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Brief strategic family therapy™ for adolescent drug abusers: A multi-site effectiveness study☆

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Abstract

Brief strategic family therapy™ (BSFT) is a manualized treatment designed to address aspects of family functioning associated with adolescent drug use and behavior problems (J. Szapocznik, U. Hervis, S. Schwartz, (2003). Brief strategic family therapy for adolescent drug abuse. (NIH Publication No. 03-4751). Bethesda, MD: National Institute on Drug Abuse). Within the National Institute on Drug Abuse's (NIDA's) Clinical Trials Network, BSFT is being compared to treatment as usual (TAU) in a multisite, prospective randomized clinical trial for drug using adolescents and their families in outpatient settings. The effectiveness of BSFT is being compared to TAU in reducing adolescent drug use, conduct problems, and sexually risky behaviors as well as in improving family functioning and adolescent prosocial behaviors. This paper describes the following aspects of the study: specific aims, research design and study organization, assessment of primary and secondary outcomes, study treatments, data analysis plan, and data monitoring and safety reporting.

Keywords

BSFT™; Effectiveness trial; Adolescent; Drug abuse; Manualized

1. Introduction and background

Adolescent drug abuse represents a pressing public health issue in the United States, impacting both male and female youth from diverse racial/ethnic backgrounds [1,2]. Experimental drug use is common [1], and a subset of adolescents who use drugs become substance dependent [2]. Drug use is associated with immediate and long-term consequences, including school failure, emotional and behavior problems, and increased risk

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of accidental injury or death [3]. Beyond these effects is the heavy toll of substance abuse and addiction absorbed by society at large [4,5], with one estimate of the economic costs of drug abuse in the U.S. amounting to a staggering total of nearly a quarter of a trillion dollars each year [6].

Despite the pervasiveness of adolescent drug abuse, there is strong evidence that specific interventions can have a dramatic and lasting impact on adolescent drug use and related behavior problems. Broad reviews of the treatment outcome literature indicate that family interventions are efficacious in reducing adolescent drug use and related behavior problems [7,8], which has prompted wide-scale dissemination of empirically-based family therapy approaches nationally and internationally.

The initial move to full scale dissemination occurred with almost no focused research conducted to examine relevant clinical outcomes, such as if therapists are able to implement complex family approaches with high fidelity or if family-based interventions are more effective than standard treatment at community agencies. Only more recently have studies been conducted to examine the impact of family therapy in real world settings, with results indicating that family-based interventions are at least as effective as other empirically-based approaches in reducing adolescent drug use [9]. Thus, effectiveness research on family therapy is still in its infancy, and more studies are needed to examine the feasibility, acceptability, and effectiveness of family interventions in community settings.

This paper describes the design and implementation characteristics of the brief strategic family therapy for adolescent drug abuse protocol. This multisite study represents one of the largest and most rigorous examinations of the impact of family therapy on adolescent drug use in community settings. This study builds on emerging research on the effectiveness of family therapy for adolescent drug users in real world treatment settings in two key ways. First, this study represents the first examination of the effectiveness of Brief strategic family therapy (BSFT; [10]) in real world settings. Support for the efficacy of BSFT is derived from three decades of clinical research studies with children and adolescents with disruptive behavior problems, including drug use [11]. Second, this study examines the effectiveness of family therapy compared to treatment as usual at community agencies, which is particularly relevant because there is a dearth of studies examining the effectiveness of standard services offered by community treatment programs.

1.1. Specific aims

The primary goal of this study is to examine the effectiveness of BSFT in the treatment of adolescent drug abusers, compared to treatment as usual (TAU). The primary hypothesis is that BSFT will be significantly more effective than TAU in reducing adolescent drug use. Secondary hypotheses examine the relative effectiveness of BSFT over TAU in: (a) engaging adolescents and family members in treatment; (b) decreasing adolescent externalizing behaviors; (c) decreasing adolescent sexually risky behaviors; (d) increasing adolescent prosocial activities (e.g., school, work); and (e) improving family functioning.

2. Study organization and research design

2.1. Study organization

This protocol was carried out within the context of the National Institute on Drug Abuse's (NIDA's) Clinical Trials Network (see Fig. 1). This network is organized by geographical regions or nodes. Each node consists of one university-based regional research training center as well several community treatment programs. Protocols are developed and led by the university-based regional research training centers and are implemented across multiple sites within the network. Each node provides administrative (IRB, fiscal) and research

oversight for protocols that are being conducted within the node. The BSFT protocol was implemented within eight community treatment agencies from six nodes: La Frontera (Tucson, Arizona), The Crossroads Center (Cincinnati, Ohio); The Village (Miami, Florida); Gateway Community Center (Jacksonville, Florida), Administración de Servicios de Salud Mental y Contra la Adicción (ASSMCA: Bayamón, Puerto Rico), Daymark Recovery Services (Salisbury, North Carolina), Tarzana Treatment Centers (Tarzana, CA), and Arapahoe House (Denver, Colorado).

2.2. Research design

This multi-site trial compared the effectiveness of BSFT to TAU in reducing adolescent drug use at eight community treatment programs. Participants were nested within site and treatment condition. Hypotheses will be tested using hierarchical linear models (HLMs) [12] to estimate differences in the growth curve trajectories of drug use (and secondary outcome variables) post-randomization. This paper has been formatted in accordance with the guidelines described in the CONSORT (CONsolidated Standards of Reporting Trials) Statement Extension for Non-Pharmacologic Treatment (NPT) Interventions [13,14]. Participants were randomized to BSFT or TAU within each site following the baseline assessment. Study interventions were initiated following randomization, and the majority of cases were expected to participate in treatment for 4 to 6 months post-randomization. Treatment in both conditions was provided in non-restrictive, community settings (e.g., clinic, home, and school). Assessment of drug use was conducted at baseline and monthly for every month post-randomization (T1–T12). Assessments of secondary outcomes were conducted at baseline, 4-, 8-, and 12-month post randomization.

2.3. Study population

Participants were adolescents and their family members. Adolescents were referred to community agencies for the treatment of problems associated with drug use. Family members consisted of biological relations as well as other individuals that resided in the adolescent's home and that were involved in the adolescent's life on a daily basis.

2.4. Inclusion and exclusion criteria

Inclusion and exclusion criteria are presented in Table 1. Criteria were defined to maximize generalizability by including the largest number of adolescents that were referred for drug abuse treatment at community agencies.

2.5. Randomization

Adolescent/family participants were randomized to BSFT or TAU (Fig. 2) at eight community treatment agencies (listed in section 2). Randomization was conducted separately by the research team at each community treatment provider using a telephone call-in procedure developed by the Department of Veterans Affairs. This procedure used an urn randomization algorithm to increase the likelihood that treatment groups would be balanced on two characteristics: ethnicity/race (Hispanic, African-American, other) and level of drug use (any drug diagnosis other than alcohol or tobacco, no drug diagnosis), as measured by the Diagnostic Interview Schedule for Children-Substance Abuse and Dependence module [15] at baseline. Each site conducted randomization by accessing an Interactive Touch–Tone Randomization System provided by the Perry Point Cooperative Studies Center at the Veteran Affairs Hospital at Perry Point, Maryland.

3. Data monitoring and safety reporting

An independent Data Safety and Monitoring Board reviewed the protocol and provided feedback to enhance data safety and monitoring procedures over the course of protocol development and implementation. Also, an intensive quality assurance plan was followed at all sites. This plan included regular on-site audits of research activities at the site. The initial quality assurance monitoring visit was intended, whenever possible, to take place no later than two weeks after the 3rd participant was enrolled at a CTP. Also, for the first 10 participants, a full on-site review was conducted for 100% of the following: (a) procedures and forms for screening, informed consent forms, baseline assessments and randomization, and (b) procedures and documentation of urine drug screens, adverse events, and all case report forms. Quality Assurance monitors randomly reviewed 10% of the remaining participants. Moreover, to monitor the quality of data for our primary outcome measure, at least 50% of the remaining timeline follow back data were randomly reviewed throughout the course of the study.

4. Study treatments (BSFT and TAU)

4.1. Brief strategic family therapy (BSFT)

BSFT is designed to address aspects of family functioning that have been shown to be associated with adolescent drug use and behavior problems [10]. BSFT is a structured, problem-focused, directive, and practical approach, following a prescribed process format. However, the family process format is flexible in that it is adapted to the content of each family's central concerns. The first step in BSFT, Joining, is to establish a therapeutic alliance with each family member and with the family as a whole. This requires that the counselor accept and respect in her/his behavior not only each individual family member, but also the way in which the family as a whole is organized. Interventions track individual family members' beliefs and emotions, but are delivered with sensitivity to the processes that the family presents early in treatment.

Steps 2–5, Diagnosis, involves identifying family strengths and weaknesses and developing a treatment plan. Step 2 involves identifying the symptom and the family relations surrounding it. This is done by encouraging and permitting the family to behave as it would usually behave if the counselor were not present. When family members speak with each other, they are likely to do so in their usual way of behaving/relating. From the observations in Step 2, the therapist is able to proceed with Steps 3 and 4, diagnosis of both family strengths and problematic relations. Emphasis is given to those family's problematic relations that are linked to the youth's problem behaviors, or that interfere with parent figures' ability to correct the youth's problem behaviors. Step 5 is to develop a treatment plan that systematically addresses the problems that are directly linked to the youth's problem behaviors. The treatment plan is strategic in that the most relevant problems that are identified in Step 4 are the primary targets of intervention.

Step 6, Restructuring, involves the implementation of those change strategies needed to transform family relations from problematic to effective and mutually supportive. In this work the therapist is planful, problem-focused, directive, and practical. Change strategies used include transforming the meaning of interactions through cognitive restructuring interventions called reframes. Reframes are intended to modify the negative affect of frustrating family interactions into more positive affect that improves communication and increase competence. Other change interventions include: (a) directing, redirecting or blocking communication, (b) shifting family alliances, (c) helping families to develop conflict resolution skills, (d) developing effective behavior management skills, and (e) fostering parenting and parental leadership skills.

BSFT consists of 12 to 16 sessions over a 4-month period, and up to 8 "booster" sessions. However, the actual number of sessions/length of service is based on the therapist's ability to achieve necessary improvements in specific behavioral criteria (e.g., drug use and family interactions). The amount of time needed to achieve improvements may increase or decrease based on: a) the extent and type of adolescent comorbidity; b) the number of family members with psychiatric disorders, including drug abuse; and c) the level of family disruption. Therapists were permitted to conduct "booster sessions" after the 12–16 sessions with cases that relapse, present adverse events during follow-up assessments, and/or in response to a family petition. However, therapists were limited to a maximum of 8 booster sessions after the completion of initial BSFT services.

The majority of therapy sessions should involve multiple family members. Services included a systematic plan for involving individuals from other relevant systems in which the adolescent is involved (e.g., school, peer, justice). Finally, location of services is flexible and should not be permitted to become an obstacle to the delivery of BSFT interventions.

4.2. Treatment as usual (TAU)

TAU varies depending on the current activities at participating CTPs. TAU in CTPs included individual and/or group therapy, parent training groups, non-manualized family therapy, and case management. At least one intervention session per week is common as well as participation in ancillary services (e.g., case management, AA, etc.). However, CTPs providing weekly, manualized family therapy sessions were excluded. By including a TAU comparison condition, this study is designed to examine the public health question of whether BSFT is more effective than standard agency services in reducing adolescent drug use.

4.3. Dose opportunity

The study was designed to ensure that participants in TAU and BSFT will have similar "dose opportunities," including the possibility of the booster sessions. A prerequisite for participation in this protocol was that the community agency's TAU must include at least 12–16 scheduled sessions over a 3–4 month period. This ensures that differences in dose between BSFT and TAU were not the result of different planned program parameters. It should be noted that CTPs that offered more services were also included in the study. For example, one TAU offered an intensive "step down" outpatient program with 3–4 h of weekly contact with adolescents for the first 3-months post-discharge, with services decreasing gradually over the year.

4.4. Tracking of dose

Dose in both conditions was tracked by conducting interviews with therapists. Using the agency's clinical charts and service delivery systems, therapists were asked to provide details for all planned and conducted services over the past month. These interviews were conducted at 12-monthly assessment points for all cases. Therapists in BSFT also completed contact logs for all attempted or actual contacts with adolescents/families.

4.5. Medications allowed in the trial

Youth in both conditions may have received medical or psychiatric evaluations at any point prior to or during the study. If deemed appropriate by medical staff, youth could receive medication for concomitant physical or psychological problems.

5. Assessment of primary and secondary outcomes

5.1. Primary outcome: adolescent drug use

The study is designed to test the hypothesis that BSFT will be significantly more effective than TAU in reducing adolescent drug use. The dependent variable in this analysis is the percentage of days of drug use within 28-day periods. Adolescent drug use was assessed using a structured interview; the Timeline Follow-back (TLFB). At baseline, the Timeline Follow-back was used to identify drug use in the 30-day period that preceded the baseline assessment. At time point 1 (T1), the TLFB was used to assess daily use for all days between randomization and the T1 assessment. At T2 and through T12, the TLFB was used to collect data on daily use from the prior assessment to the current assessment. Thus, the TLFB was used to collect 365 continuous days of data on daily drug use after randomization.

The TLFB has been adapted for use with adolescents [16–18]. The TLFB method obtains retrospective reports of daily drug use, by using a calendar and other memory prompts to stimulate recall. It gathers daily information on specific drugs used and amount of use, (number of drinks, hits, rocks, etc.).

5.2. Secondary outcomes: adolescent behavioral problems and family functioning

Secondary outcomes (adolescent externalizing behaviors, risky sexual behavior, prosocial functioning, and family functioning) were assessed using adolescent and parent self-report measures at 4-, 8-, and 12-months post-randomization.

Three measures were used to identify adolescent externalizing behaviors, including the National Youth Survey, Youth Self-Report, and the Diagnostic Interview Schedule for Children Predictive Scales. The Self-Report Delinquency Scale from the National Youth Survey [19,20] was used to identify adolescent criminal behavior. Items assess adolescent delinquent behaviors and are collapsed into five subscales: 1) total delinquency, 2) general theft, 3) crimes against persons, 4) index offenses, and 5) drug scales. The Youth Self-Report [21] was also used to identify adolescent externalizing behaviors. The Youth Self Report is designed to provide standardized descriptions of the child's functioning [21]. Problem behaviors can be scored along the dimensions of the superordinate domains of "internalizing" and "externalizing" behaviors, or along smaller syndromes of behavior problems (e.g., delinquent, aggressive anxious/depressed). The "externalizing" domain was used as an indicator of externalizing behaviors. Finally, estimates of externalizing psychiatric disorders were obtained from the Diagnostic Interview Schedule for Children-Predictive Scales. This measure was used to identify symptoms of Oppositional Defiant Disorder and Conduct Disorder) using both parent and adolescent reports. This instrument has demonstrated excellent sensitivity and specificity compared to the full Diagnostic Interview Schedule for Children [22].

Adolescent risky sexual behaviors were assessed using the *Risk Behavior Survey*, which is an abbreviated version of the Risk Behavior Assessment developed for a NIDA Cooperative Agreement (NIDA, 1991). Risky behaviors in the areas of drug use and sex were measured for the previous 30 day period. Reliability and validity assessments of the RBS support its adequacy as a research tool for populations of drug users [23].

Two scales from the Pittsburgh Youth Survey were used to identify adolescent prosocial behaviors [24]. First, the *Conventional Activities of Friends Scale* was used to measure prosocial activities of friends. This scale includes 8 questions concerning the number of friends that engaged in prosocial activities. These behaviors range from obeying school rules to participating in religious activities. Scale scores are summed for each subject, thereby

reflecting the overall degree of exposure to peers engaged in these conventional behaviors. The *Peer Delinquency Scale* is used to measure affiliation with deviant and delinquent peers. This scale consists of 15 questions that the adolescent rates on a 5-point scale based on the number of friends that have engaged in a variety of antisocial and delinquent behaviors. Rated behaviors range in severity from minor infractions to serious and violent crimes against others.

Two measures were used to assess family functioning. The *Parenting Practices Questionnaire* from The Chicago Youth Development Study was used to identify parenting practices [25]. Adolescent and parent responses to 47 items were used to identify positive and negative parenting behaviors. Factor analyses have identified four factors: 1) positive parenting, 2) discipline effectiveness, 3) avoidance of discipline, and 4) monitoring. Positive parenting refers to the use of positive rewards and encouragement of appropriate behavior. Discipline effectiveness is a measure of how effective parental discipline is in controlling the youth's behavior. Avoidance of discipline refers to the parent's avoidance of providing consequences or disciplining for fear of the youth's behavior escalating. Monitoring is a measure of monitoring and involvement in daily activity and routines and knowledge of youth's whereabouts throughout the day. Reports of discipline effectiveness and avoidance of discipline were gathered from parents only. Estimates of positive parenting and extent of monitoring were gathered from both parent and child. Internal consistency reliabilities of each of the subscales ranged from .68 to .81. Confirmatory factor analyses have consistently identified two latent constructs of Discipline and Monitoring which are the two indicators of parenting used in the family functioning composite [25].

Also, the Cohesion and Conflict scales from the Family Environmental Scale were used to measure family functioning. The Family Environmental Scale (FES; [26]) is a widely used measure that was developed to assess social and environmental characteristics of families. This measure has been used in thousands of studies to capture critical aspects of family functioning. Internal consistency reliability estimates for the subscales range from 0.61 to 0.78. Conflict and cohesiveness subscales were administered to both parents and adolescents.

The study also included measures of adolescent and family demographics, adolescent internalizing disorders (e.g. depression, anxiety), and parental drug use.

6. Current status, description of sample, and delivery of study interventions

At the time of completion of this paper, the BSFT protocol had successfully closed the implementation phase (all treatment and assessments had been completed at all sites). The study met its recruitment goal of enrolling and randomizing 480 adolescents, plus their families, into the study. This number is particularly impressive because the final sample consisted of 1894 individuals, including the adolescent participant, parents, siblings, and other significant persons in the adolescent's life. Seventy-five therapists were also consented as study participants, and 71 completed the therapist selection process. Of these, 30 therapists were assigned to the BSFT condition, 23 received the full BSFT clinical training (7 dropped out prior to completing training), and 20 therapists were certified to deliver the intervention in the study. In addition, 159 families participated in treatment and/or assessments during the pilot phase of the study. Thus, over 2000 individuals were assented or consented as research participants.

6.1. Therapist demographics

A total of 49 therapists were randomized to BSFT (N=20) or TAU (N=29) and provided clinical services to randomized family participants. Demographic information is available

for 48 therapists. Therapists were 37 females and 12 males, with a mean age of 40.37 (SD=10.78). Therapists included non-Hispanic Whites (*N*=27), non-Hispanic Black (*N*=9), Hispanic (*N*=11), Asian/Pacific Islander (*N*=1), and Other, not specified (*N*=1). Therapists reported an average of 8.29 (SD=7.42) years of experience. The majority of therapists had a master's degree (*N*=34), followed by bachelor's (*N*=8), doctorate (*N*=5), certified addiction counselor (*N*=1), and high school graduate (*N*=1). No differences in demographic variables were observed between therapists assigned to BSFT and TAU.

6.2. Demographics and baseline characteristics

As shown in Table 2, adolescents were predominately male (*N*=377 versus 103 females), with a mean age of 16.01 (SD=1.8). Based on adolescent self reports, the sample included 213 Hispanic/Latino, 148 White, non-Hispanic, and 110 Black/African Americans. Most families were biological one-parent (*N*=224) or two-parent (*N*=120) households, and approximately half of the families reported a household income of less than $25,000.

As shown in Table 3, examination of baseline characteristics of the study primary and secondary outcome variables showed mean differences between racial/ethnic groups, including substance use diagnoses, externalizing disorders, and family functioning. Of particular interest is that African American adolescents and parents consistently reported the lowest rates of substance use and externalizing problems, and the highest rates (most positive) of family functioning.

6.3. Delivery of study interventions

To participate in this protocol the community agency's TAU had to minimally include at least 12–16 scheduled intervention sessions. This requirement ensured that differences in dose between conditions were not the result of different planned program parameters. To determine if participants had similar dose opportunities, an analysis of recommended number of sessions was examined using therapist's monthly reports of therapy dose. Results indicate that therapists in TAU (*M*=32.78; SD=37.02) reported significantly more expected therapy sessions than therapists in BSFT (*M*=27.49; SD=15.70) ($t(313)=-2.02$, $p<.05$). As expected, the planned number of sessions in TAU was not less than the planned number of sessions in BSFT.

Examination of the actual number of sessions provided showed that BSFT had significantly higher levels of attendance ($\chi^2(1)=6.48$, $p<.02$) than TAU. The median number of sessions attended in BSFT was 9.5 (Q1=3.5, Q3=14). The median number of sessions attended in TAU was 6 (Q1=1, Q3=15). In contrast to the initial expectation that the majority of services would be delivered during the four month period following randomization, additional examination of families that completed therapy indicated only a minority of families had received all services by the end of month four (22% in TAU, 14% in BSFT). In fact, many families were still in treatment during month 12 (19% in TAU and 11% in BSFT).

7. Anticipated analyses

Analyses will address the following hypotheses: (1) BSFT will be significantly more effective than TAU in reducing adolescent drug use, (2) decreasing adolescent delinquent behaviors and conduct problems, (3) decreasing adolescent sexually risky behaviors, (4) increasing adolescent prosocial activities (e.g., school, employment), and (5) improving family functioning (e.g., parenting, parent–adolescent relations).

The analysis strategy for this trial was described in [27] when trial plans included two treatment modalities: residential and outpatient services and 14 sites. Since that time, the

trial was reduced in scope to include only outpatient services and only eight sites. More details of the analysis justification of the statistical methods associated with the trial are available in Feaster et al. [27]. Herein, only the essentials of the statistical model and sample size determination for the eight site study are presented.

7.1. Statistical analysis

Multilevel models [28] are used to test Hypothesis 1 to estimate the trajectory of change in drug use post-randomization between the two groups: BSFT and TAU. The multilevel approach allows us to consider treatment site as a random effect and to examine variability in treatment effects across sites [27], which is consistent with the mission of the CTN to test the general applicability of proven treatments in real world settings. The multilevel model also controls for the nesting of both repeated observations within the same adolescent over time and the nesting of adolescents within a community treatment program. This approach is flexible, allowing the inclusion of adolescents with missing assessments, modeling non-linearity of the trajectory of change in drug use and allowing for a single test of the effect of the intervention across multiple times and sites.

When considering treatment site as a random effect, this model is a three level model. These levels correspond to 1) time (repeated measures) nested within, 2) individuals who are finally nested within 3) site. Multilevel models are constructed by combining equations for the intercept, slope (the slope may involve multiple equations if more than linear change is needed to fit the data), and then a final set of equations for site which are all estimated jointly in the final analysis. It is impossible to determine a-priori how many polynomial terms are needed to adequately parameterize change over time or whether all trends in time will show significant variability across sites. Therefore, a series of models similar to that described below will be estimated blind to condition (i.e. without the condition assignment variable included in the model). These models will compare simple linear change to quadratic, cubic and quartic change models. Once the optimal polynomial in change is determined, then the importance of site variability in each of the resulting polynomial terms will be examined. The Bayesian Information Criteria [29] will be used to determine the most parsimonious model to adequately fit the data. A model with additional parameters must show more than a 15 point difference in the BIC to be considered a better fit than a more parsimonious model.

In the final test of condition assignment, time will be centered on the four-month post-randomization assessment (T4), thus the intercept term was designed to represent the difference between the two conditions of the growth trajectory at this time point which is immediately post intervention. As described in the delivery of study interventions section above, however, the T4 assessment does not appear to be an adequate point to assess for potential “end of treatment” effects for the families in this sample because only 18% of the families had completed treatment at this time. Thus, although the primary analyses will involve centering the intercept at T4, additional analyses will be conducted to re-center the intercept at T12, which more accurately reflects the “end of treatment” time-point for the majority of families in this sample.

For Hypothesis 1, the time path of percentage of days having used drugs in 28-day periods will be estimated, and the growth trajectory will be parameterized to be a function of BSFT intervention status. The stratification variables will be as specified in the urn randomization (ethnicity/race and level of drug use) and any baseline variables found to predict the occurrence of missing data. The presentation below does not include the baseline value of drug use or these other additional covariates, for a simpler equation notation. This is a three-level multilevel model in which the growth curve analysis will include the times after

baseline only, and baseline value of the dependent measure will be included as a covariate (i.e. an analysis of covariance parameterization).

Level 1 describes the trajectory over time for an individual participant:

$$y_{ijt}=\pi_{ji0}+\pi_{ij1}\cdot a_{ijt}+\varepsilon_{ijt},$$

where t_{ijt}, a_{ijt} and ε_{ijt} are % of drug use days, time, and a random (or error) term, respectively, for person *i*, in CTP *j*, at observation occasion *t*. The variable a_{ijt} will be the time from four months post randomization (assessment point T4). The variables π_{ij0} and π_{ij1} are the intercept and slope of drug use, respectively for person *i*, in CTP *j*. Level 2 describes the individual intercept, and the individual slope term, π_{ij0} and π_{ij1} respectively, as a function of BSFT:

$$\pi_{ij0}=\beta_{0j0}+\beta_{1j0}BSFT+r_{ij0},$$
$$\pi_{ij1}=\beta_{0j1}+\beta_{1j1}BSFT+r_{ij1}.$$

The BSFT variable is a dummy-coded variable that has the value 1 if the participant is receiving BSFT, and 0 otherwise. B_{0j0} and B_{0j1} and are the intercept and slope, respectively, for participants who are in the TAU condition because the equation is reduced to this term when someone has a 0 for the BSFT variable i.e. the person is receiving TAU. For participants receiving BSFT at treatment site *j* the intercept and slope will be B_{0j0} + B_{1j0} and B_{0j1} + B_{1j1} respectively. For a BSFT participant, B_{1j0} and B_{1j1}, are the increments to the intercept and slope of the TAU participants, (and, respectively). and are person-specific random terms for the intercept and slope.

In Level 3 the coefficients of the Level 2 model incorporate the variability across treatment sites

$$\beta_{0j0}=\gamma_{000}+u_{0j0},$$
$$\beta_{1j0}=\gamma_{100}+u_{1j0},$$
$$\beta_{0j1}=\gamma_{001}+u_{0j1},$$
$$\beta_{1j1}=\gamma_{101}+u_{1j1}$$

In the absence of covariates, γ_{000} is the grand mean of TAU at T4 (immediately post treatment) and γ_{000} + γ_{100} is the grand mean of BSFT at T4. The parameter γ_{100} is the treatment effect of BSFT at T4 regardless of the inclusion of covariates. In the absence of covariates, γ_{001} is the simple rate of change from T4 to T12 for TAU and γ_{001} + γ_{101} is the simple rate of change of BSFT from T4 to T12. The parameter γ_{101} is the treatment effect of BSFT at T4, again, regardless of the inclusion of treatment effects. The *u* terms are site-specific error terms.

The three distinct levels described in the above steps are estimated as one single equation with multiple fixed and random effects. Substituting in the various equations gives:

$$y_{ijt}=\left[\left(\gamma_{000}+u_{0j0}\right)+\left(\gamma_{100}+u_{1j0}\right)BSFT+r_{ij0}\right]+\left[\left(\gamma_{001}+u_{0j1}\right)+\left(\gamma_{101}+u_{1j1}\right)BSFT+r_{ij1}\right]\cdot a_{ijt}+\varepsilon_{ijt}$$

or,

$$y_{ijt}=[(\gamma_{000}+\gamma_{100}BSFT)+\left(\gamma_{001}a_{ijt}+\gamma_{101}BSFT^{*}a_{ijt}\right)+(\varepsilon_{ijt}+u_{0j0}+u_{1j0}{}^{*}BSFT+u_{0j1}{}^{*}a_{ijt}+u_{1j1}{}^{*}BSFT^{*}a_{ijt}+r_{ij0}+r_{ij1}{}^{*}a_{ijt})$$

The software and procedure used for estimating the coefficients of this model will be either SAS Proc Mixed or Proc NLMixed (if a non-linear link function is necessary).

The main test of the primary hypothesis (adolescent drug use) is a test of the significance on the coefficients on the BSFT term alone from the intercept equation—γ_{000}, and the term that includes BSFT interacted with a_{ijt} from the equation for the slope of the growth curve—γ_{001}. A statistically significant negative value for γ_{000} implies that BSFT participants (on average across all the treatment sites) would have lower drug use immediately post intervention relative to TAU participants. A statistically significant value for ($_{001}$ implies that BSFT participants (on average across all treatment sites) would have decrease in drug use relative to the TAU participants from immediately post-intervention to 12-months post randomization. Conversely, if the parameters are significantly greater than zero, then BSFT participants would have greater drug use immediately post-intervention and greater increase in drug use relative to TAU participants. Planned contrasts will also test if there are differences in levels of drug use between BSFT and TAU at approximately the 8 month and 12 month follow-up time points.

Analyses for secondary hypotheses will be conducted using the same multilevel procedures. However, these analyses will utilize composite scores generated from confirmatory factor analyses as dependent variables (e.g., adolescent behavior problems, family functioning.)

8. Sample size, power, and effect size

The procedure described by Raudenbush and Liu [30] will be used for sample size determination. This method and the accompanying computer program (Optdes) assumes a simple effect in a multi-site clinical trial where the treatment site is treated as a random effect, and there is variability in the effect-size across treatment sites. The method assumes equal numbers of participants at each site. In our sample sites with smaller potential caseloads were included, therefore it is likely that we will have varying numbers per site.

We use an adjusted *n* per site to account for the varying numbers of participants per site. This adjusted *n* is based on the recommendations of Cohen [31]. It suggests the use of a harmonic mean of the individual sample sizes when there is variability in sample sizes across conditions. A harmonic mean weights the mean more to the smaller sample sizes. Once the harmonic mean is calculated, then samples size calculations continue based on the implied effective mean associated with the variable site sizes.

Based on the examination of multiple configurations, it was determined that eight sites with approximately 60 participants per site on average or a total sample size of 480 would be needed to have adequate power. We believe that recruitment rates are relatively consistent across the eight outpatient sites resulting in an effective *n* of 57 or a 3 subjects per site penalty. This proposed sample configuration (*n*=60, *J*=8, effective *n*=57) and with an effect size of .45 the power is estimated as 87% with small (5%) site variability, 75% with moderate (10%) site variability, and 64% with high (15%) site variability.

9. Conclusions

The BSFT effectiveness study represents one of the most ambitious efforts to evaluate the transportation and effectiveness of an empirically-based family intervention. By comparing BSFT to TAU at community agencies, this protocol provides a unique opportunity for yielding findings that are particularly relevant for community agencies. Also, by including a large number of African American/Black and Hispanic adolescents, as well as 103 adolescent girls, effect sizes can be estimated to identify potentially meaningful comparisons for these traditionally understudied subgroups. The observed differences in baseline levels of the study outcome variables across race/ethnicity highlight the importance of this strategy. Future research should examine the implications of these differences for both potential heterogeneity of trial results and culturally appropriate approaches to treatment.

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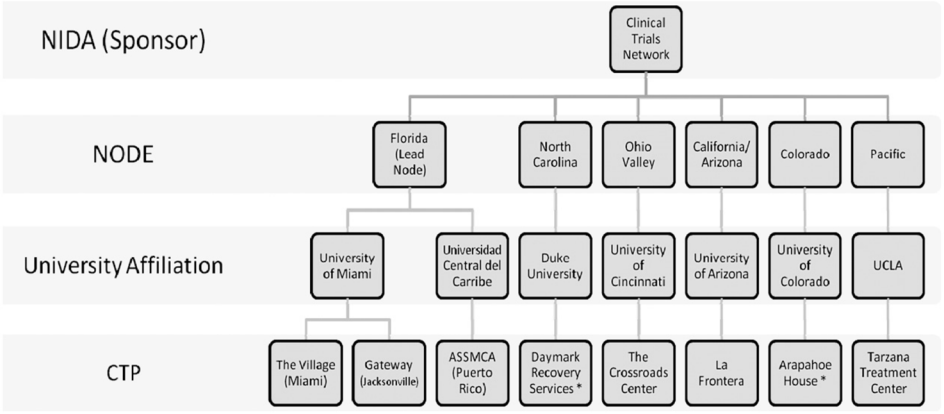

* The lead node assumed study management responsibility for Daymark Recovery Services and Arapahoe House over the course of protocol implementation.

Fig. 1.
Study organizational structure.

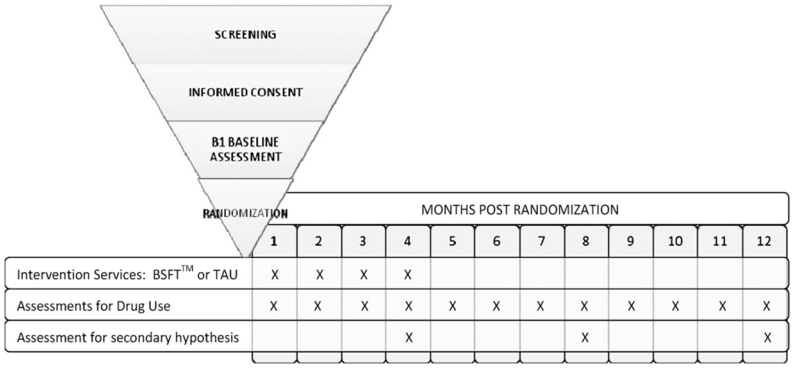

Fig. 2.
Study schema and timeline.

Table 1

BSFT™ study inclusion and exclusion criteria.

Inclusion criteria	
1	Adolescent between the ages of 12 and 17 (inclusive).
2	Adolescent who used any illicit drug (other than alcohol and tobacco) in the 30-day period that preceded the baseline assessment or that is referred from an institution (e.g., detention, residential treatment, court etc.) to the CTP for the treatment of drug use.
3	Adolescent who currently lives with or is expected to live with formal or informal "family." Family member is defined as any individual who serves in the legal or traditional role of family members, except foster family/home.
4	Adolescent and family reside in the same geographical area as their CTP (each CTP will be allowed to set its own radius of operation). This criterion is required because BSFT may involve regular home therapy sessions.
5	Adolescent and other family members under 18 years of age will sign informed assent; parent figure(s) and/or legal guardian(s) will sign informed consent to participate in study and to allow adolescent to participate. Attempts will be made to obtain consent from both guardians if guardianship is shared. Only the consent of a biological parent or a legal guardian will be accepted for consenting participation of a youth into this study.
Exclusion criteria	
1	Adolescents that are expected to live in a halfway house, institution, independent or assisted living, foster care, or outside of geographical area will be excluded.
2	Adolescents with suicidal or homicidal risk at screening or baseline will be included in the study only after crisis stabilization and consultation with crisis stabilization provider.
3	Adolescents with current/pending legal charges for severe offences will be included in the study. However, adolescents with current/pending severe criminal offenses (e.g., murder, attempted murder, aggravated assault, sexual battery/assault) that may result in short- or long-term incarceration will be excluded to maximize their availability to the protocol. Adolescents who are otherwise court involved will be included.
4	Adolescents from non-restricted settings will be excluded if they are already receiving regular (approximately 1 or more sessions per week) treatment services for drug abuse.

Table 2

Demographics table.

	N	%	Mean (SD)
Age			16.01 (1.8)
Gender			
Male	377	78.5	
Female	103	21.5	
Ethnicity			
Hispanic/Latin	213	44	
White	148	30	
Black	110	23	
Family composition			
Biological 2-parent	120	25	
Biological 1-parent	224	47	
Extended	53	11	
Blended	64	13	
Adoptive	8	1.7	
Foster	3	0.6	
Other	8	1.7	
Family Income			
<$10,000	75	15.82	
$10,000 to 19,999	121	25.53	
$20,000 to 29,999	82	17.3	
$30,000 to 39,999	50	10.55	
$40,000 to 49,999	34	7.0	
>$50,000	99	21	
Missing	13	3	

Table 3

Baseline characteristics.

	African American mean (SD)	Hispanic mean (SD)	White mean (SD)	Total mean (SD)	Significance
Adolescent drug use (adolescent only)					
Percentage of days used*	3.33% (15.00%)	13.33% (32.10%)	10.00% (46.16%)	10.00% (32.95%)	0.005
Marijuana abuse	28.4%	23.0%	27.7%	25.26%	0.03
Marijuana dependence	24.07%	50.7%	51.2%	41.84%	<.0001
Other substance abuse	0.00%	7.98%	9.46%	6.49%	0.002
Other substance dependence	3.74%	16.43%	20.27%	15.3%	<.0001
Any abuse/dependence	49.54%	76.53%	72.97%	69.1%	<.0001
Externalizing (adolescent only)					
Externalizing (YSR)	15.24 (8.83)	18.45 (9.38)	20.3 (9.50)	18.29 (9.46)	.0002
Oppositional defiant disorder	2.45 (1.83)	2.94 (1.85)	3.51 (1.88)	3.00 (1.89)	<.0001
Conduct disorder	1.16 (1.32)	1.72 (1.76)	1.49 (1.60)	1.52 (1.63)	0.01
Externalizing (parent report)					
Oppositional defiant disorder	5.81 (3.15)	6.30 (2.63)	6.71 (2.64)	6.31 (2.77)	0.04
Conduct disorder	2.91 (2.94)	3.13 (2.77)	3.81 (3.06)	3.29 (2.92)	0.03
Family functioning					
Positive parenting					
Adolescent	12.87(3.36)	12.42(3.30)	12.54(3.01)	12.57(3.22)	n.s.
Parent	14.75(2.24)	14.36(2.47)	14.18(2.11)	14.40(2.32)	n.s.
Monitoring					
Adolescent	33.34(6.53)	33.08(6.84)	34.22(6.63)	33.50(6.71)	n.s.
Parent	40.63(4.57)	38.79(4.89)	39.88(4.03)	39.56(4.62)	0.001
Discipline effectiveness (parent only)	12.04(2.47)	10.91(2.56)	10.93(2.88)	11.18(2.68)	<.001
Avoidance of discipline (parent only)	18.81(2.68)	17.35(3.09)	17.56(2.81)	17.75(2.97)	<.001
Cohesion					
Adolescent	6.76(1.77)	6.43(2.14)	5.84(2.38)	6.32(2.17)	0.009
Parent	6.57(2.22)	6.27(2.28)	5.52(2.48)	6.10(2.36)	0.001
Conflict					
Adolescent	3.70(2.20)	3.62(2.21)	4.14(2.49)	3.80(2.31)	n.s.

	African American mean (SD)	Hispanic mean (SD)	White mean (SD)	Total mean (SD)	Significance
Parent	3.29(2.20)	3.48(2.28)	3.99(2.42)	3.59(2.32)	0.034

* Due to skew in this variable the median and interquartile range are reported rather than the mean and SD. The significance test was from a Kruskal–Wallis analysis.