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TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
BACKGROUND	2
OBJECTIVES	4
METHODS	4
ACKNOWLEDGEMENTS	7
REFERENCES	8
APPENDICES	10
HISTORY	13
CONTRIBUTIONS OF AUTHORS	14
DECLARATIONS OF INTEREST	14
SOURCES OF SUPPORT	14

[Intervention Protocol]

Psychosocial interventions for problem alcohol use in illicit drug users

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To determine the effectiveness of psychosocial interventions targeting problem alcohol use versus other treatments in illicit drug users.

BACKGROUND

Description of the condition

Problem alcohol use is common among illicit drug users and is associated with adverse health outcomes, which include physical, psychological and social implications (Srivastava 2008). A review of literature on the prevalence of 'heavy drinking' among drug users enrolled in a methadone maintenance treatment found prevalence rates of 13% to 25% (Ottomanelli 1999), while more recent cross sectional studies report prevalence from one-third up to 50% in this setting (Maremmani 2007; McCusker 2001).

Problem alcohol use is an expression which represents a spectrum of distinct drinking patterns (i.e. hazardous, harmful and dependent drinking). Hazardous drinking 'is likely to result in harm should present habits persist', while harmful drinking, which is an ICD-10 diagnosis (WHO 1993), 'causes harm to the health (physical or mental) of the individual' without the presence of dependence (Babor 2001). The term 'dependent drinkers' refers to individuals who meet criteria for the alcohol dependence syndrome under DSM-IV or ICD-10 criteria (DSM-IV; WHO 1993).

Problem drug users are at high risk of liver disease resulting from hepatitis C (HCV) infection because of its high prevalence in this population (Smyth 1998). Problem alcohol use is an important factor in determining poor prognosis among people with HCV as it impacts on progression to hepatic cirrhosis, increased HCV-RNA levels or fatal opiate overdose in opiate users (Ostapowicz 1998; White 1999). Teplin 2007 note that drug users have higher rates of mood, anxiety and personality disorders, all of which are exacerbated by alcohol use. In addition, there exists some evidence that alcohol may have a negative impact on outcomes of addiction treatment (Gossop 2000).

The emerging understanding of a high prevalence of problem alcohol use among current or former drug users, allied to the clear health implications of this problem for this population, necessitates a public health response to this issue.

Description of the intervention

Psychosocial interventions are best described as 'psychologically-based interventions aimed at reducing consumption behaviour or alcohol-related problems' (Kaner 2007), which exclude any pharmacological treatments. This term refers to a heterogeneous collection of interventions, which vary depending on their: (a) theoretical underpinnings (e.g. psychodynamic, behavioural, motivational), (b) duration or intensity (e.g. brief, extended), (c) setting (e.g. primary care based, inpatient), (d) mode of delivery (e.g. group, individual, web based), or (e) treatment goals (e.g. abstinence oriented, harm reduction). To date, many psychosocial interventions specifically designed to address problem alcohol use have been described. The most frequently used interventions include: Motivational Interviewing (MI), Cognitive-Behavioural

Therapy (CBT), Psychodynamic approaches, Screening and Brief Interventions (SBI), Family therapy, Drug Counselling, 12-step programmes, Therapeutic communities (TC) and Vocational rehabilitation.

- MI is a client centred approach, but as opposed to its non-directive Rogerian origins, it is a directive therapy system. A Central role is played by the client's motivation and readiness to change. Change within this approach is facilitated over a series of stages (Prochaska 1992). Relapse is not viewed as a failure to maintain healthy behaviour, but rather as a part of the process of change (Miller 2004).

- CBT draws upon the principles of learning theory. Change in addictive behaviour is approached through altering irrational assumptions, coping skills training or other behavioural exercises. This therapy often deals with the identification and prevention of triggers contributing to the drug use. Among the modern approaches utilizing such behavioural techniques are Relapse Prevention (Marlatt 1996), Contingency Management (Budney 2001) or Community reinforcement approach, which combines both contingency management and positive reinforcement for non-drinking behaviours (Hunt 1973).

- Psychodynamic approaches are based on the assumptions of psychoanalytic theory, which focuses on addressing the inner conflicts, childhood traumas or problematic relationship themes. They include a range of different methods designed to deal with the underlying conflicts (e.g. interpersonal therapy, supportive-expressive techniques etc) (Crits-Christoph 1999).

- SBI are time limited and therefore suitable for non-specialist facilities. Usually, the length and intensity of the intervention is determined by the levels of risky alcohol consumption (i.e. screening results). It can range from a couple of minutes to several sessions (three to six) of intervention. Each session includes provision of information and advice (Babor 2001). Increasingly, brief interventions are based on the principles and techniques of motivational interviewing, so that the distinction between these two modalities is blurred in this regard.

- Family therapy: the therapeutic change is achieved via intervening in the interaction between family members. Families are directly involved in a therapy session. The family therapist must be competent in eliciting the strengths and support of the wider family system. Frequently used family therapy models include multisystemic therapy, network therapy solution-focused brief therapy etc. (CSAT 2004)

- Drug counselling: addiction is viewed as a chronic illness which has serious consequences to the health of the individual and social functioning, in consonance with the 12-step model. Recovery includes spiritual components and attendance at fellowship meetings as well. Primary focus of this approach is to help the patient attain abstinence by promoting behavioral changes including trigger avoidance, sport and other constructive activities. Both individual and group forms of drug counselling have been used in the largest collaborative cocaine treatment

study (Crits-Christoph 1999).

- 12-step model: emphasizes powerlessness of an individual over the addiction, which is seen as a disease, and a need for a spiritual recovery. The foundations of this approach lie in the twelve steps and an accompanying document - twelve traditions (Alcoholics Anonymous 1939). The largest of all twelve-step programs is Alcoholics Anonymous (AA) and all other programs evolved from it, e.g. Narcotics Anonymous, Al-Anon etc. AA meetings, besides the twelve steps, utilize well-established therapeutic factors of group psychotherapy, such as group cohesiveness, interpersonal learning (i.e. sponsorship), peer pressure etc.

- Therapeutic Community (TC): is a long-term (18-24 months), drug-free model of treatment, which usually runs in a residential form. This approach relies on community itself, as the main therapeutic factor, and also other factors, such as peer feedback, role-modelling or recapitulation of the primary family experience. Community has a high degree of autonomy, is democratic and each member has a clearly defined role and responsibilities within the structure of TC. A structured regime of daily activities in the TC often includes formal individual or group therapy sessions along with other educational and work activities (De Leon 2000).

- Vocational Rehabilitation (VR): employment is seen as an important element of a successful rehabilitation from drug addiction and is often considered as one of its key indicators (Platt 1995). VR aims to increase the employability of drug users by developing their job interview skills or obtaining further qualifications. A necessary part of increasing ex-users' access to job market is linking with potential employers and addressing their concerns and prejudices related to drug users. An example of vocational rehabilitation for unemployed methadone maintenance patients is the Customized employment supports model (Blankertz 2004).

How the intervention might work

Substantial evidence has described the value of psychosocial interventions in treating problem alcohol use:

A recent review by Raistrick 2006 presented data on the effectiveness of many such interventions, including screening, further assessment, brief interventions, more intensive treatments that can still be considered 'brief', and alcohol-focused specialist treatments. They reported mixed evidence on longer-term effects of brief interventions and whether extended brief interventions add anything to the effects of simple brief intervention.

The Mesa Grande project, which reviewed 361 controlled clinical trials (a three-year update), found brief interventions to be the most strongly supported psychosocial treatment effective in treating alcohol use disorders (Miller 2002). These findings are supported by an Australian systematic review which found brief

interventions to be effective in reducing alcohol consumption for drinkers without dependence or those with a low level of dependence (Shand 2003). Another meta-analysis found positive effect of brief interventions to be evident at the follow up points of three, six and 12 months, and these results were more apparent when dependent drinkers were excluded (Moyer 2002). Indeed, dependent drinkers have been excluded from much of the research indicating that they are possibly unsuitable for brief intervention and should be routinely referred to specialist treatment (Raistrick 2006).

While brief interventions are generally delivered across a range of settings, primary care has an important role in delivery of brief interventions for problem alcohol use among problem drug users. Brief interventions are well suited to primary care due to their feasibility, they can be delivered in general settings by non-specialist staff in a short period of time, and they can also be delivered to patients not actively seeking treatment (Kaner 2007; Raistrick 2006;).

The benefits of primary care based interventions for people with problem alcohol use have recently been demonstrated by a Cochrane review (Kaner 2007), although the authors have reported considerable variation in trials and the effect of brief interventions appeared equivocal among women. Another systematic review of brief, *multi-contact behavioural counselling* among adult patients attending primary care found a reduction of 13-34% in average of drinks per week (Whitlock 2004).

In conclusion, brief psychosocial interventions are feasible and potentially highly effective components of an overall public health approach to reducing problem alcohol use, although considerable variation in effectiveness trials exists and problem drug users from primary care settings are underrepresented in these trials (Kaner 2007; Whitlock 2004).

Because brief interventions have been developed and evaluated mainly in conventional general practice settings, it is not clear whether they can be effectively applied to excessive drinking among illicit drug users, or whether new forms of intervention need to be developed and evaluated. Could be the 'advice-giving' form of brief intervention effective in illicit drug users or are motivational techniques, in which the impetus for change comes from the user, more likely to be effective in this population?

Why it is important to do this review

The described evidence of a high prevalence and serious consequences of problem alcohol use among drug users highlights an opportunity for a Cochrane systematic review in this population. The question being asked in this review is important also because there are no other systematic reviews published which could help answer the question.

Cochrane reviews have so far examined the effectiveness of psychosocial interventions for stimulant, opiate and alcohol use disorders (Amato 2008a; Amato 2008b; Knapp 2007; Lui 2008; Mayet

2004; Minozzi 2011). Although other reviews and review protocols targeted poly drug use, they concentrated either on specific populations, e.g. women and adolescents, or particular interventions, such as case management and motivational interviewing, but not on 'alcohol-specific' interventions (Dalsbø 2010; Hesse 2007; Smedslund 2011; Smith 2006; Terplan 2007; Thomas 2008). None of the published reviews on psychosocial interventions examined the effectiveness of alcohol-specific interventions in problem drug users.

The lack of systematic evaluation, together with the anticipated differences in the responsiveness of problem drug users to psychosocial interventions, provides additional reasons for conducting this review. In other words, results of reviews on the effectiveness of this type of intervention among general population might not be applicable to specific patient groups, such as drug users, because they may have different responsiveness to psychosocial interventions (Nilsen 2010).

Several factors could possibly influence the responsiveness of drug users to treatment interventions, e.g. stability of drug use, engagement with the service, concurrent personality disorders etc. For example, evidence suggests that drug users with antisocial personality disorder are more likely to respond to rewarding than to punitive approaches (Messina 2003) and the use of more intensive psychosocial interventions is recommended in those who achieved sufficient degree of stability and compliance with service regime (Pilling 2010).

OBJECTIVES

To determine the effectiveness of psychosocial interventions targeting problem alcohol use versus other treatments in illicit drug users.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (and cluster RCTs) comparing psychosocial interventions for problem alcohol use with other treatments or no treatment. If no randomised controlled trials or controlled clinical trials are retrieved, observational studies will also be considered (only prospective controlled cohort studies -PCS and experimental controlled before-after studies - CBA).

Types of participants

Participants of trials included in the systematic review will be adult (≥ 18 years), problem drug users attending a range of services, i.e. community, inpatient or residential (including opiate substitution treatment). Problem drug use is defined by European Monitoring Centre for Drugs and Drug Addiction, as '*injecting drug use or long-duration/ regular use of opioids, cocaine and/ or amphetamines*' (EMCDDA 2008, p.10). Further terms which fall under the definition of Problem drug use (i.e. substance use, misuse, abuse, dependence or addiction) or terms which have been used in previous systematic reviews will be included as well.

Problem drug use (PDU) should be clearly stated in the study and determined either by clinical tests (e.g. urine samples) or self-report measures. Problem alcohol use is used as an umbrella term encompassing 'hazardous / harmful alcohol use' and 'alcohol dependence' as defined by WHO in ICD-10 (see description of the condition) (Babor 1994; WHO 1993).

Exclusion criteria:

Participants should be both problem drug users and problem alcohol users, i.e. we will only include studies which defined subjects as drug and alcohol users at randomisation. If a trial also included drug users who were not problem alcohol users, then this study will be excluded. People whose primary drug of use is alcohol will be excluded from this review.

Studies, which involved adolescents will be included if the data for adults could be extrapolated or obtained from the authors. Studies evaluating efficacy of screening as a stand-alone intervention will be also excluded (see below for the definition of interventions).

Types of interventions

Experimental interventions

Any psychosocial intervention which is described by the study's author as such (there is a heterogeneous range of psychosocial interventions provided in the field of addiction treatment). These include:

- interventions explicitly aimed at targeting alcohol either on its own or in combination with other substances / behaviours;
- the examples of such interventions are social skills training, self-control training, coping skills, marital / family therapy, motivational interviewing, community reinforcement, covert sensitization, stress management training, marital behavioural therapy, cognitive behavioural therapy, aversion therapy, confrontational interventions, general / drug counselling, twelve step approaches, relapse prevention, contingency management, psychodynamic therapy;
- brief (simple and extended*) psychosocial treatments will also be included.

The distinction between simple and extended brief interventions is unclear and no universal definition exists. In this review, we adopted the classification and terminology of the Alcohol Education and Research Council (AERC 2010): 1. Simple brief advice

(same as simple brief intervention), 2. Extended brief intervention (same as brief motivational interviewing) and 3. Brief treatment (i.e. Condensed CBT, Brief conjoint marital therapy, MI, MET etc.). Extended brief interventions are structured therapies taking approximately 20-30 minutes within one session and often involving one or more follow-up sessions (Raistrick 2006). Almost all of them are based on the principles of motivational interviewing, i.e. are shortened versions of MI. Interventions, which do not qualify as extended brief interventions or as full motivational interviewing, are considered as brief treatments.

The experimental intervention must be delivered by a trained person, face-to-face, individually or in groups. If the intervention is delivered as a component of a drug treatment program, the participants will be included if their drug use behaviour, which lead to the treatment, conforms to the definition of PDU.

Control interventions

- Other psychosocial interventions which will allow for comparisons between different types of interventions (e.g. cognitive behavioural, contingency management, family therapy, etc.), standard care, no intervention, waiting list, placebo / or any other non-pharmacological therapy (incl. moderate drinking, assessment only).

Types of outcome measures

Primary outcomes

1. reduction and/ or stabilization of alcohol use as measured by either biological markers or self-report tests

Secondary outcomes

1. illicit drug use outcomes (changes in illicit drug use) as measured by either biological markers or self-report tests
2. engagement in further treatment (i.e. drop-out rates, utilization of health services)
3. alcohol-related problems or harms are represented by physical and mental health outcomes which are associated with problem alcohol use. Results from individual trials will be pooled if sufficient number of studies include a measure of alcohol problems and the measures are not too heterogenous. Measures of alcohol-related harm will include following key indicators:

- Number of new injuries necessitating further visits to the Emergency Department or hospital readmission,
- Validated tests of drinking consequences, (e.g. the Drinking Problems Index, the Drinker Inventory of Consequences, Revised Injury Behaviour checklist etc.)
- Laboratory markers and liver function tests (final values and standard deviations): e.g. GGT (Serum gamma-glutamyltransferase), MCV (Mean corpuscular volume) etc.
- Health and quality of life outcomes as measured by standardised instruments, (e.g. General Health Questionnaire,

EuroQol EQ5D or health-related quality of life via SF-12 or similar)

- Psychological problems and well-being as measured by self-report questionnaires, (e.g. Mental health index, Center for epidemiological studies depression scale etc.)
- Motivation to behaviour change as measured by validated questionnaires (e.g. URICA, SOCRATES etc.)

Sustained benefit at three, six and 12 months (standard follow-up intervals) after intervention will be examined through the subgroup analyses.

Search methods for identification of studies

Electronic searches

We will search the following electronic databases:

1. MEDLINE (PubMed) (1966 - to present)
2. CINAHL (EBSCO Host) (1982 - to present)
3. CENTRAL (The Cochrane Library)
4. PsycINFO (CSA) (1872 - to present)
5. EMBASE (EMBASE.com) (1974 - to present)

Databases will be searched using a strategy developed incorporating the filter for the identification of RCTs (Higgins 2008), combined with selected MeSH terms and free text terms relating to alcohol use. Electronic searches will be conducted by the CDAG Group's Trial search coordinator (databases 1-3) and the first author of the review (4-5). The MEDLINE search strategy will be translated into the other databases using the appropriate controlled vocabulary as applicable. If the initial search does not yield any RCTs or CCTs, we will search the databases without the RCT filter.

The search strategy for MEDLINE is shown in [Appendix 1](#).

We will search for ongoing clinical trials and unpublished studies via Internet searches on the following sites:

1. <http://www.controlled-trials.com/>;
2. <http://clinicalstudyresults.org/>;
3. <http://centrewatch.com>.
4. <http://www.who.int/ictrp/en/>, International Clinical Trials Registry Platform (ICTRP)

Searching other resources

We will also search:

1. references of the articles obtained by any means.
2. conference proceedings likely to contain trials relevant to the review. These will include the Society for the Study of Addiction, International Harm Reduction Association and American Association for the Treatment of Opioid Dependence.
3. contact investigators, relevant trial authors seeking information about unpublished or incomplete trials.

All searches will include non-English language literature and studies with English abstracts will be assessed for inclusion. When considered likely to meet inclusion criteria, studies will be translated.

Data collection and analysis

Selection of studies

Two authors (JK, CAF or COG) will independently screen titles and abstracts and select studies potentially relevant to the review. Differences between selection lists will be resolved by discussion with a third author (WC or COG).

Full-text copies of each potentially relevant paper will be obtained, as well as full reports of references with inadequate information in order to definitively determine relevance.

Two authors (JK, CAF or COG) will independently re-evaluate whether studies are eligible for the review or not, according to the inclusion criteria. In case of a disagreement, a third author (WC or COG) will be consulted.

Data extraction and management

Two reviewers (JK, CAF or COG) will independently extract data from the full-text reports into an amended data extraction form of the Cochrane Drug and Alcohol review group (CDAG).

Disagreements will be resolved by mutual discussion and consultation with a third reviewer (WC or COG), if necessary.

Assessment of risk of bias in included studies

The risk of bias assessment for RCTs and CCTs in this review will be performed using the criteria recommended by the Cochrane Handbook (Higgins 2008). The recommended approach for assessing risk of bias in studies included in Cochrane Review is a two-part tool addressing five specific domains (namely sequence generation, allocation concealment, blinding, incomplete outcome data, and other issues). 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 high, low or unclear risk of bias. To make these judgments we will use the criteria indicated by the handbook adapted to the addiction field. See Table in Appendix 1 for details.

The domains of sequence generation and allocation concealment (avoidance of selection bias) will be addressed in the tool by a single entry for each study.

Blinding of participants and providers will not be possible for the kind of the intervention

Blinding of outcome assessor (avoidance of detection bias) will be considered separately for objective outcomes (e.g. drop out, use of substance of abuse measured by urine-analysis, subjects relapsed at the end of follow up, subjects engaged in further treatments) and subjective outcomes (e.g. duration and severity of signs and symptoms of withdrawal, patient self-reported use of substance, side effects, social functioning as integration at school or at work, family relationship, etc.).

Incomplete outcome data (avoidance of attrition bias) will be considered for all outcomes except for the drop out from the treatment, which is very often the primary outcome measure in trials on addiction. It will be assessed separately for results at the end of the study period and for results at follow up

The Newcastle-Ottawa Scale (NOS) will be used to assess the observational studies. The NOS scale assesses three broad areas: selection bias, attrition bias, detection bias. The Risk of Bias tables will be used both for the assessment of RCTs, CCTs, and observational studies according to the criteria recommended by the Cochrane Drugs and Alcohol Review Group. See Appendix 2 for details.

Incorporation:

To incorporate assessment in the review process we will first plot intervention effects estimates for different outcomes stratified for risk. If differences in results will be present among studies at different risk of bias, we will then perform sensitivity analysis excluding from the analysis studies with high risk of bias. We will also perform subgroup analysis for studies with low and unclear risk of bias.

Measures of treatment effect

We will analyse the treatment effect at each follow-up interval separately (e.g., post-treatment, three and six month's follow-up). For continuous outcomes: If scales used in primary studies are different, we will calculate the standard mean difference (otherwise, we will use weighted mean difference). Dichotomous outcomes will be presented as risk ratios (relative risks), with 95% CIs.

Unit of analysis issues

If all arms in a multi-arm trial are to be included in the meta-analysis and one treatment arm is to be included more than once in some comparisons, then the number of events and the number of participants in that arm will be divided by the number of treatment comparisons made. This method avoids the multiple uses of participants in the pooled estimate of treatment effect while retaining information from each arm of the trial. It compromises the precision of the pooled estimate slightly.

Dealing with missing data

Authors of original studies will be contacted in case of missing data.

Assessment of heterogeneity

We will assess the statistical heterogeneity by the I^2 statistic (Higgins 2008) and by the chi squared test (Chi^2). Substantial heterogeneity will be defined as: (a.) a statistically significant χ^2 test ($P < 0.10$) coupled with (b.) an I^2 value of 50% or greater among primary outcome studies.

Assessment of reporting biases

Publication bias will be assessed using funnel plots (i.e. plots of the effect estimate from each study against the standard error). Specifically, funnel plots will be used to assess the potential for bias related to the size of the trials, which could indicate possible publication bias.

Data synthesis

Standardized effect sizes will be calculated, if possible, and a formal meta-analysis of the research findings will be undertaken based on the methods provided in the Cochrane Handbook (Higgins 2008). The outcomes from the individual trials will be combined through meta-analysis where possible (comparability of intervention and outcomes between trials) using a fixed effect model unless there is significant heterogeneity, in which case a random effect model will be used. Results from different study designs (RCT, PCS, CBA) will not be combined.

If meta-analysis is not possible due to substantial heterogeneity, we will present the results of included studies in a tabular form (i.e. the size and direction of effect observed and the statistical significance of the studies will be included in the table) based upon the study quality.

Subgroup analysis and investigation of heterogeneity

Separate analysis will be performed for randomised (primary analysis) and observational studies (secondary analysis).

Comparison between primary and secondary analysis

Results obtained from the two analyses will be compared and contrasted, but the conclusions of the review will be based on the results of the primary analysis.

Subgroup analyses will be undertaken to explore the effect of different a) *types* of psychosocial interventions (for instance: motivational versus behavioural or brief interventions) and b) *length* of the interventions (short, medium, extended). Following subgroup analyses are also anticipated:

Anticipated subgroup analyses:

1. sustained benefit at six and 12 months after intervention
2. gender differences
3. single-drug (Alcohol) vs. poly-drug focused interventions
4. single-drug (Alcohol) vs. poly-drug focused interventions which also address other health-related behaviours

Sensitivity analysis

Sensitivity analysis will be conducted according to the methodological quality criteria used for study inclusion:

- Studies with a high risk of bias will be excluded from the analysis; this decision will be based on a pre-defined cut-off score (i.e. studies judged to be at high risk of bias for three and more risk items, including selection bias, will be excluded)

- A separate sensitivity analysis will be performed excluding CCTs.

Consumer Participation

Consumer participation in the preparation of the protocol and the review itself will be sought by: a) the first author is a member of the Cochrane Consumers Network, b) the Consumers network will be approached to assist with a plain language summary of the review, and c) one of the coauthors of this review (EK) will contribute to a consumer consultation during protocol and review development, because he is a practicing clinician in a healthcare facility with a high prevalence of this problem.

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* Indicates the major publication for the study

APPENDICES

Appendix I. Pubmed search strategy

Search strategy for PubMed:

Search terms to locate drug abuse:

1. "Substance-Related Disorders"[Mesh]
2. addict* OR overdose OR intoxicat* OR abstin* OR abstain OR withdrawal OR abuse OR use OR misuse OR disorder* OR dependen*
3. #1 or #2

Search terms to identify drugs:

4. "heroin"[Mesh] OR heroin[tiab]
5. narcotic*[tiab]
6. drug[tiab] OR polydrug[tiab] OR substance[tiab] OR opioid[tw] OR opiate[tw] OR hallucinogen[tiab] OR cocaine [tw] OR benzodiazepine*[tw] OR amphetamine*[tw] OR "anti-anxiety-agents"[tiab] OR barbiturate*[tiab] OR "lysergic acid"[tiab] OR ketamine[tiab] OR cannabis[tiab] OR marihuana[tiab] OR hashish[tiab] OR opium[tiab] OR inhalant*[tiab] OR solvent[tiab] OR steroid*[tiab] OR methadone[tiab] OR morphine[tiab] OR ecstasy[tiab] OR MDMA[tiab]
7. "Street Drugs"[Mesh]
8. "Designer Drugs"[Mesh]
9. #4 or #5 or #6 or #7 or #8

Search terms to identify alcohol:

10. alcohol*[tiab]
11. consumption[tiab] OR binge[tiab] OR intoxication[tiab] OR abuse[tiab] OR misuse[tiab] OR drink*[tiab]
12. alcoholism[Mesh]
13. alcoholic Intoxication [Mesh]
14. "Drinking behavior"[Mesh]
15. #10 or #11 or #12 or #13 or #14

Search terms to locate interventions:

16. psychotherapy [Mesh]
17. incentive*[tiab] OR voucher[tiab] OR psychotherap*[tiab] OR psychosocial*[tiab] OR "behaviour therapy" [tiab] OR "behavior therapy"[tiab] OR reinforcement[tiab] OR motivation*[tiab] OR contingent*[tiab] OR advice[tiab] OR biofeedback[tiab] OR community[tiab] OR stimulation[tiab] OR education*[tiab]
18. "brief intervention"[tiab]

19. "early intervention"[tiab]
20. "minimal intervention" [tiab]
21. "counselling"[Mesh] or counsel*[tiab]
22. "cognitive therapy" [tiab]
23. "family therapy" [tiab]
24. "social skill"[tiab]
25. "stress management training" [tiab]
26. "supportive expressive therapy" [tiab]
27. neurobehavioral* [tiab]
28. "coping skill"[tiab]
29. "self-control training"[tiab]
30. "social support"[Mesh]
31. "relaxation techniques"[Mesh]
32. "case management"[Mesh]
33. #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

Search terms to locate randomised controlled trials

34. randomised controlled trial [pt]
35. controlled clinical trial [pt]
36. random*[tiab]
37. placebo [tiab]
38. drug therapy [sh]
39. trial [tiab]
40. groups [tiab]
41. #34 or #35 or #36 or #37 or #38 or #39 or #40
42. Animals [mh] NOT Humans [mh]
43. #41 NOT #42
44. #3 AND #9 AND ##15 AND #33 AND #43

Appendix 2. Criteria for Risk of bias in RCTs, CCTs and prospective observational studies

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; minimization
	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 Observational prospective study
	Unclear risk	Insufficient information about the sequence generation process to permit judgement of high or low risk.

(Continued)

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, randomization); 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 method 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 non opaque or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure. Observational prospective study
	Unclear risk	Insufficient information to permit judgement of high or low 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
3-4. blinding of outcome assessor (detection bias) Objective outcomes Subjective 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 to permit judgement of low or high risk;
5. incomplete outcome data (attrition bias) <i>For all outcomes except retention in treatment or drop out</i>	low risk	No missing outcome data; Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; Missing data have been imputed using appropriate methods All randomized patients are reported/analyzed in the group they were allocated to by randomization irrespective of non-compliance and co-interventions (intention to treat)

(Continued)

	high risk	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; For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization;
	Unclear risk	Insufficient reporting of attrition/exclusions to permit 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);
6. Free of other bias: Comparability of cohorts on the basis of the design or analysis	low risk	Exposed and non exposed individuals are matched in the design for most important confounding factors Analysis are adjusted for most important confounding factors Randomised Controlled trial
	high risk	No matching or adjustment for most important confounding factor
	Unclear risk	No information about comparability of cohorts
7. Free of other bias: Representativeness of the exposed cohort	low risk	The sample is representative of the average population receiving the intervention in clinical practice
	high risk	The sample is a selected group of population not representative of the average population
	Unclear risk	No description of the sources of the cohort
8. Free of other bias: Selection of the non exposed cohort	low risk	The sample has been drawn from the same community as the exposed cohort
	high risk	The sample has been drawn from a different source
	Unclear risk	No description of the source of the non exposed cohort
9. Free of other bias: Ascertainment of exposure	low risk	Information in the study was obtained from a secure record (e.g. clinical records or structured interview)
	high risk	Self report
	Unclear risk	No description

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CONTRIBUTIONS OF AUTHORS

JK: Designing and coordinating the review, writing and re-drafting the protocol.

WC, CAF, COG: Contributing to design of the review and commenting on protocol drafts.

LG, EK, JS: Providing methodological advice and commenting on protocol drafts.

GB, CD: Commenting on protocol drafts.

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