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: Supplement: Long-term Effects of the Family Check-up on Depression and Suicide Across Trials and Development (a.k.a. "Middle School Success Over Stress")

Protocol Number: 09182020.014

Principal Investigator: Beth Stormshak

A. Introduction and Background

It is clear that the COVID-19 pandemic has impacted families adversely in multiple ways, including economic stressors (e.g. changes in employment status or functioning), mental health-related functioning (including depression and suicide-related behaviors), social/familial functioning (including parenting and risk for domestic violence), as well as responses to mandated safety measures (e.g. social distancing, stay-at-home orders, mask-wearing). Furthermore, families of school-age children have had to navigate online instruction and home schooling in the context of these difficult circumstances with little preparation for doing so effectively. School districts have varied widely in their ability to support parents during this crisis. These stressors are likely to have disproportionately adverse effects on lower-income and racial / ethnic minority populations, for whom economic, academic, and family-level challenges were already pronounced. For instance, health effects of COVID-19 have hit African American and Latinx populations with disproportionate severity, including higher rates of hospitalization and death (Garg et al., 2020). Given the scale of pandemic impacts for families with school-aged children, the identification of effective family-focused interventions that target core mechanisms of change with a broad range of benefits for parents and youth across diverse populations, and that can be brought to scale rapidly and with fidelity, represent critical public health goals.

This supplement will adapt and test the efficacy of the Family Check-Up Online as a treatment to foster resilient family functioning in response to the COVID-19 pandemic. We will test the effects of the adapted FCU Online program on key mechanisms of change, including parenting skills, parental depression, and parent/child self-regulation, that we predict will directly impact child and family functioning. We predict that changes in these key targets of the intervention will impact participant's response to the COVID-19 pandemic, including youth depression and behavior problems, the ability to cope with pandemic-focused stressors (e.g. dealing with changes in employment status or functioning; following mandated safety measures), and social/familial functioning (including relational support and risk for domestic violence).

B. Specific Aims/Study Objectives

Aim 1: Adapt the FCU Online for low-income parents of school-age children in response to the Covid-19 crisis. Our team will use a formative development process of adaptation to develop a new module and test existing content for the FCU Online derived from the FCU Online for middle school and the FCU Online for young children. Both of these programs draw from the original content of the FCU developed by Dishion and Stormshak and the Everyday Parenting. Modules developed as part of the FCU Online include positive parenting, limit setting, proactive parenting, healthy routines, monitoring/supervision, and parent wellness. New content developed for this supplement will include stress management and coping with pandemic-related disruptions (e.g. economic challenges, social distancing and isolation), supporting learning at home, and effective parenting practices in the context of pandemic (e.g. managing quarantine/social distancing). We will examine usability and acceptability through focus groups with stakeholders, schools, and parents (N=20).

Aim 2: Conduct a pilot test of the efficacy of the adapted FCU Online developed in Aim 1. Our team will conduct a pilot study to test acceptability and feasibility of our approach (*n*=180) that includes a pre- and post-assessment in a waitlist, controlled design. Assessments will include measures of mental health (children and parents), stress (children and parents) and problem behavior (children) as well as a range of risk factors using measures adapted for COVID 19 from the NIH toolbox.

Aim 2a: Evaluate FCU effects on proximal mechanisms. In line with the experimental therapeutics approach to treatment development, we will examine the extent to which the FCU targets the three hypothesized mechanisms, including reductions in parental depression, improvements in effective parent management practices, and improvements in parent and youth self-regulatory abilities.

Aim 2b: Evaluate FCU effects on targeted parent/ youth outcomes at post-treatment and follow-up, and examine mechanistic pathways via mediation analyses. We will examine FCU effects on core targeted outcomes at post-treatment and follow-up, and will conduct mediation analyses to examine whether hypothesized mediators explain intervention effects on targeted outcomes. We predict that the FCU will predict improved parenting skills, reduced parental depression, and improved self-regulation, which in turn will predict reduced youth depression and problem behavior, as well as improved parent and youth coping with COVID-19.

C. Methods, Materials and Analysis

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 for each of these phases of research appears below.

Phase	Timing	Research Participants	Status
1. Formulate research procedures, network with community organizations for possible participation, program app, develop survey instruments	October 2020-July 2021	n/a	completed
2. Focus groups with staff of community agencies and parents	July 2021	staff N=8; recruited from organizations selected in Spring 2021. parents N=16; recruited from community. There will be 2 groups of parents, one Spanish-speaking and one English-speaking. Participation will last one hour.	completed
3. Pilot Study	September 2021-November 2022	N=180 families with children aged 10-14 recruited from the community over 6 months. Participation will last 6 months.	completed

Focus Groups (N=24)

During the first 9 months of the study, we will design an interactive, engaging, app based on the Internet version of the FCU. Although the app version will be based upon the internet version of the FCU (and the in-person model of treatment), our development work will be guided by iterative formative research that includes use of focus groups. Three focus groups will include Spanish-speaking parents, English-speaking parents, and personnel from community agencies who work with children and families similar to those targeted by this intervention (up to 8 per group for a total of 24 users). Focus groups will be used to elicit ideas and opinions about the content, structure, and aesthetic design of the app. Focus groups will be conducted via a HIPAA-compliant version of Zoom. Focus groups will be presented with a mock-up of the "Positive Parenting" module of the app and facilitators will solicit their feedback about the proposed approach and general features. During these sessions, facilitators will follow a written guide to ensure that key topics are covered, probe for thoughts and attitudes, and encourage participation from all participants. Focus groups will be recorded via Zoom; the recording will be recorded to a facilitator's work computer and transcribed. 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. Participants' comments will guide us in terms of preferences for video models, language level, text elements, and programmatic tone.

Parent focus groups will begin with an overview of the FCU Online program, including the purpose of the app and its proposed structure. This would include coverage of the three main elements of the app: assessment, feedback, and parenting skills training modules that include brief videos and animations and interactive elements. This overview will also highlight the role of the consultant. Mock-ups of selected pages of the app will be presented, including a welcome page and the FCU assessment, feedback, and skills training elements of the "Positive Parenting" module. At various points, participants will be asked a series of questions designed to elicit opinions and set the occasion for group discussion (see "questions for parent focus groups_5.25.2021"). At the end of the session, participants will be asked to describe their overall reaction to the proposed features of the program. Candid opinions will be encouraged including what participants did not like as well as any features they thought were missing and should be added.

Focus groups with staff of community agencies will begin with the same overview of the FCU Online program described above, pausing periodically to ask questions designed to elicit opinions about the program and app (see "Questions for provider focus groups_5.25.2021"). At the end of the session, participants will be asked to describe their overall reaction to the proposed features of the program. They will also be asked their opinion on how well this program would "fit" in their agency and how we might enhance that fit.

Pilot Study (n=180 families)

We will recruit and randomly assign 180 families with school aged children between the ages of 10 and 14 to one of two conditions: (a) FCU intervention (n=90), or (b) a waitlist control group (n=90) that will receive school/ community resources as usual and then offered the intervention immediately after completing the 4-month assessment. This design will enable us to evaluate FCU effects on targeted parent/ youth outcomes. Participation in this study will be 6 months for all families, regardless of condition.

The FCU preventive intervention historically has been delivered in face-to-face sessions between family consultants and parents. Family consultants would do motivational interviewing to determine existing concerns in the family, and motivate parents to make positive change in their parenting and family dynamics. They would provide feedback on the family assessment, and offer coaching and/ or resources to help parents make desired changes. The FCU intervention is intended for prevention, not treatment, of serious youth behavior and to promote growth in positive school and social behaviors. For this project we have developed a computer app that scores family assessments, provides feedback, and provides skill-building content similar to what was previously offered to parents face-to-face. In this project, parents will use this app and receive individualized coaching over the phone or Zoom (depending on parent choice). 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." However, the coach-parent relationship may offer therapeutic benefits.

Families will be recruited from local middle schools and community organizations that serve low-income families. We will provide English and Spanish fliers to agencies and schools to distribute within their communities as they see fit. These fliers will refer potential participants to our recruitment website (www.middleschoolstudy.org), which has content in both Spanish and English. People who are interested in participating will fill out a form on the website indicating their name, phone number, and a good time to reach them. Responses to this form will be deposited in one of two project email accounts, where either an English or Spanish-speaking recruiter will retrieve them and attempt to call interested parents at the desired time. At the time of recruitment, the recruiter will determine eligibility for the study, preferred language for participation, review the key elements of the consent form, and answer parent's questions about the study. If the parent indicates willingness to participate, they will be emailed a link to a consent form in Qualtrics. They will confirm their consent to participate by typing in their name and date in the appropriate fields on the form. At the time of this phone call the recruiter will also determine if the parent has access to the web via a computer or tablet, or just with a smartphone. If they only have a smartphone, they will be scheduled to complete their parent survey as an interview because we have determined that the survey is too difficult to respond to on a smartphone. If they have access to a computer or tablet, we will ask their preference between completing the survey on their own or as an interview. Parents who choose to complete the assessment on their own will receive an email that includes a personalized link to a Qualtrics baseline assessment and a "special word," a four-letter word that will function as their unique ID for the study but is easier to remember than a standard participant ID number. Parents who choose to complete it as an interview will be scheduled for a phone or Zoom

appointment in order to complete it. Zoom will be the default choice for interviews unless parents' access to technology, data plans, etc., require the phone option. Similarly, youth will have the choice to complete their data collection via Qualtrics survey or in an interview format via Zoom or phone. Youth who chose to complete surveys on their own will complete the assent process over the phone prior to receiving a link to the survey. All Zoom interviews will take place via a HIPAA-compliant account to ensure confidentiality. During this Zoom call, a research assistant will share their screen, go over the assent form, and answer any questions posed by the youth. If the youth assents to participation, the research assistant will check a box on a Qualtrics assent form indicating they obtained youth assent, and type in the child's name, the date, and their own name. The baseline assessment includes standard, widely-used questionnaires that ask questions about the child's abilities and behavior, parenting practices, family dynamics, family demographics, family health behaviors, and life stressors. The parent assessment takes about 45 minutes to an hour to complete; the youth survey takes about 30 minutes. Data collection interviews that occur via phone or Zoom will not be recorded.

The youth survey contains a few items regarding depression and thoughts of harming the self .We have developed a protocol to handle the cases in which youth respond that they have thoughts that they would be better off dead, or of hurting themselves in some way. Each day, research staff will be assigned to review all youth assessments that are completed as surveys. If a research assistant discovers that a youth has responded to this item with any response choice other than "not at all," they will immediately notify the Family Consultant on duty, who will reach out to the youth by phone to ask a few scripted follow-up questions to gather information, assess imminent danger, and to build rapport with the youth. They will also develop a safety plan if there is current risk of self-harm. This safety plan would include informing the parent, so that they can be involved in getting support for their child. For youth who complete the assessment as an interview, the youth will be responding to this item verbally. If the youth responds anything other than "not at all" to this item, the research assistant will finish the interview, and immediately notify the Family Consultanton duty that they will need to speak to the participant. If, during an interview, the youth divulges suicide ideation without a prompt,the research assistant will ask a few scripted follow-up questions, complete the interview, and then let the participant know that a Family Consultant will be coming onto the session to ask a few more follow –up questions. Once the Family Consultant is on the call, the RA will leave the session so that the participant and family consultant can talk privately. The family consultant will then follow-up individually with the youth and conduct the suicide risk assessment described above. They will develop a safety plan if there is current risk of self-harm. This safety plan would include informing the parent, so that they can be involved in getting support for their child.

Because assessments are completed via Qualtrics, we will be able to track how quickly participants are completing the survey. If they have not yet completed the survey one week after receiving the link to the survey, a paid staff member will call the caregiver to see if the caregiver has any questions about the survey and remind them to complete it as soon as possible.

Once surveys/ interviews are completed, participating families will be randomly assigned to one of two conditions (intervention or waitlist control). Parents in the **intervention condition** will be contacted by a Consultant to schedule an initial phone or Zoom session in which the coach shares information about the FCU Online process, gathers some information from the parent, and motivates the parent to engage in the program. Parents will have the choice whether to complete these sessions over the phone or Zoom. Either way, sessions will be recorded via Zoom in order to evaluate consultants' fidelity to the intervention model (i.e., how well the consultant adhered to each element of the Family Check-Up model during their appointments with a given parent). If a parent chooses to complete these sessions by phone, the consultant will put the parent on speaker phone and start a Zoom "meeting" with themselves, recording the meeting. The only image that would be appear in this recording is the consultant's black screen. After the meeting is over, the video portion of the recording would be deleted while retaining the audio file. If a parent chooses to complete the meeting via Zoom, the meeting will be recorded. It is likely that both the parent's image and the consultant's image would be recorded (assuming they both choose to share their video), but, again, the video portion would be deleted after the meeting is over and only the audio file would be retained. After the initial meeting is over, Parents will receive an email that includes information about how to log in to the app. Participants in the **waitlist control group** will receive an email thanking them for their participation and letting them know that they will next be contacted by project staff in 2 months.

Participants in the **intervention condition** will log in to the FCU app where they will complete the first module, which includes a brief 5-minute assessment, feedback on their data, and online tools to support their parenting in areas that were identified as challenges by the assessment (see fuller description below under "Content of Skills Sessions and Web/ Mobile

Activities"). These tools include videos, animated videos, parenting tips, and interactives. Parents will also be given the opportunity to practice parenting skills. Parents will be able to log-in as often as they like and interact with any of the parenting Skills Sessions on the app. In addition, a Consultant will contact them after completion of the first module to talk through their results, help them set goals, offer support over the phone/ Zoom, and help motivate parents to improve parenting practices. Parents will be able to contact their Consultant as often as they like and will have at least 5 scheduled phone sessions with a consultant (i.e., one after the completion of each module). We anticipate that each of these check-ins might take around 20 minutes, but will adapt to the needs of the family. Each of these sessions will be recorded via Zoom, as described above.

Caregivers in both conditions will be invited to participate in follow-up questionnaires at 2 months, 4 months, and 6 months after baseline. This survey will be identical to the baseline assessment so that we can evaluate change over time in the assessed constructs. Parents will once again have options regarding completing the survey on their own or as an interview, via Zoom or phone. Youth data will only be collected at baseline and 6 months after baseline. Youth will also have the option to complete the survey on their own or as an interview over Zoom or phone. The estimated time needed for parents to complete each of these follow-up questionnaires is 45 minutes to an hour; the estimated time needed for youth to complete each follow-up interview is 30 minutes. At the time of the 2-month follow up, parents in the intervention condition will also complete a 2-page FCU Online Satisfaction Survey. This survey will also be completed via Qualtrics.

All families will be compensated for their time. Parents will receive $75 for completing assessments at baseline, 2 months, 4 months, and 6 months for a total of $300. Youth with receive $25 for completing assessments at baseline and 6 months, for a total of $50.

FCU intervention protocol. The FCU app being developed for this research study will motivate caregivers to use positive parenting skills and effective communication with their adolescent to reduce family conflict and subsequent problem behavior. The original FCU takes place in person and involves at least three sessions, including (a) an initial rapport-building interview, (b) an assessment with the caregiver(s), and (c) a feedback session during which the results of the assessment and initial interview are discussed with the caregivers, attention is focused on the caregivers' readiness to change, and specific change options are delineated. The feedback session is both strengths-based and specific. The goals of feedback sessions are to (a) share assessment findings with caregivers regarding areas of strengths and challenges, (b) engage in a motivationally enhanced discussion about promoting positive changes, and (c) provide a menu of resources to facilitate the family change process. Emphasizing areas of strengths and challenges reduces parents' defensiveness and enables them to feel empowered to pursue strategies for making changes relevant to their family's needs. At the end of the feedback session, a menu of interventions is presented and discussed collaboratively with the caregivers.

In this study, families in the intervention condition will be contacted by a consultant for an initial phone session after research staff receive their completed baseline assessment. This phone session will serve as the "initial interview" for these parents and will allow the consultant to 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. After the initial interview, parents will receive an email invitation to log into the FCU app with their name, email address, and smartphone number. This information allows parents to create a page that is exclusively viewed by the parent or parents who choose to participate. Parents will be directed to login and complete the first module of the online assessment. They will complete a brief (5-min) assessment of parenting skills in the focus area, and then receive immediate feedback in written format, generated by the app program. Web programmers have created algorithms that generate the feedback, highlighting family strengths and areas of growth. After parents receive feedback, they will be directed towards content designed to help them build parenting skills in the specific content area. The skills sessions in each parenting module are guided by our Everyday Parenting curriculum. The skills sessions will consist of content and structured activities that are designed to help parents learn each skill.

After completing the first module, parents will discuss the feedback and skill-building content with their consultant via phone or video conferencing. 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 5 skills modules, and parents will follow the 4-step process of assessment→feedback→ skills session→consultation for each module. The first check-in will occur after one module of the parenting curriculum has been completed, or after 2 months, whichever comes first. Additional meetings may be scheduled as needed. These meetings will be audio or video recorded and sessions will be evaluated for the consultant's fidelity to the intervention model.

There is no youth component to the online assessment.

After completing the FCU, families will continue to participate in the post-tests previously described. These post-tests occur at 2, 4, and 6 months after the baseline assessment for parents, and at 6 months after baseline for youth. At the end of the 2 month post-test assessment, parents will also be asked to complete a FCU Online Satisfaction Survey. This questionnaire will assess satisfaction with the content and delivery of the model and factors related to uptake and usage of the information. This questionnaire will be completed via Qualtrics. Participants will receive an email with a link to complete their survey. It should take about 10 minutes to complete.

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 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. Each skills session will also highlight behaviors that target school success at this age, including homework completion, attendance, and home-to-school planning. A description of the skills taught in each of the 5 modules is provided below.

Healthy behaviors for stressful times. This module focuses on teaching parents both the importance of, and how to support their child in, 7 areas of their child's life: emotional well-being, coping with stress, social connections, eating, body image, physical activity, and "screens" (traditional media, social media, phones, etc.).

Positive parenting. Four teaching content areas will focus on positive behavior support: encouragement and praise, spending quality time, giving directions, and using incentives for positive behavior. The "encouragement and praise" content area shows parents how to develop skills for using positive language with their adolescent. The "spending quality time" area encourages parents to see spending time together as a way to build a happier, healthier relationship. The "giving directions" area helps parents understand and learn basic skills for promoting behavior change in their child. The "using incentives" content area helps parents develop skills for using incentives and planning how to manage their child's behavior.

Rules & consequences. This skills session includes establishing clear rules, monitoring, limit setting, identifying appropriate consequences for behavior, and ignoring annoying behavior. The "clear rules" area shows parents how to establish clear commands and expectations and asks parents to track both desired and undesired behaviors over time. "Monitoring" encourages parents to keep track of their child's behavior, especially when they are not with them. "Identifying appropriate consequences" includes working with the adolescent to develop incentives and consequences that are meaningful to reduce negative behavior and increase positive behavior. "Ignoring" encourages parents to not react to behaviors that are merely pestering/ annoying.

Support School Success. This content area will provide useful guidance to parents in how to establish healthy home routines (related to meals and sleep), and how to support their child's success in school (getting to school on time, organizing homework, and supporting homework). A number of activities to help parents develop these skills will be available.

Communication. The "communication" area teaches active listening skills and effective problem solving and negotiation skills.

Training and Monitoring of Consultants. Consultants will be trained in the FCU, motivational interviewing, and school-based interventions. A lead consultant will oversee training and supervision of at least two other consultants who will also serve as the consultant for some of the participants, to decrease bias in the intervention. All consultants will be trained, supervised, and supported to help them effectively implement the FCU. The supervising consultant and two hourly consultants will be trained to reach a minimum level of competence via in-vivo role-play. Feedback with pilot families will be recorded and rated by the clinical supervisors using the COACH fidelity of implementation rating system (Dishion et al.,2010). A 9-point scale is used to rate each of the following dimensions: (a) **C**onceptual adherence to the FCU model, (b) **O**bservant and responsive to family concerns, (c) **A**ctively structures sessions for optimal behavior change, (d) **C**arefully teaches when appropriate, and (e) **H**ope and motivation are generated. Consultants are guided for the first two to three cases until they attain minimum fidelity standards; guidance is repeated quarterly. A series of studies has shown greater fidelity to the FCU is associated with improved parenting practices and reduced youth behavior problems in families with young children (Smith, Dishion, & Knoble, under review; Smith, Dishion, Shaw, et al., 2013).

Data analytic plan.

Aim 1: Adapt the FCU Online for low-income parents of school-age children in response to the COVID-19 crisis. Our investigative team will use a formative development process of adaptation to develop new modules and adapt existing content for the FCU Online derived from the FCU Online for middle school (Stormshak et al, 2019; Danaher et al., 2018) and the FCU Online for young children (currently in development). This version of the FCU Online will address risk factors associated with the COVID-19 crisis, including stress, coping, and learning at home. We will examine the usability and feasibility of the content through focus groups with stakeholders, schools, and parents (N=20).

Aim 2: Conduct a pilot test of the efficacy of the adapted FCU Online. Analyses for Aim 2 will involve two goals, first to examine evidence of feasibility and tolerability of the intervention, and second, to examine evidence that the intervention engaged the putative mechanisms (self regulation, parental depression, and effective parenting skills), and was associated with hypothesized outcomes (youth: depression and conduct problems; parent pandemic related coping). Evidence regarding feasibility and tolerability of the intervention will include descriptive information examining participants' and therapists reports on treatment process, including participant perceptions of the intervention, views regarding the utility of specific treatment components, and data regarding engagement with online materials (e.g. frequency/duration of visits to webpages for FCU-online materials).

Aim 2a and 2b: Main-effects of FCU on mechanisms and outcomes. In line with NIMH's emphasis on experimental therapeutics, a core goal of the proposed project is to demonstrate that the adapted FCU-Online program successfully engages the hypothesized mechanisms of intervention effects (improved self-regulation, improved parenting, and reduced parental depression), as well as hypothesized outcomes. We will examine the main effects of the FCUOnline on mechanisms and outcomes using intent-to-treat analyses, examining all families assigned to the intervention or control group regardless of dosage.

Because the RCT employs a waitlist control condition, with waitlist families offered the intervention following the 4-month assessment, ITT analyses of primary concern focus on possible outcomes at 2-month and 4-month assessments. Time-specific effects of treatment will be examined as regression analyses, predicting time-specific outcomes at wave 2, 3, and 4 by a binary treatment-assignment variable, controlling for baseline levels of the outcome. We will also examine trajectories of change across multiple assessment waves, employing latent growth models, with treatment assignment predicting the rate of change in the outcome over time (e.g. Singer, Willett, & Willett, 2003). We predict significant benefits of the intervention, compared to the control condition, on putative mediators and outcomes at the 2-month and 4- month assessment points. Because the waitlist control group will be offered the FCU-Online following the 4-month assessment, we expect attenuated treatment and control-group differences at the 6-month assessment.

Aim 2c: Examination of mechanisms of FCU effects. Although the main-effects analyses for Aims 2a and 2b represent our core approach to demonstrating our ability to engage both mechanisms and outcomes, we will also formally test mediation of effects on outcomes via the proposed mechanisms. Analyses for Aim 2b will involve tests of mediation, using path modeling approaches that test the statistical significance of the indirect effect of the intervention on targeted outcomes through proximal mediators. Due to the waitlist-control design, we will examine intervention effects on the mediator at 2-months, to the outcomes of interest at 4-months. We will also explore intervention effects on the mediator at 4-months, to the outcomes at 6-months, although the waitlist control condition will be offered the FCU-online between the 4-month and 6-month assessment, which may attenuate treatment and control-group differences at the 6-month assessment. Indirect effects will be tested using Bootstrapped Standard Errors(MacKinnon, Lockwood, Hoffman, West, & Sheets, 2002).

D. Research Population & Recruitment Methods

Focus Groups

Focus groups composed of parents of middle school-aged children and those who provide services to these families will be recruited from the community via snowball sampling. The family consultants on this project regularly attend a monthly community partnership meeting of various service agencies that support families at a local middle school. A flier about the provider focus groups will be shared via a listserv with this group (see "MSSOS Provider Focus Group Flier"). Harry Applebaum, the school social worker, manages this listserv and routinely sends out messages similar to this from other organizations engaged in the community partnership group. He has verbally agreed to send out a flier on our behalf. Fliers about family focus groups will also be distributed to our contacts within local community agencies via this listserv (see "MSSOS Parent Focus Group Flier" and "MSSOS Spanish Parent Focus Group Flier"). Our contacts will be asked to pass the

flier out to anyone they think would be interested in participating in the parent focus groups. Fliers will include contact information so that those interested in participating can contact project staff directly.

Potential participants in the Parent focus groups will be screened by our recruiter (see "screening and consent script_Parent focus group_5.25.2021" and "screening and consent script_Spanish Parent focus group_5.27.2021"). In order to participate in focus groups, they will need to be a parent or legal guardian of a child age 10-14, and they will need to speak and read either English or Spanish. If parents meet screening criteria, our recruiter will then go over all of the elements included in the focus group consent form (see "focus group informed consent_5.25.2021 and "Spanish focus group informed consent_5.27.2021") and answer any questions the parent might have about the project. If parents are still interested in participating, the recruiter will then send them a link to a Qualtrics version of the consent form. Once the consent form is signed, the recruiter will send them a link and password for an upcoming focus group conducted via HIPAA-compliant Zoom. Qualtrics will be programmed to automatically send participants a copy of the consent form for their records. Focus group participants will receive a $50 check or gift card to compensate them for participating in a 60-minute focus group.

Potential participants in Provider focus groups will be screened by our recruiter (see "screening and consent script_Provider focus group_5.25.2021"). In order to participate in focus groups, they will need to be a staff member at an organization that serves low-income families that include children age 10-14, and they will need to speak and read English. If providers meet screening criteria, our recruiter will then go over all of the elements included in the focus group consent form (note that this is the same consent form as the one used with parents, described above) and answer any questions the provider might have about the project. If providers are still interested in participating, the recruiter will then send them a link to a Qualtrics version of the consent form. Once the consent form is signed, the recruiter will send them a link and password for an upcoming focus group conducted via HIPAA-compliant Zoom. Qualtrics will be programmed to automatically send participants a copy of the consent form for their records. Provider focus group participants will receive a $50 check or gift card to compensate them for participating in a 60-minute focus group.

Pilot Study

Our target sample is 180 low-income families with children aged 10-14. Recruitment will occur over 6 months (September 2021- Feb 2022) from a variety of local community organizations that serve low-income families, such as Rowe Middle School, the Wichita Center for Family and Community, Northwest Family Services, and the Office for Students with Children at Portland State University. A letter of support from the principal of Rowe Middle School has been provided (see "Rowe Letter for IRB-Zerizef"). Letters of support from the other organizations will be provided in future modifications, if needed. The ethnicity of the sample is expected to be consistent with that of families in Oregon, with about 78% white, 12% Latino, 5% Asian American, and 5% African American. Although we do not have a specific recruitment target for Spanish-speaking families, we will welcome their participation in this project. All materials (including the app) will be available in Spanish and English, and a bilingual family interventionist will provide telehealth consulting for Spanish-speaking parents. We strive to be as inclusive as possible to encourage participation from a variety of caregivers: biological parents, adoptive parents, foster parents, and grandparents or other adult family members serving in the capacity of legal guardian.

Recruitment Process:

Providers in each setting will be provided with both Spanish and English fliers (see "FCU Recruitment Flyer_final copy" and "Spanish FCU Recruitment Flyer") that briefly describe the study and refer parents to our English and Spanish recruitment website (www.middleschoolstudy.org). Providers will be encouraged to distribute these flyers in their community via listservs or any other method that makes sense in their community/ organization. Once at the project website, parents can learn a bit more about the project and complete a contact form to request further information about how to enroll in the project. Our recruiters will then contact all the parents who provided contact information in order to confirm language preference, explain the goals of the study, and provide details about participation (see "MSSOS Recruitment Screening Script"). As part of the recruitment call, recruiters will go over the key elements of the consent form and answer any questions that parents might have about the study. The recruiter will clarify with the parent the type of devices available to the parent and child for completing the assessments (i.e., smart phone only, or do they have access to a tablet or PC?), and their preferences for method of completion (i.e., on their own, as an interview via a HIPAA-compliant Zoom account, or as a phone interview). If the parent has access to a PC or tablet and wants to complete the assessment on their own, the

recruiter will email them a link to complete the survey through Qualtrics, along with a "special word" that will serve as their unique identifier on the survey. If the parent only has access to a smartphone, the recruiter will schedule the parent to complete the survey as an interview with a staff member via Zoom or phone (based on the participant's preference). Similarly, youth will have the choice to complete the survey on their own through Qualtrics or as an interview via Zoom. If the parent is unable to schedule an appointment for their child at the time of the recruitment call, the recruiter will call back at a later time to schedule the youth assessment. Youth who will be completing the survey on their own will go through the assent process over the phone; Youth who complete it as an interview will go through the assent process at the time of the interview. After this recruitment phone call, parents who indicate interest in the study and meet inclusion criteria (see criteria below) will be emailed a link to a Qualtrics version of the consent form (see consent form) and asked to type their name and the date into the Qualtrics form to indicate their consent to participation. The Qualtrics form will be programmed to automatically email a copy of the signed form to the parent for their records.

The following criteria exist for inclusion/ exclusion in this research study.

To be included in the study:

- A caregiver must have a child between the ages of 10 and 14;
- the caregiver must be the parent or legal guardian of the participating youth;
- the caregiver must have a smartphone with text messaging capability and access to email; and
- the caregiver must score at least 1 or above on the Patient Health Questionnaire-2, or score at least 2 on any item of the Perceived Stress Scale-4 .

Families will be excluded from the study if:

- the caregiver is unable to read in either English or Spanish;
- the child is unable to complete the survey (or survey as interview with project staff help) without parent's help; or
- the family is already participating in another study of the Prevention Science Institute.

Two parents may participate in assessment and intervention when applicable, but compensation will be once per household.

Recruiting aids:

Parents will be compensated for their participation in the research study. Parents will be paid for all *research* assessments (as opposed to the brief 5-minute assessments that are integrated into the app) and can earn up to $300 for their participation. Intervention and waitlist control families will receive equal compensation. All parents will be asked to complete the *research* assessment 4 times within a year: at baseline, and then follow-up assessments at 2 months, 4 months, and 6 months after baseline. Parents will receive one $75 check or gift card per household after completing and returning each assessment. Youth will be paid $25 (via check or gift card) after completing the baseline assessment and again after completing the 6-month follow-up assessment.

Recruiters:

Participants will be recruited by paid research staff of the Prevention Science Institute. They will complete CITI training to ensure a basic understanding of research ethics in human subjects research. In addition they will be trained by the project coordinator to be courteous, to follow the recruitment script, and to answer all questions posed by potential participants honestly and in simple language potential participants can understand.

E. Informed Consent Process

Focus Groups

The consent process for focus group participants was described above in the recruitment section. To recap, parents and providers who indicate interest in participating in focus groups during the recruitment call and meet inclusion criteria will proceed to the consent process (see "screening and consent script_parent focus group," "screening and consent script_Spanish Parent focus group_5.27.2021," and "screening and consent script_provider focus group"). Our recruiter will

go over all of the elements included in the focus group consent form (see "focus group informed consent_5.25.2021" and "Spanish focus group informed consent_5.27.2021") and answer any questions the parent or provider might have about the focus groups or the wider project. If the parent or provider are still interested in participating, the recruiter will then send them a link to a Qualtrics version of the consent form. Once the consent form is signed, the recruiter will send them a link and password for an upcoming focus group conducted via HIPAA-compliant Zoom. Qualtrics will be programmed to automatically send participants a copy of the consent form for their records.

Pilot Study

The consent process for parents was described above in the recruitment section. To recap, our recruiter will go over the key elements of the consent form during the recruitment call, and answer any questions that parents might have about the study. Parents who indicate interest in participation and meet inclusion criteria will be emailed a link to a Qualtrics version of the consent form. They will be asked to type their name and the date into the Qualtrics form to indicate their consent to participation. The Qualtrics form will be programmed to automatically email a copy of the signed form to the parent for their records.

In the case of foster families, we will obtain permission from the foster parent to contact the child's caseworker. Our recruiter will go over the key elements of the consent form with the case worker (see case worker script), and answer any questions that he/she might have about the study. Caseworkers who agree to a child's participation will be emailed the same link to the consent form. They will be asked to type their name, title, and date into the Qualtrics from to indicate their consent to the child's participation. The Qualtrics form will be programmed to automatically email a copy of the signed form to the caseworker for their records. Once the caseworker's consent has been obtained, the recruiter will return to the foster parent and go through the parent consent process detailed above in order to obtain the foster parent's consent for their own participation.

The assent process for youth will proceed a bit differently. We will obtain verbal assent from youth. As described above, youth will have the choice to complete the assessment independently via Qualtrics survey or as interview with research staff. Youth who choose to complete the assessment independently will go through the assent process over the phone with research staff and will receive a copy of the assent form via mail or email soon thereafter. For youth who choose to complete the assessment as an interview, these appointments will occur through either a HIPAA-compliant Zoom account or phone, depending on family preference. At the time of this appointment, the research assistant will open up a Qualtrics form containing the assent form, go over each element of the form (sharing screen, if appointment occurs via Zoom, in order to allow the child to more easily follow along), and answer any questions that the child might have about the project and their participation. The child will then be asked if they assent to participate in the study. If they assent, the research assistant will check a box on the form indicating that they received verbal assent, type the child's name, their own name, and the date, and proceed with the interview. A paper copy of the assent form will be mailed to the child via USPS after the interview has been completed. If the child does not assent to participation, the child will be thanked for their time and the appointment will come to an end.

Our recruiters will conduct the consenting process for the focus groups and for the parents participating in the pilot study, and research assistants will conduct the assent process for the youth participating in the pilot study. All of these staff members will complete CITI training to ensure a basic understanding of research ethics in human subjects research and the significance of the informed consent process. They will be trained by the project coordinator to follow a consenting/ assenting protocol, to review each element of the consent document, to explain procedures in simple language, and to allow adequate opportunity for participants to have their questions answered.

We are aware of the consent form posting requirement which mandates that the informed consent form must be posted on clinicaltrials.gov after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject. We intend to fulfill this protocol requirement and will post the consent and assent forms accordingly.

Currently enrolled participants who consented/ assented to a previous version of the consent and assent document will be called on the phone and told of the changes to the study (i.e., now there are fewer waves of data collection for youth, youth will be paid for their participation, and they will have an option to complete the assessment as an online survey). Parents will be sent a copy of the new consent form and asked to sign electronically and return it. Youth will be asked to

provide verbal assent over the phone, and mailed a copy of the assent form with a payment for the assessment they previously completed.

F. Provisions for Participant Privacy and Data Confidentiality

Focus Group Confidentiality: Focus groups will be held via Zoom using a HIPAA-compliant Zoom account issued through the University of Oregon. Focus group participants will be asked to prepare for the focus group by temporarily removing their last name from their zoom profile (i.e., so that only their first name will appear in their "box"). Once in the focus group, we will ask that focus group participants only use first names when speaking to each other to help protect each other's confidentiality. We will also ask that they respect each other's privacy and not share information revealed in this focus group with persons not currently present.

One-on-One Interview Confidentiality: Interviews will be held via Zoom using a HIPAA-compliant Zoom account issued through the University of Oregon.

Initial visit and Feedback sessions: The Initial Visit and Feedback sessions will occur via phone or Zoom (based on parents' choice) and recorded via Zoom in order to evaluate consultants' fidelity to the intervention model (i.e., how well the consultant adhered to each element of the Family Check-Up model during their appointments with a given parent). If a parent chooses to complete these sessions by phone, the consultant will put the parent on speaker phone and start a Zoom "meeting" with themselves, recording the meeting. The only image that would be appear in this recording is the consultant's black screen. After the meeting is over, the video portion of the recording would be deleted while retaining the audio file. If a parent chooses to complete the meeting via Zoom, the meeting will be recorded. It is likely that both the parent's image and the consultant's image would be recorded (assuming they both choose to share their video), but, again, the video portion would be deleted after the meeting is over and only the audio file would be retained.

We will be using the HIPAA-compliant version of Zoom, which establishes strict access control rules and strong AES256 encryption to prevent transmission of any PHI (protected health information), for focus groups, interviews, and one-on-one meetings between parents and family consultants. Focus groups will be recorded in order for research staff to transcribe the key themes that arose in the meeting. One-on-one meetings between parents and family consultants will also be 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, and then deleted from the local machine once the recordings have been safely transferred to the server. The recordings saved to the server will include both audio and video files for the focus groups, but only audio files for the one-on-one meetings between parents and family consultants (the corresponding video files will be deleted prior to the upload process). All files will be saved with participant ID numbers, not names.
All records obtained from subjects will be kept on secured servers. In addition, questionnaire data will be identified by subjects' identification numbers, not by their names. 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. Video recordings obtained from the focus groups will be stored in password protected files on a University owned computer until no longer needed. They will be analyzed for feedback and development purposes and deleted at the completion of the study. Audio recordings obtained from the one-on-one meetings between parents and family consultants will be analyzed by trained coders (members of the research team), who will evaluate the degree to which the family consultants incorporated elements of the classic Family Check-Up into their coaching sessions. These recordings will be retained for the duration of the study.

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 app being developed for this project will be 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.

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. Parent consent forms will always be reviewed with participants to ensure that the parent's questions are answered and to cover all of the details.

This project is funded by NIDA, and as such we will automatically receive a Certificate of Confidentiality from NIH for this study once the initial IRB protocol is approved. This Certificate will protect the project staff from being forced to release any research data in which participants or family members are identified, even under a court order or subpoena. This protects participants from being identified in any civil, criminal, administrative, legislative, or other proceedings whether federal, state, or local. This protection, however, is not absolute. For example, the investigators will report child abuse to the appropriate authorities.

Because this research is sponsored by the National Institute on Drug Abuse, NIDA, NIH, and the Institutional Review Board and internal University of Oregon auditors may review records that identify participants or family. However, it is the policy of these agencies and of the project staff that every attempt will be made to resist demands to release information that identifies participants and their families. When results of this project are published, participant names will not be used. The Certificate of Confidentiality will not represent an endorsement of this research project by the National Institute of Health.

Per the terms of the funding contract from NIH, de-identified study data will be deposited with the NIMH National Data Archive to increase its utility to qualified inidviduals within the scientific community. De-identified data will be shared via the NIMH National Data Archive using a Global Unique Identifier (GUID) for each participant. Direct requests for data from other researchers and the public will be also considered, and data will be made available in accordance with local institution policies, IRB recommendations, local/state/federal laws and regulations, and considerations for publication. Any applicable data sharing will follow HIPAA rules. In order to access these data, the NIMH Data Archive will require a data use agreement (DUA), which will provide for (1) a commitment to using the data only for research purposes and not to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed. The data sharing agreement will also assure that the analysis being proposed is appropriate given the design and data available. This data will be shared with the National Data Archive and approved scientists without additional informed consent from the research participants.

G. Potential Research Risks or Discomforts to Participants

Potential risks are minimal and include possible psychological or emotional risks and information risks involving breach of confidentiality.

Psychological or emotional risk. Participants may feel some discomfort completing questionnaires that ask questions about their child's development and family stress and well-being. Some participants may view the questions as minimally intrusive. Participants in the focus group will be asked to maintain confidentiality, but we cannot guarantee that they will not disclose information outside of the focus group. Participants in the intervention condition may feel shy or embarrassed when participating. To minimize these risks, participants will be assured that their participation is voluntary and they may skip any questionnaire item(s) they are uncomfortable with. All participants may request discontinuation of any procedure at any time if they experience undue distress. Consent forms will include contact information for our project coordinator, Dr. Allison Caruthers. Should parents/caregivers or children experience an adverse reaction to the assessments and require medical or psychological assistance, they may contact Dr. Caruthers, who will evaluate the situation and, if necessary, contact the PI, a licensed psychologist, to make appropriate referrals.

Breach of confidentiality. Confidentiality cannot be guaranteed in focus group settings. Although participants in focus groups will be asked to maintain confidentiality, we cannot guaranteed that they will not disclose information outside of the focus group. Participants will be notified of this risk during the consent process. Once data has been collected, we will minimize the risk of violation of confidentiality by coding all data so that it cannot be associated with any individual or family. Identifying information needed for participant contact, such as names, addresses, and telephone numbers, will be kept in password protected files and in our limited-access, password protected participant database. In addition, we will have a Certificate of Confidentiality from NIH for this study once the initial IRB protocol is approved. This Certificate will protect the project staff from being forced to release any research data in which participants or family members are identified, even under a court order or subpoena. This protects participants from being identified in any civil, criminal, administrative, legislative, or other proceedings whether federal, state, or local. Thus, the risk of violation of confidentiality is minimal. All participants will be required to read and sign the consent forms prior to participating in the study. Participants will be reminded about confidentiality and the exceptions to confidentiality before each assessment.

H. Potential Benefits of the Research

Benefits to participants may include: psychological or emotional benefits, learning benefits, and benefits to the scientific community in the form of generalizable knowledge.

Psychological benefits. Participants may enjoy thinking about their child's development and family situation and, in the Intervention condition, enjoy meeting with a consultant to discuss their family's circumstances. Families who participate in the Family Check-up may find the feedback sessions and parent training modules to be informative, supportive, and helpful. They may also find it interesting and rewarding to contribute to scientific research and advance knowledge about child development and family well-being.

Learning benefits. Parents/ caregivers who participate in the intervention may gain experience and knowledge that may assist them with their child's behaviors, school success, and parenting strategies.

Benefits to scientific community. Knowledge gained from this study may assist in the development of more effective, family-friendly web-based interventions and will help illuminate risk and protective factors for the adolescent age group, including ethnic, gender, and socioeconomic considerations.

I. Investigator Experience

Arin Connell, Ph.D., is the PI of the parent R01 which this project supplements. He has expertise in family focused prevention programming, including the Family Check-Up, with an emphasis on the examination fo the effects of such programs on reductions in youth depression and suicide risk.

Elizabeth Stormshak, Ph.D., will serve as the Oregon principal investigator of this project and leader of the local research team. She will oversee all aspects of this research, including intervention implementation, coordination with schools, and collection of data, data analyses, and dissemination of results. Dr. Stormshak is a Knight Professor in the UO College of Education and the director of the PSI, a research institute at the UO. She has worked at the UO for 22 years and has conducted intervention research across early and middle childhood. Her primary research focus is on school-based prevention of problem behavior in early and middle childhood, including substance use, behavior problems, and achievement problems. She has been the PI on multiple federally funded grants to test the efficacy of the Family Check-Up model with a culturally diverse group of urban and rural families. Her research focuses on refining intervention models to engage families in the intervention process and enhance long-term positive outcomes for youth.

Dr. Allison Caruthers, Project Coordinator, is a developmental psychologist with 24 years of data collection experience, including 15 years as a Project Coordinator and Research Associate on various projects at the Prevention Science Institute. In this role she has created research protocols and consent processes, and trained and supervised dozens of research staff to adhere to these protocols.

Spanish Translation and Intervention:
Spanish translations for the FCU app and for assessment materials have been conducted by **Francisco Hernandez** and **Julia Tienson**. Francisco is a recent graduate of George Fox University, where he earned a Master's degree in Education. He also

holds undergraduate degrees in Spanish and History. Francisco's first language is Spanish and he has worked as a translator and interpreter on many projects at the Prevention Science Institute. For this project, he will work as a recruiter and will also help collect interviews with Spanish speakers. Julia is a bilingual Spanish-speaking social worker. She has utilized her Spanish language skills in a variety of roles in various school districts, and has conducted the Family Check-up in Spanish for several other projects at the Prevention Science Institute. She will be providing the telehealth consulting for Spanish-speaking participants in this project.

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 Recruiters 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.

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 the PI or another doctoral-level, licensed psychologist.