Official Title: "Rural Families Affected by Opioid Use: An Online Parenting Intervention"

And

"Supplement to Prevention Research Center: Parenting Among Women Who are Opioid Users, Project 2"

NCT Number: NCT05180487

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Document: Study Protocol

Research Plan

IMPORTANT: When completing this outline, please use the **Research Plan Guidance** for the content necessary to develop a comprehensive yet succinct Research Plan. Using the guidance to complete this outline will help facilitate timely IRB review.

Study Title: Prevention Research Center: Parenting Among Women Who Are Opioid Users, Project 2, and Supplement

Protocol Number: 10212019.029

Principal Investigator: P2 and Supplement PI: Elizabeth Stormshak, Ph.D.

A. Introduction and Background

Opioid use is rising at unprecedented levels and has reached epidemic proportions in some areas of the country, particularly rural areas (Rigg, Monnat, & Chavez, 2018). Although research on the detrimental effects of opioid use on parenting and children is relatively new, it is clear that parents with opioid use struggle with a variety of parenting skills, especially contingent responsivity and warmth (Salo et al., 2009) As such, to have long-term sustained effects on preventing OUD in parents and to help prevent substance use and related problem behaviors in the next generation, it is critical to prevent opioid use, opioid misuse, and OUD in new parents, in tandem with providing support for parenting skills. Our long-term goal is to facilitate the wide-scale dissemination of a telehealth intervention to prevent opioid misuse (i.e., prescription misuse and use of heroin and illicit synthetics) across generations by targeting parents living in rural areas who have had a history of substance misuse.

Our telehealth intervention, based on the Family Check Up (FCU) focuses on supporting parents by increasing parenting self-efficacy, stress management skills, self-regulation skills, and sleep routines, which are hypothesized to lead to the prevention of opioid misuse and OUD as well as improve mental health and increase responsive parenting. The FCU has been tested in more than 25 years of research, across multiple settings, and is an evidence-based program for reducing high-risk behavior, enhancing parenting skills, and preventing substance use through emerging adulthood (Connell et al. 2007; Dishion et al., 2008; Stormshak, Connell & Dishion et al., 2009; Stormshak et al., 2011; Stormshak et al., 2018). It is named in NIDA's "Principles of Substance Use Prevention for Early Childhood" as one of only three effective selective prevention programs for substance abuse among families with young children. The FCU has also been endorsed as an evidence-based practice by the Maternal Infant and Early Childhood Home Visiting Program (MIECHV), and has been listed as a promising program by the Blueprints for Healthy Youth Development since 2013 (Paulsell et al., 2010). Most recently, the FCU was adapted to be delivered to parents in a web-based format (protocol: 07032014.004). The current project aims to address barriers of access to prevention services by delivering the FCU in a telehealth model.

B. Specific Aims/Study Objectives

The overarching aims of the study include:

Specific Aim 1. Working with community stakeholders in rural Oregon to expand the FCU Online to target early childhood (18mo-5 years) and mothers with histories of substance use.

Specific Aim 2. Examine the efficacy of the FCU Online for Oregon families with:

a) Parents with young children (18mo-5 years) who have a history of opioid use and addiction (n=300)

b) Parents with young children (18mo-5 years) who have a history of substance misuse and/or depression (n=100).

Specific Aim 3. Examine factors related to successful uptake and implementation of the FCU telehealth model.

For the first phase of the study (April 2020- April 2021), we will be focusing on Specific Aim 1 by conducting focus groups with stakeholders. For the second phase of the study (summer 2021) we will pilot the FCU Online with 10 families so that we may fine tune recruitment procedures, screening criteria, acceptability of phone interviews and

FCU Online. The third phase of the study (fall 2021-summer 2024) will be conducting the clinical trial of the FCU Online and coaching for 400 families in Oregon.

C. Methods, Materials and Analysis

Methods

This project includes several phases of research that involve different groups of participants who are recruited and consented at different times and in different ways. We have included a chart to help orient the reader to the sequence and timing of these phases. More detail about the method of each of these phases appears below.

Phase	Timing	Research participants
1. Conduct focus groups with stakeholders (staff and parents)	Completed April 2020- April 2021	n= 4 staff members n= 2 parents
2. Pilot Study	Summer 2021	N=10 parents with a child between 18 months and 5 years old receiving services at Healthy Start, New Day, or other community partner. Participation will last 2 months.
3. Clinical Trial research study	Fall 2021- May 2023	N=400 families with a child between ages 18 months and 5 years. Recruited over 2.5 years. Participation will last 12 months.
4. Supplemental Spanish Speaking Focus Groups	December 2022- December 2023	N= 24 parents/caregivers
5. Focus groups: Spanish speaking providers	February 2024- June 2024	N= 10 community providers

1. Focus groups (n=6)

The Family Check-Up (FCU) was adapted to be delivered online in a previous project (protocol: 07032014.004). This project aims to build upon that project's success and help guide the development of the FCU as a telehealth model to be delivered in rural Oregon. Specifically, the aims of this phase of the study are to adapt the FCU to a responsive web application to be delivered via smartphones and remote coaching (via phone or Zoom) to mothers with histories of substance use in order to improve parenting skills and subsequent early childhood behavior. A "responsive web application" is actually a web page that can be accessed from a phone and looks like a typical app. It is not a "native app" that can be downloaded from the Apple or Android app stores. Throughout this document the word "telehealth" is used to refer to this "app + remote coaching" mode of delivery. The app is not "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals." However, the coach-parent relationship may offer therapeutic benefits. Data is only collected when a participant logs into the FCU web application; it does not collect passive data all the time, as is the case with many native apps. Thus, participants actively control what information is shared with the FCU team, and nothing happens if a user fails to "uninstall" it from their phone.

In order to achieve the goals of this project, feasibility and usability testing is needed from stakeholders, which will inform programmatic decisions with our smartphone programmers, Emberex Technology. Our community partners at Healthy Start and New Day have agreed to assist us in feasibility and usability testing focus groups with both a) staff members working with Healthy Start or New Day delivering services to parents with young children and b) parents receiving services from Healthy Start or New Day who also have a child between the ages of 0 and 5 years old. Healthy Start and New Day are community organizations in Josephine and Douglas Counties who provides services to women and families before, during, and after pregnancy. They are HIPAA covered entities. Staff will alert families to a focus group opportunity and only those who are interested in hearing more about the focus group will be contacted. We will hold separate focus groups for staff and parents so we can get a diversity of responses. Focus groups will be 90 minutes long and will elicit opinions on the program, including questions about its visual appeal in smartphone mock-ups, its usability, content of survey questions and

feedback, proposed health and wellness modules, and overall process (see P2_Focus group discussion

guide_02-20-20 for more details). Focus groups will be audio-recorded, and transcripts of sessions will be coded to enable content analysis of salient constructs, issues, and language that contribute to the program features and functions. Participants will be compensated $100 for their time. In light of the Covid-19 pandemic, we will first conduct focus groups with Healthy Start and New Day staff via HIPAA-compliant Zoom. Participants will be contacted initially by our contact, Lee Ann Grogan, and if interested in participating in the Zoom focus group, will agree to giving researchers their name and email address.). Research staff will email staff with focus group information, including zoom link to the meeting, a Qualtrics link to an online version of the consent form, and a pdf of the consent form for their personal records. At the beginning of the Zoom focus group, the facilitator, Milagra Tyler, will review all elements of the consent form with staff, answer any questions, and instruct participants who wish to participate to electronically sign the consent form prior to recording and proceeding to focus group content. Once it is feasible and safe, additional focus groups with Healthy Start or New Day staff may be conducted in person, as FCU telehealth development is iterative.

Likewise, we intend to conduct in-person focus groups with families receiving services from Healthy Start or New Day once it is feasible to do so. In the interim, we are considering conducting focus groups via HIPAA-compliant ZOOM as outlined above. One of the questions we will ask to staff is how to best engage potential families in testing/usability given current constraints. If staff indicate that ZOOM focus groups with families are not tenable, we will offer one-on-one Zoom interviews with individual participants using the same focus group template to illicit input from the individual participant. Lee Ann Grogan will approach parents receiving services for focus group/interview participation if the parent is over the age of 18 and speaks English fluently. If interested, she will obtain a disclosure for release of client information via HIPAA Authorization form, and obtain permission from the participant to share their name, phone number and email address with research staff. We will follow the procedure outlined above to ensure consent is gathered prior to initiation of interview/focus group. Participants will be given the option of being mailed a check, or receiving an electronic gift card to Amazon or Walmart to accommodate current constraints.

It is likely that we will conduct multiple focus groups to gauge interest/usability of FCU telehealth program as programming is iterative. We plan to incorporate stakeholder feedback through the process so that the FCU content, visual appeal, and process are acceptable and feasible.

2. Pilot study (n=10 parents).

The FCU Online program has been programmed and updated based on iterative feedback from stakeholders on FCU content, visual appeal, and usability. In phase 2 of the study, we aim to pilot the study with 10 families prior to beginning our clinical trial. We believe this is necessary as we refine working relationships with our partners, fine tune screening and recruitment procedures, and assess acceptability of study components with families. For the pilot study, we will recruit 10 families with a child between the ages of 18 months and 5 years old who receive services from Healthy Start. We will conduct a pre- and post- assessment battery for parents and have parents complete the FCU intervention with a Family Consultant. We will interview each participant about their experience and adapt procedures/materials as needed based on their feedback. Parents will have the opportunity to receive up to $175 for participating in the pilot study.

Healthy Start staff will give parents information about the study by reviewing the recruitment flyer. Healthy Start staff will email any interested parents with the Qualtrics link so parents may enter contact information to be contacted by U of O. Healthy Start will also post the flyer to their website and may send out email blasts to clients with the study brochure/link, so interested parents may complete the Qualtrics for more information from U of O. Since parents are willingly entering their information into the Qualtrics survey, HIPAA authorization is not warranted. Interested parents' contact information will be routed to study recruiters. A University of Oregon recruiter will call the family, conduct a phone screen, give eligible families more study information, and review the consent forms with parents. If parents agree to participate, they will give verbal consent. The recruiter will email a copy of the consent form. The recruiter will schedule the parent to complete their pre-assessment over the phone. The pre- and post- assessments will be conducted over the phone, and are anticipated to take approximately 1- to 1.5 hours. Once the pre- assessment has been completed, the parent will receive an email with instructions for how to log onto the FCU Online program, and the name, email, and link to a video of the Family Consultant they will be working with. The Family Consultant will contact families after they log into the FCU Online for the first time. As part of the FCU Online, parents will complete an intervention assessment, receive feedback on their data, and be provided with online tools to support their parenting in areas that were identified as challenges by the assessment. These tools include videos, animated videos, parenting tips, and interactives. Parents will also be given the opportunity to practice parenting skills and track their progress. Parents who choose to engage in this

practice will have the opportunity to receive text messaging that prompts them to try out new skills learned from the FCU Online program. Parents will be able to log-in as often as they like and interact with any of the parenting modules on the FCU Online. In addition, a Family Consultant will contact them to help them set goals, talk through their results on each module (5 total), offer support over the phone, and help motivate parents to improve parenting practices. Feedbacks may be completed over phone or Zoom depending on participant preference. Feedback sessions will be audio-recorded.

Two months after completing the Pilot study pre-test, participants will be asked to complete a post-test assessment over the phone, discuss their participation, and provide feedback on their experience. The post-test is the same survey as was completed for the pre-test, with the addition of a two-page Website Feedback Survey. At the conclusion of the phone meeting with a staff person, participants will be asked additional open-ended questions to illicit feedback on study participation and process.

Data collected from the 10 pilot participants will inform changes to process and materials before beginning the clinical trial phase. An amendment will be submitted with any changes needed prior to the clinical trial. Data collected in the pilot will not be contributed to the P50 data repository or HEAL collective.

Materials
2. Pilot study (n=10 parents).

Pre- and post- assessments- Pre- and post- assessments will be conducted by trained staff as a phone interview or over Zoom if parents prefer. Staff will enter a participant's responses into a Qualtrics survey, which is currently being finalized in Qualtrics (see attachment "FCU Opioids Research Ax_05-12-21"). Surveys will take between 1 and 1.5 hours, and may be conducted over multiple sessions if needed. Survey items include items about participant demographics, service utilization, family support, health and health behaviors, parenting young children, mental health, and substance use.

FCU Online survey- The FCU Online has five modules: Wellness and self-care, parenting and substance use, positive parenting, proactive parenting, and supervision and limit setting. To access each module, the parent completes a brief survey of 10-14 items (see attachment "FCU Opioids App Ax_05-10-21"). Based on their responses, parents are given a visual representation of areas of strengths and areas for focused attention. The FCU Online survey takes less than 5 minutes. Parents may then proceed through module content and receive additional support through phone call with their Family Consultant.

FCU Online- Content of Skills Sessions and Web/Mobile Activities. On the basis of assessment results, parents will be offered a variety of follow-up parenting skill activities. Each of the following Skills Sessions, derived from our Everyday Parenting curriculum (Dishion et al., 2011), will include content that is animated, video based, and interactive. They will each include activities for tracking of behavior and will provide ongoing feedback to parents on their success. Participants are anticipated to spend about 40 minutes a week engaging with FCU Online Content. Their Family Consultant will track progress through each module and provide support and feedback for each module via phone call, text, or Zoom check-in. Participants will have at least 5 check-ins with their Family Consultant, but may opt to have more. Check-ins with family consultants are expected to last about 20 minutes. Overall engagement with FCU Online content and consultant check-ins is anticipated to be approximately 60 minutes a week for 5 weeks.

Wellness and self-care: Parents are given information and practice opportunities in how to cope with stress, set up healthy routines, manage depression, and set up healthy sleep routines.

Parenting and substance use: Parents are given information and practice opportunities to explore how to cope without alcohol and drugs, manage cravings, set up healthy relationships with friends and family, and manage parenting responsibilities.

Positive parenting: Parents are given information and practice opportunities to build relationships with their child, learn about positive parenting principles, and how to use praise and positive behavior support with their child.

Proactive parenting: Parents are given information and practice opportunities for setting up healthy routines for parents and children, and healthy communication with parents and friends.

Supervision and limit setting: Parents are given information and practice opportunities for managing behavior in toddler years, ignoring unwanted behavior, setting limits, and keeping the home a safe environment.

Consumer Satisfaction/Exit Interview The 2-page website feedback survey administered at the end of the pilot study asks questions about acceptability, usability of the FCU Online as well as questions about working with a Family Consultant, and suggestions for improvement to the study procedures/content (see attachment "Rural Opioid website satisfaction survey and exit interview"). The consumer satisfaction/exit interview will take approximately 20 minutes.

3. Clinical trial research study (n=400 parents).

After incorporating feedback from the pilot study to materials and process, we will begin the clinical trial phase of the study, where we will recruit 400 English or Spanish speaking families with a child between the ages of 18 months and 5 years old. Two hundred families will be randomly assigned to an intervention condition where participants complete four phone interviews/ surveys over the course of a year and receive the FCU along with coaching from a Family Consultant; two hundred families will be randomly assigned to a control condition where participants complete four phone interviews/surveys over the course of a year and are given access to the FCU at the conclusion of their study participation (e.g., one year later). A quick completion bonus of $25 will be offered to families at each wave of data collection, if they complete a phone interview or survey within 2 weeks of it being offered to them. Families in the control condition will not receive coaching from a Family Consultant. All families will also be invited to opt into using the EARS tool, which is installed on the participant's phone and collects passive data to record naturalistic behavior related to mental health. Parents will have the opportunity to receive up to $425 in one year for participating in the study or up to $400 if they opt out of the EARS component. All research activities will be available to be conducted in either English or Spanish, depending on the preference of each family.

After the family has consented, the recruiter will schedule the parent to complete their baseline research assessment over the phone or notify research staff to send out the survey to those participants who prefer a self-administered format. Families will be told which condition they are in via an email sent by research staff after their Baseline assessment is completed. If the family has been randomly assigned to intervention, they will be informed that a family consultant will reach out to them within one week of their phone interview with additional opportunities for support and coaching. Parents will also be informed that the family consultant will enroll them in the FCU Online program during their first phone call with the parent. If the family has been randomly assigned to the control group, they will be informed that they will be enrolled in the FCU Online one year from now, following participation in the research assessment phone interviews/surveys.

The research assessments will be conducted for all families at baseline, 3-months, 6-months, and 1 year. Each interview/survey is expected to take approximately 1 to 1.5 hours. Families who opted into EARS will be instructed on how to download EARS to their phone at the end of the phone interview or via phone call by assessment staff after self-administered surveys.

Families in the intervention condition will be contacted by their family consultant within a few days of completing their interview. Consultants will send a link to an introduction video and attempt to set up an initial appointment with the family. This phone session will serve as the "initial interview" for these parents and will allow the consultant to enroll parents in the FCU Online program, share information about the FCU Online process, gather information from the parent about concerns for their child or parenting goals, and to motivate parents to engage in the program. As part of the FCU Online, parents will complete several "mini" assessments, receive feedback on their data, and be provided with online tools to support their parenting in areas that were identified as challenges by the assessment. These tools include videos, animated videos, parenting tips, and interactives. Parents will also be given the opportunity to practice parenting skills and track their progress. Parents who choose to engage in this practice will have the opportunity to receive text messaging that prompts them to try out new skills learned from the FCU Online program. Parents will be able to log-in as often as they like and interact with any of the parenting modules on the FCU Online. The mini assessments and skill building activities are arranged in 5 modules. After completing the first module parents will discuss the feedback and skill building content with their consultant via phone or video conferencing, depending on participant preference. The consultant will provide supportive feedback, help parents set goals in terms of intervention targets, and arrange to check in with the parent about the next module. There are five skills modules, and parents will follow the 4-step process of assessment→feedback→skills session→ consultation for each module. Additional meetings may be scheduled as needed. Meetings between participants and consultants will be video or audio-recorded and sessions will be evaluated for the consultant's fidelity to the intervention model. Each meeting is expected to take approximately 20 minutes. The active intervention period is to be completed before the 3-month follow-up research assessment.

Three months after completing the baseline research assessment, all participants will be contacted to complete their 3-month follow-up research assessment over the phone or as a self-administered survey. Participants in the intervention condition will also complete a brief FCU Online Feedback Survey to assess their experience with the

FCU Online and their Family Consultant. Those who consented to the EARS portion of the research project will be instructed to delete the app from their phone at this time. All families will be contacted 6- months and 1-year later for their final research assessment phone interviews. Families in the control condition will be on-boarded to the FCU Online program at the end of their 1-year phone interview. However, they will not receive Family Consultant coaching.

Materials
3. Clinical trial research study (n=400 parents).

Baseline, 3-mo, 6-mo, 1-year research assessments- Research assessments will be conducted by trained staff as either phone or Zoom interviews or as self-administered surveys (whichever format the parent prefers). If completed as an interview, staff will enter a participant's responses into a Qualtrics survey; if self-administered, the participant will enter a special word provided when the survey link is sent out that will allow research staff to match data with the appropriate ID. Surveys will take between 1 and 1.5 hours, and may be conducted over multiple sessions if needed. Survey items include items about participant demographics, service utilization, family support, health and health behaviors, parenting young children, mental health, and substance use. There is one question in this survey that asks about thoughts of being "better off dead" or of hurting themselves in some way. We have developed a protocol to address the needs of the participant if they answer anything other than "not at all" to this question. Please see "PYC suicide risk assessment protocol."

FCU Online survey- The FCU Online has five modules: Wellness and self-care, parenting and substance use, positive parenting, proactive parenting, and supervision and limit setting. To access each module, the parent completes a brief survey of 10-14 items (see attachment "FCU Opioids App Ax_07-15-21"). Based on their responses, parents are given a visual representation of areas of strengths and areas for focused attention. The FCU Online survey takes less than 5 minutes. Parents may then proceed through module content at their own pace. If they do not complete a module within a week, they will get a text reminder that the next module is open, ready for them to complete. Families in the intervention condition will receive additional support from their Family Consultant after each module through Zoom or phone calls.

FCU Online- Content of Skills Sessions and Web/Mobile Activities. On the basis of assessment results, parents will be offered a variety of follow-up parenting skill activities. Each of the following Skills Sessions, derived from our Everyday Parenting curriculum (Dishion et al., 2011), will include content that is animated, video based, and interactive. They will each include activities for tracking of behavior and will provide ongoing feedback to parents on their success. Participants are anticipated to spend about 40 minutes a week engaging with FCU Online Content. For families in the intervention condition, their Family Consultant will track progress through each module and provide support and feedback for each module via phone call, text, or Zoom check-in. Participants will have at least 5 check-ins with their Family Consultant, but may opt to have more. Check-ins with family consultants are expected to last about 20 minutes, but may last longer depending on participant expressed need. Overall engagement with FCU Online content and consultant check-ins is anticipated to be approximately 60 minutes a week for 5 weeks.

Wellness and self-care: Parents are given information and practice opportunities in how to cope with stress, set up healthy routines, manage depression, and set up healthy sleep routines.

Parenting and substance use: Parents are given information and practice opportunities to explore how to cope without alcohol and drugs, manage cravings, set up healthy relationships with friends and family, and manage parenting responsibilities.

Positive parenting: Parents are given information and practice opportunities to build relationships with their child, learn about positive parenting principles, and how to use praise and positive behavior support with their child.

Proactive parenting: Parents are given information and practice opportunities for setting up healthy routines for parents and children, and healthy communication with parents and friends.

Supervision and limit setting: Parents are given information and practice opportunities for managing behavior in toddler years, ignoring unwanted behavior, setting limits, and keeping the home a safe environment.

Website Feedback Survey: The 2-page website feedback survey is administered by an assessor (not Family Consultant) at the time of the 3-month research assessment phone interview/ survey for intervention families. This survey asks questions about the acceptability and usability of the FCU Online, as well as questions

about working with a Family Consultant. This survey will take approximately 15 minutes.

The EARS Tool- During the recruitment phone call, participants will have the option to opt into installing the EARS tool on their phone for an additional $25. Installation will occur during the baseline phone interview call, or as a separate phone call for those participants who completed the assessment as a self-administered survey. The EARS tool is installed on the participant's phone and has the following functions/capabilities to record naturalistic behavior:

1. *Keyboard Logger.* This keyboard logger passively collects text input across all applications on the mobile phone. The logger works by installing a specialized keyboard on the phone, which collects every word that the participant types into their phone, including SMS, social media, searching, and emails. The only words that the keyboard does not collect are passwords or any other text typed into a secure field. The output that is generated includes a time, date, and GPS stamp for each entry.
2. *Geolocation.* We will collect the variation in participants' day-to-day geographical location. This includes assessing the amount of time spent at home compared to other locations each day.
3. *Phone Usage.* The tool also collects different aspects of phone usage including application usage time, call statistics (frequency and duration), and accelerometer (motion-sensing) data. We will collect the frequency and duration of each application usage, and the total time that the phone's screen is in use per day.
4. *Daily Status Report.* In order to keep the application running in the background, users will get a single question pushed to their phone each day at 11 am ("How effective do you feel as a parent today?"). Without this question, the mobile operating system will often close the application to conserve memory, which prevents the application from collecting any more data until it is opened again. Given that we have to ask the participant to interact with the application to keep it running, it seems prudent to collect a small item of data relevant to the study goals. Unfortunately, the EARS app is only available in English for the time being. We want to make participation in the EARS piece of the study available to all participants. Although the question will show up in English, the question is the same every day and we will tell Spanish speaking participants in advance what the question is asking in Spanish.

Data quality will be monitored on a researcher dashboard, which shows metadata about data uploads. If the dashboard indicates that a participant has stopped uploading data, we will reach out to them using the attached email script, in case they have closed the EARS app by mistake.

4. Supplemental Spanish Speaking Focus Groups (n=24)

As part of this research study (PYC), the Middle School Success over Stress (MSSOS) project and the Family and Middle School Success (FMSS) project, The Family Check Up online has been translated and provided to Spanish speaking families. In order to further understand the cultural relevance of the FCU online and to get feedback from parents on the model, we will conduct focus groups with Spanish speaking parents/caregivers. Focus groups will be conducted via videoconferencing (e.g., Zoom) to enable participation from a wide-range of parents and reduce barriers such as transportation and childcare.

A total of 3 focus groups will be conducted (5-8 participants per group for a total of 24 users) and each participant will receive $25 for their time and effort. Each participant will attend one focus group. These groups will be conducted in Spanish and the materials will be presented in Spanish to facilitate participation. Focus groups will include parents/caregivers who have engaged with the FCU Online to elicit ideas and opinions about the content, structure, and aesthetic design of a web-based program in Spanish. They will also be asked about positive and negative experiences and preferences for presentation format. We will elicit feedback and ideas about the approach and general features including feasibility of the FCU Online and the family consultant feature. During these 90-minute sessions, we will follow a written guide to ensure that key topics are covered, probe for thoughts and attitudes, and encourage participation.

Transcripts of sessions will be coded to enable content analysis of salient constructs, issues, and language use that contribute to the program features and functions. Data will be used to adapt the FCU Online in Spanish in multiple ways.

In order to report on participant data including app usage and demographic information without asking the

participants to report that information again, we will include in the consent form a request to link participant data from past study participation (in PYC, MSSOS, or FMSS) to their participation in these focus groups.

Materials

4. Supplemental Spanish Speaking Focus Groups

Focus group content will include questions about feasibility and acceptability of the FCU Online and will ask the questions outlined in the submitted document, “Spanish Speaking Focus Groups Content.” These questions were developed specifically for this study.

5. Focus Groups: Spanish speaking providers (n=10)

As a follow up to the supplemental Spanish speaking focus groups with families, we will conduct one 90 minute focus group with up to 10 professionals working with Spanish speaking families to gather information about perceptions on parenting and behaviors and perceived barriers to working with Spanish speaking families in community settings. Participants will also be asked to use and review the FCU Online in Spanish prior to attending the focus group.

Focus groups will be conducted via videoconferencing (e.g., Zoom) to enable participation from a wide-range of professionals and reduce barriers such as transportation and childcare.

Each participant will receive $25 for their time and effort. Focus groups will include community stakeholders working with Spanish speaking families with the intent to understand their experiences with families and receive feedback about the FCU online from their perspectives.

Transcripts of sessions will be coded to enable content analysis of salient constructs, issues, and language use that contribute to the program features and functions. Data will be used to adapt the FCU Online in Spanish in multiple ways.

Materials

Focus group content will include questions about feasibility and acceptability of the FCU Online, and some brief demographic questions that will be used to describe the sample in reporting and future manuscripts. We will ask the questions outlined in the submitted document “Provider_FG_Questions.’ These questions were developed specifically for this study.

D. Research Population & Recruitment Methods

1. Focus groups (n=6)

For the focus group phase of this study, we will be recruiting staff at Healthy Start or New Day and parents with young children who receive services from Healthy Start or New Day. Focus group members will be identified by our community liaison, Lee Ann Grogan, at Healthy Start. Participants will be over the age of 18 and fluent in English. We anticipate focus groups with staff will have between 5-10 participants and focus groups with families will have between 5-10 participants. All participants will be given information about the focus group, including key information about voluntary consent, purpose, duration, procedures, risks, and benefits to participation before consenting to participate. Potential participants will be made aware they will be paid $100 for participating in the 90-minute session. Additionally, participants will be made aware that the sessions will be audio-recorded and kept confidential. Prior to recording, focus group facilitators will ensure that any questions have been answered and participants have signed consent forms. Due to the current pandemic, we will first focus on conducting HIPAA-compliant Zoom focus groups with Healthy Start and New Day staff. Lee Ann Grogan will approach staff about the opportunity and with permission, will give staff names and emails to research staff. Following feedback from that focus group, the research team will either conduct Zoom focus groups with participating families or individual one-on-one Zoom sessions for participants. Lee Ann Grogan will approach families about participating and if interested, she will obtain a disclosure for release of client information via HIPAA Authorization form, and obtain permission from the participant to share their name, phone number and email address with research staff. We will follow the procedure outlined above to ensure consent is gathered prior to initiation of interview/focus group. Once it is safe and feasible, we plan to conduct follow-up in-person focus groups with stakeholders.

c) We are eliciting feedback from staff and families at Healthy Start and New Day because our future project will target a population of high-risk mothers with a history of opioid use. Both staff and families receiving services will be able to give us valuable input on how to adapt the FCU telehealth to best serve a high-risk population. In the second phase, we will conduct a pilot study with 10 families from Healthy Start. This will inform our third and final phase, the clinical trial. For our future clinical trial study, we will recruit from Healthy Start and New Day to assess efficacy and effectiveness of the FCU telehealth model with a) mothers of young children (ages 18mo-5 years) with a history of opioid use and addiction (n=300) and b) parents with young children (ages 18mo-5years) with a history of substance misuse or depression (prevention sample).

2. Pilot study (n=10 parents).

A pilot study will take place during summer 2021. Ten parents with a child between the ages of 18 months and 5 years old receiving services from Healthy Start will be recruited to participate in a pilot study to help us determine if the materials and procedures that we have planned to use in the clinical trial will work as is, or if they will need to be modified before the clinical trial begins. This sample will be recruited from the same population (Healthy Start) as the clinical trial. Healthy Start staff will introduce the study to parents as they transition out of Healthy Start services. They will review key information about the study on the study brochure by reading the brochure verbatim, including collaboration with University of Oregon, paid opportunity, using a phone App for parenting support, completing interviews over the phone, and learning more about parenting (see attachment “Parenting Young Children Project Brochure_6-30-21”). If parents are interested in hearing more information from U of O, Healthy Start staff will email parents the brochure with Qualtrics survey for contact information. Interested parents will complete the Qualtrics survey, giving their name, phone, email, and best time for contact; this information will be routed to University of Oregon recruiter. A U of O staff member will call the interested parent and screen callers for eligibility. Brochures will include the study phone number, so parents may call the phone number directly to inquire about the study if they do not want to enter their information into the Qualtrics survey. Healthy Start will also post the flyer to their website and may send out email blasts to clients with the study information/link, so interested parents may complete the Qualtrics for more information from U of O or call the study phone number for more information. Inclusion criteria are:

- Parent or legal guardian of a child between the ages of 18 months and 5 years old that lives in the parent’s home at least 50% of time
- Have a smart phone with text messaging capability and access to email
- Be willing to complete phone interviews and use a telehealth program that focuses on strengthening parenting
- Respond ‘yes’ to binge drinking and/or recreational drug use in the last year, lifetime use of prescription opioids, or depressed mood in the last two weeks.

  If a parent meets inclusion criteria, the staff member will proceed in explaining the goals of the Pilot Study and providing details about participation. Parents who still indicate interest in the study after hearing these details will have an opportunity to ask and have questions answered in an informed consent process before giving verbal consent. The recruiter will email a PDF copy of the consent form for their records. The recruiter will schedule a 1-hour to 1.5-hour phone interview with the participant.

  Participants will have the opportunity to be paid up to $175 for their participation, paid in two installments. Payment breakdown is as follows:

- Pre- assessment- $75. Payment will be sent after completion of the pre-assessment phone interview.
- Post-assessment- $75
- Consumer Satisfaction/Study exit interview- $25 (added to post-assessment payment). $100 Payment will be sent after completion of post-assessment and exit interview phone call.

  If a family does not meet inclusion criteria, they will be offered the phone number for the University of Oregon’s Child and Family Center, which offers low-cost tele therapy and parenting support.

3. Clinical trial research study (n=400 parents).

The clinical trial will begin in fall 2021, and we will recruit 400 parents with a child between the ages of 18 months and 5..

HCCSO and Healthy Start staff will introduce the study to parents receiving services. They will review key information about the study on the study flyer by reading the flyer verbatim, including collaboration with University of Oregon, a paid opportunity, using a phone App for parenting support, completing interviews over the phone or

surveys on their own, and learning more about parenting. If parents are interested in hearing more information from U of O, Healthy Start or HCCSO affiliated agencies will email parents the flyer, which includes the project phone number and a link to the project website. Healthy Start and other HCCSO agencies who serve parents of young children will also post the flyer to their websites and may send out email blasts to clients with the study information/link, so interested parents may visit the project website or call the study phone number for more information.

We will also recruit via broader community outreach including print ads and community events.

In addition to recruiting via community agencies and community outreach as described above, recruitment materials will be posted on social media websites including Facebook, Instagram, Reddit, and Craigslist using the following methods:

1. Post flyers to groups relating to rural Oregon communities

2. Create targeted ads to reach participants in rural Oregon communities

3. Create targeted ads to reach participants throughout the state of Oregon (i.e., rural, suburban, and urban areas)

All recruitment materials will include a link to the project recruitment website (English version: www.parentingyoungchildren.org; Spanish version: www.estudiodecrianza.org) where there is a link to a brief contact information form in Qualtrics. This contact information will be routed to a University of Oregon recruiter.

A U of O staff member will speak with the interested parent (in person or over the phone), and screen them and determine eligibility using the "Phone Screening for Eligibility" document. Flyers will also include the study phone number, so parents may call the phone number directly to inquire about the study if they do not want to enter their information into the Qualtrics screener.

In addition to our flyers, we have developed a project "fly-over" video to aid in recruitment (see **PYC fly-over video script** for language).

Because Aim 2 of our study is to examine the efficacy of the FCU Online for families in Oregon, we have included a question in the screening form asking for the zip code of potential participants. For participants recruited from social media, we may receive more families applying from outside of Oregon and are therefore asking for zip code to help us determine location for inclusion and analytic purposes.

Inclusion criteria are:

- Parent or legal guardian of a child between the ages of 18 months and 5 years old that lives in the parent's home at least 50% of time
- Have a smart phone with text messaging capability and access to email
- Be willing to complete phone interviews or online surveys and use a telehealth program that focuses on strengthening parenting
- Respond 'yes' to binge drinking and/or recreational drug use in the last year, lifetime use of prescription opioids, or depressed mood lasting for a two week period in the past year.
- Be currently living in Oregon as indicated by listing an Oregon zip code on the screening form

If a parent meets inclusion criteria, the recruiter will proceed to the informed consent process.

Participants will have the opportunity to be paid up to $425 for their participation, paid in four installments. Payment breakdown is as follows:

- Baseline- assessment and opting into EARS ($100). Baseline assessment and opting out of EARS ($75). Payment will be sent after completion of the baseline phone interview/survey.
    - 2 Week Quick Completion Bonus-$25 payment will be sent if interview or online survey is completed within two weeks of it being offered/sent out.
- 3- month -assessment- $75 Payment will be sent after completion of the phone interview/survey.
    - 2 Week Quick Completion Bonus-$25 payment will be sent if interview or online survey is completed within two weeks of it being offered/sent out.
- 6- month -assessment- $75 Payment will be sent after completion of the phone interview/survey.
    - 2 Week Quick Completion Bonus-$25 payment will be sent if interview or online survey is

completed within two weeks of it being offered/sent out.

- 1-year assessment- $75 Payment will be sent after completion of the phone interview/survey.
    - 2 Week Quick Completion Bonus-$25 payment will be sent if interview or online survey is completed within two weeks of it being offered/sent out.

If a family does not meet inclusion criteria, they will be offered the phone number for the University of Oregon's Child and Family Center, which offers low-cost teletherapy and parenting support.

Current participants will be notified of protocol changes that impact their study participation according to the "Notification Plan" submitted with this research plan.

4. Supplemental Spanish Speaking Focus Groups (n=24)

Parents/caregivers that participated in one of three studies (this research study (PYC), the Middle School Success over Stress (MSSOS) project and the Family and Middle School Success (FMSS) project) that used the Spanish version of the Family Check Up online will be invited to participate in these supplemental focus groups.

Inclusion Criteria

1. Parent/Caregiver that originally participated in PYC, MSSOS, or FMSS projects who engaged with the Spanish version of the FCU Online
2. Over the age of 18
3. Fluent in Spanish

All study activities for these focus groups will be conducted in Spanish. The focus group leader, Jasmine - Ramirez-Miranda, is fluent in Spanish and will translate all participant facing study materials.

Inclusion criteria will be assessed via data already collected from one of the three targeted projects. A recruiter will reach out to participants that meet inclusion criteria from one of the three targeted projects via email, text, or phone call to present the opportunity using the recruitment scripts outlined in the "Spanish Speaking Focus Group Recruitment" document. As only Spanish speaking participants will be invited to participate in this phase of the study, all study materials will be translated prior to outreach and provided only in Spanish.

Participants that take part in a focus group will receive $25. Participants will have the option to receive compensation either via a check in the mail or an electronic gift card to Walmart.

5. Focus Groups: Spanish speaking providers (n=10)

Community providers serving Spanish speaking families will be invited to participate in this supplemental focus group.

Inclusion Criteria

1. Community provider in the Eugene/Springfield area
2. Working with Spanish speaking families
3. Over the age of 18
4. Fluent in Spanish

A recruiter will reach out to community providers that appear to meet inclusion criteria (based on researcher knowledge of community providers and/or information about providers available online) via email to present the opportunity using the "recruitment email" template **(Email_Template_ Community Providers).** The recruitment email includes a description of the inclusion criteria and asks participants to respond if they are eligible and interested.

Participants that take part in a focus group will receive $25. Participants will have the option to receive compensation either via a check in the mail or an electronic gift card to Walmart.

E. Informed Consent Process

1. Focus groups (n=6)

Prior to beginning focus groups, potential participants will be given information about participation and their rights by the focus group facilitator. The facilitator will review all aspects of the consent form with the participants (see attached P2_Focus Group Consent form_2-20-20). Any questions or concerns will be answered by the facilitator before participants agree to the study and sign the consent form. Participants will be given a copy of the consent form for their records. In light of the Covid-19 pandemic, the consent form will be emailed as a pdf to participants for their records as well as accessible via Qualtrics. Prior to beginning recording in the HIPAA-compliant Zoom focus group/interview, the facilitator will review all aspects of the consent, answer any questions, and make sure that participants agreeing to the study complete the consent form electronically.

2. Pilot study (n=10)

Healthy Start staff will ask participants if they would like to be contacted about a paid research study. Staff will review the Parenting Young Children Project brochure (see attachment “Parenting Young Children Project Brochure”) by reading the brochure verbatim. If parents are interested in hearing more about the project, Healthy Start staff will email parents the link to the Qualtrics survey embedded in the brochure. Interested parents will enter their name, phone number, email, and best time of contact into the Qualtrics. A University of Oregon recruiter will contact the participant soon after expressing interest in hearing more. The11ecruitter will begin by explaining that she will ask a series of screening questions to assess eligibility. The recruiter will remind participants that their responses are private and will not be shared with Healthy Start. Additionally, the participant will be made aware that if they do not meet screening criteria, they will not be told the reason why. The recruiter will proceed with screening (see attachment “FCU Online Screening Questions_5-9-21”). Parents who do not meet screening criteria will be thanked for their time and offered the phone number of the Child and Family Center. Parents who meet the screening criteria will be informed they are eligible for the study.

The recruiter will then review the Pilot Study Consent Form over Qualtrics (see attachment “Pilot Study Consent form_6-30_21”) with participants, detailing the study components, risks, and rights to privacy, pausing frequently to answer any questions. Payment will be detailed (telephone interviews $75 each, and $25 exit interview). The parent will be emailed a copy of the consent form PDF(s) for their records. Parents can earn up to $175 for participating in interviews.

2. Clinical trial research study (n=400)

Parents who receive recruitment materials who are interested in hearing more about the project will either complete a brief contact form via Qualtrics (found on the recruitment websites; available in English or Spanish) or will call the project phone number. A University of Oregon recruiter will then contact the participant soon after learning of their interest in the project. The recruiter will begin by explaining that she will ask a series of screening questions to assess eligibility. The recruiter will remind participants that their responses are private and will not be shared with Healthy Start (if the participant was recruited from Healthy Start). Additionally, the participant will be made aware that if they do not meet screening criteria, they will not be told the reason why. The recruiter will proceed with screening (see attachment “FCU Online Screening Questions”). Parents who do not meet screening criteria will be thanked for their time and offered the phone number of the Child and Family Center in case they are interested in receiving free telehealth support from the clinic. Parents who meet the screening criteria will be informed they are eligible for the study.

The recruiter will then review the Clinical Trial Consent Form with participants over Qualtrics (see attachment “PYC study consent form”), detailing the study components, risks, and rights to privacy, pausing frequently to answer any questions. Payment will be detailed (telephone interviews/surveys $75 each, $25 opting into EARS, and $25 for the quick completion bonus). The parent will be emailed a link to a Qualtrics version of the consent form to sign (by typing their name) and return. Qualtrics will be programmed to automatically send a PDF of the signed consent form to the participant’s email for their records. Parents interested in hearing more about the EARS component will be read an additional EARS consent form, have questions answered, and may consent or decline participation in the EARS component of the study. Parents opting into EARS will be emailed a link to a Qualtrics version of the EARS consent form to sign (by typing their name) and return. Again, Qualtrics will be programmed to automatically send a PDF of the signed consent form to the participant’s email for their records. Parents’ decision to opt in or opt out of EARS will not affect participation in the overall study. Parents can earn up to $400 for participating in interviews/surveys or $425 for opting into EARS and completing interviews. The recruiter will then schedule a 1-hour to 1.5-hour phone interview with the participant or send an email with a link to the baseline survey to those participants who choose the self-administered option. The consent process will be available to be completed in either English or Spanish but will follow the same process regardless of language.

The informed consent form must be posted on the federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subjects, as required by the protocol.

4. Supplemental Spanish Speaking Focus Groups (n=24)

Participants who express interest in participating in focus groups after the initial outreach will receive a link to complete the consent form via Qualtrics either by email or text message (see “Spanish Speaking Focus Group Recruitment" for more information). Participants will be encouraged to reach out if they have any questions regarding the consent form. Participants will be emailed a copy of their consent form after completing it via Qualtrics.

5. Focus Groups: Spanish speaking providers (n=10)

Participants who express interest in participating in focus groups after the initial outreach will receive a link to complete the consent form via Qualtrics by email (using the “consent email” template in the “**Email_Template_ Community Providers**” document). Participants will be encouraged to reach out if they have any questions regarding the consent form. Participants will be emailed a copy of their consent form after completing it via Qualtrics.

F. Provisions for Participant Privacy and Data Confidentiality

1. Focus groups (n=6)

Data collection from participants is limited to consent forms and audio recordings of focus groups. Consent forms will be stored separately from the audio recording and will be stored in locked file cabinets with access limited to authorized staff. The audio recording file will be transferred to a secure, password-protected server and only accessed by authorized staff. Prior to beginning audio recording, participants will be asked to limit conversations about people to first names only so the risk of a full name being audio recorded is reduced. Similarly, participants will be asked to respect other participants’ privacy by agreeing not to share information revealed in the focus group with persons not currently present.

Participants will be reminded that despite our best efforts to maintain confidentiality, we can never fully guarantee privacy will be protected. For instance, the researchers cannot guarantee that participants will use full names in the focus group or disclose information from the focus group to others.

Focus group/interview recordings and consent forms will be retained through the end of the P50 center grant as Phase 1 will inform Phase 2 of the research study. At the conclusion of the P50 center grant, the audio recordings and consent forms of Phase 1 participants will be destroyed. Data collected during Phase 1 will not be contributed to the P50 center data repository as it will be limited to feedback related to usability/feasibility testing.

2. Pilot study (n=10)

Data collection in the Pilot study is limited to engagement with FCU Online, survey completion, and interviews. Parents will be made aware that surveys and phone interviews are kept private and will not be shared with Healthy Start or other entities (pilot study data will not be contributed to the P50 center data repository). Surveys will be identified by unique ID numbers and names will not be included in survey administration. Feedback sessions will be audio recorded, stored on our secure server under participant ID numbers. They will be made aware that despite our best efforts to maintain confidentiality, we can never fully guarantee privacy will be protected. Additionally, parents will be made aware that we are Mandatory Reporters if harm or threat of harm to children or others is disclosed. Consent forms and surveys will be conducted via Qualtrics with trained staff, and study records will be only accessed by key staff trained in privacy protections.

Participants will be made aware of the project’s Certificate of Confidentiality during consenting, as well as the limitations to the Certificate of Confidentiality. These limitations include: the Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm self or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.

3. Clinical trial research study (n=400)

Data collection includes engagement with FCU Online, survey completion, interviews, and passive data from

smartphones (if opting into EARS). Participants will be made aware that surveys and phone interviews are kept private and individual responses will not be shared with Healthy Start or other HCCSO agencies. Participants will be assigned a unique UO PSI study identification number and their names will not be on any study materials. ID numbers and identifying information will be stored separately in password-protected files and restricted areas on the computer systems and retained for five years through the end of the research study, and will be destroyed at the end of the study. Participant consent forms will always be reviewed with participants to ensure that their questions are answered and to cover all of the details.

All data will be reported in aggregate form, without identifying information or individual cases. Project staff will receive training on confidentiality, including data collection, data management, and reporting procedures.

Feedback sessions will occur via phone or Zoom. Those that occur via Zoom will be conducted using the HIPAA-compliant version of Zoom, which establishes strict access control rules and strong AES256 encryption to prevent transmission of any Protected Health Information. Feedback sessions will be video or audio recorded so that trained members of the research team can evaluate family consultants' fidelity to the intervention model. In each of these cases, meetings will be recorded to the local machine (not the cloud), uploaded to the project file on the PSI secure server under participant ID numbers, and then deleted from the local machine once the recordings have been safely transferred to the server.

To ensure confidentiality, the participant database will be restricted to staff members whose jobs require this information for participant contact and will require a username and password. Individual network and database passwords will be changed on a regular basis according to UO guidelines. All staff members are trained to close password-protected applications or lock their workstation when they are away from their desks and the door to lab offices will remain locked unless in use by research staff members. Entrances to staff and data storage areas are locked and accessible only to authorized staff.

The FCU Online app that was developed for this project is housed at the PSI. PSI servers are hosting and housed in the University of Oregon's data center and virtually in the University of Oregon's VMWare cluster. Backups are done nightly via Cohesity and a few other methods for redundancy. Firewall and intrusion protection are done with Fortinet's Fortigate unified gateway devices. All data files are protected via access control using Microsoft Active Directory and Duo for two-factor authentication, and access is provided to only a small group of trusted users who require it, thus reducing the exposure of sensitive data.

Contact information collected through Qualtrics is protected by Qualtrics' high-end firewall systems. Their servers are scanned regularly to ensure that any vulnerabilities are quickly found and patched, and complete penetration tests are performed yearly. Their confidential system component design uses multiple checks to certify that packets from one subsystem can only be received by a designated subsystem. Access to systems to severely restricted to specific individuals, whose access is monitored and audited for compliance. Qualtrics uses TLS encryption for all transmitted data, and they protect surveys with passwords and HTTP referrer checking. Qualtrics' services are hosted by trusted data centers that are independently audited using the industry standard SSAE-16 method.

Data collected using the EARS tool will be securely uploaded from each participant's phone to a University of Oregon account in a secure cloud service (Amazon Web Services, or AWS), using encrypted communication protocols. The data stored in the cloud service will be encrypted, with access limited to researchers involved in this study.

Data collected by the app will be removed from participants' phones daily. However, participants will also be advised to include a passcode on their phone (if they do not use one already) to add another layer of security between an outsider and any EARS data stored on the phone.

How each aspect of the mobile sensing data will be kept confidential is detailed below:

- **Keyboard Logger.** The keyboard logger is designed to collect every text input that is entered into a user's smartphone while the application is installed, with special provisions in the software to protect users' privacy and confidentiality. The keyboard logger does not record anything typed into a secure field, such as passwords or credit card numbers. The data will be encrypted and stored on the Amazon Cloud service, and only researchers involved in this study will be able to unlock it.
- **Geolocation and Phone Usage.** The geolocation and phone usage data will be treated similarly to the keyboard logger data in its encryption on Amazon Cloud, and only researchers involved in this study will

have the ability to download and decrypt it.

When transmitting the data to the Amazon cloud service (AWS), the EARS tool uses the latest version of TLS available (TLS 1.2 or greater) to connect to the server, meaning all data in transit are encrypted using the industry standard for encrypting data travelling between networks. After transmission to the Cloud, the EARS tool then deletes the data from the phone's memory. Upon upload to AWS, the data are then protected by Amazon's Server Side encryption, which uses 256-bit AES encryption. Upon completion of or withdrawal from the study, a participant's uninstallation of the EARS tool automatically deletes all EARS data still residing on the phone.

Participants will be made aware during consenting that their deidentified data will be submitted to a centralized data repository for the Center on Parenting and Opioids (CPO) and to the HEAL Prevention Coordinating Center (HPCC). They will be informed that deidentified data will be accessible to other researchers, but other researchers will not contact participants directly about individual data.

They will be made aware that despite our best efforts to maintain confidentiality, we can never fully guarantee privacy will be protected. Additionally, participants will be made aware that we are Mandatory Reporters if harm or threat of harm to children or others is disclosed. Consent forms and surveys will be conducted via Qualtrics with trained staff, and study records will only be accessed by key staff trained in privacy protections.

Participants will be made aware of the project's Certificate of Confidentiality during consenting, as well as the limitations to the Certificate of Confidentiality. These limitations include: the Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm self or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.

4. **Supplemental Spanish Speaking Focus Groups (n=24) & 5. Focus Groups: Spanish speaking providers (n=10)**

Data collection from participants is limited to consent forms and audio recordings of focus groups. Consent forms will be stored separately from the audio recording and will be stored in a password protected Qualtrics account. The audio recording files will be saved to a secure, password-protected server and only accessed by authorized staff. Prior to beginning audio recording, participants will be asked to limit conversations about people to first names only so the risk of a full name being audio recorded is reduced. Similarly, participants will be asked to respect other participants' privacy by agreeing not to share information revealed in the focus group with people not currently present.

Participants will be reminded that despite our best efforts to maintain confidentiality, we can never fully guarantee privacy will be protected. For instance, the researchers cannot guarantee that participants will use full names in the focus group or disclose information from the focus group to others.

Consent forms will be retained through the end of the P50 center grant then will be destroyed. Upon completion of the focus groups, the audio recordings will be transcribed, and any identifiers included in the discussion will be removed. After transcription is complete, the audio recordings will be destroyed and the de-identified transcriptions will be retained for future data use. Data collected during Phase 4 & Phase 5 will not be contributed to the P50 center data repository as it will be limited to feedback related to usability/feasibility testing.

G. Potential Research Risks or Discomforts to Participants

1. Focus groups (n=6)

The research risks are minimal in this focus group phase of our study. Participants may feel uncomfortable sharing their opinions with other focus group participants or facilitators. Topics of the focus group include eliciting opinions about the FCU telehealth program itself as well as opinions about parenting and/or dealing with young childhood behavior. It's possible that participants could feel upset by some of these topics, but all participants will be reminded that they may decline to answer any question they don't want to answer. The other potential risk participants will be made aware of is risk of identity being revealed, though we will take many measures described in section F to minimize the likelihood of that occurrence.

2. Pilot study (n=10)

The research risks are minimal in the pilot study phase of our study. Participants may feel uncomfortable

answering some questions in phone interviews, but always have the option to skip questions they do not want to answer. It is possible that participants could feel uncomfortable talking with Family Consultants on the phone or receiving feedback on their parenting practices, but Family Consultants are sensitive to participant needs and apply a strengths-based lens to work with families. The other potential risk participants will be made aware of is risk of identity being revealed, though we will take many measures described in section F to minimize the likelihood of that occurrence.

3. Clinical trial (n=400)

The research risks are minimal in the clinical trial. Participants may feel uncomfortable answering some questions in phone interviews/surveys, but always have the option to skip questions they do not want to answer. It is possible that participants in the intervention condition could feel uncomfortable talking with Family Consultants on the phone or receiving feedback on their parenting practices, but Family Consultants are sensitive to participant needs and apply a strengths-based lens to work with families. Participants may be uncomfortable about the data collected by EARS, but may opt out at the start of the study, or request to be unenrolled at any time. The other potential risk participants will be made aware of is risk of identity being revealed, though we will take many measures described in section F to minimize the likelihood of that occurrence.

The EARS Tool- Participants will face no more than minimal risk, meaning that they will experience no more psychological discomfort greater than what they might experience in everyday life.

There is always the possibility that participant data could become lost or stolen, or confidentiality could be breached. Although this scenario is unlikely, to protect against loss of participant confidentiality and data, all passive data (some of which could be personally identifying) will be stored on a secure cloud service, and permissions will only be given to research personnel associated with this project. Participants will be assigned a randomized participant ID code after consenting to the installation of the EARS tool. This code will be used to access the EARS tool and to link the EARS data to data collected from other sources. Participants will not be able to successfully install the EARS tool without this code.

The EARS developers have taken steps to maximize the acceptability of the EARS tool by prioritizing phone use impact. The EARS tool runs in the background at all times. In order to minimize the impact on the user's day-to-day experience, the EARS tool has been made as lightweight as possible. First, memory usage is minimized in both the Android and iOS versions. Early versions of the Android tool used only about 1-2% of memory. Second, the usage of phone sensors can have a large impact on the battery life of a phone, as they draw relatively large amounts of power. In order to combat this, we have moved most Cloud uploads to late at night when the phone is usually plugged in, and when the device is connected to a Wi-Fi network. The Android version limits GPS readings to once every 15 minutes, and if possible, gets location data from known Wi-Fi points rather than connect to satellite. The iOS version only collects GPS readings once a user moves above a given threshold. Early testing on a range of phones indicated the tool consumed no more than 15% of the battery over a 16-hour period, and battery usage for both versions is continually monitored and improved by our development team. Third and finally, installation of the EARS tool causes minimal change in the User Interface/User Experience (UI/UX). Once installation is completed, the only difference the user will notice is the custom keyboard for iOS. Everything else is collected in the background with no user interaction.

Regarding the keyboard logger, this data may be seen as able to flag risk if the participant includes information about harm to self or others (e.g. "I want to kill myself"). However, keyboard data will not be monitored in real time, and therefore we would be unable to intervene and manage this risk. Moreover, computer algorithms, and not humans, will conduct the analysis of keyboard data. This will be explained to participants during the consent process.

4. **Supplemental Spanish Speaking Focus Groups (n=24) & 5. Focus Groups: Spanish speaking providers (n=10)**

The research risks are minimal in this focus group phase of our study. Participants may feel uncomfortable sharing their opinions with other focus group participants or facilitators. Topics of the focus group include eliciting opinions about the FCU telehealth program. It's possible that participants could feel upset by some of these topics, but all participants will be reminded that they may decline to answer any question they don't want to answer. The other potential risk participants will be made aware of is risk of identity being revealed, though we will take many measures described in section F to minimize the likelihood of that occurrence.

H. Potential Benefits of the Research

1. Focus groups (n=6)

Participants may enjoy thinking about parenting and sharing their opinions about parenting, strategies for managing child behavior, and the FCU telehealth model with other participants and focus group facilitators. Participants will also be informed that their opinions will shape the future study and contribute to helping other families with young children. Lastly, focus groups will include showing modules addressing health, wellness, and parenting strategies, so it's possible that participants could learn some additional tips or strategies to try in their own life.

2. Pilot study (n=10)

Participants may enjoy thinking about parenting, strategies for managing child behavior, and engaging with the FCU telehealth model. Additionally, participants may enjoy working with a Family Consultant to identify their goals, strengths and progress through the program. Participants may enjoy knowing their participation and input on the study informs the clinical trial.

3. Clinical trial (n=400)

Participants may enjoy thinking about parenting, strategies for managing child behavior, and engaging with the FCU telehealth model. Additionally, participants in the intervention condition may enjoy working with a Family Consultant to identify their goals, strengths and progress through the program.

4. **Supplemental Spanish Speaking Focus Groups (n=24) & 5. Focus Groups: Spanish speaking providers (n=10)**

Participants may enjoy thinking about their experience with the FCU Online app and sharing their opinions about the FCU telehealth model with other participants and focus group facilitators. Participants will also be informed that their opinions will shape the way we adapt the app in the future to better fit the language and cultural needs of the Spanish Speaking Latinx community.

I. Investigator Experience

The research team for this study includes investigators with complementary expertise who have worked together across multiple research projects during the past 20 years. Drs. Elizabeth Stormshak and Leslie Leve have worked together closely at the University of Oregon (UO) for the past 6 years as leaders of the Prevention Science Institute. With Dr. John Seeley, they direct an IES-funded postdoctoral training grant focused on prevention science. Dr. Daniel Shaw has worked closely with Dr. Leve for the past 12 years to examine long-term developmental trajectories of adopted children and with Dr. Stormshak as a collaborator and co-author of the FCU. Drs. Seeley and Stormshak are Co-PIs on the FCU Online intervention for middle school families and on Project 2 of the P50 center, have conducted multiple studies together, and have published together about outcomes associated with the FCU. Dr. Nick Allen has worked with Drs. Leve and Seeley on the prevention of depression, including coauthored publications, and has expertise in Internet-based assessment and digital learning. He directs the Center for Digital Mental Health at UO; his expertise in this area will guide the development of our assessment and data processing and extraction activities that use mobile data collection and mobile sensing approaches.

Dr. Stormshak has had an active collaboration with community partners in Douglas County, Oregon, for the past eight years. In the proposed study, our community partners include Healthy Start in Douglas and Josephine Counties. One of 36 Oregon counties, Douglas County is largely rural and has high rates of substance abuse and addiction. The 5-year average NAS rate in Douglas County is 76% higher than the overall state average, and the poverty rate for children is 33%, 10 points above the state average.62 Healthy Start serves 700 families in Douglas and Josephine Counties (both rural) per year, with a goal of preventing infant mortality and health disparities for mothers and children in rural Oregon. Approximately one-third of the parents enrolled in Healthy Start have substance abuse problems and could benefit from parenting support. Managed by the Health Care Coalition of Southern Oregon, Healthy Start provides a variety of support services to parents and manages a perinatal task force focused on improving outcomes for young adult parents. We will work collaboratively with Healthy Start to identify parents in their programs who meet the study enrollment criteria, and we will coordinate

recruitment with the community agencies.

Lee Ann Grogan, a community partner and collaborator, will serve as the liaison in the community. Ms. Grogan is the former program manager of Healthy Start of Southern Oregon, has extensive experience working with young adults at high risk in rural Oregon, and has close connections to other health agencies in Douglas and Josephine Counties. She will assist with the adoption of the intervention in agencies that deliver Healthy Start during the proposed implementation phase, help identify providers for training and support, and identify strategies to engage young adult parents in the prevention model. Ms. Grogan will also serve as a family consultant and provide telehealth services to some families in the intervention condition. Drs. Stormshak and Leve have worked with Ms. Grogan during the co-development of this project and have provided professional training workshops for staff and professionals in southern Oregon who serve this population.

Focus Groups: Roles and Research Duties

Focus group facilitators and support staff from Prevention Science include Milagra Tyler, Whitney Nash, Kevin Moore, Jordan Matulis, Felice Resnik, and Jasmine Ramirez-Miranda. All staff will receive training on focus group facilitation and all staff have completed CITI training and Good Clinical Practice (GCP) training. Milagra Tyler will lead the Phase 1 focus groups with support from others and will step the group through the technical features of the FCU Online and telehealth model. Jasmine Ramirez-Miranda will lead the Phase 4 focus groups.

Pilot and Research Clinical Trial: Roles and Research Duties

The Principal Investigator and Co-PI will be in charge of oversight of all project activities and data analysis, as well as training and supervision of clinical staff.

The project coordinator will be in charge of all day-to-day research activities and communications with PI and Co-PI.

The Assessment Coordinator will be in charge of training and supervising research assistants and ensuring high quality data collection.

The Data Manager will be in charge of randomly assigning participants to condition, and cleaning and organizing data to prepare for analysis.

The recruiter will be in charge of conducting phone screens to determine eligibility to participate in the research study.

Data Collectors will be in charge of conducting interviews with participants.

Interventionists will be serve as telehealth consultants for families participating in this study.

Spanish speaking translators and recruiters are native bi-lingual speakers with multiple years of prior research experience and have completed CITI training.

Training and Oversight

All research staff who will have contact with participants and/ or data will complete the CITI training course, including the Good Clinical Practice training module, in order to ensure proper understanding of ethics involved in human subjects' research.

Research staff involved in the collection of questionnaires will be trained by the assessment coordinator to follow the protocol written for this project to ensure uniformity in data collection and handling.

Family interventionists/ telehealth consultants will be trained and supervised by a doctoral-level, licensed psychologist.

In order to ensure accurate Spanish translation of English materials, we will adopt a translation process in which materials are translated by one translator, reviewed by a second translator who makes corrections and suggestions for improvement and finally reviewed by a third translator who would make a final decision about which version to use when the first two translations differ.