Parent Emotion Socialization and Child Emotion Regulation in FASD
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1. STUDY OVERVIEW – PURPOSE AND BACKGROUND

Children with fetal alcohol spectrum disorders (FASD) have high rates of mental health problems and incur physical and mental health expenditures that are 9 times higher than other children (Amendah, Gross, & Bertrand, 2011; O'Connor, 2014; Streissguth et al., 2004). These mental health problems contribute to poor social adjustment for children with FASD and result in considerable emotional and financial burden for families. Emotion regulation is a core area of impairment in FASD (Kable et al., 2015) and is implicated in most mental health disorders (Zeman, Cassano, Perry-Parrish, & Stegall, 2006). Research on empirically validated interventions for children with FASD is limited (Petrenko, 2015). Results from two interventions targeting emotion regulation in FASD demonstrate that child-focused interventions are insufficient to habilitate children's emotion regulation to adaptive levels (Nash et al., 2014; Wells, Chasnoff, Schmidt, Telford, & Swartz, 2012). Research is needed to identify alternate targets for intervention (e.g., parent training, environmental modifications) to improve the emotion regulation difficulties of children with FASD.

This study investigates a novel intervention target to improve the emotion regulation and adaptive functioning of children with FASD. Research with other populations provides ample evidence for the impact of parent emotion socialization on the development of child emotion regulation and other outcomes (e.g., Eisenberg, Cumberland, & Spinrad,1998; Katz, Maliken, & Stettler, 2012). In addition, studies demonstrate that parent emotion socialization is amendable to intervention and results in improved child and parent outcomes (e.g., Havighurst, Wilson, Harley, Prior, & Kehoe, 2010). However, no studies have investigated the emotion socialization practices utilized by parents of children with FASD or whether interventions targeting parent emotion socialization result in improved child emotion regulation and behavior in this population.

This study will address this critical gap by initiating an empirical test of a promising emotion-focused intervention, *Tuning In To Kids* (TIK; Havinghurst & Harley, 2007), with families raising children with FASD. Results from this initial efficacy trial will determine whether parent emotion socialization is a promising intervention target for this population. Consistent with a developmental psychopathology perspective (Toth, Petrenko, Gravener-Davis, & Handley, 2016), multi-level data from the efficacy trial will be leveraged to test theorized associations between parent emotion socialization and child emotion regulation and identify possible factors contributing to individual differences. These results will inform possible intervention adaptations for this population and provide the necessary foundation for larger-scale efficacy trials. The long-term goals of this research are to better understand the complex factors influencing emotion regulation in children with FASD and improve mental health interventions and outcomes for this population.

2. CHARACTERISTICS OF THE RESEARCH POPULATION

2.1. Subject Characteristics

Participants will include children (ages 4-12) with FASD who reside in some form of out-of-home care (e.g., adoptive parent, relative, or legal guardian) and their primary caregiver.

a) **Number of Subjects:** Power analyses suggest a minimum sample size of 72 caregiver-child dyads to detect medium effects or larger across study aims. We will aim to enroll up to 120 families to achieve a sample size of 72 dyads with adequate data at study timepoints and have sufficient power to detect effects. This sample size will account for families who

consent to the study but do not begin study visits and an expected 10% attrition of families randomized to treatment condition (based on our prior trials). In families with multiple caregivers, families will be asked to indicate the primary caregiver or the caregiver with whom the child spends the most time to complete research visits. In families with more than one child with FASD in the study age range, families will be asked to randomly choose the child that will participate in research visits.

b) **Gender and Age of Subjects:** Children will be between age 4 and 12 years. Caregivers will all be over age 18. Participants will not be recruited or selected based on gender; participants will be both male and female. The proportion of female caregivers participating in research visits will likely be higher than for males, given that females are more likely to take on the role of primary caregiver. We aim to enroll approximately equal numbers of boys and girls with FASD in the study.

c) **Racial and Ethnic Origin:** Participants will not be recruited or excluded from participation on the basis of race or ethnicity. Given that children with FASD will be in out-of-home care, the rates of racial/ethnic backgrounds may differ between caregivers and children. Based on US census records for counties in the project catchment area, it is expected that samples may include 5% of families who report their ethnic identify as Hispanic. Racial breakdown is estimated as: 80% White/Caucasian, 15% Black/African American, 1% American Indian/Alaskan Native, 2% Asian, 0% Native Hawaiian/Other Pacific Islander, and 2% more than one race. Historical recruitment rates suggest children with FASD will have higher rates of Black/African American, American Indian/Alaskan Native, and more than one race. Racial estimates for children are: 64% White/Caucasian, 21% Black/African American, 4% American Indian/Alaskan Native, 3% Asian, 0% Native Hawaiian/Other Pacific Islander, and 8% more than one race.

d) **Vulnerable Subjects:** The inclusion of children with FASD is integral to the proposed research aimed at understanding the association between parent emotion socialization and child emotion regulation skills. Children between the ages of 4 and 12 were selected for this study as prior research with other populations documents the relevance of targeted constructs across this age span (e.g., Katz et al., 2012) and the TIK intervention is appropriate for families of preschoolers through preadolescents. Dr. Petrenko has considerable experience working with children with FASD and their families in both research and clinical settings. Clinical and research staff will be carefully selected and well trained to establish rapport and engage children and families, as well as handle sensitive and confidential information with care and respect for the participants who provide it.

2.2. Inclusion and Exclusion Criteria

a) **Inclusion Criteria:** Families will be eligible for the study if they:

- Have a child between the age of 4 and 12 with a diagnosis of an FASD based on the Revised 2016 Hoyme criteria (Hoyme et al., 2016) or the DSM-5 criteria for Neurobehavioral Disorder Associated with Prenatal Alcohol Exposure (ND-PAE).
- The child is in some form of out of home care (e.g., adoptive, foster, relative, or other legal guardian)
- The child has resided with the primary caregiver for at least a year and be expected to remain in that placement for at least 6 months (study duration).

FASD diagnostic records will be obtained for each child at study entry (from the child's electronic medical record, from outside medical providers directly with appropriate release,

and/or directly from the parent) to confirm diagnosis and prenatal exposure history. The University of Rochester is currently the only specialty diagnostic clinic for FASD in New York State. Dr. Petrenko is one of the primary clinicians involved in diagnosis of FASD at URMC Developmental & Behavioral Pediatrics and has eRecord access as part of her role there.

For children with a suspected FASD diagnosis who have not been formally evaluated yet, Dr. Petrenko will review existing records and can complete a brief diagnostic interview with the parent to determine if DSM-5 criteria for ND-PAE are met (see DSM-5 Diagnostic Criteria Checklist for ND-PAE). If met, children will be eligible to participate in this study. Children who meet criteria for ND-PAE will also be referred to the FASD Diagnostic Clinic at URMC for further medical diagnostic evaluation and treatment planning. When screening is inconclusive or additional information is needed to determine diagnosis (e.g., confirmation of alcohol exposure), children will be referred to the URMC FASD Diagnostic Clinic for further evaluation and will not be eligible for the study unless an FASD diagnosis is rendered at a later date.

b) **Exclusion Criteria:**
- A history of other genetic, neurological, or significant medical conditions, traumatic brain injury, serious psychiatric illness or disability that would preclude data collection
- Child has a moderate to severe intellectual disability (IQ < 55)
- Child or caregiver has insufficient proficiency in English
- Caregiver is a biological parent of the child with FASD

3. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT

3.1. Method Of Subject Identification And Recruitment

Recruitment of caregivers raising children with FASD will occur via provider referrals, an existing database of families who have consented to be contacted about future research (RSRB00055352), and presentations at parent support groups and conferences.

The small number of providers who serve this population in the region will be informed about the study and can tell interested families to contact the research team to learn more. A study flyer and contact form will be provided to providers that they can give to interested families.

The largest provider of diagnostic and intervention services for FASD in the area is Developmental and Behavioral Pediatrics (DBP) at URMC. Lynn Cole, MS PNP is the clinical director of this service and is in full support of this project. Ms. Cole co-directs a multidisciplinary FASD diagnostic with Dr. Petrenko. In addition, Ms. Cole and other developmental pediatricians regularly see children with FASD for initial diagnosis (especially children 6 and under) and medical follow-up. Ms. Cole, will inform families about the study and can provide them with the flyer and/or contact form. She has also agreed to send out a letter about the study to families of existing patients with FASD seen at DBP.

When Dr. Petrenko informs families about the study during diagnostic evaluation feedback sessions or at parent support group meetings she runs, she will direct families to contact the study coordinator if they are interested to complete eligibility screening. Families will also have the option to complete a contact form for a research team member to call them. Potential coercion will be reduced by providing families information about all applicable services and supports available to them during interpretation sessions, as is standard practice.

3.2. **Process of Consent**

Upon receiving the appropriate name release or being contacted by interested families, research staff will describe the study to families in more detail and screen for eligibility. During the recruitment phone call, verbal consent will be obtained from caregivers prior to completing the screening questionnaire and family contact information form.

During the screening process, research staff will confirm that the caller has the authority to give permission for the child to participate in research. A copy of the court order (or other legal appointment document) appointing the person as the guardian will be obtained and maintained in participant records. The research team will also verify that the guardian's authority applies to granting permission for health care/research and is not limited to just financial matters. If the caregiver/guardian does not have authority to give permission (e.g., foster child in county custody), the appropriate authority (e.g., caseworker, biological parent) will be consulted by a research staff member to determine if permission will be granted. The initial research visit will not be scheduled in these cases until permission has been obtained.

Once recruited, families will be sent a visit reminder letter and a copy of the consent/permission form to review prior to their first research visit. At the first research visit, project staff will obtain written consent from caregivers for their participation and permission for the child to participate (if not previously obtained). For children ages 8 or older, the study will be described in developmentally appropriate language and assent obtained. During the consent/permission/assent process, research staff will ask if the participant understands the content and will offer to answer any questions.

COVID-19 modifications: The approved study consent form has been modified for remote procedures during the COVID-19 pandemic. It can be administered through REDCap using the eConsent module to allow documentation of consent (following implementation with Research and Academic IT). At the end of the screening call, research staff will obtain verbal permission from eligible families to send the eConsent by email (see screening addendum form). With permission, research staff will then send a REDCap link for the study eConsent to eligible participants. Participants can review the consent using their personal computer, tablet, or smartphone. Participants can review it prior to speaking with research staff or at the start of the baseline data collection call/Zoom session. At the start of the call/Zoom session, research staff will ask participants if they have any questions relating to the consent document. Participants can sign the eConsent in the signature field with their finger, stylus, or mouse. Identity will be verified by including several demographic questions after the consent form. These will be compared with the demographic information gathered during screening. Research staff will confirm the eConsent is signed prior to initiating any data collection. The call will be cancelled or rescheduled if needed. After signing the consent, a pdf version of the consent will appear on the screen, which participants can download for their records. Participants can also choose to have the hard copy study consent form mailed to them instead of doing the eConsent. Research staff would then go over the consent with them on the phone or Zoom. Participants would then send back the form signed before data collection can begin. A modified version of the verbal assent has also been created for children 8 or older if families agree to complete the Family Narrative Task (FNT). Research staff will administer this verbally with children over the phone/Zoom before this task is completed. Video will be used when possible to facilitate child's

engagement/attention.

4. METHODS AND STUDY PROCEDURES

4.1. Study Procedures and Assessments

Study Design: Study aims will be tested within the context of a pilot RCT using a waitlist comparison group. Data will be collected at three time points: baseline (T1), immediate post-intervention (T2), and a 3-month follow-up (T3). Baseline data collection will involve multi-method and multi-level (standardized questionnaires, interviews, observations, physiological measurements) assessment of primary constructs. After baseline data is collected, families will be randomly assigned within blocks to the TIK intervention group (TIK) or the delayed intervention waitlist comparison group (WLC). The TIK group will then receive the group-based TIK intervention over the course of 8 weeks. All participants will complete multi-level and multi-method assessments at T2. Families in the TIK group will also complete a measure of intervention satisfaction at the end of the last TIK session to maintain blindness of RAs to group membership. Therapists will also complete a group cohesiveness measure for each participant. An abbreviated assessment battery will be administered 3-months post-intervention to both groups to assess the maintenance of effects and to test for mediation. Following T3 research visits (~5-6 months post study entry), families in the WLC group will be offered the TIK intervention.

Assessments: Table 1 lists the assessment battery for children and caregivers for each time point. Primary constructs include parent emotion socialization attitudes and practices, child emotion regulation, and child behavior problems. Sample descriptors and potential predictors will also be collected. Research assistants will be trained in all measures. Research visit sessions will all take place at MHFC and will be audio and/or video recorded to enable later coding. A copy or description of each measure is included in the RSRB application for review. Detailed visit protocols are also included for child and parent for each time point.

COVID-19 Modifications: Due to the COVID-19 global pandemic, any cohorts already in progress may complete an abbreviated battery at T2 and T3 by alternate means when in-person data collection is not possible. These alternate means may include: via HIPAA-complaint Zoom, telephone, and/or by mail. These participants will have already consented to the study and completed T1.

New cohorts can also be enrolled using the COVID-19 modifications described above via REDCap. For any participants enrolled remotely, in-person visits will be encouraged once we are allowed to return, but if families start the study remotely, they can choose to complete remaining visits remotely as well. If participants from new cohorts come in for in-person visits for follow-up, the K-BIT2 may be administered to the child at T2 or T3.

Measures included in the abbreviated batteries are marked with an asterisk* in Table 1. These measures are questionnaires and interviews that can be completed with parents remotely. Parent-report questionnaires can be sent by email/mail and returned, completed via REDCap, or administered over the phone/Zoom depending on participant preference and ability. Participants can also complete the FNT with their child in one of two ways. The first is to have the parent complete the task with the child while on Zoom with a research staff member. Alternately families can complete the task at a convenient time for them and record with their phone/tablet and sent to

research staff. A REDCap survey can be set up to facilitate secure upload/transmission of videos for families. Families can also elect not to complete this task.

When needed, remote telephone communication by staff will be completed using encrypted and password protected personal cellular phones. Staff will block caller ID through their phones or use *67. See phone and email scripts.

Table 1: Assessment Battery	**T1**	**T2**	**T3**
CHILD			
Height and weight	X	X	X
Kaufman Brief Intelligence Test-2 (20 min)	X		
Baseline ECG (Activewave Cardio)	X	X	X
Disappointment Task (5 min) with Activewave Cardio	X	X	
NIH Toolbox Cognition Battery (24min)	X	X	
Dimensional Change Card Sort Task (4min)	X	X	
Flanker Inhibitory Control & Attention test (3min)	X	X	
Pattern Comparison Processing Speed (3min)	X	X	
Picture Sequence Memory (7min)	X	X	
List Sorting Working Memory (7min)	X	X	
Pictorial Depression Scale (age 4-6) OR Child Depression Inventory-2 (ages 7-12)	X	X	
Qualitative Emotion Interview	X	X	
Behavior Assessment & Validity Ratings (by examiner)	X	X	X
PARENT			
Health & Services Interview (5-8min) / Update	X*	X*	X*
Demographic Survey via REDCap (3-5min) / Update (5min)	X*	X*	X*
Parent Emotion Socialization			
Meta-emotion interview (25-45min)	X*	X*	
Difficulties in Emotion Regulation Scale (2-5min)	X*	X*	X*
Parent Emotion Styles Questionnaire (3-10min)	X*	X*	X*
Child Emotional & Behavioral Functioning			
Emotion Regulation Checklist (2-10min)	X*	X*	X*
Strengths and Difficulties Questionnaire (2-5min)	X*	X*	X*
Eyberg Child Behavior Inventory (5-10min)	X*	X*	X*
Parent Factors			
Parenting Relationship Questionnaire (5-10min)	X*	X*	X*
Parenting Daily Hassles Scale (3-10min)	X*	X*	X*
Brief Symptom Index (8-10min)	X*	X*	X*
Adverse Childhood Experiences Scale (1-3min)	X*		
Couples Satisfaction Index (3-5) if applicable	X*	X*	X*
Child Factors			
Dimensions of Temperament – Revised (5-10min)	X*	X*	X*
Traumatic Events Screening Inventory (5-10min)	X*		
Client Satisfaction Questionnaire (intervention only)		X*	
CHILD-PARENT			
Family Narrative Task (15min)	X*	X*	X*
Prosody Speech Sample (segment selected from Family Narrative Task)	X*	X*	X*
THERAPIST			
Group Engagement Measure (for each participant)		X	

All data will be securely stored, processed, and analyzed at MHFC. Two sets of data files will be sent to Keri Heilman at the University of North Carolina, Chapel Hill for processing with proprietary software: 1) de-identified heart-rate variability data, and 2) brief prosody speech samples. De-identified Heart Rate Variability data are collected using Activewave Cardio before and after the Disappointment Task. Processing of these data involve extracting the ECG and inter-beat-interval data into 2 separate files and aligning then with time-stamps of task conditions. Files are then returned to the UR research team for further processing and analysis. For the Prosody Speech Samples, brief segments of the child speaking will be selected from the Family Narrative Task during discussions of positive and negative family experiences. Only about 20 seconds of audio is needed for each event. Segments will be selected by study staff that do not include the child's name or other identifying information. Processing involves spectrographic analysis and multiple indicators of prosody are produced using proprietary software. Data will be returned to UR research team for further analysis. Video recordings of study visits (10%) will be periodically evaluated for fidelity to research protocols by Dr. Petrenko. Data scoring and entry will be re-checked to ensure data quality.

A team of coders not involved in data collection will receive training in the coding systems used for the Meta-Emotion Interview, Family Narrative, and Disappointment tasks. Trained coders will include advanced undergraduate students, graduate students, and MHFC research support staff. Inter-rater reliability will be assessed on 20% of measures requiring coding. Regular reliability meetings will be held with periodic checks of inter-rater reliability to reduce potential for rater drift.

Tuning in to Kids Intervention: TIK (Havighurst & Harley, 2007) is a manualized, group-based intervention delivered to parents to improve their awareness, understanding, and responses to children's emotions. In addition to teaching parents the 5 steps of emotion coaching identified by Gottman and colleagues (1997), TIK helps parents understand how their family of origin experiences with emotion contribute to their current beliefs and responses to their children's emotions. Parents are also taught skills in how to be mindful of their own emotions when responding to their children. An 8-session version of TIK will be used in this study, which is recommended for groups of families whose children have significant behavior problems. Two trained clinicians will co-lead groups on a weekly basis, with an optimal number of 6 families per group. Each session lasts 2 hours and includes exercises, role plays, DVD clips, and psychoeducation. Childcare will be offered to families to facilitate participation in the program. TIK will be delivered at MHFC or other community locations (e.g., church, community center; for groups of families that live farther away from MHFC). During COVID-19 restrictions, group sessions may be held via HIPAA-compliant Zoom if needed.

4.2. Payment for Participation

At T1 and T2 research visits, caregivers receive $50 per visit and children receive $20 or toy equivalent per visit. At T3, caregivers receive $25 for the abbreviated visit (1-1.25hr in length for caregiver, 15 minutes child) and the child selects a small toy from a prize box (e.g., bulk small toy assortment from Oriental Trading). Caregivers do not receive payment for participating in the intervention sessions.

COVID-19 modifications: Parents who complete research visits by alternative methods will receive the same payment as they would have for in-person data collection ($50 T1 or T2, $25 T3), as the measures they will be completing are all the same. The child portion of the visit will not be completed remotely, with the exception of the Family Narrative Task.

5. RISK/BENEFIT ASSESSMENT

5.1. **Risks to Subjects**

Risks:

A risk of discovery is possible for families who contact the study whose child has not yet been been diagnosed with an FASD. In these cases, Dr. Petrenko will review existing records and can complete a brief diagnostic interview with the parent to determine if DSM-5 criteria for ND-PAE are met to determine eligibility (see DSM-5 Diagnostic Criteria Checklist for ND-PAE). Thus, parents may learn their child has an FASD diagnosis in this process (which many are seeking when contacting the study).

Participants may experience psychological risks associated with participation in this study, such as discomfort in discussing feelings or aspects of parenting. Some children may not like the physical feeling of the ECG recorder used during the Disappointment task. All data collected will be kept confidential to the extent allowed by law. If participants disclose (or there are significant concerns based on observations) that someone is being maltreated or is a danger to self or others, research or clinical staff will need to break confidentiality to make a report to the appropriate authority to ensure safety, as mandated by law. It is also possible that caregivers in the TIK groups might disclose personal information about other group members to people outside of the research studies. We believe that all identified risks are minimal given the proposed procedures for protecting against risk.

Protections Against Risk:

To add protections relating to the risk of discovery, children with confirmed or inconclusive NP-PAE symptoms will be referred to URMC FASD Diagnostic Clinic for further medical evaluation to ensure all appropriate treatment and care is being provided.

To minimize risk associated with psychological discomfort, every effort will be made to create a non-judgmental and warm environment for all participants in research visits and TIK sessions. All research staff will be well trained to administer assessments in a sensitive and supportive manner. Participants will also be given the option to skip items during assessments if they feel uncomfortable and will be offered breaks as needed. All observational paradigms will be monitored by research staff and tasks will be discontinued if the parent or child becomes overly distressed or unsafe. TIK groups will be co-led by at least one licensed clinician with a Masters-level degree or higher in social work, counseling, psychology, or related fields and experience with individual and group-based interventions. TIK group leaders will work to create an atmosphere were all parents are comfortable participating and all parents' experiences are respected. Although parents will be encouraged to participate in group discussions, they will be permitted to not answer questions or share their experiences if they are not comfortable.

The well-being of children and their families will be continually monitored throughout the course of the proposed research. If there are concerns regarding a participant during research visits or TIK sessions, staff will immediately contact Dr. Petrenko for consultation and a plan will be developed to address the concerns raised. During the course of the intervention, clinical staff will meet weekly to discuss curricula and the intervention process, as well as any concerns about individual children or families. Dr. Petrenko will be on call for any pressing concerns that arise during intervention sessions. Additionally, because MHFC provides other treatment programs, there are other back-up clinical supervisors available for consultation. Ethically, we are committed to ensuring the welfare of children and their families. Any significant mental health or safety issues detected during the conduct of this investigation will be discussed with participants and options for the receipt of services presented. In the unlikely event of adverse

effects of the intervention or evaluation on participants, adverse events would be reported to the RSRB and NIAAA. See Data and Safety Monitoring Plan below.

All information obtained for research will be kept strictly confidential (as allowed by law) by research staff. Participants will be told about all exceptions (e.g., child/dependent adult abuse, harm to self or others) to confidentiality during the consent process. Research and clinical staff will be closely supervised and instructed on confidentiality, including what information is confidential, the limits of confidentiality, and to whom to report concerns. If maltreatment is suspected, staff will first discuss their concerns with the caregiver and inform him/her that, as indicated in the consent form that she/he had previously signed, our staff are ethically and legally obligated to file a report with Child Protective Services. We have found that this approach conveys respect for the family and mitigates parental anger that might otherwise emanate from filing a report. In our experience, when situations requiring filing a maltreatment report are handled sensitively and framed as stemming from concern for the welfare of the entire family, caregivers often perceive the process as being helpful to them. Finally, while it is not possible to control what participants do outside of group settings, we will thoroughly explain the concept and importance of confidentiality and give real life examples of what is appropriate and inappropriate to discuss with people outside of the group.

In terms of data storage and management, all hard copy data, including videotapes, will be secured in locked file cabinets within locked offices, available only to program staff. Electronic data will be stored in secured servers, and only program staff with knowledge of the password will be able to access the data. Forms with identifying information will be separated from the data collected and only subject numbers will be retained in data analysis files.

5.2. **Benefits to Subjects**

Children and their families might not benefit from their participation in TIK intervention (both the intervention and delayed-waitlist group will receive intervention). If the TIK intervention is found to be efficacious and is subsequently made available, other nonparticipating children with FASD may benefit from future participation in this intervention. Parent training interventions on emotion socialization have the potential to better support the emotion regulation development of children with FASD and reduce mental health problems in this population.

5.3. **Alternatives to Participation**

The alternative to participation is not to participate. Participation in the project does not prevent families from continuing or seeking other services of interest to them.

6. CONFIDENTIALIATY OF DATA AND INFORMATION STORAGE

Sources of data will include: screening questionnaire from initial enrollment call to establish study eligibility; data obtained from participants during research visits on questionnaires, interviews, standardized child tasks, and observational coding of parent and child during research paradigms; heart rate data collected with Activewave Cardio ECG equipment; parent satisfaction ratings and qualitative interviews post-intervention; rating forms completed by clinicians for each participant following each TIK session; and intervention fidelity checklists.

All data will be used solely for research purposes and will be permanently securely locked in designated file cabinets or secure data servers at MHFC. Only senior key personnel and relevant research staff will have access to data. Identifying information, records (e.g., FASD evaluations, legal records) and consent/permission/assent forms will be stored separately from other data, which will be stored by subject number. The electronic file linking identifying information and subject number will

be maintained indefinitely, but will be stored separately where only the PI and senior research staff have access. De-identified data will be entered and scored in secure electronic databases for later analysis. Data will be reported in aggregate with no participant identifying information provided.

7. RESEARCH INFORMATION IN MEDICAL RECORDS

No information about study participation or research responses will be recorded in eRecord.

8. DATA ANALYSIS AND DATA MONITORING

8.1. Planned Statistical Analysis

Data reduction plan. Data reduction procedures will establish indicators for planned analyses. First, reliability indices will be calculated to confirm scales have adequate internal consistency. Next, preliminary exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) will be used to determine the appropriate factor structure for the Meta-Emotion Interview (MEI) in this sample for further analysis. Associations between the resulting MEI scales and the Emotion Coaching and Emotion Dismissing scores from the Family Narrative Task will be examined to evaluate construct validity and determine whether they provide unique information for analyses. EFA and CFA will also be used to determine whether the multi-method indicators of child emotion regulation and parent socialization of emotion can be combined to create latent factors to be used in Aims 2 and 3.

Aim 1: To test the hypothesis that specific baseline parent and child characteristics are related to individual differences in parent emotion socialization. Zero-order correlations will be examined between measures of parent emotion socialization and proposed parent (psychopathology, perceived stress, ACEs) and child (sex, age, temperament) characteristics. Multivariate regression modeling will be conducted to evaluate the unique associations of significant zero-order predictors when controlling for the variance accounted for by other factors. For example, multivariate regression will be employed to determine how one characteristic, such as child temperament, uniquely relates to indices of emotion socialization, over and above child age and sex.

Aim 2: To test the hypothesis that specific parent emotion socialization attitudes and practices at baseline are associated with more adaptive levels of emotion regulation in children with FASD. Correlations will be examined between indices of parent emotion socialization and child emotion regulation. Multivariate correlation and regression analyses will then be conducted. For example, child emotion regulation will be modeled as the dependent variable and indices of parent emotion socialization and child sex will be included as independent variables. Canonical correlation procedures will also be considered to address aim 2. Standardized canonical coefficients for individual parent emotion socialization variables can provide information on the relative strength of association with the emotion regulation variable set. In the case that emotion regulation variables do not load on a single factor during data reduction procedures, separate multiple regression analyses will be considered.

Aim 3: To test whether the *Tuning In To Kids* intervention results in significant improvements in parent and child outcomes and to determine whether parent emotion socialization represents a mediator of the TIK intervention effect on child emotion regulation and/or behavior. Intent-to-treat analyses will be conducted and missing data will be handled using Full Information Maximum Likelihood (FIML) techniques in structural equation modeling (SEM) when appropriate. Covariates such as child age, baseline severity of problems, type of caregiver, etc will be considered. Propensity score (PS) procedures will test for bias in randomization (Rosenbaum & Rubin, 1983). PS estimates the probability that a subject is assigned to a

particular condition given a set of known covariates. PS is used to reduce selection bias by equating groups based on these covariates.

A series of repeated measures analysis of covariance (ANCOVAs) will be conducted to determine stability and change in parent emotion socialization, child emotion regulation, and child behavior problems. Covariates will include child sex and age. We will investigate intervention group status by time interactions to test whether changes in outcomes (i.e., parent emotion socialization, child emotion regulation, child behavior problems) over time depend on intervention group status (intervention group X time effects). Latent growth curve modeling (e.g., Curran & Muthen, 1999) will also be used to examine the effect of TIK on trajectories of parent emotion socialization, child emotion regulation, and child behavior problems across the 3 time points.

To test whether changes in parent emotion socialization practices at post-intervention (T2) mediate the effects of TIK on child outcomes including child emotion regulation and child behavior problems at the 3-month follow-up (T3), re-sampling methods, such as the bias-corrected bootstrap will be used. This approach to mediation testing has been recommended by MacKinnon and colleagues (2004) because the distribution of the indirect effect is rarely normally distributed. In addition to significance testing, the effect sizes of the mediated effects will be examined and compared (MacKinnon, 2008). Regarding model specification for the mediation analysis, the effect of TIK on the hypothesized T2 mediator parent emotion socialization ('a' path), will be represented by the effect of TIK on the T2 mediator, controlling for mediator at T1. The effect of TIK on T2 child emotion regulation, controlling for T1 child emotion regulation, will also be modeled. To examine the effect of T2 parent emotion socialization on T3 child emotion regulation ('b' path), T2 child emotion regulation will be partialed out. For ease of interpretation, only the primary mediational paths of interest ('a' and 'b' paths) are depicted in Figure 3.

8.2. **Data and Safety Monitoring**

Because the proposed research involves the provision of group-based emotion-focused parenting program, the risk for a serious adverse event due to provision of the intervention is low. Adverse events that could occur in children with FASD or their caregivers could include aggression or violence towards others, maltreatment, self-harm or suicidality, or the need for inpatient hospitalization. However, these occurrences are unlikely to be a direct consequence of participation in the proposed research or interventions.

Ongoing safety of research participants will be monitored by an independent safety monitor. Fred Rogosch, Ph.D. is a clinical psychologist and senior researcher at MHFC who has served as a long-standing member of the RSRB. He also has experience serving on Data Safety Monitoring Boards for high-risk studies at MHFC. Dr. Rogosch will have no direct involvement in the project. In his role as an independent safety monitor for this study, he will review and suggest modifications to research protocols and consent documents to assure scientific integrity and adherence to human subjects protection policies. He will meet with the PI and co-Investigators bi-annually to monitor safety issues and provide feedback on scientific and ethical issues relating to project implementation. The RSRB will be notified immediately of any adverse events via telephone and submission of a "University of Rochester Serious Adverse Event Report." Such events would also be reported to NIAAA.

Dr. Petrenko will assume ultimate responsibility for the safety and well-being of research participants and the integrity of data collected. Dr. Petrenko has conducted one small-scale RCT and several pilot feasibility studies with children and teens with FASD and their families.

Drs. Petrenko, Handley, and Toth are licensed psychologists in the state of New York and are competent assessing and responding appropriately to adverse events. Drs. Petrenko, Handley, and Toth are involved in other clinical and research activities at MHFC where maltreatment and suicidality are commonly reported. Dr. Toth has also conducted several large-scale RCTs with high-risk populations at MHFC. She was a mentor on Dr. Petrenko's Career Development Award and continues to meet with Dr. Petrenko at least twice a month. She will provide continued consultation on the current project and will advise on data integrity and participant safety.

Quality control and participant safety will be ensured via weekly supervision of research and clinical staff by Dr. Petrenko. Survey data will be examined immediately after interviews have been conducted, to ensure that any reportable information will receive immediate and appropriate action. Such action will be to report knowledge of: 1) new child abuse or neglect, or 2) information that someone is at risk of being harmed or of harming themselves. This information will be reported to the appropriate authorities and child's legal guardian. If participants are at imminent risk, they will receive prompt medical attention. Limits of confidentiality will be clearly delineated in the consent, permission, and assent forms. Program staff will ensure that informed consent documents are properly explained and signatures obtained prior any subject's participation. Clinical staff will regularly monitor participant safety and well-being during intervention sessions and will follow procedures discussed above. All staff will be instructed to report any adverse events to the Principal Investigator immediately and the investigator will subsequently report this to the RSRB and NIAAA. Fidelity to research and intervention protocols will be monitored through weekly supervision and spot-checking of audiotapes of sessions.

In terms of data storage and management, all hard copy data, including videotapes, will be secured in locked file cabinets within locked offices, available only to program staff. Electronic data will be stored on a secured server, and only program staff with knowledge of the password will be able to access the data. Forms with identifying information will be separated from the data collected and only subject numbers will be retained in data analysis files.

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