

Official Title: Prevention of Substance Use in At-Risk Students: A Family-Centered Web Program

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Study Protocol

Research Plan

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Protocol Number: 07032014.004

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Research Plan Version Date: **March 18, 2019**

NOTE: The version date must be updated each time this Research Plan is revised whether or not the revisions are being requested by RCS during the review process or being proposed by the investigator through the submission of an Amendment Application.

A. Introduction and Background

This study aims to develop and experimentally evaluate a web-based version of the Family Check-Up (FCU) intervention for reduction of adolescent risk behavior and substance use. Substance use in adolescence is a clear public health concern, with developmental research suggesting an increase in substance use during the transition from middle to high school. Parent-child relationships are a consistent mediator between early-onset risk behavior and progression to adolescent substance abuse. Effective family management during adolescence can reduce risk behavior and substance use into the early adult years (Dishion & Patterson, 2006; Stormshak, Fosco, & Dishion, 2010).

During the past 20 years we have developed the FCU, a school-based model-driven intervention that targets early adolescence, reduces problem behavior and substance use, and promotes successful transition into high school. The FCU has been iteratively revised on the basis of multiple intervention trials and is designed to motivate parents to engage in positive parenting practices and to change problematic parenting (Dishion & Stormshak, 2007; Stormshak & Dishion, 2002). It has been tested across several school-based, randomized controlled trials with diverse populations (Connell et al, 2007; Dishion et al, 2008; Stormshak et al., 2009; Stormshak et al., 2011). Because school systems lack the necessary infrastructure and resources to deliver such an intervention, they would benefit from an online package that is evidence-based and accessible to parents. Yet, few family-centered, web-based interventions for substance use prevention exist, and few if any are derived from empirically based programs. In this study we will develop an internet version of the FCU for middle school youths, test the feasibility and uptake of the FCU on a small sample, and examine the efficacy of the FCU-Online version on a larger sample of middle school youths randomly assigned to receive either a web/mobile-only version, a web/ mobile+coach version, or services as usual.

B. Specific Aims/Study Objectives

Aim 1: Design and evaluate a web-based FCU intervention for at-risk families of early adolescents (ages 11-14) that is guided by feedback from focus groups and targets known risk factors of later substance use. The program will feature online assessment and feedback to caretakers delivered either via phone or internet. An intervention website application and mobile messaging will support delivery of program modules and help motivate and facilitate tracking of activities.

Aim 2: Examine the efficacy of the FCU-Online intervention by conducting a randomized, controlled trial of 300 at-risk middle school youths. Research suggests that a live coach enhances outcomes associated with web-based interventions; however, a web-based intervention that requires no coaching can be widely disseminated and has greater potential for a large public health impact. We will examine outcomes associated with a web/ mobile + coach version and a web/ mobile-only version of the FCU. Families will be randomly assigned to the FCU-Online intervention (100 web/ mobile+coach, 100 web/mobile-only) or a waitlist control group that receives middle school as usual for 12 months and then access to the web/mobile only condition (n=100).

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Aim 2.1: Evaluate main effects of both versions of the FCU-Online, including academic achievement, behavioral control, family cohesiveness, and delayed onset of substance use.

Aim 2.2: Test a developmental, mediational model in which parenting skills and behavior mediate changes in youth behavior over time. It is expected that families who receive the FCU will show reductions in growth of youths' risk behavior, compared with the waitlist control group. Reductions will be mediated by positive changes in parenting behaviors and parenting skill development.

Aim 2.3: Examine moderators, including gender, ethnicity, and socioeconomic status, and model intervention effects by testing moderators over time. We will assess the feasibility of the FCU as an internet-delivered intervention in middle schools, the extent to which participants engaged in the intervention and complete the program, satisfaction with the program, and effects of the FCU on improved parenting skills, positive youth adjustment, and reductions in youth problem behavior over two years.

Aim 2.4: Examine factors related to successful uptake and implementation of the intervention in schools. The public health impact of an internet intervention is diminished if uptake of the intervention is poor. To understand factors related to implementation in schools, we will train school personnel at the end of the project in delivery of the FCU-Online intervention. We will assess feasibility, usage, coach fidelity, and uptake through engagement data collected via the website. Data from teachers and school administrators will be collected to examine factors that promote implementation in schools and that further our understanding of how this intervention will be applied in a real-world setting.

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, recruit schools for participation, program website, develop survey and questionnaires	Current – Fall 2016	N/A	Completed
1a. Focus groups with school staff and parents	May/ June 2016	Staff N=16; recruited from the schools selected in Spring 2016. Parent N=16; recruited from community. Participation will last 45 min.	Completed
1b. Usability testing	Fall 2016	N=5; recruited from Prevention Science Institute staff.	Completed
2. Pilot Study	Fall 2016	N=12 families with middle school-aged youth recruited from community.	Completed

3. Main research study	Winter 2017-Winter 2019	N=300 families of participating youth. Recruited over two school years. Participation will last 12 months.	Completed for Cohort 1; On-going for Cohort 2
4. Focus groups with parents of young children to modify existing website	Winter 2019	N=16; recruited from community. Participation will last 90 min.	On-going
5. Implementation in schools	2019	N= 5-10 school personnel; recruited from the schools who participated in the main research study. Participation will require about 15 hours of time spread out over 6 months. N=50-60 parents of middle school youth; recruited from the schools who participated in the main research study. Participation will require about 2 hours of time, spread out over 6 months.	Not yet started; will begin in April 2019

Formative Research Procedures

1a. Focus groups (N = 32). During the first year of the study, we will design an interactive, engaging, Internet-based version of the FCU. Although the Internet-based version will be based upon the FCU model of treatment, our development work will be guided by iterative formative research that includes use of focus groups and usability testing. Four focus groups will include parents and school personnel (8 per group for a total of 32 users) to elicit ideas and opinions about the content, structure, and aesthetic design of a web-based program. Focus groups will be held in a private setting in the school, such as a conference room or empty classroom. We will elicit feedback and ideas 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 audio-taped 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 questions about their perceptions about parenting and child behavior and perceived barriers to receiving family support. Parents will also be asked about positive and negative experiences with computer education systems and preferences for presentation format. We will then provide an overview of the FCU Online program, including the purpose of the website and its proposed structure. This would include coverage of the three main elements of the website: an appraisal (aka the FCU assessment), feedback, and "Things to Try", a series of parenting skills training units that include brief videos and animations, interactive elements, tracking tools, quick tips, and a library of relevant articles and resources. This overview will also highlight the use of text messaging and the role of Coach consultations. Mock-ups of selected webpages will be presented, including a welcome page, the FCU assessment, the feedback page, and one or more of the skills training units (e.g., Encouragement and Praise; Using Incentives; Limit Setting; Open Communication). At various points, participants will be asked a series of questions designed to elicit opinions and set the occasion for group discussion (see attached discussion

questions). 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 school staff will begin with questions about parenting resources available to parents at their school and perception of barriers to working with parents in schools. We will then provide the same overview of the FCU Online program described above, pausing periodically to ask questions designed to elicit opinions about the program and website. (See attached discussion questions.) 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 schools and how we might enhance that fit.

1b. Usability testing (N = 5). The web-based intervention will embody established usability standards (Lynch& Horton, 2008, 2013). After functional program components have been created, usability testing will begin. Usability testing will help us improve the web-based programs and the manner in which participants are likely to use them. Five participants will be recruited to participate in usability testing. Individual participants will sit with a research staff member and log in to the website. Participants will be given tasks to do such as complete the online assessment, view videos, use interactive tools, and evaluate text messaging prompts. As they complete these tasks, participants will be asked to talk about what they are doing, what they are paying attention to, what is burdensome, what they like and dislike, and what’s confusing. Participants will provide feedback on program completeness and relevance and on the extent to which the program functions properly (e.g., that buttons work when clicked). Participants may be prompted to provide more detail about their comments, as needed. Participants will also complete the Website Feedback Survey. Hearing participants’ running commentary will enable the staff member to take notes in real time about aspects of the website that need to be improved before releasing it for the pilot study. We will then refine measures and website tools to ensure that instructions are clear and that they do not present too much burden on users. Usability testing will be scheduled to occur after the focus groups so the program can benefit from this feedback. Usability testers will receive \$100 for their time and effort. These participants will be recruited from the Prevention Science Institute via flyer and word of mouth. We anticipate that total participation time for an individual would be 90 minutes.

2. Pilot study (N=12 families). The pilot study will be a test of the main study. After preparing materials and receiving feedback from the focus groups and usability testing groups, we will complete our final version of the survey and a close-to-final version of the FCU online application. At this point we will run a short **Pilot Study** that will approximate the main research study described below in Section C3. **For the pilot study,** we will recruit 12 8th grade families from the same middle schools as the main study. We will assign half the families to the web-/mobile + coach condition and half to the web/mobile-only version (see details about recruitment in section D below). We will collect a pre- and post- assessment battery from each family and have parents complete the FCU-Online intervention. We will interview each participant about their experience and adapt the materials as needed, based on their feedback. Families will receive \$200 for participating in the pilot study.

Participating families will be sent a packet that includes a parent consent form(see attached), youth assent form (see attached), the parent and youth surveys (see attached), and 4 self-addressed, stamped envelopes so that each consent and survey may be mailed back separately to project staff. One week after mailing this packet, a paid staff member will call the caregiver, go over the Pilot Study consent and assent forms over the phone, and see if the caregiver or youth have any questions about the consent form or the survey. If the family has not yet returned the surveys, they will be reminded to do so as soon as possible.

Once project staff receive the surveys and consent forms, participating families will be randomly assigned to one of two conditions (web/mobile- only or web/mobile + coach). Participants will then receive an email that provides instructions about next steps. This email will vary based on condition. Participants in the web/mobile- only condition will receive an email with an explanation about the website and information about how to log in. Participants in the web/mobile + coach condition will receive an email with an explanation of the website, information about how to log in, and the name and email address of the coach who will be working with them. The coach will contact families in this second condition after they log in to the website for the first time, unless the participant reaches out to the coach first.

Participants in the web-mobile only condition will log on to the FCU Online website where they 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 (see fuller description below in section 3). 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 website. Parents will be able to log-in as often as they like and interact with any of the parenting modules on the website. Note that the website will not be complete at this time. Although participants are welcome to browse as much of the website as they desire, they will be asked to focus their attention and feedback on the online assessment and “positive parenting” skills training.

Participants in the web-mobile + coach condition will log on to the same FCU Online website where they will have access to the same assessment, materials, and tools. In addition, a Family Coach will contact them to help them set goals, talk through their results, offer support over the phone, and help motivate parents to improve parenting practices. Parents will be able to log-in as often as they like and interact with any of the parenting modules on the website. They will also be able to contact their Family Coach as often as they like and will have at least 2 scheduled phone sessions with a coach.

Two weeks after completing the Pilot study pre-test, participants will be asked to complete a post-test assessment and schedule a meeting with a staff member to 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 (see attached). During the meeting with a staff person, participants will be asked a subset of the questions used in the earlier focus groups about what they liked and didn't like about the website, surveys, tools, etc.

3. Main Research Study

We will recruit and randomly assign 300 families with middle school youths (6th and 7th grade) to one of three conditions: (a) web/mobile + coach intervention (n=100), (b) web/ mobile-only intervention (n=100), or (c) waitlist control group (n=100) that will receive middle school as usual and then offered the web/mobile-only intervention immediately after completing their final time point of data collection (12 months after enrollment). This design will enable us to compare outcomes associated with the web/ mobile-only intervention with a coach version. Participants will be randomly assigned to condition within school such that each school will have a similar number of participants in each of the three conditions. Participation in this study will be 12 months for all families, regardless of condition.

Families in all three conditions will be mailed a packet that includes a parent consent form, youth assent form, the parent and youth surveys, and 4 self-addressed, stamped envelopes so that each consent and survey may be mailed back separately to project staff. This “pre-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 and take about 30 minutes to complete. At the time of the pre-assessment, parents will also be asked to provide research staff with their driver's license number. We collect these because they assist us in relocating families for subsequent phases

of this longitudinal research project if they were to become lost. Our research team subscribes to a service which allows us to search for individuals by DL numbers to obtain a new address or phone number from items such as utility bills. Driver's license numbers will be retained for the duration of the research project. Participants will be assured that this information will be kept private, consistent with other data collected, and will be destroyed no later than 5 years after the end of the project.

One week after mailing this packet, a paid staff member will call the caregiver to see if the caregiver or youth have any questions about the consent form or the survey. If the family has not yet returned their surveys, they will be reminded to do so as soon as possible.

Once project staff receive the completed surveys and consent forms, participating families will be randomly assigned to one of three conditions (web/mobile- only, web/mobile + coach, or waitlist control). Participants will then receive an email that provides instructions about next steps. This email will vary based on condition. Participants in the **web/mobile-only condition** will receive an email with an explanation about the website and information about how to log in. Participants in the **web/mobile + coach condition** will receive an email with an explanation of the website, information about how to log in, and the name and email address of the coach who will be working with them. The coach will contact families in this second condition after they log in to the website for the first time, unless the participant reaches out to the coach first. 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 3 months.

Participants in the **web-mobile only** condition will log on to the FCU Online website where they 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 (see fuller description below in section 3). 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 website. Parents will be able to log-in as often as they like and interact with any of the parenting Skills Sessions on the website.

Participants in the **web-mobile + coach condition** will log on to the same FCU Online website where they will have access to the same assessment, materials, and tools. In addition, a Family Coach will contact them to help them set goals, talk through their results, offer support over the phone, and help motivate parents to improve parenting practices. Parents will be able to log-in as often as they like and interact with any of the parenting Skills Sessions on the website. They will also be able to contact their Family Coach as often as they like and will have at least 2 scheduled phone sessions with a coach.

Families in all three conditions will be invited to participate in follow-up questionnaires at 3 months, 6 months, and 12 months that will be identical to the pre-assessment so that we can evaluate change over time in the assessed constructs. The estimated time needed for parents and youth to complete each of these follow-up questionnaires is 30 minutes. At each of these three assessment points parents and youth will be mailed a questionnaire packet and return them independently to the research team in their own self-addressed stamped envelope. At the time of the 3-month follow up, parents in the two intervention conditions will also complete a 2-page Website Feedback Survey. These surveys will also be completed by mail.

All families will be compensated for their time. Each family will receive \$100 for completing assessments at baseline, 3 months, 6 months, and 12 months for a total of \$400. Because sustained family involvement in a longitudinal study is critical to maintain, families will be offered a \$50 bonus if they complete all 4 assessment points.

Unfortunately, the website is only offered in English. However, Spanish-speaking families at these schools will still be offered options to allow them to participate in the study and/ or receive the intervention if they desire. Spanish speakers who are comfortable reading English will be randomly assigned to one of the three experimental conditions described above, but will have an option to complete the pre-assessment and follow-up assessments in either English or Spanish (and the website in English). Those who are not comfortable reading English will still be offered the opportunity to participate and be compensated, but will be assigned to a **nonexperimental tele-health condition** described below. All of the information available online in the parenting skills modules has been translated into Spanish and will be presented to these families via pamphlets.

FCU intervention protocol. The FCU-Online version being developed for this research study will motivate caregivers to promote and 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 two intervention conditions will be invited to participate in the intervention once research staff receive their completed pre-assessment. Parents in **both conditions** will receive an email invitation to log into the FCU website with their "special word". This step allows families to create a page that is exclusively viewed by the parent or parents who choose to participate. Parents will then create goals and learn about the FCU-Online process. Parents will then be directed to an online assessment, which is brief and informative. This assessment is very similar to the parent survey of the pre-assessment, but is briefer and takes about 20 minutes to complete. There is no youth component to the online assessment. After the assessment has been completed, parents in the **web/mobile only condition** will complete their feedback session online. They will receive feedback in written format, generated by the program, and will choose from a menu of options to engage in follow-up intervention. We will create algorithms that generate the feedback and that highlight family strengths and areas of growth. Written feedback will be interactive as parents select different areas highlighted by the feedback form to learn more about their strengths and areas of growth, guided by motivational interviewing text that is tailored to the particular parent assessment.

For the **web/mobile + coach condition**, a coach will contact the parent for an initial phone session after they have logged into the website for the first time to conduct an "initial interview" over the phone. The initial interview will set the stage for the assessment and intervention and motivate parents to engage in the program. Parents will then be directed to complete the online assessment, which is identical to the one used in the web/ mobile only condition. After completing the assessment, parents will view the feedback online, with either phone or video conferencing support from the coach, who will be using motivational interviewing to provide feedback on both strengths and areas of growth based on the assessment. The coach will help parents set goals in terms of intervention targets and will then arrange to check in with the parent another 2-5 times about their progress. The first check-in will occur after one skills session of the online parenting curriculum has been completed, or after 2 months, whichever comes first. Families may then contact the coach by posting a question or concern online in an "ask the expert" format. The coach will respond within 24 hours via text, email, or phone. Additional meetings may be scheduled as needed.

The **nonexperimental tele-health condition has been developed for Spanish-speaking populations** and is somewhat similar to the web/mobile +coach condition. Participants in this condition will complete pre-assessments and follow-up assessments in Spanish, and will receive a tele-health version of the intervention via mail and phone communication with a Spanish speaking coach. Over the phone, a Spanish speaking coach will provide feedback to the parents on the data that they provided, and suggest areas for skill development. The family and coach will decide together which areas they want to work on, and the coach will mail the relevant pamphlets to the family. The coach and family will continue to meet over the phone as desired to make progress towards the parents' goals.

After the feedback, a menu of options tailored for the family and based on the assessment will be presented to families in **both treatment conditions**. These options, described below under "Content of follow-up sessions" will be Skills Sessions-guided by our Everyday Parenting curriculum. The Skills Sessions will be delivered online to both treatment conditions and consist of content and structured activities that are designed to help parents learn each skill. In the **web/mobile+ coach condition**, a coach will check in with parents to assess progress and support gains in positive behavior. In the **web/mobile-only condition**, parents will complete the Skills Sessions at their own pace without these check-ins. Parents in either of these conditions may log in to the website as many times as they like to learn more or participate in any of the other Skills Sessions.

After completing the FCU, families will continue to participate in the post-tests previously described. These post-tests occur at 3, 6, and 12 months after the pre-assessment. At the end of the 3 month post-test assessment, parents will also be asked to complete a Website Feedback 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 mailed to participants along with the 3 month post-test. 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 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. Each Skills Session will also highlight behaviors that target school success at this age, including homework completion, attendance, and home-to-school planning.

Positive parenting. Three teaching content areas will focus on positive behavior support: encouragement and praise, 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 "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.

Limit setting. This skills session includes establishing clear rules, limit setting, and identifying appropriate consequences. 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, such as homework completion. "Identifying appropriate consequences" includes working with the adolescent to develop incentives and consequences that are meaningful for reducing negative behavior and increasing positive behavior.

Monitoring. This content area will provide useful guidance to parents in how to monitor their child's behavior when they are away from home, how to encourage their child to keep them informed, 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.

Open communication. The "open communication" area teaches active listening skills and effective problem solving and negotiation skills. Activities and interactive content will be delivered to improve problem solving and communication skills, including activities online and via mobile texting.

Training and Monitoring of Coaches. Coaches will be trained in the FCU, motivational interviewing, and school-based interventions. A lead coach will oversee training and supervision of at least two other coaches who will also serve as the coach for some of the participants, to decrease bias in the intervention. All coaches will be trained, supervised, and supported to help them effectively implement the FCU. The supervising coach and two hourly coaches will be trained to reach a minimum level of competence via in-vivo role-play. Feedback with pilot families will be audio-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. Coaches 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).

4. Focus groups (N = 16). After the main study has been completed, two focus groups of 8 parents each will be conducted to elicit ideas and opinions about ways in which the content, structure, and aesthetic design of a web-based program may need to be adapted to accommodate parents of younger children. Focus groups will be held in a private setting. We will elicit feedback and ideas about the current 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 audio-taped 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 questions about their perceptions about parenting and child behavior and perceived barriers to receiving family support. Parents will also be asked about positive and negative experiences with computer education systems and preferences for presentation format. We will then provide an overview of the FCU Online program, including the purpose of the website and its current structure. This will include coverage of the three main elements of the website: an appraisal (aka the FCU assessment), feedback, and "Things to Try", a series of parenting skills training units that include brief videos and animations, interactive elements, tracking tools, quick tips, and a library of relevant articles and resources. This overview will also highlight the use of text messaging and the role of Coach consultations. Select pages of the website will be presented, including a welcome page, the FCU assessment, the feedback page, and one or more of the skills training units (e.g., Encouragement and Praise; Using Incentives; Limit Setting; Open Communication). At various points, participants will be asked a series of questions designed to elicit opinions and set the occasion for group discussion (see attached discussion questions). At the end of the session, participants will be asked to describe their overall reaction to the various features of the current 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.

5. Implementation in schools (N=70). In the last year of the project, we will train school personnel (e.g., school counselors) to deliver the FCU-Online intervention in their respective schools. These school staff members will now take on the role of “coach” that was described in the main study. For this phase of the research study, these staff members (and their ability to use the website to serve their communities) are the focus of study rather than parents. We will assess feasibility, usage, coach fidelity, and uptake through engagement data collected via the website. We will also interview these staff members to examine factors that promote implementation in schools to further our understanding of how this intervention could be applied in a real-world setting.

We will meet with principals at the schools participating in the main research study to gauge their interest in participating in this phase of the project and whether or not they have staff who regularly work with families and who have time to participate in the study. At most schools these staff members are likely to be the school counselors, but that may vary by school depending on school resources. After receiving principal approval, the appropriate staff members (n=5-10) would then be recruited directly via email to participate in the project.

Once they consent to participate, these “coaches” would be trained by a member of the research team to use the website designed for coaches/ school personnel. This training will take about 6 hours and will cover both the technical skills needed to use the website as well as training in ways to use the information provided by parents to facilitate conversations about parenting and student behavior. Coaches would then each identify 5-10 families (total parent N= 50-60) at their respective schools that they think could benefit from the intervention. To participate in the study, parents will need to speak and read English and have computer access so that they can access the website, and not have participated in the main research study. To make it easier to identify families who have not already participated in the main research study, coaches will be asked to only recruit 6th grade families (because families who already participated now have 7th and 8th grade students). All families who participate in the implementation study would be assigned to the **web/mobile + coach condition** described previously because we are mainly interested in assessing how school personnel function in the coach role.

Because the focus of the implementation study is school staff rather than parents, we will not be collecting baseline surveys or any of the follow-up surveys used in the main research study. Rather, parents will be identified by coaches, and enrolled directly in the website. After providing informed consent, parents will complete a qualtrics form that includes the information needed to enroll them in the website. The data provided via this form will be sent directly to research staff, who will use it to enter participants into the administrative website that triggers an email to participants thanking them for their willingness to participate and includes log-in information and directions for how to get started. Parents will complete the survey that is built into the website, receive computer generated feedback, and will then meet with their coach to discuss the feedback and the parenting modules presented on the website. The survey takes about 30 minutes to complete; parents may log-in and use the parenting resources as little or as often as they would like.

At the end of the study, parents will be asked to complete a 2-page Website Satisfaction Survey which will take about 10 minutes to complete. This survey will be administered via Qualtrics. An email with a link to the survey will be sent to parents approximately 6 months after they are enrolled in the study.

At the end of the study, coaches will be interviewed one-on-one by a member of the research team about the ways that they were able to use the website to work with families, any challenges that they encountered, and their insights into factors that could be improved to enhance implementation in schools. This interview will take approximately 1 hour.

Analysis

For our preliminary analyses, we will compare baseline characteristics of participants across conditions to test for significant differences; characteristics that differ across conditions will be used as covariates in subsequent analyses. Logistic regression analyses will be used to examine potential differences by study condition between dropouts and continuing participants on baseline measures. Attrition analyses will provide information about the external validity of the study, and interaction effects between condition and predictors will provide information about potential confounding effects (Cook & Campbell, 1979).

Aim 1: Design and evaluate a web-based FCU intervention that is guided by feedback from focus groups.

Stakeholder interviews, focus groups, and usability testing will be audio recorded for subsequent transcription. Content analysis techniques will be used to analyze the transcript text from open-ended questions. Coding of text will proceed in two stages. First, a topical indexing coding dictionary will be developed to identify the text pertaining to particular topics generated by focus group and usability testing questions. A more detailed coding scheme will be developed to capture the content, themes, or sentiment of responses within topics. Specific themes (i.e., content codes) within central concepts will be identified by the evaluation team, and all text pertaining to a specific topic will be coded individually by trained coders. Coder reliability for content will be determined through interrater comparisons of at least 20% of the randomly chosen text in major topical categories. This system of coding will allow us to understand the themes, or issues, related to particular topics, such as barriers to program engagement. It will also enable us to retrieve text illustrating the vocabulary used by participants to describe these issues. Analysis of participants' discourse may reveal statements such as the way they describe program engagement and features that may contribute to intervention modifications. This qualitative data will be categorized into general themes, and the proportions responding to each category will then be tabulated. These responses will be used to evaluate strengths and weaknesses of the intervention approach and to guide further program refinement.

Aim 2: Evaluate efficacy of the FCU-Online intervention

Aim 2.1: Analysis of main effects. The hypotheses tested in this aim are (a) families in each intervention condition will show significant improvements on the outcome variables, compared with youths in the control condition, and (b) families assigned to the web/mobile+ coach condition will have significantly better outcomes compared with those assigned to the web/mobile-only condition. The primary outcomes include academic competence, youth behavioral control, delayed onset of youth substance use, reduced family conflict, increased family cohesion, and positive family relationships. The secondary outcomes include the putative mediating mechanisms of parenting skills and behaviors. Families will be randomized to condition and will be the unit of analysis for all models. Mixed-effects analyses will be based on a hierarchical linear modeling approach in which students are nested within schools, primary outcomes are nested within individual students at Level 1 of the model, and between-subject predictors (fixed effects), such as treatment condition and child/parent demographics, will be examined at Level 2. For each of the three pairwise contrasts between conditions, intervention effects will be examined by modeling longitudinal trajectories across time with mixed-effects models using SAS PROC MIXED or mPlus software.

Aim 2.2: Mediation model testing. We will test whether change in the putative mediating mechanisms of parenting skills and behaviors (e.g., change from baseline to 3-month follow-up) mediate the association between study conditions and longitudinal trajectories of the youth and family outcomes.

Aim 2.3: Examine moderating effects and intervention process measures. The moderation analyses will follow recommendations by Kraemer and colleagues (2002) and analytic methods of Aiken and West (1991), Jaccard and Turrisi (2003), and Preacher et al. (2006). Because we do not have specific hypotheses

regarding the potential moderating mechanisms, these analyses are considered exploratory. Each of the potential moderating effects (e.g., child sex, race/ethnicity, SES, baseline severity of child behavior, primary caretaker sex) will be investigated by conducting the above-mentioned mixed-effects analyses for each outcome that incorporate the Moderator × Condition interaction term. Significant moderating effects will be further probed to understand the nature of the conditional relation, using computational tools recommended by Preacher et al. (2006; www.quantpsy.org). Treatment acceptability will be demonstrated by achievement of the following benchmarks: (a) high level of program usage (e.g., 80% of targeted parents completing the FCU assessment and feedback sessions), and (b) high degree of consumer satisfaction (e.g., mean ratings > 4 on a 5-point rating scale on the Website Feedback Survey). We will also examine whether baseline participant characteristics (e.g., child sex, ethnicity/race, SES, severity of child behavior) are associated with treatment acceptability, program usage, and program usability.

Aim 2.4: Uptake and usage assessment of FCU-Online implementation. Uptake and receptiveness of the intervention by participating schools will be evaluated based on the FCU-Online program use data and the FAM-SET implementation assessment. We will use benchmarks to evaluate uptake and receptiveness similar to those described in Aim 2.3. We will compare program use metrics and FAM-SET scores between the controlled efficacy trial and the open trial using descriptive statistics. The qualitative feedback from the FAM-SET will be used to identify themes related to the barriers and facilitators of successful uptake, implementation, and sustainability.

D. Research Population & Recruitment Methods

Focus groups composed of parents of middle school-aged children will be recruited from the community via flyers posted at schools and the public library and asked to contact our project office if they are interested in participating. Participants need to be a parent or legal guardian of a child attending middle school in Oregon; they need to speak and read English; and they need to have web access at home. Parents will be excluded from participation if their child has severe developmental disabilities or physical disabilities (e.g., autism, genetic disorders, Down syndrome). When parents call the project office, they will be screened using the parent focus group screening script. When a parent emails a response noting their interest to participate, we will thank them for their interest and ask for a phone number so that we may ask them a couple of questions; we will then screen the parent using the parent focus group screening script. Participants will receive a \$100 check to compensate them for participating in a 90-minute focus group.

Parent focus group participants will be provided written consent forms at the time of the focus group. The focus group facilitator will go over the consent form with the group to make sure that participants understand their rights and responsibilities as research participants. Participants will be given a copy of the consent form for their records.

Focus groups composed of school staff will be recruited from the schools who have agreed to participate in our focus groups. An email will be sent out to all staff members from the school secretary describing the focus group procedures. Interested staff members will be asked to respond directly to our project office. We will ask for their name, phone number, and email address in order to notify them of when and where the focus group will occur. Participants will receive a \$100 check to compensate them for participating in a 90-minute focus group.

Like parents, school staff participating in focus groups will be provided written consent forms at the time of the focus group. The focus group facilitator will go over the consent form with the group to make sure that participants understand their rights and responsibilities as research participants. Participants will be given a copy of the consent form for their records.

Usability testing will be conducted after the focus groups so the web-based program can benefit from user feedback regarding program completeness, relevance, and on the extent to which the program functions properly (e.g., that buttons work when clicked). Five individuals who work for the Prevention Science Institute will be recruited to participate in Usability Testing. These individuals will be recruited via flyer and word of mouth. Individuals interested in participating will contact project staff, who will screen for exclusion criteria. Potential participants will be excluded if they have ever received FCU training or if they have never worked with a computer at home or work. They will be required to meet face-to-face with a research team member. They are not required to be a parent in order to participate. If an individual meets screening criteria, project staff will schedule a time for the usability testing to take place. At this meeting, a staff member will explain the goals of usability testing, provide details about participation, risks, benefits, etc. Participants will then sign a consent form.

Usability testers will receive \$100 for their time and effort. We anticipate that total participation time for an individual would be 90 minutes.

A Pilot Study will take place during the winter of 2016/ 2017. Twelve families with a child in 8th grade 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 main study will work as is, or if they will need to be modified before the main study begins. This sample will be recruited from the middle schools participating in the main study. Principals will be asked to handpick 8th grade families who might be interested in participating in the pilot study. Principals will be given an email to forward to these families. This email will contain a link to Qualtrics to put in basic information: names, email, phone number, best time to call or contact, best way to contact (phone/ email/ text), child's school, and child's current grade. Parents will fill out the qualtrics form online. Once they are finished, the screen will tell them that someone from the project will contact them shortly about their participation and explain the project in more detail. A staff member will get an automated email from Qualtrics telling him/ her that another participant is interested. He/ she will call the interested parent and screen callers for eligibility. Inclusion criteria are:

- having a child in 8th grade at one of the enrolled middle schools;
- the child is free of severe developmental disabilities or physical disabilities (e.g., autism, genetic disorders, Down syndrome);
- the caregiver is the parent or legal guardian of the child;
- the caregiver must have a cell phone with text messaging capability; and
- the caregiver must have web access at home or be willing to access the web via computers located in the school or public library.

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 then be sent a packet that includes a parent consent form, youth assent form, the parent and youth surveys, and 4 self-addressed, stamped envelopes so that each consent and survey may be mailed back separately to project staff. One week after mailing this packet, a paid staff member will call the caregiver, go over the Pilot Study consent form over the phone, and see if the caregiver has any questions about the consent form or the survey. If the caregiver has not yet returned the surveys, he/ she will be reminded to do so as soon as possible.

Pilot Study families will be paid \$200 for their participation, paid in two chunks of \$100 each. Families will receive one \$100 check per household after completing the baseline pre-assessment; they will receive a second \$100 check after completing the post-test and attending a short meeting with a staff member to provide feedback on their research experience. As additional compensation, pilot study participants will have unlimited access to the full website after it is finalized for the main study and may utilize the tips and tools as often as desired.

Main Project Participant population and research setting:

All families of 6th and 7th grade students enrolled at one of 6 middle schools during the 2016-2017 or 2017-2018 school year will be recruited to participate in the main research study. Our target sample is 300 middle school students and their parents. 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. Because our target sample size is 300 students, we plan to accept approximately 50 families from each of the 6 schools. Recruitment will occur over two years, with approximately 100 intervention and 50 control families recruited for the study each year.

The sample will be recruited from 6 economically disadvantaged middle schools in Oregon, 2 each in urban, suburban, and rural areas of the state. We selected schools based on the percentage of students who qualify for free and reduced lunch. The percentage of qualifying students at each school is higher than the state average of 55%. We chose to recruit families from these three settings to increase the generalizability of our findings. Youths in these three settings may have different community norms regarding problem behaviors, and differential access to public transportation may mean different manners of engaging in problem behavior (i.e., different degrees of access to drugs, alcohol, and deviant peers). Families in these three settings may have different community norms regarding parenting behavior, and different degrees of access to mental health services or support for positive parenting. They may also utilize web-based resources with different frequency. Thus, it is important to see whether there are community effects on the successful uptake of a web-based parenting intervention.

Recruitment Process:

The principal at each school will send out an email to parents of 6th and 7th graders advertising this research opportunity (“Principal Recruitment Email” and “Spanish Principal Recruitment Email”). This email will explain the study, and include a link to a Qualtrics contact form where interested parents could list their contact information. A paid staff member would then contact all the parents who provided contact information in order to explain the goals of the study and provide details about participation. Parents who indicate interest in the study and meet inclusion criteria will then be mailed a packet that includes a parent consent form, youth assent form, and the parent and youth surveys. Spanish speakers will be asked whether they are more comfortable reading information in English, Spanish, or either. Those who indicate Spanish as the preferred language will be assigned to the nonexperimental tele-health treatment group and will receive all materials and contact with project staff in Spanish. Those who indicate that they are comfortable reading in either language will be given a choice of English or Spanish surveys and then randomly assigned to one of the three experimental conditions.

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

- All students enrolled in 6th or 7th grade at one of the 6 participating middle schools will be eligible for inclusion, with the exception of children with severe developmental disabilities or physical disabilities (e.g., autism, genetic disorders, Down syndrome).
- To be eligible for inclusion, caregivers must be the parent or legal guardian of the participating youth and have web access at home or be willing to access the web via computers located in the school or public library.
- We will collect assessments from any parent or legal guardian who would like to participate, but will use only data from the primary caregiver for our main data analyses. Mothers and fathers will be equally recruited. We anticipate that about 25% of families will include 2 parents.

Recruiting aids:

Schools and families will be compensated for their participation in the research study.

- Schools will be paid \$1000 in one lump sum upon enrollment in the study. This payment will provide incentive and support for school to partner with us around the delivery of this intervention. They will be paid via check and may use the funds as they wish.
- Families will be paid for all *research* assessments and can earn up to \$450 for their participation. Intervention and control families will receive equal compensation, although intervention families will also complete the FCU assessment. All families will be asked to complete the *research* assessment 4 times within a year: a pre-assessment, and then follow-up assessments at 3 months, 6 months, and 1 year. Families will receive one \$100 check per household after completing and returning each assessment. In addition, families will receive a \$50 bonus for completing all 4 assessments. This bonus will also be paid via check.

Recruiters:

Participants will be recruited by paid research staff of the Prevention Science Institute. They will not be recruited by the Family Consultants who serve as coaches in the FCU online + coach condition.

Focus groups composed of parents of preschool and elementary school-aged children will be recruited from the community via flyers posted at Umpqua Health New Day Program in Roseburg and asked to contact our project office if they are interested in participating. Participants need to be a parent or legal guardian of a preschool or elementary school-aged child; they need to speak and read English; and they need to have web access at home. Parents will be excluded from participation if their child has severe developmental disabilities or physical disabilities (.e.g., autism, genetic disorders, Down syndrome). When parents call the project office, they will be screened using the parent focus group screening script. When a parent emails a response noting their interest to participate, we will thank them for their interest and ask for a phone number so that we may ask them a couple of questions; we will then screen the parent using the parent focus group screening script. Participants will receive a \$50 check to compensate them for participating in a 90-minute focus group.

Parent focus group participants will be provided written consent forms at the time of the focus group. The focus group facilitator will go over the consent form with the group to make sure that participants understand their rights and responsibilities as research participants. Participants will be given a copy of the consent form for their records.

Implementation study

The principals of participating schools will identify staff who regularly work with families and who have time to participate in the study. At most schools these staff members are likely to be the school counselors, but that may vary by school depending on school resources. After being identified by principals, the appropriate staff members (n=5-10) would then be contacted via email to schedule an appointment to discuss the study. Potential “coaches” would be provided with a paper copy of a consent form and research staff would go over each element of the consent form to ensure that participants are informed of their rights and responsibilities as research participants. Research staff will answer any questions that arise and give participants a copy of the consent form for their records. “Coaches” will receive no compensation for their participation in this research study.

The “coach” at each school would then identify 5-10 families (total parent N= 50-60) at their respective schools that they think could benefit from the intervention. To participate in the study, parents (1) need to speak and read English, (2) need to have computer access so that they can access the website, and (3) should not have participated in the main research study. To make it easier to identify families who have not already participated in the main research study, coaches will only recruit 6th grade families (because families who already participated now have 7th and 8th grade students).

“Coaches” will schedule in-person meetings with potential participating parents, in keeping with their typical approach to working with families. During this meeting “coaches” will tell parents about the FCU-Online website and about the research study. If a parent seem interested in participation, the coach will give the parent access to a electronic version of the consent form via Qualtrics. If the parent is ready to sign the consent form, they will do so . If the parent has questions about the study, they will be referred to the Project Coordinator. If, after speaking with the Project Coordinator, the parent is willing to participate in the study, they will be emailed a link to the Qualtrics consent form. The Qualtrics form will be set up so as to automatically email the parent a copy of the consent form for their own records after they submit it. Parents will receive no compensation for their participation in this research study.

E. Informed Consent Process

Parents who provide contact information via the English or Spanish version of the Qualtrics form will be contacted by a paid member of our research team who will explain the goals of the study and provide details about participation, making sure to cover each of the main points listed in the consent form. Parents who indicate interest in participation will then be mailed a packet that includes a parent consent form, youth assent form, and the parent and youth surveys. One week after mailing this packet, a staff member will call parents to see if they have any questions about the consent form, assent form, or the surveys. Families will be given 4 self-addressed stamped envelopes so that each consent and survey may be mailed separately to project staff.

The implementation study includes two separate sets of participants: school staff who function as “coaches” for the FCU (and are interviewed about their use of the website in a school setting), and parents who work with these coaches, use the FCU Online website, and complete Website Satisfaction Surveys at the end of the study. Coaches will be consented in person by a paid member of our research team who will explain the goals of the study and provide details about participation, making sure to cover each of the main points listed in the consent form. Coaches will sign a paper consent form and receive a copy for their records.

As for parent participants, Coaches will tell parents in their caseload about the FCU-Online website and about the existence of the research study. If parents seem interested in the study, coaches will provide access to an electronic version of the consent form via Qualtrics. This consent form will explain the goals of the study and provide details about participation. If the parent is ready to sign the consent form, they will do so by typing their name. This will function as a signature in the online consent form. If they have questions about the study, they will be referred to the Project Coordinator. If, after speaking with the Project Coordinator, the parent is willing to participate in the study, the Project Coordinator will email the parent a link to the Qualtrics consent form. This consent form will be programmed such that parents will automatically receive an email copy once they “submit” their signed consent form.

F. Provisions for Participant Privacy and Data Confidentiality

Focus Group Confidentiality: When speaking to each other, we ask that focus group participants only use first names to help protect each other’s confidentiality. We also ask that they respect each other’s privacy and not share information revealed in this focus group with persons not currently present. In addition, the sessions will be held in a private location such as an empty classroom, empty library, or other private location.

One-on-One Interview Confidentiality: Interviews will be held in a private location, such as an empty classroom or private office.

All records obtained from subjects are kept in locked file cabinets in locked rooms or on secured servers. In addition, questionnaire data are 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. Data recycling is arranged through a contracted, bonded recycler and the University of Oregon. PSI has a locked, confidential recycling bin into which materials are disposed of properly and securely. Audio tapes obtained from the focus groups will be stored in locked offices in locked filing cabinets. They will be analyzed for feedback and development purposes and destroyed at the completion 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 website being developed for this project will be housed at the PSI. Our primary data storage is held on a custom-built 40TB, highly available, RAID 6 array configuration. Data backups are performed each evening. Our servers are port-restricted from the rest of the UO network using high-end network firewall appliances and are accessible only through secure means. Our network uses industry-standard IPsec VPN protocol, which uses Triple DES Encryption, one of the strongest encryption types currently in use. All data files are protected by an authentication scheme, 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 is 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 locked 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.

We plan to apply for a Certificate of Confidentiality from NIH for this study once the initial IRB protocol for the main study 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.

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 web/mobile + coach 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 guarantee 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 locked file cabinets and our limited-access, password protected participant database. In addition, we plan to apply for 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 web/mobile + coach condition, enjoy meeting with a coach 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

Spanish Translations have been conducted by Lucia Cardenas, Francisco Hernandez, and Ryan Lutz. Lucia has a Bachelor of Arts in Spanish Literature from the University of California, Berkeley. Lucia's first language is Spanish as well as Francisco's and they have both worked as translators and interpreters on several projects at the Prevention Science Institute. Lucia will be conducting the intervention with Spanish speakers on this project. Ryan is not a native speaker but studied Spanish in college and is a fluent speaker. Ryan also worked for AmeriCorps on the Texas-Mexico border and taught Elementary School classes to native Spanish speakers. Ryan has worked as a bilingual research assistant for Prevention Science Institute for several years and will be working as a phone recruiter for this project. Francisco assisted with translations but will not be working on this project.

PI's CV is on file with Research Compliance