Study Protocol and Statistical Analysis Plan

Enhancing Adolescent Substance Abuse Treatment

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SCIENTIFIC RIGOR

The proposed study will achieve robust and unbiased results via several features, including a priori hypotheses; explicit inclusion/exclusion criteria; use of well-established measures and multi-method validation of primary constructs; ensuring data collection staff are blind to treatment assignment; carefully delineated data analysis plans; power estimates; and plans for retention, missing data, and potential confounds. Biological variables (age, sex) are incorporated into the analytic plan. Study details are reported in a transparent way to support replication, and investigators expose results of all their studies to high quality peer-review procedures.

PRELIMINARY STUDIES

Several areas of past work culminate in this proposal: (a) mediation studies and research on the proposed direct (parent management) and indirect (behavioral regulation, peer relations) targets, (b) clinical research involving family-based CM and other EBPs, and (c) dissemination research with CM and other EBPs.

STUDIES INVOLVING THE PROPOSED TARGETS AND MEDIATORS OF EBPS.

PARENTING AND PEER RELATIONS. The PI and Co-I's have collaborated on many studies evaluating parent management, as well as numerous studies evaluating peer relations and impacts on youth behavior (see Biosketches). In fact, the Oregon Social Learning Center (OSLC) and the PI's former institution, the Family Services Research Center (started by Co-I Henggeler), are internationally known for their contributions to studying parenting, peer relations, and high-risk youth. Thus, the team is optimal for leading this research.

NEUROCOGNITIVE PROCESSES UNDERLYING BEHAVIORAL REGULATION. For over a decade, OSLC researchers have examined the effects of stress on youths' neurocognitive functioning. Co-I Bruce has expertise in acquisition, analysis, and interpretation of data measuring risk taking and inhibitory control abilities in adolescents.[119–123] She also has expertise with neurobiological measures collected in studies of foster care and a family-based school readiness intervention for at-risk youth.[28,124–125] Of importance, results from studies employing event-related potential and event-related functional magnetic resonance imaging suggest parenting interventions can alter the neural systems underlying behavioral regulation.[28,124,126] Bruce, therefore, is well equipped to guide examination of the putative mediating effects of risk taking and inhibitory control.

MEDIATION OF EBPS. Several trials conducted by the team have produced papers examining mediators of experimental interventions.[94-95,127–128] For one manuscript,[127] McCart and Chapman co-led the complex mediation analyses. Thus, the team is equipped to accomplish the proposed work. The approach to mediation (experimental mediation) is a unique innovation, although the methods integrate standard RCT and data collection techniques with which the team has vast experience. However, to further strengthen the team's expertise, David MacKinnon, a leading experimental mediation expert, will serve as a consultant.

CLINICAL RESEARCH INVOLVING FAMILY-BASED CM AND OTHER EBPS.

RCTS AND IMPLEMENTATION EFFORTS INVOLVING FAMILY-BASED CM. As noted, family-based CM is one of several validated adolescent interventions.[13] A variation of family-based CM developed by Azrin, Donohue et al. produced positive results in several studies.[32–33,129-130] Following that work, our team conducted an RCT, in collaboration with Donohue, evaluating CM combined with MST for substance abusing juvenile offenders.[55] More recently, our team collaborated on an RCT integrating family-based CM into juvenile drug courts,[34] as well as the aforementioned RCT comparing CM and an HIV-risk reduction protocol to TAU for delinquent youth.[107,131] Study results have demonstrated significantly better outcomes for youth in CM conditions relative to controls; however, treatment effects have tended to fall in only the small to medium range.[34,107]

With extensive understanding and use of Instructional Design Theory (advocated by educational researchers[132-134]), the investigative team has focused on developing family-based CM suited for training and implementation in real world settings. In fact, McCart and Sheidow started a clinic at their prior institution that utilized Master's level practitioners to deliver CM to the local community and have developed a similar capacity at their current institution's clinic. Aside from studying its effectiveness, the team has extensive knowledge on implementation of CM, a requisite for the proposed study. Specifically, the team has experience with: (a) the range and magnitude of incentives for youth, (b) developing reward systems that leverage the empirically demonstrated impact of escalating reinforcers and rapid resets (a "leveled" system),[135–136] and (c) blending immediate reinforcers (immediate access to most valued privileges) with a token economy system (accruing points to purchase from individualized and varied reward/privilege menus). With this experience delivering family-based CM in clinical research and real-world practice settings, the team is primed for the proposed trial.

RCTS AND IMPLEMENTATION EFFORTS INVOLVING OTHER EBPS. The PI and Co-I's also have conducted numerous RCTs on interventions other than family-based CM. For example, McCart, Sheidow, and Chapman are collaborating on RCTs of interventions for victims of child sexual assault (R01DA031285) and youth with comorbid mental health and substance use problems (R01DA025616). Further, Henggeler has 3+ decades of experience conducting RCTs on MST and other family-based youth treatments (e.g., several RCTs with violent juvenile offenders,[137-139] two with substance abusing juvenile offenders,[34,55] and one for youth with serious emotional disturbance[140]). Similarly, Chamberlain conducted several RCTs of TFCO for antisocial youth.[141-142]

Of note, these trials all included close collaboration with community agencies, random assignment, evaluation of multiple outcomes, and minimal exclusion criteria to enhance external validity. These trials also

had diverse samples (e.g., up to 32% Latino, 81% African American, 12% Native American) and high recruitment rates (see details in *Recruitment and Retention Rates* section). Thus, the investigators are skilled at implementing intervention protocols, recruiting diverse youth and families into clinical research, executing data collection protocols, and performing advanced data analyses to answer research questions.

DISSEMINATION RESEARCH WITH FAMILY-BASED CM AND OTHER EBPS.

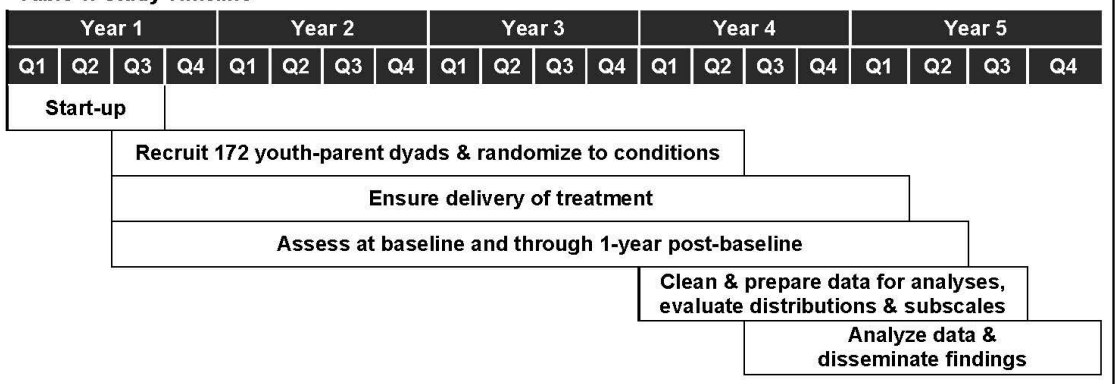
The study also is supported by our work transporting CM and other EBPs to community settings. The investigators completed several NIDA-funded studies examining CM transport to the public sector including: a study of quality assurance on CM fidelity among providers in Connecticut[117] and a replication in Norway;[143] a 44-site Statewide Study on training 432 therapists in CM and examining their adoption;[35–36] and a CM Training Study evaluating relative effectiveness of different training methods among 100+ public sector therapists.[144] Findings from the Statewide Study indicated strong interest, with 80% attending a workshop and 58% adopting CM. Adoption was related to individual characteristics and attitudes toward EBPs; negative attitudes toward CM was not a barrier cited. Other investigators have examined transportability of CM to community settings and found high adoption rates.[145-147] The team also has researched transportability of other EBPs. For example, Sheidow and Chapman collaborated with Sonja Schoenwald on a 45-site MST transportability study, which indicated (a) a complex intervention can be transported to community-based therapists, (b) fidelity predicts outcomes, and (c) clinician and organizational factors affect fidelity and outcomes.[148]

CONCLUSION. The team has extensive experience evaluating and transporting EBPs. Our research suggests that while family-based CM is a well-validated EBP for adolescent SUD, its effects, like other adolescent SUD EBPs, are modest. Thus, this study will use an experimental mediation approach to identify mediating processes in treatment, with the ultimate aim of improving SUD treatment effectiveness. Backed by our experience conducting mediation and clinical studies, this study is poised to produce crosscutting implications for improving youth SUD treatments. Given the clear need to enhance effectiveness and durability of existing interventions, such work could have a dramatic impact on outcomes and services for youth.

DESIGN TIMELINE AND OVERVIEW

Data will be from a longitudinal two-armed parallel group design with 172 youth randomized to CM vs. CM+. In-person assessments will be at baseline, 2-, 4-, 6-, 9-, and 12-months post-baseline. Phone assessments will be at 1-, 3-, 5-, 7-, and 8-months post-baseline.

Table 1. Study Timeline



STUDY SITES

The proposed study will be conducted with the OSLC outpatient clinic and Centro Latino Americano (CLA). Both are Medicaid-approved, HIPAA-compliant clinics employing Certified Alcohol and Drug Counselors (CADC) to deliver treatment services. While the two clinics serve all Lane County residents, CLA clients are predominantly Latino. As noted in the *Introduction*, adding CLA as a second site for this trial allows for oversampling of Latino youth, permitting an examination of differential mediation effects by ethnicity (see *Data Analysis*). Importantly, OSLC scientists regularly collaborate with OSLC clinic staff on intervention trials involving methods consistent with the proposed study. Similarly, OSLC scientists have a long history of collaborating with CLA on research and implementation projects.[149-150] Thus, the sites are optimal for ensuring adequate recruitment numbers, protocol fidelity, and successful completion of study procedures.

The trial will involve 6 CADCs across the sites; 3 CADCs (2 from OSLC and 1 from CLA) will be randomly selected to deliver CM+ and the other 3 CADCs (2 from OSLC and 1 from CLA) will deliver standard family-based CM. Based on our experience with RCTs, we anticipate turnover and have planned for as-needed recruitment of new CADCs and case re-assignment to ensure cases remain within condition. To ensure high fidelity and reduce confounding variables (e.g., access, insurance), the study will pay for treatment in both conditions, and investigators will train and closely monitor CADC staff.

Adolescents presenting to OSLC and CLA for SUD treatment during Study Months 7-42 will be screened, and those meeting inclusion criteria will be offered the opportunity to participate pending available slots. Power calculations (presented subsequently) indicate an optimal sample size of 172. Given case flow at the clinics, and our desire to oversample Latino families, we anticipate achieving the required sample size in 3 years. Specifically, CLA treats 23 adolescents with SUD per year on average, and all of these will be approached to participate in

the trial. Assuming an 80% recruitment rate (see subsequent rationale for this rate), we expect to recruit 55 families from CLA across the 3 years. OSLC serves just over 100 cases/year on average, so case flow will provide more than enough families to recruit the remainder of the sample (49/year x 3 years = 117). Based on information from OSLC and CLA, the following demographic characteristics are expected for youth recruited across both clinics: average age = 15 years (range = 12-17 years); 84% White, 13% African American, 2% American Indian/Alaska Native, 1% Asian; 35% Latino (of any race); and 30% female.

PARTICIPANTS

Participants will include 172 youth and their primary parent/guardian. Inclusion criteria for the youth are: 1) age 12-17 years; 2) presence of current SUD; and 3) availability of a parent/guardian willing to participate. Exclusion criteria are: 1) actively psychotic, suicidal, or homicidal; and 2) PDD or mental retardation. To increase external validity, youth will be included regardless of co-morbid mental health or physical difficulties.

RESEARCH SCREENING, RECRUITMENT, AND RETENTION

INITIAL SCREENING. All cases presenting to the OSLC and CLA clinics meet initially with an intake worker to determine appropriateness for an outpatient level of care. The intake worker will make a preliminary determination regarding study eligibility and refer them and their parents to Project Assessors.

STUDY RECRUITMENT AND SCREENING. Assessors will meet with youth and parents at a time and place convenient to the family (clinic, family's home, private community location) to obtain parental consent/youth assent. Protections will be assured, including IRB approval and a federal Certificate of Confidentiality. After this, SUD will be confirmed via the Global Appraisal of Individual Needs-Initial, Lite (GAIN-I, Lite),[151-154] a diagnostic interview aligned with the DSM-5. If lacking a SUD, youth and parents will each be provided $10 gift cards. If SUD is present, a 2-hour baseline interview will be conducted and subsequent interviews scheduled.

RECRUITMENT AND RETENTION RATES. In over 15 years conducting treatment research with families, we have achieved recruitment rates ranging from 85-100% and retention rates exceeding 90% for 12-month follow-ups.[34,55,107] The research team has been very successful at recruiting and retaining participants from challenging populations, and the majority of these studies were conducted in real world (rather than research) clinics where youth/families could receive treatment without consenting to research. We will replicate our successful recruitment and retention strategies in this trial. First, to establish collaborative relations with families, assessments are scheduled at their convenience, contacts are as friendly as possible, and families are reimbursed for their time. Second, direct contact helps maintain the cohort, with families contacted regularly during their 12 months of study participation. At each contact, families are asked if they plan to move and for up to 4 phone numbers and email addresses of best friends, relatives, and schools/places of employment. Third, we obtain consent to use technology such as text messaging and Facebook (using private messaging functions). When participants cannot be located, Assessors track them using the various contacts, other Internet resources (e.g., reverse look-up), and post office forwarding. Fourth, the same Assessor follows participants over time to encourage rapport. Fifth, contacts are defined as confidential and independent of treatment. Reasons for missed interviews will be recorded to assess impact on proposed methods.

RANDOMIZATION TO CONDITIONS

An adaptive urn randomization procedure,[155-158] implemented using the Microsoft Access application gRand, will balance potential confounding variables among participants randomized to each condition and also will manage condition sizes. This method is recommended for trials of SUD treatments.[155] Based on the population and outcomes of interest, factors on which the urn will operate are youth age, sex, baseline substance use severity, and a weighted percentage schedule for condition balance. The urn will minimize variability in these pre-treatment variables across the two conditions. To keep Assessors blind to condition, the Assessment Coordinator will conduct the randomization procedure immediately following a family's baseline assessment and will convey results directly to parents. The Coordinator also will inform the clinic intake worker of the randomization result so the family can be assigned to a CADC in the correct condition: CM+ or CM only.

DATA COLLECTION PROTOCOL

Assessors will meet with youth and parents for (1) a 2-hour, in-person baseline interview, (2) in-person, 1.5-hour follow-up assessments at 2-, 4-, 6-, 9-, and 12-months post baseline, and (3) 30-minute phone interviews at 1-, 3-, 5-, 7-, and 8-months. If youth and parent have to be assessed at different sessions, they will be scheduled within one week of each other. This schedule provides frequent measurement of constructs during active treatment (both CM+ and family-based CM are expected to last 5-6 months on average), while also providing a longer view on durability of change than is typical in adolescent SUD treatment research.[19]

To compensate for their time, families are paid $50 for baseline and $40 for each in-person follow-up assessment. Families will be paid $10 for each brief telephone assessment (maximum total compensation = $300). Based on our experience, 1.5- to 2-hour assessments rarely present a significant response burden, but Assessors are trained to use breaks with snacks and to attenuate circumstances that threaten validity of assessments. Participant protections are detailed in the Human Subjects Protocol and include IRB approval.

MEASURES

Multiple methods or perspectives will enhance construct validity. Consistent with intention-to-treat principles,

data from all time points will be collected even if families drop out of treatment.

Table 2. Research Instruments

Descriptive Variables [*Baseline only*]

Structured Adolescent Interview[159] for demographics and to supply relevant data for the urn randomization.

Ultimate Outcomes [*Months 0, 2, 4, 6, 9, & 12*]

SUBSTANCE USE:

Urine samples collected by researchers from youth; lab testing for THC, synthetic THC, amphetamines, opiates, PCP, cocaine, and alcohol metabolites (EtG/EtS); selected lab's testing procedures are of high scientific quality.

GAIN[151-154] scales measuring self-reported youth substance use and substance-related problems; 16-item substance abuse index/substance dependence, substance problem scales assessing DSM-5 criteria for substance use disorders and lower severity symptoms, recovery environment risk and social risk subscales that predict substance-related problems in youth with substance abuse, and the substance frequency scale assessing substance use for past 90 days; GAIN scales have good reliabilities and sensitivity to change, and are highly associated with results from Form-90 and urine testing.[160-161]

EXTERNALIZING BEHAVIOR: Externalizing subscale of parent-completed **Child Behavioral Checklist** and corresponding subscale of **Youth Self Report**;[162] scales provide valid measures of youth externalizing behavior from multiple perspectives.[163]

Direct Target [*Months 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, & 12*]

PARENT MANAGEMENT:

Alabama Parenting Questionnaire (APQ)[164] administered to youth and parents, measuring monitoring/supervision, positive parenting (social/tangible reinforcement), and consistent discipline (removal of privileges); scales have been used to document treatment outcomes and distinguish families of youth with and without behavior problems;[164] scales have established reliability and validity;[165] an additional rules and expectations subscale added to the APQ assesses enforcement of household rules.

CM Adherence Measure (CAM) developed using Rasch methods and validated across several studies with substance using adolescents;[37,166-167] subscales measure cognitive behavioral (antecedent-behavior-consequence assessments, self-management planning) and behavioral (drug screening, contingency contracting) techniques used within family-based CM. Originally, this tool was designed for families to rate their therapist's delivery of CM in session. However, as noted previously, a central feature of CM is to train parents to continue implementing CM at home. Thus, for this study, parent and youth CAM reports will be obtained to assess parents' implementation of CM both between the sessions and after treatment has ended.

Indirect Targets [*Months 0, 2, 4, 6, 9, & 12*]

PEER RELATIONS: Pittsburgh Youth Study[111] scales with strong reliability and validity;[168] youth-reported peer delinquency scale and drug activity scale measuring proportion of youths' friends who engage in antisocial behaviors per youth report, youth-reported conventional activities of peers scale measuring proportion of friends who engage in prosocial activities, and bad friends scale assessing youth contact with peers disapproved of by parents per youth and parent report.

BEHAVIORAL REGULATION - RISK TAKING:

Behavioral Inhibition System (BIS) and Behavioral Activation System (BAS) Scales completed by youth and parents;[169–170] BIS is sensitive to signals of punishment and non-reward; BAS is sensitive to signals of reward; BAS includes three subscales: drive (persistent pursuit of desired goals), fun seeking (spontaneous desire for new rewards), and reward responsiveness (positive responses to the anticipation of rewards); scales have satisfactory reliability and validity.[169–170]

Balloon Analogue Risk Task - Youth assesses risk-taking propensity.[81,171] Adolescents earn points every time they pump to inflate a computer-generated balloon, a computer algorithm randomly determines the number of pumps that will cause the balloon to pop, and the adolescents lose points if the balloon pops. An index of risk taking is calculated by averaging the number of pumps for balloons that did not explode.[81] The task has good internal consistency and convergent validity.[81]

BEHAVIORAL REGULATION – INHIBITORY CONTROL:

Early Adolescent Temperament Questionnaire–Revised[172–173] completed by youth and parents; scales include inhibitory control and higher-order factors: effortful control, negative affect, affiliativeness, extraversion; good internal consistency.[173]

Go/No Go Task of inhibitory control; youth selectively respond to target stimuli and inhibit responses to equally salient, non-target stimuli.[121,174] Consists of 252 trials: a letter is presented for 500-ms with a fixed, 1,500-ms interstimulus interval. Youth is instructed to press button as quickly as possible for every letter (go stimuli) except X (no go stimuli); 75% "go" trials and 25% "no go" trials; activates dorsolateral prefrontal cortex, ventral prefrontal cortex, and anterior cingulate cortex.[174] Consistent with prior research,[175–176] we will compute an index of inhibitory control: subtract percent correct on highly interfering stimuli ("no go" trials) from percent correct on minimally interfering stimuli ("go" trials). Lower scores indicate better inhibitory control.

TREATMENT CONDITIONS

FAMILY-BASED CM. Family-based CM is rooted in behavioral and cognitive behavioral theories and is designed for delivery in outpatient clinic settings (weekly 50-60 minute sessions). Treatment duration is criterion-based, determined by achievement of substance use goals, but the protocol is typically 5-6 months (20-24 sessions). CM has strong empirical support in the adult SUD treatment literature,[177] and family-based CM has also proven efficacious for youth SUD.[13,178] Moreover, its relative simplicity and low cost[179] makes family-based CM highly amenable to adoption. The protocol components are listed in Table 3.

Table 3. Family-Based CM Components

Clinical assessment. A semi-structured interview conducted separately with the youth and parent gathers type, frequency, quantity, and administration route of drug use; and data on treatment, medical, and educational history.

Introducing CM. CM is introduced to the youth and parent, and the therapist begins to engage them both in treatment.
Antecedent-behavior-consequence (ABC) assessment. ABC assessments of the youth's substance use are conducted in collaboration with the youth and parent (similar to functional analyses), in which they are asked to identify environmental, cognitive, and affective triggers (i.e., antecedents) for recent episodes of use or abstinence and to reflect on both the positive and negative consequences of that use/abstinence. ABC assessments are completed in each session, but parents and youth also are trained to complete these together as homework following each drug test completed at home (see below).
Self-management planning. The triggers identified in ABC assessments are targeted via self-management plans developed by the therapist, youth, and parent. Plans commonly fall into three categories: (a) avoiding triggers (e.g., avoiding certain peers, decreasing time spent in places/with people that trigger use while increasing time spent in places/with people that trigger abstinence), (b) rearranging environment (e.g., purging items associated with drug use), and (c) developing effective drug refusal skills for unavoidable triggers such as peer pressure. Once a list is generated, the therapist helps the youth and parent weigh the potential costs, benefits, and difficulty level of each strategy so they can choose the best plan.
Drug testing and contingency contracting. Concurrent with developing self-management plans, parents are taught to conduct random urine drug screens and breath scans at home. Screens also are conducted at every scheduled treatment session. Finally, the therapist and parent arrange for periodic random clinic visits to conduct screens. The therapist, youth, and parent create a contingency contract that specifies consequences based on the results of the screens. The contingency contract follows a well-specified protocol for behavior plans. First, the therapist, youth, and parent generate a menu of rewards that can effectively compete with the youth's substance use. The therapist ensures there is a balance between natural incentives parents can provide (e.g., cell phone access; later curfew) and items to be purchased with gift cards (i.e., therapists have access to $250/youth for gift cards). To assist therapists and parents in identifying rewards with the best odds of competing with substance use, rewards are rank ordered by the youth based on preference. From this reward menu, the youth and parent choose the youth's "most valued privilege" (MVP), which is almost always a natural incentive a parent can provide regularly. Remaining menu items are assigned point values by the parent and therapist, usually 1 point ≈ $1. Once the menu is finalized, a point-and-level system is implemented and the youth receives a 50-point starting balance. The youth earns or loses MVP access from the parent depending on each drug screen result. During the first month (Level I of the contract), youth keep their points if they have negative drug screens, but lose 12 points for each week they test positive. Regardless of screen results, youth cannot redeem their points in this period. From the fifth week on (Level II of the contract), negative screens result in youth being able to earn additional points and also to use their points to "purchase" items on the reward menu. To provide a greater incentive (i.e., escalating reinforcer), the number of points youth can earn each week starts at 12 and then increases to 24 after eight consecutive weeks of negative drug screens (Level III of the contract; rapid reset is also used). When making a purchase, youth may use as many points as they would like from their balance. Rewards are provided as immediately as possible, consistent with behavioral principles. If a youth has a positive screen from the fifth week on, the youth does not earn points and cannot make a "purchase" until the next negative screen. As treatment progresses, emphasis shifts to using natural incentives provided by parents to sustain abstinence and also expansion of the behavior plan to include any other behaviors the parent wants to target.

CM+ TO ENHANCE PARENT MANAGEMENT. As discussed, although family-based CM involves parent participation, evidence indicates it does not yield reliable improvements in parent management skills. Consistent with the enhancement manipulation-of-mediator design, an approach was chosen to target the putative parenting mediator more intensely in CM. In selecting the approach, the following criteria had to be met. It needed to be: (a) powerful enough to generate meaningful changes in parenting, (b) conceptually consistent with CM, and (c) feasible for delivery in outpatient settings. Various approaches were considered, and the well-validated *behavioral assessment and teaching system* from PMTO[2] was ultimately chosen. This system was selected for three reasons. First, PMTO is supported by five decades of efficacy, effectiveness, and implementation research, and it is the leading parent training intervention for youth.[180] Indeed, evaluations of PMTO with child and adolescent samples demonstrate it produces substantial reductions in youth externalizing behavior.[181] Second, and of central importance to the present proposal, mediation studies indicate that the *behavioral assessment and teaching system* in PMTO produces improvements in parent management skills, and those improved skills largely account for PMTO's effects on youth outcomes.[180] In fact, <u>of all parenting interventions, PMTO has the most support for improved parenting as the key mechanism of action</u>.[180] Third, PMTO has been extensively tested and validated for use with diverse samples, including Latino families.[182]

PMTO was developed and validated by OSLC scientists in the 1970s, and this EBP is currently being implemented in over 100 national and international sites.[2] The model is comprised of a *behavioral assessment and teaching system* as well as *clinical content*. In PMTO, the *clinical content* is typically behavioral concepts focused on externalizing problems, but can be tailored by subpopulation. Thus, CM strategies (detailed above) can be the clinical content. PMTO's *behavioral assessment and teaching system* was developed as the specific therapeutic processes used to deliver the clinical content and the system is viewed as critical to achieving PMTO's meaningful change in parenting.[182] In essence, the system involves "parallel processes" in that it employs behavioral principles, the same behavioral principles employed to change the child's behavior, to facilitate parents' active learning and rapid skill acquisition. As such, the PMTO *behavioral assessment and teaching system* can be seamlessly adopted by other conceptually consistent interventions. Indeed, Co-I Chamberlain has incorporated this system into both TFCO[183] and KEEP.[184] Similarly, with oversight from

Chamberlain, the CM+ protocol will add the *behavioral assessment and teaching system* from PMTO to standard CM to enhance parent's skill acquisition more intensely (see Table 4).

Table 4. PMTO Behavioral Assessment and Teaching System Incorporated Into CM

This system uses three fundamental **Processes** (listed below) to bring about changes in parenting. These processes are interdependent therapeutic operations,[185] forming the fundamental skills a therapist employs. The basis for these processes is to address a youth's behavior problems using methods based on behavioral principles to change the parent's behaviors. These processes are the therapeutic skills used to deliver clinical content (i.e., to assess and teach parent management) and are based on principles of *behavioral chaining, shaping, fading, generalization, immediacy, reinforcement, differentiation*, *cueing,* and *modeling*.

Parent Daily Report (PDR[1]). The PDR procedures entail highly structured phone calls to the parent. Although the PDR typically includes daily phone calls, we believe it would be more feasible and prevent potential barriers if phone calls were conducted every other day (i.e., approximately twice between sessions). Calls are pre-arranged to occur at convenient times for the parent. Parents are oriented to PDR procedures so they are prepared for how the structured call will be conducted. First, the therapist ensures the parent can speak confidentially (ensure privacy). The therapist then asks a series of brief questions assessing occurrence/non-occurrence during the past 48 hours of specific adolescent behaviors (e.g., adherence to rules, substance use confirmed by urine drug screens), parental responses to those behaviors (e.g., reinforcement, limit setting, supervision), and the youth's reactions to the parental response. The therapist then offers guidance and feedback (*cueing*) to parents on effective parent management techniques. These include breaking complex parenting behaviors into smaller steps (*behavioral chaining*) and providing positive feedback (*reinforcement*) in proximity to specific parent management accomplishments (*immediacy*). Rather than focus on all parenting behaviors, the parenting behaviors (including smaller steps in the *behavioral chain*) are rank ordered by the therapist prior to the calls so the therapist can focus on a single parenting behavior for each phone call (based upon the combination of prioritization and occurrence/nonoccurrence of behaviors; *fading* and *shaping* of parent management skills). The therapist also graphs parenting behaviors based on PDR data collected in each call; the graph is used to illustrate progress during in-person treatment sessions. Research indicates that when implemented with other behavioral interventions, the PDR is highly feasible and has good utility for improving parent management skills.[186-189] Also of importance, the PDR is easy to implement and fits within the practice parameters of outpatient therapists (contacting and guiding parents in specific skills related to the youth's treatment).

3-D Role-Play. Therapists are trained in this method to help parents develop and refine the use of parenting skills. Although role-play is not a new technique, OSLC scientists developed the 3-D method in collaboration with Salvador Minuchin (developer of Structural Family Therapy) to enhance its capacity as a teaching tool.[190] The therapist first meets individually with the parent to Demonstrate an ineffective response to a problematic youth behavior, such as lecturing. Next, the therapist models a more effective strategy, such as swiftly implementing a consequence in a calm voice, to Differentiate it from the ineffective approach (*differentiation* and *modeling*). Finally, the therapist and parent Debrief to consider positive and negative consequences of the ineffective and effective strategies. Reflective questioning during debriefing increases parents' awareness of how their verbal and nonverbal behaviors influence interactions with their youth (*cueing*). For example, therapists might ask, "What did I do to make you want to cooperate? How was my tone of voice?" Such 3-D role-plays are used in every session to facilitate step-by-step learning of complex skills (*behavioral chaining*), with each step representing a small change that contributes to successful implementation (*shaping*). Once a parent becomes proficient with a skill, s/he is assigned homework to try it in real-life situations (*generalization*). After opportunities for testing, skills are revisited during sessions and PDR calls and refined for future application (*generalization*).

Anti-Coercive Problem-Solving. Teaching a parent to change his/her parent management skills requires instruction. A collaborative problem-solving approach was developed based on research indicating that parental resistance to this instruction (a high base rate phenomenon in parenting interventions) can be exacerbated or abated by therapist responses.[191] Instead of straightforward instruction, therapists are trained to demonstrate (*modeling*) problem-solving steps (identifying goal statements, brainstorming options, identifying manageable steps to achieve goals) and to use those steps as clinical skills to prevent or manage resistance. Problem-solving begins in the first session as therapists help parents articulate goals for their child's treatment. Parents learn to break goals into small achievable steps (*behavioral chaining*), and progress is tracked and praised at every session (*shaping* and *reinforcement*). Brainstorming becomes a strategy to engage parents and manage resistance. For example, if parents express doubt about their ability to complete a task, such as withholding an MVP if their youth tests positive for drugs, the therapist avoids engaging in a coercive interchange and collaboratively brainstorms solutions instead. Parents might decide to solicit assistance from another adult family member in withholding the MVP or decide to change the MVP to an item they can more confidently withhold (*shaping*). Thus, active problem-solving is always emphasized. Further, because behavior plans rarely work perfectly on first attempts, therapists provide strategic warnings to help parents anticipate that their plans might need revision (*cueing*). This approach increases parents' comfort in reporting challenges with implementing a behavior plan. Whenever this occurs, the therapist emphasizes positive aspects of the parent's effort at implementing the plan (*shaping*) while identifying areas for refinement, helping the parent create a new plan, and rehearsing new skills via role-play practice, as needed.

Of importance, our team's decades of clinical experience with the PMTO *behavioral assessment and teaching system* supports feasibility of implementing it as part of CM+. Indeed, OSLC staff implement the PDR each day with hundreds of foster parents participating in TFCO throughout the U.S., with PDR completion rates ranging from 70-100%. In addition, the *behavioral assessment and teaching system* is actively being utilized in programs at the OSLC outpatient clinic. As an example, for over seven years, OSLC therapists have served a population of parents referred by child welfare due to serious substance abuse and neglect of their children. As a central component of that outpatient treatment, therapists administer PDRs to parents every other day (consistent with the proposed CM+ schedule) and use the PMTO role-play and problem-solving strategies to enhance parents' delivery of effective parent management skills. OSLC staff have achieved a PDR collection

rate of 79% and a treatment completion rate of 81% with these high-risk substance-abusing parents, highlighting the feasibility of delivering these strategies in an outpatient clinic.

ACHIEVING AND ASSESSING FIDELITY. Treatment fidelity is essential for internal validity (ensuring standard family-based CM and CM+ are implemented as intended and differ from one another only with regard to the experimental enhancement). Thus, strong treatment fidelity is critical to establishing effectiveness, and a well-developed protocol will be used for training and ongoing quality assurance. Specifically, therapists in both conditions will receive training and ongoing quality assurance from McCart and Sheidow. The training protocol follows that used in our other family-based CM research and large-scale transport of CM to community-based practitioners.[35–36] An initial 3-day workshop orients clinicians to program philosophy and all intervention methods. Clinical supervision further supports therapists' implementation, modeled on a structured CM supervisory manual.[192] Following workshop training, clinicians practice treatment delivery to families and have individual supervision weekly to review progress and problem-solve barriers. As high fidelity becomes consistent, weekly phone coaching is provided, focusing on fidelity and solutions to difficult clinical problems. Bi-annual booster trainings are conducted on difficulties in fidelity or achieving clinical outcomes.

Further, therapist implementation of interventions will be measured from the perspective of the youth, parent, and therapists (via self-report) and McCart and Sheidow (via coding of taped treatment sessions and PDR calls). As noted, the 34-item CM Adherence Measure (CAM) was developed using Rasch methods and validated across several studies.[166] CAM subscales measure the cognitive behavioral and behavioral interventions used in CM. Using the same format, items will be created to capture PMTO enhancements in CM+. Using standard procedures employed in our other CM studies, parents and youth will complete CAMs monthly by phone (for duration of treatment) to report on therapist's CM implementation. Investigators will monitor CAMs monthly for ongoing quality assurance and as-needed therapist remediation. In addition, a more immediate fidelity assessment and remediation mechanism will be therapists completing CAMs after each session and phone call to report on their own behavior. Further, therapists will record all treatment sessions and phone calls. McCart and Sheidow will complete observational ratings[167,193] on randomly selected (20%) treatment sessions and (20%) calls. Employing procedures used successfully in Azrin et al.[129] to monitor and improve fidelity, ratings will be compared to therapist report from the same session/call. Inconsistencies between therapist self-report and observational ratings will trigger remediation training and more intensive supervision. Session/call notes and reports also will be evaluated weekly to ensure fidelity across conditions.

BALANCING THERAPIST CHARACTERISTICS ACROSS CONDITIONS. We anticipate that 3 therapists will deliver CM, and 3 different therapists will deliver CM+. Prior to beginning youth recruitment, therapists will be randomized to provide services in either the CM or CM+ conditions. To minimize bias, therapists will be balanced as much as possible, given the small sample, by age, sex, race, and years of experience.

ADDRESSING RISK OF CONTAMINATION. Both treatment arms are conducted within a clinic, raising concerns of potential contamination between therapists in the same clinic. Nevertheless, based on our experience conducting RCTs, we view this risk as low. Indeed, CM and the PMTO enhancements are highly structured, requiring initial training and supervision specific to identifying barriers to treatment fidelity. Across numerous trials for similar interventions, we have found therapist fidelity varies.[194-196] More generally, research indicates even experienced therapists revert to prior/usual practice in the absence of formal structures such as ongoing supervision.[36] Thus, it is unlikely that a standard CM therapist who inadvertently hears about PMTO strategies would be able to implement them with fidelity, especially in the absence of training or access to materials and supervision. Nevertheless, contamination risk will be mitigated in several ways. First, therapists deliver treatment in only 1 condition. Second, only therapists within the condition have access to resources to facilitate implementation. Third, clinical supervision is conducted individually, not in groups. Fourth, therapists formally agree not to discuss CM and CM+, except with therapists in the same condition. Fifth, as described, we measure implementation in both conditions, allowing close monitoring for potential contamination during the trial. Any evidence of contamination will be addressed immediately with therapists.

DATA ANALYSIS STRATEGY

The design leads to 11 measurements of the direct target (parent management; level-1), 6 measurements of indirect targets (behavioral regulation, peer relations; level-1), and 6 measurements of ultimate outcomes (substance use, externalizing behavior; level-1) nested within 172 youth/parents (level-2). Analyses will use latent growth curve formulations of mixed-effects regression models.[197-198] These highly flexible models accommodate variability in number and spacing of measurements, discrete (i.e., urine drug screens [UDS]) and continuous (i.e., parent management, behavioral regulation, peer relations, GAIN scores, externalizing behavior) outcomes, and separate patterns of change for distinct phases (i.e., during- and post-treatment).

EXPERIMENTAL MEDIATION AND CAUSAL INFERENCE. The experimental mediation design emphasizes evidence supporting causal inferences, and there are important conceptual and statistical considerations. As reviewed by MacKinnon,[199] by randomizing youth/parents, the effect of CM+ on parent management is a causal estimate. However, the effect of parent management on drug use and externalizing behavior is not straightforwardly causal, it is potentially influenced by unmeasured confounding variables. Following MacKinnon's

recommendations, and to support causal inferences, this is addressed in 3 ways. First, the enhancement design directly targets the mediator—increasing probability of a causal effect between mediator and outcome. Second, longitudinal measurements of the mediator and outcomes address temporal sequencing—demonstrating that mediator effects occur before outcome effects. Third, supplemental models evaluate confounding variables—providing evidence that mediator effects are not due to confounders.

MODEL FORMULATION. The underlying model is a mixed-effects latent growth curve model with repeated measurements (level-1) nested within youth/parents (level-2), implemented in Mplus (v7.31;[197]). As reviewed by MacKinnon,[200] there are several options for modeling longitudinal mediation. Flexibility of growth models for targeting phase-specific change[201] are leveraged and combined with parallel process models for mediation.[202] In a single model, there are separate change estimates for during- and post-treatment phases, directly addressing temporal sequencing of mediators and outcomes. The UDS outcome is modeled using a Bernoulli distribution, and remaining ultimate outcomes, direct targets, and indirect targets are modeled with normal distributions. Time terms are computed using assessment dates.[203] Treatment condition is a youth/parent-level predictor (level-2; CM = 0, CM+ = 1), and cross-level interactions are specified between condition and level-1 growth and phase terms. Models, as indicated, control for age, sex, race, ethnicity, SES, and treatment history. Likewise, preliminary models test, and control, for differences in outcomes across therapists and clinics. Follow-up models determine whether individual paths and mediated effects differ for males and females.

STATISTICAL TEST FOR MEDIATION. The test for mediation is based on the product of coefficients (i.e., αβ) with asymmetric bootstrapped *SE*s and 95% CIs for the product.[204] This test requires estimation of two parameters and their *SE*s, where, for example, α is the effect of CM+ on parent management and β is the effect of parent management on substance use and externalizing behavior. Parameters are obtained from Mplus and supplied to PRODCLIN[205] for the asymmetric boostrapped *SE*s and CIs. This approach offers enhanced statistical power[206] and applies both to multilevel data[207] and longitudinal mediation.[200]

EVALUATION OF SPECIFIC AIMS

AIM 1: DETERMINE WHETHER PARENT MANAGEMENT SKILLS (DIRECT TARGET) MEDIATE THE EFFECT OF TREATMENT ON YOUTH SUBSTANCE USE & BEHAVIOR PROBLEMS (ULTIMATE OUTCOMES). The test for mediation requires the coefficient and *SE* for CM+'s effect on parenting (a-path) and parent management's effect (controlling for treatment) on substance use and externalizing behavior (b-path). Of note, a preliminary model evaluates the direct effect of CM+ on substance use and externalizing behavior (c-path), though as noted by MacKinnon,[199] mediation should be tested regardless of this path's significance.

a-path. This model is specified with 11 repeated measurements of parenting as the outcome. To address temporal sequencing, the model estimates separate change rates for during- and post-treatment phases. This is tailored to each youth's course of treatment using coding strategies for discontinuous (piecewise) change (see Singer and Willett[201]). Changes during treatment phase are modeled with linear and quadratic terms for number of months since baseline. A dichotomous phase indicator differentiates post- and during-treatment measurements, and post-treatment change is modeled as linear and quadratic terms for number of months since treatment end. This provides three estimates: during-treatment slope (estimate of interest for mediation test), overall shift in parenting levels from during- to post-treatment, and post-treatment slope.

b-path. This model is more complex, simultaneously evaluating the mediator and outcome processes. To obtain this coefficient, the a-path is modeled along with the outcome model (c-path; testing for differences between CM+ and CM on substance use and externalizing behavior). With fewer outcome measurements, the model includes a during-treatment slope term and indicators to differentiate 9- and 12-month assessments, providing three estimates: during-treatment slope, change at 9 months, and change at 12 months. To obtain the b-path coefficient, a regression is specified with *during-treatment mediator slope* as a predictor of *outcome at 9 and 12 months*. This provides a targeted test of mediation, with during-treatment change in the mediator as a predictor of post-treatment outcomes.

Ethnicity effects. In close consultation with project consultant MacKinnon, and to address potential for differential effects across project clinics, formal moderated mediation tests can be performed.[208-209] These tests determine whether observed mediation effects differ for Latino and non-Latino youth/parents. Sample size means that results are hypothesis-generating and thus will focus on estimation of confidence intervals. The same approach will be used to evaluate moderated mediation for ethnicity in Aims 2 and 3.

Confounding variables. Although randomization, the enhancement mediation design, and models addressing temporal sequencing increase the likelihood of valid causal inferences for mediation, a remaining assumption is that there are no unmeasured confounding variables for the mediator's effect. Cox et al.[210] recommends sensitivity analyses for confounder bias be used. First, VanderWeele's[211] formulas identify youth/parents with the same value on the mediator but different values on the outcome, as well as youth/parents with the same value on the mediator across both CM and CM+ groups. Second, residuals from the models just detailed should be uncorrelated, and Mplus code from Imai et al.[212] is used to determine whether the mediated effect differs based on unmeasured pre-treatment variables. Third, Mauro's[213] correlational method evaluates the sources of error variance from the mediation model, determining how large the effect of an omitted variable

would need to be to negate the mediated effect.

AIM 2: DETERMINE WHETHER PARENT MANAGEMENT SKILLS (DIRECT TARGET) MEDIATE THE EFFECT OF TREATMENT ON YOUTH BEHAVIORAL REGULATION & DEVIANT PEER RELATIONS (INDIRECT TARGETS). In the parallel process model for Aim 2, the *a-path* is identical to that for Aim 1. The "outcome" model is nearly identical, the only difference being that the "outcomes" are indirect targets of treatment, behavioral regulation and peer relations. The b-path coefficient represents the association between the during-treatment slope for parent management and the 9- and 12-months post-treatment levels of behavioral regulation and peer relations.

AIM 3: DETERMINE WHETHER BEHAVIORAL REGULATION & DEVIANT PEER RELATIONS (INDIRECT TARGETS) MEDIATE THE EFFECT OF PARENT MANAGEMENT SKILLS (DIRECT TARGET) ON YOUTH SUBSTANCE USE & BEHAVIOR PROBLEMS (ULTIMATE OUTCOMES). Aim 3 uses the same approach, with one key difference: rather than treatment condition, the initial variable is parent management (the direct target of treatment) and, as such, there are repeated measurements. The *a-path* represents the effect of parent management on behavioral regulation and deviant peer relations. With both measured longitudinally, this takes the form of the during-treatment slope for parent management predicting the during-treatment slope for behavioral regulation and deviant peer relations. Although this could confound timing and sequencing of a-path effects, the results of Aim 2 will have established the extent to which there is evidence supporting a causal association between the direct and indirect targets of treatment. The outcome model is identical to that for Aim 1. The *b-path*, holding constant the effect of parent management, is the effect of the during-treatment slopes for behavioral regulation and peer relations on the post-treatment levels of substance use and behavior problems.

STATISTICAL POWER FOR MEDIATED EFFECTS. The proposed mediation models include estimates of: (1) the effect of the initial variable on the hypothesized mediator (α-path), (2) the effect of the hypothesized mediator on the outcome (β-path), and (3) the mediated effect (αβ). Using Monte Carlo simulations implemented in Mplus,[214-215] power is determined by the percentage of replications with a significant effect for the path of interest. Using covariance algebra provided by Thoemmes et al.,[215] parameters (path coefficients, variances, residuals) were tailored to reflect α- and β-paths with small-to-medium (R^2 = .07) effects. For each model, sample size, conservatively assuming 10% attrition, was 155, with 10000 replications from the population. For a-path, power was >.90 to detect a small-to-medium effect of the initial variable on the mediator. For β-path, power was .85 to detect a small-to-medium effect of intermediate targets on ultimate outcomes. For the mediated effect, power was .83. This estimate is conservative due to the simulation's Sobell *SE* method. As an upper bound on power, and based on simulations using the proposed asymmetric *SE* method, Fritz and MacKinnon[216] found a sample of N=74 sufficient for .80 power to detect medium effects for α- and β-paths.

ATTRITION AND MISSING DATA

Participants will be retained in research measurement independent of CM/CM+ participation following intent-to-treat principles.[217] Along with this, the successful participant tracking and retention protocols used in OSLC research will minimize missing data. However, because some data will inevitably be missing, methods recommended by Schafer and Graham[218] will evaluate assumptions and guide analyses. Three steps will be used: (1) For a small proportion of missing data with evidence of Missing at Random (MAR), data will be analyzed using the estimation procedures described above. (2) For a non-trivial amount of missing data and evidence of MAR, multiple imputation for repeated measurements will generate complete data.[219] (3) For a non-random missing data mechanism, pattern mixture models will identify and control its effects.[203–204]

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