BEHAVIORAL INCENTIVES TO INCREASE CAREGIVER ENGAGEMENT IN JUVENILE DRUG COURT
NCT03051997

PRINCIPAL INVESTIGATOR:

Dr. Phillippe B. Cunningham
Medical University of South Carolina
College of Medicine
176 Croghan Spur Road Suite 104
Charleston, South Carolina 29407-7555
(843) 876-1840
(843) 876-1840
cunninpb@musc.edu

Dr. David Ledgerwood
Wayne State University School of Medicine
Psychiatry & Beh. Neuroscience
2761 E. Jefferson Avenue
Detroit, Michigan 48207-4105
(313) 993 -1380
dledgerw@med.wayne.edu

CO- or SUB-INVESTIGATORS:

Dr. Stacy R. Ryan
Baylor University
Address: 801 Washington Ave, 8th Floor, Waco, TX 76701
Phone #
Email: Stacy_Ryan@Baylor.edu

Dr. Sharon L. Foster
Alliant International University
10455 Pomerado Road
San Diego, California 92131-1799
(858) 635-4858
fosterbarton@aol.com

Dr. Colleen A. Halliday-Boykins
Medical University of South Carolina
176 Croghan Spur Road suite 104
Charleston, South Carolina 29407-7555
(843) 876-1800
hallidca@musc.edu

Dr. Debra M. Kawahara
Alliant International University
CA School of Prof. Psychology
10455 Pomerado Road
San Diego, California 92131-1799
(858) 635-4613
dkawahara@aliant.edu

Dr. Michael R. McCart
Medical University of South Carolina
176 Croghan Spur Road Suite 104
Charleston, South Carolina 29407-7555
(843) 792-4415
mccartm@musc.edu

Dr. Jeff Randall
Medical University of South Carolina
176 Croghan Spur Road Suite 104
Charleston, South Carolina 29407-7555
(843) 876-1816
randallj@musc.edu

FUNDING AGENCY: National Institute on Minority and Minority Health Disparities

PROTOCOL VERSION: 9/6/2017

Synopsis

Title	Behavioral Incentives to Increase Caregiver Engagement in Juvenile Drug Court
Study Duration	08/16 – 02/21
Study location(s)	Bexar County Juvenile Drug Court and Affiliated Treatment Cites
Objectives	Although juvenile drug court has emerged as a promising model for reducing the cycle of drug use, crime, and delinquency among youth, the effectiveness of drug courts, as well as adolescent drug treatment, is often compromised by the lack of caregiver engagement (attendance and active participation). The current study will use an efficacious behavioral intervention, contingency management, to reinforce caregiver engagement in both juvenile drug court and adolescent drug treatment. **Specific aims include:** **Aim 1:** Evaluate whether caregivers receiving incentives for attendance and participation in juvenile drug court and adolescent drug treatment show greater attendance and participation in juvenile drug court and adolescent drug treatment relative to caregivers not receiving incentives (i.e., juvenile drug court treatment as usual. **Aim 2:** Examine whether youth whose caregivers receive incentives have greater reductions in drug use and criminal re-offending relative to youth receiving treatment as usual. **Aim 3:** Examine whether caregiver attendance and participation explain condition-related changes in youth drug use and criminal offending. Secondary Aim: **Aim 4:** Determine the acceptability and feasibility/disseminability challenges of the caregiver contingency management parent engagement strategy for parent participants, drug treatment providers, and juvenile drug court personnel (judges, court liaison officers/juvenile drug court coordinators).
Number of Subjects	180
Main Inclusion/Exclusion Criteria	To increase external validity of study findings, and consistent with the aim of conducting implementation research if the present results are promising, and because our previous juvenile drug court study found that outcomes were not moderated by demographic characteristics or co-occurring psychiatric disorders, caregivers and adolescents will be included regardless of co-morbid mental health problems (i.e. ADHD, conduct disorder, depression, anxiety disorder), with the exception of thought disorder (i.e. schizophrenia, autism), suicidality or mental retardation. Eligible primary caregivers of any adolescent (aged 13-17) served by the Bexar County Juvenile Drug Court must be willing to participate in treatment.

TABLE OF CONTENTS

1.0 BACKGROUND AND RATIONALE

Juvenile Drug Courts Increasingly Used with Substance Abusers. There were 268 juvenile drug courts (JDCs) in operation by December, 2003,[26] which grew to 476 as of June, 2013 (National Institute of Justice). Over a 6-year period, state appropriations for drug courts grew 35% and federal appropriations increased over 250%.[27] The number of and funding for JDCs are expected to continue growing as they increasingly become the intervention of choice for dealing with substance abusing juvenile offenders.

Mixed Evidence of JDC Effectiveness. JDCs have proliferated despite mixed evidence of their effectiveness. Reviews and meta-analyses have reported only modest effect sizes and slight reductions in recidivism among program participants.[2,3,4,5] One primary factor that may account for the variability in effect sizes in drug court outcomes is the lack of parental involvement (i.e., caregiver participation). Family involvement in JDC improves adolescent drug treatment attendance, increases submission of negative drug screens, and leads to fewer judicial sanctions.[8] However, juvenile offenders enrolled in JDC often attend court by themselves, and when family members do attend their responses are often rated as fair or poor.[8]

A major emphasis of the present study is to examine a caregiver incentive program (caregiver contingency management, CCM) to enhance caregiver engagement, with the goal of improving youth JDC outcomes. Because practical interventions are the most likely to be widely implemented, adding an easy-to implement parent engagement intervention to a promising JDC intervention permits assessment of whether this caregiver intervention can enhance JDC effects. It is important from both conceptual and methodological perspectives to assess the results of CCM when added to JDC procedures that have consistent guidelines for caregiver participation Evaluating the effects of CCM when added to JDC in comparison to treatment as usual (TAU) permits evaluation of the additive effect of the caregiver component, above and beyond the mandates imposed by JDC. In addition, we will examine whether improved caregiver participation in JDC contributes significantly to reductions in youth drug use outcomes, and whether caregiver engagement explains reductions in youth drug use when compared with TAU.

Importance of Family Engagement in JDC. When caregivers are involved in JDC, outcomes improve. Salvator et al.[8] found that family involvement in JDC led to improved adolescent drug treatment attendance, increased submission of negative urine drug screens, and fewer judicial sanctions. These results should not be surprising: the role of family variables in the etiology and maintenance of adolescent substance abuse is well established, and risk factors that characterize families of youths in JDC are no exception.[20,21] Although some adolescent-focused drug treatments can reduce drug use and criminal offending,[22] family-based drug treatments are superior to other treatment modalities.[23] For example, in randomized controlled clinical trials, family-based treatments for adolescent substance abuse have been found to be more effective than other treatments in retaining youth in treatment, reducing youth drug abuse, and mitigating co-occurring emotional/behavioral problems associated with drug use.[23] To be effective, however, families must attend and actively participate in implementing treatment strategies known to impact adolescent problem behavior. The only study we are aware of documenting family involvement in drug court[8] indicated that 69% of the offenders had a family member appear in court at least once (over the course of 12 months) and family members typically only attended 40% of the sessions. Results from this non-randomized study are quite concerning as these same researchers found family participation in drug court was a critical factor in improved outcomes.[8]

Rationale for CM to Increase Caregiver Engagement in JDC. Contingency Management (CM) is based on behavior learning theories, and is one of the most extensively researched, best validated interventions in the field of substance abuse treatment.[28,29,30] For treatment resistant adult populations, an extensive literature provides strong evidence that CM is efficacious in promoting treatment attendance,[13] participation[14] and retention,[25] and improving completion of treatment related activities such as medication compliance[15] and competing behaviors that are incompatible with drug use (e.g., family activities, employment).[16] As such, CM is ideally suited to engage parents in JDC and treatment activities shown to decrease adolescent drug use (e.g., parental supervision of the youth). Incentives or rewards to

increase parent participation in treatment have been used in parenting prevention and intervention studies,[31,32,33] but seldom outside this context. [34]

We are aware of only two studies that have used CM to increase parent participation in their child's drug treatment. Researchers[33,34] used CM to motivate parents of marijuana abusing adolescents to actively participate in various treatment components (attend therapy, attend mid-week urine testing appointments, implement a self-monitoring contract, homework, administer breathalyzer tests, etc.) as part of a larger package of interventions that also included CM for adolescent drug use. Despite improved adolescent drug use outcomes, the impact of parent attendance and participation above and beyond adolescent CM was not examined. Prize-based CM[35,36,37,38], developed by Petry et al.[17] and utilized by Co-PI Ledgerwood[12] will be used in the present study to reinforce caregiver engagement. Prize-based CM has been effective with several different substance abusing populations, including cocaine dependent and methadone maintained opioid dependent patients,[14,15,16] and alcohol dependent[17] and nicotine dependent individuals. Prize-based CM has also been applied to treatment engagement outcomes such as treatment attendance,[12,39] and has been efficacious when implemented by community therapists working independently of research personnel.[12,36] Several studies have used prize-based CM to encourage both adult[12,13,37,38,40] and adolescent[41] substance abusers to complete treatment-related activities consistent with treatment goals (other than abstinence and treatment attendance). For example, prize-based CM has demonstrated effectiveness in improving antiretroviral therapy adherence[40] and increasing completion of pre-arranged activities among attendees of a HIV drop-in center.[13] One study examining prize-based CM for participation in family activities found greater engagement to be associated with longer treatment retention, longer duration of abstinence and greater reductions in family conflict.[42]

Thus, the general feasibility and effectiveness of prize-based CM has been demonstrated. Furthermore, prize-based CM approaches are comparable to other CM treatments (e.g., voucher approaches) in efficacy.[43,44] Nevertheless, no studies have examined the application of this approach to caregivers in a JDC setting. This novel application of an effective treatment provides an innovative and disseminable approach for addressing the important issue of improving youth JDC outcomes.

Advantages of Using CM in a JDC Context. CM and its variations have strong empirical support when implemented with adults and in contexts other than drug court. Several published reviews in the area of adolescent substance abuse[45,46,47,48,49,50,51,52] and from the adult substance abuse treatment literature[49,53] support the effectiveness of behavior therapy approaches that include close monitoring of substance use and use of incentives. A meta-analysis found that CM had the largest effect sizes of psychosocial interventions for substance use disorders.[53] The ultimate goal of this proposal is to enhance the effectiveness of JDCs across the nation by facilitating the integration of low-cost evidence-based services that can be readily provided by clinicians in community settings.

Why Reinforce Caregivers? There are several practical reasons to reinforce caregiver attendance and participation. First, poor caregiver participation often compromises effective empirically supported treatments,[55] resulting in continuing substance abuse and criminal offending. Second, the substantial resources devoted to developing effective interventions are literally wasted when families do not engage in these interventions. For example, in a study of drug abusing adolescents, only 250 families out of 650 initial contacts came in for a screening interview; of these only 145 completed intake procedures; and of these only 72 completed treatment.[56] Third, most EBTs for antisocial behavior require considerable effort on the part of caregivers to attend sessions and implement behavior change strategies (e.g., responding consistently to misbehavior, monitoring the youth's whereabouts). The stress associated with managing a difficult child can undermine caregivers' motivation to undertake these efforts. Finally, because CCM is relatively simple to apply, a wide range of professionals can implement CCM with high fidelity. In sum, CCM has the potential to a) improve parent attendance and participation,[9] essential ingredients of effective intervention with substance-using youth, b) improve drug court outcomes, c) lower societal cost (in terms of reductions in re-offending and victim suffering, and incarceration), and d) be integrated into JDC and other real-world practice settings.

2.0 STUDY OBJECTIVES

The previous section highlighted the need for practical, easy-to-implement ways of improving caregiver participation in JDC and youth drug treatment. An extensive literature provides strong evidence that CM is efficacious with both youth and adults in promoting drug abstinence,[10,11] treatment attendance[12,13] and participation,[14] and completion of treatment related activities such as medication compliance[15] and competing behaviors that are incompatible with drug use (e.g., family activities, employment[16]). The purpose of the proposed study is to evaluate the effects and acceptability of Prize CM procedure[17] designed to reinforce caregivers' engagement in JDC and their child's drug treatment (Caregiver CM; CCM). If successful, this study will provide important information that can be used to reduce youth offending and drug use, and importantly, inform clinical care practices in the emerging field of JDCs. **Specific aims of this study include**:

Aim 1: Evaluate whether caregivers receiving prize incentives (CCM) for attendance and participation in JDC and adolescent drug treatment show greater attendance and participation in JDC and adolescent drug treatment relative to caregivers not receiving CCM (i.e., JDC TAU).
Hypothesis 1: We predict that caregivers who receive CCM will have higher rates of attendance/participation in JDC and in therapy than will TAU caregivers.

Aim 2: Examine whether youth whose caregivers receive prize incentives (CCM) have greater reductions in drug use and criminal re-offending relative to youth receiving TAU.
Hypothesis 2: We predict that youth in the CCM condition will experience greater reductions in drug use and less re-offending.

Aim 3: Examine whether caregiver attendance and participation explain condition-related changes in youth drug use and criminal offending.
Hypothesis 3: We predict that caregiver engagement in drug court processes and adolescent drug treatment activities will be associated with stronger reductions in adolescent drug use and other problem behavior, which do not specifically focus on caregiver engagement.

Aim 4. Determine the acceptability and feasibility/disseminability challenges of the CCM parent engagement strategy for parent participants, drug treatment providers, and JDC personnel (judges, court liaison officers/juvenile drug court coordinators). This aim is exploratory, so *no hypotheses are offered*.

3.0 SUBJECT SELECTION, RECRUITMENT, AND ENROLLMENT

3.0.1 SUBJECT SELECTION

Given the aims of this study, this protocol includes 4 populations of participants (1) youth involved in juvenile drug court, (2) caregivers of youth involved in juvenile drug court, (3) counselors providing substance abuse treatment services to youth involved in juvenile drug court, and (4) juvenile drug court personnel. The targeted enrollment is 180 youth and their families (the total number of caregivers for each youth enrolled could be greater than or equal to 1). We estimate that 374 youth and caregivers will complete the study. We will enroll up to 24 pilot cases (24 youth-caregiver pairs) for therapists training. The targeted enrollment for counselors is 8. The targeted enrollment for juvenile drug court personnel is 15. This study population will include children and may include pregnant women and prisoners. To follow is justification for including these vulnerable populations, specific benefit to their inclusion, and additional protections.

Justification for the participation of children as research subjects. The importance of the knowledge to be gained from this study lies in its compatibility with our national efforts to address the problems of adolescent substance use and maximize the benefits of juvenile drug court. The focus of this study is on whether providing incentives to caregivers participating in their adolescent's drug treatment and drug court proceedings is related to improved drug court outcomes among youth. This study is significant in that information about whether incentives may be used to effectively engage caregivers will be used for larger scale dissemination efforts.

Specific benefit to including children. There are anticipated benefits to children assigned to the intervention procedure and to children assigned to treatment as usual. The potential benefit of the

intervention is that caregivers may engage in their youth's drug treatment and drug court proceedings, leading to improved behavioral and emotional outcomes among youth in the caregiver contingency management group. Caregivers and youth may experience greater closeness and/or family involvement because of the nature of the contingency intervention. Among youth in the control group, responding to questionnaires that monitor mood and behaviors may lead to spontaneous changes due to self-reflection.

The anticiapted benefit from monitoring procedures in treatment as usual that is likely to contribute to the well being of children is that caregivers and adolescents will complete questionnaires and interviews during and after the intervention. This monitoring procedure includes questions about mood and behaviors. Having the opportunity to self-reflect can lead to self-initiated behavioral changes. Also, this monitoring procedure also includes an interview about thoughts and feelings about the treatment process as well as about the drug court process. Having the opportunity to provide feedback about treatment and the drug court process presents an opportunity that is typically not available. This could offer reflief to participants in both groups.

Additional protections to participating children. Protections for children participating in this study will include provisions for soliciting the assent of the children, methods for evaluating dissent of the children, and procedures for re-consenting subjects when he/she reaches 18 years of age.

Provisions for soliciting assent: Upon approach to determine eligibility, caregivers will give verbal consent prior to initiating the screening questions. After completing the screening questions with the caregiver, written consent (parent) and assent (adolescent) for participation in the study will be obtained by study staff. Informed consent and assent will be obtained in a private place. Participants will be informed that their information is kept confidential. During the consent/assent process, parent(s) and adolescents will be provided information about study procedures and the risks associated with participating. As with any research study, it will be communicated with caregivers and adolescents that participation is voluntary and participants are free to withdraw from the study at any time, either at the parent's or adolescent's request. It will be explained to the adolescents that participation is voluntary even if parents provide consent. Adolescents will be given multiple opportunities during the study to assent and dissent. The consent/assent form will provide a thorough description of the purpose of the study, the requirements, time commitment, and risks of participation. Documentation of informed consent/assent will include a signed copy of the consent/assent form, where the adolescent, caregiver, and researcher sign their names and date the form. A copy of the completed consent/assent form will be provided to the parent and adolescent. Additionally, at each follow-up assessment, research staff will review the study procedures, risks, and reaffirm consent/assent.

Description of how parental consent will be obtained: Key personnel will obtain informed consent/assent from both the adolescent participant and their caretaker in a private area. The consent/assent forms thoroughly describe the purpose of the study, requirements of participation, recruitment methods, length of participation, risks, and the compensation provided in exchange for participation. Prior to signing the consent form, the study staff member will answer any questions about participation, and a witness to the consent (who is not a study staff member) will be introduced to the adolescent and their caretaker. In private (without study staff present), the witness will inquire whether the adolescent and caretaker understand the study or have any questions. The witness, the adolescent and their caretaker, and the study staff member will each sign the consent form, including the date and time of signature. The participants will be provided a copy of the signed consent form and encouraged to ask questions at any time thereafter. All investigators have completed training in protection of human research subjects. Documentation of informed consent includes a signed copy of the consent form, where the adolescent, caretaker,

and researcher sign their names and date the consent. A copy of the completed consent form will be provided to the caretaker of each participant. Prior to any assessments, all questions about the study that are raised by the caretaker or adolescent participant will be answered before the consent/assent forms are signed. The consent form will contain details on who to contact in case of an adverse event, details on how to reach the PI, and how to contact the Institutional Review Board to register a complaint.

Methods for evaluating dissent: Dissent will be evaluated based on non-attendance at assessment and or follow-up visits, poor eye contact, lack of interest, and verbal expression of not wanting to participate. In such cases, the participant would be interviewed individually and confidentially by research staff to confirm whether or not he/she wants to continue participation. Participants will be reminded that they can voluntarily end their participation at any time with no penalty to themselves or their family.

Justification for the participation of pregnant women. The proposed research involves a behavioral intervention, which does not include a focus on behaviors related to pregnancy or the fetus. Nineteen percent of target youth participants are expected to be female, and approximately 85% of caregiver participants are expected to be female; and 50% of counselors and juvenile drug court personnel are expected to be women. Excluding participants based on pregnancy status would bias our sample.

Specific benefit to including pregnant women. The benefit to pregnant youth and caregivers is that the intervention or observations as part of treatment as usual will offer symptom relief and reduction for the teen and greater parent-child relationship for the caregivers. The only risk of the research is breach of confidentiality for the pregnant woman.

Additional protections to participating pregnant women. Pregnant women will be granted the same level of protection as provided in other areas of this protocol given that the risk for participation is not above that of other participants.

Justification for the participation of prisoners. This study seeks to test whether providing incentives to caregivers involved in treatment with their juvenile drug court involved youth leads to better outcomes among youth. There may be times when youth are arrested and detained during the course of our study. In these cases, we will seek permission to complete follow-up visits at the detention facility. The ability to complete follow-up assessments on time, would help us to better determine whether and to what extent our incentive program is related to improved health and well-being among youth at high-risk for detention.

Specific benefit to including prisoners. As noted above, participants will not be prisoners at intake, but some may become prisoners depending on their drug court adjudication. As such continued participation during detention allows for the youth and the caregiver to be exposed to protocol procedures, which has the benefits detailed above.

Additional protections to participating prisoners. In the present study, juvenile drug court staff members and probation officers may have knowledge that a family is participating in the present study, but will not know the reasons for study non-participation (e.g., declined vs. ineligible). We will work with juvenile drug court and probation staff to ensure they understand that 1) study participation must be separate from drug court participation and probation, 2) families have the right to decline study participation, and 3) declining study participation should, in no way, influence the care/services received from the drug court or probation. Each participating family (youth and caregiver) will be informed that the drug court and probation officer have been told that

their participation in the study should not impact on any decisions made regarding drug court, probation or adjudication.

3.0.2 RECRUITMENT AND ENROLLMENT

Caregivers and Youth. Bexar county drug court supervisors and drug court probation officers, study therapists, or research assistants will identify potentially eligible families who are participating in drug court. These families will be given cursory information about the study (see study script and brochure) and asked if they wish to receive more in depth information from a research assistant. For those who agree to receive more in depth information from a research assistant, the probation officer will complete a study referral form (see attached form). This referral form will be hand delivered or emailed in a password protected file to research assistants. Research assistants will then approach the family before or after a drug court session, upon enrollment at their treatment facility, or research assistants will contact the family by phone and inform them about the study. Families expressing continued interest will be screened for eligibility by research assistants. Among eligible families that agree to participate, research assistants will explain the study more fully, answer questions, and obtain signed informed consent (caregiver)/ assent (youth) in a private place convenient for the family. Caregiver consent and youth assent will emphasize that the family is entitled to services from the provider organization and juvenile drug court regardless of their participation in the research.

Therapists. Protocol therapists recruited from organizations that are contracted to provide services with the Bexar County Juvenile Drug Court will deliver the caregiver contingency management protocol. Within these organizations, therapists who completed a two-day workshop (and have pre-post training assessment measures [**Knowledge of CM Principles, CCM Training Questionnaire**] on caregiver contingency management will be invited to participate in this study during a site engagement visit after IRB approval. At this visit, therapists will be informed of the study and knowledge of the protocol will be monitored (**JDC Therapist Protocol Quiz**).

Juvenile drug court personnel. Personnel who provided a letter of support (or the individual now holding the position) will be provided with full details of the grant, be provided with the opportunity to express necessary changes to protocol, and consented during a site engagement visit after IRB approval.

All participants will be consented in-person and in a private location at juvenile probation, their treatment facility, or an agreed upon location in the community by a research assistant trained in obtaining consent or by the site investigator (Dr. Stacy Ryan). Additionally, families will be consented according to the procedures discussed above. All participants will be given as much time as they need to consider whether to participate in the research study. We will minimize the perception of undue influence or coercion by ensuring participants understand that participation is voluntary and will not impact their participation in drug court (families) or jobs at their organizations (therapist and juvenile drug court personnel). This assurance will be stated in the consent form and restated at follow-up visits.

Participants will be allowed to withdrawal at any point during the study. Participants who wish to withdraw from the study will be contacted for a study exit assessment. Should participants wish not to engage in the study exit assessment, they will be withdrawn without the assessment and no further contact will be made. Participants will keep any incentives and gifts earned up to that point.

3.0.3 INCLUSION/EXCLUSION CRITERIA

Study Population Being Recruited	Inclusion Criteria:	Exclusion Criteria:
Youth involved in juvenile drug court	Involved in juvenile drug court Ages 13-17 years old at enrollment Teen willing to participate At least one caregiver willing to participate in treatment Live in San Antonio	Diagnosed with intellectual disability or autism spectrum disorder.

	Fluent in English or Spanish	
Caregivers of youth involved in juvenile drug court	Caregivers of youth involved in juvenile drug court Caregiver willing to participate Lives in San Antonio Fluent in English or Spanish	Diagnosed with intellectual disability or autism spectrum disorder
Counselors providing substance abuse treatment services to youth involved in juvenile drug court	Counselor providing substance abuse treatment to an adolescent involved in drug court	N/A
juvenile drug court personnel	Juvenile drug court supervisors and probation officers working in Bexar County Juvenile Drug Court	N/A

3.0.4 RANDOMIZATION PROCESS

Caregivers and youth willing to participate will be consented and either complete study entry assessments and randomization or will be consented and then scheduled for an appointment for completion of study entry assessments and randomization at a more convenient time. Caregivers and youth will be randomized to either the caregiver contingency management or treatment as usual group. The proposed urn randomization procedure is a randomization method that aims to achieve balance across groups on factors that, if unaddressed, could bias estimates of the intervention effect. There is an exception to the randomization procedure. Some families will be placed into the caregiver contingency management group for the purpose of training therapists prior to receiving randomized participants.

4.0 RESEARCH DESIGN & METHODS

Design Overview:

A well-specified intervention, Contingency Management, will be adapted to reinforce caregiver participation in drug court (CCM). We propose a randomized clinical trial examining the utility of caregiver contingency management to increase caregiver engagement in juvenile drug court and adolescent drug treatment activities. The proposed study follows a 2 (treatment type: Drug Court plus treatment as usual (TAU); Drug Court and TAU plus Caregiver CM [CCM] x 10 (time: pretreatment [T0], 1-month [T1], 2-month [T2], 3-months [T3], 4-month [T4], 5-month [T5], 6-months [T6], 9-months [T7], 12-months [T8], and 18-months [T9-six months post-juvenile drug court involvement]) factorial design, with random assignment of 180 caregivers/youths to one of the two treatment conditions. Repeated measures of caregiver and youth functioning will be collected at pre-treatment (T0), and each of the post-randomization time points (T1 – T9). We choose a randomized trial because this is the most valid way to test the efficacy of our proposed intervention. We choose the follow-up time line to measure short-term and long-term maintenance of change. Our randomization procedure will help mitigate bias across the treatment groups, providing groups that are equally distributed across a number of characteristics known to influence outcomes.

Study Timeline:

The first 6 months of the project have been devoted to start up activities that have included hiring and training research assistants; finalizing data collection protocols; finalizing the CM manual, obtaining informed consent from JDC personnel and stakeholders, and collecting the first wave of drug court stakeholder measures during site visits (a more detailed project timeline, goals, and responsibilities can be found in the Budget Justification). Months 7 through 42 of the proposed study will involve data collection and CCM implementation. Months 42 through 54 will focus on completing data collection and data cleaning; and months 54 through 60 will be devoted to data analyses and manuscript preparation.

Measures:

As shown more extensively in the attached Schedule of Assessment table, different sets of measures will be collected at different time intervals (weekly, monthly, quarterly, and annually).

Measures will assess caregiver participation in JDC and adolescent drug treatment, youth outcomes, therapist fidelity, and descriptive and moderator variables. To enhance construct validity most constructs will be measured from multiple sources (e.g., caregiver report, youth report, therapist report, JDC personnel, archival records) using **reliable** and **valid instrumentation**. A copy of each measure is included with this protocol submission.

Caregiver Participation Measures. Multiple measures and multiple informants will be used to assess caregiver participation in JDC weekly status hearings and treatment sessions. Caregiver attendance in JDC will be independently recorded by the JDC supervisors or research assistant using the **Parent/Caregiver Drug Court Attendance Form** and collected weekly at drug court. Differences between research assistants and supervisor reports will be reconciled using court records. **Drug court records** will also be reviewed for caregiver and youth attendance and unexcused absences at drug court sessions. Quality of caregiver participation in drug court will be recorded using the **Juvenile Drug Court Caregiver Participation Ratings** form, which will be completed by a research assistant. Barriers to Drug Court participation will be measured using the **Barriers to Drug Court Participation measure,** which will be completed by the caregiver. Similarly, caregiver attendance at youth treatment sessions will be recorded by therapists and measured as a percent of scheduled sessions using the **Caregiver Contingency Management Session Tracking Sheet (CM Group)** or **Caregiver Treatment as Usual Session Tracking Sheet (Treatment as Usual Group);** Barriers to Treatment participation will be measured using the **Barriers to Treatment Participation measure,** which will be completed by the caregiver. See the schedule of assessments table below for timing of assessment.

Implementation fidelity. The 12-item **Contingency Management Competence Scale** (CMCS) assesses fidelity to prize-based CM procedures. The CMCS has good inter-rater reliability, internal consistency, discriminant, concurrent and predictive validity in substance abusing outpatients. In the present study, the CMCS will be used to rate CCM audiotapes. Initially, 100% of audiotapes will be reviewed to establish inter-rater reliability. Subsequently, the CMCS will be used to assess treatment fidelity. Treatment implementation will also be measured using the **Caregiver Contingency Management tracking sheet**, which will be completed by the therapist. The **Caregiver Contingency Management tracking sheet** will track number of prize draws provided to families at each session and the associated activities. To maintain balance across the treatment groups, a comparable measure will be given to the treatment as usual group, **Caregiver Treatment as Usual** session tracking sheet.

Adolescent substance use outcome measures. Adolescent substance use will be assessed through two well validated methods -- youth self-reports and biological indices. (1) While youth are under the supervision of juvenile probation, **Urine Drug Screen Results** will be obtained from juvenile probation. Screened substances will include Amphetamine, Benzodiazepine, Cocaine, Marijuana, Methamphetamine, MDMA, Oxycodone, Opiate, Methadone, PCP, and Barbiturates. When families are discharged from the supervision of juvenile probation, **Urine Drug Screens** will be collected and screened for Amphetamine, Benzodiazepine, Cocaine, Marijuana, Methamphetamine, MDMA, Oxycodone, and Opiate. (2) Several scales from the **Global Appraisal of Individual Needs** (GAIN) will be used to measure self-reported youth substance use and substance related problems. These include the Substance Abuse Index/Substance Dependence and Substance Problem Scales, which assess DSM-IV-TR criteria for substance abuse and dependence as well as lower severity symptoms; the Recovery Environment Risk and Social Risk subscales that have predicted substance-related problems in a longitudinal study with substance abusing youths; and the GAIN Substance Frequency Scale, which assesses youth substance use for the past 90 days and has good reliabilities and sensitivity to change. Importantly, this latter scale is highly associated with results from both the Form-9087 and urine testing. (3) In addition, **drug court graduation rates** will be tracked using the **Parent/Caregiver Drug Court Attendance Form** as an indication of reduced drug use.

Adolescent problem behavior outcome measures. We will assess problematic behavior across three areas: problematic behavior on a broad scale, criminal activity specifically, and incarceration: (1) **Archival records** maintained by state juvenile justice authorities will be used to examine youths' involvement in the juvenile justice system with regard to charges, arrests, adjudication, and incarceration.

In addition, because youths 16 years and older can be waived to adult court for new arrests, adult arrest records will be obtained for such youths. (2) The 47-item **Self-Report Delinquency Scale** (SRD) will assess youth involvement in delinquent acts (both status and index offenses) during the past 90 days. The SRD includes an overall general delinquency scale and subscales pertaining to person offenses (e.g., assault) and property offenses (e.g., vandalism), and is considered one of the best validated self-report delinquency measures.

Adolescent mental health outcome measure. Mental health functioning will be measured based on parent report and youth report: (1) **Child Behavior Checklist** (caregiver report) and (2) the 12-item **Brief Problem Checklist** (BPC) provides an efficient and highly reliable and valid measure of youth internalizing and externalizing symptoms from caregiver and youth perspectives.

Measures of treatment acceptability. Interviews and questionnaires will be used to gather qualitative and quantitative data on treatment acceptability issues. The 47-item **Survey of Counselor's Perceptions of Incentive Programs** (SCPIP) measures the attitudes of treatment providers towards the use of tangible incentives and social incentives in the treatment of substance abuse problems. The SCPIP has been used with professionals involved in drug treatment including program administrators, program directors, and medical staff. The SCIPP will be completed by JDC personnel at the start of CCM and yearly, thereafter. A modified version of the SCIPP (that will be piloted during start-up) will be completed by caregivers and youth at baseline and end of CCM. In addition, caregivers and youth will complete the **Client Satisfaction Questionnaire-8** (CSQ), which evaluates perceptions of the therapist and treatment. The Caregiver Satisfaction with Caregiver Contingency Management (CCM) measure (CM group only) will also be collected to gather data on caregivers who participated in the Contingency Management (CM) group assessing caregiver's perspective of the CCM program – this measure will be collected at Month 5, or end of treatment, whichever comes first.

Refinement of intervention/assessment protocols. Research assistants will conduct **semi-structured exit interviews (Qualitative Interview- Caregiver, Qualitative Interview- Therapist, Qualitative Interview- Youth, Qualitative Interview- Drug Court)** with the caregivers, youths, therapists, and JDC personnel to assess their perceptions of intervention components, study procedures, and suggestions for research and intervention refinement. Therapists and JDC personnel will be asked about their views of CCM during each year of clinical implementation. Youth and caregivers will be interviewed separately and asked about their general opinions of drug court and CCM procedures at the conclusion of treatment. Analysis of the qualitative exit interview data will inform the refinement of CCM in terms of intervention content and delivery and will be used to plan dissemination efforts. We will collect semi-structured exit interviews from a subset (20%, n=36; randomly selected throughout the study) of families regardless of intervention attendance or treatment success. All exit interviews will follow semi-structured interview guides and be conducted in accord with standard qualitative procedures (e.g., allowing the interviewer to elaborate on relevant and important issues that emerge during the interview). Interviews will be audio recorded, transcribed, and analyzed using grounded theory qualitative methods. Given the cyclical nature of data collection and analysis in qualitative research, the guides may change during data collection to incorporate questions raised by emerging themes and issues in the interviews. Dr. Kawahara (Co-I) will participate in developing the interviews and overseeing their analysis, drawing from her substantial experience conducting qualitative research using grounded theory methods and teaching qualitative methods of inquiry.

Control Measures. To control for the quality of the relationship with the therapist (CCM, TAU) as a potential confound, caregivers, youth, and therapists will complete the 36-item **Working Alliance Inventory** (WAI), which measures three aspects of the therapeutic alliance; emotional bond, agreement on goals, and agreement on tasks. The WAI will be completed monthly during active treatment. To assess and control for other services the youth may receive besides research treatment conditions the caregiver will be asked during the monthly assessments if the youth received mental health or substance abuse services beyond TAU.

Additional Measures. These instruments will be used to describe the sample; some will be examined in supplemental analyses as possible moderators of outcomes. (1) **Demographics and Service**

Utilization Survey completed by caregivers and **Demographics** forms completed by therapists, youth, and drug court personnel , (2) The presence of substance use disorders and specific psychiatric co-morbidities (e.g., anxiety, mood, disruptive behavior disorders) will be assessed by research staff using scales from the **Global Appraisal of Individual Needs-Initial** (GAIN-I), (3) The self-report version of the **Addiction Severity Index** (ASI), (4) The widely-used 21-item **Beck Depression Inventory-2nd Edition** (BDI-II) will assess caregiver depression, (5) **Homework Rating Scale** will assess parent compliance with homework, (6) **Parent-Adolescent Sexual Communication scale** will assess parent and adolescent perception of the quality and quantity of sexual communication, (7) **Termination Questionnaire** will provide information about why a family left treatment and will be completed by study therapists, and (8) **Choice Questionnaire** (Kirby Delay Discounting) measure, will provide information about impulsive choice – a personal characteristic CM interventions attempt to augment.

5.0 STUDY ACTIVITIES

Study Entry Assessment (Time 0). Research assistants will meet with families at an agreed upon location to complete study entry assessments. During this assessment, youth will provide demographic information and complete interviews and questionnaires that assess substance use (Brief Problem Checklist, Global Appraisal of Individual Needs), mental health symptoms (Brief Problem Checklist, Self-Report of Delinquency, Global Appraisal of Individual Needs), criminal activity (Self-Report Delinquency), sexual behavior (demographics form), sexual communication patterns with their caregiver (Parent-Adolescent Sexual Communication – Adolescent Version) and impulsivity (Choice Questionnaire); and the teen's most urine drug screen results to the study entry assessment date will be obtained from probation.

At the same visit, caregivers will provide demographic information and service utilization history; complete interviews and questionnaires about their teen's behavior (Child Behavior Checklist), mental health symptoms (Child Behavior Checklist), impulsivity (Choice Questionnaire); and their own perception of incentive programs (Perception of Incentive Programs). Parents will also provide information about their own substance use history (Addiction Severity Index), mental health symptoms (Beck Depression Inventory), and communication patterns with their child about sex (Parent-Adolescent Sexual Communication – Caregiver Version)

Research assistants will meet with juvenile drug court personnel at juvenile probation offices to have juvenile drug court personnel provide demographic information and complete a questionnaire about their perception of incentive programs (Perceptions of Incentive Programs).

Selected therapists will provide demographic information and complete a questionnaire about their perception of incentive programs (Perceptions of Incentive Program). This information will be collected by research assistants prior to therapist's training.

Study Months 1 through 4. During study months 1 – 4, caregivers in the CCM group will engage in treatment as they normally would plus the prize-based contingency management intervention with the therapist at the provider agency. Caregivers in the TAU group will engage in treatment as they normally would with the therapist at the provider agency only.

Once a month (for 4 months), caregivers and youth in both groups will be asked to complete survey's online through RedCap. If the program is not working, caregivers and youth will complete study assessments using paper forms (or offered the opportunity to complete by phone with a research assistant). During these assessments, families will complete measures of therapeutic alliance (Working Alliance Inventory) and questionnaires that assess substance abuse and mental health symptoms in youth (Brief Problem Checklist; except in Month 3 for caregivers). Caregivers will also complete measures

assessing perception of quality/quantity of assigned homework (Homework Rating Scale). Youth will also either provide a sample for drug screen testing or the most recent results will be obtained by juvenile probation. Additional assessments will be given to the caregivers in-person to assess adolescent's substance use and mental health symptoms (Child Behavior Checklist, Month 3 only;) since the last visit; and youth will be given the Global Appraisal of Individual Needs and the Self-Report Delinquency Scale as additional measures at Month 3 only. In months 1 and 3 only, caregivers will complete the Barriers to Treatment Participation; and in month 3 (or month 4 if family is still enrolled in drug court during month 3) caregivers will also complete Barriers to Drug Court Participation. In month 4 only, caregivers will complete the Choice Questionnaire.

Study therapists will complete the Working Alliance Inventory, rating the caregiver and the youth and the Homework rating scale. During this time, Therapists in the CCM and TAU groups will also complete the Session Tracking sheets on a weekly basis.

Research assistants will rate caregiver participation weekly during months 1-4.

Follow-up Visits (Months 5, 6, 9, 12, and 18 months after study entry). Youth will complete Brief Problem Checklist, Self-Report Delinquency Scale, and Global Appraisal of Individual Needs at all months post-study entry. In addition, the Parent-Adolescent Sexual Communication – Youth Version, Client Satisfaction Questionnaire-Clinic Version, Client Satisfaction Questionnaire-JDC Version, Working Alliance Inventory-Youth measure, and qualitative interview will only be completed at Month 5. At all follow-up visits, youth will also provide a urine sample to be tested for drugs of abuse or the most recent results obtained by Juvenile Probation will be collected. Caregivers will complete the Child Behavior Checklist measure at all months post-study entry. At Month 5 only, caregivers will complete the Beck Depression Inventory, Addiction Severity Index, Perceptions of Incentive Programs, Homework Rating Scale-Caregiver, Working Alliance Inventory, the Client Satisfaction Questionnaire-Clinic Version, the Client Satisfaction Questionnaire-JDC Version, the Caregiver Satisfaction with Caregiver Contingency Management (CM group only) and the Qualitative Interview. At Month 6, the Parent-Adolescent Sexual Communication-Caregiver Version will be administered.

At the 5th month, therapists treating youth in both groups, will complete a questionnaire that assesses reasons for termination. Therapists will also complete the Working Alliance Inventory-Therapist Report on Caregiver, Working Alliance Inventory-Therapist Report on Youth, and the Homework Rating Scale-Therapist. Yearly, therapists and juvenile drug court personnel will also complete a qualitative interview about their opinions of juvenile drug court and how caregiver incentives may have influenced drug court proceedings and outcomes. All follow-up visits will be completed by a research assistant with families at an agreed upon location.

If a caregiver or youth are unable to complete a measure at the prescribed visit, the assessment will be attempted at the next study visit.

Compensation. Caregivers in both groups will receive a $25 gift card at the their study entry visit and at their 3, 6, 9, 12, and 18 month assessments for completion of study related forms, questionnaires, and interviews. Caregivers in both groups will also receive at $5 gift card once a month during the time of the CCM intervention (4 months) each time they complete the monthly online assessment (or phone interviews). Caregiver have the potential to earn a total of $170 worth of gift cards for participating. Caregivers assigned to the CCM group, may also earn up to $737.10 in prizes (see more details below).

Youth in both groups will receive a $25 gift card at the their study entry visit and at their 3, 6, 9, 12, and 18 month assessments for completion of study related forms, questionnaires, and interviews. Youth in both groups will also receive a $5 gift card once a month during treatment for a total of 4 month each time

they complete the monthly online assessments (or phone interviews). Youth have the potential to earn a total of $170 worth of gift cards for participating.

Provider organizations will be issued a sponsor provided check to cover therapist effort related to study procedures. The organization will receive yearly checks that cover a percentage of therapist's salary for time spent on this project. The amount of this check will vary depending on individual therapists' juvenile drug court caseload. Compensation will be mailed directly to the treatment facility.

The juvenile probation department will receive sponsor issued checks in the among of $10,000 per year for having juvenile drug court personnel participate; and $300 per year for the juvenile drug court supervisor's collection of information on the caregiver's drug court attendance. This is part of the contract for services. Compensation will be mailed directly to the juvenile probation department.

Intervention specifications:

Treatment as Usual. All participants will receive TAU regardless of whether they also receive CCM. The CCM protocol was designed as a flexible intervention that can either stand alone or be added to usual clinical practice. Given JDC's treatment contracts with the Center for Healthcare Services (CHS), Family Services Association (FSA), and Elite Counseling caregivers and youth will be receiving treatment as usual from either CHS, FSA, or Elite Counseling. CHS and Elite use the Cannabis Youth Treatment (CYT) project protocol and the parent group focuses on support and substance use education (modeled after the Family Support Network protocol). The theoretical orientation of the CYT treatment is cognitive-behavioral theory. Groups focus on promotion of abstinence from drugs and alcohol, anger/stress management, conflict resolution, identifying triggers, relapse prevention, and decision-making skills. At the FSA, uses the home-based Multidimensional Family Therapy (MDFT) approach. MDFT includes a mix of individual therapy for the adolescent, interventions with the parent, and family-based sessions. Individual therapy with the adolescent is cognitive-behavioral based and focuses on helping teens build skills in (1) identifying links between their feelings and thinking patterns, (2) using effective communication strategies, (3) using problem solving skills, (4) using anger and impulse control skills, and (5) building social competence. The parent interventions focus on rebuilding the caregiver-parent relationship by working to increase parental commitment and involvement with their adolescent. Sessions also focus on supporting parents in consistent and appropriate limit setting, regular monitoring of activities and school performance. Family-based sessions focus on changing the parent-child interaction patterns and may involve other family members.

Caregiver Contingency Management (CCM). In addition to receiving the TAU described above, caregiver participants will receive prize draws similar to those developed and used by Petry et al. for engaging in verifiable activities consistent with their adolescents' successful completion of the JDC program during the time the youth is actively involved in JDC and substance abuse treatment. Specific activities that may be reinforced include: attendance at drug court status hearings; accompanying the teen to probation meetings; participating in scheduled home visits; attendance to the youth's drug treatment sessions; attendance at mental health provider meetings; attending groups for parents of youth with substance abuse issues; and completing other verifiable treatment-related activities. Some additional planned activities that may not be directly related to JDC, but nevertheless could positively enhance the teen's outcomes, might include: the parent attending one's own treatment or mutual support group (in the case where the caregiver is also in recovery); meeting with the youth's teachers to enhance his/her educational support; enrolling in and attending a parenting class; attending or engaging in pro-social activities with the youth (e.g., enrolling the youth in a sport or arts program, engaging in a family outing with the youth). All activities should meet the goals of (directly or indirectly) enhancing caregiver participation in the JDC and/or treatment process. Caregivers will receive escalating chances for tangible reinforcers each week for completing up to 3 of the activities agreed upon by the caregiver and the therapist. Activities must be

agreed upon by the CCM therapist and the caregiver a priori each week. It is expected that these activities will vary from week to week and from family to family. For example, adolescents will not have court dates every week and clinicians occasionally cancel substance abuse treatment sessions (making it impossible for the family to attend). Thus, we plan some flexibility around reinforced activities while also requiring that the activities reinforced must be related to drug court outcomes. Importantly, regardless of the activities planned, the therapist and caregiver must establish an a priori way to verify that the activity was completed. The verification will be required for the caregiver to receive reinforcement. The specific activities reinforced will be documented and tracked each week by the CCM therapist in collaboration with the caregiver. Caregivers will be allowed escalating numbers of draws from a prize-urn for completing the pre-arranged and verified target activities. The CCM prize-urn will be implemented by the therapist once per week. Following the initial session with the CCM therapist, the caregiver will receive one draw from a prize-urn for each successfully completed activity (up to three). For each subsequent session in which the caregiver completes the target activities, the number of draws will increase by one, and keep increasing weekly up to a maximum of five draws per behavior on any one occasion. Thus, it would be possible for caregivers to reach a maximum of 15 draws per week. If the caregiver does not meet an agreed upon target (e.g., does not attend JDC, drug treatment, or does not complete homework assignments), he/she will not receive a prize draw and the number of draws will be reset to one for each target behavior at the next session. Thus, although caregivers may receive reinforcement for one or two completed behaviors (out of a possible three), failure to complete three assigned behaviors will result in a reset of prize draws for the next session. The only exception to this rule will be if the caregiver: 1) experiences an event that is out of his/her control that prevented completion of the target behavior (e.g., documented family emergency or cancelled court date); and 2) he/she was unable to reach the CCM therapist to arrange for another activity. "Excused misses" will not result in a reset of prize draws. The prize-urn in the present study is similar to the one used in two recent studies of adults in substance abuse treatment. It will be filled with 500 slips of paper, with 50% (250) not resulting in a prize ("good job"), 175 (35.0%) small prizes (worth about $1), 74 (14.8%) large prizes (worth $20), and one (.2%) jumbo prize (worth $100). Thus, the average value of each prize draw is $3.51, and a caregiver who participates for 16 weeks can earn up to a maximum average of $737.10 in prizes.

Training and Treatment Fidelity. Strong treatment fidelity is critical to internal validity of the study, and well-developed protocols will be used. An expert in CM (Dr. Randall) and prize-based CM procedures (Co-PI Ledgerwood) will provide training and ongoing quality assurance support for therapists in CCM using protocols that we used in geographically distant sites with out-of-state therapists. Training: CCM. Providers at the participating organizations and others interested in and around the San Antonio area will receive training in caregiver contingency management. Training will be based on procedures from a recent NIH funded study designed to train community clinicians to effectively administer CM. Dr. Ledgerwood (Co-PI) will conduct two half-day trainings that include didactic instruction on CCM, demonstration of procedures for monitoring and tracking target behaviors, practice role-play exercises, and developing homework and clinical tasks for caregivers to complete. Before and after completing the CCM didactic training, the therapist will complete a 15-item test that assesses general knowledge about contingency management and behavior therapy principles. Therapist that are selected to participate (i.e., willingness to participate and those who work at the identified participating providers) will receive additional training about the specifics the study protocol and will be asked to complete an additional multiple choice-test that assesses therapist understanding of the specific protocol procedures of the present study. Selected therapist must successfully complete role-play tests with either Dr. Randall or Dr. Ledgerwood to ensure he or she can administer CCM effectively. The role plays will provide brief descriptions about scenarios in which the therapists are expected to demonstrate specific skills relevant to CCM (e.g., describe treatment to a caregiver; provide increasing reinforcement to a caregiver who meet the behavioral targets for the week). CM experts (study PIs and Co-Investigators) will rate audiotapes of the role-plays using the Contingency Management Competence Scale (CMCS). Initially, raters will establish interrater reliability, and minimum coefficients of .80 will be required for acceptable ratings.

The therapist must obtain scores of at least 80% on relevant objective tests and minimum average scores of 4/7 on the role-play tests before being eligible to treat study participants. Therapists will implement the conditions with 1-2 closely-supervised pilot cases prior to beginning treatment with study participants. Ongoing supervision. Dr. Randall will provide quarterly 1-day booster trainings for protocol therapists in areas identified as presenting difficulties in adherence or achieving clinical outcomes. Protocol therapists will also receive telephone consultation from Dr. Randall approximately once per week. These calls focus on promoting adherence to CCM components and developing solutions to difficult clinical problems (e.g., developing strategies for helping caregivers effectively communicate with the court and adhere to judicial recommendations, designing plans to overcome youth barriers encountered in drug treatment). Ongoing Assessment of Fidelity to CCM. To ensure ongoing fidelity to the prize-based CM procedures, CM experts and or RAs will rate 25% of all audio-recorded sessions (randomly selected within condition) for fidelity using the CMCS observational rating system described by Co-PI Dr. Ledgerwood and colleagues.[84] In the case that the therapists' ratings fall below a minimum average score of 4/7, or if there are precipitously low scores on any specific aspect of CM (e.g., therapist never assesses desire for prizes), we will conduct additional training with the therapist until his/her ratings have reached an acceptable level.

Please see the attached "Schedule of Assessments" for more information about which procedures occur at a visit.

6.0 RISKS & BENEFITS

Caregivers and Youth Risks related to the assessments include those that are less likely (less than 5-20 subjects out of 100) and Not Serious:

(1) **Coercion**. Several steps will be taken to make sure study participants do not feel coerced into participating in this research study: (a) all researchers who have contact with participants will have completed training courses in how to protect people who are in research studies, (b) if caregivers or youth indicate an unwillingness to be in this study, caregivers and youth will be allowed to withdraw from the study, and (c) all researches will make sure that the people working in juvenile drug court will not attempt to influence the caregiver or youth's participation, beyond providing the initial referral.

(2) **Embarrassment**. Selected research assistants and all investigators have been trained in how to help participants not to feel embarrassed while serving as a study participant. To help particpants not feel embarrassed while in the study: (a) research staff will be carefully chosen and trained by the investigators; (b) participants will be reminded throughout this study that they can stop being in this study at any time; and (c) if problems do come up, the site Investigator (Dr. Stacy Ryan) or the Site Coordinator will arrange to meet with participants to talk about the problems.

(3) **Discomfort.** During the interview, there may be times when a particpant feels a little uncomfortable or has some negative emotions because of what is being talked about. However, it is expected that the feeling(s) will be no more than what people feel on a daily basis from similar topics, discussions, situations, and/or interactions.

(4) **Disclosure.** For youth, results from the surveys, observations, interviews, and urine drug test could be shared with caregiver(s) should they ask to view their youth's responses. If caregiver(s) requests to see their youth's responses or results, we will meet with the caregiver(s) first to discuss their concerns and give suggestions for methods that will address their concerns and be more helpful immediately and in the long term. After this meeting, if your caregiver(s) still wish

to review their youth's results, the site coordinator will meet with the youth and the caregiver together to help there be a discussion of the information that is helpful for the youth.

Juvenile Drug Court Personnel Risks related to the assessments include those that are less likely (less than 5-20 subjects out of 100) and Not Serious:

(1) **Discomfort**. While answering questions or during the interview, participants may become uncomfortable answering questions or feel increased emotions because of what is being asked or discussed. If participants feel uncomfortable answering questions, one of the investigators will speak with the participant to help clarify doubts. Participants responses will be kept confidential and they will be told that they do not have to answer questions that make them feel uncomfortable. However, it is expected that the feeling(s) will be no more than the usual level that individuals experience on a daily basis from similar topics, discussions, situations, and/or interactions.

Therapists' Risks related to the assessments include those that are less likely (less than 5-20 subjects out of 100) and Not Serious:

(1) **Discomfort**. While answering questions or during the interview, participants may become uncomfortable answering questions or feel increased emotions because of what is being asked or discussed. If participants feel uncomfortable answering questions, one of the investigators will speak with the participant to help clarify doubts. Participants responses will be kept confidential and they will be told that they do not have to answer questions that make them feel uncomfortable. However, it is expected that the feeling(s) will be no more than the usual level that individuals experience on a daily basis from similar topics, discussions, situations, and/or interactions.
(2) **Increased stress.** Taking part in a research study as a research therapist might feel stressful at times because participants will be asked to complete forms, paperwork, and participate in an interview that you would not otherwise complete for a family in treatment. If participants feel burdened by study related procedures, questionnaires, and/or interview, one of the investigators will speak with the participant to help resolve stress. As part of this study, the time required to complete the procedures, paperwork, and interview is compensated as described in the compensation section above.

Caregivers and Youth, Juvenile Drug Court Personnel, and Therapists Risks that are Rare (less than 5 subject out of 100) and Serious**:**

(1) **Breach of confidentiality**. It is possible in a rare situation that there may be a violation of participant confidentiality. However, the researchers have taken steps to make sure this does not happen such as keeping audio recordings and all research materials in a secure, locked location and coding materials with numbers rather than names

7.0 STATISTICAL ANALYSIS

The research and measurement design leads to a two level data structure with repeated measurements of youth and caregiver outcomes (level-1) nested within youth/caregiver (level-2). Accordingly, the data will be analyzed using mixed-effects regression models (MRMs). This highly flexible approach accommodates several features of the proposed outcomes, including variability in the number and spacing of measurements within and between participants, a variety of outcome distributions, and potential for linear, non-linear, and discontinuous patterns of change over time.

Individual trajectories. Prior to modeling, the observed trajectory of each youth/caregiver on each outcome will be plotted using "spaghetti plots." This will illustrate sample variability in trajectories over time, within and between youth/caregiver, and will inform subsequent model specification.

Model building & estimation. The data will be analyzed using MRMs. This approach provides a variety of options for modeling change over time, including linear, non-linear, and phase-specific (e.g., during-treatment, post-treatment) patterns of change. Prior to analysis, each outcome will be graphically and descriptively evaluated to determine the best distribution for modeling. The model building approach detailed by Singer and Willett will be used to specify fixed and random effects. First, a fully unconditional model will be estimated to determine the proportion of within- and between-subject outcome variance. Second, at the repeated measurements level, and informed by the spaghetti plots, growth terms (e.g., linear, quadratic) will be specified to explain the within-subject variance. These terms will be computed using participants' actual assessment dates, tailoring the model to the observed spacing of measurements.[100] Third, the effect of CCM will be modeled by an uncentered, dichotomous indicator (i.e., CCM = 1, TAU = 0) at youth/caregiver level (i.e., level-2), and cross-level interaction effects will be specified between the CCM indicator and the level-1 growth term(s). Before estimating the final model, fixed effect indicators will be included to test for systematic differences across therapists, providers, and districts/judges, and if identified, differences will be statistically controlled in the final model. The analyses will use an intention-to-treat approach, with youth/caregivers retained in the research measurement portion of the study independently of participation in the intervention. The models will be performed using HLM software.[101] Significance tests for variance components will be based on the likelihood ratio test, tests for fixed effects will be based on the Wald test (i.e., β / SE), and 95% CIs will be computed to reflect the magnitude and precision of the effects.

Aim 1: Evaluate whether caregivers receiving prize incentives (CCM) for attendance and participation in JDC and adolescent drug treatment show greater attendance and participation in JDC and adolescent drug treatment relative to parents not receiving CCM (i.e., JDC TAU). The data for evaluating this aim have a unique structure – caregivers will have different numbers of opportunities for attendance and participation. MRMs, however, readily accommodate this feature. The data will be structured with multiple scheduled dates for each youth/caregiver, and for each date, a value of 0 or 1 will reflect the attendance and participation status. The dichotomous attendance and participation outcomes will be modeled using a Bernoulli outcome distribution with a logit link function and Laplace approximation of the maximum likelihood function.[102] For each outcome, the level-1, level-2, and cross-level terms will be specified as described above. This formulation will compare CCM and TAU on their change over time in attendance and participation. Of note, if the model building steps reveal low within-caregiver variability in attendance and participation, an unconditional level-1 model will compare CCM and TAU on the overall average level of attendance and participation.

Aim 2: Examine whether youth whose caregivers receive prize incentives (CCM) have greater reductions in drug use and criminal re-offending relative to youth receiving treatment as usual (TAU). Aim 2 will be evaluated using a series of two-level MRMs with repeated measurements of drug use and antisocial behavior (level-1) nested within youth (level-2). For urine drug screens (UDSs), the number and spacing of measurements will vary both within and across youth. For the GAIN subscales and SRD, there will be six measurements per youth, scheduled to occur at 0, 3, 6, 9, 12, and 18 months following baseline. The archival criminal charge data, which will be comprised of charge dates within youth, will be evaluated to determine the most appropriate modeling approach. For instance, if charges occur infrequently, the outcome could be the total count of charges during the 18 month period, evaluated using a single-level generalized linear model with a negative binomial outcome distribution. Alternatively, if charges occur more frequently, the outcome could be specified as the count, or any occurrence, during time periods that correspond to the research measurements. The models for Aim 2 will test for differences between CCM and TAU on the drug use and antisocial behavior outcomes at baseline and in the rate (and/or acceleration) of change over time.

Aim 3: Examine whether caregiver attendance and participation explain condition-related changes in youth drug use and criminal offending. Aim 3 will be tested using the product of coefficients

test for mediation and intervening variable effects reviewed by MacKinnon et al. (2002) and extended to multilevel applications by Krull and MacKinnon. For each outcome, the statistical test for mediation will be based on the estimation of two coefficients and their standard errors. These coefficients will be obtained from models that control for the level of therapeutic alliance, isolating the unique mediating effect of caregiver attendance and participation. The first coefficient (α), controlling for therapeutic alliance, represents the effect of CCM on caregiver attendance and quality of participation. The second coefficient (β), controlling for therapeutic alliance and the effect of CCM, represents the effect of caregiver attendance and quality of participation on youth drug use and antisocial behavior. Following estimation of these paths, the significance test will be conducted using asymmetric bootstrapped standard errors and confidence intervals for the product of coefficients (i.e., α×β) using the approach developed by MacKinnon and colleagues and implemented in the program PRODCLIN. Because the proposed mediators and outcomes follow longitudinal processes, a longitudinal formulation of the mediation model just described will be applied – the parallel process latent growth curve mediation model (e.g., Cheong et al.). This model will be implemented in Mplus software. Alternative longitudinal specifications, as detailed by MacKinnon, will also be considered.

Evaluation of Secondary/Exploratory Aim 4: Determine the acceptability and feasibility/disseminability challenges of the CCM parent engagement strategy and of YCM for parent participants, drug treatment providers, and JDC personnel. There are no inferential statistical analyses associated with Aim 4. Qualitative interviews will be recorded on audiotape, transcribed for analysis, and analyzed using traditional qualitative analysis (constant comparative method), in which categories and themes emerge during the analysis. The team will use a standard text retrieval and indexing software (NVivo) to facilitate the team in organizing and analyzing the data. This approach will yield conceptual dimensions rather than quantitative categories, and will highlight themes within and across interviews. At least three individuals will examine the data to permit triangulation of key themes across evaluators.

Attrition & missing data**.** Youth will be retained in the research portion of the study independently of participation in the clinical intervention according to ITT principles (e.g., Nich & Carroll). This strategy, along with the successful participant tracking and retention protocols used in FSRC research, will minimize the amount of missing data. However, some data will inevitably be missing. The methods recommended by Schafer and Graham will be used to evaluate missing data assumptions and determine the best analytic strategy. A three-step approach will be used: First, for a small proportion of missing data and evidence that they are Missing at Random (MAR), the available data will be analyzed using the maximum likelihood-based estimation procedures described above. Second, for a non-trivial amount of missing data and evidence that they are MAR, multiple imputation for repeated measurements will be used to generate complete data. Third, if there is evidence of a non-random missing data mechanism (i.e., NMAR), pattern mixture models will be used to evaluate and control the effect of the missing data pattern in the models.

8.0 DATA MANAGEMENT & PRIVACY/CONFIDENTIALITY

Use of identifiers with private information						
List of identifiers	Looked at by research team	Recorded on an enrollment log, subject list, key list, or stored in a database	Recorded on data collection tools (CRFs, surveys, spreadsheets, etc.)	Recorded on specimen containers	Shared with others (outside research team)	Stored after study completed
Names	☒	☒	☐	☐	☐	☒

a study code that is linked to the individual's identity using a key that is only accessible by the researcher	N/A	☒	☒	☒	☐	☒
Address	☒	☒	☒	☐	☐	☒
Dates (except year)	☒	☒	☒	☒	☐	☒
Phone or Fax numbers	☒	☒	☒	☐	☐	☒
E-mail addresses	☒	☒	☒	☐	☐	☒
- Biometric Identifiers, including finger and voice prints - Full face photographic images and any comparable images	☒ Specify: Results of urine screens & audio recordings	☒ Specify: Results of urine screens & audio recordings	☒ Specify: Results of urine screens & audio recordings	☐ Specify:	☐ Specify:	☒ Specify: results of urine screens & audio recordings
All study related measures/assessments	☒	☒	☒	☐ Specify:	☐ Specify:	☒ Specify:
Any other pre-existing unique identifying number, characteristic, or code: **Number associated with juvenile and/or adult arrest records**	☒	☒	☒	☐	☐	☒

Coding Plan	
Describe the method that will be used to create and assign a unique study code to the data	A unique study identifier will be assigned to each participant corresponding to the order of their enrollment
Describe the method that will be used to create and assign a unique study code to the specimens	The subject's ID will be used for labeling urine specimens. See above for how subject IDs will be assigned.
What is the format of the key?	☐Paper ☒Electronic
Who will have access to the key?	Access to this data is limited to study staff with IRB approval for working on this protocol. Study staff will access identified data for the purpose of data entry and analyses. Study staff requires access to identified data to conduct and monitor the study.
Where will the key be stored and how will it be protected?	Location(s): All results and data will be filed using this identifier, and the codebook (linking the identifier to the participant's name) will be stored in a double password protected file on a university sponsored server that is HIPAA compliant. Data entry and database management will be done in an ongoing manner by project staff using a web-based data entry and project management tool (REDCap) hosted by a university on a password protected server that is password compliant. This interface will provide password protected, secure (128 bit SSL) data entry and project management tools. Describe confidentiality measures: All staff will be trained in Human Subjects Protection. There are a series of procedures in place to protect the confidentiality of the participants. Biological specimens (urine samples) and psychiatric screening exams, drug-use information, behavioral and psychometric data will be obtained solely for research purposes. Individuals who elect to participate will be assigned

	an identification number. PHI will not be transferred to another institution (detailed in the consent form). This transfer will only occur via a secure server that is double password protected. Only IRB approved study staff (who have been granted access) at the institution will have access to the data.

Data / Specimen Storage Plan		
☒	Paper data	Data are designed to be captured using electronic means. However, there may be instances when paper forms are necessary. Paper forms will be handled in one two ways: (1) Immediately scanned into RedCap (see below) and attached as a PDF file to a participant's study record. The remaining hard copies will be destroyed using a shredder. Upon entry into RedCap the paper forms are stored in a double password protected encrypted server. (2) Paper copies will be mailed, signature required, to the Site PI (Dr. Ryan) at Baylor. Upon arrival at Baylor, the paper forms will be entered into RedCap and then stored in HIPAA compliant, locked filing cabinets, housed within locked offices in the department of Psychology and Neuroscience.
☒	Electronic data	A MUSC (see coordinating center information below) laptop with encryption will be used to administer some of the research questionnaires. Data will be collected via the Research Electronic Data Capture (REDCap; a data collection tool) and managed using SPSS. Data quality will be ensured by real-time data validation in REDCap and standard data cleaning procedures in SPSS. This study will use REDCap hosted at the Medical University of South Carolina (MUSC; a collaborating site; and PI of the Sponsor Protocol) and is a secure (128 bit SSL), web-based application designed exclusively to support data capture for research studies. Other research questionnaires will be hand entered into REDcap by research staff using desktop computers plugged into the Baylor server. Voice recordings and participant tracking logs will be stored on Box hosted by Baylor. Non-identifying information obtained via voice recording and tracking logs will be uploaded to Box at MUSC, a collaborating site and PI of the Sponsor Protocol. Box is a MUSC approved online file sharing system that is a secure and HIPAA compliant way to organize and store data. MUSC has signed a "business associate agreement (BAA) with Box that provides additional security safeguards for sharing protected data.
☒	Specimens	Biological specimens (urine samples) will be obtained solely for research purposes. Urine samples will be tested

		for drugs of abuse immediately and then the collection cups and testing strips will be disposed of immediately.
☒	Long-term storage (following completion of the study and inactivation of IRB approval)	Data will be stored in RedCap, the Box, and Baylor protected servers.

Sharing of Research Data/Specimens to Entities Outside Baylor University								
Entity		**Identifiable materials**		**Limited Data Set (i.e. may include elements of dates, city, state, zip)**		**Non-identifiable materials**		**Describe how the materials will be transferred from one location to another.**
		Viewed	**Transferred**	**Viewed**	**Transferred**	**Viewed**	**Transferred**	
☒	Coordinating Center: Medical University of South Carolina			☒	☒	☒	☒	Describe: Data will be collected via and entered into the Research Electronic Data Capture (REDCap) hosted at the Medical University of South Carolina (MUSC) and is a secure (128 bit SSL), web-based application designed exclusively to support data capture for research studies. Additionally, data will be stored on the Box hosted at MUSC. The box is a MUSC approved online file sharing system that is a secure and HIPPA compliant way to organize and store data. MUSC has signed a "business associate agreement (BAA) with Box that provides additional security safeguards for sharing protected data.
☒	Other sites, investigators or collaborators participating in this study. Specify: Alliant International University, Wayne State University			☒	☒	☒	☒	Describe: Collaborators participating in this study will have access to the same REDCap and Box described above. Collaborating institutions are deferring to MUSC for IRB review.

Study Intervention(s)						
Study Intervention(s)	Routine **or** Research Only	# encounters per subject	Who will administer the intervention?			
			Research Team	Study Site Employees	Commercial Source	Other
Caregiver Contingency	Research	16	☐	X	☐	Providers at

Management						Center for Health Care Services, Family Services Association, and Elite Counseling where therapist are also study participants

Laboratory/Specimen collection							
Laboratory procedures		# Procedures (per subject)	Who is performing the lab procedure				
			Research Team	Study Site Employees/Services			
				Obtain specimen	Perform the analysis		
Urine Specimens		Up to 6	☒	Research assistant affiliated with Baylor University	Research assistant affiliated with Baylor University		

ALL Other Research Activities							
Activities, Procedures, Services, Surveys, Chart Reviews, Tests, etc.		# Research Activities (per subject)	Who is performing the activity / service?				
			Research Team	Study Site Employees/Services			
				Collect	Perform the analysis		
Eligibility Screener		1	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University		

					Wayne State University		
Demographics and Service Utilization Survey		1	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Demographics –Youth		1	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Demographics – Therapist		1	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Demographics – Juvenile Drug Court		1	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina		

					Alliant International University Wayne State University		
Child Behavior Checklist		6	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Brief Problem Checklist – Caregiver		4	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Brief Problem Checklist – Youth		10	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Addiction Severity Index Self-Report		2	☒	Research assistant affiliated	Baylor University ;		

				with Baylor University	Medical University of South Carolina Alliant International University Wayne State University		
Beck Depression Inventory-II		2	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Working Alliance Inventory – Caregiver		5	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Working Alliance Inventory – Youth		5	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		

Working Alliance Inventory – Therapist Report on Caregiver		5	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Working Alliance Inventory – Therapist Report on Youth		5	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Caregiver Contingency Management Session Tracking Sheet		20	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Caregiver Treatment as Usual Session Tracking Sheet		20	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International		

					University Wayne State University		
Homework Rating Scale – Caregiver		20	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Homework Rating Scale – Therapist		20	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Client Satisfaction Questionnaire – JDC Version		1	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Client Satisfaction Questionnaire – Clinic Version		1	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South		

					Carolina Alliant International University Wayne State University		
Termination Questions		1	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Qualitative Interview – Caregiver		1	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Qualitative Interview – Therapist		1	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Qualitative Interview – Youth		1	☒	Research assistant	Baylor University ;		

				affiliated with Baylor University	Medical University of South Carolina Alliant International University Wayne State University		
Qualitative Interview – Drug Court		1	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Self-Report Delinquency Scale		6	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Global Appraisal of Individual Needs		10	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina		

					Alliant International University Wayne State University		
Youth Urine Drug Screen Form		6	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Adherence Measure for Rating Audiotapes		20	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Caregiver Contingency Management Prize Sign Out Sheet		20	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
JDC Therapist Protocol Quiz		1	☒	Research assistant affiliated	Baylor University ;		

				with Baylor University	Medical University of South Carolina Alliant International University Wayne State University		
Knowledge of CM Principles		1	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Perceptions of Incentive Programs – Therapist		2	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Perceptions of Incentive Programs – Drug Court		2	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		

Perceptions of Incentive Programs – Caregiver		2	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Parent/Caregiver Drug Court Attendance Form		52	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Arrest Records		1	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Barriers to Drug Court Participation		1	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International		

					University Wayne State University		
Barriers to Treatment Participation		2	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Parent-Adolescent Sexual Communication		3	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Juvenile Drug Court Caregiver Participation Ratings		4-6 (for the number of months an individual is enrolled in drug court)	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		
Caregiver Satisfaction with Caregiver Contingency Management		1	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South		

					Carolina Alliant International University Wayne State University		
Choice Questionnaire		2	☒	Research assistant affiliated with Baylor University	Baylor University ; Medical University of South Carolina Alliant International University Wayne State University		

12.0 DATA & SAFETY MONITORING

Subject Safety	
Specify the procedure(s) you will be conducting to assess safety on an ongoing basis.	
At each assessment period, youth complete forms that assess mental health symptoms including depression and symptoms of depression such as suicidality. Additionally, substance use involvement is assessed, along with withdrawal symptoms. Upon completion, study staff will examine these items for participant response to determine whether safety protocols should be implemented. At the first assessment and at the 5 month assessment, similar questions will be asked of the caregiver. Counselors and juvenile drug court personnel will not complete similar questions.	
Monitoring: How often are you collecting the safety data listed above?	
At each visit for youth, these data are collected on at least one assessment form. At the first assessment and month 5 assessment for caregivers. Research assistants will review these responses and initiate safety protocols as needed.	
Assessing: **How often** and **who** will assess results of the safety data? Describe your plan to ensure that all safety data is timely and appropriately assessed for reportable events.	
Describe plan for reviewing safety data including **how often** it is assessed?	
Research assistants will review the ratings obtained. For endorsing suicidal thoughts or withdrawal symptoms, the RA will notifiy the PI and the PI will interview the participant to assess safety and risk. Should the interview indicate further intervention is necessary, a safety plan will be implemented, parents will be notified (if the particpant is the youth), and referrals or an escort for immediate treatment will be provided.	
Who is responsible for assessing data for safety?	☒ PI ☒ Research Team Member

Data Integrity		
Describe the specific **data elements** to be reviewed (e.g., inclusion/exclusion criteria met, accuracy of data transcription, units of measure are appropriately recorded, accuracy of calculations). Also, include who is responsible for confirming the data is correct.		
Time point: *(Check all that apply)*	Information to be reviewed: *(Complete as applicable)*	Who will review the information? *(Check all that apply)*

☒ Each study visit	For youth, ratings on the Global Appraisal of Individual Needs and the Brief Problem Checklist at months 1, 2, 3, 4, and 5.	☒ PI ☒ Research Team Member
☒ Monthly	At study entry and at the end of the intervention, caregiver's report on the Addiction Severity Index and Beck Depression Inventory will be reviewed.	☒ PI ☒ Research Team Member

Study Stopping Rules
Under what conditions will study treatment be stopped on a **single subject**?
1) If a participant verbally declines participantion; (2) If a participant passively declines particpation by not providing answers/not engaging in study procedures and it is determined that they understand the instructions; (3) If a participant becomes distressed by the intervention and concerns are not remediated with counseling.
Who will make the decision to stop treatment on a **single subject**?
The PI
Under what conditions will the **entire study** be stopped?
If a serious adverse event as a result of participation in the study occurs, recruitment will be discontinued until the Data and Safety Monitoring Officer has reviewed the information and the participant has received adequate care. Subject recruitment will commence again only after the Data and Safety Monitoring Officer has given the investigators the permission to continue. In addition, if during the course of the trial new information becomes available about the effects of physical activity intervention for adolescents and caregivers that significantly impacts treatment approaches, then the Data Safety Monitoring Officer may review the evidence to make a decision about discontinuing the trial.
Who will make the decision to stop the study?
The PI
Who will monitor and report deviations and adverse events; and what documentation will be used to record these problems occurred?
The occurrence of deviations and adverse events will be monitored two ways. One, the site PI will regularly (weekly) examine the database for protocol deviations and research assistant notes indicating an event that could be adverse; (2) research assistants will follow a well-established protocol of contacting the site PI immediately when there is a question about whether and event qualifies as a deviation or adverse event; (3) the site PI will meet with research assistants weekly to review completed assessments and this review will include quires of possible deviations and adverse events. Deviation or adverse events that seem unclear, will be discussed during weekly investigator calls. Final reported to the IRB will be made by the site investigator. Final reported to the funder will be made by one of the PIs, Dr. Cunningham or Dr. Ledgerwood. All protocol deviation will be reported to the IRB, including (but not limited to): failure to obtain consent form, informed consent ob the initiation of the study procedures, omitting study procedures required by approved protocol, performing a study procedure that is not outlined in the IRB-approved protocol, failure to report an adverse event, enrolling participants outside of inclusion criteria, use of unapproved consent form, use of unapproved measures All adverse events will be reported to the IRB and to the funder, including (but not limited to): any participant distress that can be reasonably linked to the study protocol, death, and hospitalization.

10.0 REFERENCES

26. Brown, S. A. (1989). Life events of adolescents in relation to personal and parental substance use. *American Journal of Psychiatry, 146,* 484-489.
27. Kirby, K. C., Benishek, L. A., Dugosh, K.L., & Kerwin, M.E. (2006). Substance abuse treatment providers' beliefs and objections regarding contingency management: Implications for dissemination. Drug and Alcohol Dependence, 85, 19-27.

2. McLellan, A. T., Luborsky, L., Cacciola, J. I., Griffith, J., Evans, F., Barr, H., & O'Brien, C. P. (1985). New data from the Addiction Severity Index: Reliability and validity in three centers. Journal of Nervous Mental Disease, 173, 412-423.
3. Hodgins, D. C., & El-Guebaly, N. (1992). More data on the Addiction Severity Index: Reliability and validity with the mentally ill substance abuser. Journal of Nervous and Mental Disease, 180, 197-201.
4. McLellan, A. T., Luborsky, L., Cacciola, J. I., Griffith, J., McGahan, P, & O'Brien, C. P. (1988). Guide to the Addiction Severity Index: Background, Administration, and Field Testing Results (US Publication No (ADM) 88-1419) Washington DC: U.S. Department of Health and Human Services.
5. Hendricks, V. M., Kaplan, C. D., Van Limbeek, J., & Geerlings. P. (1989). The Addiction Severity Index: Reliability and validity in a Dutch addict population. Journal of Substance Abuse Treatment, 6, 133-141.
8. Achenbach, T. M. (1991a). Manual for the Child Behavior Checklist/4-18 and 1991 profile. Burlington, VT: University of Vermont Department of Psychiatry.
8. Achenbach, T. M. (1991a). Manual for the Child Behavior Checklist/4-18 and 1991 profile. Burlington, VT: University of Vermont Department of Psychiatry.
8. Achenbach, T. M. (1991a). Manual for the Child Behavior Checklist/4-18 and 1991 profile. Burlington, VT: University of Vermont Department of Psychiatry.
20. Dennis, M. L., Funk, R., Godley, S. H., Godley, M. D., & Waldron, H. (2004). Cross-validation of the alcohol and cannabis measures in the Global Appraisal of Individual Needs (GAIN) and timeline followback (TLFB; Form 90) among adolescents in substance abuse treatment. Addiction, 99, 120-128.
21. Godlely, M. D., Kahn, J. H., Dennis, M. L., Godley, S. H., & Funk, R. R. (2005). The tability and impact of environmental factors on substance use and problems after adolescent outpatient treatment for cannabis abuse or dependence. Psychology of Addictive Behaviors, 19, 62-70.
22. Elliott, D. S., Ageton, S. S., Huizinga, D., Knowles, B. A., & Canter, R. J. (1983). The prevalence and incidence of delinquent behavior: 1976-1980 (Tech. Rep. No 26). Boulder, CO: Behavioral Research Institute.
23. Huizinga, D. (1991). Assessing violent behavior with self-reports. In J. S. Miller (ed.), Neuropsychology of Aggression. Boston: Kluwer.
23. Huizinga, D. (1991). Assessing violent behavior with self-reports. In J. S. Miller (ed.), Neuropsychology of Aggression. Boston: Kluwer.
8. Achenbach, T. M. (1991a). Manual for the Child Behavior Checklist/4-18 and 1991 profile. Burlington, VT: University of Vermont Department of Psychiatry.
8. Achenbach, T. M. (1991a). Manual for the Child Behavior Checklist/4-18 and 1991 profile. Burlington, VT: University of Vermont Department of Psychiatry.
28. Hawks, R. L., & Chiang, C. N. (1986). Urine Testing for Drugs of Abuse. Research Monograph #73. National Institute for Drug Abuse: Rockville, MD.
29. Substance Abuse Testing Committee (1988). Clinical issues in urinalysis of abused substances. Clinical Chemistry, 34, 605-632.
30. Horvath, A. O., & Greenberg, L. S. (1989). Development and validation of the Working Alliance Inventory. Journal of Counseling Psychology, 36, 223-233.
13. Attkisson, C. C., & Greenfield, T.K. (2004). The UCSF Client satisfaction Scales: I. The Client Satisfaction Questionnaire-8. In M. Maruish (Ed.), The use of psychological

testing for treatment planning and outcome assessment (3rd. Ed.). Mahwah, NJ: Lawrence Erlbaum Associates.
14. Attkisson, C. C., & Greenfield, T. K. (1996). The Client satisfaction Questionnaire (CSQ) Scales and the Service Satisfaction Scale-30 (SSS-30). In Sederer L. I. & Dickey B. (Eds.), Outcomes Assessment in Clinical Practice (pp. 120-127). Baltimore: Williams & Wilkins.
25. Lyon, J. M., Henggeler, S. W., & Hall, J. A.(1992). The family relations, peer relations, and criminal activities of Caucasian and Hispanic-American gang members. Journal of Abnormal Child Psychology, 20, 439-449.
15. Attkisson, C. C., & Zwick, R. (1982). The Client Satisfaction Questionnaire, Psychometric properties and correlations with service utilization and psychotherapy outcome. Evaluation and Program Planning, 5, 233-237.
16. Petry, N.M., Alessi, S.M., Ledgerwood, D.M., & Sierra, S. (2010). Psychometric properties of the Contingency Management Competence Scale. Drug and Alcohol Dependence, 109, 167-174.
31. Martin, D. J., Graske, J. P., & Davis, M. K. (2000). Relation of the therapeutic alliance with outcome and other variables: A meta-analytic review. Journal of Consulting and Clinical Psychology, 68, 438-450.
32. Buchan, B. J., Dennis, M. L., Tims, F. M., & Diamond, G. S. (2002). Cannabis use: consistency and validity of self-report, on-site urine testing and laboratory testing. Addition, 97, 98-108.
17. Dennis, M. L., Titus, J. C., White, M. K., Unsicker, J. I., & Hodgkins, D. (2003). Global Appraisal of Individual Needs: Administration guide for the GAIN and related measures. Bloomington, IL: Chestnut Health Systems.
12. Henggeler, S. W., Melton, G. B., & Smith, L. A. (1992). Family preservation using Multisystemic therapy: An effective alternative to incarcerating serious juvenile offenders. Journal of Consulting and Clinical Psychology, 60, 953-961.
14. Attkisson, C. C., & Greenfield, T. K. (1996). The Client satisfaction Questionnaire (CSQ) Scales and the Service Satisfaction Scale-30 (SSS-30). In Sederer L. I. & Dickey B. (Eds.), Outcomes Assessment in Clinical Practice (pp. 120-127). Baltimore: Williams & Wilkins.
15. Attkisson, C. C., & Zwick, R. (1982). The Client Satisfaction Questionnaire, Psychometric properties and correlations with service utilization and psychotherapy outcome. Evaluation and Program Planning, 5, 233-237.
16. Petry, N.M., Alessi, S.M., Ledgerwood, D.M., & Sierra, S. (2010). Psychometric properties of the Contingency Management Competence Scale. Drug and Alcohol Dependence, 109, 167-174.
17. Dennis, M. L., Titus, J. C., White, M. K., Unsicker, J. I., & Hodgkins, D. (2003). Global Appraisal of Individual Needs: Administration guide for the GAIN and related measures. Bloomington, IL: Chestnut Health Systems.
12. Henggeler, S. W., Melton, G. B., & Smith, L. A. (1992). Family preservation using Multisystemic therapy: An effective alternative to incarcerating serious juvenile offenders. Journal of Consulting and Clinical Psychology, 60, 953-961.
39. No Citation Listed

12. Henggeler, S. W., Melton, G. B., & Smith, L. A. (1992). Family preservation using Multisystemic therapy: An effective alternative to incarcerating serious juvenile offenders. Journal of Consulting and Clinical Psychology, 60, 953-961.
36. No Citation Listed
12. Henggeler, S. W., Melton, G. B., & Smith, L. A. (1992). Family preservation using Multisystemic therapy: An effective alternative to incarcerating serious juvenile offenders. Journal of Consulting and Clinical Psychology, 60, 953-961.

13. Attkisson, C. C., & Greenfield, T.K. (2004). The UCSF Client satisfaction Scales: I. The Client Satisfaction Questionnaire-8. In M. Maruish (Ed.), The use of psychological testing for treatment planning and outcome assessment (3rd. Ed.). Mahwah, NJ: Lawrence Erlbaum Associates.
13. Attkisson, C. C., & Greenfield, T.K. (2004). The UCSF Client satisfaction Scales: I. The Client Satisfaction Questionnaire-8. In M. Maruish (Ed.), The use of psychological testing for treatment planning and outcome assessment (3rd. Ed.). Mahwah, NJ: Lawrence Erlbaum Associates.
9. Achenbach, T. M. (1991b). Manual for the Youth Self-Report & 1991 profile. Burlington, VT: University of Vermont Department of Psychiatry.
10. Schoenwald, S.K., Halliday-Boykins, C. A., & Henggeler, S.W. (2003). Client-level predictors of adherence to MST in community service settings. Family Process, 42, 345-359.
11. Brown, T. L., Henggeler, S. W., Schoenwald, S. K., Brondino, M. J., & Pickrel, S. G. (1999). Multisystemic treatment of substance abusing and dependent juvenile delinquents: Effects on school attendance at posttreatment and 6-month follow-up. Children's Services: Social Policy, Research, and Practice, 2, 81-93.
12. Henggeler, S. W., Melton, G. B., & Smith, L. A. (1992). Family preservation using Multisystemic therapy: An effective alternative to incarcerating serious juvenile offenders. Journal of Consulting and Clinical Psychology, 60, 953-961.
13. Attkisson, C. C., & Greenfield, T.K. (2004). The UCSF Client satisfaction Scales: I. The Client Satisfaction Questionnaire-8. In M. Maruish (Ed.), The use of psychological testing for treatment planning and outcome assessment (3rd. Ed.). Mahwah, NJ: Lawrence Erlbaum Associates.
14. Attkisson, C. C., & Greenfield, T. K. (1996). The Client satisfaction Questionnaire (CSQ) Scales and the Service Satisfaction Scale-30 (SSS-30). In Sederer L. I. & Dickey B. (Eds.), Outcomes Assessment in Clinical Practice (pp. 120-127). Baltimore: Williams & Wilkins.
15. Attkisson, C. C., & Zwick, R. (1982). The Client Satisfaction Questionnaire, Psychometric properties and correlations with service utilization and psychotherapy outcome. Evaluation and Program Planning, 5, 233-237.
16. Petry, N.M., Alessi, S.M., Ledgerwood, D.M., & Sierra, S. (2010). Psychometric properties of the Contingency Management Competence Scale. Drug and Alcohol Dependence, 109, 167-174.
17. Dennis, M. L., Titus, J. C., White, M. K., Unsicker, J. I., & Hodgkins, D. (2003). Global Appraisal of Individual Needs: Administration guide for the GAIN and related measures. Bloomington, IL: Chestnut Health Systems.

17. Dennis, M. L., Titus, J. C., White, M. K., Unsicker, J. I., & Hodgkins, D. (2003). Global Appraisal of Individual Needs: Administration guide for the GAIN and related measures. Bloomington, IL: Chestnut Health Systems.
28. Hawks, R. L., & Chiang, C. N. (1986). Urine Testing for Drugs of Abuse. Research Monograph #73. National Institute for Drug Abuse: Rockville, MD.
63. No Citation Listed
82. No Citation Listed
12. Henggeler, S. W., Melton, G. B., & Smith, L. A. (1992). Family preservation using Multisystemic therapy: An effective alternative to incarcerating serious juvenile offenders. Journal of Consulting and Clinical Psychology, 60, 953-961.

APPENDIX 1

ASSESSMENT TABLE

Measure	Respondent	Study Entry	Month 1	Month 2	Month 3	Month 4	Month 5 (post)	Month 6	Month 9	Month 12	Month 18
Eligibility Screener	Caregiver										
Demographics –CG	Caregiver	X									
Child Behavior Checklist	Caregiver	X			X		X	X	X	X	X
Beck Depression Inventory-II	Caregiver	X					X				
Addiction Severity Index Self-Report	Caregiver	X					X				
Working Alliance Inventory – Caregiver	Caregiver		X	X	X	X	X				
Homework Rating Scale – Caregiver	Caregiver		X	X	X	X	X				
Choice Questionnaire	Caregiver	X				X					
Client Satisfaction Questionnaire – JDC Version	Caregiver						X				
Client Satisfaction Questionnaire – Clinic Version	Caregiver						X				
Qualitative Interview - Caregiver	Caregiver						X				
Brief Problem Checklist – Caregiver	Caregiver		X	X		X					
Perceptions of Incentive Programs - Caregiver	Caregiver	X					X				
BASELINE Parent-Adolescent Sexual Communication-Caregiver	Caregiver	X									
FOLLOW-UP Parent-Adolescent Sexual Communication-Caregiver	Caregiver							X			
Barriers to Drug Court Participation	Caregiver				X	X*					
Barriers to Treatment Participation-Clinic Version	Caregiver		X		X						

Client Satisfaction Questionnaire – JDC Version for Caregiver	Caregiver						X				
Client Satisfaction Questionnaire – Clinic Version for Caregiver	Caregiver						X				
Demographics - Youth	Youth	X									
Brief Problem Checklist – Youth	Youth	X	X	X	X	X	X	X	X	X	X
Working Alliance Inventory - Youth	Youth		X	X	X	X	X				
Qualitative Interview - Youth	Youth						X				
Self-Report Delinquency Scale	Youth	X			X		X	X	X	X	X
Global Appraisal of Individual Needs	Youth	X			X			X	X	X	X
Choice Questionnaire	Youth	X									
Global Appraisal of Individual Needs (Section 2 only)	Youth		X	X		X	X				
Client Satisfaction Questionnaire – JDC Version for Youth	Youth						X				
Client Satisfaction Questionnaire – Clinic Version for Youth	Youth						X				
BASELINE Parent-Adolescent Sexual Communication for Youth	Youth	X									
FOLLOW-UP Parent-Adolescent Sexual Communication for Youth	Youth							X			
Urine Drug Screen	Youth	X			X		X	X	X	X	X
Demographics - Therapist	Therapist	X									
Working Alliance Inventory – Therapist Report on Caregiver	Therapist		X	X	X	X	X				
Working Alliance Inventory – Therapist Report on Youth	Therapist		X	X	X	X	X				

Caregiver Contingency Management Session Tracking Sheet (CM condition only)	Therapist		collected weekly during months 1-4								
Caregiver Treatment as Usual Session Tracking Sheet (treatment as usual condition only)	Therapist		collected weekly during months 1-4								
Homework Rating Scale – Therapist	Therapist		X	X	X	X	X				
Termination Questions	Therapist						X				
Qualitative Interview - Therapist	Therapist	administered yearly									
Perceptions of Incentive Programs - Therapist	Therapist	X									
Demographics – Juvenile Drug Court	JDC personnel	X									
Qualitative Interview - Drug Court	JDC personnel	administered yearly									
Perceptions of Incentive Programs – Drug Court	JDC personnel	X									
Juvenile Drug Court Caregiver Participation Ratings	RA		X	X	X	X	X*				