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Intervention to Change Attributions that are Negative (ICAN): A Feasibility Study on Reducing Anger After Brain Injury

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Abstract
Objectives: Explore the early efficacy of a treatment to modify anger, aggression, negative attributions, and perspective-taking in participants with traumatic brain injury (TBI). **Design:** Randomized waitlist-controlled trial. **Participants:** Twenty-four adults with a TBI (≥ 1-year post-injury) who had above average aggression and either negative attribution bias or poor perspective-taking. **Intervention:** Intervention to **C**hange **A**ttributions that are **N**egative (ICAN). **Measures**: Epps Scenarios (attributions of intent, hostility, blame; anger and aggression responses); Aggression Questionnaire (AQ); PROMIS-Anger; Interpersonal Reactivity Index Perspective-taking; and Participant Global Impression of Change (PGIC) for anger and perspective-taking. **Results**: Twenty-one participants completed the study (ICAN = 8; Waitlist control [WLC] = 13). Post-treatment, ICAN participants had lower anger responses to Epps Scenarios ($p = 0.03$) compared to WLC participants who had not yet received treatment. Other between-group comparisons were not significant. Analyses comparing pre/post-intervention changes in the pooled sample (n=21), revealed reduced attributions of intent ($p < 0.01$) and blame ($p = 0.05$), and anger ($p = 0.01$) and aggression responses to Epps scenarios ($p < 0.01$) after receiving treatment. Post-intervention scores on the AQ and PROMIS-Anger were also significantly reduced ($p < 0.01$). On the PGIC, 83% and 45% reported noticeable changes in perspective-taking and anger, respectively. **Discussion**: ICAN may reduce anger and negative attributions after TBI and merits further investigation.

Keywords anger; aggression; attributions; empathy; brain injury

A traumatic brain injury (TBI) is caused by an external force that results in disrupted brain function (e.g., a motor vehicle accident, fall, assault) (Langlois et al., 2006). *Traumatic* brain injuries do not include other types of acquired brain injuries that result from non-external sources (e.g., strokes, brain tumors, hypoxia). While individuals with TBI often experience a broad range of deficits, problems with anger and aggression are among the most common and challenging sequelae, and are often chronic (Neumann et al., 2017b; Rao et al., 2009). Anger and aggression are interrelated constructs in which the former represents an emotional response, and the latter is a behavioral response that can be verbal or nonverbal (Buss & Warren, 2000). One study in participants with TBI found that 39%, 41%, and 26% had anger, verbal aggression, and physical aggression scores, respectively, that were above average (Neumann et al., 2017b). In this study, "above average" was defined as having T scores that fell into classifications ranging from "High Average" to "Very High" defined by the Aggression Questionnaire manual (Buss & Perry, 1992).

Anger and aggression after TBI have been associated with relationship problems, caregiver burden, social isolation, criminal behaviors, arrests, and difficulty acquiring and sustaining employment

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(Alderman, 2003; Burke et al., 1988; Demark & Gemeinhardt, 2002; Eames & Wood, 2003; Felmingham et al., 2001; Harris, 1997; Khan et al., 2003; Lezak, 1987; Lezak & O'Brien, 1988; Oddy et al., 1985; Prigatano, 1987; Sansone et al., 2012; Slaughter et al., 2003; Winkler, 2006). Considering the prevalence and negative impact of anger and aggression on outcomes after TBI, it is critical to have clinically relevant evidence-based treatments for these issues. The evidence for interventions designed to reduce anger aggression after TBI (e.g., cognitive behavioral therapy, problem solving, self-monitoring) is currently largely inconclusive due to studies having small sample sizes, lack of rigorous designs, contradictory findings, and / or small advantages compared to control groups (Aboulafia-Brakha et al., 2013; Alderman, 2003; Hart et al., 2017; Hart et al., 2020; Hart et al., 2012; Medd & Tate, 2000; Persel et al., 1997; Walker et al., 2010). As such, there is still a major need for continued discovery of mechanisms and interventions that can help improve outcomes for anger and aggression in the TBI population.

Recent research in participants with TBI has linked some of their anger and aggression to negative attributions, or appraisals, that they make about others' behavior (Neumann et al., 2017a; Neumann, Sander, Perkins, et al., 2021; Neumann et al., 2020; Neumann, Sander, Witwer, et al., 2021). Specifically, the more participants with TBI perceived others' actions (in a hypothetical situation) to be intentional or hostile, or the more they felt others' actions were to blame for a negative outcome, the stronger their anger response (Neumann et al., 2017a). The negative attributions made by participants explained a large percent of the variance observed in their anger responses to the situations (50% - 75%) (Neumann et al., 2017a; Neumann, Sander, Perkins, et al., 2021). Related research has further shown that when participants with TBI were asked how they would respond to the hypothetical situations, their self-reported anticipated reactions were more aggressive than participants without TBI (Neumann et al., 2020). Similar to their anger responses, these aggressive behavioral reactions were significantly associated with the negative attributions they made about the person's actions (Neumann et al., 2020). The relationship between attributions and aggression was further substantiated in a study showing that negative attribution scores are a fairly accurate indicator of whether or not an individual has above-average trait aggression (Neumann, Sander, Witwer, et al., 2021).

The relationship of negative attributions with anger and aggression after TBI is consistent with attribution theories of emotion and similar to findings in the general population (Combs et al., 2007; De Castro et al., 2002; Dodge, 2006; Jeon et al., 2013; Kelley & Michela, 1980). However, some individuals have a tendency to perceive others' actions as more negative than what might be expected or warranted for the situation (negative attribution bias); this type of bias is often observed in individuals with affective disorders and conduct disorders (An et al., 2010; Bailey & Ostrov, 2008; Dodge, 2006; McNiel et al., 2003; Steinberg & Dodge, 1983). Research suggests participants with TBI may also be susceptible to negative attribution biases. For instance, our studies have shown that compared to controls without TBI, on average, participants with TBI judge others' behaviors as more intentional, hostile, and blameworthy, even in situations when people's actions are described as benign or unclear (Neumann et al., 2017a; Neumann, Sander, Perkins, et al., 2021; Neumann et al., 2020). Findings from one of our earlier studies suggests that negative attribution biases after TBI may be related to impairments with interpreting others' mental states (i.e., deficits in social inferencing, sometimes referred to as Theory of Mind or Mentalizing) (Neumann, Sander, Perkins, et al., 2021). In this study, the less accurate participants were at interpreting what others were trying to do and say, and inferring what others were thinking and feeling, the more intentional and hostile they judged others' actions to be. In sum, people with TBI are prone to distorted negative attributions, which in turn, appear to be contributing to <u>*some*</u> of their problems with anger and aggression. In other words, negative attributions appear to be one mechanism partially contributing to anger and aggression after TBI, and therefore should be targeted as part of treatment.

To address post-TBI anger and aggression that is associated with negative attributions, an intervention (Perspective Training) was created and initially examined as part of a two-person case study (Winegardner et al., 2016). The treatment taught participants to think about and experience situations from other people's perspectives (perspective-taking) as a way to generate alternative explanations and more benign interpretations (or social inferences) of others' actions. Both participants in the case study showed substantial reductions in their aggression after participating in the intervention. The current study sought to build support for the Perspectives Training, which was renamed as *Intervention to Change Attributions that are Negative (ICAN)*. The aims of this randomized waitlist-controlled trial in participants with TBI who had co-existing problems with aggression and negative attributions were to explore the feasibility and acceptability of the ICAN intervention, as well as to determine effect sizes of ICAN on negative attributions, perspective-taking, anger, and aggression. When available, feedback was also sought from care-partners/ observers on changes in observed anger and

aggression, perspective-taking and empathy. We hypothesized ICAN would be found feasible and acceptable. We set a benchmark of medium effect sizes on outcomes of interest, as we believed this would be indicative of change that was substantial enough to justify a larger trial.

Method

Design

This was a single site study conducted at a rehabilitation facility for patients with brain injury. The research design was a randomized waitlist-controlled trial with 4 data collection timepoints (Time 0, Time 1, Time 2, and Time 3). The study was conducted in four consecutive waves (n = 6-8 participants per wave). For each wave, participants were randomized after Time 1 data collection. Participants randomized to the ICAN group started the intervention within two weeks after Time 1 testing; those randomized to the Waitlist control (WLC) group started treatment after Time 2. Only WLC participants completed Time 3 data collection. Some data regarding the behavior of participants with TBI was collected from available care-partners/observers. Care-partners/observers could be a family member, spouse, or close friend with whom the participant interacted with on a regular basis. This study was approved by the University's Institutional Review Board and all participants with TBI provided informed consent prior to their participation. This study was registered on clinicaltrials.gov (NCT03648476).

Sample

Twenty-four participants with TBI who met inclusion criteria were enrolled into the study and randomized to ICAN or WLC. To be included in the study, participants had to be ≥ 18 years old and ≥ 1-year post-TBI. Participants had to have a history of complicated mild to severe TBI, with injury severity being defined either by (Malec et al., 2007) Glasgow Coma Score at time of injury (≤ 12), or post-traumatic amnesia (≥ 1 day), or loss of consciousness (≥ 30 minutes), or positive head CT scan consistent with TBI. Participants also had to have above average aggression (>55 T score on the Aggression Questionnaire- Total or subscale). Because ICAN was designed to treat anger that is related to negative attributions and poor perspective taking, participants also had to have screening scores that suggested problems in one of these areas: negative attribution scores on the Epps (Epps & Kendall, 1995) or the Ambiguous Intentions Hostility Questionnaire (Combs et al., 2007), or poor perspective-taking on the Interpersonal Reactivity Index subscale (Davis, 1983). Participants also had to demonstrate adequate comprehension determined with the Discourse Comprehension Test (Brookshire & Nicholas, 1993), which was evaluated during screening. Medications had to be stable for 30 days prior to their participation. Participants also had to have a reliable mode of transportation. Based on self-report or medical record review, participants were excluded for pre-morbid neurological disorders that could affect mood and/or cognition (e.g., stroke); progressive central nervous system disorders; developmental disability; major psychiatric disorders; severe depression and / or perceived risk to self or others; or receiving active treatment for anger or currently participating in any other clinical research trial for irritability, anger or aggression. Participants were excluded if they did not have adequate vision, hearing, and speech/ language skills to participate in assessments and group therapy, which was determined based on interaction with the participant at screening. Although the study sought input from available care-partners/ observers regarding participants' anger and empathy, having a care-partner / observer was not required for study inclusion. Care-partners/observers were not considered subjects themselves as they only answered questions about the participant with the TBI and not themselves.

Measures

Outcome Measures.

Aggression Questionnaire (AQ; Buss & Warren, 2000). The AQ is a standardized measure comprised of 34 statements to assess overall aggression and the following subcomponents: anger, hostile thoughts, and physical and verbal aggression. Participants rate statements using a 5-point scale. Raw and scaled scores (adjusted by age and gender) are provided for aggression subcomponents and total aggression. Total aggression scaled T scores were used to analyze outcomes. The AQ is a widely used and accepted aggression measure, including for TBI studies (Dyer et al., 2006; Greve et al., 2001; Holtzworth-Munroe et al., 2000; Hoptman et al., 2009; Palmer & Thakordas, 2005). It has good test-retest reliability (.72-.80) and good internal consistency (.76-.94) (Buss & Warren, 2000). The AQ was the designated primary outcome measure because changing overall aggressive behavioral tendencies was of greater interest than changing anger affect (captured by the PROMIS-Anger measure and angry responses to Epps scenarios).

PROMIS-Anger_(Pilkonis et al., 2011). This 5-item subjective questionnaire requires participants to indicate the frequency they experienced anger symptoms in the past week using a 5-point Likert scale. Developed as part of National Institutes of Health (NIH) initiatives for better outcomes measurement, this tool has good validity and reliability (Pilkonis et al., 2011).

Epps Scenarios (Epps & Kendall, 1995). Epps Scenarios are 21 brief hypothetical scenarios which

portray benign, ambiguous, and hostile behaviors. On a 9-point scale, participants rated how angry they would be if the scenario happened to them, followed by how hostile and intentional they felt the character's behavior was and how much they blamed the character for the outcome. To measure anticipated level of aggression in response to the scenarios, participants were also asked an open-ended question as to what they would do if this happened to them. This item was later scored for aggression by a trained rater who was blinded to randomization. Epps Scenarios have been found to have acceptable construct and predictive validity in the TBI population (Neumann, Sander, Witwer, et al., 2021).

Perspective-Taking subscale of the Interpersonal Reactivity Index (IRI; Davis, 1980, 1983). The IRI is a subjective questionnaire that measures perspective-taking, empathic concern, fantasy, and personal distress. Only questions from the perspective-taking subtest were evaluated. Participants with TBI and care-partners/ observers completed this survey. Participants with TBI rated how well statements described them, and care-partners/ observers reported how well the statements described the person with TBI. The IRI has good test-retest reliability and internal reliability (Davis, 1980, 1983).

Global Impression of Change (Knapp et al., 1994; Solomon et al., 2002). The Patient Global Impression of Change (PGIC) and Caregiver Global Impression of Change (CaGIC) were used to determine overall sense of change in the participant's 1) anger/aggression and 2) perspective-taking / empathy after treatment as rated by participants with TBI and their care-partners/ observers, respectively. A 7-point Likert scale was used to rate the degree of change (1=no change; 7=a great deal better). Because this survey asks about post-treatment change, it was only administered to participants after receiving the intervention. See Table 1.

Client Satisfaction Questionnaire (CSQ-8; Larsen et al., 1979). The CSQ-8 is a 4-point Likert scale that participants use to answer questions about perceived satisfaction with the program (e.g., To what extent has our program met your needs?; Have the services you received helped you to deal more effectively with your problems? In an overall, general sense, how satisfied are you with the service you have received?). Higher scores indicate greater satisfaction. The test has good reliability and validity (Larsen et al., 1979).

Subsidiary Measures.

Depression. The Patient Health Questionnaire-9 (PHQ-9)(Kroenke et al., 2001) was used to assess depression. This self-report measure uses a 3-point Likert scale (maximum score 27) and has established validity and reliability, including in the TBI population (Fann et al., 2005; Kroenke et al., 2001). Participants rate the frequency of specified problems during the past 2 weeks.

Cognitive Measures. A limited set of cognitive assessments were administered due to time constraints, which prohibited a more extensive cognitive evaluation. The following measures of attention and executive control were selected because of their relations to negative attributions in earlier work (Neumann, Sander, Perkins, et al., 2021). The Stroop Color-word interference test (Scarpina & Tagini, 2017; Stroop, 1935) was used to assess attention and disinhibition. Verbal fluency was examined with letter and category fluency tests. Letter fluency was evaluated with the Controlled Oral Word Association Test (COWAT; F-A-S) (Spreen & Strauss, 1991). The COWAT is a measure of verbal fluency that requires participants to generate as many words as they can think of, in one minute, that start with a specific letter, while adhering to certain rules such as giving no proper names. There are three letter trials and the total score is the number of words recalled across the three trials. For Category Fluency participants were required to generate the names of as many animals they could think of in one minute, followed by two other trials requiring generation of fruits and vegetables, respectively (Lucas et al., 1998). The total score is the number of examples generated across the three trials.

ICAN Intervention

The ICAN intervention is comprised of six two-hour group therapy sessions that were delivered by two co-facilitators once a week for six weeks (See supplemental Table 1 for description of the structure and sessions). Groups ranged in size between two to four participants. The facilitators followed a treatment manual, which outlined session content and exercises. During all sessions, content and exercises were visually shared with participants via a power point display on a large screen television. Participants were also provided a notebook with lesson content and exercises. Session 1 began with a process to set the stage (described below). All sessions included a review of ICAN's core principles, followed by two interactive exercises. ICAN's Core Principles were: ICAN put myself in someone else's shoes; ICAN change my perspective; ICAN change how I think about others' actions; ICAN change how I feel about others' actions; ICAN change how angry I get about others' actions; and ICAN change how I react to others' actions. ICAN's two key exercises were: 1) Role-playing exercises with video-based scenarios; 2) Perspective-positioning exercises with personal experiences. After the second exercise, a brief calming exercise was often conducted. To assist in helping participants to remember important concepts, as well as generalize strategies in their personal environments, the last part of each session was

spent in review; additionally, participants were asked to reflect on the lessons and exercises in-between sessions.

Setting the Stage (Session 1 Only). At the start of Session 1, an ice-breaking exercise was conducted to help participants feel comfortable and establish rapport with others. This was followed by a review of group expectations (e.g., coming on time, confidentiality) and housekeeping items (e.g., what to do in case of inclement weather or an emergency). Psychoeducation was then provided on the nature and normality of anger after brain injury; common triggers for anger; the relationship between anger and the inferences made about others' behaviors; what perspective-taking is; and how perspective-taking can help to better understand and consider more benign reasons for others' behaviors. Next, the overall goals of the intervention were reviewed, which were to: help them see situations from others' perspectives; help them learn to interpret others' actions in a more positive way; teach them to give others the benefit of the doubt; and reduce their anger and change how they respond to others' actions. This was followed by an introduction to ICAN's Core Principles (described above). Next, participants were asked to identify their reason or motivation to work on reducing their anger. They were asked to write this down in their notebooks as a means to be able to continually relate their reasons for participating in this program to the goals of the program.

ICAN Exercises (Sessions 1-6; More information in Supplemental Table 2).

1. Role-Playing Exercise (Video Scenarios). Each session, participants were shown a short video clip, lasting approximately 60 seconds. These video clips, which were mostly acquired from YouTube, were selected by the primary author, and were mutually agreed upon by the group facilitators (S.B. and B.H.) and one of the co-authors who was the original creator of the intervention (J.W.). Criteria for the video clips were that they needed to depict an unpleasant scenario in which an actor's motives (i.e., the 'perpetrator') were ambiguous towards a person who was a perceived victim of the action (e.g., someone bumped into you; took a parking spot you wanted). After watching the video clip, participants were asked to generate and write down as many possible motives on their own for the 'perpetrator's' behavior. They were also asked to write down how they would have felt if the situation happened to them. Next, the group brainstormed together on reasons for the perpetrator's behavior. Ideas were written on a large whiteboard for all to see. After the brainstorming activity, the group agreed on the most benign reason for the action, which was then used to carry out role-playing exercises. Each participant engaged in the role-play activity twice, with slightly different approaches. For the first role play, the perpetrator (played by one of the facilitators) explicitly stated the benign reason for their behavior. For example, in this role-play exercise, the facilitator would bump into the participant, and the facilitator would say: "I'm sorry. I just lost my balance". After participants took turns, they were asked questions to help them process this experience. They were asked questions like: "What changed for them?; Did they feel different hearing a more benign explanation for someone's 'ambiguous' behavior?; Did they notice anything about themselves?". In the second version of the role-play activity, the participant was instructed to just think the benign thought to themselves. The reason for this second version is that it more likely mimics real-life scenarios in that people often do not share why they do things. When we are recipients of others' behaviors, we have to practice interpreting those actions with a "benefit-of-the-doubt" mentality. Participants took turns in this version of the role-playing activity, after which they were asked to process their thoughts and feelings (e.g., How did that feel? Was it harder this time and what felt harder? Were they able to maintain their belief that the behavior was benign?). Facilitators demonstrated these role-playing exercises before the participants were asked to participate.

2. Perspective-Positioning Exercise (Personal Experiences). This exercise, a modified Gestalt two-chair technique, (Wagner-Moore, 2004) was facilitated by one of the group facilitators who was a psychologist. It usually took somewhere between 15-30 minutes to complete, depending on the complexity of the situation, insight of the participant, and how emotionally provoked the participant became during the exercise. As such, for most sessions only 1-2 participants would have the opportunity to do this activity. Facilitators made a concerted effort to ensure that all participants had a chance to take part in this exercise at least a couple of times during the course of the intervention. Participants were asked to come to the session prepared with personal situations in which someone's behaviors led to an unpleasant outcome for the participant, and possibly perceived as purposeful. During this exercise, the participant started off by expressing their own thoughts and feelings (self-perspective) about the situation represented by the imagined person sitting in one chair (Chair A), followed by physical repositioning to a second chair (Chair B) to express thoughts and feelings as the other person. The group facilitator 'moves' the participant through each of the perspectives, using calm and skillful questioning to help the participant connect to the "other" person's cognitive perspective (e.g., "Tell what happened from your viewpoint,") as well as emotional experience ("What was that like for you?

How did that feel to you when …?"). Participants were prompted when to move back and forth between Chairs A and B. The facilitator would gently conclude the exercise when they believed that the participant had obtained a benign shift in their understanding of the other person's actions. It is believed that this shift occurs as a result of thinking and feeling like the other person might have through "experiencing" the situation as the other person. During this entire perspective positioning activity, other group members were instructed to silently watch. After this activity, all participants were allowed an opportunity to process their reactions. The facilitators asked guided questions such as how it felt to "be" the other person, what they learned about the other person's feelings and motives for their actions, and how that in turn changed how they felt about the situation and the person's actions. Because this exercise would often elicit intense emotions and realizations, the activity was immediately following with a one to two minute calming exercise (from the list they generated during the first session) of the participant's choice if they believed they needed it. Not every participant reported they needed a calming exercise.

Each session concluded with instructions on the "Take Home" activities in which they were encouraged to tell someone about what they learned or what they did during the session, reflect on any new insights, and to try to use the perspective-taking strategy in any new scenarios that arise during the week, as well as to think of a new personal situation for the following week. The Take-Home activity was the first thing reviewed at the next session.

Intervention Training and Treatment Fidelity. Principles were followed from the Treatment Fidelity Checklist (Theory, Provider Training, Treatment Implementation, Treatment receipt, and Treatment Enactment (Bellg et al., 2004)). The ICAN intervention was developed based on well-known theories of emotion, such as the appraisal theory (Moors et al., 2013) and hostile attribution style theory (Combs et al., 2007; Dodge, 2006; Jeon et al., 2013), which similarly propose that emotions, particularly anger, are largely influenced by the way in which one evaluates the actions of others. As described earlier, empirical research supports these theories in individuals with TBI (Neumann, Sander, Perkins, et al., 2021; Winegardner et al., 2016). The group facilitators were involved in the final refinement of the intervention protocol and procedures. They received approximately 20 hours of training and practice before delivering the treatment to study participants. The facilitators also received a clinician manual to follow and attended clinical supervision meetings, which were held in-between sessions 2-4 for each group undergoing treatment. The group was always co-led by two facilitators, typically a neuropsychologist and either a speech language pathologist or master's level psychologist. All group facilitators had greater than 5 years of experience treating individuals with TBI. For all sessions, facilitators completed a treatment fidelity checklist, recorded session attendance, and took notes on participant engagement. Due to time constraints, participants had to take turns each week at participating in the perspective-positioning exercises. However, all participants contributed to the post-exercise discussions. Occasionally there were challenges that required slight modifications to the treatment protocol. One common challenge was the participants forgetting to come to the session prepared with a personal experience for the perspective-positioning exercise. When this happened, a list of common situations to trigger their memory of a personal incident was provided to the participant. A couple participants did not have the cognitive capacity to properly engage in the perspective-positioning exercise as intended. When this happened, facilitators encouraged brainstorming to generate alternative reasons for others' actions, similar to the approach used with video scenarios, but this time for their personal experiences. Last, some participants initially declined participating in the perspective position exercise due to not being comfortable with the activity; however, all participants ultimately did participate in the activity at least once prior to the end of the six sessions.

Procedures

Participants were recruited in four waves of six to eight participants. For Waves 1 - 3, assessment visits were conducted in-person. For Wave 4, assessment visits were modified due to the COVID-19 pandemic. The number of in-person interactions and the amount of time spent in-person were minimized as much as possible. To this end, we used a combination of truncated in-person visits along with telephone, and/or secured Zoom video-conference calls to conduct Assessments for Wave 4. When in-person visits could not be avoided, social distancing of six feet and PPE guidelines were followed (surgical face masks over mouth and nose). The intervention was always delivered in-person. Again, during the pandemic, the intervention was delivered while wearing PPE and following social distancing rules.

Recruitment and Prescreening. Recruitment letters were sent to individuals in patient databases and registries approved for research recruitment. Various mechanisms, such as social media outlets, university newsletters, local brain injury support groups, and the state Brain Injury Association, were also used to distribute study flyers and advertisements. Anyone

Table 1. Event Timeline for Participants with TBI and their Care Partners

	T0 (Week 0)	T1 (Week varied by subject. Range: 0-23 weeks)	6-week intervention ICAN group only (started within 2 weeks of TI)	T2 (within 2 weeks of intervention ending)	6-week intervention WLC group only (started within 2 weeks of T2)	T3 (WLC only) (within 2 weeks of intervention ending)
Consent/ HIPAA	TBI					
Demographics and medical history	TBI					
Medication and therapy status	TBI	TBI		TBI		TBI WLC
Discourse Comprehension Test	TBI					
Aggression Questionnaire	TBI			TBI		TBI WLC
Attributions, anger, aggression response to Epps scenarios	TBI			TBI		TBI WLC
IRI Perspective Taking	TBI	CP		TBI + CP		TBI WLC+ CP WLC
PHQ9 (Depression)	TBI			TBI		TBI WLC
PROMIS-Anger		TBI		TBI		TBI WLC
PGIC Anger and Aggression				TBI		TBI WLC
PGIC Perspective Taking						
CaGIC Anger and Aggression				CP ICAN		CP WLC
CaGIC Perspective Taking						
Client Satisfaction Questionnaire 8 (CSQ-8)				TBI ICAN		TBI WLC
Post-Treatment Qualitative Interview				TBI ICAN		TBI WLC
Verbal fluency	TBI					
Color word interference (Stroop)	TBI					
Assessments not associated with primary aims of the study (not discussed)		TBI		TBI		TBI WLC

Note. Abbreviations: CP=Care-partner; CaGIC= Caregiver Global Impression of Change; HIPAA= Health Insurance Portability and Accountability Act; IRI= Interpersonal Reactivity Index; PGIC=Patient Global Impression of Change; PHQ9= Patient Health Questionnaire-9. TBI=Traumatic Brain Injury; WLC=Waitlist control. *Notes.* Cells with "TBI" indicate that all participants with TBI were expected to complete that assessment at that timepoint. Cells that specify either "TBI ICAN" or "TBI WLC", indicate that only participants with TBI in that arm were expected to complete that assessment at that time point. Cells with "CP" indicate the care-partners/ observers of all participants were expected to complete that assessment at that timepoint. Cells with "CP ICAN", indicate that only care-partners of participants with TBI who were randomized to ICAN were expected to complete that assessment at that timepoint. Cells with "CP WLC", indicate that only care-partners of participants with TBI who were randomized to WLC were expected to complete that assessment at that timepoint.

who expressed interest in the study was pre-screened by telephone to ensure they met some basic study criteria (e.g., time post-injury). Those who met prescreening criteria were scheduled for their Time 0 Assessment.

Assessment Visits and Data Collection. All participants were to complete Time 0 (T0), 1 (T1), and 2 (T2) testing, and only WLC participants were to complete Time 3 (T3) testing. See Table 1 for data collection points for each measure. Aside from the PROMIS Anger measure, all primary baseline assessments were administered at Time 0 because they were also used to determine eligibility. For each wave, Time 1 testing for participants did not occur until after the Wave was filled with eligible participants. Baseline assessment of the PROMIS anger measure was collected at Time 1 in order to obtain an evaluation of anger immediately before the start of the intervention and a set amount of time (six weeks) prior to Time 2 testing. Depending on when the participant completed Time 0 testing, the duration between Time 0 and Time 1 testing varied (median number of weeks: seven; range: 0 - 23). Regardless of group assignment, Time 2 and 3 testing occurred within approximately two weeks of the intervention period. Most assessments were administered by a research assistant (RA) who was blinded to treatment allocation. Surveys that were likely to shed light on group assignment (i.e., PGIC, CSQ8, the Post-Treatment Qualitative Interview, and care-partner/ observer assessments) were administered by an RA aware of group allocation (unblinded RA). For the post-treatment qualitative interview, participants were asked: "Have you noticed changes in yourself since going through the therapy?"; "What

Table 2. Demographics and Injury Related Characteristics at Baseline

Baseline characteristic	Full sample (n=24)	WLC (n=14)	ICAN (n=10)	P[a]
Age, M (SD)	42.2 (11.9)	43.1 (12.7)	40.9 (10.7)	0.66
Sex, n (%)				1.00
Male	17 (70.8)	10 (71.4)	7 (70.0)	
Female	7 (29.2)	4 (28.6)	3 (30.0)	
Ethnicity, n (%)				1.00
Not Hispanic	23 (95.8)	13 (92.9)	10 (100)	
Hispanic	1 (4.2)	1 (7.1)	0 (0)	
Race, n (%)				0.74
White	20 (83.4)	11 (78.6)	9 (90.0)	
Black	2 (8.3)	1 (7.1)	1 (10.0)	
Other	2 (8.3)	2 (14.3)	0 (0)	
Cause of TBI, n (%)				0.34
Vehicular	14 (58.3)	7 (50.0)	7 (70.0)	
Fall	2 (8.3)	2 (14.3)	0 (0)	
Assault	1 (4.2)	0 (0)	1 (10.0)	
Sport related	1 (4.2)	0 (0)	1 (10.0)	
Pedestrian	4 (16.7)	3 (21.4)	1 (10.0)	
Other	2 (8.3)	2 (14.3)	0 (0)	
Loss of consciousness, n (%)				1.00
30 minutes	2 (8.3)	1 (7.1)	1 (10.0)	
>30 minutes but <1 day	2 (8.3)	1 (7.1)	1 (10.0)	
1 day	4 (16.7)	2 (14.3)	2 (20.0)	
Unknown	16 (66.7)	10 (71.4)	6 (60.0)	
Duration of PTA[b], n (%)				1.00
>1 day	20 (83.3)	12 (85.7)	8 (80.0)	
<1 day	0 (0)	0 (0)	0 (0)	
Unknown	4 (16.7)	2 (14.3)	2 (20.0)	
Total GCS Score[c], M (SD)	11.3 (5.6)	3.0 (0)	14.0 (1.0)	-
Years Post-injury, M (SD)	12.9 (14.6)	12.1 (16.4)	14.2 (12.2)	0.74
Depression (PHQ-9), mean (SD)	10.0 (5.1)	9.2 (3.2)	11.1 (7.4)	0.86
Stroop, M (SD)	50.3 (10.8)	50.8 (10.3)	49.6 (12.1)	0.26
Letter Fluency, M (SD)	12.7 (4.3)	13.0 (4.7)	12.3 (4.0)	0.71
Category Fluency, M (SD)	17.7 (4.6)	17.7 (5.4)	17.6 (3.5)	0.96

Note. Abbreviations: ICAN: Intervention to Change Attributions that are Negative; PTA: Post-traumatic amnesia; PHQ-9: Patient Health Questionnaire-9; TBI: Traumatic Brain Injury; SD: Standard Deviation; WLC: Waitlist control.
[a]For continuous variables, p-values are based on a two-sample t-test comparing the means of the WLC and ICAN groups. For dichotomous or categorical variables, p-values are based on the Fisher's exact test comparing the frequencies of the WLC and ICAN groups.
[b]Fisher's Exact test is performed only using two categories: >1 day and Unknown.
[c]Data available from only 4 subjects (1 from WLC and 3 from ICAN).

changes have you noticed?"; and "What parts of the therapy were most helpful?". At the end of T2, the blinded RA completed a survey on their belief regarding group allocation. This was completed at Time 2 instead of Time 3 since only WLC participants completed Time 3 and blinding was therefore irrelevant.

Allocation, Randomization and Stratification. Randomization was blocked by wave (n = 6 - 8 participants per wave) and stratified by sex, with a target group allocation ratio of 1 : 1. Since some studies have found sex differences in factors related to negative attributions, such as social inferencing (Turkstra et al., 2020), we thought it prudent to control for the potential influence of sex. The unblinded RA used a random number generator created by the study biostatistician to randomize participants to ICAN or WLC groups after their Time 1 testing. The unblinded RA contacted participants to inform them of their group assignment and did all the participant scheduling, visit reminders, and adverse event documentation. This method allowed blinded RAs to remain blinded to group assignment.

Statistical Analyses

Demographic and injury-related clinical variables were compared between the WLC and ICAN groups. Variables measured on an interval scale were compared between groups with a two-sample test. Variables not normally distributed were tested with nonparametric statistics. The Fisher's exact test was employed for variables measured on the nominal scale.

Key outcomes of interest were the Epps scores (intent, hostility, blame, anger and aggression), Aggression Questionnaire total score (primary outcome measure), PROMIS Anger total score, and IRI

Table 3. *Participant Ratings on CSQ-8*

1. How would you rate the quality of service you have received?
Excellent=71%; Good=29%; Fair=0%; Poor=0%.
2. Did you get the kind of service you wanted?
Definitely yes=62%, Generally yes=33%, Not really=5%, Definitely no=0%
3. To what extent has our program met your needs?
Almost all needs met=43%; Most needs met=38%; Only a few needs met=19%; None met= 0%
4. If a friend were in need of similar help, would you recommend our program to him or her?
Definitely yes=76%; Yes, I think so=24%; No, I don't think so=0%; Definitely not=0%
5. How satisfied are you with the amount of help you have received?
Very satisfied=57%; Mostly satisfied=38%; Indifferent or mildly dissatisfied=5%; Quite dissatisfied=0%
6. Have the services you received helped you to deal more effectively with your problems?
They helped a great deal=38%; they helped=57%; they really didn't help=5%; seemed to make things worse=0%
7. In an overall, general sense, how satisfied are you with the service you have received?
Very satisfied=71%; Mostly satisfied=19%; Indifferent or mildly dissatisfied=10%; Quite dissatisfied=0%
8. If you were to seek help again, would you come back to our program?
Definitely=62%; I think so=38%; I don't think so=0%; Definitely not=0%

Perspective-taking scores from participants and care-partners. For the between-group analysis, the mean scores of each of the nine outcome measures recorded at T2 were compared between the WLC and ICAN groups using one-way ANCOVA with respective baseline scores (T0: Aggression Questionnaire, Epps ratings, IRI Perspective-taking; T1: PROMIS Anger) as a covariate. Two effect size statistics, partial eta squared (η^2_p) and partial omega squared (ω^2_p) were also calculated to index the magnitude of between-group difference. Partial eta squared is calculated as the ratio of the between-group sum of squares to the sum of between-group and error sum of squares and quantifies how much variance in the response variables (outcome measures) are accounted for by the explanatory variables (treatment) (Maher et al., 2013). Partial omega squared has the same interpretation but is a lesser biased alternative to partial eta squared, especially when sample sizes are small (Lakens, 2013). Both effect size statistics are interpreted as follows: 0.01 = small effect; 0.06 = medium effect; and 0.14 = large effect (Cohen, 1988).

For the within-group analysis, we first combined data from WLC and ICAN groups at respective pre-intervention (T2 for WLC and T0/T1 for ICAN) and post-intervention (T3 for WLC and T2 for ICAN) periods, and then performed paired t-test on this pooled sample to determine whether each of the outcome measures changed significantly between the two periods. We also calculated Cohen's d and Hedges' g to facilitate interpretation of the magnitude of intervention effect. Cohen's d represents the standardized mean difference of the outcome measures between the pre- and post-intervention periods. Hedge's g has the same interpretation and corrects Cohen's d for small sample bias (Lakens, 2013). Both effect size statistics are interpreted as follows: 0.2 = small effect; 0.5 = medium effect; and 0.8 = large effect (Cohen, 1988). All statistical analyses were performed using SAS®. A p-value < 0.05 was considered statistically significant.

The original target sample size was 32 participants (16 per group) after accounting for dropouts and exclusion criteria and was derived to detect an effect size of 0.9 standard deviations with 80% power using an ANCOVA model with pre/post correlation of 0.5 in the between-group analysis at the 0.05 level of significance. This sample size requirement, however, was not met due to difficulty in participant recruitment during the unprecedented COVID-19 pandemic (13 participant in WLC group and eigh participants in ICAN group; see consort diagram), and thus the findings from the proposed between-group analysis are exploratory rather than confirmatory and should be interpreted with caution. On the other hand, we originally derived that 16 participants with pre- and post-intervention data from both groups combined were needed to detect a difference in means of 0.78 standard deviations with 80% power using a two-sided paired t-test in the within-group analysis. The collected pooled sample of 21 participants with pre- and post-intervention data meets this requirement.

Results

Participant Flow and Retention

Flow. See Figure 1 for CONSORT diagram. In sum, 48 participants were screened with 24 enrolled and randomized to either WLC (n = 14) or ICAN (n = 10) group. A research assistant completed a treatment allocation belief form and guessed correctly 23.8% (5/21) of the time which arm the participant was randomized to (ICAN or WLC). Reasons for exclusion of the 20 participants between T0 and T1 (before

Table 4. ANCOVA Between-group Analysis Comparing ICAN and WLC at T2, while Adjusting for Baseline Scores

Scale	WLC Group LS Mean (SE)	ICAN Group LS Mean (SE)	Difference[a] (SE)	F(1,18)	P[b]	η^2_p [c]	ω^2_p [d]
Patient variables							
EPPS Intent	5.5 (0.3)	4.7 (0.4)	0.77 (0.44)	3.03	0.10	0.14	0.09
EPPS Hostility	4.7 (0.3)	4.5 (0.4)	0.17 (0.48)	0.12	0.73	0.01	-0.04
EPPS Blame	6.1 (0.4)	5.7 (0.5)	0.41 (0.63)	0.42	0.53	0.02	-0.03
EPPS Anger Response	6.1 (0.2)	5.3 (0.3)	0.78 (0.34)	5.34	**0.03**	0.23	0.17
EPPS Aggressive Response	1.9 (0.1)	1.7 (0.1)	0.15 (0.12)	1.73	0.21	0.09	0.03
Aggression Questionnaire	58.8 (1.2)	60.6 (1.6)	-1.80 (1.90)	0.92	0.35	0.06	0.00
PROMIS Anger Total	11.6 (1.0)	14.2 (1.2)	-2.71 (1.80)	2.15	0.16	0.13	0.06
IRI Perspective-taking[e] (WLC: n=8; ICAN: n=6)	16.3 (1.0)	14.1 (1.2).	2.24 (1.59)	1.98	0.19	0.15	0.07
Care-partner/observer variables							
IRI Perspective-taking[f] (WLC: n=7; ICAN: n=3)	8.6 (1.2)	10.2 (1.9)	-1.55 (2.23)	0.49	0.51	0.07	-0.05

Note. Abbreviations: ICAN= Intervention to Change Attributions that are Negative; IRI= Interpersonal Reactivity; SE = standard Error; n = sample size for each group and variable; WLC=Waitlist control. Bolded P values indicates significance ($p < .05$). Unless otherwise specified, sample sizes for the WLC and ICAN groups were 13 and eight, respectively.

[a]Difference in the least squares (LS) mean scores between WLC and ICAN groups at T2, adjusted for baseline (T1) scores (LS mean of WLG group – LS mean of ICAN group). This value represents the effect of the ICAN intervention. SE of the difference in the LS mean scores is also reported.

[b]P-value of the ANCOVA F-test comparing the mean scores between WLC and ICAN groups at T2, adjusted for baseline (T1) scores.

[c]Partial eta-squared is a measure of effect size for ANOVA. $\eta^2_p = 0.01$ denotes small effect, $\eta^2_p = 0.06$ denotes medium effect, and $\eta^2_p = 0.14$ denotes large effect.

[d]Partial omega-squared is a bias-corrected measure of effect size for ANOVA. $\omega^2_p = 0.01$ denotes small effect, $\omega^2_p = 0.06$ denotes medium effect, and $\omega^2_p = 0.14$ denotes large effect

[e]The test statistic is distributed as F(1, 11).

[f]The test statistic is distributed as F(1, 7).

randomization) were: exclusionary psychological comorbidity (n=1); major depression or suicidality (n = 2); did not meet comprehension criteria (n = 2); did not have above average aggression (n = 11); did not meet negative attribution criteria (n = 4). Baseline demographic and injury-related clinical characteristics of the study participants are shown in Table 2. The WLC and ICAN groups were well-matched with respect to baseline factors ($p > 0.05$ for all variables). Data was collected from 15 care-partners/ observers (WLC: n = 12; ICAN: n = 3).

Retention. One participant from the WLC group and two participants from ICAN group withdrew from the study after randomization (two were due to work conflicts, and one was unable to return during COVID-19 pandemic due to medical vulnerabilities). As a result, 13 participants in WLC group and 8 participants in ICAN group had complete data on all primary outcome measures across the four time points (T0, T1, T2 and T3).

Changes in Medications or Therapy Status

Four participants had medication changes and two started professional psychotherapy during their participation in the study. One participant stopped medications for depression and anxiety. A WLC participant started methylphenidate for attention one month prior to Time 2 testing. Another WLC started aripiprazole for anxiety 3 weeks before Time 3 testing. Finally, another WLC participant switched the medication they were being prescribed for irritability from buspirone to amantadine the day before Time 2 testing. Two WLC participants began psychotherapy during their study participation: one of these

Table 5. *Repeated measures ANOVA Comparing Pre-intervention (T1 for ICAN; T2 for WLC) and Post-intervention (T2 for ICAN; T3 for WLC).*

Scale	Pre-intervention M (SD)	Post-intervention M (SD)	Difference[a] (SE)	F(1,20)	P[b]	Cohen's d[c]	Hedges' g[d]
Participant with TBI variables							
EPPS Intent	5.6 (1.3)	4.6 (1.6)	0.94 (0.29)	10.6	**<0.01**	0.68	0.65
EPPS Hostility	4.9 (1.4)	4.3 (1.7)	0.55 (0.38)	2.1	0.16	0.30	0.29
EPPS Blame	6.3 (1.6)	5.5 (1.9)	0.75 (0.35)	4.5	**0.05**	0.45	0.43
EPPS Anger	6.2 (1.6)	5.4 (1.7)	0.75 (0.26)	8.8	**0.01**	0.60	0.58
EPPS Aggression	2.0 (0.6)	1.7 (0.5)	0.29 (0.08)	13.3	**<0.01**	0.76	0.73
Aggression Questionnaire	58.6 (8.4)	56.2 (8.4)	2.49 (0.70)	31.2	**<0.01**	0.74	0.72
PROMIS Anger Total	15.5 (4.2)	12.5 (4.4)	2.91 (0.80)	32.3	**<0.01**	0.76	0.73
IRI Perspective taking[e] (n=15)	14.7 (5.5)	15.3 (5.1)	-0.81 (1.32)	0.38	0.55	0.15	0.14
Care-partner/observer variables							
IRI Perspective taking[f] (n=13)	7.9 (5.4)	8.6 (5.0)	-0.19 (0.68)	0.07	0.78	0.07	0.07

Note. Abbreviations. IRI= Interpersonal Reactivity; SD = standard deviation; SE = standard error; n = sample size at pre and post-intervention for each variable.
Notes. Bolded P values indicates significance ($p < .05$). The pooled sample size of ICAN and WLC participants was 21, unless otherwise specified.
[a]Difference = Difference in the mean score between Pre-intervention (T1 for ICAN; T2 for WLC) and Post-intervention (T2 for ICAN; T3 for WLC) periods (mean score at Pre-intervention - mean score at Post-intervention). SE of the difference in the mean scores is also reported.
[b]P-value of the paired t-test assessing whether there is a significant change in the test scores between pre- and post-ICAN intervention periods.
[c]Cohen's d is a measure of effect size for t-test. d = 0.2 represents a small effect; d = 0.5 represents a medium effect; and d = 0.8 represents a large effect.
[d]Hedges' g is a bias-corrected measure of effect size for t-test. g = 0.2 represents a small effect; g = 0.5 represents a medium effect; and g = 0.8 represents a large effect.
[e]The test statistic is distributed as F(1, 14).
[f]The test statistic is distributed as F(1, 12).

participants had three psychotherapy sessions and the other participant had two psychotherapy sessions in between their Time 2 and Time 3 testing.

Feasibility/Acceptability (Satisfaction, Attendance, and Adverse Events)

With respect to treatment satisfaction, 67% of participants had *total* CSQ-8 scores that were above standard averages; however, 95% felt the services helped them deal more effectively with their problems (Q6) and 90% were mostly-to-very satisfied with services received (Q7). See Table 3 for detailed CSQ-8 ratings. Regarding attendance, 76% attended ≥ 5/6 treatment sessions. Reasons for missing sessions included work conflict (23%); vacation/ out of town (23%); no-shows (23%); sick (18%); transportation (9%); and car accident (4.5%). There were 21 unrelated and two probably related adverse events. One of the events that was probably related to the study was an angry reaction when introduced to the session exercises. The participant claimed he was not aware of the types of exercises he was going to be expected to participate in and was upset. This event was classified as probable because it was unclear that the study led to an *increase* in this participant's anger, or if this response was a normal reaction for him. Despite this event, the participant continued with study and ultimately participated in the exercises. The other event that was classified as "probably related" was a situation for which a participant reported that she continued to perseverate and be upset about the personal experience she shared in the session that evening until the following day.

Between Group Comparisons on Outcomes

Table 4 presents the results of the between-group analyses comparing outcome measures of WLC and ICAN groups at T2 with adjustment for respective baseline (T0 / T1) values. Specifically, the least squares (LS) mean value of each of the outcome measures at T2, evaluated at the average baseline value under the ANCOVA model, is reported by study arm (WLC and ICAN). The between-group differences in the LS means (i.e., treatment effect, or equivalently, effect of ICAN intervention) and the corresponding F-test results on their significance are also presented. As

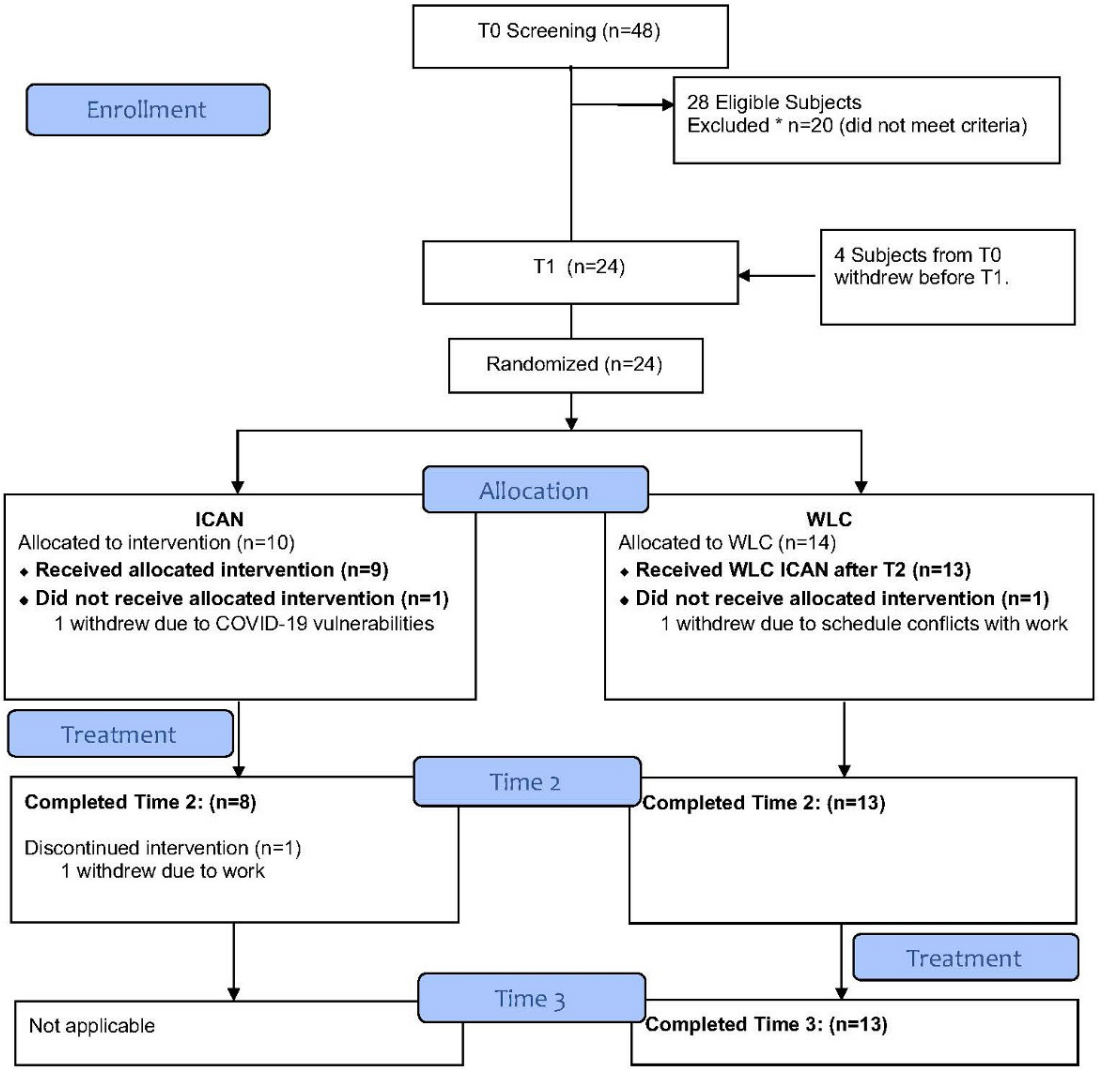

Figure 1. CONSORT Flow Diagram

shown in Table 4, the LS mean value of Epps total anger was significantly higher in the WLC group compared to that of the ICAN group ($p = .03$), with large effect sizes. No significant treatment effect was found on other outcome measures ($p > .05$). For the IRI Perspective-taking measure, data was missing from four participants with TBI and one care-partner/ observer. The IRI Perspective-taking measure was often administered as an electronic survey sent to the participant and care-partners/ observers, which were not completed by everyone.

Pre/Post-intervention Comparisons in Pooled Sample of ICAN and WLC Participants

Table 5 presents the results of the within-group analyses comparing the values of the outcome measures between the pre- and post-intervention periods based on the pooled sample (n=21; WLC + ICAN). There was significant reduction ($p < 0.01$) in the Aggression Questionnaire scores between pre- and post-intervention, with large effect sizes (Cohen's $d = 0.74$ and Hedges' $g = 0.72$). We also found significant reductions of PROMIS-Anger total ($p < 0.01$), Epps total intent ($p < 0.01$) Epps total blame ($p = 0.05$), Epps total anger ($p = 0.01$) and Epps total aggression ($p < 0.01$) scores between pre- and post-intervention periods. The corresponding values of Cohen's d and Hedges' g ranged from 0.43-0.76, indicating medium to large treatment effects. Again, IRI Perspective-taking data was missing from four participants with TBI and one care-partner/ observer.

Global Impression of Change Outcomes (Post-intervention for all participants)

Table 6 presents findings on the Global Impression of Change ratings for participants with TBI (PGIC) and care-partners / observers (CaGIC) for perspective-taking and anger/ aggression. With regards to perspective taking, a noticeable change (rating of 5-7) was reported by 83.3% of participants with TBI (PGIC)

and by 40% of care-partners/ observers (CaGIC). With regards to anger and aggression, a noticeable change was reported by 45% of participants with TBI (PGIC) and by 40% of care-partners/ observers (CaGIC). There was some missing data for the PGIC perspective taking (n = 9) and anger and aggression (n =1). Like the IRI, these global impression of change surveys were administered electronically. At the end of the study, it was learned that the PCIC Perspective-taking survey was accidentally not sent to all participants, resulting in a large portion of missing data for this assessment. See Supplemental Table 3 for participants' qualitative comments regarding what changes they noticed in themselves as a result of the intervention.

Discussion

More evidence-based treatments are needed to address problems with anger and aggression following TBI. This Phase I study examined the early efficacy of ICAN, a novel intervention that specifically targets negative attributions and poor perspective-taking, which are mechanisms known to underly anger and aggression in some individuals with TBI (Neumann et al., 2015, 2017a; Neumann, Sander, Perkins, et al., 2021; Neumann, Sander, Witwer, et al., 2021). Because not all individuals' anger and aggression are related to negative attributions, participants had to have co-existing issues with negative attributions and/ or perspective-taking to be included in the study. This approach meant the ICAN intervention would likely be addressing at least one of the mechanisms relevant to our participants' anger/ aggression problems, as opposed to trying to treat individuals who did not have anger-related negative attributions.

Findings from this preliminary study suggest ICAN is acceptable (good satisfaction and low number of adverse events) and may help reduce negative judgments that people with TBI make regarding others' actions, as well as situation-specific anger and aggression responses. Given that this study was largely underpowered for group comparisons, the majority of this Discussion will focus on the outcomes from the pooled sample (n=21) after all participants received the intervention, unless otherwise specified. After participating in the ICAN intervention, participants judged characters' actions in the Epps Scenarios to be less intentional and blameworthy, and they also reported they would feel and act less angry and aggressive in response to the situation. Although participants' judgments of hostility did not change significantly (p=.16), there was a small to medium effect size noted. Importantly, changes in anger and aggression extended beyond responses to hypothetical situations, as indicated by the significant reductions on the Aggression Questionnaire and the PROMIS-Anger measure, as well as reports of noticeable change on the PGIC and CGIC. Notably, the effect sizes of the pre/post-intervention changes in attributions of intent and blame, anger, and aggression ranged between medium and large. Findings regarding improvements in perspective-taking were mixed. While no significant differences were observed on the IRI Perspective-taking subscale, ratings on the Global Impression of Change measure suggested a substantial portion of participants had noticeable improvements in their perspective-taking, as reported by participants and their care-partners/observers (83% and 40%, respectively). Moreover, qualitative comments by participants substantiated their perceived self-improvement with regards to perspective-taking (Supplemental Table 3). It is possible that findings on the IRI perspective-taking subscale were not significant due to missing data on this measure (completed by only 17 participants and 14 care-partners/observers), and/or lack of sensitivity of this measure to capture change.

These findings support and extend those of the initial case study (Winegardner et al., 2016) using these techniques. While in general these findings appear promising, especially after only 6 treatment sessions in individuals who were on average around 13 years post-injury, it is important to remember the sample size was small. Additionally, when comparing ICAN to WLC to one another (prior to WLC participants receiving the intervention), the only significant difference was that ICAN participants reported less severe anger responses to the Epps Scenarios, compared to the WLC participants. It is unclear if the lack of significance on other between group comparisons was a factor of small, unbalanced sample sizes in each of the randomized groups (ICAN = 8; WLC = 13). Findings must be interpreted with caution at this time, as more work is needed to understand the efficacy of ICAN relative to a comparison group.

ICAN, which takes a unique and distinctive approach to anger management, provides an additional potential intervention for the treatment of anger problems in people with TBI. Specifically, ICAN may be effective in people with TBI who have difficulty managing anger by targeting pre-anger appraisals of ambiguous situations. That is, if a person appraises a situation as neutral or benign from the beginning, then anger is less likely to arise, or if it does, to be less severe. Therefore, ICAN may assist with the prevention of unwarranted anger responses and/or reduction of the anger experience. ICAN encouraged participants to generate a wide range of different interpretations of scenarios. This approach was intended to stimulate generativity, flexible thinking, and "thinking outside the box". As such, it is possible that ICAN may be improving participants' ability to

Table 6. Global Impression of Change Outcomes for Perspective-taking and Anger and Aggression

	Perspective-taking		Anger and Aggression	
	PGIC (n=12)	CGIC (n=15)	PGIC (n=20)	CGIC (n=15)
1 – No change (or condition has gotten worse)	0	2 (13.3%)	2 (10.0%)	1 (6.7%)
2 – Almost the same, hardly any change at all	0	2 (13.3%)	3 (15.0%)	5 (33.3%)
3 – A little better, but no noticeable change	1 (8.3%)	3 (20.0%)	4 (20.0%)	1 (6.7%)
4 –Somewhat better, but the change has not made any real difference	1 (8.3%)	2 (13.3%)	2 (10.0%)	2 (13.3%)
5 – Moderately better, and a slight but noticeable change	4 (33.3%)	5 (33.3%)	5 (25.0%)	4 (26.7%)
6 – Better, and a definite improvement that has made a real and worthwhile difference	6 (50.0%)	1 (6.7%)	2 (10.0%)	2 (13.3%)
7 – A great deal better, and a considerable improvement that has made all the difference	0	0	2 (10.0%)	0

Note. Abbreviations: CGIC= Caregiver Global Impression of Change (responses of the Care-partner / observer); PGIC= Patient Global Impression of Change (responses of participants with TBI).

think more abstractly beyond their immediate concrete impression of a situation. It is also possible that the ICAN exercises may be improving participants' social inferencing skills. Our past work showed that lower social inferencing performance in participants with TBI was related to more negative attributions (Neumann, Sander, Perkins, et al., 2021). Through teaching alternative interpretations of others' behaviors, ICAN may also be facilitating more accurate inferences regarding reasons for others' behaviors. More work is needed to understand the mechanisms by which ICAN is altering negative attributions, anger and aggression (e.g., executive functioning, social inferencing).

It is important to note that ICAN may not be appropriate for individuals with significant cognitive impairments, especially for those with greater executive dysfunction and difficulty with abstract reasoning / mental flexibility skills. These individuals may lack the fundamental skills needed to engage in the cognitive task of generating additional new ideas or the more abstract perspective-positioning exercise. Thus, future research is needed to understand characteristics of individuals who respond versus those who do not respond to ICAN. Finally, while six sessions might be more practical and clinically feasible compared to some longer interventions for emotion regulation (e.g., 16 sessions) (Tsaousides et al., 2017), it is unclear if six sessions are enough for lasting effectiveness. It is possible other models with more sessions or sessions scheduled at longer intervals (a la spaced retrieval) would provide a more robust treatment effect that could be maintained over time.

Limitations

The COVID-19 pandemic was a barrier to achieving our targeted sample size, and also resulted in modifications to the Wave 4 assessment methods. The smaller than anticipated sample size resulted in being under-powered for between group comparisons. While the data from the pooled sample is promising, it is important to keep in mind that changes may have occurred for reasons other than the intervention (e.g., attention; interpersonal interaction with facilitators and other group members; Hawthorne effect; change in life circumstances). There was some missing data on the IRI and PGIC for perspective taking. A few participants experienced unanticipated medication changes or started psychotherapy during the study which may have impacted their outcome ratings. The majority of the sample was male and white, and therefore, the findings may not represent those of other demographic makeup. The participants did not attend all of the intended intervention exposure, with only 76% attending at least 5 sessions. Since care-partners/observers were not required for participation, observer ratings are only available for a subset of the sample, thereby limiting generalizability of observer report. Additionally, the IRI and the Global Impression of Change measures have not been validated for use in care-partners/ observers; therefore Care-partner results should be treated with extra caution. The study examined short-term but not longer-term outcomes, and thus, maintenance of the observed treatment effects were not studied. The time from Time 0 to Time 1 testing and randomization varied across participants as Time 1 testing did not occur until after the Wave was filled in order to ensure Time 1 testing occurred shortly before the intervention started. Some treatment modifications for the perspective positioning exercise (e.g., brainstorming to generate reasons for others'

actions and using a list of common situations to help identify personal incidents) were made to facilitate overcoming barriers to participation, some of which may be directly related to brain injury (e.g., remembering to prepare for sessions, as well as cognitive capacity for and comfort with perspective positioning). Last, some participants initially declined participating in the perspective position exercise due to not being comfortable with the activity; however, all participants ultimately did participate in the activity at least once.

Conclusions

The quantitative and qualitative findings from this pilot study suggest that ICAN is a well-tolerated and feasible intervention that may reduce anger and negative attributions after TBI. Further investigation is warranted with a larger sample size and assessment of longer-term outcomes.

Additional Information

Supplementary Materials

Supplementary materials for this article can be viewed here:
Supplemental Table 1
Supplemental Table 2
Supplemental Table 3

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Conflict of Interest

The authors report no conflict of interest.

Ethical Approval

This study was reviewed and approved by the Institutional Review Board of Indiana University.

Data Availability

De-identified data will be made available upon request.

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