Brief Strategic Family Therapy (BSFT) for young people in treatment for non-opioid drug use

Maia Lindstrøm, Pernille Skovbo Rasmussen, Krystyna Kowalski, Trine Filges and Anne-Marie Klint Jørgensen

PROTOCOL

For administrative use:

ID NO. SW2011-05

Protocol approval date: 16 January 2012

PROTOCOL/REVIEW
1st submission date: 29 June 2011
Action letter date: 26 July 2011
2nd submission date: 31 August 2011
Action letter date: 14 November 2011
3rd submission date: 29 November 2011

Review approval date:

Template version 08 March 2011

THE CAMPBELL COLLABORATION

Table of contents

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-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 et al., 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 (National Institute on Drug Abuse, 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 Brief Strategic Family Therapy (BSFT) (Szapocznik, Hervis & Schwartz, 2003; Robbins & Szapocznik, 2000) as aggregated evidence for BSFT's effects is needed. The review seeks to clarify the effects of the BSFT 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 (BSFT) is delivered in outpatient treatment settings[3] to young people age 11-21 living with their family. The review will focus primarily on non-opioid drugs use[4], and will consider poly-drug use if relevant.
This 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

BSFT is a manual-based family-oriented prevention and treatment intervention for young people's drug use. BSFT is *a problem focused* family therapy, aiming at creating changes in interactions relevant to the identified problems within families, and in individual family members resisting changes.

[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: Family Behavior Therapy (FBT) 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

BSFT 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, 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).

BSFT was developed at the Centre for Family Studies, University of Miami. The program was developed in the 1970s as an intervention targeting Hispanic minority young people, primarily immigrants from Cuba (Robbins & Szaspocznik, 2000). BSFT was developed to be culturally sensitive, originally in relation to Cuban immigrants in Miami, but has since been revised and is now a broadly applied intervention for young people, primarily with problematic behavior and drug use problems (Robbins & Szaspocznik, 2000). BSFT is adaptable and incorporates relevant issues depending on the population served and is supposedly sensitive to different cultural and ethnic groups as well as rural versus inner-city conditions (Robbins, Szapocznik & Horigian, 2009).

1.2.1 **Theoretical background**

BSFT is a family systems approach that relies on both structural family theory and strategic family theory (Robbins & Szapocznik, 2000; Szapocznik et al., 2003).

BSFT 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 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; Madanes & Haley, 1977).

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

1.2.2 **BSFT components**

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

Joining

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

Diagnosing

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

Restructuring

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

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

Reframing. The aim of reframing is to disrupt maladaptive interaction patterns and create a new context for family interactions. Reframing offers positive alternatives to the family, i.e., by shifting the family members' view of the young drug user from a 'troubled young person' to e.g.,

a ‘vulnerable young person in pain’. Highly gendered interaction patterns in the family may also be adjusted in the reframing process.

Working with boundaries and alliances. According to BSFT families with drug using young people need strong parental leadership, meaning a strong alliance between parents, with the power to make executive decisions together. For single parents there is a need for a strong parental position. The therapist will work to restore the parent alliance in families with weak or disrupted parent alliances. For single parents the therapist will work to establish and/or reinforce a strong parental position. In BSFT the therapist will also aim to set clear boundaries between family members, thereby allowing all members some privacy and independence within the family. Boundaries and alliances may vary according to e.g. gender and age, and can be attended to in this process.

Intervention components in BSFT are tailored to the young person and his/her family needs and are based on the components’ likelihood of positively affecting the young drug user and family in a desired direction (e.g., reduced drug use, improved family interactions). Therefore, BSFT intervention varies in distribution of components to suit the needs of family members. The tailoring of the BSFT program and the focus on family system and family functioning potentially catalyze side effects such as improved overall family functioning, improved educational outcome for the young person in treatment and siblings affected by better family functioning, and other related outcomes.

1.2.3 **Duration and setting**

The average length of BSFT intervention is 12-16 sessions[6], however the program is flexible and can be tailored to individual needs (Robbins, Bachrach & Szapocznik, 2002). Likewise BSFT is flexible in its implementation and can be delivered in a variety of settings including clinical or community facilities or in the family home (Robbins et al., 2002).

[6] Despite the program title *Brief* Strategic Family Therapy, the duration of BSFT is comparable to other family therapy programs.

1.3 HOW THE INTERVENTION MIGHT WORK

BSFT has two primary objectives: 1) to eliminate or reduce young people's drug use, and 2) to change the family interactions associated with young people's drug use. Randomized controlled trials and systematic reviews show that BSFT reduces drug use in participants and contributes to reduction in conduct problems and delinquency (Robbins et al., 2002; Santisteban et al., 2003; Waldron & Turner, 2008; Austin et al., 2005). The program outcomes may be affected by participant characteristics and program mechanisms. Participant characteristics that have been found to predict program drug use reduction or abstinence are history and severity of drug use pretreatment, general peer and parental support, particularly in relation to non-drug use, and higher levels of school attendance and functioning pretreatment (Williams et al., 2000). 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 impacts on treatment outcomes have been identified across reviews of a range of treatments for youth drug use (Waldron & Turner, 2008; Williams et al., 2000).

Treatment completion is the variable with most consistent relationship to drug use reduction (Williams et al., 2000; Waldron & Turner, 2008). Early alliance building predicts the likelihood that adolescent complete treatment and that they reduce drug use (Waldron & Turner, 2008). It remains unclear if this is a direct treatment impact, or an indicator for treatment motivation, which is another key to positive treatment outcome. Either way, these findings points to the importance of the BSFT component 'joining' as a key mechanism, influencing treatment compliance and attendance. Studies show that BSFT positively affects engagement and retention of young people and families (Santisteban et al., 2003; Coatsworth et al., 2001; Santisteban et al., 1996), which can be linked directly to the joining effort. In BSFT, joining has two aspects: joining is the steps a therapist takes to prepare the family for change, and joining occurs when a therapist gains a position of leadership within the family. A number of techniques can be used to prepare the family to accept therapy and to accept the therapist as a leader of change. For

example the therapist can present him/herself as an ally, appealing to family members with the greatest dominance over the family unit, and attempting to fit in with the family by adopting the family's manner of speaking and behaving. These techniques are adaptable to the needs of various clients groups.

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 BSFT. Studies find that BSFT positively influences family interaction changes, family functioning, and contributes to the reduction in young people's drug use (Santisteban et al., 2003; Robbins et al., 2002). For example, Robbins et.al., (2009) find that parent participants in the BSFT intervention gain from the parenting training and education in youth and family struggles, leading to reduction in the young person's drug use. According to Robbins et.al. (2009) parent participants in the BSFT intervention have been found to display improved ability to identify signs of for instance youth gang participation, improved ability to communicate with the young person about gang issues and drug issues, and improved knowledge about parent's responsibility related to youth gang and drug participation. In addition, BSFT participating parents also display improved knowledge about the negative health and legal consequences of substance use.

The young person's participating in BSFT also display positive behavior improvements over the course of the treatment intervention, such as improved conflict resolution skills, improved self-concept and sense of personal resources, and reduced gang and drug identification (Robbins et.al., 2009). Improvements are gained through the reframing phase, during which the therapist work with both the young person and family members, to change their ways of behavior towards a more constructive behavior (Robbins et al., 2009). The therapist coaches the young person and family members on constructive interaction methods, and ensures that new interaction patterns are practiced at home in naturally occurring situations (e.g., when setting a curfew or when eating meals together) (Szapocznik et al., 2003).

The quality of the therapeutic alliance predicts the family's engagement, retention and gains from therapy (Robbins et al., 1998). Robbins et al. (2004) have demonstrated how unbalanced alliances between therapist and young person and/or family in early BSFT session were associated with program dropout. In BSFT, one of the most useful strategies a therapist can

employ in joining is to support the existing family power structure. Szapocznik et al., (2003) concludes that

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

The family systems focus and the joining effort in BSFT are both key ingredients in BSFT, and influence family functioning and facilitate changes in young people's drug problems.

1.4 WHY IT IS IMPORTANT TO DO THIS REVIEW

Persistent drug use among young people is a significant social problem, and treatment of young people's drug use is challenging and costly, not least because the treatments for young people's drug use problems is 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 (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. 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 BSFT is a promising treatment for young people with non-opioid drug use. By aggregating individual studies' results on BSFT, 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 BSFT for relevant client groups.

2 Objective of the review

The aim of this review is to evaluate the current evidence on the effects of BSFT 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 BSFT 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[7] (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:
The aim of this review is to evaluate the current evidence and synthesize all of the potentially high quality international evidence in this topic area. If only RCTs are included, studies from

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

countries that do not have a tradition for conducting RCTs in the area of youth drug use (at the time this protocol was written) would be excluded[8]. There is a long tradition for doing randomized controlled trials on social interventions in North America. However this is not the case in Europe.

3.1.2 **Types of participants**

The population included in this review will be young people aged 11-21 years enrolled in manual based BSFT 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 BSFT on youth living with their family, since family interactions are cardinal in BSFT.

No universal international consensus exists concerning what categories to use when classifying drug users[9], 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

[8] Lipsey, Tanner-Smith, & Wilson (2010) have conducted a meta-analysis of the findings from experimental and quasi-experimental studies on the effectiveness of adolescent substance abuse interventions. They found and included a limited number of non-randomized studies in their analysis (8%). However it should be noted that the searches had a number of restrictions including language (searches were limited to studies reported in English), dates (date filter 1980-2008) and participant inclusion criteria was narrower (12 to 17 years of age).

[9] 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).

Organization (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.

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 BSFT interventions of any duration delivered to young people and their families (see 1.2 Description of the intervention). The BSFT intervention must be an outpatient intervention that does not include overnight stays in a hospital or other treatment facility. The BSFT 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[10] (e.g., detention centers, institutions for sentence-serving juvenile delinquents) will be excluded.

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

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

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 peoples' drug use) the likelihood of no treatment control group is small. We expect that the most frequent comparison will be alternative interventions (Lipsey, Tanner-Smith, & Wilson, 2010).

3.1.4 **Types of outcomes**

Primary outcome(s)

- 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) (Fals-Stewart, O'Farrell, Freitas, McFarlin & Rutigliano 2000);
    - 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 BSFT's effects on drug use reduction for 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 language or date 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 other databases in the completed review.

1. BSFT.af.
2. (Brief adj1 Strategic* adj1 Famil*).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 any other published, unpublished or ongoing studies relevant for the review.

3.2.4 **Searching other resources**

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.

3.2.5 **Grey literature**

Additional searches will be made by means of *Google* and *Google Scholar* and we will check the first 1500 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[11]). 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),

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

intervention characteristics and control conditions, research design, sample size, outcomes and results.

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-Randomized Studies Methods Group (Reeves, Deeks, Higgins, & Wells, 2011) [12]. 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 & 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 formalised and structured approach for the assessment of selection bias in non-randomised studies[13] by adding an explicit item about confounding (Reeves, Deeks, Higgins & Wells, 2011). It is based on a list of confounders considered important and defined in the protocol for the review. The assessment of confounding is made using a worksheet where for each confounder it is 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

[12] 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).

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

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 judgement* 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 judgements and provides justification for not including a study with a very high risk of bias in the meta-analysis.

Risk of bias judgement 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, 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 will be based on pre-specified questions (see Appendix 5.3). “Yes” indicates a low risk, “No” indicates a high risk of bias, and “Unclear” indicates an unclear or unknown risk of bias. In the 5 point scale 1 corresponds to No/Low risk of bias (e.g.1 = a high quality RCT) and 5 corresponds to Yes/High risk of bias (e.g. 5= too risky, too much bias, e.g., a poor quality

study). A judgement of 5 points on any one of the 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). A judgment of 5 is given with precaution and only in cases of extreme biases. Judgements will be justified and reported.

Confounding

An important part of the risk of bias assessment of nonrandomized studies is how the studies deal with confounding factors. Selection bias is understood as systematic baseline differences between intervention vs. control (or comparison) groups that can therefore compromise their comparability.

For this review, the following confounding factors are considered as the most relevant: age, gender, and drug use history. If other confounders are considered by study investigators in the included studies they will be assessed in the same manner (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 drug use, i.e., males generally have higher drug use than females (Østergaard & Bastholm 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 PRS, ML, MS, & KK) will independently assess the risk of bias for each included study as described in the previous sections. Disagreements will be sought by a third reviewer with content and statistical expertise (FT). 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 the 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 SMDs 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 storing data and 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 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. BSFT 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 at available time points 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 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 (see Donner 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 run separate meta-analysis with studies that did not use ITT. 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 BSFT will involve comparing BSFT to no treatment and to untreated wait list controls. The relative effects of BSFT (versus other interventions) will be conducted separately and will include studies that compare BSFT 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 available time points within 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 (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 BSFT 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 participants' 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 et al., 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 on developer bias effect sizes, we will run sensitivity analysis on studies conducted by program developers vs. studies conducted by independent researchers. Developer bias can occur in studies conducted by developers who may unconsciously influence the success of an intervention (Petrosino & Soydan, 2005; Eisner, 2009; Sherman & Strang, 2009).

We will also consider sensitivity analysis for program fidelity, i.e. compliance with program manual and requirements for therapist training.

4 References

Amato, L., Minozzi, S., Davoli, M., & Vecchi, S. (2011). Psychosocial combined with agonist maintenance treatments versus agonist maintenance treatments alone for treatment of opioid dependence. *Cochrane Database of Systematic Reviews*. (Issue 10). Art. No.: CD004147. DOI: 10.1002/14651858.CD004147.pub4.

American Psychiatric Association (1994): *Diagnostic and Statistical Manual of Mental Disorders. Fourth edition. DSM-IV*. Washington, DC: American Psychiatric Association.

American Psychiatric Association (2000): *Diagnostic and Statistical Manual of Mental Disorders*. Fourth edition. Text Revision. *DSM-IV-TR*. Washington, DC: American Psychiatric Association.

Austin A. M., Macgowan M. J., Wagner E. F. (2005). Effective Family-Based Intervention for Adolescents With Substance Use Problems: A Systematic Review. *Research on Social Work Practice*, 15, 67-83.

Beavers, R., & Hampson, R.B. (2000). The Beavers Systems Model if Family Functioning. *Journal of Family Therapy, Volume 22*, Issue 2, 128–143.

Borenstein, M., Hedges L.V., Higgins J.P.T & Rothstein H.R. (2009). *Introduction to Meta-Analysis*. Chichester: Wiley.

Coatsworth, J.D., Santistiban, D.A., McBride, C.K. & Szapocznik (2001). Brief Strategic Family Therapy Versus Community Control: Engagement, retention, and an exploration of the moderating role of adolescent symptom severity. *Family Process*, 40, 313-332.

Crowley, T.J, Macdonald, M.J., Whitmore, E.A. & Mikulich, S.K. (1998). Cannabis dependence, withdrawal, and reinforcing effects among adolescents with conduct symptoms and substance use disorders. In *Drug and Alcohol Dependence,* 50, 27–37

Danish Youth Council (2011). Definition of youth and young people. Retrieved at http://duf.dk/english/key_issues/

Deas, D., & Thomas, S. E. (2001). An Overview of Controlled Studies of Adolescent Substance Abuse Treatment. *The American Journal of Addiction 10*, 178-189

Doherty, W.J. & McDaniel S.H. (2010). *Family Therapy*. Washington, DC: American Psychological Association.

Donner A, Piaggio G, Villar J. (2001). *Statistical methods for the meta-analysis of cluster randomized trials*. Statistical Methods in Medical Research 10:325-38.

Eisner, M. (2009). *No effects in independent prevention trials: can we reject the cynical view?* Journal of experimental Criminology. 5:163-183

Essau, C. A. (2006). Epidemiological trends and clinical implications of adolescent substance abuse in Europe. In H.A. Liddle & C.L. Rowe (eds.), *Adolescent Substance Abuse – Research and Clinical Advances*. New York: Cambridge University Press.

European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) (2010). *Annual Report 2010 – The State of the Drugs Problem in Europe*. Office for Official Publication of the European Communities, Luxembourg.

Fals-Stewart, O'Farrell, Freitas, McFarlin & Rutigliano (2000). The timeline followback reports of psychoactive substance use by drug-abusing patients: Psychometric properties. Journal of Consulting and Clinical Psychology, 68 (1):134-144.

Galanter, M. & H.D. Kleber (eds.) (2008). The American psychiatric publishing textbook of substance abuse treatment. Washington, DC, American Psychiatric Publ.

Goldenberg, H. & Goldenberg, I. (2008). *Family Therapy – An Overview*. Belmont, CA. Thomsons books, seventh edition

Hartung, J., Knapp, G. and Sinha, B. K. (2008). Statistical meta-analysis with applications. New York: Wiley.

Health Canada (2010). Canadian Alcohol and Drug Monitoring Survey. Retrived on 11.11.2011 at www.hc-sc.ca

Hibell, B., Guttormsson, U., Ahlstr¨0m, S., Balakireva, O., Bjarnason, T., Kokkevi, A., & Kraus, L. (2009): The 2007 ESPAD Report; Substance Use Among Students in 35 European Countries. Stockholm: The Swedish Council for Information on Alcohol and Other Drugs.

Higgins JPT, Green S (eds) (2008). Cochrane Handbook for Systematic Reviews of Interventions. Chichester:Wiley-Blackwell.

Higgins, J.P., Thompson, S.G., Deeks, J.J., Altman, D.G. (2003). *Measuring inconsistency in meta-analyses*. British Medical Journal 327(7414):557-60.

Horigian, V., Robbins, M. & Szapocznik, J. (2004). Brief Strategic Family Therapy. *Brief Strategic and Systematic Therapy European Review*, 1, 1994.

Kaminer, Y. (2008). Adolescent Substance Abuse. In Galanter, M. & Kleber, H.D., (Eds.). *The American Psychiatric Publishing Textbook of Substance Abuse Treatment*, fourth edition. Washington: American Psychiatric Publications, Inc.

Kaminer, Y. & Slesnick, N (2005). Evidence-Based Cognitive-Behavioural and Family Therapies for Adolescent Alcohol and Other Substance Use Disorders. In *Alcoholism, vol.17. Alcohol Problems in Adolescents and Young Adults*. Eds. Marc Galanter. 2005. New York:New York University.

Konstantopoulos, S. (2006). Fixed and Mixed Effects Models in Meta-Analysis. IZA DP no. 2198.

Labouvie, E. & White H. R. (2002). Drug Sequences, Age of Onset, and Use Trajectories as Predictors of Drug Abuse/Dependence in Young Adulthood. In Kandel D.B (ed). *Stage and Pathways of Drug Involvement*. Cambridge: Cambridge University Press,

Liddle, H. A., Dakof, G. A, Parker, K., Diamond, G. S., Barrett, K. & Tejeda, M. (2001). Multidimensional Family Therapy for adolescent drug abuse: Results of a randomized clinical trial. *American Journal of Drug and Alcohol Abuse,* 27, 651-688

Lipsey, M.W., Tanner-Smith, E.E., Wilson, S.J. (2010): *Comparative Effectiveness of Adolescent Substance Abuse Treatment: Three Meta-Analyses with Implications for Practice, Final Report* March 2010, Peabody Research Institute, Vanderbilt University.

Lipsey, M.W. & Wilson, D.B. (2001). *Practical Meta-Analysis.* Thousand Oaks: Sage Publications.

Madanes, C. & Haley, J. (1977): Dimensions of family therapy. *The Journal of Nervous Mental Disease.* Vol. 165(2):88-98.

McCabe, S.E., Morales, M., Cranford, J.A., Delva, J., McPherson, M.D., & Boyd, C.J. (2007) Race/Ethnicity and Gender Differences in Drug Use and Abuse Among College Students. *Journal of Ethnicity in Substance Abuse*. Vol. 6, No.2 pp. 75-95.

McLellan, A. T., Luborsky, L. 0., O'Brien, C. P., and Woody, G. E. (1980). An Improved Evaluation Instrument for Substance Abuse Patients: The Addiction Severity Index. *Journal of Nervous and Mental Disease 168,* 26-33.

Minozzi, S., Amato L., Vecchi, S., & Davoli, M. (2011). Psychosocial treatments for drugs and alcohol abusing adolescents (Protocol). *Cochrane Database of Systematic Reviews*. (Issue 3). Art. No.: CD008283. DOI: 10.1002/14651858.CD008283.pub2.

Minuchin, P. (1985). Families and Individual Development: Provocations from the Field of Family Therapy. *Child Development, 56,* 289-302

Muck, R., Zempolich, K. A., Titus, J. C., Fishman, M., Godley, M. D. & Schwebel, R. (2001). An Overview of the Effectiveness of Adolescent Substance Abuse Treatment Models. *Youth Society, 33*, 143-168.

Najavits, L.M. & Weiss, R.D. (1994). Variations in therapist effectiveness in the treatment of patients with substance use disorders: an empirical review. *Addiction*, Volume 89, Issue 6, pages 679–688, June 1994

National Institute on Drug Abuse (2009). *Principles of Drug Addiction Treatment.* Bethesda, MD. National Institutes of Health.

National Survey on Drug Use and Health, The Report (NSDUH) (2007): Young Adult's Need for and Receipt of Alcohol and Illicit Drug Use Treatment: 2007. Office of Applied Studies, Substance Abuse and Mental Health Service Administration. Retrieved November 2, 2009, from http://www.oas.samhsa.gov/2k9/157/YoungAdultsDrugTxt.htm)

Nordegren, T. (2002). *The A-Z Encyclopedia of Alcohol and Drug Abuse.* Parkland: Brown Walker Press.

O'Farrell, T, Fals-Steward, W. (2008). Family Therapy. In Galanter M. & Kleber, H.D. (eds) *The American Psychiatric Publishing Textbook of Substance Abuse Treatment.* Washington DC: American Psychiatric Publishing, Inc.

Office of National Drug Control Policy (ONDCP) (2000). Drug-related crime. Office of National Drug Control Policy (ONDCP), Drug Policy Information Clearinghouse, fact sheet.

Petrosino, A. & Soydan, H. (2005). The impact of program developers as evaluators on criminal recidivism: Results from meta-analyses of experimental and quasi-experimental research. *Journal of experimental Criminology*. *1*:435-450.

Poulsen S. (2006). *Psykoterapi – en introduktion. [Introduction to Psychotherapy]* Frederiksberg*:* Frydenlund

Reeves B.C , Deeks J.J., Higgins. J.P.T., & Wells G.A. (2011). Including non-randomized studies. Unpublished manuscript.

Robbins, M. S., Bachrach, K. & Szapocznik, J. (2002). Bridging the research-practice gap in adolescent substance abuse treatment: the case of brief strategic family therapy. *Journal of Substance Abuse Treatment, 23,* 123-132

Robbins, M., Horigian, V. & Szapocznik, J. (2004). Brief Strategic Family Therapy. *Brief Strategic and Systemic Therapy European Review, 1,* 251-271

Robbins, M.S. & Szapocznik, J. (2000): Brief Strategic family Therapy. *Juvenile Justice Bulletin*. Washington DC: Office of Juvenile Justice and Delinquency Prevention. Downloaded from http://www.ncjrs.gov/html/ojjdp/jjbul2000_04_3/contents.html on May 16, 2011.

Robbins, M.S., Szapocznik, J., Alexander, J.F., & Miller, J.R. (1998). Family systems therapy with children and adolescents (pp. 149-184). In M. Hersen & A.S. Bellack (Series Eds.) & T.H. Ollendick (Vol. Ed.) *Comprehensive Clinical Psychology: Vol. 5 Children and adolescents: Clinical formulation and treatment*. Oxford: Pergamon.

Robbins,M.S.; Szapocznik,J.; Horigian,V.E. (2009): Brief Strategic Family Therapy for Adolescents with Behavior Problems. In Bray, J.H. & Stanton, M. (Eds.) *The Wiley-Blackwell Handbook of Family Psychology*.

Robbins,M.S.; Szapocznik,J.; Horigian,V.E.; Feaster,D.J.; Puccinelli,M.; Jacobs,P.; Burlew,K.; Werstlein,R.; Bachrach,K.; Brigham,G. (2009). Brief strategic family therapy for adolescent drug abusers: a multi-site effectiveness study. *Contemporary clinical trials, vol.30, pp.269-278.*

Rowe, C. L. & Liddle, H. A. (2006). Treating adolescent substance abuse: state of the science. In H.A. Liddle & C.L. Rowe (eds.), *Adolescent Substance Abuse – Research and Clinical Advances*. New York: Cambridge University Press, 1-21

Sáchez-Meca, J., Marín-Martínes, F., & Chacón-Moscoso, S. (2003): Effect-Size Indices for Dichotomized Outcomes in Meta-Analysis. *Psychological Methods, 8*(4), 448-467.

Santisteban, D. A., Szapocznik, J., Perez-Vidal, A., Kurtines, W. M., Murray, E. J. & LaPerriere, A. (1996). Efficacy of intervention for engaging youth and families into treatment and some variables that may contribute to differential effectiveness. J*ournal of Family Psychology, 10,* 35-44.

Santisteban, D. A., Perez-Vidal, A., Coatsworth, J. D., Kurtines, W. M., Schwartz, S. J., LaPerriere, A. & Szapocznik, J. (2003). Efficacy of Brief Strategic Family Therapy in Modifying Hispanic Adolescent Behavior Problems and Substance Use. *Journal of Family Psychology, 17,* 121-133.

Shelton, K.H., P.J. Taylor, A. Bonner & M. van den Bree (2009). Risk factors for homelessness: Evidence from a population-based study. Psychiatric Services 60, 465-472.

Sherman, L.W. & Strand H. (2009). Testing for Analysts' Bias in Crime Prevention Experiments: Can We Accept Esiner's One-tailed Test? *Journal of experimental Criminology*. *5*:185-200

Simmonds, M.C. and J.P.T. Higgins (2007). Covariate heterogeneity in meta-analysis: Criteria for deciding between meta-regression and individual patient data. *Statistics in Medicine, 26*: 2982-2999.

Simmons, R., Ungemack, J., Sussman, J., Anderson, R., Adorno, S., Aguayo, J., Black, K., Hodge, S., & Tirnady, R. (2008). Bringing Adolescents into Substance Abuse Treatment Through Community Outreach and Engagement: The Hartford Youth Project. In *Journal of Psychoactive Drugs,* 40 (1), 41-54.

Stanton,M.D. & Shadish,W.R. (1997): Outcome, attrition, and family–couples treatment for drug abuse: A meta-analysis and review of the controlled, comparative studies. *Psychological Bulletin*, Vol 122(2), Sep 1997, 170-191.

Substance Abuse and Mental Health Services Administration [SAMSHA] (2008): *National Survey of Substance Abuse Treatment Services (N-SSATA): 2007 – Data on Substance Abuse Treatment Facilities*. Office of Applied Studies, DASIS Series: S-44, DHHS Publication no. SMA 08-4348, Rockville, MD, USA.

Substance Abuse and Mental Health Services Administration (SAMHSA). (2010). Results from the 2009 National Survey on Drug Use and Health: Volume I. Summary of National Findings (Office of Applied Studies, NSDUH Series H-38A, HHS Publication No. SMA 10-4586Findings).

Szapocznik, J., Hervis, O. & Schwartz, S. (2003). *Therapy Manuals for Drug Addiction*. Bethesda, Maryland: U.S. Department of Health and Human Services

Szapocznik, J. & Williams, R. A. (2000). Brief Strategic Family Therapy: Twenty-Five Years of Interplay Among Theory, Research and Practice in Adolescent Behavior Problems and Drug Abuse. *Clinical Childand Family Psychology Review, 3*, 117-134.

Townsend, E., Walker, D. M., Sargeant, S., Stocker, O., Vostanis, P., Sithole, J., Hawton. K. K. E. (2008). Interventions for mood and anxiety disorders, and self harm in young offenders (Protocol). *Cochrane Database of Systematic Reviews.* (Issue 2). Art. No.: CD007195. DOI: 10.1002/14651858.CD007195.

United Nations (2011). What does the UN mean by "youth," and how does this definition differ from that given to children? Retrieved form http://social.un.org/index/Youth/FAQ.aspx .

United Nations Office of Drugs and Crime (UNODC) (2010), World Drug Report 2010. United Nations Publication.

Waldron, H. B. (1997). Adolescent substance and family therapy outcome: A review of randomized trials. *Advances in clinical child psychology*, 4, 199-234

Waldron, H. B., Turner, C. W. & Ozechowski, T. J. (2006). Profiles of change in behavioural and family interventions for adolescent substance abuse and dependence. In H.A. Liddle & C.L.

Waldron, H. B. & Kaminer, Y. (2004). On the learning curve: the emerging evidence supporting cognitive-behavioral therapies for adolescent substance abuse. *Addiction, 99* (Suppl. 2), 93-105.

Waldron, H. B., & Turner, C. W. (2008). Evidence-based Psychosocial Treatments for Adolescent Substance Abuse. *Journal of Clinical Child and Adolescent Psychology*, 37, 238-261.

Weller, S. (2006). Situating (Young) Teenager in Geographies of Children and Youth. *Children's Geographies, Vol 4,* No.1 pp.97-108.

White, V. & Smith, G. (2009). Australian secondary school students' use of tobacco, alcohol, and over-the-counter and illicit substances in 2008. The Cancer Counsil, Victoria.

Williams, R. J, Chang, S. Y., & Addiction Centre Adolescent Research Group (2000). A comprehensive and comparative review of adolescent substance abuse treatment outcome. *Clinical Psychology, Science, and Practice*, 7, 138-166.

World Health Organisation [WHO] 2011: Abuse (drug, alcohol, chemical, substance or psychoactive substance. Retrieved at www.who.int/substance_abuse/terminology/abuse/en/index.html.

Østergaard, J. & Bastholm Andrade S. (2011). Young people's transition to a lifestyle of risk and pleasure. *Paper presented at SFI Advisory Research Board Conference, May 2011.* Copenhagen.

5 Appendices

5.1 STUDY ELILGIBILITY 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 Brief Strategic Family Therapy (BSFT) 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 report 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 were 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? (BSFT counts as one)**

   One (BSFT)

   Two (BSFT plus what?)

   Three (BSFT plus what?)

10. **How many intervention groups are relevant for this review?**

    One (BSFT)

    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	BSFT*	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

	BSFT*	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)

BSFT characteristics

20. Characteristics of BSFT

	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 BSFT

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

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

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

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 who provided services to control cases (education, demographics, etc.)

Outcome measures

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

Baseline

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 BSFT 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)	BSFT Comparison 	BSFT Comparison 	BSFT Comparison 	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)	

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)	BSFT	BSFT	BSFT	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 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.[14] 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

[14] 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).

- 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
     - 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 ASSESMENT OF RISK OF BIAS FOR INCLUDED STUDIES: CODING SHEET

RISK OF BIAS FORM – BSFT 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

SFI Campbell, The Danish National Centre for Social Research.

8.2 EXTERNAL SOURCES

None.