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Brief Strategic Family Therapy (BSFT) for Young People in Treatment for Non-Opioid Drug Use

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Colophon

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Key messages

PLAIN LANGUAGE SUMMARY

This publication is a Campbell Systematic Review of the effect of the family therapy approach Brief Strategic Family Therapy (BSFT) for treatment for non-opioid drug use (cannabis, amphetamines, ecstasy or cocaine) among young people aged 11-21 years. The misuse of prescription drugs and the use of ketamine, nitrous oxide and inhalants such as glue and petrol are not considered in this review.

Recent reports describe an alarming trend of drug use by young people and a lack of available treatment for those who require it. BSFT is a manual-based family therapy approach that seeks to reduce drug use among young people and to correct the problem behavior that often accompanies drug use by addressing the mediating family risk factors. This approach is based on the assumption that the family exerts a profound influence on child and youth development. It is also assumed that interventions needs to be well planned, problem-focused, and tailored to the unique characteristics of the individual family. BSFT initially targets those patterns of interactions that most directly influence the youth's behavior.

After a rigorous search for all relevant studies conducted to date, we identified three studies with 806 participants that met the inclusion criteria. The effectiveness of BSFT on reducing drug usage, family functioning, and treatment retention was explored though meta-analysis. The findings are as follows:

- On drug usage: There is no evidence that BSFT has an effect on reducing the frequency of drug use compared to community treatment programs, group treatment, and minimum contact comparisons¹.

- On family functioning: There is no evidence that BSFT has an effect on family functioning compared to community treatment programs, group treatment, and minimum contact comparisons¹.

¹ Control conditions were: individual and group therapy, parent training groups, non-manualized family therapy, case management, participatory learning group intervention, minimum contact group, and 12-step program.

- On treatment retention: BSFT may improve treatment retention in young drug users compared to community treatment programs, group treatment, and minimum contact comparisons¹.

The evidence found was limited. Only three studies were included in the data analysis, which provides very low statistical power to detect an effect of BSFT. The evidence is also limited in terms of outcomes reported on education, risk behavior and other adverse effects, and is therefore insufficient to allow any firm conclusions to be drawn regarding the effectiveness of the treatment.

The review found that the methodological rigor and the adequacy of reporting in the included studies were generally insufficient to allow confident assessment of the effects of BSFT for young drug users. Two of the three included studies provided insufficient information on core issues to allow us to assess the risk of bias (e.g. methods of sequence generation, allocation concealment and completeness of outcome data). This methodological weakness makes us question the validity of these two studies.

Overall, Brief Strategic Family Therapy for treating young people's drug use has not been evaluated with sufficient rigor to allow its effectiveness to be determined. Welldesigned, randomized controlled trials within this population are needed.

Executive summary/Abstract

BACKGROUND

Youth drug use is a severe problem worldwide. This review focuses on a treatment for non-opioid drugs² such as cannabis, amphetamines, ecstasy and cocaine, which are strongly associated with a range of health and social problems. Brief Strategic Family Therapy (BSFT) is a manual-based family therapy approach concerned with identifying and ameliorating patterns of interaction in the family system that are presumed to be directly related to the youth's drug usage. BSFT relies primarily on structural family theory (i.e. how the structure of the family influences the youth's behavior) and strategic family theory (i.e. treatment methods are problem-focused and pragmatic).

OBJECTIVES

The main objectives of this review are to evaluate the current evidence on the effects of BSFT on drug use reduction for young people in treatment for non-opioid drug use and, if possible, to examine moderators of drug use reduction effects to determine whether BSFT works better for particular types of participants.

SEARCH STRATEGY

An extensive search strategy was used to identify qualifying studies. A wide range of electronic bibliographic databases were searched in June 2011, along with government and policy databanks, grey literature databases, and citations in other reviews. We additionally searched the reference lists of primary studies, hand-searched relevant journals, and searched the Internet using Google. We also maintained a correspondence with researchers within in the field of BSFT. Neither language nor date restrictions were applied to the searches.

² Use of ketamine, nitrous oxide and inhalants such as glue and petrol will not be considered in this review.

SELECTION CRITERIA

Studies were required to meet several criteria to be eligible for inclusion. Studies must:

- have involved a manual-based outpatient BSFT treatment for young people aged 11-21 years enrolled for non-opioid drug use.
- have used experimental, quasi-randomized or non-randomized controlled designs.
- have reported on at least one of the following eligible outcome variables: drug use frequency, family functioning, education or vocational involvement, treatment retention, risk behavior or any other adverse effect.
- not have focused exclusively on treating mental disorders.
- have had BSFT as the primary intervention.

DATA COLLECTION AND ANALYSIS

The literature search yielded a total of 2100 references, of which 58 studies were deemed potentially relevant and retrieved for eligibility determination. Six papers were data-extracted, two of which were subsequently excluded for not focusing on treatment effect. Four papers describing three unique studies were included in the final review. Meta-analysis was used to examine the effects of BSFT on drug use reduction, family functioning and treatment retention compared to Treatment as Usual (TAU) in the included studies, where TAU encompassed a range of conditions and interventions³.

RESULTS

The results of the review should be interpreted with great caution, given the extremely small amount of data available and thus the low statistical power to detect the effects of BSFT.

For drug use reduction, there is no evidence that BSFT has an effect on drug use frequency at the end of treatment compared to community treatment programs, group treatment, and minimum contact comparisons³. The random effects standardized mean difference was -0.04 (95% CI -0.25, 0.34), based on three studies with 520 participants.

³ Control conditions were: individual and group therapy, parent training groups, non-manualized family therapy, case management, participatory learning group intervention, minimum contact group, and 12-step program.

For family functioning, there is no evidence that BSFT has an effect on family functioning at the end of treatment compared to control conditions³. The random effects standardized mean difference was 0.06 (95% CI -0.13, 0.25) for family functioning as reported by parents, based on three studies with 568 participants. The random effects standardized mean difference for family functioning reported by the youth themselves was 0.16 (95% CI -0.19, 0.51), based on two studies with 416 participants.

For treatment retention, we found evidence that BSFT may improve treatment retention in young drug users compared to control conditions⁴. The random effects standardized mean difference was 0.55 (95% CI 0.39, 0.76), based on two studies with 606 participants.

Meta-analysis was not feasible for the outcome of risk behavior due to differences in the measures used in the individual studies. Horigian et al. (2010) did not report significant effects on risk behavior. Santisteban et al. (2003) used the socialized aggression scale of RBPC, and reported that youth in BSFT intervention showed greater reduction in peer-based delinquency. The random effects standardized mean difference at end of treatment was -0.27 (95% CI -0.72, 0.18).

Only Horigian et al. (2010) reported on adverse effects; here more than 50 percent of the young people in the study experienced risk behavior or other adverse events during the trial. The most common event noted was arrest, followed by suspension from or dropping out of school, and absconding from home. However, the distribution of events in both BSFT and control conditions does not indicate clear differences between BSFT and the control conditions.

No studies reported on the outcome of education or vocational involvement.

We found that the methodological rigor and the adequacy of reporting in the included studies were generally insufficient to allow confident assessment of the effects of BSFT for young drug users. Two of the three included studies provided insufficient information on core issues to allow us to assess the risk of bias (e.g. methods of sequence generation, allocation concealment, and completeness of outcome data). These flaws in methodology have forced us to question the validity of the two studies. Correspondingly, caution should also be placed on any interpretation of the results.

Due to the small number of studies included in the review, it was not possible to assess possible moderators of drug use reduction effects.

⁴ Control conditions were: individual and group therapy, parent training groups, non-manualized family therapy, case management, participatory learning group intervention, and minimum contact group.

AUTHORS' CONCLUSIONS

There is insufficient firm evidence to allow conclusions to be drawn on the effect of BSFT on non-opioid drug use in young people. While additional research is needed, there is currently no evidence that BSFT treatment reduces the drug use or improves family functioning for young non-opioid drug users compared to other treatments⁴.

The review provides us with mixed findings: on one hand, BSFT does not seem to have better or worse effects on drug use frequency and family functioning than community treatment programs, group treatment, or minimum contact comparisons, but has positive effects on treatment retention compared to control conditions⁴, and longer retention in treatment has been identified as a consistent predictor of a favorable outcome from drug use treatment. Although the possibility remains that the length of follow up in the included studies was insufficient to detect significant changes, it should be noted that the evidence we found was limited, both in terms of the number of studies and in their quality.

The aim of this systematic review was to explore what is known about the effectiveness of BSFT for reducing drug use in young people who use non-opioid drugs. The information currently available does not provide a sufficient basis for drawing conclusions about actual outcomes and impacts. Consequently, no substantive conclusion about the effectiveness of BSFT can be made, and we can neither support nor reject the BSFT treatment approach examined in this review. There is a need for well-designed randomized controlled trials in this area. New trials should report their results clearly and include long-term follow-up to allow the tracking of effects after treatment cessation.

1 Background

1.1 DESCRIPTION OF THE CONDITION

Youth drug use⁵ of the kind that persists beyond the experimentation phase is a severe problem worldwide (United Nations Office of Drugs and Crime (UNODC), 2010), and the use of non-opioid drugs such as cannabis, amphetamines and cocaine is strongly associated with a broad range of health and social problems, including delinquency, poor academic achievement, fatal car accidents, suicide and other individual as well as social tragedies (Deas & Thomas, 2001; Essau, 2006; Office of National Drug Control Policy (ONDCP), 2000; Rowe & Liddle, 2006; Shelton, Taylor, Bonner & van den Bree, 2009). More than 20 million of the 12 to 25 yearolds in the US, and more than 11 million of the 12 to 34 year-olds in Europe, had used illicit⁶ drugs during the month prior to survey interviews in 2009 (Substance Abuse and Mental Health Services Administration (SAMSHA), 2010; European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), 2010). Seven percent of Australian 12-17 year olds had used some kind of drug during the month prior to survey interviews in 2008 (White & Smith, 2009). In Canada, 26 percent of 15-24 year olds questioned had used some form of illicit drugs during the past year (Health Canada, 2010).

Although by no means all young drug users progress to severe dependence, many of them do and may therefore require treatment (Liddle et al., 2004; Crowley, Macdonald, Whitmore & Mikulich, 1998). For example, 8.4 percent of 18 to 25 year-olds in the US are classified as needing treatment for illicit drug use, though less than one tenth of these young people actually receive treatment (National Survey on Drug Use and Health (NSDUH), 2007). Likewise, among young people aged 12 to 17, 4.5 percent were estimated to be in need of treatment for a drug use problem, but only one tenth of this group actually received any (SAMSHA, 2010). Research calls attention to the significant gap between the number of young people classified as in need of treatment and the number of young people who actually receive such treatment (SAMSHA, 2010; NSDUH, 2007).

⁵ The terms 'use', 'abuse' and 'dependence' are used interchangeably throughout this review and refer to an addiction stage of non-medical drug usage; this definition implies that the term 'use' refers to the consumption of drugs beyond experimentation and into addiction.

⁶ Cannabis, amphetamines, cocaine and other non-opioid and opioid drugs are illegal in most, but not all countries (the use of cannabis in small amounts is tolerated in the Netherlands, for example).

There is growing public concern regarding the effectiveness and high costs of available treatments for young people, and regarding the high rates of treatment dropout and post treatment relapse to drug use (Austin, Macgowan & Wagner, 2005; Najavits & Weiss, 1994; Stanton & Shadish, 1997). Accordingly, treatment to help young drug users should be attractive and available in order to minimize the chance of dropout and relapse (Simmons et al., 2008; National Institute on Drug Abuse, 2009). Furthermore, the services provided should be empirically supported to increase the likelihood that, (a) treatment will be successful, and (b) public spending supports the interventions that are the most effective.

Researchers point to the fact that many research projects have empirically validated different kinds of treatment approaches for young drug users as effective (e.g. Rowe & Liddle, 2006; Waldron, Turner & Ozechowski, 2006; Williams, Chang & Addiction Centre Adolescent Research Group, 2000; Austin et al., 2005). The current dilemma in the field of substance abuse treatment for young people is that it is not clear what works best, with research suggesting that almost all interventions lead to reduced drug use. While there are some promising individually-based cognitive and motivational therapies (Waldron & Turner, 2008; Kaminer, 2008; Deas & Thomas, 2001; Galanter & Kleber, 2008), family-based approaches may be equally effective. Family therapy encompasses a range of different interventions with varying theoretical sources, including behavioral and cognitive behavioral theory, structural and strategic family theory, and family systems theory (Williams et al., 2000; Austin et al., 2005). Some reviews have suggested that these family-based therapies are superior to individual-based programs in reducing youth drug use (Williams et al., 2000: Lipsey, Tanner-Smith & Wilson, 2010; Waldron, 1997).

Young people with persistent drug use have unique needs due to their particular cognitive and psychosocial development. Young people are especially sensitive to social influence, with family and peer groups being highly influential. Youth drug treatments which facilitate positive parental and peer involvement, and which integrate other systems in which the young person participates (such as schools, social services, and justice authorities) are thus key to reducing drug use by young people (National Institute on Drug Abuse, 2009). A number of studies and reviews have showed positive results for family therapies in general, but there is a need to synthesize individual study results for specific family therapies to determine whether and to what extent specific family therapy interventions work for young drug users (Williams et al., 2000; Austin et al., 2005; Waldron & Turner, 2008; Kaminer, 2008; Deas & Thomas, 2001).

This review is concerned specifically with Brief Strategic Family Therapy (BSFT; Szapocznik, Hervis & Schwartz, 2003; Robbins & Szapocznik, 2000) as a strong body of evidence on the effects of this form of family-based intervention is sorely lacking. This review has attempted to clarify the effects of the BSFT program for relevant groups of young people aged 11-21, and has focused on young people enrolled in treatment for drug use, irrespective of how their problem was defined. Enrolment in treatment is taken to imply that the severity of the young person's drug use has compelled a close, significant adult (for example, teacher, parent, social services employee, or school counselor) to demand that the young person enters treatment. BSFT is an intervention offered as outpatient treatment⁷ to young people age 11-21 who are living with their families.

This review focuses solely on non-opioid drug use⁸ and is one in a series of reviews on manual-based family therapy interventions for young people in treatment for non-opioid drug use⁹.

1.2 DESCRIPTION OF THE INTERVENTION

BSFT is a manual-based, family-oriented prevention and treatment intervention that targets a young person's drug use. It is a *problem focused* family therapy, aiming at creating changes in those interactions relevant to the identified problems within families, and in individual family members who appear particularly resistant to change.

BSFT is a family therapy approach that targets young people *and* their families *as a system* throughout the treatment, and thereby recognizes the importance of the family system in the development and treatment of young people's drug use problems (Liddle et al., 2001; Muck et al., 2001). BSFT was developed at the Center for Family Studies, University of Miami. The program was developed in the 1970s as an intervention targeting Hispanic minority young people, primarily immigrants from Cuba (Robbins & Szaspocznik, 2000). The program was originally developed to be culturally sensitive in relation to Cuban immigrants in Miami, but has since been revised and is now a broadly applied intervention for young people; primarily those displaying problem behavior and drug use (Robbins & Szaspocznik, 2000). BSFT can be adapted to make it more relevant to the population it serves, and is thus considered to be sensitive to different cultural and ethnic groups, as well as rural versus inner-city conditions (Robbins, Bachrach & Szapocznik, 2002).

1.2.1 Theoretical background

BSFT applies a family systems approach that relies on both structural and strategic family theory (Robbins & Szapocznik, 2000; Szapocznik et al., 2003). Along with other family systems-based therapies, it builds on the assumption that families can

⁷ A Cochrane review has evaluated psychosocial interventions for substance abuse and misuse in young offenders in locked facilities (Townsend et al., 2009).

⁸ Two Cochrane reviews have evaluated psychosocial treatments for treatment of opioid dependence (Amato et al., 2011; Minozzi et al., 2010).

⁹ See the following Title Registrations in the Campbell Library: Family Behavior Therapy (FBT) for young people in treatment for illicit non-opioid drug use, (Lindstrøm M, Rasmussen PS, Kowalski K, Filges T & Jørgensen A-M); Functional Family Therapy (FFT) for young people in treatment for illicit non-opioid drug use, (Kowalski K, Lindstrøm M, Rasmussen PS, Filges T & Jørgensen A-M); Multidimensional Family Therapy (MDFT) for young people in treatment for illicit non-opioid drug use, (Rasmussen PS, Lindstrøm M, Kowalski K, Filges T & Jørgensen A-M).

be viewed as systems and, as such, each individual in the family is important for the family system as a whole (Poulsen, 2006). In family systems theory, the family is perceived as a unique system consisting of interdependent and interrelated members. The family members are influenced by each other's actions and relate strongly to each other, and as such they can be viewed as a unique and changeable system. The behavior of each family member must be understood in relation to the family context. The problem behavior of young family members is seen as generally associated with maladaptive social interaction patterns in the family, and therefore any interventions must be implemented at family level. The family itself is part of a larger social system, and just as young people are influenced by their families, so are families influenced by the larger social (and cultural) systems in which they exist (Poulsen, 2006; Doherty & McDaniel, 2010; O'Farrell & Fals-Steward, 2008; Kaminer & Slesnick, 2005; Austin et al., 2005). Family therapies are concerned with the wider social context in which both the individual and the family are embedded.

Structural family theory is based on the idea that subsystems, structures and hierarchies within families influence or determine the actions of individual family members (Goldenberg & Goldenberg, 2008; Minuchin, 1985). In structural family theory, social interactions are understood structurally, as repetitive patterns of interaction. The family structure can range from a supportive structure to a maladaptive structure. Either way, the structure of interactions affects the family members and can play a pivotal role in maintaining positive as well as problem behavior (Poulsen, 2006; Doherty & McDaniel, 2010; O'Farrell & Fals-Steward, 2008; Kaminer & Slesnick, 2005; Austin et al., 2005; Madanes & Haley, 1977).

BSFT is a strategic approach whereby components are planned, practical and problem-focused. Intervention components are tailored to the young person and his or her family. Components are selected based on their likelihood of targeting the identified core problems and of positively affecting the young person and their families in the desired direction (e.g. reduced drug use, improved family interactions). The components are problem-focused in the sense that only those interactions that most directly affect the young person's drug use problems are targeted. The intervention components are well-planned in the sense that the therapist determines which interactions are directly linked to the symptomatic behavior of the young person and determines which of these will be targeted. The therapist thus creates a tailored plan to help the family develop more appropriate patterns of interaction (Szapocznik et al., 2003; Horigian et al., 2010, Robbins & Szapocznik, 2004; Szapocznik & Williams, 2000; Robbins & Szapocznik, 2000).

1.2.2 BSFT components

BSFT contains three major components: 'joining', 'diagnosing' and 'restructuring' (Szapocznik et al., 2003; Horigian et al., 2004; Szapocznik & Williams, 2000; Robbins & Szapocznik, 2000).

Joining

Joining is the process of engaging young people and family members in treatment through the establishment of a good therapeutic relationship. Joining occurs at the individual level (the therapist establishes a relationship with each family member) and at the family level (the therapist joins with the family system to create a new therapeutic system by becoming a temporary member of the family). Through recognizing, respecting and maintaining the family's characteristic interactional patterns, the therapist attempts to establish an alliance with the individual family members and the family as a whole (Szapocznik et al., 2003; Horigian et al., 2004; Szapocznik & Williams, 2000; Robbins & Szapocznik, 2000).

Diagnosing

BSFT focuses on identifying inappropriate family alliances, family boundaries, and maladaptive interaction patterns. Prior to the diagnosis, BSFT therapists must create a therapeutic context in which family members are free to interact in their typical style. These 'enactments' permit the therapist to observe directly how the family behaves, and to diagnose on this basis (Horigian et al., 2004). The 'diagnosis' of alliances, boundaries, and patterns will reveal how the characteristics of family interactions contribute to the family's difficulties in meeting the objective of eliminating or reducing the young person's drug problems. The therapist analyzes family interactions on five interactional dimensions: Structure, resonance, developmental stage, identified patient, and conflict resolution (Robbins & Szapocznik, 2000; Horigian et al., 2004; Szapocznik et al., 2003). Diagnosing includes seeing the patterns of family interaction and their influence on the young person's problems in context (e.g. the young person's network and social setting). Individual risk, social risk, and protective factors must therefore be taken into consideration by the therapist when evaluating the impact of family interactions on the young person's drug problems (Szapocznik et al., 2003). The diagnosis component allows the BSFT program to be flexible and adaptable to different social settings, family structures and cultures, and also to co-occurring conditions such as juvenile justice system issues, or comorbid mental health conditions.

Restructuring

The goal of restructuring is to change maladaptive family interaction patterns related to the young drug user's problems into more adaptive and successful ways of interacting (Horigian et al., 2004; Robbins & Szapocznik, 2000; Szapocznik et al., 2003). Key restructuring components are 'working in the present', 'reframing' and 'working with boundaries and alliances' (Horigian et al., 2004; Robbins & Szapocznik, 2000; Szapocznik et al., 2003).

Working in the present. BSFT focuses primarily on the current interaction among family members, and distinguishes between process and content. The main focus during therapy sessions is on interaction processes between family members.

Reframing. The aim of reframing is to disrupt maladaptive interaction patterns and create a new context for family interactions. Reframing offers positive alternatives to the family by, for example, shifting the family members' views of the young drug user from a 'troubled young person' to (for example) a 'vulnerable young person in pain'. Highly gendered interaction patterns in the family may also be adjusted in the reframing process.

Working with boundaries and alliances. According to BSFT, families of young drug users need a strong parental leadership, in the form of a strong alliance between parents with the power to make executive decisions together. For single parents, there is a need for a strong parental position. The therapist will work to restore the parent alliance in families where this is weak or disrupted. For single parents, the therapist will work to establish and/or reinforce a strong parental position. In BSFT, the therapist will also aim to set clear boundaries between family members, thereby allowing all members some privacy and independence within the family. It is recognized that boundaries and alliances can vary according to gender and age, and that this process will be sensitive to such issues.

Intervention components in BSFT are tailored to the young person and his/her family needs, and are based on the components' likelihood of positively affecting the young drug user and his or her family in the desired direction (e.g., reduced drug use, improved family interactions). The distribution of components in the BSFT intervention will therefore vary to suit the needs of family members. The tailoring of the BSFT program and its focus on family system and family functioning could act as a catalyst for positive side effects including improved overall family functioning, and improved educational outcome for the young person in treatment, as well as for siblings who will also be affected by better family functioning.

1.2.3 Duration and setting

Despite the inclusion of the word 'Brief' in the program title, the duration of BSFT is comparable to other family therapy programs. The average length of the BSFT intervention is 12-16 sessions. The program is flexible, however, and can be tailored to individual needs (Robbins et al., 2002) and can be implemented in a variety of settings, including clinical or community facilities or in the family home (Robbins et al., 2002).

1.3 HOW THE INTERVENTION MIGHT WORK

BSFT has two primary objectives: 1) to eliminate or reduce young people's drug use and 2) to change the family interactions associated with young people's drug use. Randomized controlled trials and systematic reviews have indicated that BSFT can reduce drug use in participants and can contribute to a reduction in conduct problems and delinquency (Robbins et al., 2002; Santisteban et al., 2003; Waldron & Turner, 2008; Austin et al., 2005). The program outcomes may be affected by participant characteristics and program mechanisms. Participant characteristics that have been found to predict program drug use reduction or abstinence were: history and severity of drug use pretreatment; level of general peer and parental support, particularly in relation to non-drug use; and higher levels of school attendance and functioning pretreatment (Williams et al., 2000). More information is required by practitioners on highly relevant participant characteristics, such as age, gender, ethnicity, family composition (e.g. single parents), and co-occurring conditions. These participant characteristics are potential predictors of treatment outcome and practitioners need to be able to assess the program's relevance for all types of client.

1.3.1 Intervention mechanisms

Treatment variables with positive impacts on treatment outcomes have been identified in a number of reviews of a range of treatments for youth drug use (Waldron & Turner, 2008; Williams et al., 2000).

Treatment completion was the variable most consistently related to reduction in drug use (Williams et al., 2000; Waldron & Turner, 2008). Building an alliance early in treatment was found to predict the likelihood that young people completed treatment and reduced their drug use (Waldron & Turner, 2008). It remains unclear if this was a direct treatment impact, or an indicator for treatment motivation, which has been noted as another key to positive treatment outcome. Either way, these findings point to the importance of the BSFT component joining as a key mechanism, influencing treatment compliance and attendance. Studies have shown that BSFT positively affected the involvement and retention in treatment of young people and their families (Santisteban et al., 2003; Coatsworth et al., 2001; Santisteban et al., 1996). This can be linked directly to the joining effort. In BSFT, joining has two aspects: joining refers both to the steps the therapist takes to prepare the family for change, and to the point when the therapist gains a position of leadership within the family. A number of techniques can be used to prepare the family to accept therapy and to accept the therapist as a leader of change. For example, the therapist can present him/herself as an ally, appealing to those family members with the greatest dominance over the family unit, and attempting to fit in with the family by adopting the family's manner of speaking and behaving. These techniques can be adapted to the needs of various client groups.

Motivation, as a key to positive treatment outcome (Williams et al., 2000; Waldron & Turner, 2008), was also linked to the support and influence of the family system. The family system's ability to influence the young person toward a lifestyle that does not involve drug use is a possible mechanism of change related the inherent focus on family system in BSFT (Ozechowski & Liddle, 2000; Hogue & Liddle, 2009). Studies have found that BSFT positively influenced family interaction changes, family functioning, and contributed to the reduction in young people's drug use (Santisteban et al., 2003; Robbins et al., 2002; Ozechowski & Liddle, 2000). For example, Valdez and Cepeda (2008) found that parents participating in the BSFT

intervention benefited from the parenting training and education in youth and family conflict, which led to a reduction in the young person's drug use. According to Valdez and Cepeda (2008), parents who participate in the BSFT intervention have been found to display improved ability in identifying signs of, for instance, youth gang participation; improved ability to communicate with the young person about gang issues and drug issues; and improved knowledge about a parent's responsibility related to youth gang and drug participation. In addition, parents who participated in BSFT displayed improved knowledge about the negative health and legal consequences of substance use.

Youth coping mechanisms have also been identified as predictors of treatment outcome (Waldron & Turner, 2008). The young people participating in BSFT also displayed positive behavior improvements over the course of the treatment intervention, such as improved conflict resolution skills, improved self-identity and sense of personal resources, and reduced gang and drug identification (Valdez & Cepeda, 2008). Improvements were gained through the reframing phase during which the therapist works with both the young person and family members to change their ways of behavior towards a more constructive behavioral pattern (Horigian et al., 2004; Robbins & Szapocznik, 2000; Szapocznik et al., 2003). The therapist coaches the young person and family members on constructive interaction methods, ensuring that new interaction patterns are practiced at home in naturally occurring situations, such as when setting a curfew or when eating meals together (Szapocznik et al., 2003).

The quality of the therapeutic alliance predicted the family's engagement, retention in treatment, and gains from therapy (Robbins et al., 1998). Robbins et al. (2004) have demonstrated how unbalanced alliances between the therapist and the young person and/or the family in early BSFT sessions have been linked to higher program dropout rates. In BSFT, one of the most useful strategies a therapist could employ in joining was to support the existing family power structure. Szapocznik et al. (2003) concluded that:

The BSFT counselor supports those family members who are in power by showing respect for them. This is done because they are the ones with the power to accept the counselor into the family; they have the power to place the counselor in a leadership role, and they have the power to take the family out of counseling. In most families, the most powerful member needs to agree to a change in the family, including changing himself or herself. For that reason, the counselor's strongest alliance must initially be with the most powerful family member (Szapocznik et al., 2003:26).

The family systems focus and the joining effort were both found to be key ingredients in BSFT, influencing family functioning and facilitating changes in young people's drug problems.

1.4 WHY IT IS IMPORTANT TO DO THIS REVIEW

Persistent drug use among young people is a significant social problem, and the treatment of young people's drug use is challenging and costly, not least because the treatments for such problems are plagued by high dropout rates and post-treatment relapse. Research suggests that nearly half of all young drug users who enter treatment never complete it (SAMSHA, 2008). There is a need to identify effective treatments for addressing young people's drug use problems and to reduce dropout from treatment programs and post-treatment relapse. Furthermore, the growing interest among policymakers in increasing funding for evidence-based interventions was a strong motivation for collecting further evidence with a systematic review on a promising treatment for young drug users.

There are a number of studies indicating that BSFT does show potential as an effective treatment for young people with non-opioid drug use. By aggregating the results from individual studies on BSFT, this review contributes to the body of knowledge on the treatment of young drug-users and their families. The review informs practice by exploring the effects of BSFT for relevant client groups.

2 Objectives

The aim of this review was to evaluate the current evidence on the effects of BSFT on drug use reduction for young people in treatment for non-opioid drug use.

3 Methodology

3.1 TITLE REGISTRATION AND REVIEW PROTOCOL

The title for this systematic review was approved in The Campbell Collaboration on 20 June, 2010. The review protocol was approved on 16 January, 2012. Title registration and protocol are available at: <u>http://www.campbellcollaboration.org/library.php</u>.

3.2 CRITERIA FOR INCLUDING STUDIES IN THE REVIEW

3.2.1 Types of studies

The study designs eligible for inclusion were:

Controlled trials¹⁰ where all parts of the study are prospective, i.e. recruitment of participants, assessment of baseline characteristics, allocation to intervention, selection of outcomes and generation of hypotheses, see Higgins & Green, 2008):

- randomized controlled trials (RCTs);
- quasi-randomized controlled trials (QRCTs), where participants are allocated by means such as alternate allocation, person's birth date, the date of the week or month, case number or alphabetical order;
- non-randomized controlled trials (NRCTs), where participants are allocated by other actions controlled by the researcher such as location difference or time difference.

We did not find any relevant quasi-randomized or non-randomized studies for inclusion in this review.

3.2.2 Types of participants

The population included in this review was young people aged 11-21 years enrolled in outpatient manual-based BSFT drug treatment for non-opioid drug use. Nonopioid drugs were defined as cannabis, amphetamines, ecstasy or cocaine. The

¹⁰ A controlled trial typically includes at least two groups, an intervention/experimental group and a control group, and outcome measures recorded pre- and post-treatment.

misuse of prescription drugs and the use of ketamine, nitrous oxide and inhalants such as glue and petrol were not considered in this review.

Definitions of young people, and the age at which someone is considered to be a young person and may be entitled to special services such as drug treatment, vary internationally (United Nations, 2011). Age group distinctions for young people are unclear as the boundaries are fluid and culturally specific (Weller, 2006). Furthermore, young people start experimenting with illegal drugs at different ages in different countries (Hibell et al., 2009). Similarly, patterns of independence from parents and of independent living vary internationally for young people. In order to encapsulate these international differences we have set the age range from 11 to 21 (Hibell et al., 2009; United Nations, 2011; SAMHSA, 2010; Danish Youth Council, 2011).

We included only interventions delivered in an outpatient setting in order to evaluate the effects of BSFT on youths living with their families, since family interactions are fundamental to BSFT.

We defined the population as young people referred to or in treatment for using non-opioid drugs. No universal international consensus exists concerning which categories should be used when classifying drug users¹¹, and different assessment tools and ways of classifying the severity of drug use are applied in different research studies (American Psychiatric Association, 2000; World Health Organization (WHO), 2011; Nordegren, 2002). We included all participants, regardless of any formal drug use diagnosis. The main criterion for inclusion was that the young person was enrolled to participate in the treatment (i.e. intervention or comparison condition). Referral to and enrolment in drug use treatment suggests a level of drug use such that a significant other or authority (or the young person themselves) has found it necessary to seek treatment.

In conducting the review, we became aware that there are a number of reasons why a young person may become enrolled in BSFT treatment for non-opioid drug use. One is that there is clear evidence of drug use, either observed or self-reported; another is that the young person is seen as at significant risk of using drugs by nature of his/her environment or peer group. Given this complexity, the fact that an individual may fall into more than one of these groups, and the inherent difficulty in determining accurately the proportion of non-opioid drug users in any sample of young people, we chose to include studies where at least 50% of participants had

¹¹ Clients who use drugs are variously classified as users, misusers and dependents. These specific categorizations are used in the Diagnostic and Statistical Manual of Mental Disorders (DSM) (American Psychiatric Association, 1994, 2000). While DSM-IV is widely usedl, s the International Statistical Classification of Diseases and Related Health problems (ICD, now ICD-10) developed by the World Health Organisation (WHO) is also in widespread use. Differences between these rubrics concern both terminology and categorization criteria. For example, DSM-IV includes the category 'abuse', while ICD-10 explicitly avoids this term on the grounds of its ambiguity; harmful use and hazardous use are the equivalent terms in WHO usage, but the categories are not identical; and while ICD-10 uses only physical and mental criteria, DSM-IV also includes social criteria (WHO, 2011; Nordegren,2002).

either used or were suspected of using drugs, and the rest of the sample were at risk for drug use through having peers that did.

3.2.3 Types of interventions

The review included outpatient manual-based BSFT interventions of any duration delivered to young people and their families (see 1.2: Description of the intervention). The interventions included were delivered in outpatient settings and did not include overnight stays in a hospital or other treatment facility. The BSFT interventions took place in the home, at community centers, in a therapist's office, or at other outpatient facilities.

BSFT is a family intervention requiring the active participation of the young drug user and his or her family, with one of the primary aims being the improvement of family functioning. In cases where the young drug user is placed outside the family home, as with inpatient treatment or incarceration in a locked facility, the core condition of the program would be seriously compromised.

Eligible comparison conditions included no intervention, waitlist controls and alternative interventions including Treatment as Usual (TAU), as we were interested in both absolute and relative effects. Due to ethical considerations and the nature of the problem (i.e. young peoples' drug use), the likelihood of finding a no treatment control condition was small. We expected (and found) that the most frequent comparison condition was an alternative intervention (Lipsey, Tanner-Smith, & Wilson, 2010).

3.2.4 Types of outcomes

We considered the following outcomes:

Primary outcome(s)

Abstinence or reduction of drug use, as measured by (for example):

- Biochemical test (e.g. urine screening for drug use);
- Self-reported estimates of drug use (e.g. Timeline Followback TLFB; Sobell & Sobell, 1992);
- Psychometric scales (e.g. Addiction Severity Index; McLellan, Luborsky, Woody & O'Brien, 1980).

Secondary outcomes

• Family functioning (e.g. as measured by the Beavers Interactional Competence Scale; Beavers & Hampson, 2000).

- Education or vocational involvement (e.g. as measured by grade point average, attendance, self-reported or reported by authorities, files, registers, or employment record).
- Treatment retention (e.g. as measured by days in treatment, completion rates and/or attrition rates).
- Risk behavior, such as crime rates, prostitution (e.g. as, measured by self-reports or reports by authorities, administrative files, registers).
- Other adverse effects (e.g. as measured by length and frequency of hospitalization, suicide and overdose).

The primary outcome was abstinence or reduction of drug use, as the main review objective was to evaluate current evidence on BSFT's effects on drug use reduction for young people in treatment for drug use. We were looking for evidence on how to best reduce or eliminate drug use, as drug use is understood as the young people's primary problem.

3.3 SEARCH METHODS FOR IDENTIFICATION OF STUDIES

The searches were run by one review author (AKJ) and a member of the review team (PVH¹²).

3.3.1 Electronic searches

Relevant studies were identified through electronic searches of bibliographic databases, government and policy databanks. No language or date restrictions were applied to the searches.

The following bibliographic databases were searched:

- Medline searched until June 12, 2011
- Embase searched until June 12, 2011
- Cinahl searched until June 12, 2011
- Social Science Citation Abstract searched until June 8, 2011
- Science Citation Abstract searched until June 8, 2011
- Socindex searched until June 17, 2011
- PsycINFO searched until June 12, 2011
- Cochrane searched until June 12, 2011
- Social Care Online searched until June 12, 2011
- ERIC searched until June 17, 2011
- Criminal Justice Abstracts searched until June 17, 2011

¹² Pia Vang Hansen was a member of the review team and assisted the review authors with the literature searches.

- Bibliotek.dk searched until June 12, 2011
- Libris searched until June 12, 2011
- Bibsys searched until June 12, 2011

3.3.2 Search terms

An example of the search strategy for MEDLINE searched through the Ovid platform is listed below. This strategy was modified for the different databases (see section 11.1 for details).

- 1. BSFT.af.
- 2. (Brief adj1 Strategic* adj1 Famil*).af.)
- 3. 1-2/or

3.3.3 Searching other resources

The review authors checked reference lists of other relevant reviews and each of the included primary studies for new leads. We identified 16 leading international experts who had published in this subject area, and contacted them individually to identify unpublished and ongoing studies. We provided the experts with the inclusion criteria for the review along with the list of included studies, asking for any other published, unpublished or ongoing studies relevant for the review.

3.3.4 Hand search

The following five international journals were hand searched for relevant studies:

- Addiction
- Journal of Consulting and Clinical Psychology
- Journal of Substance Abuse Treatment
- Journal of Clinical and Adolescent Psychology
- Research on Social Work Practice

Searching was performed on journal editions from January to September 2011 in attempt to identify any recently published studies that may not have been found in the systematic search.

3.3.5 Grey literature

Additional searches for relevant studies and useful leads were made using *Google* and *Google Scholar*, where we checked the first 150 hits. OpenGrey (<u>http://www.opengrey.eu/</u>) was used to search for European grey literature. Copies of relevant documents were made and we recorded the exact URL and date of access for each relevant document.

In addition, we searched the following sites for relevant ongoing or unpublished research projects and useful leads:

- National Institute on Drug Abuse (NIDA) http://www.nida.nih.gov/nidahome.htm
- The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) http://www.emcdda.europa.eu/index.cfm
- Substance abuse and Mental Health Services administration (SAMHSA) http://www.samhsa.gov/

3.4 DATA COLLECTION AND ANALYSIS

3.4.1 Selection of studies

One review author (MS) and one member of the review team (SLO¹³) independently screened titles and available abstracts to exclude studies that were clearly irrelevant. Studies considered eligible by at least one of the reviewers were retrieved in full text. The full texts were then screened by one reviewer (MS) and one member of the review team (SLO) to determine study eligibility based on the inclusion criteria. Any disagreements about eligibility were resolved by discussion. Reasons for exclusion were documented for each study that was retrieved in full text (see sections 4.2.2 and 10.2). The study inclusion screening sheet was piloted and adjusted as required by the review authors and used throughout screening. The overall search and screening process is illustrated in a flow-diagram (figure 12.1).

3.4.2 Data extraction and management

Two review authors (ML & MS) independently coded and extracted data from the included studies. The data extraction sheet was piloted and revised as necessary. Any disagreements were resolved by discussion. Data were extracted on the characteristics of participants (e.g. age, gender, and drug use history), characteristics of the intervention and control conditions, research design, sample size, outcomes, and results. Extracted data were stored electronically. Analysis was conducted in Excel and RevMan 5.1.

3.4.3 Assessment of risk of bias in included studies

We assessed the methodological quality of studies using a risk of bias model developed by Prof. Barnaby Reeves in association with the Cochrane Non-Randomized Studies Methods Group (Reeves, Deeks, Higgins, & Wells, 2011)¹⁴. This model, an unpublished extension of the existing Cochrane Collaboration's risk of

¹³ Stine Lian Olsen was a member of the review team and assisted the review authors with screening.

¹⁴ This risk of bias model was introduced by Prof. Reeves at a workshop on risk of bias in non-randomized studies at SFI Campbell, February 2011. The model is developed by the Cochrane Non-Randomized Studies Method Group (NRSMG).

bias tool (Higgins & Green, 2008), covers both risk of bias in RCTs and in NRCTs that have a well-defined control group.

The extended model is organized and follows the same steps as the existing Risk of Bias model according to the Cochrane Handbook, chapter 8 (Higgins & Green, 2008). The extension to the model is explained as follows:

1) The existing Cochrane risk of bias tool needs elaboration when assessing nonrandomized studies because, for non-randomized studies, particular attention must be paid to selection bias/risk of confounding. The extended model therefore specifically incorporates a formalized and structured approach for the assessment of selection bias in non-randomized studies¹⁵ by adding an explicit item on confounding (Reeves, Deeks, Higgins & Wells, 2011). It is based on a list of confounders considered important and defined in the protocol for the review. The assessment of confounding is made using a worksheet where, for each confounder, it is noted whether the confounder was considered by the researchers; the precision with which it was measured; the imbalance between groups; and the care with which the adjustment was implemented (see section 10.5). This assessment informs the final risk of bias score for confounding.

2) Another feature of non-randomized studies that make them at greater risk of bias compared to RCTs is in most countries, RCTs must have a protocol in advance of starting to recruit, whereas the protocol requirements for non-randomized studies are less consistent. Therefore, the item concerning selective reporting also requires assessment of the extent to which analyses (and potentially other choices), could have been manipulated to bias the findings reported, e.g. choice of method of model fitting, potential confounders considered/included. In addition, the model includes two separate "yes/no" items asking reviewers whether they think the researchers had a pre-specified protocol and analysis plan.

3) Finally, the risk of bias assessment is refined, making it possible to discriminate between studies with varying degrees of risk. This refinement is achieved with the addition of a 5-point scale for certain items (see the following section, *Risk of bias judgment,* for details).

The refined assessment is pertinent when considering data synthesis as it operationalizes the identification of studies (especially in relation to nonrandomized studies) with a very high risk of bias. The refinement increases transparency in assessment judgments and provides justification for not including a study with a very high risk of bias in the meta-analysis.

Risk of bias judgment items and assessment

¹⁵ The extended model was developed to ensure standardization of guidelines and procedures in the Risk of Bias assessment of NRS.

The risk of bias model used in this review is based on nine items (see section 11.3 for guidelines and risk of bias coding sheets).

The nine items refer to

- **sequence generation** (Judged on a low/high risk/unclear scale NRCTs will automatically have a high risk of bias)
- **allocation concealment** (Judged on a low/high risk/unclear scale)
- **confounders** (Judged on a 5 point scale/unclear, only relevant for non-randomized studies)
- **blinding** (Judged on a 5 point scale/unclear)
- **incomplete outcome data** (Judged on a 5 point scale/unclear)
- **selective outcome reporting** (Judged on a 5 point scale/unclear)
- other potential threats to validity (Judged on a 5 point scale/unclear)
- **a priori protocol** (Judged on a yes/no/unclear scale)
- a priori analysis plan (Judged on a yes/no/unclear scale)

The assessment was based on pre-specified questions (see section 11.3). "Yes" indicates a low risk, "No" indicates a high risk of bias, and "Unclear" indicates an unclear or unknown risk of bias. In the 5 point scale, 1 corresponds to No/Low risk of bias (e.g.1 = a high quality RCT) and 5 corresponds to Yes/High risk of bias (e.g. 5= too risky, too much bias, or a poor quality study). A score of five points on any of the items assessed translates to a risk of bias so high that the findings would not be considered in the data synthesis (because they are more likely to mislead than inform, see section 11.3). None of the included studies or parts thereof was judged as 5 on the risk of bias scale.

Confounding was not relevant in the review since we did not find any NRCTs meeting the inclusion criteria.

Assessment

Review authors (ML & MS) have independently assessed the risk of bias for each included study as described in the previous sections. Disagreements were resolved by discussion and, where necessary consulting a third reviewer with content and statistical expertise (TF). We have reported the risk of bias assessment in risk of bias tables for each included study, see section 10.5.

3.4.4 Measures of treatment effect

Reduction of drug use is measured in terms of frequency of drug use.

When available, standardized mean differences (SMD) were used as the effect size metric. For family functioning and drug use, SMDs were available in the studies by Santisteban et al. (2003) and Valdez & Cepeda (2008), and were used as the effect size matrix. Drug use outcome means and standard deviations were not available in Robbins et al., (2011) where only binary data were available. For this study we transformed the odds ratio to a SMD using the Cox transformation (Sáchez-Meca, Marín-Martínes & Chacón-Moscoso, 2003). Hedges *g* was used for estimating SMDs.

Odds ratios were used as the effect size metric for treatment retention. Computations were carried out with the natural logarithm of the odds ratio.

For outcomes where effects sizes could not be pooled (e.g. education or vocational involvement, risk behavior and other adverse effects), we have reported the study level effects in as much detail as the included studies permit. Software used for storing data and statistical analyses was RevMan 5.0 and Excel.

3.4.5 Unit of analysis issues

We planned to take into account the unit of analysis of the studies to determine whether individuals were randomized in groups (i.e. cluster randomized trials), whether individuals had undergone multiple interventions, whether there were multiple treatment groups, and whether there were multiple publications for some studies.

Multiple interventions per individual

We did not find any studies with multiple interventions per individual. In two studies, BSFT was adapted to participants' needs as suggested in the BSFT manual.

Multiple time points

Two of the included studies report at the time point coinciding with the termination of treatment (Santisteban et al., 2003; Valdez & Cepeda, 2008). Robbins et al. (2011a) reports follow-up at 4, 8, and 12 months post baseline. We used the 8 months post baseline follow-up in Robbins et al., (2011) as equivalent to the end of treatment time points for Santisteban et al. (2003) and Valdez & Cepeda, (2008). The motivation for this choice is the fact that this would be close to termination for the majority of participants in Robbins et al., (2011). There is no indication in Robbins that the prolonged duration of treatment included more sessions than originally planned. Furthermore, choosing the 4 month post baseline time point would mean analyzing incomplete treatments for the majority of participants. We decided that the interventions were comparable at the end of treatment for Santisteban et al. (2003) and Valdez & Cepeda (2008) and at 8 months post baseline for Robbins et al., (2011).

Multiple intervention groups

We did not find any studies with multiple intervention groups.

Cluster randomized trials

No cluster randomized trials were included in the review.

3.4.6 Dealing with missing data and incomplete data

The reviewers have assessed missing data and recorded attrition rates for the three included studies. None of the included studies reported any reasons for attrition, however. The reviewers contacted study authors for further details on missing data in November 2011.

Intention to treat analysis

None of the included studies used ITT methods which could be used in the metaanalysis.

3.4.7 Assessment of heterogeneity

Heterogeneity among primary outcome studies was assessed with Chi-squared (Q) test, and the I-squared, and τ -squared statistics (Higgins, Thompson, Deeks, & Altman, 2003).

3.4.8 Assessment of publication bias

Reporting bias refers to both publication bias and selective reporting of outcome data and results. Selective reporting was dealt with in the risk of bias assessment and any concerns reported in section 4.3.6.

As the opportunities for meta-analysis were few within this review, our plans for funnel plots and related methods were not feasible.

3.5 DATA SYNTHESIS

None of the included studies were coded at 5 on the Risk of Bias 5 point scale (described in section 3.4.3), and all three studies are included in the data synthesis where possible. We did not find any studies comparing BSFT to no treatment or to untreated wait list controls and we could not therefore draw any conclusions on the absolute effects of BSFT. The analysis of the relative effects of BSFT (versus other interventions) was conducted on studies that compared BSFT to other interventions and/or to treatment as usual (TAU). We were able to group time points at the end of treatment, as described in section 3.4.5.

We pooled results from primary studies based on outcomes and performed metaanalysis. All analyses were inverse variance weighted using random effects statistical models that incorporated both the sampling variance and between-study variance components into the study level weights. Random effects weighted mean effect sizes were calculated using 95 percent confidence intervals.

A random effects model was chosen to represent the overall effect as we expected the studies to deal with diverse populations of participants. We have reported the 95 percent confidence intervals and provided a graphical display (forest plot) of effect sizes in section 4.4.

3.5.1 Moderator analysis/subgroup analysis and investigation of heterogeneity

We did not identify enough studies to conduct any subgroup analysis.

3.5.2 Sensitivity analysis

There were too few studies to conduct sensitivity analysis.

4 Results

4.1 RESULTS OF THE SEARCH

We ran the main searches in June 2011.

We searched 14 international and Nordic bibliographic databases, performed an extensive search for grey literature, and hand searched five core journals in October 2011 (see section 3.3 for more information).

The total number of potential relevant records was 2100, after excluding duplicates from the database search (database: 265, grey: 1165, hand search and other: 670).

The balance between the search results from the different resources is somewhat different from other reviews. The approved strategy used in the bibliographic databases was simple, precise and focused in order to locate studies with BSFT, resulting in a relatively low number of records. In comparison, the numbers of results from the grey literature search and from the hand search appear relatively high.

All 2100 records were screened based on title and abstract and 58 records were retrieved and screened in full text. Of these, 52 did not fulfill the screening criteria and were excluded. One paper which was identified through contact with the study author (snowball search) was included.

Six papers met the inclusion criteria and were data-extracted by the review's authors. Two studies which had been data-extracted were later excluded due to irrelevant focus of the studies.

A total of three unique studies, reported in four papers, were included in the review. See section 10 for further details on included and excluded studies.

4.2 DESCRIPTION OF THE STUDIES

4.2.1 Included studies

Three studies met our inclusion criteria:

One study is an RCT on the effects of BSFT on drug-using youths aged 13-17, performed at eight sites across the US. The study is reported in two articles: Robbins et al. (2011a) summarized the trial and reported on outcomes related to drug use and family functioning and was published in the Journal of Consulting and Clinical Psychology in December 2011, whereas Horigian et al. (2010) investigated and reported adverse effects of the Robbins et al. (2011a) trial and was published in Clinical Trials, July 2010. In the following description, we will refer to this first trial as Robbins et al. (2011a), unless specific results regarding the paper by Horigian et al. (2010) are mentioned, in which case we will cite Horigian et al. (2010).

The second included study is Santisteban et al. (2003), which is an RCT on the effects of BSFT on drug-using Hispanic youths aged 12-18, performed in Miami, Florida. Santisteban et al. (2003) reports on the second phase of a two-phase study. The first phase included a pretreatment activity, where participants received an engagement intervention (Santisteban et al. 1996). The current study was published in the Journal of Family Psychology in March 2003.

The third study (Valdez & Cepeda, 2008) is an RCT on the effects of BSFT adapted to Mexican-American drug-using and gang-affiliated youths aged 12-17, performed in San Antonio, Texas. This study was presented to the American Sociological Association in Boston, MA, on August 2008.

In the following, we will refer to the second and third included studies as Santisteban et al. (2003) and Valdez & Cepeda (2008) respectively.

Location

All studies were performed in the US. Robbins et al. (2011a) took place at multiple community treatment facilities: Tucson, Arizona; Cincinnati, Ohio; Miami, Florida; Jacksonville, Florida; Bayamon, Puerto Rico; Salisbury, North Carolina; Tarzana, California and Denver, Colorado. Santisteban et al. (2003) was performed at the Spanish Family Guidance Center, Miami, Florida. Valdez & Cepeda (2008) was performed in collaboration between the Office of Drug and Social Policy Research, University of Houston and a community-based treatment center in San Antonio, Texas.

Design

All included studies were described by the investigators as RCTs. Robbins et al. (2011a) and Valdez & Cepeda (2008) were randomized by family. Santisteban et al. (2003) did not report a unit of randomization (awaiting author's response). All three studies were two armed studies (Robbins et al., 2011; Santisteban et al., 2003; Valdez & Cepeda, 2008).

Sample size

Robbins et al. (2011a) randomized 480 participants. Santisteban et al. (2003) randomized 126 participants. Valdez & Cepeda (2008) randomized 200 participants. These numbers reflect the sample sizes at the point of randomization (not at recruitment or completion).

Participants

Participants in the included studies were aged between 12 and 18 years. The majority of participants included within the review were males, ranging from 59 to 78 percent of the study population. Family composition for participants in Robbins et al. (2011a) and; Valdez & Cepeda, (2008) was 47 percent and 58 percent single parent households respectively, and was 70% two parent households in Santisteban et al. (2003). Participants were mainly Hispanic. The main drug used by participants across all studies was cannabis.

	Robbins et al. (2011a)	Santisteban et al. (2003)	Valdez & Cepeda (2008)
Age range (Mean)	13-17 (15.5)	12-18 (15.6)	12-17 (15)
Gender, males	78%	75%	59%
Family composition, single parent households	47%	-	58%
Family composition, two parent households	-	70%	-
Ethnicity, White	31%		
Ethnicity, Hispanic	44%	100%	100%
Ethnicity, Black	23%	-	-
Ethnicity, Other	2%	-	-
Main drug used	Cannabis	Cannabis	Cannabis

Table 4.2.1 Participant characteristics

Inclusion criteria in included studies

Inclusion criteria in Robbins et al. (2011a) were that participants needed to be age 13-17, and have self-reported use of illicit drugs or be referred from an institution (e.g. detention, residential treatment) for drug use treatment. Participants also had to be living with a family (defined to include any parental/adult guardian, except foster) in the geographical area of the treatment facility.

Inclusion criteria in Santisteban et al. (2003) were that participants needed to be self-referred or referred by a school counselor and be exposed to parental or school complaints of externalizing behavior problems (e.g. drug use, violent or disruptive behavior, trouble with police). Whereas the inclusion criteria in Santisteban et al. (2003) imply that the study did not exclusively recruit participants with a significant drug use problem, the report on the first phase of this study regarding engagement enhancement by; Santisteban et al. (1996) described the participants as "... [eds.] "Hispanic families of adolescents who were suspected of, or at risk for, drug abuse. These adolescents were identified using a revised version of the Drug Abuse Syndrome Check List" (Santisteban et al. 1996, p. 36). We chose to include the study based on this information.

Inclusion criteria in Valdez & Cepeda (2008) were that participants needed to be Mexican American adolescents between the ages 12 - 17 who had used one or more illicit substances or alcohol during the month prior to assessment, or who had used illicit substances or alcohol on at least six occasions in the past year. Participants had to be gang-affiliated and not already undergoing treatment. The inclusion criteria in Valdez & Cepeda (2008) make it difficult to assess the proportion of participants with significant drug use problem. However, data from the youths' selfreported alcohol and/or drug use (past 30 days) reveals that 55 percent had consumed alcohol, and 77 percent had consumed marihuana. We chose to include the study based on this data.

Exclusion criteria

Robbins et al. (2011a) excluded adolescents with current (at time of recruitment) or pending severe criminal offences that would likely result in incarceration in order to ensure availability for follow-up interviews. Santisteban et al. (2003) did not report any exclusion criteria. In Valdez & Cepeda (2008) exclusion criteria were: chronic illness, developmental delay, parents in residential treatment for psychiatric or substance abuse disorders, youths diagnosed to be in active phase psychosis, and youths who were wards of the court.

Experimental interventions in included studies

In Robbins et al. (2011a) participants were allocated to manual-based BSFT, and for some families, booster sessions were added within the BSFT program. The booster sessions were given based on an assessment and addressed other systems either as content within the planned BSFT sessions or as extra sessions (e.g. parents were coached on how to communicate with school personnel or probation officers). Participation in generally available agency-based ancillary services (such as case management or AA) was permitted with 97 percent of sessions classified as family therapy. The BSFT sessions included the youth in question and one family member in 22 percent of sessions, two family members in 24 percent of sessions, and three or more family members in 54 percent of sessions. Duration of therapy was planned to be 12-16 weekly, one-hour sessions over 4 months; however, treatment lasted much
longer than expected. Data on the mean number of sessions were not available, although the median month of last treatment session for those participants who remained in treatment was the eighth month.

Santisteban et al. (2003) allocated participants to manual-based BSFT for experimental intervention although some participants had been exposed to engagement enhancement interventions in an earlier stage of the study (Santisteban et al., 1996). In Santisteban et al. (2003), all family members who lived in the household or were significantly involved in child rearing were asked to participate in the therapy, although detailed information on therapy participants was not provided. Duration of BSFT treatment in Santisteban et al. (2003) was 4-20 weekly, one-hour sessions of therapy; the mean number of sessions was 11.2 (SD 3.8).

Valdez & Cepeda (2008) allocated participants to manual-based BSFT adapted to the specific needs of the included population (gang-affiliated Mexican-American youths), with education on sexually transmitted disease/HIV reduction and gang enhancement added to the intervention. Detailed information on therapy participants was not provided, although it seems likely that only one parent or family caregiver participated in the treatment, and that siblings or other family members were not included. Data on the mean number of sessions were not available, although therapy duration was reported as 8-16 weekly sessions.

Control conditions for included studies

The control condition in Robbins et al. (2011a) is TAU, which was the standard agency service provided at the included facilities. TAU in Community Treatment Programs included individual and/or group therapy, parent training groups, non-manual family therapy, and case management. Participation in generally available agency-based ancillary sessions (such as case-management or AA) was typical. Booster sessions were a common aspect of clinical practice. To allow both BSFT and TAU to be approximately parallel in sessions allowed, both conditions permitted booster sessions. During the study, 6 percent (i.e. 32 in total, distributed as 17 in BSFT; 15 in TAU) of young people/families received a booster session. The study was designed to ensure that participants in TAU received at least as many sessions as participants in BSFT. All agencies were expected to provide at least 12-16 scheduled sessions over three to four months. However, treatment lasted much longer than expected. The median month of last treatment session for those participants who retained in treatment was the eighth month.

In Santisteban et al. (2003) the control condition is group treatment, which was a participatory learning group for young people only. The participatory learning groups consisted of four to eight young people. The sessions were led by a facilitator and the young people were encouraged to discuss and solve problems amongst themselves. The number of sessions received by any given group participant ranged between 6 and 16 weekly sessions (M= 8.8, SD= 2.6)

The control condition in Valdez & Cepeda (2008) is described as minimum contact, although some participants received 12-step intervention. The condition is not described further in the paper, and the small amount of information provided raises concerns as to whether the control condition is a no treatment or an alternative treatment. We have chosen to categorize the intervention as an alternative intervention, due to the fact that at least a proportion of the young people in the control group received 12-step intervention. Information regarding the control condition has been requested from the study author; unfortunately we have yet to receive a response.

Time points for measurements

Robbins et al. (2011a) provided assessments at baseline, and at 4, 8, and 12 months post randomization. The median length of treatment in BSFT and the control condition was 8 months, and 15 percent of youths were still enrolled in treatment at 12-months post randomization. Santisteban et al. (2003) reported measurements at baseline and at end-of-treatment. Valdez & Cepeda (2008) provided measurements at baseline and end-of-treatment. Valdez & Cepeda (2008) and Santisteban et al. (2003) did not report any details of the timing of the end-of-treatment measurements. Furthermore, Valdez & Cepeda (2008) planned a follow-up measurement at six months, but did not report the results from this measurement.

Table	4.2.2	Duration	of treatment	(BSFT	and	control	conditions)	and
time p	oints	for measu	rement					

	BSFT duration (months)	Control condition duration (months)	Time points for measurement (months post baseline)
Robbins et al. (2011a) & Horigian et al. (2010)	Average 8 (planned 4)	Average 8 (planned 3- 4)	4, 8, 12
Santisteban et al. (2003)	2-6	2-4	Treatment termination
Valdez & Cepeda (2008)	2-4	NR	Treatment exit

Primary outcome

Youth drug use

Abstinence or reduction of drug use was measured by drug use frequency.

Robbins et al. (2011a) administered the Timeline Follow-back (TLFB) which measures self-reported drug use, and a decrease in the number of days using drugs indicates a reduction in drug use. Robbins et al. also administered urine drug screens immediately prior to all monthly TLFB assessments using SureStep Drug Screen Card 10A and urine cups, and administered the Diagnostic Interview Schedule for Children to diagnose drug abuse or dependence.

Santisteban et al. (2008) used an interview-based measure of drug use, the Addiction Severity Index (ASI), to assess use of alcohol and marijuana and concurrent psychopathology. In ASI, items measure the number of days using a variety of drugs during the month prior to assessment. A decrease in the number of days using drugs again indicates a reduction in drug use. Santisteban et al. (2003) additionally used urine drug screens to substantiate self-reported marihuana use.

Valdez & Cepeda (2008) used the SAMSHA Center for Substance Abuse Treatment (CSAT) Government Performance and Results Act (GPRA) measure to assess change in drug use, based on interviews revealing days of drug use during the 30 days prior to assessment. The CSAT-GPRA incorporates self-reported items that have been selected from widely used data collection instruments (e.g., the Addiction Severity Index). Outcome measures include substance use, criminal activity, mental and physical health, family and living conditions, education/employment status, and social connectedness.

Secondary outcomes

Family functioning

Family functioning was measured using the cohesion and conflict scales from the Family Environment Scale (FES) in Robbins et al. (2011a) and Santisteban et al. (2003). The cohesion scale measured the extent to which the parent or youth viewed the family as harmonious and close. Increased ratings on the cohesion scale indicate better family functioning. The conflict scale measured the extent to which the youth or parent viewed the family as characterized by frequent quarrels and disagreements. An increased rating on the conflict scale indicates poorer family functioning. Additionally, Robbins et al. (2011a) used the Parenting Practices Questionnaire (PPQ) to measure parenting practices. PPQ is an inventory of four factors, indicating: 1) positive parenting, e.g. rewards and encouraging appropriate behavior, 2) discipline effectiveness, 3) avoidance of discipline, and 4) monitoring. In PPQ higher scores indicate better parenting.

Santisteban et al. (2003) used Structural Family Systems Rating (SFSR) to measure the family's organizational system and flow of communication; the family's closeness, distance and boundaries between family members; the age appropriateness of family members' behavior; the extent to which a single family member, usually the youth, is labeled as the family's "problem"; and the degree to which the family is able to communicate, discuss, and resolve differences of opinion. In SFSR higher scores indicate better family functioning. Valdez & Cepeda (2008) used the Family Adaptability and Cohesion Evaluation Scale (FACES) to measure family functioning. FACES contain three scales: cohesion, adaptability, and social desirability.

Education or vocational involvement

No study reported educational or vocational outcomes.

Treatment retention

Treatment retention was reported as failure to remain in treatment in Robbins et al. (2011a), and as drop-out rates in Santisteban et al. (2003). Valdez & Cepeda (2008) did not report the rate of treatment retention.

Risk Behavior

Robbins et al. (2011a) did not report risk behavior, although this was reported by Horigian et al. (2010) as measured by a series of undesirable events, including arrests, absconding, being thrown out of the home, school suspension and violence. A greater number of events indicates a poorer outcome.

Santisteban et al. (2003) reported the Socialized Aggression subscale from the Revised Behavior Problem Checklist (RBPC), assessing the degree to which parents report youth delinquency in the company of peers. An increased score on the Socialized Aggression scale of RBPC indicates more delinquent activity.

Other adverse effects

Horigian et al. (2010) reported suicidal behavior, homicidal behavior, hospitalization for psychiatric or drug-related reasons and death as serious adverse effects.

General description of included studies

Overall, the included studies vary on a number of core items. The participants were all young people, mainly suffering a number of behavioral problems in addition to their drug use. There is a contrast between participants in Robbins et al. (2011a) where youth with pending criminal offences were excluded, and in Valdez & Cepeda (2008) where all participants were gang affiliated.

Interventions given to participants were all variations of BSFT. Robbins et al. (2011a) adapted BSFT by giving booster sessions to some families. Santisteban et al. (2003) had given some participants engagement enhancement treatment in an earlier stage of the study. Valdez & Cepeda (2008) adapted BSFT to gang-affiliated youth, and gave extra education within sessions or as added sessions. In each case, the control condition was a less structured intervention than the BSFT model implemented in the experimental condition, and for Valdez & Cepeda (2008) the control condition was minimum contact.

Time points for measurements varied across studies. Robbins et al. (2011a) does not define the end of treatment and reported measurements at 4, 8, and 12 months post randomization. Santisteban et al. (2003) reported at the end-of-treatment without specification of the timing, and with no follow-up. Valdez & Cepeda (2008) provided baseline and end-of-treatment measures without specification of the timing. A planned 6 months follow-up was not reported.

For further details on included studies, see section 10.1: Characteristics of included studies.

4.2.2 Excluded studies

Many studies which initially appeared (by title or abstract) to be eligible did not ultimately meet our inclusion criteria. Some studies were excluded for more than one reason. Primary reasons for exclusion are listed below.

Not a primary study of a BSFT intervention

Sixteen studies were excluded for not being primary studies of a BSFT intervention (Blecha et al., 2010; Briones et al., 2008: Cannon & Levy, 2008; Eisenberg & Wahrman, 1991; Feaster et al., 2010; Fischer, 2007; Hervis et al., 2009; Prado et al., 2008; Richeport-Haley, 1998; Robbins et al., 2002b; Robbins et al., 2003; Robbins et al., 2007; Santisteban et al., 2006 and Shachar et al., 2004; Szapocznik et al., 1991 and Szapocznik et al., 2002).

Descriptive reviews

Four studies were excluded because they were descriptive reviews (Austin et al., 2005; Szapocznik & Williams, 2000; Szapocznik et al., 2006 and Thompson et al., 2005).

Focus of the study

Two studies which were initially data extracted were later excluded due to irrelevant focus in the studies. One of the two studies (Coatsworth et al., 2001), focused on the difference in clinical profiles of engaged versus non-engaged cases and retained versus non-retained cases. The participants were not in treatment for drug use but for conduct disorder and anxiety withdrawals. The second of the two studies (Szapocnik et al. 1988) focused on testing the idea that the same systemic and structural principles that apply to treatment also apply to the family's resistance to engagement. The intervention was intended to overcome resistance to treatment. Another study not selected for data extraction (Robbins et al., 2008) focused on the family-therapist alliance. Robbins et al., (2011b) was excluded because focus was on therapist adherence to the BSFT treatment model, and Szapocznik et al., (1986) was excluded because focus was on a comparison between conjoint and one-person family therapy. Santisteban et al., (1997) was excluded for having a behavioral focus.

Other reasons for exclusion

Child Trends (2009) was not a primary study, but a program description; Feaster et al., (2004) was excluded because it included inpatient treatment; Szapocznik et al., (2004) was a protocol describing the trial implementation phase; Robbins (2009a) was a protocol for the included Robbins (2011) study; results from the trial were reported in Robbins (2011); Robbins et al., (2002a) was a descriptive study.

For further details on excluded studies, please see section 10.2: Characteristics of excluded studies.

4.2.3 Studies awaiting classification

Jungkuntz (2007) is a dissertation which proposes an approach to the treatment of comorbid youths, and which incorporates three strategies for engaging this population (Brief Strategic Family Therapy, Multiple Family Group Therapy, and Cognitive Behavioral/Motivational Enhancement Therapy) combined into one multimodal program. We are still awaiting access to this dissertation.

4.3 RISK OF BIAS IN INCLUDED STUDIES

Our judgments on risk of bias varied between the three studies. Robbins (2011) is a robust RCT judged as low risk of bias on all assessed items. Santisteban et al. (2003) is an RCT with some uncertainty regarding core risk of bias items (e.g. method of randomization and allocation concealment). Valdez & Cepeda (2008) is an RCT with many uncertainties regarding the core risk of bias items (e.g. sequence generation, allocation concealment, and blinding) and some obvious deficiencies (e.g. selective reporting).

The ratings of each study in relation to the nine domains in the Risk of Bias tool are listed below (see also Risk of Bias tables in section 10.4 and 10.5). The risk of bias judgments are based on pre-specified questions and a 5 point scale with ratings of 1=low risk and 5=high risk (see section 11.3: Risk of Bias tools).

Study authors have been contacted for details on any uncertainties in relation to risk of bias assessment items. Unfortunately we have not received any response from investigators.

Further details on risk of bias are provided in section 10.5: Risk of bias for individual included studies.

4.3.1 Sequence generation

All studies were described by investigators as randomized, and two of the three studies reported that they were randomized on a family level (Robbins 2011; Santisteban et al., 2003). Robbins (2011) reported the procedure for randomization and was judged as having a low risk of bias for sequence generation. Santisteban et al. (2003) and Valdez & Cepeda (2008) did not report the randomization procedure, and were therefore judged as having an unclear risk of bias for sequence generation.

4.3.2 Allocation concealment

Only Robbins (2011) reported procedure for allocation concealment, and was judged as having a low risk of allocation concealment bias. Santisteban et al. (2003) and Valdez & Cepeda (2008) did not report how allocation was handled, and both were therefore judged as having unclear risks of allocation concealment bias.

4.3.3 Confounders

This item is only relevant for non-randomized studies and consequently was not judged.

4.3.4 Blinding

As is common in social intervention, especially when outcomes are self-reported, there is inherent bias given the impossibility of blinding participants or those delivering the interventions. We rated Robbins (2011) with a bias of 1 on the 5 point scale as this study reported blinding procedures. The TLFB was administered by research assistants who were blind to the treatment condition. Research assistants were requested to indicate if the blind was broken at each of the 12 follow-up assessments. Only in 1.2 percent of participants did research assistants note that the blind was broken (Robbins 2011). Santisteban et al. (2003) was rated 2 on the 5-point scale, as this study reported that data were collected in a standardized manner by trained associates. Valdez & Cepeda (2008) was rated unclear for blinding due to a lack of reporting of data collection and blinding procedures.

4.3.5 Incomplete outcome data

Dropout rates were reported in Robbins (2011) and Santisteban et al. (2003), and both studies performed analysis for any imbalance in attrition. Robbins (2011) and Santisteban et al. (2003) were rated 1 for attrition bias. Valdez & Cepeda (2008) did not report treatment retention or analysis of attrition imbalance, and is rated unclear for attrition bias.

4.3.6 Selective reporting

The original trial protocol was available for Robbins (2011), and data for all planned outcomes has either been reported or are under publication and the study was rated 1 for selective reporting bias. Data for all reasonable outcomes has been reported in

Santisteban et al. (2003), and the study was rated 1 for selective reporting bias. Valdez & Cepeda (2008) failed to report a planned 6 month follow-up assessment, and was therefore rated 4 for selective reporting bias.

4.3.7 Other potential sources of bias

As previously noted, Santisteban et al. (2003) reported on the second phase of a two-phased study with a possible risk of carry-over effect from the pretreatment activity conducted in the first phase, where participants received an engagement intervention. Therefore, Santisteban et al. (2003) was rated unclear for other potential sources of bias.

4.3.8 A priori protocol

Explicitly stating a priori hypotheses and methods without prior knowledge of results minimizes bias. Only Robbins (2011) stated that an a priori protocol had been complied with. Santisteban et al. (2003) and Valdez & Cepeda (2008) did not report whether an a priori protocol was produced and if so, whether it was followed.

4.3.9 A priori analysis plan

Only Robbins (2011) stated it had complied with an a priori analysis. Santisteban et al. (2003) and Valdez & Cepeda (2008) did not report whether an a priori analysis plan was produced and, if so, whether it was followed.

4.4 EFFECTS OF THE INTERVENTIONS

In the protocol for this review the following comparisons/analysis were planned:

- *Absolute effects,* comparing BSFT to no treatment and untreated waitlist controls
- *Relative effects*, comparing BSFT to other interventions and/or treatment as usual (TAU)

The experimental interventions given to participants are all manual-based BSFT. However, Robbins (2011) adapted BSFT by providing booster sessions for some participants, while Valdez & Cepeda (2008) adapted BSFT to gang-affiliated Mexican American youths by including a gang dimension component and educational enhancement with sessions on STD/HIV reduction, as described in section 4.2.1 under "Experimental interventions in included studies". We are unable to comment on the absolute effects of BSFT since the available comparisons were all against other interventions.

Meta-analysis was not feasible for risk behavior outcomes, due to differences in outcome measures. Education and vocational involvement was not reported in any of the included studies and adverse effects were reported in one study only.

The outcomes were reported at varying time points. We grouped the outcomes at end of treatment, estimating the eighth month outcome measure time point in Robbins (2011) to be equivalent to the end of treatment outcome measure time points in Santisteban et al. (2003) and Valdez & Cepeda (2008). The end of treatment measure in Robbins (2011) was originally planned to be at four months post randomization. However, treatment duration in Robbins (2011) was prolonged and the median month for end of treatment for those who remained in treatment was the eighth month

4.4.1 Primary outcome results

Drug use reduction is measured by drug use frequency. The three studies provided data that enabled calculation of effect estimates on drug use frequency at the end of treatment. Robbins (2011) reported no significant effect of BSFT on drug use frequency. Santisteban et al. (2003) and Valdez & Cepeda (2008) reported results that indicate a positive effect of BSFT on drug use frequency Robbins reported the TLFB data on drug use frequency as medians at the 25th and 75th percentiles which could not be transformed to allow generation of a SMD and used in the meta-analysis. However, Robbins did report percentage of positive urine drug screens, which has been transformed as described in section 3.4.4.

The meta-analysis was performed based on drug use frequency measured as positive urine drug screens from Robbins (2011), ASI from Santisteban et al. (2003) and CSAT GPRA from Valdez & Cepeda (2008). Pooled results do not reveal a statistically significant effect of BSFT on drug use frequency. The pooled estimate SMD is -0.04 (95% CI -0.37, 0.30) with statistically significant heterogeneity between studies (p=0.06). In conclusion, the meta-analysis shows no statistically significant effect of BSFT for drug use frequency compared to community treatment programs, group treatment, and minimum contact comparison.

Figure 4.4.1 Drug use frequency, forest plot

Study or Subgroup	Std. Mean Difference	SE	Experimental Total	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI	Std. Mean Difference IV, Random, 95% Cl
Robbins 2011. Community	-0.26	0.15	144	140	37.3%	-0.26 [-0.55, 0.03]	
Santisteban 2003. Group	-0.11	0.23	56	29	26.8%	-0.11 [-0.56, 0.34]	
Valdez 2008. Min. contact	0.25	0.16	70	81	35.9%	0.25 [-0.06, 0.56]	+
Total (95% CI)			270	250	100.0%	-0.04 [-0.37, 0.30]	-
Heterogeneity: Tau ² = 0.05; Chi ² = 5.53, df = 2 (P = 0.06); l ² = 6 Test for overall effect: $Z = 0.22$ (P = 0.83)		= 64%				-1 -0.5 0 0.5 1 Favours control Favours BSFT	

4.4.2 Secondary outcomes

Family functioning

Three studies provided data on family functioning as reported by parents, and two studies report family functioning as reported by the young drug users.

Robbins (2011) and Santisteban et al. (2003) reported improved family functioning, indicating a positive effect of BSFT on family functioning. No significant effect on family functioning was found in Valdez & Cepeda (2008). Meta-analysis of parent-reported family functioning is performed on the composite family functioning outcome in Robbins (2011), the FES cohesion scale in Santisteban et al. (2003), and the family adaptability and cohesion evaluation scale in Valdez & Cepeda (2008). Pooled results show no statistically significant effects of BSFT on family functioning reported by parents, SMD= 0.06 (95% CI -0.13, 0.25), with no statistically significant heterogeneity between studies (p= 0.29).

Figure 4.4.2 Family functioning, parent report, forest plot

	Exp	eriment	tal	0	Control			Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Robbins 2011. Community	0.31	0.96	169	0.25	0.97	164	54.1%	0.06 [-0.15, 0.28]	— — —
Santisteban 2003. Group	5.46	2.3	56	4.67	2.3	29	16.4%	0.34 [-0.11, 0.79]	
Valdez 2008. Min. contact	52.94	9.292	69	53.91	9.742	81	29.5%	-0.10 [-0.42, 0.22]	
Total (95% CI)			294			274	100.0%	0.06 [-0.13, 0.25]	+
Heterogeneity: Tau ² = 0.01; Chi ² = 2.45, df = 2 (P = 0. Test for overall effect: Z = 0.61 (P = 0.54)			.29); I² =	= 18%				-1 -0.5 0 0.5 1 Favours control Favours BSFT	

Meta-analysis of youth reported family functioning is performed on the composite family functioning outcome in Robbins (2011), and the FES cohesion scale in Santisteban et al. (2003). Pooled results show no statistically significant effects of BSFT on family functioning reported by youth SMD= 0.16 (95% CI -0.19, 0.51), with no statistically significant heterogeneity between studies (p= 0.15).

Figure 4.4.3 Family functioning, youth report, forest plot



In conclusion, the meta-analysis shows no statistically significant effect of BSFT on family functioning reported by parents or youth compared to community treatment programs, group treatment, and minimum contact comparison.

Education or vocational involvement

No study reported this outcome.

Treatment retention

Robbins (2011) and Santisteban et al. (2003) reported data that enabled calculation of effect estimates on treatment retention. Robbins (2011) reported lower levels of failure to remain in BSFT. Santisteban et al. (2003) did not reveal any significant difference between conditions. Pooled results show a statistically significant effect of BSFT for treatment retention, OR = 1.83 (95% CI 1.32, 2.54), with no statistically significant heterogeneity between studies (p= 0.41). In summary, the meta-analysis shows a statistically significant effect of BSFT for treatment programs, group treatment, and minimum contact comparison.

BSFT Control Odds Ratio Odds Ratio Study or Subgroup Events Total Events Total Weight IV, Random, 95% CI IV, Random, 95% CI Robbins 2011. Community 147 245 102 235 81.7% 1.96 [1.36, 2.81] Santisteban 2003. Group 1.37 [0.64, 2.94] 56 80 29 46 18.3% Total (95% CI) 281 100.0% 1.83 [1.32, 2.54] 325 Total events 203 131 Heterogeneity: Tau² = 0.00; Chi² = 0.68, df = 1 (P = 0.41); l² = 0% 0.2 0.5 Ż 5 Test for overall effect: Z = 3.61 (P = 0.0003) Favours control Favours BSFT

Figure 4.4.4 Treatment retention, forest plot

Risk behavior

Meta-analysis was not feasible for risk behavior due to differences in outcome measures collected in the individual studies. Horigian et al. (2010) did not report significant effects on risk behavior. Santisteban et al. (2003) used the socialized aggression scale of RBPC, and reported that youth in BSFT intervention showed greater reduction in peer-based delinquency. The random effects standardized mean difference at end of treatment was -0.27 (95% CI -0.72, 0.18).

Other adverse effects

Only Horigian et al. (2010) reported adverse effects, noting that more than 50 percent of the youths in the study experienced risk behavior or other adverse events during the trial. The most common adverse event experienced by the youths was arrest, followed by suspension/dropout from school and absconding from home. However, the distribution of events in BSFT and control conditions does not indicate clear differences between BSFT and control environments.

5 Discussion

5.1 SUMMARY OF THE MAIN RESULTS

Our main objective was to evaluate the current evidence on the effect of BSFT on drug use reduction for young people in treatment for non-opioid drug use. To summarize, we found the following results:

Abstinence or reduction of drug use

Meta-analysis of data from the three included studies (Robbins 2011, Santisteban et al., 2003, Valdez & Cepeda 2008) does not show a statistically significant relative effect of BSFT for reduction of youth drug use frequency at the end of treatment. The available data do not therefore support the hypothesis that there is a drug use reduction effect from using BSFT with young drug users compared to community treatment programs, group treatment, and minimum contact comparison¹⁶.

Family functioning

Meta-analysis of the three included studies (Robbins 2011, Santisteban et al., 2003, Valdez & Cepeda 2008) does not show a statistically significant effect for BSFT on family functioning reported by parents at the end of treatment compared to community treatment programs, group treatment, and minimum contact comparison¹⁶. Meta-analysis of the effects of BSFT on family functioning reported by youths at the end of treatment in two studies (Robbins 2011, Santisteban et al., 2003) did not show any statistically significant effect for BSFT compared to community treatment programs, group treatment, and minimum contact comparison¹⁶.

Treatment retention

Two studies (Robbins 2011, Santisteban et al., 2003) reported on treatment retention. Here meta-analysis favors BSFT for treatment retention of participants. The comparisons for the two studies were treatment as usual (TAU), which was the standard agency service provided at the included facilities (Robbins 2011), and group treatment, which was a participatory learning group for young people only (Santisteban et al. 2003). Treatment retention may be positively affected by

¹⁶ Control conditions in the included studies include: individual and group therapy, parent training groups, non-manualized family therapy, case management, participatory learning group intervention, minimum contact group, and 12-step program.

structured BSFT treatment compared to community treatment programs, group treatment, and minimum contact comparison¹⁷. These results should be interpreted with great caution due to the very limited number of studies.

Opportunities for meta-analysis were limited for risk behavior due to differences in outcome measures in the included studies. Horigian et al. (2010) did not report significant effects on risk behavior. Santisteban et al. (2003) used the socialized aggression scale of RBPC, and reported that youth in BSFT intervention showed greater reduction in peer-based delinquency. The random effects standardized mean difference at end of treatment was -0.27 (95% CI -0.72, 0.18).

Only Horigian et al. (2010) reported on adverse effects, noting that more than 50 percent of the youths included in the study experienced risk behavior or other adverse events during the trial. The most common adverse event was arrest, followed by suspension from/ dropping out of school and absconding from home. However, the distribution of events in BSFT and control conditions does not indicate clear differences between BSFT and control environments.

No studies reported on education or vocational involvement. In addition, it was not possible to assess the second review objective concerned with moderators of drug use reduction effects, and whether BSFT works better for particular types of participants.

We found that the methodological rigor and the adequacy of reporting in the included studies were generally insufficient to allow confident assessment of the effects of BSFT for young drug users. Two of the three included studies did not provide adequate information on core issues to allow us to assess the risk of bias (e.g. methods of sequence generation, allocation concealment, and completeness of outcome data). This methodological weakness makes us question the validity of the two studies.

In short, the primary result of this review is that there is currently insufficient good quality evidence for conclusions to be drawn. The small number of available studies, and design deficiencies for two of the most relevant studies, preclude any conclusions concerning effectiveness, ineffectiveness or potential damage of BSFT for young people in treatment for non-opioid drug use.

¹⁷ Control conditions in the included studies include: individual and group therapy, parent training groups, non-manualized family therapy, case management, participatory learning group intervention, minimum contact group, and 12-step program.

5.2 OVERALL COMPLETENESS AND APPLICABILITY OF EVIDENCE

We found very few trials that examined whether BSFT reduced youth drug use, and the included studies implemented different adaptations of BSFT on different populations. All studies were performed in the US, and all lacked post intervention follow-up which would have allowed for documentation of accumulated or longerterm effects. There is therefore the possibility that follow-up time was not long enough to detect significant changes.

5.3 QUALITY OF THE EVIDENCE

The review found that the methodological rigor and the adequacy of reporting in the included studies were generally insufficient to allow confident assessment of the effects of BSFT for young drug users. Two of the three included studies did not provided adequate information on core issues to allow us to assess the risk of bias (e.g. methods of sequence generation, allocation concealment, and completeness of outcome data), despite genuine efforts to contact authors. This methodological weakness makes us question the validity of the two studies.

5.4 POTENTIAL BIASES/LIMITATIONS IN THE REVIEW PROCESS

The narrow search strategy performed in this review may limit the likelihood of identifying all relevant studies. However, we attempted to minimize the risk of missing relevant studies by conducting an extensive search for grey literature, by extensive hand searching and by contacting international experts within the field of BSFT. Indeed, the large number of grey literature and hand searched literature that has been assessed for relevance attests to this effort.

5.5 AGREEMENTS AND DISAGREEMENTS WITH OTHER REVIEWS

The identified narrative reviews (Austin et al., 2005; Briones et al., 2008; Cannon et al., 2008; Santisteban et al., 2006; Szapocznik et al., 2000; Szapocznik et al., 2006; Thompson et al., 2005) report a general pattern of positive effect of BSFT treatment for drug-using youth. Consistent with our findings, the narrative reviews also report that more research is desired.

Of the two identified quantitative reviews (Waldron & Turner, 2008; Vaughn & Howard, 2004), Vaughn & Howard (2004) includes data on BSFT from Santisteban et al. (2003) in a meta-analysis of various program modalities, and as a result classifies BSFT under the category: *"Evidence of indeterminate effect, mixed or incomplete findings"*. Waldron & Turner (2008) includes data on BSFT from

Santisteban et al. (2003) in a meta-analysis of various program modalities, and as a result classifies BSFT among other family therapy models as *"probably efficacious"*. These findings are not consistent with the findings of the current review for two main reasons: 1. the current review uses the final values in Santisteban et al. (2003) in the meta-analysis, as final values provide the best comparability across studies, whereas Santisteban et al. and the reviewers above use change scores; and 2. The current review includes two additional studies on BSFT in the meta-analysis. Consistent with our expectations, the apparent statement from the two reviews is that more research is needed, not least with regard to moderators and identification of which particular subgroups of young people may be more likely to respond to specific interventions and how treatments can be adapted or tailored to the individual needs of youth to improve drug use outcomes. These are similar issues to those we planned to assess in our review. However, the lack of empirical evidence has prevented the possibility of assessing moderators of effect and effects on subgroups.

6 Authors' Conclusion

Even though reliable conclusions about the effectiveness of BSFT are lacking, some observations are worth mentioning.

6.1 IMPLICATIONS FOR PRACTICE

The current landscape of family therapy approaches for treatment of youth drug use shows that many initiatives have been tried. A certain inconsistency seems to be developing: while existing BSFT programs have not yet been evaluated properly, new BSFT interventions continue to surface. This is not only costly, it is also risky, as initiatives backed only by unclear research could ultimately be damaging. It is therefore crucial to know more about the effectiveness of treatments to understand where money should be spent and to understand exactly what kind of support young drug users can benefit from.

6.2 IMPLICATIONS FOR RESEARCH

Firstly, it is important to address the need for more research in the field. A small body of evidence exists in relation to the treatment of young drug users, with only a very modest number of controlled evaluations of treatments for this group. Most of the few available studies of effectiveness have methodological problems, such as small sample sizes and varied methods of assessing drug use; such problems make definitive conclusions difficult, if not impossible. Well-designed, randomized controlled trials within this population are needed and should be reported clearly in accordance with the principles of the CONSORT 2010 statement.

Secondly, it is also important to consider the possibility of adverse effects of these interventions. The popular belief is that BSFT, as well as other family therapy approaches, is harmless, but there has actually been very little research made that focuses on the potential harms of such family therapy approaches.

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The review authors take full responsibility for the content of this publication.

8 Changes to the protocol

Based on editorial comments, we have deleted the secondary objective which stated: A further objective of this review is, if possible, to examine mediators of drug use reduction effects, specifically analyzing whether BSFT works better for particular types of participants. This was deleted as this objective was not obtainable at the concluding stage.

In response to feedback from editors and external peer reviewers, we now clarify that we chose to interpret the inclusion criteria for this review as relevant to studies where a significant proportion of the sample had either used or were suspected of using drugs, and the rest of the sample were at risk for drug abuse through having peers that did. The relevant studies applied different inclusion criteria and not all recruited solely on the basis of evidence of drug use, although in each case a reasonable proportion of youth had used non-opioid drugs recently.

In conducting the review, we became aware that there are a number of reasons why a young person may become enrolled in BSFT treatment for non-opioid drug use. One is that there is clear evidence of drug use, either observed or self-reported; another is that the young person is seen as at significant risk of using drugs by nature of his/her environment or peer group. Given this complexity, the fact that an individual may fall into more than one of these groups, and the inherent difficulty in determining accurately the proportion of non-opioid drug users in any sample of young people, we chose to include studies where at least 50% of participants had either used or were suspected of using drugs, and the rest of the sample were at risk for drug use through having peers that did.

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None

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10 Characteristics of studies

10.1 CHARACTERISTICS OF INCLUDED STUDIES

1 The Brief Strategic Family Therapy (BSFT) Effectiveness Study: Robbins et al. 2011a; Horigian et al. et al. 2010

Methods	Design: RCT (8 sites, 2 intervention arms) total n= 480
Participants	Age: 13-17 years (mean age 15.5).Gender: 78% male.Ethnicity: 44% Hispanic, 31% White, 23% Black, 2% other.Family status: 25% biological 2 parent, 47% biological 1 parent, 11% extended family,13% blended family, 2% adoptive, 1% foster family.Main drug of use: Cannabis.Severity: 67% met marijuana abuse (25.9%) or marijuana dependence (41.4%) criteria;approx. 20% met other drug abuse (6.7%) or other drug dependence (14.6%). 21%met either abuse or dependence criteria for both marijuana and other drugs.Comorbidity: Not reported.Inclusion criteria: Age 13-17; Self-report use of illicit drug use or be referred from aninstitution (e.g. detention, residential treatment) for drug abuse treatment; living withfamily and in geographical area of treatment facility.Exclusion criteria: Youths with current or pending severe criminal offences that wouldlikely result in incarceration were excluded. Youths living in foster family were excluded
Interventions	 <u>Intervention</u>: Manual- based BSFT. n=245. Whenever appropriate, other systems were addressed, either as content within the sessions or included in the session (e.g. parents were coached on how to communicate with school personnel or probation officers). Participation in generally available agency-based ancillary services (e.g. case management, AA, etc.) was permitted. Booster sessions were permitted because such sessions were common aspects of clinical practice (on average, the number and timing of booster sessions were not significantly different across BSFT and TAU). <u>Duration</u>: 12-16 sessions over 4 months planned. Treatment lasted much longer than expected. The median months of the last treatment session for those participants who remained in treatment was the 8th month. Weekly 1 hour sessions. 97% of sessions were classified as family therapy. BSFT sessions included the adolescent and 1 family member in 22% of sessions, 2 family members in 24% of sessions, 3 family members in 22%, 4 in 18%, and 5 in 14% of sessions. <u>Location</u>: Community treatment facilities in Tucson, Arizona; Cincinnati, Ohio; Miami, Florida; Jacksonville, Florida; Bayamon, Puerto Rico; Salisbury, North Carolina; Tarzana, California; Denver, Colorado. <u>Comparison</u>: TAU in participating community treatment programs (CTPs). n=235 TAU varies depending on the current activities at the participating CTP. TALL in CTPs

	included individual and/or group therapy, parent training groups, non-manualized family therapy, and case management. The study was designed to ensure that participants in TAU received at minimum as many sessions as participants in the BSFT condition. A prerequisite for participation was that program managers expected TAU to include at least 12-16 scheduled sessions over a 3-4 month period.
Relevant Outcomes Baseline	Primary outcomes: Youth drug use. <u>Measures</u> : Days of drug use measured by Timeline Follow-back (Sobell & Sobell, 1992) and urine drug screens. Youth drug abuse or dependence was measured by the computerized Diagnostic Interview Schedule for Children (DISC)
4mth from	Socondary outcomes: Family functioning, rick behavior, and adverse offects
8mth from BL	<u>Measures</u> : Family functioning was measured by the Parenting Practices Questionnaire and Family Environment Scale. Risk behavior was measured by arrests, number of
12mth from BL	times a youth has been kicked out of home, school suspension, and violence. Adverse effects measured by hospitalization, suicidal behavior and deaths.
Notes	

2 Santisteban et al. 2003

Methods	Design: RCT (1 site, 2 intervention arms) total n= 126					
Participants	Age: 12-18 years, 78% between ages 13 and 17. (Mean age 15.6).					
	Gender: 75% male.					
	<u>Ethnicity</u> : All Hispanic. 64 Cuban origin, 18 Nicaraguan origin, 12 Colombian origin, 8 Puerto Rican origin, 4 Peruvian origin, 2 Mexican and 18 from other Hispanic nationalities.					
	<u>Family status</u> : 70% of families were two-parent households. Head-of-household education: 36% some high school or less, 27% high school graduate, 36% some college or more. Head-of-household occupation: 24% unskilled/unemployed, 33% unskilled labor, 16% clerical/technical, 27% professional. Families had been in the US for a median of 12 years, range 2-44 years.					
	Main drug of use: Cannabis.					
	<u>Severity</u> : Drug use not required in inclusion criteria. 52% of participants reported use of either alcohol or drugs during past month. 30% of sample reporting marijuana use during the previous month, 15% reporting 5 or more days of use during the previous month.					
	<u>Comorbidity</u> : In addition to externalizing behavior problems, many participants reported a broad range of co-occurring problems such as internalizing problems (e.g. anxiety or depression).					
	Inclusion criteria: Parental or school complaints of externalizing behavior problems (e.g. violent or disruptive behavior, drug use, trouble with police). Exclusion criteria: Not reported					
Interventions	Intervention: Manual-based BSFT. n=80 All family members who lived in the household or were significantly involved in child rearing were asked to participate in the therapy. <u>Duration:</u> 4-20 weekly one hour sessions of therapy. Mean 11.2, SD 3.8 <u>Location</u> : Spanish Family Guidance Center, Miami, Florida.					
	<u>Comparison</u> : Group Control Condition (GC). n=46. Each group consisted of 4-8 adolescents. Number of sessions per group ranged between 6 and 16 weekly sessions. Mean 8.8, SD 2.6. Mean amount of treatment					

	received was 11.4 hrs. in the GC. To limit the possibility that control-condition group facilitators might intervene directly in the family system, facilitator contacts with family members were limited to one 15-min session per month.
Relevant Outcomes	Primary outcomes: Youth drug use. <u>Measures</u> : Days of drug use measured by urine drug Screens. Youth drug use or dependence was measured by the Addiction Severity Index (ASI)
Baseline Termination	<u>Secondary outcomes</u> : Family functioning. <u>Measures</u> : Structural Family Systems rating and Family Environment Scale.
Notes	Investigators were contacted for details on the group control condition, time points for baseline and end of treatment measures, allocation, reasons for excluding use of other substances in analysis, missing data, blinding, exclusion criteria, attrition and a priori protocol. Unfortunately, we have not yet received any response from study authors.

3 Valdez & Cepeda, 2008

Methods	Design: RCT (1 site, 2 intervention arms) total n=200					
Participants	Age: 12-17 years (mean age15).					
	Gender: 59% males.					
	Ethnicity: All participants were Mexican American.					
	<u>Family status</u> : 58% lived with mother only. 13% have children. Average household composition of 5.5 members. 40% of parents employed (full time or part time), 48% of parents unemployed. 64% of parents reported a household income \$0-10.000, and 25% \$10,.001-20,.000.					
	Main drug of use: Cannabis. 77% of youths had used cannabis during the previous month, 22% had used cocaine/crack, 13% heroin and 11% barbiturates.					
	Severity: Not reported.					
	<u>Comorbidity</u> : Not reported.					
	current (past month) use of one or more illicit substances or alcohol, use of illicit substances or alcohol on at least 6 occasions in the past year, not currently under treatment, and gang affiliated.					
	Exclusion criteria: Exclusion criteria were chronic illness, developmental delay, parents in residential treatment for psychiatric or substance abuse disorders, youths known to be in active phase psychosis, and youths that are wards of the court.					
Interventions	Intervention: Enhanced BSFT model adapted to include a gang dimension component and educational enhancement. n=96 Only one parent/family caregiver participated in therapy sessions. <u>Duration</u> : Weekly sessions for 8-16 weeks. <u>Location</u> : San Antonio, Texas, US.					
	<u>Comparison</u> : Minimum contact control group. n= 104 Some youths were also provided with alternative referrals for 12 step self-help programming, although evaluation data was not gathered on these youths.					
Relevant Outcomes	Primary outcomes: Youth drug use. Measures: Change in substance use across time, measured by SAMSHA CSAT GPRA.					
Baseline						

	<u>Secondary outcomes</u> : Youth risk behavior. <u>Measures</u> : Gang-affiliation as measured by the Gang Identification Scale (GISA).
Notes	The study was presented at the American Sociological Association conference, but was not published in a peer reviewed journal or other reviewed media. The investigators were contacted for details on control conditions, modifications to BSFT, allocation, comorbidity and drug use severity at baseline, time points for baseline and end of treatment measures, data from the non-reported 6 months follow up measurement, data on 12-step recipients in control group, missing data, blinding, exclusion criteria, attrition, and a priori protocol. Unfortunately, we have not yet received any response from the study authors.

10.2 CHARACTERISTICS OF EXCLUDED STUDIES

Austin 2005 A descriptive review. Blecha 2010 Not a primary study about a BSFT intervention. Briones 2008 Not a primary study about a BSFT intervention. Cannon 2008 Not a primary study about a BSFT intervention. Child Trends 2009 Not a primary study but a program description. Coatsworth 2001 Focus is not on drug treatment. Eisenberg 1991 Not a primary study about a BSFT intervention. Feaster 2004 Not outpatient treatment only. Feaster 2010 Not a primary study about a BSFT intervention. Fischer 2007 Not a primary study about a BSFT intervention. Hervis 2009 Not a primary study about a BSFT intervention. Prado 2008 Not a primary study about a BSFT intervention. Richeport-Haley 1998 Not a primary study about a BSFT intervention. Robbins 2002b Not a primary study about a BSFT intervention. Robbins 2002a Descriptive study. Robbins 2003 Not a primary study about a BSFT intervention. Robbins 2007 Not a primary study about a BSFT intervention. Robbins 2008 Focus is on family-therapist alliance. Robbins 2009a Protocol for Robbins et al., 2011.

Study and reason for exclusion:

Robbins 2011b	Focus is on therapist adherence to the BSFT treatment model.
Santisteban 1997	Behavioral focus.
Santisteban 2006	Not a primary study about a BSFT intervention.
Shachar 2004	Not a primary study about a BSFT intervention.
Szapocznik 1986	Focus on comparison between conjoint and one-person therapy.
Szapocznik et al., 1988	Focus is to overcome resistance to treatment.
Szapocznik 1991	Not a primary study about a BSFT intervention.
Szapocznik 2000	A descriptive review.
Szapocznik 2002	Not a primary study about a BSFT intervention.
Szapocznik et al., 2004	Protocol.
Szapocznik 2006	A descriptive review.
Thompson 2005	A descriptive review.

10.3 CHARACTERISTICS OF STUDIES AWAITING CLASSIFICATION

Jungkuntz, 2005	Dissertation abstract. Awaiting access to full text dissertation to determine relevance of intervention

10.4 RISK OF BIAS ACROSS INCLUDED STUDIES

	Robbins, 2011	Santisteban, 2003	Valdez, 2008
Sequence generation	Low	Unclear	Unclear
Allocation concealment	Low	Unclear	Unclear
Blinding	1	2	Unclear
Incomplete outcome data	1	1	Unclear
Free of selective reporting	1	1	4
Free of other bias	-Yes	Unclear	- Yes
A priori protocol	Yes	Unclear	Unclear
A priori analysis plan	Yes	Unclear	Unclear

Confounding	NA	NA	NA

NA: Not Applicable.
10.5 RISK OF BIAS FOR INDIVIDUAL INCLUDED STUDIES

Robbins et al., 20	11; Horigian et al., 2010		
DIMENSION	ITEM	ASSESSMENT	DESCRIPTION
Selections /Sample bias	Adequate sequence generation	Low Risk of Bias	Families were randomized to BSFT or TAU conditions using an urn randomization procedure. The urn randomization procedure was used to increase the probability that participants in the treatment condition would be balanced in terms of ethnicity/race and level of drug use at baseline.
	Allocation concealment	Low Risk of Bias	Research assistants performed the randomization through an automated telephone system programmed and run by the US Veterans administration. Therapist randomization was conducted within therapist pairs that were balanced to the fullest extent possible in terms of academic qualifications and years of experience. At two of the sites, therapists were also balanced in terms of language (i.e. Spanish) so as to include Spanish-speaking participants in each condition.
DETECTION BIAS OUTCOMES: Drug use reduction, family functioning, treatment retention	Blinding of outcome assessors	1	The TLFB was administered by research assistants who were blind to the treatment condition. Research assistants were requested to indicate if the blind had been broken at each of the 12 follow- up assessments. Only with 1.2% of participants did research assistants note that the blind had been broken. Participants were not blinded, but lack of blinding is unlikely to have affected the outcome of the assessment.
ATTRITION BIAS	Incomplete outcome data	1	There were no significant differences in engagement and treatment retention between the BSFT

OUTCOMES: Drug use reduction, family functioning, treatment retention	adequately accounted for		condition and TAU. There were 18 participants in TAU and 13 in the BSFT condition who were excluded from the analysis because they did not have any follow-up drug use data.
REPORTING BIAS OUTCOMES: Drug use reduction, family functioning, treatment retention	Free of selective and/or incomplete outcome reporting	1	All planned analysis was conducted and has been reported.
OTHER SOURCES OF BIAS	Free of other potential threat to validity		None known
A PRIORI PROTOCOL	Is there an a priori protocol (and was it followed)	Yes	
A PRIORI ANALYSIS PLAN	Is there an a priori analysis plan (and was it followed)	Yes	The analytic plan was developed in collaboration with an independent group, Duke Clinical Research Institute, and was approved by the sponsor prior to the authors being able to match randomized participants to follow-up data. The Duke Clinical Research Institute team also confirmed the results of the analyses separately.

Santisteban et al., 2003						
DIMENSION	ITEM	ASSESMENT	DESCRIPTION			
SELECTIONS /SAMPLE BIAS	Adequate sequence generation	Unclear Risk of Bias	Random assignment was performed, but no reporting of how. Still awaiting response from author.			
	Allocation concealment	Unclear Risk of Bias	No reporting of allocation concealment. Still awaiting response from author.			
DETECTION	Blinding of outcome	2	Unclear whether outcome assessors were blinded.			
DIAS	033633013		Unlikely that it has influenced the outcome assessment			
OUTCOMES: Drug use reduction, family functioning, treatment retention	,		"Data were collected in a standardized manner by trained master's-level associates" (p.7) Awaiting response from author.			
ATTRITION BIAS	Incomplete outcome data adequately accounted for	1	A series of two-way analyses of variance were conducted on the continuous variables collected at intake to explore whether the study had been biased by either general attrition rates, which limit the generalizability of the results, or by differential attrition" (p.7)			
reduction, family functioning, treatment			"There were no differences with respect to attrition rates on any of these variables in either of the two conditions" (p.7)			

retention			"To maximize statistical power for all treatment efficacy analyses, we elected to use all available data for each analysis, regardless of whether the participant had valid data on measures in other domains" (p.8) Termination data was not collected on cases who dropped out prematurely. Investigators performed analysis to examine if dropouts/completers are different.
REPORTING BIAS OUTCOMES: Drug use reduction, family functioning, treatment retention	Free of selective and/or incomplete outcome reporting	1	All outcomes are reported
OTHER SOURCES OF BIAS	Free of other potential threat to validity	Unclear	Santisteban 2003 reports on the second phase of a two-phased study with a possible risk of carry- over effect from the pre-treatment activity conducted in the first phase, where participants received an engagement intervention.
A PRIORI PROTOCOL	Is there an a priori protocol (and was it followed)	Unclear	Not reported. Awaiting response from author.
A PRIORI Analysis Plan	Is there an a priori analysis plan (and was it followed)	Unclear	Not reported. Awaiting response from author.

Valdez & Cepeda, 2008					
DIMENSION	ITEM	ASSESMENT	DESCRIPTION		
SELECTIONS /SAMPLE BIAS	Adequate sequence generation	Unclear Risk of Bias	Random assignment performed, but no report of how it was carried out.		
	Allocation concealment	Unclear Risk of Bias	Not reported. Awaiting response from author.		
DETECTION BIAS (Per relevant outcome) OUTCOMES: Drug use reduction, family functioning, treatment retention	Blinding of outcome assessors	Unclear	Not reported. Awaiting response from author.		
ATTRITION BIAS (Per outcome) OUTCOMES: Drug use reduction, family	Incomplete outcome data adequately accounted for	Unclear	Dropouts are reported, but an analysis of dropouters/completers is lacking. Analysis was performed on participants who completed assessments. Awaiting response from author.		

functioning, treatment retention			
REPORTING BIAS OUTCOMES: Drug use reduction, family functioning, treatment retention	Free of selective and/or incomplete outcome reporting	4	A planned 6 months follow-up was not reported. Awaiting response from author.
OTHER SOURCES OF BIAS	Free of other potential threat to validity		None known.
A PRIORI PROTOCOL	Is there an a priori protocol (and was it followed)	Unclear	Not reported. Awaiting response from author.
A PRIORI ANALYSIS PLAN	Is there an a priori analysis plan (and was it followed)	Unclear	Not reported. Awaiting response from author.

11 Appendices

11.1 SEARCH HISTORIES FROM THE BIBLIOGRAPHIC DATABASES

Criminal Justice Abstract 1968 - current	
June 17, 2011. Ebsco platform.	
S1 TI (BSFT or Brief n1 Strategic* n1 Famil*) or AB (BSFT or Brief n1 Strategic* n1 Famil*)	8
ERIC 1966 - current	
June 17, 2011. Ebsco platform.	
S1 (BSFT or Brief n1 Strategic* n1 Famil*) or	
AB (BSFT or Brief n1 Strategic* n1 Famil*)	10
SocIndex 1908 - current	
June 17, 2011. Ebsco platform.	
S1 TI (BSFT or Brief n1 Strategic* n1 Famil*) or AB (BSFT or Brief n1 Strategic* n1 Famil*)	116
Cinahl 1981 - current June 12, 2011. Ebsco platform.	
S1 TI (BSFT or Brief n1 Strategic* n1 Famil*) or AB (BSFT or Brief n1 Strategic* n1 Famil*)	5

Medline 1948 - current June 12, 2011. Ovid platform.

S1 (BSFT.af.) or (Brief adj1 Strategic* adj1 Famil*)).af.	19
Embase 1980 - current June 12, 2011. Ovid platform.	
S1 (BSFT.af.) or S2 (Brief adj1 Strategic* adj1 Famil*)).af.	27
PsycInfo 1806 - current June 12, 2011. Ovid platform.	
S1 (BSFT.af.) or (Brief adj1 Strategic* adj1 Famil*)).af.	64
Social Science Citation Index. 1956 - current June 8, 2011.	
# 1 Topic=(BSFT or Brief same Strategic* same Famil*)	26
Science Citation Index. 1899 - current June 8, 2011.	
# 1 Topic=(BSFT or Brief same Strategic* same Famil*)	34
Cochrane June 12, 2011	
1 (bsft):ti,ab,kw) or (Brief adj1 Strategic* adj1 Famil*):ti,ab,kw	8
Social Care Online 1980 - current June 12, 2011	
S1 ("Brief and Strategic* and Famil*") or bsft	4
Bibsys June 12, 2011	
S1 Brief and Strategic? and Famil?") or bsft	3

Libris

June 12, 2011

S1 (Brief and Strategic* and Famil*") or bsft

Bibliotek.dk

June 12, 2011

S1 (Brief og Strategic? og Famil?") eller bsft

0

5

11.2 CODE BOOK FOR DATA EXTRACTION

Author	Study v
Voar	Situdy X
Country	
Is this study about a BSET intervention evaluation?	
Are the participants 11 - 21 years of are?	
Are the participants in outpatient drug treatment for illicit non-opioid drug use?	
Is the report a P=Primary study RE=Review (Effect/meta-analysis) RD=Review (Descriptive) D=Descriptive T=Theoretical paper O=Other	
Is the study an RCT with a control group?	
Is the study a non-randomized controlled study with a control group?	
Is the study	
Notes	
State reason (if necessary) for excluded or uncertain.	
If lack of info., state question(s) to be sent to study authors.	
Objectives of the study	
How many separate sites/facilities are included in the study?	
If an RCT, was random assignment performed in the same way in all sites?	
List all the treatment groups in the study	
Were there any implementation differences between groups?	
Location of treatment	
Location details	
If multiple sites, were there any implementation differences between sites?	
Was participant inclusion criteria mentioned?	
If yes describe.	

Was participant exclusion criteria mentioned?

If yes describe.

Describe how the participants were referred to the intervention.

Is the intervention mandated?

If yes by whom and how many?

Gender (e.g. % male)

Age (details on age as presented in the study)

Race/ ethnicity

Socioeconomic status

Family composition

Other characteristics

Specify the main drug

Provide short description of the distribution of drug

use

List/describe history/severity of drug use

List any comorbid condition

Report total no. of participants randomized

Intervention	

Name the intervention

How is the intervention delivered?

If Family, Other or Combination, describe the way it is delivered

Describe any practical circumstances relevant to the intervention

If deviation from manual, describe/list the components given in the intervention

Describe any co-interventions given with the intervention

Frequency of the intervention

Intensity

Duration of the intervention

Who delivered the intervention ?

List program delivers qualifications.

List program delivers characteristics.

Describe methods used to ensure adherence to the intervention (specific to the the intervention)

What did the investigators do to check/measure treatment fidelity?

Other important information

Control group
Name the control/comparison condition intervention
How is the control intervention delivered?
If Family, Other or Combination, describe the way it is delivered
Describe any practical circumstances relevant to the intervention
If deviation from manual, describe/list the components given in the intervention
Describe any co-interventions given with the comparison intervention
Frequency of the intervention
Intensity
Duration of the intervention
Who delivered the intervention?
List program delivers qualifications
List program delivers characteristics
Describe methods used to ensure adherence to the intervention
What did the investigators do to check/measure treatment fidelity?
Did they measure session attendance?
Other important information

Baseline time - describe how baseline is defined

End of treatment (from baseline time) to...

...1st follow-up

...2nd follow-up

...3rd follow-up

...Other

Author's main conclusion

Limitations of the study, as reported by the study authors

Researcher's affiliation with program (if any)

Your own concerns and notes

Question(s) for review authors

OUTCOMES

Outcome measurement

What does it measure?

Reliabiltiy & Validity

Outcome measurement format (continuous or binary)

Direction

Mode

If other, describe

Source

If other, describe

NOTES

N's	INTERVENTION1*	COMPARON1*	Comparison 2	TOTAL	Pg. # & NOTES etc on drops outs (& reason if given) and missing data	Drop out n's - % in intervention group	Drop out n's - % in control group
Referred to study or recruited							
Consented							
Completed base line measures							
Randomly assigned							
Or non randomly allocated							
Started treatment							
Completed treatment							
Completed first measure after baseline							
Completed 1st follow up							
Completed 2 nd follow up(add rows for as required for additional follow ups)							
*Add columns as required							

11.3 RISK OF BIAS TOOL

Risk of bias table

Item	Judgement ^a	Description (quote from paper, or describe key information)
1. Sequence generation		
2. Allocation concealment		
3. Confounding ^{b,}		
4. Blinding? ^b		
. Incomplete outcome data addressed?b		
6. Free of selective reporting?b		
7. Free of other bias?		
8. A priori protocol?d		
9. A priori analysis plan?e		

- ^a Some items on <u>low/high risk/unclear scale</u> (double-line border), some on <u>5</u> <u>point scale/unclear</u> (single line border), some on <u>yes/no/unclear</u> scale (dashed border). For all items, record <u>"unclear"</u> if inadequate reporting prevents a judgement being made.
- ^b For each outcome in the study.
- ^c This item is based on a list of confounders considered important at the outset and defined in the protocol for the review (*assessment against worksheet*).
- ^d Did the researchers write a protocol defining the study population, intervention and comparator, primary and other outcomes, data collection methods, etc. <u>in</u> <u>advance of starting the study?</u>
- ^e Did the researchers have an analysis plan defining the primary and other outcomes, statistical methods, subgroup analyses, etc. <u>in advance of starting the study?</u>

Risk of bias tool

Studies for which RoB tool is intended

The risk of bias model is developed by Prof. Barnaby Reeves in association with the Cochrane Non-Randomised Studies Methods Group.¹⁸ This model, an extension of the Cochrane Collaboration's risk of bias tool, covers both risk of bias in randomised controlled trials (RCTs and QRCTs), but also risk of bias in non-randomised studies (in this case, non-randomised controlled trials NRCTs).

The point of departure for the risk of bias model is the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2008). The existing Cochrane risk of bias tool needs elaboration when assessing non-randomised studies because, for non-randomised studies, particular attention should be paid toselection bias / risk of confounding.

Assessment of risk of bias

Issues when using modified RoB tool to assess included non-randomised studies:

- Use existing principle: Score judgment and provide information (preferably direct quote) to support judgment.
- Additional item on confounding used for RCTs and NRCTs.
- 5-point scale for <u>some</u> items (distinguish "unclear" from intermediate risk of bias).
- Keep in mind the general philosophy assessment is <u>not</u> about whether researchers could have done better but about risk of bias; the assessment tool must be used in a standard way whatever the difficulty / circumstances of investigating the research question of interest and whatever the study design used.
- Anchors: "1/No/low risk" of bias should correspond to a high quality RCT.
 "5/high risk" of bias should correspond to a risk of bias that means the findings should not be considered (too risky, too much bias, more likely to mislead than inform)

1. Sequence generation

- Low/high/unclear RoB item
- Always high RoB (not random) for a non-randomised study

90

¹⁸ This risk of bias model was introduced by Prof. Reeves at a workshop on risk of bias in nonrandomised studies at SFI Campbell, February 2011. The model is a further development of work carried out in the Cochrane Non-Randomised Studies Method Group (NRSMG).

- Might argue that this item is redundant for NRS since it is always high but it is important to include it in a RoB table ('level playing field' argument)
- 2. Allocation concealment
- Low/high/unclear RoB item
- Potentially <u>low</u> RoB for a <u>non-randomised study</u>, e.g. quasi-randomised (so high RoB to sequence generation) but concealed (reviewer judges that the people making decisions about including participants didn't know how allocation was being done, e.g. odd/even date of birth/hospital number)
- 3. RoB from confounding (assess for each outcome)
- Assumes a <u>pre-specified</u> list of potential confounders defined in the protocol
- Low(1) / 2 / 3 / 4 / high(5) / unclear RoB item
- Judgment needs to factor in:
 - o proportion of confounders (from pre-specified list) that were considered
 - whether most important confounders (from pre-specified list) were considered
 - \circ resolution/precision with which confounders were measured
 - o extent of imbalance between groups at baseline
 - care with which adjustment was done (typically a judgment about the statistical modeling carried out by authors)
- Low RoB requires that all important confounders are balanced at baseline (<u>not</u> <u>primarily/not only</u> a statistical judgment OR measured 'well' <u>and</u> 'carefully' controlled for in the analysis.

Assess against pre-specified worksheet. Reviewers will make a RoB judgment about each factor first and then 'eyeball' these for the judgment RoB table.

- 4. RoB from lack of blinding (assess for each outcome, as per existing RoB tool)
- Low(1) / 2 / 3 / 4 / high(5) / unclear RoB item
- Judgment needs to factor in:
 - nature of outcome (subjective / objective; source of information)
 - who was / was not blinded and the risk that those who were not blinded could introduce <u>performance or detection</u> bias
 - o see Ch.8

5. RoB from incomplete outcome data (<u>assess for each outcome</u>, as per existing RoB tool)

- Low(1) / 2 / 3 / 4 / high(5) / unclear RoB item
- Judgment needs to factor in:
 - reasons for missing data
 - whether amount of missing data balanced across groups, with similar reasons
 - o see Ch.8

6. RoB from selective reporting (<u>assess for each outcome</u>, NB different to existing Ch.8 recommendation)

- Low(1) / 2 / 3 / 4 / high(5) /unclear RoB item
- Judgment needs to factor in:
 - o existing RoB guidance on selective outcome reporting
 - o see Ch.8
 - also, extent to which analyses (and potentially other choices) could have been manipulated to bias the findings reported, e.g. choice of method of model fitting, potential confounders considered / included
 - look for evidence that there was a protocol in advance of doing any analysis / obtaining the data (difficult unless explicitly reported); NRS very different from RCTs. RCTs must have a protocol in advance of starting to recruit (for REC/IRB/other regulatory approval); NRS need not (especially older studies)
 - Hence, separate yes/no items asking reviewers whether they think the researchers had a pre-specified protocol and analysis plan.

Confounding Worksheet

Assessment of how researchers dealt with confound	nding					
Method for <i>identifying</i> relevant confounders described by researchers: yes						
no						
If yes, describe the method used:						
Relevant confounders described:		yes 🗖				
no						
List confounders described on next page						
Method used for controlling for confounding						
At design stage (e.g. matching, regression discontinuity, instrument variable):						
At analysis stage (e.g. stratification, multivariate regression, difference-indifference):						

Describe confounders controlled for below

Confounders described by researchers

Tick (yes[0]/no[1] judgment) if confounder considered by the researchers [Cons'd?] Score (1[good precision] to 5[poor precision]) precision with which confounder measured

Score (1[balanced] to 5[major imbalance]) imbalance between groups Score (1[very careful] to 5[not at all careful]) care with which adjustment for confounder was carried out

Confounder	Considered	Precision	Imbalance	Adjustment
Gender				
Age				
History of drug use				
Other				
Other:				
Other:				

12 Figures

12.1 FLOW CHART FOR LITERATURE SEARCH

