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[Intervention Protocol]

# Effectiveness of psychosocial interventions for reducing parental substance misuse

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## ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

### Primary objective

To assess the effectiveness of psychosocial interventions at reducing the substance misuse (alcohol and/or illicit drugs excluding tobacco) of parents with children of dependent age (from birth to 21years). Intervention impact will be examined separately for different substances.

### Secondary objectives

To examine whether interventions can increase drug and/or alcohol treatment engagement, retention and completion; affect the welfare of the child; whether intervention effects differ by intervention type and duration or according to who receives them.

## BACKGROUND

### Description of the condition

Substance misuse, defined as dependence upon, or regular excessive consumption, of psychoactive substances leading to physical, mental or social problems (NICE 2016), is a major public health concern worldwide (Degenhardt 2013; World Health

Organization 2011). Whilst there is significant variation in consumption levels globally, alcohol and drug use has been rising over recent decades in many low-income countries, with high-income countries currently experiencing the greatest burden (Degenhardt 2013; World Health Organization 2009). As well as contributing to more than 60 diseases, many fatalities are attributable to alcohol misuse (Health and Social Care Information Centre 2013). Indeed, alcohol misuse represents the fifth leading cause of morbidity and premature death worldwide (Lim 2012), with 3.8% of all

deaths being attributed to it (R hm 2009), and a further 0.4% of deaths being attributed to illicit drug misuse (Degehardt 2012). Moreover, 4.6% of the global disability-adjusted life-years are attributable to alcohol misuse (R hm 2009), and 0.8% to illicit drug misuse (Degehardt 2013). As well as causing a significant risk to individuals, substance misuse is harmful to others, with alcohol being the most harmful substance (Nutt 2010). Indeed, there are numerous social risks associated with alcohol and drug misuse including family disruption and deprivation (Holland 2014), violent and anti-social behaviour (Hughes 2008), interpersonal violence (Anderson 2009), and child abuse and neglect (Tiplin 2015). Substance misuse may lead to dependence and associated consequences for health, social stigma (Earnshaw 2013), and social exclusion (Anderson 2009).

Research estimates that between 5% and 30% of children in European countries live with at least one parent who misuses substances (EMCDDA 2010). In the UK 30% of children under the age of 16 years (3.3 to 3.5 million) live with at least one parent who misuses alcohol, and 8% with a parent who misuses illicit drugs (980,000) (Manning 2009). Almost 12% of children in the USA (SAMHSA 2009), and 13% of children in Australia (Dawe 2007), live with at least one substance misusing parent. Many of these children are infants. In the UK it is estimated that 124,500 babies under the age of one year live with at least one parent who misuses alcohol, and 70,500 live with a parent who misuses illicit drugs. In total, over 14% of UK infants are exposed to parental problem-drinking or illicit drug use (Manning 2011).

In addition to well documented harms of substance misuse to the individual user, parental substance misuse has been found to be associated with adverse childhood experiences and poor outcomes for children. Research has shown that children of parents who misuse substances are more likely to sustain an unintentional injury (Barczyk 2013), as well as injuries of greater severity than children whose parents do not misuse substances (Damashek 2009). Children whose mothers' medical records showed a history of alcohol misuse have a significantly higher chance of long bone fracture (Baker 2015) - as well as medicinal poisoning (Tyrrell 2012) - than those children whose mothers do not have a record of alcohol misuse. Parental substance misuse has an impact upon child mental health (Kelley 2010; J askel inen 2016), with both mothers' and fathers' substance misuse being significantly associated with childhood externalising disorders such as conduct disorder, oppositional defiant disorder (Kendler 2013; Torvik 2011), and internalising disorders such as depression and anxiety disorder (Ohannessian 2012). Children whose parents misuse substances are significantly more likely to engage with early onset substance use (Malone 2002; Malone 2010), harmful substance misuse (J askel inen 2016), and street-involvement (defined as homelessness or those young people who experience physical, psychological or social risks of street-culture) (Baker 2014), than children whose parents do not misuse substances. Furthermore, parental

substance misuse is significantly associated with the development of mental disorders and substance use disorders when children enter adulthood (Donaldson 2016; Yoon 2013).

Due to the potentially negative impact on the child, parental substance misuse is often identified as a risk factor in child welfare and child protection assessments. In the UK, 18% of all child-in-need assessments identify parental drug misuse and 19% identify parental alcohol misuse (Department for Education 2016), furthermore, 52% of child protection cases have parental substance misuse identified as a risk factor (Forrester 2000). In the USA parental substance misuse has been associated with up to two-thirds of all child maltreatment cases (Traube 2012). Furthermore, a study conducted in Finland found that children whose mothers misused both alcohol and drugs were nine times more likely to be placed in care than children of parents who did not misuse substances (Raitasalo 2015). There have been a number of trials of interventions relating to substance-using parents that sought to address this risk factor by reducing the need for protective services, and to promote family reunification. However, at present, there is no agreed way to intervene. As such, there is a need to review the literature systematically, in order to identify effective psychological and social interventions to reduce parental substance misuse.

## Description of the intervention

Interventions that address psychosocial substance misuse are non-pharmacological therapeutic interventions delivered to individuals or groups, which seek to tackle the psychological, social, personal and relational problems associated with substance misuse. There are many different psychosocial interventions, with approaches and techniques that vary according to their theoretical underpinnings. We will include a range of psychosocial interventions within this review. These include, but are not limited to: motivational interviewing; cognitive behavioural therapy; psychodynamic therapy; case management; residential rehabilitation; parent skill training, couples therapy, and family therapy. This broad range of psychosocial interventions maybe delivered to an individual, family or delivered at a social level.

## Motivational interviewing

Motivational interviewing is a person-centred, directive approach, which seeks to resolve the conflict inherent in behaviour change (Miller 1991). Unlike cognitive behavioural interventions, motivation to change is not assumed. Rather ambivalence to change is typical; motivation is viewed as malleable and formed within the context of the therapist-client relationship. The therapist employs specific strategies to develop motivation, seeking to mobilise the client's inner resources and intrinsic motivation and, in doing so, to enable the client to initiate and achieve behaviour change. Motivational interviewing was first developed for use with alcohol before being extended to drug treatment services (Miller 1983;

Miller 2003). A recent systematic review and meta-analysis of motivational interviewing delivered as alongside or within medical care found the approach to have a statistically significant effect of modest size. This review found the approach was particularly promising for a range of behaviours including alcohol and tobacco use (Lundahl 2013).

### **Cognitive behavioural therapy**

Cognitive behavioural therapy believes that an individual's thoughts, emotions and behaviour are connected (Meichenbaum 1977). Within the context of substance misuse, individuals are perceived to hold dysfunctional beliefs about themselves and the world around them (Marlatt 1985), and to exhibit behaviours based upon a range of automatic and nonautomatic responses to urges (Tiffany 1990). Through the development of self-awareness, performing experiments, and development of coping strategies and skills, individuals can alter their thoughts and feelings and change their behaviour (Beck 1993).

### **Psychodynamic therapy**

Psychodynamic therapy exists on a supportive-interpretive continuum, the essence of which is the exploration of the parts of the self that are not known and are therefore unconscious. The therapeutic approach involves a focus on the patient's emotion, active exploration of avoidance, identification of recurring themes, discussion of past events, interpersonal relationships - including that with the therapist - and exploration of the patient's fears and desires (Shedler 2010).

### **Case management**

Case management is the organisation and co-ordination of intensive treatment programmes within the community. This outpatient approach emerged as an alternative to hospital and residential units for the treatment of disorders including substance misuse and mental health disorders (McLellan 1999).

### **Residential rehabilitation**

Residential rehabilitation is an inpatient treatment programme typically consisting of an intensive programme of individual and group psychosocial interventions. There are a wide range of residential rehabilitation models including those based upon the 12-step programme (Alcoholics Anonymous 2002) and therapeutic community model (De Leon 2000). The treatment goal of residential rehabilitation units is predominately abstinence.

### **Parent skill training**

The introduction of parent skill training in the late 1960s marked a move towards parents, as well as professionals, being viewed as having the potential to address children's problematic behaviours (Kaminski 2008). Alongside the appreciation that parents could contribute to children's desirable behaviours, there was an increasing appreciation of the potential for parents to contribute to the formation of undesirable behaviours (Bandura 1969). While, Initially, parenting programmes focussed on teaching parents skills to manage and address children's behaviour, they have proliferated to include programmes designed to address poor parenting practices (Barth 2005).

### **Couples therapy**

Couple therapy for drug and alcohol problems involves both the user and his/her partner attending therapy. The approach is informed by research that showed a high prevalence of discord within relationships where substance misuse is present (O'Farrell 1993), in which a direct relationship exists between substance problems and relationship difficulties (Raistrick 2006). The approach assumes that resolving issues within a relationship, and promoting relational support, will facilitate a positive change in substance misuse (Klostermann 2011).

### **Family therapy**

Family therapy is an approach that seeks to address problems within the system of relationships, rather than treating individuals outside their central context. There are many forms of family therapy, including multidimensional and systemic therapy. In a similar way to couples therapy, the approach seeks to mobilise the strengths and support within relationships, and seeks to address issues systemically (Stratton 2011).

### **How the intervention might work**

Individual level interventions, whilst they may vary in their theoretical stance and the determinants upon which they focus, share the assumption that change must be located within the individual. Motivational interviewing highlights the spirit of the approach as being the effective therapeutic mechanism. This spirit is concerned with a partnership between the therapist and patient, wherein the patient's autonomy is respected within strengths-based model for promoting change (Miller 2013). Cognitive behavioural approaches assume that substance-abuse relapses can be prevented by addressing skill deficits and enabling people to cope with high-risk situations (Monti 1989). Family-level interventions, which may include couples and families, assume these contexts to be a potential source of both stress and support, and therefore tend to seek to affect relational and system change (Stratton 2011). Environmental and ecological interventions delivered on a social level, for

example housing and employment training, assume that change must occur within the wider social context of the individual and his/her ecological system (Slesnick 2013).

There is evidence that the longer an individual is retained in treatment, the better the outcome will be (Simpson 2008). As such, many interventions focus upon engaging and supporting retention of the individual in a treatment programme, rather than focusing upon the characteristics of the therapy itself. Interventions such as case management (Dobkin 2002), and those that utilise peer mentors (Pallaveshi 2014), focus upon providing support to deal with life stresses and promote treatment engagement and retention. The therapeutic effect of shared experience and understanding is emphasised within peer mentoring (Gates 2007).

Interventions designed for substance misusing parents are likely to operate within a context of, or with the specific aim of, child welfare. Given the well documented association between individual and family risk from parental substance use, an intervention that reduces parental substance misuse is likely to benefit both the parent and the child (Kaner 2016). The reverse hypothesis is also evident within intervention logic models. Systemic therapy, that is, those based upon attachment theory, and parenting skills training may seek to enhance effective and acceptable parenting, believing that improvement in parental understanding and abilities is likely to bring about changes in substance use, and that through this parents become aware of the incompatibility that exists between their substance use and positive parenting practices (Catalano 1999).

### **Why it is important to do this review**

There are a number of other Cochrane Reviews published or planned that aim to investigate interventions for pregnant women who use alcohol (Lui 2008), or illicit drugs (Terplan 2015), and lactating women who drink alcohol (Cassidy Giglia 2012), as well as for children of problem drinkers (McLaughlin 2014). However, there are no Cochrane Reviews that have evaluated the effectiveness of interventions for parental substance misuse after the birth of a child. Moreover, there are no reviews that have investigated interventions for substance misusing fathers. Pregnancy and the postpartum period are periods in women's lives that are often considered to be times of leverage and opportunity for change (Davies 2013; Daley 1998; McBride 2003). As such, the interventions offered and their effects are likely to differ from those during established parenthood.

Given the significant evidence that substance misuse is harmful to the individual, and that parental substance misuse is associated with a variety of problems for children, intervening with this population is both a public health and safeguarding priority. Despite this, the majority of parents who use substances are untreated (Forrester 2006). By reviewing the evidence of the effectiveness of psychosocial interventions, this review will inform commissioners' decisions about the type of interventions to invest in, and will also

inform practitioners working with substance misusing parents and their children.

## **OBJECTIVES**

### **Primary objective**

To assess the effectiveness of psychosocial interventions at reducing the substance misuse (alcohol and/or illicit drugs excluding tobacco) of parents with children of dependent age (from birth to 21 years). Intervention impact will be examined separately for different substances.

### **Secondary objectives**

To examine whether interventions can increase drug and/or alcohol treatment engagement, retention and completion; affect the welfare of the child; whether intervention effects differ by intervention type and duration or according to who receives them.

## **METHODS**

### **Criteria for considering studies for this review**

#### **Types of studies**

We will include randomized controlled trials (RCTs) including individually and cluster-randomised designs, factorial design, stepped wedge, and trials which have a quasi-experimental design. Studies will only be included if they have a minimum follow-up period of six months from the start of the intervention. This will enable identification of both shorter-term (6-11 month) and longer-term impacts (12 month and over).

#### **Types of participants**

Participants will be parents who misuse substances; this will include mothers and fathers of children (sons and daughters) under the age of 21 years, regardless of custodial or residency status of the children. Same sex parents and foster parents will be included. Substance misuse includes the misuse of alcohol or illicit drugs (including cannabis and prescription drugs which are used other than in accordance with medical or legal guidance), or both. Studies that consider interventions delivered to populations that include both parents and non-parents will be excluded. Studies of parental interventions where the child is the only misuser of substances will

be excluded. Studies will be included if the parent has been identified as a substance misuser by a reliable, valid, formal assessment (validated screening tool, assessment by a health or child welfare practitioner) or diagnostic tool (DSM III, DSM IIIR, DSM IV, ICD8, ICD 9, ICD 10), or both. The administration of agonist or detoxifying prescriptions will be considered as a proxy measure of substance misuse in participants and therefore trials that include people taking them will be eligible for inclusion. Studies of primary prevention interventions, where adult participants are not identified as substance misusers will be excluded. Intervention studies for pregnant substance users only, where the intervention phase is restricted to the prenatal period, will be excluded.

### Types of interventions

Complex psychosocial interventions that target substance misuse in parents directly or indirectly will be included in this review. No limit will be placed upon duration, frequency or intensity of intervention. Multiple-focused interventions will be included if the impact of the intervention upon parental substance misuse is assessed. Studies of pharmacological interventions only will be excluded. Where a study combines a pharmacological component with psychosocial interventions, this will be included providing the comparison group meets the inclusion criteria.

Interventions may be delivered to an individual parent (directly or via digital technologies), couples or the wider family unit. Approaches which seek to engage with individual parents may include, but are not limited to: motivational interview, cognitive behavioural therapy, psychodynamic therapy, parental skill training, case management, and residential rehabilitation. Interventions aimed at couples may include couples marital and relational therapy, where one or both parents misuse substances. Family-level interventions may include: home visits, supported housing, family therapy and residential rehabilitation (parent and child facilities). Social level interventions may include support housing interventions or those which aim to promote employment.

The intervention may be delivered by a variety of professionals as well as non-professionals. Professional groups may include social workers, drug and alcohol treatment specialists, nurses, psychiatrists, psychotherapists and nurses. Non-professionals may include peer interventionists, advocates, mentors and parents with previous personal experience of substance misuse or the child welfare system, or both. Interventions may be delivered with an individual, couples or in a group context, including a family.

Control or comparison groups will include: no intervention, waiting list/delayed treatment control arms, attention control, alternative active intervention, and treatment as usual.

### Types of outcome measures

#### Primary outcomes

#### Parental substance misuse

The primary outcome is a reduction in the frequency of parental substance misuse. Parental substance misuse will be considered to have reduced if there is a reduction in the number of episodes of heavy drinking (defined as five units or more at a time) or in the frequency of illicit drug use from baseline to the follow-up assessment (minimum period of six months). This may be reported in a number of ways: percentage of days of use during follow-up period; percentage of days of abstinence during follow-up period; or percentage of days of use/abstinence by specified substance during follow-up period. These measures will be converted to number of days of heavy episodic drinking/illicit drug use in the past 30 days to enable comparison between them.

#### Secondary outcomes

The secondary outcomes of interest concern are change in relation to parental substance misuse and child welfare from baseline to the follow-up assessment.

#### Parental substance misuse

- Amount of use measured as levels of use per using occasion
- Sustained abstinence during assessment period (measured as the number of participants with continuous abstinence during the treatment)
  - Dependence/disorder symptomology measured by a reliable, valid, formal assessment tool (such as the addiction severity index) or diagnostic tool (DSM III, DSM IIIR, DSM IV, ICD8, ICD 9, ICD 10), or both
  - Number of participants engaged in structured treatment (defined as attending at least one session of structured treatment)
  - Retention in treatment measured as number of participants completing the treatment

#### Child welfare outcomes:

- Child substance misuse (delayed onset, reduction in levels of use)
- Change in legal status (measured as a reduction in the number of children taken into care, reduction in the time for which children are in care, increased rates of family reunification following temporary care orders)
- Reduction in recorded child welfare incidents (including incidents of maltreatment, abuse or neglect)

### Search methods for identification of studies

We aim to identify all relevant RCTs regardless of language or publication status (published, unpublished, in press, or in progress).

## Electronic searches

The following databases will be searched from their inception:

- the Cochrane Drugs and Alcohol Group Specialised Register via the Cochrane Register of Studies (CRS-Web);
- the Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library;
- MEDLINE (Ovid) (1966 onwards);
- Embase (Ovid) (from 1974 onwards);
- PsycINFO (Ovid) (1806 onwards);
- CINAHL - Cumulative Index to Nursing & Allied Health Literature (1982 onwards);
- Applied Social Science (ASSIA) (1987 onwards);
- Sociological Abstracts (1963 onwards);
- Social Science Citation Index (SSCI) (1956 onwards);
- Scopus (1960 onwards).

The subject strategies for databases will be modelled on the search strategy designed for MEDLINE in [Appendix 1](#). Where appropriate, these will be combined with subject strategy adaptations of the highly sensitive search strategy designed by Cochrane for identifying randomized controlled trials and controlled clinical trials (as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Lefebvre 2011)).

We will search the following trials registries:

- The World Health Organization International Clinical Trials Registry Platform ([www.who.int/trialsearch](http://www.who.int/trialsearch));
- ClinicalTrials.gov ([www.clinicaltrials.gov](http://www.clinicaltrials.gov));
- TRoPHI - The Trials Register of Promoting Health Interventions ([epi.ioe.ac.uk/webdatabases/Search.aspx](http://epi.ioe.ac.uk/webdatabases/Search.aspx)).

## Searching other resources

We will handsearch the reference lists of relevant studies to identify further relevant studies, as well as contacting authors who publish in the field to identify ongoing trials and unpublished work. In addition, we will search the reference lists of relevant Cochrane Reviews.

## Data collection and analysis

### Selection of studies

We will import all references obtained from databases and other resources into Endnote and remove duplicates. The use of a reference management software will promote consistency of reference screening. Two researchers will independently screen all titles and abstracts using the specified inclusion and exclusion criteria, retrieve full-text papers for potentially eligible studies and will evaluate these. They will resolve any discrepancies at each stage by discussion, or by consulting a third researcher, if consensus can not be reached. We will not apply any language restrictions. We

will translate articles written in languages other than English that we consider to be potentially relevant from inspection of the title and abstract.

### Data extraction and management

Two researchers will independently extract the data from the included studies using a standard data extraction form. Two reviewers will pilot the data extraction form to ensure it effectively captures the data relevant to this review. We will resolve disagreements by discussion and by consulting a third researcher if consensus cannot be reached. We will extract the following data.

- Author details, title, unique identifier and date
- Eligibility verification and reason for exclusion
- Key features of the study: aim, design, setting
- Participant details: inclusion/exclusion criteria, baseline characteristics, number entering trial, number randomized to intervention groups
  - Intervention and comparator details: duration, frequency, intensity, professional delivering intervention, intervention type, theoretical underpinning
  - Outcome measures: pre and post intervention, units of measurement
    - Duration of follow-up(s) and attrition
    - Measures for primary and secondary outcomes of interest at each time point
    - Method of analysis

Where multiple papers are included that relate to one trial, we will identify an index paper and we will extract data from the index and linked papers on one data extraction form.

### Assessment of risk of bias in included studies

Two researchers will independently assess each study for risk of bias. Disagreements will be resolved by discussion and where necessary a third researcher will independently assess the study to enable agreement to be reached. The 'Risk of bias' assessment for RCTs used in this review will be conducted using the criteria recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). This two-part, domain-based tool addresses seven domains: random sequence generation and allocation concealment (selection bias); blinding of participants and providers (performance bias); blinding of outcome assessor (detection bias); incomplete outcome data (attrition bias); selective outcome reporting (reporting bias); and other sources of bias. The first part of the tool involves describing what was reported to have happened in the study. The second part of the tool involves assigning a judgement relating to the risk of bias for that entry, in terms of low, high or unclear risk. To make these judgements we will use the criteria indicated by the *Cochrane Handbook for Systematic Reviews of Interventions* adapted to the addiction field (see [Appendix 2](#) for details).



We will address the domains of sequence generation and allocation concealment (avoidance of selection bias) in the tool by a single entry for each study. We will consider blinding of participants, personnel and outcome assessor (avoidance of performance bias and detection bias) separately for objective outcomes (e.g. dropout, use of substance of abuse measured by urine analysis, subjects engaged and/or retained in further treatments, number of child welfare incident reports, legal and care status of the child) and subjective outcomes (e.g. participant self-reported use of substance). We will consider incomplete outcome data (avoidance of attrition bias) for all outcomes except for dropout from the treatment, which is very often the primary outcome measure in trials on addiction. We will use 'Risk of bias' assessments to carry out sensitivity analyses (see [Sensitivity analysis](#)).

### Measures of treatment effect

We will analyse dichotomous outcome data by calculating the risk ratio (RR) for each trial with the uncertainty in each result being expressed with a 95% confidence interval (CI). We will analyse continuous outcome by calculating mean differences (MDs), if all studies use the same measurement scale. We will use standardised mean differences (SMD) if studies use different measurement scales to measure the same outcome, each with 95% confidence intervals.

### Unit of analysis issues

In studies that compare more than one intervention arm to a control arm, we will combine the relevant intervention groups into a single group and we will compare it with the control to avoid double counting of participants in the control groups. When trials use a factorial design, we will combine sample size, mean and standard deviation from separate intervention arms in accordance with Cochrane recommendations ([Higgins 2011](#)). Cluster randomized trials will be considered for this review, as randomisation may occur by recruitment setting. We anticipate that the investigators will have controlled for the susceptibility of cluster designs to unit-of-analysis error and artificially small P values ([Higgins 2011](#)). Where this is not the case, we will contact authors and request participant data to enable the calculation of the intracluster correlation coefficient (ICC).

### Dealing with missing data

We will contact authors to try to obtain missing data. Where this is impossible, we will attempt to estimate missing outcome measures using other outcome measures provided; for example, estimating quantity of alcohol consumed using data about frequency and intensity of consumption. We will use data from intention-to-treat analyses in preference to completer-only data, and we will contact authors if insufficient data are provided, to enable intention-to-treat analysis. We will extract post-intervention outcomes reported

as mean and standard deviations for synthesis, but we will use mean change scores if post intervention outcome data are not available. If a study fulfils the inclusion criteria, but does not provide useful data on outcomes to be extracted or included in the meta-analyses, we will report this in the characteristic of included studies table and in the main text.

### Assessment of heterogeneity

It is anticipated that studies included in this review will be heterogeneous with regard to participants, interventions, substance use targeted and outcomes analyzed. We will assess the magnitude of heterogeneity using the  $I^2$  statistic, and the statistical significance of the heterogeneity using P values derived from  $\text{Chi}^2$  tests ([Deeks 2001](#)). We will consider a P value less than 0.05 to be significant, and  $I^2$  values higher than 50% to be indicative of substantial heterogeneity, although we will interpret the percentage within the context of the size and direction of effects ([Higgins 2011](#); [Ryan 2014](#)). We will conduct subgroup analysis to investigate heterogeneous results, should the data be available.

### Assessment of reporting biases

We will investigate publication bias using funnel plots, plotting the study effect size against the sample size (if a minimum number of 10 studies are included in a meta-analysis). If asymmetry is apparent, we will consider and discuss possible reasons for it.

### Data synthesis

If studies are sufficiently homogeneous to enable meta-analysis, we will pool the data for each outcome using a random-effects model because a certain degree of heterogeneity is expected. We will perform separate meta-analyses for the following types of substance use/misuse: opioids, cocaine, alcohol, cannabis, and poly-substance. The meta-analysis will be performed using Review Manager 5 ([Review Manager 2014](#)). The method of meta-analysis used will depend upon the available outcome data (dichotomous, ordinal, continuous) as discussed in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)). We are anticipating heterogeneity between studies. The magnitude of this may prohibit meta-analysis. If this is the case, we will conduct a narrative synthesis, using appropriate headings to illuminate the findings of the included studies. These headings may include the type of intervention, target substance and the duration of the intervention.

### Subgroup analysis and investigation of heterogeneity

We will investigate the cause of heterogeneity between studies by the following subgroup analyses, should sufficient data be available.

- Types of psychological or social interventions (e.g. behavioural, motivational or attachment-based), or both
- Recipients of intervention (individual, couple, family, mothers, fathers)
- Duration of intervention (short intervention of one session, medium intervention of up to 6 sessions, extended intervention of more than 6 sessions)
- Length of follow-up
- Family composition (number of children, parents within household)

### Sensitivity analysis

We will conduct a sensitivity analysis by repeating all previous analyses with the exclusion of study data that are:

- at high risk of selection bias (random sequence generation or allocation concealment);
- converted for the purposes of data entry (e.g. where standard deviations have been estimated from the standard error of the mean, 95% CIs);
- completer-only rather than intention-to-treat; and
- mean change scores rather than post-intervention scores.

### 'Summary of findings' table

We will assess the overall quality of the evidence for the primary outcome using the GRADE system. The Grading of Recommendation, Assessment, Development and Evaluation (GRADE) Working Group developed a system for grading the quality of evidence (Guyatt 2008; Guyatt 2011; Oxman 2004), which takes into account issues not only related to internal validity but also to external validity, such as directness of results. We will present the main findings of the review in a transparent and simple tabular format in a 'Summary of findings' table. This will provide key information concerning the quality of evidence, the magnitude of effect of the interventions examined and the sum of the available data for the main outcomes.

The GRADE system assigns four levels of evidence, that should be interpreted as follows.

- High: we are very confident that the true effect lies close to that of the estimate of the effect.
- Moderate: we are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
- Low: our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
- Very low: we have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

Data from RCTs start at the high level of evidence, and then are lowered by one or two levels for the following reasons.

- Serious (reduced by one level) or very serious (reduced by two levels) study limitation for risk of bias.
- Serious (reduced by one level) or very serious (reduced by two levels) inconsistency between study results.
- Some (reduced by one level) or major (reduced by two levels) uncertainty about directness (the correspondence between the population, the intervention, or the outcomes measured in the studies actually found, and those under consideration in our review).
- Serious (reduced by one level) or very serious (reduced by two levels) imprecision of the pooled estimate.
- Strong suspicion of publication bias (reduced by one level).

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\* Indicates the major publication for the study

## APPENDICES

### Appendix I. MEDLINE search strategy

1. substance-related disorders/ or alcohol-related disorders/ or amphetamine-related disorders/ or cocaine-related disorders/ or drug overdose/ or inhalant abuse/ or marijuana abuse/ or opioid-related disorders/ or phencyclidine abuse/ or psychoses, substance-induced/ or substance abuse, intravenous/ or substance withdrawal syndrome/ or alcohol withdrawal delirium/ or alcohol withdrawal seizures/
2. ((stimulant\* or polydrug\* or drug\* or substance) adj6 (abus\* or dependen\* or addict\* or disorder\* or intoxicat\* or misuse\*)).ab,ti.
3. exp alcohol drinking/
4. (alcohol adj3 (dependen\* or drink\* or intoxicat\* or abus\* or misus\* or risk\* or consum\* or excess\* or reduc\* or intervention\*)).ab,ti.
5. (drink\* adj3 (excess or heavy or heavily or harm or harmful or hazard\* or risky or binge or harmful or problem\*)).ab,ti..
6. (addict\* or abstain\* or abstin\*).ab,ti.
7. (heroin or methadone or temegestic or subutex or opiate\* or crack cocaine or cocaine or ecstasy or methamphetamine\* or crystal meth or amphetamine\* or cannabis or marijuana or marihuana or lsd or magic mushrooms or mephedrone or khat or cathinone or ketamine or steroid\* or performance enhancing drug\* or gammahydroxybutyrate or ghb or amyl nitrate).ab,ti.
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. maternal deprivation/ or parent-child relations/ or father-child relations/ or mother-child relations/ or parenting/ or paternal behavior/ or paternal deprivation/ or nuclear family/ or exp parents/ or single-parent family/
10. (parent or parents or parental or guardian\* or mother or maternal or father or paternal or mum or dad).ab,ti.
11. 9 or 10
12. psychotherapy/ or exp behavior therapy/ or exp cognitive therapy/ or exp relaxation therapy/ or gestalt therapy/ or narrative therapy/ or nondirective therapy/
13. play therapy/ or exp psychoanalytic therapy/ or exp psychotherapeutic processes/ or psychotherapy, brief/ or psychotherapy, multiple/ or psychotherapy, psychodynamic/
14. psychotherapy, rational-emotive/ or reality therapy/
15. socioenvironmental therapy/
16. counseling/ or exp directive counseling/
17. (motivat\* adj5 (interview\* or therap\* or consult\* or intervention\* or enhance\*)).ab,ti.
18. (brief adj3 intervention\* ).ab,ti.
19. (cognit\* adj2 (train\* or behavior\* or therap\* or technique\* or skill\*)).ab,ti.
20. ((psychodynamic or psychosocial) adj2 (therap\$ or treatment\$ or intervention\$ or program\$)).ab,ti.
21. (psychotherap\* or counsel\* or residential rehabilitation).ab,ti.
22. ((relaxation or imagery) adj2 (therap\$ or technique\$)).ab,ti.
23. (family adj2 therap\*).ab,ti.
24. (case adj2 management).ab,ti.
25. ((coping skill\* or cbst or self control or assertive\*) adj2 (training or therap\*)).ab,ti.
26. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
27. (randomized controlled trial or controlled clinical trial).pt.
28. (randomized or placebo).ab.
29. clinical trials as topic.sh.
30. randomly.ab.
31. trial.ti.
32. 27 or 28 or 29 or 30 or 31
33. exp animals/ not humans.sh.
34. 32 not 33
35. 8 and 11 and 34

## Appendix 2. Criteria for 'risk of bias' assessment adapted to the addiction field

Item	Judgment	Description
1. Random sequence generation (selection bias)	Low risk	The investigators describe a random component in the sequence generation process such as: random number table; computer random number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots; minimisation
	High risk	The investigators describe a non-random component in the sequence generation process such as: odd or even date of birth; date (or day) of admission; hospital or clinic record number; alternation; judgement of the clinician; results of a laboratory test or a series of tests; availability of the intervention
	Unclear risk	Insufficient information about the sequence generation process available to permit a judgement of low or high risk
2. Allocation concealment (selection bias)	Low risk	Investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based, and pharmacy-controlled, randomisation); sequentially numbered drug containers of identical appearance; sequentially numbered, opaque, sealed envelopes
	High risk	Investigators enrolling participants could possibly foresee assignments because one of the following methods was used: open random allocation schedule (e.g. a list of random numbers); assignment envelopes without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered); alternation or rotation; date of birth; case record number; or any other explicitly unconcealed procedure
	Unclear risk	Insufficient information available to permit a judgement of low or high risk This is usually the case if the method of concealment is not described, or not described in sufficient detail to allow a definite judgement
3. Blinding of participants and providers (performance bias) Objective outcomes	Low risk	No blinding, or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken
	High risk	No blinding, or incomplete blinding, and the outcome is likely to be influenced by lack of blinding Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding
	Unclear risk	Insufficient information available to permit a judgement of low or high risk



(Continued)

4. Blinding of participants and providers (performance bias) Subjective outcomes	Low risk	Blinding of participants and providers ensured and unlikely that the blinding could have been broken
	High risk	No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding
	Unclear risk	Insufficient information available to permit a judgement of low or high risk
5. Blinding of outcome assessor (detection bias) Objective outcomes	Low risk	No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken
	High risk	No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding
	Unclear risk	Insufficient information available to permit a judgement of low or high risk
6. Blinding of outcome assessor (detection bias) Subjective outcomes	Low risk	Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken
	High risk	No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding
	Unclear risk	Insufficient information to permit judgement of low or high risk
7. Incomplete outcome data (attrition bias) For all outcomes except retention in treatment or dropout	Low risk	Any one of the following: <ul style="list-style-type: none"> <li>● no missing outcome data;</li> <li>● reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias);</li> <li>● missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups;</li> <li>● for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk is not enough to have a clinically relevant impact on the intervention effect estimate;</li> </ul>

(Continued)

		<ul style="list-style-type: none"> <li>• for continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes is not enough to have a clinically relevant impact on observed effect size;</li> <li>• missing data have been imputed using appropriate methods</li> <li>• all randomized patients are reported/analyzed in the group they were allocated to by randomisation irrespective of non-compliance and co-interventions (intention-to-treat).</li> </ul>
	High risk	<p>Any one of the following:</p> <ul style="list-style-type: none"> <li>• reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups;</li> <li>• for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk is enough to induce clinically relevant bias in the intervention effect estimate;</li> <li>• for continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes is enough to induce clinically relevant bias in observed effect size;</li> <li>• 'as-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation.</li> </ul>
	Unclear risk	Insufficient information available to permit a judgement of low or high risk (e.g. number randomized not stated, no reasons for missing data provided; number of drop out not reported for each group)
8. Selective reporting (reporting bias)	Low risk	<p>Either of the following:</p> <ul style="list-style-type: none"> <li>• the study protocol is available and all of the study's prespecified (primary and secondary) outcomes that are of interest in the review have been reported in the prespecified way;</li> <li>• the study protocol is not available, but it is clear that the published reports include all expected outcomes, including those that were prespecified (convincing text of this nature may be uncommon).</li> </ul>
	High risk	<p>Any one of the following:</p> <ul style="list-style-type: none"> <li>• not all of the study's prespecified primary outcomes have been reported;</li> <li>• one or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not prespecified;</li> <li>• one or more reported primary outcomes were not prespecified (unless clear justification for their reporting is provided, such as an unexpected adverse effect);</li> <li>• one or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis;</li> <li>• the study report fails to include results for a key outcome that would be expected to have been reported for such a study.</li> </ul>
	Unclear risk	Insufficient information available to permit a judgement of low or high risk

(Continued)

9. Other bias	Low risk	No difference in the importance covariates (e.g. gender or type of substance misused) between study groups at baseline No risk of contamination of intervention effects (e.g. practitioner is not delivering more than one study intervention)
	High risk	Any one of the following: <ul style="list-style-type: none"><li>• Baseline between study group imbalance on important covariates (e.g. gender or type of substance misused)</li><li>• Contamination of intervention effects (e.g. practitioner delivers more than one study intervention to different participants)</li></ul>
	Unclear risk	Insufficient information to form judgement of low or high risk for confounding or contamination

## CONTRIBUTIONS OF AUTHORS

Ruth McGovern drafted the initial protocol, revised the protocol and approved the final protocol as submitted.

Michelle T Addison, James J Newham, Matthew Hickman and Eileen FS Kaner jointly reviewed and revised the protocol, and approved the final protocol as submitted.

## DECLARATIONS OF INTEREST

Ruth McGovern is funded by the National Institute of Health Research.

Matthew Hickman is a member of CDAG.

Michelle T Addison, James J Newham and Eileen FS Kaner have no interests to declare.

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