THE CAMPBELL COLLABORATION

Protocol:
Functional Family Therapy (FFT) for young people in treatment for non-opioid drug abuse

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1 BACKGROUND

1.1 Description of the condition

Youth drug abuse[1] of the kind that persists beyond the experimentation phase is a severe problem worldwide (United Nations Office on Drugs and Crime (UNODC), 2010). Abuse of non-opioid drugs such as cannabis, amphetamine and cocaine is strongly associated with a broad range of negative health implications such as traffic accidents, sexually transmitted diseases, mental problems and suicide as well as social problems including poor academic achievement, delinquency and violent behavior (Deas & Thomas, 2001; Essau, 2006; Rowe & Liddle, 2006; ONDCP, 2000; Shelton, Taylor, Bonner & van den Bree, 2009; Nordstrom & Levin, 2007; Lynskey & Hall, 2000).

While cannabis, amphetamine, cocaine and other non-opioid drugs remain illegal in most countries, surveys indicate widespread prevalence. In the US, 25.5 percent of 12th-grade students report having used an illicit drug (any kind) within the last month (Johnston, O'Malley, Miech, Bachman & Schulenberg, 2014). In Canada, 21 percent of 15-24 year olds report having used of some kind of illicit drugs within the last year (Health Canada, 2011). In Australia, seven percent 12-17 year olds report using some kind of drug within the last month (White & Smith, 2009). The European Monitoring Centre for Drugs and Drug Addiction has found that that within Europe prevalence differs significantly from country to country but that overall around a quarter of Europeans report having used some kind of illicit drug in their lifetime (European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), 2013).

The prevalence of specific kinds of illicit drug abuse varies significantly, with cannabis generally being the most commonly used drug. In the US, 22.7 percent of 12th-grade students report having used marijuana/hashish (types of cannabis), 4.1 percent amphetamine, and 1.1 percent cocaine during the last 30 days before the National Survey on Drug Use conducted in 2013 (Johnston et al., 2014). The European Drug Report of 2013 indicates that 11.7 percent of the 15 to 34 year-olds in Europe have used cannabis, 1.3 percent amphetamine, and 1.9 percent used cocaine during the last year (EMCDDA, 2013).

Although not all young drug users progress to severe dependence, some do and may therefore require treatment (see e.g. Crowley, Macdonald, Whitmore & Mikulich, 1998). Research draws attention to the significant gap between the number of young people classified as in need of treatment and the number of young people who actually receive such treatment (SAMHSA, 2010; National Survey on Drug Use and Health (NSDUH), 2007). In the US, for example, 7.2 million people aged 12 or older are classified as needing treatment

[1] The terms 'use', 'abuse' and 'dependence' are often used interchangeably and refer to an addiction stage of non-medical drug usage.

for illicit drug abuse, but only 1.4 million of these young people actually receive treatment at a specialty facility for an illicit drug abuse problem (SAMHSA, 2011).

The treatment usually provided to young people is delivered in outpatient settings. Accordingly, 90 percent of the 89,521 clients under age 18 registered in substance abuse treatment in 2012 by SAMHSA were in outpatient treatment, which is the same proportion as the total treatment population (SAMHSA, 2013). Equal proportions of the clients under age 18 were enrolled in facilities with a primary focus on substance abuse treatment and in facilities whose primary focus were provision of a mix of mental health and substance abuse treatment services; this differs from the total treatment population as youth tend to be treated in dual focus facilities more often than adults (SAMHSA, 2013). Cognitive-behavioral therapy and motivational interviewing are specific therapeutic approaches that are used at least sometimes by most (respectively 91 and 87 percent) treatment facilities (SAMHSA, 2013).

There is growing public concern about the effectiveness and high costs of available treatments for young people, and the high rates of treatment dropout and post-treatment relapse to drug abuse (Austin, Macgowan & Wagner, 2005; Najavits & Weiss, 1994; Stanton & Shadish, 1997). While relapse must be acknowledged as an expected part of any treatment process targeting individual drug use, efforts should be made to make treatment as attractive, accessible and relevant as possible for young people in order to minimize the risk of unwarranted dropout and continuous relapse (Simmons et al., 2008; National Institute on Drug Abuse (NIDA), 2009). Furthermore, the services provided should be empirically supported to increase the likelihood that (a) treatment will be successful, and (b) public spending supports the interventions that are the most effective.

Researchers point to the fact that many research projects have empirically validated different types of treatment approaches as effective for young drug users (e.g. Rowe & Liddle, 2006; Waldron, Turner & Ozechowski, 2006; Williams, Chang & Addiction Centre Adolescent Research Group, 2000; Austin et al., 2005). The effectiveness, however, depends upon the interplay between a specific intervention and individual factors such as gender, ethnicity, family composition, co-morbidity and history of drug abuse (Brannigan, Schackman, Falco & Millman, 2004; Hawkins 2009; Horsfall, Cleary, Hunt & Walter 2009). For example, research suggests that treatment outcomes of a specific program such as Functional Family Therapy may vary for different ethnic groups (Hops, Ozechowski, Waldron, Davis, Turner, Brody & Barrera, 2011; Flicker, Waldron, Turner, Brody & Hops, 2011). The current challenge in the field of substance abuse treatment for young people is therefore to establish not only what works best but also what works for different subgroups.

In terms of treatment types, there is some documentation of promising individually-based cognitive and motivational therapies (Waldron & Turner, 2008; Kaminer, 2008; Deas & Thomas, 2001; Galanter & Kleber, 2008). Family-based approaches on the other hand may be equally effective. Family therapy encompasses a range of different interventions with

varying theoretical sources, including behavioral and cognitive behavioral theory, structural and strategic family theory, and family systems theory (Williams et al., 2000; Austin et al., 2005). Some reviews have suggested that these family-based therapies are superior to individual-based programs in reducing youth drug abuse (Williams et al., 2000; Lipsey, Tanner-Smith & Wilson, 2010; Waldron, 1997).

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

This review is concerned specifically with Functional Family Therapy (hereafter FFT) (Alexander & Parsons, 1973; Alexander & Parsons, 1982; Rowe & Liddle, 2003), as aggregated evidence for the effects of this approach is lacking. The review will seek to clarify the effects of the FFT program for relevant groups of young people aged 11-21, and will focus on young people enrolled in treatment for drug abuse, irrespective of how their problem is defined. Enrolment in treatment is taken to imply that the severity of the young person's drug abuse has compelled a close, significant adult (for example, teacher, parent, social services, or school counselor) to demand that the young person enters treatment. FFT is an intervention offered as an outpatient treatment[2] to young people age 11-21 that are living with their families.

This review focuses solely on non-opioid drug abuse[3], and is one in a series of reviews on manual-based family therapy interventions for young people in treatment for non-opioid drug abuse[4].

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

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

[4] See the following Protocols in the Campbell Library: Brief Strategic Family Therapy (BSFT) for young people in treatment for non-opioid drug use, (Lindstrøm, M., Rasmussen, P.S., Kowalski, K., Filges, T., Jørgensen, A-M.); Family Behavior Therapy (FBT) for young people in treatment for non-opioid drug use, (Kowalski, K., Lindstrøm, M., Rasmussen, P. S., Filges, T., Jørgensen, A-M.); Multidimensional Family Therapy (MDFT) for young people in treatment for non-opioid drug use, (Rasmussen, P.S., Lindstrøm, M., Kowalski, K., Filges, T., Jørgensen, A-M.).

1.2 Description of the intervention

Functional Family Therapy (FFT) is a short-term, manual-based, behaviorally oriented family therapy program for young people with behavior problems such as drug abuse, juvenile delinquency and violence. Delivered in an outpatient setting, it aims to help young people *and* their families by improving family interactions and relationship function by addressing dysfunctional individual behavior (Sexton & Alexander, 2000; Sexton & Turner, 2011).

In an FFT program, the therapist provides intensive family therapy in an attempt to change the patterns of family interaction that are contributing to the problem behavior and to help family members develop specific skills in, for example, communication, conflict resolution, problem solving, and effective parenting. After the desired behavioral change has been achieved within the family, the therapist helps the family generalize changes to other situations and settings, such as school, community, and peers, and identifies support that can help to maintain the progress made (Sexton & Alexander, 2003; Onedera, 2006).

As with many other forms of family therapy, FFT targets young people and their families as a system. As such, it recognizes the important role of the family system in the development and treatment of young people's drug abuse problems (Ozechowski & Liddle, 2000). While a specific FFT intervention may focus on improving specific problems such as drug abuse, the FFT approach in itself adds a broader view of the change process and clinical outcomes by switching from an individual problem focus to a relational perspective. The intervention is designed to help families recalibrate their interaction patterns and improve family relations, and through this achieve individual goals such as decreased drug abuse (Alexander, Waldron, Robbins & Neeb, 2013).

FFT was developed in the late 1960s and early 1970s (Alexander & Parsons, 1973) with the model described in full by Alexander and Parsons in the early 1980s (Alexander & Parsons, 1982). It was developed to serve diverse populations of under-served and at-risk adolescents and their families because these populations lacked resources, were difficult to treat, and were often perceived by professionals as lacking the motivation for change. The founders of FFT realized that successful treatment of these populations required service providers who were sensitive to the needs of these diverse families, who were competent to work with them, and who understood why the families had traditionally resisted treatment (Sexton & Alexander, 2003). The development of the FFT program has continued, and the therapy has been refined in response to the results of research and the experiences from successful implementation (Alexander & Robbins, 2010).

In a systematic review conducted by Austin, Macgowan & Wagner (2005), FFT appeared as one of five interventions identified as consistent with the majority of guidelines for effective treatment for adolescents with substance abuse. Austin et al. (2005) also note, however, that there is some inconsistency in the research on outcomes of FFT and that long-term follow-up assessment is needed. In a meta-analytical study, Waldron & Turner (2008) synthesized

findings from 17 studies evaluating outpatient treatments for substance-abusing youth, including several therapy models, among them FFT, other family therapy approaches, group CBT, individual CBT and minimal treatment conditions. Waldron & Turner (2008) found that the effect size associated with reductions in drug abuse was significantly larger for family therapy relative to the minimal treatment condition, but the meta-analysis did not establish one of the treatment approaches as clearly superior to any other in terms of treatment effectiveness for substance-abusing youth.

1.2.1 Theoretical background

FFT is derived from both family system theory (Alexander & Parsons, 1973) and cognitive behavioral theory and techniques (Alexander & Robbins 2010). The therapy focuses on family functioning, and is thus based on the premise that both positive and negative behavior can have a direct influence, and are influenced by multiple relational systems (Alexander & Sexton, 2002; Sexton & Alexander 2000). It assumes that young people's problem behavior can serve a function within the family. Family members develop ways of interacting that help them meet their relational needs for closeness or distance, but these patterns of interacting may also create or maintain behavioral problems. When changes are made in how the family interacts (by, for example, improving communication, problem-solving, and parenting skills), behavioral problems will be resolved. Interventions must take into account the needs of each family member and be tailored to the family's unique risk and protective factors (Alexander & Sexton, 2002; Sexton & Alexander, 2003; Alexander et al., 2013).

While FFT is established as a distinctly unique approach, it has not emerged in a vacuum and is related to other current treatment approaches. Accordingly, Calley (2011) states that one of the most striking elements of the functional family therapy approach is its similarity to other therapeutic models, such as multisystemic family therapy, motivational enhancement therapy and solution-focused brief therapy. She emphasizes that this is not a deficit of the FFT model but rather a reminder of the evolutionary nature of the theories informing psychotherapy in general. Some of the characteristics that make FFT stand out are the emphasis on relational functions (hence the title *Functional* Family Therapy), the level of implementation of detailed treatment manuals and protocols for training and supervision, as well as the distinctive phase model (Alexander et al., 2013). Furthermore, FFT is a multi-systemic treatment focusing on the multiple domains and systems of which the adolescent is part, such as the community, school and the juvenile justice system (Sexton & Alexander, 2003). Finally, FFT is a multilevel intervention in which the therapist works first to develop the family's inner strengths and sense of being able to improve their situation. This provides a foundation for change and future functioning that extends beyond the direct support of the therapist and other social systems. As FFT is a strength-based model, its philosophy is that

the intervention offers self-sufficiency through a platform for change for the family (Sexton & Alexander, 2000; Sexton & Turner 2011).

FFT therapists have diverse professional backgrounds. In one FFT intervention targeting youth with behavioral problems that was carried out in a community practice setting, the majority of therapists were Master's degree clinicians; others were Bachelor's level, and the therapists' clinical experience ranged from 1 to 40 years. Regardless of the variations in training and experience, all therapists received ongoing group-based FFT training, and outcome studies suggested that rather than the professional background, the decisive therapist characteristic was the level of treatment model adherence. Thus, the FFT intervention was found to be effective only when the therapists adhered to the treatment model (Sexton & Turner, 2011). In a previous study, undergraduate paraprofessionals trained in FFT produced significant reductions in recidivism rates among youth offenders (Barton, Alexander, Waldron, Turner, and Warburton, 1985), giving some indication of the level of training that might be required to successfully reproduce FFT (cf. Sexton 2011). In general, the FFT model emphasizes the importance of ongoing training and supervision to maintain therapists' model fidelity, and FFT provides training and supervision protocols to facilitate adherence in real-world settings (Alexander et al., 2013).

1.2.2 FFT components

As a clinical model, FFT is both flexible and structured: flexible because it requires individualized treatment strategies to be formulated by sensitive clinicians, and structured because it offers a fixed sequence of treatment strategies (Alexander & Sexton, 2002).

The FFT treatment contains five interdependent and sequentially linked phases, in addition to pre-treatment and post-treatment activities. Each of the five phases has specific assessment and intervention components that are tailored to the unique characteristics of each family: (1) Engagement in change; (2) Motivation to change; (3) Relational/interpersonal assessment and change planning; (4) Behavioral Change; (5) Generalization across behavioral domains and multiple systems (Alexander & Robbins, 2010; Alexander et al, 2013).

Research on FFT outcomes has emphasized investigations of the intervention's effectiveness in relation to desired outcomes (Alexander et al., 2013 p. 37-62) rather than investigating possible adverse effects (Dishion, McCord & Poulin, 1999) of FFT. Critics have suggested that future evaluations of FFT need to be carried out by a broader group of researchers to ensure rigorous evaluation of the approach in practice settings and to nuance the documentation of outcomes (Calley, 2011). Stressing desired outcomes at the expense of turning attention to the investigation of adverse effects is characteristic of much research into effects of psychotherapy, not just FFT (cf. Barlow 2010). Nonetheless, research suggests

that possible adverse effects of therapy include exacerbating clients' problematic symptoms or initiating an experience of passive dependence (Dishion et al., 1999, Barlow 2010).

Pre-treatment Preparation and Engagement phase

Before the therapist contacts the family, he or she will gather all information available about the youth and his or her family (including from formal assessments and official records). The ultimate goal of the Pre-treatment phase is that the therapist is fully ready both to assist the youth and family, and also to anticipate potential barriers and utilize strengths so that a positive experience for the family may be created (Alexander & Robbins, 2010; Onedera, 2006).

The engagement phase involves activities that encourage the family to attend sessions. The therapist strives to create a positive contact with the family by, for example, scheduling appointments via telephone rather than by letter (this has the additional advantage of allowing the therapist to form a first impression of the family and to identify potential problems such as resistance to or confusion about treatment). It is considered important that the therapist be culturally competent and able to assist the family in feeling respected and comfortable (Alexander et al, 2013).

Motivation phase

The goal of this phase is to create a positive and motivational context within which change can occur. Alexander (interview in Onedera, 2006) stresses that motivation is fundamental for subsequent behavioral change. It is considered important that any negativity is decreased in this early phase before targeting actual behavioral change; this is because negative emotions can prevent family members from making a realistic commitment to change (Onedera, 2006). Using a range of therapeutic techniques, the family members are helped to feel a reduction of blame, anger, and hopelessness and an increase in hopefulness (Alexander & Sexton, 2002; Sexton & Alexander, 2003).

The phase consists of two major domains of activity: Changing Focus and Changing Meaning. 'Change Focus interventions' attempt to disrupt negativity and unproductive family interactions by shifting, stopping or redirecting communication. 'Change Meaning interventions' seek to change the meaning of how family members understand themselves and each other (Alexander & Robbins, 2010; Alexander et al., 2013).

Relational assessment

The goals of relational assessment are to elicit and analyze information pertaining to relational processes, and to develop plans for the further process.

Relational assessment focuses on two family relationship domains: (a) the degree of connection between members of the family, and (b) the hierarchical pattern involved in those connections. In this phase, the therapist identifies how to approach specific changes in the family to meet the least resistance and create the most lasting effects. Relational assessment provides a framework that addresses not only the specific problem behavior (e.g. youth drug abuse) but also the unique abilities and styles of the family members with respect to each other. The focus is directed to intra-family and extra-family capacities which include values, attributions, functions, interaction patterns, and sources of resistance (Alexander & Robbins, 2010; Alexander et al., 2013).

Behavior change

In this phase, the main goals are to develop an implementation plan for change. It is important that the plan matches the unique family, each of its members, and their relational functions. The therapist provides concrete behavioral interventions to guide and model specific behavior changes (e.g. communication training, problem solving, negotiating, parental skills training, and conflict management). It is seen as important that the techniques used are individualized and developmentally appropriate, and that they fit the family relational system (Alexander & Sexton, 2002; Alexander et al., 2013).

Generalization

In the last phase, the goals are to generalize, maintain and support change by incorporating community resources. The aim is to encourage family members to solve their problems using the identified strengths and skills they have learned, and to reduce dependence on the therapist. Interventions seek to help the family to generalize across different situations, to be more efficacious in overcoming setbacks or relapse, and to use community resources. There is a focus on motivating the families to continue attending sessions after family life has improved whilst at the same time encouraging the family to rely on their own capacities. Community resources are actively mobilized in the generalization phase. Behavior is seen as indicative of the functionality of the family system (Alexander & Sexton, 2002; Alexander & Robbins, 2010; Alexander et al., 2013).

1.2.3 Duration and setting

FFT is a short-term intervention comprising on average 8-12 sessions for mild cases and up to 30 sessions for more complex cases. The sessions are normally spread over a period of between three and six months. The therapist spends at least one hour per week with the youth and his or her family. The program is flexible and can be implemented in a variety of settings, including at a clinical or community facility or with in the family home (Sexton & Alexander, 2003).

1.3 How the intervention might work

FFT has two primary objectives: 1) to eliminate or reduce young people's drug abuse, and 2) to change behaviors associated with drug abuse in young people and their families. Randomized controlled trials and systematic reviews have indicated that FFT can reduce drug abuse in participants, can contribute to a reduction in behavioral problems and delinquency, and is associated with improvements in family communication patterns and relationships (Austin et al., 2005; Waldron, Slesnick, Brody, Turner & Peterson, 2001; Waldron & Turner, 2008; Hogue & Liddle, 2009; Stanton & Shadish, 1997).

Psychodynamic, behavioral, and social learning have been the key theories that shaped have FFT (Alexander et al., 2013). Fundamentally, this theoretical bedrock indicates that problem behavior is not approached as a mere reflection of individual psychopathology. Rather both positive and negative behavior is viewed in the social context, meaning that therapists focus their attention more on interactional dynamics. Furthermore, FFT is influenced by family systems and communication theories infusing the holistic perspective and implying that therapists view social roles and relationships as central, if not causative, aspects of problem behavior (Alexander et al., 2013). Building on these theories, FFT requires that the therapists focus on the relational functions of all family members' behaviors relevant to the problem behavior (e.g. drug abuse) of the referred youth. In other words, FFT theorizes that changing individual drug abuse may be achieved through improving family relations and reducing dysfunctional interaction.

A basic premise of FFT is therefore that family members of the referred substance-abusing youth participate in the treatment process. The decision about who is to participate in FFT sessions in a particular case is based on the therapist's understanding of which family members will be important for the change process involving the referred youth (Alexander et al., 2013). While parents (or parental figures) are expected to participate, they are not necessarily expected to be motivated at the treatment outset to keep the family integrated. Parents, especially stepparents, may enter FFT motivated to have the youth removed from the home, and FFT treatment encompasses specify strategies to engage them in a positive change process (Alexander et al., 2013).

The program outcomes may be affected by mediating factors such as participant characteristics and program mechanisms. Participant characteristics that have been found to predict program drug abuse reduction or abstinence were: history and severity of drug abuse pretreatment; level of general peer and parental support, particularly in relation to non-drug use; and higher levels of school attendance and functioning pretreatment (Williams et al., 2000). More information is required by practitioners on the impact of other characteristics such as age, gender, ethnicity, family composition (e.g., single parenting), and co-occurring conditions. These participant characteristics are potential predictors of treatment outcome and practitioners need to be able to assess the program's relevance for any particular type of client.

Treatment variables with positive impacts on treatment outcomes have been identified in a number of reviews of a range of treatments for youth drug abuse (Waldron & Turner, 2008; Williams et al., 2000). Treatment completion is the variable most consistently related to reduction in drug abuse (Williams et al., 2000; Waldron & Turner, 2008). While it is established that building a therapeutic alliance early in treatment increases the likelihood that young people complete treatment and reduce their drug abuse (Waldron & Turner, 2008), it remains unclear whether this is a direct effect or an indicator of treatment motivation (which itself has been shown to have a positive impact on treatment outcome). Either way, these findings point to the importance of the FFT components of 'engagement' and 'motivation' as influences on treatment compliance and attendance.

1.3.1 *Intervention mechanisms*

The focus on family systems, the behavioral nature of the approach, and the requirement to address engagement and motivation issues are all possible explanations of intervention impact. These mechanisms influence family behavior and functioning, and ultimately facilitate changes in young people's drug abuse.

In FFT, the Engagement componentis the first step a therapist takes to prepare the the family for change. This component stresses the importance of the therapist's capacity to create a positive relation to all family members. The therapist prepares for the meeting with the family by gathering all available information about the youth and his or her family. The goal of this is to be culturally equipped to meet the family with respect to and to understand as much as possible about, the context.

The Motivation phase is closely linked to the Engagement phase and contains a number of intervention techniques (e.g. 'divert and interrupt', 'reframing', and developing positive themes) which can be used by the therapist to gain change within the family. By using the intervention technique of 'reframing', the therapist creates alternative cognitive and attribuonal perspectives that help redefine meaningful events and thus reduce negativity. Reframing challenge clients to identify new directions for future change help to link family members to one another, so that each one feels a joint responsibility for the family's struggles.

Motivation, as key to positive treatment outcome (Williams et al., 2000), is also linked to the support and influence of the family system. The family system's ability to influence the young person toward a non-drug-using lifestyle is a possible mechanism of change related to the family systems focus of FFT. Studies have found that FFT positively influences family interaction, and contributes to the reduction in young people's drug abuse (Ozechowski & Liddle, 2000).

Therapeutic alliances are described as crucial in the mechanisms of change associated with FFT. Within FFT, therapeutic alliances are associated with interventions delivered in a fashion whereby each family member 1) trusts the therapist and his/her expertise, 2) believes the therapist is working hard to respect and value them regardless of their behavior, 3) believes the therapist is working hard to understand their emotions and values (Robbins, Turner, Alexander & Perez, 2003). Research into the importance of therapeutic alliances suggests, that therapists who were able to achieve a balanced or similar level of alliances (i.e. avoiding unbalanced alliances in which therapists are more closely aligned with parents than youth or vice versa) were more likely to retain family in treatment (Robbins et al., 2003). These results underline the importance of the therapist's success in creating a positive, balanced family-therapist alliance in the engagement and motivation phase.

1.4 Why is it important to do this review

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

By aggregating the results from all available individual studies on FFT, this review will contribute to the body of knowledge on the treatment of young drug-users and their families. The review will inform practice by exploring the effects of FFT for relevant client groups.

2 OBJECTIVES

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

3 METHODOLOGY

3.1 Title registration

The title for this systematic review was approved in The Campbell Collaboration on 20. June 2011.

3.2 Criteria for including studies in the review

3.2.1 Types of studies

Study designs eligible for inclusion are:

Controlled trials[5] where all parts of the study are prospective, i.e. recruitment of participants, assessment of baseline characteristics, allocation to intervention, selection of outcomes and generation of hypotheses, see Higgins & Green, 2008:

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

Our justification for including NRCTs, given the aim of this review is to be as comprehensive as possible, is that there may be relevant information contained in NRCTs that is not captured in RCTs.

NRCTs must demonstrate pre-treatment group equivalence via matching, statistical controls, or evidence of equivalence on key risk variables and participant characteristics. These factors are outlined in section 3.4.3 under the subheading of *Confounding*, and the methodological appropriateness of the included studies will be assessed according to the risk of bias model outlined in Appendix 3.

3.2.2 Types of participants

The population included in this review will be young people aged 11-21 years who are enrolled in outpatient manual-based FFT drug treatment for non-opioid drug use. Non-opioid drugs are defined as cannabis, amphetamines, ecstasy or cocaine. The misuse of prescription drugs and the use of ketamine, nitrous oxide and inhalants such as glue and petrol will not be considered in this review.

Definitions of young people, and the age at which a person is considered a young person and may be entitled to 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

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

with illegal drugs at different ages in different countries (Hibell et al., 2009). Similarly, patterns of independence from parents and of independent living vary internationally. In order to encapsulate these international differences we have set the age range from 11 to 21 years (Hibell et al., 2009; United Nations, 2011; SAMHSA, 2010; Danish Youth Council, 2011).

We will include only out-patient interventions in order to evaluate the effects of FFT on youths living with their families, since family interactions are fundamental to FFT.

We define the population as young people referred to or in treatment for using non-opioid drugs. No universal international consensus exists on classifying drug users[6], and different assessment tools and ways of classifying the severity of drug use are applied in different research studies (American Psychiatric Association, 2000; World Health Organization (WHO), 2011; Nordegren, 2002). We will include participants regardless of formal drug use diagnosis. The main criterion for inclusion is that the young person is enrolled to participate in the treatment (i.e. intervention or comparison condition). Referral to and enrolment in drug use treatment suggests a level of drug use such that a significant other or authority (or the young person themselves) has found it necessary to seek treatment.

In the literature on youth drug use, it is evident that there are various reasons why young people become enrolled in drug treatment programs, including FFT. One is that there is clear evidence of drug use, either observed or self-reported; another is that the young person is seen as at significant risk of using drugs by nature of his/her environment or peer group. Given this complexity, the fact that an individual may fall into more than one of these groups, and the inherent difficulty in determining accurately the proportion of non-opioid drug users in any sample of young people, we will include studies where at least 50% of participants have either used or are suspected of using drugs, and the rest of the sample are at risk for drug use through having peers that do.

We will include poly drug users only if 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., 2011) and we wish to avoid duplication of effort. Populations who exclusively use alcohol will be excluded.

[6] 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, currently 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).

3.2.3 Types of interventions

The review will include outpatient manual-based FFT interventions of any duration delivered to young people and their families (see 1.2 Description of the intervention). The FFT intervention must be delivered in an outpatient setting and not include overnight stays in a hospital or other treatment facility. The FFT 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, detention centers, institutions for sentence-serving juvenile delinquents or other locked institutions[7] will be excluded.

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

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

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

3.2.4 Types of outcomes

We will consider the following outcomes:

Primary outcome(s)

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

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

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

Secondary outcomes

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

The primary outcome is abstinence or reduction of drug use, as the main review objective is to evaluate current evidence on FFT's effects on drug use reduction for young people in treatment for drug use. We are looking for 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 over 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)

3.3 Search methods for identification of studies

3.3.1 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 Abstracts

Science Citation Abstract

Socindex

PsycINFO

Cochrane library

Bibliotek.dk

Libris

Bibsys

Social Care Online

Eric

Criminal Justice Abstracts

3.3.2 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. FFT.af.
2. Famil* adj1 Functional* adj1 therap*.af.
3. 1-2/or

3.3.3 Searching other resources

The review authors will check reference lists of other relevant reviews and each of the included primary studies for new leads. Citation searching in the Web of Science will also be carried out. We will identify leading international experts who have published in this subject area and contact them individually to identify unpublished and ongoing studies. We will provide the experts with the inclusion criteria for the review along with the list of included studies, asking for any other published, unpublished or ongoing studies relevant for the review.

3.3.4 Hand search

The following 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
- Research on Social Work Practice

Searching will be performed on editions from January 2013 to review submission in an attempt to identify any recently published studies that may not be found in the systematic search.

3.3.5 Grey literature

Additional searches for relevant studies and useful leads will be made using *Google* and *Google Scholar*, where we will be checking 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 the following sites for relevant ongoing or unpublished research projects and useful leads as well as possible dissertations:

- 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/
- Dissertations Express: http://dissexpress.umi.com/dxweb/search.html.
  A public web accessible search facility for dissertations, with limited searching options

3.3.6 Description of methods used in primary research

An example of a study that would be considered eligible for this review is an RCT on the effects of individual cognitive-behavioral therapy (CBT), family therapy (FFT), combined individual and family therapy, and a group intervention for drug-using Hispanic and Anglo American youths aged 13-17, performed in New Mexico, USA (Waldron et al. 2001).

3.4 Data collection and analysis

3.4.1 Selection of studies

Two members of the review team (TLF & LH[8] under the supervision of ML) will independently screen titles and available abstracts to exclude studies that are clearly irrelevant. 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 discussion. 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 1). The overall search and screening process will be illustrated in a flow-diagram.

3.4.2 Data extraction and management

Two review authors (DLS, ML) 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 2). Any disagreements will be resolved by discussion. Data will be extracted on the characteristics of participants (e.g. age, gender, drug use history), characteristics of the intervention and control conditions, research design, sample size, outcomes, and results. Extracted data will be stored electronically. Analysis will be conducted in Excel and RevMan 5.1.

3.4.3 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)[9]. 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.

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[8] Therese Lucia Friis and Louisa Henriksen are members of the review team and will assist the review authors with screening titles and abstracts.

[9] 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).

The extended model is organized and follows the same steps as the existing Risk of Bias model according to the Cochrane Handbook, chapter 8 (Higgins and Green, 2008). The extension to the model is explained in the following three 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[10] 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 3 & 4). 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.

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 nine items (see Appendix 3 for guidelines & Appendix 4 for risk of bias coding sheets).

The nine items refer to:

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

- **sequence generation (**Judged on a low/high risk/unclear scale – QES 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. QES)
- **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 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 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 3 and 4). A judgment of five will be given with caution 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 we find that other confounders are considered by the investigators in the included studies, these will be assessed in the same manner (see appendix 3).

We will focus on three confounders - age, gender and drug use history -as these are the major predictors of drug use. Young people are in a transitional and developmental 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 an important factor because males generally have a higher drug use than females (Østergaard & Andrade, 2011;

McCabe et al., 2007). Finally, history of drug use and persistent patterns of use have been shown to affect treatment outcomes (Labouvie & White, 2002; Kaminer, 2008).

Assessment

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

3.4.4 Measures of treatment effect

Discrete data

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

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 principal investigators. If no information is forthcoming, we will use the methods outlined by Lipsey and Wilson (2001) to derive SDMs from, for example, 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). Examples of continuous outcomes relevant to this review include scales related to drug use, family functioning, or education grade.

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 as, for example, when abstinence and reduction of drug use is measured using both binary and continuous data.

When effect sizes cannot be pooled, study-level effects will be reported in as much detail as possible. RevMan 5.1 and Excel software will be used for statistical analyses.

3.4.5 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, and whether there were multiple treatment groups. We will check for cases where several studies are based on the same data source (multiple publications).

Multiple intervention groups

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

Multiple interventions per individual

Multiple interventions per individual (e.g., FFT 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, 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 these are different. When appropriate analytic methods have been used, we will meta-analyse effect estimates and their standard errors (Higgins & Green, 2008). In cases where study investors have not applied appropriate analytic methods that control for clustering effects, we will estimate the intra-cluster correlation coefficient (Donner, Piaggio, & Villar, et al., 2001) and correct standard errors.

The effective sample size of a single intervention group in a cluster-randomised trial is its original sample size divided by a quantity called the *design effect*. A common design effect is usually assumed across intervention groups. The design effect is 1+(m - 1)r, where m is the average cluster size and r is the *intra cluster correlation coefficient* (ICC). The standard errors of the effect estimates (from an analysis ignoring clustering) should be multiplied by the square root of the design effect. The total variance in the outcome can be partitioned into variance between groups (VBG) and variance within groups (VWG).The intra cluster correlation is calculated as VBG/(VBG+VWG). The ICC is seldom reported in the primary

studies but if enough information is available we will approximate the intra-cluster correlation coefficient (see Donner et al., 2001) and correct standard errors.

3.4.6 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 primary study authors will be contacted and the missing data requested. We will record attrition rates and reasons for attrition from included studies where possible.

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.

3.4.7 Assessment of heterogeneity

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

3.4.8 Assessment of publication bias

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

We will use funnel plots to provide 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.

3.5 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 FFT will involve comparing FFT to no treatment and to untreated wait list controls. The relative effects of FFT (versus other interventions) will be conducted separately and will include studies that compare FFT to other interventions and/or active Treatment-As-Usual (TAU) conditions. All follow-up durations reported in the primary studies will be recorded and we will perform separate analyses for short-term, medium-term and long-term outcomes if possible.

Meta-analysis will be used when effect sizes are available or can be calculated and when studies include similar design features (e.g., randomized studies will be analyzed separately

from non-randomized studies), intervention modalities (e.g., intervention duration), methodology (e.g., time point measurements) and outcome measurements.

As the intervention deals with diverse populations of participants, all analyses of the overall effect will be inverse variance weighted using random effects statistical models that incorporate both the sampling variance and between study variance components into the study level weights. Random effects weighted mean effect sizes will be calculated using 95% confidence intervals and we will provide a graphical display (forest plot) of effect sizes. Heterogeneity among primary outcome studies will be assessed with Chi-squared (Q) test, and the I-squared and τ-squared statistics (Higgins, Thompson, Deeks, & Altman, 2003). Any interpretation of the Chi-squared test will be made cautiously on account of its low statistical power.

When meta-analysis is inappropriate, a narrative description of the individual study results will be provided; in this case, any conclusions about the effectiveness of FFT will be made with caution.

Subgroup analysis, moderator analysis and investigation of heterogeneity

If possible, we will investigate the following study-level covariates 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. These characteristics are gender, age, family composition, ethnicity, co-morbidity, history of drug use (such as prior drug use and longevity of use), and comparison intervention characteristics.

If the number of included studies is sufficient and the spread of the study means of the covariates and study sizes is appropriate (Borenstein, Hedges, Higgins, & Rothstein, 2009; Simmonds & Higgins, 2007), we will perform moderator analyses using meta-regression and a mixed effects model to explore how observed variables are related to heterogeneity. 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.

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 checklist. To check for the possible influence of developer bias on effect sizes, we will run a sensitivity analysis to compare those studies conducted by program developers with 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 the program manual) and requirements for therapist training.

APPENDIX 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 Functional Family Therapy (FFT) intervention? (**The review will include outpatient manual-based FFT interventions of any duration delivered to young people and their families (see 1.2 Description of the intervention).)
   Yes
   No (if no stop here and exclude)
2. **Are the participants in outpatient drug treatment primarily for non-opioid drug use?**
   Yes
   No (if no stop here and exclude)
3. **Are the participants within age 11-21?**
   Yes
   No (if no stop here and exclude)
4. **Is the study a quantitative primary/impact/outcome study**
   Yes
   No (if no stop here and exclude)

The reported reference is excluded if one of the answers to question 1 to 4 are no.
If the answers are yes the full report is retrieved for second level screening. All 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
6. **Is the report a quasi-randomized controlled trial (with a control group that is TAU, alternative intervention, or no intervention)?**
   Yes
   No
7. **Is the report a quasi-experimental study with control group (with a control group that is TAU, alternative intervention, or no intervention)?**
   Yes
   No
8. **Is the study:**
   Included
   Excluded

Uncertain (state reason)

APPENDIX 2 – CODE BOOK FOR DATA EXTRACTION

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

If yes by whom and how many?	
Gender (e.g. % male)	
Age (details on age as presented in the study)	
Race/ ethnicity	
Socioeconomic status	
Family composition	
Other characteristics	
Specify the main drug	
Provide short description of the distribution of drug use	
List/describe history/severity of drug use	
List any comorbid condition	
Report total no. of participants randomized	

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

Control group	
Name the control/comparison condition intervention	
How is the control intervention delivered?	
If Family, Other or Combination, describe the way it is delivered	

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

Baseline time - describe how baseline is defined	
End of treatment (from baseline time) to...	
...1st follow-up	
...2nd follow-up	
...3rd follow-up	
...Other	
Author's main conclusion	
Limitations of the study, as reported by the study authors	
Researcher's affiliation with program (if any)	
Your own concerns and notes	
Question(s) for review authors	

OUTCOMES	
Outcome measurement	
What does it measure?	
Reliability & Validity	
Outcome measurement format (continuous or binary)	
Direction	
Mode	
If other, describe	
Source	

If other, describe	
NOTES	

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

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)	FFT	FFT	FFT	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)	FFT	FFT	FFT	P t F Df ES Covariates Other	
			Comparison	Comparison	Comparison		

*Repeat as need

APPENDIX 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 judgment 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.[11] 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
        - whether most important confounders (from pre-specified list) were considered
        - resolution/precision with which confounders were measured

[11] 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).

    - 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:	☐	☐	☐	☐

APPENDIX 4 - ASSESSMENT OF RISK OF BIAS IN INCLUDED STUDIES: CODING SHEET

RISK OF BIAS FORM – FFT 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 QED – 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 judgment 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 Judgment**	**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 judgment**	**1; 2; 3; 4; 5; unclear**
BLINDING		
Were outcome assessors 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 participants blinded, and if not do the review authors judge that the outcome in question	Outcome 1 Outcome 2	1; 2; 3; 4; 5 Unclear: 1; 2; 3; 4; 5

was unlikely to be influenced by lack of blinding?		Unclear:
Blinding	**Final judgment**	**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 judgment**	**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 judgment**	**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 judgment**	**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**

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SOURCES OF SUPPORT

SFI Campbell

DECLARATIONS OF INTEREST

None

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ROLES AND RESPONSIBLIITIES

Please give brief description of content and methodological expertise within the review team. The recommended optimal review team composition includes at least one person on the review team who has content expertise, at least one person who has methodological expertise and at least one person who has statistical expertise. It is also recommended to have one person with information retrieval expertise.

Who is responsible for the below areas? Please list their names:

- Content: Dorte Laursen Stigaard and Ditte Andersen
- Systematic review methods: Maia Lindstrøm and Trine Filges
- Statistical analysis: Maia Lindstrøm and Trine Filges
- Information retrieval: Anne-Marie Klint Jørgensen

PRELIMINARY TIMEFRAME

Approximate date for submission of the systematic review (please note this should be no longer than 2 years after protocol approval. If the review is not submitted by then, the review area may be opened up for other authors).

20. December 2014

PLANS FOR UPDATING THE REVIEW

Reviews should include in the protocol specifications for how the review, once completed, will be updated. This should include, at a minimum, information on who will be responsible and the frequency with which updates can be expected.

AUTHORS' RESPONSIBILITIES

By completing this form, you accept responsibility for preparing, maintaining and updating the review in accordance with Campbell Collaboration policy. The Campbell Collaboration will provide as much support as possible to assist with the preparation of the review.

A draft review must be submitted to the relevant Coordinating Group within two years of protocol publication. If drafts are not submitted before the agreed deadlines, or if we are unable to contact you for an extended period, the relevant Coordinating Group has the right to de-register the title or transfer the title to alternative authors. The Coordinating Group also has the right to de-register or transfer the title if it does not meet the standards of the Coordinating Group and/or the Campbell Collaboration.

You accept responsibility for maintaining the review in light of new evidence, comments and criticisms, and other developments, and updating the review at least once every five years, or, if requested, transferring responsibility for maintaining the review to others as agreed with the Coordinating Group.

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The support of the Campbell Collaboration and the relevant Coordinating Group in preparing your review is conditional upon your agreement to publish the protocol, finished review and subsequent updates in the Campbell Library. Concurrent publication in other journals is encouraged. However, a Campbell systematic review should be published either before, or at the same time as, its publication in other journals. Authors should not publish Campbell reviews in journals before they are ready for publication in the Campbell Library. Authors should remember to include a statement mentioning the published Campbell review in any non-Campbell publications of the review.

I understand the commitment required to undertake a Campbell review, and agree to publish in the Campbell Library. Signed on behalf of the authors:

Form completed by: Trine Filges

Date: 13 October 2014