

PROMISE: Promotion of Successful Parenting
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1. STUDY OVERVIEW – PURPOSE AND BACKGROUND

Child maltreatment represents a pathogenic relational environment that confers significant risk for maladaptation (Cicchetti & Toth, 2015). The deleterious sequelae accompanying child maltreatment result in adverse physical and mental health consequences during childhood, as well as initiate a negative developmental cascade that continues throughout the life course (Masten & Cicchetti, 2010). The proximal environment involving the nuclear family, as well as more distal factors associated with the community and culture more broadly, transact to undermine normal, biological and psychological developmental processes in these vulnerable children (Cicchetti & Lynch, 1993). Developing early preventive interventions to reduce harsh/insensitive parenting, promote positive mother-child relations, and prevent child abuse and neglect are thus of high public health significance. Given the lifelong cascades that accompany maltreatment, the provision of preventive interventions to at-risk mothers is highly significant (Toth, Petrenko, et al., 2016). Project 1 examines whether adding Child-Parent Psychotherapy (CPP) to community home visitation (CHW) intensifies intervention results and positive outcomes compared with CHW support alone. We will determine when these interventions are optimally delivered (beginning prenatally or postnatally), the optimal duration of services (6 vs. 12 months), mechanisms of action (mediator analyses), and determine which intervention strategy works best for mothers with varying risk factors (moderator analyses).

CPP has demonstrated efficacy in transforming disorganized attachments in maltreated infants to secure attachment organizations (Cicchetti, Rogosch, Toth, 2006) that endure one year post intervention (Stronach et al., 2013). However, mechanisms of action and parenting outcomes have yet to be determined. CPP holds promise as an early intervention that improves parenting and prevents child maltreatment, yet further work is needed to identify issues such as the processes through which change occurs and for whom specific forms of treatment delivery are most efficacious. Attention to these dimensions will significantly advance intervention feasibility and community uptake. Findings will yield greater insight into the mechanisms of change and the interrelations between biological and psychological processes.

Our Specific Aims are:

Aim 1. To evaluate whether CPP delivered prenatally, at 3 months postpartum, or both, to high-risk low-income women promotes sensitive and responsive parenting, fosters a secure mother-infant attachment relationship at child age 1 year, and protects against child maltreatment, beyond CHW home visitation alone.

Hypotheses: Mothers who receive CPP will demonstrate more sensitive and responsive parenting at child age 9 months and their infants will evince more secure mother-infant attachment and developmental competencies and fewer instances of child maltreatment at child age 1 year, compared to mothers/infants randomized to CHW home visitation alone.

Aim 2. To evaluate the efficacy of different implementation strategies for CPP in combination with CHW.

Hypotheses: Each of the three individual CPP intervention strategies (i.e., 12 months CPP, brief prenatal CPP, brief postnatal CPP) will demonstrate superior outcomes compared to CHW alone. Overall, mothers/infants in the 12 months CPP condition will show more positive outcomes than those in the 6 months CPP that begins prenatally is expected to be superior to CPP that is initiated postnatally.

Aim 3. To identify the significant mechanisms of CPP preventive intervention effects. We will investigate three primary pathways of CPP efficacy: mothers' improvement in 1) internal representations, 2) parenting cognitions, and 3) stress responsivity.

Hypotheses: The CPP group will show greater improvements in maternal attachment representations, parenting cognitions, and stress reactivity, which will protect against child maltreatment and predict superior parenting and child outcomes at one-year post-intervention follow-up compared with CHW alone.

Aim 4. To increase precision in identifying for whom each CPP intervention strategy (i.e., 12 months CPP, brief prenatal CPP, brief postnatal CPP) may be particularly efficacious, we will examine whether maternal characteristics at baseline (e.g., maternal depression, trauma history and intimate partner violence (IPV)) moderate the efficacy of implementation strategies.

Hypotheses: Mothers without a history of maternal maltreatment, depression, or IPV will benefit from the shortened versions of CPP, whereas mothers with higher levels of risk will require more intensive CPP preventive intervention (i.e., 12 months CPP).

Child maltreatment is a significant problem that impacts millions of children. According to the most recent statistics, over seven million children were involved in referrals to Child Protective Service (CPS) nationwide during 2015 (USDHHS, 2017). The risk for maltreatment is most profound in early childhood. Infants have the highest rate of victimization

(24.2/1000), and 74.8% of child fatalities occurred between birth and age three years (USDHHS, 2017). Because of formative and rapid physiological and brain development, infancy is a particularly vulnerable period, and maltreatment in infancy may set the stage for a cascade of negative developmental processes (Masten & Cicchetti, 2010). Moreover, in families characterized by poverty, single-parent households, and pervasive community violence, parenting resources become further strained and may lead to severe parenting dysfunction that culminates in the occurrence of child maltreatment.

Multidisciplinary approaches to prevention that incorporate developmental understanding within a context of ecological and transactional processes are needed to leverage advances in developmental science to prevent lifelong negative outcomes for maltreated children (Shonkoff et al., 2011). Parents with a history of maltreatment and trauma may have negative sequelae including emotional dysregulation, mental health disorders, social isolation, and violent relationships that disrupt the parent-child relationship and pose risks for harsh parenting and maltreatment (Sturge-Apple et al., in press). Parental negative perceptions of their children, combined with difficulties in coping with stresses of rearing young children, in the context of poverty, may also exacerbate risks of maltreatment. Negative representations of the fetus have implications for parenting and parent-child relationships, and predict less sensitive and involved mother-child interactions in the months following birth (Goodman et al., 2017; Siddiqui & Hagglof, 2000). Attachment theory suggests that these parental and familial factors impact intergenerational patterns of relationships in which caregiving perceptions and behaviors may be transmitted from parental histories into relationships with their own children and provides a compelling and substantiated framework for understanding processes impacting risk for maltreatment as well as providing opportunities for intervention (Carlson et al., 1989; Moss et al., 2011; Toth et al., 2013). In concert with this, relationally-based approaches to intervention have been demonstrated to be effective in ameliorating risk, especially for women with histories of maltreatment, above and beyond parenting skills training approaches (Stronach et al., 2013; Toth, Petrenko, Gravener-Davis, & Handley, 2016). However, methodologically rigorous models incorporating multiply-determined risk and protective factors are needed to determine optimal prevention strategies that reduce risk for the perpetration of maltreatment among low-income families. Moreover, the optimal timing of intervention provision during infancy towards the prevention of harsh parenting and maltreatment is not established. Finally, the efficacy of shorter intervention compared with those of longer duration is unknown. To address these critical gaps, the present application will document the potential for Child-Parent Psychotherapy (CPP), a preventive intervention for families at risk of child maltreatment that focuses on parent-infant relationships, in conjunction with a Community Health Worker outreach model to eradicate risk for maltreatment and provide a strong foundation for positive family functioning early in development (beginning in the prenatal period), an imperative time to break the intergenerational cycle of maltreatment.

CPP is based on Selma Fraiberg's work (Fraiberg, Adelson, & Shapiro, 1975), and has been enhanced by Alicia Lieberman and her colleagues (Lieberman, Ghosh Ippen, & Van Horn, 2015). In this model, difficulties in the parent-child relationship are not considered to be due solely to lack of parenting knowledge and skill. Rather, mothers' own experiences of caregiving during their childhoods are viewed as contributing to a lack of sensitivity and responsivity. CPP focuses on the mother-child relationship and includes developmental guidance based on maternal concerns. The approach is supportive and nondidactic. By helping mothers to understand the influence of their past on their current parenting, increases in responsiveness, sensitivity, and attunement to the infant foster the development of secure attachment. CPP not only addresses the mother-child relationship, but it also helps mothers develop a more supportive relational environment.

Research documents that CPP is effective at promoting attachment security in maltreated infants (Cicchetti et al., 2006). Outcomes include improved maternal empathy and interactiveness toward their infants (Lieberman, Weston, & Pawl, 1991), sustained efficacy of attachment, positive self-representations in maltreated preschoolers (Toth et al., 2002), reduced maternal mental health symptoms, and decreased behavioral problems and trauma symptoms in preschool children exposed to intimate partner violence (IPV; Ghosh Ippen et al., 2011; Lieberman et al., 2005, 2006). Improvements in parent-child relationships in maltreating families following CPP intervention were significantly better than provision of parenting skills treatment (Stronach et al., 2013; Toth et al., 2002). When CPP was implemented beginning during pregnancy, CPP was associated with decreases in maternal depressive and posttraumatic stress symptoms and increases in positive child-rearing attitudes, with greatest improvements among mothers with low fetal attachment in pregnancy (Lavi et al., 2015). Because CPP is typically 12 month duration, research on the length of treatment is necessary. The time and financial demands accompanying CPP delivery highlight the importance of investigating whether shorter length CPP treatment might be comparably efficacious. Additionally, adding CPP psychotherapeutic intervention to a CHW home visitation approach to address concrete service needs provides an innovative strategy for determining the optimal approach for promoting positive parenting and reducing child maltreatment. Thus, the proposed longitudinal randomized control trial will examine CPP preventive intervention within CHW home visitation services compared to CHW visits without CPP in families at risk for child maltreatment. The evaluation will address whether more intensive intervention better protects against child maltreatment compared with CHW support alone and will determine when these interventions are optimal (beginning

prenatally or postnatally), the duration of optimal services (6 vs. 12 months), mechanisms of effect (mediator analyses), and which intervention strategy works best for mothers with varying risk factors (moderator analyses).

Consistent with determinants of parenting models in maltreating families (Belsky, 1980; Cicchetti & Rizley, 1981), the present application takes a multilevel perspective on potential processes underlying treatment effects through providing a systematic test of the relative role of three conceptually rich mediators including maternal internal representations of infants, maternal cognitions, and maternal stress-response system reactivity in the parenting context. Our examination of three potential pathways advances the next generation of novel research questions and hypotheses for the prevention of child maltreatment as well as for clinical initiatives aimed at providing interventions to high risk families.

Internal Representations Pathway. Representational frameworks suggest that previous histories of emotional experiences are organized into affective schema that serve as guides for efficiently processing, interpreting, and responding to subsequent interpersonal events (Baldwin, 1992; Bretherton, 2005; Ogilvie & Ashmore, 1991). Translated to understanding the etiology of harsh/insensitive parenting and child maltreatment, parental representations of caregiving and their caregiving figure arise from repeated childhood interactions. These coalesce into an organized working model of how relationships unfold and serve as interpretive filters of environmental cues and guide actions in parent-child contexts (e.g., McGillicuddy-DeLisi, 1982). Two separate meta-analytic studies have documented associations between caregiver representations of childhood attachment experiences and offspring attachment classification (Van IJzendoorn, 1995; Verhage et al., 2016). Thus, mother's internal representations of caregiving experiences may promote sensitive/ responsive caregiving behaviors and reduce the likelihood of maltreatment with offspring.

Maternal Cognitions Pathway. Another proposed mechanism of CPP effects on child maltreatment prevention is via changes in maternal negative parenting cognitions. Research on social cognitive processes among maltreating parents has highlighted errors in emotion recognition, sensitive/empathic responding, perceptual and attributional biases of child behavior, and behavioral reactivity to child-rearing situations (for review, see Camilo et al., 2016). Overly simplistic or developmentally inappropriate child-related schemas (such as viewing children as adults) increase the likelihood of negative or developmentally inappropriate attributions and evaluations of child behavior, which in turn guide the selection of poor caregiving practices (Azar et al., 1984; Azar et al., 2012). Maltreating mothers may have poorer empathic ability (Rodriguez, 2013) and negative attributional errors in interpersonal situations, such as child blaming, that may exacerbate caregiver's faulty attributions of child behavior, and higher rates of annoyance to stressful child and non-child related noises (e.g., infant cries; Bauer & Twentyman, 1985).

Stress Response System Pathway. The stress response system (SRS) plays a pivotal role in orchestrating how environmental conditions influence individual psychosocial functioning (e.g., McEwen & Wingfield, 2010; Repetti et al., 2002). There are two primary pathways of the stress response including the autonomic nervous system (ANS) and the hypothalamic-pituitary-adrenal (HPA) axis which have been shown to be associated with perturbations in parenting and child maltreatment. In particular, parasympathetic functioning in the ANS (e.g., respiratory sinus arrhythmia) has been shown to be involved in the regulation of emotion and behavioral responsiveness within the context of stressful caregiving situations (Skowron et al., 2013; Sturge-Apple, Skibo, Rogosch, Ignatovic, & Heinzelman, 2011), with maltreating parents displaying irregularities in their autonomic stress reactivity (Reijman et al., 2014; Wolfe et al., 1983). Research on how autonomic activity may contribute to the etiology of different forms of maladaptive caregiving and maltreatment has been relatively scarce (Reijman et al., 2016).

As a second component of the SRS, elevated cortisol reactivity in stressful parenting contexts has been associated with harsh and intrusive parenting practices (Martorell & Bugental, 2006; Mills-Koonce, et al., 2009). Moreover, trauma-informed interventions with children have shown effectiveness in recalibrating cortisol reactivity (e.g., Cicchetti, Rogosch, Toth, & Sturge-Apple, 2011; Fisher et al., 2007). Specifically, Toth and colleagues (2015) reported that trauma-focused child-parent interventions (e.g., CPP; Lieberman, et al., 2015) may reduce child-related stress experienced by neglectful mothers, which in turn may "reset" hypothalamic-pituitary-adrenal axis activity.

Moderating Conditions. Open systems conceptualizations of family functioning in developmental psychopathology highlight the importance of examining characteristics that may alter cascade mechanisms. Thus, the form and magnitude of intervention effects may vary depending on pre-existing attributes in the family system. We will examine the role of three potentiating factors: maternal trauma history, maternal psychopathology, and family IPV. Understanding what works best for whom will identify which preventive intervention strategy (i.e. type, timing, and duration) is most effective for mothers at highest risk and identify whether mothers with lower levels of risk may benefit from less intensive intervention (i.e., a shortened version of CPP or CHW home visitation only).

2. CHARACTERISTICS OF THE RESEARCH POPULATION

2.1. Subject Characteristics

Participants for this RCT include 250 pregnant women age 18 or older in the second or third trimester of pregnancy referred to CHW Baby Love or another CHW program and their 250 infants once they are born. If the mother gives birth to multiple children, the first born of these children would be considered the target child. Through community outreach by CHWs, at-risk pregnant women are engaged in prenatal care through University of Rochester Medical Center (URMC)'s Baby Love program or through a similar CHW program. Mothers from URMC Obstetrics Department identified with psychosocial risks are referred to Baby Love. Services include initial social work assessments (to identify family strengths, perceived challenges, available resources, and focal areas), regular home visitation (to assist families in accessing resources, preparing for childbirth and parenting, improving health behaviors and life management skills, and addressing safety concerns), transportation to medical and social service appointments, education on child development, and referrals and enrollment in other support services as needed. Goals include reducing risk factors that impact health and wellness, enhancing the safety of the home environment, and optimizing pediatric and postpartum follow up care for newborns and mothers. The CHW program is embedded in the families' medical homes, and through exchange of information in parents' and children's medical records, CHWs ensure coordination with medical teams to address medical needs.

- a) **Number of Subjects:** 250 pregnant women will participate; upon the birth of the child, women will be asked to provide permission for their 250 children to participate.
- b) **Gender and Age of Subjects:** Only women will be enrolled because the focus of the study is pregnant women. Only those women ages 18 years and above will be enrolled. Their children will be newborns when they begin their involvement in the study.
- c) **Racial and Ethnic Origin:** There are no enrollment restrictions based upon race or ethnic origin. The sample of pregnant mothers is expected to be approximately 68% African-American, 12% Caucasian, and 20% multiracial/other, as well as 21% Hispanic.
- d) **Vulnerable Subjects:** Pregnant women are included because the study evaluates preventive intervention approaches for supporting pregnant and parenting mothers and their babies (once born). Risks to expectant mothers include possible stress of answering questionnaires, and possible identification of depression or suicidal ideation. Risks to fetuses and children are minimal. Because evaluating the potential value of prenatal psychosocial interventions with mothers must occur during pregnancy, it is necessary to involve pregnant women in the research to develop biomedical knowledge that cannot be obtained by other means. In the event that a participant's safety or the safety of others becomes a concern during a research assessment, staff members will evaluate the participant's safety and emotional functioning by discussing the participant's suicidal or homicidal ideation. The staff member will ask the participant about their thoughts, any planned methods of self- or other-harm, access to weapons or materials related to those plans, and intent to harm self or other. If a staff member determines that the participant is in immediate risk of harm, in conjunction with consultation with PI and/or designated coverage clinical staff member, emergency care will be accessed through URMC Emergency Department (ED), including, if needed, contacting University Security for an escort to the Psychiatric Emergency Department for evaluation, and calling the Psychiatric Emergency Program to provide a verbal alert that the patient is en route to the ED for evaluation. The staff member will accompany the participant to the ED to provide support and information to the ED team. Dr. Cerulli and the HEAL Program will be resources for participants who have intimate partner violence concerns. Dr. Cerulli also can refer project staff to URMC staff with suicide expertise for consultation as necessary. Additionally, the Baby Love program has procedures in place for addressing risks to their service participants that will be followed in the event that stressors or risks are identified.

2.2. Inclusion and Exclusion Criteria

- 1. **Inclusion Criteria:** Participants will be low-income pregnant adult women eligible for Medicaid, WIC, SNAP, TANF, or whose income is 225% of the poverty level or lower, and who have been referred to or will be referred to the Baby Love CHW program or a similar CHW program based on their high psychosocial risk status.
- 2. **Exclusion Criteria:** Mothers will be excluded if they have:
 - a. significant cognitive limitations,
 - b. age less than eighteen years,
 - c. severe psychiatric disorders requiring a higher level of care (e.g., imminent suicidal ideation requiring

- hospitalization, psychotic features),
- d. non-English proficiency,
- e. physical disability that impedes ability to complete study procedures.
- f. psychiatric needs or substance use that requires inpatient treatment
- g. If the mother terminates the pregnancy or does not deliver a live birth
- h. If child has prolonged NICU stay or is unable to complete tasks
- i. If the family is currently receiving CPP elsewhere or has recently closed.

3. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT

3.1. Method Of Subject Identification And Recruitment

We will utilize a multi-pronged approach to identify and recruit low-income families from University of Rochester Medical Center's Obstetric and Gynecological Department, in partnership with the Baby Love Community Health Worker (CHW) program. Families who are involved with a Community Health Worker program through other service delivery systems will also be eligible. Families who are not involved with a Community Health Worker program will receive a referral to a Community Health Worker program. This approach allows us to recruit low-income families who are at risk for child maltreatment. Recruitment will occur through the URM C Baby Love home visitation program provided by CHWs who are supervised by social workers. CHWs will provide information about the study to Baby Love families, and ask interested families to sign Name Release forms or contact the program directly. Additionally, information about PROMISE through flyers and brochures will be made available in medical offices, child care settings, and other forums in which families who may be pregnant and involved in CHW programs frequent. Research staff may communicate with providers who work with families who may be pregnant to increase project visibility and encourage making referrals. Interested families may sign Name Release forms or contact the program directly. These forms will then be shared with research staff members, who will schedule research visits. To provide additional information on the program, a video was created that can be shared with potentially interested participants. The partnership with CHWs and MHFC research staff has been extremely effective for 10 years in enrollment and retention for our Building Healthy Children (BHC) program, in which to date over 850 families have participated in a CHW and therapy partnership model. Only research personnel with routine access to prospective subjects (or subject records) will recruit those individuals directly. Research personnel who do not have routine access to prospective subjects will not contact subjects directly. In order to remain in consistent contact with families across the longitudinal design, research staff will use People Finders, a comprehensive database system comprised of public information. People Finders will allow for identification of current and last known addresses and phone numbers of participants. This study will identify potential subjects for recruitment using the UR CTSI Research Participant Registry, STUDY00001720 by various means including email, phone calls, or letters. This study will also use ResearchMatch.org for recruitment with a contact message, outlined in the ResearchMatch.org request form. Facebook and Instagram ads will be placed through the CTSI to recruit participants. Additionally, the CTSI may perform electronic medical record pulls based off current pregnancy, age, and insurance to identify low-income pregnant adult women. Their medical care providers will be contacted to request a release of information to recruit the identified patients.

COVID-19 Modifications. Flyers and brochures can be mailed or shared electronically to interested families by CHWs and other programs and providers that interface with pregnant women. CHWs and providers can complete electronic Name Release forms for interested families and share them electronically with research staff.

3.2. Process of Consent

Pregnant women who are enrolled in the Baby Love or other CHW program will be asked by their CHWs whether they are interested in learning about the study. The parent may call and express interest on their own, or if they express interest and sign a Name Release form, then their contact information will be shared with project Research staff members, who will explain the study and schedule research visits. Participants will be given the option of texting as a method of contact for scheduling visits if they indicate that preference on the Name Release form. Text messages to participants will only be for scheduling purposes, and the messages will contain no protected health information. Text messages will be sent from encrypted MHFC computers on URM C's secure network from a Google Voice account. If the participant is not already working with a CHW, the researcher will make a referral to connect them with one. The Research Assistant will answer any questions about the study, review the consent form, and have interested women sign the consent form and HIPAA Authorization. If they agree to participate, their information will be stored in study files. After the participant gives birth, the Research Assistant will obtain parental permission for the infant to participate in the study at the subsequent research visit. Because the study will be funded by the National Institute of Child Health

and Human Development, a Certificate of Confidentiality will be included, and that language will be included in the consent documents. Mothers who are interested in participating in a qualitative analysis of how aspects of their experiences relate to service delivery and parenting outcomes will complete a Release of Information form giving permission for interviews and audiotapes collected during counseling sessions to be transcribed and included in research analyses. These interviews are described in the CPP section below.

To ensure participant comprehension for those with limited reading ability, the consent forms and measures will be read to the participant, and any questions the mother may have will be answered. After birth, when infant participation is included, all measures will be developmentally appropriate and do not require child assent, but parental permission will be obtained as described above, and any procedures during which the infant exhibits distress will be discontinued to minimize any discomfort for the child or parent.

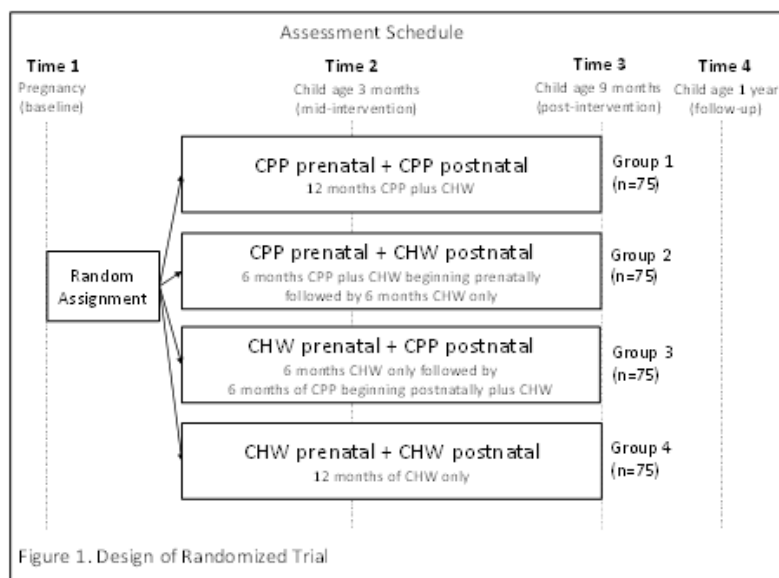
COVID-19 Modifications. The approved study consent form has been modified for remote procedures during the COVID-19 pandemic. It can be administered through REDCap using the eConsent module to allow documentation of consent (following implementation with Research and Academic IT). Research assistants will obtain verbal permission over the phone or HIPAA compliant Zoom to send the REDCap link for the study eConsent by email. Participants will verify their identity prior to signing consent by inputting the year they were born in the consent security verification via RedCAP. Participants can review the consent using their personal computer, tablet, or smartphone, and can follow along as staff reads it aloud. Staff will check throughout reading the eConsent to see if they have any questions or concerns. Participants can sign the eConsent in the signature field with their finger, stylus, or mouse. Staff will confirm the eConsent is signed prior to initiating any data collection. After signing the eConsent, a pdf version of the consent will appear on the screen, which participants can download for their records. Participants can also choose to have a pdf version of the consent emailed to them by providing their email address on the final page of the consent form in REDCap. If a participant accidentally fills out a form incorrectly after submitting, the research assistant will reach out to the project coordinator to review the form, and if the form needs to be completed again, the project coordinator will download the incorrect form to save on file and then clear the form so it can be filled out again. These procedures apply both to obtaining subject consent and parental permission.

4. METHODS AND STUDY PROCEDURES

4.1. Study Procedures and Assessments

Group Assignment. Following completion of all baseline assessments, we will randomly assign families to one of four conditions: Group 1: CPP beginning prenatally and continuing for 12 months, Group 2: CPP beginning prenatally and continuing for 6 months, until the child's age of approximately 3 months, Group 3: CPP beginning six month after the baseline visit and continuing for 6 months, and Group 4: CHW home visitation without CPP for 12 months (see Figure 1). All families will have CHW support throughout the 12 month period, and 3 groups will have CPP (in differing doses and at differing developmental time periods) in addition to CHW services.

Interventions Procedures: Home visitation has been demonstrated to reduce harsh parenting, improve maternal sensitivity, and improve health outcomes (Howard & Brooks-Gunn, 2009). Programs such as Nurse-Family Partnership (NFP) have documented success in preventing documented CPS reports (Olds et al., 1997). However, because NFP is designed for first time mothers, and it is less effective for families with IPV (Eckenrode et al, 2000), alternative preventive approaches are needed. Home visitors may be ill-equipped to address mental health concerns and trauma histories among the families who are at greatest risk. If programs are designed to address mental health symptoms and co-occurring risks that may be barriers to participation (e.g., improving accessibility, flexibility, and collaborative



planning), and staff are well-trained and supervised, these programs provide considerable promise for preventing maltreatment and promoting positive child and family outcomes (Goodman & Garber, 2017). For example, connecting families with infants to community resources predicted fewer trips to emergency departments, more positive parenting skills, enhanced family safety, and lower maternal anxiety (Dodge et al., 2014). The necessary and sufficient components of home visitation models for preventing maltreatment and the optimal strategies for addressing the complex needs of high-poverty families with mental health and trauma-related challenges remain to be determined.

Baby Love's CHW program has contributed to a 40% decrease in Neonatal Intensive Care admissions among participants. Approximately 225 medically and psychosocially at-risk pregnant women are served annually. Baby Love clients are low-income pregnant women from Rochester; at least 14% are Hispanic and 56% are non-Hispanic African-American, 7% are non-Hispanic Caucasian, and 23% are Biracial/Other. We will evaluate whether the addition of a therapeutic intervention designed to address risks augments the positive outcomes of home visitation alone. The timing of service delivery will be examined, along with the processes resulting in positive change to determine which approach is optimal for which families.

Child-Parent Psychotherapy (CPP). A primary goal of CPP is to support and strengthen the relationship between parent and child to improve family functioning and child security of attachment. CPP traditionally is conducted over a 12 month period. We will evaluate whether a shortened course of CPP, with a 6-month duration, has similar outcomes to a 12 month course. Additionally, we will evaluate whether beginning prenatally or postnatally provides stronger child maltreatment prevention effects. Masters level therapists, trained and supervised by national CPP trainers, will meet weekly during home-based sessions. A guiding assumption of CPP is that difficulties in the parent-child relationship do not result from deficits in parenting knowledge and skill alone but rather from insecure internal representational models that evolved in response to the mother's own traumatic experiences. During the sessions, therapists and mothers engage in joint discussions about perceptions of children when CPP begins prenatally and observations of children after they are born. The therapist's empathic responsiveness with the mother and the child allows for expansion of parental understanding and exploration of maternal misperceptions of the child. Through respect, empathic concern, and positive regard, the therapeutic relationship provides the mother with a corrective emotional experience, through which the mother is able to differentiate current from past relationships, form positive internal representations of herself and of herself in relationship to others, particularly her child. Parents are encouraged to process their experiences of trauma and restore parental roles as protective shields, improving affective regulation capacities, enhancing understanding of the meaning of behavior, acknowledging the impact of trauma, and supporting the children in a more positive developmental trajectory. As a result, mothers expand their responsiveness, sensitivity, and attunement to the child, fostering security in the mother-child relationship. Intervention implementation will be monitored through weekly clinical supervision of therapists and therapist group meetings as well as nationally-developed CPP fidelity forms. Therapists will collect assessments that include a Life Stressors Checklist, the Angels in the Nursery interview, and a discrimination question that will be used therapeutically. These measures are part of routine care related to the provision of CPP. Findings from studies assessing The Angels in the Nursery Interview in CPP "... indicate that the Angels Interview can identify pathogenic intrusions rooted in childhood maltreatment and protective factors to promote maternal mental health and buffer the intergenerational transmission of trauma." (Narayan, Ghosh Ippen, Harris, & Lieberman, 2017, p. 461). Angels in the Nursery interviews that are audio recorded, will be transcribed by research assistants. Angels in the Nursery interview, the Discrimination Question, and the Five Minute Speech Sample will be analyzed qualitatively by research and clinical staff using an Interpretive Phenomenological Analysis approach (Smith, Flowers, & Larkin, 2009). The Angels in the Nursery interviews will also be coded using a quantitative coding system developed by Narayan et. al., (2017). Relationships between trauma, Angels in the Nursery, and positive associations with motherhood will be explored to provide information regarding how aspects of clinical service provision are related to family outcomes and how family experiences relate to parenting outcomes, for those families receiving CPP. Aspects of the therapeutic process in CPP will be assessed through the Brief Working Alliance Inventory (Mallinckrodt & Tekie, 2015).

COVID-19 Modifications. Therapy sessions are available through telehealth.

Research Procedures: Mothers will participate in 2 research sessions spaced 7 days apart at MHFC at each of four time points (with a single visit prenatally to reduce participant burden). Time 4 will also involve a third in-person visit. Beginning at Time 2 (six months after the baseline visit), these visits will include mother-child interaction assessments. Trained RAs will conduct study visits and administer all paradigms and measures. RAs will provide transportation to/from the center to facilitate participation. The same RA will conduct both sessions with each individual to promote rapport and trust. Each session will last approximately 2 hours with sufficient breaks. During the research sessions, participants will complete a series of questionnaires, structured interviews, observational interactions, and psychophysiological assessments. Participants will be paid \$25 for Visit 1 and \$50 for Visit 2 for each time period (with

a \$50 payment for the single prenatal visit). There will also be an additional \$10 payment for an in-person visit at the 1st time point, and an additional \$50 payment for a final in-person visit at the 4th timepoint. With permission from New York State Office of Children and Family Services, Child Protective Services (CPS) records will be reviewed at child age 15 months (T4), and we will utilize discretionary funds, if available, to conduct an additional review of records at child age 4 years. In the event that any parents discontinue participation because their babies are stillborn or are too medically frail to participate in research visits, referrals for additional supports will be made as appropriate.

Measurement Battery: Measures were selected on the basis of strong psychometric properties, and their developmental appropriateness for assessing parenting during the prenatal and postnatal periods. For brevity, we do not describe the validity and reliability of the measures. Table 1 provides an overview of the measurement battery for the central variables. For measures that are repeated at multiple time points, instructions for timeframes will indicate “since the last time we saw you...” to obtain information between study visit time points.

COVID-19 Modifications. Participants that enrolled prior to the COVID-19 outbreak may complete an abbreviated battery at T2, T3, and T4 by HIPAA compliant Zoom, phone, and/or by mail. These participants have already consented to the study and completed T1. T4 visits will be completed at the child’s age of 15 months to allow in person visits, which are necessary for key variables at T4. New participants can also be enrolled using the COVID-19 modifications described above, while also completing an abbreviated battery. To ensure appropriate safety precautions when conducting in-person study procedures for conducting in-person visits outlined in the Guidance for Human Subject Research and at the following link: <https://www.urmc.rochester.edu/coronavirus/coronavirus-research/guidance-for-researchers/human-subjects-research.aspx> will be followed, and partial in-person visits may now be completed. Measures included in the abbreviated batteries are marked with an asterisk* in the measures table. These measures are questionnaires and interviews that can be completed with parents remotely. Questionnaires and interviews can be administered over the phone or HIPAA compliant Zoom, and questionnaires can also be sent by email/mail and returned. The Client Satisfaction Questionnaire and the Discrimination Questionnaire can be completed via Qualtrics or sent by email/mail and returned. Video and audio tasks can be recorded with permission via HIPAA compliant Zoom. Releases of information can be completed via REDCap. Data will be saved on the Mt. Hope Family Center secure server, or on URMH HIPAA Compliant Box, both of which require Duo Two Factor Authentication to access. When necessary, remote telephone communication by staff will be completed using encrypted password protected personal cell phones. Staff will block caller ID through their phones or use *67, or use the Google Voice phone number.

1. **Physiological Reactivity.** Maternal physiological reactivity to infant distress will be collected around the video clip task at the prenatal assessment and the emotion-eliciting tasks at the postnatal assessments. Baseline assessments will be taken during a silent 5-minute baseline period prior to tasks.
Maternal HPA Reactivity. Salivary cortisol will be collected using the Salivette Cortisol Code Blue method from mothers surrounding parenting tasks collected in the morning. Cortisol will be assessed at: (1) baseline prior to the task; (2) post-I: 15 min. after task; and (4) post-II: 20 min. following task. Indices of cortisol reactivity will be calculated in MPlus utilizing a latent growth model controlling for time of day, slope scores will be retained for analysis. We have utilized this strategy within several previous studies examining reactivity within this system (Sturge-Apple, Davies, Cicchetti, & Manning, 2012).
Maternal ANS Reactivity: Mother ECG signals will be recorded using Heart Monitors through an E4 watch on the wrist. In order to create a stable baseline assessment, a “vanilla baseline” task will be presented for five minutes that involves a simple color detection task to create an awake resting condition (Jennings, Kamarck, Stewart, Eddy, & Johnson, 1992). The ECG signal is sampled at 300 Hz and has a voltage range of -2.5 to 2.5 V. The digitalized ECG signals will be examined for artifactual R-wave occurrences and corrected using CardioPro Infiniti’s HRV Analysis Module. The square root of the mean of successive differences (RMSSD) in inter-beat intervals will be calculated as a time-domain estimate of HRV. This measure has been shown to provide a reliable estimate of cardiac vagal activity (Task Force, 1996). Reactivity across the paradigm will be calculated in MPlus utilizing a latent basis growth model (Sturge-Apple et al., 2011), slope scores will be retained for analysis.
2. **Child Maltreatment and Parenting:** The current application will utilize observational methods, self-report and CPS records to assess: (1) parental sensitivity as indexed by (a) awareness of infant’s needs and moods; (b) warmth and support; and (c) facilitating child’s engagement in task and (2) hostility characterized by parental (a) angry and hostile expressions; and (b) critical, disapproving and/or rejecting behavior (3) occurrence of child maltreatment. Mothers also will be interviewed using the Maternal Interview on Child Maltreatment (MICM; Cicchetti, Toth, & Manly, 2003) to obtain additional information on maltreatment that the child may have experienced that may not be captured in CPS records.
 - a. **Child Protective Services Records** from the New York State Central Registry will be accessed at infants’ age of 12 months to obtain any reports of indicated CPS reports since birth. CPS records will also be accessed at

child age 4 years of age (T5) using financial resources outside of the proposed research project budget to allow for a childhood follow-up.

b. **Prenatal Task:** To assess emotional reactivity to infant distress prenatally, we will utilize an audio paradigm that has been demonstrated to be effective in eliciting emotional arousal in expectant mothers (Leerkes, et al., 2015). Mothers will listen to recordings of infant cries. Mothers will be asked to report on their attributions about why the infant was crying and their emotional reactions to hearing the infant cries (see below). The Maternal Fetal Attachment Scale (Cranley, 1981) will be administered to assess expectant women's perceptions and representations of their babies.

c. **Postnatal Tasks:** Mothers will participate with their infants in videotaped research paradigms which are designed to elicit parental sensitivity/responsiveness and harsh parenting during infancy (Leerkes, et al., 2015). Videotaping is necessary for interactions to be coded later. They will be securely stored and accessible only to research staff members. Mothers will then be provided with two developmentally-appropriate toys and will be instructed to interact with her baby for 10 minutes (interaction task). Similar to prenatal assessments, mothers will rate their perceptions of their infant's distress and identify the infant's dominant emotion from a list of 20 emotion terms after the task is completed. To obtain assessments of insensitive/harsh parenting, maternal behaviors across the three tasks will be coded using Sensitivity/Insensitivity, Cooperation/Interference, Availability/ Ignoring, and Acceptance/Rejection of Baby's Needs subscales adapted from Ainsworth Maternal Sensitivity Scales (Ainsworth, Bell, & Stayton, 1974). Observational assessments will be completed by independent RAs who are unaware of study hypotheses and are trained to reliability by project PIs. At 15 months the Strange Situation will be conducted (SS; Ainsworth & Wittig, 1969). The SS is a 21-minute laboratory procedure designed to elicit low-level stress and activate the attachment behavioral system. The SS has been demonstrated to be a reliable and valid measure for assessing the quality of the mother-infant attachment relationship (Ainsworth et al., 1978). The Parent Development Interview – Revised – Short Version (PDI-R-S) will also be administered with mothers when the child is 15 months old (Slade et al., 2020). The PDI-S is a 30 item semi-structured clinical interview intended to examine parents' representations of their children, themselves as parents, and their relationships with their children. The participant is asked to describe their child's behavior, thoughts, and feelings in various situations, as well as her responses to their child in these situations. The participant is also asked to describe themselves as a parent and discuss emotions stimulated by the experience of parenting. The Similarities and Vocabulary subtests of the WASI-II (Wechsler Abbreviated Scale of Intelligence 2nd Edition) will be completed alongside the PDI-R-S to account for verbal ability (Wechsler, 2011). The Attachment Script Assessment (ASA) will also be administered at the final time point, which assesses

Research Project 1, Table 1. Measurement Battery

	T1	T2	T3	T4
1. Child Maltreatment and Parenting:				
1a) Child Protective Service (CPS) Records* MICM*				X X
1b) Observational Assessments				
Prenatal Infant Cry Stimuli*	X		X	
Interaction task*		X	X	X
Strange Situation Paradigm				X
1c) Questionnaire Measures				
Parental Acceptance-Rejection Quest.*		X	X	X
Postpartum Bonding Questionnaire*		X	X	X
1d) Interviews				
Parent Development Interview Revised Short* WASI-II*				X X
1e) Scripts				
Attachment Script Assessment (ASA)*				X
Mechanisms:				
2. Internal Representations				
Five Minute Speech Sample*	X		X	
GNAT-Child	X	X	X	X
Maternal Fetal Attachment Scale*	X			
Faces Dot Probe task		X	X	X
3. Maternal Cognitions about Parenting				
Maternal Attributions about Infant Crying*	X		X	
Parenting Stress Index – Short Form*		X	X	X
Maternal Efficacy Questionnaire*		X	X	X
4. Physiological Reactivity				
Maternal HPA Reactivity –cortisol	X	X	X	X
Maternal ANS Reactivity -- ECG	X	X	X	X
Sleep and medication questionnaire *	X	X	X	X
5. Moderators:				
Infant Behavioral Inhibition paradigm				X
Lab Temperament Assessment Battery			X	
IBQ-R*			X	
CTQ-SF*	X			
Trauma History Screen*	X	X	X	X
Beck Depression Inventory – II*	X	X	X	X
Beck Anxiety Inventory*	X	X	X	X
ASSIST*	X	X	X	X
Conflict Tactics Scale 2 Short*	X	X	X	
Family Events Questionnaire FII*	X	X	X	
Demographics Questionnaire*	X	X	X	X
MOS Social Support*	X	X	X	X
Benevolent Childhood Experiences*	X			
Discrimination Questionnaire*			X	
6. Child Health and Development				
ASQ-3 and ASQ-SE*		X	X	X
Medical Record Data*				X
7. Service Utilization				
Service Participation Records*		X	X	
CPP Fidelity Checklists*		X	X	
Service Utilization Questionnaire*	X	X	X	X
Client Satisfaction Questionnaire*			X	
Brief Working Alliance Inventory*			X	
8. COVID-19 Related Measures				
F-COPES*	X	X	X	X
CIS*	X	X	X	X
Prenatal COVID Survey*	X			
Postnatal COVID Survey*		X	X	X
COVID Vaccine Survey*	X	X	X	X

a person's knowledge and access to a secure base script (Waters & Waters, 2006). The ASA involves the participant creating three stories using a list of word prompts as a guide for each story.

3. **Parenting and Maltreatment.** The Parental Acceptance-Rejection Questionnaire Infancy (PARQ; Rohner, 2005) contains 24-Likert type scale items which assess parental warmth/affection, indifference/neglect, and rejection in infancy. The Postpartum Bonding Questionnaire (PBQ; Brockington et al., 2006) is a 25 item questionnaire about how a parent feels about her infant.
4. **Internal Representations.** Mothers will complete Five Minute Speech Samples (FMSS; Gottschalk & Gleser, 1969) regarding thoughts and feelings about their own mothers, themselves, and their children and their relationships with them. Mothers are asked to speak for five uninterrupted minutes about their maternal caregiver from their own childhood and then, in separate speech samples, about themselves and their child. FMSS assesses expressed emotion (EE; Brown et al., 1972; Magaña-Amato, 1993; Magaña et al., 1986), namely caregivers' statements of criticism and emotional overinvolvement as well as coherence of narrative. FMSS-EE has proven to be highly effective in indexing the quality of caregiver–relative relationships (Magaña et al., 1986; Yan et al., 2004) and in predicting parenting over time (Lucassen et al., 2015). At T1, we will use the prenatal version of the FMSS protocol (Lambregtse-Van den Berg et al., 2013) in which instructions are modified: “I would like you to tell me about your baby. What I would like to hear from you is what you expect or hope your baby will be like and how you would like to relate to your baby.” At postnatal assessments we will utilize standard instructions. EE will be independently scored using standard procedure by three extensively trained and regularly supervised RAs who are unaware of other data concerning the mother and through qualitative analyses. Mothers' statements will be scored using categories from the original FMSS procedure for Criticism and Emotional Overinvolvement (EOI). In addition, coherence in the FMSS will be coded (Sher-Censor & Yates, 2015). Qualitative thematic analyses of the FMSS also will be coded using an Interpretive Phenomenological Analysis approach (Smith, Flowers, & Larkin, 2009).

To obtain implicit assessments of mother's internal representations of her caregiver and her child, we utilize two computerized tasks (Sturge-Apple et al., 2015). In particular, the GNAT-Child are formatted as a word-sorting game where participants quickly categorize stimuli words (e.g. “caring”) and participant-generated descriptors (e.g., family member's first name) by pressing keys when a word belonging to a pre-determined category flashes on the screen. Faster speeds imply stronger associations (i.e., a faster response associating loving words with the child compared to unloving words indicates an internal evaluation by the parent of the child as the relationship being loving rather than rejecting). The GNAT-Child is designed to assess maternal representations of her own child as loveable or unloveable. Accuracy of sorting serves as the main performance index. Previous work utilizing the GNAT has documented associations with attachment processes (Lee et al., 2010) and maternal sensitivity (Sturge-Apple, et al., 2015).

Emotion Bias: Mothers will complete an adapted version of the Faces Dot Probe Task to measure attention bias towards facial display of emotions (e.g., MacLeod, Mathews, & Tata, 1986). Notably, the dot-probe task is a well-established computerized task measuring attention biases towards emotional faces, which has been linked to early experiences of environmental adversity and subsequent development (e.g., Cole, Zapp, Fetting, & Perez-Edgar, 2016). We propose to adopt the developmentally appropriate children's facial expressions as the stimulus (Schindler, S., Zell, E., Botsch, M., & Kissler, J., 2017). This approach provides us a unique opportunity to illuminate parents' biases/understanding of children's emotions when interacting with their children.

5. **Maternal Cognitions.** Measures assessing maternal cognitions coalesce across three broad domains implicated in the etiology of child maltreatment including causality which reflect attributions about the causes of infant behavior, self-efficacy which reflects maternal belief in her capabilities in the parental role, and evaluative cognitions around parental goals in the parenting role and children's desirable behaviors. Four measures are selected which capture these three domains and have been empirically validated within high risk and racially diverse samples. Maternal Attributions about Infant Crying (MAIC; Cohen-Bendahan et al., 2014) is a 13-item Likert-type scale assessing parental attributions about infant crying. Two subscales include child-oriented (CO) attributions and Child-blaming (CB). Parenting Stress Index-Short Form (PSI-SF; Abidin, 1995) is a 36-item questionnaire designed to measure stress in the parent–child system. The PSI-SF has three subscales: Parental Distress, Parent–Child Dysfunctional Interaction, and Difficult Child. Maternal Efficacy Questionnaire (MEQ; Teti & Gelfand, 1991) is a 10-item scale developed to assess parental self-efficacy (PSE) in mothers of infants. It is primarily a domain-specific measure of PSE through determining mothers' self-efficacy in specific parenting tasks (e.g., soothing the baby; feeding, changing, and bathing the baby) and one item assesses general PSE.
6. **Moderator Constructs.** Moderator variables will be drawn from the following measures: Infant temperament will be assessed via mother's self-report with the Infant Behavioral Questionnaire-Revised (IBQ-R; Rothbart &

Gartstein, 2003) using the Distress to Limitations, Fear, and Smiling and Laughter scales. Infant temperament will also be assessed observationally with the Laboratory Temperament Assessment Battery Prelocomotor Version 3.1 (Lab-TAB; Goldsmith & Rothbart, 1999) using the Unpredictable Mechanical Toy, Restraint in a Car Seat, Cognitive Assimilation Game, and Modified Peek-a-Boo Game episodes. Mothers' report of their own childhood maltreatment also will be obtained via the 25 item Childhood Trauma Questionnaire-Short Form (CTQ-SF; Bernstein et al., 2003). Conversely, Benevolent Childhood Experiences (Narayan, et al., 2018) will be assessed to determine positive experiences in childhood. Trauma History Screen (THS; Carlson et al., 2005, 2011) assesses exposure to 12 traumatic events during adulthood. Age of occurrence and further details are probed. Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996). The BDI-II is a 21-item self-report instrument designed to assess severity of depression. Items measure current affective, cognitive, motivational, and physiological symptoms. Beck Anxiety Inventory (BAI; Beck, Steer, & Brown, 1996) is a 21-item self-report questionnaire which asks about common symptoms of anxiety, such as feeling nervous, scared, and fear of dying, and was designed to distinguish anxiety symptoms from depressive symptoms. Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST, WHO ASSIST Working Group, 2002) is an 7 item questionnaire to assess lifetime substance use, and past 3 month substance use, including alcohol, tobacco, and cannabis, with 3 additional items added to assess prenatal use. Conflict Tactics Scale-2 (short form) (CTS2S; Straus & Douglas, 2004) is a 20-item shortened version of the CTS2 used to assess intimate partner violence. The items are answered on an 8-point frequency scale and comprise five subscales, Physical Assault, Injury, Psychological Aggression, Negotiation, and Sexual Coercion. Family Events Questionnaire (FEQ; Ackerman et al., 1999; Forman & Davies, 2003) is designed to assess the frequency of unstable events in the family, including caregiver turn-over, formation and dissolution of caregiver intimate relationships, and geographical mobility. Demographics Interview (Cicchetti & Carlson, 1979) has been used extensively in our studies with high-risk populations. Information obtained includes: parent's education and occupation, income level, number of adults in the household, marital status, number of siblings, etc. These data will enable us to ensure that all groups of families are matched on socio-economic status (Hollingshead, 1975). The Medical Outcomes Study (MOS) Social Support Survey (short form) will be utilized to assess dimensions of social support that may impact family functioning (Moser, Stuck, Silliman, Ganz, & Clough-Gorr, 2012). The Discrimination Questionnaire will be utilized to assess dimensions of discrimination that may impact family functioning (Kreiger, 1990), with the addition of 2 questions on discrimination due to physical illness/disability status or mental health problems.

7. **Child Health and Development.** Information from children's medical records will be extracted by medical social workers. Data will include birth weight, Apgar scores, toxicology reports for prenatal substance exposure, prematurity status, frequency of prenatal visits, well-child visits, immunizations, ED visits with injuries, CPS reports, Failure to Thrive diagnoses, and medical complications. Ages and Stages Questionnaire, Third Edition (ASQ-3) and ASQ: Social-Emotional (ASQ:SE) will be administered with mothers (Squires & Bricker, 2009a; 2009b). This 30-item questionnaire measures communication, fine and gross motor skills, personal, social and problem-solving domains for 3-66 month old children.
8. **Service Participation.** Details of service participation in the program will be tracked by CHWs and CPP therapists, including the number of visits scheduled/attended, dates of involvement, type of services provided, reasons for discontinuation (if applicable), and referrals to other services. Intervention Fidelity. CPP Clinician will complete foundational, core, and termination phase fidelity checklists that are reviewed with supervisors (Lieberman, Ghosh Ippen, & Van Horn, 2015). Also, monthly in-home video-recordings of CPP sessions will be made by therapists, and evaluated for intervention fidelity by the clinical director. Social work supervisors of CHW will assess CHW activities. CHW case notes will be reviewed for CHW activities. Services Utilization Questionnaire will provide maternal report of intervention services received, including DHS preventive services, parent training, family counseling, and mental health/substance use treatment.). Client Satisfaction Questionnaire will provide maternal report of satisfaction with CPP and overall program experience.
9. **COVID-19 Modifications.** The Coronavirus Impact Scale or CIS (Stoddard & Kaufman, 2020) contains 12 questions rating the impact the COVID-19 pandemic has had. Information about family coping surrounding the COVID-19 outbreak will be captured with the Family Crises Oriented Personal Evaluation Scales, or F-COPES (McCubbin, Olson, & Larsen, 1987). Additional questions will be asked about how COVID-19 has impacted different areas related to pregnancy and infancy, and care providers. These questions are modified from the Thomason Graham Perinatal Survey (M. Tomason & A. Graham, personal communication, April 10, 2020). A brief face-valid COVID Vaccine Survey will assess attitudes and challenges towards administering COVID-19 vaccines for participants and their children.

4.2. Data & Specimen Banking for Future Research Use

Research data will be maintained for five years after the study is complete. Extensive coding of observations via audio, video, and physiological recordings will be required, and this is a lengthy process. Additionally, the data from this study will require intensive and elaborate data analyses. This work will continue for a good number of years by the research team. When all research data are analyzed and no further findings are likely to be forthcoming, paper data will be shredded and disposed of through a secure disposal company. All electronically stored data on the server system and backups will be erased.

4.3. Costs to the Subject There is no cost to participants for participation in the project. Funding for the project is provided by the National Institute of Child Health and Human Development.

4.4. Payment for Participation

Participants will be paid \$50 for Visit 1 and after children are born payment will be \$25 for the first visit and \$50 for the second visit at each time period. There will also be an additional \$10 payment for an in-person visit at the first timepoint, and an additional \$50 payment for a final in-person visit at the 4th timepoint. Compensation for all possible research visits totals to \$335.

Participants will be reimbursed for reasonable out of pocket transportation expenses for necessary rideshare or RTS services after submission of receipts to the study team, up to a maximum amount of \$15 per one way fare.

5. SUBJECT WITHDRAWALS

Subjects will be advised during the consent process that they have the right to withdraw from the study at any time without prejudice. Their participation also may be withdrawn if they fail to complete research visits.

6. REPORTABLE EVENTS

The RSRB and the DSMB will be kept apprised of all serious adverse events and will have the authority to determine whether participants should be removed from the study. Although project therapists will be empowered to take immediate action to safeguard participant safety, input from the DSMB will be solicited to render judgments in the event of serious adverse events, and the UR RSRB will be contacted as well.

7. RISK/BENEFIT ASSESSMENT

7.1. Risks to Subjects

A potential risk is stress that may occur from answering questionnaires and participating in research visits. Although we do not anticipate stress reactions from participation based on our prior experiences in testing parents and young children under similar conditions, research staff members and therapists are trained to recognize signs indicative of an adverse emotional reaction, as well as to offer reassurance and support. If an extreme reaction does occur during a research assessment, clinical staff members are on call at Mt. Hope Family Center to provide assistance to the research staff and/or to meet with the family directly. If an adult participant becomes upset, then a clinical staff member will meet with the participant and, if necessary, assist the participant in obtaining additional mental health services or other needed supports.

The potential risk of being reported to DHS in the event that research staff members uncover evidence of maltreatment is specifically addressed in the consent form. Thus, families are fully informed of this potential risk attendant to participation in the research. If maltreatment is suspected, then our staff will first discuss their concerns with the mother and inform her that, as indicated in the consent form that she had previously signed, our staff are ethically and legally obligated to file a report with DHS. Through decades of research with similar populations, we have found that this approach conveys respect for the family and mitigates against 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, parents often perceive the process as being helpful to them through connecting them with supports.

Intimate partner violence may be present in the recruited families. Every effort will be made to interview mothers in private. When intimate partner violence is revealed during the administration of these interviews, or if women share any information suggesting they are being victimized, then mothers will be given a small card to fit in her wallet with the names of local agencies that provide services for intimate partner violence and a referral to the HEAL Clinic at UPMC. Consultation with our clinical staff also will occur to determine an appropriate course of action to insure maternal and child safety. All Mt. Hope Family Center research project staff members have access to designated clinical staff members who are available via cell phone whenever research interviews are being conducted. The center has a

strong affiliation with a local agency, Willow Domestic Violence Center, and the onsite PI will facilitate referrals as necessary. Additionally, Dr. Cerulli is internationally recognized for her expertise in intimate partner violence, and she is the Director of the Laboratory of Interpersonal Violence and Victimization for UR. She is also Principal Investigator on a project providing and evaluating an integrated hospital-based violence intervention program. On another project Dr. Cerulli recruited women within the Department of Obstetrics and Gynecology for the past 5 years, her team created IRB protocols and procedures to help recruit and retain this high-risk vulnerable group of women. This PCORI-funded project ended with a 94% recruitment rate over a 10-month time period, suggesting that these procedures have been successfully implemented with this population. As a licensed attorney and faculty in the Department Psychiatry, she brings expertise from both legal and mental health perspectives. She will be available to consult with research or clinical staff members in situations in which intimate partner violence is reported and safety concerns are present.

Maternal substance use may also be present and may pose a risk to the fetus or child. Community Health Workers have existing protocols and relationships with chemical dependency treatment programs that they can access and facilitate referrals as necessary. Additionally, Dr. Christie Petrenko, who is an Investigator in the Community Engagement Core of the project, is a national expert in the area of Fetal Alcohol Spectrum Disorder, and she can provide guidance as needed to address substance use in families.

Because mental health symptoms will be assessed, maternal depression or suicidal ideation may be identified. In the event that a participant's safety or the safety of others becomes a concern during a research assessment, staff members will evaluate the participant's safety and emotional functioning by discussing the participant's suicidal or homicidal ideation. The staff member will ask the participant about their thoughts, any planned methods of self- or other-harm, access to weapons or materials related to those plans, and intent to harm self or other. If a staff member determines that the participant is in immediate risk of harm, in conjunction with consultation with PI and/or designated coverage clinical staff member, emergency care will be accessed through UPMC Emergency Department (ED), including, if needed, contacting University Security for an escort to the Psychiatric Emergency Department for evaluation, and calling the Psychiatric Emergency Program to provide a verbal alert that the patient is en route to the ED for evaluation. The staff member will accompany the participant to the ED to provide support and information to the ED team. UPMC has an Injury Control Research Center for Suicide Prevention.

For other risks to confidentiality and privacy, please see below.

7.2. Benefits to Subjects

Participating mothers and children will receive Community Health Worker home visitation regardless of their research arm. Participants randomized to three of the four research arms will also receive Child-Parent Psychotherapy (CPP) services in addition to CHW home visitation. The interventions in each of these conditions may improve mother-child relationships, reduce subsequent maltreatment, and promote adaptive child functioning. All services are coordinated with UPMC medical providers and will assist families in maintaining children's health services for well-child appointments as well as services for any medical needs. There also is the potential benefit of incidental learning that may occur due to participation in a scientific study.

7.3. Alternatives to Participation

Participation is voluntary and families may opt not to participate. If they choose not to participate in the study, they can continue their involvement in their CHW program. No health care services will be impacted by their decision whether or not to participate.

8. CONFIDENTIALITY OF DATA AND INFORMATION STORAGE

All subject data will be identified by code number (subject identification number) only, with no identifying information (Personal, Private, or Sensitive Information: PPSI) associated. All forms of data, including paper questionnaires, video, audio, and physiological data, will only be distinguished by the subject identification number.

A master list of research participants containing identifying information, including name, date of birth, and address, along with the subject identification number, will be stored on the Project Coordinator's password-protected and whole disk encrypted computer in her locked office. All research data in paper form will be stored in locked file cabinets in a locked research space available only to authorized research staff. Audio, video, and physiological recordings are stored in digital format on the Mt. Hope Family Center secure server. All project data are stored in a separate project-specific folder on the server, accessible only to authorized research staff. Data files of subject responses on questionnaires and variables coded from audio, video, and neurophysiological recordings also are stored in this project-specific folder on the MHFC server. Access to data on the server is only available to authorized research staff through project-specific,

password-protected computers in the locked project research offices. We also will obtain a federal Certificate of Confidentiality for further protection of confidentiality and privacy of all study information. Data will only be used for the purposes of the research study described herein.

User accounts that provide access to the data stored on the server conform to these rules:

- Each user has a unique user-ID and password;
- Passwords are changed at regular intervals; Passwords contain a mix of at least 8 alphabetic, numeric, and upper/lower case characters. Additionally, password always have 3 of the following four types of characters: alpha, upper and lower, numeric and symbol;
- Data are not accessible by multi-user login accounts or passwords;
- The workstations used to access the data automatically lock after five minutes of non-use (example: screen saver) and require a login or other password to unlock; and
- Laptops and workstation desktops use whole disk encryption

Mt. Hope Family Center is part of the HIPAA covered entity of the University of Rochester Medical Center. Accordingly, all research strictly maintains compliance with HIPAA protection of personal health information of participants (including all PPSI), and all associated data security requirements and safeguards. All HIPAA regulations and strict confidentiality and privacy protections are maintained, and staff members are trained on adherence to confidentiality and privacy standards.

Undergraduate student interns will support full-time research staff with data collection. Students may be from the University of Rochester or other surrounding institutions (non-UR students). As with all study team members, undergraduate student interns from UR and other institutions will be required to complete CITI trainings on human subjects protection. The PIs will oversee the scope of the work through regular meetings with the interns. Interns will be directly supervised by the Project Coordinator. Agreement from the department has been obtained to allow undergraduate students to complete research activities under the PI's oversight.

Facilities at the Mt. Hope Family Center ensure the physical security of all evaluation materials and equipment through the use of an electronically controlled security system including video surveillance and electronic locks. The security system is directly linked the University of Rochester's security division. Saliva samples for cortisol assay will be stored in a locked -80°C laboratory freezer at Mt. Hope Family Center with security monitored by University of Rochester Security.

9. RESEARCH INFORMATION IN MEDICAL RECORDS

Because the Community Health Workers are embedded in the families' medical homes, and through exchange of information in parents' and children's medical records, CHWs ensure coordination with medical teams to address medical needs. Therefore, participation in the study may be included in the child's medical record via Community Health Worker staff, and this will be described in the consent form. Research test results will not be included.

10. DATA ANALYSIS AND DATA MONITORING

10.1. Planned Statistical Analysis

DATA ANALYSIS PLAN: Intent to treat (ITT) analyses will be performed and propensity scoring (PS) procedures will be employed to determine if bias is present in our randomization to treatment (e.g., Rosenbaum & Rubin, 1983). PS estimates the probability that a subject is assigned to a particular condition in a study given a set of known covariates. PS can then be used to reduce selection bias by equating groups based on these covariates. As suggested by Luellen et al. (2005), we will construct different sets of PS using different methods and examine whether treatment effects are robust across the sets. If systematic selection bias is uncovered, then we will explore whether study analyses should be stratified on PS. To account for non-independence of the data (i.e., nesting of mothers/infants within therapists), we will use the "type = complex" feature of Mplus (Muthén & Muthén, 1998-2014). Two tailed-probability values of .05 and Holm adjusted Bonferroni method (Jaccard, 1998) for controlling experiment-wise error rates (Jaccard & Guilamo-Ramos, 2002) will be used. Missing data will be handled using Full Information Maximum Likelihood (FIML) techniques (Enders & Bandalos, 2001) as appropriate. Structural equation modeling (SEM; Bollen, 1989) will include confirmatory factor analysis for data reduction. Specifically,

we will conduct measurement modeling to determine the appropriate factor structure of the pathways of CPP (see Aim 3). We will also employ measurement modeling to determine the appropriate factor structure of parenting. Standard fit indices will be considered to evaluate model fit (Hu & Bentler, 1999). Maternal and infant prenatal and postnatal physical health variables (e.g., APGAR score, birth weight, prematurity, birth complications) as well as demographic characteristics will be included as appropriate as covariates.

Hypotheses and Analyses:

Aim 1 Hypothesis: Mothers who receive CPP will demonstrate more sensitive and responsive parenting at child age 9 months and their infants will evince more secure mother-infant attachment and developmental competencies and fewer instances of child maltreatment at child age 1 year, compared to mothers/infants randomized to CHW home visitation alone. Latent growth modeling (LGM; Aber & McArdle, 1991; McArdle, 1988; Muthén, 1997) will compare the effectiveness of CHW alone versus CPP plus CHW (Group 4 vs. Group 1 + Group 2 + Group 3) on change in parenting over time. The basic LGM is comprised of 2 factors, one representing the initial status/intercept and the other representing change over time/slope. Means of factors represent the average group parameter and the variance represents the amount of individual variability around group parameters. Intervention group (group 4 vs. groups 1+2+3) will be included as an exogenous variable predicting slope of the parenting outcome across 3 and 4 time points. Additionally, analysis of covariance (ANCOVA) will be used to compare the groups on parenting at Time 2 (mid-intervention), Time 3 (post-intervention), and Time 4 (follow-up). Repeated measures ANCOVA will be used to determine whether change in parenting over time varies across groups. Chi-square test will compare intervention groups on Time 4 mother-child attachment using the four primary attachment classifications: avoidant, secure, resistant/ambivalent, and disorganized. The chi-square test will be a 2 (intervention group) x 4 (attachment classification) design. Chi-square will also compare intervention groups on rates of child maltreatment (2x2 design).

Aim 2 Hypotheses: Each of the three individual CPP intervention strategies (i.e. 12 mo. CPP, brief prenatal CPP, brief postnatal CPP) will demonstrate superior outcomes compared to CHW alone. Overall, mothers/infants in the 12 mo. CPP condition will show more positive outcomes than those in the 6 mo. CPP that begins prenatally is expected to be superior to CPP that is initiated postnatally. ANCOVA will be used to compare the 4 groups on parenting at Time 3 and Time 4. Chi-square test will compare the groups at Time 4 on mother-child attachment and child maltreatment. For example, using the four primary attachment classifications: avoidant, secure, resistant/ambivalent, and disorganized, the chi-square will be a 4 (intervention group) x 4 (attachment classification) design. The chi-square to examine different rates of child maltreatment will be a 4 (intervention group) x 2 (maltreatment status) design.

Aim 3 Hypotheses: The CPP group will show greater improvements in maternal attachment representations, parenting cognitions, and stress reactivity, which will protect against child maltreatment and predict superior parenting and child outcomes at one-year post-intervention follow-up compared with CHW alone. Structural equation modeling (SEM; Bollen, 1989) will be used to test mediation of Child Parent Psychotherapy. Latent constructs of mediators and parenting outcomes will be specified as appropriate based on results of preliminary measurement modeling described above. For instance, given that constructs within the stress responsivity pathway (i.e. HPA axis and ANS) may not be highly inter-correlated, results of measurement modeling may suggest that these constructs are best represented as manifest variables. Also, implicit and explicit cognitions may be differentiated within the parenting cognitions pathway to examine the relative mechanistic role of each. Regarding temporal ordering, the effect of CPP on each mediator will be tested over and above baseline or prior levels of the mediator. Similarly, in models in which parenting is the endogenous variable, prior levels of the parenting constructs will be included in the model so that change in parenting behaviors can be tested. Because the mediated effect is rarely normally distributed, the significance of each mediated effect will be determined using the bias-corrected bootstrap method (MacKinnon, 2008). The effect sizes of the three mediated pathways will be calculated using the proportion of the total effect that is mediated method and then compared (MacKinnon, 2008). Details on analyses of the stress response pathway (i.e., HPA axis and ANS) are described in the description of the measurement of this pathway.

Aim 4 Hypotheses: Mothers without a history of maternal maltreatment, depression, or IPV will benefit from the shortened versions of CPP, whereas mothers with higher levels of risk will require more intensive CPP preventive intervention (i.e. 12 mo. CPP). Moderation of CPP will be tested within a structural equation modeling framework following traditional methods described by Aiken and West (1991) including cross-product interaction terms and multiple group SEM (Bollen, 1989) depending on the distributional properties of the moderator variables. A series of repeated measures analysis of variance (ANOVA) will also be used to determine whether change over time in parenting varies by intervention group and moderator status (time x intervention group x moderator status).

Power Analyses: All power estimations were calculated considering $\alpha = .05$. Power for the latent growth models (Aims 1) was estimated using the Monte Carlo simulation method (Muthén & Muthén, 2002). The Monte Carlo approach

generates a large number of random samples (e.g., 1000) from a hypothesized population model. A growth model is fit to each of the simulated samples, and power is determined by computing the proportion of samples in which a particular parameter value was statistically significant. With a sample size of 300, a series of simulation studies were conducted to examine power to detect different rates of change across 3 and 4 time points. Power to detect a rate of change that produced a .50 standard deviation mean difference (moderate effect size) in the outcome by intervention group ranged from .92 to .96. GPOWER3 (Faul et al., 2007) was used to examine power for group comparisons described in Aim 1. There will be power for ANCOVAs ranging from .99 - .86 to detect moderate ($f=.25$) and small/moderate effects ($f=.175$). Estimates of power for the repeated measures ANCOVAs with 3 and 4 time points and for effect sizes ranging from moderate ($f=.25$) to small ($f=.10$) and correlations among repeated measures from .30 to .50, ranged from .90 to close to 1.00. Power to determine intervention group differences between mothers/infants who received any CPP versus those who received CHW home visitation only in attachment classifications and child maltreatment was estimated at .99 for moderate effect sizes ($w=.30$) and from .84 to .93 to detect a small/moderate effect sizes ($w=.20$). Regarding Aim 2, there will be power .96 for medium effect sizes ($f=.25$) for the ANCOVAs comparing the 4 intervention groups ($N=300$) on parenting outcomes. There will be power .86 for medium effect sizes ($d=.50$) for t-tests comparing 2 intervention groups ($N=150$). Power to detect moderate effect sizes ($w = .30$) was estimated from .97 to .99 for the chi-square tests. Power for the mediation paths for Aim 3 was determined using the power tables by Fritz and MacKinnon (2007). Power to detect a mediated effect depends on the size of both paths involved in the mediation effect. To detect small/medium effects, a sample of 148 is required for the proposed bias-corrected bootstrap method. Thus, we will be adequately powered to detect small/medium effect sizes within a mediation model comparing at least 2 of the intervention groups ($N=150$) as well as analyses involving other group comparisons. Finally, regarding Aim 4, power for repeated measures ANCOVA was estimated at .99 to detect small/moderate effect sizes ($f=.175$), with 3-4 time periods, a repeated measures correlation of .30, 4 intervention groups, and a 2 level moderator variable (e.g., current IPV yes/no). Therefore, the proposed study is adequately powered to detect medium effect sizes for all aims.

In summary, we propose an innovative, multi-method, multi-level approach to evaluating the efficacy of a preventive intervention provided to at-risk women pre- and post-natally. The identification of timing, dosage, and intensity, in combination with mediators and moderators of outcome, possesses high public health significance for this vulnerable population.

10.2. Data and Safety Monitoring

Because the proposed research involves the provision of a preventive intervention, the risk for a serious adverse event due to provision of the intervention is very low. Adverse events that could occur in work with mothers and children include the identification of incidents of child abuse or neglect or incidents of domestic violence. However, these occurrences are not likely to be a consequence of participation in the research or interventions. Ongoing safety of research participants, including mothers and children taking part in the preventive intervention, will be monitored via a Data and Safety Monitoring Board (DSMB). The DSMB will be coordinated with the TRANSFORM Data and Safety Monitoring Committee chaired by Dr. Lynch, Professor of Psychology at SUNY Geneseo. The DSMB will serve as a liaison among the project investigators, the University of Rochester Research Subjects Review Board (UR RSRB), the Office for Human Research Protections (OHRP), and the National Institute of Child Health and Human Development.

DSMB Membership. The DSMB will be comprised of people who have no direct involvement in the project and no conflict of interest with the research team. The DSMB will be comprised of community members who have expertise in the following areas: 1) evaluation of preventive interventions with high-risk populations, 2) prevention and intervention with child maltreatment, 3) clinical and research experience with racially and ethnically diverse groups, and 3) provision of community-based services for mothers and children.

DSMB Responsibilities.

1. Reviewing and suggesting modifications to research protocols and consent documents to assure scientific integrity and adherence to human subjects protection policies, including confidentiality.
2. Monitoring safety issues, providing feedback, and reporting on scientific and ethical issues related to project implementation for the protection of human subjects.
3. Advising on ethical issues related to adverse events, monitoring adverse events reporting, and reporting any unanticipated problems involving risks to subjects. The IRB would be notified immediately of any adverse events via telephone and submission of a "University of Rochester Serious Adverse Event Report." Such events also would be reported to NICHD.
4. Monitoring efficacy of preventive intervention efficacy. The DSMB will provide guidance on subject

discontinuation criteria and stopping rules. The DSMB will review accumulating data for outcomes for each group. If differences in results appear to be clinically significant, the DSMB will review whether the project should continue with or without further enrollment of new subjects. The DSMB has the authority to halt the project as needed.

5. **Monitoring data management activities.** The DSMB may ask to review data for quality control purposes. The DSMB will review requests for interim analyses and approve, disapprove, require additional information, or defer decisions.

Meeting schedule. The DSMB will convene on an annual basis, at a minimum. Additional meetings and telephone conferences will be held at the recommendation of the DSMB. During Year 1, the DSMB will convene after the first 20 children/mothers have been randomized. The DSMB Chair and the PI will decide the format of the meetings and meeting logistics, based on clinical urgency and the availability of DSMB members.

Data Reporting. The investigators will submit statistical reports to the DSMB at least one week prior to scheduled meetings. These reports will include all reported data up to and including 14 days prior to the reporting deadline (with the exception of Serious Adverse Events, which will be reported within 24 hours of the event). At each annual meeting, the PI (ST) will present an overall progress report, which will include safety considerations for participants. Results of interim analyses will be reviewed to determine whether any emerging patterns of findings regarding responses to the preventive program alters the risk-benefit ratio that would require modifications to protocols or discontinuation of the project. Interim analyses will be planned to provide information on any possible problems in recruitment, attrition, or other procedures that would affect the integrity of the study. The DSMB will be kept apprised of all serious adverse events and will have the authority to determine whether participants should be removed from the study. Although project therapists will be empowered to take immediate action to safeguard participant safety, input from the DSMB will be solicited to render judgments in the event of serious adverse events, and the UR RSRB will be contacted as well.

Additional quality control and participant safety will be ensured via weekly supervision of research and clinical staff by the PIs (ST and JTM).

Therapists conducting the intervention will be experienced with regard to serving low-income families, and mothers and young children, in particular. They will be familiar with referral procedures around suspected child abuse and neglect, as well as intimate partner violence problems. The PIs (ST and JTM) will be on call should any interim emergencies arise.

A second risk to minimize is the possible loss of privacy with regard to family maltreatment status. All information gathered through questionnaires, audio-recordings, and video-recordings will have only subject codes and no identifying information pertaining to the mother and child. Mailings to families will carry the Mt. Hope Family Center return address, as MHFC provides multiple services to families in the community and is seen as a resource commonly used by the population being targeted for this study.

As part of the consent process, the limits of confidentiality involved in the intervention, as well as the possible consequence of child maltreatment of harm to self or others will be explained to mothers. Additionally, the need for family members as contacts to facilitate the follow-up of families over the course of the project will be explained.

One of the PI's (ST) also will be responsible for monitoring the integrity of the data. Weekly meetings for supervision of the research staff will allow for review of recruitment rates, retention, and monitoring of the quality of data collection. The PI and Investigators also will spot check the quality of data collection throughout the course of the project. In addition to weekly clinical supervision of the therapists providing the preventive intervention, plans are in place to monitor the integrity of the provision of the intervention and their adherence to the specifications of the Child-Parent Psychotherapy model. This fidelity check will occur through periodic monitoring of videotapes of intervention sessions and the completion of a fidelity checklist. Social work supervisors of CHWs will assess CHW activities. CHW case notes will be reviewed for monitoring of CHW activities.

Given the relatively low risk of the preventive intervention and the past experience of the research team to minimize risks to low-income culturally diverse families participating in research on child maltreatment, the MPI's propose to contact the NICHD project officer with semi-annual updates regarding these areas of data safety and monitoring.

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