

PROJECT TITLE: Adolescents with Substance Use Disorders Transitioning from Residential Treatment to the Community: Improving Outcomes via a Computer Assisted Parenting Program

PRINCIPAL INVESTIGATOR: Sara Becker, Ph.D.

CLINICALTRIALS.GOV IDENTIFIER: NCT03592186

DOCUMENT DATE: Created for Brown University IRB October 4, 2018

Uploaded to ClinicalTrials.Gov July 2, 2020

PROJECT TITLE: Adolescents with Substance Use Disorders Transitioning from Residential Treatment to the Community: Improving Outcomes via a Computer Assisted Parenting Program

PRINCIPAL INVESTIGATOR: **Sara Becker, Ph.D.**

A. SUMMARY OF PROPOSED PROJECT

Adolescents with substance use disorders (ASUD) in residential treatment have the most serious substance use disorders and the highest rates of psychological, motivational, behavioral, legal, environmental, and vocational problems. ASUD in residential treatment are also at extremely high risk of relapse, with follow-up studies suggesting that 60% of ASUD will relapse within the first 90 days of discharge. Parenting practices have been established as a key influence on adolescents' initiation and maintenance of substance use, as well as their substance use outcomes and likelihood of relapse. However, therapists who treat ASUD have reported a myriad of systemic barriers to engaging parents in treatment. Findings such as these deem ASUD in residential treatment a high priority population and argue for the value of easily accessible parenting interventions during this critical time.

The proposed study will evaluate one potential low cost, low intensity model for delivering parenting skills to parents preparing for their adolescent's discharge from residential substance use treatment. Specifically, this project will adapt the delivery of a computerized parenting intervention (Parenting Wisely; PW) that has preliminary evidence of efficacy in improving parenting skills and reducing youth behavior problems. PW delivery will be adapted for a new population (parents of ASUD preparing for discharge) and new setting (residential treatment), and preliminary data will be obtained on its feasibility, acceptability, and effectiveness. The open trial has been completed and consisted of recruitment, intervention, and assessment procedures with 10 parents to adapt the delivery of PW to include moderate engagement strategies relevant to this population. Initial engagement strategies have been developed based on focus groups and interviews with 13 parents, 11 ASUD, and three staff members and include up to four sessions of individualized coaching that begin prior to discharge (incorporated into standing family appointment times) and the use of technology (e.g., text messaging and an online parent message board) to maintain contact between staff and parents post-discharge.

Use of a low-cost, low-intensity intervention paired with moderate engagement strategies represents a marked change from traditional office-based treatment delivery methods. The approach has the potential to advance public health by: addressing a high-needs population; targeting parenting practices (putative mediators of change) that have been shown to influence ASUD outcomes; working with parents during a critical treatment juncture; improving parental engagement and access to care, and increasing ease of dissemination and implementation.

B. APPLICATION/PROPOSAL FOR FUNDING/SUPPORT

The initial grant awarded by the National Institutes on Drug Abuse proposed two phases – an open trial and a randomized controlled trial. This protocol pertains only to the **randomized control trial** portion of the study procedures proposed in the funding application at a new site.

Please note the primary difference between the current proposal and the original application. In the original application, the target site was Gateway Residential Services (GRS). By the end of the study, the facility changed its name to the Caritas ARTS Program. In addition, we added a second site after consultation with the Project Officer, both to ensure we met the pre-specified recruitment target and to enable us to inform the design of a fully powered trial. The two programs are:

Caritas ARTS Program – short term residential facility with 16 beds, average length of stay 6-10 days

Rosecrance Health Network – long term residential facility with 80 beds, average length of stay 30-45 days

C. SPECIFIC AIMS AND DETAILED STUDY METHODOLOGY

1. Specific Aims

The goal of this pilot study is to adapt the delivery of PW for a new population (parents of ASUD preparing for discharge) and new setting (residential treatment), and to obtain initial data on its feasibility, acceptability, and effectiveness. The study began with an open trial of 10 parents to demonstrate feasibility, acceptability, and preliminary evidence of effectiveness over time.

Specific research aims of the protocol are:

Aim 1: To examine the feasibility and acceptability of an adapted PW intervention that includes moderate engagement strategies for parents of ASUD preparing for discharge from residential.

Hypothesis 1a: Adapted PW will be both feasible and acceptable to parents. Feasibility will be indicated by enrollment rates ($\geq 80\%$) and indicators of parent engagement: attendance of ≥ 2 coaching sessions for $\geq 75\%$ of parents, and online usage patterns of 2+ PW logins, viewing of video vignettes embed in text messages, 1+ parent board posts. Criteria for acceptability will be withdrawal rates ($\leq 20\%$), $\geq 80\%$ of ratings on a consumer satisfaction scale in the highest two categories, and positive feedback from exit interviews with parents.

Secondary Aims 2-4: To examine the preliminary effectiveness of the experimental intervention on: substance use outcomes, related high-risk behaviors, and parenting skills (the putative mediators of change).

Hypotheses: At baseline, 6-week follow up, 12-week follow up, and 24-week follow-up, the experimental intervention will demonstrate superior outcomes, relative to treatment as usual on:

- 2a: indicators of substance use: substance use frequency, severity of substance use symptoms, rates of relapse, and biological markers (i.e., urine drug screens).
- 3a: high-risk behaviors commonly related to substance use: externalizing behavior, sexual risk behavior, school truancy, and criminal behavior.
- 4a: parenting behaviors: parental monitoring and communication, as demonstrated by both parent and adolescent report and observed during an in vivo task.

2. Detailed Study Methodology

STUDY PURPOSE. We are seeking approval to conduct a randomized control trial of 60 parents whose adolescents are preparing for discharge from residential substance use treatment at a new remote site. The goals of this project are to: (1) examine if the adapted intervention and the study assessment procedures are feasible and acceptable to study participants; (2) evaluate the preliminary effectiveness of the adapted intervention.

STUDY POPULATION. We are currently seeking approval to enroll 60 parent-adolescent dyads (i.e., a total of 12- participants) for a randomized trial.

Inclusion / Exclusion Criteria. Parents must meet the following **inclusion criteria**: (1) be the parent or legal guardian of an adolescent aged 12 years -17 years inclusive, at the start of the project; (2) had adolescent admitted to residential treatment facility due to concerns about frequency and/or severity of substance use; (3) will be the primary guardian living with the adolescent after the adolescent's discharge from treatment; (4) access to internet and a phone that can receive text messages; (5) fluent in English or Spanish; and (6) willing to provide written consent and teen willing to provide written assent. Adolescents automatically qualify for the study if their parents meet the aforementioned criteria. There are no exclusion criteria for participation in this study beyond failure to meet the inclusion criteria. If during the consent or assent process, the teen exhibits any conditions or behaviors that would preclude participation in the baseline assessment (e.g., mania, psychosis), then the interview will be paused and the research staff member conducting the consent / assent process will immediately notify the Medical or Clinical Director (Dr. Selby Conrad at Caritas, Dr. Thomas Wright at Rosecrance) at the residential facility to ensure adequate clinical assessment of the adolescent. The interview will be rescheduled for a time when residential staff has determined that the adolescent can participate in an interview. Behaviors that would cause a delay in the interview are expected to occur with extreme rarity, as there is no access to substances within the residential center and adolescents with acute conditions such as mania and psychosis are typically not admitted to the residential center.

Recruitment and Enrollment Procedures. Parents of adolescents receiving residential substance use treatment will be referred from the residential center. Parents will be told that a research project is currently taking place at the residential facility to test a technology-assisted parenting skills intervention and that they can choose to complete a Consent to Contact Form if they would like research staff to contact them with additional information. Dr. Becker, a licensed clinical psychologist and recipient of the grant award, and/or a hired study Research Assistant, Study Assessor/ Postdoctoral Fellow or project staff, will contact parents that complete Consent to Contact Forms to provide a brief overview of the study and see if parents would like to schedule an informed consent meeting (with sufficient time allocated for the baseline assessment if parents decide to participate). One of the aforementioned research team members will conduct the informed consent process either in person or via Zoom, using an instance specifically recommended by Brown CIS. Parents will provide electronic consent and adolescents will provide electronic assent prior to being enrolled in the study. Whenever possible, we opt to use electronic assent and consent to reduce risk to adolescents and their parents associated with having written consent forms stored at an offsite facility. Once informed consent is obtained, an intake assessment will be scheduled at a time that is convenient for the family, which could include a time immediately before or during the next family session.

Racial/ethnic and gender considerations. Consistent with the primary parent participating in treatment in previous research, we expect at least 75% of the parents to be mothers. Prior residential treatment research, have demonstrated prevalence rates of approximately 30% girls and 70% boys, so we expect a comparable split between boys and girls. Data from the facilities has also showed ethnic/racial distribution of approximately 62% White/European American families and 38% racial/ethnic minority families, most of whom identified as Hispanic/Latino (18%), African-American (7%), or 2+ races (5%).

Retention procedures. At baseline, multiple sources of contact information will be recorded for parents and ASUD to prevent attrition. A demographic form will be administered aloud by a research staff member at Brown via Zoom and information will be obtained and stored in hard copy form in locked filing cabinets in the PI's office at Brown University. Contact information will be updated by periodic phone calls and during assessments. Reminders will be made via phone and mail. The PI will hold weekly case review meetings to review no-shows and outreach attempts, and discuss plans to complete contact with missing participants. Compensation for completion of questionnaires and interviews/discussions escalates slightly from \$40 at baseline, 6 and 12 weeks to \$60 at 24 week followThis compensation schedules recognizes the increased effort associated with scheduling a follow-up and providing a urine screen after the teen has been discharged. We have used these retention procedures (e.g., reminder calls, periodic update calls, escalating compensation) with success in current and prior projects.

Randomization. In the randomized pilot trial, parent-adolescent dyads will be randomized to the adapted PW condition or to residential treatment as usual using urn randomization balanced by biological sex (male vs female), race/ethnicity (White, Non- Hispanic vs Non-White, Hispanic), and days of substance use (1-45 vs 45+). Randomization will be done by the research staff using a randomization spreadsheet immediately at the end of the baseline assessment; condition assignments will then be immediately told to the family. Those assigned to the adapted PW condition will be scheduled for their first remote coaching session approximately 4 weeks prior to discharge (described below).

Protecting confidentiality. Steps taken to protect the confidentiality of participants are detailed in **Section D, “Possible Risks and Anticipated Benefits”** in the paragraphs focused on minimizing risk of loss of confidentiality.

INTERVENTION. Parents and adolescents will begin to receive the PW intervention shortly after intake. The residential treatment team works with each adolescent's family, insurance provider, and any auxiliary decision makers (e.g., Child and Protective Services, Youth Probation Officers) to devise a preliminary treatment plan and tentative discharge date. All adolescents and parents will receive the standard treatment offered by the residential facility. In addition, they will receive the additional treatment elements below.

Parenting Wisely (PW). PW is a self-administered, interactive, multimedia online program. PW is available in both English and Spanish (Ser Padres Con Sabiduría). In PW, parents view video vignettes of ten common family

problems (e.g., adolescent substance abuse, curfews, household chores, monitoring of friends, sibling conflict, improving in school, getting up on time, sharing technology, etc.). After selecting a problem, parents view a video clip depicting a family struggling with that problem. Parents are given three possible solutions to the problem to select from, and then receive feedback according to the solution they selected. The feedback is presented in a video enactment of their selected solution and in an explanation of the pros and cons to each choice. This feedback is a critical part of the program, for it points out any errors parents made, explains why ineffective solutions lead to problems, and discusses why effective parenting solutions prevent and solve common family problems. The main parenting behaviors emphasized by each vignette include: 1) problem solving; 2) limit setting; 3) praising; 4) effective communication through I-messages and active listening; 5) supervision and monitoring, and 6) clear communication of teen's behavioral expectations. The program comes with a parent workbook that outlines all of the vignettes included in the program, along with the potential problems and solutions. The workbook also contains a glossary of terms, sample behavior charts, and practice exercises, so that parents can gain additional practice with the skills. The complete PW program takes from 3 to 5 hours to complete depending on the users speed and depth of use. Parents will be asked to create an unidentifiable login and password at enrollment so that they have the option to practice sessions or view any additional sessions at home; parents will then be prompted to generate their own password after the first time they login to the system if they would like. As discussed in the analysis section, we will use these unique logins to monitor parent participants' usage of PW for analyzing parental engagement. The parent coach will encourage parents to complete any sessions at home that they view as relevant to their parenting concerns. Based on parent-adolescent discussion task feedback, we recommend 3-4 PW modules to each family. We encourage parents to tailor the program to their own needs by watching the sessions that apply to them with staff feedback around which sessions may highlight the skills parents are seeking to practice. After discharge, parents will be encouraged via text messages and the online message board to complete additional sessions.

Individual Coaching Sessions. Individual coaching sessions are designed to individually tailor the PW skills to each parent's presenting concerns. Parents may receive up to 4 sessions by the first follow-up assessment (scheduled 6 weeks post discharge). Based on PI Becker's consultation with PW developer Consultant Gordon, we have selected 4 core parenting skills to emphasize in the sessions: I-statements, Contracting, Active Listening, Reframing. The initial session will be 60-75 minutes and will consist of several sections: 1) Rationale for parenting skills, 2) Review of feedback from the baseline in vivo parent-adolescent interaction task in order to cater the computerized parenting program to the families' specific needs 3) Overview of four core parenting skills; 4) Review of PW substance use module, and 5) practice applying the skill to a current problem. Subsequent sessions will be 45-60 minutes and will follow the same basic outline, while introducing the remaining core skills. When parents have questions or introduce problems/complaints about their teen, the coach will first provide validation and then discuss how the parents' problems can be addressed using a skill. Parents will be offered sessions remotely via phone or video-conference technology.

Text-based messaging. Immediately upon enrollment in the PW condition, parents will receive daily text messages for 6 months to reinforce skills from PW, to motivate continued participation in PW, and to encourage participation in the online parent message board (described below). Parents will be able to choose if they want to receive the text messages in English or Spanish. Approximately half of the texts reinforce material taught in PW, along with a link to a video clip enacting a core PW skill. For example, a message might contain a simple reminder statement about a parenting strategy such as limit- setting, monitoring, and communication with a link to a video clip demonstrating this strategy. The second half of all text messages either offer an encouragement for the parent to complete more PW sections or an encouragement to

participate in the web- and smartphone-based parent message board. These messages will contain links to the appropriate website. We intentionally do not propose interactive texting because we will direct parents to ask questions via the parent board, which we believe will be ultimately more transportable. Nonetheless, this limited application of texting is a potential important ingredient to extending parents' engagement in the parenting skills intervention, similar to the use of texting to increase uptake of flu vaccinations and outpatient clinic attendance. These text messages will be automated and delivered by an external vendor called Silent Disclosure.

Online parent board. Silent Disclosure created a secure project website with two interactive message boards for adolescent parenting related questions. The two message boards include: 1) "Ask an Expert", in which parents could post a question to a licensed clinical psychologist with expertise in adolescent substance use and mental health problems and have their question answered within 24-48 hours, and 2) "Connect with Parents", in which parents can seek social support from other parents of adolescents in residential treatment by either posing questions or answering questions posed by other parents. This interactive message board can be accessed both as a website on a computer or as a phone-based application (similar to the way that other popular websites for email, airlines, or networking sites can be viewed in easier to read app form). This website was based on <http://www.men2menri.org/get-health-facts/ask-r-is-doctor-phil-chan/>, a model developed by a colleague at Brown University and collaborator of Co-I Spirito and Hernandez. Based on parent feedback in our pilot data, the website includes basic substance use and parenting skills information, links to sections of PW, as well as an interactive message board. Consistent with our colleague's approach, all questions submitted will be reviewed by the project team to determine suitability for the board and responded to within 24-48 hours. Questions posted in English will be answered by PI Becker, while questions posted in Spanish will be translated by the bilingual Research Assistant, answered by PI Becker, then posted in Spanish by the bilingual Research Assistant. To ensure that all participants can contribute and read all of the messages, the website uses Google translate to offer parents the opportunity to view content in English or Spanish. A Spanish-speaking bilingual RA reviews the translations generated by Google Translate and makes edits to ensure accurate conceptual translations prior to approving the messages to the site. At the start of the program, parents will be informed that the online message boards are a place to ask parenting related questions and not a place to request crisis support. Answers to questions will direct parents to a specific PW module(s) most relevant to their parenting question. Parents' comments will be anonymous and will not be visible to others until approved for posting by the team. Participation will be encouraged until the final study assessment (24 weeks post-discharge). Each parent selects a unique non-identifiable username. Use of a unique login will allow research staff to measure, at the individual participant level, the number of logins to access the site, the number of page views of others participants' questions and responses, and frequency of message postings.

THERAPIST TRAINING / SUPERVISION.

Treatment will be delivered by Bachelor's or Master's-level parent coaches from the Brown University research team, one of whom is bilingual in English and Spanish.. All therapists will be trained to demonstrate sufficient adherence and competence by PI Becker. As a first training step, therapists will be required to review the manual, PW workbook, and modules of the PW computerized intervention. The PI and two therapists will then role-play and videotape the 4 core sessions. PI Becker will view these role plays, complete measures of therapist adherence and competence, and provide brief written summaries. Competency will be rated with 6 items that comprise the "General Therapeutic Skills" section of the Cognitive Therapy Rating Scale (CTRS), which is routinely used to assess therapist competence in Co-I Spirito's protocols. The CTRS is well suited to assess the in-person coaching sessions, since these sessions use a structured, skills- based, and collaborative approach. A score ≥ 24 is the

criterion to indicate competence on the 6 item version. PI Becker will calculate a consensus CTRS score and provide a synthesis of written feedback to each therapist. Adherence measures will be developed in collaboration with Consultant Gordon based on the in-person manual. Therapists will be required to earn a satisfactory consensus CTRS score of ≥ 24 on 3 of 4 role plays and satisfactory adherence ratings to be assigned a participant.

Once the Brown therapists are assigned participants, sessions will be audio recorded and rated for competence and adherence. PI Becker will review and rate the first two tapes for adherence and competence. If ratings are satisfactory, PI Becker and the post-doctoral fellow will collectively review 25% of tapes (i.e., 1 of the 4 remote sessions per client) moving forward. PI Becker will meet weekly with therapists for supervision focused on adherence to the protocol, therapist skill in protocol delivery, and how to tailor the PW protocol to each parent's unique presenting concerns.

MEASURES. Parents and teens will complete a baseline assessment either immediately after providing informed consent / assent or shortly thereafter via phone or video conference by Brown University staff. Follow-up measures will also be conducted by phone or video conference by Brown University staff at 6, 12, and 24 weeks following the teen's discharge. The baseline assessment will be about 1.5 hours for the adolescent and 1 hour for the parent and the follow-up assessments will be about 1.5 hours for both the adolescent and parent. Parents and adolescents have been able to complete assessments of this length or longer in our team's prior and current studies.

The measures used in this study are outlined below. Based on our team's experience working with 100s of families on clinical research projects in Rhode Island, we have decided to translate all of the **parent** measures into Spanish. We retain all of the adolescent measures in English. It is well established that adolescents tend to acculturate to the U.S. culture more quickly than their parents, and we have found that adolescents in our studies from Spanish-speaking families are typically comfortable speaking and completely measures in English or Spanish, while parents tend to prefer to speak in Spanish. If adolescents prefer to speak in Spanish, we will use a translator to administer all of the adolescent measures aloud.

Rationale for Measures: Aim 1. To address Aim 1, we will assess feasibility and acceptability.

Feasibility. PW feasibility will be assessed based upon the percent of parents willing to participate as well as indicators of parental engagement, including: number of coaching sessions attended before teen's discharge, number of coaching sessions attended after discharge, number of PW logins, number of PW online sessions completed, amount of time spent logged into PW program, number of logins to the parent message board, number of questions posted to the message board, and amount of time spent logged into the board.

Acceptability. Acceptability will be assessed at two time points: 1) after the 4 remote coaching sessions and 2) at 6, 12, and 24 week follow-up, using exit interviews and the Consumer Satisfaction Questionnaire (CSQ). Parent exit interviews contain questions about each aspect of the intervention, including the coaching sessions (e.g., number, content, format), text messages (e.g., content, frequency, format), and online message board (e.g., ease of access, content, format). Parents will also complete the 16-item CSQ, which rates their satisfaction with treatment delivery, their teen's treatment progress, and their ability to manage their teen's problems. Parents rate 11 items along a 7-point scale and answer 5 open-ended questions about their experience in treatment.

Rationale for Measures: Aims 2-4. Residential staff typically conduct a comprehensive interview with the adolescent to assess substance use, school/vocational functioning, family functioning, environmental risk, and other high risk behaviors. We therefore use the quick

version of the Global Appraisal of Individual Needs (GAIN-Q3), a well-validated, comprehensive, structured interview with the teen to assess substance use (Aim 2) and other risk behaviors (Aim 3), rather than a battery of measures. The quick version of the GAIN has both an intake (GAIN-Q3-MI) and follow-up module (GAIN-Q3- Standard), which assess adolescent's problems across several domains including: substance use, school, mental health, physical health, risk behaviors, work, and sources of stress. The GAIN was specifically developed for use with adolescents age 11 and older, and has extensive normative data with over 30,000 adolescents across the continuum of substance use care. The GAIN is one of the most widely used assessments for adolescent substance users in research and clinical practice. As of 2008, the GAIN had been used in over 60 adolescent research grants through SAMHSA's Center for Substance Abuse Treatment (CSAT). A major advantage of using the GAIN is that the extensive normative data will enable us to compare the adolescents in this study's sample to other adolescents in residential treatment.

By using the GAIN at follow-ups, we will capture continuous data on the teen's use and high-risk behaviors following discharge. We will also include measures of parental communication and monitoring (Aim 4), as these outcomes are not included in the GAIN and parenting practices are a key factor associated with ASUD. PI Becker is a certified GAIN trainer and has experience analyzing GAIN data. Specific scales that we will analyze to address Aims 2 and 3 are described below.

Demographics. The GAIN Background section collects routine socio-demographic variables including age, sex, ethnicity, race, and grade in school. Items in other GAIN sections indicate the teen's history of substance use or mental health treatment utilization, data that will be used to control for additional treatment received.

Substance Use. The following GAIN items/scales and biological markers will address Aim 2 (substance outcomes).

Days of Use (Past 90 Days). A series of GAIN items evaluate days of substance use over the past 90 days. These items have shown excellent comparability to the well-validated Timeline Follow-Back Interview (TLFB). Like the TLFB, the GAIN assesses days of alcohol and drug use using a calendar with temporal cues (e.g., holidays, special events) to facilitate recall. We will analyze three variables, separately for alcohol, marijuana, and other drugs: total number of use days, total days abstinent, and latency to first use.

Substance Frequency Scale (SFS). The SFS scale averages the percent of days in the past 90 during which there was use of alcohol, marijuana, or heavy drugs; use to intoxication; and failure to perform activities due to use. This scale has good reliability ($\alpha = .85$) and predicts substance-related problems as well or better than biometric (e.g., urine) markers of use.

Biological markers. Biological markers will **only be used at the follow-up assessments (6, 12, and 24 weeks)**, since adolescents are not expected to have access to substances at the time of the baseline assessment (likely to be at least 1-2 days after admission). 8-panel urine screens that detect the presence of marijuana, cocaine, amphetamines, methamphetamines, MDMA, opiates, oxycodone, and benzodiazepines mailed to each family and administered to the teens by the parents will be used to provide a biological indicator of abstinence. Teens who present as acutely intoxicated based on researcher observations, parent-report, or adolescent-report will be rescheduled.

High-Risk Behaviors Related to Substance Use. The following GAIN items/scales will address Aim 3. These specific scales have been selected based on the well-documented association between adolescent substance use and externalizing behavior, school truancy, high-risk sexual behavior, and criminal behavior.

Risky Sexual Behavior. The GAIN contains a series of items that assess sexual behavior over the past 90 days. Specific data obtained includes: number of partners (male and female), number of sexual contacts, number of times had unprotected sex, and recency of last sex.

Days of School Attendance. Using a 90-day recall, the GAIN assesses number of days the

teen: attended school, was absent from school due to illness, and intentionally skipped school. The method is comparable to that used in the Days of Use substance use items.

Days of Legal Involvement. Using a 90-day recall, the GAIN assesses number of days the teen: did something, other than drug use, that would have gotten them into trouble with the police and number of days the teen was on probation, on parole, in juvenile detention, or in jail.

Parenting. We use the measures below to address Aim 4, which tests the effects of PW on parental monitoring and communication. We use self-report measures with strong psychometric properties, as well as in-vivo assessment to increase the comprehensiveness of our assessment. If a parent loses custody after the teen's discharge, we will not administer the parenting measures at the subsequent follow-up (treating parent data as missing). Based on prior protocols, we expect parent data loss of less than 5% with this approach.

Parent Monitoring Questionnaire (PMQ). The PMQ is a 24 item youth and parent report measure designed to assess parental monitoring and sources of parental knowledge. The monitoring subscale has demonstrated good reliability ($\alpha = .82$ parents, $.85$ youth) and correlates with adolescent internalizing and externalizing maladjustment, deviant peer relationships, and family discord.

Parent-Adolescent Communication Scale (PACS). The PACS is a youth and parent report measure that assesses positive and negative aspects of general parent-teen communication and the content and process of parent-teen interactions. The two subscales have good reliability ($\alpha = .77 - .88$) and have been shown to correlate with teen engagement in risk behavior.

FAsTask Video Code. The FAsTask is an interactive family problem solving task that will be used to provide an in-vivo assessment of parenting behaviors. We have limited the assessment to three tasks that align with our primary aims: 1) Limit Setting (parent leads a 5 min discussion about a time they had to set a limit); 2) Substance Use Norms (parent leads a 5 min discussion on family views about substance use); and 3) Monitoring and Listening (teen leads a 5 min discussion on their peers and parent listens and reacts). Co-I Spirito has created a structured clinical codebook that defines each item to be coded and gives specific examples of high and low-scoring observations. Interactions will be observed during each phone or video conference assessment and will be audio recorded. Tapes will be coded by raters blind to condition: 20% of tapes will be double coded.

Data Analysis Plan.

All 60 parents will be included in statistical analyses consistent with an intent-to-treat (ITT) model. Prior to the main analyses, we will run descriptive statistics on key variables to examine distributional properties, identify outliers, and transform variables as needed. The two treatment conditions will be compared on all baseline demographic and clinical variables. Pre-existing differences on any variables and any additional treatment received will be controlled in subsequent analyses.

Missing data. GAIN data is entered into the GAIN's proprietary software, which offers instant error checks and validation reports to prevent missing data. Other forms will be entered directly into study laptops using REDCap (Research Electronic Data Capture), a secure web-based application, to reduce missing data and entry errors. Attrition analyses will compare follow-up completers and non-completers on baseline clinical and demographic variables to determine if they differ systematically. If necessary, we will use standard methods of multiple imputation [123] for variables where unplanned missingness is an issue. For each follow-up time point, we will conduct analyses to identify systematic biases that may have arisen due to non-random dropout.

Aim 1. In the RCT, feasibility will be examined via enrollment rates ($\geq 80\%$) and indicators of engagement, with these preliminary targets: attendance of ≥ 3 of 4 coaching sessions pre-

discharge and ≥ 1 of 2 sessions post-discharge for $\geq 75\%$ of parents, and online usage patterns of 3+ PW logins, 2+ parent board logins, and 2+ hours logged in for $\geq 75\%$ of parents. Criteria for acceptability include withdrawal rates ($< 20\%$), satisfaction ratings ($\geq 80\%$ of CSQ items rated “agree” or “strongly agree”) and positive feedback from the exit interviews with parents and therapists. Criteria will be finalized based on parent and staff feedback in Phase 1.

Aims 2 - 4. The dependent variables (DVs) include substance use (Aim 2), related high-risk behaviors (Aim 3), and parental monitoring and communication (Aim 4, putative mediators). By nature of residential treatment, we expect teens’ level of substance use and risk behavior to start high at intake, drop off for the duration (~ 3.5 months) of treatment and then increase over the follow-up period. Trajectories that begin at baseline would be misleading, since all teens will have a sustained period of abstinence (with minimal variance). We therefore compare trajectories of use over the follow-up period, while controlling for baseline status as covariates.

We will begin by comparing the DV scores (means of continuous DVs and percentages of categorical DVs) at each assessment. We will conduct separate mixed models predicting each DV by condition, controlling for the following covariates: baseline status on the DV, baseline differences between groups, and any mental health or substance use treatment received over the follow-up period. We will analyze the effect of PW dosage on each DV and calculate partial eta squared (η^2) to estimate the proportion of variance caused by PW. We are underpowered to test mediation, but will examine the effects of PW on our putative mediators (Aim 4), and correlations between change in the mediators and change in the primary outcomes (Aims 2-3), with the goal of finding promising trends to pursue in a larger trial. We will cautiously attempt more sophisticated analyses using hierarchical modeling, a flexible approach to analyzing change that has been frequently used by the PI [37, 90, 91]. Mixed models are ideally suited to address Aims 2-4, by enabling us to compare the conditions at each time point while accounting for the correlation of observations over time. Although convergence is challenged in a small sample, it is feasible. Our primary goal will be to provide measures of association and 95% confidence intervals to reveal the ES of PW on each DV.

Sample Size, Power, and R01. We chose to recruit 60 subjects for the RCT conservatively estimating that 15-20% may be lost to follow-up, leaving 50 subjects with complete parent-teen data. This number will allow us to make judgments regarding feasibility and acceptability. As noted in Preliminary Studies, ES estimates in prior PW studies have ranged from small to very large; the only ASUD study found small to medium ES, but unlike this application, that study did not offer in-person support or an online parent board. We therefore may find ES in the medium range. Despite issues with ES stability in small samples [124], a small to medium ES paired with high levels of feasibility and acceptability would be an indication that the adapted PW intervention should be tested in a larger trial. Based on the detected ES, post-hoc power analyses will be conducted to determine the number of parents required for a fully powered RCT. For instance, for power of .8, a small ES ($d = .3$) would require a sample of 175 per group, while a medium ES ($d = .5$) would require a much smaller sample of 64 per group. If our results are promising, we will develop a fully powered R01 application in Months 31-36 (see Table 2) to evaluate the adapted PW under ecologically valid conditions. To speed the translation of research findings to practice, our R01 will use a hybrid effectiveness-implementation design to simultaneously test the effectiveness of the intervention and inform the ideal implementation strategy [125].