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Family Behavior Therapy (FBT) for Young People in Treatment for Non-opioid Drug Use: A Systematic Review

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Campbell Systematic Reviews

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Key messages

This publication is a systematic Campbell review of the effect of the family therapy approach Family Behavior Therapy (FBT) for treatment for non-opioid drug use (e.g., cannabis, amphetamine, ecstasy or cocaine) among young people aged 11-21 years.

Youth drug use is a severe problem worldwide. Recent reports describe concerning trends in the use of drugs by young people and a lack of available treatment. FBT is a manual-based family therapy approach that seeks to reduce drug use among youth by identifying stimuli and triggers for drug taking, and teaching self-control and other skills to correct the problem behaviors related to drug use. This approach is based on the therapeutic premise that the family carries a profound influence on child and youth development and that interventions need to be flexible and tailored to the unique characteristics of the families. It is also argued that there is a need for interventions to be problem-focused, targeting first those patterns of behavior that most directly influence the youth's drug use.

After a rigorous search for all relevant studies conducted to date, we identified two randomized controlled trials with, respectively, 56 and 26 participants. We used meta-analysis to synthesize the empirical evidence on the effects of FBT on reduction of drug use frequency, family functioning, and risk behavior. The findings are as follows:

- On drug usage: There is no evidence that FBT has an effect on reduction of drug use frequency compared to Individual Cognitive Problem-Solving (ICPS) and supportive counseling (SC).
- On family functioning: FBT may improve family functioning as reported by parents compared to Individual Cognitive Problem-Solving (ICPS) and supportive counseling (SC). There is no evidence that FBT has an effect on family functioning as reported by youth compared to Individual Cognitive Problem-Solving (ICPS) and supportive counseling (SC).
- On risk behavior: There is no evidence that FBT has an effect on risk behavior compared to Individual Cognitive Problem-Solving (ICPS) and supportive counseling (SC).

The evidence found was limited, as only two studies with very few participants were included in the data-analysis. The quality of the evidence is also limited. We were therefore unable to draw any firm conclusion regarding the effectiveness of the treatment.

Overall, Family Behavior Therapy for the purpose of treating young people's drug use has not been evaluated with sufficient rigor to unequivocally determine its effectiveness.

Executive summary/Abstract

BACKGROUND

Youth drug use is a severe problem worldwide, and the use of cannabis, amphetamine ecstasy and cocaine, referred to as non-opioid drugs, are strongly associated with a range of health and social problems.

This review focuses on Family Behavior Therapy (FBT) as a treatment for young people who misuse non-opioid drugs. FBT is a manual-based family therapy approach. The program is behavior and skill-oriented. It is concerned with identifying psychological and situational stimuli and triggers presumed to be directly related to the youth's drug use, and skills training to improve self-control. FBT is designed to accommodate diverse populations of youth with a variety of behavioral, cultural and individual preferences. FBT incorporates behavioral theory (reduction of undesired behavior by manipulating external reinforcement), structural family theory (in which the structure of the family influence the youth's behavior) and strategic family theory (where treatment methods are problem-focused and pragmatic).

OBJECTIVES

The main objective of this review is to evaluate the current evidence on the effects of FBT on reduction of drug use frequency for young people in outpatient treatment for non-opioid drug use and, if possible, to examine moderators of drug use reduction effects, specifically analyzing whether FBT works better for particular types of participants.

SEARCH STRATEGY

A relatively narrow search strategy to identify qualifying studies was performed. A wide range of electronic bibliographic databases were searched along with government and policy databanks, grey literature databases, citations in other reviews and in the included primary studies, hand searches of relevant journals, and Internet searches using Google. We also corresponded with researchers in the FBT field. Neither language nor date restrictions were applied to the searches.

SELECTION CRITERIA

Studies eligible for inclusion in the review are required to meet several eligibility criteria. Studies must:

- have involved a manual-based FBT treatment for young people aged 11-21 years enrolled in outpatient treatment for non-opioid drug use;
- have used experimental, quasi-experimental or non-randomized controlled designs;
- have reported at least one eligible outcome variable measuring abstinence, reduction of drug use, family functioning, education or vocational involvement, retention, risk behavior or any other adverse effects;
- not have focused exclusively on treating mental disorders; and
- have had FBT as the primary intervention.

DATA COLLECTION AND ANALYSIS

The literature search yielded a total of 10,779 records which were screened for eligibility based on title and abstract. 99 potentially relevant records were retrieved and screened in full text, of which 7 studies were potentially relevant. Of these, two studies were data-extracted by the authors and included in the review. Meta-analysis was performed to examine the effects of FBT on drug use reduction, family functioning and risk behavior.

RESULTS

For the primary outcome of reduction in drug use frequency, measured at end of treatment, the standardized mean difference was 0.49 (95% CI -0.51, 1.50). At 12 month post-intake, Azrin et al. (2001) found no statistically significant difference between FBT and the comparison treatment, SMD=-0.03 (95% CI -0.58, 0.52). For family functioning, measured at end of treatment, the standardized mean difference was 0.58 (95% CI 0.02, 1.13) reported by parents and 0.29 (95% CI -0.72, 1.30) reported by youth. At 12 month post-intake, Azrin et al. (2001) found no statistically significant difference between FBT and the comparison treatment for parent satisfaction or youth satisfaction with family functioning, SMD= -0.30 (95% CI -0.86, 0.26) and SMD= 0.47 (95% CI -0.09, 1.04). For risk behavior, measured at end of treatment, the standardized mean difference was 0.29 (95% CI -0.16, 0.74). At 12 month post-intake, Azrin et al. (2001) finds a statistically significant difference that favors the comparison treatment, SMD= -0.56 (95% CI -1.13, 0.00).

Meta-analysis was not possible for the education outcomes as the measures are incomparable. None of the studies reported statistically significant effect sizes for school outcomes. Due to lack of data for the number randomized in both studies it is

not possible to report effects for retention. No other adverse effects are reported in the studies.

AUTHORS' CONCLUSIONS

The main conclusion of the review is that there is a lack of firm evidence on the effect of FBT. There is a need for more research, and particularly a need for more methodologically rigorous studies in the field of treatment for young drug users.

The aim of this systematic review is to explore what is known about the effectiveness of FBT for the purpose of reducing youth drug use, in order to contribute to an evidence-based approach in the treatment of young non-opioid drug users. The evidence found does not provide a basis for drawing conclusions about actual outcomes and impacts. Consequently, no substantive conclusion about the effectiveness can be made, resulting in neither support nor rejection of the present FBT treatment approach.

1 Background

1.1 DESCRIPTION OF THE CONDITION

Youth drug use[1] that persists beyond curious experimentation is a severe problem worldwide (United Nations Office of Drugs and Crime (UNODC), 2010). Use of non-opioid drugs such as cannabis, amphetamine and cocaine is strongly associated with a range of health and social problems, including delinquency, poor scholastic attainment, fatal automobile accidents, suicide and other individual and public calamities (Deas & Thomas, 2001; Essau, 2006; Rowe & Liddle, 2006; Office of National Drug Control Policy (ONDCP), 2000; Shelton, Taylor, Bonner & van den Bree, 2009). More than 20 million of the 12 to 25 year-olds in the US, and more than 11 million of the 12 to 34 year-olds in Europe have used illicit[2] 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 to 17 year-olds have used some kind of drug during the month prior to survey interviews in 2008 (White & Smith, 2009). In Canada 26 percent of 15 to 24 year-olds had used illicit drugs during the past year (Health Canada, 2010).

Not all young drug users progress to severe dependence. However, some 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, but 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 in this group actually received any (SAMSHA, 2010). Research calls attention to the significant gap between young people classified in need of treatment and young people actually receiving treatment (SAMSHA, 2010; NSDUH, 2007).

There is a 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,

[1] The terms use, abuse and dependence will be used interchangeably throughout the review and refer to an addiction stage of non-medical drug usage.

[2] Cannabis, amphetamine, cocaine and other non-opioid and opioid drugs are illegal in most, but not all countries. For instance, use of cannabis in small amounts is tolerated in the Netherlands.

2005; Najavits & Weiss, 1994; Stanton & Shadish, 1997). Accordingly, treatment to help young drug users should be as engaging as possible in order to minimize dropouts and relapse (Simmons et al., 2008; National Institute on Drug Abuse (NIDA), 2009). The services provided should be empirically supported in order to increase the likelihood that (a) treatment will be successful, and (b) public spending is used to support the interventions with the most effect.

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 youth substance abuse treatment is that it is not clear what works best, as the research suggest that most interventions lead to reduced drug use. While there are some promising individual-based cognitive, cognitive-behavioral and motivational therapies (Waldron & Turner, 2008; Kaminer, 2008; Deas & Thomas, 2001; Galanter & Kleber, 2008), family-based approaches may also show some promise. Family therapy covers a range of different interventions and is based on different manuals and varying theoretical sources such as 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 specifically sensitive to social influence, with family and peer groups being highly influential. Youth drug treatments facilitating positive parental and peer involvement, and integrating other systems in which the young person participates (such as schools, social services, justice authorities) are key to youth drug reduction (NIDA, 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 explores the specific family-based intervention Family Behavior Therapy (FBT) (Azrin, Donohue, Besalel, Kogan & Acierno, 1994a; Donohue & Azrin, 2001; Donohue et al., 2009). The review attempts to clarify the effects of the FBT program for relevant groups of young people aged 11-21 years. It focuses on young people enrolled in treatment for drug use regardless of how their problem is labeled. Enrolment in treatment means that the severity of the young person's drug use has caused a significant adult close to the young person (such as a teacher, parent, social services, or school counselor) to require treatment. FBT is delivered as outpatient

treatment[3] to young people age 11-21 years living with their family. The review focuses primarily on non-opioid drug use[4].

This review is one in a series of reviews on manual-based family therapy interventions for young people in treatment for non-opioid drug use[5].

1.2 DESCRIPTION OF THE INTERVENTION

FBT is a manual based family-oriented intervention for young people with drug use problems. FBT is *a behavior focused* family therapy in which young people's drug use is understood in relation to family behavior problems.

FBT is one of many family therapies that meet the general characteristics of manual-based family therapies as it targets young people *and* their families *as a system* throughout treatment, and thereby recognizes the important role of the family system in the development and treatment of young people's drug use problems (Liddle et al., 2001, Muck et al., 2001).

FBT was developed in the late 1980s on request from the US National Institute on Drug Abuse (NIDA) (Donohue et al., 2009). The development of FBT was initially heavily inspired by the alcohol abuse program Community Reinforcement Approach (CRA), which was aimed at restructuring the environment to reinforce non-alcohol associated activities. FBT developed to have more emphasis on contingency contracting, impulse control strategies specific to drug use, and increased emphasis on involvement of family members in treatment. FBT is designed to accommodate diverse populations of youths with a variety of behavioral, cultural and individual preferences. FBT has evolved for use in severe behavioral disturbances known to co-exist with substance use and dependence, and the core interventions have been enhanced to address several mental health related problems commonly occurring as comorbid conditions in drug use treatment participants (Austin et al., 2005; Donohue et al., 2009).

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

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

[5] Please see the following Protocols in the Campbell Library for further information:

Maia Lindstrøm, Pernille Skovbo Rasmussen, Krystyna Kowalski, Trine Filges, Anne-Marie Jørgensen: Brief Strategic Family Therapy (BSFT) for young people in treatment for illicit non-opioid drug use. Campbell Systematic review 2011:05

Krystyna Kowalski, Pernille Skovbo Rasmussen, Trine Filges, Madina Saidj, Maia Lindstrøm, Anne-Marie Jørgensen: Multidimensional Family Therapy (MDFT) for young people in treatment for illicit non-opioid drug use. Campbell Systematic Review 2011:04

And the Title Registration:

Krystyna Kowalski, Maia Lindstrøm, Pernille Skovbo Rasmussen, Trine Filges, Anne-Marie Jørgensen: Functional Family Therapy (FFT) for young people in treatment for illicit non-opioid drug use.

1.2.1 Theoretical background

FBT is a family systems approach that relies on structural and strategic family theory as well as behavioral family theory (Robbins & Szapocznik, 2000; Szapocznik, Hervis & Schwartz, 2003; Azrin et al., 1994a; Donohue & Azrin, 2001).

Along with other family-systems based therapies, FBT builds on the assumption that families can 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 are strongly related to each other, and as such they can be viewed as parts of a unique and changeable system. The behavior of each family member must be understood in relation to the family context. Young family member's problematic behavior is associated with maladaptive social interaction patterns in the family, and therefore interventions must be implemented at the family level. The family itself is part of a larger social system, and as young people are influenced by their families, the family is 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 the individual and the family is embedded.

The structural family theory is based on the idea that subsystems, structures and hierarchies within families influence or determine individual family members' actions (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 could play a pivotal part 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). The strategic theory-based dimension of FBT focuses on creating changes in behavior and interactions relevant to the identified problems within families, and in individual family members resisting changes (Goldenberg & Goldenberg, 2008).

Behavioral theory focuses on observable behavior (i.e. symptoms, problems). It is characterized by an ongoing assessment of the behavior to be altered and a focus on enhancing or reducing targeted undesired/unwanted behavior(s) by manipulating external contingencies of reinforcement. Therapists teach and coach communication and problem solving skills, and the members of the young drug user's family are trained to monitor and modify their own reinforcement contingencies. FBT is based on a behavioral conceptualization of drug use and drug use problems, where drugs are considered a strong primary reinforcer which is further reinforced by both physiological and situational stimuli (Austin et al., 2005; Donohue & Azrin, 2001).

FBT emphasizes contingency management, utilization of impulse control strategies specific to drug use scenarios, and explicitly monitors environmental stimuli relevant to drug use (Donohue et al., 2009).

1.2.2 FBT components

FBT incorporates multilevel components to target young people's drug use, as well as the young person's behavior, problem solving skills, family relationships and communication skills (Donohue & Azrin, 2001). The young person attends therapy sessions with at least one family member, typically one of the parents. In addition, the FBT program encourages involvement and participation of siblings and peers in therapy.

FBT includes the following *core foundation components*:

1. **Program orientation**

The therapist will initially provide an overview of FBT to engage participants in treatment. During the sessions the reasons for referral and support methods that are most helpful to the young drug user and his or her family will be discussed. Furthermore the therapist will clearly "differentiate" him or herself from third parties, such as social service authorities and probation agencies (Donohue & Azrin, 2001). It is important for the therapist to take an independent role in order to gain family members' confidence and to navigate on behalf of the family to solve their problem (the young person's drug use).

2. **Development of behavioral goals and contingency management**

The young person will be asked to identify relevant triggers and stimuli for drug use. These triggers and stimuli are targeted in treatment and guides the identification of behavioral goals. The aim of the behavioral contracting procedures is to establish an environment that facilitates reinforcement of behaviors associated with drug abstinence (Donohue & Azrin, 2001; Donohue et al., 2009; California Evidence-Based Clearinghouse (CEBC), 2011; Achievement Center, 2011). The goals can be adjusted and new goals can be added during treatment, as needs may change and develop during the work with various FBT components during treatment. Focus can shift between different goals based on participants' changing needs and behavioral development (Donohue et al., 2009).

3. **Standardized treatment plan**

When goals and contingencies are established, treatment is planned. In this process the young person and his/her parents are asked to determine which skill-based components are the most appropriate to include in treatment (Donohue et al., 2009; CEBC, 2011; Achievement Center, 2011).

4. **Assurance of basic necessities**

Young people using drugs often experience problematic situations and difficulties such as dismissal from school or work, economical problems, and violence, which often disrupt treatment. The FBT component Assurance of basic necessities (Donohue et al., 2009) aims at teaching the young person (and parents) how to monitor conditions that have been found to increase the likelihood of problematic situations and difficulties, and integrate "urgency management" in their treatment plan (Donohue et al., 2009; CEBC, 2011; Achievement Center, 2011).

5. Stimulus control

The young person and his or her parents are asked to create two comprehensive lists; 1) *A safe list* of behavioral stimuli that *decrease* the young person's likelihood of using drugs and 2) *A risk list* of behavioral stimuli that *increase* the likelihood of drug use. The young person and their parents are asked to monitor the time the young person spends on safe and risk behaviors. The therapist assists treatment participants in finding methods of spending more time with safe stimuli and less time with risk stimuli (Donohue & Azrin, 2001; Donohue et al., 2009; CEBC, 2011; Achievement Center, 2011). The therapist reviews the stimulus control items, and in this process the therapist has the opportunity to add goals to the "behavioral goals and contingency management" treatment component.

Furthermore, within FBT young people and their parents are asked to select from a range of the following *optional therapy components*:

Self control

The young person is instructed to avoid locations, objects and events that stimulate drug cravings. Recognition of the stimuli is regarded as key in self-control, in order to stop or discipline drug related thoughts and reward goal-oriented, drug incompatible behavior (Donohue et al., 2009; Donohue & Azrin, 2001; CEBC, 2011; Achievement Center, 2011).

Communication skills training

Communication skills training is aimed at improving family communication through different component options:

- *I've got a great family*. This component is aimed at assisting families in appreciating each other and the family's positive qualities.
- *Positive request*. This component assists the family in developing clear and positive communication, and aims at increasing the positive exchange between family members.
- *Arousal management*. Various illicit drugs have been associated with increased irritability and stress, which could influence family relations negatively. The arousal management component aims at decreasing anger and aggression in the young people by teaching identification of the antecedents of anger and aggression (Donohue et al., 2009; Donohue & Azrin, 2001; CEBC, 2011; Achievement Center, 2011).

Training for skills associated with attending school and/or getting a job

The aim of this optional component is to assist young drug users in achieving consistent school attendance or obtaining a job. Training is focused on disclosing positive qualities and skills relevant for schooling or work, such as interviewing techniques, and meeting potential employers or school officers.

Financial management

FBT focuses on teaching the young person to identify stimuli, prioritize spending and methods to manage and gain income in order to appropriately allocate resources and avoid financial crisis that may stimulate drug use (National Registry of Evidence-based Programs and Practices (NREPP), 2011; Donohue et al., 2009; Donohue & Azrin, 2001; CEBC, 2011).

All FBT core and optional components aim at skills development and behavior change, and use role play and behavior rehearsals actively in treatment. FBT is designed to accommodate a diverse population of young people with varying cultural backgrounds, behavioral patterns and individual preferences. The range of eligible and optional components provides the opportunity for FBT to be flexible and tailored to the individual needs of the young person and family (CEBC, 2011; Donohue & Azrin, 2001; NREPP, 2011; Austin et al., 2005).

Methods of enhancing motivation for treatment

Retention being a challenge in drug treatments, FBT incorporates weekly phone calls to participants to enhance session attendance (Donohue et al., 2009). Furthermore, participants are screened prior to enrollment in FBT to determine issues that are contraindicative with participation in FBT treatment, such as the lack of a stable local residence or the lack of a significant other to attend sessions with. Therapists are trained to manage drug user's lack of motivation for treatment and any non-compliance with therapeutic guidelines (such as refusing to do role-playing, forgetting to do assigned home-work, or arguing during therapy). Therapists evaluate participant's behavior efforts and disclose this information to relevant authorities (e.g. the juvenile justice system, or social services). Participants are asked to rank the helpfulness of each intervention component immediately after termination, and the therapist can adjust the program based on these rankings in attempt to resolve discontent early in the therapeutic process. Therapists also rate participant's level of active participation and these rating are sent to the referral agency. In cases of recurring non-compliance, the program supervisor will co-lead the next session with the therapist and provide on-site supervision and facilitate the management of difficult cases (Donohue et al., 2009).

1.2.3 Duration and setting

FBT is a behavior and skill-oriented intervention that can include up to 20 treatment sessions of 1-2 hours. Duration ranges from 6-12 months. Delivery is flexible and the intervention can be delivered in an office-based setting or in the family home (Donohue et al., 2009).

1.3 HOW THE INTERVENTION MIGHT WORK

FBT has two primary objectives: 1) to reduce the young person's drug use, and 2) to change behaviors associated with drug use in the young person and their family. The intervention aims at engaging young people and their families in therapy, improving family interactions, and skills training to assist in changing behaviors related to young people's drug use. Randomized controlled trials and systematic reviews have shown that FBT can reduce drug use in participants, and contribute to reduction in behavioral problems (Austin et al., 2005; Deas & Thomas, 2001; Azrin et al., 1994a; Azrin et al., 1994b; Azrin et al., 1996; Azrin et al., 2001). The program outcomes may be affected by participant characteristics and program mechanisms. The participant characteristics that have been found to predict program drug use reduction or abstinence are history and severity of drug use, and higher levels of school attendance and functioning pretreatment (Williams et al., 2000). Practitioners require information about highly relevant participant characteristics such as age, gender, minority background, 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 and tailor the program to particular types of young drug users.

1.3.1 Intervention mechanisms

Treatment variables which have a positive impact on treatment outcomes have been identified across reviews of a range of treatments for youth drug use (Williams et al., 2000; Austin et al., 2005).

Treatment completion is the variable which has the most consistent relationship to drug use reduction (Williams et al., 2000; Austin et al., 2005). Early alliance building has been found to predict the likelihood that the young people complete treatment and reduce drug use (Waldron & Turner, 2008). Consequently, it remains unclear if this is a direct treatment impact, or an indicator for treatment motivation, which is identified as another key variable to positive treatment outcome. Either way, these findings point to the importance of the FBT components 'program orientation' and 'methods for enhancing motivation for treatment' as key mechanisms, influencing treatment compliance and attendance. In FBT, the motivational enhancement mechanisms has two aspects: program orientation are

the steps a therapist takes to prepare the family for change, and methods for enhancing motivation for treatment are techniques performed by the therapist to ensure participants *active* participation and retention in treatment.

Engagement and retention strategies as well as strategic multi-component treatment planning based on behavioral assessment are other possible mechanisms to behavior change, related to the strategic focus of FBT. Engagement and retention are major challenges in treatment of young people with drug use problems. FBT includes pre-treatment engagement strategies as well as active involvement of young people and their parents in treatment planning. Furthermore, the intervention is based on behavioral assessments and tailored to the participants as well as family behavioral problems, which is assumed to be part of the explanation for FBT's impact on young people's drugs use.

Motivation is seen as being key to positive treatment outcome (Williams et al., 2000), and is also linked to the support and influence of the family system. The ability of the family system to influence the young person to a non-drug-using lifestyle is a possible mechanism of change related to the family systems focus of FBT. Studies have found that FBT positively influences parent satisfaction with youth, family relations, youth psychological functioning (particularly there is a decrease in youth depression among recipients of FBT), and contributes to the reduction in young people's drug use (Azrin et al., 1994a; Austin et al., 2005; Azrin et al., 1994b; Azrin et al., 2001; Deas & Thomas, 2001). Azrin et al., 1994b and Azrin et al., 1996 attribute reductions in drug use to active parental participation in the young person's drug treatment. Family and peer support for non-drug usage is related to improved relapse management (Williams et al., 2000).

Communication skills training and positive reinforcement are possible mechanisms of behavior change, related to the behavioral focus of FBT. Studies have found that FBT participants experience improved family relations (Azrin et al., 1994a; Austin et al., 2005; Azrin et al., 2001; Deas & Thomas, 2001). Improvements in family relations and family behavior may be related to the FBT skills training in family communication, social support and contracting procedures (Azrin et al., 1994a). Some studies have suggested that problem behavior is reduced from pre- to post-treatment measurement, also for young people with conduct disorder diagnosis (Austin et al., 2005; Azrin et al., 1994a; Azrin et al., 2001; Deas & Thomas, 2001, William et al., 2000). These findings suggest that youth behavior is improved and that skills training and positive reinforcement may support the young people in abstaining and dealing with possible relapse to drug use. Azrin et al. (1996) suggest that the use of direct contingencies of reinforcement by the therapist or family on drug usage positively affect drug use in the short and long term.

The behavioral focus, family systems focus, and the strategic focus are all possible explanations of intervention impact. These mechanisms influence family behavior

and functioning, and ultimately facilitate changes in young people's drug use problems.

1.4 WHY IT IS IMPORTANT TO DO THIS REVIEW

Persistent drug use among young people is a significant social problem, and treatment of young people's drug use is challenging and costly, not least because treatments for drug use problems in youth are plagued by high dropout rates and post-treatment relapse to drug use. Research suggests that nearly half of the young drug users never complete drug use treatment (Substance Abuse and Mental Health Services Administration (SAMSHA), 2008). There is a need to identify effective treatments for addressing young people's drug use problems, and to reduce treatment dropout and post-treatment relapse. Young drug users who remain untreated are at risk of progression to severe dependence. Furthermore the growing interest among policy makers in increasing funding for empirically supported interventions is a strong motivation to add to the evidence base with a systematic review on a potentially promising treatment for young drug users.

We identified five narrative reviews and four quantitative reviews that examined FBT for drug using youth. The majority of these conclude that more research is needed on the effects of FBT, on its moderators, on identifying of which subgroups of youth may be more likely to respond, and on how treatments can be tailored to individual need. Each of the five narrative reviews considered more than one intervention. Austin et al., 2005, Williams et al., 2000, Deas & Thomas, 2001, and Hogue & Liddle, 2009 all reported generally positive effects for FBT. However, all base their conclusions about FBT solely on the results of a single study; Hogue & Liddle review was based on Azrin et al., 2001, whereas the other three reviews based their conclusions on Azrin, Donohue, Besalel, Kogan & Acierno, 1994a. We also identified four quantitative reviews (Bender, Tripodi, Sarteschi & Vaughn, 2011; Vaughn & Howard, 2004; Bender, Springer & Kim, 2006; Waldron & Turner, 2008). Bender et al., 2011 and Vaughn & Howard, 2004 drew conclusions about FBT based on a single study (Azrin et al., 1994a). Vaughn & Howard, 2004 concluded that for FBT there was *"evidence of clinically meaningful effect (ES > .20) with relatively strong designs and less than 1-year follow-up and no replication"*. Bender et al., 2011 used meta-analysis to evaluate family therapy and individual therapy for drug-using youth, and found that FBT yielded large effects (> .80), again based solely on Azrin et al., 1994a. Waldron & Turner (2008) concluded, based on the Azrin et al. (2001) study, that "other family models," which included FBT, *"are probably efficacious, pending replication by independent research teams."* Bender et al., 2006 reviewed the effectiveness of several interventions for dually diagnosed adolescents and concluded there was *"a small treatment effect favoring the FBT group"* for the reduction of substance use, although this too was based on a single study (Azrin et al., 2001).

There have thus been several studies which have indicated that FBT could be a promising treatment for young people with non-opioid drug use. By aggregating individual studies' results on FBT this review will contribute to the knowledge about treatment of young drug-users and their families. The review will inform practice by exploring the effects of FBT for relevant user groups.

2 Objective of the review

The aim of this review is to evaluate the current evidence on the effects of FBT on drug use reduction for young people in treatment for non-opioid drug use.
A further objective, if possible, is to examine moderators of drug use reduction effects, specifically analyzing whether FBT works better for particular types of participants.

3 Methods

3.1 TITLE REGISTRATION AND REVIEW PROTOCOL

The title for this systematic review was registered in The Campbell Collaboration on 20 June, 2011. The review protocol was approved on 18. April, 2012. Title registration and protocol are available at: http://www.campbellcollaboration.org/library.php.

3.2 CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

3.2.1 Types of studies

The study designs eligible for inclusion in the review were:

- Controlled trials (all parts of the study are prospective, i.e. recruitment of participants, assessment of baseline, allocation to intervention, selection of outcomes and generation of hypotheses; Higgins & Green, 2008):
    - RCTs - randomized controlled trials
    - QRCTs - quasi-randomized controlled trials (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)
    - NRCTs - non-randomized controlled trials (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 comprised young people age 11-21 years who were enrolled in a manual-based FBT out-patient treatment for non-opioid drug use (e.g., cannabis, amphetamine, ecstasy or cocaine).

Definitions of young people, and the age in which a person is considered a young person and may be entitled special services, such as drug treatment varies 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 set the age range from 11 to 21 years (Hibell et al., 2009; United Nations, 2011; SAMHSA, 2010; Danish Youth Council, 2011).

Because family interactions are cardinal in FBT, we included only out-patient interventions in order to evaluate effects of FBT on youth living with their family..

No universal international consensus exists concerning what categories to use when classifying drug users[6], 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 Organisation (WHO), 2011; Nordegren, 2002). We chose to include participants regardless of formal drug use diagnosis: the main criterion for inclusion was that the young person had been enrolled in treatment for drug use (i.e. intervention or comparison condition). Referral to and enrolment in treatment required a level of drug use to the extent that the young person, his/her parent or significant other, or a representative of a statutory authority, had found it necessary to solicit or require treatment. We therefore defined the population as young people referred to treatment, or in treatment, for using non-opioid drugs.

3.2.3 Types of interventions

The review includes outpatient manual-based FBT interventions of any duration delivered to young people and their families (see 1.2 Description of the intervention). We included FBT outpatient interventions that did not include overnight stays in a hospital or other treatment facility.

We also excluded cases where the young drug user was placed outside the family home (e.g., in-patient treatment and incarceration in a locked facility) where the core condition of the program will be seriously compromised.

[6] Different systems classify clients into different categories, e.g., 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 the DSM-IV is a widely used classification systems, other relevant classification systems such as the International Statistical Classification of Diseases and Related Health problems (ICD, now ICD-10) developed by the World Health Organisation (WHO) are also in wide use. Differences between the classification systems concern both terminology and categorization criteria. For example the DSM-IV includes the category 'abuse', while the 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 while the ICD-10 solely operates with physical and mental criteria, the DSM-IV also includes social criteria (WHO, 2011, Nordegren, 2002).

Eligible comparison conditions were no intervention, waitlist controls and alternative interventions, as we are interested in both absolute and relative effects. Due to ethical considerations and nature of the problem we anticipated the likelihood of a no treatment control group to be small. We expected and found that the most frequent comparison was alternative interventions (Lipsey et al., 2010).

3.2.4 Types of outcomes

We included the following outcomes:

Primary outcomes

- Abstinence or reduction of drug use as measured by:
    - Biochemical test (e.g., urine screen measures for drug use);
    - Self-reported estimates of drug use (e.g., Time-line Follow Back interview; Sobell & Sobell, 1992);
    - Psychometric scales (e.g., Addiction Severity Index; McLellan, Luborsky, Woody & O'Brien, 1980).

Secondary outcomes

- Family functioning (e.g., measured by the Beavers Interactional Competence Scale; Beavers & Hampson, 2000).
- Education or vocational involvement (e.g., measured by grade point average, attendance, self-reported or reported by authorities, files, registers, or employment record).
- Retention (e.g., measured by days in treatment, completion rates and/or attrition rates).
- Risk behavior, such as crime rates, prostitution (e.g., measured by self-reports or reports by authorities, administrative files, registers).
- Other adverse effects (e.g., measured by rates of hospitalization, suicide and over-doses).

The primary outcome is abstinence or reduction of drug use as the overall review question is to evaluate current evidence on FBT's effects on young people in treatment for drug use. We sought 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 PVH).

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.

The following bibliographic databases were searched:

Bibliotek.dk searched until October, 2014
BIBSYS searched until October 12, 2014
CINAHL searched until June 12, 2011
Cochrane Library searched until October, 2014
Criminal Justice Abstracts searched until October, 2014
Embase searched until October, 2014
ERIC searched until October, 2014
LIBRIS searched until October, 2014
Medline searched until October, 2014
PsycINFO searched until October, 2014
Science Citation Abstract searched until October, 2014
Social Care Online searched until October, 2014
Social Science Citation Abstract searched until October, 2014
SocINDEX searched until October, 2014

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 other databases (see appendix 12.1).

1. FBT or BFT.af.
2. Famil* adj1 Behavio$r* adj1 therap*.af.
3. 1-2/or

Due to the narrow search strategy, we performed extensive searches of the grey literature and conducted hand searches, as described below.

3.3.3 Searching other resources: Snowball search

The review authors checked the reference lists of other relevant reviews and the two included primary studies for new leads. We identified 16 leading international experts who have published on the subject, and contacted them individually in attempt 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 Searching other resources: Hand search

The following international journals were hand searched:

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

Searching were performed on editions from 2011 to the point of review in attempt to capture any relevant studies recently published and therefore not identified in the electronic search.

3.3.5 Grey literature

Additional searches were made using *Google* and *Google Scholar* and we checked the first 150 hits. OpenGrey (http://www.opengrey.eu/) 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 these sites:
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 (SLO[7]) independently screened all titles and available abstracts to exclude studies that were clearly irrelevant. Studies considered eligible by at least one of the reviewers was 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 on eligibility were resolved by discussion.

Reasons for exclusion were documented for five studies that initially appeared relevant for the review. However none of these fulfilled our inclusion criteria and all were excluded (see sections 4.2.2, 8.2 and 9.2). The study inclusion screening sheet

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

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 11.1).

3.4.2 Data extraction and management

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

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-Randomised Studies Methods Group (Reeves, Deeks, Higgins, & Wells, 2011) [8]. This model, an unpublished extension of the existing Cochrane Collaboration's risk of 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 Hand book, chapter 8 (Higgins & Green, 2008). The extension to the model is explained in the three following points:

1) The existing Cochrane risk of bias tool needs elaboration when assessing non-randomized 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 studies[9] by adding an explicit item about confounding (Reeves et al. 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 marked whether the confounder was considered by the researchers, the precision with which it was measured, the imbalance between groups and the care with which adjustment was carried out. This assessment will inform 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 that RCTs must have a protocol in advance of starting to recruit

[8] 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).

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

whereas non-randomized studies need not. The item concerning selective reporting therefore 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 thinking of data synthesis as it operationalizes the identification of studies (especially in relation to non-randomized 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

The risk of bias model used in this review is based on 9 items (see section 10.2 for Risk of Bias tool).

The 9 items refer to

- **sequence generation** (Judged on a low/high risk/unclear scale – NRCT will automatically have 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, i.e. NRCT)
- **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 priory analysis plan** (Judged on a yes/no/unclear scale)

The assessment was based on pre-specified questions (see section 10.2). “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, e.g., a poor quality study). A judgment of 5 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 10.2). None of the included studies in the review or parts thereof were judged 5 on the risk of bias scale.

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

Assessment

Two review authors (ML & MS) independently assessed the risk of bias for each included study as described in the previous sections. Disagreements were resolved by discussion and consulting a third reviewer with content and statistical expertise (TF). We reported the risk of bias assessment in tables (section 9.3) for both included studies.

3.4.4 Measures of treatment effect

Standardized mean differences (SMD) were used as the effect size metric for drug use, family functioning and risk behavior; the data used for these calculations were means, standard deviations and sample size. RevMan 5.0 and Excel software were used for storing data and statistical analyses.

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 may have undergone multiple interventions, whether there were multiple treatment groups and whether there were multiple publications for some studies.

Cluster randomized trials

No cluster randomized trials were included in the review.

Multiple interventions per individual
We did not find any studies with multiple interventions per individual.

Multiple intervention groups

We did not find any studies with multiple intervention groups.

Multiple publications

We did not find multiple publications for any studies.

Multiple time points and outcomes

All follow-up durations reported in the primary studies were recorded. It was possible to group time points at end of treatment (6 month post-intake). Only one study reported outcomes at the 12 month post-intake and we performed separate analyses for these time points. Multiple measures of drug use were reported. We analyzed the measure that studies had in common; days of drug use per month. Multiple measures of risk behavior were reported. We analyzed the measure that studies had in common; number of arrests.

3.4.6 Dealing with missing data and incomplete data

We assessed missing data and recorded attrition rates for the two included studies. We were not able to discern reasons for attrition for either study. We contacted primary authors for both studies requesting data that was missing on the exact number of participants randomized, but received no reply.

Intention to treats analysis

Neither of the included studies used ITT methods.

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). Any interpretation of the Chi-squared test was made cautiously on account of its low statistical power.

3.4.8 Assessment of publication bias

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

As we were able to include only two studies in this review, our plans for funnel plots and related methods were not feasible.

3.5 DATA SYNTHESIS

Neither of the two included studies were coded as 5 on the Risk of Bias 5 point scale (described in section 3.4.3), and both studies are included in the data synthesis where possible. We did not find any studies comparing FBT to a no treatment condition, or to untreated wait list controls, and we are therefore unable to reach any conclusion about the absolute effects of FBT. The analysis of the relative effects of FBT (versus other interventions) was conducted on studies that compared FBT to

Individual Cognitive Problem-Solving and Supportive Counseling. All follow-up durations reported in the primary studies were recorded. The two studies both reported averaged scores over the six months during treatment, which could be pooled. Only one study reported outcomes at 12 months post-intake and we performed separate analyses for these time points.

All analyses were inverse variance weighted using random effects statistical models that incorporate both the sampling variance and between study variance components into the study level weights. Random effects weighted mean effect sizes were calculated using 95% confidence intervals. We provide 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 sufficient studies to allow subgroup analysis to be conducted.

3.5.2 Sensitivity analysis

We did not identify sufficient studies to allow any sensitivity analyses to be conducted.

4 Results

4.1 RESULTS OF THE SEARCH

We ran the searches during May and June 2011 and updated them in October 2014. The joint results of the searches are summarized in the flow chart in Section 11.

We searched fourteen bibliographic databases, and performed an extensive search for grey literature, and hand searched five core journals from 2011 to submission (see section 3.3).

A total of 10,799 potentially relevant records were obtained from the electronic search after excluding duplicates (database search: 5,612 records, grey literature search: 977 records, hand search, snowball etc.: 4,190 records).

The results were screened based on title and abstract and 99 records were retrieved and screened in full text. Of these, 97 did not fulfill the screening questions and were excluded. Five of the 97 excluded studies appeared relevant at first sight, but were excluded after careful screening.

One paper from the database literature search was included, and one paper from snowball search was included. No papers from hand searching and grey literature were included.

A total of 2 studies, reported in 2 separate papers, met the inclusion criteria and were vetted by the reviews authors.

See section 4.2 for further details of the included and excluded studies.

4.2 DESCRIPTION OF THE STUDIES

4.2.1 Included studies

Two studies met our inclusion criteria:

Azrin, Donohue, Teichner, Crum, Howell & DeCato (2001) is an RCT on the effects of FBT on drug using youth aged 12-17 with a dual diagnosis of substance use and conduct disorder, performed in the US. The study was funded by the National

Institute of Mental Health, and published in Journal of Child & Adolescent Substance Abuse, volume 11 (1), 2001. In the following we will refer to this study as Azrin 2001.

Azrin, Donohue, Besalel, Kogan & Acierno (1994a) is an RCT on the effects of FBT on drug using youth age 13-18, performed in the US. The study was funded by the National Institute of Drug Abuse, and published in Journal of Child & Adolescent Substance Abuse, volume 3 (3), 1994. We will refer to this study as Azrin 1994.

Nathan Azrin is the developer of the FBT program and Bradley Donohue is the current program director for FBT.

Design

Both included studies are described by the investigators as RCTs. Participants in Azrin 2001 were randomized by matched pairs when possible. Matching was based on age, days of monthly drug use, types of drugs used, and the problem and intensity scales of the Eiberg Child Behavior Inventory (ECBI). Participants in Azrin 1994 were randomized in matched pairs at the family level. Fourteen of the participants in Azrin 1994 had participated in an earlier trial by Azrin, McMahon, Donohue, Besalel, Lapinski, Kogan, Acierno & Galloway (1994b) and it is unclear how these 14 participants were distributed in the current study design.

Sample size

Sample size for both studies is unclear as total number of participants randomized to treatment and control is not reported. In Azrin 2001, 178 participants met inclusion criteria, and 88 participants attended 3 assessment sessions and completed at least 1 treatment session. 56 participants completed 8 or more treatment sessions and are included in the analysis. However, it remains unclear how many participants were randomized. In Azrin 1994 the number of participants randomized is not reported. Azrin 1994 state as an inclusion criterion that participants needed to have completed 4 or more treatment sessions, and be willing to provide drug use data for 6 months following initiation of treatment. 26 participants completed 4 or more treatment sessions and were included in the analysis.

Participants

The age of participants in the two included studies ranged from 12 to 18 years. The majority were male. In Azrin 2001, 25 percent of participants were living in single parent families. The proportion with a minority background in the two included studies ranged from 19 to 21 percent. Cannabis was the main drug used by the participants in both studies.

Table 4.2.1 Participant characteristics

	Azrin 1994	Azrin 2001
Age range (Mean), years	13-18 (16.0)	12-17 (15.4)
Gender, male	77%	82%
Family composition, single parent households	-	25%
Ethnicity, Minority	19%	21%
Main drug used	Cannabis	Cannabis

Comorbidity was present in the majority of participants in Azrin 2001, where 76 percent had a dual diagnosis of substance use/dependency and conduct disorder. Azrin 1994 provided no information on comorbidity.. Azrin 2001 excluded youth with a diagnosis of mental retardation or psychotic disorder, whereas Azrin 1994 excluded youth receiving psychological or psychiatric treatment. There may therefore be an imbalance in the population's comorbidity between the two studies. The two studies differed in the way participants were recruited: in Azrin 2001 71% were externally mandated by the court or by another outside agency; in Azrin 1994 participants were recruited from agencies, schools, and newspaper advertisements.

Inclusion criteria in included studies

Inclusion criteria in Azrin 2001 were:

- participants aged 12-17 years;
- present symptoms consistent with DSM-V diagnosis of conduct disorder plus substance abuse/dependency;
- participants living with parents and within 30 minutes of the assigned clinic;
- no diagnosis of mental retardation or psychotic disorder;
- not receiving psychological intervention;
- at least one parent is willing to provide transportation to treatment and participate in treatment.

Inclusion criteria in Azrin 1994 were:

- participants aged 13-18 years;
- have engaged in illegal drug use other than or in addition to alcohol use during past month;
- not receiving psychological/psychiatric treatment;
- residing within 12 miles of the counseling facility;
- have resided locally for 6 months prior to enrollment, and not have plans for moving outside local area.

Exclusion criteria

Neither of the two included studies reported any exclusion criteria.

Experimental interventions in included studies

In Azrin 2001, youth and parents attended sessions together and separately, and performed assessments and ratings together and individually. Treatment duration was fifteen sessions delivered over the course of 6 months. During the first three months, participants had weekly sessions, decreasing to biweekly sessions, and eventually to monthly. Sessions were of 90 minutes duration initially, decreasing to 60-75 minute sessions from the seventh to fifteenth session. The average number of FBT sessions attended was 13.48.

In Azrin 1994, parents participated in all sessions. Duration of treatment was 6 months with sessions twice weekly initially, and then reduced in frequency as progress became apparent. The average number of 2-hour sessions attended was fifteen.

Control conditions in included studies

The control condition in Azrin 2001 was manual based Individual Cognitive Problem- Solving (ICPS), with a cognitive focus on problem solving and without behavioral features. Duration of treatment was 15 sessions delivered over 6 months. During the first three months participants had weekly sessions, decreasing to biweekly sessions, and eventually to monthly. Sessions were 90 minutes initially, decreasing to 60-75 minute sessions from the seventh to fifteenth session. The average number of ICPS sessions attended was 13.70.

The control condition in Azrin 1994 was Supportive Counseling, designed to include the principal features of supportive counseling, emphasizing expression of feeling, self-attempts at insight, discussion of drug related experiences and feelings, and group interaction. Youth attended individual one-hour sessions weekly and two-hour group sessions weekly, parents attended sessions once monthly. Treatment duration was 6 months with a mean of 15 sessions attended.

Time points for measurements

Azrin 2001 provided assessments at six months prior to the initial intake session, during the six months of treatment, and at six months post-treatment for measures of drug use and arrests. Drug use (reported as days per month using drugs) was measured continuously during the 6 months preceding treatment, during the treatment period and during the six months following the end of treatment. The reported results were averaged scores over each six month period. Arrest scores were reported as frequency of arrests during the six months period preceding,

during and after treatment. Family functioning measures were based on interviews performed at intake, end of treatment and six months after end of treatment.

Azrin 1994 provided assessments one month preceding treatment and during the six months of treatment. Drug use, family functioning and arrests were measured repeatedly and scores averaged over one month prior to treatment and during the six months of treatment.

Primary outcome

Youth drug use
Abstinence or reduction of youth drug use was reported using urine drug screens in Azrin 2001 and Azrin 1994. Both studies measured days using drugs during a 28-30 day period. A decreased number of days using drugs indicates reduction of drug use. Azrin 2001 combined the urine screens with Timeline Follow Back (TLFB) interviews by youth and parents separately. TLFB measures self-reported drug use, and a decreased number of days using drugs indicates a reduction of drug use. Azrin 1994 combined the urine screens with reports on drug use type and frequency by the young person and parents at each session.

Secondary outcomes

Family functioning
Azrin 2001 measured family functioning using the Parent Happiness with Youth Scale (PHYS) and Youth Happiness with Parents Scale (YHPS). PHYS and YHPS are measures developed from the Parent and Youth Satisfaction Scales used in Azrin 1994. The PHYS measures parent's degree of satisfaction with youth on a series of behavioral domains (Communication, Friends and activities, Curfew, Household rules, School, Response to rewards, Response to discipline, Chores, Alcohol use, Drug use, Illicit behavior) on a scale from 0-100%. The YHPS measures the young person's satisfaction with parents on the same scale and over the same behavioral domains as the PHYS.

In Azrin 1994, family functioning was measured using the Parent Satisfaction Scale and Youth Satisfaction Scale. The Parent Satisfaction Scale and the Youth Satisfaction Scale were used to measure the overall satisfaction of the parent-youth relationship on a scale from 0-100% by youth and parents.

Education or vocational involvement

Azrin 2001 reported on the school scale of the Child Behavior Checklist (CBCL) which is a measure of emotional and behavioural adjustment completed by teachers, and Azrin 1994 provides school or work attendance reported by youth and parents. Although Azrin 2001 further report on satisfaction in this domain by the school scale

in PHYS and the school aspect of the Life Satisfaction Scale for Adolescents (LSS-A) reported by the young person, educational measures in the two included studies are non-comparable.

Retention

Retention is unclear in Azrin 2001 and Azrin 1994, due to the lack of information on total number of participants randomized in the studies.

Risk behavior

Risk behavior is reported by arrests history records in Azrin 2001. Azrin 1994 measures risk behavior by arrests reported by youth and parents.

Other adverse effects

There are no reports on other adverse effects in the included studies.

Independence
The two included studies are conducted by FBT program developer Nathan Azrin and the current Program Director Bradley Donohue (Azrin 1994, Azrin 2001).

For further details on included studies see section 9.1 Characteristics of included studies.

4.2.2 Excluded studies

Studies without a control group
Two studies were excluded because they did not have a control group (Bry, Conboy & Bisgay, 1986; Bry & Krinsley, 1992).

Case studies
Three case studies were excluded (Donohue & Azrin, 2002; Juhnke & Liles, 2000; Moncher, Holden, Schinke & Palleja, 1990).

None of these five studies fulfilled our inclusion criteria and were therefore excluded from review (see section 8.2 and section 9.2).

4.3 RISK OF BIAS IN INCLUDED STUDIES

Neither of the two included studies can be characterized as a robust RCT as both had at least one assessed item judged to have a risk of bias greater than 'low'. A key issue in regards to assessment of risk of bias in the two studies is the lack of information on the number of participants randomized in the trials.

The ratings of the two studies in relation to the nine domains in the Risk of Bias tool are listed below, and summarized in table 4.3. See section 9.3 for further details on risk of bias in included studies. The risk of bias judgments were based on pre-specified questions and a 5 point scale with ratings of 1=low risk and 5=high risk (see section 10.2 Risk of Bias tool).

Nathan Azrin was contacted for details on any uncertainties in relation to risk of bias assessment items, but unfortunately no response has been received.

4.3.1 Sequence generation

Both included studies were described as randomized controlled trials, with randomization reported as being at the level of the family. Azrin 2001 reported a procedure for randomization in matched pairs that was judged as having a low risk of bias for sequence generation. Azrin 1994 also reported randomization in matched pairs, although here there was a lack of clarity on how 14 participants who had participated in an earlier study were allocated in the current trial. The risk of bias for sequence generation in Azrin 1994 was therefore judged as 'unclear'.

4.3.2 Allocation concealment

Both included studies randomized using the toss of a coin, and were judged as having a low risk of bias for allocation concealment.

4.3.3 Blinding

As is common in social interventions, especially when outcomes are self-reported, there is inherent bias given the impossibility of blinding participants or those delivering the interventions. Outcome assessors could be blind to participant's group allocation, but only Azrin 2001 report that outcome assessors were blinded to participant's treatment assignments, and is rated 1 for blinding. Azrin 1994 did not report on blinding and the risk of bias for this item was therefore assessed as unclear for this study.

4.3.4 Incomplete outcome data

Drop-outs were reported in both studies. Analysis is performed for attrition imbalance and only imbalance found in Azrin 2001 is a higher percentage of male primary caregivers for treatment completers. Azrin 1994 analyze potential imbalance in days of drug use prior to treatment for completers and non-completers, and find no imbalance in this measure.

Both studies lack information on total number of participants randomized in the trials, which is obscuring the possibility to assess missing data. Both studies exclude participants from the analysis based on number of sessions attended.

Azrin 2001 excludes participants with less than 8 sessions completed. Azrin 2001 use mean substitution when data are missing from follow up measurements for all outcomes but Urine analysis and the school subscale of the CBCL (among those included in the analysis). Due to the lack of clarity on number of participants randomized and missing data Azrin 2001 is rated unclear risk of bias for incomplete outcome reporting.

Azrin 1994 excludes participants who completed less than 4 sessions from the analysis. Azrin 1994 does not report details on dealing with missing data. Due to the lack of information on N's randomized and missing data Azrin 1994 is rated unclear risk of bias for incomplete outcome reporting.

4.3.5 Selective outcome reporting

Both studies lack information on the total number of participants randomized in the trials, and the proportion of participants included in the analysis compared to those potentially missing from the analysis is therefore unknown. In Azrin 2001, only participants who completed 8 or more treatment sessions were included in analysis raising the possibility that a significant proportion of participants might have been excluded from the analysis. Azrin 2001 was therefore rated 4 for risk of bias related to selective outcome reporting.
In Azrin 1994 participants were excluded from the analysis if they had not completed at least 4 sessions, raising the possibility that a proportion of participants are likely to be excluded from the analysis. Azrin 1994 was rated unclear for risk of bias related to selective outcome reporting.

4.3.6 Other potential sources of bias

We were not able to locate protocols for any of the two studies.

Table 4.3 Risk of bias across included studies

	Azrin et al., 2001	Azrin et al., 1994a
Sequence generation	Low	Unclear
Allocation concealment	Low	Low
Blinding	1	Unclear
Incomplete outcome data	Unclear	Unclear
Free of selective reporting	4	Unclear
Free of other bias	-	-

A priori protocol	Unclear	Unclear
A priori analysis plan	Unclear	Unclear
Confounding	*NA*	*NA*

NA: Not Applicable.

4.4 EFFECTS OF THE INTERVENTIONS

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

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

The experimental intervention given to participants was manual based FBT in both included studies. Comparison conditions were Individual Cognitive Problem-Solving (ICPS) and Supportive Counseling. No conclusion could therefore be drawn on the absolute effects of FBT.

Meta-analysis was performed on the primary outcome, drug use reduction, and on the secondary outcomes family functioning and risk behavior. Meta-analysis was not feasible for the outcomes of education, retention or other adverse effects due to differences in outcome measures, or to lack of data.

We grouped the outcomes of both studies at end of treatment. For drug use frequency, averaged scores over the course of the six months treatment period were used. Azrin 2001 additionally reported drug outcomes averaged over the six months period from end of treatment to 12 month post-intake. For family functioning, Azrin 2001 interviewed at end of treatment and at 12 month post-intake, whereas Azrin 1994 measured repeatedly during the six months of treatment; the outcome reported and grouped at end of treatment is an average score over the six months. For arrests (risk behavior),
Azrin 2001 reported accumulated scores over the course of the six months treatment and accumulated scores over the six month post-treatment period, whereas Azrin 1994 reported an average of the number of arrests per month over the six month treatment period.

4.4.1 Primary outcome results

The two included studies report drug use reduction in terms of number of days of drug use per month. For Azrin 2001, there was no statistically significant difference between FBT and the comparison treatment at end of treatment. For Azrin 1994, however, there was a statistically significant difference in favor of FBT at end of

treatment. Pooled results show no statistically significant effect of FBT on drug use reduction. The pooled estimate is SMD = 0.49 (95% CI -0.51, 1.50) with statistically significant heterogeneity between studies (p=0.04, Tau^2=0.40, I^2=75%).

For Azrin 2001, there was no statistically significant difference between FBT and the comparison treatment at 12 months post-intake; SMD=-0.03 (95% CI -0.58, 0.52).

Figure 4.1: Drug use reduction. End of treatment.

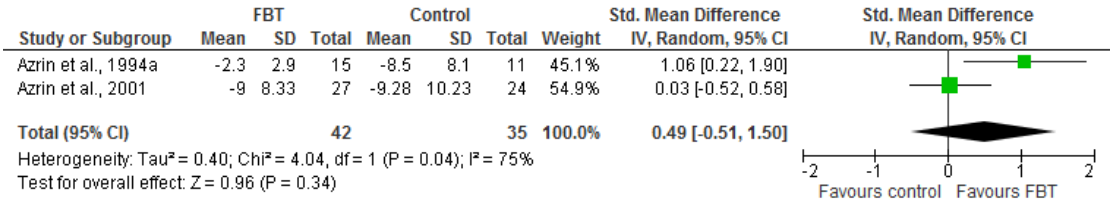
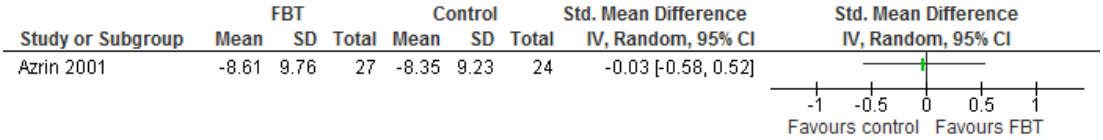


Figure 4.2: Drug use reduction. 12 month post-intake



4.4.2 Secondary outcomes results

Family functioning

Family functioning was reported using the Parent Happiness with Youth Scale (PHYS) and the Youth Happiness with Parents Scale (YHPS) in Azrin 2001, and the Parent and Youth Satisfaction Scales in Azrin 1994. In Azrin 1994, there was a statistically significant difference in parent satisfaction at the end of treatment favoring FBT, whereas no significant difference emerged in Azrin 2001 on this outcome. Pooled results for parent satisfaction show statistically significant effects of FBT on family functioning reported by parents; SMD= 0.58 (95% CI 0.02, 1.13) with no statistically significant heterogeneity between studies (p= 0.26; Tau^2 = 0.04, I^2=22%). Neither study demonstrated a statistically significant effect of FBT on youth satisfaction at end of treatment; pooled results were SMD= 0.29 (95% CI -0.72, 1.30) with a statistically significant heterogeneity between studies (p=0.05, Tau^2=0.40, I^2=74%). For Azrin 2001 at 12 month post-intake, there was no statistically significant difference between FBT and the comparison treatment, for either parent satisfaction or youth satisfaction with family functioning; the SMD for parent satisfaction was -0.30 (95% CI -0.86, 0.26) and the youth was 0.47 (95% CI -0.09, 1.04).

Figure 4.3: Family functioning, parent report. End of treatment.

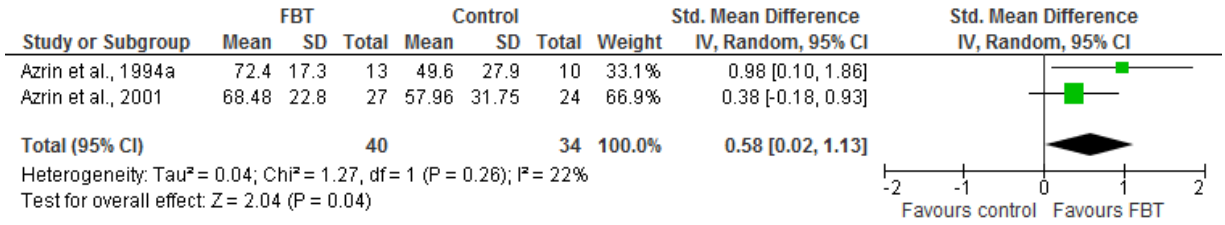


Figure 4.4: Family functioning, youth report. End of treatment

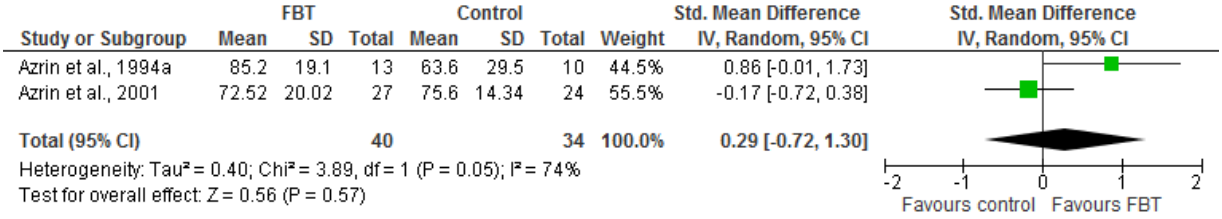


Figure 4.5: Family functioning, parent report. 12 month post-intake

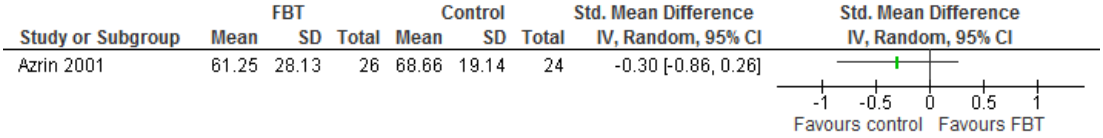
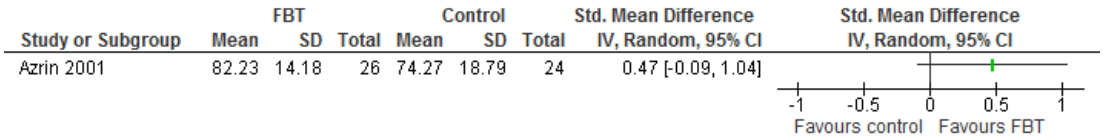


Figure 4.6: Family functioning, youth report. 12 month post-intake



Education or vocational involvement

The measures for education and vocational outcome are not comparable between the two studies. Azrin 2001 uses the school subscale of the Child Behavior Checklist (CBCL). Azrin 1994 reported combined school and work attendance. At end of treatment there were no statistically significant differences found in either study; SMD=0.01 (95% CI -0.63, 0.66) and SMD=-0.11 (95% CI -0.90, 0.68). For Azrin 2001, there was no statistically significant difference at 12 month post-intake; SMD= 0.31 (95% CI -0.45, 1.07)

Figure 4.7: Education or vocational involvement, Child Behavior Checklist (CBCL) and combined school and work attendance (CSWA). *End of treatment.*

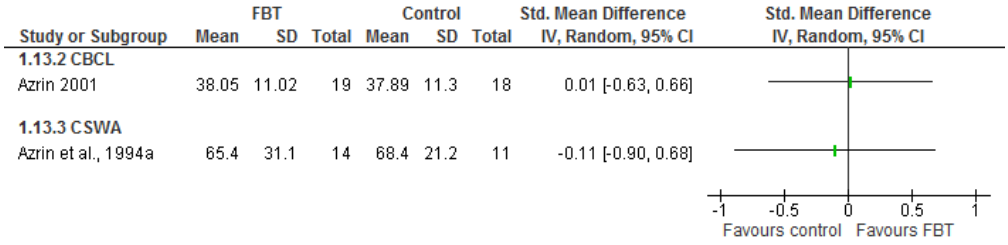
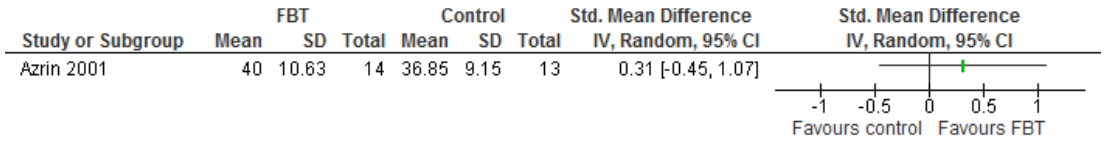


Figure 4.8: Education or vocational involvement, Child Behavior Checklist (CBCL). 12 month post-intake.



Retention

It was not possible to perform meta-analysis on retention because no information was available in either study on the number of participants randomized.

Risk behavior

Both studies provided delinquency measures in terms of the number of arrests. No statistically significant effect emerged in either study. Pooled results show no statistically significant effect for FBT on arrests; SMD= 0.29 (95% CI -0.16, 0.74) with no statistically significant heterogeneity between studies (p= 0.60, Tau^2= 0.00, I^2=0%). For Azrin 2001, however, there was a statistically significant difference favoring the comparison treatment at 12 months post-intake; SMD= -0.56 (95% CI -1.13, 0.00).

Figure 4.9: Risk behavior, arrests. End of treatment.

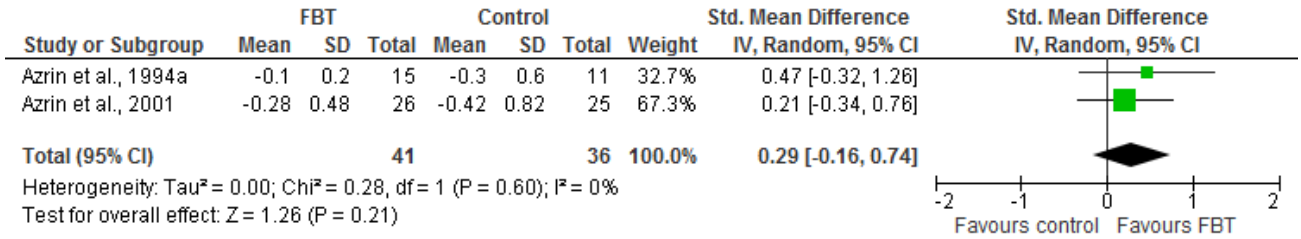
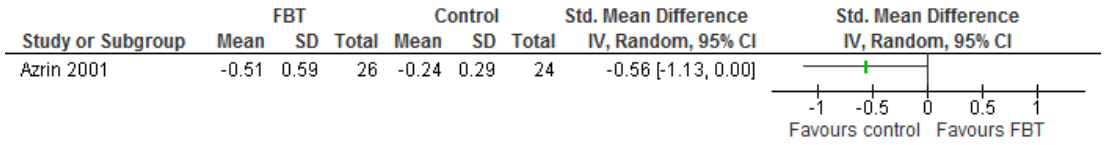


Figure 4.10: Risk behavior, arrests. 12 month post-intake.



Other adverse effects

No other adverse effects (as measured, for example, by rates of hospitalization, suicide and overdoses) were reported in the two included studies.

5 Discussion

5.1 SUMMARY OF THE MAIN RESULTS

Two randomized controlled trials of FBT met the inclusion criteria for this review. It was not possible to analyze the absolute effects of FBT. Both studies compared FBT to other active interventions, namely Individual Cognitive Problem Solving (ICPS) and Supportive counseling.

The outcomes were reported at varying time points. We grouped the outcomes at 6 months post randomization, which corresponds to the end of treatment for all treatment conditions. Only one study reported outcomes at 12 month post-intake.

Our main objective was to evaluate the current evidence on the effect of FBT on drug use reduction for young people in treatment for non-opioid drug use. Further objectives were to examine the moderators of drug use reduction effects and to examine if FBT works better for particular groups, although it was not possible to assess these due to the limited number of studies.

When interpreting the results, consideration should be given to the limited number of studies included in the analysis and to the limited number of participants included in those two studies. The conclusions that can be drawn from providing FBT to young drug users compared to other active treatments would be more convincing if more studies were available.

To summarize on the main objective, we found the following results:

Abstinence or reduction of drug use
Meta-analysis of the two included studies (Azrin 2001, Azrin 1994) did not show a statistically significant effect of FBT for youth drug use reduction at end of treatment and there was no statistically significant difference for Azrin 2001 at 12 month post-intake. . Thus available data does not support the hypothesis that there is a drug use reduction effect of giving FBT to young drug users compared to Individual Cognitive Problem-Solving (ICPS) and supportive counseling (SC).

Family functioning
Meta-analysis of the two included studies showed a statistically significant effect of FBT on family functioning as reported by parents compared to ICPS and SC,

although the confidence intervals are wide. Meta-analysis of family functioning reported by youth did not show any statistically significant effect of FBT compared to ICPS and SC. At 12 month post-intake, effect sizes for family functioning (as reported by parent or youth) were not statistically significant.

Education or vocational involvement
It was not possible to perform meta-analysis on the outcomes of education or vocational involvement as the measures used in the two studies were not comparable. Neither of the studies reported any statistically significant effect on school outcomes for FBT compared to ICPS and SC.

Retention
It was not possible to perform meta-analysis on retention due to lack of data.

Risk behavior
Meta-analysis of the two studies showed no statistically significant effect for FBT on arrests in comparison to ICPS and SC. At 12 month post-intake, however, Azrin 2001 showed a statistically effect favoring the comparison treatment ICPS. There is no evidence of any significant difference between FBT and comparison treatments on arrests at the end of treatment, and there is indication of an effect favoring the comparison treatment at 12 month post-intake.

Other adverse effects
No other adverse effects (as measured by, for example, rates of hospitalization, suicide and overdoses) were reported in the included studies.

In conclusion, the few available studies preclude any firm conclusions being drawn on the effectiveness, ineffectiveness or potential damage of FBT for young people in treatment for non-opioid drug use.

5.2 OVERALL COMPLETENESS AND APPLICABILITY OF EVIDENCE

We found only two trials that examined whether FBT reduce youth drug use; both studies include outpatient manual based FBT intervention. Both were performed in the US by the FBT program developer. It was not possible to analyze the absolute effects of FBT. Both studies compared FBT to other active treatments. The majority of participants in the two included studies were male (77% and 82 % respectively).

It was only possible to pool outcomes at 6 months post baseline, which equates to the end of treatment. Only one of the two studies provided follow up at 12 months post baseline, allowing for documentation of accumulated or longer-term effects. Thus there is the possibility that the follow up period is insufficient for significant changes to be detected.

Both studies provide data on the primary outcome reduction of drug use. Data on secondary outcomes are reported. However, the data provided on education and retention is non-comparable or inconsistent.

5.3 QUALITY OF THE EVIDENCE

Both included studies are randomized controlled trials. However, neither can be characterized as a robust RCT with a low risk of bias on all assessed items. The two included studies provide insufficient information on core issues to allow us to assess the risk of bias (e.g. number of participants randomized) despite genuine efforts to contact study authors. These methodological weaknesses may reflect inadequate reporting, flawed methodology, or both, and therefore compromise our confidence in the validity of the two studies.

5.4 POTENTIAL BIASES IN THE REVIEW PROCESS

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

5.5 AGREEMENTS AND DISAGREEMENTS WITH OTHER STUDIES OR REVIEWS

We identified five narrative reviews and four quantitative reviews on FBT treatment for drug using youth. All but one of these reviews base their FBT findings on one of the two FBT trials included in this review (Azrin 2001 or Azrin 1994).

All five narrative reviews review several interventions for drug-using youth. Four of the five (Austin et al., 2005; Williams et al., 2000; Deas & Thomas, 2001; Hogue & Liddle, 2009) report a general pattern of positive effects of FBT. Three of the five base their conclusions on the effects of FBT solely on Azrin 1994 (Austin et al., 2005; Williams et al., 2000; Deas & Thomas, 2001), and one is based solely on Azrin 2001 (Hogue & Liddle, 2009). Consistent with our findings, the narrative reviews also conclude that more research is needed. One review, Becker & Curry (2008), examines the quality of evidence in trials on outpatient interventions for youth substance use, and rates the quality of the trials on FBT (Azrin 1994 and Azrin 2001) as methodologically weaker.

We identified four quantitative reviews (Bender, Tripodi, Sarteschi & Vaughn, 2011; Vaughn & Howard, 2004; Bender, Springer & Kim, 2006; Waldron & Turner, 2008). Bender et al., 2011 and Vaughn & Howard, 2004 reviewed several interventions for drug using youth; their conclusions regarding FBT are based on one study, Azrin 1994. Based on this study, FBT is described by Vaughn & Howard, 2004 (p. 334) as *"Evidence of clinically meaningful effect (ES > .20) with relatively strong designs and less than 1-year follow-up and no replication"*. Bender et al., 2011 used meta-analysis to evaluate family therapy and individual therapy for drug-using youth, and found that FBT yielded large effects (> .80), again based solely on Azrin 1994. Waldron & Turner, 2008 used meta-analysis to evaluate family therapy, CBT (individual and group) and 'minimal treatment control conditions' for drug-using youth. The conclusion from Waldron & Turner (2008) is that *"Other family models, including MST, BSFT and BFT [FBT, red.], are probably efficacious, pending replication by independent research teams."* (p. 255), based on the Azrin 2001 study.

Finally, Bender et al., 2006 reviewed treatment effectiveness of several interventions for dually diagnosed adolescents by examining between-group effect sizes and within-group changes. Their conclusions regarding FBT are based on Azrin 2001 only, and are summarized by the authors as *"a small treatment effect favoring the FBT group"* for the reduction of substance use (Bender et al., 2006 p. 192).

Consistent with our expectations, the majority of these reviews conclude that more research is needed on the effects of FBT, on possible moderators of that effect, on identification of which subgroups of youth may be more likely to respond to specific interventions, and on how treatments can be adapted or tailored to the individual needs of youth to improve drug use outcomes. These are similar to the issues we had planned to assess in our review. However, the lack of empirical evidence obscured the possibility of assessing the effects of FBT, any moderators of that effect, and the effects on subgroups.

6 Authors' Conclusion

6.1 IMPLICATIONS FOR PRACTICE

We are unable to draw firm conclusions on the effects of FBT, and so the review does not have implications for practice.

6.2 IMPLICATIONS FOR RESEARCH

Research in the field of treatment for young drug users is challenging to conduct, and available studies reflect the challenges in the field. There are a very modest number of controlled evaluations of treatment for drug-using youth, and most of the few available studies have methodological problems such as small sample sizes with insufficient power to test for differences between treatment groups, and the use of a variety of methods to assess drug use. Such problems make definitive conclusions difficult if not impossible. Thus, there is not only a need for more research, but a need for clear methodological attributes to be incorporated in the design of future studies in order to improve the evidence base for drug use treatments for young drug users.

Only evidence about the relative effects of FBT is available. Evidence about the absolute effect could be achieved if future studies were to incorporate a waitlist control condition, for example.

There is also a need for more uniform reporting in the publications generated by outcome studies. If adherence to the CONSORT 2010 statement was required by a broader array of journals, we believe this would promote more uniform reporting and stronger methodological quality across disciplines.

Finally, it is also important to consider the possibility of any adverse effects these interventions might have. The popular belief is that FBT, as well as other family therapy approaches, is harmless, but there has actually been very little research conducted that focuses on the potential harm of such family therapy approaches.

7 Acknowledgements

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

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9 Characteristics of studies

9.1 CHARACTERISTICS OF INCLUDED STUDIES

Azrin et al., 2001

Methods	Design: RCT (2 intervention arms) total n= 88
Participants	Age: 12-17 years, mean age 15.4. Gender: 82% male Ethnicity: 21% ethnic minority. Family status: 25% of participants are living in single parent families. Median gross family income per year was $44,000. 77% of participants were previously arrested. 40% were enrolled in special education programs. Main drug of use: Cannabis. Severity: All youth had used marijuana at least once, and most had used alcohol or hard drugs (illicit drugs other than marijuana). Youths estimates of their total number of days using substances in their lifetime are 385 for marijuana. Comorbidity: 76% dual diagnose of substance use/dependency and conduct disorder. A great percentage in addition to the conduct disorder and substance use diagnoses, received ADHD or Dysthymia diagnosis. Inclusion criteria: Age 12-17, symptoms consistent with DSM-V diagnosis of conduct disorder plus substance abuse/dependency, live with parent, live within 30 mins. of clinic, no diagnosis of mental retardation or psychotic disorder, not receiving psychological intervention, at least 1 parent will provide transport and participate in treatment. Exclusion criteria: Not reported
Interventions	Intervention: Manual based FBT. Baseline n not reported, treatment completers = 29 Youth and parents attend sessions together and separately, and perform assessments and ratings together and individually. Duration: 15 sessions delivered over 6 months. Sessions once per week for first 3 months, decreasing to every other week, and eventually to once per month. 90 minutes sessions initially, decreasing to 60-75 minutes from the seventh to fifteenth session. Average number of sessions attended for FBT is 13.48. Location: Transportation required so no home location. Florida, US. Comparisons: Manual based Individual Cognitive Problem-Solving (ICPS). Baseline n not reported. Treatment completers = 27. 15 sessions delivered over 6 months. Sessions once per week for first 3 months, decreasing to every other week, and eventually to once per month. 90 minutes sessions initially, decreasing to 60-75 minutes from the seventh to fifteenth session. Average number of sessions attended for ICPS 13.70.

Relevant Outcomes **Baseline** **6 mths post BL** **12 months post BL**	Primary outcomes: Youth drug use. Measures: Days of drug use per month measured by a combination of Urine Drug Screens and Timeline Follow Back (TLFB). Percent abstinent based on urine analysis only. Secondary outcomes: Family functioning, education and risk behavior. Measures: Family functioning measured by Parent Happiness with Youth Scale and Youth Happiness with Parents Scale. Education measured by Child Behavior Checklist, and satisfaction in this domain by Parent Happiness with Youth Scale school and Life Satisfaction Scale school. Risk behavior measured by arrest history records, Youth Self Report delinquency and Child Behavior Checklist delinquency.
Notes	

Azrin et al., 1994a

Methods	Design: RCT (2 intervention arms) total n= 29
Participants	Age: 13-18, mean age 16.0 years. Gender: 77% male. Ethnicity: 19% minority background. Family status: Not Reported. Youth mean education 9.5 years. 19% school drop outs. Main drug of use: Cannabis. Severity: 96% marijuana users, 35% cocaine users, 31% LSD users, 4% methamphetamine user, 4% benzodiazipine user Comorbidity: Not reported. Inclusion criteria: 1. age 18 or younger and had engaged in illegal drug use other than, or in addition to, alcohol use, during past month, 2. not receiving psychological/psychiatric treatment, 3. resided within 12 miles of the counselling centre, 4. resided locally for the past 6 months and no moving plans outside local area, 5. completed 4 or more treatment sessions, 6. willing to provide drug use data for 6 months following initiation of treatment.. Exclusion criteria: Not Reported.
Interventions	Intervention: Manual based Family Behavior Therapy. n=15. Parents attended all sessions. Duration: 6 months, twice weekly during initial stages of treatment, and then reduced in frequency when progress was apparent. Mean 15 two hour sessions. Location: Not Reported. Comparisons: Supportive counseling. n=14 Designed to include principal features of supportive counseling, emphasizing expression of feeling, self-attempts at insight, discussion of drug related experiences and feelings, and group interaction, with no specific directives by the counselor. Youth attended individual sessions, parents attended sessions once per month. 6 months duration, mean 15 sessions. One hour sessions weekly for individual counseling, 2 hour sessions for group counseling.
Relevant Outcomes **Baseline**	Primary outcomes: Adolescent drug use. Measures: Urine Drug Screens, youth self-report and parent report. Urine samples collected at all sessions, 1 monthly sample underwent a broad screen assay for all commonly used drugs by the National Health Labs. Days per month of drug use based on a combination of urine analysis, self-report and parent report. Months of drug use based on a combination of urine analysis, self, or parent report and based on urine analysis only.

6mth from BL	Secondary outcomes: Family functioning, education and risk behavior. Measures: Family functioning measured by Parent Satisfaction Scale and Youth Satisfaction Scale. Education measured by school or work attendance. Risk behavior measured by arrests and institutionalization.
Notes	

9.2 CHARACTERISTICS OF EXCLUDED STUDIES

Study	Reason for exclusion
Bry et. al (1986)	Study without a control group
Bry et. al (1992)	Study without a control group
Donohue et. al (2002)	Case study
Juhnke et. al (2000)	Case study
Moncher et. al (1990)	Case study

9.3 RISK OF BIAS FOR INDIVIDUAL INCLUDED STUDIES

Azrin et al. 2001			
DIMENSION	**ITEM**	**ASSESSMENT**	**DESCRIPTION**
SEQUENCE GENERATION	**Adequate sequence generation?**	Low Risk of Bias	Attempts were made to match participants based on age, days of monthly drug use, types of drugs used, and the Problem and Intensity scales of the ECBI. When two or more participants were available for assignment, they were matched on the aforementioned variables; one participant was assigned by coin toss to one of the treatment conditions, and the other person was assigned to the other treatment condition. If an appropriate match was not available for a participant by the end of the baseline period (i.e., app 4 weeks after the initial assessment sessions was conducted), the participant was randomly assigned by coin toss. 178 participants met inclusion criteria, and 88 attended 3 assessment sessions and completed at least 1 treatment session. However, it remains unclear how many participants were randomized.
ALLOCATION CONCEALMENT	**Allocation concealed?**	Low Risk of Bias	
BLINDING	**Blinding of outcome assessors?**	1	The persons who administered the post and follow-up assessments were blind, independent assessors who were not aware of the participants' treatment assignment, nor were these assessors involved in the treatment program.
INCOMPLETE OUTCOME DATA	**Drop-outs reported?**	Unclear Risk of Bias	Drop-outs were reported.
	Analysis for difference between prop-outs and completers?		Analysis of demographic characteristics revealed no difference between treatment completers and treatment non-completers, apart from treatment completers had more male primary caregivers.
	Missing data reported?		Missing data is unclear since the article does not provide the total number of participants randomized. Analysis included only participants who completed 8 or more sessions. Awaiting response from author.
	Missing data dealt with?		For outcomes based on Urine analysis and the school subscale of the CBCL missing data was not dealt with.

			For all other outcomes; When missing data were present, series mean substitution was utilized.
SELECTIVE OUTCOME REPORTING	**Free of selective and/or incomplete outcome reporting?**	4	Since the study does not provide the total number of participants randomized we do not know the proportion of participants included in the analysis compared to those potentially missing from the analysis. Only participants who completed 8 or more treatment sessions were included in analysis. A large proportion of treatment participants are excluded from the analysis for not having completed minimum 8 sessions. Awaiting response from author.
OTHER POTENTIAL THREATS TO VALIDITY	**Free of other potential threat to validity?**	-	
A PRIORI PROTOCOL	**Is there an a priori protocol (and was it followed)?**	Unclear Risk of Bias	Not reported. Awaiting response from author.
A PRIORI ANALYSIS PLAN	**Is there an a priori analysis plan (and was it followed)?**	Unclear Risk of Bias	Not reported. Awaiting response from author.

Azrin et al. 1994a			
DIMENSION	**ITEM**	**ASSESSMENT**	**DESCRIPTION**
SEQUENCE GENERATION	**Adequate sequence generation?**	Unclear Risk of Bias	Families were randomized into groups by coin toss in matched pairs (as described in Azrin et al. 1994b, p. 858). When 2 youth were concurrently available for assignment to condition, the coin flip determined which one was assigned to the behavioral treatment, the other being assigned to the supportive treatment if a match was available. When no match was available at the end of the baseline period, the participant was randomly assigned by coin toss. Despite the adequate sequence generation described above, the study is judged with unclear Risk of Bias for sequence generation due to the following: 14 participants had been used in a previous trial and it is unclear how they were allocated in this trial. Awaiting author reply.

ALLOCATION CONCEALMENT	**Allocation concealed?**	Low Risk of Bias	Coin toss is not potentially predictable.
BLINDING	**Blinding of outcome assessors?**	Unclear Risk of Bias	Not reported. Awaiting response from author.
INCOMPLETE OUTCOME DATA	**Drop-outs reported?**	Unclear Risk of Bias	Dropouts were reported
	Analysis for difference between prop-outs and completers?		Analysis on days of drug use pre-treatment for dropout/completers show no statistical difference.
	Missing data reported?		Missing data is unclear since the article does not provide the total number of participants randomized. Analysis included only participants who completed 4 or more sessions. Awaiting response from author.
	Missing data dealt with?		No
SELECTIVE OUTCOME REPORTING	**Free of selective and/or incomplete outcome reporting?**	Unclear Risk of Bias	Since the study does not provide the total number of participants randomized we do not know the proportion of participants included in the analysis compared to those potentially missing from the analysis.
OTHER POTENTIAL THREATS TO VALIDITY	**Free of other potential threat to validity?**	-	
A PRIORI PROTOCOL	**Is there an a priori protocol (and was it followed)?**	Unclear Risk of Bias	Not reported. Awaiting response from author.
A PRIORI ANALYSIS PLAN	**Is there an a priori analysis plan (and was it followed)?**	Unclear Risk of Bias	Not reported. Awaiting response from author.

10 Appendices

10.1 SEARCH HISTORIES FROM THE BIBLIOGRAPHIC DATABASES

PsycINFO Ovid 1806 to June Week 2 2011

(FBT or BFT or (Famil* adj1 Behavio$r* adj1 therap*)).af.	369

PsycINFO Ovid 1806 to October 2014

(FBT or BFT or (Famil* adj1 Behavio$r* adj1 therap*)).af.	217

MEDLINE(R) Ovid 1948 to June Week 2 2011

(FBT or BFT or (Famil* adj1 Behavio$r* adj1 therap*)).af.	339

MEDLINE(R) Ovid 1948 to October 2014

(FBT or BFT or (Famil* adj1 Behavio$r* adj1 therap*)).af.	79

Embase Ovid 1980 to 2011 Week 24

FBT or BFT or (Famil* adj1 Behavio$r* adj1 therap*)).af.	891

Embase Ovid 1980 to October 2014

FBT or BFT or (Famil* adj1 Behavio$r* adj1 therap*)).af.	175

SocIndex search history Tuesday, May 17

S1 TX FBT or TX BFT or TX Famil* n1 Behavio#r* n1 therap*	1747

SocIndex search history October 2014

S1 TX FBT or TX BFT or TX Famil* n1 Behavio#r* n1 therap* 109

Social Care Online search history May 2011

freetext="Famil* Behavio* therap*" or freetext="FBT" or freetext="BFT" 7

Social Care Online search history October 17

freetext="Famil* Behavio* therap*" or freetext="FBT" or freetext="BFT" 5

Libris search History 10-06-2011

FBT OR BFT or Famil* Behavio* Therap* 240

Libris search History October 2014

FBT OR BFT or Famil* Behavio* Therap* 63

ERIC search history Tuesday, May 2011

S1 TX FBT or TX BFT or TX Famil* n1 Behavio#r* n1 therap* 362

ERIC search history October 2014

S1 TX FBT or TX BFT or TX Famil* n1 Behavio#r* n1 therap* 31

Cochrane search History 10-06-2011

#1 FBT or BFT or Famil* near/1 Behavio* near/1 Therap* 36

Cochrane search History October 2014

#1 FBT or BFT or Famil* near/1 Behavio* near/1 Therap* 30

CJA search history Tuesday, May 2011

S1 TX FBT or TX BFT or TX Famil* n1 Behavio#r* n1 therap* 33
base – Criminal Justice Abstract

CJA search history Tuesday, October 2014

S1 TX FBT or TX BFT or TX Famil* n1 Behavio#r* n1 therap*	
base – Criminal Justice Abstract	11

Cinahl search history Tuesday, May 2011

S1 TX FBT or TX BFT or TX Famil* n1 Behavio#r* n1 therap*	263

Science citation abstract May 18, 2011

1	833
Topic=(Famil* same Behavio$r* same session*) OR Topic=(Famil* same Behavio$r* same Therap?*) OR Topic=(fbt) OR Topic=(bft) Databases=SCI-EXPANDED Timespan=All Years	

Science citation abstract May 18, 2011

1	106
Topic=(Famil* same Behavio$r* same session*) OR Topic=(Famil* same Behavio$r* same Therap?*) OR Topic=(fbt) OR Topic=(bft) Databases=SCI-EXPANDED Timespan=All Years	

Social Science citation abstract May 18

1	859
Topic=(Famil* same Behavio$r* same session*) OR Topic=(Famil* same Behavio$r* same Therap?*) OR Topic=(fbt) OR Topic=(bft) Databases=SSCI Timespan=All Years	

Social Science citation abstract May 18

1	82
Topic=(Famil* same Behavio$r* same session*) OR Topic=(Famil* same Behavio$r* same Therap?*) OR Topic=(fbt) OR Topic=(bft) Databases=SSCI Timespan=All Years	

Bibliotek.dk search History October 2014

FBT OR BFT or Famil* Behavio* Therap*	99

Bibliotek.dk search History October 2014

FBT OR BFT or Famil* Behavio* Therap*	28

BIBSYS search History June, 2011

FBT OR BFT or Famil* Behavio* Therap*	332

BIBSYS search History October 2014

FBT OR BFT or Famil* Behavio* Therap*	74

10.2 CODE BOOK FOR DATA EXTRACTION

Author	**Study x**
Year	
Country	
Is this study about an FBT intervention evaluation?	
Are the participants 11 - 21 years of age?	
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 a 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 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 co-morbid condition	
Report total 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)	
...1st follow-up	
..2nd follow-up	
..3rd follow-up	
..Other	
Author's main conclusion	
Limitations of the study as reported by the study authors	
Researchers affiliation with program	
Your own concerns and notes	
Question for review authors	

10.3 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]		
5. 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 low/high risk/unclear scale (double-line border), some on 5 point scale/unclear (single line border), some on yes/no/unclear scale (dashed border). For all items, record "unclear" if inadequate reporting prevents a judgement being made.

[b] For each outcome in the study.

[c] This item is is based on 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. in advance of starting the study?

[e] Did the researchers have an analysis plan defining the primary and other outcomes, statistical methods, subgroup analyses, etc. in advance of starting the study?

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.[10] 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 to selection 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 some items (distinguish "unclear" from intermediate risk of bias).
- Keep in mind the general philosophy – assessment is not 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
    - Might argue that this item redundant for NRS since always high – but important to include in RoB table ('level playing field' argument)

2. Allocation concealment
    - Low/high/unclear RoB item
    - Potentially low RoB for a non-randomised study, 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 pre-specified list of potential confounders defined in the protocol
    - Low(1) / 2 / 3 / 4 / high(5) / unclear RoB item
    - Judgment needs to factor in:
        - proportion of confounders (from pre-specified list) that were considered

[10] This risk of bias model was introduced by Prof. Reeves at a workshop on risk of bias in non-randomised 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).

    - whether most important confounders (from pre-specified list) were considered
    - resolution/precision with which confounders were measured
    - 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 (not primarily/not only a statistical judgment OR measured 'well' and '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 performance or detection bias
    - see Ch.8

5. RoB from incomplete outcome data (assess for each outcome, 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
    - see Ch.8

6. RoB from selective reporting (assess for each outcome, NB different to existing Ch.8 recommendation)
- Low(1) / 2 / 3 / 4 / high(5) /unclear RoB item
- Judgment needs to factor in:
    - existing RoB guidance on selective outcome reporting
    - 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 confounding	
Method for *identifying* 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

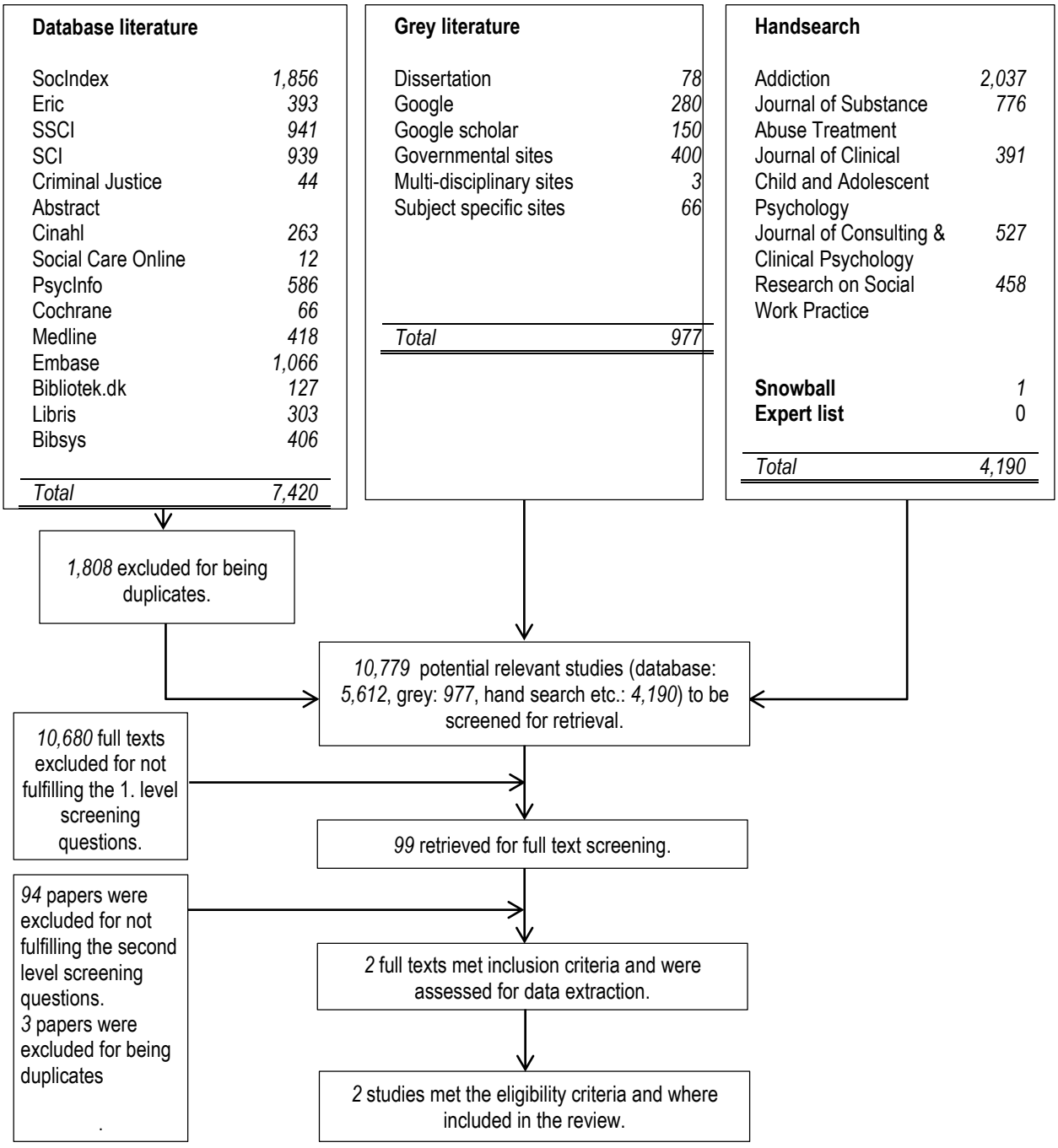
Score (1[balanced] to 5[major imbalance]) imbalance between groups

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:	☐	☐	☐	☐

11 Figures

11.1 FLOWCHART FBT



12 Differences between review and protocol

In the protocol it was stated in section 3.4.7 that statistically significant heterogeneity among primary outcome studies will be been assessed with Chi-squared (Q) test and I-squared (Higgins, Thompson, Deeks, & Altman, 2003). A significant Q (P<.05) and I-squared of at least 50 per cent will be considered as statistical heterogeneity. The assessment of heterogeneity has been changed to: 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). Any interpretation of the Chi-squared test was made cautiously on account of its low statistical power.