


Internet-based Interacting Together Everyday, Recovery After Childhood TBI (I-InTERACT): Protocol for a multi-site randomized controlled trial of an internet-based parenting intervention

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Abstract

Objectives: We discuss the rationale and description of the Internet-Based Interacting Together Everyday, Recovery After Childhood TBI (I-InTERACT), a telehealth intervention designed to promote positive parenting skills through live in-session skills practice and coaching. A second objective is to describe the protocol of a three-armed (Internet Resource Comparison, I-InTERACT, and I-InTERACT Express) multi-site randomized controlled trial (RCT) designed to examine intervention effectiveness.

Method: Participants included parents of children ages 3–9 who sustained a moderate or severe traumatic brain injury (TBI) any time since birth. Measures assessing parenting behaviors, parent–child interaction, parent/family factors, and child factors were collected prior to intervention, 3 months after enrollment and 6-months after enrollment.

Results: This protocol manuscript was submitted before the completion of data collection and prior to any data analysis. It is expected that the I-InTERACT and I-InTERACT Express interventions will be associated with an increase in positive parenting behaviors, and a decrease in negative parenting behaviors, parental distress, and child behavior problems. Finally it is expected that socioeconomic status, life stressors, and social resources will moderate treatment effects.

Conclusions: The study described in this protocol paper represents one of the first large multi-site RCTs of a parenting intervention designed to promote positive parenting skills in families with young children who sustained a TBI. We plan to disseminate findings to patients and families as well as clinical and research professionals, and begin to develop a research base for this telehealth intervention.

Keywords

Pediatric traumatic brain injury, telehealth, parenting intervention, live coaching

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Introduction

Each year in the United States, approximately 475,000 children between 0 and 14 years of age sustain a traumatic brain injury (TBI),¹ making it the leading cause of

acquired disability in children in the United States,² with the incidence of TBI greater among children ages 0–4 than any other age group.¹ TBI often results in deficits in

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cognition, behavior, and social development.^{3–5} Behavioral changes, characterized by increases in externalizing problems, including impairments in inhibitory control and self-regulation, as well as increased oppositional behavior, are common.^{6–8} Further, existing data suggest that TBI in the preschool years results in potentially more severe sequelae than for older, school-aged children.^{9–11} Certain skills, such as executive functioning, self-control, social competence, and language, emerge during the preschool years and provide the foundation for subsequent academic achievement and social adjustment. Because these skills are undergoing rapid change during the preschool years, they may be particularly vulnerable to disruption by brain trauma.¹²

In addition to injury characteristics, parental distress and poor parent–child interactions have been associated with less recovery over time after childhood TBI.^{7,13–18} Further, parent and family functioning are adversely affected by TBI.^{19–21} The negative impact of poor family functioning coupled with the impact TBI has on families highlights the need for interventions that facilitate positive family and parental functioning following pediatric TBI.

While some aspects of a child's family environment may be difficult to change, parental responsiveness and disciplinary practices can be improved through intervention.^{22,23} In fact, a number of empirically supported parenting-training interventions have been developed, including the Incredible Years,²⁴ Parent–Child Interaction Therapy (PCIT),²⁵ and the Positive Parenting Program.²⁶ These programs instruct parents in building a warm, responsive parent–child relationship, and encourage consistent positive parenting behaviors which play an important role in the emergence of behavior regulation and social competence during typical development, and reduced externalizing behavior problems.^{27,28} Reviews assessing the efficacy of these parent training programs report moderate to large effects of treatment on the reduction of parental stress and improved internal locus of control, as well as fewer child behavior problems.^{29–34} Kaminski and colleagues³⁰ noted larger treatment effects in programs that emphasized positive parent–child interactions and emotional communication while instructing caregivers in consistency and the use of time out. In contrast, smaller effects were evident in programs that focused on parental problem solving or on the child's cognitive, academic, or social skills. In terms of intervention delivery, programs incorporating live, in-session practice of parenting skills are associated with greater gains in these skills and fewer child externalizing behaviors as compared with similar programs that did not involve in-session practice.³⁰

Behavioral interventions for young children with TBI are severely lacking. Given the frequency of new or exacerbated behavior problems following pediatric

TBI, training in parenting skills with live in-session coaching, skills practice, and an emphasis on consistent limit-setting may provide an effective means for increasing positive parenting and ameliorating parenting stress and child behavioral difficulties.³⁵ Moreover, one of the few randomized clinical trials (RCTs) for pediatric brain injury provided evidence that using parents as therapists (the PCIT model) may be more effective in improving outcomes than using rehabilitation personnel.³⁶ In addition, Woods and colleagues^{37,38} demonstrated that positive parenting interventions (Signposts for Building Better Behavior³⁹) were effective at reducing challenging child behaviors and improving parenting behaviors following pediatric TBI in a group setting as well as via telephone delivery.

A number of barriers may prevent families from seeking or receiving services for children's behavioral problems after TBI.⁴⁰ Outpatient services may be unavailable altogether, or families may have to travel significant distances to obtain appropriate care. Further, access to professionals with experience in treating patients and families with pediatric TBI is even more limited, with only a small subset of providers having sufficient training in both TBI and behavioral intervention programs. The use of internet technology makes it possible to deliver interventions online without a negative impact on adherence to or satisfaction with treatment.^{41,42} By reducing barriers to treatment, online training programs designed to promote parenting skills can reach clients that traditional office-based programs cannot.⁴³

In response to the need for an accessible evidence-based intervention to improve behavioral functioning in young children with TBI, we developed and tested an online intervention designed to promote positive parenting skills through live coaching and in-session skills practice, with the goal of reducing the behavioral consequences of TBI in young children. This intervention, Internet-based Interacting Together Everyday, Recovery After Childhood TBI (I-InTERACT), represents an integration and modification of the evidence-based, online treatment program for families of school-aged children with TBI,^{44,45} with in-session practice accompanied by real-time coaching.^{46,47}

The goal of the current manuscript is to provide rationale for and information regarding the I-InTERACT and I-InTERACT Express programs, and to describe how intervention effectiveness will be evaluated. This protocol manuscript was developed and submitted prior to the completion of data collection and prior to any data analysis. The aim of the trial presented here was to evaluate the effectiveness of two parent training interventions in young children with a history of TBI. Specific objectives were to: (1) examine the effectiveness of I-InTERACT and an abbreviated version of this program, I-InTERACT Express, in promoting parenting

behaviors, (2) investigate the effectiveness of I-InTERACT and I-InTERACT Express in reducing parental distress, (3) assess the effectiveness of I-InTERACT and I-InTERACT Express in reducing child behavior problems, and (4) identify moderators of treatment response. In addition, the content of I-InTERACT and I-InTERACT Express interventions are described.

Method

The effectiveness of the interventions was examined using a three-arm (I-InTERACT, I-InTERACT Express, and Internet educational Resource Comparison), multi-site, RCT. Institutional review board (IRB) approval of the RCT protocol was obtained by all study sites prior to initiation of data collection. Participants were consecutively recruited from four children's hospitals and one general medical center, at locations in the United States (Ohio and Colorado) from 2010 to 2015. All participating institutions were Level 1 trauma centers. All baseline and follow-up assessments were completed in the family's home. The first therapy visit was completed in the family's home, and all subsequent therapy sessions took place via videoconference. This trial was registered at Clinicaltrials.gov (assigned identifier: NCT01214694). This is the first published version of the trial protocol.

Participants

Parents of children between the ages of 3 and 9 years who sustained a moderate to severe TBI any time since birth were recruited. Consistent with previous definitions, severe TBI was defined as a post-resuscitation Glasgow Coma Scale (GCS) score of <8, and moderate TBI was defined as a GCS score of 9–12 or a GCS >12 with accompanying abnormal clinical imaging. Additional eligibility requirements included completion of inpatient rehabilitation (if clinically indicated), residence of the child with parents or legal guardians, and English as the primary spoken language in the home. Children and families were not restricted from participating in other medical, rehabilitation, mental health or behavioral health services during their enrollment in the trial. While there were no participant discontinuation rules with regards to level of parental or child distress, eligibility criteria dictated that families did become ineligible for the trial if the child no longer resided with the participating parent. In addition, if the therapist noted elevated levels of parental or child distress that were not addressed by or responsive to the intervention, referrals for additional services would be provided.

Recruitment strategies included identification of potential participants from trauma registries and screening of hospital admissions at participating institutions.

In addition, information about the trial was disseminated to clinical care staff, and study staff screened outpatient appointments at relevant clinics (outpatient rehabilitation follow-up clinics) to identify potentially eligible participants. Potentially eligible families were first mailed basic information about the study, after which they were contacted via phone to further discuss details about trial. They were given information about the three potential treatment groups, time commitments for each of the groups, and likelihood of being assigned to each of the study groups. They were given the chance to ask any additional questions about the study, and if they were interested in participating in the study, a baseline assessment visit was scheduled. Of those who were successfully contacted and provided with detailed information about participating in the trial, 45.5% agreed to participate and were randomized. Participants were not paid for their participation in treatment sessions; however, they were reimbursed for completion of each data-collection visit.

Once informed consent was obtained and all baseline measures were administered, the family was given an envelope informing them of their group assignment. To ensure comparable representation across treatment groups, randomization was stratified by child gender and race. Group assignments were generated prior to study initiation using a computer program developed by the CCHMC Division of Biostatistics. Group assignments were placed in an envelope by staff not involved with recruitment or data collection to maintain blinding, and envelopes were selected in order within each strata. Study staff completing the baseline assessment were unaware of group assignment until the envelope was opened by the family at the end of the baseline visit. Data from all study visits (baseline, 3-month, and 6-month) were collected by trained BA or MA-level research coordinators. Therapists were not involved in the collection of any outcome data. See below for a description of measures collected at baseline and follow-up visits to assess primary outcomes and secondary outcomes.

Procedures

Baseline visit. Baseline assessment measures were completed during a home visit. At that visit, the project coordinator also set up the computer and internet connections. The parent completed measures about themselves and their child, while the child completed a brief assessment of cognitive functioning. The parent was then videotaped playing with their child for 15 minutes.

Follow-up visits. Follow-up visits were conducted 3 and 6 months after the baseline visit. At each of the follow-up visits, the parent completed self-report measures and a short interview with the project coordinator.

The coordinator again videotaped the parent playing with the child for 15 minutes. The coordinator was not blind to group assignment at follow-up visits. Because data collected consisted of parent-report forms and interviews about their experience in the trial, rather than measures where the coordinator would have to make subjective judgments regarding outcome measures, lack of blinding is anticipated to have minimal impact. However, it should be noted that those coding the videotaped interactions remained blind to group assignment.

Treatment protocol. Both the I-InTERACT and I-InTERACT Express interventions were delivered by therapists with at least a master's degree in psychology or related field. All therapists received training on the consequences of TBI and delivery of both I-InTERACT and I-InTERACT Express programs (see description below). For both treatment groups, the first treatment session was conducted in the family's home. During this session the therapist showed parents how to log in to and navigate the treatment site, and set up a Skype account. The therapist also evaluated the stressors the family was experiencing and helped the parents identify goals for treatment. All subsequent therapy sessions were completed via videoconference. Each session had two parts: (1) a self-guided web session with information about a particular skill or set of skills (e.g. reflective listening, specific praise and relaxation skills), video clips showing parents modeling the skill(s), and exercises to practice the skill(s), and (2) a follow-up videoconference session in which the therapist reviewed the web session, the parent role-played the new parenting skills with the therapist, and the parent received practice in implementing the new skills in play with the child while receiving live therapist feedback via blue tooth headset. Each time a parent completed a web session, an automatic email message was sent to the therapist that indicated completion and documented the time the parent spent on each page. See Figure 1 for a timeline of all study activities.

Interventions

All intervention content is described in greater detail below. All families enrolled in the study received a computer, printer, and high-speed internet access if they did not currently have these in their home. Families were also provided with a website with brain injury resources and links described in more detail below.

Internet Resource and Education Comparison Group

Families in the Internet Resource and Education Comparison (IRC) group were provided with a website

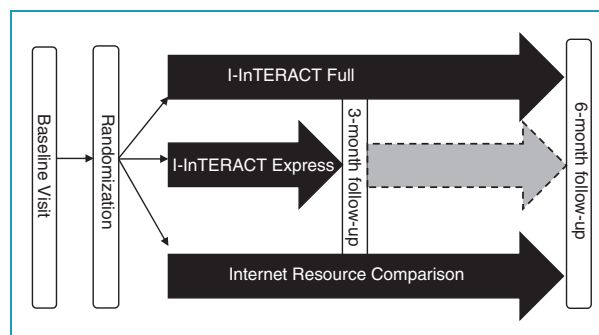


Figure 1. Timeline of study activities from baseline visit through completion of 6-month follow-up. Gray arrow with dashed outline indicates that the I-InTERACT Express group was not engaged in the intervention between 3-month and 6-month follow-up. I-InTERACT Express families did receive one booster video conference session prior to completion of 6-month follow-up.

with brain injury resources and links but did not have access to session content for either of the parenting skills interventions. The resources were selected to help families learn more about TBI and available services. Resources included informational sources about brain injuries and recovery, brain injury associations (local, state, and national organizations), support group websites, educational and vocational resources, rehabilitation and coping resources, family and caregiver resources, and transportation organizations. In addition, more general resources were included (i.e. general disability information, general brain and neurological information). Families were asked to spend at least 1 hour per week engaged in activities utilizing the resources provided on the website. In order to gauge engagement, families were asked to maintain a log of websites they visited related to TBI functioning and recovery, as well as the time spent on these websites. This information was collected from families at the 6-month visit. Families were also asked to report and rate the five websites they visited most frequently.

I-InTERACT

The I-InTERACT homepage featured the above-noted links, study staff contact information, and I-InTERACT session materials. Participants were able to login and access the self-guided content and track their completion of homework. Sessions were delivered in a fixed order, and content for the next session became available to the family upon completion of the previous session and review of its content during a synchronous videoconference with the therapist.

The I-InTERACT program consisted 10 separate core sessions and seven supplemental sessions. The core sessions (Table 1) addressed positive parenting

Table 1. 10 core sessions of I-InTERACT program.

Session	Format	I-InTERACT Topic	I-InTERACT Express Topic
Session 1	Home Visit	Introduction to I-InTERACT program	Introduction to the I-InTERACT Express Program
Session 2	Online	Positive parenting skills and special play time	Positive parenting skills and special play time
Session 3	Online	Staying positive and coping with stress	Lead your child
Session 4	Online	Behavior management	Behavior management
Session 5	Online	Introduction to “lead your child” (parent-directed interaction)	Time-out technique
Session 6	Online	Dealing with anger	House rules and using positive parenting skills in real life
Session 7	Online	Introduction to consequences for not following directions	Closing thoughts
Session 8	Online	Cognitive Problems	
Session 9	Online	House rules and using positive parenting skills in real life	
Session 10	Online	Closing thoughts	

skills, consistent discipline techniques, and antecedent behavior management. Sessions also provided didactic information about the cognitive and behavioral consequences of brain injury together with strategies for managing those consequences. I-InTERACT placed an emphasis on identifying antecedents to behavioral dysregulation and developing strategies for “setting the child up for success,” rather than focusing on consequences for behavior. This approach is grounded in evidence that indicates that children with TBI, particularly those with damage to the frontal lobes, may have difficulty anticipating consequences and learning from their experiences.⁴⁸ As such, consequence-focused strategies must be complemented with antecedent approaches that examine how the environment can be structured differently to facilitate better behavior (e.g. fewer distractions). The core sessions also provided didactic training in stress management (session 3) and anger management (session 6) to address the caregiver and family stresses associated with caring for a child with TBI.^{21,49} Following completion of session 9, families were given the option of completing up to four of the seven supplemental sessions (Table 2) based on their specific needs and interests. Supplemental sessions provided tailored didactic information regarding specific impairments following injury (such as pain management), and were developed based on research evidence and focus group feedback to address issues of relevance to select families. Following completion of selected supplemental sessions, the final 10th core session was completed, during which families reflected on progress towards

Table 2. Supplemental session topics. Families are able to choose up to four supplemental sessions to be completed between core sessions and 10.

Session	Format	Title
Supplementary session 1	Online	Marital communication
Supplementary session 2	Online	Parents and siblings
Supplementary session 3	Online	Pain management
Supplementary session 4	Online	Guilt and grief
Supplementary session 5	Online	Working with the school and transition issues

goals, reviewed skills learned throughout the intervention, and worked with the therapist to plan for continued utilization of skills.

Each self-guided online web session included videos of real parents talking about how TBI affected their child and family, didactic content regarding the skill (e.g. specific and detailed praise), video clips showing a parent modeling the skill with his or her child (e.g. praising the child’s actions or behavior), and exercises giving the parent an opportunity to practice the skill. Participating caregivers were able to experience the target content in a variety of modalities (text, video, activity), to take into account different learning styles.⁵⁰ Each videoconference session consisted of three parts: (1) a 15–20 minute review of website content with the caregiver(s) to facilitate comprehension;

(2) 5 minutes observing and coding each caregiver playing with the child; and (3) 20–30 minutes of live coaching of targeted parenting skills with each participating caregiver.

I-InTERACT Express

The I-InTERACT Express program was modified from the full I-InTERACT program, with guidance from advisory boards (i.e. professionals and parents of young children with TBI) and input from consultants and developers of the CARE+ program (Barbara Boat, PhD and Erna Olafson, PhD⁵¹). Input from consumers played a crucial role in guiding the content development of the Express intervention.

The purpose of the Express program is to engage families immediately with a condensed program to minimize family burden, maximize family benefit, and optimize family retention. The program included parenting skills training and materials only, omitting a majority of the didactic information about the consequences of TBI and ancillary caregiver sessions focused on issues such as stress and anger management. These changes resulted in seven sessions in contrast to the 10–15 sessions in the full I-InTERACT program (Table 1). The Express intervention targeted positive parenting skills and behavior management techniques from the first session onward. The abbreviated intervention was designed to be completed prior to the 3-month follow-up assessment, and families received a booster videoconference session with the therapist prior to completion of the 6-month follow-up.

Adherence and timeline of interventions

Families were able to complete the assigned online modules on their own, as their schedule permitted, with the goal of completing the module prior to their scheduled videoconference therapy session. Therapists maintained close contact with families, and sent reminders via text, phone call, or email (based on the families identified preference) regarding timely completion of online session and upcoming videoconference therapy sessions. In addition, website functionality allowed for the therapists to determine if the family had started or completed the online module, and enabling them to send additional reminders to the family as needed. Therapists released subsequent sessions to families (one at a time) after completion of videoconference therapy session. The initial sessions of the intervention were completed weekly to help build and maintain rapport and engage families in the process. These initial sessions also provided the families with the skills they would be practicing throughout the intervention. After parents have received training in positive parenting

behaviors, sessions could be completed on a more flexible (e.g. biweekly) schedule to allow parents adequate time to practice and consolidate parenting behavior skills. Therapists did have the flexibility to schedule sessions at a pace that worked best with the family's situation (for example, allowing more time between sessions for parents with shared custody) with the goal of completing all required intervention components by the 3-month follow-up for I-InTERACT Express group and the 6-month follow-up visit for the I-InTERACT group. To promote adherence, therapist-guided sessions were scheduled during non-traditional hours (evenings and weekends).

Therapist training

A comprehensive treatment manual was developed for I-InTERACT and I-InTERACT Express. Therapists were trained by Dr. Wade in a 2-day training program. The training included background information regarding the interventions, rationale for content included in the interventions, practice role-playing positive parenting skills, and practice coaching and coding positive parenting skills. Prior to treatment, therapists had to gain mastery on observed positive parenting skills (30 positive parenting behaviors in a 5 minute interaction), be accurate in coding observed parenting behaviors, and demonstrate proficiency in coaching parents during live in-session parent–child interactions. All therapists received weekly supervision with a licensed clinical psychologist (Dr. Wade) to discuss goals and progress of patients in the program and address any concerns or issues that develop during treatment. To ensure fidelity, therapists also kept notes regarding the content of each videoconference session and these notes were reviewed during weekly supervision.

Primary outcomes

Parent–child interaction. The Dyadic Parent–Child Interaction Coding System-II (DPICS) was used to provide observer ratings of parenting skills and parent–child interaction. Observational outcomes were chosen as the primary outcome as they are sensitive to treatment-related changes and better predict long-term adjustment than parent and teacher ratings.⁵² Trained observers coded parent and child verbalizations (e.g. commands, praise, and critical comments), vocalizations, and physical behaviors. All video coders were not involved in data collection, and remained blind to group assignment through completion and finalization of video coding. Adequate reliability and validity have been established for the DPICS.^{53,54} The DPICS was used to rate positive and negative parenting behaviors (e.g. praise, responsiveness, and criticism)

and child compliance during three 5-minute interactions varying in the degree of parental control (child-directed play, parent-directed play, clean-up activity). To assess inter-rater reliability over time 10% of tapes were randomly chosen to be independently rated by two raters.

Secondary outcomes

Parent. The Symptom Checklist-90-R (SCL-90-R⁵⁵), a 90-item self-report inventory, was used to assess global psychiatric functioning. The SCL-90-R has well-documented reliability and validity and has established clinical cut-offs.⁵⁵ The Global Severity Index provided a measure of general psychological distress. The Center for Epidemiologic Studies Depression Scale (CES-D) is a 20 item self-report questionnaire. The CES-D demonstrates acceptable reliability and excellent concurrent validity, making it one of the most commonly used screening tools for depression in research.⁵⁶

Child adjustment and adaptive functioning. The Eyberg Child Behavior Inventory (ECBI) is a 36-item parent-report questionnaire regarding the current frequency and severity of disruptive behaviors in the home and the extent to which the parent finds the behavior distressing.^{53,57} On the ECBI, the parent rates how often each behavior occurs (7-point intensity scale) and whether or not the behavior is a problem (Yes/No Problem Scale) for him/her. The ECBI has acceptable test-retest reliability, internal consistency, and sensitivity to the effects of parenting skills treatment. The Child Behavior Checklist (CBCL) was used to assess change in child behavioral functioning. The CBCL has well-established reliability and validity and is sensitive to treatment-related changes following TBI.^{44,45,58}

Additional parent and family outcomes. The Caregiver Self-Efficacy Scale is a 25-item parent-report measure assessing parenting confidence and efficacy.⁵⁹ The Parenting Stress Inventory (PSI-Short form), a 36-item scale with documented reliability and validity, was used to assess parental distress, parenting-child interactions, and difficult child behaviors.⁶⁰ The total parent stress score was used as a global index of parenting stress.

Statistical analyses and data management plan

Power analysis. The attrition rate in a previously completed pilot trial of the I-InTERACT program was 33% over 6 months.⁶¹ It was anticipated that the reduced time commitment for I-InTERACT Express group would result in lower attrition in the current trial. Power for the current trial was calculated based on

effect sizes found in similar investigations and our pilot. Although previous investigations using PCIT have documented large effect sizes on measures of parenting skills and child behavior problems, effect sizes for parental distress have been more modest. Using the nQuiry software, it was estimated that with a sample of 40 per group (120 total), we had >90% power to detect an effect size of $r > .12$.

Missing data. Data were collected from all participants including participants who remained enrolled but failed to complete the intervention. An intent-to-treat method will be used to analyze study data, including data from all participants regardless of whether or not they completed the intervention or follow-up visits. The number of sessions completed and proportion of intervention completed has been collected and will be examined as potential moderators of treatment response. Maximum likelihood estimation techniques will be used to allow for the inclusion of all available data, and prevent the list-wise deletion of participants who are missing outcome variables.

Hypotheses

Hypothesis 1. Parents receiving I-InTERACT or I-InTERACT Express will display more positive parenting behaviors (warmth, responsiveness), and fewer negative parenting behaviors (criticism) than parents in the IRC group. To evaluate this hypothesis, we will examine group differences in parenting behaviors on the DPICS-II⁵⁴ and the Family Assessment Device-Communication subscale (FAD – Communication),⁶² respectively, at the post-treatment assessment controlling for baseline levels.

Hypothesis 2. Families receiving the I-InTERACT or I-InTERACT Express will report lower levels of parental distress and fewer child behavior problems than those in the IRC group. The active intervention will be effective both in ameliorating problems evident at the initiation of treatment and in preventing the emergence of additional problems across treatment and follow-up. Parental distress will be assessed using the Symptom Checklist-90 revised (SCL90-R⁵⁵), the Center for Epidemiologic Studies Depression Scale (CES-D⁵⁶), and the Parenting Stress Inventory (PSI⁶⁰). Child behavior problems will be assessed using the ECBI and the Child Behavior Checklist (CBCL⁶³). A further hypothesis is that improvements in child behavior will be mediated by improvements in parent-child interaction and parental psychological distress and that these mediation effects will be greater following I-InTERACT than following I-InTERACT Express.

Analytic plan (hypotheses 1 & 2). Group differences in outcomes (DPICS-II and FAD – Communication) will be assessed using multivariate analysis of covariance, with intervention group as the independent variable and the pre-test value of each outcome treated as a covariate to reduce variance in the outcomes that is attributable to pre-existing individual differences. Separate models will be tested for parent and child outcomes, with the alpha level for statistical significance adjusted for multiple comparisons. Additional covariates will include injury severity, socioeconomic status (SES), and time since injury. Other demographic covariates, such as race and child age, will be included if findings indicate group differences in these factors or associations with outcomes. Mediation analysis will be conducted using procedures described by Preacher and Hayes⁶⁴ to investigate possible mechanisms of treatment effects on child outcomes. Specifically we will examine if treatment-related improvements in parenting behaviors and distress mediate the effects of the intervention on child behavior and functioning.

Hypothesis 3. Our preliminary research suggested that factors such as SES, race, interpersonal stresses and resources, and parental coping were related to parent and child adaptation to the injury. Others have shown that at-risk or socially disadvantaged families require more intensive intervention (i.e. greater number of sessions) and are more likely to be non-adherent than those without identified risks.^{65,66} We thus hypothesized that treatment effects would be moderated by SES, life stresses, and social resources (as assessed by the Stressors and Social Resource Inventory – Adult Version (LISRES-AI⁶⁷), such that families with greater social disadvantage (i.e. lower SES, more stresses) will benefit more from I-InTERACT than from I-InTERACT Express.⁴⁵

Analytic plan (hypothesis 3). Hierarchical multiple regression analyses will focus on examining the differential effects of I-InTERACT, I-InTERACT Express, and IRC as a function of certain moderators. Moderators to be tested include injury severity, SES, race, interpersonal resources/supports and stressors, baseline levels of behavior problems, and parental coping at baseline. Moderation will be tested by examining the interactions of intervention group and moderator variables as predictors of outcomes post-treatment, covarying for the pre-test value of each outcome.

Data management

All data were collected via paper forms at the participant's home. Prior to leaving the home, questionnaires were reviewed by study staff to ensure that all items were completed, and note why items were left blank if

appropriate. A data-tracking sheet was created and used to document the completion, checking, scoring, and entry of each form for each study participant. Study staff completing each of these steps also initialed this tracking sheet to allow for clarification of issues during the data-cleaning process. If a form or data item was missing, this, along with the reason for why the item was missing, was noted on the tracking sheet. All data from all sites were entered into a single RedCap database. A number of steps will be completed to ensure completeness and accuracy of the final dataset. First data management staff will work with study coordinators to reconcile all missing data (identifying items that are missing in the RedCap database, investigating whether or not that item should be missing, entering missing items if possible, and making a note of items that are truly missing). Once it is determined that all collected data have been entered into RedCap, range checks will be used to ensure that entered values are within the appropriate range. A report including items with values that appear out of range will be highlighted and sent to study staff for investigation and correction.

Confidentiality

The trial was approved by the IRB at all participating sites, and standards for maintaining confidentiality as required by the IRB were followed. All participants were assigned a study ID at the time of enrollment. This was kept separate from all identifiable information, and the document linking the study ID to the participant contact information was kept in a password-protected file which is stored in a network drive that is only accessible to those involved in the study, and maintained behind the institution's secure firewall. All data were kept in locked filing cabinets, with signed informed consent documents kept in a physically separate locked cabinet. Once the dataset has been finalized it will be de-identified, and only those with authorization will have access to the dataset.

Data monitoring/protocol adherence

While all sites obtained IRB approval, the IRB at the main site served as the IRB of record for the trial and functioned to ensure and maintain protocol adherence for trial. All adverse events related to the trial and instances of protocol deviations were reported to the IRB. Records indicate that no adverse events or protocol deviations were reported throughout the study period. All sites participated in weekly conference calls to discuss recruitment, participant enrollment, data collection, and ensure adherence to protocol. In addition, the IRB maintained oversight throughout

the trial and required annual reviews of the protocol. Data were maintained in accordance with IRB requirements as any active study was subject to a random audit to examine adherence to approved protocol (although this study was not selected for audit during the trial period). Finally, the sponsor of the trial did not require a data-monitoring committee for this trial; therefore one was not created.

Summary/plan for dissemination

The present manuscript discusses the rationale and details of two online parenting interventions to promote positive parenting behaviors, and describes the trial protocol used to assess the effectiveness of these interventions among families of young children who have sustained a TBI. To our knowledge, this is the only large multi-site RCT examining the comparative effectiveness of two parenting skills interventions within this at-risk population. The feasibility of delivering the intervention via a telehealth medium has been documented,⁴⁶ and it is hoped that findings from the described RCT will begin to document an evidence base for the I-InTERACT intervention, and provide preliminary potential utility for an abbreviated intervention.

Data collection from the described trial has been completed; however, data analysis has not yet been completed. We have identified a number of outlets for dissemination and hope to spread findings to families and caregivers, clinical care professionals working with these patients, related professionals, and the community more broadly. In addition to completing analyses and manuscripts for publication in peer-reviewed journals, we hope to reach participants and families who may not be part of the research community. First, our research lab publishes a bi-annual newsletter that discusses updates within the lab including personnel and new study opportunities, as well as summaries of findings from completed studies. In addition, we will work with media relations at our institution, who work to disseminate clinical findings to both patient families and clinical and research professionals, to publish findings of the trial. Media relations will also work to disseminate findings to websites or organizations utilized by patients and families, as well as the public media. Our group has a history of giving presentations in a variety of settings including research seminars and conferences, clinical care organizations, and educational settings. We plan to utilize these resources to ensure that meaningful findings are disseminated to broad audience.

Contributorship: SLW researched literature and conceived of study SLW, HGT, KOY, TS, and MWK assisted in protocol development, gained IRB approval, oversaw patient recruitment, and supervised data collection. MEN wrote the first draft of the

manuscript. All authors reviewed and edited all drafts of the manuscript, and approved final version of manuscript.

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