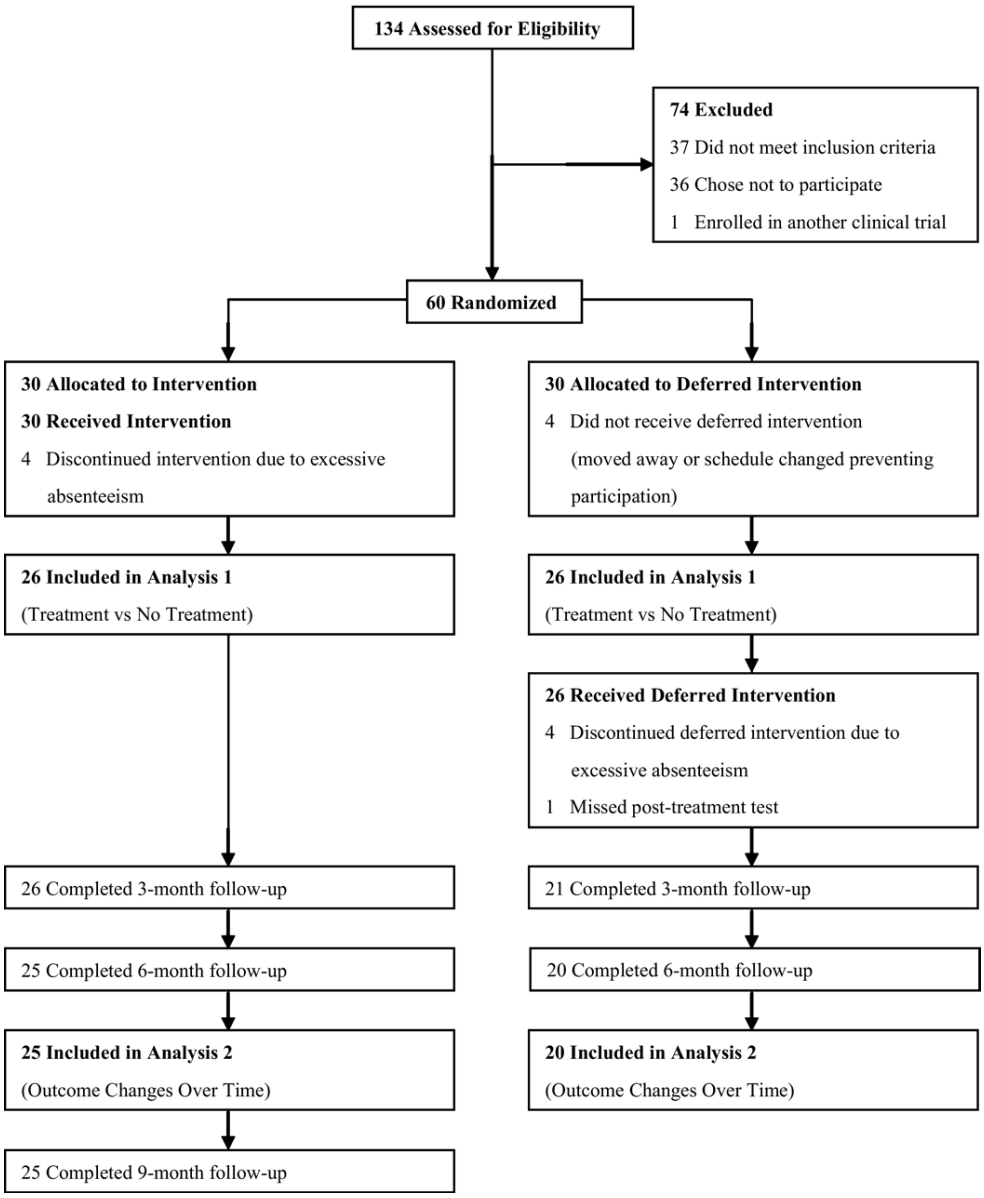

Fig 2. Participant flow. Any participant missing more than 2 of the 12 sessions was not considered to have received the full treatment and thus was not included in the final analysis.

possible in the treatment group because they were not administered a second set of baseline outcome measures, per the study's methodology.

The treatment group, however, did complete an additional set of follow-up outcome measures at 9 months post-treatment that the delayed treatment group did not complete. These longer-term outcomes were compared with initial baseline outcomes utilizing paired samples *t* tests with a 2-tailed significance level of .05. We did this set of secondary analyses to assess change from baseline to 9 months post-treatment.

We made a conservative effort to accommodate missing data in the analyses. First, for subscales comprised of multiple questions that could not be scored because of sporadic missing data, we used mean substitution techniques at the item level. Mean substitutions were specific to both the treatment group and the time period. Second, for the blinded PFIC videotape ratings, there were 2 tapes that were only rated by 1 of the 2 raters because of technical problems with the tapes. In these instances, the available rating was used in lieu of an averaged rating. Finally, for 1 case, a baseline 2 score was substituted for a missing baseline 1 score in the repeated-measures analysis. These accommodations were believed to be necessary as SPSS handles repeated-measures missing data with list-wise case deletion (ie, if data for any of the 4 time periods were missing, the entire case was omitted from the analysis).

Table 2: Treatment Versus No-Treatment Comparisons

	Treatment Group				Delayed Treatment Group				
		Baseline	Post-Treatment			Baseline 1	Baseline 2		
Ratings	N	Mean ± SD	Mean ± SD	Diff*	N	Mean ± SD	Mean ± SD	Diff*	*P*
Blinded objective ratings†									
PFIC: LC	25	0.78±0.99	0.58±0.66	−0.20	20	0.75±0.87	0.78±0.82	0.03	.292
PFIC: GP	25	2.78±1.02	1.86±1.11	−0.92	20	2.50±1.06	2.68±1.23	0.18	**.001**
PFIC: QN	25	1.64±0.74	1.06±0.67	−0.58	20	1.38±0.76	1.35±0.81	−0.03	**.024**
PFIC: QL	25	0.54±0.71	0.36±0.55	−0.18	20	0.73±0.88	0.78±0.92	0.05	.177
PFIC: IR	25	1.70±0.84	1.00±0.69	−0.70	20	1.58±1.05	1.63±1.00	0.05	**.009**
PFIC: ER	25	2.26±0.96	1.46±1.11	−0.80	20	1.60±1.02	1.80±1.06	0.20	**.005**
PFIC: CE	25	1.68±0.86	1.12±0.71	−0.56	20	1.53±1.03	1.58±0.89	0.05	**.024**
PFIC: SS	25	1.78±0.87	1.00±0.82	−0.78	20	1.40±0.97	1.58±0.99	0.18	**<.001**
PFIC: SM	25	1.30±0.87	0.84±0.92	−0.46	20	1.20±0.92	1.30±0.91	0.10	.076
PFIC: AE	25	1.90±1.03	1.36±1.03	−0.54	20	1.58±1.00	1.68±0.92	0.10	**.014**
TBI self-report ratings									
SCSQ-A	26	131.30±22.39	148.00±19.61	16.70	26	140.32±22.29	143.52±17.96	3.20	**.005**
CIQ: SI	25	7.96±2.11	7.72±2.23	−0.24	26	8.62±2.26	8.58±2.12	−0.04	.697
CIQ: P	25	4.08±1.66	3.88±1.62	−0.20	26	4.31±1.26	3.73±1.71	−0.58	.327
CHART: O	25	61.56±34.45	53.84±32.81	−7.72	26	70.58±34.02	64.46±35.48	−6.12	.803
CHART: SI	25	71.60±26.68	72.16±21.74	0.56	26	87.42±19.29	86.65±18.67	−0.77	.804
SWLS	26	18.46±8.86	20.81±9.32	2.35	26	22.62±7.52	23.96±6.39	1.34	.605
Significant other ratings									
SCSQ-A	14	134.86±18.49	143.93±22.16	9.07	14	132.12±17.51	133.57±17.84	1.45	.145
CIQ: SI	14	8.50±2.47	7.21±2.58	−1.29	14	8.50±1.95	8.57±2.47	0.07	.144
CIQ: P	14	3.50±1.65	3.07±1.90	−0.43	14	3.86±1.92	4.21±1.42	0.35	.141
CHART: O	14	56.57±30.96	61.64±33.46	5.07	14	68.57±32.62	70.21±29.32	1.64	.746
CHART: SI	14	77.00±29.92	72.07±27.54	−4.93	14	88.00±20.94	93.43±13.56	5.43	.394

NOTE. Boldface denotes statistical significance.
Abbreviations: AE, aesthetics; CE, clarity of expression; Diff, difference; ER, external relation; GP, general participation; IR, internal relation; LC, logical content; O, occupation; P, productivity; QL, quality; QN, quantity; SD, standard deviation; SI, social integration; SM, subject matter; SS, social style.
*Differences were compared using independent samples *t* tests.
†Lower scores indicate less impairment on the PFIC; therefore, negative differences reflect improvement.

RESULTS

Participant Flow

Of the 60 participants enrolled in the study, 30 were assigned to each arm of the study. Per study protocol, any participant missing more than 2 of the 12 sessions was not considered to have received the full treatment and thus was not included in the change over time analysis. Figure 2 shows the details of the participant flow. There were no deviations from the study's planned protocol.

Treatment Versus No-Treatment Comparisons

Differences between baseline measures and 12-week post-treatment and no-treatment measures for subjects who completed the treatment per protocol are illustrated in table 2. Primary outcomes included the PFIC and the SCSQ-A. Secondary outcomes included the social integration, productivity, and occupational subscales of the CIQ and the CHART-SF, as well as the SWLS.

Significantly more improvements in 7 of the 10 PFIC summary scales were identified in the treatment group compared with the no-treatment group. The largest comparative improvement in the treatment group was on the general participation summary scale of the PFIC. As indicated in table 2, the average baseline general participation rating in the treatment group was 2.78, higher than any other PFIC summary scale and therefore indicative of the area of greatest impairment. At the second data collection for the treatment group (after the intervention), the general participation summary scale score averaged 1.86, or an improvement of .92 points on a 6-point scale. In contrast, the baseline assessment of the no-treatment group averaged 2.5 (also the highest score of any subscale), while the second assessment (after no treatment) averaged a .18 decline. The difference between the .92 improvement in the treatment group compared with the .18 decline in the no-treatment group was statistically significant at the *P* equal to .001 level.

Table 2 reports similar results found in another 6 PFIC summary scales when average improvements in the treatment group were compared with the average changes in the no-treatment group. There were significantly greater improvements in the treatment group on quantity, internal relation, external relation, clarity of expression, social style, and aesthetics. The remaining 3 PFIC summary scales—logical content, quality, and subject matter—indicated trends toward greater treatment group improvement, but were nonsignificant.

After 12 weeks, those participants who had received treatment reported average improvements of about 17 points on the SCSQ-A, compared with average improvements of about 3 points for participants who had not received treatment. These differences were statistically significant ($P=.005$). No statisti-

Table 3: Change Over Time Comparisons

Ratings	N	Baseline	Post-Treatment			3 Months Post-Treatment			6 Months Post-Treatment		
		Mean ± SD	Mean ± SD	Diff	*P*	Mean ± SD	Diff	*P*	Mean ± SD	Diff	*P*
Blinded objective ratings											
PFIC: LC	33	0.80±0.87	0.47±0.65	−0.33	**.010**	0.47±0.67	−0.33	**.007**	0.45±0.58	−0.35	**.001**
PFIC: GP	33	2.68±1.07	1.98±1.09	−0.70	**.001**	2.23±0.99	−0.45	**.005**	2.08±1.06	−0.60	**.009**
PFIC: QN	33	1.64±0.77	1.21±0.69	−0.43	**.008**	1.20±0.67	−0.44	**.002**	1.21±0.79	−0.43	**.007**
PFIC: QL	33	0.70±0.84	0.52±0.63	−0.18	.129	0.58±0.73	−0.12	.174	0.58±0.76	−0.12	.283
PFIC: IR	33	1.77±0.94	1.21±0.86	−0.56	**.003**	1.35±0.86	−0.42	**.005**	1.32±0.83	−0.45	**.011**
PFIC: ER	33	2.03±0.96	1.52±1.00	−0.51	**.009**	1.62±0.94	−0.41	**.008**	1.65±1.00	−0.38	.071
PFIC: CE	33	1.73±0.95	1.24±0.79	−0.49	**.006**	1.24±0.77	−0.49	**<.001**	1.33±0.81	−0.40	**.012**
PFIC: SS	33	1.61±0.90	1.05±0.84	−0.56	**.002**	1.29±0.88	−0.32	.022	1.18±0.83	−0.43	.020
PFIC: SM	33	1.36±0.86	0.85±0.89	−0.51	**.003**	1.05±0.86	−0.31	.025	0.86±0.76	−0.50	**.004**
PFIC: AE	33	1.80±1.05	1.36±0.92	−0.44	**.004**	1.52±0.98	−0.28	.042	1.50±0.82	−0.30	.079
TBI self-report ratings											
GAS	37	2.32±0.79	3.61±0.72	1.29	**<.001**	4.21±0.59	1.89	**<.001**	4.51±0.54	2.19	**<.001**
SCSQ-A	44	133.82±22.32	146.72±20.95	12.90	**<.001**	149.42±199.86	15.60	**<.001**	150.92±18.48	17.10	**<.001**
CIQ: SI	42	8.21±2.24	8.21±2.16	0.00	>.999	8.74±2.06	0.53	.170	8.33±2.19	0.12	.649
CIQ: P	42	4.12±1.52	4.00±1.31	−0.12	.507	4.07±1.40	−0.05	.800	4.21±1.41	0.09	.682
CHART: O	44	65.52±33.88	66.05±33.22	0.53	.898	69.16±33.86	3.64	.301	64.14±32.45	−1.38	.711
CHART: SI	44	79.20±24.25	79.55±23.01	0.35	.922	84.61±21.22	5.41	.164	81.95±25.11	2.75	.451
SWLS	44	20.07±8.60	22.64±8.37	2.57	**.011**	23.43±7.77	3.36	**.003**	23.77±7.27	3.70	**<.001**
Significant other ratings											
GAS	17	2.39±0.59	3.39±0.95	1.00	**<.001**	3.99±0.65	1.60	**<.001**	4.02±0.96	1.63	**<.001**
SCSQ-A	17	138.75±17.35	144.68±17.16	5.93	.131	143.31±18.20	4.56	.299	149.52±19.61	10.77	.072
CIQ: SI	17	8.88±2.06	8.12±2.09	−0.76	.236	8.12±1.73	−0.76	.180	8.12±2.20	−0.76	.165
CIQ: P	17	4.00±1.58	3.76±1.82	−0.24	.543	3.94±1.60	−0.06	.842	4.53±1.50	0.53	.166
CHART: O	16	63.63±29.64	66.50±30.36	2.87	.712	66.38±28.84	2.75	.705	67.88±30.32	4.25	.633
CHART: SI	16	88.25±26.67	80.69±28.22	−7.58	.374	76.00±26.05	−12.25	.122	89.06±14.39	0.81	.882
Group leader ratings											
GAS	26	1.80±0.45	3.52±0.66	1.72	**<.001**	4.08±0.66	2.28	**<.001**	4.51±0.65	2.71	**<.001**

NOTE. Boldface denotes statistical significance. Alpha level equal to .05/3 (.017) adjusted for multiple comparisons.
Abbreviations: See table 2.

cally significant differences were identified among the self-reported secondary outcomes.

The significant others of TBI participants reported 9-point gains on the SCSQ-A for subjects who received treatment, compared with less than 2-point gains for those who had not received treatment, but the differences were not statistically significant. As with the TBI subjects, there were no statistically significant differences among the secondary outcomes reported by significant others.

The ITT analysis for the treatment versus no-treatment comparisons did not differ from the per-protocol analysis reported in table 2. Although slight variations in mean differences and *P* values were identified, the overall results of the 2 analyses did not differ.

Change Over Time Comparisons

Table 3 shows the differences between outcome ratings collected at baseline, post-treatment, 3 months post-treatment, and 6 months post-treatment for all participants who received the intervention. Primary measures included the PFIC, SCSQ-A, and GAS. Statistically significant improvements from baseline to post-treatment evaluations were identified for 21 of the 30 comparisons made on the PFIC (*P* range, <.001 to .012). For 5 of the 10 PFIC summary scales, scores were significantly better at each of the 3 post-treatment evaluations than they were at baseline.

Participant ratings on the SCSQ-A showed significant improvement over time (difference post-treatment from baseline [difference post-treatment], 12.9; difference at 3 months from baseline [difference at 3mo], 15.6; difference at 6 months from baseline [difference at 6mo], 17.1; all $P<.001$). As with the treatment versus no-treatment comparisons, ratings by significant others indicated a trend of improvement from baseline to each post-treatment evaluation on the SCSQ-A (difference post-treatment, 5.93; difference at 3mo, 4.56; difference at 6mo, 10.77). These differences, however, were not statistically significant (*P* range, .072−.299).

The TBI subjects reported significant improvements from baseline on the GAS for all subsequent post-treatment evaluations (difference post-treatment, 1.29; difference at 3mo, 1.89; difference at 6mo, 2.19; all $P<.001$). Their significant others rated the TBI subjects better on the GAS at each post-treatment evaluation than they did at baseline (difference post-treatment, 1.00; difference at 3mo, 1.60; difference at 6mo, 1.63; all $P<.001$). Group leaders also rated the TBI participants significantly better on the GAS at each post-treatment evaluation than at baseline (difference post-treatment, 1.72; difference at 3mo, 2.28; difference at 6mo, 2.71; all $P<.001$).

Table 4: Baseline Versus 9 Months Post-Treatment Comparisons

Ratings	n	Treatment Group: Baseline Mean ± SD	Treatment Group: 9 Months Post-Treatment Mean ± SD	*P*
Blinded objective ratings				
PFIC: LC	21	0.86±1.03	0.69±0.75	.349
PFIC: GP	21	2.81±1.04	2.21±1.03	**.012**
PFIC: QN	21	1.69±0.80	1.29±0.70	**.034**
PFIC: QL	21	0.60±0.74	0.57±0.73	.853
PFIC: IR	21	1.79±0.86	1.40±0.77	.053
PFIC: ER	21	2.21±0.96	1.64±0.98	**.018**
PFIC: CE	21	1.79±0.89	1.36±0.92	.068
PFIC: SS	21	1.83±0.93	1.10±0.74	**.001**
PFIC: SM	21	1.31±0.94	0.86±0.90	**.022**
PFIC: AE	21	1.90±1.07	1.50±0.85	.053
TBI self-report ratings				
GAS	22	2.12±0.80	4.41±0.76	**<.001**
SCSQ-A	25	131.10±22.88	153.42±19.86	**<.001**
CIQ: SI	25	7.84±2.19	7.64±2.43	.685
CIQ: P	25	4.08±1.66	4.00±1.55	.799
CHART: O	24	59.96±34.23	60.83±37.17	.908
CHART: SI	24	70.42±26.57	76.21±25.26	.305
SWLS	25	18.52±9.04	22.80±7.98	**.003**
Significant other ratings				
GAS	9	2.07±0.66	4.07±0.74	**<.001**
SCSQ-A	12	127.13±19.98	143.21±28.16	**.002**
CIQ: SI	12	7.33±2.50	7.58±2.75	.651
CIQ: P	12	4.08±1.24	4.33±1.67	.571
CHART: O	12	48.33±30.82	46.42±32.52	.800
CHART: SI	12	71.50±34.56	77.33±23.59	.514
Group leader ratings				
GAS	20	1.70±0.43	4.53±0.75	**<.001**

NOTE. Boldface denotes statistical significance.
Abbreviations: see table 2.

There were 3 significant differences in the secondary outcome measures, all on the SWLS. The TBI subjects showed significant improvements from baseline to post-treatment (difference post-treatment, 2.57; $P=.011$), 3 months post-treatment (difference at 3mo, 3.36; $P=.003$), and 6 months post-treatment (difference at 6mo, 3.70; $P<.001$) on the SWLS. There were no significant differences among the secondary outcomes measures (CHART-SF, CIQ) as rated by participants or their significant others.

Subsequently, we did a repeated measure GLM analysis comparing the post-treatment scores to the 3- and 6-month follow-up as a measure of maintenance of treatment effect and found no significant decline in any outcome measure and continued improvements in the GAS ratings. Participants with TBI had significant improvements on the GAS when post-treatment scores were compared with follow-up scores (difference at 3mo, .61; difference at 6mo, .90; both $P<.001$). Significant others rated TBI subjects significantly better on the GAS at each follow-up when compared with post-treatment (difference at 3mo, .57; $P=.004$; difference at 6mo, .58; $P=.023$). The same was true for group leader GAS ratings (difference at 3mo, .56; difference at 6mo, .99; both $P<.001$). These results show that gains were maintained from post-treatment on 3- and 6-month follow-up and furthermore, that participants continued to make progress toward meeting their individual social communication goals after the treatment period.

In the first of 2 secondary analyses, we made pairwise comparisons of the 2 baseline measures for the delayed treatment group to assess whether significant changes occurred after a 12-week interval without any intervention. Of the 21 outcomes compared, only the CIQ productivity subscale rated by the TBI subjects trended toward significance ($P=.053$). Ratings for this measure were .58 points lower at baseline 2 than at baseline 1.

We also made pairwise comparisons between baseline and 9 months post-treatment outcomes for 25 participants allocated to the treatment group (table 4) to determine statistically significant improvements from baseline in communication skills. This analysis indicated that participants showed improved performance on 5 of the 10 subscales of the PFIC (general participation, quantity, external relation, social style, subject matter) from baseline to 9 months (P range, .001−.034). Improvement was statistically significant for the SCSQ-A, as rated by the participant ($P<.001$) and the significant other ($P=.002$), and for the GAS, as reported by the participant, significant other, and group leaders (all $P<.001$). Participant ratings on the SWLS were significantly improved at 9 months compared with baseline ($P=.003$). There were no significant differences in the other secondary measures.

DISCUSSION

Treatment efficacy of a replicable intervention to improve social communication skills in TBI subjects was demonstrated through a randomized controlled treatment and deferred treat-

ment research design with adequate statistical power. We found statistical significance with 4 of the outcome measures (PFIC, SCSQ-A, GAS, SWLS). On the PFIC—an objective, blinded outcome measure—the treatment group showed significant improvement in 7 of 10 summary scales. The most improvement was in their general participation in conversation, followed by external relation (listener role in relating comments to the other's preceding comments), social style, internal relation (speaker role, ideas are cohesive, relevant and related), quantity, clarity of expression, and aesthetics (speech characteristics). Conversely, there were no significant changes in the deferred treatment group. These areas of change, as measured by the PFIC, corresponded with the focus of the social skills training. The findings support our hypothesis 1—that social communication skills training in a group setting would improve specific individual communication deficits for people with postacute TBI. Furthermore, this is the only RCT of which we are aware that shows the efficacy of social communication skills training of TBI subjects using published treatment materials, which makes possible replication of the study.

Our second hypothesis, that overall social integration and satisfaction with life would be improved through group training, was partially supported. The data showed that overall satisfaction with life as measured by the SWLS was significantly improved over baseline at post-treatment and at 3-, 6-, and 9-month follow-up. The participation measures we used, however, did not identify significant improvement after the treatment. The lack of change in the participation measures may be because the measures are too broad, or not sensitive enough to capture changes in the complex outcomes involved with participation in society. For example, participants would not necessarily be expected to increase their hours of paid work or to make a best friend within the 12-week intervention. Or possibly, we needed to follow the participants for a longer period to note changes in areas that may require more time to develop, for example, productivity or social relationships. A third consideration is that social communication represents only a fraction of the skills needed to participate fully in society, and our original hypothesis was overly ambitious.

The treatment effect was maintained at 3-, 6-, and 9-month follow-up. Furthermore, participants continued to improve on individual communication goals at follow-up. These results demonstrate that TBI subjects can continue to learn and improve their skills, even 10 years postinjury; they also generally support our third hypothesis—that skills gained in treatment would be maintained at 6 months post-treatment.

The findings in this study support past studies that have concluded that social communication skills can be improved. Several studies[22-28,56] have demonstrated that specific communication behaviors improved with treatment, using pre- and post- rating scales with a single case study or small case series. The 1 RCT we found concerning treatment efficacy in people with TBI showed improved communication skills as rated by clinicians, however, the subjects' perceived skill rating was not significant, which is in contrast with our findings.[21] Goals for improved social communication skills have been reportedly achieved as a segment of a comprehensive rehabilitation program, along with improved outcomes in independent living and work.[31,57] This study focused on the efficacy of group training to improve specific communication skills with associated changes in participation and satisfaction with life, and maintenance of the treatment effect.

Strengths of the study include the randomized control design, statistical power, and stringent inclusion and exclusion criteria, which defined a specific subset of the overall TBI population. The tools selected for the primary outcome measures of social communication skills were sensitive enough to detect improvement. Finding that a treatment of relative short duration was efficacious almost 10 years post-TBI was very encouraging. Additionally, the follow-up showed that the treatment effect was maintained. The study had a relatively low dropout rate; there were no deviations from the established protocol and no adverse events as a result of the treatment. This is among the few reported studies to include TBI subjects' perceptions about their communication skills, community participation, and satisfaction with life. Congruent with our study results, Goldblum et al[58] reported on perceived effects of group therapy over a 2-year period and noted improved communication skills and quality of life as subjectively reported by 6 people with TBI and their significant others. An added strength of our study is that the treatment materials are available so that our results can be replicated, similar to the use of a published workbook reported in the study by Wiseman-Hakes et al.[26]

Study Limitations

Although the stringent inclusion and exclusion criteria were identified as strengths of the study, they can also be considered a limitation. That people with past or current psychiatric, psychologic, or substance abuse issues were excluded is not representative of the overall group of people who experience TBI. This issue is being addressed in a follow-up pilot study with expanded inclusion criteria, using the same treatment regimen and outcome measures. Assignment of subjects without blinding is a limitation, although those involved in the project did not identify any significant bias in the process used. Another limitation is the greater extent of missing data for the PFIC, the primary blinded objective measure used in this study. For the repeated-measures analyses, 11 fewer cases were available for the PFIC than for some of the other measures after list-wise deletion of cases with missing data points in SPSS. This disparity occurred because videotaped conversations required in-person follow-ups, whereas other measures could be collected by telephone interviews. There were also technical issues with some of the videotapes. To address the potential bias associated with list-wise deletion methods, we conducted paired samples *t* tests to compare baseline with all subsequent PFIC scores using all available data. Results of these tests did not differ significantly from the reported results, which indicates that there was no bias introduced by the selected analysis.

This study only tested the efficacy of 2 group leaders who had more than a decade of experience in developing and refining this intervention. The transferability of the intervention to other group leaders is needed. Also, participants in the study had relatively higher levels of education and less diversity than the general TBI population, thus applicability to the overall TBI population is not known and any conclusions from this data must be carefully drawn. Women represented 15% of the study sample, and this small sample size may limit generalization to all women with TBI. Another limitation is the lack of availability of widely used measures in social communication skills; 1 primary measure was not originally designed as a measurement tool (SCSQ-A), and was adapted for this study. The PFIC was designed for use with TBI subjects, but there are few published studies in which the tool was used. Finally, the study design used treatment/deferred treatment rather than a comparison to an alternative treatment, thus changes noted from the intervention might be from nonspecific treatment effects (eg, socialization).

Future research is needed to expand the inclusion criteria for subjects, and to determine efficacy of treatment for a broader TBI population, specifically former and current substance abusers, or people with psychologic issues. Additionally, train-

ing other group facilitators to use the treatment program to see if other group leaders can achieve the treatment effect is a future goal. Outcome measures need to be refined, with more sensitive measures of social integration and participation. Comparison of this intervention with alternative treatments would also further define the treatment effect identified in this study.

CONCLUSIONS

This RCT showed that a specific, replicable group intervention to improve social communication skills for people with TBI was efficacious, and gains were maintained on follow-up. In addition, overall life satisfaction for participants significantly improved. The group leaders and significant others noted progress in the TBI subjects in the postinjury chronic phase, thus supporting the clinical significance of the treatment. Hopefully, future multicenter trials will establish the effectiveness of the treatment intervention and its positive effect on the lives of people with TBI.

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The opinions expressed herein are those of the authors and do not necessarily reflect the views of the U.S. Department of Education.

APPENDIX 1: INTERVENTION STRATEGIES FROM SOCIAL SKILLS AND TBI: A WORKBOOK FOR GROUP TREATMENT

Topics for each 1.5 hour weekly session	
Session 01:	Group Overview: Learning the Skills of a Good Communicator
Session 02:	Self-Assessment and Setting Goals
Session 03:	Presenting Yourself Successfully and Starting Conversations
Session 04:	Developing Conversation Strategies and Using Feedback
Session 05:	Being Assertive and Solving Problems
Session 06:	Practice in the Community
Session 07:	Developing Social Confidence through Positive Self-Talk
Session 08:	Setting and Respecting Social Boundaries
Session 09:	Video Taping, and Problem Solving
Session 10:	Video Review and Feedback
Session 11:	Conflict Resolution
Session 12:	Closure and Celebration

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Supplier

a. Version 13.0; SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.