Setting Families on a Positive Path to Recovery after Pediatric TBI:
Road-to-Recovery, A Randomized Control Trial

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1. Background Information and Scientific Rationale

1.1 Background Information

Traumatic brain injury (TBI) is a leading cause of acquired disability in childhood, impacting long-term health and functioning. Hospitalizations and rehabilitation visits leave families with worries, guilt, and questions regarding longer-term issues. The impact of pediatric TBI on caregivers and families is clearly documented, with numerous studies showing poorer psychological functioning, greater stress, and more family problems among caregivers of children with TBI relative to caregivers of non-injured children (e.g., Aitken et al., 2009; Hawley et al., 2003; Rashid et al., 2014). Mounting evidence has supported the critical role of parent/family functioning and parent-child interactions in child recovery following TBI (Yeates et al., 1997; Taylor et al., 2001, Gerring & Wade, 2012), and recent investigations have continued to underscore the role of the family and home environment in the child's recovery.

Risk factors for poorer recovery include nonmodifiable factors such as greater severity of injury (Catroppa et al., 2008; Rassovsky et al., 2015), younger age at injury (Catroppa et al., 2008; Keenan et al., 2019), and lower household income (Cohen-Zimerman et al., 2019). However, there is a growing body of research documenting the critical role of caregiver and family functioning on child recovery following pediatric TBI (e.g., Ryan et al., 2016). Poor caregiver psychological functioning and family dysfunction have been found to exacerbate child behavior problems following injury (e.g., Raj et al., 2014a; Taylor et al., 2001). This association is particularly notable given that parents of children with TBI report more family problems, higher rates of depression and anxiety, and greater levels of stress than parents of non-injured children (e.g., Aitken et al., 2009; Hawley et al., 2003; Rashid et al., 2014). The influence of caregiver functioning is apparent in the initial months post injury, with poorer caregiver psychological health predicting more adolescent externalizing behavior problems, and more positive parent-adolescent communication predicting fewer behavior problems (Raj et al., 2014a).

To our knowledge, there are no interventions specifically targeting caregiver needs and well-being, and/or positive parenting in the acute phase following injury. Indeed, there is a general lack of interventions for families impacted by pediatric TBI (Brown et al., 2013). A number of existing interventions focus on chronic needs, and not on functioning in the immediate weeks after injury (McLaughlin et al., 2013, Wade et al., 2017). Parents of infants and toddlers may be especially unlikely to receive support; Keenan and colleagues (2019) found that more than 25% of parents of young children with TBI reported developmental concerns, yet only 5% of these children received early childhood intervention services.

Numerous factors can hamper intervention efforts with parents impacted by pediatric TBI. Parents already burdened with increased child needs may have not have time, resources, or inclination to seek supports for themselves (e.g., Roscigno & Swanson, 2011). Both traditional barriers to help seeking, such as perceived stigma (Corrigan, 2004), and logistical challenges such as living in rural areas or lack of transportation and financial resources (Syed et al., 2013) render traditional in-office psychological services difficult to access.

1.2 Rationale

The early recovery period constitutes a critical window to set families on a positive road-to-recovery by supporting parental self-care, positive parent-child interactions, and awareness of potential longer-term concerns. The latter would facilitate parental recognition of behavioral and psychosocial needs that might otherwise go unmet.

Recognizing that (1) caregivers of children who have sustained TBI are at risk of worsening psychological health and that (2) caregiver functioning and parenting behaviors have a direct impact on child recovery and outcomes; intervening and supporting caregivers in the acute phase following injury may set children and families on a positive path to recovery. Intervening at the acute phase may reduce the cascading effects of parental burden/distress and concomitant negative parent-child interactions on child recovery and functioning over time.

Because families of children with TBI and other chronic health conditions may have difficulty accessing services due to transportation and cost issues, particularly lower income families (Syed et al., 2013), the R2R-TBI program is designed to be accessed via any web-enabled device (e.g., smartphone, computer, tablet) with any form of internet connection. We will also offer the intervention (via tablet) to parents while they wait for their child to complete outpatient therapies (e.g., speech, physical, and occupational therapy). Delivery of web-based behavioral health interventions may reduce barriers to help-seeking and promote evidence-based interventions that are both accessible and efficient (e.g., Linardon et al., 2019; Luxton et al., 2011). The PEW Research Center (2019) indicates that about 92% of US adults ages 30-49 years and 96% of adults ages 18-29 years own a smartphone. Importantly, the common practice of seeking health information online (PEW Research, 2015) is correlated with changes in medical decision making, suggesting that online information seeking affects subsequent health-related decisions (Chen et al., 2018). Among 151 caregivers of children with TBI, 71% rated a self-guided online treatment format as convenient (versus only 18% who rated face-to-face treatment as convenient), providing further support for the acceptability of this approach (Wade et al., 2019).

2. Objectives and Purpose

The overarching aims of this project are to: (1) refine and enhance the R2R-TBI intervention, and (2) examine the efficacy of the R2R-TBI intervention in a randomized control trial.

Findings from our pilot usability trial were largely positive and are described in Raj et al., (2021). The R2R-TBI program targets caregiver psychological functioning, parenting behaviors, and family functioning in the first three months following pediatric TBI. Research shows that the impact of parent functioning and behaviors on child outcomes are apparent in the initial months following injury (e.g., Raj et al., 2014a), and intervening during this acute phase may serve a protective function to children and families. This project is unique as it shifts the emphasis on recovery and neuroprotection that is typically delivered exclusively to the child, to the caregiver/family. Moreover, intervening in the acute phase post-TBI may provide a new opportunity for preventative behavioral health care and set families on a positive path to recovery.

3. Study Design

3.1 Overview

This study has two main goals: 1) to refine and enhance the R2R-TBI intervention; and 2) to examine the efficacy of the R2R-TBI intervention in a randomized control trial. To achieve the second goal, we will employ a between-groups randomized treatment design with repeated measures at baseline, one-month post-randomization, and at a six-month follow-up. The two conditions will be: a) usual medical care plus access to internet resources regarding pediatric brain injury (Internet Resources Comparison group, IRC), and b) usual medical care plus the R2R-TBI intervention (Road-to-Recovery group, R2R-TBI).

3.2 Infrastructure

Participants will be recruited from Cincinnati Children's Hospital Medical Center (CCHMC) and Nationwide Children's Hospital (NCH). CCHMC and NCH are fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), which promotes the highest quality research. To earn accreditation, organizations must provide tangible evidence – through policies, procedures, and practices – of their commitment to scientifically and ethically sound research and to continuous improvement. Potential participants will also be recruited through sharing of study information and study flyer at other hospitals and through organizations and associations serving children/families impacted by pediatric TBI.

3.3 Study Measures

Participants will complete the following self-report measures at baseline, one-month post-baseline, and six-month follow-up. The measures described below were chosen based on the following criteria: 1) brevity (to minimize respondent burden), 2) high levels of reliability and evidence of validity with this population, 3) sensitivity to the effects of TBI, and 4) sensitivity to the effects of intervention. All data will be collected online via REDCap.

Family demographics: Parents will complete a demographic survey that includes items related to annual family income, child and parent race/ethnicity, relationship to child, and services child is receiving.

Parent mental health functioning: The Patient-Reported Outcomes Measurement Information System (PROMIS) Anxiety Measure 4a (4 items) will be used to assess parent anxiety. The Center for Epidemiological Studies Depression Scale (CES-D; 10-items), will be used to measure parent depression. The CESD-10 is the short form of the original 20 item CES-D (Radloff, 1977). The Primary Care PTSD Screen for DSM-5 (PC-PTSD-5) will be used to asses for parent post-traumatic stress symptoms. The measure consists of 5-items (Prins, et al., 2015).

Parent wellbeing: Parent resilience will be assessed using the Connor-Davidson

Resilience Scale (10 items, Connor and Davidson, 2003) and parent self compassion and self-care behaviors will be assessed using the Mindful Self-Care Scale – Brief (24 items, Cook-Cottone, C. P. (2015)

Perceived parenting efficacy. The Caregiver Self-Efficacy Scale (CSES) is a 25 item self-report scale that measures parenting confidence and efficacy. Parents rate how comfortable they are in aspects of parenting, including their ability to control their child's behavior, praise their child, and say no to their child. Scores on the measure range from 25 to 100, with higher scores indicating greater perceived parenting efficacy. The CSES is a reliable and valid measure and has been shown to be sensitive to the effects of online, family-centered interventions for TBI (Wade et al., 2014).

Family functioning. Family functioning will be assessed using the 12 item Global Functioning Scale of the McMaster Family Assessment Device (FAD-GF, Epstein et al., 1983), a self-report measure of family functioning with established reliability and validity (Miller et al., 1985). Primary caregivers will rate their level of agreement (i.e., strongly agree, agree, disagree, strongly disagree) to statements reflecting their family's functioning. Scores on the FAD-GF range from 1 to 4 with higher scores indicating poorer family functioning. The FAD-GF is recognized by the Pediatric Common Data Elements (CDE) workgroup as a core measure of family functioning following TBI (McCauley et al., 2012).

Child/adolescent socioemotional functioning. Caregivers will complete the Pediatric Quality of Life Inventory (PedsQL – Short Form, for ages 2-18 years; Varni et al., 1999) or the Pediatric Quality of Life Infant Scales (for ages 1-24 months; Varni et al., 2011). The PedsQL is a reliable, valid, and widely used measure of child/adolescent quality of life and socioemotional functioning (Varni et al., 1999, 2011), with established validity and reliability in pediatric TBI samples (McCarthy et al., 2005). The measure provides a total scale score as well as two summary scores - physical health and psychosocial health. The psychosocial health summary score will be used as an outcome measure and the physical health summary score will be used to describe the sample. Scale scores are reported as mean scores for each scale, with higher scored indicating better functioning.

Burden of injury. The Family Burden of Injury Interview (FBII, Burgess et al., 1999) will be used to assess injury-related stress in the domains of child functioning and behavior, spousal relationship, and relationship with other members of the family in the acute phase following injury. The FBII is a reliable and valid assessment measure of injury-related burden for families affected by TBI (Burgess et al., 1999).

Feasibility and satisfaction. Ease of use of the program will be assessed by several measures of feasibility including usage analytics (i.e., trace data that captures time spent using the intervention, number of modules completed, time spent in each section/page of the intervention, keyboard input, etc.), as well as the System Usability Scale (SUS; Brooke, 1996). The SUS is an industry-standard scale consisting of 10 items with five Likert-scale response categories (*strongly agree* to *strongly disagree*). The SUS is easy to administer, widely used, and produces reliable and valid results (Bangor et al., 2008; Lewis, 2018). Parents will also complete an intervention satisfaction survey that has been adapted from prior web-based intervention studies (e.g., Kurowski et al., 2018;

Wade et al., 2012). The satisfaction survey captures both satisfaction with the content as well as with the web-delivery of the intervention. Caregivers will also provide qualitative feedback and suggestions via telephone and in-person interviews.

3.4 Eligibility Criteria

3.4.1 Study Subjects

3.4.1.1 Participant Inclusion Criteria

Caregivers will be eligible if they are over 18 years of age, and if their child meets all of the following criteria:

- Ages 3 months to 18 years at time of discharge from hospital
- Sustained a complicated mild to severe TBI as defined by a Glasgow Coma Scale (GCS) of 13-15 with imagining abnormalities or GCS 3-12 with or without imaging abnormalities
- Admitted overnight to the hospital
- 0-3 months post-discharge

3.4.1.2 Participant Exclusion Criteria

The caregiver will be excluded from participation if any of the following occur:

- Child did not survive the injury
- Child’s head trauma was self-inflicted
- Child does not reside with parent/caregiver for study duration
- English is not primary language spoken in the home

3.5 Recruitment Procedures

Up to 200 participants will be enrolled in this RCT. Potential participants will be identified and recruited from the CCHMC and NCH Trauma Registry, inpatient units, and outpatient clinics such as rehabilitation clinics. Potential participants will also be recruited through sharing of study information and study flyer at other hospitals and through organizations and associations serving children/families impacted by pediatric TBI.

Recruitment at CCHMC and NCH

Parents/caregivers who are eligible to participate will receive the study brochure or flyer while they are at the hospital, when their child is discharged from the hospital and/or at follow-up visits or clinics. Eligible parents/caregivers may also receive the study brochure or flyer via mail and or email (see recruitment email). The study brochure and flyer includes a QR code to a website that has the information sheet for the study. Research personnel will connect with families at the hospital (e.g., at follow-up clinics or discharge) or via phone (see phone /in-person recruitment script). Parents will be provided information about the study during this contact and will have the opportunity to review the information sheet/consent form and ask questions. Study staff will document this consent process on a form that will be included in the study binder.

Recruitment through sharing of study information and flyer

Potential participants may also reach out to the study staff and request to be screened for the study. Study staff at CCHMC will screen potential participants for eligibility and families who meet criteria will be provided information about the study during this contact and will have the opportunity to review the information sheet/consent form and ask questions (see Road-to-recovery telephone script for potential participants who self refer). Study staff will document this consent process on a form that will be included in the study binder

For all

If the parent or individual is not interested, they will be thanked for their time and no further contact about the study will be made. If interest in the study is expressed, the parent will be sent a link to the study REDCap site. Parents will also be given the option to meet with study staff via videocall to orient the parent to the REDCap and/or study site and provide technical support. The study REDCap site opens with the study information sheet that provides contact details for study personnel. Participants who choose to participate will indicate consent by clicking a button at the bottom of the REDCap information sheet that reads, "YES, I acknowledge that I have viewed the information sheet and am voluntarily choosing to participate in this study." Participants who click "YES" will then begin the baseline questionnaires. Participants who choose not to participate with click the "NO, I acknowledge that I have viewed the information sheet and I do not wish to participate in this study," and they will receive a notification thanking them for their time and they will not be able to access the questionnaires.

After baseline measures have been completed, the predetermined randomization sequence will be used to randomize caregivers into one of the two conditions (R2R-TBI vs. IRC). Stratified randomization will be used to achieve balance in child's age (< 5 years; ≥ 5 years) and injury severity. The randomization sequence will be based on a design with blocks of four or six chosen randomly within the sequence with equal probability. A pseudorandom number generator in R will be used, and the randomization sequence will be maintained by the statistician. Randomly varying block size reduces the chance that research staff will guess the next group assignment, minimizing unconscious bias. Block randomization with randomly mixed block sizes will then be performed with equal probabilities of assigning a participant to one of the two intervention groups.

4. Study Procedures

4.1.1 Screening

During the initial contact, potential participants will be informed about the study and will be asked whether they would like to be screened for the study (see telephone/in-person recruitment script and telephone script for potential participants who self-refer). Parents/caregivers who are eligible will then be provided further information about the study as detailed in the recruitment procedures.

4.1.2 Enrollment/Baseline

Eligible caregivers who provide consent via REDCap will be presented with the baseline survey queue on REDCap. The baseline forms are expected to take about

45 minutes to complete. Once study staff receive complete baseline forms, participants will be randomly assigned to either IRC or R2R-TBI and will be sent a link, password, and instructions on how to access the R2R-TBI application or IRC website.

4.1.2.1 Obtaining Consent

Study staff will review the consent form with prospective participants (via phone or in-person; see phone/in-person recruitment script) and parents will have the opportunity to ask questions. Study staff will document this consent process on a form that will be included in the study binder. A waiver of documentation of consent will be requested for this study and study staff will accept participant acknowledgement on REDCap as consent for the study. (i.e., participants clicking "YES, I acknowledge that I have viewed the information sheet and am voluntarily choosing to participate in this study"). The consent form/information sheet will be viewable on REDCap prior to beginning baseline measures. All pertinent aspects of the study will be included in the information sheet, including, contact information of the researcher, study purpose, risks/benefits, confidentiality, and right to withdraw.

4.1.3 Study Groups

4.1.3.1 R2R-TBI Intervention

Caregivers assigned to the R2R-TBI intervention will receive a link to the web-based intervention as well as a username and password. Caregivers will receive weekly text, email, or phone reminders (participants will choose their preferred method of contact) to engage with the website. Time caregivers spend on the intervention as well as details on how often they log-on and devices used when accessing the intervention will be recorded.

The R2R-TBI intervention was developed to be interactive and encourage active participation. Caregivers choose their own navigation paths through the web platform, allowing them to tailor the program to their specific needs. To encourage active engagement, caregivers have opportunities to practice skills taught in the intervention (e.g., questions with multiple responses and immediate feedback) and the format of these activities is varied. Each of these different components were tested in the usability testing sessions, and caregivers reported ease of use.

Figure 1 provides a brief overview of the R2R-TBI modules. Each module is designed to take less than 20 minutes to complete and parents have access to all modules when they access the site. While we will encourage caregivers to move sequentially through the first four modules before selecting supplemental modules, feedback from the pilot trial suggests that caregivers benefit from flexibility to navigate to content that is most relevant for them. For example, parents with immediate school concerns or greater relationship concerns may want to access that content earlier. Note that participants in both conditions will continue to receive usual care.

Figure 1. Summary of R2R-TBI modules

MODULE 1: WHAT TO EXPECT?

Parents often desire information about potential outcomes and benefit from ongoing information which may help reduce parental distress (Savage et al., 2005, Prigatano & Gray, 2007). In this module, caregivers are provided information about TBI and common sequelae of injury. Caregivers may select and learn more about symptoms that their child is experiencing.

MODULE 2. PROBLEM SOLVING YOUR CHILD'S RECOVERY

Problem-solving therapy approaches show promise in improving outcomes among children and families impacted by chronic health conditions (Law et al., 2014). As parent/guardians adjust to their *new normal*, this module teaches skills and a problem-solving framework that has been successfully used by caregivers of children with TBI (e.g., Wade et al., 2014; 2018).

MODULE 3. POSITIVE PARENTING

Parents learn positive parenting skills such as how to set their child up for success, and strategies to strengthen the parent-child relationship, set boundaries, and manage externalizing behaviors. Parents are able to select information that is specific to their child's age and developmental level.

MODULE 4. TAKING CARE OF YOURSELF

Caregivers experience a lot of stress in the acute phase post injury, which can persist for many years. In this module, parents are taught stress management strategies such as progressive muscle relaxation, relaxed breathing, and guided imagery.

MODULE 5. WORKING WITH YOUR CHILD'S SCHOOL

Parent perspectives of quality of communication with their child' school during re-entry and affects child outcomes (Andersson et al., 2016). In this module, parents learn how to work collaboratively with the school to support their child's re-entry and needs. Information about services/supports (e.g., IEP, 504-Plan) is provided.

MODULE 6. GUILT, GRIEF, AND CAREGIVING

Parents of children with TBI often experience feelings of guilt and grief (Aitken et al., 2009; Kirk et al., 2015). This module works to normalize feelings of guilt and grief and shares experiences of other caregivers. Parents are provided strategies to manage difficult emotions and information on respite care and other services/support.

MODULE 7. PARENTAL COMMUNICATION

Parents learn about common relationship stressors following pediatric TBI (e.g., differing parental expectations, poor communication, financial concerns, etc.; Kirk et al., 2015). Parents also learn tips for improving communication with their spouse/partner and practice effective talking/listening skills.

MODULE 8. SLEEP ISSUES

Many children with TBI experience sleep difficulties (Sumpter et al., 2013). This module covers possible reasons for their child's sleep issues, and strategies for supporting healthy sleep for both child and parent.

MODULE 9. PARENTS AND SIBLINGS

Siblings of children with TBI are at risk of poorer psychological functioning and reduced quality of life (Sambuco et al., 2008). In this module, parents learn about typical sibling reactions and strategies they can use to support all their children. Parents are also taught to differentiate between normal sibling reactions and warning signs of more serious problems, as well as resources on services/supports for siblings.

MODULE 10. AFTER HIGH SCHOOL

This module is for parents of children with post-TBI challenges transitioning out of high school. It contains information on their child's legal rights around education and job training and links to organizations that support transition, such as the State Vocational Rehabilitation Agency.

4.1.3.2 Internet Resources Condition (IRC)

Caregivers in the web-based resources condition will be provided with a link and password to a website that provides links to a range of resources on pediatric TBI including local, state, and national brain-injury associations. These resources will also be provided to families in the R2R-TBI intervention. Essentially, families in the IRC condition will have access to the same links to resources without the specific intervention content/modules. This will enable us to equate the groups with regard to access to information and resources available on the internet. Parents in this group will also have access to technical support as well as the opportunity to contact the researchers with any questions/concerns.

Participants in both conditions will continue to receive usual care.

4.1.4 Check-ins

Study staff will check-in with study participants at regular intervals during their participation in the study via phone calls, texts and/or emails. These check-ins will allow study staff to keep participants engaged and to provide reminders to use the website.

4.1.5 Follow-ups

Follow-up 1 (30 – 45 days after receiving study login)

Approximately 30 to 45-days after receiving their login, parents will be contacted via phone, email, and/or at follow-up clinics and will be provided a link to the REDCap site to complete the post-intervention questionnaires. Participants will also be given the option to meet with study staff via videocall if they would like to orient the participant to the REDCap site and provide technical support.

Follow-up 2 (6 months after baseline)

Approximately 6 months after receiving their login, parents will be contacted via phone, email, and/or at follow-up clinics and will be provided a link to the REDCap site to complete the long-term follow-up measures. Participants will also be given the option to meet with study staff via videocall if they would like to orient the participant to the REDCap site and provide technical support.

Brief interview

A subset of participants may be contacted via phone, email, and/or at follow-up clinics to complete a brief qualitative interview (10-15 minutes) about their experience with the intervention that may be audio recorded. This interview will be conducted anytime after follow-up 1 and may be done via email, phone, or in-person.

4.1.6 Participant Withdrawal or Termination

4.1.6.1 Reasons for Withdrawal or Termination

Participants are free to withdraw from the study at any time upon verbal or written request.

An investigator may terminate participation in the study if:

- Any adverse event, medical condition, or situation occurs such that continued participation in the study would not be in the best interest of the participant
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

4.1.6.2 Handling of Participant Withdrawals or Termination

Participants are free to withdraw from the study at any time upon verbal or written request. If a family indicates they would like to withdraw, they will be given the option to discontinue intervention modules but remain in the study for follow-up or discontinue from the intervention modules and future follow-up. Existing data will remain in the study database. If a participant wishes to have all research being conducted on his/her data stopped, the data will not be included in the analysis.

5. Statistical and Analytical Approaches

5.1 Statistical and Analytical Plans

Caregiver functioning is examined as the primary and most proximal outcomes of the R2R-TBI intervention. Through targeting caregiver functioning, we expect the R2R-TBI intervention to have downstream effects (through reductions in caregiver depression and distress) on the secondary outcomes of child recovery and family functioning. We further anticipate that the same risk and protective factors that have been shown to moderate child recovery and the efficacy of other family-centered interventions for pediatric TBI, such as household income and baseline family functioning, will moderate the efficacy of the R2R-TBI intervention (e.g., Antonini et al., 2014; Raj et al., 2014b; Wade et al., 2012, 2015). Specifically, we anticipate that the R2R-TBI intervention will be most effective among low-income families and among caregivers with high levels of baseline distress. Our hypotheses are as follows:

Hypothesis 1: Caregivers receiving the R2R-TBI intervention will report lower levels of depression, anxiety, post-traumatic stress, and higher levels of caregiver self-efficacy and mindful self-care at follow-up, compared to caregivers in the IRC condition, after controlling for baseline levels.

The R2R-TBI intervention is designed to promote caregiver psychological well-being and positive parenting in the acute phase post-injury. This hypothesis represents an important test of whether the intervention is successful in improving these areas of functioning that are targets of the intervention. To evaluate this hypothesis, we will examine group difference in caregiver depression (CES-D-10, Radloff, 1977), anxiety (PROMIS Anxiety 4a), post traumatic stress (PC-PTSD-5, Prins et al., 2015), caregiver self-efficacy (CSES, Boothroyd & Evans, 1997), and mindful self-care (MSCS-25; Cook-Cottone, 2015) at one and six-months post-baseline, controlling for baseline scores. Given the challenges in the acute phase post-injury, we expect caregivers in the R2R intervention to report stable functioning while caregivers in the IRC group to report increasing levels of depression and distress at both one and six-month follow-ups.

Hypothesis 2: Caregivers receiving the R2R intervention will report better child and family functioning at follow-up, compared to caregivers in the IRC condition, after controlling for baseline functioning.

We anticipate that the R2R-TBI intervention will be effective in both ameliorating problems evident at baseline and in preventing emergence of additional problems in family and child functioning at one and six-months post-baseline. To test this hypothesis, we will examine group differences in family functioning (FAD-GF, Epstein, Baldwin, & Bishop, 1983), family burden of injury (FBI, Burgess et al., 1999) and child socioemotional functioning (PedsQL Psychosocial Summary Score, Varni et al., 1999) at one and six-months post-baseline.

Hypothesis 3: We hypothesize that treatment effects will be moderated by household income and level of caregiver distress at baseline.

We expect families with greater social disadvantage (lower income, more stress) will benefit most from the R2R-TBI intervention. This hypothesis is consistent with previous research findings (e.g., Antonini et al., 2014; Raj et al., 2014b; Wade et al., 2012, 2015).

Variable distributions will be examined before carrying out inferential statistical procedures, and transformations will be made in cases where distributions are skewed or fail to meet the assumptions of normality. Non-parametric procedures will be employed in cases where transformations would be inappropriate or where analysis of frequencies is justified. Preliminary work will also involve computation of reliabilities and creation of derived variables that summarize performance on measures that are highly inter-correlated. To evaluate potential attrition bias, caregivers who drop out (i.e., those who access < 3 modules and/or who do not complete baseline or follow-up measures) will be compared to those who remain in follow-up on background characteristics as well as on outcomes measured prior to dropout. Factors related to dropout will be included as covariates in the analysis.

Analytic plan for hypotheses 1 and 2. The primary analysis will consist of a linear mixed-effect models used to examine changes in caregiver, family, and child functioning among participants in the R2R-TBI intervention and IRC groups from baseline to 6-months post-baseline. In addition, the one-month data will be included in a mixed model repeated measures analysis. This model allows for flexible modeling of the pattern of change in outcomes over time and uses all the data for a given participant, even if that participant is not seen at all assessments, allowing us to retain participants with missing assessments.

Analytic plan for hypothesis 3. Existing literature and findings from our other studies suggest that demographic factors such as household income as well as baseline caregiver functioning impact adaptation to injury, and we hypothesize that these factors will moderate the efficacy of the intervention. Hierarchical multiple regression analyses which include the interaction of group, moderator (household income, baseline functioning), and time in the model will be used to test hypothesis 3. Variable selection using backward elimination will be used to remove non-significant higher- and then lower-order terms. In order to avoid selection bias, bootstrapping will be used on the backward elimination process (Austin, 2008). Post hoc analyses will be used to compare treatment groups on each outcome at different levels of the moderators at 1 and 6-months post-baseline.

6. Data Management

6.1 Data Safety and Monitoring Plan

Risks to the patient and family's privacy are minimal, and every effort will be made to safeguard confidentiality according to HIPAA specifications. Personnel involved in data collection will be instructed regarding the importance of confidentiality and the steps that must be taken to protect it. Confidentiality of participant's names will be ensured by replacing names with subject numbers. The master list linking the two will be kept in a locked file drawer.

A licensed psychologist and staff trained in working with families of children and teens with TBI will be conducting this study. Participants and their families will be able to reach the study PI or designee to report any adverse effects or concerns.

Participants will complete a W9 form embedded in the REDCap survey to obtain compensation. After a participant completes the W9, this information will be uploaded to Cincinnati Children's Hospital Medical Center secured G: Drive and deleted from REDCap. All data will be presented and published in aggregate form without identifying information. All paper and pencil data will be secured in locked file cabinets and on-line data will be password protected and encrypted using 128-bit encryption software. Should participants disclose any unnecessary PHI on the questionnaires; the PHI will be redacted using black permanent marker and will be initialed and dated by the coordinator noting redacted PHI. PHI will also be edited out in audio recordings as well as resultant transcripts.

7. Quality Assurance and Quality Control

7.1 Quality Control Procedures

Regular meetings of the PI and project staff will serve to review recruitment, baseline, and follow-up assessment scheduling and completion, to address questions regarding administration and scoring of assessments, and to evaluate progress toward study milestones.

8. Human Subject Considerations

8.1 Potential Risks

Participants will encounter no more than minimal risks due to enrollment in this study. All of the questionnaire measures have been used extensively in previous research with no negative psychological reactions reported.

8.2 Potential Benefits

Regardless of the intervention condition the participant is assigned to, they will be provided links to resources on pediatric TBI that may be helpful.

9. Compensation and Costs

9.1 Compensation

Participants will be compensated as follows:

- $50 after completing the first set of online questionnaires (baseline)

- $50 after participating in the online self-guided intervention (or control condition) and completing the 1 to 1.5 month online questionnaires
- $50 after completing the 6-month follow-up online questionnaires
- $25 to parents who participate in the qualitative interview

9.2 Costs

There are no costs to participants or their insurance providers**.**

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