PROTOCOL TITLE:

Examine the Feasibility and Acceptability of Project Support

PRINCIPAL INVESTIGATOR:

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1.0 Objectives / Specific Aims

- Examine the feasibility and acceptability of delivering Project Support via telehealth. Conduct a mixed-methods proof-of-concept pilot trial with n = 30 families waiting for trauma-focused services.
- Hypothesis (1) Project Support will be feasible and acceptable as evidenced by benchmarks for recruitment, retention at post assessment, engagement, fidelity, and program satisfaction.
- Hypothesis (2) participants who receive Project Support will report improvements in supportive parenting, parenting self-efficacy, hopefulness, and child mental health symptoms.

2.0 Background

Over two-thirds of children experience traumatic events such as child maltreatment, violence, or sudden or violent loss. Many of these children sustain significant emotional and developmental difficulties including trauma symptoms, aggression, and suicidality. Emotional support from a caregiver is theorized to buffer against the effects of trauma; however, many caregivers lack the self-efficacy and skills to effectively support their child, or struggle to apply these skills during the stressful time following trauma. Unfortunately, programs designed for caregivers following child trauma are scarce. Existing interventions are lengthy (lasting 8-20 sessions) and result in families placed on long waitlists. This proposal asserts the adverse effects of child trauma can be interrupted though a brief intervention (the Project Support Positive Parenting Module) that enhances supportive parenting – delivered via telehealth to families on waitlists for trauma-focused services.

The objective is to examine the telehealth delivery of the Project Support Positive Parenting Module (Project Support) among families waiting for trauma-focused services. Project Support uses didactic instruction to teach caregivers how to listen to and comfort their child. In my preliminary work, I found this intervention can be delivered by paraprofessionals, improve parenting self-efficacy and emotional support, and increase later trauma-focused treatment attendance (Rancher et al., 2023). While it shares some features of stepped care models, Project Support is the only brief, empirically-supported program designed to enhance parenting and engagement following child trauma.

Long-term, this research will generate an effective intervention that addresses the needs of families affected by trauma, which can be scaled up to address other public health epidemics that impede supportive parenting and child development.

3.0 Intervention to be studied (if applicable)

This research involves a proof-of-concept pilot trial to examine the feasibility and acceptability of delivering the Project Support Positive Parenting module via telehealth to families on the waitlist for trauma-focused services. The Project Support Positive Parenting Module is a subset of a longer, efficacious parenting intervention, Project Support, that uses didactic, tailored instruction to teach caregivers how to attentively listen to and comfort their child (Jouriles et al. 2018, Rancher et al., 2021). The core components of the intervention are outlined in Table 1.

Table 1. Project Support Positive Parenting Module Components

Program Components	Short-term Objectives	Midterm Objectives	Long-term Goals
Psychoeducation on the importance of listening to and comforting your child	Increase knowledge about parent-child communication	Increase caregiver's motivation for spending time listening to and comforting their child	Improve caregiver emotional support
Handouts and discussion of "Do's" and "Don'ts" for the Listening and Comforting skills	Increase knowledge and awareness of skills	Increase supportive and responsive parenting behaviors	Improve parenting self-efficacy
Didactic instruction and role-play practice with service provider	Increase efficacy and ability to use listening and comforting skills	Increase the time and frequency the caregiver spends listening to and comforting their child	Decrease child adjustment problems
After mastery of skills is obtained with provider, use of skill with child	Increase efficacy and ability to use listening and comforting skills with child		

Caregivers will receive up to four, 60- to 90-minute sessions focused on teaching two parenting skills – attentive listening and comforting. Attentive listening involves providing accurate and timely responses to show interest and keep the child engaged until they are ready to end the conversation. This skill involves both verbal and nonverbal listening behaviors including requests for clarification, reflecting what the child is saying, reflecting feelings, and simple verbal responses to encourage conversation (e.g., "Interesting!"). Comforting involves using the same attentive listening skills when the child is upset or distressed. Effective mastery of the listening and comforting skills also requires caregivers to withhold any non-listening or non-comforting responses, such as interruptions, accusations, judgements, criticisms, or dismissive gestures.

The program is individually tailored to the caregiver's parenting abilities: caregivers with stronger skills, or those who mastered the skills more quickly, could complete the program in less time (i.e., fewer sessions) than those who need more time to master implementation of the skills. Service providers educate caregivers about the skills, using handouts to summarize their purpose and correct use; then engage in an iterative process of modeling the skills, engaging the caregivers in behavioral practice using the skills; and provide stepped, tailored, supportive feedback designed to help caregivers gain mastery. Most session time is focused on behavioral practice and feedback, with caregivers learning and mastering the skills incrementally through role-plays with the service provider (for further refinement and feedback) and the child (for observation and determination of mastery). Caregivers are deemed to have met mastery if they can provide at least six appropriate listening and/or comforting responses and refrain from providing any non-listening/non-comforting responses during a 3- to 5- minute interaction. Caregivers who demonstrated mastery of the skills are considered to have received the full "dosage" of the intervention.

Previous randomized-controlled trials conducted by the Principal Investigator of this proposed research (Rancher, McDonald, Cook, et al., 2023; Rancher, McDonald, Ostner, et al., 2023). have

found that Project Support can effectively improve caregiver support, parenting self-efficacy, and later engagement in therapy services. Project Support has been delivered by paraprofessionals with high fidelity to a range of caregivers, including mothers, fathers, kinship caregivers, and grandparents. Project Support has been administered in English, Spanish, and Swedish. This current evaluation will examine whether it is feasible and acceptable to deliver Project Support via telehealth to families on the waitlist for trauma-focused services.

4.0 Study Endpoints (if applicable)

- N/A

5.0 Inclusion and Exclusion Criteria/ Study Population

- Participants will be screened for eligibility during an initial phone call from a member of the research team.
- Inclusion Criteria:
  (1) Family is seeking trauma-focused services for their child as measured by their placement on the waitlist for services at the National Crime Victims Center;
  (2) Child is between 5 – 12 years old;
  (3) Caregiver agreed to be contacted for volunteer research opportunities;
  (4) Caregiver and child can communicate in either English;
  (5) Child has been living with caregiver for at the last 6 months or longer;
  (6) Family is able to participate in services delivered via telehealth.
- Exclusion Criteria:
  (1) Child or caregiver has a diagnosis that would impair their ability to participate in or benefit from services (e.g., traumatic brain injury, developmental disability, psychosis);
  (2) Child is in Foster Care or Department of Social Services custody;
  (3) The caregiver is unwilling or unable to give informed consent and/or the child is unwilling and unable to give assent.
- We plan to include children in the present study as we are explicitly interested in evaluating a parenting intervention for families of school-aged children on the waitlist for trauma-focused services.

6.0 Number of Subjects

Total N = 30 child and caregiver pairs

7.0 Setting

- All procedures will take place remotely via telehealth.

8.0 Recruitment Methods

- Potential participants will be contacted by phone by a member of the research team.

- Potential participants will be identified from a review of the waitlist at the trauma mental health clinic (e.g., National Crime Victims Center). The waitlist will provide initial information on child age and whether the family was willing to be contacted for volunteer research opportunities.
- Research team members will continuously monitor the waitlist for potential participants.
- Research team members will verbally describe the research study during a phone call with potential participants. This recruitment script and phone screen are attached in the eIRB application.

9.0 Consent Process

We will be obtaining informed consent and assent.

- We will collect electronic consent and assent remotely (e.g., at the subject's home or another convenient venue) since all study procedures will take place remotely.
- The consent and assent process will take place in a private setting.
- Adult subjects will be given the opportunity to read the consent and ask questions before signing the consent.
- The study involves children between ages 5-12 years old, however, consistent with HRPP Section 8.5 – Research Involve Children, only child subjects aged 12 years or older will complete assent procedures. Children ages 12 years or older will have the assent form read aloud to them and will be given the opportunity to ask questions before signing the assent form.
- Parental permission will be obtained by first having each caregiver complete the consent process. Only for those adult caregivers who provide consent will we ask their child to provide assent.
- Children in the current study will not reach the age of majority during the study, so they will not complete any re-consent procedures.
- Participants will provide an electronic signature using the REDCap eConsent feature. A member of the research team is a NEXUS Research Coordinator (Emma McLeod) at MUSC SCTR and will facilitate accurate use of this eConsent feature.
- Participants will be provided a copy of the signed consent via email. Adult caregivers will also receive a copy of their child's assent via email.

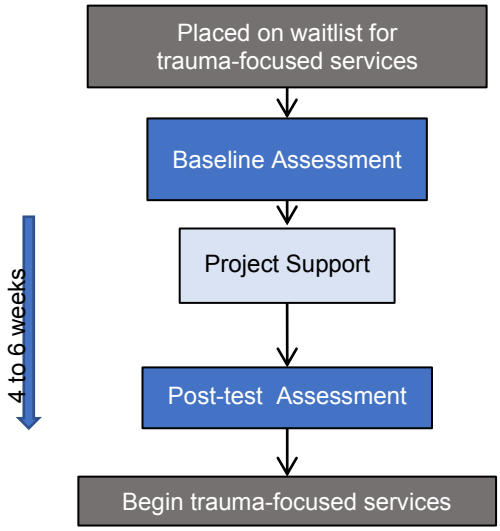
10.0 Study Design / Methods

- All participants (caregivers and children) will complete a baseline survey assessment on demographics, parenting behaviors, and mental health symptoms (surveys are attached in the eIRB application.
- All caregivers will then receive the Project Support intervention (described above in "Intervention to be Studied"). Briefly this entails up to four 60-minute live sessions focused on teaching caregivers how to listen to and comfort their child. Participants will receive one-on-one didactic instruction and feedback on their real-time use of the skills in role-plays with a treatment provider. The caregiver and provider will meet on a videoconferencing platform (e.g., MUSC COM licensed Zoom). In the role-

plays the provider first demonstrates how to use the skill in a brief example of typical situations in which the skill could be used. In these examples the caregiver takes on the role of their child and the provider takes on the role of the caregiver. Subsequently the caregiver and provider switch roles so the caregiver has an opportunity to practice executing the skill. The provider helps the caregiver process their experience of each role-play and provides real-time, targeted feedback to help the caregiver develop their ability to use the skills.

- Project Support sessions will be recorded to facilitate coding of treatment fidelity and to provide ongoing training in group supervision.
- Approximately 4-6 weeks after the baseline assessment, all participants (caregivers and children) will complete a post-test survey assessment. This will also include measures of service satisfaction and acceptability of the Project Support intervention.
- Both the baseline and post-test survey assessments should take less than 30 minutes to complete.
- We anticipate participation time will be up to 6 weeks, including the baseline assessment, up to four Project Support sessions, and the post-test assessment. Participating in this research study will not delay or impact scheduling the trauma-focused treatment. We will closely monitor the waitlist to note when intakes are scheduled, so that study participation will be completed by the onset of clinical services. Part of our research questions include the feasibility of completing the intervention during the time families are waiting for services, so we will closely track the number of sessions families are able to complete during that time. Over the last 2 years, families spend, on average, 12-15 weeks on the waitlist.
- All services and data collection will take place remotely, via telehealth and a secure web-based platform. Specifically, Project Support intervention sessions will be held using a HIPAA-compliant videoconferencing platform (e.g., MUSC COM licensed Zoom). Surveys will be administered using REDCap survey software.
- Caregivers will be invited to complete the survey assessments independently. Research staff will be available to read items aloud via video conferencing or phone to ensure comprehension and attention. Research staff will read items aloud to child participants.
- Participant flow through the study is described in Figure 1.

Figure 1. Participant Flow Through Study



11.0 Specimen Collection and Banking (if applicable)

N/A

12.0 Data Management

- The aim of this pilot study is to determine feasibility and acceptability; therefore, sample size was determined for pragmatic reasons as advocated by Hertzog (2008). With 30 participants, I will be able to estimate proportions with a 95% Confidence Interval of (.02, .28) and (.14, .46) for values of the true population proportion (p) of 0.15 and 0.30, respectively (Hertzog, 2008). I used Kraemer's guidelines (Kraemer, 2010) to identify appropriate benchmarks for dissemination feasibility:
    - Recruitment: Proportion of caregivers who agree to participate relative to the number approached. I will consider it successful if participation is > 60% of approached families.
    - Retention: Proportion of participants who complete both assessments vs. only the baseline assessment. I will consider it successful if > 70% of participants are retained for the post-test assessment.
    - Engagement: Participation in the Project Support treatment sessions. I will consider it successful if > 75% of participants attend 1+ treatment session.
- To examine trends in supportive parenting, parenting self-efficacy, hopefulness, and child mental health symptoms I will use multilevel modeling (MLM). Consistent with an intent-to-treat approach, MLM includes all participants, regardless of missing data. Further MLM can be used in samples as small as 10 participants and still produce unbiased coefficient estimates (Maas & Hox, 2005). I will conduct separate analyses for each of the outcome variables and examine the effect of time – the change in outcome from baseline to post-test – as a preliminary test of intervention effect.
- All data (Project Support sessions and survey data) will be stored via a password protected secure server maintained by MUSC for a minimum of six years, per MUSC

policy. Only the investigators associated with this study will have access to study information.

13.0 Provisions to Monitor the Data to Ensure the Safety of Subjects (if applicable)

The present study was funded by NICHD. This section is based on the recommendations in NICHD's "Data and Safety Monitoring (DSM) Policies for Extramural Clinical Trials and Clinical Research." (https://www.nichd.nih.gov/sites/default/files/inline-files/NICHD_DSM_Policy_2020.pdf).

Overall Summary

The purpose of this study is to examine the telehealth delivery of a brief parenting intervention (Project Support) for caregivers on the waitlist for trauma-focused services for their child. I will conduct a proof-of-concept pilot trial to examine the feasibility and acceptability of the intervention with n = 30 caregivers. The sample will be recruited from agencies providing services to children exposed to trauma (e.g., MUSC National Crime Victims Center).

The Principal Investigator (PI), Dr. Rancher, will be responsible for monitoring the safety and efficacy of this study, executing the Data and Safety Monitoring (DSM) plan, and complying with the reporting requirements. Dr. Rancher will provide a summary of the DSM report to NICHD on an annual basis as part of the progress report. The DSM report will include the participants' sociodemographic characteristics, expected versus actual recruitment rates, study retention rates, any quality assurance or regulatory issues that occurred during the past year, summary of adverse events, serious adverse events, unanticipated problems, and any actions or changes with respect to the protocol. The DSM report to NICHD will also include, when available, the results of any data analysis conducted.

Data monitoring plan

All services and data collection will take place via telehealth and a HIPAA-compliant secure web-based platform (i.e., RedCap). Participant data will only be identified with a study ID. The codes that link the name of the participant and the study ID will be kept confidential by the Principal Investigator in a secured cabinet. SPSS software will be used to analyze the data. The quality of the data will be monitored once per month. Data quality will be monitored by random inspection of the data files by a research assistant and any problems detected will be discussed with the PI.

Safety monitoring plan

Potential participants will complete a phone screen to determine their eligibility and safety of their participation in this study. History of suicidal ideation or suicide attempts, and other suicidal risk factors, including suicidal ideation, intent, and plan will be carefully assessed and monitored through the study. The PI will be contacted immediately regarding clients who are at risk to commit suicide to aid in safety assessment and will be offered additional treatment (e.g., hospitalization) as needed and appropriate.

All adverse events (AEs) will be reported to the MUSC Institutional Review Board (IRB) and NIH within 10 working days. AEs are reportable if they are unexpected AND related or possibly related to study participation AND serious or more prevalent than expected. The IRB definition of unexpected is that the AE is not identified in nature, severity, or frequency in the current proposal, informed consent, or with other current risk information.

The definition of related is that there is a reasonable possibility that the adverse event may have been caused by the study device, drug, or intervention. Serious adverse events (SAEs) will be reported within 24 hours. SAEs are defined as any event associated with the subject's participation in research that meets any of the following criteria: death, a life-threatening event, requires or prolongs inpatient hospitalization, persistent or significant disability/incapacity, or a congenital anomaly or birth defect. Important medial events that may not result in death, be life-threatening or require hospitalization may be considered a SAE when, based upon appropriate medical judgement, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Any SAE, whether or not related to study intervention, will be reported to the MUSC IRB and NIH. The initial SAE report will be followed by submission of a completed SAE report to both institutions. In the event that a client either withdraws from the study or the investigator decides to discontinue a patient due to SAE, the client will be monitored by the investigators via ongoing status assessment until 1) a resolution is reached i.e., the problem requiring hospitalization has resolved or stabilized with no further changes expected 2) the SAE is determined to be clearly unrelated to the study intervention, or 3) the SAE results in death. Outcome of SAEs will be periodically reported to NIH. A summary of the SAEs that occurred during the previous year will be included in the annual progress report to NIH.

All research staff involved with adverse event reporting will receive training including identification, evaluation, and documentation and reporting. All research staff will identify any potential AEs or Unanticipated Problems (UPs) during the course of the study from self-report and interview data and administration of assessments and the brief intervention. This information will be reported to the PI (Dr. Rancher), all mentors and co-investigators, the MUSC IRB, the NICHD Program Officer, and the Data and Safety Monitoring Board Members.

Data and Safety Monitoring Board (DSMB)

We have recruited a DSMB to monitor overall participant safety, the rate and severity of adverse events, the progress of the study, and to review procedures for maintaining the confidentiality of data, the assent and consent process for all participants, the quality of data collection, and data management and analyses. Frequency of meetings of the DSMB will be determined by recruitment milestones (e.g., after 20% of participants have been recruited, etc.), and will follow each SAE report, but meetings will occur no less than once per year. The purpose of these meetings will be to review study progress, data quality, and participant safety. DSMB members include an array of disciplinary backgrounds (e.g., clinical researchers, statisticians) that are not directly involved in the project.

Members include:

- *Rochelle Hanson,* PhD, Professor at the MUSC National Crime Victims Center has extensive experience with the population of interest and clinical research among families who have experienced trauma.
- *Rosmary Ros-Demarize,* PhD, Assistant Professor at MUSC Developmental-Behavioral Pediatrics has expertise in parenting interventions, telehealth service delivery, and implementation science.

- *Elizabeth Baumler,* PhD, Director of Biostatistics for the Center of Violence Prevention and Associate Professor at UT Health has extensive expertise in design and analysis of clinical trials.

Data will be presented in a blinded manner during the open sessions of the DSMB. At DSMB meetings, data and discussion are confidential. Participant identities will not be known to the DSMB members.

Conflict of Interest for DSMB's

DSMB members will have no direct involvement with the study investigators or intervention (e.g., no portion of their effort will be covered by the study). Each DSMB member will sign a Conflict of Interest statement which includes current affiliations (if any) with pharmaceutical and biotechnology companies (e.g., stockholder, consultant), and any other relationship that could be perceived as a conflict of interest related to the study and/or associated with commercial interests pertinent to study objectives.

14.0 Withdrawal of Subjects (if applicable)

- N/A

15.0 Risks to Subjects

- Although not a direct component of our study, participants may feel distress related to the trauma experience and their referral to the trauma mental health clinic.
- Breaches of confidentiality are a concern with Internet-based components of any study. For example, it is possible that other people could overhear the participants' intervention sessions with a treatment provider. However, such risks are minimized by procedures such as informing the participant that it is possible to reschedule at a more convenient time or telling the participant to take steps to insure their privacy (e.g., private location, use of headphones).
- Survey assessments of psychological symptoms and history of traumatic event exposure may cause participants to feel small to moderate amounts of distress.

16.0 Potential Benefits to Subjects or Others

- Caregivers and children will directly receive the benefit of an evidence-based parenting intervention, Project Support, that has been found to increase emotional support, parenting self-efficacy, and reduce child distress. Caregivers will receive the intervention at no cost.

17.0 Sharing of Results with Subjects

No study results will be shared with participants or others.

18.0 Drugs or Devices (if applicable)

- N/A

References

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