Cover page:

Individual and Family Motivational Interviews for Substance Using Truant Teens
1 R34 DA0029871

NCT01170026

7-1-13

Study Design

The project will begin with an open trial with 20 families to review and adapt the protocol. Then a two group randomized design will be used to test the primary hypothesis that an Individual Motivational Intervention (IMI) plus Family Check-Up (FCU) will lead to lower rates of SU and improved family management practices at follow-up among 13-16 year old adolescents in the truancy court program who report they have already begun to use substances compared to a group that receives psychoeducation (PE) plus Standard Care services provided by truancy court. Adolescents will be randomly assigned to the experimental condition (IMI/FCU) or the comparison condition (PE). All participants will complete baseline, 3 and 6 month follow-up assessments.

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5B. Participants

A total of 120 families (20 in open trial, 100 in RCT) with children primarily in mid-adolescence (commonly considered ages 14-16 years old) but some in early (13 years old) adolescence (Steinberg, 1999) will be recruited and randomized to receive either IMI/FCU or SC. **Inclusion criteria** are: (1) the target child is between the ages of 13-16 at the start of the project and living at home with at least one parent/guardian, (2) the target child must be seen in Truancy Court and must screen in with a t- score of 70 or above on one of the DSM-oriented scales (internalizing or externalizing problems) on the Child Behavior Checklist (i.e. reach the clinical cut-off), (3) the child must report 6 or more incidences of substance use in the last 90 days, and (4) parental consent and child assent are obtained. **Exclusion criteria** are: (1) adolescent meets diagnostic criteria for substance dependence suggesting need for more intensive services, and (2) the family is not able to speak and understand English or Spanish well enough to complete study procedures.

Ethnic and gender considerations. We expect to have approximately 60% to 70% boys in this sample. We will over-sample girls to lower the ratio of boys to girls. The ethnic racial distribution of Truancy Court is approximately 60% minority families, most of these being of Hispanic and low income status.

Sample size projections. Recruitment will take place in months 4 - 28. The RI Truancy Court has a current active roster of over 2,000 adolescents. In our pilot, we have worked with only one of the 4 magistrates in only 3 schools. If we consent approximately one-half of the referrals (in our pilot we have consented slightly more than half of referrals to date), baseline evaluations will easily be completed with about 100 families. This projection allows a 20% drop-out rate by 6 month follow-up (100 x .8 = 80).

Piloting. The PI, Co-I and treatment provider hired to conduct this study will each pilot 5-8 additional families at the start of this study. Final changes in the IMI/FCU will be made after these additional 20 families are piloted. Particular emphasis will be placed on adapting the school performance/attendance and sexual risk taking sections of both the individual and family motivational interventions.

5B1. Procedure. Parent(s) or legal guardian(s) (hereafter referred to as “parents”) of adolescents in the targeted age range will be recruited from the RI Truancy Court Program (see letters of support). Following arraignment procedures, families will be given information about the project by study staff who will be present at all truancy court arraignments and who will also answer any questions parents may have. Interested participants will be contacted by study staff at their second Truancy Court arraignment appointment. During this meeting, they will receive an oral and written description of the study, including a description of the project procedures, number of appointments and compensation for participation, potential risks and benefits, and confidentiality. Families who provide parental consent and adolescent assent will be administered the screening battery. If the child does not meet the substance use and CBCL inclusion criteria, they will be given a package of educational materials regarding truancy and SU.

Assignment of participants to conditions. In the open trial portion, the first 20 families will receive the IMI/FCU in order to inform adaptations to the current protocol and to examine its feasibility and acceptance. After this open trial, 100 families will be recruited and randomized into either the experimental or the comparison control condition. These assignments will be made soon after completing the baseline assessment and through random assignment using the urn method (Stout et al., 1994). Urn randomization assigns participants in a given subgroup to intervention conditions, but systematically biases the randomization in favor of balance among the intervention conditions. Participants will be randomized according to gender, substance abuse (yes or no), and meeting CBCL cut-off for internalizing only versus externalizing only or externalizing/internalizing.

5B2. Baseline and follow-up assessments (IMI/FCU and PE). Parents and teens will complete the

assessment battery described below at their local school. In person follow-up assessments will be held at 3 and 6 months following the baseline assessment. An RA who will be blind to condition assignment will conduct each follow-up assessment. The follow-up assessment battery will be identical to baseline.

5B3. Protection against attrition. At baseline, multiple sources of contact information will be recorded for all adolescents and parent/guardians for the purpose of collecting follow-up data. We will obtain a release of information from parents in order to ask the school and truancy court for contact information during the time

period of the study. When applicable, the parent's cell phone number, employer phone number, and shifts at work will be recorded. Locator information will include name, address, phone number, relation to the patient, and the best times of day to reach the locator (**See Appendix 2**). Contact information will be updated by periodic phone calls and at each assessment session, including the names and telephone numbers of two friends or family members who can be contacted if research staff is unable to reach the family. Parents will be asked to sign a form letter addressed to each of the locators, which explains that they are participating in a research project with Brown University and that they have named this person as a locator. Locators will be contacted only if all efforts to reach the family fail. Participants will also be given refrigerator magnets and pens with contact information as well as a card with the dates for each of the subsequent follow-up assessments. Reminder postcards will also be sent out and phone calls will be made. Weekly case review meetings will be held between staff and the PI to review no-shows, non-verified and non-confirmed cases, and plans to complete contact with the participant. We have used these procedures with success in our current projects.

Table 1. Timeline for assessment and intervention activities

Design	Week 0	Week 1	Week 13	Week 25
	Baseline incl. video assess.	In person mtg.	3-month FU + Booster	6-month FU
IMI/FCU	X	feedback	X	X
PE	X[a]	education	X	X

Note. IMI/FCU = Individual MI/Family Check-Up ; PE = Psychoeducation.
[a]Two video tasks only.

Compensation for participation. Parents and teenagers will each be compensated $75 for the time it takes to complete baseline and $75 for follow-ups.

5C1. Individual Motivational Interview/Family Check-Up Condition

The experimental condition consists of both the individual motivational interview (IMI) for the adolescent and the Family Check-Up (FCU). Both adolescents and parents complete baseline assessment measures including videotaped interactional tasks in their first session.

Individual Motivational Intervention (**Appendix 3**). The basic MI described here has been used with over 200 adolescents in our previous studies. Because we are covering more material, i.e. alcohol, school behavior and performance and sexual risk-taking, we are adapting the original MI to take place over two sessions. It incorporates open-ended exploration, personalized feedback, and discussion about the adolescent's substance use, and the consequences of these behaviors. Our procedures incorporate the central principles described by Miller and Rollnick (1991). The intervention will consist of four components: establishing rapport, assessing motivation for change, motivational enhancement, and establishing goals for change. The first component, establishing rapport, aims to present the counselor as empathic, concerned, nonauthoritarian, and nonjudgmental. The session will begin by introducing the interview as a chance for the adolescent to talk about his/her thoughts and feelings about SU. The counselor will emphasize that the intention is not to tell the adolescent what to do, rather it is up to the adolescent to make decisions and choices about SU and things he/she does while using substances. Next, level of motivation for change will be assessed by asking the adolescents to talk about their likes and dislikes about SU. Open-ended questions and reflective listening statements will be used to encourage adolescents to generate as many salient positive and negative aspects of SU as possible, and to talk about the effects that matter most to them. The counselor then tailors the MI to these pros and cons. **In this application, the MI will be adjusted to address both truancy and sexual risk taking in addition to SU.**

Enhancement of motivation to change will be accomplished by utilizing the MI strategies of individualized normative feedback, examining decisional balance, and providing information and advice. The individualized feedback will be derived from the assessment and will be provided in both written and graphic formats to assist the adolescent in understanding the information. The feedback form will have the following six sections: 1) participant SU and normative information from age matched peers, 2) physical dependence on alcohol, marijuana, and other substances, 3) family risk, 4) consequences of SU use (i.e. truancy, engaging in unsafe sex practices), 5) attitudes toward peer substance use; and, 6) participant risk for STD/HIV and pregnancy and normative information for high school students. In the SU section information about marijuana use will be presented first followed by other drugs**.** The information will include frequency of marijuana use, drinking, and use of other substances, average number of joints, drinks and other incidences of drug use per week, frequency of heavy marijuana and other drug use and drinking, and average and peak BAC. In addition to providing concrete feedback, this section is designed to correct overestimations (i.e., the false consensus effect) common among adolescents about the prevalence of smoking marijuana, drinking and heavy drinking, and use of other substances (Baer et al., 1991) and to provide the opportunity to discuss the increased problems that are associated with episodic heavy substance use (Midanik & Clark, 1995). National data for substance use (i.e., marijuana, alcohol and other substances) among adolescents (Johnston et al., 2009; SAMHSA, 2007) will be used as a source for normative comparisons on frequency, quantity, and frequency of substance use. Information about BAC and metabolism also will be presented. The section on physical dependence will also address the fact that many adolescents are proud of their ability to tolerate marijuana and

alcohol and have misconceptions about tolerance. Adolescents who receive a family-history positive score will be informed that due to their parental substance abuse history, they are at greater risk for developing an SU disorder themselves. Substance-related consequences will be presented and comparisons will be made with norms for this measure. National data will also be presented and discussed for sexual risk taking behaviors (CDC, 2007). This feedback will include a section discussing the likelihood of engaging in unprotected sex while high or drunk and rates of STD/HIV and pregnancy among high school students. The feedback section is designed to increase the adolescents' motivation to alter risky behavior by helping them to recognize their susceptibility to harm and the costs of their behavior. For each of the feedback topic areas the counselor will review the feedback with the adolescent, elicit the adolescent's reaction, and provide further information when relevant. Counselors will explore which aspect of the feedback has raised the most concern and respectfully express their own concerns when necessary.

Following the presentation of the feedback, counselors will examine the patients' decisional balance by asking the adolescent to “envision the future,” and to think about what positive things might happen if their SU were to decrease and what would be the worst thing that could happen if their SU were to stay the same. This part of the MI is designed to develop the adolescents' sense of discrepancy between current behavior and future goals, and should serve to increase the adolescents' ambivalence.

In the final phase of the intervention, the adolescent and counselor will collaborate to develop a plan for the future. This will include identifying goals for behavior change, exploring barriers to these changes, and providing strategic advice. A "goals sheet," which contains a variety of SU moderation goals, and harm reduction goals as well as some blank spaces for filling in other goals, including school attendance and performance, will be used here. Adolescents will be asked to select the preprinted goals that they would like to attempt and to generate other goals. This phase of the intervention was designed based on several research findings: first, that motivation is enhanced by encouraging participation in all decision-making regarding SU (Cooney et al., 1995), that using individualized strategies leads to more positive outcomes (Miller & Hester, 1986), and that most people prefer to select their own goals rather than having goals set for them (Sobell et al., 1993). Finally, it provides the opportunity for the counselor to support the adolescents' self-efficacy about making changes. At the completion of the session the counselor will provide the personalized feedback, the goals sheet, and informational handouts about SU to participants. In this adaptation, we expect the MI session takes about 90 minutes, spent over 2 sessions. The IMI covers the three constructs - intentions to use, normative beliefs about peer use, and attitudes towards peer use which have been shown to have the most consistent overall effects on adolescent SU (Stephens et al., 2009) as well as motivation to abstain which as been shown to have specific effects on marijuana use (King et al, 2009).

Family Check-Up (FCU). The FCU begins with using self-report assessments and the family videotape (FAsTask). The Research Assistant administers the self-report measures. The Treatment Providers administer the FAsTask in order to keep the RA who conducts the follow-ups blind to treatment condition as well as to observe the family interactions firsthand through a one-way mirror to assist in the feedback session.

Videotaped Family Assessment Task (FAsTask). The video-taped family problem-solving task format (Forgatch, 1989; Robin & Foster, 1989) adapted by Dishion et al. (1996a) will be used to assess parent-child interactions and provide additional assessment information for feedback in the FCU. A complete script of the FAsTask which will be adapted in order to make it more appropriate for truancy court families is included in Appendix 4. The following FAsTask was used in our previous projects with alcohol-positive teens. The proposed adaptations are included **in bold text**.

3 minutes	Parents and target child plan an activity (relationship quality)
5 minutes	Parents lead a discussion about a behavior they would like to increase and how they would encourage the process (encouraging growth).
5 minutes	Child leads a discussion about a time without supervision and parents seek additional information (monitoring)
5 minutes	Parents lead a discussion on setting limits over the previous month (limit setting)
5 minutes	Family discusses a “hot” family problem pre-selected by parents (i.e. problem solving)
5 minutes	**Family discusses school performance and attendance issues and try to come up with a solution (problem solving-truancy)**
5 minutes	Parents lead a discussion on the family beliefs about marijuana, alcohol, cigarettes and other SU (substance-use norms)
5 minutes	Teen discusses his/her observations on SU by teens and school attendance (peer relations)
5 minutes	**Parents lead a discussion on their beliefs on how SU can result in risk taking behavior such as unprotected sex (risk behavior norms)**

3 minutes Parents recognize a positive attribute of the target child (positive recognition)

These proposed adaptations may be modified or further adaptations may be considered based on feedback that is received during the open pilot trial.

FAsTask Clinical Coding. Dr. Spirito was trained in the coding system for this task by Dr. Kavanagh from the Oregon Research Institute and has created a structured clinical codebook that defines each item to be coded and gives specific examples of high and low-scoring observations (**see Appendix 4**). An inter-rater reliability estimate (i.e., % of ratings within two points on a 9-point scale) was created for ratings in our current trial. Percentage of inter-rater reliability within each case ranged from 71 to 96%, mean=86%. New codes will be created in the open trial for the new tasks developed for this adaption of the FAsTask.

All FAsTask videos will be coded by the Treatment Provider and the PI or Co-I, who will watch each segment of the videotape together and complete separate coding sheets. Ratings assigned to the family will then be discussed and consensus will be reached. When consensus cannot be achieved, the PI will review the tape segment to determine the coding. Ratings reached by consensus will be used during the feedback session. "Macro" clinical scores are calculated and coded as an area of "strength," "needs improvement," or "challenge," and provided as feedback during the Family Check-up session. Macro scores include positive relationships, monitoring, limit setting, problem solving, school importance and substance use norms. Norms were derived from 120 multi-ethnic families whose children had good school attendance and no disruptive problems in school (Dishion & Kavanagh, 2003). This coding method was used in Project REFRAME with 79 families and has been found to be the most effective method for coding the task for the purposes of providing feedback to families. These data along with parent self-report measures (see **Table 2**) will be used to generate the individualized feedback report for use in the parent feedback session.

Parent Feedback Session (FCU). The primary component of the FCU is feedback about the assessment (self-report and video) obtained at baseline. The measures provide data which are incorporated into the feedback given to the parents along with the FAsTask data (**see Appendix 5**) for how measures are tied into the FCU feedback for parents). A week after the family completes the baseline assessment including FAsTask, parents will participate in their feedback session (i.e., the FCU). In our current study, for families referred from the Emergency Department (ED), 20% never returned for the first family assessment session to complete the FAsTask. (**Note:** We do not anticipate this to be a substantial problem in this application because there is frequent contact between families and the Truancy Court compared to one time contact with the ED.) Nonetheless, of the 79 families randomized to the FCU who completed the FAsTask, 77 returned for the feedback sessions of the FCU. All of these sessions will be audiotaped to evaluate fidelity. The session, which is based on MI techniques (Miller & Rollnick, 2002), is designed to support appropriate parenting and provide motivation to change maladaptive parenting (Dishion & Kavanagh, 2003). The FCU supports the parents in limit setting and also addresses the parent/adolescent relationship, parental understanding of the autonomy needs of the adolescent and greater involvement in the peer activities of the adolescent (Dishion et al., 1996a). The principles and techniques utilized in the parent session are based on techniques with demonstrated effectiveness in engaging families and motivating them to change. These include approaching the change process collaboratively (Patterson & Chamberlain, 1994), sharing assessment results with parents to build collaboration (Sanders & Lawton, 1993), providing a flexible menu of resources in the community (Dishion & Owen, 2002) and supporting motivation to change.

Dishion and Kavanagh (2003) outline four specific phases of the feedback session: (1) Self-assessment: Parents are asked if they learned anything about their family from participating in the assessment. (2) Support and clarification: The interviewer supports the family's self-assessment efforts, assesses their level of understanding of the family, and clarifies issues within the family. (3) Feedback: In this phase, a summary form of the assessment findings is reviewed with the parents. Rather than give specific results from individual scales, this information is summarized into categories including family context (e.g., parent SU, life stress), parenting practice (e.g., monitoring and SU, school and sexual behavior expectations for teens), child behavior (e.g., positive behaviors, problem behaviors), and peer and sibling relationships (e.g., peer involvement with school, experimentation with drugs and alcohol).Normative information regarding escalation in SU rates from 7th through 12th grades is also presented. The August 26, 2009 release of the National Survey of American Attitudes on Substance Abuse XIV: Teens and Parents is cited which indicated that adolescents who have seen their parents intoxicated are more than twice as likely to get drunk themselves and three times as likely to use marijuana and smoke cigarettes. (4) Menu of options: Parent motivation for change and steps for making positive changes are discussed, including potential barriers to change. Parents are also asked to consider how they anticipate their child reacting to any proposed changes, problem-solving any potential negative reactions.

Booster Mailings (IMI/FCU only). Parents will receive brochures at 1-month intervals for 5 months. These brochures were used in REFRAME and are currently being used in the current trial and focus on SU and parenting (**see sample in Appendix 6**). These brochures help refresh the FCU content for parents in our trial.

3-Month Booster Sessions. Parents and adolescents will receive a booster session at 3-month follow-up. These booster sessions will review the content that was discussed during the IMI and FCU sessions. Interventionists will specifically focus on checking-in with participants regarding the action plans that were generated during their first session and ask about whether they were able to implement their action plans, what

the experience was like, and whether they experienced any other positive changes as a result. If the change plan was successfully implemented, participants will be encouraged to identify another change or goal that they would like to work towards and develop another action plan. If parents and adolescents either struggled or did not successfully implement their change plan, obstacles will be discussed along with strategies for overcoming these obstacles. Motivation, readiness, and confidence to change will also be discussed.

Interventionist Training (IMI/FCU). Manualized training in adolescent IMI for ongoing NIH-funded clinical trials has been conducted for over 10 years at our Center. The training sequence is approximately 30 hours in length and includes didactic presentations, viewing of the videotaped training series created by Miller and Rollnick (1998), readings on MI by Miller and Rollnick (2002), and extensive supervised role-plays...

Therapist training materials developed for our current FCU grant will be used for FCU training procedures (**see Appendix 7**). The training program includes the following components: 1) participation in the structured workshop on MI described above, 2) review of the FCU manual, 3) use of videotapes demonstrating examples of the FCU, and 4) functioning as a co-therapist using the FCU approach.

5C2. Psychoeducation Condition (PE)

In the Psychoeducation (PE) condition, participants will complete the same baseline assessment as the IMI/FCU group. In order to control for contact time, families in PE will return for the same number of visits as the IMI and FCU sessions of the IMI/FCU condition. An interventionist will review a set of educational materials with the parents regarding teen SU use, truancy and risk behaviors and parenting a teenager. A similar set of materials will be reviewed with the adolescent (**see Appendix 8**).

Training (PE). Interventionists in the PE condition will be trained in reviewing psychoeducational materials. A primary goal of training will be to ensure there is no carryover of motivational techniques into the PE condition.

5C3. Fidelity to Interventions The PI, Co-I and a masters-level clinician will serve as the counselors for this project and will first run 20 families before the randomization phase. In this proposal, Drs. Spirito and Hernandez will train and supervise counselors and Dr. Barnett will evaluate fidelity on a real time basis and provide feedback. After training, counselors will receive weekly supervision by Drs. Spirito and Hernandez. Adherence to the IMI/FCU feedback session will be evaluated using two methods. First, the individual MI and FCU will be audiotaped as will the PE condition. The MI will be rated for both IMI/FCU adherence and competency. The first 10 sessions of each counselor and 50% of randomly selected session tapes thereafter will be coded by the Co-I Dr. Barnett to objectively evaluate clinician competence in using MI techniques as well as adherence to the IMI or FCU protocol. Criteria for adherence are defined in terms of specific content areas, as well as adherence to basic MI principles outlined in the IMI and FCU manuals (**see Appendices 3 & 5 for IMI and FCU fidelity ratings**). We have developed a system for assessing adherence, which includes a measure both of the degree to which counselors adhere to stylistic and strategic imperatives of MI and the degree to which they adhere to the protocol itself (Barnett et al., 2001; Monti et al., 1999. This information is incorporated into supervision. These procedures are identical to those used successfully in our current project. Second, following the IMI and FCU sessions the counselor and the adolescent/parent will separately complete an adherence rating form that will indicate the extent to which the counselor engaged in the behaviors consistent with IMI/FCU and those required by the intervention protocol; both will include length of time of the session. These forms will be reviewed by the PI, and clinical training will be tailored to project clinicians, as needed. This will provide data for evaluating both the fidelity and the quality of the IMI/FCU from the perspective of both the participant and the counselor. We have used this system in our two previous and current adolescent studies with success. The PE condition will be rated using the IMI adherence sheet to ensure that none of the MI techniques are used in the PE condition.

5D. Measures (see Appendix 9 for non-copyrighted measures)

Rationale. The measures for the assessment battery were chosen for three main reasons: first, to provide information and normative data whenever possible that can be used in the feedback portion of the FCU; second, to assess changes in outcomes over time; and third, to assess potential mediators. Although there are a large number of measures, most are brief. With the exception of the measures used specifically for feedback in the FCU (**see bottom of Table 2**), all measures will be administered to both groups. We felt it was important to conduct some form of dynamic (i.e., in vivo) assessment with both groups because changes in parenting behaviors and parent-child relationships are complex and may not be captured by self-report measures alone.

Screening Measure. Because teens seen at truancy court are very heterogeneous in their presentation, we will require that all participants meet minimum criteria for internalizing or externalizing disorders on the well-validated Child Behavior Checklist (CBCL). The CBCL (ASEBA: Achenbach & Rescorla, 2001) is a widely-used, parent-rated checklist to assess behavior problems. Well-accepted clinical cut-off scores on the internalizing or externalizing problems of the DSM-oriented scales (≥ 70), that are reasonable indicators of youth with diagnosable psychiatric disorders, will be used to screen in for this study. The Timeline Follow Back (described below) will be used to assess the inclusion criterion of 6 or more instances of substance use in the prior 90 days. Teens will also be administered the Schedule for Affective Disorders and Schizophrenia for School- Age Children - Present and Lifetime Version (K-SADS- PL) Substance Use module to rule out substance dependence. The K-SADS-PL (Kaufman et al., 1997) is semi-structured diagnostic interview which

provides an assessment of DSM-IV psychopathology in children and adolescents. Inter-rater agreement on screens and diagnoses is high (range: 93% to 100%).The K-SADS is available at http://www.wpic.pitt.edu/ksads/default.htm.

1. Background Variables

Demographics. Routine socio-demographic variables will be recorded including age, gender, race, school status, and history of mental health or substance use treatment. Locator information is also collected.

Table 2. Measures	Parent/Adol	Baseline	3 mos.	6 mos.
1. Background				
Demographics	A/P	X	X	
Locator Information	A/P	X		
2. Substance Use				
Parent Substance Use	P	X	X	X
Adolescent Drinking Questionnaire (ADQ)	A	X	X	X
Drug Use Questionnaire	A	X	X	X
Timeline Follow-Back – Substance Use	A	X	X	X
3. Family Management				
Parent Monitoring Questionnaire (PMQ)	A/P	X	X	X
Parent Reactions to Youth AOD Use	P	X	X	X
Parent-Adolescent General Communication Scale	A/P	X	X	X
Parent-Adolescent Alcohol and Drug Communication Scale	A/P	X	X	X
Parent-Adolescent Sexual Communication Scale	A/P	X	X	X
Conflict Behavior Questionnaire (CBQ)	A/P	X	X	X
Video Code – Parent Limit Setting and Monitoring	A/P	X	X	X
4. Other Problem Behaviors				
Child Behavior Checklist (CBCL)	P	X		X
Reckless Behavior Questionnaire (RBQ)	A	X	X	X
School Attendance - TLFB	A	X	X	X
School Truancy and Performance	A	X	X	X
Sexual History/Perceived Risk of HIV/STDs	A	X	X	X
5. Peer Influences				
Peer Use/Tolerance of Use	A	X	X	X
Parental Management of Peers (PMPI)	A	X	X	X
Peer Social Skills (Child)	A	X	X	X
Peer Social Skills (Parent)	P	X	X	X
6. Teen Cognitions				
Marijuana Effect Expectancy Questionnaire	A	X	X	X
Motivation to Abstain and Perceived Difficulty - Marijuana	A	X	X	X
Youth Alcohol and Drug Survey Subscales	A	X		
Brief Situational Confidence Questionnaire	A	X	X	X
7. Substance Use and Mental Health Treatment History(CASA)	P	X	X	X
8. Intervention Acceptability				
Exit Interviews	P	X[a]		
Session Evaluation Form	P	X[a]		
9. Family Check-Up Only Measures				
Parent Substance-Related Beliefs	P	X		
Family Stress (on PSSC)	P	X		
House Rules Questionnaire	P	X		
Parent Support-Questionnaire	P	X		
FAsTask Video (10 tasks)	P/A	X		

[a]Administered after 2-session intervention

2. Substance Use Consumption

Because parents underestimate their teen's involvement with SU (Cantwell et al., 1997), including reporting lower frequency of drinking than their children (Velting et al., 1998), parents will not be questioned about their child's SU. Using peers as corroborators raises issues of confidentiality, and to the extent that it leads to aggregating children around SU may lead to unintentional harm (Dishion et al., 1999), thus peers will not be assessed. Several procedures will be employed to maximize the fidelity of teens' self-reported data. First, assurance of confidentiality is primary; teens self-reported substance use has been shown to be accurate and reliable when confidentiality is assured (Haley et al., 1983; Luepker et al., 1981; Needle et al., 1983, Pechacek et al., 1984). Second, prior to each follow-up assessment teens will be administered a breath alcohol test, as research has shown that a positive test for alcohol is related to underreporting of alcohol use (Sobell et al., 1979b). Patients who test positive will be rescheduled for another interview.

Timeline Follow-Back – Substance use (TLFB). Substance use will be assessed at each contact point using the Timeline Follow-back Interview (TLFB; Sobell et al., 1980; Sobell & Sobell, 1992, 1996). The TLFB is a widely-used research and clinical assessment tool with good reliability and validity for various groups of individuals with alcohol use problems. Alcohol and drug consumption information is collected using a calendar format with temporal cues (e.g., holidays, special occurrences) to assist in recall of days when alcohol and drugs were used. The TLFB will be conducted for the last 90 days at baseline, 3-month, and 6-month follow-ups. Data from the TLFB will be summarized to yield the following variables: total number of alcohol use/drug

use days, total days abstinent from alcohol/drugs, average number of drinks per drinking day, and latency to first drink/first drug use. We have experience using this measure with adolescents in both our MI grants.

Adolescent Drinking Questionnaire (ADQ). The ADQ (Jessor, Donovan & Costa, 1989) consists of 4 items that assess recent drinking frequency (days per month), quantity (drinks per occasion), frequency of high-volume drinking (≥ 5 drinks per occasion), and frequency of intoxication (feeling "drunk" or "very, very high").

Drug Use Questionnaire. This measure used in both MI grants assesses the number of days in the past 30 days teens used nicotine, marijuana, cocaine, LSD, PCP, inhalants, etc. Internal consistency in our sample was .75 (alpha = .80 when inhalants was dropped). Test/retest for mean number of days each substance was used was .83 from 3 to 6 month follow-up and .94 from 6 to 12 month follow-up.

Parent Substance Use. Parents will report on the extent to which they use alcohol, marijuana, and other drugs, and if they report no current use of a substance, whether they have stopped using the substance because they had a problem with use of the substance in the past. This information will be used for feedback purposes during the FCU.

3. Family Management

There are a number of parenting practices (e.g., limit-setting, problem-solving, coercive processes, reinforcement), but studies suggest that these dimensions of parenting are highly correlated (Dishion et al., 1998). Consequently, we will focus on monitoring and communication with measures completed by both teens and their parents.

Parent Monitoring Questionnaire (PMQ). The PMQ (Kerr & Stattin, 2000) is a 24 item youth and parent report measure designed to assess parental monitoring and sources of parental knowledge (child disclosure, parental solicitation, parental control). The monitoring subscale has demonstrated good reliability (α =.82 for parents; α =.85, r_{tt} =.83 for child) and correlates with adolescent internalizing and externalizing maladjustment, deviant peer relationships, and family discord (Kerr & Stattin, 2000).

Parent Reactions to Youth AOD Use. Parents and teens will complete an 8-item questionnaire, adapted from Chassin et al. (1998a) to be inclusive of alcohol or drug use, about the likelihood of parents using various parent strategies to deal with children's AOD use.

Parent-Adolescent General Communication Scale. This is a youth and parent report measure that assesses the positive and negative aspects of general parent-adolescent communication and the content and process of parent-teen interactions. Internal consistency of the two subscales, Open Family Communication and Problems in Family Communication, ranges from .77 to .88 (Barnes & Olson, 1982).

Parent-Adolescent Alcohol and Drug Communication Scale. This scale is an adapted version of the PASCS described above, and assesses the process and content of alcohol and other drug use communication between parents and teens.

Parent-Adolescent Sexual Communication Scale (PASCS). The PASCS is a youth and parent report measure that assesses the process and content of sexual communication between parents and teens (e.g., when to start having sex). Internal consistencies range from .65 to .86 (Dutra et al.,1999; Miller et al. 1998).

Conflict Behavior Questionnaire (CBQ). The CBQ (Robin & Foster, 1989; Prinz, Foster, Kent, & O'Leary, 1979) measures perceived conflict and negative communication in the family in the two to three weeks preceding the assessment session. Parallel forms are completed by the adolescent and the parent. In two parent families, the adolescent completes two CBQ's, one with reference to each parent. Each form yields an appraisal of the other, and an appraisal of the relationship between the respondent and the other.

FAsTask Video Code. The FAsTask (described previously) provides an in vivo assessment of parenting behaviors and parent-child relationships. We limited the video assessment to 3 tasks (Problem-solving truancy, substance use norms and risk behavior norms) because these are the primary outcomes examined in this application. We also tried to limit reactive effects by limiting the number of tasks. The first follow-up is 3 months after the baseline assessment, so any reactive effects are likely to be small.

4. Other Problem Behaviors

Child Behavior Checklist. See description under Screening Measures (above).

Reckless Behavior Questionnaire (Shaw et al., 1992) is 10 items that assess how often the adolescent engaged in a variety of risk-taking behaviors and selected items from the Adolescent Health Behavior Questionnaire (Jessor et al., 1980) will be used to assess risky sexual behavior.

School Attendance TLFB. Incidences of cutting classes and skipping school will be assessed at each contact point using the Timeline Follow-back Interview (TLFB; Sobell et al., 1980; Sobell & Sobell, 1992, 1996). The procedures for collecting information regarding school truancy will be similar to the ones used on the TLFB for substance use. These procedures will not only allow us to collect data on school truancy but will also allow us to examine the co-occurrence of SU and school truancy. Similar to the TLFB for substance use, information will collected for the last 90 days at baseline, 3-month, and 6-month follow-ups.

Truancy and Academic Performance. With permission from both school personnel and parents, data on truant behavior and grade point average will also be obtained for each student from school records provided by the school office personnel. These procedures have been successfully implemented in previous school-based studies examining school performance (Zimmerman et al., 2002).

5. Peer Influences

Peer Substance Use and Peer Tolerance of Substance Use (Chassin et al., 1993, 1996). Using items adapted from The Monitoring the Future Study, children estimate how many of their friends used alcohol, marijuana, and other drugs occasionally and regularly. They also indicate how their close friends would feel about their use of these drugs. Chassin et al. (1996) report high coefficient alphas (.89 - .93) for both measures. Because the two scales are highly correlated (.r = .59 - .63), a mean composite score is calculated.

Parental Management of Peers Inventory (PMPI; Mounts, 2002) is a 25-item child-report measure of how much the child perceives their parents to be involved in their peer relationships. Four factors summarize the valence of friendship choice and encouragement of friendships (Mounts, 2002).

Parent's Beliefs and Peers and Child Peer/Social Skills measures degree of deviant and prosocial peers (Dishion & Kavanagh, 2003). Separate scores will be derived for parents and adolescent. Deviant peers is the percentage of friends involved in problem behavior and drug use. Both parent and adolescent measures have demonstrated reliabilities within the acceptable range: Cronbach's alpha for parent reports = .75, for adolescent report .67 (Stormshak, Comeau & Shepard, 2004).

6. Teen Attitudes Toward AOD Use

Marijuana Effect Expectancy Questionnaire (MEEQ). The MEEQ (Schafer & Brown, 1991) is a 48-item child self-report measure that assesses both positive and negative expectations associated with use of marijuana. Six scales are derived – Cognitive & Behavioral Impairment, Relaxation & Tension Reduction, Social & Sexual Facilitation, Perceptual & Cognitive Enhancement, Global Negative Effects, and Craving & Physical Effects. The MEEQ has been validated in children as young as age 12 (Aarons et al., 2001). The MEEQ demonstrates adequate internal consistency (Kuder-Richardson-20 coefficients from 0.82-0.66). The MEEQ, as compared with the well-established adolescent version of the Alcohol Expectancy Questionnaire (AEQ-A, Christiansen et al., 1982), demonstrated convergent validity with AEQ-A scales of like content (*r*'s=.25-.43) and divergent validity with AEQ-A scales of contrasting content (*r*=-.36).

Brief Situational Confidence Questionnaire (BSCQ). The BSCQ is a modified version (Sobell, 1996) of the original 100-item Situational Confidence Questionnaire (SCQ; Annis, 1986) which was designed to tap eight self-efficacy situations clients report as being precipitants to relapse. The eight items are derived from Marlatt's relapse prevention model (Marlatt & Gordon, 1985) and correspond to the subscales defined by Annis and Davis (1988) for the SCQ-100. These subscales are include negative emotional states, negative physical states, positive emotional states, interpersonal conflict, social problems, and, positive emotional states. Responses are provided on 10-point Likert scales (i.e., 10% increments, from 0%=not at all confident to 100%=completely confident). The Cronbach's alpha coefficient was 0.85 in one study (Breslin et al., 2000). This measure will be used to examine changes in adolescents' confidence levels as a result of the intervention.

Motivation to Abstain and Perceived Difficulty of Abstaining from Marijuana. Adolescents will respond to items asking "How motivated are you to abstain from marijuana use in the next 30 days?" and "How difficult will it be for you to abstain from marijuana for the next 30 days?" on a 10-point scale. Single-item measures of readiness and motivation to change substance use behavior have demonstrated satisfactory validity in adult samples (Amodei & Lamb, 2004; Miller & Johnson, 2008) and in adolescent samples (King et al., 2009).

Youth Alcohol and Drug Survey (Werch, 1996) is a child self-report measure that has subscales which assess SU-related cognitive, social, behavioral, and environmental risk and protective factors. Perceived susceptibility and severity of alcohol-related consequences (alpha coefficients = .84 and .90), benefits of avoiding alcohol (alpha = .84), motivation to avoid alcohol (alpha = .93), intention to use alcohol (alpha = .82), and cues to avoid alcohol (alpha = .89; Werch et al., 1997) will be used in data analysis.

7. Substance Abuse and Mental Health Treatment Contacts

Additional substance abuse and mental health services that families obtain will be counted and reviewed at each of the follow-up points using the Child and Adolescent Services Assessment (CASA). The CASA (Burns et al., 1997) is a semi-structured interview that obtains information about service use for substance and mental health problems across multiple sectors (e.g., juvenile justices, schools). Adequate reliability has been demonstrated for this measure (ICCs=.74-.76) (Farmer et al., 1994).

8. Intervention Acceptability

Exit interviews. An "exit interview" will be completed with parent(s) in the experimental condition specifically about the FCU. In addition, the parent report forms on FCU session content used to track treatment fidelity and competence also provide valuable feedback regarding the intervention. Adolescents will also be interviewed regarding the IMI. Similarly, treatment providers will also be interviewed regarding acceptability of the intervention to each client as well as themselves.

Session Evaluation Form (SEF; Harper et al., 2003). The SEF is a brief 13-item questionnaire that will be given to participants at the end of the IMI and FCU. This questionnaire consists of 10 items on a 4-point response scale about the participant's experience (i.e., was it interesting, was it relevant to their life, etc). Three open-ended items query participants about what was most and least useful about the interventions.

5e. Data Analysis Plan

First, all forms will be checked for any missing data following interviews and prior to data entry. All data will be entered into the project computer twice using double entry. Back-up copies of data will be made on a regular basis, and copies of data will be kept on a server to avoid accidental loss. Attrition effects will be evaluated by testing whether systematic differences exist between those participants who complete the research versus those who drop out. We will initially inspect distributions for outliers and deviations from normality and will perform the necessary modifications to adjust for these issues. We will also examine any pre-existing differences between the two conditions in demographic composition and all measures collected at baseline. Pre-existing group differences in these variables will be controlled in subsequent analyses, using baseline scores as covariates. While both parents can participate in the intervention, we will use the assessment of the primary caretaker in all data analyses. On outcomes such as parental monitoring we expect to find discrepancies between child and parent report; thus, all analyses will be conducted separately for parent and child. With data from only 80 subjects (40 per group) in intent-to-treat analyses, our primary emphasis will be on calculating effect sizes for between group differences.

Sample representativeness and data imputation. Following Little and Rubin (1987) and Diggle and Kenward (1994), we distinguish between completely random drop-outs (independent of phenotype or covariate, MCAR), random drop-out (drop-out may depend upon past measures, but is not dependent on what the measure would have been at the time of missed assessment, MAR) and informative drop-out (may depend on prior variables and on state at possible time of missed assignment). We are concerned with informative drop out. If necessary, standard methods of multiple imputation (Little, 2002; Schafer, 1997) will be used for variables where unplanned missingness is an issue. For each time point, we will conduct analyses to identify systematic biases that may have arisen through non-participation (non-random dropout).

Aim 1. Treatment manual development does not require statistical analyses. The research team will meet with the PI at the beginning of the project, at the end of the open trial and end of the RCT to review the manual and suggest adaptations. With regard to feasibility, the following information will be calculated: refusal and enrollment rates, average number of days to intervention completion, and withdrawal rates of enrolled families. Acceptability will be examined by calculating percentage of “agree” or “strongly agree” answers on the SEF, with 80% set as an acceptable criterion. Treatment provider ratings conducted at post-intervention will also be calculated to determine clinician acceptability. Open-ended question responses at post-intervention and at completion of the follow-up assessment will also be qualitatively reviewed.

Aims 2 - 4. The domains to be analyzed, outlined in Table 2, include substance use (Aim 2), other problems (school, risky sexual behavior, Aim 3), and potential mediating processes including family management (Aim 4a), peer influences (Aim 4b) and teen cognitions (Aim 4c).The basic analytic strategy entails latent growth modeling to assess change in outcomes over time. This model allows for the inclusion of both categorical and continuous independent variables and for appropriate modeling of covariance structures when observations are correlated over time. Each teen and family outcome will be entered as a dependent variable in separate analyses with intervention condition serving as the primary independent variable. Appropriate time invariant covariates (e.g., age, sex, etc.) will be included as determined by preliminary analyses described above. Substance use in general, and marijuana use in particular, at baseline will be co-varied in one analysis to determine if there are any differential effects of the interventions by prior substance use. Post-hoc power analyses will be conducted using the beta weight and standard error of the estimate for intervention group to determine the number of subjects necessary for the given differences in outcomes to be significant in future studies. Measures of association (adjusted mean differences) and 95% confidence intervals will also be calculated to assess the effect size of the IMI/FCU.

The basic analytic strategy described above is limited by the small sample size of this treatment development study. Although the investigation of all outcomes using latent growth modeling will lay the groundwork for a future R01 trial, additional analyses will be helpful to provide more information about effect sizes. An estimate of the intervention effect sizes at each assessment with appropriate covariates, as well as the correlation between the same dependent variable at adjacent assessments, will be conducted. These parameters will be used to determine necessary sample sizes for a future clinical trial by conducting power analyses for repeated measures designs.

5f. Sample Size Considerations

A large trial is not justified given that adaptations need to be made to the protocol to make it appropriate for the population in this proposal. In this treatment development grant, we chose to recruit 100 subjects in the RCT conservatively estimating that 20% may be lost at follow-up, leaving 80% of subjects with complete data. This number will be sufficient to allow us to make judgments regarding feasibility and acceptability. Despite problems in the stability of effect size calculations with small samples (Kraemer et al., 2006), if a large effect size is detected between groups, this would be an indication that the experimental treatment is sufficiently innovative and that further testing in a larger trial is indicated.

We will test *planned paired comparisons* of our two groups. All power calculations are based on asymptotic results using the t test on the means of independent samples. Statistical power of rejecting the null hypothesis

at the 5% significance level was calculated. Power calculations involved generating the expected effect size and within-population standard deviations and fitting false alternative models to these data. **Table 3** summarizes statistical power to reject the null hypothesis of AIM 2 using the independent samples t test model that there is no mean difference between intervention types [PE v. IMI/FCU]. Findings reported in Preliminary Studies for adolescents with a prior history of problematic alcohol use are most relevant to the sample to be studied in this application. Effect sizes for the IMI/FCU condition effect on marijuana use compared to the IMI alone was substantial at 3 months (h = .61) and 6 month (h = .46) follow-ups. We also had a medium effect on heavy episodic drinking at 3 months (h=.57) and 6 months (h=.59). **Given that we were comparing two active treatments in REFRAME, FCU/IMI vs IMI alone, a medium effect is substantial. Therefore, we anticipate at least a medium effect in this application given that we are comparing the IMI/FCU to a less active condition, psychoeducation.**

As shown in Table 3, we have 60% power to detect an effect size of .5 or greater with 40 subjects per group for continuous variables such as number of days smoking marijuana. For power to detect the difference between two proportions (e.g., percent endorsing marijuana use at follow-up in the PE group vs. IMI/FCU group), the effect size was defined as the arcsine-transformed proportions (Cohen, 1988).Our data from REFRAME, described above, suggests a medium effect can be reasonably anticipated. **Table 4** shows power to test the null hypothesis of no difference in proportions between groups for a range of small to medium effect sizes (h). Not surprisingly, for our proposed sample size (N=40 per intervention group; 80 total), we do not have adequate power; however, we do indicate the necessary sample sizes to reach acceptable power for planned future R01s. While we do not anticipate achieving a true effect of that magnitude within this treatment development phase, we do expect to be able to generate a reasonable effect size estimate. For example, if we obtain a true effect size of 0.50, we will be aware that a sample size of 63 participants per treatment group will be needed to obtain the desired treatment effect in the full-scale clinical trial.

Table 3. Estimated statistical power (=.05) of rejecting null models of no mean differences between groups for substance use and sample size needed for 80% power.

Effect size (d)*	Power with N=40 each group	N* in each group for 80% power
.20	.15	388
.30	.26	171
.40	.42	98
.50	.60	63

* Based on existing literature, see text for references.

Table 4. Marijuana Use/Heavy Volume Drinking

Effect Size (h)*	Power for between group differences (*N=40 in each group*)	N* per group for 80% power
.20	*.23*	*393*
.30	*.38*	*174*
.40	*.56*	*98*
.50	*.72*	*63*

* Based on existing literature, see text for references.