

Transporting Clinical Research to Community Settings: Designing and Conducting a Multisite Trial of Brief Strategic Family Therapy

This paper describes the development and implementation of a trial of Brief Strategic Family Therapy (BSFT), an evidence-based drug intervention for adolescents, in eight community substance abuse treatment programs. Researchers and treatment programs collaborated closely to identify and overcome challenges, many of them related to achieving results that were both scientifically rigorous and applicable to the widest possible variety of adolescent substance abuse treatment programs. To meet these challenges, the collaborative team drew on lessons and practices from efficacy, effectiveness, and implementation research.

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Brief Strategic Family Therapy (BSFT) is an evidence-based treatment (EBT) that addresses family relationships associated with adolescent drug use (Szapocznik, Hervis, and Schwartz, 2003). BSFT has been shown to be efficacious in reducing adolescent drug use and conduct problems and in improving family functioning overall (Santisteban et al., 2003; Szapocznik et al., 1983; Szapocznik et al., 1986; Szapocznik et al., 1988). Here we describe the implementation of a multisite trial to determine whether BSFT can be effective in the community-based programs where adolescent drug abusers typically receive treatment.

We focus on the study design and protocol adjustments that we devised to meet two challenges that are common to all attempts to evaluate EBTs in community settings:

- to produce results that combine scientific rigor with validity for the range of community programs that treat the types of patients that the intervention is designed to help;
- to address the complex interplay between therapists, the interventions they deliver, and the service-delivery contexts into which interventions are to be implemented (Aarons and Sawitzky, 2006; Backer, 2000; Ducharme et al., 2007; Henderson, MacKay, and Peterson-Badali, 2006; Simpson, 2002).

The requirement to achieve both rigor and broad validity has led to the development of hybrid research designs. Such designs combine features typically associated with efficacy studies, which measure benefits in a research setting, with criteria of effectiveness research, which assesses the impact of interventions in community

settings. As is typical of such designs, our study sought to preserve the integrity of treatment comparisons by including intensive therapist training and supervision and well-developed procedures for assessing fidelity to interventions, while enhancing the generalizability of findings by enrolling a heterogeneous patient sample that reflects those typically seen in community programs (Carroll and Rounsaville, 2003; Clarke, 1995; Schoenwald and Hoagwood, 2001).

The need to consider the service-delivery environment has given rise to implementation research, which focuses on the modifications to interventions and adjustments to service-delivery systems that affect success in community settings. The community programs in our study made a number of such adjustments, including, for example, altering their normal procedures for training therapists and for billing.

We hope that this account of our experience will help researchers and community programs prepare for collaborative effectiveness studies by providing examples of issues that may arise and one group's solutions. Some of the strategies we describe are relevant to implementation research in general. Others are particularly suitable for studies of family-based treatments of adolescent drug abuse (Dennis et al., 2004; Henggeler, 2004; Liddle et al., 2006; Schoenwald, Brown, and Henggeler, 2000).

STUDY OVERVIEW

The BSFT effectiveness study was a collaboration between the clinical research faculty at the University of Miami Center for Family Studies, where BSFT was developed and its efficacy established, and the Clinical Trials Network (CTN) of the National Institute on Drug Abuse. The CTN is a consortium of a Federal funding agency, treatment researchers, and community-based treatment agencies that was formed to implement and test EBTs in community settings (Ducharme et al., 2007; Marinelli-Casey, Domier, and Rawson, 2002; Reback et al., 2002). Our trial compared BSFT to adolescent outpatient treatment as usual at eight community-based treatment agencies belonging to the CTN: Arapahoe House (Thornton, Colorado); Crossroads Center (Cincinnati, Ohio); Daymark (Salisbury, North Carolina); Gateway Community Services, Inc. (Jacksonville, Florida); La Frontera Center (Tucson, Arizona); Universidad Central del Caribe (Bayamón, Puerto Rico); Tarzana Treatment Centers (Tarzana, California); and The Village South (Miami, Florida).

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evaluations of a family-based intervention for drug abuse to date. Participants included 480 adolescents, their families, and other significant individuals in their lives—1,894 individuals altogether. Seventy-five therapists took part. Of these, 30 were assigned to deliver BSFT, and 23 of these received the full BSFT clinical training.

Treatment as usual varied considerably from agency to agency. It might include individual, group, and family therapy, as well as case management and psychiatric consultation. At one agency, it consisted of intensive outpatient services with several hours daily of individual and group therapy sessions. Because we anticipated variability in treatment as usual, we planned to analyze differences in the effects of BSFT and treatment as usual at each site as well as across all sites.

The primary study hypothesis was that BSFT would reduce adolescent drug use more than treatment as usual would. Secondary hypotheses were that BSFT would be more effective in engaging families in treatment; in reducing teens' risky sexual behaviors, delinquency, and externalizing disorders; and in improving family functioning and positive social activities. Patients' primary and secondary outcomes were measured for 1 year after they were randomly assigned to one or the other treatment. All BSFT-related treatment and assessments have been completed, and analysis of the data is currently under way. The study findings will be reported elsewhere.

PROTOCOL DEVELOPMENT

The first step in the trial was to establish a team to develop

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the study protocol. Initially, representatives from the University of Miami's Center for Family Studies and from four community agencies across the State of Florida made up the entire team. Over time, however, the team expanded to include individuals from universities and community agencies across the Nation. With the goal of obtaining the widest possible array of research and community viewpoints, we welcomed any professionals from community agencies who expressed an interest in developing the protocol, whether or not their agency planned to participate in the study. Collectively, the team of 12, led by BSFT developer José Szapocznik, had expertise in conducting clinical trials with scientific integrity and also in administering community-based treatments.

The team's first challenge was to determine the appropriate community treatment setting for examining BSFT. Community providers on the team considered three potential designs: (1) BSFT integrated into standard residential treatment, (2) BSFT as a followup intervention for adolescents released from residential programs, and (3) BSFT as an outpatient intervention. The first design was rejected, because the trials that had established BSFT's efficacy had all tested it as a stand-alone intervention. The second and third designs were adopted.

The protocol team also had to select an appropriate comparison condition. Most prior family therapy effectiveness studies have compared the trial intervention with a specific alternative treatment regimen; however, the results of such studies are applicable mainly to treatment programs that use the particular regimen used as a comparison and so have limited potential impact on public health. The team instead adopted the commu-

nity providers' suggestion that treatment programs and policymakers would be most interested in a comparison of BSFT with the participating programs' treatment as usual. Because the programs varied in the services they offered substance-abusing adolescents, this approach would yield information about how BSFT compared with a broad range of services (e.g., individual, group, intensive day treatment, or case management) that adolescents typically receive.

A design variant that had considerable appeal would have deployed BSFT as an add-on intervention and compared treatment as usual versus treatment as usual plus BSFT. Among its advantages, this design would have provided a within-site control, required no changes to be made to treatment as usual, omitted the need to randomize the therapists, and would have been the easiest approach to implement. However, the increased burden for clients and therapists (potentially double the number of sessions) and costs associated with providing two treatments would have threatened the sustainability of the intervention for community programs. Hence, the final consensus was to implement BSFT as a stand-alone intervention.

Throughout the planning and carrying out of the study, the researchers and community practitioners of the protocol team worked together as equal partners rather than in a hierarchical relationship. Level partnership established a basis for the team members to maintain effective communication throughout the project's development and implementation. Communication occurred via weekly conference calls that included all collaborators, as well as weekly calls with the University of Miami research team and research assistants at the sites. Calls were dedicated to identifying problems and developing solutions. Changes to the research protocol were implemented only after they were discussed and a consensus achieved. These procedures are consistent with the components that were previously identified as essential for the successful dissemination of EBTs (Reback et al., 2002).

ASSEMBLING RESEARCH TEAMS IN COMMUNITY PROGRAMS

The first step in moving from discussion to implementation was to create a research structure at each community treatment program that would enable the program to carry out the complex study protocol. Each program identified a site principal investigator, a research coordinator, and research assistants. Four programs already



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had research departments and experience in conducting clinical trials: They could use their existing personnel and organizational structures and, as one research coordinator noted, they “did not need to sell the importance of the study to anyone on the project team.” The other four sites had to create new research infrastructures and educate their staff concerning what research involves and its value. In the end, the advantage enjoyed by sites with research experience was relative: The scope and complexity of the BSFT trial—as illustrated, for example, by its use of 14 different assent/consent forms—was daunting for even the most research-savvy agencies. Although sites varied in how quickly they integrated new procedures into their daily activities, ultimately they all successfully implemented the research protocol and contributed data that were used in the final analysis.

The principal investigator at each agency was responsible for onsite monitoring and oversight of the study protocol. Among the challenges principal investigators addressed during the trial were coping with competition among different agency programs for new clients, negotiating BSFT protocol demands versus agency therapist productivity pressures (e.g., number of hours billed and completion of paperwork), securing adequate funding and other resources for both study implementation and agency clinical services, and promoting the benefits of the project to all involved agency departments. The principal investigator became the most important factor determining each program’s degree of success in implementing the protocol. In general, the more involved the principal investigator was with the daily activities of the protocol, the more quickly the program identified potential problems and developed solutions. Similarly, the stronger his or her leadership position was before the study, the more successful the site was in overcoming barriers.

Research assistants were critical to the protocol’s success as well. They helped to recruit participants, conduct assessments, and relay completed measures to data management. The protocol team encouraged sites to hire research assistants who were proficient in attending to the details of research forms and procedures but could also engage and interact simultaneously with several family members, some of whom had serious mental or behavioral problems or were at odds with each other. Another goal in recruiting research assistants was to find individuals who possessed a specific set of clinical skills that included communicating enthusiasm about treatment and the study, listening and validating each person’s concerns, working around family conflicts, and providing

appropriate care in chaotic home environments. The assistants would have to overcome considerable client ambivalence and resistance because adolescents and their families typically do not see themselves as being in need of change.

THERAPIST SELECTION

Community treatment programs that have training slots available—whether for BSFT, another family therapy, or other interventions—generally offer them to their “best” or most appropriate clinicians. Doing so enables the programs to obtain the maximum benefit from their investments in training. We were concerned, however, that if the community programs in our study selected their most skilled clinicians to learn and deliver BSFT, our results would be biased in favor of BSFT. To prevent this, the study conducted formal assessments of agency clinicians’ interpersonal skills, willingness to participate in intensive training, and other factors necessary to provide treatment as usual and to learn BSFT. Only therapists whose scores on these assessments demonstrated aptitude for both interventions were accepted into the study. We assigned these therapists randomly to either receive training and deliver BSFT or provide treatment as usual. By randomizing their assignments, we ensured that the range of aptitudes was similar among the therapists in both treatment groups.

Some participating agencies’ adolescent outpatient departments were too small to supply the minimum of four therapists that we needed to be able to distinguish BSFT effects from therapist effects independently at each study site. To make up the difference, these agencies recruited volunteers who worked in other departments or in the community, or who had not previously treated adolescents with substance abuse problems. This liberal approach should enhance the generalizability of our results to programs whose therapists may have less experience treating adolescent substance abuse. Because of it, our study results may suggest how much therapists with a wide range of skill levels can achieve with BSFT, while underrepresenting what programs that follow normal practices for therapist selection and training might achieve.

When a site recruited therapists who were not from its adolescent outpatient department into the study, its principal investigator had to reorganize staff to meet both the agency’s contractual obligations and the requirements of the protocol. For example, the protocol required BSFT therapists to devote approximately 20 percent of

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a full-time work week to BSFT training, supervision, and study-related paperwork. Some agencies could draw from a pool of part-time staff to fill the personnel gaps created by this shift in BSFT therapists' responsibilities. However, the allocation of time to the research protocol presented a major challenge to agencies whose clinical staff were already spread thin covering existing obligations. When therapists added BSFT training to their full existing caseloads, their workloads became unmanageable, and this impeded implementation of the intervention.

THERAPIST TRAINING

The BSFT training process evolved over the course of the project in response to challenges faced by the therapists. At the beginning of the trial, we provided therapist training as specified in the protocol:

- a 4-day workshop consisting of a 3-day overview of BSFT and 1 day of training on research forms and study procedures;
- three additional 1-day workshops over the next 13 weeks;
- weekly group supervision sessions delivered in 3-hour conference calls with a certified BSFT trainer/supervisor at the University of Miami.

However, high rates of therapist turnover at all the sites forced us to adapt and condense the training program for replacements so that they could be deployed promptly. For example, a trainer traveled to one agency and delivered the first and second workshops back-to-back and then returned a month later to give the third and fourth workshops back-to-back.

Therapist training times during the study ranged from 4 to 12 months. Some of the variability represents a downside of our "open" therapist selection process. The length of training was burdensome to the community treatment programs because every delay in certifying therapists translated into delays in other research activities. We originally estimated that we would require 6 months to train the study therapists, and we scheduled the shorter research assistant training to begin later and end simultaneously, at which time we would also begin enrolling study participants. At the first four sites, however, therapist training took longer than anticipated, and programs ended up retaining research assistants while they waited for the therapists to attain certification. This had direct implications for the budget, and research assistants' newly learned skills may have atrophied during the long wait to put them into practice. Despite these

experiences, therapists successfully implemented BSFT in a manner consistent with the theoretical underpinnings of the therapy. Independent ratings of therapy sessions revealed that the therapists adhered to the core techniques of BSFT. They also, however, documented substantial variability in the quality of therapy sessions across therapists and even for the same therapist between cases and over time. This finding is consistent with our own observations, during supervision, that therapists waxed and waned in the quality of sessions. Thus, as other research teams have substantiated (Henggeler et al., 2002), adherence to systemic family therapies may be difficult to maintain in community agencies without intensive monitoring and supervision. Another indicator of therapist effectiveness was that client and family engagement and retention rates were similar to those in a recent BSFT efficacy trial (Santisteban et al., 2003).

PATIENT SELECTION AND RECRUITMENT

We set patient inclusion and exclusion criteria to include most of the adolescents referred for drug abuse treatment at the participating community agencies. For example, we accepted youths who had used illicit drugs in the 30 days preceding baseline assessment even if they did not meet diagnostic criteria for drug abuse or dependence, as had been required for participation in the efficacy trials. After we launched the protocol, we learned that many youths were being excluded because they had been referred from residential treatment settings or juvenile detention facilities where they did not have opportunities to use drugs, and we expanded our criteria to include these adolescents. To account for differences in the level of use for youths being referred from restricted settings, we included "referral for drug treatment from an institution" as a covariate in planned analyses. In other ways as well, we redesigned our analyses of drug outcomes in response to the considerable variability in baseline drug abuse among youths referred to outpatient services in community settings.

In another departure from the inclusion and exclusion standards of the efficacy trial, we did not take into account co-occurring psychiatric disorders. Consequently, our sample included youths with a mix of co-occurring psychiatric disorders, which is representative of most community programs.

The most important factor for successful participant recruitment was the systematic integration of the protocol into the community agencies' existing intake procedures. We recommended that the research staff

conduct or at least attend all intake interviews to ensure that every potential participant who entered the agency received information about the study. We observed that research staff who were committed to the study were most successful in engaging adolescents and family members into the protocol.

Most agencies, we found, did not highlight family services among the constellation of services provided, even though all eight considered family therapy a critical component of their treatment of adolescents. Working closely with each site's principal investigator, we developed a strategic plan that included integrating the presentation of family services into the initial discussions with potential participants. This approach helped promote the agency, as well as the study, to each family. Principal investigators also helped to convey the emphasis on family involvement to agency staff.

Court mandates provided an important referral stream of adolescents for many of the agencies. However, the courts sometimes required much more stringent treatment parameters than BSFT uses. For example, the court that sent adolescents to one agency usually recommended one of two programs: three treatment sessions per week for 6 months or an intensive program of five sessions per week for 1 year. In this instance, the site principal investigator met with the primary referring judge to present BSFT as a viable treatment alternative. He highlighted the national study, the voluntary nature of participation, the research showing that family therapy was an efficacious treatment for drug-using adolescents, and the lack of evidence that intensive interventions are more efficacious than less intensive ones. The judge agreed to permit court-referred cases to be enrolled in the study.

AGENCY ACCOMMODATION OF RESEARCH AND BSFT

The community treatment programs had to adjust various practices to integrate BSFT into their service offerings. Although many changes were logistical and concrete in nature, such as securing the equipment and room for group supervision conference calls, others involved a philosophical shift.

Strengthening the Family Focus

Although all the agencies acknowledged the importance of family involvement in the treatment of adolescents, most had few clinical staff with training, or even experience, working with families. Treatment as usual typi-

cally consisted of individual and group therapy; even when parents participated, the treatment models tended to be cognitive and behavioral rather than focused on family systems. This lack of orientation to family led to challenges in several areas of the project, including recruitment of families into the study.

To address this issue, the research team at the University of Miami worked with sites individually to elicit their views on the role of families in the treatment of drug-using adolescents. At several sites, the principal investigator expressed strong agency commitment to involving families in treatment, but admissions staff did not always communicate this to families being recruited for the study. Consequently, many parents opted not to participate based on the misunderstanding that the treatment as usual did not require family involvement. This was particularly the case for families experiencing high levels of conflict and families that viewed the adolescent as the primary problem. To remedy this situation, site principal investigators were encouraged by the research team at the University of Miami to meet regularly with their admissions teams and research assistants to inform them about all the services, including family services, provided at the agency. These conversations were essential for integrating the study into the agency's daily activities and convincing agency staff of the value of the research.

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The early difficulty in recruiting families served as a warning sign. We put into place procedures to avoid this problem with sites that began training later and during the study. For example, research assistants were required to complete a weekly tracking list that included



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Termination of Treatment

Most community treatment programs have policies that will terminate treatment of patients who miss sessions or violate rules. Because therapists carry large caseloads and often have waiting lists, agencies often close a case if the client has missed appointments and does not respond to telephone calls and a letter. However, this practice is inconsistent with BSFT's philosophy, which regards missed sessions as occasions for therapists to increase their efforts to retain and engage clients, if necessary, by phoning and conducting home visits. Agencies need to view these efforts as productive, even though they may not receive reimbursement for client contacts that are not face-to-face.

information about all new referrals to the agency and an update on the research assistants' contact with each of them. Members of the University of Miami research team reviewed this tracking list weekly.

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Billing for Family Services

Clinics need to know not only whether they will be able to achieve desirable outcomes with a new therapy but also whether they can sustain it financially. Therefore, in contrast to efficacy trials, where the research sponsors typically pay for the treatment, our BSFT effectiveness study did not fund any clinical services. Agencies were reimbursed for time that therapists spent in training and supervision on par with the financial support that hundreds of national and international agencies have received for training and supervision in empirically based family therapy over the past decade through local, State, and Federal contracts or grants and private foundations. Therapists in the study received a \$3,000 incentive to participate in training and complete research forms.

Most of the community programs in the study already had a standard line on their billing forms for family therapy, but some had to revise their procedures to bill for BSFT. Likewise, some agencies had to modify their billing practices to reimburse for family sessions in which the adolescent participant was not present, but the therapist worked with the parents on issues that affect the adolescent.

A BSFT therapist often will go to a family's home during the evening or on a weekend. To support this flexibility, the agencies in the BSFT protocol needed to allow therapists to work atypical hours and reimburse for transportation, insurance, mileage, and other incidental expenses.

Some agencies expel patients whose urine tests positive for drug use. Successful integration of the BSFT intervention, however, required that the community treatment programs in our study allow adolescents to remain in treatment even after numerous positive urine screens. Further, the research team at the University of Miami consulted with each site about potential BSFT clinical terminations, reviewing the efforts to engage the adolescent or family and recommending intensified engagement efforts when appropriate.

CONCLUSION

The BSFT trial was designed to evaluate the effectiveness of an evidence-based family intervention with adolescent substance abusers and their families in community treatment centers. In the process of designing and implementing the study, key features of efficacy studies (e.g., intensive therapist training and ongoing supervision, assessment of treatment fidelity) were combined with features that are more characteristic of effectiveness research (e.g., inclusion of participants with co-occurring disorders, recruitment of therapists

already employed at the agencies). Close collaboration between university-led research training centers and community providers sought to ensure that the protocol not only met the highest standards of scientific integrity, but also yielded results that are generalizable to community practitioners. The strategies described in this paper are particularly relevant for furthering implementation research focused on family-based treatments of adolescent drug abuse (Dennis et al., 2004; Henggeler, 2004; Liddle et al., 2006; Schoenwald, Brown, and Henggeler, 2000).

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