



Group Therapy with Parents and Adolescents

Abstract

The project goals are to continue the development and refinement of a novel group therapy intervention and examine ostensible mediators of the model used in treating substance abusing adolescents. In this project, we will adapt an existing group-oriented therapy to a substance abusing and dependent clientele. The project's significance stems from a need to incorporate evidence-based group therapy models with adolescents who are either or both substance abusing and dependent. Current models, based largely on 12-Step treatment protocols have little empirical support. We will conduct a Stage Ib clinical trial of the intervention. The first aim is to compare the group therapy intervention against a 12-Step based comparison group to assess whether the intervention is effective in reducing adolescents who with comorbid diagnoses of substance abuse/dependent and conduct disorders. By providing a rigorous outcome study, the investigators will also derive an effect size for the model that can be used in Stage II trials. The second aim is to examine hypothesized mediators and moderators of the intervention and to generate other possible mediators using a qualitative research design. The information collected in this Stage 1b study will provide guidance in conducting a Stage II trial in which there can be more definitive conclusions on the mediators and mechanisms of change. The three hypothesized mediators of the model are group cohesion, parental nurturance, and motivation (i.e., readiness to change). One benefit of this project will also be to implement and refine the treatment and fidelity manuals. In this project, the investigators will use a concurrent mixed research model that consists of a randomized experimental design with assignment to two treatment conditions: the model and a group treatment model based on a 12-Step philosophy. The qualitative methods include focus groups, ethnographic interviews and Interpersonal Process Recall.

Study Locations: Research staff will be located at _____ Counseling and Psychiatric Services, _____ State University, and at _____ State University. The Principal Investigator, Dr. _____, will be located at _____ State University and will supervise project staff located there. The co-Principal Investigator, Dr. _____, Professor at _____ State University. The Executive Director of the _____ Counseling and Psychiatric Services, Dr. _____, the Project Data Manager, and the Research Interviewer will be located onsite in _____. As Principal Investigator, Dr. _____ will provide the overall coordination of the research activities that occur at _____ State University, _____ State University, and _____ Counseling and Psychiatric Services. The co-Principal Investigator, Dr. Scott Sells, will coordinate all aspects of the Intervention and training, including ensuring the treatment fidelity of the implemented model.

Type the name of the principal investigator/program director at the top of each printed page and each continuation page. (For type specifications, see instructions on page 6.)



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A: Specific Aims

While group therapy remains the most commonly used treatment modality in community drug treatment settings, there are only 20 controlled outcome studies (NIDA, 2003). Group therapy is also the modality of choice with adolescents, yet there are no definitive efficacy studies (Dennis, Dawud-Noursi, Muck, & McDermeit, 2003; Rowe & Liddle, 2003). Furthermore, the extant literature reveals that none of the outcome studies had treatment protocol manuals with sufficient detail for easy transportability into large numbers of community-based settings (_____s & Morral, 2003). Adolescent group therapy programs were also using adult treatment models with only minimum modifications (Dennis et. al., 2003; Lamb, Greenlick, and McCarty, 1998). Other key areas of concern included a lack of process research to identify key mechanisms of change (Diamond & Diamond, 2001), the mobilization of parents to increase adolescent treatment engagement (DeCivita, Dobkin, and Robertson, 2000), the treatment of co-morbid conduct disorders in reducing adolescent substance abuse (Kaminer & Burlson, 1999; Leshner, 1997), the lack of treatment fidelity measures (Henggeler et al., 1997), the impact of rebuilding parent and adolescent emotional attachments (Schmidt, Liddle, & Dakof, 1996); and the impact of peer (Dishion, McCord, & Poulin, 1999; Scheier and Newcomb, 1991) and parent group cohesion during the treatment process (Dishion, Reid, and Patterson, 1988).

To address these areas, a Stage Ib project was chosen. Even though the existing literature showed promise in identifying possible key mediators (e.g., rebuilding emotional attachments, parent and teen group cohesion, parent engagement) these were not connected to substance abuse group therapy studies but rather to individual or family therapy with adolescents. In addition, there is controversy on whether group therapy for adolescent substance abuse may actually create iatrogenic effects or clinical deterioration (Dishion et al, 1999; Santisteban, Coatsworth, Perez-Vidal, & Kurtines, 2003). Therefore, we concluded that putting forth a key mechanism of the model and testing it was premature until key mediators could be identified and operationalized. With mediators in place, we believed that we would be able to make inferences about the therapeutic mechanism. We also believed that it was essential to determine key moderators (e.g., severity of teen dysfunction, parent stress, socioeconomic disadvantage, etc.) that might mask the effectiveness of treatment. Taken together, determining mediators, moderators and possible mechanisms of change would provide a major accomplishment and lead to significant changes to treatment protocol and fidelity manuals.

To accomplish the project aims, the investigators adapted an existing group therapy model for adolescents that showed promising initial results but had not yet been studied systematically. The _____ Model (Sells, 2002) was originally developed for work with conduct and oppositional defiant disorders but showed promise in its adaptation and treatment of 102 adolescents who experienced serious substance abuse and dependency (_____, Sells, Rodman, & Reynolds, in press-See Appendix C). Although the results were promising, the study suffered from methodological limitations. The lack of a control group and a comprehensive measurement package were among the weaknesses that needed to be remedied.

It was crucial to locate a study design and analysis that would allow the research question to guide the study. Although quantitative designs provide a rigorous test of efficacy, they are not the ideal design for examining process data. Our central research questions are (a) Whether the treatment model consisting of key mediators such as rebuilding emotional attachments, parent and teen group cohesion, parent engagement would reduce substance abuse and co-morbid symptoms of conduct disorders over a 18 month period? (b) If unexpected change did occur, could we locate and isolate the key moderators associated with this effect? and (c) If unexpected mediators emerged in Year 1 of the study, could they be operationalized and tested in the second outcome study during Year 2 and emerge as possible mechanisms of change?



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These research questions required an innovative concurrent mixed model that employed both a qualitative research design to discover key mediators and moderators (Barron & Kenny, 1986) and a quantitative experimental design to test the efficacy of any identified key mechanisms of change. This concurrent mixed model emerged from the Sells, Smith, and Sprenkle (1998) qualitative/quantitative bidirectional continuum (See Appendix D for a view of this model). The concept of “bidirectionality” is defined as a recursive and iterative relationship between qualitative and quantitative results. First, qualitative theory development guides hypothesis formulation and theory testing. In turn, quantitative results lead to further qualitative investigations when surprising results lead researchers to pursue additional data to reformulate unsupported portions of a theory.

We will implement this bidirectional research model (i.e., concurrent mixed methods) by simultaneously employing both quantitative and qualitative methods in Year 1 and Year 2 to discover mediators and moderators and connect these to outcomes to refine the group therapy and fidelity manuals. For example, the qualitative discovery of a new mediator such as “conflict through button pushing” in Year 1 will inform us to redirect our outcome measures in Year 2 to test the efficacy of this concept. This surprising qualitative finding will guide new quantitative hypothesis formulation and theory testing. By the same token, the quantitative finding that “positive parent cohesion” correlated with a subsequent decrease in substance abuse in Year 1 will redirect our efforts to conduct a more intensive qualitative study in this area to uncover additional key mediators within the construct of parent cohesion that led to this positive correlation. In this way, qualitative and quantitative methods in this study will build upon each other and offer information that neither one alone could provide in a very bidirectional and reciprocal fashion. This type of concurrent mixed model is ideal for a Stage I research design in which the goal is to discover key mediators and moderators for group therapy development.

In sum, the aims of this project are implement a Stage Ib project to refine and test the existing group therapy and fidelity manuals, estimate effect sizes, pilot data on the efficacy of the Group Therapy Model (i.e., outcome) and identify key mediators and moderators of change (i.e., process). The outcome study will randomly assign adolescent substance abusers treated with the co-morbid diagnosis of conduct disorder (APA, 2000) to the Parenting Love and Limits group therapy intervention (model) (See Appendix A) versus a modified 12-Step program adapted for adolescents within juvenile justice and mental health services. The qualitative process study will triangulate measures from ethnographic interviews of adolescents and parents, analysis of treatment fidelity videotape, and the in-depth review of actual group therapy sessions using Interpersonal Process Recall (IPR). Taken together, these sources of data can provide us with the mediators to refine the existing group therapy and fidelity manuals.

In summary, this research project seeks to begin to answer the questions of “Does it work?” and “How does it work?” by addressing these specific aims:

- Aim 1: To provide pilot data on the overall efficacy of the group therapy approach in reducing substance use, abuse, and dependency and comorbid symptoms of conduct disorders**
- Aim 2: To examine the possible mediators (e.g., nurturance, group cohesion, and motivation) and moderators (e.g., race, socioeconomic status) of treatment effects.**



B: Background and Significance

There is a growing concern in our society about the dramatic increase of adolescent drug and alcohol abuse and dependence. There is no shortage of reports describing these alarming trends of drug use in teenagers (e.g., Muck, Zempolich, Titus, Fishman, Godley, et. al., 2001; Weinberg, Rahdart, Colliver, & Glantz, 1998; Rowe & Liddle, 2003). According to The Substance Abuse and Mental Health Services Administration (SAMHSA) (2001), among those ages 12 to 17, drug use rose from 9.7 percent in 2000 to 10.8 percent in 2001. This rise is especially worrisome since adolescent drug use has been linked to other problems such as school dropout rates (Ellickson, Bui, Bell, & McGuigan, 1998), low academic achievement (Kohn & Henderson, 2002), truancy, fighting, and defiance (Fisher & Harrison, 2000), running away (Slesnick, Myers, Meade, & Segelken, 2000), suicide (Bolognini, Plancherel, Laget, & Halfon, 2003), high tendency for breaking boundaries (Terry, 1999), and other delinquent behaviors (Garnier & Stein, 2002; Schmidt, et al.1996).

Changes in teen substance use have lead to a greater need for theoretically based and empirically supported treatments (Brown, Monti, Myers, Waldron, & Wagner, 1999). Indeed the number of studies devoted to substance abuse and treatment in youth is continually growing (e.g., Coatsworth, Santisteban, McBride, & Szapocznik, 2001; Latimer & Newcomb, 2000; Liddle, Dakof, Parker, Diamond, Barrett, et. al, 2001). However, many agree that a gap still exists between research on adolescent substance abuse and the treatments currently being provided (Liddle, Rowe, Quille, Mills, et. al., 2002; Robbins, Bachrach, & Szapocznik, 2002; Rowe & Liddle, 2003).

Aim 1: To provide pilot data on the overall efficacy of the group therapy approach in reducing substance use, abuse, and dependency and comorbid symptoms of conduct disorders

Group Therapy Efficacy Studies in Reducing Adolescent Substance Abuse

Although group therapy is the modality of choice with substance abusing adolescents, there are no definitive efficacy studies (Dennis, Dawud-Noursi, Muck, & McDermeit, 2003; Rowe & Liddle, 2003). A review of the literature by _____s and Morrall (2003) reveal that the group therapy outcome studies that do exist are limited by small samples spread over many different programs, low treatment duration (generally about two months) and marginal follow-up rates (50 to 70 percent).

The exception to this problem is the study conducted by Liddle, Dakof, Parker, Diamond, Barrett, and Tejada (2001) in which there were 152 cases assigned to either MDFT (multidimensional family therapy) (n=47), multi-family group (n=52), or adolescent group therapy (n=53). The general pattern of results indicated an overall improvement among youths in each of the three treatments. Parents of youths in each treatment reported similarly on their adolescents' acting out behaviors, indicating significant improvement over time in problem behaviors. However, differential outcomes among the three treatments also were found. Results concerning adolescent drug use and family functioning bring the differences between the three treatments into relief, rendering a portrait in which those receiving MDFT showed the most improvement, followed by those receiving the adolescent group therapy and then multi-family group. The results suggest that adolescent group therapy is effective just not as much as MDFT. It was unclear what constituted the group therapy; the formal treatment adherence manuals were targeted for MDFT rather than the comparison condition interventions.



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Other group therapy studies have also showed promising results. Several studies showed improvement in adolescent substance abuse using group therapy if the co-morbid symptoms of depression or conduct disorders were reduced (Kaminer, Berleson, & Goldberger, 2002; Kaminer & Burleson, 1999; Lowenstein, 1991; Pressman, Brook, Maidman, & Orlowski, 2001). Another study by Schmidt, et al., (1996) of 29 parents and their drug-abusing adolescents showed a statistically significant association between improvement in parenting and reduction in both adolescent substance abuse and behavior problems. Other pilot studies include the effects of a Teen Abuse Group (TAG) on interpersonal violence and substance abuse (Miller, 1995) and the role of early recollections using Adlerian theory and substance abuse (Mansager, Barnes, Boyce, & Brewster, 1995).

However, these promising results must also be weighed with studies that showed less favorable outcomes. There is evidence that group therapy may be contraindicated and in fact contribute to iatrogenic effects or increased deviant behavior in substance abusing adolescents (Dishion, Capaldi, Spracklen, & Li, 1995; Dishion, et al, 999; Santisteban, et al., 2003). Dishion's et. al. (1999) findings from two controlled intervention studies suggested that peer-group interventions increase adolescent problem behavior and negative life outcomes in adulthood, compared with control youth. The data from both studies suggested that high-risk youth are particularly vulnerable to peer aggregations, compared with low-risk youth. They concluded that peer aggregation during early adolescence, under some circumstances, inadvertently reinforces problem behavior. Santisteban et. al. (2003) reached a similar conclusion when they stated: "Although group therapy may be less costly to implement, any consideration of cost-effectiveness must also consider the possibility of clinical deterioration" (p. 131). This may be an underestimate, given the "file drawer" problem: traditionally, intervention researchers are reluctant to publish null effects and, least of all, negative effects (Dawes, 1994; Glass & _____, 1978).

Another controversy is that adolescent group therapy programs use adult treatment models (12-Step self-help groups such as Alcoholics Anonymous (2001) with only minimum modifications (Dennis et. al., 2003; Lamb, Greenlick, and McCarty, 1998). These 12 Step groups are the most utilized form of help for alcohol problems (Emrick, Tonigan, Montgomery, & Little, 1993; Ogborne, 1993; Weisner, Greenfield, & Room, 1995) with an estimated 9% of the U.S. population having attended an AA meeting (Room and Greenfield, 1993). Yet, the few quasi-experimental studies examining the adolescent twelve-step approach do not show a correlation between 12-step approaches and posttreatment substance use reduction (Alford, Koehler, & Leonard, 1991; Brown, 1993; Hsieh, Hoffmann, & Hollister, 1998; Kelly, Myers, & Brown, 2000; Vik, Grizzle, & Brown, 1992; Winters, Stinchfield, & Henly, 1993; Winters, Stinchfield, Opland, Weller, & Latimer, 2000). Due to the lack of controlled comparative outcome studies, it is currently not known which treatment modalities or components of 12-Step programs may be optimally effective with adolescents (Brown, Kelly, & Myers, 2002).

Another problem was that none of the outcome studies had treatment adherence manuals with sufficient detail for easy transportability into large numbers of community-based settings (_____s & Morral, 2003). Although the Dakof et. al. (2001) study cited a multi-family and adolescent group therapy manual, it was not clear whether they had the same degree of sophistication that of the MSFT intervention.

A sophisticated manualized treatment protocol is critical to any study because without one, measuring treatment fidelity is not possible. Without treatment fidelity, one can never sure of treatment adherence to the essential theoretical and procedural steps of the model and the results of the entire study are suspect (Waltz, Addis, Koerner, & Jacobson, 1993). Several treatment fidelity studies have been conducted on family therapy models for adolescent drug abuse in recent years (Henggeler, Melton, Brondino, Scherer, & Hanley, 1997; Hogue, Liddle, Rowe, Turner, & Dakof, 1998; Huey, Henggeler, Brondino, & Pickrel, 2000), and demonstrated



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that complex manualized treatments can be implemented with a high degree of adherence. However, these manuals have been used for family therapy treatments and not adolescent group psychotherapy. In addition, a current study by Liddle, Rowe, Quille, Dakof, et al. (2002) revealed that the dissemination or transportability of empirically based interventions into community settings may represent the greatest area of concern in drug treatment research. Without a treatment protocol manual that shows treatment fidelity, transportability is unlikely.

To address these gaps, we will conduct a two-year randomized clinical trial, testing the intervention against a modified 12-Step program. Our research site in _____ averages 1,500 adolescent substance abusers with the dual diagnosis of conduct disorder per year. The juvenile court judge has agreed to court order adolescents and their families in support of this project (See Appendix I-Letters of Intent). In addition, there will be the added benefit of having a control group that is a modified 12-Step group psychotherapy model adapted for adolescents. In addition to the outcome data, it may be possible to examine the mediators in a 12-Step program. A final advantage is using a “business-as-usual” model that is comparable to many of those used throughout the United States. This type of comparison group is more rigorous than the classical pure no-treatment control since the difference between treatments should be smaller. The treatment model has both a treatment manual (See Appendix A) and a treatment fidelity manual (See Appendix B). Although both manuals are still in the developmental stages, it will allow the group therapists the opportunity to deliver the program in a standardized format thereby increasing treatment adherence and reliability.

This investigation will also address the controversies outlined by the Dishion, McCord, and Poulin (1999) and Santisteban, et. al. (2003). Both authors hypothesized that the group therapy intervention might have shown positive results if the parents were actively involved in the group therapy classes with their adolescents. In both articles, however, the parents were not involved in the group therapy treatment. They were peer only groups. In this study, however, the parents are actively involved in treatment sessions. In addition, another important implication of the project is to determine whether the iatrogenic effects found by Dishion et al will be replicated in this study.

Co-Morbidity of Substance Abuse and Conduct Disorders

One of the most consistently reported findings in the study of juvenile delinquency is the positive relation between conduct disorders and substance use (e.g., Ensminger, Brown, & Kellam, 1982; Jessor & Jessor, 1977; Windle, 1990). For example, using data from the National Longitudinal Study of Youth, Windle (1990) found that early nondrug-related delinquency predicted later substance use, even after the effects of early substance use had been controlled. The association between substance use and antisocial behavior appears to be genuine and robust, and, indeed, some theorists consider the two sets of behaviors simply to be different expressions of a single underlying “problem behavior syndrome” (Feehan, Henry, Mcgee, Moffitt, Silva, & Stanton, 1993). Because of the intricate relationship between conduct disorders and adolescent drug abuse, interventions must actively target and impact these associated problems. Failure to do so will result in compromised treatment and poor outcomes (Grella, Hser, Joshi, & Rounds-Bryant, 2001).

Controlled outcome studies of outpatient family therapy based interventions for adolescent drug abuse and related conduct disorders “appears to be superior to other forms of outpatient treatment” (Williams & Chang, 2000, p. 159). Waldron (1997) concluded that “when compared to alternative, non-family interventions, family therapy appears to emerge as the superior treatment” (p. 229). Multisystemic treatment (MST) has been shown to be effective in treating co-occurring conduct disorder and substance abuse problems (Henggeler,



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1999; Schoenwalk, Borduin, Rowland, & Cunningham, 1998). Other family therapy models have had similar success rates (Liddle, Dakof, Parker, Diamond, Barrett, & Tejada, 2001; Friedman, 1989, Liddle, 2002; Szapocznik et. al., 1988). However, while there have been many family-based interventions, there are only several co-morbid group therapy studies involving both the parents and their substance abusing teenager (Dakof et. al., 2001; Joanning, Quinn, _____, & Mullen, 1992; Schmidt, 1996).

One of the best known community-based treatment models, multisystemic treatment (MST) does not employ a group therapy treatment program. Of these studies, only the Liddle et. al. (2001) study had control groups, treatment manuals, and measured treatment fidelity. Other non-family based research on the relationship between conduct disorder behaviors and substance abuse lacked control groups and large enough sample sizes (Kaminer, Berleson, & Goldberger, 2002; Kaminer & Burleson, 1999; Lowenstein, 1991; Pressman, Brook, Maidman, & Orlowski, 2001). These studies also did not specify key mechanisms of change and their subsequent relationship in reducing both adolescent substance abuse and conduct disorders. The focus on outcome data have taken priority over more process oriented studies that might identify the mechanisms of change.

To address these gaps, this study will employ a controlled family-based group outcome study with adolescents who are diagnosed with both substance abuse and conduct disorders that actively involves their parents throughout the treatment process. Parents will be active participants throughout the group therapy process; doing so follows the potentially therapeutic impact of family involvement. Because of the therapeutic impact of parental involvement on substance abuse and conduct disorders, we have emphasized its role on the reduction of these co-morbid behaviors. Because parental involvement may be a key mediator, the connection between it and outcomes will be followed and tested in both years of this project.

Aim 2: To examine the possible mediators (e.g., nurturance, group cohesion, and motivation) and moderators (e.g., race, socioeconomic status) of treatment effects

Lack of Process Research to Identify Key Mediators and Moderators

The processes through which therapeutic change is achieved in child and adolescent research are rarely studied (Kazdin, 2003). Moreover, when the mediators are studied, studies are not designed to establish the time line between the process or mechanism and the observed therapeutic change (Weersing & Weisz, 2002). Once an intervention is found to be efficacious, tests of such processes are essential to ensure that we understand why and how treatment works. In short, research to date has not been developed and designed to answer this critical question about treatment. As Kazdin (2003) noted:

Much of the adolescent outcome research reflects empiricism at its best and its worst, namely, repeated demonstrations that various treatments produce change and are better than no treatment. Very little in the way of theory guides therapy research and hypotheses about mechanisms of change. The net effect is that we really do not understand very much about therapy, why and how it achieves change, for whom it is and is not effective and why, and how to optimize therapeutic change (p. 1).

In addition, multiple child, parent, family, and contextual factors (moderators) may also influence responsiveness to treatment. The sparse evidence suggests that multiple factors contribute to treatment outcome in the way that risk factors accumulate in predicting onset (Kazdin, 2000). Although moderators of therapy are



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studied rarely in child and adolescent therapy, one can point to a number of demonstrations in which the effectiveness of treatment depended on such other factors as severity of child dysfunction, parent stress and psychopathology, and socioeconomic disadvantage (Webster-Stratton & Hammond, 1990). Identifying moderators will significantly influence application of treatment with better triage of patients toward interventions to which they are likely to respond. Understanding how and why moderators exert their influence will significantly improve treatment effectiveness. By knowing how a treatment is effective, existing models can be refined to emphasize therapeutic mechanisms.

The process research studies on adolescent drug abuse have not focused on the mechanisms of change in group therapy (Rowe & Liddle, 2003). For example, Diamond and his collaborators examined the impact of adolescent engagement on improving poor therapist-adolescent alliances (Diamond, Liddle, Hogue, & Dakof, 1999). Diamond and Liddle (1996) used a task analysis to identify the correct combinations of clinical interventions and family interactions necessary to resolve in-session impasses in the MDFT (multidimensional family therapy) model. This task analysis held promise in identifying a mechanism of change. However, it is also clear that they needed to go further to complete their investigation. Process research by MST (multisystemic therapy) revealed a clear association between improved family functioning (i.e., increased parent monitoring and cohesion) and reduced delinquency in adolescents and affiliation with delinquent peers (Huey, Henggler, Brondino, & Pickrel, 2000).

Although these studies examined important mediators of family therapy treatment with substance abusing adolescents, they did not, with the exception of the Huey et. al.'s (2000) study, link process to outcomes (Waldron, 1997) or investigate the process variables that are responsible for change in group therapy with this population. In addition, moderators in these studies were not explored. Instead, the vast majority of adolescent studies compared a treatment to no treatment or contrasted two or more competing interventions or combinations of interventions (Kazdin, Bass, Ayers, & Rodgers, 1990). Rarely (e.g., < 3% of the studies) are there efforts to understand therapeutic processes (Kazdin, 2000).

This project will address the lack of process research using a bidirectional qualitative/quantitative continuum to answer the question, "What processes or mechanisms mediate therapeutic change in the area of adolescent substance abuse?" Sells (c.f., Sells, 1998) successfully used the bidirectional model to locate key mediators (e.g., button pushing, troubleshooting) with conduct disorders using a family therapy paradigm. This information was used in the pilot study on the model (_____, Sells, Rodman, & Reynolds, in press). This concurrent mixed model emerged from the development and implementation of the Sells, _____, & Sprenkle (1995) qualitative/quantitative bidirectional continuum. In this investigation, we will employ the same bidirectional continuum (See Appendix C for a view of this model).

The investigators will closely examine the outcome results in Year 1 to determine if the key mediators hypothesized to decrease adolescent substance abuse (i.e., parent and adolescent motivation, rebuilding parent nurturance, and parent and peer group cohesion) were statistically significant. These results will be compared with those from the qualitative IPR and ethnographic study. If the results from both the qualitative and quantitative studies match, further outcome efficacy studies with new adolescents randomly assigned to the same two groups (vs. 12-Step Program) will be conducted in Year 2. If the results in Year 2 also produce the same statistically significant results as in Year 1, a case will be made that these mediators can be redefined as "key mechanisms of change".

After key mediators and moderators are discovered in Year 1, further outcome and process measures will be employed to fine tune both the treatment fidelity and treatment protocol manuals. This bidirectional feedback loop between process and outcome will enable us to discover the key mechanisms of change to refine



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the group therapy model. This is done to address a key issue in the field: That the processes through which therapeutic change is achieved in child and adolescent research are rarely studied (Kazdin, 2003). We must address these issues otherwise we may continue to understand that a model works without ever understanding “how it works?” Clinicians need answers to both questions.

In a Stage Ib project, we will likely locate and operationalize the key mediators--engagement, rebuilding emotional attachments, and positive peer and parent group cohesion through our bidirectional design. We are also likely to discover new mediators through the qualitative study that will be unexpected and can be tested in Year 2 for efficacy. However, we may or may not achieve Aim #3, identifying possible key mechanisms of change. This is because we define “key mechanisms” as a well-tested mediator. The mediators described below will only graduate to the status of “mechanism” if they show statistical significance with two different cohorts of adolescents in Year 1 and Year 2. Since there is no existing rule or test of when a mediator graduates to mechanism status, we are noting our comfort level. Once these conditions are realized, in Year 3 we will make a strong argument that certain mediators can be seen as a key mechanism.

The manual will be refined accordingly and a Stage II project proposed to test the effectiveness of these mechanisms in a larger scale outcome study. If these mechanisms still show significance in reducing adolescent substance abuse, they may move to mini-theory status and ready for a Stage III project. Stage II and Stage III are beyond the scope of this proposal but included here to illustrate our thinking process behind the inclusion of Aim #3.

Mobilization of Parents to Increase Adolescent Treatment Engagement:

Adolescent drug abusers are extremely difficult to engage and retain in any form of drug treatment (Rowe & Liddle, 2003). However, parent involvement and connectedness will greatly increase the adolescent’s involvement in the treatment process to prevent or delay drug involvement and are related to a decrease in adolescent drug use even after a pattern has been established (Schmidt, et al., 1996; Steinberg, Fletcher, Darling, 1994). By the same token, poor parental monitoring and lack of parent-adolescent involvement are critical factors in the initiation of early adolescent substance use (Prinz & Miller, 1994). In turn, this creates an adversarial family environment that often contributes to adolescents’ secretive drug use and abuse (Barrera, Castro, & Biglan, 1999).

Studies have highlighted the utility of psychoeducation groups in adolescent substance abuse treatment, that includes parent training (Bamberg, Toumbourou, Blyth, & Forer, 2001; Schmidt, et. al., 1996) and skills training (McGillicuddy, Rychtarik, Duquette, & Morsheimer, 2001; Wagner, Brown, Monty, Myers, & Waldron, 1999) to actively engage the parent into treatment with their adolescent. Research by Chamberlain and colleagues revealed that mobilizing adult caregiving is a critical and viable intervention target for even the most severe adolescent delinquent (Chamberlain & Moore, 1998 ; Chamberlain & Reid, 1998). Moreover, interventions with high-risk parents have shown results in improved parenting, concomitant reductions in child and adolescent problem behavior (Dishion et al., 1995 ; Dishion, Capaldi, & Spracklen, 1995).

However, one problem with traditional parenting groups is the significant dropout rates of both parents and teens (Slesnick, Meyers, Meade, & Segelken, 2000). Parents too often accept their adolescent’s substance abuse. Not surprisingly, they state that their adolescents are solely responsible for their own difficulties. Hence, they resent coming to parent education groups to learn new skills because their teen “got caught” abusing drugs or alcohol. Parents are subsequently resistant in helping their teen overcome their substance abuse. Studies are needed that demonstrate how to increase both parent and teen motivation to engage and continue in treatment which will likely lead to lower parent and teen dropout rates (Cormack & Carr, 2000).



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Within the area of engagement and motivation, one concept that has been receiving attention in the literature is the level of readiness of individuals to change as described by Prochaska, DiClemente, and Norcross (1992). Over the past 12 years, these authors have researched self-initiated and professionally facilitated change of addictive behaviors using key Transtheoretical constructs of stages and processes of change. These authors delineate five stages of readiness to change: precontemplation, contemplation, preparation, action, and maintenance. Precontemplation is the stage at which there is no intention to change behavior in the foreseeable future. Contemplation is the stage at which there is awareness that a problem exists and some serious thought has been given to overcoming it, but no commitment to take action has been made. The preparation stage combines intention and behavioral criteria. The individual will initiate action that may lead to change (e.g., seek help). Action is the stage at which individuals modify behavior experiences or environment to overcome their problems. Maintenance is the stage at which individuals work to prevent relapse and consolidate the gains attained during action.

These stages of readiness have also been shown to predict treatment drop out rates of substance abusing patients (Miller & Tonigan, 1996; Neff & Zule, 2002). This is especially important given that dropping out of treatment limits the likelihood of services being effective (Orlando, Chan, & Morral, 2003), while treatment completion is linked to favorable outcomes in substance abuse treatment in teens (Williams & Chang, 2000).

To address the issue of parental engagement and high drop out rates, the Model will use Prochaska's (1999) Stages of Readiness scale to determine both the parents and teen's motivation levels before and after receiving the _____ group therapy model. For example, if the parent or adolescent begins treatment at the precontemplative level can the group move them to the levels of contemplative, preparation, or even action? If this occurs, we will then investigate the key mechanisms (i.e., mediators) in the group that led to this change in motivation. We will also investigate whether this change in motivation engaged the adolescent and parent to stay in treatment and not drop out. Measuring resistance and motivation is a key activity for a client population that has a history of dropping out of treatment and failing to engage in the overall process.

The Impact of Rebuilding Parent and Adolescent Emotional Attachments

Numerous studies indicate that family emotional closeness and support are directly and inversely related to alcohol and drug use among children and adolescents (Barnes et al., 1986, 1995; Brook et al., 1989; Coombs & Landsverk, 1988; Coombs et al., 1991; Farrell & White, 1998; Hundleby & Mercer, 1987; Jessor & Jessor, 1977; Johnson & Pandina, 1991; Smart et al., 1990; Vicary & Lerner, 1986). In addition, the lack of parental nurturance leads to poor parent-child communication (e.g. Kafka & London, 1991; Wills, Vaccaro, & McNamera, 1992); lack of parental monitoring (e.g. Dishion, Patterson, & Reid, 1988; Steinberg, Fletcher, & Darling, 1994); and high levels of family or parent-adolescent conflict (e.g., Baer, Garmezzy, McLaughlin, Pokomy, & Wernick, 1987).

Despite the preponderance of research examining the relationship between family attachments or nurturance and adolescent substance use, at least two important gaps remain in the literature. First, there are no adolescent group therapy studies that examine the impact of rebuilding parent and adolescent nurturance and its effect on reducing substance abuse. Second, if nurturance does have a positive impact on reducing adolescent substance abuse, we need to know the key mechanisms that led to this change. By using nurturance as a mediator variable, we hope to determine its role in reducing substance abuse. Combining both quantitative and qualitative methods, we will triangulate the role of nurturance as a mediator of change with an eye toward examining it as a mechanism of change.



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The Impact of Positive Peer and Parent Group Cohesion

Clinically, adolescents are at a stage of development in which group interaction accounts for either positive or negative change. It is a well known truism that adolescents are influenced greatly by their peers. Studies show that adolescents choose friends with the same psychological attributes and behavioral experiences (Steinberg, 1991). Intimate peer relationships with conflictual adolescents may create antipathy toward parents that will be conducive to drug abuse (Diamond & Liddle, 1996). Thus, it is not surprising that adolescents with positive lifestyles are apt to choose prosocial peers while those with troubled backgrounds are apt to identify and consort with antisocial peers. As a result, association with drug abusing peers is a significant risk factor (Brook, Kessler, & Cohen, 1999; Brooks, Finch, & Whiteman, 2002; Rowe, Liddle, McClintic, & Quille, 2002).

On the positive side, peer-related protective factors such as sports, academics, and school clubs may actively deter drug use (Youniss, McLellen, & Strouse, 1994). Because the choice of peers is a critical developmental factor, group therapy is the treatment modality of choice for adolescent substance abuse treatment (Hoag & Burlingame, 1997; Liddle, Dakof, Parker, Diamond, Barrett, & Tejada, 2001; Shklyarevsky, 1997). Moolchan and Ruckel (2002) suggested that adolescents' orientation to peers influences group participation that may enhance adherence to the treatment process. Zayat (2001) highlights the valuable peer feedback and the way that the group structure can serve as a microcosm of _____ for the adolescent.

With adolescents, group cohesion with substance abusing patients with comorbid psychiatric disorders has been shown to be associated with higher levels of emotional involvement with group members (Sena, 2003). Group treatment services can enhance prosocial behavior in participants (Messina, Nemes, & Wish, 2001). However, several studies have found that peer group cohesion with high risk adolescents can increase deviant behaviors and substance abuse (Dishion, Capaldi, Spracklen, & Li, 1995; Dishion, McCord, & Poulin, 1999). Both studies suggest that repetition of contact within the peer-group intervention creates an iatrogenic effect, especially among those youth likely to engage in deviant talk and behavior in the company of other peers during group sessions. Dishion showed that the reinforcement processes within the peer groups are quite subtle and potentially powerful. Feldman (1992), however, found that mixing antisocial youth with prosocial youth in interventions was an effective strategy in reducing negative group cohesion. Aggregation of high-risk youth, then, may be helpful when groups also enforce interactions with prosocial children who do not respond to their conflictual peers (Dishion et. al. 1999).

While we have information of both the positive and negative effects of peer group cohesion, we do not know the effects of parent group cohesion in adolescent substance abuse groups. Although several studies report the importance of parental involvement (Bamberg, et. al., 2001; McGillicuddy, et.al., 2001; Schmidt, et. al., 1996; Slesnick, Meyers, Meade, & Segelken, 2000; Wagner, Brown, Monty, & Waldron, 1999), there are no studies that look at parent group cohesion as it relates to adolescent substance abuse. One possible reason for this deficit may be because most group therapy interventions available do not actively involve the parents in the group with their adolescents. Failing to include parents in adolescents' substance abuse groups is ironic since parent involvement has been cited a critical in reducing adolescent deviant behavior and substance abuse (Schmidt, et al, 1996; Steinberg, Fletcher, & Darling, 1994).

To address these gaps, we will investigate the effects of group cohesion as experienced by peers and parents using a cohesion scale to assess it role in effective group treatment and qualitative research to assess the context for this mediator. The Intervention is a multiple family group therapy intervention of 7 sessions with three weeks of follow-up and maintenance. The intervention stresses families learning from each other in a group setting in which group cohesion is used to institute therapeutic change. One novel aspect of the



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Intervention is its focus on concurrent group treatment of parents and adolescents both separately and conjointly. In this intervention, parents and adolescents start together, go into breakout groups, come back together, and finish up together. The synergy formed by this process allows parents and adolescents to come together in an unprecedented manner. It combines limit setting with parental nurturance of adolescents. The use of parent-led follow-up sessions allows for a generalizability of effects beyond the initial duration of the group therapy.

C: Preliminary Studies

The investigators have been conducting qualitative and quantitative studies for the last decade, some directly concerning the intervention and others directed at interventions aimed at reducing adolescent conduct disorders and substance abuse. In all, the investigators have extensive experience in conducting both process and outcome therapy and published on a process-outcome concurrent methods research model.

The investigators started by conducting several process research studies with Reflecting Teams (Sells, _____, Coe, Yoshioka, & Robbins, 1994 (Appendix F); Sells, _____, & Clevenger, 1994d; Sells, _____, & Moon, 1996). Reflecting Teams were the precursor of the "Inner/Outer Circle" session of the Intervention (See Appendix A, p. 36). Parents and adolescents to sit in the "outer circle" and act as expert consultants to help a parent and teen in the "inner circle" while they role play a technique like "how to produce an ironclad contract".

One integral part of our process research efforts was the use of Interpersonal Process Recall (_____, Sells, Pereira, Todahl, & Papagiannis, 1995) (Appendix E). This research procedure allows investigators to study the therapeutic moment of change (as reported by clients). The information allowed us to refine our intervention activities, leading to a more precise model of a Reflecting Team intervention. This series of studies culminated with describing a process-outcome methodology that was termed, "Bi-Directional Research Methods." This methodology was a form of concurrent mixed models (integrated qualitative and quantitative research procedures (cf., Sells, _____, & Sprenkle, 1995 (Appendix D); Sells, 1998).

This methodology was a form of concurrent mixed models (integrated qualitative and quantitative research procedures). In concurrent mixed models, investigators conduct either a qualitative or a quantitative study. We started with ethnography. From the ethnography, we formulated research questions. One key aspect of ethnographies is their ability to generate "theoretical assertions." These assertions provide the foundation of theoretical investigations by setting forth research questions. Once research questions are asked, then quantitative research projects can be devised that attempt to answer them. Since the results of quantitative results are seldom definitive and leave much unanswered, qualitative studies can then be employed to study the context of the findings. The results of the qualitative study provide investigators with insight into asking a second of research questions. This iterative process continues as investigators refine their understanding of the phenomena and produce key mechanisms of change or mini-theories.

The Principal Investigator, Dr. _____, has been conducting outcome studies for nearly 20 years with his first outcome published in the late seventies. More recently, he conducted two outcome studies that demonstrated his skill in assembling a team, planning and implementing an outcome study of novel interventions. In the first study, he worked with his doctoral students and a senior colleague in conducting a quasi-experimental study with 1450 adolescents in community settings in _____ (Arnold, _____, Harrison, & Springer, 1999, 2000)(Appendix G). The project was on adolescent sexuality and required tact in conducting the research activities in rural and urban communities throughout the State of _____.



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project showed that the intervention had a small effect size. This study with its quasi-experimental design was a classical effectiveness design, with an emphasis on understanding interventions being delivered in natural settings. The second study was a classical efficacy study with an emphasis on rigor (Valentine & _____, 2001)(Appendix H). This randomized clinical trial was conducted in a federal corrections setting with 123 female inmates. A novel intervention, Traumatic Incident Reduction (TIR), was implemented. Once a team, Dr. _____ assembled a team, trained the clinicians, negotiated with the prison authorities, and abided by security constraints in evaluating the efficacy of a novel intervention, TIR. Although these studies were not with substance abusing adolescents, they demonstrate the experience and skill of the Principal Investigator in conducting efficacy and effectiveness outcome studies. Together with his skill in conducting qualitative studies, he is ideally suited to conduct a concurrent mixed methods outcome study.

In preparing to submit a funding proposal, the investigators conducted an early pilot of the treatment model. The group therapy intervention was originally developed for work with conduct and oppositional defiant disorders but showed promise in its adaptation and treatment of 102 adolescents who experienced serious substance abuse and dependency (_____, Sells, Rodman, & Reynolds, in press). Claims of program effectiveness were supported by the 12 month follow-up that showed that over 90% of the adolescents had no further contact with the legal system. This study provided an early effort to document the feasibility and utility of the model for a clinical trial. Because the pilot study used an early version of the model, no treatment fidelity manual was used, and the complete set of measures were not implemented, no effort was made to estimate an effect size. Notwithstanding these shortcomings, the group therapy model showed promise. The positive results were tempered by methodological limitations. The lack of a control group and a comprehensive measurement package were among weaknesses that needs to be remedied. Our goal in pursuing funding is to remedy those deficits and subject the model to a Stage Ib trial to measure its efficacy, measure its effect size, refine the treatment and fidelity protocol, and examine mediators and moderators of the treatment model.

D: Research Design and Methods

Overall Design:

A concurrent mixed model will be utilized in this study: a qualitative process research design and a quantitative experimental design, each informing the other in an iterative process. This concurrent mixed model emerged from the development and implementation of the Sells, et al (1995) qualitative/quantitative bidirectional continuum (See Appendix C for a view of this model). Using our mixed model design, we employed the concept of “bidirectionality”. As Sells et al (1995) state:

Over time, a bidirectional relationship exists between qualitative and quantitative results, as qualitative theory development guides hypothesis formulation and theory testing. In turn, quantitative results can lead to further qualitative investigations when surprising results lead investigators to pursue additional data to reformulate unsupported portions of a theory (p. 203)

Traditional research employs unidirectional studies that test the efficacy of an existing treatment model in answering the question “Does it work?” without answering the question, “How does it work?” The net result are studies that fail to recognize the reciprocal, bidirectional impact that qualitative and quantitative have on one another to examine mechanisms of change and connect them to outcomes (Kazdin, 2000, Wynne, 1988).

To address this problem, we will employ a bidirectional continuum by simultaneously employing both quantitative and qualitative methods to examine hypothesized mediators in the therapy model and study their



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relationship to treatment outcomes. Once mediators are empirically identified, they can be studied further to determine whether they might be a mechanism of change. Knowledge of mediators and mechanisms of change can be used to refine the treatment and fidelity manuals. For example, the qualitative discovery of a mediator such as “parent group cohesion through venting” in Year 1 will inform us to redirect our outcome measures in Year 2 to ascertain the variance associated with this mediator.

Because we are using a concurrent mixed method design, we will be able to test the viability of hypothesized mediators and be alert for other mediators. Qualitative findings on new mediators will guide new quantitative hypothesis formulation and model testing. By the same token, a quantitative finding in Year 1 that “rebuilding parent and adolescent nurturance” is correlated with a subsequent decrease in substance abuse will redirect our efforts to conduct more intensive qualitative study to uncover the key mediators that led to this positive correlation. In turn, this will allow us to further refine and test our existing treatment manual based on this bidirectional research and not clinical assumptions. The advantage of concurrent mixed methods is its iterative nature: qualitative results provide direction for quantitative studies and vice versa. In this way, qualitative and quantitative methods will build upon each other and offer information that neither one alone could provide. Concurrent mixed methods are ideal for this project's Stage I research design whose goal is to discover mediators and moderators for group therapy development.

1. *Experimental Comparison Design:*

The quantitative study design is a Pretest-Posttest Comparison Group Design with random assignment to two treatment conditions; the Model or a 12-Step program modified for adolescents. Because this design allows the isolation of the effects of a treatment condition, it is well-suited in implementing a Stage I pilot study on the efficacy of the novel group therapy. More importantly, this study will provide a rigorous determination of the effect size of the intervention. In addition, each hypothesized mediator of therapeutic outcome will be measured using one of the standardized measures. With mediators so measured, we will be able to determine the variance that they contribute to the overall treatment model outcomes. This knowledge will give us some idea on whether the mediator may be a key mechanism of change. In addition, the quantitative design will provide a feasibility of using the proposed measurement battery. Specifics on the measurement battery and the new instrument are given later in this proposal. Measurement and data analyses of results from the comparison of the two conditions are presented in the sections of this proposal on Measurement and Data Analyses.

2. *Interpersonal Process Recall (IPR) and Ethnographic Interviews*

Interpersonal Process Recall (cf., Elliott, 1989; Elliott & Shapiro, 1988) will be used to examine hypothesized mediators of change and find evidence whether other mediators exist within the model. Interpersonal Process Recall is the technique of playing back videotape recordings to assist therapists or clients in describing their experiences during particular moments in the therapy session. This method, referred to by such names as *stimulated recall*, *playback*, *videotape inquiry*, and the *retrospection method* has been independently developed by a number of different investigators (Elliott, 1984; Mahrer & Nadler, 1986).

In this project, clinicians will review video recordings of “significant events” chosen by investigators. Significant events (generally 4-8 minutes in length) occur within each of the nine group therapy classes and represent moments in which clinicians witness a meaningful degree of positive or negative change from parents or adolescents (Elliott & Shapiro, 1988). By focusing on these significant events, we increase the likelihood that we will be able to examine mediators or mechanisms of change.



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First, we will review videotapes of each parenting class and select one or two positive change events and two negative change events from each of the nine group therapy classes. In this project, there are three teams of two clinicians for a total of six clinicians. From the three teams, three therapists will be randomly selected for the IPR study. Including both positive and negative events will enable us to answer the questions, "What mediates positive change in group therapy with adolescent substance abusers?" and "What moderators cause negative or unexpected changes?" Clinicians will use Likert scales to rate their perceptions of the significant event. Then, the investigators will interview clinicians on their understanding on what happened during these events that made them significant. From transcriptions of the interviews, we will be able to make inductions about mediators and moderators within the model. What follows is the protocol for the IPR interviews that will be given to clinicians.

Protocol for IPR Interview

A meaningful moment is an event in the group therapy session (i.e., parenting class) where at least one client member (parent or adolescent) made some change (positive or negative) as a result of the group therapy intervention. On the scale below, please rate the significance of the event:

1 -----2 -----3 -----4 -----5
 Very Negative Event Neutral Very Positive Event

Now, please give me a brief description of event. In your own words, describe what happened during that meaningful event. In your own words, what were the key processes or variables that were responsible for the positive or negative change (depending on your scale rating score) in the parent or adolescent?

The on-site research assistant will also conduct ethnographic interviews in a focus group format with parents and teenagers during the last 15 minutes of every parenting class without the presence of the clinicians. Our past experience (i.e., Sells, _____, & Moon, 1996) has shown us that the clinician's presence in the room significantly skewed the clients' responses. These questions will be asked:

- Question #1: What did your group leader do or say that was most helpful?
- Question #2: What did your group leader do or say that was least helpful?
- Question #3: What things were done tonight that were the most helpful?
- Question #4: What things were done tonight that were the least helpful?

Using the same methods that we used in the IPR, transcribed interviews will be analyzed to locate possible mediators and moderators. The results of these client interviews will be triangulated with the IPR clinician interview data to enhance the "trustworthiness" (i.e., validity of our conclusions on what are possible mediators and moderators (Moon, Dillon, & Sprenkle, 1990)) of our conclusions. The multiple sources and data collection methods ensure that the interpretations do not result from any one informant source (i.e., clients, clinicians) or data collection source (i.e., IPR, focus groups with ethnographic interviews).

Using this triangulated qualitative process research methods, mediators and moderators will likely emerge in Year 1 of this project. They will be compared to scores on the scales that measure the hypothesized



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mediators (i.e., group cohesion, parental nurturance, and motivation to change). Discrepancies between the hypothesized mediators and those that emerge from the qualitative research methods will be reconciled through additional focus groups and a reexamination of the IPR data. Any discrepancies will be reconciled at the end of Year One; efficacy data will be examined to see if scores between participants in the two treatment conditions differed.

For example, if the measures of the hypothesized mediators significantly differed between the two treatment conditions, there could be a prima facie conclusion that they mediated treatment outcomes. However, we would also ask whether these same mediators emerged throughout the qualitative study? If the answer were “yes,” we would have triangulated the results and have a greater degree of confidence that we have discovered a mediator of change in the Year One cohort. If the mediator repeatedly is found in efficacy and ethnographic investigations, it may approach characterization as a key mechanism of change in the intervention. In line with that reasoning, we will conduct a second efficacy study in Year Two to ascertain whether these same mediators (i.e., parental nurturance, group cohesion, motivation) continued to be a significant contributor to the overall regression model.

Replication of the role of these mediators would create a justification for a Stage II or III study determine the efficacy of the identified mediators as a mechanism of change. One heuristic finding will be that the same mediator predict both interventions; this would provide guidance in determining whether mediators in the group treatment are unique to it or fulfill a more generic role in treatment outcome studies.

Although the IPR is a key component of the process research aspect of this proposal, it will also be used to determine adherence of group co-facilitators to the treatment model (see Appendix B, p. 59). During group supervision with their supervisor, each group therapist will show a video clip (edited down to 5 minutes) of their parenting class that they conducted with both the parents and teens. This video clip will likely be the same one used for the IPR significant event interview since it will shows the therapist delivering the parenting class using the treatment manual. As one group therapist shows their video clip from their group, the supervisor and other group therapists will use the PLL rating scale (see below) to independently rate adherence to the model and treatment protocol manual (See Appendix A for a copy of this manual):

_____ (PLL) Rating Scale

#1 On a scale of 1 to 5 how closely did you follow the manual transcript in this section of the class as demonstrated by the video clip shown?

1 ----- 2 ----- 3 ----- 4 ----- 5

Followed the Manual Not at all	Followed the Manual Sometimes	Followed the Manual All of the Time
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Please note: The raters will have the treatment protocol manual (i.e., Leader’s Guide) in front of them and open to the page that matches the corresponding video clip being shown.



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#2 On a scale of 1 to 5 how closely did the co-facilitator demonstrate the central concept or technique as illustrated in the video clip shown?

1 -----2 -----3 -----4 ----- 5
 Demonstrated the Concept Demonstrated the Concept Demonstrate the Concept
 None of the Time Some of the Time All of the Time

Please note: The raters will have the treatment protocol manual (i.e., Leader’s Guide) in front of them and open to the page that matches the corresponding concept or technique with the video clip being shown. This same rating scale will be used for all nine parenting classes.

If the group therapist, scores lower than a “4” on either Likert scale, role plays are then conducted until the technique in question is mastered as determined by the supervisor. Mastery is defined that the specific techniques are demonstrated. For example, in Class 2, one technique is called the “Inner/Outer Circle.” This IPR process will allow the clinician to refine his/her knowledge the treatment fidelity model but it can also point to the need for additional training of all clinicians. For example, if the concept of “contracting” continues to give group therapists difficulty, as measured by the PLL Rating Scale, we will adjust or modify our training in this area to determine which areas in contracting need to be changed to increase fidelity or adherence.

Implementation of the Concurrent Mixed Model Design:

The quantitative design to measure outcomes follows the customary randomized clinical trial format: Participants are recruited, randomly assigned to two conditions, and followed for 18 months. There will be two separate efficacy outcome studies with two different cohorts of adolescents. Cohort 1 in Year 1- Adolescents with the dual diagnosis of substance abuse and conduct disorder will be randomly assigned to either the group therapy model or a modified 12-Step program for adolescents. These adolescents will be court ordered into treatment by the juvenile court judge (see letter of support-Appendix D). A urine analysis and *The Personal Experience Inventory* (PEI) will be used to establish a baseline of substance abuse. After treatment is concluded, both will be followed through juvenile court records and probation officers to see if there is a relapse in both substance abuse and/or conduct disordered behaviors over an 18 month period.

As stated earlier, if there is a discrepancy between the outcome results and qualitative results in Year 1, we will redirect both our outcome study and qualitative study in Year 2 to reflect these differences. The same process will occur if there is a discovery of new and unexpected mediators or moderators in the qualitative study. For example, if the outcome results in Year 1 reflect a significant correlation between positive peer cohesion and a decrease in adolescent substance abuse but the qualitative results show no effect, we will redirect our efforts to find what possible moderators could account for this difference. By the same token, if the qualitative study in Year 1 reveals that limit setting is a key mediator, then we will redirect our outcome measures to test this new mediator in Year 2.

The Cohort 2 outcome study in Year 2 will include a new set of adolescents but the design will be driven using the bidirectional qualitative and quantitative results from Year 1. In this way, we will be addressing one of NIDA’s (2002) major recommendations of “letting the research question guide the study design and analysis, not the other way around.” The time frame of research activities is given below:



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Brief Timeframe :

Cohort One: Treatment (Months 7 to 12); 6-Month Follow-up (Months 18-19); 12-Month Follow-up (Months 24-25); 18-Month Follow-up (Month 30-31); IPR and Ethnographic Interviews with Cohort One participants (Months 5 -30).

Cohort Two: Treatment (Months 16 to 20); 6-Month Follow-up (Months 26-27); 12-Month Follow-up (Months 32-23); IPR and Ethnographic Interviews of Cohort Two participants (Months 16 - 30).

Extended Timeframe:

Months	1-3	Hire Grant Manager and research staff; draft recruiting materials; train clinicians in treatment fidelity protocol; orient Data Manager and Research Interviewer to their respective activities
Months	4-6	Recruit and randomly assign participants; begin ethnographic study
Months	7-8	Administer pretest measures; continue ethnographic study
Months	7-12	Implement and comparison condition interventions; continue ethnographic study; implement Interpersonal Process Recall every two weeks
Months	12-14	Administer posttest measures to first cohort; revise treatment manual to reflect the interim ethnographic study results and the Interpersonal Process Recall results; revise ethnographic questions to reflect initial findings about therapeutic mediators and moderators
Months	15	Train clinicians in treatment fidelity protocol of the revised intervention; administer pretest measures for second cohort; continue ethnographic study
Months	16-17	Implement revised intervention for second cohort; continue ethnographic study;
Months	18-20	Administer posttest measures for second cohort; continue ethnographic study; revise Intervention; create revised set of ethnographic questions and continue ethnographic study; administer six month follow-up assessment measures to first cohort of participants; implement Interpersonal Process Recall every two weeks.
Months	21-25	Compare revised Intervention with ethnographic data and IPR data; revise model if necessary, create revised set of ethnographic questions and continue ethnographic study; administer 12 month follow-up assessment measures to first cohort of participants
Months	25-30	Compare revised Intervention with ethnographic data; revise model if necessary, create revised set of ethnographic questions and continue ethnographic study; administer 6 month follow-up assessment measures to second cohort of participants
Month	30-31	Draft treatment and supervision fidelity handbook for Group Therapy Intervention; elicit comments about handbook from clinicians and supervisors; submit manuscripts for publication; administer 18 month follow-up assessment measures to first cohort of participants; end ethnographic study
Month	32-33	Submit manuscripts for publication; administer 12 month follow-up assessment measures to second cohort of participants
Months	34-36	Produce final treatment and supervision fidelity handbook for final group model; write results of three year ethnographic study of the process and outcome of group therapy.



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Description of Project Activities

During Month 1 through Month 4, the project staff will be recruited and hired. During these months, investigators will train the Data Manager and research interviewer in data collection and management procedures. In addition, clinicians will be instructed in the treatment fidelity protocol (see Appendix A) using the previously developed intervention manual (see Appendix B). Within the _____ Counseling and Psychiatric Services, the comparison condition group therapy is the multifamily group psychoeducational treatment. It is the customary group treatment service provided to substance abusing families. Clinicians and their supervisors will be tested in therapeutic procedures outlined in the treatment manual until they reach a 90% threshold of knowledge and skills. The research facility at _____ State University and at _____ Counseling and Psychiatric Services will be equipped and prepared for research interviews, and data management. Starting in Months 4 through 6, study participants will be recruited and randomly assigned to treatment conditions. Details of recruitment and sampling are discussed in the section on sampling. Participants will be adjudicated adolescents with comorbid substance abuse and conduct disorders who are under court supervision and have been referred for treatment. Only after participants understand and give informed consent will they be randomly assigned to the experimental and comparison conditions. The intervention in both the experimental and comparison will be controlled for “dosage” and setting. Prior to delivering either the experimental and comparison, clinicians will be examined on their knowledge and skill in delivering the two different treatments. A comparison condition is being used in this project because a no-treatment control may not be a rigorous test of the efficacy of the intervention. Because the goal of this study is to ascertain the efficacy of a novel intervention, it is being compared against a program with comparable dosage and setting, but with a putatively different therapeutic treatment model.

Second, after random assignment but prior to treatment implementation, participants will be administered a pretest assessment battery (assessment instruments are described below) in Months 7 and 8. Participants in both conditions will be informed of a graduated schedule of incentives for completing the measures completely and on a timely fashion. Incentives for completing pretests will \$10, posttests, \$20, 6-month follow-up, \$25, 12-month follow up, \$30, and 18 month follow up, \$40. Although no reason exists on why there should be a systematic difference in the selection and attrition between different conditions, their comparability will be monitored at every measurement period. The interventions will be delivered during Months 7 through 12. The Interpersonal Process Recall protocol will be administered during two weeks during Months 7 through 12. During Months 12 through 14, posttest measures will be administered to the first cohort..

During Months 7 through 12 during which interventions are being delivered, treatment fidelity checks will be employed randomly. These fidelity checks serve two purposes. The first is that they will ensure that the intervention that is delivered is in fact what they are purported to be. The second is to provide one source of information as part of an ethnographic study. Although all groups and their clinicians will follow the treatment fidelity protocol, randomly selected members from all three groups will be followed weekly using an ethnographic protocol. Because ethnographies can be used to winnow organizing themes as perceived by a subgroup of people, it is an ideal method to ascertain the mediators and moderators of the intervention. Beginning Month 12, interim results of the ethnographic study will be used to revise and refine the model. In addition, the ethnographic questions will be revised to reflect the information gained in the outcome data. For example, if participants in the intervention condition score high marks on one instrument and not on another, questions that delve into this discrepancy will be posed to participants in both conditions.



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During the Month 15, clinicians will be trained in the revised procedures and pretest measures will be administered to participants in the second cohort. The ethnographic study will continue. Beginning in Months 16 and 17, participants in the second cohort will receive the revised group therapy intervention. After treatment is completed in Months 19 through 20, participants will complete posttest measures. A revised set of ethnographic questions will be formulated to ask participants. During Months 18 and 19, 6 month follow-up assessment measures to the first cohort of participants; every two weeks during Months 18 through 20, an Interpersonal Process Recall procedure will be administered to randomly selected clinicians from the second cohort of participants.

In Months 21 through 25, the intervention will once again be revised to reflect the experiences of the different ethnographic and IPR respondents. In addition, the ethnographic study will continue after the ethnographic questions are revised to reflect the IPR and ethnographic interview data. During Months 24 and 25, the 12 month follow up will be administered to the first cohort of participants. During the following two months, Months 26 and 27, the six month follow-up to the second cohort will be administered. The ethnography will continue until Months 30 and 31 when the Draft treatment and supervision fidelity handbook for Group Therapy Intervention will be drafted and comments elicited from clinicians and supervisors. During Months 32 and 33, 12-month follow up to the second cohort will be administered. During the last four months, the 18 month follow up will be completed by the first cohort of participants, the ethnographic study will be submitted for publication, and the treatment fidelity manual will be finalized. The final report will be submitted in addition to the overall manuscripts that describe the project and its results.

MEASUREMENT AND DATA ANALYSES

Participants will be administered the measures described below using Snap Survey Software (Mercator, 2001). Snap Survey Software is a suite of integrated software programs for questionnaire design, publication, data collection and analysis. It consists of a core product, Snap Professional, and specialist modules that may be added to extend the capabilities to Internet, PDAs, scanning and telephone interviewing. This will decrease the time and effort needed to enter data from the measures listed below. SNAP performs automated data entry of electronically-submitted surveys and integrates with all major statistical analysis applications, including SPSS and SAS. It allows ODBC connection to Microsoft Office products

Aim 1: *To provide pilot data on the overall efficacy of the group therapy approach in reducing substance use, abuse, and dependency and comorbid symptoms of conduct disorders*

Hypothesis #1: *The intervention will be effective in reducing adolescents' substance abuse and dependency.* The first hypothesis is whether substance abuse and dependency was alleviated as a result of the intervention. Two measures, the Personal Experience Inventory and urinalysis, will be used to assess the efficacy of the intervention: One measure of efficacy will be comparing the condition respondents' before and after scores on the PEI with those from the comparison condition. The PEI will be administered before, after and during 6-month, 12-month, and 18-month follow-up periods.

The Personal Experience Inventory (PEI) is a self-report inventory that documents the onset, nature, degree, and duration of substance abuse and dependency in 12- to 18 year-olds. It identifies personal risk factors that may precipitate or sustain substance abuse. In addition, five problem screens alert you to the possibility of family chemical dependency, sexual abuse, physical abuse, eating disorder, suicide potential, and need for psychiatric referral. 7 scales, 12 Psychosocial Scales, 10 Problem Severity Scales, 6 Problem Screens, plus Use, Frequency, Duration, and Age of Onset for 12 Drug categories



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The *Juvenile Court records* (JC) will document respondents' contact with law enforcement agencies. Urinalyses are required by Juvenile Court as a means to ascertain that respondents are abiding by their commitment to abstain from use. Probation officers will administer the urinalyses to participants using a standardized protocol that will ensure quality control. Urinalyses measure the level of substance use and thus pose the same requirements for analyses as does the PEI. A multi-level survival analysis controls for nesting of separate therapy groups and data collected across time. Nesting occurs when respondents' scores are not independently drawn. Because respondents are in small groups, a control for the non-independence of responses is necessary. Given these design requirements, multi-level survival analyses are well suited for this research projects. A more detailed description of survival analysis in section on Data Analysis.

Hypothesis #2: The intervention will be effective in reducing adolescents' conduct disorders/oppositional defiant disorders. Adolescents' progress will be measured using the Child Behavior Checklist and Court records of recidivism.

The Child Behavior Checklist (CBCL) was designed to address the problem of defining child behavior problems empirically. It is based on a careful review of the literature and carefully conducted empirical studies. It is designed to assess in a standardized format the behavioral problems and social competencies of children as reported by parents. It consists of 118 items related to behavior problems which are scored on a 3-point scale ranging from not true to often true of the child. There are also 20 social competency items used to obtain parents' reports of the amount and quality of their child's participation in sports, hobbies, games, activities, organizations, jobs and chores, friendships, how well the child gets along with others and plays and works by him/herself, and school functioning. Because the PEI and CBCL share the same levels of data, a growth curve analysis will measure the effects of the intervention on participants.

The Juvenile Court (JC) will document respondents' contact with law enforcement agencies regarding substance abuse and conduct disorders offenses. In this project, the number of contacts with law enforcement agencies will be used in the data analyses. Because JCA data record whether there are additional occurrences of substance abuse or conduct disorder activities that come to the attention of the Juvenile Court, multi-level survival analyses measure the length of time until there are future occurrences (i.e., survival until infractions), A more detailed description of the survival analysis is in the section on Data Analysis.

Aim 2: To examine possible mediators (i.e., group cohesion, nurturance, and motivation) of treatment effects and moderators (e.g., race, socioeconomic status).

Mediating variables are intervening variables between predictor and outcome variables. Identifying their relationship to both the predictor and outcome variables are critical endeavors in constructing effective treatment models. The difficulties in identifying mediating variables are similar to those in identifying the moderating variables. Mediating variables may take the form of parental nurturance or parental skills mediating the outcome variable of reducing substance abuse and conduct disorders. In this project, parental nurturance, restoring parental nurturance and motivation (i.e., readiness to change) are **formative outcome variables** while level of substance abuse and incidents of conduct disorders are **summative outcome variables**. If these formative outcome measures (i.e., mediators) are indeed the therapeutic mechanism by which the intervention is able to achieve its objectives, their role will be measured using both the qualitative and quantitative methods. Ethnographic interview questions might take the form of asking, "What types of things helped you to use fewer drugs and alcohol besides the group therapy?" "Do you think that the things that you learned had any effect on what you did about drugs and alcohol? What were the connections between what you learned and your ability to stay off drugs and not get into trouble with the court?"

Hypothesis #3: Group cohesion is a key mediator in group centered intervention.



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The rationale behind this hypothesis is that group cohesion accentuates gains made by adolescents and their parents. This construct will be measured using the Group Atmosphere Scale--Cohesion.

The Group Atmosphere Scale--Cohesion (GAS-C) is one of three subscales. The cohesion subscale consists of 40 items that include openness, perceptions of affiliation, support and shared expectations. With its high Cronbach's coefficient alpha, the measure will provide a measure of the cohesiveness of the group. Because the relationship of group alliance to alleviating adolescent substance abuse is unclear, we propose to ask ethnographic questions to supplement the use of the GAS-C. The questions might be "In thinking back to your group, what sorts of things helped it? Which were not helpful?" Another question might be "When your group worked together, what types of things made your group come together and work as a team? What type of things made your group members not get along?" We expect that the results of the qualitative and quantitative measures will be used in revising the intervention with the second cohort of participants. More details about ethnographic interviewing and concurrent mixed models research will be provided in the section on Data Analyses.

Hypothesis #4: Because restoring parental nurturance is an integral component of the intervention, we hypothesize that it is a key mediator. As such, we will measure it using the

Child Rearing Practices Report--Revisited Shorter Form 2 (CRPR) (Dekovic, Janssens, Gerris, 1991) is a shorter form of the original instrument developed by Block (1965) with more stable factor structure, better reliability and validity. The questionnaire consists of 40 six-point Likert scale type questions (1 = "not at all descriptive of me"; 6 = "highly descriptive of me") and is divided into two subscales: (i) Parental Restrictiveness, which is characterized by a high degree of control, setting narrow limits on the child's behavior, endorsement of strict rules, requirement, and restrictions; and (ii) Parental Nurturance, which is characterized by a willingness of parents to share feelings and experiences with their children, and to show affection, acceptance, and responsiveness to the child's needs. Parents are asked to focus upon a specified child in the family when responding to the items. Subscale internal consistency reliabilities = .65 and .71, for Parental Restrictiveness and Parental Nurturance, respectively. To further examine these mediators closely, we will ask clinicians and clients questions about these concepts. Questions might take the form of "What happened when your parent showed that she (he) cared you?" to adolescents and "What happened when you showed your son (daughter) that you cared about him (her)?"

Hypothesis #5: Because parents' readiness to change (i.e., motivation) is an integral part of the Intervention, we hypothesize that it is a key mediator. As such, we will measure it using the Parents' Readiness Scale (PRS). The PRS is a modified version of the URICA scale (McConaughy, Prochaska, & Velicer, 1983). It has 32 Likert items and is designed to be a single factor, unidimensional scale. The scale is designed to be a continuous measure. Thus, subjects can score high on more than one of the four stages of readiness (i.e., precontemplative, contemplative, preparation, action, and termination). Stage scores (i.e., means on each set of 8 items for each subject) have been converted to standard score (i.e., T-scores: mean=50, standard deviation=10). The cluster analysis was run on the standard scores of all 155 subjects, producing nine cluster profiles. The questions take the form of "As far as I'm concerned, I don't have any problems as a parent that need changing?"; or "Being here is pretty much a waste of time for me because the problem doesn't have to do with me it has to do with my teenager?" .

Hypothesis #6: Because adolescents' motivation and readiness to change is a central tenet of the model, we hypothesize that it is a key mediator. As such, we will measure it using the Adolescents' Readiness Scale (ARS). The Adolescents' Readiness Scale has the same origins and format as the Parents' Readiness Scale although the wording of the items are altered for an adolescent clientele. For example, instead of "As far



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as I'm concerned, I don't have any problems as a parent that need changing?" the question now reads "As far as I'm concerned, I don't have any problems as a teenager that need changing?".

Hypothesis #7: Moderating variables attenuate the effect of a predictor variable on an outcome variable. Identifying and controlling for their impact is a critical endeavor in constructing effective treatment models. In this project, moderating variables may obscure the true effects of the intervention. For example, respondents' age or socioeconomic status may have an interactive relationship with their assignment to the intervention condition. Because demographics are not considered in randomly assigning participants into conditions, the true effect of the intervention may be obscured. Because our pilot work with the intervention has not focused on identifying moderating variables, the current project will begin such efforts using both qualitative and quantitative analyses. Respondents will be asked throughout the study questions such as "Besides the group, what affected your answers on the measures that you completed?" These unfocused questions will allow participants to comment on their response set that they used in completing the research measures. We believe that a series of ethnographic interviews administered over time with participants will allow us to identify which moderating variables are affecting participants' responses. In addition, the measures administered to examine the Hypotheses One through Six will be examined to see what type of variance each measure contributes to the overall regression model. Although a purely quantitative analysis can be used to identify the moderating variables, the lack of pilot studies on that have focused on moderating variable, it is crucial to conduct a qualitative study to identify variables that are not captured in the purely quantitative analysis.

Hypothesis #8: The hypothesized mediators (i.e., cohesion, nurturance, and motivation) from Year One will be modified (based on the qualitative and quantitative data) and used to refine the Treatment and Fidelity Manuals. Although the investigators began with three hypothesized mediators, we anticipate that these mediators may be augmented, modified, or eliminated. Given the speculative nature in including these mediators, there is a distinct likelihood that the relationship between the predictor and outcome variables is complex. The use of a qualitative analysis combined with the quantitative analyses will guide the investigators in modifying the originally proposed mediator variables.

Hypothesis #9: Other mediators will emerge from the triangulation of data sources and data collection methods. Given the sensitive nature of the IPR and ethnographic focus groups, we anticipate that other mediators will emerge at the end of Year One if they are present. Once these mediators emerge, then they will be incorporated into the treatment manuals for use in Year Two wherever possible.

SAMPLING

Sampling: Power Analysis: A power analysis was conducted to determine and consider the balance of sample size, effect size, and power in controlling most effectively for Type I and Type II errors. There are no published estimates of the effect size of the intervention among the target population. Because of the dearth of published estimates, we will rely on Cohen and Cohen's (1983) guidelines for assessing effect sizes (ES) in sociobehavioral research. We anticipate that the proposed intervention will have a medium effect (ES= .45) on participants as measured by a comparison between the outcome variables on the experimental and control conditions. In striving for a balance of Type I and Type II errors, we set $\alpha=.05$ and power = .80 (i.e., $\beta=.20$ and power = .80). Given these assumptions, the sample size needed in each condition is 80 or 160 for the entire study. Although this estimate of the effect size will be used in this study, one objective of the current proposal will be to empirically determine the treatment effect size prior to undertaking future studies.



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Sampling: Recruitment and Retention Strategy Participants will be recruited through the intake procedures at _____ Counseling in Psychiatric Services. The Juvenile Court in _____ refers adolescents and their families to _____ Counseling to receive treatment. Participation in the treatment services is mandatory. After a hearing in Juvenile Court, adolescents and their families will meet with a research assistant who will explain the project to them. It will be stressed that participation in the project is voluntary; they will be informed that if they decline to participate that they will not be adversely affected. They will be informed that they will receive the services that are normally provided for court-ordered treatment participants.

If they agree to participate, they will be randomly assigned to either the usual services (US) that consists of a group treatment program or to the group therapy. The random assignment will continue there are enough participants to complete two groups in each treatment condition. This process will continue until there are 100 participants in each treatment condition. Discussions with Dr. _____ suggest that it will initially require about 3 months to complete the sample size for both conditions. Alternating assignments will be used in populating the treatment conditions; the first intake will be assigned to the condition and the next one to the 12-Step program.

Because participation is part of a court ordered treatment, retention is not expected to be a problem. However, random treatment fidelity checks will be implemented to ensure that participants are fully involved in the treatment process. Follow-up measurements should also not present any difficulties. Adolescents and their families will report to the court as part of a probation process. At that time, they will receive the follow-up measurement battery. Dr. _____ received assurances from the Juvenile Court judge and probation officers that all project participants will be available to complete measures for the entire 18 month follow-up period.

Sampling: Inclusion Criteria: Youth mandated to receive treatment at _____ Counseling will be eligible for the present study. Inclusion criteria are 1) Adolescents who are characterized as having Substance Abuse or 2) Substance Dependency. The criteria are based in part on diagnoses of the same name as listed in, Substance Abuse and Substance Dependency, as defined in the Diagnostic and Statistical Manual of Mental Disorders (Fourth Edition, Text Revision). Abuse will be defined as history of frequent use with concomitant negative consequences; Dependency will be defined as a history of the pursuit of a regular use of substances despite negative consequences with significant time and effort devoted in securing substances.

Sampling: Exclusion Criteria: Adolescents with low levels of problems associated with substance use will be excluded. In addition, adolescents with high levels of problems associated with conduct disorders but not with substance use will be excluded. Adolescents with preexisting mental or physical health difficulties will not be excluded as long as the primary reason for assignment to the agency is their substance abuse and delinquency. However, psychotic disorders, debilitating developmental disabilities, or major depressive episodes that include suicidal attempts will be excluded in light of the focus of the treatment services of the agency. On the other hand, adolescents with school-related, behavioral and less serious mental health disorders (i.e., dysthymic, anxiety disorders) will NOT be excluded. Given the focus on adolescents and their parents, adolescents without parents or caretakers or those who are NOT willing to participate in the project will be excluded.

Sampling: Suitability of Research Site: _____ Counseling is located in _____, _____. It is ideally suited to host the research project. It has a long and amicable collaborative with both Juvenile Court and Family Services. It is a private, non-profit mental health and drug and alcohol services agency. _____ deploys a multidisciplinary professional staff of thirty persons, which is composed of licensed psychologists, mental health counselors, drug and alcohol counselors, and social workers. The agency is fully certified by the



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_____ Department of Mental Health and the _____ Department of Alcohol and Drug Addiction Service. _____ served 1715 families in 2003. The agency works in close relationship with Richland County Juvenile Court and Richland County Children Services. The director, Dr. _____, has strong personal collaborative bonds with administrators and judges in the _____ locality. His enthusiasm to host the project has ensured the type of cooperation that will be necessary to successfully implement the project. Given typical number of referrals, we have confidence that a suitable number of adolescents and their families will be recruited as participants in the project.

DATA ANALYSES

1- Multi-level growth curve modeling. The first type of analytic procedure involves multilevel modeling of growth curves. Growth curves or change curve analyses occur in two linked phases. The growth curve approach permits examination of individual change over time, as well as systematic differences in the patterns of change based on covariates, such as service type or client characteristics. First, individual change is modeled across time for each subject. The result is a growth curve: a within-subject summary of the growth of each person over time, represented by initial status (intercept), the rate of change (slope), and the type of change (e.g., linear, quadratic, cubic).

In addition to rich description at the individual level, the change curve approach allows for hypothesis testing at the group level with the use of covariates, variables predicted to vary systematically in relation to the curves (Raudenbush, Bryk, Cheong, & Congdon, 2000). This is accomplished by analyzing change curves with hierarchical general linear modeling (HGLM; Raudenbush et al., 2000).

The HLM5 software program (Raudenbush et al., 2000) analyzes data at two levels: (1) at the individual (within-person) level, and (2) at the group level using covariates. At Level 1, individual parameter estimates (intercept, linear, and quadratic slopes) are created using a least-squares regression equation. At Level 2, the Level 1 parameter estimates (intercept, linear and quadratic slope) are used as dependent variables in a new equation, and predictors of systematic change (covariates) become the independent variables. The program computes between-person curves based on the covariates using Empirical Bayes estimation. The individual curve parameters are recomputed with weights that reflect the relative error of each phase, and the same recomputation then occurs for the between person model using the new weighted parameters. The resulting parameter estimates will be optimal estimates of the population parameters. The ability to analyze data at two levels controls for the nesting effect that will be a necessary characteristic of the design.

The procedure can accommodate missing data points, as well as varying data points, and all data for each subject are utilized to accurately portray the variation in individual patterns of change that is obscured by traditional analysis and treated as error. Either varying or constant covariates (subject or treatment variables that may be associated with outcome), can be included in the model, and variance/covariance structures can assume fairly general forms, instead of the traditional assumptions of compound symmetry. Finally, a growth curve approach provides both a conceptual foundation and a statistical procedure for the assessment of change that offers solutions to problems that have confounded traditional methods.

First, individual change is modeled across time for each subject. The result is a growth curve: a within-subject summary of the growth of each person over time, represented by initial status (intercept), the rate of change (slope), and the type of change (e.g., linear, quadratic, cubic). Second, the presence of systematic differences in the rate and type of change based on covariates is examined. The within-subject summaries provide the basis for the between-subject analyses. Variation in growth from person to person is related to the effect of selected background characteristics or covariates. Covariates of change are studied by developing a



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model that predicts growth parameters from subject characteristics. The covariates may be time-invariant (such as gender or ethnicity), or those that change in relation to the growth process (such as socio-economic functioning) (Willett, 1988).

The growth curve or change curve approach has several advantages over other methods of longitudinal data analysis: First, all data points for each subject are used to create change curves at the individual level. Each person will have intercept, slope, and parameter estimates of more complex curves that combine to accurately describe one person's change over time. This allows for the heterogeneity in response to the intervention to be examined for each participant. An individual growth model perspective extends the Aptitude by Treatment Interaction (ATI) approach to the study of change (Francis et al., 1991). The ability to measure independent responses to treatment is especially vital in research on human behavior, where group trends across time are insufficient for capturing the complex and heterogeneous nature of response to treatment (Gibbons et al., 1993).

The use of a multi-level growth curve analysis allows us to propose answers to the questions posed in Hypotheses 1 and 2 on whether the PEI and CBCL demonstrate treatment gains by participants more so than the comparison condition participants. Because the participants are in formed groups and are measured over time on ordinal and interval level data, a growth curve analysis is the best data analytic approach. Hypothesis 3 from Aim #2 is measured by GAS-C (i.e., cohesion); its ordinal level data make it suitable for the growth curve analysis as well. The same is true for the CRPR (i.e., parental nurturance) in Hypothesis 4, the PRS and ARS in Hypotheses in 5 and 6 (i.e., readiness to change, motivation). Because these measures all use ordinal or interval level data that require comparison of the formed groups across treatment conditions over several time periods, the multi-level growth curve analyses are appropriate as the data analytic approach.

2-Multi-level survival analysis: When the outcome variable is a count of the number of occurrences of a particular event such as a drug offense, Poisson regression is a reasonable choice for the model. Poisson regression can be formulated in the framework of generalized linear model (McCullagh & Nelder, 1990) with a log link function. It can include person characteristic variables as predictors to estimate the effects of the variables on the frequency of the event occurrence during a particular period of time.

One could use a binary outcome in a Poisson regression model, such that 0 indicating censoring and 1 indicating event occurrence. When the time until the occurrence of event or censoring are taken into account in such a model, the coefficients of predictor variables in the model are equivalent to relative risks for individual characteristic variables in Cox Proportional Hazards model.

The Poisson regression model has been generalized to multilevel model (e.g., Bryk, Raudenbush, & Congdon, 1996; Hedecker & Gibbons, 1993). A Cox Proportional Hazards model with repeated events can be modeled as a 2-level model. In the 2-level formulation, the level-1 model is a time-point-level model. The model contains logged duration as a term with a coefficient of 1. Each person can have a different number of observations (i.e., events or censoring), and time-varying characteristics can be added. The estimated coefficients are equivalent to relative risks.

In the proposed study, the use of Poisson regression model on recidivism data allow answers to questions posed in Hypotheses One and Two on whether there are additional occurrences of substance abuse or conduct disorder activities that come to the attention of the Juvenile Court. Because survival analyses measure the length of time until there are future occurrences (i.e., survival until infractions), this analytical procedure is well suited to answer the question of treatment outcome.

Qualitative Analysis: We will use ATLAS.ti (Scientific Software Development, 2002) as a means of analyzing the ethnographic and IPR data. It allows a "context of discovery" by creating an analytic framework



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that provides means of supporting the inferences that are being made about the text. It also has an important network building feature that allows a visual connection between codes, memos, textual excerpts using diagrams. The resulting visual display allows construction of concepts and theories while at the same time being able to switch back to the transcribed text. This software will allow the type of constant comparative analysis that can be used to develop themes drawn from transcripts of the ethnographic interviews. Mini-ethnographies of novel clinical interventions can reveal important facets about what makes them effective especially when used in conjunction with quantitative studies (Sells et al, 1995). The mini-ethnographies will generate constructs that can then be tested in subsequent studies.

Starting with generic questions that do not reveal the investigators' research questions, participants will be urged to respond fully and candidly. These taped interactions will be transcribed. Project staff will enter text from the transcriptions into data screen in ATLAS. From there, the investigators will be able to visually see the relationships between the transcribed responses from subjects in this study. Once the relationships are placed into perspective, the objective will be to discern themes underlying participants' responses. The ethnographic methodology being proposed for this project calls for multiple iterations of interviews with each series of interviews increasingly focused on the emergent themes. The end point of the ethnographic analysis will be to create theoretical constructs that can be tested in subsequent studies. A starting place for the non-directive questions will revolve around the hypothesized mediators and moderators. The iterative method allows for the continual entry of new insights and comments. This strength of ethnographies will allow us to discern other mediators and moderators of the model. Past studies by the investigators used such qualitative methods and the IPR to study mediators that were subsequently subjected to quantitative analyses (Sells, _____, & Moon, 1996; Newfield, Sells, _____, & Newfield, 1996; _____, Sells, Pereira, Todahl, & Pappagiannis, 1995). In this study, the iterative nature of the bidirectional research model is essential in formulating and testing mediators on way to proposing mechanisms of change.

Strategies to Address Potential Methodological Shortcomings

One problem with outcome studies is whether they are generalizable to the clinical population from which they are drawn. By drawing from a sample of adolescents and their families who are currently mental health clientele, we have a greater likelihood of the project results being generalizable. A second threat to the generalizability of results is whether the therapists are unique and not found in the general population of clinicians. We will choose clinicians who have at least five years of experience and meet the threshold of competence in the model. The use of treatment fidelity protocol also allows replicability and generalizability to other settings.

Another frequent problem is the comparability of subjects in experimental and comparison conditions. One method of addressing pretreatment differences is adjusting for differences statistically using pretests as a covariate. Another method is to ascertain whether differences exist by comparing the means of the measures before the treatment is implemented and again at the end of treatment to ensure that there is no differential attrition between the two conditions. A third problem is whether the therapists in the different conditions are equally enthusiastic about the intervention for which they are responsible. This potential problem will be addressed by allowing therapists to only use one treatment modality and monitor their enthusiasm. Dr. _____ has begun to orient therapists that both treatment conditions are equally good but each has a different focus without specifying the focus. He will continue to ensure that clinicians assigned to both conditions will not fall prey to demoralization.



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Attrition is an expected problem in any study with 12 to 18 month follow-up. This problem will be attenuated because all subjects who are diagnosed with substance abuse/conduct disorder are mandated to be seen by probation officers. The outcome measures will be administered by probation officers with assistance from project staff. Participant fatigue may also cause attrition. We attempted to minimize participant fatigue by some pilot tests on the feasibility of using the proposed measurement battery. Pilot testing for this proposal conducted with a small group of parents and adolescents showed that the entire battery could be completed within a 60 minute window even without incentives. Use of incentives should increase compliance and willingness to complete the measurement package at each assessment period.

E. Human Subjects Procedures

All individuals who are referred from Juvenile Court will be asked whether they wish to hear information about a project in which participation is strictly voluntary. Those individuals who volunteer will hear a presentation by research team members about participation in the research project. Research staff will describe the experimental and comparison conditions, Interpersonal Process Recall protocol, and details about participating in ethnography. The possible benefits and harm in participation will be explained. Research staff will stress that participants may elect to withdraw from the study at any time without fear of penalty.

Participants will be fully informed on the benefits and risks of participation in the study. Care will be taken to fully inform potential participants that confidentiality will be provided within the limits of the law; those limits will be explicitly stated. The consent form will specifically state that the purpose of the study is to determine the efficacy of a new form of an intervention designed to assist families and their adolescents in coping with substance abuse and familial conflict. It will stipulate that their involvement includes participating in completing measures at specific periods. The consent form will stipulate any risks and discomfort that may ensue from participating in the intervention and completing the measures. It will be stressed that participation is voluntary and that they may refuse to answer any specific questions; all interaction will be ended whenever they choose. Participation in the study will not affect participants' access to existing services.

If participants choose not to participate in the research study, it will not affect their access to other services and programs. All participants will be informed that they may discontinue involvement at any time without incurring any penalty or prejudice. The investigators will take all reasonable measure to protect the confidentiality of records, and their identity will not be revealed in any publication that may result from the study. All findings from the experimental study will be presented as aggregated results. The confidentiality of all study-related records will be maintained in accordance with applicable state and federal laws. Participants will be provided access to investigators who can answer any questions they have about the study. Prior to use, university, local, and state Institutional Review Boards will review and approve all procedures, measures, and forms.



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