Cognitive-Behavioural Therapies for Young People in Outpatient Treatment for Non-Opioid Drug Use PROTOCOL

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Title approval date: 28 April 2010
Protocol approval date: 31 August 2012

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).Drugs such as cannabis, amphetamines, ecstasy, and cocaine, referred to in this review as non-opioids[2] are widely available and used among young people in western countries (European Monitoring Centre for Drugs and Drug Addition [EMCDDA], 2010; Substance Abuse and Mental Health Services Administration [SAMHSA], 2010). Non-opiates such as amphetamines, cocaine, ecstasy and cannabis, characterized by young peopleas social drugs, are often taken in recreational settings such as dance clubs and music events. For young people these non-opiates are often associated with “pleasure” and experimental drug taking (Østergaard & Bastholm Andrade, 2011; Järvinen & Ravn, 2011). However non-opioid drug use, like other drugs,is strongly associated with a range of health and social problems including delinquency, poor scholastic attainment, and suicide (Deas & Thomas, 2001; Essau, 2006; Rowe & Liddle, 2006; Shelton, Taylor, Bonner & van den Bree, 2009).

The 2009 US National Survey on Drug Use estimated that 21.8 million (8.7 percent) people in the US aged 12 or older have used drugs during the past month.The most commonly used drug was marijuana. In 2009, 16.7 million people aged 12 or older (6.6 percent) used this drug. In the same year, 1.6 million people aged 12 or older (0.7 percent) used cocaine, 760,000 (0.3 percent) used ecstasy and 502,000 (0.2 percent) used methamphetamine. The highest rate of drug use in

[1] The terms use, abuse and dependence are used interchangeably throughout the protocol and refer to an addiction stage of non-medical usage.
[2]Use of ketamine, nitrous oxide and inhalants e.g., glue and petrol will not be considered in this review.

the US was found among persons aged 18 to 20. In this age group 22.2 per cent used drugs, while the rate was10 per cent among 12 to 17 year olds (SAMHSA, 2010)[3].

The European Monitoring Report estimated that 19.5 million (30.9 percent)of Europeans aged 15-24 years used cannabis at some point in their life with the highest prevalence in the Czech Republic, France, Denmark and Germany (EMCDDA, 2010). Within the month preceding the survey,5.5 million (8.4 per cent) young people in Europe aged 15-24 years had used cannabis. Synthetic drugs were the second most used drug (EMCDDA, 2010). In 2009 2.5 million (1.7 percent) European 15-34 year-olds used ecstasy, 1.5 million (1.2 percent) used amphetamines, and 3 million (2.3 per cent) used cocaine (EMCDDA, 2010).

Non-opioid substances are associated with varying patterns of behaviour and the potential for addiction (Rawson & Ling, 2008; Weaver & Schnoll, 2008;Kosten, Sofuoglu& Gardner, 2008).While for some young people drug use is controlled and part of developmental experimentation that will not constitute a clinical problem, a proportion of these users will advance to more serious levels of drug usethat at some point in the future requires treatment (Yamaguchi & Kandel, 1984; Shelder & Block, 1990; Labouvie & White, 2002; Järvinen &Ravn, 2011).

Drug use is connected to three aspects: 1) individual characteristics, 2) the interaction between the individual and their environment and 3) certain stimulus gained from the drug use (Nielsen & Thomsen, 2005; Carroll, 2008).

The treatment needs of young people differ from those of adults because of their special stage of psychological and physical development, and therefore researchers advocate distinct interventions for this population (Holmbeck, O'Mahar, Abad, Colder &Updegrove, 2006; Knudsen, 2009). Kendall (2006) argues that it is not enough to encourage young people to gain insight into their drug taking and ask them to consider changes to address their sometimes problematic drug use without providing them with opportunities to practice new coping skills aimed to compensate for cognitive limitations and distortions closely linked to their developmental stage. Other researchers concur with the need for practice-oriented and targeted treatment interventions that are developmentally appropriate for this population (Weisz&

[3] Statistics on drug use are for the main based upon subjective measures such as self-reported survey data and surrogate indices.

Hawley, 2002;Holmbecket.al., 2006, Shirk &Karver, 2006). Cognitive-Behavioural Therapy (CBT) interventions include a variety of such practical elements. As a structured yet flexible, individualized and multi component intervention, CBT is adaptable and tailored to deal with the challenges associated with specific substances and young people's individual needs.

The focus of this review is on young people enrolled in treatment for drug use, independent of how their problems are labelled. Enrolment in treatment denotes that the degree of the young person's drugs use has caused the young person or a significant other close to them (parent, teacher, social worker, etc.,) to require treatment. This review will focus on CBT delivered as an outpatient treatment[4]and to avoid duplication of effort this review will focus primarily on non-opioid drug use[5].

1.2 DESCRIPTION OF THE INTERVENTION

In CBT interventions drug use is perceived as a complex, multi-determined cognitive and behavioural pattern influenced by several domains including family history, environmental genetic factors, and comorbid psychopathologies that all play a contributing role in the development of and/or perpetuation of drug use (Carroll, 2008). The primary focus of CBT is on reducing users' positive expectations about druguse, enhancing their self-confidence to resist drugs, and improving their problem solving skills and skills for coping with daily life stressors (Moos, 2007; Kaminer, Burleson, Blitz, Sussman, & Rounsaville, 1998).

CBT aims to address the learned association between drug-related cues or stimuli and drug use by understanding and changing undesirable cognitive and behaviour patterns (Carroll, 2008; Shirk & Karver, 2006).CBT combines behavioural and cognitive therapy. While *behavioural therapy* mainly focuses on external settings and observable behaviour, *cognitive therapy* is concerned with internal cognitive processes.

[4] A Cochrane review in progress will evaluate CBT for substance abuse in young offenders (Campbell et. al., 2010).
[5] A Cochrane review evaluated psychosocial treatments for opiate abuse and dependence (Mayet et. al., 2010), another will evaluate psychosocial treatments for drug and alcohol abusing adolescents (Minozzi, Amato, Vecchi& Davoli, 2011), and another psychosocial interventions for benzodiazepine harmful use, abuse or dependence (Darker, Sweeney, Barry, Farrell, 2012).

Behavioural therapy

Behavioural therapy was developed from the ideas of classical and operant conditioning (Poulsen, 2006, McGuire, 2000). In classical conditioning, behaviour is believed to be affected by stimulus-response mechanisms in the immediate surroundings of the individual; for instance,urges and cravings for drugs can be perceived as responses to external stimuli cues (Sherman, Jorenby & Baker, 1988). Identifying external stimuli cues would enable the individual to avoid settings that work as triggers to drug taking (Carroll, 2008). Operant conditioning is based on associations within a context of events (e.g.,an antecedent stimulus) and a given behaviour and its consequences, whereby perceived rewards can (negatively or positively) reinforce such behaviour (Skinner, 1988). For example, negative reinforcement is when peers do not condone drug use and positive reinforcementis for example when the psychological effect of a drug is experienced as pleasurable (Waldron & Kaminer, 2004). In a treatment context non-drug using behaviour is rewarded and thus reinforced.

Cognitive therapy

The assumption in cognitive therapy is that thoughts shape feelings and thereby, behaviour, so that it is hypothesized that by changing thought patterns, behaviour can be changed as well (Beck, Wright, Newman, & Liese 1993; Kendal l 2006; Nielsen & Thomsen, 2005). In the early 1960s cognitive therapy was aimed at treating depression, and has since been extensively modified and adapted to deal with a wide range of clinical problems and populations including people with drug use issues (Beck, 2008; Holmbeck et al., 2006;Weisz& Hawley, 2002).

Cognitive and behavioural therapy

The foundation and premise of CBT for drug use is that cognitive techniques and skills training can tackle drug-related beliefs and automatic thoughts that lead to urges and craving, while additional behavioural techniques can deal with actions that interact with the individual's cognitive processes that trigger and maintain drug using behaviour (Beck et al., 1993).Irrational and erroneous assumptions can cause and/or maintain undesirable behaviour (ibid.). CBT callsspecific attention to the propensity among substance users to mistakenly believe that the perceived advantages of using drugs (e.g., pleasure, anxiety relief) are greater than the disadvantages (e.g., financial, interpersonal) as such misconceptions help sustain the avoidance of a realistic assessment of the disadvantages (ibid.; Carroll, 2008; Nielsen & Thomsen, 2005). Thus, it is believed that the users' assessment of the possibilities for ceasing to use drugs might

be based on cognitive distortions. In CBT, clients are helped to identify and challenge dysfunctional beliefs (such as 'I cannot be happy unless I am using' or 'the withdrawal will be too painful'), because thinking that one is incapable of controlling the urge to use drugs will create a self-fulfilling prophecy, as users who believe they are incapable will not even try (Beck et al., 1993).

The common denominator in all CBT interventions is to make and support continuous positive change in the client's feelings and behaviour by examining and reframing the basic maladaptive assumptions and thoughts underlying drug use (Beck, 2008; Carroll, 2008, Moos, 2007; McGuire, 2000).

CBT outlines a pattern and series of phases of drug use from the first stimulating cue to the actual act of drug using that is specific to the client. The activating stimulus can be both external (e.g., a gathering of friends using cocaine) or internal (e.g., anxiety or boredom) (Beck et.al., 1993; Beck, 2008; McGuire, 2000; Nielsen & Thomsen, 2005; Carroll, 2008). These stimuli can trigger basic assumptions (e.g., 'I am socially isolated') that trigger automatic thoughts (e.g. 'A little cocaine will make me feel better'), which in turn trigger cravings and permissive beliefs that make it easier for the person to engage in the behaviour (e.g., 'It is okay as long as I don't inject'). The individual would then form a mental strategy for obtaining the drugs and the actual drug using act could then take place. CBT would tackle this pattern of drug use by enlisting a number of techniques and strategies.Through problem solving, coping strategies, rehearsal, social skills and communication training, as well as helping young people to respond to criticism and refusing drugs, the therapist can help the young person to identify stimulating cues, discuss how to cope, and avoid drug taking behaviour. However, some stimulating cues (e.g., emotional states) may be unavoidable and consequently modifying maladaptive beliefs and automatic thought patterns that maintain drug using behaviour would be equally important (Beck et al., 1993; Beck, 2008; McGuire, 2000)

CBT components and therapy sessions

CBT interventions couldincludepermutations of various components such as thought diaries, social skills training, problem solving strategies, coping strategies, self-control and stress management techniques, and relapse prevention training. CBT has different modalities and can be implemented in an individual and/or group setting (Moos, 2007).

CBT is a highly structured intervention and is organised closely around well-specified and individualized treatment goals (Carroll, 2008). Each CBT session is structured by an articulated agenda and discussions remain focused around issues directly related to substance use. In some cases, the therapist may lead thetherapy session with 'motivational interviews'[6] (Carroll, 2008; Nielsen & Thomsen, 2005).

Typical Therapy Sessions

To exemplify:a therapy session typically (but not invariably)includes the following three parts: First, aclient's substance use and general functioning would be assessed (and would vary according to degree of dependency and individual conditions). A specific cognitive technique that can help identify and modify drug-related beliefs is an'advantages-disadvantages' analysis (Beck et al.,1993). In this analysis, the therapist guides the client through the process of listing and re-evaluating the advantages and disadvantages of drug use to help the young person gain a more accurate, objective and balanced view of drug use.

The second part of the therapy session is typically didactic in structure and devoted to skills training, coping and problem-solving strategies and practice. One technique for examining beliefs and considering their validity in a more systematic way is 'The Daily Thought Record'. Clients are asked to record their thoughts and feelings and then re-evaluate their validity, identify possible patterns of cognitive distortions and develop strategies for change (Beck et al., 1993, Nielsen & Thomsen, 2005; Carroll, 2008). The therapist may also encourage the client to try new behaviours through role playing, for the purpose of teaching the client new effective interpersonal skills, e.g., how to handle interpersonal conflicts without drug taking and develop effective repertoires of social behaviour to reduce undesirable drug use and deal with relapse if it occurs (Beck et al., 1993; Kaminer & Waldron, 2006).

Finally, the third part of the therapy session is usually dedicated to plan for the week ahead and discuss how new skills and strategies could be implemented (Carroll, 2008). This kind of collaborative empiricism that characterises CBT is particularly important when dealing with young substance users, to assist them in learning self-regulation and to exert self-control. However this kind of collaboration may also be a point of concern for the intervention's

[6] Motivational interviewing (MI) is sometimes referred to as an independent treatment form but can also function as an element of other treatment forms including CBT. CBT interventions can use MI as a means to motivate clients for change. The aim of MI is to activate and capitalize on the client's motivation and commitment to change and MI seeks to help clients to resolve their ambivalence about change (Moos, 2007, Miller &Rollnick, 2002).

effectiveness, as participation in CBT demands a certain (above average) level of verbal articulation and self-awareness (Nielsen & Thomsen, 2005).

CBT interventions can range from 5 to 24 weeks in duration and delivery settings can vary from outpatientto community facilities, and can be delivered to individuals, groups, families and a combination of these (Dennis et al., 2004; Carroll, 2008). Purely behavioural (e.g., a stand-alone contingency intervention) will not be considered in this review.

1.3 HOW THE INTERVENTION MIGHT WORK

Existing research

Along with a handful of other interventions, CBT is one of the most researched treatment forms (Becker & Curry, 2008; Carroll, 2008).CBT has shown promising potential for young drug users in the number of primary studies (Kaminer et. al., 1998; Kaminer & Burleson, 1999;Waldron, Slesnick, Brody, Peterson, & Turner, 2001; Kaminer,Burleson & Goldberger 2002; Dennis et al., 2004; Azrin, Donohue, Teichner, Crum, Howell & DeCato 2001; Liddle et al., 2001; Liddle, Dakof, Turner, Henderson & Greenbaum, 2008; Latimer, Winters, D'Zurilla & Nichols, 2003).

Several reviews (that for the most lack pre-published protocols)[7] on CBT interventions targeting young drug users already exist (Waldron & Kaminer, 2004; Vaughn & Howard, 2004; Becker & Curry 2008; Waldron & Turner 2008; Lipsey, Tanner-Smith, & Wilson, 2010). However, with only one exception (Waldron & Kaminer, 2004), all of the abovefocus broadly on psychosocial therapies in general, rather than CBT specifically. Generally, the most recent reviews conclude that CBT is associated with reduced drug use in young people (Waldron & Kaminer, 2004;Waldron & Turner, 2008; Lipsey, Tanner-Smith, & Wilson et al., 2010).

The findings of the aforementioned studies and reviews indicate that CBT can reduce drug use in young people in treatment. However,closer interpretation of findings reveals a complex

[7]Although, two Cochrane reviews have evaluated psychosocial/psychotherapeutic interventions for substance users, these reviews have focused on treatments for adult cannabis users (Denis et al., 2006) and adultsubstance users with severe mental illness(Cleary et al., 2008) respectively. Moreover, the Cochrane reviews focus broadly on psychosocial/psychotherapeutic interventions for adults and not on CBT as a specific intervention for young people. In contrast, in our review we are only interested in CBT interventions that specifically target treating young people for non-opioid drug use.

picture that is far from clear cut. CBTs reduction in drug use is relative to the comparison interventions used in the individual studies (Lipsey, Tanner-Smith, & Wilson, 2010) and dependent on the types of CBT interventions and modalities used in the studies.

CBT Mechanisms

Lack of research on mechanisms of change specifically underpinning CBT (Waldron & Kaminer, 2004)makeany identification of key mechanisms speculative. Nevertheless, problem solving and coping strategy skills may be a key to change.Myers and Brown (1990) found that young drug abstainers and minor relapsers had higher levels of these skills than major relapsers and non-abstainers. The particular focus of CBT for substance abuse on problem solving, coping strategies, communication and social skills may support younger people positively in abstaining and dealing with possible relapse.

Moderators

Whether certain population characteristics moderate CBT outcomes for non-opiates remains largely unknown (Morgenstern & McKay, 2007). In a study including 13 to 18 year olds Kaminer, Burleson and Goldberger (1998) found that only older males in the CBT group had a significant reduction in drug use in comparison to the psychoeducational therapy group. This could indicate that CBT is more appropriate forthe older males in the study (i.e., 16 to 18 year olds). Alternatively, the group delivery aspect may provide an additional explanation. Study findings suggest that group CBT has a greater effect in reducing drug use than individual CBT (Waldron, Slesnick, Brody, Peterson & Turner, 2011;Liddle, Rowe, Dakof, Ungaro, & Henderson, 2004). The group aspect may be a more conducive and realistic setting for practicing new skills and strategies with peers in the same situation. The group environment may also contribute to the support and promotion of cognitive and behavioural change among participants (Waldron & Kaminer, 2004).

Finally, the clients' motivation also plays an important role, as the more motivated the client is to change, the better the engagement, attendance and outcome of the therapy should be (Waldron & Turner, 2008), although this finding seems to apply to all drug treatment therapies. The duration of therapy may also moderate treatment outcomes and several studies found that shorter CBT interventions were more than, or just as effective as longer durations (Dennis et al., 2004; Kaminer, 2008).

1.4 WHY IT IS IMPORTANT TO DO THIS REVIEW

Drug use among young people is strongly associated with delinquency, poor scholastic attainment, mental and physical health problems, suicide and other individual or public calamities (Lynskey & Hall, 2000; Tims et al., 2002; Essau, 2006; Rowe & Liddle, 2006; Knudsen, 2009). Yet research has documented a significant gap between young people in need of treatment and young people actually receiving treatment[8]. McLellan (2006) linked this *treatment gap* to a public concern regarding the effectiveness of the available treatments for young people and suggests that the public feeling is that *nothing works* for substance use among young people. There is a need for identifying effective interventions for young drug users to inform treatment policy and practitioners' decisions. Current evidence suggests that CBT for the treatment of young people's drug use is a promising intervention. Research also points to the need for more solid and specific knowledge on what moderates CBT treatment effects, and for whom (Moos, 2007; Kaminer & Waldron 2006; Kaminer 2008; Waldron & Turner, 2008). A protocol-led systematic review on CBT for non-opioid druguse in young people has the potential to provide this knowledge and inform policy and practice.

[8]For example 8.4 percent of 18 to 25 year olds in the US are classified as needing drug use treatment (based on the criteria specified in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorder, version DSM-IV), but less than one tenth of these young people actually receive treatment (NSDUH, 2009). Likewise among youth aged 12 to 17, 4.5 per cent were estimated to be in need of treatment for an drug use problem, but only one tenth in this group actually received any (SAMSHA, 2008).

2 Objective of the review

The objective of this review is to assess the effectiveness of CBT for young people (aged 13-21) in outpatient treatment for non-opioid drug use and to explore factors that may moderate positive outcomes.

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:

- 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 trials (i.e., participants are allocated by other actions controlled by the researcher)

The rationale for including NRCTs is as follows:
The aim of this review is to be as comprehensive as possible. There may be information that is contained in NRCTs that may be of relevance to this review that are not captured in RCTs.

3.1.2 Types of participants

The population to be included in this reviewis young people aged 13-21years, enrolled in a CBT outpatient 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 13 to 21 (Hibell et al., 2009; United National, 2011; SAMHAS 2010; Danish Youth Council, 2011).A study with age groups well beyond the 13 to 21 age threshold, for example a study with 13 to 65 year olds will only be included if they report findings by age group for the intervention and control group.

No universal international consensus exists concerning what categories to use when classifying drug users, and different assessment tools and ways of classifying the severity of drug use are applied in different research studies (American Psychiatric Association, 2000; WHO, 2011; Nordegren, 2002). We include participants regardless of formal drug use diagnosis. The main criterion for inclusion is that the young person is enrolled in treatment for drug use (i.e., intervention or comparison condition). Referral to and enrolment in treatment requires a level of drug use, such that the young person, his/her parent or significant other, or a representative of a statutory authority found it necessary to solicit or require treatment. We therefore define the population as young peoplereferred to or in treatment for using non-opioiddrugs.

The focus of this review is on non-opioid use to avoid duplication of effect, as psychosocial interventions for the treatment of youth opioid use have been evaluated in Cochrane reviews (Amato et al., 2011; Minozzi et al., 2010).We will include participants with poly-drug use as long as the majority of drug users in the study are non-opioid users. Study populations with severe mental illnesses (e.g., schizophrenia, psychoticillness) will be excluded.We expect that some study populations may include young people with 'common' non-severe comorbid conditions (e.g.,behavioral, emotional, mental health issues)(Hawkins, 2009). These studies will not be excluded as long as the CBT intervention's focus is on treating drug use[9]. A study will be excluded if the primary intervention focus is to treat the comorbid condition (e.g., depression) in young people who also use drugs.

3.1.3 Types of interventions

The review will include outpatient CBT interventions(as defined in section 1.2,*Description of the intervention*) of any duration delivered to young people individually or in groups (e.g., peers or

[9] Any such conditions will be reported and taken into account in the reviews analysis, results and conclusions.

families), described by the authors as CBT or judged by the review authors to represent CBT. We will only include studies with CBT interventions specifically directed at treating '*young people*' for non-opioid drug use.

The intervention must be an outpatient intervention that does not include overnight stays in a hospital or other treatment facility. The CBT intervention can take place in the home, at community centres, in a therapist's office or at outpatient facilities, and can be delivered to individuals, groups, families and a combination of these

CBT interventions conducted by non-professionals (e.g., lay volunteers) will be excluded. Interventions in restrictive environments, such as prisons or other locked institutions (e.g., detention centres. institutions for sentence-serving juvenile delinquents) will be excluded. Interventions focusing exclusively on treating mental disorders will also be excluded

Studies where CBT is delivered in combination with add-on components (such as motivationalinterviewing) will be included as long as CBT is the primary intervention.

Eligible control and comparisons will include no intervention, waitlist controls and alternative interventions, as we are interested in both absolute and relative effects. Due to ethical considerations and nature of the problem (i.e., young peoples' drug use) the likelihood of a no-treatment control group is small. We expect that the most frequent comparison will be alternative interventions (Lipsey, Tanner-Smith, & Wilson, 2010). Alternative interventions as the comparison will complicate synthesis possibilities and analyses. We will pay careful attention to the types of comparison as is reflected in the Data Synthesis section (3.4).

3.1.4 Types of outcomes

Primary outcome

- Abstinence or reduction of drug use as measured by:
    - Biochemically test (e.g., urine screen measures for drug use);
    - Self-reported estimates on drug use (e.g., Time-line Follow Back interview) (Fals-Stewart, O'Farrell, Freitas, McFarlin & Rutigliano, 2000); and

- Psychometric scales (e.g., Addiction Severity Index) (McLellan, Luborsky, Woody & O'Brien, 1980).

Secondary outcomes

- Social functioning and 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 behaviour such as crime rates, prostitution (e.g., measured by self-reports or reported by authorities, administrative files, registers)
- Other adverse effects (e.g., measured by rates of suicide and over-doses)

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 the following bibliographic databases and government policy databanks. No language or date restrictions will be applied to the searches.

MEDLINE
EMBASE
CINAHL
Web of Science
SocIndex
PsycINFO
Cochrane Controlled Trial Register (CENTRAL)
Bibliotek.dk

LIBRIS
BIBSYS
Social Care Online
ERIC
SweMed+
Criminal Justice Abstracts
Bibliography of Nordic Criminology (up to summer 2008)

3.2.2 Search terms

An example of the search strategy for MEDLINE on the OVID platform is listed below. The strategy will be modified for the different databases. We will report full details of the modifications used for other databases in the completed review.

1	Behavior Therapy/
2	Cognitive Therapy/
3	(cognitive adj3 (therap* or train* or techni* or modif* or factor* or question* or approach* or experiment* or assess*)).ab,kw,sh,ti.
4	cbt.ab,kw,sh,ti.
5	((psycholog* or social or cognitive) adj1 (skill* adj1 train*)).ab,kw,sh,ti.
6	(behavio?r* adj3 (therap* or train* or techni* or modif* or factor* or question* or approach* or experiment* or assess*)).ab,kw,sh,ti.
7	((cognitive* or mental*) adj3 (map* or model*)).ab,kw,sh,ti.
8	(cognitive behavio?r* adj1 (factor* or therap*)).ab,kw,sh,ti.
9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10	Adolescent/
11	(Adolescen* or youth* or teen* or young* or juvenile*).ab,kw,sh,ti.
12	10 or 11
13	(misuse or abuse* or use or addict* or depend#n$).ab,kw,sh,ti.
14	(drug* or substance*or polydrug*).ab,kw,sh,ti.
15	14 and 15
16	Marijuana Smoking/

17 amphetamine-related disorders/ or cocaine-related disorders/ or marijuana abuse/
18 Narcotic*.ab,kw,sh,ti.
19 Stimulan*.ab,kw,sh,ti.
20 (Cannabis or Marijuana or Hashish).ab,kw,sh,ti.
21 exp Cannabinoids/ or Cannabis/
22 blunts.ab,kw,sh,ti.
23 Designer Drugs/
24 (Designerdrug* or (designer adj1 drug*)).ab,kw,sh,ti.
25 Streetdrug*.ab,kw,sh,ti.
26 N-Methyl-3,4-methylenedioxyamphetamine/
27 Ecstasy.ab,kw,sh,ti.
28 Amphetamine/
29 Methamphetamine/
39 Fantasy.ab,kw,sh,ti.
31 (Methamphetamin* or Amphetamin*).ab,kw,sh,ti.
32 ice.ab,kw,sh,ti.
33 Flatliner*.ab,kw,sh,ti.
34 exp cocaine/
35 (Cocaine or crack).ab,kw,sh,ti.
36 (free adj1 base).ab,kw,sh,ti.
37 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36
38 15 or 37
39 9 and 12 and 38
40 limit 39 to humans

3.2.3 Searching other resources

The review authors will check the reference lists of other relevant reviews and included primary studies to identify new leads. Citation searching in the Web of Science will also be considered. In addition, we will contact international experts to identify unpublished and on-going studies.

3.2.4 Grey literature

We will use Google and Google Scholar search engines and the advanced search options to search the web to identify potential unpublished and/or studies in progress. We will check the first 150 hits.OpenSIGLE(http://opensigle.inist.fr/) and OpenGrey (http://www.opengrey.eu/) will also be used to search for European grey literature. Sites such as NCJRS: National Criminal Justice Reference Service will be searched. Copies of relevant documents will be storedand we will record the exact URL and date of access.

In addition we will search the following websites:
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/

3.2.5 Hand searching journals

The following journals that we consider most likely to include relevant primary studies will also be hand searched from 2012:

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

3.3 DATA COLLECTION AND ANALYSIS

3.3.1 Selection of studies

Two members of the review team (AK & SF[10]) will independently screen titles and abstracts in order to exclude studies that are clearly irrelevant under the supervision of the first author (KK). Studies considered eligible by at least one of the review authors will be retrieved in full text. The

[10] Simon Filges (SF) is a member of the review team who will assist the review authors with screening titles and abstracts.

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

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

3.3.2 Data extraction and management

Two review authors (KK & AK) 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 6.2). 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, drug use severity and history), 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-Randomised Studies Methods Group (Reeves, Deeks, Higgins & Wells, 2011).[11] This model, an unpublished extension of the existing Cochrane Collaboration's risk of bias tool (Higgins & Green, 2008), covers risk of bias in RCTs, quasi-randomised trials and non-randomised studies that have a well-defined control group. The extended model is organised and follows the same steps as the existing Risk of Bias model according to the Cochrane Hand book, chapter 8 (Higgins and Green, 2008). The extension to the model is explained thus:

1) The existing Cochrane risk of bias tool needs elaboration when assessing non-randomised studies because, for non-randomised studies, particular attention must be paid to selection bias / risk of confounding. The extended model therefore specifically incorporates a formalised and

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

structured approach for the assessment of selection bias in non-randomised studies[12] 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 12.3 Appendix 3, p. 50). This assessment will inform the final risk of bias score for confounding.

2) Another feature of non-randomised 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-randomised 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-randomised studies) with a very high risk of bias. The refinement increases transparency in assessment judgments and provides justification for not including a study with a very high risk of bias in the meta-analysis.

Risk of bias judgment items and assessment

The risk of bias model used in this review is based on 9 items (for guidelines and coding sheets see Appendices 3 and 4).

The 9 items refer to

- **sequence generation** (Judged on a low/high risk/unclear scale – NRCTs will automatically have high risk of bias)

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

- **allocation concealment** (Judged on a low/high risk/unclear scale)
- **confounders** (Judged on a 5 point scale/unclear, only relevant for non-randomised studies i.e., NRCTs)
- **blinding** (Judged on a 5 point scale/unclear)
- **incomplete outcome data** (Judged on a 5 point scale/unclear)
- **selective outcome reporting** (Judged on a 5 point scale/unclear)
- **other potential threats to validity** (Judged on a 5 point scale/unclear)
- ***a priori*** **protocol** (Judged on a yes/no/unclear scale)
- ***a priori*** **analysis plan** (Judged on a yes/no/unclear scale)

The assessment will be based on pre-specified questions (see Appendix 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 judgment of five on any item assessedtranslates 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).

Confounding

An important part of the risk of bias assessment of non-randomised studies is how the studies deal with confounding factors.Selection bias is understood as systematic baseline differences between interventionvs.control (or comparison) groups that can compromise their comparability.We will code baseline equivalence of groups for the NRCTs.

For this review, the following confounding factors are considered to be the most relevant: age, gender, and drug history (including drug severity).If other confounders are considered by study investigators in the included studies they will be assessed in the same manner (Appendix 4).

We focus on the three confounders - age, gender and drug use history -as they are 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 a confounding factor, becausemales generally have higher drug use than females (Østergaard & Bastholm Andrade, 2011; McCabe et al., 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, AK & KK) will independently assess the risk of bias for each included study as described in the previous sections. Disagreements will be solved by a third review author with content and statistical expertise (TF). We will report the risk of bias assessments in risk of bias tables for each included study in the completed review. These assessments will also informthe data synthesis.

3.3.4 Measures of treatment effect

Discrete data

For dichotomous outcomes we will calculate odds ratios with 95% confidence intervals and p-valuesfor the meta-analysis(see Higgins, 2008; Deeks, 2002). When reporting results we will transform odd ratios (OR) to a more intuitive and substantively interpretable statistic.

Continuous data

For continuous outcomes, effects sizes will be calculated if means and standard deviations are available. If this information is notreported in the studies 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. If this is not possible, the review authors will requestmeans and standard deviationsfrom the principle investigators. 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).

There are statistical approaches available to re-express dichotomous and continuous data to be pooled together (Sánchez-Meca, Marín-Martínes & Chacón-Moscoso, 2003). We will only transform dichotomous effect sizes to SMD if appropriate e.g., as may be the case with the

primary outcomes 'abstinence and reduction' of drug use that can be measured with binary and continuous data.

When effect sizes cannot be pooled, study-level effects will be reported in as much detail as possible. Software for statistical analyses will include RevMan 5.1 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 randomised in groups (i.e., cluster randomised trials), whether individuals may have undergone multiple interventions, and whether there were multiple treatment groups.

Multiple intervention groups
Multiple intervention groups (with different individuals) within a study with one control group will not be pooled, nor will multiple controls be pooled. Data will be rigorously checked to avoid overlapping samples in the meta-analysis's (See 3.4 Data Synthesis).

Multiple interventions per individual
Multiple interventions per individual e.g. CBT plus an add-on component such as motivational 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 pooled and analysed 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).

Cluster randomised trials
If cluster randomised trails 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-analysed (Higgins & Green, 2008). In cases where study investigators 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 review authors 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.
Information on intention to treat analysis (ITT) will be recorded. We will run separate meta-analyses with studies that did not use ITT. We will perform sensitivity analysis to examine influences on effectsin 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, tau-squared and I-squared (Higgins et al., 2003). A significant Q or tau-squared ($P<.05$)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 and report possible reasons for this.

3.4 DATA SYNTHESIS

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

Meta-analysis will be used when effect sizes are available or can be calculatedand when studies include similar design features (RCTs vs. Non-RCTS), intervention modalities (e.g., individual or group CBT and duration), methodology (e.g., intervention duration, measurement, time points etc.) and outcome measurements.

Thus, when interventions, control groups, and outcomes are sufficiently similar, pooled effects will be calculated. 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 CBT will not be possible.

3.4.1 Subgroup analysis/moderator 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), 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. Otherwise, single factor subgroup analysis will be performed.

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.

Time frame

The review will be submitted within six months from the protocol approval date.

4 Acknowledgements

The review team wishes to thank Ditte Andersen wrote the first draft protocol; Mette Deding, Madina Saidj and Maia Lindstrøm for their useful comments on protocol drafts, and Grace and Leonard for their faithful support.

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6 Appendices

6.1 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 report about a CBT intervention?**
   Yes
   No (if no stop here and exclude)
   Uncertain

2. **Are the participants 13 to 21 years of age?**
   Yes
   No (if no stop here and exclude)
   Uncertain

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

The report reference is excluded if one of the answers to question 1 to 3 are no.
If the answers are yes or uncertain the full report is retrieved for second level screening.
All uncertain questions for 1-3 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, questions 4 - 7

4. **Is the report a ?**
   Primary study (that is a CBT outcome evaluation)
   Review
   Descriptive or case study
   Theoretical or position paper editorial or book review
   Treatment manual or guidelines for practice
   Other

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

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

7. **Is the study?**
   Included
   Excluded
   Uncertain (state reason)

6.2 APPENDIX 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. **Who performed group assignment**?

   Research staff

   Clinical staff

   Can’t tell

   Other (specify)

4. **How was random assignment performed?**

   Computer generated

   Random numbers table

   Coins or dice

   Other (describe)

   Can't tell

5. **How many separate sites were included in the study?**

   One

   Two

   Three

Specify number

6. **Was random assignment performed in the same way in all sites**

   Yes

   No (explain)

   Can't tell

7. **How many intervention groups were there? (CBT counts as one)**

   One (CBT)

   Two (CBT plus what?)

   Three (CBT plus what?)

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

   One (CBT)

   More than one (explain)

9. **How many *different* control/comparison groups were there? (i.e., groups that received different treatments, not counting multiple sites)**

   One

   Two or more (explain)

10. **How many control/comparison groups are relevant for this review?**

    One

    More than one (explain)

11. **Study sample size**

N's	CBT1*	COMPARISON1*	TOTAL	Pg. # & NOTES
Referred to study				
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)				

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

Participant/sample Characteristics:

12. Was participant inclusion criteria mentioned?

No

Yes (describe & cite pg#)

13. Was participant exclusion criteria mentioned?

No

Yes (describe & cite pg#)

14. Participant Characteristics

	CBT*	CONTROL*	TOTAL	Pg. # & NOTES
Gender (e.g. % male)				
Youth Ages				
Race/ethnicity				
Socioeconomic status				
Profession				
Family composition				
Other characteristics				

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

15. Specify and describe type of drug use

Cannabis

Cocaine

Amphetamine

Combination (specify, pg. #)

Other (specify, pg. #)

16. Were there any differences between intervention and comparison groups at baseline (For NRCT only)?

No

Yes (describe differences & cite pg#)

Unclear

17. Was there any analysis of differences between completers and dropouts in the intervention group and/or comparison group?

No

Yes (describe differences & cite pg#)

Unclear

18. Was there any analysis of differences between completers and dropouts in the intervention group and/or comparison group?

No

Yes (pg. # & describe)

Unclear

19. Was intention to treat analysis used?

No

Yes (pg. # & describe)

If yes is this a true ITT analysis

Unclear

Settings

20. Location of interventions (check all that apply)

Urban

Suburban

Rural

Can't tell

21. Location details (city, state, country)

Primary service sector

Mental Health

Child Welfare

Other (specify)

21. A Referred by?

School

Social worker

Juvenile justice system

Family

Other (specify)

22. CBT Characteristics

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

23. Was the CBT?

Group based

Individual

Combination

24. Other characteristics of CBT

25. Characteristics of treatment staff (education, demographics, etc.)

26. Describe methods used to insure quality of CBT (supervision, training, consultation)

27. Is there any information on adherence (fidelity) to CBT?

Yes (describe)

No

Not sure

28. If multiple sites, were there any implementation differences between sites?

Yes (describe differences)

No (how do we know?)

Can't tell

Services provided to control cases

29. Type of control group

Usual services (treatment as usual)

Alternative service (describe)

No service

30. Describe services provided to control group

31. Characteristics of staff that provided services to control/comparison groups (education, demographics, etc.)

Outcome measures

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

Baseline

Post-tx

1st follow-up (when?)

2nd follow-up (when?)

3rd follow-up (when?)

4th follow-up (when?)

5th follow-up (when?)

Other

33. Who conducted interviews?

Research staff

Clinical staff

Both

No interviews

34. Were data collected in the same manner for CBT and control groups?

Yes

No (what were the differences?)

Can't tell

35. Analysis

Describe how the authors deal with ITT?

Did they use ITT and if yes was the approach used adequate (i.e., was it a true ITT) (specify) ?

Yes

No

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	Youth Parent Teacher 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	N W/ EVENT	% WITH EVENT	STATISTICS	Pg. # & NOTES
	•1st measure after baseline •1st follow-up • 2nd follow-up • 3rd follow-up •4th follow-up • other	• youth • parent • teacher • clinician • admin data • other (specify)	CBT Comparison	CBT Comparison	CBT Comparison	Risk ratio OR (odd ratio) 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	• youth • parent • teacher • clinician •admin data • other (specify)	CBT	CBT	CBT	P t F Df ES Covariates Other	
			Comparison	Comparison	Comparison		

6.3 APPENDIX 3: ASSESSMENT OF RISK OF BIAS FOR INCLUDED STUDIES GUIDELINES

Risk of bias table

Item	**Judgement**[a]	**Description** (quote from paper, or describekey information)
1. Sequence generation		Automatically high for NRCT
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.[13] 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 lowRoB 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

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

    - whether most important confounders (from pre-specified list) were considered
    - resolution/precision with which confounders were measured
    - extent of imbalance between groups at baseline
    - care with which adjustment was done (typically a judgment about the statistical modeling carried out by authors)
- Low RoB requires that all important confounders are balanced at baseline (not primarily/not only a statistical judgment OR measured 'well' and 'carefully' controlled for in the analysis.

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

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

5. RoB from incomplete outcome data (assess for each outcome, as per existing RoB tool)
- Low(1) / 2 / 3 / 4 / high(5) / unclear RoB item
- Judgment needs to factor in:
    - reasons for missing data
    - whether amount of missing data balanced across groups, with similar reasons
    - see Ch.8

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

Confounding Worksheet

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

Confounders described by researchers

Tick (yes[0]/no[1] judgment) if confounder considered by the researchers [Cons'd?]

Score (1[good precision] to 5[poor precision]) precision with which confounder measured

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

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

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

6.4 APPENDIX 4: ASSESSMENT OF RISK OF BIAS FOR INCLUDED STUDIES

RISK OF BIAS FORM – 6549 CBT 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 NRS – 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:
Notes *(e.g. queries to the author)*	

RISK OF BIAS		
SEQUENCE GENERATION - SELECTION BIAS		
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*	Yes: No:

	cannot foresee assignment. *(NRS always No - NRCT can be concealed adequate)*	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		
FOR NRCTs Describe baseline differences (if any):	Were baselines for intervention and comparison groups reported and checked?	Yes: No: Unclear:
FOR NRCTs Describe how the authors controlled for baseline differences:	If baseline differences that are likely to affect outcomes, were they adequately controlled for? *E.g. any adjustment methods.*	Yes: No: Unclear:
Confounding – use the confounder sheet in the appendix. Report if it is not possible to distinguish between outcomes	Did the authors describe the method for identifying relevant confounders? Outcome 1 Outcome 2	Yes: No: Unclear: 1; 2; 3; 4; 5 Unclear 1; 2; 3; 4; 5 Unclear
Confounding	**Final judgment**	**1; 2; 3; 4; 5 Unclear**
BLINDING - DETECTION BIAS		

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 judgment**	**1; 2; 3; 4; 5 Unclear**
INCOMPLETE OUTCOME DATA - ATTRITION BIAS		
	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:
SELECTIVE OUTCOME REPORTING - REPORTING BIAS		

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 sourced od bias in the study:	Is the study free from and/or have the study authors adequately dealt with other sources of bias?	
Other threats		
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**

APPENDIX A

CONFOUNDING, OUTCOME 1					
No.	**Confounder**	**Considered**	**Precision**	**Imbalance**	**Adjustment**
1	Age				
2	Gender				
3	History of drug use				
4	Other				

5	Other				
6	Other				

CONFOUNDING, OUTCOME 2					
No.	**Confounder**	**Considered**	**Precision**	**Imbalance**	**Adjustment**
1	Age				
2	Gender				
3	History of drug use				
4	Other				
5	Other				
6	Other				

GUIDE

Enter pre-specified list of confounders.

- Considered - is the confounder considered by the researchers? *Yes, No*
- Precision - the precision with which confounder is measured. *1, 2, 3, 4, 5 where 1=good precision, 5=poor precision*
- Imbalance - between groups. *1, 2, 3, 4, 5 where 1=balanced, 5=major imbalance*
- Adjustment - care with which adjustment for confounder was carried out. *1, 2, 3, 4, 5 where 1=very careful, 5=not at all careful*

7 Contribution of authors

Krystyna Kowalski and Pernille Skov Rasmussen wrote and revised the background section. Krystyna Kowalski and Trine Filges wrote and revised the methods section. Anne Marie Klint Jørgensen designed the search strategy. Anne-Sofie Due Knudsen, Lars Benjaminsen and all authors commented on protocol drafts.

8 Declarations of interest

None known

9 Sources of support

9.1 INTERNAL SOURCES

SFI Campbell, Copenhagen, Denmark

9.2 EXTERNAL SOURCES