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Family Behavior Therapy (FBT) for young people in treatment for non-opioid drug use

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PROTOCOL

THE CAMPBELL COLLABORATION

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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 on Drugs and Crime (UNODC), 2010). Use of non-opioids 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 12-17 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 15-24 year olds had used any 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 (for further reading, see e.g. 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

[1] The terms use, abuse and dependence will be used interchangeably throughout the protocol 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.

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 by the high rates of treatment dropout and post-treatment relapse to drug use (Austin, Macgowan & Wagner, 2005; Najavits & Weiss, 1994; Stanton & Shadish, 1997). Accordingly, treatment to help young drug users should be as engaging as possible in order to avoid dropout and relapse (Simmons et al., 2008; National Institute on Drug Abuse, 2009), and services provided should be empirically supported in order to increase the likelihood that 1. Treatment will be successful, and 2. Public spending supports 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 individually based cognitive and motivational therapies, i. e. Cognitive Behavioral Therapy (CBT) (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, 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 suggest 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 show 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 will specifically explore the family-based intervention Family Behavior Therapy (FBT) (Azrin, Donohue, Besalel, Kogan & Acierno, 1994a; Donohue & Azrin, 2001; Donohue et al., 2009) as aggregated evidence for the effects of FBT is needed. The review seeks to clarify the effects of the FBT program for relevant groups of young people age 11-21. The review focus on young people enrolled in treatment for drug use, independent 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 (teacher, parent, social services, school counselor, etc.) to require treatment. The intervention in focus is FBT delivered as outpatient treatment[3] to young people age 11-21 living with their family. Furthermore the review will focus primarily on non-opioid drug use[4], and will consider poly-drug use if relevant.

The review will be 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, where young people's drug use is understood in relation to family behavior problems.

FBT is one of many family therapy forms that meet the general characteristics of manual-based family therapies as it targets young people *and* their families *as a system* throughout treatment,

[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 Title Registrations 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
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
Pernille Skovbo Rasmussen, Maia Lindstrøm, Krystyna Kowalski, Trine Filges, Anne-Marie Jørgensen: Multidimensional Family Therapy (MDFT) for young people in treatment for illicit non-opioid drug use

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).

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).

FBT along with other family-systems based therapies 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 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 stimuli 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, e.g. 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 Centre, 2011).

4. Assurance of basic necessities

Young people using drugs often experience problematic situations and difficulties (i.e. dismissed from school or work, economical problems, violence), which often disrupts 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 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, i.e. lack of stable local residence, lack of significant other to attend sessions.

Therapists are trained to manage drug user's lack of motivation for treatment and non-compliance with therapeutic guidelines (i.e. refusing to do role-playing, forgetting to do assigned home-work, and arguing during therapy). Therapists evaluate participant's behavior efforts and disclose this information to relevant authorities (e.g. juvenile justice, social service). Participants are asked to rank the helpfulness of each intervention component immediately after termination, and therapist can adjust the program based on the rankings and solve discontent early in the therapeutic process. Furthermore therapists 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 young people's drug use, and 2) to change behaviors associated with drug use in young people and their family. The intervention aims at engaging young people and their family 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 show that FBT reduces drug use in participants and contributes 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. 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 need knowledge on 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 the programs relevance for any particular type of client.

1.3.1 Intervention mechanisms

Treatment variables with 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 with 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 points 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 assumingly part of the explanation to FBT's impact on young people's drugs use.

Motivation, being key to positive treatment outcome (Williams et al., 2000), is also linked to the support and influence of the family system. The family systems ability 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 find 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 to non-drug usage is related to improved relapse management (Williams et al., 2000).

Communication skills training and positive reinforcement to change the behavior of the young person are possible mechanisms of behavior change, related to the behavioral focus of FBT. Studies find 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). Studies suggest 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 facilitates 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 young people's drug use problems 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 promising treatment for young drug users.

There are a number of studies indicating that FBT is 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 of this review is, if possible, to examine mediators of drug use reduction effects, specifically analyzing whether FBT works better for particular types of participants.

3 Methods

3.1 CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

3.1.1 Types of studies

The study designs included in the review will be:

- Controlled trials[6] (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, see Higgins & Green, 2008):
    - RCT - randomized controlled trials
    - QRCT - quasi-randomized controlled trials (i.e. 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)
    - NRCT - non-randomized controlled trial (i.e. participants are allocated by other actions controlled by the researcher such as location difference or time difference)

We will include study designs that use a well-defined control group. Comparison will be no intervention, wait list control, TAU and alternative active intervention. Studies using single group pre-post comparison will not be included.

The rationale for including NRCTs is as follows:

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

3.1.2 The aim of this review is to be as comprehensive as possible. There may be information that is contained in NRCTs that may be of relevance to this review that are not captured in RCTs.Types of participants

The population included in this review will be young people age 11-21 years enrolled in manual based FBT drug 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). Patterns of young people's independence from parents and independent living patterns likewise vary internationally. In order to capture international differences we have set the age range from 11 to 21 (Hibell et al., 2009; United Nations, 2011; SAMHSA, 2010; Danish Youth Council, 2011).

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

No universal international consensus exists concerning what categories to use when classifying drug users[7], 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 include participants regardless of formal drug use diagnosis. The main criteria for inclusion is the fact that the young person is enrolled to participate in treatment (i.e. intervention or comparison condition). Referral and enrolment in drug use treatment requires a level of drug use such that a significant other, or authority (or the young person) finds it necessary to solicit or require treatment. We define the population as young people referred to or in treatment for using non-opioid drugs.

[7] Different tools 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 as an assessment tool, other relevant tools 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 tools 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).

We will include poly drug users, as long as the majority of drug users in a study are non-opioid drug users. Psychosocial interventions for youth opioid dependence has been evaluated in Cochrane reviews (Amato et al., 2011; Minozzi et al., 2010), and we wish to avoid duplication of effort. Populations who exclusively use alcohol will be excluded.

3.1.3 Types of interventions

The review will include outpatient manual based FBT interventions of any duration delivered to young people and their families (see 1.2 Description of the intervention). The FBT intervention must be an outpatient intervention that does not include overnight stays in a hospital or other treatment facility. The FBT intervention can take place in the home, at community centers, in a therapist's office or at outpatient facilities. Interventions in restrictive environments, such as prisons or other locked institutions[8] (e.g., detention centers, institutions for sentence-serving juvenile delinquents) will be excluded.

FBT is a family intervention requiring the active participation of the young drug user and his or her family, and with the aim of improving family functioning. In cases with the young drug user placed outside the family home (e.g. in-patient treatment and incarceration in any locked facility) the core condition of the program will be seriously compromised.

Interventions focusing exclusively on treating mental disorders will also be excluded.

Studies where FBT is delivered with add-on components will be included as long as FBT is the primary intervention.

Eligible control and comparisons will include 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 (i.e., young people's drug use) the likelihood of no treatment control group is small. We expect that the most frequent comparison will be alternative interventions (Lipsey et al., 2010).

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

3.1.4 Types of outcomes

Primary outcomes

- Abstinence or reduction of drug use as measured by e.g.,:
    - 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/0r 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 seek evidence on how to best reduce or eliminate drug use, as drug use is understood as the young people's primary problem.

Outcomes will be considered in the following intervals:

- Short term (end of treatment to less than 6 months after end of treatment)
- Medium term (6 to 12 months after end of treatment)
- Long term (more than 12 months after end of treatment)

3.2 SEARCH METHODS FOR IDENTIFICATION OF STUDIES

3.2.1 Electronic searches

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

The following bibliographic databases will be searched:

Medline

Embase

Cinahl

Social Science Citation Abstract

Science Citation Abstract

Socindex

PsycINFO

Cochrane

Danbib

Libris

Bibsys

Social Care Online

Eric

SweMed+

Criminal Justice Abstracts

Bibliography of Nordic Criminology

3.2.2 Search terms

An example of the search strategy for MEDLINE searched through the Ovid platform is listed below. This strategy will be modified for the different databases. We will report details of the modifications used for the other databases in the completed review.

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

3.2.3 Searching other resources

The review authors will check reference lists of other relevant reviews and included primary studies for new leads. Citation searching in the Web of Science will also be considered.
We will contact international experts to identify unpublished and on-going studies, and provide them with the inclusion criteria for the review along with the list of included studies, asking for other published, unpublished or on-going studies relevant for the review.

The following international journals will be hand searched for relevant studies:

- Addiction
- Journal of Consulting and Clinical Psychology
- Journal of Substance Abuse Treatment
  Journal of Clinical and Adolescent Psychology

Searching will be performed on editions from 2011 to review submission of the journals mentioned, in order to capture any relevant studies recently published and therefore not captured in the systematic search.

3.2.4 Grey literature

Additional searches will be made by means of *Google* and *Google Scholar* and we will check the first 150 hits. OpenGrey (http://www.opengrey.eu/) will also be used to search for European grey literature. Copies of relevant documents will be made and we will record the exact URL and date of access for each relevant document.

In addition we will search 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/

3.3 DATA COLLECTION AND ANALYSIS

3.3.1 Selection of studies

Two members of the review team will independently screen titles and abstracts in order to exclude studies that are clearly irrelevant under the supervision of ML (SLO & MS[9]). Studies considered eligible by at least one of the reviewers will be retrieved in full text. The full texts will then be screened by two members of the review team to determine study eligibility based on the inclusion criteria. Any disagreements about eligibility will be resolved by a third review author (TF). Reasons for exclusion will be documented for each study that is retrieved in full text. The study inclusion coding sheet will be piloted and adjusted if required by the review authors (see Appendix 5.1).

The overall search and screening process will be illustrated in a flow-diagram.

3.3.2 Data extraction and management

At least two review authors (ML, MS, PSR, & KK) will independently code and extract data from the included studies. A data extraction sheet will be piloted on several studies and revised as necessary (see Appendix 5.2). Extracted data will be stored electronically. Any disagreements will be resolved by consulting a third reviewer with extensive content and methods expertise (TF). Analysis will be conducted in RevMan5 and/or STATA. Data and information will be 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.

[9] Stine Lian Olsen and Madina Saidj are members of the review team and will assist the review authors with screening titles and abstracts.

3.3.3 Assessment of risk of bias in included studies

We will assess 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).[10] 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 non-randomized studies 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 and 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[11] 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 (see Appendix 5.3). 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 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.

[10] 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-Randomised Studies Method Group (NRSMG).
[11] The extended model was developed to ensure standardization of guidelines and procedures in the Risk of Bias assessment of NRS.

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 Appendix 5.3 for guidelines & Appendix 5.4 for risk of bias coding sheets).

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, e.g. 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 will be based on pre-specified questions (Appendix 5.4). “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 five on any one of the assessed items assessed translates to a risk of bias so high

that the findings will not be considered in the data synthesis (because they are more likely to mislead than inform) (See Appendix 5.3 and 5.4). A judgment of five is given with precaution and only in cases of extreme biases. Judgments will be justified and reported.

Confounding

An important part of the risk of bias assessment of non-randomized studies is how the studies deal with confounding factors. Selection bias is understood as systematic baseline differences between groups that can therefore compromise their comparability.

For this review, the following confounding factors are considered as the most relevant: age, gender, and history of drug use. If other confounders are considered by the study investigators in the included studies they will be assessed in the same manner (see appendix 5.3).

We focus on three confounders - age, gender and drug use history -as they are major predictors of drug use. Young people are in a transitional and development life phase, and their patterns of drug use are connected to age (Labouvie & White, 2002; Kaminer, 2008; Waldron & Kaminer, 2004). Gender is also identified as confounding factor for drug use, i.e., males generally has higher drug use than females (Østergaard & Andrade, 2011; McCabe, Morales, Cranford, Delva, McPherson, & Boyd, 2007). And finally history of drug use and persistent patterns of use affect treatment outcomes (Labouvie & White, 2002; Kaminer, 2008).

Review authors (at least two PSR, ML, MS, & KK) will independently assess the risk of bias for each included study as described in the previous sections. Disagreements will be solved by a third reviewer with content and statistical expertise (TF). We will report the risk of bias assessment in risk of bias tables for each included study in the completed review. This assessment will also inform data synthesis.

3.3.4 Measures of treatment effect

Discrete data

For dichotomous outcomes we will calculate odds ratios or risk ratios with 95 % confidence intervals and p-values. Urine Drug Screen data is an example of a relevant dichotomous outcome in this review.

Continuous data

For continuous outcomes, effects sizes with 95% confidence intervals will be calculated if means and standard deviations are available. If means and standard deviations are not available, the review authors will request this information from principle investigators. If no information is yielded, we will use methods by Lipsey and Wilson (2001) to calculate SDMs from e.g., F-ratios, t-values, chi-squared values and correlation coefficients. Hedges *g* will be used for estimating standardized mean differences (SMD) where scales measure the same outcomes in different ways (e.g., reduction of drug use). If there is a mix of studies with some reporting change scores and others reporting final values, we will contact authors and request the final values. If we do not obtain these values, we will analyze change scores and final values separately (Higgins & Green, 2008, section 9.4.5.2). Any scales related to drug use, family functioning, education (grade score), etc. are examples of relevant continuous outcomes in this review.

There are statistical approaches available to re-express dichotomous and continuous data to be pooled together (Sáchez-Meca, Marín-Martínes & Chacón-Moscoso, 2003). We will only transform dichotomous effect sizes to SMD if appropriate e.g., as may be the case with the primary outcomes 'abstinence and reduction' of drug use that can be measured with binary and continuous data.

When effect sizes cannot be pooled, study-level effects will be reported in as much detail as possible. Software for statistical analyses will be RevMan 5.0, Excel and STATA 10.0.

3.3.5 Unit of analysis issues

We will 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 we will check for multiple publications for the some studies (i.e., whether several studies are based on the same data source).

Multiple intervention groups

Multiple intervention groups (with different individuals) within a study with one control group will not be pooled, nor will multiple controls groups be pooled. Data will be rigorously checked to avoid overlapping samples.

Multiple interventions per individual

Multiple intervention per individual e.g., FBT plus add on components such as motivation interviewing or a pharmacological treatment will be analyzed separately.

Multiple time points

When the results are measured at multiple time points, as a guideline they will be analyzed in the following groups: short-term (0- <6 months after participation), medium term (6- 12 months after participation) long term (at least 12 months after participation). We will not pool different time points, due to the sensitivity of outcomes in relation to time from end of treatment.

Cluster randomized trials

If cluster randomized trials are included in this review we will check for consistency in the unit of allocation and the unit of analysis, as statistical analysis errors can occur when they are different. When suitable cluster analysis is used, effect estimates and their standard errors will be meta-analyzed (Higgins & Green, 2008). In cases where study investors have not applied appropriate analysis methods controlling for clustering, we will approximate the intra-cluster correlation (Donner, Piaggio, & Villar, et al., 2001) and correct standard errors.

3.3.6 Dealing with missing data and incomplete data

The reviewers will assess missing data and attrition rates in the included studies. In the case of missing data (e.g. valid Ns, means and standard deviations) the reviewers will contact primary study authors for missing data. The review authors will record attrition rates and (if possible) reasons for attrition from included studies.

The reviewers will record information on intention to treat analysis (ITT). We will run separate meta-analysis with studies that did not use ITT analysis. We will perform sensitivity analysis to examine influences on effects in studies using ITT analysis vs. studies not using ITT analysis.

3.3.7 Assessment of heterogeneity

Statistically significant heterogeneity among primary outcome studies will be 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% will be considered as statistical heterogeneity.

3.3.8 Assessment of publication bias

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

We will use funnel plots for information about possible publication bias if we find sufficient studies (Higgins & Green, 2008). However asymmetric funnel plots are not necessarily caused by publication bias (and publication bias does not necessarily cause asymmetry in a funnel plot). If asymmetry is present, we will consider possible reasons for this.

3.4 DATA SYNTHESIS

Studies that have been coded with a very high risk of bias (5 in any of the items judged on the 5-point scale) will not be included in the data synthesis. Analysis of the absolute effects of FBT will involve comparing FBT to no treatment and to untreated wait list controls. The relative effects of FBT (versus other interventions) will be conducted separately and will include studies that compare FBT to other interventions and/or Treatment-As-Usual (TAU). All follow-up durations reported in the primary studies will be recorded and we will do separate analyses for short-term, medium-term and long-term outcomes.

Meta-analysis will be used when effect sizes are available or can be calculated and when studies include similar design features (e.g., RCTs vs. Non RCTs), intervention modalities (e.g., intervention duration), methodology (e.g., time point measurements) and outcome measurements. Random effects meta-analysis will be used. We will report the 95% confidence

intervals and provide a graphical display (forest plot) of effect sizes. When meta-analysis is inappropriate, a narrative description of the individual study results will be provided, and in this case any conclusions about the effectiveness of FBT will not be possible.

3.4.1 Moderator analysis/subgroup analysis and investigation of heterogeneity

We will investigate the following study-level covariates (if possible) with the aim of explaining observed heterogeneity: intervention characteristics (e.g., treatment duration, treatment intensity, composition of components), and study level summaries of participant characteristics (e.g., gender, age, family composition, ethnicity, co-morbidity, and history of drug use) and comparison intervention characteristics.

If the number of included studies is sufficient (dependent on the spread of the study means of the covariates and study sizes, see Borenstein, Hedges, Higgins, & Rothstein (2009) and Simmonds & Higgins (2007)), we will perform moderator analyses (meta-regression) to explore how observed variables are related to heterogeneity using a mixed model. We will estimate the (new) residual variance component to be used in a weighted least squares analysis conditional on this variance component estimate.

The residual variance component will be estimated using the method-of-moments estimator (Hartung, Knapp, & Sinha, 2008; Konstantopoulos, 2006). We will report the 95% confidence intervals for regression parameters. Conclusions from meta-regression analysis will be cautiously drawn and will not be based on significance tests.

Otherwise single factor subgroup analysis will be performed. The assessment of any difference between subgroups will be based on 95% confidence intervals. No conclusions from subgroup analyses will be drawn and interpretation of relationships will be cautious, as they are based on subdivision of studies and indirect comparisons.

3.4.2 Sensitivity analysis

Sensitivity analysis will be used to evaluate whether the pooled effect sizes are robust across study design and components of methodological quality. For methodological quality, we will consider sensitivity analysis for each major component of the risk of bias checklists. To check for the possible influence of developer bias on effect sizes, we will run sensitivity analysis in studies

conducted by program developers vs. studies conducted by independent researchers. Developer bias can occur in studies conducted by the intervention developers who unconsciously influence the success of an intervention (Petrosino & Soydan, 2005; Eisner, 2009; Sherman & Strand, 2009). We will also consider sensitivity analysis for program fidelity, i.e., compliance with program manual and requirements for therapist training.

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5 Appendices

5.1 STUDY ELIGIBILITY SCREENING LEVEL ONE & TWO

Screening level one (on the basis of titles and abstracts)

Reference id. no.
Study id. no.
Reviewer's initials
Year of publication:
Author:

1. **Is the study about a Family Behavior Therapy (FBT) intervention?**
   Yes
   No (if no stop here and exclude)
   Uncertain

2. **Are the participants in outpatient drug treatment primarily for non- opioid drug use?**
   Yes
   No (if no stop here and exclude)
   Uncertain

3. **Are the participants primarily within age 11-21?**
   Yes
   No (if no stop here and exclude)
   Uncertain

4. **Is the study a quantitative primary/impact/outcome study**
   Yes
   No (if no stop here and exclude)
   Uncertain

The reported reference is excluded if one of the answers to question 1 to 4 are no.

If the answers are yes or uncertain the full report is retrieved for second level screening. All uncertain questions for 1-4 need to be posed again based on the full text. If information is not available or the report is unclear report authors will be contacted to clarify study eligibility.

Additional questions for second level screening

5. **Is the report a RCT study (with a control group that is TAU, alternative intervention or no intervention)?**
   Yes
   No
   Uncertain

6. **Is the report a quasi-randomized study (with a control group that is TAU, alternative intervention, or no intervention)?**
   Yes
   No
   Uncertain

7. **Is the report a non-randomized controlled study (with a control group that is TAU, alternative intervention, or no intervention)?**
   Yes
   No
   Uncertain

8. **Is the study:**
   Included
   Excluded
   Uncertain (state reason)

5.2 DATA EXTRACTION

Study design

1. **How was comparison/control groups formed?**
   Random assignment
   Other (specify)

2. **If random assignment, specify design**
   Simple/systematic (individuals/families)
   Stratified/blocked (identify stratifying variables)
   Yoked pairs (created by timing of enrolment into the study)
   Matched pairs (identify matching variables)
   Cluster (group) randomized

Other (specify)
Can't tell

3. **If non-random assignment, specify how groups were formed**
   Quasi randomization
   Time difference
   Location difference
   By action of researcher
   By action of therapist
   By participant preferences
   Other (please specify)

4. **Who performed group assignment**?
   Research staff
   Clinical staff
   Can't tell
   Other (specify)

5. **How was random assignment performed?**
   Computer generated
   Random numbers table
   Coins or dice
   Other (describe)
   Can't tell

6. **How many separate sites were included in the study?**
   One
   Two
   Three
   Specify number

7. **Was random assignment performed in the same way in all sites**
   Yes
   No (explain)
   Can't tell

8. **If non randomized study – what parts of the study was prospective**
   Identification of participants
   Assessment of baseline and intervention allocation
   Assessment of outcomes
   Generation of hypothesis

9. **How many intervention groups were there? (FBT counts as one)**
   One (FBT)
   Two (FBT plus what?)

Three (FBT plus what?)

10. How many intervention groups are relevant for this review?
One (FBT)
More than one (explain)

11. How many *different* control/comparison groups were there? (i.e., groups that received different treatments, not counting multiple sites)
One
Two or more (explain)

12. How many control/comparison groups are relevant for this review?
One
More than one (explain)

13. Study sample size

N's	FBT*	CONTROL1*	TOTAL	Pg. # & NOTES
Referred to study				
Consented				
Completed base line measures				
Randomly assigned Or non-randomly allocated				
Started treatment				
Completed treatment				
Completed 1st follow up (.... months)				
Completed 2nd follow up (.... months) **				

* Add columns for additional intervention and control/comparison groups.
** Add rows for as required for additional follow ups.

Participant/sample Characteristics:

14. Was participant inclusion criteria mentioned?

No
Yes (describe & cite pg#)

15. Was participant exclusion criteria mentioned?

No
Yes (describe & cite pg#)

16. Participant Characteristics

	FBT*	CONTROL*	TOTAL	Pg. # & NOTES
Gender (e.g. % male)				
Young people's Ages				
Race/ethnicity				
Socioeconomic status				
Profession				
Family composition				
Family or peers involved in intervention				
Other characteristics				

* add columns for additional intervention and control/comparison groups.

17. Specify and describe type of drug use

Cannabis
Cocaine
Amphetamine
Opiates
Combination (specify, pg. #)
Combination of drugs and alcohol (specify, pg. #)
Other (specify, pg. #)

Settings

18. Location of interventions (check all that apply)

Urban

Suburban
Rural
Can't tell

19. Location details

Office based
Family home setting
Other (specify)

FBT characteristics

20. Characteristics of FBT

	Min	Max	Mean	SD	Pg# & Notes
Duration in Days Weeks Months					
Hours of contact (therapist) with young person Per week Per month Other (explain)					
Hours of contact (therapist) with family members Per week Per month Other (explain)					
Total hours of contact					

21. Other characteristics of FBT

22. Characteristics of treatment staff/therapist (education, FBT training, demographics, etc.)

23. Describe methods used to ensure FBT quality (supervision, training, consultation)

24. Is there any information on adherence or fidelity to FBT?

Yes (describe)
No
Not sure

Services provided to control cases

25. Type of control group

Usual services (treatment as usual)
Alternative service (describe)
No service

26. Describe services provided to control group

27. Characteristics of staff that provided services to control cases (education, demographics, etc.)

Outcome measures

28. When data were collected (check all that apply)?

Baselibe
Post-tx
1. Follow up (when)
2. Follow up (when)
3. Follow up (when)

Other

29. Who conducted interviews?

Research staff
Clinical staff
Both
No interviews

30. Were data collected in the same manner for FBT and control groups?

Yes
No (what were the differences?)
Can't tell

Outcome measures

Instructions: Please enter outcome measures in the order in which they are described in the report. Note that a single outcome measure can be completed by multiple sources and at multiple points in time (data from specific sources and time-points will be entered later).

#	Outcome & measure	Reliability & Validity	Format	Direction	Source	Mode Admin	Blind (outcome assessors)?	Pg# & notes
1		Info from: Other samples This sample Unclear Info provided:	Dichotomy Continuous	High score or event is Positive Negative Can't tell	Researcher Clinician Admin data Other Unclear	Self-admin Interview Other	Yes No Can't tell	

* Repeat as needed

OUT COME DATA

DICHOTOMOUS OUTCOME DATA

OUTCOME	TIME POINT (record exact time taken from baseline	SOURCE	VALID Ns	CASES	NON-CASES	STATISTICS	Pg. # & NOTES
	•1st measure after baseline •1st follow-up • 2nd follow-up • 3rd follow-up •4th follow-up • other	• researcher • clinician • admin data • other (specify)	FBT	FBT	FBT	RR (risk ratio) OR (odds ratio) SE (standard error) 95% CI DF P- value (enter exact p value if available) Chi2 Other Covariates (control variables)	
			Comparison	Comparison	Comparison		

Repeat as needed

CONTINUOUS OUTCOME DATA

Enter change and gain scores under Statistics (Other)

OUTCOME	TIME POINT (record exact time taken from baseline	SOURCE (specify)	VALID Ns	Means	SDs	STATISTICS	Pg. # & NOTES
	•1st measure after baseline •1st follow-up • 2nd follow-up • 3rd follow-up •4th follow-up • other	• researcher • clinician •admin data • other (specify)	FBT	FBT	FBT	P t F Df ES Covariates Other	
			Comparison	Comparison	Comparison		

*Repeat as need

5.3 ASSESSMENT OF RISK OF BIAS IN INCLUDED STUDIES: GUIDELINES

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.[12] 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

[12] 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:	☐	☐	☐	☐

5.4 ASSESSMENT OF RISK OF BIAS: CODING SHEET

RISK OF BIAS FORM – FBT SUBSTANCE ABUSE	
Reference ID: Study ID:	Reviewer ID: Date:
Author: Year:	
Notes: Queries to the author: Date contacted: Author's contact details:	

STUDY DESIGN	
QUESTION	*JUDGEMENT*
How was the intervention group(s) formed?	Random assignment: Other (specify): Not reported: Unclear:
Was the control groups(s) formed the same way?	Yes: No: Unclear:
- If no, then how were they formed?	Describe:
Give a description of the randomization as described by the authors	Describe:
How was the random sequence generated?	Computer generated: Random no. table: Coin tosses: Shuffling: Dice: Other (specify): Not reported: Unclear:
What was the unit of randomization?	Individual/family: Yoked / Matched pairs: Stratified: Blocked: Cluster: Other (specify):

	Not reported: Unclear:
Notes *(e.g. queries to the author)*	
NOTE: THIS PART IS ONLY FOR NRCT – GO TO NEXT PART IF THE STUDY IS A RCT	
QUESTION	*JUDGEMENT*
How was the intervention group(s) formed?	Describe:
Is the intervention group formed before (historical/retrospective) or after (prospective) the hypothesis generation?	Before: After: Not reported:
How was the comparisons group(s) formed? *(if the same as intervention groups - note same as TX)*	Describe:
Is the control group formed before (historical/retrospective) or after (prospective) the hypothesis generation?	Before: After: Not reported:
Sequence generation	**Final jugdement High/Low/unclear**
Notes *(e.g. queries to the author)*	

RISK OF BIAS		
SEQUENCE GENERATION		
Describe the sequence generation:	Was the used sequence generation adequate?	Yes: No: Unclear:
Sequence generation	**Final judgment**	**High/ Low/Unclear**
ALLOCATION CONCEALMENT		
Describe the concealment of the allocation:	Was allocation adequately concealed regarding participants? *Meaning that they cannot foresee assignment.* *(NRS always No - NRCT can be concealed adequate)*	Yes: No: Unclear:
Describe the concealment of the allocation:	Was allocation adequately concealed regarding staff? *Meaning that they cannot foresee assignment.* *(NRS always No - NRCT can be concealed adequate)*	Yes: No: Unclear:
Describe the concealment of the allocation:	Was allocation adequately concealed regarding researchers? *Meaning that they cannot foresee assignment.* *(NRS always No - NRCT can be concealed adequate)*	Yes: No: Unclear:
Allocation concealment	**Final Judgement**	**High/Low/Unclear**
CONFOUNDING		
	Did the authors describe the method for identifying relevant confounders?	Yes: No:

		Unclear:
Confounding - *use the confounder sheet in the appendix.* *Report if it's not possible to distinguish between outcomes.*	Outcome 1 Outcome 2	1; 2; 3; 4; 5 Unclear 1; 2; 3; 4; 5 Unclear
Confounding	**Final judgement**	**1; 2; 3; 4; 5; unclear**
BLINDING		
Were <u>outcome assessors</u> blinded, and if not do the review authors judge that the outcome in question was unlikely to be influenced by lack of blinding?	Outcome 1 Outcome 2	1; 2; 3; 4; 5 Unclear: 1; 2; 3; 4; 5 Unclear:
Were <u>participants</u> blinded, and if not do the review authors judge that the outcome in question was unlikely to be influenced by lack of blinding?	Outcome 1 Outcome 2	1; 2; 3; 4; 5 Unclear: 1; 2; 3; 4; 5 Unclear:
Blinding	**Final judgement**	**1; 2; 3; 4; 5; unclear**
INCOMPLETE OUTCOME DATA		
	Do they report drop-outs or lack of drop-outs?	Yes: No: Unclear:
	Did they perform analysis to examine if drop-outs/completers are different? *(Random or systematic)*	Yes: No: Unclear:

Describe how the authors deal with missing data:	Did the authors deal with missing data?	Yes: No: Unclear:
See description above.	Could the imputation method chosen influence the outcome? Outcome 1 Outcome 2	 Yes: No: Unclear: Yes: No: Unclear:
Incomplete outcome data	**Final judgement**	**1; 2; 3; 4; 5; unclear**
SELECTIVE OUTCOME REPORTING		
Describe incomplete or missing outcome reporting:	Is the study free of selective or incomplete outcome reporting? Outcome 1 Outcome 2	 1; 2; 3; 4; 5 Unclear: 1; 2; 3; 4; 5 Unclear:
Selective outcome reporting	**Final judgement**	**1; 2; 3; 4; 5; unclear**
OTHER POTENTIAL THREATS TO VALIDITY		
Describe other sources of bias in this study:	Is the study free from and/or have the study authors adequately dealt with other sources of bias?	1; 2; 3; 4; 5 Unclear:

Description can be seen in the data extraction sheet.	Did the staff delivering the intervention make use of manuals, check lists, supervision, and/or have suitable qualifications/certification?	1; 2; 3; 4; 5 Unclear:
Description can be seen in the data extraction sheet.	Did the study authors check for treatment fidelity?	1; 2; 3; 4; 5 Unclear:
	- If so, was treatment fidelity OK?	1; 2; 3; 4; 5 Unclear:
Other potential threats to validity	**Final judgement**	**1; 2; 3; 4; 5; unclear**
A PRIORI PROTOCOL		
	Did the study follow a priori protocol?	Yes: No: Unclear:
A priori protocol	**Final judgment**	**Yes/No/Unclear**
A PRIORI ANALYSIS PLAN		
	Did the study follow a priori analysis plan?	Yes: No: Unclear:
A priori analysis plan	**Final judgment**	**Yes/No/Unclear**

6 Contribution of authors

Maia Lindstrøm and Pernille Skovbo Rasmussen wrote the background section. Trine Filges and Krystyna Kowalski wrote the methods section. Anne-Marie Klint Jørgensen developed the search strategy. All authors have commented on the protocol.

7 Declarations of interest

None known

8 Sources of support

8.1 INTERNAL SOURCES

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8.2 EXTERNAL SOURCES

None