Title of Project: Promoting resilience and lowering risk in early childhood: An mHealth intervention study

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Principal Investigators:
David Bard; PhD; Dept of Pediatrics, University of Oklahoma Health Sciences
Helen Milojevich; PhD; Dept of Pediatrics, University of Oklahoma Health Sciences

RESEARCH PROTOCOL OUTLINE

Abstract

Early adversity exposure profoundly influences diverse aspects of brain and behavioral development and long-term risk for mental and physical illness. Rates of adverse childhood experiences (ACEs) in the United States remain high, with 1 in 6 adults experiencing 4 or more ACEs. Nationwide, numerous efforts have been initiated to reduce rates of ACEs and promote resiliency of high-risk children. One such effort is home visiting (HV), which provides one-on-one coaching to help high-risk parents (e.g., living in poverty, mental health issues) learn skills to promote child development and improve family functioning. Findings on the impact of HV programs have at times been mixed and we have yet to significantly improve psychosocial adjustment of adversity-exposed children. Here we propose to conduct an intervention study to provide in-the-moment parenting tips with the goal of increasing healthy parent-child interactions leading to resiliency in high-risk children. Specifically, in a sample of parents participating in a HV program, we propose to use a smartphone app (mHealth app) to deliver twice-daily tailored messages with tips on monitoring and promoting child development. Daily assessments of parents' emotions, parenting behaviors, and interactions with their children will also be collected via the app. We expect that parents will evidence greater engagement in positive parenting practices on days when they receive the mobile-based parenting tips and strategies relative to on days when they do not receive this content.

A. Specific Aims

This is an intervention study to provide in-the-moment parenting tips with the goal of educating parents about monitoring and promoting child development, thereby increasing healthy parent-child interactions leading to resiliency in high-risk children. Specifically, in a sample of parents participating in a HV program, we will use a smartphone app (mHealth app) to deliver twice-daily tailored messages with tips on monitoring and promoting child development. Ecological momentary assessments (EMA) of parents' emotions, parenting behaviors, and interactions with their children will also be collected via the mHealth app. Building off our previous work we expect that parents will evidence greater engagement in positive parenting practices on days when they receive the mobile-based parenting tips and strategies relative to on days when they do not receive this content.

We hypothesize that in-the-moment parenting tips delivered around peak times of parent-child interactions (i.e., before work/school, mealtimes, and bedtime) will promote positive parenting practices in a sample of parents at increased risk of adversity exposure. We aim to use EMA methodology to measure both group level differences (i.e., intervention vs. services as usual) and within-person fluctuations in harsh parenting, children's emotional and behavioral functioning, and positive parenting practices. The study will evaluate the following aims and hypotheses:

Aim 1. Conduct a 2-arm, randomized, controlled crossover trial to examine the feasibility and effectiveness of a mobile-based parenting app with parents participating in HV services.

Hypothesis 1a. Parents will report high rates of satisfaction and usability. Hypothesis 1b. Parents will evidence greater engagement in positive parenting practices on days when they receive the mobile-based parenting tips and strategies relative to days when they do not receive this content.

Hypothesis 1c. Groups will evidence increases in positive parenting subscale scores after a month of app engagement.

Aim 2. Utilize EMA data and follow-up assessments to examine the impact of positive parenting practices on the promotion of child development.

Hypothesis 2a. Hypothesis 2a. Children will demonstrate less challenging and more positive behavioral functioning on days when their parents receive positive parenting tips.

Hypothesis 2b. Groups will evidence increases in developmental scores after a month of app engagement.

B. Background and Significance

Background:

Exposure to early adversity has significant public health implications. A recent surge of empirical work has focused on how early experiences impact children's developmental trajectories and ultimately the health and well-being of individuals across the lifespan. This increased attention is in part a result of large-scale epidemiological studies, such as the Adverse Childhood Experiences (ACEs) study[1], documenting the far-reaching and lasting consequences of childhood adversity on a diverse set of outcomes, including rates of morbidity and mortality. ACEs capture a wide range of potentially traumatic events experienced in childhood (0-17 years), including exposure to violence, abuse, or neglect, witnessing home or community violence, and having a family member attempt or die by suicide. Rates of early adversity in the United States remain high, with 1 in 6 adults experiencing 4 or more ACEs[2]. Moreover, ACEs tend to have a cumulative impact, such that as ACE exposure increases so too does the risk of experiencing negative developmental outcomes[3-4]. ACEs also place a heavy burden on society, with an estimated annual financial loss of $748 billion due to criminal justice costs, productivity losses, and mental health services[5]. Overall, these figures underscore ACEs as a pressing public health issue with widespread implications for individuals, families, and society as a whole.

As scientific evidence of the far-reaching consequences of ACEs has increased, so have surveillance efforts at both the state and national level, leading to a better understanding of the burden of childhood adversity and population level differences[6]. More recently, the shift from assessment to action is reflected in policies and practices that focus on increasing awareness of the negative outcomes associated with ACEs, alongside the promotion of strategies that mitigate risk and improve child outcomes and family well-being[7]. Importantly, despite widespread consequences of ACEs, some individuals demonstrate resilience and experience healthy functioning. While less is known about how, and under what circumstances, protective mechanisms and positive experience buffer ACEs, safe, stable, nurturing relationships are key to child health and development. For children and families most at risk, promoting strategies that build

protective capacities is critical to reducing risk and improving outcomes, which in turn can mitigate the societal burden associated with ACEs.

Influence of positive parenting. One particularly robust predictor of resilience in the face of adversity is parenting. Parents play a profound role in shaping their children's developmental trajectories. Recently, the National Academy of Sciences, Engineering, and Medicine released Parenting Matters: Supporting Parents of Children Ages 0–8, which underscores the importance of quality parenting for child development[8]. Additionally, Sege and Browne[9] proposed The Healthy Outcomes from Positive Experiences (HOPE) framework, which focuses on promoting positive childhood experiences to prevent or mitigate the effects of ACEs. HOPE identifies four broad categories of positive experiences and their effects on child development, including the need for (1) sustained supportive relationships, (2) growing and learning in safe, stable environments, (3) opportunities for constructive social engagement and connectedness, and (4) social and emotional competencies. Parents play direct and indirect roles in cultivating all four categories[10-11]. Positive parenting practices are associated with dose-dependent reductions in adult mental health and relational health impairments resulting from ACE exposures[12]. Moreover, positive parenting practices, including engaging the child in reading stories, storytelling/singing, eating meals together, playing with similar-age children, and family outings, are linked with behavioral, emotional, and cognitive improvements in children exposed to adversity[13]. Positive parenting practices are also tied to alterations in brain structure and functioning. For example, shared reading interactions between mothers and their children have been associated with activation in left-sided brain areas supporting expressive and complex language, socio-emotional functioning, and working memory[14].

Intervention efforts. Nationwide, numerous efforts have been initiated to promote positive parenting practices and reduce rates of ACEs in high-risk children. One such effort is home visiting (HV), which provides one-on-one coaching to help high-risk parents (e.g., living in poverty, mental health issues) learn safety, health, and parenting skills to promote child development and improve family functioning. Findings on the impact of HV programs on child development have at times been mixed and we have yet to move the needle on significant improvement in the psychosocial adjustment of adversity-exposed children[15-16]. Specifically, findings indicate that the potential of HV to improve child developmental outcomes depends in part on the model of HV, the training level of the provider, and the domain of child development in question[17]. Evidence also suggests that the effects of HV on child development may at times be indirect. For example, work by our team found that the association between HV and child development was mediated by the home environment, such that as parents received more home visits, they reported providing more emotional support and cognitive stimulation to their child, which in turn was associated with higher developmental scores for their children[18]. Moreover, the National SafeCare Training and Research Center recently administered an attitudinal survey to SafeCare providers on incorporating mHealth apps into programming. Findings suggested that the vast majority of providers felt that an mHealth app would improve client outcomes and help supplement existing curriculum, however over 70% reported never using an app of any kind (mHealth or otherwise) with their clients. Given the overwhelming public health crisis due to ACEs, the importance of positive parenting practices, and the inconsistent findings on HV's impact on child

development, there is a dire need for low-cost, impactful interventions that can enhance and extend HV to large portions of high-risk families in a consistent and reliable manner. The goal of this project is to test such an intervention.

Significance: Despite empirical support for HV models, evidence suggests that HV programs reach on average less than 4% of the population in need of such intervention, particularly low-income families and can be prohibitively costly to bring to scale[17]. Moreover, family engagement and retention in HV services are impeded by life circumstances such as unpredictable or inflexible work schedules, the need for visits outside of the typical work day, and living in other family members who may not want the services[19]. To address these obstacles, service providers and researchers alike are increasingly turning to technology, including mobile health apps, as a means to widespread, low cost service delivery. Mobile health interventions (mHealth) are particularly appealing given their popularity, mobility, and extensive technological capabilities. Crucially, mHealth interventions can bolster service delivery to large numbers of high-risk individuals and families by (1) reaching resource-poor environments, (2) targeting content in an individualized and customized manner, and (3) delivering content at specific times when it is the most relevant and potentially impactful. As such, the project has the potential to develop a much-needed intervention that could be targeted to families receiving HV to bolster the effectiveness of those services, as well as, other at-risk population not involved in HV, but who would similarly benefit from the parenting tips and strategies.

In addition to the service delivery benefits, mHealth apps also allow for researchers to collect extensive data from service recipients via ecological momentary assessment (EMA). EMA has emerged as one of the most promising ways to collect ecologically valid information about temporal and contextual factors that impact behavioral dynamics in real-world settings. EMA involves repeated sampling of participants' current behaviors and experiences in real time, in their natural environments. As such, EMA minimizes recall bias, maximizes ecological validity, and permits the examination of microprocesses that influence behavior in real-world contexts. Through the use of EMA, the proposed study will move beyond examining parenting behaviors as a *static* marker of risk and resilience by testing for a more dynamic or proximal relation between parenting behaviors and developmental outcomes in at-risk children's daily lives. Thus, the study would pilot test a much-needed low cost, far reaching intervention, provide preliminary data on dynamic relations of risk and resilience in high-risk families.

C. Preliminary Studies/Progress Report

The evaluation will be led by the Biomedical and Behavioral Methodology Core (BBMC) of the Department of Pediatrics. The development and implementation consultation will be provided by faculty and staff at the Center on Child Abuse and Neglect (CCAN), which is also housed in the Department of Pediatrics. The BBMC is a shared resource that consists of three primary and three jointly-appointed faculty members, 5 academic support staff and 2 administrative support staff. The BBMC mission is to support and enhance study design, data capture, and analytics for biomedical and behavioral research,

and this Core currently provides a variety of methods support for several ongoing clinical and translational research studies in the Department of Pediatrics as well as several other outside Departments and Colleges. BBMC faculty represent established federally funded scientific researchers with statistics, methods, and informatics expertise and extensive publication records. BBMC faculty and staff offer specialized methods expertise in Bayesian methods, clinical trials, field trials and survey research, study design and management, measurement and psychometrics, analysis of complex sampling designs, generalized linear modeling, generalized latent variable modeling, longitudinal and spatial analysis, time series and dynamic modeling, quantitative genetics, population genetics, computational programming and statistics, software development, database design and management, bioinformatics, and qualitative data methods. Faculty and staff participate in both independent and collaborative research, provide general research consultation, teach and mentor graduate and undergraduate students, and supervise research assistants at all levels of academic and non-academic rank. The BBMC has a strong working relationship with the Center on Child Abuse and Neglect (CCAN). CCAN is a university-based, interdisciplinary center dedicated to the prevention and treatment of child abuse and neglect, and has a long-standing history in the community, state, and nation in conducting clinical implementation and dissemination research on the prevention and treatment services for child maltreatment. As a research group, they have been able to demonstrate the capacity to accommodate reasonable scientific rigor within the demands and realities of services research, along with well-established research-practice partnerships with state authorities and front-line service provider agencies. The overall focus of these collaborations has been to develop, adapt, rigorously test, refine and move to scaled-up implementation with evidence-based child welfare intervention models. The focus has been both on developing or adapting the evidence-based practices (EBPs) themselves and on improving strategies for how these models can be implemented with fidelity at-scale within large public sector child welfare service systems. CCAN team members include established federally funded scientific researchers with extensive publication records, including experience conducting treatment outcome trials in real-world field settings. Funding sources and implementation efforts related to the current demonstration project have included: NIMH (e.g., Effectiveness Trial of SafeCare for Neglect. (NIMH R01MH065667; Chaffin [PI], Hecht); Developing Multi-Component Evidence Based Practice for Child Abuse Service Systems. (NIMH-1R34MH076972; Hecht [PI]), Mixed Methods Study of a Statewide EBP Implementation (NIMH R01MH072961; Aarons [PI], UCSD; Chaffin, Hecht, OUHSC); ACYF, Children's Bureau (e.g., State of Oklahoma Title IV-E Waiver Demonstration Project, 2015-2019. Bard, lead evaluator, PI of subcontract; Evidence-Based Child Maltreatment Prevention for High Risk Families: Expanding to Latino Communities, Enhancing Family Violence Prevention, and Sustaining Prevention Programs. USDHHS (90CA1764). Silovsky [PI]); The Centers for Disease Control and Prevention (e.g., Alternatives for Families III. # CCR622338. Chaffin [PI]); and HRSA (e.g., Maternal, Infant and Early Childhood Home Visiting (MIECHV) Competitive Grant Program, Independent Evaluator subcontract. D89MC23154 Bard, PI of subcontract). These projects demonstrate capabilities in evaluating EBP uptake at client, provider, organizational, and systems levels, and use of mixed methods approaches (quantitative/qualitative methods).

Personnel and Duties
Principal Investigator: David Bard, Ph.D. Dr. Bard's project responsibilities will include: (1) overseeing the day-to-day administration of the evaluation project and personnel, (2) maintaining regular contact with funding agencies as needed, (3) overseeing of the progress reports on the project, (4) proposing the research design and methodology, and (5) overseeing data collection and analysis. Note: Dr. Bard began fulfilling this role in July of 2022 due to a location change of Co-PI Milojevich.

Co-Principal Investigator: Helen Milojevich, Ph.D. will assist Dr. Bard as a Co-PI. Roles and responsibilities include supervision of personnel, oversight of all contracts and sub awards, continued data base development, implementing the methodology for the study, conducting the data management and analysis, and disseminating findings. Note: Dr. Milojevich switched from PI to Co-PI in July of 2022 due to a location change.

Co-Investigator: Sixia Chen, Ph.D. will serve as a data analyst on this project. He will advise the PIs in all statistical analyses required for the completion of this proposed study. Dr. Chen will also assist in writing reports and manuscripts.

Co-Investigator: Debra Hecht, Ph.D. will assist in the design of the mHealth app content. Dr. Hecht will also assist in writing reports and manuscripts.

Co- Investigator: Adam Alexander, Ph.D. will provide guidance in the development of the mHealth app and provide support throughout the grant on the use and functioning of the app and EMA data collection efforts. Dr. Alexander will also assist in writing reports and manuscripts.

Postdoctoral Researcher: Amy Treat, Ph.D. will assist the PIs with IRB protocols, methodology development, guiding the GRA on participant recruitment and data collection, data coding and analysis, and writing up reports and manuscripts.

Research Assistant: TBH is will recruit and test participants at all waves of data collection (baseline, EMA, and follow-up). They will also be in charge of android phone management and distribution as well as distribution of participant payments.

Contract/Grant Coordinator: Angela Raper will provide financial management, budget monitoring, effort tracking, financial record keeping, contract set-up for the mHealth app, and purchasing management. She will supervise the android phone management and distribution.

Senior Accounting Specialist: Tiffany Burris will assist with financial and purchasing management and record keeping. She will purchase and track participant incentives and project android phones as well as set up service and data plans. She will assist with android phone management and distribution.

Contractor: Lana Beasley, Ph.D. will conduct the focus group on app and intervention feedback, analyze the qualitative focus group data, aid in the interpretation of results, and assist in writing reports and manuscripts.

Contractor: Kathryn Bigelow, Ph.D. will advise the PIs and research team on the content of the parenting app tips and OnDemand materials, meet quarterly to discuss project progress and help problem-solve any challenges, and assist with writing reports and manuscripts.

Research Coordinator – The research coordinator will work closely with the PIs and Co-Is on managing day-to-day study operations.

Data Collection Supervisor – The data collection supervisor will work with the research coordinator to ensure timely and accurate data collection.

Graduate Research Assistant: The GRA will work with the rest of the team to clean and analyze data collected during the surveys. This individual will ensure the data are structured, cleaned, and stored properly.

D. Research Design and Methods (What, When, How, Where)

Study Design

We will use a 2-arm randomized, controlled cross over trial design to evaluate the effectiveness of the mHealth Intervention. We will recruit up to 50 participants from three home visiting programs (SafeCare at NorthCare, Latino Community Development Agency [LCDA], and Parent Child Center [PCCT]). All three of these programs utilize the SafeCare home visiting model, which includes modules on healthy parent-child interactions and promoting parenting skills in high-risk families. We plan to recruit existing and new families in these programs and randomly assign them to receive either 2 weeks of the mHealth intervention + EMA data collection followed by 2 weeks of only EMA data collection or to receive 2 weeks of only EMA data collection followed by 2 weeks of mHealth intervention + EMA data collection. All participants will receive both conditions in counterbalanced order.

Study participation involves consenting to administrative record release and immediate baseline questionnaires assessing demographics, the child's exposure to adversity, parental exposure to childhood adversity, parent's emotional expression, emotion reactivity, and emotion regulation and the child's emotion regulation and development, ecological momentary assessment (EMA) at fixed times twice a day (morning and evenings), and final assessments, which will be the same as the baseline assessments.

EMA Only Condition In the EMA only condition, families will continue to receive services utilizing the SafeCare home visiting model, including modules on healthy parent-child interaction and promoting parenting skills in high-risk families, but they will not receive parenting tips via the mHealth app during this period. We plan to administer brief surveys via the mHealth app twice a day at pre-determined times (morning and evening). These surveys will ask parents to provide information about where they are and

with whom, their emotional state, recent parent-child interactions, current stressors or challenges, and their child's emotional and behavioral functioning. Parents will receive these twice daily surveys every day for two weeks.

mHealth Intervention Condition

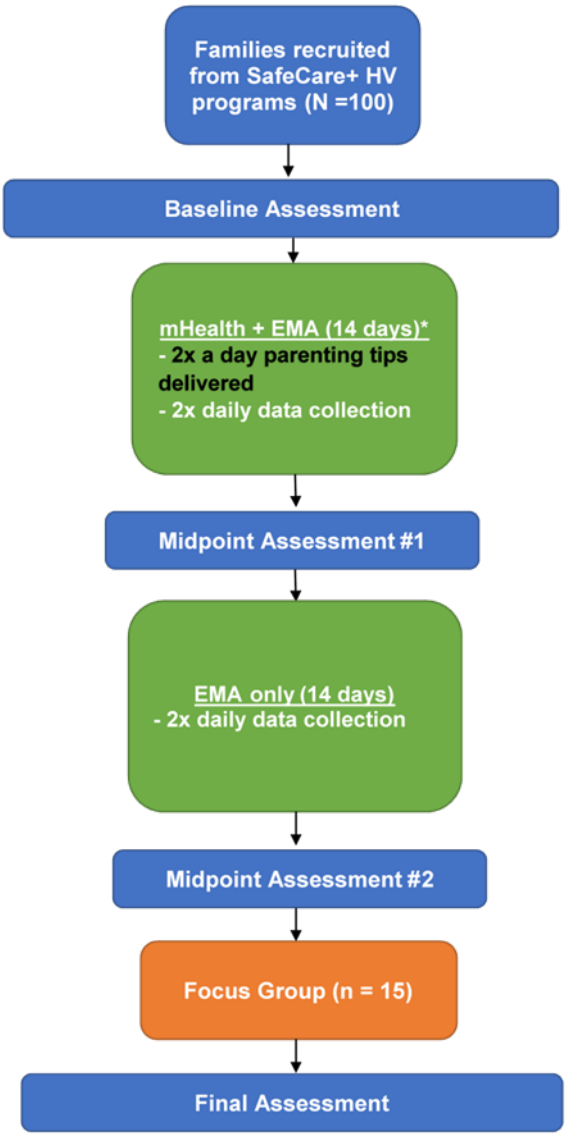
When families are in the mHealth intervention condition, the mHealth app will deliver parenting tips and strategies twice daily for 14 days. Furthermore, we plan to administer brief surveys via the mHealth app twice a day at pre-determined times (morning and evening). These surveys will ask parents to provide information about where they are and with whom, their emotional state, any recent parent-child interactions, and any current stressors or challenges. Parents will receive these twice-daily surveys and the parenting tips for every day for two weeks.

Of note, during the 4-week EMA study, parents will receive either 2 weeks of the mHealth intervention + EMA data collection followed by 2 weeks of only EMA data collection or to receive 2 weeks of only EMA data collection followed by 2 weeks of mHealth intervention + EMA data collection.

The order of mHealth intervention and EMA data collection will be counterbalanced across participants to allow for a within-subjects comparison.

See the study diagram below for a visual depiction of our data collection schedule.

Figure 1: Proposed Study Design



***Note.* Order of mHealth + EMA and EMA only portions of the study will be counterbalanced across participants**

Research Questions

This investigation will: (1) test a low-cost, far reaching, evidence-based intervention delivered via mHealth app technology, (2) examine the effectiveness of a mHealth app intervention at improving positive parenting practices, and (3) investigate within and between person differences via EMA thereby strengthening causal implications. This data will be used to inform the following key study questions:

Research Question 1: How effective and feasible is a mobile-based parenting app intervention for parents participating in Home Visiting services.

Research Question 2: What is the impact of positive parenting practices on the promotion of child development?

Data Sources

Quantitative Researcher- Assisted Surveys and Assessments

Participants will complete baseline and follow-up assessments with a trained research assistant. The parent receiving HV services with the index child will complete questionnaires assessing demographics, adversity exposure, positive parenting practices, child development, and relevant covariates and potential mediators/moderators.

Ecological Momentary Analysis (EMA) Data

Parents will be asked to complete brief surveys via the mHealth app twice a day at pre-determined times (morning and evening). These surveys will ask parents to provide information about where they are and with whom, their emotional state, recent parent-child interactions, current stressors or challenges, and their child's emotional and behavioral functioning via the mHealth app.

App Feasibility and Effectiveness Data

We will also collect data on parents' perceptions of app feasibility and effectiveness via survey and a focus group selected from a subset of the 50 participants (up to n =30). We will also track app use (e.g., assessment response rates, number of missing assessments, time spent on app, type of OnDemand content viewed) to provide insight into participant compliance and app interaction.

Administrative Data

The Oklahoma State Department of Health (OSDH) will provide access to administrative data housed in their centralized Efforts To Outcomes (ETO) data system in use by all Maternal, Infant, and Early Childhood Home Visiting (MIECHV) contracted agencies (which includes the three SafeCare programs participating in the proposed study). This system stores benchmark outcome data the research team can utilize to examine whether individual characteristics of parents and families (e.g., number of home visits, completion level of the SafeCare curriculum) predict app utilization outcomes.

E. Procedures

Recruitment and enrollment

All participants in the proposed study will be recruited from three home visiting (HV) programs that deliver the SafeCare+ HV model, which includes modules on healthy parent-child interactions and promoting parenting skills in high-risk families. Families who are eligible for SafeCare+ services generally have one of the following risk factors: mental health issues, intimate partner violence, or substance abuse. We plan to recruit existing and new families in these programs and randomly assign them to one of the two counterbalanced intervention arms.

Consenting procedures

All project consents and HIPAA forms will be collected electronically using REDCap regardless of if the assessment occurs in-person or via telehealth services. REDCap has a feature which allows for version control, automatic time and date stamp, and electronic signature (using a fingertip, computer mouse, or stylus on a tablet screen). After the consent and HIPAA forms are signed in REDCap, these documents will automatically be sent to and stored on the OUHSC secure server as .pdf files. An electronic version of this signed consent and HIPAA form can be emailed directly, or if the participant requests, a paper copy will be provided. If a participant requests additional time to discuss the study with family/friends, a paper or electronic copy of the forms will be provided to the participant to review.

Quantitative procedures

Baseline assessments. The research assistant will administer all baseline assessment measures in a virtual interview that will take place via zoom or phone (in person interviews in the participant's home may take place if COVID-19 precautions are lifted). The parent receiving HV services with the index child will complete questionnaires assessing demographics, the child's exposure to adversity, positive parenting practices, child development, and relevant covariates and potential mediators/moderators. (See list of measures below).

Adversity exposures. Parents will report on their own (PHL ACEs) and their child's (ACEs) adversity exposure. Children's maltreatment exposure will be assessed via the Parent-Child Conflict Tactics Scale52 and the Child Abuse Potential Inventory.

Positive Parenting Practices. Positive parenting practices will be assessed via the Alabama Parenting Questionnaire- Parenting Form. Three subscales of relevance to the aims will be scored and assessed: Inconsistent Parenting, Punitive Parenting, and Positive Parenting.

Child Development. The Developmental Profiles-4 will be administered to assess child development. This measure covers multiple domains of development including gross and fine motor skills, adaptive behavior, social-emotional functioning, cognitive functioning, problem-solving, and communication skills.

Covariates. Relevant covariates and potential mediators and moderators include family demographics, parent mental health (Center for Epidemiological Studies Depression), parent emotional functioning (Self-Expressiveness in the Family Questionnaire, Emotion Reactivity Scale, Difficulties in Emotion Regulation Scale), child emotional functioning (Emotional Regulation Checklist), parent's protective and compensatory experiences (PACEs), and family economic disadvantage (MacArthur Scale).

These measures will be administered in the baseline and follow-up assessments. For the EMA portion of the proposed project at least one measure from each construct will be administered in a condensed, briefer format.

Ecological momentary analysis (EMA) study. Parents will receive twice daily parenting tips and strategies throughout the day. These tips will focus on educating parents about positive parenting practices as a way to promote healthy development in

their child via an adapted SafeCare curriculum. Parents will also be asked to complete brief surveys via the mHealth app once a day at a pre-determined evening time. These surveys will ask parents to provide information about where they are and with whom, their emotional state, recent parent-child interactions, current stressors or challenges, and their child's emotional and behavioral functioning. Parents will receive these once daily surveys and the twice daily parenting tips for two weeks. Of note, during the 4-week EMA study, parents will receive either 2 weeks of the mHealth intervention + EMA data collection followed by 2 weeks of only EMA data collection or to receive 2 weeks of only EMA data collection followed by 2 weeks of mHealth intervention + EMA data collection. The order of mHealth intervention and EMA data collection will be counterbalanced across participants to allow for a within-subjects comparison. Assessment responses will be continuously tracked and stored on a university data server. Additionally, a subset (n =30) of parents will be asked to participate in a brief focus group, during which parents will discuss their experiences with the mHealth app.

Follow-up assessments. At the end of the EMA study, parents in both groups will be asked to complete a series of measures in the same manner as the baseline assessment. All measures completed at the baseline assessment will also be completed at follow-up. This final assessment will also include an ease of use and satisfaction survey about the overall app experience.

Withdrawal criteria

The participant will be withdrawn from the study at their request, or if the questions in the survey are causing severe emotional distress, she may be involuntarily withdrawn at the discretion of the PI. If they become incarcerated, they will also be withdrawn, but if they are released at a subsequent interview, they may be re-consented and resume the original data collection schedule.

Disclosure to participants

In the instance of clinically relevant research results affecting the health and well-being of the participant/child, participants will be contacted and notified. Published results using study data will be made available upon request to all participants. Identifiers might be removed and the de-identified information may be used for future research without additional informed consent from the subject.

Information security

All survey data are collected using REDCap. REDCap is a secure web application for managing survey data. REDCap allows for live data capture, meaning data are immediately stored on secure University servers. REDCap data may only be accessed by study staff using University encrypted devices. Access to study survey data is provided only to data collectors (so they may keep in contact with survey participants) and to personnel who will use data for analysis and reporting.

All trial data related to the parenting intervention will be collected and monitored via the Insight mHealth Platform. The Insight™ Platform will enable the researcher team to create an innovative mobile application that: 1) identifies proximal and distal antecedents to imminent risk behaviors using self-report surveys (i.e., ecological momentary assessments [EMAs]); and 2) conduct a Just-in-Time Adaptive Intervention (JITAI) that

tailors intervention content in real-time based upon survey responses. Insight™ is utilizes a web-based content management system (CMS) for easy access across multiple browsers, and uses architecture that enables the incorporation of new features. Users of this service log into a web-based CMS and follow step-by-step guidance to create and manage research studies, enroll and monitor study participants, create EMA items, create different types of EMAs (e.g., random, daily, participant-initiated) and create specific assessment rules (e.g., two vs. four random assessments per day). Once study parameters and content have been created in the CMS, researchers transfer their study materials into the smartphone application shell. The customized smartphone application can be made available on the Android app store, and will soon be available on the Apple app store. Data are encrypted within the smartphone application and automatically and securely uploaded into mHealth servers. Encrypted data can be downloaded from the server by users at any time. The PIs will monitor the incoming data from the Insight™ platform on a monthly basis to ensure that the trial is conducted according to the approved protocol.

All paper forms are kept in locked filing cabinets behind a locked door in an office requiring a security badge for entry.

Consents will be collected electronically through REDCap and stored electronically on a secure OUHSC server.

F. Inclusion / Exclusion Criteria

Inclusion Criteria

Any new or currently enrolled parent in Oklahoma or Tulsa County in MIECHV-funded SafeCare home visiting programs.

Exclusion Criteria

Parents residing outside of Oklahoma or Tulsa Counties will not be recruited (although if they move to another county between baseline and follow-up, they may be eligible to complete the follow-up survey at the discretion of the Principal Investigator).

Parents who cannot read/speak English or Spanish at an 8th-grade level or higher will not be recruited.

Parents under age 16 will not be recruited. Parents ages 16-17 meeting other eligibility requirements may be recruited using the assent form with signatures from both of his/her parents.

G. Gender/Minority/Pediatric Inclusion for Research

Women and minorities will be recruited as a part of this study, including pregnant women. Data collectors are trained on fully explaining the consent with the participant, including emphasizing the voluntary of nature of research and reminding them that refusal to participate will not affect services they would otherwise receive.

H. Risks and Benefits

There is little-to-no risk to participant health, but there is a risk of some emotional distress due to the sensitive nature of some of the measures contained in the survey. The data collector will assure participants that refusal to respond to a particular question (with exception of certain demographic measures) or measure will not make them ineligible to participate. If a participant seems to be reacting negatively to items asked (e.g., questions about their history of trauma or intimate partner violence), the data collector may help the participant skip that specific measure.

There may be some risks to privacy. This is addressed in the following section.

Minimizing risks
To address the risks related to information security, all survey data are collected using REDCap. REDCap is a secure web application for managing survey data. REDCap allows for live data capture, meaning data are immediately stored on secure University servers. REDCap data may only be accessed by study staff using University encrypted devices. Access to study survey data is provided only to data collectors (so they may keep in contact with survey participants) and to personnel who will use data for analysis and reporting.

Data collected via the mHealth app are encrypted within the smartphone application and automatically and securely uploaded into mHealth servers. Encrypted data can be downloaded from the server by users at any time. All paper forms are kept in locked filing cabinets behind a locked door in an office requiring a security badge for entry. Consents will be collected electronically through REDCap and stored electronically on a secure OUHSC server.

Describe potential benefits and importance to the participants and others
There are no direct benefits to participating. Information obtained as part of this study will serve as pilot data for federal grant applications launching a more comprehensive expansion of the intervention study regionally and through our international collaborations. Moreover, this work will inform the feasibility and scalability of a novel intervention aimed at (1), the promotion of resiliency and child development in children growing up in high-risk environments, (2) the prevention of child maltreatment and early adversity exposure, and (3) the reduction of lifetime disease and health consequences linked to adversity.

Discuss why risks are reasonable in relation to benefit
The risks in this protocol are minimal to participants. Families are connected to SafeCare programs designed to improve child and family outcomes. The benefits of this study aid in the improvement of services for families exposed to adversity.

I. Statistical Methods

Data Analysis
Analyses. Analyses will be guided by Drs. Bard (Quantitative Psychologist) and Chen (Biostatistician).

For **Hypothesis 1a** we will analyze the satisfaction and usability responses gathered at the post-intervention, follow-up assessment using descriptive and inferential statistics. Descriptively, we will report central tendency (means, medians) and dispersion (standard deviation, interquartile range) measures for response distributions. To evaluate the significance of app appeal, we will conduct one sample Wilcoxon signed rank tests to determine if the central location of the data departs from point values that reflect slight or minimal satisfaction/usability.

Additionally, analysis of the qualitative focus group transcription will be completed using NVivo software. Broad themes within the transcription will be identified using a template approach[67]. Dr. Beasley (qualitative contractor) will code a sample and develop a specific codebook. Reliability will be established between Dr. Beasley and one of her graduate students. Themes identified from the focus group will be used to update and finalize the mHealth app for future grants and studies.

Hypothesis 1b will involve mixed effects model analyses where positive parenting outcomes are regressed on a Tips indicator (tips delivered vs tips not delivered), a period indicator, and a random intercept term. The period indicator will assess outcome variability associated with the first two weeks vs the last two weeks of app engagement. An interaction term between the Tips factor and period factor will also be examined to determine if the intervention effect differs by order of presentation. We expect that parents will evidence greater engagement in positive parenting practices on days when they receive the mobile-based parenting tips and strategies relative to on days when they do not receive this content. Assuming no Tips by period interaction, the focal effect for testing this hypothesis will be the main effect of Tips Delivered.

Hypothesis 1c will be tested using a mixed effects model analysis where parenting subscale scores at baseline and post-intervention are regressed on an assessment time indicator, a randomization condition indicator, and a random intercept term. Assuming no interaction between assessment time and randomization group, the focal effect is the main effect of assessment time, which represents the pre-to-post difference in parenting scores.

Hypothesis 2a will be analyzed in the same manner as Hypothesis 1b replacing the parenting outcomes with child challenging and positive behavior counts. The hypothesis of behavioral improvement during weeks where parents receive tips will be tested by focusing on the main effect of the Tips indicator.

Finally, **Hypothesis 2b** will be analyzed in the same fashion on Hypothesis 1c. We hypothesized the child development scores will increase at the post-intervention assessment and this will be evaluated by testing the main effect of assessment timing.

Power Analysis

Hypothesis 1a is largely descriptive in nature, but all other hypotheses involve inferential tests of a within-group (repeated measures) effect. To evaluate statistical power, we calculated necessary sample sizes for a paired t-test. Analyses considered both a medium (0.35) and large (0.55) Becker g pre-post standardized mean difference ($[M_{post} - M_{pre}]/SD_{pre}$) under two pre-post correlation conditions. With a Type I and II error set at 0.05 and 0.20, we estimated necessary sample sizes of 79 and 34 for medium and large

effect detection with the pre-post correlation equal 0.40. If the pre-post correlation was somewhat higher, at 0.60, necessary sample sizes drop to 54 and 23. Results suggest the study is powered to detect a moderate to large effect provided the pre-post correlation is of moderate strength.

J. Data and Safety Monitoring Plan

Participant safety will be monitored in the following ways. First, the service agency will routinely complete Critical Incident Reports (CIR's) on all cases experiencing any sort of adverse event, regardless of whether the event might be related to study participation. This includes incidents such as any hospitalization, any child welfare reports, any serious medical condition, etc. This also includes incidents that are not adverse events such as unplanned dropout from service. The research team has established a procedure to receive these CIR's electronically on all study subjects, and each report will be reviewed by the PI, and passed on to the IRB as prescribed in our IRB regulations. Second, data collectors are trained to recognize and report any potential adverse events they might observe or that are reported to them by participants. Other organizations, such as the OUHSC Institutional Review Board may inspect and/or copy research records for quality assurance and data analysis.

K. Confidentiality

All consent forms will be collected and retained automatically on the OUHSC server in a group user protected folder. If paper copies are collected, they will be scanned to the server and stored in a folder in a locked cabinet behind a locked door in CCAN (which also requires a security badge for entry).
Data will be stored with identifiers for up to 10 years past the study conclusion date. Data will be stored in REDCap and on SQL Server. Some data may be manipulated and stored on the CCAN group rights protected folder on the server. SQL Server and REDCap have user rights protected groups, and to access SQL Server, the user must be connected to Pulse Secure VPN.

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