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Study Protocol
Study Title: Longitudinal Follow-up of Brief Parenting Interventions to Reduce Risk of Child Physical Maltreatment
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1. Study aim, background, and design

Background

Child maltreatment is a major public health problem with over 6 million children involved in 3.4 million referrals to Child Protective Services and over 600,000 substantiated cases in the US annually [1]. Child physical abuse threatens physical, mental, and behavioral health as well as epigenetic, brain, and physiological development in children.[2-4] Some of the most effective, evidence-based interventions we have for preventing child maltreatment to date are home visitation programs [5]. However, such programs are aimed at narrowly selected, high-risk target populations. They also are high-resource intensive and might not be appropriate or feasible for universal implementation. Yet interventions designed for broader segments of the population might have larger benefits for society as a whole, even when producing smaller reductions in risk [6]. Such interventions can target highly prevalent norms in a population that raise risk for child physical abuse, such as use of physical discipline and other harsh parenting strategies. In doing so, such interventions may lower rates of abuse and other poor outcomes for children linked with poor parenting and childhood stress [7,8]. There is a need to test such parenting interventions that are relatively low-cost, low-resource intensive, and adaptable to larger and more universal target populations, such as Special Supplemental Nutrition Program for Women, Infants and Children (WIC) and pediatric clinics, for the prevention and reduction of child abuse and violence in general.[9-11]

Objectives and Specific Aims Our long-term goal is to enlarge the evidence base for low resource-intensive and widely adaptable interventions that effectively target parenting outcomes to reduce risk of child physical abuse in settings with broad reach, such those serving WIC and other pediatric populations. The objective of this study is to test the effectiveness of two such interventions in promoting effective parenting and reducing child physical abuse risk as compared with "usual care" parenting education. The central hypothesis is that each of two brief interventions, *Triple P-L2 and Play Nicely*, will be more effective in improving parenting effectiveness and reducing child behavioral and emotional problems than the "usual care" condition. Full scale *Triple-P* is an evidence-based, five-level system of interventions shown to reduce risk for child maltreatment when all 5 levels are implemented [12]. However, implementation of a single level would be much less costly, more easily disseminated, and might in itself reduce risk in a broader population. *Play Nicely* is a brief computer-based intervention that has shown preliminary evidence for shifting attitudes about use of physical discipline when implemented in a pediatric primary care setting [13,14]. However, it has yet to be tested within a large RCT or in a WIC population. The rationale for this study is to be able to inform policy for parent service or clinic centers serving high-volumes of parents that are interested in adopting relatively low-resource intensive interventions in order to reduce risk of child physical abuse and improve child health and development trajectories. We plan to test our central hypothesis by pursuing the following specific aims:

(1) Test brief clinic-based interventions (*Triple P-L2* and *Play Nicely*) aimed at addressing parenting effectiveness in managing difficult child behavior in a selected population of families. Our working hypothesis is that parent and child outcomes will be improved in each of these conditions compared to the control condition.

(2) **To establish sustained effects of brief parenting interventions on both parenting behaviors and child outcomes.** Our working hypothesis is that parent and child outcomes will be improved (e.g., reduced parental use of CP and reduced child emotional and behavioral maladjustment) in both intervention conditions compared to controls at long term follow-up. In addition, when compared to controls, children and parents randomized to either intervention will exhibit better physiologic responses when playing or talking together.

(3) Determine if intervention effectiveness is modified by parents' perceived norms. Our working hypothesis is that stronger perceived injunctive norms by parents of professionals (e.g.,

pediatricians, mental health, and religious) supportive of physical discipline will be associated with reduced intervention effectiveness.

(4) **To establish the sustained effects of two brief parenting interventions on <u>perceived injunctive norms about CP and support for CP use</u>.** Our working hypothesis is that parents will have and perceive less support for CP use (including amongst professionals trusted for parenting advice) in both intervention conditions compared to the control condition at long-term follow-up.

<u>Study Design</u>

This is a community-based randomized controlled trial. Parents (n=1200) with children 2 to 7 years of age will be recruited from local WIC clinics and by open recruitment. Once consented, they will be enrolled, a baseline interview will be conducted, and they will be randomly assigned to one of 3 conditions: (1) *Triple P-Level 2 only (L2)* intervention, (2) *Play Nicely* intervention, or (3) a "usual care" control group. Three months later, a follow-up interview will be conducted in order to test for intervention effects. 1 year later, a follow-up interview will be conducted. Due to funding restraints, all participants may not receive a 1 year follow-up. In addition, a long term follow-up will be conducted to test sustained effects of the intervention. Participants' children (n=1200) will be enrolled for the long term follow-up. Children will be invited to participate in order for the adult participant to be observed interacting with the child in several very benign behavioral activities. Adult participants that do not want to enroll their child may participate in the long term follow-up survey which they will have previously consented to. These low-resource intensive parenting interventions are expected to shift parenting attitudes, self-efficacy, and behaviors linked with child physical abuse risk. Even small reductions in such risk across large selected or universal target populations can result in large benefits to the whole population (i.e., Prevention Paradox [15]). Lowered rates of problematic parenting practices will lead to improved child development and behavior. Further, by contributing to a reduction in cumulative adverse childhood experiences, these interventions also are expected to contribute to a long-term reduction in health disparities and risk for major public health problems such as smoking, obesity, drug abuse, risky sexual behavior, mental health disorders, and heart disease among others [3,4,16-23].

Our study name for presentation in the local community is "Tulane Innovations in Positive Parenting Study" (TIPPS).

2. Subject Population

We will recruit a total number of 2400 participants for this study. We will recruit 1200 adult participants from City of New Orleans and Jefferson Parish WIC Clinics and by open recruitment. Open recruitment will allow eligible moms to participate regardless of whether they hear about the study at WIC or from other sources, such as current participants or TIPPS community partners. Our planned recruitment sites are the New Orleans East, Central City, Algiers, and Crescent City WIC clinics. Our eligibility criteria include women who are (1) English-speaking, (2) adults, age 18 or older, (3) the parent of at least one child between 2 and 7 years of age (4) the primary caregiver of that child (5) able to return to a TIPPS study site in approximately 3 months for a follow-up appointment, and (6) available for up to 2 hours on date of recruitment to complete the baseline visit. Pregnant women meeting the above-mentioned criteria will not be excluded. During the long-term follow-up visit, one child for each adult with be enrolled (n=1200).

3. Procedure

Recruitment: For all recruitment at the WIC clinics, parents will arrive at the WIC clinic for their regularly scheduled WIC visit. Recruitment will begin in WIC clinic waiting rooms, at which time a TIPPS Team Member (Program Manager, Research Coordinator, Research Assistant, or Triple P Specialist) will tell the parent Tulane University is conducting a study on positive parenting and provide a brief description

of the study. If the parent is interested in learning more, the TIPPS Staff Member will then assess the parent's eligibility status. If the parent is eligible and interested, the TIPPS Staff Member will then confirm that she has completed all necessary WIC documentation and that she is scheduled for a follow-up appointment with WIC before moving forward with consent and enrollment. This allows WIC staff to complete the necessary data entry for the appointment and ensures that the parent's time with us does not interrupt WIC's appointment process. Once the TIPPS Staff Member confirms that WIC documentation is complete and has been returned to WIC's intake staff, our staff will notify WIC staff that the parent is beginning their TIPPS Baseline appointment. Basic screening of potential participants will be tracked using a recruitment tracking form (i.e., number of persons screened, eligibility status, declines, and enrollment status).

WIC clients may also learn about the study before they arrive at WIC for their regularly scheduled appointments (i.e. before we would typically recruit them, per the above). WIC has offered and kindly agreed to mail a TIPPS recruitment flyer to WIC Clients' homes along with WIC's appointment reminder packets. This new "mailer flyer" presents basic study information and informs interested individuals how to contact our TIPPS staff. At the time they call, a TIPPS Research Coordinator will confirm the individual's eligibility and request that she alert WIC staff of her intention to enroll in TIPPS when she arrives for her WIC appointment.

For open recruitment, anyone that learns about the study via another source will contact TIPPS and schedule an appointment at a study site.

Consent and Enrollment: A TIPPS Team Member will then take the parent through the informed consent process utilizing the Updated Informed Consent – New Participant form. This will include providing a copy of the consent form to the parent, reviewing the content of the consent form with the parent, answering any questions she might have, and, if she agrees to participate, having her initial each page and sign and date the final page. Our staff will also sign and date the final page. Our staff will then administer a comprehensive Contact Information Form. Once this is complete, our staff will assign a participant ID and perform random group assignment. The Team Member conducting the baseline interview will remain blinded to the group assignment until the interview is complete.

Baseline Interview: A TIPPS Team Member will then conduct the Baseline interview. Participant responses will be entered by the interviewer into the computer and saved on a secure server via REDCAP. (If WiFi is not available for any reason, the interviewer will provide a paper copy of the survey to the participant and will administer the questionnaire using the paper copy. The paper copy will be kept secure and confidential until the responses can be entered and saved on REDCap.) Response Cards may be provided so that participants can see as well as hear the response options. Whenever possible, our staff will offer childcare in order to minimize distractions. Water and snacks (e.g., pretzels, goldfish) may be offered to participants or their children when available. A series of sensitive questions (Maternal Adverse Childhood Experiences; Hits, Insults, Threatens and Screams; Alcohol Use) will be answered by the participant privately on a paper copy of the survey in order to maximize participant confidentiality and reduce social desirability bias. If an individual indicates suicidal ideation, either by answering affirmatively (i.e. 1=A little bit, 2=Moderately, 3=Quite a bit, 4=Extremely) to "Thoughts of ending your life" in the Brief Symptom Inventory or by mentioning experiencing suicidal feelings or contemplating suicide at any other time during the interview, the Staff Member will follow the Suicide Risk Protocol to connect the participant with the appropriate type of resources.

Once the Baseline Interview is complete (approximately 45 minutes), the participant will be informed of their random assignment to one of three conditions: (1) Triple P-Level 2, (2) Play Nicely, or (3) Control. The next procedure will then depend upon which of the three groups the person is assigned to as follows:

Intervention Procedures:

(1) Triple P-Level 2: The Triple P Specialist will conduct this intervention. This intervention will take

no more than 60 minutes and childcare will be provided when available to minimize distractions. When the intervention is complete, the Triple P Specialist will complete an "Intervention Fidelity Checklist" to confirm some key aspects of the intervention such as: length of consultation, positive parenting booklet provided, whether or not and which parenting tip sheet(s) were provided. The Triple P Specialist will also schedule an appointment to call the participant within the next two weeks for a follow-up consult to assist and support the parent as needed with their consultation.

(2) Play Nicely: If assigned to Play Nicely, a TIPPS Team Member will escort the participant to a room where this intervention module will be completed on a computer. The Team Member will introduce the program and provide headphones and childcare when available to minimize distractions. This intervention will take approximately 30 minutes. The participant will be instructed to notify the Team Member once they have finished viewing the program. The Team Member will conduct an "Intervention Fidelity Checklist" to confirm some key aspects of the intervention such as: length of time spent on the module, number of discipline options selected, and which discipline options they are most likely to use or not use. The Team Member will then provide a "Play Nicely Strategies" handout.".

(3) Control: If assigned to the control group, a TIPPS Team Member will give the participant the "control" WIC Resource Guide and record that this was done. This Resource Guide will be the "Health Care and Social Service Programs You May Qualify For" pamphlet currently provided to all families in the Louisiana WIC Program.[24]

Debrief: Once both the Baseline Interview and the Intervention phase are complete, a TIPPS Team Member will schedule the 3-month Follow-Up Appointment, provide the control condition (WIC's pamphlet entitled "Health Care and Social Service Programs You May Qualify For"), provide an area-specific resource guide, provide a children's book partially donated by the New Orleans Public Library Foundation (NOPLF) as long as supplies last, and give the participant our incentive (a $25 gift card). The whole procedure (enrollment, baseline interview, intervention, and debrief) is expected to take no more than 2 hours.

Prior to 3-Month Follow-up: We will make every effort to maximize retention in our study at this 3-month follow-up visit. Participants will receive appointment reminders according to modes of contact they described as most preferable in the Contact Information Form. Reminder postcards will be sent to mailing addresses provided in the Contact Information Form. Approximately one week before the scheduled 3-month Follow-Up visit, our team will work with WIC staff to note any modifications to the planned appointment dates and times.

3-Month Follow-Up Visit: If the participant has a WIC appointment, when they return to WIC for their 3-month visit and once they've completed their WIC documentation, a TIPPS Team Member will conduct the 3-month interview with them. This interview should take no more than 45 minutes. As with the baseline visit, childcare will be offered when available and the Suicide Risk Protocol will be followed if needed. Once the interview is completed, a TIPPS Team Member will give the participant a $25 gift card, for a total of $50 for completing both baseline and 3 month interviews. In the event that the participant cannot return to the study site for their 3-month visit, the TIPPS team member will schedule the 3-Month interview as a phone interview. If the participant is unwilling or unable to complete the follow–up interview over the phone, a follow-up interview will be scheduled at a more convenient location for the participant, such as a local business or the participant's home. The participant will be mailed a $25 gift card to the address she has provided after the phone interview is complete.

If the participant has not yet consented to the revised Updated Baseline Consent – Current Participants form, which is dependent upon the date of their enrollment, the TIPPS staff member will review the updated form with the participant. The TIPPS staff member will highlight the additions to the informed consent with the participant, which include Consent for Future Contact and consent to additional interviews, including a one Year Follow-Up interview. For in-person visits, this will include providing a

copy of the consent form to the participant, reviewing the content of the consent form with the parent, answering any questions she might have, and, if she agrees to participate, having her initial each page and sign and date the final page. Our staff will also sign and date the final page. For telephone interviews, this will include reviewing the oral consent script before beginning the interview, answering any questions she might have, and, recording written documentation if she agrees to participate. The Updated Baseline Consent Form ensures all participants are presented with the opportunity to participate in future TIPPS interviews, as well as be contacted to participate in future research. Parents that express interest in additional parenting advice or services will be given a Resource Guide and, if needed, provided with a referral to the Children's Bureau for additional help and guidance.

It is common for as many as 50% of WIC participants to miss their scheduled WIC visits. If a participant misses her 3-month follow-up visit for our study, our team will contact the participant and try to reschedule the visit. We will continue trying to reschedule and complete this visit for up to 6 months. If the participant has moved or is otherwise unable to return to WIC, but is willing to complete the interview via phone, we will do so. After 6 months post baseline, if no follow-up data is obtained, we will code the participant as "lost to follow-up."

Despite our best efforts to retain all of our study participants, we anticipate a 75% retention rate. In other words, we expect that at least 25% of our baseline sample (n=1200) will not return to provide follow-up data. Hence, we expect our final 3-month sample to include 900 participants.

Data Security: Data will be stored on Tulane's secure REDCAP server. Only the PI, CoIs, and the Program Manager will be able to download the data onto their own computers for data analysis. All computers are password protected.

Due to grant funding limits, not all participants may be able to participate in a 1-Year Follow Up. The protocol below is for those participants who are scheduled to complete their 1-Year Follow-Up before grant funding for TIPPS is complete.

Prior to 1 Year Follow-Up Visit: Our team will contact participants to schedule a 1-Year Follow Up interview starting up to eleven months after participants have completed their Baseline Interview. Only participants who have who have completed their 3-Month Follow-Up Visit as well as signed the Consent to Future Contact or Updated Consent Form will be contacted. A TIPPS Team member will contact the participant according to modes of contact they indicated as most preferable in the Contact Information Form. Interviews will be scheduled either in person at the study site, in person at a location that is more convenient for the participant, or over the telephone. Interviews conducted over the telephone will be offered to participants who have moved out of the area, or when their schedule does not allow them to attend an interview at the WIC office during available TIPPS appointment times. After an appointment date and time has been set, participants will receive appointment reminders a week before the appointment according to modes of contact they described as most preferable in the Contact Information Form.

1-Year Follow-Up Visit: A TIPPS Team Member will conduct the 1-year Follow Up interview with the participant either over the phone or in-person at the WIC clinic. In the event that the participant cannot or is unwilling to return to the study site for their 1-Year Follow Up visit, the TIPPS team member will schedule the 1- Year interview as a phone interview. If the participant is unwilling or unable to complete the follow–up interview over the phone, a follow-up interview will be scheduled at a more convenient location for the participant, such as a local business or the participant's home. The interview should take no more than 45 minutes. As with the baseline and 3- month visit, childcare will be offered when available and the Suicide Risk Protocol will be followed if needed. Once the interview is completed, a TIPPS Team Member will provide the participant with comparable compensation to previous interviews, either in person or mailed to the address provided.

If the participant has not yet consented to the revised Updated Baseline Consent – Current Participants form, which is dependent upon the date of their enrollment, the TIPPS staff member will review the updated form with the participant. The TIPPS staff member will highlight the additions to the informed consent with the participant, which include Consent for Future Contact and consent to additional interviews, including a one Year Follow-Up interview. For in-person visits, this will include providing a copy of the consent form to the participant, reviewing the content of the consent form with the parent, answering any questions she might have, and, if she agrees to participate, having her initial each page and sign and date the final page. Our staff will also sign and date the final page. For telephone interviews, this will include reviewing the oral consent script before beginning the interview, answering any questions she might have, and, recording written documentation if she agrees to participate. The Updated Baseline Consent Form ensures all participants are presented with the opportunity to participate in future TIPPS interviews, as well as be contacted to participate in future research. Parents that express interest in additional parenting advice or services will be given a Resource Guide and, if needed, provided with a referral to the Children's Bureau for additional help and guidance.

If a participant misses her 1 year follow-up visit for our study, our team will contact the participant and try to reschedule the visit. We will continue trying to reschedule and complete this visit for up to 6 months. If the participant has moved or is otherwise unable to return to the study site, but is willing to complete the interview via phone, we will do so. After 1 year and 6 months post baseline, if no follow-up data is obtained, we will code the participant as "lost to follow-up."

Prior to Long Term Follow-Up Visit: Our team will contact participants to schedule a Long Term Follow Up interview starting at least twenty-three months after participants have completed their Baseline Interview. In order to be eligible to participate in the long term follow up assessment, a participant must have completed the baseline assessment, and also must have ongoing frequent interactions with the index child as assessed by a screener question. If participant has not signed the Consent to Future Contact and/or Updated Consent Form, our team will contact participant via phone to obtain oral consent to future contact or via mail to obtain written consent to future contact before scheduling a Long Term Follow up interview. Mailed consent forms will include information on current and ongoing opportunities to participate in the study, and similar information will be relayed over the phone when attempting to obtain oral consent to future contact. A TIPPS Team member will contact the participant according to modes of contact they indicated as most preferable in the Contact Information Form.

In order to improve our participant retention rate, we are introducing a few additional methods for reconnecting with our participants.

First, if attempts to contact the participant using primary contact information fail, and the participant has indicated a secondary contact person, the secondary contact will be offered a $10 incentive payment if we are able to successfully reach the participant and the participant goes on to complete the long term follow up visit.

Second, if we are unable to reach the participant through provided contact information (for example, if the number is no longer working, or the mail was returned), a member of the study team may confirm or update the participant's given contact information using a publicly available registry. This supports the integrity of the study by ensuring that to the extent possible, all participants are offered an opportunity to participate in long term follow up.

Third, our study partners may send a message to their own client lists with contact information for the TIPPS study, so any of these clients that were previously enrolled in the study that we have not been able to reach through other means will be aware that follow up opportunities for participation are available.

When contacted, participants will be notified about the new follow-up, which includes enrolling their child. Participants will be told that there are new follow-up activities similar to what they might do at a doctor visit as well as a few activities that involve interacting with their child. They will be told that when they arrive for the appointment the full procedures will be explained and a new consent form will be signed at the in person visit to indicate participant consent and parental permission. Participants will have all questions answered during this call and the follow-up visit. If the participant is interested in engaging in the long-term follow up assessment, they will be screened for eligibility before scheduling. Participants may decline participation in any portion of the follow-up visit and still be part of the study.

Follow-up Visits will be scheduled in person at the Tulane University School of Medicine, or the survey portion of the visit may be completed remotely by phone or by zoom if the participant is unable to attend in person. After an appointment date and time has been set, participants will receive appointment reminders a week before the appointment according to modes of contact they described as most preferable in the Contact Information Form.

Long Term Follow-Up Visit: Participants will arrive at the research site with their index child, the child indicated in the baseline survey as being age 2-7. Children participating in the follow-up will be ages 4-15. A trained research team member will conduct the informed consent procedures followed at the baseline visit. If the adult participate does not want her child to participate, she may complete the long-term follow-up survey which she has consented to previously. If she agrees to participate and gives permission for her child to participate, she must review and sign a new consent form before participating in any Long Term Follow-Up activities. The informed consent form will be a record of the mother's agreement for *both* her and her child to participate. Additionally, each child between the ages of 7-15 must provide assent. The informed consent process and the informed assent process will include: providing a copy of the consent form to the participant, reviewing the content of the form, answering any questions they might have, and, if they agree to participate, having them initial each page and sign and date the final page. The participant will also initial as to whether or not they consent to being recorded and whether or not they consent to have video recordings stored for future studies after the close of the study, all of which will be tracked in the REDCap database and used to guide data collection, video storage procedures and data cleaning and analysis. Our staff will also sign and date the final page. If the survey is conducted remotely, the child will not participate, the informed consent process will be completed with the adult only using the oral consent script, and no video recordings will be created. The participant will be asked whether or not they consent for the phone interview to be recorded for quality assurance purposes, and that will be recorded in the oral consent form as well as in the participant's record in the REDCap database.

Upon completion of the informed consent process, a research assistant will conduct the Long Term Follow-Up interview with the adult participant. The interview should take no more than 45 minutes, or up to 90 minutes remotely due to inherent communication delays. Once the interview is completed, a TIPPS Team Member will distribute the Child Behavioral Checklist to the caregiver to complete on paper, orally if remotely, or it can be completed either previous to the visit or after the survey using an electronic delivery format. This will be the end of the visit if conducted remotely, and the participant will be given a $50 gift card incentive for their time. For participants completing the survey by phone, the following portion of the visit described below, consisting of observational activities done in the clinic, can be scheduled and completed at a later date, if and when feasible. If the observational activities are scheduled at a later date due to Coronavirus precautions or safety concerns, a subsection of this survey will be repeated at the beginning of that visit, which relates specifically to the impacts of the pandemic and will take approximately 10-15 minutes. As with the baseline and 3- month visit, childcare will be offered when available for additional children and the Suicide Risk Protocol will be followed if needed. Additionally, if the participant indicates that their child is undergoing a period of crisis or trauma and would like additional resources, she will be offered a referral to Children's Bureau of New Orleans

(CBNO) Crisis response unit. If desired, the participant can grant us permission to release her contact information to CBNO; this permission will be indicated on the CBNO referral form. If this permission is provided, we will send this release form via encrypted email to the CBNO crisis team, and their team will then contact the participant directly. Water and snacks (e.g., pretzels, goldfish) may be offered to participants or their children when available with caregiver approval.

A separate research assistant will engage the child participant in several tasks. The first task will be the Marshmallow Test, an inhibitory control task where the child is told to wait for 1 minute to eat a marshmallow, and if they are able to wait, they will get two marshmallows. The time before the child eats the marshmallow is a validated measure of inhibitory control; inhibitory control has been found to be a significant predictor of child health and development outcomes across the life course. Cognitive flexibility and executive function will also be measured using the NIH toolbox, administered by tablet. This will be operationalized by several tasks from cognitive domain of the NIH toolbox to assess executive function, working memory, inhibitory control and cognitive flexibility described in in the table below.[10] The NIH toolbox is a valid and reliable instrument shown to be appropriate for ages 3-85 years old.

Following the surveys, ECG data will be collected on the child and mother concurrently, acquired using Mindware Technologies mobile recorders, and transmitted via wireless signals to a computer monitored by a research assistant. The ECG signals will also be synchronized with video recordings using Mindware Biolab technology. A research team member will attach soft, mildly adhesive stickers to the child and mother; the plastic lead wires for the measurement will be placed under clothes for comfort and safety. The child's leads will always be attached by a trained research assistant with the mother present. After participant and child leads have been connected to ECG machines, the participant and child will do 3 very benign behavioral activities together: 1) watch a short video, 2) tell a story together, and 3) engage in a cooperative task (drawing with an Etch A Sketch). Interactions will be video recorded with parental consent and child assent and coding of parent and child behaviors will be done using the Coding Interactive Behavior (CIB) codes that have been internationally validated. ECG data will then be processed offline using Mindware software; research assistants will visually inspect the data for missing heartbeats, as well as for erroneously identified peaks, which will be manually deleted or inserted as appropriate. The software will also give estimates of respiration and cardiac activity. Respiratory Sinus Arrhythmia (RSA) values will be processed in 30-second epochs across tasks for mothers and for children, and multilevel growth models will be built examining each 30-second epoch over the course of the task, relative to the individuals' baseline RSA. Dr. Drury will have full oversight of the dyadic coding of video recorded interactions between mother and child. Lastly, a TIPPS Team Member will provide the participant with locally-based health care resources and a gift card to thank her for her time. If the participant completes both the survey and observational activities in the clinic in one visit, she will receive in total a $125 gift card. If she has previously completed the survey by phone, she will receive a $75 gift card for completing the observational activities in the clinic. Also, after the survey is administered by phone, or otherwise after the clinic visit, the participant may be provided with directions to take an optional, anonymous participant satisfaction survey. Further, participants may be offered an opportunity to stay engaged with the study as we pursue efforts to share results with the community.

If a participant misses her Long Term Follow-Up visit for our study, our team will contact the participant and try to reschedule the visit. We will continue trying to reschedule and complete this visit for the remainder of the funded data collection period. If a participant indicates they no longer want to be contacted, we will discontinue contact with them immediately. Data Security: Data will be stored on Tulane's secure REDCAP server. Only the PI, Co-Is, and the Program Manager will be able to download the data onto their own computers for data analysis. All computers are password protected.

Community Advisory Board: A community advisory board (CAB) will be formed to achieve three goals: 1) Improve our internal processes to maximize participant engagement, retention and satisfaction by seeking feedback from participants who have completed all data collection activities outlined in our IRB protocol in order to ensure culturally relevant and appropriate communication strategies and materials are being used within our study; 2) Optimize the dissemination of our study findings by gaining feedback about messaging content, format and mode of sharing results with our study population and other community audiences.; and 3) Facilitate conversations about ways our study findings could be translated into action (e.g., policy change).

CAB members may consist of community partners (e.g., NOHD personnel), parents or other interested persons in the community, and study participants who have completed all study procedures outlined in this study protocol. CAB activities might take many forms to obtain information from members in a way that is most feasible and preferable to them (e.g, individual or group conversations, which may take place over phone, zoom, or in-person).

For goal #1, we plan to engage roughly 6 to 8 CAB members, drawing from participants who have completed all study activities outlined in the IRB protocol. Potential CAB members will be contacted via phone to discuss the opportunity to become a CAB member and to answer their questions based on a prepared script.

4. Follow up

If either intervention condition is found to be more effective than the control condition, these findings will be made available to the control group along with information about how they can access the effective intervention if they wish. This information will be made available to the study participants by email, phone, or snail mail dependent on contact information provided.

5. Risks

Loss of privacy is a possible risk; the subjects' privacy will be protected by using subject ID numbers and keeping identifying information separate from the data. Once the data have been collected, only the research team will have access to the data via a secure server. Specifically, the contact information form, consent form, and "consent to future contact form" (if signed) will be stored in the participant folders, which will be stored in a locked cabinet in the Program Manager's office. Raw data will be entered directly and securely through data management software. Files and video recordings will be kept in locked cabinets in the Program Manager's office and Dr. Drury's laboratory. All information will be coded with a subject identification number and only Dr. Taylor, Dr. Drury, and the Program Manager will have access to the decoding information so that no study information will contain actual identifying information. Identifying information will not be used in publications or presentations.

We may keep the data from the long term follow-up, including the video recordings with written consent, for purposes of the study for up to 5 years after the end of the study. We may also remove information that identifies the participant from the data and may keep and use the de-identified data. We will not use or share the data, even if identifying information is removed, for any research that is not part of the study unless we have contacted the participant and obtained written consent.

Children may experience momentary discomfort during the removal of the adhesive ECG leads, much like the removal of a Band-Aid. A member of the research team will remove the adhesive leads, unless the mother feels that the child may be less uncomfortable if she removes them herself. The mother will be present at all times during the placement and removal of the adhesive leads.

Parents that express an interest in additional parenting advice or services will be provided with a referral to the Children's Bureau for additional help and guidance.

If subjects participate at WIC, the research will be conducted at the same time and place where subjects regularly obtain their WIC voucher so as to be convenient for the subjects.

Participants always have the choice NOT to answer questions if they choose not to or have the ability to withdraw from the study at any time without penalty.

As noted in our consent form, if the participant "indicates that your child is in danger of being seriously harmed, or you or your child are in danger of hurting someone, the research staff is required by law to report this information to the appropriate agency personnel." We have established a clear child abuse reporting protocol for our staff. This protocol has been developed and reviewed in collaboration with Paulette Carter, Director of CBNO.

Minimizing Risks and Monitoring Data: The investigators will ensure that proscribed confidentiality measures are followed and will provide extensive training to all staff to ensure that protocols are being followed. As part of their employment contract, all staff will be asked to sign a form stating that they will not breach any of the confidentiality protocols. All information will be coded with a subject identification number. Any identifying information collected will remain separate from study database and hard copies will be stored in locked cabinets in the PI's secure office and will be destroyed following study conclusion. Only aggregated data will be reported in the study results; no names or other identifying information will be reported.

Subject code numbers for each child will be assigned at the time of consent and will be based on their mother's ID number and will not include any other information.

Materials generated under the project will be disseminated in accordance with University and funder policies. Publication of data shall occur during the project, if appropriate, or at the end of the project, consistent with normal scientific practices. Research data which documents, supports and validates research findings will be made available after the main findings from the final research data set have been accepted for publication. Such research data will be redacted to prevent the disclosure of personal identifiers.

Computers that will be utilized during all phases of this proposal are password and software encrypted to prevent inappropriate access to information. All data will be stored in electronic format using password protection and encryption on the database. All unique identifiers will be protected as described above.

6. Benefits

There will be no direct benefits to subjects for participating in this research, but the knowledge gained from the study may benefit society in general. Anticipated benefits might include a participant's greater understanding of positive parenting techniques.

7. Remuneration

At the Baseline visit, a Team Member will pay the participant with a $25 gift card to a local retailer as recommended by our WIC partners before the participant leaves the site. Then, at the 3-month follow-up visit to the study site, once the follow-up interview is completed, a Team Member will pay the participant with another $25 gift card, for a total of $50 in gift cards. If the participant completes the 1-year follow interview, a Team Member will provide the participant with comparable remuneration to the first two interviews.

Upon completion of the Long Term follow-up visit, a participant will receive a $50 gift card for completion of the Long Term follow-up survey if completed by phone, and a $75 gift card for completion

of the in-clinic observational activities - if and when they are completed at a later date. Alternatively, if the participant completes both components of the visit at the same time in the clinic, they will receive a $125 gift card.

8. Academic or Extra Credit

N/A

9. Costs

There will be no costs to the subject for participating in this research study.

10. Alternatives

Subjects always have the option to not participate in the research.

11. Consent process and documentation

The informed consent process will include providing a copy of the consent form to the parent, reviewing the content of the consent form with the parent, answering any questions she might have, and, if she agrees to participate, having her initial each page and sign and date the final page of the consent form. On the long term follow-up consent form, the participant will also initial as to whether or not they consent to being recorded and whether or note they consent to have video recordings stored for future studies after the close of the study, all of which will be tracked in the REDCap database and used to guide data collection, video storage procedures and data cleaning and analysis. Our staff will also sign and date the final page. Once the parent has finished reading each page, the Team Member will review the content of the consent form and highlight particularly important points, namely: (1) their decision to participate is completely voluntary in nature and (2) does not affect their receipt of WIC services, (3) they will be randomly assigned to one of three groups, (4) they may withdraw or refuse to answer any questions at any time, and (5) their personal information will be kept confidential.

The Team Member conducting the interview will remind the participant that all responses are optional, that she can choose to end her participation at any point and will ask the participant if she has any questions. This reminder will be reiterated before all follow-up surveys and throughout the course of all interviews.

The reminder call made one week before the second scheduled meeting will be made using a script to prevent unintentional coercion.

If a Follow-Up Survey is conducted via telephone, the team member will read the Oral Consent Script, receive oral consent from participant for additional interviews, and the team member will provide written documentation of consent.

Because the compensation is a maximum of $75 per visit or study section, there is little possibility of coercion or undue influence.

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