Randomized Comparison of Evidence-Based Protocols for Adolescents with ADHD in Specialty Care: Behavioral Only versus Integrated Behavioral and Medication Interventions

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Study Protocol

Project Abstract

Attention-Deficit/Hyperactivity Disorder (ADHD) exists in 20-50% of the 3 million adolescents annually enrolled in outpatient mental health and substance use treatment. Adolescents with ADHD present deficits in attention, self-regulation, and social competence that significantly impede achievement of developmental and educational milestones. Currently there are only two evidence-based treatment options for this age group: academic training and stimulant medications. Both options remain vastly underutilized. Academic training is not available in most school settings and rarely implemented in clinical care. Similarly, ADHD medications are rarely utilized with adolescents in primary or specialty care for a host of reasons related to stigma, misinformation about effects and side effects, and adolescent autonomy issues. Moreover, the widespread fragmentation of pharmacological versus behavioral services prevents families from making informed treatment selections.

The primary objective of this randomized parametric trial is to compare the effectiveness of behavioral only versus integrated (behavioral plus medication decision-making) interventions for adolescents with ADHD in outpatient behavioral services. The behavioral intervention, Changing Academic Support in the Home for Adolescents with ADHD (CASH-AA), contains three components: ADHD psychoeducation, family-based motivational interventions, and academic training. The medication decision-making intervention, Medication Integration Protocol (MIP), contain three components: psychoeducation about ADHD medication, family decision-making, and medication management. The study will compare the effects of two legitimate treatment options for adolescents with ADHD on service utilization, behavioral symptoms, and quality of life. It will generate new evidence on patient-centered treatment selection that aligns with family-specific principles and treatment goals.

This parametric comparative trial will randomly assign 140 inner-city adolescents with ADHD to (1) CASH-AA Only or (2) CASH-AA + MIP. Treatment will occur in community behavioral health clinics. All participants will receive behavioral interventions (CASH-AA): family psychoeducation in ADHD symptoms, executive functioning, and developmental impacts; family-based motivation and ADHD accommodation interventions; and academic training focused on home environment support and organizational skills. Half of the participants

will also receive medication decision-making interventions (MIP): ADHD medication psychoeducation, family decision-making interventions, and (for those who elect to start medication) coordinated medication management. Half of the sample will have comorbid substance use problems. Treatment will occur in three community clinics; therapists will be randomly assigned to study condition. Caregivers and adolescents will complete assessments at baseline, 3, 6, and 12-month follow-up. Multilevel modeling will compare the effectiveness of each condition on key patient and service use outcomes. Patient-centered analyses will explore differential treatment effects based on (a) Medication decision (yes/no); (b) Substance use comorbidity (yes/no); (c) Race/Ethnicity (Hispanic, African American).

Quantitative outcome analyses will test for service use effects, symptom reduction, and quality of life improvements that are primary reasons for seeking clinical services. Qualitative interviews will document family-specific rationale for decisions about medication, compliance with behavioral and medication interventions, and suggestions for improving services and service integration. Note that families assigned to CASH-AA Only will retain the option of pursuing ADHD medication through treatment-as-usual procedures at their respective clinic. Similarly, families assigned to CASH-AA + MIP will not be required to start ADHD medication. Instead, they will receive informed-choice interventions and can choose when and if to start medication; the study will assess the impact of these decisions on clinical outcomes.

If proven efficacious, the CASH-AA and MIP protocols could be rapidly disseminated individually or as an integrated protocol into routine behavioral healthcare settings. The protocols can also be readily combined with other behavioral treatments to form a multicomponent treatment package for adolescents with co-occurring behavior problems. In addition, the family-based, patient-centered CASH-AA and MIP protocols could be delivered in conjunction with other family-based treatments or with individual approaches that flexibly include caregivers in multiple treatment sessions. This makes CASH-AA and MIP highly efficient clinical resources for addressing ADHD-related problems in any outpatient setting that serves adolescents and their families.

Study Purpose And Aims

For childhood ADHD, treatments that combine behavioral and pharmacological interventions have proven to be more efficacious than either behavioral treatment alone or

medication alone. Current practitioner guidelines, which do not differentiate between children and adolescents, stipulate that medication is the first-line treatment option for all youth. However, the evidence base on adolescent treatment outcomes does not readily support this generalization. For example, the most rigorous longitudinal study of ADHD treatment to date found that the superiority of combined treatment during childhood years dissipated in adolescence, possibly due to medication desistance and/or stronger maintenance effects for behavioral interventions. Moreover, long-term medication use by itself does not seem to provide significant benefits to academic functioning. Thus there are several compelling reasons to test medications combined with behavioral interventions during the teenage years. Yet combined treatment has not been systematically tested among adolescents, leaving many important issues about treatment choices for teens unresolved.

The proposed study will help fill this alarming gap in the evidence base for adolescents with ADHD. The study is significant for several reasons. It will occur in existing behavioral health clinics to test front-line treatment effectiveness. Both protocols (CASH-AA and MIP) are evidence-based, affording a rigorous test of the best available treatment options for this clinical group. The test has immediate real-world implications: Families enrolled in specialty treatment settings invariably prefer behavioral services only, but they need to know whether integrated medication interventions can provide a meaningful boost to outcomes that are most important to them. Importantly, whereas ethnic minorities and also girls with are severely underserved and under-researched, the current study will focus on urban minority teens, and about half the sample will be female. Also, this study will be among the first to test evidence-based ADHD treatment options for adolescents who use substances, another significantly underserved and high-priority clinical risk group.

This comparative trial will randomly assign 140 adolescents with ADHD to Behavioral Only (containing CASH-AA) or Integrated (containing CASH-AA + MIP) treatment. The CASH-AA and MIP protocols will be incorporated in existing services in four clinics that support both study conditions. Adolescents and caregivers will complete research interviews at baseline and 3, 6, and 12-months follow-up. Multilevel modeling will compare conditions on symptom, quality of life, and service use outcomes and also test patient-centered heterogeneity of treatment effects and individual difference effects. Semi-structured interviews will document

family-specific rationale for decisions about initiating and continuing in behavioral and medication interventions, along with suggestions for improving the respective treatment services. The study has three specific aims:

Aim 1: Comparative Impact on Client Functioning

Hypothesis 1: Reduced Symptoms. Integrated clients will show greater decreases in ADHD symptoms (inattention, hyperactivity/impulsivity) and comorbid problems (conduct problems, drug use) than Behavioral Only clients.

Hypothesis 2: Improved Quality of Life. Integrated clients will show greater improvements in executive functioning (self-regulation, self-organization) and school functioning (grades, attendance, motivation) than Behavioral Only.

Aim 2: Comparative Impact on Service Utilization

Hypothesis 3: Better Treatment Attendance. Integrated clients will attend more behavioral therapy sessions and medication management sessions than Behavioral Only clients.

Hypothesis 4: Greater Medication Acceptance and Treatment Satisfaction. Integrated clients will more often consent to medication, show greater medication compliance, and report greater overall satisfaction than Behavioral Only.

Aim 3: Examine Patient-Centered Outcomes

Research Question 1: Heterogeneity of Treatment Effects. Will clients with co-occurring substance use problems have worse treatment outcomes than those without? Will there be outcome differences based on age, ethnicity, sex?

Research Question 2: Analysis of Individual Differences. Across treatment conditions, will clients who choose to start a medication regimen have better treatment outcomes than those who do not?

Study Design

This study emphasizes ecological validity: Both protocols will be implemented in existing outpatient behavioral services by agency clinicians. To promote internal validity, randomization will occur within site at both the client and therapist level (i.e., study therapists at

each site will be randomly assigned to condition). The primary benefit of "doubly randomized" designs is that they minimize potential bias related to site effects—because randomization occurs within each site—and therapist sampling bias—because therapists are randomly assigned to condition. The use of a Behavioral Only condition will control treatment expectancy effects. Therapists will be trained and supervised to implement CASH-AA and MIP as part of their otherwise routine duties; that is, the protocols will be additional components of their usual practice for study cases. To maximize protocol exposure, and to promote consistency in the timing of protocol implementation across conditions and cases, therapists will be asked to implement CASH-AA and MIP at the start of treatment (unless contraindicated).

Note: (1) ADHD medication will be available to all Behavioral Only cases via routine site practices for ADHD treatment; and (2) MIP supports family decision-making about medication but does not require families to start a medication regimen.

Sample Description

Study eligibility criteria will be: (1) Adolescent age 12–18; (2) Primary caregiver able to participate in treatment; (3) Adolescent meets DSM-5 diagnostic criteria for ADHD; (4) Adolescents who use substances (estimated 20-50% of sample) meet ASAM criteria for non-intensive outpatient services; (5) Adolescent not enrolled in any other behavioral treatment; (6) Caregiver expresses desire, and adolescent expresses willingness, to participate in outpatient treatment; (7) Family has health benefits that meet the requirements of study treatment sites, all of which accept a broad range of insurance plans including Medicaid. Exclusion criteria will be: mental retardation or autism-spectrum disorder; medical/psychiatric illness requiring hospitalization; current psychotic symptoms; active suicidal ideation; severe substance use problems that require immediate relief (detox or residential placement).

The study sample will be drawn from similar referral streams to those that produced cases for the recently completed CASALEAP RCT and the CASH-AA and MIP pilot studies, as well as from the existing clinical referral stream of each treatment site. Thus the following projections for study demographic and psychiatric characteristics are based on data from those affiliated studies. Participants will include both males (52%) and females and averaged approximately 15.7 years of age (SD = 1.5). Self-reported ethnicities will be Hispanic (59%), African American (21%), multiracial (15%), and other (6%). Households will be headed by a

single parent (66%), two parents (26%), or grandparents (6%). Among caregivers, 71% will have graduated high school and 64% worked full- or part-time. Also, 45% will have earned less than $15,000 per year, 17% on public assistance, and 51% with a history of child welfare involvement. Many adolescents will report current or past year involvement in an individualized education program (30%) and/or school-based counseling (41%); 17% will have received some outpatient mental health care during the past year; 7% will have been on probation in the prior year. Psychiatric diagnoses will be based on DSM-5 criteria; following convention, diagnoses will be given for meeting threshold based on either adolescent or caregiver report. According to study eligibility criteria, 100% of teens will be diagnosed with ADHD. About 33% will have been diagnosed with ADHD during childhood, and 20% will have been prescribed ADHD medication during childhood but not adolescence. We estimate the following rates of other diagnoses: Oppositional Defiant Disorder (ODD) = 87%, Conduct Disorder (CD) = 53%, SUD = 30% (79% for cannabis, 21% for alcohol) [Note; an additional 20% will meet ASAM requirements for outpatient treatment of sub-threshold substance use problems], Mood Disorder or Dysthymia = 42%, Generalized Anxiety Disorder = 17%, PTSD = 17%. We expect 89% will be diagnosed with more than one disorder.

Procedures

Participant Consent and Enrollment Procedures

Participant recruitment. The PI has previously organized a clinical referral network of high schools, family agencies, and community programs serving youth in inner-city areas of lower Manhattan. Partners will make study referrals to research staff during site visits and also by phone. Additionally, we will also leverage the existing referral stream of the participating treatment sites, whereby clinical staff will ask eligible families for permission for research staff to contact them to discuss the study. Project staff will contact referred families by phone and offer them an opportunity to participate in a brief phone screening to assess the reason for study referral and, if desired, discuss study enrollment.

Eligibility screening. Research staff will contact the primary caregiver of referred adolescents by phone, identify our project as being affiliated with the referral source, and explain the nature of the proposed study. Staff will then seek verbal consent from the caregiver to administer a behavioral health screening instrument. Phone screens will be conducted in English

or Spanish at the preference of the family. Families will receive a $25 honorarium for completing phone screens. Families eligible at this initial screening, based on meeting clinical cut-score criteria for ADHD and endorsement of problems consistent with at least one co-occurring behavioral disorder, will be offered the opportunity to participate in a full baseline eligibility interview. Those who agree will be scheduled for a home-based baseline evaluation prior to enrolling in outpatient services. Non-eligible families will be offered a referral to appropriate behavioral services as requested.

Baseline Eligibility Interviews and Consent into the Follow-Up Study. Baseline research interviews will be conducted primarily in the home or in the partnering clinic site, but also in other locations upon request. Caregivers and adolescents will be consented and interviewed separately; caregivers will consent for themselves and their teens, and teens will assent for themselves. Assessment measures will consist of structured clinical interviews and audio computer-assisted self-report measures. Caregiver assessments will be administered in English or Spanish as preferred. Each member will receive a $40 honorarium in store vouchers for completing the interview (60-75 minutes). After members complete the baseline interview, staff will confer regarding eligibility for the follow-up study. Eligible families will then be consented to participate in the follow-up study (caregivers and adolescents will again consent separately), which includes assisted enrollment in a partnering treatment site in which site clinicians have been trained in the study protocols (MIP, CASH-AA). Following this final consenting process, staff will meet with both family members to answer any questions, and for consenting families, prepare the family for linking to treatment (described below). Families will then be scheduled for follow-up interviews to be conducted 3, 6, and 12 months from the date of the baseline; each member will receive a $50 honorarium in store vouchers for completing the 3- and 6-month interview (60 minutes apiece), and $100 in certificates for the 12-month interview (75 minutes). Non-eligible and non-consenting families will be offered a referral to appropriate behavioral services as requested.

Linking to treatment. The goal of treatment linking is to ensure that families enrolled in the study complete an intake appointment at the designated treatment site. Families drawn from community referral partners will be assigned to a designated site based on site capacity and geographical proximity; families drawn from the referral stream of a partnering site will continue in that site's enrollment process. Once assigned to a designated site, research staff will use

intensive family engagement and family-agency coordination efforts to help families overcome barriers to enrolling in services, procedures especially valuable for enrolling hard-to-engage families. Linking procedures will cease upon completion of the first intake interview (after which randomization will occur). After linking is completed, research staff will maintain contact with families solely to complete follow-up interviews, which will occur with every randomized family regardless of treatment attendance.

Randomization to study condition and therapist assignment. Cases will be randomly assigned to study condition after completing an intake interview at the assigned site. Urn randomization will promote balance between conditions on 3 variables: sex, ethnicity (Hispanic, African-American, Other), and ASU problems (Yes, No). Once randomized, cases will be assigned to a study therapist in alternate turns. Note that in some sites, it will be necessary to follow "nearly random" assignment to condition, if the given site assigns cases to clinicians based on a shared rotation of case assignment. That is: Any given case is assigned to the next available clinician in the duty rotation, or, the clinician who is on duty during the given intake appointment. Treatment site therapists who agree to participate as study therapists will be consented in their private offices by research staff. We anticipate some degree of therapist dropout due to staff turnover during two years of enrolling study cases. When a study therapist drops out in either condition, the given site will be asked to nominate two potential replacements, and the new therapist will be randomly selected from that pair. All partnering treatment sites will be in close proximity to assigned study participants and easily accessible via public transportation. Each site will routinely prescribe weekly treatment sessions and offer in-house psychiatric support for all cases. All therapists at each site who treat adolescent clients and who volunteer to participate will be accepted into the study randomization pool.

Study Conditions

Behavioral Only Condition: Changing Academic Support in the Home for Adolescents with ADHD (CASH-AA)

Clients assigned to this condition will participate in routine services at the designated treatment site. In addition, therapists will be trained and monitored in the CASH-AA protocol. That is, CASH-AA will be delivered as one component of the client's treatment plan; the remaining components will be determined according to the site's usual assessment and treatment

planning procedures. For study clients, all of whom will carry an ADHD diagnosis confirmed by research interview, this may or may not include provision of medication in accord with site routines. The study will carefully track but not directly influence medication interventions in this condition.

CASH-AA is a family-based clinical protocol intended for use with adolescents diagnosed with ADHD as either a primary or secondary disorder. It can be delivered in conjunction with family-based treatment or with individual-based treatment that can include caregivers in multiple sessions. It consists of four flexibly delivered treatment modules:

Module 1 Motivation & Preparation: Home Academic Environment. Module 1 in intended to engage adolescents as active participants in therapeutic activities focused on improving school performance, link ADHD traits to school functioning, reframe adolescent school problems as family problems with family solutions, assess characteristics of the home environment that support or impede school success, and determine caregiver and adolescent readiness to make changes in the home academic setting. Clinicians actively engage teens in the treatment process by crafting personally meaningful treatment goals and fostering a collaborative approach to problem solving. Clinicians also facilitate more constructive family engagement in school problems by utilizing relabeling (altering negative attributions about an ADHD-related behavior by emphasizing an unrecognized or mislabeled cause, thereby casting it in a more benign light) and reframing interventions (change focus of discussion about ADHD-related school deficits from "individual" problems to "family" problems that affect, and are affected by, the larger family environment). Reframing also creates the opportunity to collaboratively assess caregiver capacity to participate in reconfiguring the home academic environment.

Module 2 Behavior Change: School Attendance & Homework Plan. Module 2 in intended to implement family-centered interventions designed to boost school attendance (as needed) and homework quality. For adolescents with lateness or truancy issues, clinicians and families design a developmentally calibrated behavior contract featuring incentives for regular school attendance. All cases will receive two evidence-based training interventions specifically designed for adolescents with ADHD. First, the Homework Management Plan is used to train adolescents to develop good study habits while decreasing family anxiety and conflict over homework completion. The plan involves helping caregivers identify things they can no longer control (e.g., knowing the homework assignments each day) and make renewed effort to

influence things they can (e.g., minimizing schoolwork distractions in the home). The goal is to increase the amount of time teens spend on schoolwork each evening. Caregivers and teens negotiate an amount of time and establish contingencies for adherence. Clinicians review the progress of the plan each week, seeking a fixed routine that allows completion of all assigned homework. Second, the Bookbag Organization System helps adolescents take relatively small steps to create a more efficient and reliable organization of school materials. It takes place in the clinic office, follows a series of detailed checklists, and requires a few inexpensive school supplies.

Module 3 Collaboration: Therapist-Family-School Partnership. Module 3 is intended to establish a partnership among clinicians, families, and school personnel to serve the educational interests of teens, in line with evidence-based principles of family-school collaboration for youth with ADHD. The first aim is to provide the family with education and advocacy training on special education rights and school-based services (modifications, accommodations, and interventions) available to adolescents with ADHD. The second aim is for clinicians to complete at least one school visit (if feasible) to solidify partnerships with school advocates and, as indicated, construct a mutually determined plan for tailored educational services. Clinicians then assist caregivers in developing the skills needed to work in conjunction with school staff to monitor and revise the educational plan as schooling progresses.

Integrated Condition: CASH-AA combined with the Medication Integration Protocol (MIP)

Clients assigned to this condition will also participate in routine behavioral services at the given site. In addition, therapists will be trained on both CASH-AA (described above) and the MIP protocol. MIP is a family-based protocol designed to integrate pharmacological interventions for ADHD into outpatient behavioral treatment for teens with ADHD and co-occurring disorders. As with CASH-AA, the 5 MIP Tasks are modular and flexibly delivered:

Task 1: ADHD Assessment and Medication Consult. Therapist consults with psychiatrist to confirm ADHD diagnosis and adolescent eligibility for medication; helps family understand the psychiatric evaluation and its results.

Task 2: Psychoeducation in ADHD Medication. Therapist provides psychoeducation about the common benefits, expected course, and potential side effects of ADHD medications;

details the trial-and-error approach to appropriate dosing; and summarizes other key factors that inform eventual decision-making about medication initiation (see Task 4).

Task 3: ADHD Symptoms and Family Relations: Congruent with CASH-AA Module 1 (w/o school-specific focus).

Task 4: ADHD Medication and Family Decision-Making. Therapist and family discuss ongoing consultations with the psychiatrist regarding medication-related issues. Therapist helps family understand unique benefits of medication in general and its potential specific benefits for the adolescent in home, school, and peer contexts. Therapist discusses stigma, side effects, trial-and-error titration, and substance use issues on a regular basis. Supported by the therapist, the family accepts, refuses, defers, or is declared ineligible (due to chaotic/unsupervised home setting) for medication.

Task 5: Medication Management and Integration Planning. Therapist formulates a case coordination framework for medication compliance tailored to each family, with therapist and psychiatrist working in integrated fashion to support compliance and monitor benefits and side effects. Psychiatrist implements a titration schedule for the client and arranges ongoing medication management visits. Therapist establishes routine inquiry about medication issues during behavioral sessions, including progress of management visits with the psychiatrist. Psychiatrist and therapist create a working arrangement for regular communication and integrated case planning.

Therapist Training and Fidelity Monitoring Procedures

As occurred during the pilot tests of the MIP and CASH-AA protocols, the proposed study will provide on-site training in CASH-AA (3 hours) to all study therapists, led by study investigators. Study investigators will then continue training therapists in the Integrated condition in MIP (additional 3 hours). After initial training, two separate monthly fidelity monitoring meetings will occur at each site, one for each study condition. Ad hoc training will be provided to new therapists whenever there is staff turnover.

Fidelity monitoring (FM) meetings will be organized using principles of localized quality assurance procedures for promoting the sustainability of evidence-based practices in usual care. Specifically, FM meetings will feature data from the therapist-report CASH-AA and MIP fidelity measures, along with a therapist-report measure of evidence-based practices for adolescent

conduct and substance use problems, as quality assurance tools and clinical supervision aids. Also, over the course of the study FM meetings will follow a multistep process to develop on-site clinical expertise and incrementally increase on-site supervision responsibilities in proportion to decreased extramural involvement.

Study Measures

Client Demographics, Multidomain Risk Factors, and Psychiatric Diagnoses

The *Comprehensive Addiction Severity Index for Adolescents (CASI-A)* collects demographic information on high-risk adolescents and their families and also assesses risk factors in education (academics, attendance, behavior, attitudes), family relations (history of drug use/criminality, abuse/neglect), and legal involvement (illegal activities, involvement in juvenile justice). The CASI-A has demonstrated strong reliability and validity with clinical chart reviews of adolescents receiving inpatient psychiatric or substance use treatment and with diagnostic interviews such as the CIDI and DISC. The *Mini International Neuropsychiatric Interview (MINI)* (Version 5.0) is a brief structured diagnostic interview that assesses DSM diagnoses in adolescent and adult populations: ADHD, ODD, CD, SUD, GAD, PTSD, MDD, and Dysthymia. It has demonstrated interrater and test-retest reliability on international samples of psychiatric and non-psychiatric patients, has shown excellent convergent validity with the SCID and the CIDI, and is designed to be administered to treatment-seeking clients by lay interviewers. As in previous studies, the 18 ADHD diagnostic items on the MINI will also be administered at each FU interview to provide a dimensional assessment of ADHD symptoms.

Adolescent Behavioral Symptoms

The *Child Behavior Checklist (CBCL)* is a parent self-report measure that assesses children's externalizing and internalizing symptoms. It has demonstrated strong reliability, criterion validity, and convergent validity with other established measures of child psychological symptoms. The *Youth Self-Report* is a youth-report version of the CBCL with equivalent items, dimensions, and psychometric properties. The *Self-Report Delinquency Scale* assesses adolescent criminal behavior and peer criminal behavior; it is well-validated and has been used extensively with African American and Hispanic populations. The *Timeline Follow-Back method (TLFB)* measures quantity and frequency of daily consumption of substances using a

calendar and other memory aids to gather retrospective estimates. It is frequently used to assess substance use in treatment-referred, ethnic minority adolescents.

Quality of Life Indicators

Executive functioning will be measured with the *Behavior Rating Inventory of Executive Function*, a parent-report measure of behavior problems linked to executive functioning and commonly found in ADHD youth. It has been validated on ADHD outpatient samples and teens with mixed diagnoses. School functioning indicators will derive from three sources. Therapists will acquire school transcripts to document grades and attendance. The *CASI-A* will yield data on past-year academic, attendance, and behavior problems. The *Bonding to School (BTS)* is a self-report measure of adolescent bonding to teachers and orientation to school used with high-risk samples.

Service Utilization, Treatment Satisfaction, and Semi-Structured Post-treatment Interview

Research staff will ask study therapists to gather data from *Clinical Contact Logs* at each site on the total number of sessions attended by study clients and the type and amount of medications prescribed. The *Services Assessment for Children and Adolescents* (SACA) is a structured assessment of parents' reports of their children's behavioral health service utilization, perceived need for services, barriers to services receipt, and retrospective estimate of days of ADHD medication use. It has demonstrated strong agreement with administrative service records; test-retest reliability of lifetime and past year service use are also strong. The *Client Satisfaction Questionnaire (CSQ)* measures consumer satisfaction with the quality and effectiveness of treatment services and will be completed by adolescents and caregivers. Internal consistency ranges are high, and concurrent validity is supported by strong correlations with therapist and client improvement ratings. Study therapists will collect weekly medication use logs during each session via caregiver and/or teen report: type and dose of current prescription, and number of days that medication was taken since last log entry. This will yield interval-level prospective data, the most rigorous self-report method for medication use. *Semi-structured qualitative interviews* will be administered to teens and caregivers at 12-month FU to capture judgments about treatment acceptability and effectiveness of intervention components as well as family-specific rationale for medication decisions.

Therapist Measures

Study therapists will be asked to provide four kinds of study data: (1) Upon consenting to participate in the study, therapists will complete one questionnaire documenting their demographic characteristics and clinical training background, and a second questionnaire documenting their clinical strengths and preferred clinical practices. (2) When treating study cases, therapists will complete and submit the CASH-AA fidelity checklist and, for those in the Integrated condition, the MIP fidelity checklist after every session; and each condition will complete a brief checklist of evidence-based practices for adolescent behavior problems; all checklists (total completion time: 5 minutes) will be collected by research staff on a regular basis. (3) When treating study cases, therapists will audiorecord every session with consenting clients and submit the recordings to research staff on a regular basis. (4) Upon closing a study case, therapists will complete a termination summary of clinical activity that documents information about sessions held, participants in sessions, and treatment procedures that were the main foci of session activity.

Data Analysis

Preliminary Analyses and Refuser Analyses

All analyses will be preceded by examining distributional properties of variables, outliers, and need for using transformed variables or non-parametric tests. We will examine whether randomization successfully created equivalent study groups by conducting *t*-tests or chi-square tests on demographics and other variables; those that differ between groups will be entered as covariates in subsequent analyses. Logistic regression will examine potential biases due to failure to contact clients at follow-up on baseline characteristics, study condition, and their interactions. These analyses will determine whether the followed sample differs from the randomized sample and whether there is differential attrition by condition. Also, analyses on refuser characteristics will be conducted to inform the generalizability of the sample, as follows. Families completing the phone eligibility screening instrument will provide information on personal and family demographics. Families of eligible adolescents who refuse to participate in the baseline interview, or who participate in the baseline interview but do not complete an intake appointment at the assigned treatment site, will be asked to complete a brief study refuser

measure. Also, phone screening data from the engaged versus non-engaged samples will be compared to test for significant differences in demographic or family characteristics.

Analytic Strategy to Account for Nesting Effects

The proposed study has a nested design: clients are nested within therapists, and therapists are nested within treatment sites. In a nested design, the application of a standard fixed effects GLM typically produces biased inferential tests because the error terms of units within each level are often correlated. We will use multilevel modeling with random effects that includes the sandwich estimator to adjust parameter estimates and standard errors for nested structure. This approach is used to analyze nested data when the goal is to examine outcome effects at the level of the individual (i.e., client), and the hierarchical structure of the data (i.e., client nesting at therapist level) is akin to a nuisance factor to be accounted for, but inference about the degree of correlation is not of interest. Also, the design is nested at the level of treatment site: therapists are nested within site. Recommendations stipulate that 10-20 sites are needed to produce stable estimates for random effects modeling. Because this study will include only four sites, we will adopt the typical alternative of modeling site as a fixed effect included as a nuisance covariate in analyses. This approach is the norm for multisite studies in behavioral sciences whenever there is a small number of participating sites. If the fixed effect of treatment site is significant for any given client outcome analysis, we will re-conduct the given analysis using a within-site approach; due to small sample size this would be considered an exploratory analysis.

Plan of Analysis for Main Outcomes: Aims 1 & 3

Latent growth curve modeling (LGC) will be used to examine the impact of treatment Condition on change over time in client outcomes: symptoms (ADHD, conduct problems, substance use) and QOL indicators (executive and school functioning). LGC produces estimates for the growth curves of each individual and then aggregates individual trajectories to estimate mean growth parameters (intercept and slope), characterizing the sample in terms of the average baseline value of the dependent measure (intercept) and the rate and shape of change over time (slope). Analyses will utilize a 2 (treatment condition) by 2 (baseline substance use) by 4 (time) repeated measures intent-to-treat design; missing data will be handled with robust maximum likelihood estimation (described below).

LGC will proceed using Mplus version 7, as follows. First, we will test a series of growth curve models for each outcome, representing three forms of growth (no change, linear change, quadratic change), to determine the overall shape of the individual change trajectories; overall model fit will be evaluated by examining the chi-square, RMSEA, CFI, and TLI indices. Second, we will test unconditional models for all outcomes to obtain the average effect for change over time in outcome, without including treatment condition or other covariates. Third, we will add the two predictors, Condition (Behavioral Only vs. Integrated) and baseline Substance Use (SU+ vs. SU-) to the models in order to test the impact of each predictor on initial status and change over time. We will also test Condition X SU interactions, and if any are significant for a given outcome, we will re-run that model separately for the SU+ and SU- participants to test simple effects. Treatment effects (Aim 1) for any given outcome will be shown by a statistically significant effect parameter, as tested by the pseudo z test—calculated by dividing the coefficient by its standard error—associated with Condition. Heterogeneity of Treatment Effects (HTE; Aim 3) for any given outcome will be identified by a significant effect for the Condition X SU interaction term; post-hoc analyses will be used to explore these interactions to determine whether Integrated effects appeared to be stronger or weaker in SU+ versus SU- cases. Initially, all models will be adjusted for nuisance covariates: sex, age, and ethnicity; family income; caregiver education level; and treatment site. We will then further explore HTE (Research Question 1) by testing for outcome differences based on age, ethnicity, and sex subgroups. Per above we will use the sandwich estimator to control for therapist nesting. Effect size estimates for significant findings in Aims 1 and 3 analyses will be calculated based on Feingold's procedures for calculating effect sizes for LGC analyses. Also, for any outcome that deviates substantially from normality—typical for delinquency and SU data—we will use two-part growth curve models, which allow for the simultaneous estimation of separate but correlated continuous and categorical LGC models. Two-part models are used when a large number of participants report the absence of the given variable (i.e., no delinquent activities or SU), resulting in highly skewed data. In two-part models, the original distribution of the outcome is separated into categorical and continuous parts, each modeled by separate but correlated growth functions. In the categorical part, a binary indicator variable is created to indicate any vs. none of the outcome in question. The continuous part models the frequency of occurrence of the outcome given any positive occurrence.

Finally, for Research Question 2 pertaining to Individual Differences, we will use methods in which days of ADHD medication use since study entry is positioned as a predictor of client outcomes. Because medication use will be dependent on client choice and not randomly assigned, the first step is to create 2 new groups: High Use vs. Low/No Use (or 3 groups, depending on data distributions). This will be done via propensity score matching analyses for ordinal treatment variables. Propensity scores will be calculated using an ordinal logit model to represent each client's probability to be medicated over time as a function of multiple baseline variables presumed to influence medication choice (condition, demographics, ADHD symptom severity, comorbid symptoms). Clients will be matched on these variables to minimize differences in propensity scores and maximize differences in medication use days at 12-month FU. This will statistically control for observed variables that might influence the likelihood of natural selection into medication use over time. Once propensity score-based groups are created, we will conduct matched-pair analyses for each outcome, using dependent *t*-tests for continuous and McNemar's chi-square test for dichotomous variables[78].

Plan of Analysis for Main Outcomes: Aim 2

Multilevel modeling will examine Condition effects on time-invariant client outcomes: treatment attendance, medication acceptance, and client satisfaction (averaged across caregiver and adolescent); separate models will be run for each variable. Outcomes will be analyzed using multilevel regression analysis with random intercepts and slopes in Mplus version 7. Condition will be entered as a level-1 predictor and regressed directly on the outcome variable; the influence of the predictor is examined by testing the significance of the effect parameter. As discussed above, to control for therapist nesting effects we will use the sandwich estimator; all models will be adjusted for the nuisance covariates listed above; and missing data will be handled with robust maximum likelihood estimation (see below).

Analytic Plans for Missing Data

Based on 20 years of experience engaging high-risk adolescents and their families into longitudinal research, we expect to have rates of missing assessment data on outcome variables between 10-15%. All proposed analyses involving client outcome data will be carried out in Mplus, which provides full information maximum likelihood estimation (MLE), which produces unbiased parameter estimates under the assumption that data are missing at random. Moreover,

MLE outperforms other missing data approaches, such as listwise deletion, even when MAR is not met.

Risks And Benefits

Potential Study Risks

Potential Risks for Client Participants: Research Interviews and Treatment Session Recording

Interview Risks. Because this study will involve participants answering questions, and enrolling in and attending treatment services, there are minimal risks associated with participation in the study. We believe the risks to participants are reasonable in relation to the anticipated benefits (see below). Study participants might feel uneasy about answering personal questions during the research assessment interviews. No side effects have been noted in the current literature in association with the behavioral questionnaires, interviews, or assessments used in this study, although, as with many assessment batteries, some people may experience mild fatigue or momentary concern about their ability to do well. It is unlikely that participants will experience more than minor discomfort; however, research assistants (RAs) will be trained to deal with this issue if it does occur. RAs will take a computerized suicide assessment training course through QPR Institute, which we have used in prior studies. Additionally, the PI (a licensed Clinical Psychologist) will be available via cellular phone for consultations with clients if deemed necessary. Adolescents and families who participate in individual and family treatment sessions may experience some intrapersonal and interpersonal anxiety or discomfort during the routine practice of clinical counseling for ADHD and related behavior problems; risk of this discomfort will be minimized by the presence of professionally licensed providers at the clinical treatment sites who are implementing the study protocols in addition to routine clinical services. Another concern involves the ability of adolescents to provide informed assent. Because recruited adolescents will be ages 12-18, they are very likely to have the developmental-cognitive capacity to understand the nature of the research interview procedures and the treatment process. There is some risk in this study because of the higher than average incidence of child abuse and neglect and suicidal ideation in adolescent behavior problem populations that may require us to report some information to outside agencies. In both instances, however, we will take every precaution to ensure that these procedures do not result in additional harm to the family or any of its members. Although participant confidentiality will be protected, there is a

slight risk that it may be broken. However, every effort will be made to keep all materials private and confidential and to protect the identity of adolescents and families who take part in the study. Also, all project staff will be required to complete videotape training courses on identifying and reporting child abuse and neglect that are produced by the New York City Administration for Children's Services, as well as available training videotapes for identifying and intervening with participants at risk for suicidal behavior.

Session Recording Risks. Study therapists will be asked to audiorecord all sessions with all consenting study clients, using recording devices supplied by research staff. There is potential loss of privacy related to the reviewing of audiorecorded therapy sessions, given in some instances, surnames or other identifying information may be spoken by the therapist or one of the participants. To protect the privacy and confidentiality of the participants, project staff and research partners who listen to recordings for the purpose of fidelity monitoring and assessment will be trained on ethical standards related to privacy and confidentiality in psychotherapy and psychosocial intervention research.

Potential Risks for Client Participants: ADHD Behavioral and Medication Interventions

The two study protocols, CASH-AA and MIP, are drawn from evidence-based interventions for adolescents with ADHD and are not associated with any documented risks. Both protocols will be delivered by licensed and qualified behavior therapists as part of routine clinical services offered at the partnering treatment sites. Medications for ADHD will be prescribed and monitored only licensed and qualified physicians as part of their routine clinical activities at the partnering sites.

Although medication interventions will be assessed and delivered by agency staff as part of routinely available services at each site, because one protocol (MIP) is designed to help families make informed decisions about ADHD medication and (when selected) coordinate those services with behavioral services, it is prudent to describe the general risks that pertain to all youths who elect to use ADHD medications. The most commonly prescribed ADSHD medications are psychostimulants such as methyphenidate (Ritalin, Concerta), Adderall, and Straterra. These stimulants act to increase the activity of the central nervous system. They are used to increase alertness, reduce fatigue, and improve daily functioning at home, school, and work settings. They help manage the symptoms of inattention, hyperactivity, and impulsivity in

persons diagnosed with ADHD. They also increase wakefulness, attentiveness, and in some cases, cognitive functioning. Stimulant medication is about 70 percent effective in decreasing the symptoms of ADHD at FDA-approved dosages.

Despite these potential benefits, stimulants should not be used by people with marked anxiety or agitation, glaucoma, or tics. They should not be used for those already being treated with monoamine oxidase inhibitors. The medical community has not yet determined the long-term effects of having psychostimulants in the bloodstream for prolonged hours every day for numbers of years. The first few days of ingestion should be carefully monitored by a qualified physician to detect common side effects and titrate of desist the medication as indicated. Common physical side effects for many stimulants include: abdominal pain; aggravation, nervousness, hostility, sadness; dizziness and/or shortness of breath; headache; tics; insomnia and prolonged sleepiness; loss of appetite, depressive symptoms, or depression; increased coughing, sinusitis, or upper respiratory tract infection; vomiting; allergic reaction; increased blood pressure and/or tachycardia; and in rare cases, psychosis (abnormal thinking or hallucinations).

Note also that the FDA mandates that a "black box" warning label be affixed to bottles of several brands of stimulants that contains the following consumer safety information: (1) chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior; (2) frank psychotic episodes can occur, especially with abusive use; (3) should be given cautiously to patients with a personal or family history of drug dependence or alcoholism; (4) careful supervision given during drug withdrawal from abusive use since severe depression may occur: (5) withdrawal during chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up. In addition, the FDA recommends caution in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate, for example, those with preexisting hypertension, heart failure, recent myocardial infarction, or hyperthyroidism, or those already using vasopressor agents. There are additional cautions related to taking long-acting, osmotic-release medication (OROS-MPH, aka Concerta): (1) If not taken early in the morning, doctors often recommend skipping the dose for that day, as the stimulants will affect normal sleep patterns. (2) Some people find that even with early morning dosing, stimulants disrupt normal sleep patterns. (3) Changing the dosage by any amount requires a new prescription.

Potential Risks for Therapist Participants

The potential risks to therapists who consent to participate in the study are minimal. Only full-time behavioral health clinicians at partnering treatment sites will be asked to participate as therapists in the study. Therapists will be briefed about the goals and procedures of the study and recruited to volunteer for the study by their respective Site Directors so that recruited therapists will be knowledgeable about the basic risks, demands, and benefits of study participation. Upon agreeing to participate in the study, therapists will complete a brief baseline questionnaire that requests information about demographics. The project will seek to collect digital audiorecordings of all treatment sessions with all study cases. Also, study therapists will be asked to provide the following data from clinical charts and records for all study cases: client retention, number of contacts with parents and adolescents (in and out of session), total number of sessions held, number an identity of participants in every session. These data will be requested only for families that have signed the appropriate consent to release such information to the research project. Participating therapists will also be asked to provide self-report fidelity measures (CASH-AA for both conditions, MIP for the Integrated condition only) immediately following each completed session. In addition, they will be asked to participate in weekly Fidelity Monitoring meetings with the research team members to review study cases (described above in Section 3).

Therapists will not be required to expand their active caseloads or to change the nature of their job requirements in any way. They will be clearly assured that they can refuse to participate or drop out of the study at any time. Therapists will be reimbursed for completing the questionnaires and providing the self-report and taped session data to research staff in a timely manner, activities which will take place outside their normal working hours and duties: $25 for completing the baseline questionnaire, $25 for completing treatment termination summaries using clinical chart data, $10 for completing post-session fidelity therapy checklists, and $10 for reviewing and submitting an audiorecording to research staff in a timely manner. The risk that therapists will feel coerced into study participation by site administrators will be minimized by ensuring them that a decision not to participate will not result in any penalty from the agency whatsoever, and that once agreeing to participate, they can withdraw at any time without any negative consequences whatsoever.

Potential Study Benefits

The adolescents and families participating in the proposed study will benefit from the treatment services they will receive. The risks to all study participants are reasonable in relation to the anticipated benefits to the subjects and others. Procedures have been developed and will be in place throughout the study to minimize these risks to the greatest degree possible. These procedures have been successful in preventing risk in past studies using similar procedures. Study therapists stand to gain in their professional development and in their intervention activities for study cases by participating in weekly fidelity monitoring meetings.

Protections Against Risk

Protection Against Study Risks for Clients: Research Interviews and Treatment Session Recording

If acute mental or physical health issues arise during the course of the study, the family will be referred immediately to the nearest hospital emergency room. If the initial family assessment indicates very severe adolescent problems that would not be adequately served by the outpatient counseling services provided in conjunction with the study, adolescents will be referred to a residential treatment center or inpatient hospital unit, where they would receive more intensive treatment, or to another appropriate care facility.

The issues surrounding confidentiality are of supreme importance and sensitivity because highly personal clinical information will be obtained from the adolescent and their caregivers. Adolescents and caregivers will sign a statement that attests to their understanding that the information they provide will be held as confidential to the extent permitted by law. Consent forms will clearly state the right to refuse participation or to withdraw at any time. Further, refusal to participate will not influence any of the services the adolescent and family may receive at the behavioral healthcare clinics to which they are referred. During recruitment of participants, it will be made clear that this study is being conducted by an independent research team and is not part of any of the collaborating referral agencies or the partnering treatment sites. Thus, all research assessment information collected by project staff will be kept confidential from referral agencies and treatment sites with which participants may be involved.

In order to address any concerns regarding coercion, adolescents and caregivers will be informed that they are free to choose not to participate and may withdraw at any time (this is included in the consent forms). Because this study involves minors, particular caution will be exercised in obtaining informed consent separately and independently from caregiver consent. To this end, as described above, an initial step in subject enrollment involves obtaining caregiver permission for participation by the adolescent. Once caregiver consent is secured, adolescents will be asked separately and independently for informed assent (i.e., caregiver consent will not be used to persuade teens to assent). This approach is considered very effective in minimizing coercion to participate. In addition, the reimbursement rate of $40-$100 apiece for adolescents and caregivers for completing each assessment interview is a moderate amount that is appropriate for the time investment and therefore is not considered to be coercive. Persons who are hesitant to consent/assent or express the desire to withdraw will not be offered additional financial incentives to continue with interviews.

Protection Against Study Risks for Clients: ADHD Medication

Medication needs assessment, dosage monitoring, and tolerance and effectiveness monitoring will be conducted at the respective partnering treatment sites by an on-site psychiatrist as part of routine child psychiatric services provided during the course of behavioral health counseling. All partnering sites are licensed to provide pharmacological interventions for youth with mental health disorders, and all operate in compliance with state-mandated safety monitoring and adverse event protocols, in addition to safety and best practice guidelines put forth by the American Psychiatric Association, in the dispensation of pharmacological services for minors. Prior to prescribing medication, site psychiatrists will carefully review all safety information and precautions (including information contained on FDA black box warning labels) with both the adolescent and primary caregiver(s), and the psychiatrist will conduct all assessment procedures necessary to determine whether medication is indicated and safe to prescribe for a given client. If medication is ultimately prescribed and accepted, site psychiatrists will meet on a regular basis with adolescents and families for medication titration and management, per routine site procedures. Medication management will be coordinated with the site behavioral clinicians throughout the course of treatment. Any adverse events (AEs) or serious adverse events (SAEs) related to medication interventions will be clinically managed by

site psychiatrists, including toxicity assessment, downward titration, termination of the medication regimen, and emergency treatment or hospitalization as indicated. Any AEs/SAEs that occur at any treatment site will be reported directly to the CASAColumbia IRB by the Principal Investigator per established institutional protocols.

Protection Against Study Risks for Therapists

All data provided by study therapists for this project will be kept confidential by CASAColumbia research staff and will not be made available to any employee of the respective treatment sites for use in evaluating job performance or for any other use whatsoever. The respective site clinical administrators will not require their clinical staff to participate—that is, participation will be completely voluntary—and there will be no negative consequences if therapists decline to participate or if they initially agree to participate but then withdraw their participation at any time. No one at any clinical site, nor anyone outside the CASAColumbia research team, will know the answers that therapists provide on any self-report questionnaire, case termination summary, or post-session therapy technique checklist. No identifying information will be attached to the session recordings. Any member of the CASAColumbia research team, or any of the study therapists who participate in either study condition, who listens to recorded sessions will be subject to confidentiality with regard to all aspects of the given session. All information contained in research documents and materials will be password protected and accessible only to members of the CASAColumbia research team.

Confidentiality

Regarding assessment data and other records, the study investigators have an established set of procedures designed to ensure the protection of data confidentiality. All staff who participates in research with human subjects will be required to complete an on-line course on protection of human subjects (including confidentiality). Additionally, staff will be trained on and strictly monitored for adherence to federal guidelines for maintaining the privacy and confidentiality of participants throughout the research process. Assessment data will be collected at the participant's home or in assessment offices at one of the referral sites. All assessments will have a computer administration platform, which ensures greater confidentiality in transporting and storing the data. No identifying information will appear on any form. Upon

completion of each interview, the data will be transferred to a database at CASAColumbia, where all participant records will be coded and filed numerically according to a unique project identification number, with no names attached to the database. Access to the database and data files will be strictly controlled by the PI. Passwords will be used to restrict entry into the database. A master list linking participants to project identification codes will be kept in a double locked filing cabinet at CASAColumbia in the office of the Project Coordinator, along with any other identifying information used to track clients for the purpose of completing follow-up assessment interviews. Follow-up contacts will be made by project staff under explicit guidelines that preserve confidentiality when telephoning or mailing information to participants. Only the PI and research assistants who recruit or follow the participants have access to identifying information.

Digital audio recordings, which represent sensitive clinical material, will be regularly harvested from site recording devices, stored in password protected electronic files in CASAColumbia office at all times, and subsequently erased from site recording devices once properly stored. Use of the recordings will be restricted to the CASAColumbia research team. All adolescents and adults will be asked to sign a separate consent form that provides permission for recording sessions for the purposes of fidelity monitoring and evaluation. Consent forms will clearly specify that any family member has the right to request that their recordings be destroyed in part or in whole at any time during the course of the study or thereafter. In addition, no identifying information other than case numbers will be associated with recordings. Any researcher or professional who listens to the recordings will be subject to confidentiality with regard to all aspects of the recorded session. It should be noted that in the PI's twenty years of clinical research using these procedures, not a single incident of violation of confidentiality has occurred.

All project staff will be required to successfully complete the NIH online course in the protection of human subjects in research studies; certificates of completion will be kept on file in the office of the PI and in the CASA IRB office. In addition, project staff will observe the following data security procedures:

Digital recordings, which represent very sensitive clinical material, shall be kept in secured and encrypted databases on CASAColumbia laptops at all times. The laptops will be equipped with a standard industry leading AES 256-bit hardware-based encryption engine to

ensure the safety of data even if the laptop is stolen or the hard drive is removed. In addition, they will be equipped with Symantec PGP software level encryption which also uses industry standard NIST certified AES 256-bit encryption which is in accordance with FIPS PUB 140-2. It creates secure drive or folders where data is stored in the drive. The CASAColumbia laptops shall not leave research offices and shall be secured behind locked doors when not in use. All coding shall be done behind closed doors to ensure that only authorized researchers have access to the recorded material. In addition, when the laptop is on but not in use, the Windows screen shall be locked. In the event any laptop is stolen, the incident shall be reported to the CASAColumbia IT department immediately upon discovery. The laptops are equipped with Absolute Computrace which allows CASAColumbia to persistently track IP address, location, software installed, etc. If at any point a laptop is reported stolen, it can be locked up. Computrace partners with law enforcement officials to retrieve the stolen hardware.

Procedures For Obtaining Informed Consent

Clients: Caregivers and Adolescents

Client research interviews (phone screen, baseline interview, and 3-, 6- and 12-month follow-up interviews) will conducted by research staff primarily in the home or site clinical offices but also in other locations upon request. Caregivers and teens will be consented and interviewed separately; caregivers will consent for themselves and for their adolescents, and adolescents will assent for themselves. Recruitment procedures, randomization procedures, and assessment measures and procedures are fully described above. Caregiver consents and assessments will be administered in the preferred language: English or Spanish. Many assessment measures have Spanish versions available from the vendor; all other measures, and all consents, will be translated by a professional translation agency using back-translation techniques that are high-standard methods in the field. Clients will be fully informed about the general treatment services to be offered—with at least some focus on attention and impulsivity problems—and about randomization procedures prior to consenting to participate, in the following manner: “You and your teen agree to enter a lottery at the counseling program. Half of families in the study will be assigned to therapists who will use research tools to educate their clients about attention problems in adolescents, and half will be assigned to therapists who will use their regular procedures to educate clients. All study families will receive the same access to

all available services at the clinic." Research staff will give a copy of the consent/assent form (consent/assent to participate in the study; consent/assent to audiotape sessions) to caregivers and adolescents, read them aloud, and then ask family members if they have any questions, clarifications, or concerns before signing. After consenting/assenting to study participation and completing the Baseline interview, families will then be linked to services at a partnering treatment site by research staff using intensive family-based engagement strategies (also described above). Caregivers will receive $25 in vouchers for completing the Phone Screen, and caregivers and adolescents will each receive $40 for completing the Baseline interview, $50 apiece for the first two follow-ups, and $100 apiece for the final follow-up interview

Site Therapists

Treatment site therapists who agree to participate voluntarily as study therapists will be consented in their private offices by research staff. Research staff will give a copy of the single consent—addressing consent to participate in the research study and consent to audiotape sessions—to therapists, read the consent aloud, and then ask therapists if they have any questions, clarifications, or concerns before signing. Therapists will be reimbursed for providing demographic data ($25), for submitting self-report checklists and session recordings in a timely manner ($10 apiece), and for submitting post-treatment clinical logs and procedures checklists for each study case ($50), according to the institutional policy of the given site.