

HHS PUDIIC ACCESS

Author manuscript

J Head Trauma Rehabil. Author manuscript; available in PMC 2018 September 01.

Published in final edited form as:

J Head Trauma Rehabil. 2017; 32(5): 286–295. doi:10.1097/HTR.00000000000277.

Reductions in Alexithymia and Emotion Dysregulation after Training Emotional Self-awareness Following Traumatic Brain Injury: A Phase I Trial

Dawn Neumann, PhD [Assistant Research Professor],

Indiana University School of Medicine, Department of Physical Medicine and Rehabilitation, Rehabilitation Hospital of Indiana, 4141 Shore Drive, Indianapolis, IN 46254, dmneuman@iupui.edu, Phone: 317-329-2188

James F. Malec, PhD [Professor and Research Director], and

Indiana University School of Medicine, Department of Physical, Medicine and Rehabilitation, Rehabilitation Hospital of Indiana, Indianapolis, IN

Flora M. Hammond, MD [Professor and Department Chair]

Indiana University School of Medicine, Department of Physical, Medicine and Rehabilitation, Chief of Medical Affairs, Rehabilitation Hospital of Indiana, Indianapolis, IN

Abstract

Objectives—To examine the acceptability and initial efficacy of an emotional self-awareness treatment at reducing alexithymia and emotion dysregulation in participants with traumatic brain injury (TBI).

Setting—Outpatient rehabilitation hospital.

Participants—Seventeen adults with moderate to severe TBI and alexithymia. Time post-injury ranged 1–33 years.

Design—Within subject design, with 3 assessment times: baseline, posttest, and 2-month follow-up.

Intervention—Eight lessons incorporated psycho-educational information and skill-building exercises teaching emotional vocabulary, labeling and differentiating self-emotions; interoceptive awareness; and distinguishing emotions from thoughts, actions and sensations.

Measures—Alexithymia (TAS-20); Emotional Awareness (LEAS); Trait Anxiety (TAI); Depression (PHQ-9); Anger (STAXI); Emotion Dysregulation (DERS); and Positive and Negative affect (PANAS).

Results—Thirteen participants completed the treatment. Repeated measures ANOVA revealed changes on the TAS-20 (p=.003), LEAS (p<.001), TAI (p=.014), STAXI (p=.015), DERS (p=.020) and Positive Affect (p<.005). Paired t-tests indicated significant baseline to posttest improvements

Correspondence to: Dawn Neumann. Reprint requests to Dawn Neumann, PhD on these measures. Gains were maintained at follow-up for the TAS, LEAS, and Positive Affect. Treatment satisfaction was high.

Conclusion—This is the first study published on treating alexithymia post-TBI. Positive changes were identified for emotional self-awareness and emotion regulation; some changes were maintained several months post-treatment. Findings justify advancing to the next investigational phase for this novel intervention.

Keywords

Alexithymia; Brain Injury; Emotion; Anxiety; Aggression; Emotion Regulation; Affect

INTRODUCTION

Anxiety, depression, anger and overall emotion dysregulation are common after traumatic brain injury (TBI).^{1–4} These emotional impairments are often challenging to treat and ultimately become chronic problems for many survivors of TBI. These emotional sequelae typically have an adverse impact on psychosocial functioning, relationships, community reintegration, and quality of life.^{5–9}

After a TBI, it is not unusual to have problems processing emotions.¹⁰ Of particular interest here are emotion-processing deficits characteristic of a psychological construct referred to as *alexithymia*. Quintessential features of alexithymia are poor awareness for personal emotions; reduced acknowledgement of physical sensations and association with emotional responses (e.g., elevated heart rate and fear); difficulty describing and/or trouble distinguishing emotions (e.g., differentiating anger from sad); and a preference for discussing concrete or superficial facts rather than emotions.¹¹ The prevalence of alexithymia after TBI ranges from 30–61%^{10,12,13} compared to 10%¹⁴ in the non-TBI population. Since alexithymia has been associated with emotion dysregulation deficits after TBI, such as anxiety, depression, and anger,^{13,15–17} it is a deficit that warrants considerable attention and concern.

There are several theoretical assumptions regarding the association of alexithymia with emotion dysregulation. One assumption is that emotional awareness is needed to consciously regulate emotions.¹⁷ Also, reduced awareness and difficulty describing emotions has been associated with avoidant coping skills.¹³ If one avoids a problem that causes emotional distress, that problem is likely to remain unresolved and may compound and/ or surface through behavior. Furthermore, neuroimaging research suggests that the cognitive process of labeling emotions helps down regulate the emotional limbic reaction^{18–21}; therefore people who have trouble describing their emotions may have difficulty regulating unpleasant feelings.

There are currently no evidence-based, standard treatment approaches for reducing alexithymia after TBI. To date, there have been two publications examining a treatment specifically designed for alexithymia; neither of which were in the TBI population. One study involved thirteen otherwise normal male participants with alexithymia (likely the result of poor developmental socialization).²² Participants were taught an emotional

Page 3

vocabulary and to use an emotional diary to describe their feelings. Problems with alexithymia were significantly less after treatment. There was also a case study of a patient who had alexithymia after a stroke. This patient was similarly taught an emotional vocabulary, and in addition, video-feedback and heart rate biofeedback were used to enhance the patient's awareness for his own emotional responses.²³ This patient showed substantial reductions in alexithymia, suggesting that alexithymia may be minimized after brain damage with such targeted treatment.

Given the prevalence of alexithymia after TBI and associated negative outcomes, we developed a treatment to target characteristics of alexithymia in people with TBI. In adherence with recommendations for a phased developmental approach towards rehabilitation studies, which encourages appropriate preliminary studies before proceeding to randomized controlled trials, this study was designed as a Phase I trial to examine proofof-concept and feasibility of this novel intervention.²⁴ Therefore one aim was to examine initial efficacy on primary and secondary outcomes through changes in effect sizes. Primary outcomes were alexithymia and emotional awareness, while secondary outcomes pertained to emotion regulation variables (i.e., anxiety, depression, anger, positive and negative affect, and general emotion dysregulation). With respect to feasibility, we were particularly interested in participant acceptability (satisfaction) with the program. A within subject design with three assessment periods was used: baseline, immediate post-test and two-month follow-up. We hypothesized moderate to large effect sizes on our alexithymia and emotional awareness measures since we were explicitly teaching these skills. We had several hypotheses regarding the potential outcomes on emotion regulation. Based on the theories described above regarding the association of alexithymia with emotion dysregulation, one might expect that teaching emotional awareness and labeling skills would position participants to better regulate their emotions. Therefore, one hypothesis was that we would observe significant improvements in anxiety, depression, anger, affect, and overall emotion dysregulation. In contrast, it is possible that training emotional awareness and labeling would not generalize to emotion regulation because teaching emotional control was not part of treatment. Also, poor emotion regulation was not an inclusion criterion and therefore may not have been a problem for some participants. Another possibility is that changing behavior (emotion regulation) takes time and might not appear until follow-up. Alternatively, the immediate effect of newfound emotional self-awareness might be overwhelming and unpleasant for some individuals, and therefore result in an initial increase in anxiety, depression, or overall negative affect.

METHODS

Participants

When the goal of a study is to estimate initial effect sizes for the purposes of designing a larger trial, statistical guidelines recommend using a sample size of 12 for a pre-post design.²⁵ In anticipation of a possible 20% drop-out rate we aimed to enroll a minimum of 15 participants. Recruitment letters were sent to current and former patients of a local rehabilitation hospital. Also, flyers were posted in the hospital's outpatient clinic and were disseminated at local brain injury support groups. Recruitment materials specified that we

were looking for people who had had a moderate to severe TBI to participate in an investigational treatment study on emotional problems after brain injury. Many participants who were interested in the study initiated contacting us directly after receiving a recruitment letter or flyer; we also followed-up recruitment letters with a phone call. Ultimately, we made phone contact with 72 people; 57% declined participation for the following reasons: not interested (44%); too busy (16%); felt they did not have emotional problems/ need treatment (15%); had transportation challenges (15%); or had communication problems that would prohibit their participation (10%). Those who expressed interest in the study (n=31) were prescreened; 25 participants passed prescreening criteria, of which seventeen met the full study criteria and were enrolled into treatment.

Eligible participants had sustained a moderate to severe TBI, as defined by at least one of the criteria outlined by the Mayo classification system for TBI²⁶: Glasgow Coma Scale score <13 (at the time of injury), post-traumatic amnesia 24 hours, loss of consciousness 30 minutes, or abnormal neuroimaging results consistent with moderate to severe brain injury. Participants were between 18 and 75 years old and were a minimum of one-year post-TBI. Consistent with inclusion criteria, eligible participants had moderate to severe alexithymia (52 on the Toronto Alexithymia Scale-20 determined at screening). Participants were allowed to continue medications and ongoing therapies. They were excluded if they had a pre-morbid acquired brain injury (e.g. stroke), neurological disorder (e.g. autism), or a major psychiatric disorder (e.g. schizophrenia) other than depression or posttraumatic stress disorder (PTSD). Since depression and PTSD are so common after TBI and strongly correlated with alexithymia, we did not exclude patients with these conditions in order to achieve a more representative sample. See Table 1 for details regarding participant demographics and relevant medical history.

Primary Measures

Toronto Alexithymia Scale (TAS-20)^{11,27}—This self-report questionnaire measures total alexithymia, and three subconstructs: difficulty identifying feelings (awareness), difficulty describing feelings, and externally-oriented thinking. Scores range from 20–100; 52 indicates moderate alexithymia, and 61 indicates high alexithymia. Participants had to score a 52 for treatment eligibility. The TAS-20 has been used in the TBI population^{10–13,15,17}, and is reported to have good internal consistency, validity, and test-retest reliability.^{11,27}

Levels of Emotional Awareness Scale (LEAS)²⁸—The LEAS is a performance-based measure of emotional awareness and vocabulary. In response to 10 hypothetical scenarios, participants must say how they think they and a character in the scenario would feel. Responses were open-ended and later entered into a computerized scoring system.²⁹ Scores range from 0–50, with higher scores indicating better emotional awareness and vocabulary. The LEAS consists of parellel versions (A and B). This test has been used in people with TBI.³⁰ The LEAS has significantly correlated with other measures of emotion perception and has good reliability indicators.^{28,31}

Secondary Measures

State Trait Anxiety Inventory (STAI)³²—This self-report measure has a State Anxiety scale, which inquires about feelings in that moment, and Trait Anxiety scale which asks about general feelings over time. Scores range from 20–80 for each subscale. Higher scores indicate greater anxiety. Age and gender norms were used to convert raw scores to standard scores. For the purposes of this study, we only report trait anxiety scores. The STAI has been shown to have concurrent validity with other anxiety measures.³³

Patient Health Questionnaire (PHQ-9)³⁴—The PHQ-9 is a self-report assessment of depression with a Likert scale ranging from 0–3 (max score 27). Participants rate the frequency of specified problems during the past two weeks. The PHQ-9 has established validity and reliability.^{35,36}

State Trait Anger Expression Inventory-2 (STAX-2I)—This self-report assessment uses a 4-point Likert scale to measure three constructs: 1) state anger; 2) trait anger; and 3) behaviors and reactions when angry. Scores from these constructs are used to calculate an Anger Index T score (using age and gender norms), which provides an overall estimate of the person's likelihood to express anger outwardly or inwardly. The STAXI-2 has been shown to have good internal consistency.^{37,38}

Positive and Negative Affect Scale (PANAS)³⁹—Using a 5-point scale, participants rate the extent to which they have experienced 10 positive mood states (Positive Affect) and 10 negative mood states (Negative Affect) during a specified time frame. The measure has shown good reliability and validity in a variety of populations. The scales are shown to be internally consistent and stable over several weeks.^{39,40}

Difficulty with Emotion Regulation Scale (DERS)⁴¹—Using a 5-piont Likert Scale, participants rate the frequency they utilize specific emotion regulation behaviors. There are six scales: Lack of Emotional Awareness, Lack of Emotional Clarity, Difficulties Controlling Impulsive Behaviors when Distressed, Difficulties Engaging in Goal-Directed Behavior When Distressed, Nonacceptance of Negative Emotional Responses, and Limited Access to Effective Emotion Regulation Strategies. Items are summed to provide a Total Emotion Dysregulation score. The DERS has high internal consistency test-retest reliability, and good construct validity.⁴¹

Satisfaction Questionnaires—Satisfaction questions were created by the authors and administered at post-test and follow-up. Questions were designed to evaluate overall satisfaction; perceived relevance to their needs; implementation of strategies to their daily life; clarity of information; translation to emotion regulation and quality of life. See Table 4 for questions and responses.

Intervention

The intervention was comprised of eight sessions involving psycho-educational lessons and skill-building exercises to accomplish the following goals: understand the benefits of emotional awareness; enhance emotional vocabulary; improve accuracy for describing

personal emotions; acknowledge and differentiate multiple emotions; increase awareness for emotional responses, including changes in physical sensations; and distinguish emotions from thoughts, actions and physical sensations. These objectives were chosen based on the aforementioned characteristics typically associated with alexithymia. A clinical research assistant (RA) delivered the treatment, which was comprised of lessons that were presented on a computer through a 3rd party learning management system, Lesson.ly. The standardized treatment content was outlined on the computer and closely followed by the clinical RA. In order to make the sessions more engaging and natural, the treatment content was not read verbatim; the RA was given the liberty to paraphrase the content. The psycho-educational content was to be used as a guideline for points of discussion; the RA was instructed to address all of these points with the participant as part of their sessions. Elaborated discussions between the RA and participant were encouraged and focused on personalizing the content (i.e. examine how the content applied to them). The RA had the liberty to determine which content needed more or less discussion based on the participants' performance on the session exercises.

The first four lessons focused on teaching the principles underlying the key objectives, followed by interactive discussions and practice exercises. Lessons five through eight were exercises that used first-person perspective videos simulating emotional scenarios to give participants the opportunity to practice processing their emotional responses to events (e.g. getting yelled at by a boss in front of colleagues). See Table 2. An Emotional Compass was used throughout training to guide participants' discovery of their emotions by leading them from vague emotional descriptors (e.g bad) to more specific emotions (e.g. worried). The compass delineates emotions by valence (pleasant and unpleasant) and emotional arousal (high and low). Participants were given a notebook with the lessons, and take home exercises for each session. Take home lessons encouraged participants to personalize and incorporate the lessons into their daily life and to discuss what they learned with their family members.

Procedures

This study was registered on clinicaltrials.gov (NCT02432300) and approved by the Institutional Review Board. Interested participants were prescreened on the telephone; those who met initial screening criteria were scheduled for baseline testing. All participants provided consent prior to baseline testing. At each testing point, the Research Assistant (RA) read the questions from the assessments to participants and hand-recorded their responses. Responses to the LEAS were written and audio recorded for later verification of the subjects' responses. LEAS versions A and B were alternated between assessment time points. To minimize potential bias, the RA who conducted the participant's post-testing was always different from the RA who conducted that person's baseline testing. The "clinical RA" who was responsible for treatment administration never tested participants.

Baseline Testing, Post-test and Follow-up Testing—Following consent, baseline testing involved a demographics and medical history questionnaire, followed by the TAS-20, LEAS, PHQ-9, TAI, PANAS, DERS, and STAXI-2. Participants who scored 52 on the TAS-20 at baseline were enrolled into treatment. Post-testing occurred within one week of

finishing the training program. Follow-up testing aimed to assess participants approximately 2-months after posttest; however due to scheduling conflicts some follow-up testing occurred closer to three and four months later (mean 80.46; range 57–127 days). Baseline and post-testing always occurred in-person at the rehabilitation hospital, with the exception of the final assessments, which could be performed by telephone in order to minimize chances for lost to follow-up; two participants selected this option. Post-testing and follow-up testing involved all of the same assessments as baseline, minus the demographics and medical history form, and with the addition of the satisfaction questionnaire. Participants were also asked at post-test and follow-up about receipt of psychological counseling and any changes in medication.

Intervention—The clinical RA delivering the treatment was a 4th year doctoral psychology student who had experience working with the TBI population. He was trained for 16 hours on treatment delivery, followed by 16 hours of observation and feedback. Sessions lasted between 60–90 minutes and were delivered individually to participants twice a week for 4 weeks. Treatment content was displayed on a computer in order to standardize the information to be covered. The material guided an interactive discussion between the clinical RA and participant. Participants completed skill-building exercises and quizzes on the computer. Visual aids were used to illustrate certain points.

Data Analyses

Descriptive statistics were calculated for participant characteristics, injury related variables, and all outcome variables. Associations of alexithymia with participant characteristics and injury related variables were examined with Pearson correlations. Changes on outcome measures were calculated with repeated measures ANOVA. Greenhouse-Geisser was used to determine significance of within subjects effects when Maulchy's Test of Sphericity was violated. When repeated measures of ANOVA were found significant, planned comparisons were calculated using paired t-tests to evaluate changes from Time 1(baseline) to Time 2 (posttest) and Time 1-Time 3 (2 month follow-up). The alpha level for these comparisons was adjusted for two comparisons (α =.025). The percent of participants who changed in level of severity on the TAS over the course of treatment is reported. Since the other primary outcome measure (LEAS) does not have normative data regarding categorical impairment levels like the TAS, we report the percent of participants who obtained at least a ¹/₂ standard deviation change (effect size of .5). This level of change is considered to be a reasonable estimation of the Minimal Clinically Important Difference (MCID) for a measure in the absence of more definitive determination of the MCID.⁴² Because a primary goal of the study was to determine effect sizes, dCohen effect sizes were calculated for all variables from Time 1-Time 2 and Time 1-Time 3 (.2=small; .5=medium and .8=large effect sizes).⁴³

RESULTS

Participants

Of the 17 participants who were eligible and enrolled into the treatment, 13 participants completed the treatment, resulting in a 23.5% dropout rate. One person reported the day after his first session that he did not like the program, even though he indicated high

satisfaction on the session satisfaction questionnaire; two said they could no longer do it (one after 5 sessions and the other after 1, despite positive feedback on their session satisfaction questionnaires); and the fourth participant had unrelated medical complications that interfered with study participation after his second session. There was a100% retention rate at post-test and follow-up for the participants who completed the treatment.

Between baseline and pretest, three participants continued to receive ongoing psychological counseling (1 to 3 sessions) which had been initiated prior to enrollment; however, according to these participants the sessions did not focus on improving emotional awareness. In terms of medication changes, one participant started an antibiotic. Between post-test and follow-up, five participants continued to receive ongoing psychological counseling which had been initiated prior to enrollment; for three of these participants, sessions did address emotional awareness to some degree. Three participants changed medication between post-test and follow-up; one went off an anti-depressant; one changed antidepressants from tricyclic antidepressant amitriptyline to serotonin reuptake inhibitor sertraline; and one started a pain medication.

Correlations calculated on the 17 enrolled participants showed no significant associations of alexithymia with sex, age, and years of education, years post-injury, self-reported duration of post-traumatic amnesia, or loss of consciousness duration (p>.05).

Post-treatment Changes on Primary Outcome Measures

Repeated measures of ANOVA showed significant improvements on the TAS-20 (alexithymia) and the LEAS (emotional awareness) over time. Additional t-tests revealed that post-test and follow-up scores for both measures were significantly improved from baseline scores, even after adjusting for multiple comparisons (α =.025). Eight (62%) participants changed to a less severe alexithymia category on the TAS-20 at post-test, of which 6 were lowered to normal (<52); five of the six remained in the normal category at 2-month follow-up. Findings also revealed that 46.2% of participants improved by >.5 SD at posttest on the LEAS (6) and 61.5% showed this degree of improvement at 2-month follow-up. See Table 3.

Post-treatment Changes on Secondary Outcome Measures

Findings from the repeated measures of ANOVA showed significant improvements on the TAI (anxiety), STAXI (anger), Positive Affect, and DERS (emotion dysregulation) over time. Scores on the PHQ-9 (depression) and the Negative Affect measures did not change significantly. Greenhouse-Geisser was used to determine within subject effects for the TAI and Negative Affect. Posttest scores were significantly better than baseline for the TAI, STAXI, Positive Affect, and the DERS; after adjusting for multiple comparisons (α =.025), all differences remained significant except the STAXI (p=.027). Two-month follow-up scores were significantly better than baseline for the TAI and Positive Affect; after adjusting for multiple comparisons the TAI was no longer significant (p=.038). See Table 3.

Treatment Satisfaction

Descriptive statistics were calculated for treatment satisfaction at posttest and the 2-month follow-up. Results indicate participants were largely satisfied with the treatment and felt the treatment helped them. See Table 4.

DISCUSSION

Alexithymia and commonly related emotion dysregulation deficits are quite prevalent after TBI.^{1–4,10,12,13} While a few emotion regulation treatment studies in the TBI population have incorporated some emotional self-awareness training, it has typically been a small part of a holistic approach and changes in alexithymia were not evaluated.^{44–48} Consequently, this is the first study to examine proof of concept for a treatment that focused primarily on improving components of alexithymia (e.g. emotional awareness, labeling, interoceptive awareness) in people with TBI.

Participants' emotional self-awareness and ability to describe and differentiate emotions were significantly improved immediately after treatment, and 2-months later. This suggests the benefits were maintained over time. As hypothesized, effect sizes for the TAS and LEAS were quite large at posttest, and medium-to-large 2-months later. Furthermore, 62% of participants reduced the categorical severity of their alexithymia, with 6 participants changing to "low" (normal) alexithymia at post-test, of which five remained in that category 2-months after treatment ended. Almost half (46.2%) of the participants had a clinically meaningful improvement on the LEAS.

Another goal of the study was to examine changes in emotion dysregulation post-treatment. Despite not being explicitly trained to regulate unpleasant emotions as part of this intervention, initial improvements were found for anxiety, positive affect, and overall emotion dysregulation, and there was a trend towards a reduction in anger. Two months posttreatment, significant improvements were maintained for positive affect, and a maintenance trend emerged for anxiety. Although some findings were no longer significant after correcting for multiple comparisons, it should be recalled that effect sizes, not statistical p values, were the primary concern for this phase I trial. Effect sizes immediately after treatment ranged from medium to large for alexithymia, emotional awareness, positive affect, anxiety, and overall emotion regulation (DERS); effect sizes were small for anger. Two months later, positive affect and anxiety effect sizes were still large and medium, respectively. Depression and negative affect did not change significantly at either time point. It is possible that scores on the PHQ-9 did not change substantially because items such as fatigue, sleep, and concentration, may not have actually been indicative of depression, but rather mere effects of the TBI that would not expect to be impacted by this treatment; potentially another measure of depression may have been more appropriate. However, another possibility is that the treatment had different effects on depression in different individuals. Upon closer inspection of the PHQ-9 scores, it appears depression increased for some and decreased for others, averaging to no change. It is possible that increased emotional self-awareness initially resulted in more depression for some individuals, suggesting depression should be monitored during this type of treatment.

When comparing the treatment effects on our primary and secondary outcomes, the distinction between emotional self-awareness and emotion regulation becomes apparent: we observed large immediate and long-term effects for the former, and a few shorter-lived changes for the latter. These preliminary findings suggest that improving emotional awareness and labeling can partially help people to better control some unpleasant emotions, however, it is not sufficient on its own to make a robust and lasting effect. This supports the notion that this type of training should be considered as a precursor or supplement to other techniques that explicitly teach patients how to regulate their emotions. Future work should further investigate the degree of impact that training emotional awareness has on emotion regulation, and to what degree emotion regulation needs to be specifically targeted.

Determining consumer acceptability of interventions is an important component of phase I clinical testing. Responses to post-treatment satisfaction questions, as seen in Table 4, indicate that the 13 participants who completed the treatment were quite satisfied with the program. Ultimately four people withdrew from treatment; however, only one person withdrew from the program because he was dissatisfied with the treatment. The remaining three who withdrew from the program showed high satisfaction on their session satisfaction ratings. Unfortunately, one participant was unable to complete the program due to unrelated medical complications. The other two participants did not elaborate on their reasoning for withdrawing beyond saying they could no longer do it; however, both claimed their decision to withdraw was unrelated to the program. Future studies with ample sample size should continue to explore dropout rates and reasoning for withdraw in order to better understand consumer acceptance of this intervention.

Limitations

The lack of a control group, and not controlling for some potentially confounding variables (medication and outside counseling) clearly prevents us from making any cause-effect inferences about the treatment on the outcomes. It is possible that spending time with our clinical RA could have had an impact on participants' anxiety, positive affect, and overall emotion regulation. With respect to other counseling, their outside sessions during the alexithymia intervention did not focus on emotional awareness (according to the participants), and therefore unlikely the reason for their improvement on the TAS and LEAS at posttest. Further, the fact that the outside sessions were a stable part of these participants' routines pre-study, combined with the low number of sessions between baseline and posttest, also reduce the likelihood they played a significant role in post-test changes.

The small sample size, while adequate to determine effect size, reduces generalization of these results to the larger TBI population. Small sample sizes and within subject designs are considered appropriate for the exploratory stage of this novel intervention. This was a critical stepping-stone, justifying the time and money needed to execute a larger, more definitive study to determine the effectiveness of this novel treatment for alexithymia in the TBI population. Until an adequately powered RCT substantiates these results, current findings should be viewed with caution.

Another study limitation is that most measures were subjective, and due to the nature of being alexithymic (poor emotional awareness), there may be some concern about their

accuracy on the subjective emotional measures. However, it is important to note that even though people with alexithymia may not always be aware of their emotions in the moment, they are often able to acknowledge general emotional deficits. Most are generally aware they have problems with their own emotional awareness (an indicator which qualified them for the study), and are capable of acknowledging symptoms of anxiety, depression and anger as they are described on these measures. That said, having input from caregivers or possibly some objective assessments for behavioral changes would have strengthened the study. However, if participants feel that they had fewer or less severe emotional problems after the treatment, this positive change in self-perception is also meaningful. Moreover, a change on the performance-based LEAS was an objective indicator of improved emotional awareness. Since alternate forms were used for the LEAS, it is unlikely these changes were due to a learning effect.

CONCLUSION

This is the first study to collectively examine post-treatment changes in alexithymia and emotion dysregulation in people with TBI. Post-treatment changes indicated moderate to large effects sizes, with improvements in alexithymia, emotional awareness, anxiety, positive affect and overall emotion regulation. Some of these changes were maintained over two months. These preliminary findings are encouraging, especially since the treatment was only eight sessions and participants were many years post-injury (average almost 9 years). However, further investigation is needed to have a more definitive understanding of the treatment effect. These promising results support the next phase of investigation involving a larger controlled study. If validated through a controlled study, this training program has the potential to have a substantial impact on the way emotion dysreguation deficits are treated after TBI. It is anticipated that this type of intervention would not be administered in isolation. If it is found that this treatment can help people with TBI effectively recognize and describe their emotions, additional studies should evaluate the benefit of adding it as a precursor to treatments that explicitly teach modification of unpleasant emotional responses (e.g CBT), to achieve a more robust effect on both emotion awareness and regulation.

Acknowledgments

This work is supported by NIH NICHD/ NCMRR STTR Phase I grant 1R41HD077967-01A1 and the Indiana University Funding Opportunities for Research Commercialization and Economic Success

Disclosures: Dr. Neumann is the owner of a small business funded by an NIH STTR Phase I grant. She was financially compensated for efforts pertaining to this research and has a commercial interest in the training program described in the manuscript. Drs. Malec and Hammond, and Mr. Langston received funds through Indiana University's subcontract with the business for their work on this project.

The authors thank Dr. Ronald Levant for sharing his expertise in alexithymia; Dr. Susan Perkins who provided statistical consultation; and Trevor Langston, MS who delivered the intervention to the participants.

REFERENCES

 Ashman TA, Gordon WA, Cantor JB, Hibbard MR. Neurobehavioral consequences of traumatic brain injury. Mount Sinai Journal of Medicine. 2006; 73(7):999–1005. [PubMed: 17195886]

- Baguley IJ, Cooper J, Felmingham K. Aggressive behavior following traumatic brain injury How Common Is Common? Journal of Head Trauma Rehabilitation. 2006; 21(1):45–56. [PubMed: 16456391]
- Draper K, Ponsford J, Schönberger M. Psychosocial and emotional outcomes 10 years following traumatic brain injury. The Journal of head trauma rehabilitation. 2007; 22(5):278–287. [PubMed: 17878769]
- Rao V, Rosenberg P, Bertrand M, et al. Aggression after traumatic brain injury: prevalence and correlates. The Journal of neuropsychiatry and clinical neurosciences. 2009; 21(4):420–429. [PubMed: 19996251]
- 5. Hammond FM, Davis CS, Whiteside OY, Philbrick P, Hirsch MA. Marital Adjustment and Stability Following Traumatic Brain Injury: A Pilot Qualitative Analysis of Spouse Perspectives. The Journal of Head Trauma Rehabilitation. 2011; 26(1):69. [PubMed: 21209564]
- Wedcliffe T, Ross E. The psychological effects of traumatic brain injury on the quality of life of a group of spouses/partners. S Afr J Commun Disord. 2001; 48:77–99. [PubMed: 14968697]
- Wells R, Dywan J, Dumas J. Life satisfaction and distress in family caregivers as related to specific behavioural changes after traumatic brain injury. Brain Inj. 2005; 19(13):1105–1115. [PubMed: 16286324]
- Winkler D, Unsworth C, Sloan S. Factors that lead to successful community integration following severe traumatic brain injury. Journal of Head Trauma Rehabilitation. 2006; 21(1):8–21. [PubMed: 16456388]
- 9. Wood RL, Liossi C, Wood L. The impact of head injury neurobehavioural sequelae on personal relationships: preliminary findings. Brain Inj. 2005; 19(10):845–851. [PubMed: 16175844]
- Neumann D, Zupan B, Malec JF, Hammond F. Relationships between alexithymia, affect recognition, and empathy after traumatic brain injury. The Journal of Head Trauma Rehabilitation. 2014; 29(1):E18–E27.
- Bagby RM, Parker JDA, Taylor GJ. The 20-Item Toronto-Alexithymia-Scale .1. Item Selection and Cross-Validation of the Factor Structure. Journal of Psychosomatic Research. 1994; 38(1):23–32. [PubMed: 8126686]
- Williams C, Wood RL. Alexithymia and emotional empathy following traumatic brain injury. Journal of Clinical and Experimental Neuropsychology. 2010; 32(3):259–267. [PubMed: 19548166]
- Wood RL, Doughty C. Alexithymia and avoidance coping following traumatic brain injury. The Journal of head trauma rehabilitation. 2013; 28(2):98–105. [PubMed: 22495103]
- Kokkonen P, Karvonen JT, Veijola J, et al. Prevalence and sociodemographic correlates of alexithymia in a population sample of young adults. Comprehensive psychiatry. 2001; 42(6):471– 476. [PubMed: 11704938]
- Henry J, Phillips L, Crawford J, Theorodou G, Summers F. Cognitive and psychosocial correlates of alexithymia following traumatic brain injury. Neuropsychologia. 2006; 44:62–72. [PubMed: 15896816]
- Koponen S, Taiminen T, Honkalampi K, et al. Alexithymia after traumatic brain injury: its relation to magnetic resonance imaging findings and psychiatric disorders. Psychosomatic Medicine. 2005; 67(5):807–812. [PubMed: 16204442]
- Neumann D, Malec JF, Hammond FM. The relationship of aggression with alexithymia, depression, and anxiety after traumatic brain injury. Journal of Head Trauma Rehabilitation. 2016 Jul. In press.
- Fakra E, Salgado-Pineda P, Delaveau P, Hariri AR, Blin O. Neural bases of different cognitive strategies for facial affect processing in schizophrenia. Schizophrenia Research. 2008; 100(1–3): 191–205. [PubMed: 18234477]
- Foland-Ross LC, Altshuler LL, Bookheimer SY, et al. Amygdala reactivity in healthy adults is correlated with prefrontal cortical thickness. The Journal of neuroscience. 2010; 30(49):16673– 16678. [PubMed: 21148006]
- 20. Hariri AR, Bookheimer SY, Mazziotta JC. Modulating emotional responses: effects of a neocortical network on the limbic system. Neuroreport. 2000; 11(1):43. [PubMed: 10683827]

- Hariri AR, Tessitore A, Mattay VS, Fera F, Weinberger DR. The amygdala response to emotional stimuli: a comparison of faces and scenes. Neuroimage. 2002; 17(1):317–323. [PubMed: 12482086]
- 22. Levant RF, Halter MJ, Hayden EW, Williams CM. The efficacy of alexithymia reduction treatment: A pilot study. The Journal of Men's Studies. 2009; 17(1):75–84.
- 23. Prince, L., Ford, C. Can alexithymia be improved? A case study. Poster presented at 9th Conference of the Neuropsychological Rehabilitation Special Interest Group of the World Federation for NeuroRehabilitation; July 2012; Bergan; Norway.
- 24. Whyte J, Gordon W, Rothi LJG. A phased developmental approach to neurorehabilitation research: the science of knowledge building. Archives of physical medicine and rehabilitation. 2009; 90(11):S3–S10. [PubMed: 19892072]
- 25. Julious SA. Sample size of 12 per group rule of thumb for a pilot study. Pharmaceutical Statistics. 2005; 4(4):287–291.
- Malec JF, Brown AW, Leibson CL, et al. The Mayo classification system for traumatic brain injury severity. Journal of Neurotrauma. 2007; 24(9):1417–1424. [PubMed: 17892404]
- Bagby RM, Taylor GJ, Parker JDA. The 20-Item Toronto-Alexithymia-Scale .2. Convergent, Discriminant, and Concurrent Validity. Journal of Psychosomatic Research. 1994; 38(1):33–40. [PubMed: 8126688]
- Lane RD, Quinlan DM, Schwartz GE, Walker PA, Zeitlin SB. The Levels of Emotional Awareness Scale: a cognitive-developmental measure of emotion. J Pers Assess. 1990; 55(1–2):124–134. [PubMed: 2231235]
- Barchard KA, Bajgar J, Leaf DE, Lane RD. Computer scoring of the levels of emotional awareness scale. Behavior Research Methods. 2010; 42(2):586–595. [PubMed: 20479190]
- Radice-Neumann D, Zupan B, Tomita M, Willer B. Training emotional processing in persons with brain injury. Journal of Head Trauma Rehabilitation. 2009; 24(5):313–323. [PubMed: 19858965]
- Torrado M, Ouakinin S, Lane R. Measuring emotional awareness from a cognitive-developmental perspective: Portuguese adaptation studies of the Levels of Emotional Awareness Scale. Acta Médica Portuguesa. 2013; 26(2):145–153. [PubMed: 23809747]
- Spielberger, CD., Gorsuch, RL., RE, L. Manual for the State-Trait Anxiety Inventory. Palo Alto, CA: Consulting Psychologists Press; 1970.
- 33. Spielberger, CD., Reheiser, EC., Ritterband, LM., Sydeman, SJ., Unger, KK. Assessment of Emotional States and Personality Traits: Measuring Psychological Vital Signs, Clinical Personality Assessment: Practical Approaches. Butcher, JN., editor. New York: Oxford University Press; 1995.
- 34. Beck, AT.Steer, RA., Brown, GK., editors. The Beck Depression Inventory-Second Edition. San Antonio, TX: The Psychological Corporation; 1996.
- Fann JR, Bombardier CH, Dikmen S, et al. Validity of the Patient Health Questionnaire-9 in assessing depression following traumatic brain injury. The Journal of Head Trauma Rehabilitation. 2005; 20(6):501–511. [PubMed: 16304487]
- Kroenke K, Spitzer RL, Williams JBW. The PHQ-9. Journal of General Internal Medicine. 2001; 16(9):606–613. [PubMed: 11556941]
- Etzler SL, Rohrmann S, Brandt H. Validation of the STAXI-2: A study with prison inmates. Psychological Test and Assessment Modeling. 2014; 56(2):178.
- Spielberger, CD. Manual for the State-trait Anger Expression Inventory-2 (STAXI-2). Odessa, FI: Psychological Assessment Resources; 1999.
- Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: The PANAS scale. Journal of Personality and Social Psychology. 1988; 54:1063– 1070. [PubMed: 3397865]
- Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: the PANAS scales. J Pers Soc Psychol. 1988; 54(6):1063–1070. [PubMed: 3397865]
- Gratz KL, Roemer L. Multidimensional assessment of emotion regulation and dysregulation: Development, factor structure, and initial validation of the difficulties in emotion regulation scale. Journal of Psychopathology and Behavioral Assessment. 2004; 26(1):41–54.

- Jaeschke R, Singer J, Guyatt GH. Measurement of health status: ascertaining the minimal clinically important difference. Controlled clinical trials. 1989; 10(4):407–415. [PubMed: 2691207]
- 43. Cohen, J. Statistical Power Analysis for the Behavioral Sciences. Hillsdale, New Jersey: Lawrence Erlbaum Associates; 1988.
- 44. Cantor J, Ashman T, Dams-O'Connor K, et al. Evaluation of the short-term executive plus intervention for executive dysfunction after traumatic brain injury: a randomized controlled trial with minimization. Archives of physical medicine and rehabilitation. 2014; 95(1):1–9. e3. [PubMed: 23988395]
- 45. Hart T, Vaccaro MJ, Hays C, Maiuro RD. Anger self-management training for people with traumatic brain injury: a preliminary investigation. The Journal of head trauma rehabilitation. 2012; 27(2):113–122. [PubMed: 21407088]
- 46. Medd J, Tate RL. Evaluation of an anger management therapy programme following acquired brain injury: A preliminary study. Neuropsychological Rehabilitation. 2000; 10(2):185–201.
- Walker AJ, Nott MT, Doyle M, Onus M, McCarthy K, Baguley IJ. Effectiveness of a group anger management programme after severe traumatic brain injury. Brain Injury. 2010; 24(3):517–524. [PubMed: 20184408]
- Tsaousides T, D'Antonio E, Varbanova V, Spielman L. Delivering group treatment via videoconference to individuals with traumatic brain injury: A feasibility study. Neuropsychological rehabilitation. 2014; 24(5):784–803. [PubMed: 24810148]

Demographic and medical history. N=17 unless otherwise specified.

	Participants enrolled in treatment (n=17) Mean (S.D.) or % (raw)		
Age	46.12 (11.41)		
Sex (% male)	76.5% (13)		
Education (years)	14.06 (2.36)		
Race			
%White	94.1% (16)		
% Other	5.9% (1)		
Cause of Injury			
Motor Vehicle Accident	44% (8)		
Fall	32% (5)		
Assault	8% (1)		
Other	16% (3)		
Years post-injury	8.73 (8.10)		
PTA (days)	95.35 (187.45)		
Loss of Consciousness (days)	14.18 (25.39)		
Abnormal neuroimaging (n=13)			
% Cerebral Contusion	23% (3)		
% Hematoma	46% (6)		
% Post-traumatic Hemorrhage	77% (10)		

Intervention Components. All sessions (aside from session 1) started with a review of take home exercises and ended with assigning the next take home exercise.

Lesson	Activity				
Lesson 1:	• Benefits of emotional awareness: better emotional control, better relationships, coping, quality of life, decision- making				
	Emotional responses: Triggers, sensations, emotions; and behavior				
	Definition of alexithymia				
	• Emotional vocabulary Part I: vague emotions versus specific emotions; presentation of some common emotions, their definitions, and synonyms that participants are asked to use in sentences.				
Lesson 2:	Review of Emotional vocabulary Part I				
	• Emotional vocabulary Part II: presentation of more common emotions, their definitions, and synonyms that participants are asked to use in sentences.				
	• Differentiating emotions from thoughts, actions and physical sensations.				
Lesson 3:	• Physical sensation awareness, emotional arousal, and association to emotions (Part I);Exercises to increase awareness of heart rate, body temperature, breathing, body movement and overall emotional arousal (e.g. Body scan)				
Lesson 4:	Physical sensation awareness and association to emotions (Part II)				
	• Multiple emotions, differentiating emotions, and emotions beyond anger				
Lessons 5–8	Simulated first person point of view emotional scenarios, followed by discussions of thoughts, desired actions, physical sensations, and emotional responses in response to the scenarios. Afterwards, participants described similar personal events and their emotions, thoughts, actions and feelings response.				

Descriptive Statistics, Repeated Meaures ANOVA and Paired test results, and effects sizes.

	Baseline (T1) Mean (S.D.)	Post- test (T2) Mean (S.D.)	Follow-up (T3) Mean (S.D.)	Repeated Measures ANOVA (partial eta squared) Paired t-tests (dCohen Effect Size)
TAS-20 (Alexithymia)	61.54 (7.26)	52.54 (11.95)	54.62 (12.38)	F=7.688, p=.003 (.390) T1-T2: t=3.527, p=.004 (-1.240)* T1-T3: t=2.688, p=.020 (953)*
LEAS (Emotional Awareness)	36.92 (7.88)	44.23 (5.23)	42.23 (8.29)	F=11.76, p<.001 (.495) T1–T2: t=–4.766, p<.001.(.928)* T1–T3: t=–2.894, p=.013 (.674)*
PHQ-9 (Depression)	10.77 (4.82)	9.69 (5.25)	10.31 (5.89)	F=.411, p=.668 (.033) T1–T2: (–.224) T1–T3: (–.095)
TAI (Trait Anxiety t-score)	68.38 (11.45)	61.54 (12.08)	62 (15.15)	F=6.640, p=.014 (.356) T1–T2: t=3.715, p=.003 (597) * T1–T3: t=2.336, p=.038 (557)
STAXI Index t- score (anger)	56.31 (11.40)	52.31 (10.42)	56.46 (11.11)	F=4.995, p=.015 (.294) T1–T2: t=2.523, p=.027 (351) T1–T3: t=099, p=.923 (.013)
Positive Affect	25.85 (6.49)	31.77 (8.96)	31 (10.08)	F=6.655, p=.005 (.357) T1-T2: t=-3.211, p=.007 (.924)* T1-T3: t=-3.022, p=.011 (.803)*
Negative Affect	23.23 (7.6)	19.69 (7.34)	19.85 (7.22)	F=2.674, p=.121 (.182) T1-T2: (466) T1-T3: (445)
DERS (Emotion Dysregulation)	97.77 (21.43)	84.08 (25.36)	87.31 (24.33)	F=4.601, p=.020 (.277) T1-T2: t=2.618, p=.022 (639)* T1-T3: t=2.171, p=.051 (488)

* Indicates differences that remained significant after adjusting for multiple comparisons.

Satisfaction Questions and Responses

Post-test Satisfaction Questions (5-point Liker scale to rate their level of agreement (1=Strongly Disagree; 2=Disagree; 3=Neutral; 4=Agree; 5=Strongly Agree)	Mean (S.D.) % Agreed/ Strongly agreed (N=13)
I am satisfied with the information in this training program	4.62 (.506)100%
The lessons taught in the training are relevant to my needs	4.62 (.650) 92.3%
I will try to use lessons I learned in my daily life	4.69 (.630) 92.3%
The information provided was easy to understand	4.08 (.760) 77%
If a friend or family member was in need of similar help, I would recommend the program to him or her	4.62 (.506) 100%
I think the training program has helped me to deal more effectively with my emotions	4.38 (.768) 85%
Follow-up Satisfaction Questions	Mean (S.D.)
How often would you say you have used the skills you were taught in the training program in the last several months (1=Never; 2=Not often; 3=Often; 4=Very often)	3.15 (.689) 85% often or very often
Generally speaking, how much do you think the training program has helped you in the last several months? (1=Did not help; 2=helped a little; 3=moderately helpful; 4=helped a lot)	3.00 (.707) 77% moderately helpful to helped a lot
Since the training, I feel my quality of life has improved as a result of the information I learned in this program. (1=Strongly Disagree; 2=Disagree; 3=Neutral; 4=Agree; 5=Strongly Agree)	4.08 (.641) 85% agreed or strongly agreed