Interventions to build resilience in children of problem drinkers

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Interventions to build resilience in children of problem drinkers (Protocol)

McLaughlin AE, Macdonald G, Livingstone N, McCann M

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[Intervention Protocol]

Interventions to build resilience in children of problem drinkers

Aisling E McLaughlin[1], Geraldine Macdonald[2], Nuala Livingstone[3], Mark McCann[4]

[1]Institute of Child Care Research, Queen's University Belfast, Belfast, UK. [2]School of Sociology, Social Policy and Social Work, Queen's University Belfast, Belfast, UK. [3]Institute of Child Care Research, School of Sociology, Social Policy and Social Work, Queen's University Belfast, Belfast, UK. [4]MRC/CSO Social and Public Health Sciences Unit, University of Glasgow, Glasgow, UK

Contact address: Aisling E McLaughlin, Institute of Child Care Research, Queen's University Belfast, 6 College Park, Belfast, Antrim, BT7 1LP, UK. aisling.mclaughlin@qub.ac.uk.

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ABSTRACT

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

To assess the effects of interventions for building resilience in children or young people living with parents/carers who are problem drinkers.

BACKGROUND

Description of the condition

Problem drinking by parents or carers is a significant social problem and varying prevalence rates across race and ethnic groups indicate that some children and young people may be at greater risk than others. Problem drinking by parents may be determined by environmental risk and prognostic factors such as cultural attitudes toward drinking and intoxication, the availability and price of alcohol, and stress levels (DSM-5). In the USA, an average of 7.5 million children under the age of 18 years are estimated to live with a parent who had an alcohol use disorder in the past year, equating to 10.5% of all children (SAMHSA 2012). Nine million children and young people in the European Union (EU) are estimated to live with at least one parent addicted to alcohol (Eurocare 2012). In Australia, 13.2% of children are estimated to be at risk of exposure to short-term risky drinking by at least one adult in households (Dawe 2007) whereas data from the UK (in 2000) suggest that 22% (2.6 million) of children (aged 16 years and under) live with a hazardous drinker, 6% (705,000) with a dependent drinker and 3% (300,000) with a harmful drinker (Manning 2009).

Alcohol use disorders

Alcohol use disorders are typically defined using the Diagnostic and Statistical Manual of Mental Disorders (DSM), 5th edition (DSM-5) (DSM-5) and the International Classification of Diseases and Related Disorders, 10th edition (ICD-10) (WHO 2010), which categorise the severity of an individual's alcohol consumption in relation to a spectrum of distinct drinking patterns. *Harmful use* refers to a pattern of alcohol use that is causing damage to an individual's physical or mental health (WHO 2010). *Alcohol dependence* is defined by ICD-10 as "a cluster of behavioural, cognitive and physiological phenomena that develop after repeated use and that typically include a strong desire to take the drug, dif-

ficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal state" (WHO 2010).The text revision of the fourth edition of the DSM (DSM-IV-TR) contained seperate diagnoses for *alcohol abuse* and *dependence,* which are combined in the recently published DSM-5 (DSM-5). Criteria are provided for alcohol use disorder, accompanied by criteria for intoxication, withdrawal, other alcohol-induced disorders and unspecified alcohol-related disorders. An *alcohol use disorder* is defined as a problematic pattern of alcohol use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period: alcohol is often taken in larger amounts or over a longer period than was intended; there is a persistent desire or unsuccessful efforts to cut down or control alcohol use; a great deal of time is spent in activities necessary to obtain alcohol, use alcohol or recover from its effects; craving or a strong desire to use alcohol; recurrent alcohol use resulting in a failure to fulfill major role obligations at work, school or home; continued alcohol use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of alcohol; important social, occupational or recreational activities are given up or reduced because of alcohol use; recurrent alcohol use in situations in which it is physically hazardous; alcohol use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by alcohol; tolerance (a need for markedly increased amounts of alcohol to achieve intoxication or desired effect; or a markedly diminished effect with continued use of the same amount of alcohol) and withdrawal (the characteristic withdrawal syndrome for alcohol; or alcohol is taken to relieve or avoid withdrawal symptoms). In addition to the above, a diagnostic term which does not appear in either the ICD-10 or the DSM-5 but which often appears in the extant literature is *hazardous* (risky) *drinking,* a pattern of alcohol consumption that increases the risk of harmful consequences for the user or others (Babor 2001).

Problem drinking

When considering the effects of parental problem drinking on children, it is not appropriate to restrict one's definition solely to the diagnostic categories of the DSM-5 (DSM-5) or the ICD-10 (WHO 2010) for a number of reasons. Neither treatment agency records nor clinical studies accurately reflect the 'hidden' nature of problem drinking (e.g. Chalder 2006; Christensen 2000; Colder 1997; Obot 2004; Orford 1990; Orford 2003; Sher 1991), and studies of clinical samples may overestimate pathology by focusing on more severely impaired individuals (Chassin 1999). Clinical diagnoses do not encompass those who have not acknowledged or who are unaware that their drinking is problematic and are undiagnosed. In addition, parents may be less willing to enter treatment than non-parents due to a fear that their children may be taken into care by social services (Powis 2000). Parents who are not willing to participate in programmes may, nevertheless, endorse the benefits their children receive from a prevention programme (Broning 2012). With this in mind, this review uses the broader definition of '*problem drinking*' to include any form of hazardous drinking, harmful drinking, alcohol dependence and alcohol use disorders by carers.

Impact on children

The extant literature on the impact of parental alcohol use on child outcomes reflects the cultural nature of the problem, with the vast majority of studies emerging from the USA, Europe (e.g. UK and Ireland) and Australia. Children depend on their families to meet their physical, psychological and social needs, their economic security and well-being, all of which can be jeopardised by parents misusing substances (NACD 2011). Children living with parental alcohol problems often: have feelings of guilt, loneliness, anger, worry and uncertainty (Cuijpers 2005, Velleman 1990) or low self-esteem (Rangarajan 2008); experience disharmonious family environments and family instability (Velleman 1990; Velleman 1993a; Velleman 1993b; Velleman 1999); are at risk of higher levels of childhood difficulties (Velleman 1993a; Velleman 1993b); or may have to adopt adult roles (Velleman 1990). Velleman 1992b reported that the negative effects of having a problem-drinking parent are mediated via family disharmony, and that in the absence of such disharmony the offspring will not be damaged. These children are also at risk of developing a range of negative health outcomes (Passon 2009) due to dysfunctional coping strategies including alcohol and drug problems (Copello 2005; Corte 2007; Schor 1996; Velleman 1992a), and emotional and behavioural problems (Copello 2005) such as depression or anxiety disorders (Velleman 2004; Velleman 2007). Furthermore, it is common for children of alcoholics to have misunderstandings about alcoholism (Emshoff 1999).

It is not unusual for families to contain multiple problem drinkers (Percy 2008) and an increased risk of alcohol problems in adulthood has been associated with having had two parents with drinking problems (Orford 1990). Maternal drinking problems frequently occur in the context of paternal drinking problems and maternal drinking may actually be a proxy for "two alcoholic parents" (Keller 2005; Keller 2008). Variations in the role of maternal and paternal alcoholism in predicting outcomes amongst children have been reported to confer different risks according to the gender of the offspring (Balsa 2009; Corte 2007). Males have higher rates of psychosocial problems in childhood and adolescence (Werner 1986) as do the offspring of alcoholic mothers (Werner 1986) who tend to report more negative childhood experiences (Velleman 1990). Females generally lean towards withdrawal and social isolation, whereas males more often display antisocial behaviour (Velleman 2003).

Despite the evidence of increased risks to children living with problem drinkers, a large body of evidence suggests that most are remarkably well-adjusted (Sher 1991) or resilient (Velleman 1999). Resilience has been variously defined as "an interactive concept that is concerned with the combination of serious risk experiences

and a relatively positive psychological outcome despite those experiences" (Rutter 2006) and "good adaptation under extenuating circumstances and, from a developmental perspective, meeting age salient developmental tasks in spite of serious threats to development" (Masten 2002). Resilient children are those who display an ability to bounce back from tough times, or have the capacity to overcome challenge or adversity. Resilience is not a fixed trait of individual children; rather, it is best viewed as an interactive concept concerned with the interplay of environmental threats or risk and relatively combined with relatively good outcomes. Velleman 2007 identified a range of factors that provide evidence of resilience in children of substance misusers, including: deliberate planning by the child that their adult life will be different; high self-esteem and confidence; self-efficacy; an ability to deal with change; skills and values that lead to good use of personal ability; a good range of problem-solving skills; feeling that there are choices; feeling in control of their own life; and previous experience of success and achievement. Research suggests that having a supportive adult or confidant, either within the immediate family (if only one parent has a drink problem) or in the extended family and beyond, can help to build resilience, encouraging the development of functional coping behaviours. The social support provided by these significant adults (e.g. relatives, teachers) can help to alleviate the risk of developing maladaptive coping strategies (such as drug and alcohol use) and the onset of emotional or mental health problems.

Description of the intervention

This review focuses on interventions designed to build resilience in children living with a problem-drinking parent. Despite an increase in the development and evaluation of services and interventions targeting these children (Templeton 2010), few theory-driven programmes of prevention or intervention have been developed (Cuijpers 2005). Typically, those programmes that have been developed share some common components (see Cuijpers 2005; Emshoff 1999). A key component of interventions is to assist young people in developing skills to cope with a parent's drinking. Coping skills may take various forms. They may be emotion focused, problem focused or may prepare young people to actively seek help or social support. Interventions designed to promote emotion-focused coping skills seek to help young people to identify and discuss their feelings (e.g. feelings of sadness or distrust, or worry about their parents) and adaptively manage their feelings using various strategies (e.g. relaxation, playing a game, listening to music). Those focusing on problem-solving skills consist of teaching participants skills on how to deal with alcohol-related problems (e.g. appraising the situation, determining the problem and the desired solution, trying alternative solutions, knowing how to react when a parent is drunk, dealing with conflict in the home, explaining the situation to friends). Social skills or support-seeking skills can assist a young person with help-seeking behaviour (e.g. talking to a teacher or other professional). Many programmes are group-based. Group-based programmes provide children and young people with opportunities to share common experiences (reducing feelings of isolation and personal responsibility); find social and emotional support (including from a significant adult role model); exchange experiences; and learn problem-solving skills. Most interventions, whether individual- or group-based, provide information or education on alcohol use, problem drinking, the consequences of drinking and other terminology (e.g. tolerance, blackouts, withdrawal) so that the child may understand the behaviour of the parent. Selective interventions designed specifically for children of problem drinkers that contain any/all of the above components will be included in the review.

How the intervention might work

Hypotheses as to how these interventions may prevent or attenuate the development of risk factors associated with a parent/carer's problem drinking vary. Social learning theorists suggest a modelling effect whereby a person learns from the example of another (Bandura 1977). The most effective models appear to be those individuals who command respect (perhaps because they are well known, or someone who is admired or powerful) but at the same time are not too dissimilar to ourselves. Interventions based on this theory of change, which use positive role models to promote problem solving or the use of social and emotional support, may be beneficial. Bandura 1986 regarded behaviour as an outcome of "reciprocal determinism" (i.e. the mutual interaction of the person's internal characteristics, the environment and behaviour itself). In a similar vein, resilience theory states that the development of resilience is based on three factors: the individual attributes of children or young people, aspects of their families, and the characteristics of their wider social environments (Garmezy 1984; Luthar 2000; Luthar 2003; Rutter 1979, Rutter 1987; Rutter 2008; Werner 1982; Werner 1992; Werner 2001). As resilience is the product of an interaction between the individual and their social context, it is potentially open to influence (Velleman 2007). Therefore, the identification of a set of potentially modifiable risk and protective factors could form the basis of programmes designed to build resilience. Studies of resilient children from substance-affected homes suggest these children are more likely to have social resources outside the home, such as other competent adults or caring relatives (McCabe 1999; Werner 2004). An involvement in a range of stabilising activities, such as school, clubs, sports, religion, also appears to be beneficial in helping a young person to develop a sense of self and self-esteem (Velleman 2007). Resilient children exhibit traits such as high stress resistance, good adaption skills in new situations and high self-efficacy (Velleman 2007). Broning 2012 suggest that children's development is influenced by their own cognitive appraisal of life with a substance-abusing parent as well as by their emotional and behavioural strategies of coping with the difficult situations that

arise from parental substance use. In line with resilience theory, programmes that focus on providing access to social resources or stabilising activities outside the home environment, and encourage the development of problem- and emotion-focused coping skills in children may be a promising form of intervention. For example, the 5-Step Method (Copello 2000a, Copello 2000b) was developed based on the stress-strain-coping-support model (SSCS) (Orford 1998; Orford 2005; Velleman 2003). An important principle of the model is that living with a highly stressful experience such as the impact of an addiction problem in the family, may lead to psychological and physical symptoms of ill health in family members other than the substance user (Copello 2010). In addition to the methods outlined earlier, this approach may benefit children by reducing the levels of stress they experience, and the provision of relevant information may help the child to understand concepts (such as 'tolerance,' 'blackouts' and 'withdrawal') and the parent's behaviour, helping to reduce self-blame and guilt about parental drinking (Emshoff 1999). While these theoretical underpinnings outline how the intervention may work, it is important to note that demographic variables may have an impact on intervention outcomes; for example, 'Gance-Cleveland 2008 reported that girls in the intervention group demonstrated improved resilience measured by increased coping compared to the control group. The authors suggested that adolescent boys and girls are frequently at different stages in their development with girls tending to be more socially integrated and mature than boys.

Why it is important to do this review

Practitioners will benefit from the review via the provision of evidence on which interventions are most likely to attenuate the adverse impact of this social problem on the next generation. The review will also be of timely relevance for policy makers. An EU strategy to support Member States in reducing alcohol-related harm (CEMC 2006) outlined an aim to reduce the harm suffered by children in families with alcohol problems. The high prevalence of problem alcohol use by parents and its adverse consequences for their children (see 'Impact on children'), reinforce the importance of knowing how best to support children whose parents are problem drinkers. These children are at risk of a number of long-term consequences including alcohol and drug problems (Copello 2005; Corte 2007), mental health or behavioural problems (Copello 2005, Velleman 2007), early pregnancies (Werner 1993), difficulties forming relationships as adults (Kelley 2010), academic underachievement (Torvik 2011) and dysfunctional coping strategies (Schor 1996). To date, only a couple of reviews have investigated the effectiveness of interventions in children of problem drinkers in an attempt to understand how to prevent these long-term consequences. A review by Templeton 2010 focused on psychological interventions for families (including spouses, partners and children) affected by alcohol misuse. However, a broad review methodology was used allowing for the inclusion of randomised and quasi-randomised study designs, comparative studies (including control or cohort), other observational studies (case series, time series, before and after studies) and qualitative studies, with the results analysed using a thematic, narrative approach. Furthermore, the review considered a broad range of outcomes (any physical, psychological or other outcome) and age groups (children and adult children of alcoholics). A systematic review by Broning 2012 considered programmes for children aged 0 to 17 years from substance-affected families. In contrast to the current protocol, their review focused on substance-affected families (as opposed to alcohol-affected families only), included studies with a range of designs (randomised controlled trials (RCTs), and controlled or quasi-experimental, descriptive and qualitative studies) and had a number of date and language restrictions (the authors searched for studies over a 15-year period (1994 to 2009) that were published in English or German).

OBJECTIVES

To assess the effects of interventions for building resilience in children or young people living with parents/carers who are problem drinkers.

METHODS

Criteria for considering studies for this review

Types of studies

We will include RCTs, CCTs and prospective controlled observational studies.

Types of participants

Children and adolescents aged 4 years to 18 years and 11 months. The majority of the sample in any included study must fall within this age range and must meet the following inclusion criteria:

- have at least one primary carer (biological, step, foster, adoptive parent/carer, grandparent) who currently meets (or in the recent past met) the criteria for problem alcohol use (i.e. hazardous or harmful drinking, alcohol dependence or alcohol abuse). While diagnosis may be based on DSM or ICD criteria, in order to address the 'hidden nature' of the problem, parental drinking may have been diagnosed/assessed in a range of ways, including: by a clinician (e.g. parents who are in contact with alcohol-treatment centres); via parental self-report (e.g. Alcohol use Disorders Identification Test (AUDIT)) (Babor 2001); via child reports of parental drinking (e.g. Children of Alcoholics

Screeing Test (CAST)) (Jones 1983; Pilat 1984); or by a third party (e.g. a therapist);

- live with the parent/carer or at least have had regular contact with them (visitation) in the case of parents/carers living apart.

Types of interventions

Any face-to-face (either individual- or group-based) intervention, targeted at children (or both carers and children), designed to enhance resilience, irrespective of duration, intensity or frequency, and delivered in any setting (schools, home, community) by either professionals or non-professionals, compared with no intervention, wait-list control or standard care. We will exclude guided self-help interventions, or those delivered via the internet, compact disc or other media.

Types of outcome measures

Primary and secondary outcome measures may be child, parent or teacher self-report measures completed at the end of the intervention and at one year follow up. While a wide range of outcomes can be considered in determining resilience in children living with problem-drinking parents (see Velleman 2007), this review will focus on the following primary and secondary outcomes.

Primary outcomes

- Coping behaviours,* as measured by improvements in the child's emotion-focused strategies, problem-solving strategies and social support-seeking strategies. Examples of measures include the Coping Responses Inventory (Moos 1993; Moos 2004) and the Coping Strategies Inventory (Wills 1985)

Secondary outcomes

- Social support,* as measured by an improvement in the child's level of feeling supported (from groups or significant individuals)
- Knowledge of alcohol use,* as measured by an increase in the child's knowledge of alcohol use (e.g. information and terminology)
- Self-esteem, as measured by an improvement in the child's self-esteem scores
- Emotional or behavioural problems,* as measured by an improvement in scores on mental health measures (e.g. Strengths and Difficulties Questionnaire (Goodman 1997) and the Children's Depression Inventory (Kovacs 1985)
- Use of alcohol or drugs, or both,* as measured by the number of participants who do not initiate/become involved/or do not progress to problematic levels in their use of alcohol or drugs, or both (assessed, e.g., using the Alcohol Use Disorders Identification Test) (Babor 2001)
- Self-efficacy
- Psychological well being
- High risk behaviour
- Quality of life
- Social functioning

We will use outcomes indicated by an asterix (*) to populate the 'Summary of findings' table for the main comparison, where data permit. Where data are insufficient, we will provide a narrative account of the outcomes.

Search methods for identification of studies

Electronic searches

We will identify relevant trials from the following sources.
1. Electronic bibliographic databases:

- The Cochrane Central Register of Controlled Trials (CENTRAL, part of *The Cochrane Library*), which contains the Cochrane Drugs and Alcohol Group Specialised Register;
- MEDLINE (January 1946 to present);
- EMBASE (January 1980 to present);
- PsycINFO (2002 to present);
- Cumulative Index to Nursing and Allied Health Literature (CINAHL) (1982 to present);
- International Bibliography of Social Sciences (IBSS); Sociological Abstracts; Web of Science (ISI); Wiley Interscience; DrugScope Library; Electronic Library of the National Documentation Centre on Drug Use; National Subtance Abuse Web Index (NSAWI).

We will use no language or date restrictions in the search for trials. We will use a combination of Medical Subject Headings terms and free text terms relating to problematic alcohol use (by parents/carers). We will develop detailed search strategies for each database, accounting for differences in controlled vocabulary and syntax rules. We show the search strategy for MEDLINE in Appendix 1.
2. Electronic grey literature databases:

- Dissertation Abstracts;
- Index to Theses.

3. Targeted searches of websites:
a structured search will also be applied to the following web resources:

- Current Controlled Trials (http://www.controlled-trials.com);
- ClinicalTrials.gov (http://www.clinicaltrials.gov/);
- CentreWatch (http://www.centerwatch.com/);

- World Health Organization International Clinical Trials Registry Platform (http://www.who.int/ictrp/en/);
- U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Adminstration (http://www.samhsa.gov/);
- US National Library of Medicine Drug Information Portal (http://druginfo.nlm.nih.gov/drugportal/drugportal);
- US National Institute on Alcohol Abuse and Alcoholism (http://www.niaaa.nih.gov/);
- Australian New Zealand Clinical Trials Registry (http://www.anzctr.org.au/).

Searching other resources

We will also search conference proceedings likely to contain trials relevant to the review. References from obtained reviews and web resources will be examined to identify related resources. We will contact authors and researchers to source unpublished or incomplete studies. We will conduct a structured handsearching of relevant journals and include those not covered by *The Cochrane Library*. We will include non-English language studies in all searches and will assess all non-English abstracts for inclusion. When considered likely to meet inclusion criteria, we will translate non-English full studies.

Data collection and analysis

Selection of studies

Two review authors (AMcL, NL) will independently inspect all titles or abstracts, or both, extracted from the searches. We will discard any clearly irrelevant studies. We will resolve any disagreements in the selection of studies at the initial selection stage by discussion. We will retrieve full copies of all potentially relevant studies. Two review authors (AMcL, NL) will independently determine whether studies should be included, excluded or classified as unclear. We will resolve any differences in opinion via a reviewer team discussion.

Data extraction and management

Data will be extracted independently by two review authors (AMcL, MMcC) using a standard data extraction form. The form will include the following domains: study design and method, allocation process, participant data, intervention and outcomes. We will discuss any disagreements, which if not resolved will be referred to a third reviewer (GM). If necessary, we will seek additional information from the study authors. We will collect information on study design and implementation in a format that will enable us to populate the 'Risk of bias' tables in the completed review.

Assessment of risk of bias in included studies

Two review authors (AMcL, NL) will independently assess each study for risk of bias. We will undertake the 'Risk of bias' assessment for RCTs and CCTs in this review using criteria recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). The recommended approach for assessing risk of bias in studies included in a Cochrane Review is a two-part tool, addressing seven specific domains: 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 using a single entry for each study.

We will consider the blinding of participants, personnel and outcome assessors (avoidance of performance bias and detection bias) separately for objective outcomes (e.g. dropouts) and for subjective outcomes (e.g. social functioning as integration at school or at work, family relationships).

The criteria drawn from the Newcastle-Ottawa Scale (NOS) will be used to assess observational studies. The 'Risk of bias' tables will be operationalised to be used for the assessment of RCTs, CCTs and prospective observational studies, according to the criteria recommended by the Cochrane Drugs and Alcohol Review Group. See Appendix 2 for details.

Measures of treatment effect

We will calculate unadjusted treatment effects using Review Manager (RevMan) 2012 where possible.

Dichotomous outcome data

Dichotomous outcomes will be analysed by calculating the relative risk (RR) for each trial, with the uncertainty in each result expressed using 95% confidence intervals (CIs).

Continuous outcome data

Continuous outcomes will be analysed by calculating mean differences (MDs) if all studies use the same measurement scale, or standardised mean differences (SMDs) if studies use different measurement scales, each with 95% CIs.

Unit of analysis issues

Cluster randomised trials are possible in this area of research, as allocation to the intervention group may occur by school or community. It is recognised that cluster designs are susceptible to unit-of-analysis error and that P values may be artificially small (Higgins 2008). We anticipate that investigators will have controlled for a clustering effect when presenting their results. Where the clustering effect has not been controlled for, we will request participant data to calculate an estimate of the intracluster correlation coefficient (ICC). If participant data are not available we will search for external estimates of the ICC from similar studies.

Dealing with missing data

We will contact authors to follow up missing outcome data, missing summary data or missing study level characteristics for subgroup analyses. If standard deviations are missing from continuous data, we will scan studies for any other statistics (CIs, standard errors, T values, P values, F values) that allow for its calculation. We will describe missing data and all forms of attrition for each included study in the 'Risk of bias' table, and discuss the extent to which missing data could impact on the conclusions of the review. Missing data will be treated according to whether data is 'missing at random' or 'not missing at random'. In relation to the former, the main option will be to analyse the available data and ignore the missing data.

It is possible that missing data may not be missing at random. For example, if a participant did not experience any positive outcomes from the intervention they may be more likely to drop out of the intervention programme, or to fail to return and complete all necessary follow-up assessments. In the event that data are not missing at random, we will use replacement values to impute the missing data. When imputing missing dichotomous data, we will assume that missing data are negative (e.g. the participant demonstrated high risk behaviour). When imputing missing continuous data, we will use a 'last observation carried forward' approach.

Some relevant studies may fail to provide summary data (e.g. standard deviations). Where this occurs we will, if possible, obtain these data using calculations provided in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Assessment of heterogeneity

We will examine clinical heterogeneity by inspecting each included study for variability in the participants, interventions or outcomes described. If unexpected variability arises, we will discuss this in full in the review. Methodological heterogeneity will be examined by inspecting each included study for variability in the study design and risk of bias. If any unexpected variability arises, we will discuss this in full in the review. We will assess statistical heterogeneity using the Chi^2 test and its P value, by visual inspection of the forest plots and the I^2 statistic. A P value of the test lower than 0.10 or an I^2 statistic of at least 50% will indicate significant statistical heterogeneity.

Assessment of reporting biases

We will use funnel plots (plots of the effect estimate from each study against the sample size or effect standard error) to indicate possible publication bias. We acknowledge that asymmetry in the plot could be due to publication bias, but this can also reflect a real relationship between trial size and effect. We will use tests for funnel plot symmetry only when at least 10 studies are included in the meta-analysis, as a smaller number of studies will render the power of the tests too low to distinguish chance from real asymmetry.

Data synthesis

Regression analyses will be run using Stata (StataCorp 2013) and imported into Review Manager (RevMan) 2012. The outcome measures from the individual trials will be combined through meta-analysis where possible. We plan to synthesise results from studies using an RCT design in a meta-analysis where the interventions are similar with regard to: i) method of delivery (individually/groups); ii) setting (school-, home- or community-based); and iii) intensity, frequency and duration of the programme. We will perform a random-effects meta-analysis using an inverse variance weighting method using Review Manager (RevMan) 2012 as we expect a certain level of heterogeneity among the included studies. We will perform both fixed-effect and random-effects analyses as part of our sensitivity analyses. If some primary studies report an outcome as a dichotomous measure and others use a continuous measure of the same construct, we will convert results for the former from an odds ratio to a SMD, provided that we can assume that the underlying continuous measure has approximately a normal or logistic distribution (otherwise we will carry out two separate analyses). If meta-analysis is not appropriate, we will report results from individual studies. We will provide narrative summaries of the non-randomised studies (NRS).

Subgroup analysis and investigation of heterogeneity

We will explore heterogeneous results by conducting the following subgroup analyses:

- participant stage of development (i.e. children (aged 4 years to 12 years and 11 months) and adolescents (aged 13 years to 18 years and 11 months);
- gender of child/young person;
- gender of parent/carer;
- child living with parent/carer OR child living away from parent/carer/currently in care;
- severity of parental drinking.

We will carry out subgroup analyses only if 10 or more studies are retrieved during the data collection process, as it is unlikely

that the investigation of heterogeneity will produce useful findings unless there is a substantial number of studies (Higgins 2008).

Sensitivity analysis

If more than 10 studies are included in the analysis we will perform sensitivity analyses. To incorporate quality assessment in the review process we will first plot intervention effect estimates stratified for risk of bias for each relevant domain. If differences in results are present among studies at different risk of bias, we will then perform a sensitivity analysis, excluding from the analysis studies with a high risk of bias. We will perform subgroup analyses for studies with low and unclear risks of bias.

We will also perform both fixed-effect and random-effects analyses as part of our sensitivity analyses.

We will also perform sensitivity analyses by re-analysing the data without imputing data for the missing participants, and by re-analysing the data imputing data for the missing participants assuming they experienced a positive outcome.

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REFERENCES

Additional references

Babor 2001
Babor TF, Higgins-Biddle JC, Saunders JB, Monteiro MG. *AUDIT the Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Care*. 2nd Edition. Geneva: World Health Organization, 2001.

Balsa 2009
Balsa A, Homer JF, French MT. The health effects of parental problem drinking on adult children. *Journal of Mental Health Policy and Economics* 2009;**12**(2):55–66.

Bandura 1977
Bandura A. *Social Learning Theory*. Englewood Cliffs: Prentice-Hall, 1977.

Bandura 1986
Bandura A. *Social Foundations of Thought and Action: A Social Cognitive Theory*. Englewood Cliffs, NJ: Prentice-Hall, 1986.

Broning 2012
Bröning S, Wiedow A, Wartberg L, Ruths S, Haevelmann A, Kindermann SS, et al.Targeting children of substance-using parents with the community-based group intervention TRAMPOLINE: a randomised controlled trial - design, evaluation, recruitment issues. *BMC Public Health* 2012; **12**:223.

CEMC 2006
Commission of the European Communities. *An EU strategy to support Member States in reducing alcohol related harm*. Brussels: Commission of the European Communities, 2006.

Chalder 2006
Chalder M, Elgar FJ, Bennett P. Drinking and motivations to drink among adolescent children of parents with alcohol problems. *Alcohol and Alcoholism* 2006;**41**(1):107–13.

Chassin 1999
Chassin L, Pitts SC, DeLucia C, Todd M. A longitudinal study of children of alcoholics: predicting young adult substance use disorders, anxiety, and depression. *Journal of Abnormal Psychology* 1999;**108**:106–19.

Christensen 2000
Christensen HB, Bilenberg N. Behavioural and emotional problems in children of alcoholic mothers and fathers. *European Child & Adolescent Psychiatry* 2000;**9**(3):219–26.

Colder 1997
Colder CR, Chassin L, Stice EM, Curran PJ. Alcohol expectancies as potential mediators of parent alcoholism effects on the development of adolescent heavy drinking. *Journal of Research on Adolescence* 1997;**7**(4):349–74.

Copello 2000a
Copello A, Templeton L, Krishnan M, Orford J, Velleman RA. A treatment package to improve primary care services for the relatives of people with alcohol and drug problems. *Addiction Research* 2000;**8**:471–84.

Copello 2000b
Copello A, Orford J, Velleman R, Templeton L, Krishnan M. Methods for reducing alcohol and drug related family harm in non-specialist settings. *Journal of Mental Health* 2000;**9**:329–43.

Copello 2005
Copello AG, Velleman RDB, Templeton LJ. Family interventions in the treatment of alcohol and drug problems. *Drug and Alcohol Review* 2005;**24**:369–85.

Copello 2010
Copello A, Templeton L, Orford J, Velleman R. The 5-Step Method: principles and practice. *Drugs: Education, Prevention and Policy* 2010;**17**(Suppl 1):86–99.

Corte 2007
Corte C, Becherer M. Differential effects of maternal and paternal alcoholism and gender on drinking, alcohol-related self-cognition and psychopathology. *Journal of Addictions Nursing* 2007;**18**(4):175–85.

Cuijpers 2005
Cuijpers P. Prevention programmes for children of problem drinkers: a review. *Drugs: Education, Prevention and Policy* 2005;**12**(6):465–75.

Dawe 2007
Dawe S, Frye S, Best D, Moss D, Atkinson J, Evans C, et al.*Drug use in the family: Impacts and implications for children*. Canberra, ACT: Australian National Council on Drugs, 2007.

DSM-5
American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. *Diagnostic and Statistical Manual of Mental Disorders*. 5th Edition. Arlington, VA: American Psychiatric Association, 2013.

DSM-IV-TR
American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders Text Revision*. 4th Edition. Washington DC: American Psychiatric Association, 2000.

Emshoff 1999
Emshoff JG, Price AW. Prevention and intervention strategies with children of alcoholics. *Pediatrics* 1999;**103**(5):1112–21.

Eurocare 2012
Eurocare. European Alcohol Policy Alliance. *Eurocare recommendations for a future EU strategy*. Brussels, Belgium: Eurocare. European Alcohol Policy Alliance, 2012.

Gance-Cleveland 2008
Gance-Cleveland B, Mays MZ. School-based support groups for adolescents with a substance-abusing parent. *Journal of the American Psychiatric Nurses Association* 2008;**14**(4):297–309.

Garmezy 1984
Garmezy N, Masten AS, Tellegen A. The study of stress and competence in children: a building block for developmental psychopathology. *Child Development* 1984;**55**(1):97–111.

Goodman 1997
Goodman R. The Strengths and Difficulties Questionnaire: a research note. *Journal of Child Psychology and Psychiatry, and Allied Disciplines* 1997;**38**(5):581–6.

Higgins 2008
Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.2 [updated September 2009]. The Cochrane Collaboration, 2009. Available from www.cochrane-handbook.org.

Higgins 2011
Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Jones 1983
Jones JW. *Children of Alcoholics Screening Test (CAST)*. Chicago, Ill: Camelot Unlimited, 1983.

Keller 2005
Keller PS, Cummings EM, Davies PT. The role of marital discord and parenting in relations between parental problem drinking and child adjustment. *Journal of Child Psychology and Psychiatry, and Allied Disciplines* 2005;**46**(9):943–51.

Keller 2008
Keller PS, Cummings EM, Davies PT, Mitchell PM. Longitudinal relations between parental drinking problems, family functioning and child adjustment. *Development and Psychopathology* 2008;**20**:195–212.

Kelley 2010
Kelley ML, Schroeder VM, Cooke CG, Gumienny L, Platter AJ, Fals-Stewart W. Mothers' versus fathers' alcohol abuse and attachment in adult daughters of alcoholics. *Journal of Family Issues* 2010;**31**(11):1555–70.

Kovacs 1985
Kovacs M. The Children's Depression Inventory (CDI). *Psychopharmacology Bulletin* 1985;**21**:995–9.

Luthar 2000
Luthar SS, Cicchetti D, Becker B. The Construct of Resilience: A Critical Evaluation and Guidelines for Future Work. *Child Development* 2000;**71**(3):543–62.

Luthar 2003
Luthar SS. *Resilience and Vulnerability: Adaption in the Context of Childhood Adversities*. New York: Cambridge University Press, 2003.

Manning 2009
Manning V, Best DW, Faulker N, Titherington E. New estimates of the number of children living with substance misusing parents: results from UK national household surveys. *BMC Public Health* 2009;**9**:377.

Masten 2002
Masten AS, Reed MJ. Resilience in development. *Handbook of Positive Psychology*. New York: Oxford University Press, 2002:74–88.

McCabe 1999
McCabe KM, Clark R, Barnett D. Family protective factors among urban African American youth. *Journal of Clinical Child Psychology* 1999;**28**(2):137–50.

Moos 1993
Moos R. *Coping Responses Inventory Youth Form: Professional Manual*. Odessa, FL: Psychological Assessment Resources, 1993.

Moos 2004
Moos RH. *Coping responses inventory: An update on research applications and validity (manual supplement)*. Odessa, FL: Psychological Assessment Resources, 2004.

NACD 2011
National Advisory Committee on Drugs. *Parental Substance Misuse: Addressing its Impact on Children. A Review of the Literature*. Dublin: NACD, 2011.

Obot 2004
Obot IS, Anthony JC. 'Mental health problems in adolescent children of alcohol dependent parents: Epidemiologic research with a nationally representative sample'. *Journal of Child & Adolescent Substance Abuse* 2004;**13**:83–96.

Orford 1990
Orford J, Velleman R. Offspring of parents with drinking problems: drinking and drug-taking as young adults. *British Journal of Addiction* 1990;**85**(6):779–94.

Orford 1998
Orford J. The coping perspective. In: Velleman R, Copello A, Maslin J editor(s). *Living with Drink: Women Who Live with Problem Drinkers*. London: Longman, 1998.

Orford 2003
Orford J, Krishnan M, Velleman R. Young adult offspring of parents with drinking problems: a study of childhood family cohesion using simple family diagrams. *Journal of Substance Use* 2003;**8**(3):139–49.

Orford 2005
Orford J, Natera G, Copello A, Atkinson C, Tiburcio M, Velleman R, et al.*Coping with alcohol and drug problems: the experiences of family members in three contrasting cultures*. London: Taylor & Francis, 2005.

Passon 2009
Passon AM, Santos S, Lüngen M. *Children Affected by Parental Alcohol Problems (ChAPAPs). Evaluation of Direct Preventive Interventions with Children of Alcoholics*. Cologne: Institut für Gesundheitsökonomie und Klinische Epidemiologie, Uniklinik Koln, 2009.

Percy 2008
Percy A, Thornton M, McCrystal P. The extent and nature of family alcohol and drug use: findings from the Belfast Youth Development Study. *Child Abuse Review* 2008;**17**: 371–86.

Pilat 1984
Pilat JM, Jones JW. Identification of children of alcoholics: two empirical studies. *Alcohol, Health and Research World* 1984;**9**:27-33.

Powis 2000
Powis B, Gossop M, Bury C, Payne K, Griffiths P. Drug-using mothers: social, psychological and substance use problems of women opiate users with children. *Drug and Alcohol Review* 2000;**19**:171–80.

Rangarajan 2008
Rangarajan S. Mediators and moderators of parental alcoholism effects on off-spring self-esteem. *Alcohol and Alcoholism* 2008;**43**(4):481–91.

Review Manager (RevMan) 2012
Review Manager (Revman). Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2012.

Rutter 1979
Rutter M. Protective factors in children's responses to stress and disadvantage. In: Kent MW, Rolf JE editor(s). *Primary Prevention in Psychopathology*. Vol. **3: Social competence in children**, Hanover, NH: University Press of New England, 1979:49–74.

Rutter 1987
Rutter M. Psychological resilience and protective mechanisms. *American Journal of Orthopsychiatry* 1987;**57** (3):316–31.

Rutter 2006
Rutter M. Implications of resilience concepts for scientific understanding. *Annals of the New York Academy of Sciences* 2006;**1094**:1–12.

Rutter 2008
Rutter M. Developing concepts in developmental psychopathology. In: Hudziak JJ editor(s). *Developmental Psychopathology and Wellness: Genetic and Environmental Influences*. Washington, DC: American Psychiatric Publishing, 2008:3-22.

SAMHSA 2012
Substance Abuse and Mental Health Services Administration. More than 7 million children live with a parent with alcohol problems. http://www.samhsa.gov/data/spotlight/Spot061ChildrenOfAlcoholics2012.pdf 2012 (accessed 4 July 2014).

Schor 1996
Schor EL. Adolescent alcohol use: social determinants and the case for early family-centred prevention. Family-focused prevention of adolescent drinking. *Bulletin of the New York Academy of Medicine* 1996;**73**(2):335–56.

Sher 1991
Sher KJ, Walitzer KS, Wood PK, Brent EE. Characteristics of children of alcoholics: putative risk factors, substance use and abuse and psychopathology. *Journal of Abnormal Psychology* 1991;**100**(4):427–48.

StataCorp 2013
StataCorp. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP, 2013.

Templeton 2010
Templeton L, Velleman R, Russell C. Psychological interventions with families of alcohol misusers: a systematic review. *Addiction Research & Theory* 2010;**18**(6):616–48.

Torvik 2011
Torvik FA, Rognmo K, Ask H, Roysamb E, Tambs K. Parental alcohol use and adolescent school adjustment in the general population: results from the HUNT study. *BMC Public Health* 2011;**11**:706.

Velleman 1990
Velleman R, Orford J. Young adult offspring of parents with drinking problems: Recollections of parents' drinking and its immediate effects. *British Journal of Clinical Psychology* 1990;**29**:297–317.

Velleman 1992a
Velleman R. Intergenerational effects- a review of environmentally oriented studies concerning the relationship between parental alcohol problems and family disharmony in the genesis of alcohol and other problems.

I: The intergenerational effects of alcohol problems. *The International Journal of the Addictions* 1992a;**27**(3):253–80.

Velleman 1992b
Velleman R. Intergenerational effects- a review of environmentally oriented studies concerning the relationship between parental alcohol problems and family disharmony in the genesis of alcohol and other problems. II: The intergenerational effects of family disharmony. *The International Journal of the Addictions* 1992b;**27**(4):367–89.

Velleman 1993a
Velleman R, Orford J. The importance of family discord in explaining childhood problems in the children of problem drinkers. *Addiction Research and Theory* 1993a;**1**:39–57.

Velleman 1993b
Velleman R, Orford J. The adult adjustment of offspring of parents with drinking problems. *British Journal of Psychiatry* 1993b;**162**:503–16.

Velleman 1999
Velleman R, Orford J. *Risk and Resilience: Adults who were the children of problem drinkers*. Oxon: Routledge, 1999.

Velleman 2003
Velleman R, Templeton L. Alcohol, drugs and the family: results from a long running research programme within the UK. *European Addiction Research* 2003;**9**:103–12.

Velleman 2004
Velleman R. Alcohol and drug problems in parents: an overview of the impact on children and implications for practice.. In: M Gopfert, J Webster, M Seeman editor (s). *Seriously Disturbed and Mentally Ill Parents and their Children*. Cambridge: Cambridge University Press, 2004.

Velleman 2007
Velleman R, Templeton L. Understanding and modifying the impact of parents' substance misuse on children. *Advances in Psychiatric Treatment* 2007;**13**:79–89.

Werner 1982
Werner EE, Smith R. *Vulnerable but invincible: a study of resilient children*. New York: McGraw-Hill, 1982.

Werner 1986
Werner EE. Resilient offspring of alcoholics: a longitudinal study from birth to age 18. *Journal of Studies on Alcohol* 1986;**47**(1):34–40.

Werner 1992
Werner EE, Smith RS. *Overcoming the Odds: High Risk Children from Birth to Adulthood*. Ithaca, NY: Cornell University Press, 1992.

Werner 1993
Werner E. Risk, resilience and recovery. Perspectives from the Kauai Longitudinal Study. *Development and Psychopathology* 1993;**5**:503–15.

Werner 2001
Werner EE, Smith RS. *Journeys from Childhood to Midlife: Risk, Resilience, and Recovery*. Ithaca, NY: Cornell University Press, 2001.

Werner 2004
Werner EE, Johnson JL. The role of caring adults in the lives of children of alcoholics. *Substance Use & Misuse* 2004; **39**(5):699–720.

WHO 2010
World Health Organisation. *International Statistical Classification of Diseases and Related Health Problems*. 10th Edition. Geneva, Switzerland: World Health Organization, 2010.

Wills 1985
Wills TA. Stress, coping and tobacco and alcohol use in early adolescence. In: Shiffman S, Willis TA editor(s). *Coping and Substance Use*. New York: Academic Press, 1985:67–94.

* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy - OVID platform

1. exp Alcohol-Related Disorders/
2. Alcohol Drinking/
3. (alcohol adj3 (drink$ or intoxicat$ or use$ or abus$ or misus$ or risk$ or consum$ or withdraw$ or detox$ or treat$ or therap$ or excess$ or reduc$ or cessation or intervention$)).ti,ab
4. (drink$ adj3 (excess or heavy or heavily or harm or harmful or hazard$ or binge or harmful or problem$)).ti,ab
5. 1 or 2 or 3 or 4
6. (drink$ adj5 (carer$ or care-giver$ or caregiver$ or father$ or famil$ or fosterparent$ or grandparent$ or grand-parent$ or grandmother$ or grand-mother$ or grandfather$ or grand-father$ or maternal$ or mother$ or parent$ or paternal$ or stepfather$ or step-father$ or stepmother$ or step-mother$)).tw.

7. (alcohol$ adj5 (carer$ or care-giver$ or caregiver$ or father$ or famil$ or fosterparent$ or grandparent$ or grand-parent$ or grandmother$ or grand-mother$ or grandfather$ or grand-father$ or maternal$ or mother$ or parent$ or paternal$ or stepfather$ or step-father$ or stepmother$ or step-mother$)).tw.
8. (substance$ adj5 (carer$ or care-giver$ or caregiver$ or father$ or famil$ or fosterparent$ or grandparent$ or grand-parent$ or grandmother$ or grand-mother$ or grandfather$ or grand-father$ or maternal$ or mother$ or parent$ or paternal$ or stepfather$ or step-father$ or stepmother$ or step-mother$)).tw.
9. 6 or 7 or 8
10. 5 and 9
11. exp parents/ or single parent/
12. family/ or exp family relations/
13. Caregivers/
14. 11 or 12 or 13
15. 5 and 14
16. 10 or 15
17. adolescent/ or exp child/
18. (child$ or preschool$ or pre-school$ or teen$ or preteen$ or pre-teen$ or adolescen$ or student$ or boy$ or girl$ or young people$ or youth$).tw.
19. "Child of Impaired Parents"/
20. 17 or 18 or 19
21. 16 and 20
22. exp Psychotherapy/
23. exp Adaptation, Psychological/
24. (psychologic$ adj (adjust$ or adapt$)).tw.
25. exp Motivation/
26. exp Relaxation Therapy/
27. Social Support/
28. (social adj (support or network$)).tw.
29. (support adj2 group).tw.
30. ((coping or social or training) adj2 skill$).tw.
31. (behav$ adj (therap$ or intervention$)).tw.
32. (advice or cope or copes or coping or counsel$ or or motivation$ or psychotherapy$ or psychosocial$).tw.
33. or/22-32
34. 21 and 33

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

Item	Judgement	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 Observational prospective study

(*Continued*)

	Unclear risk	Insufficient information to permit 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 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 nonopaque 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 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
4. Blinding of participants and providers (performance bias) Subjective outcomes	Low risk	Blinding of participants and providers, 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 to permit 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 Record linkage
6. Blinding of outcome assessor (detection bias) 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

(*Continued*)

	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 dropouts	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 standardised 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 randomised participants are reported/analysed in the group they were allocated to by randomisation, irrespective of non-compliance and cointerventions (intention to treat)
	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 standardised 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 randomisation
	Unclear risk	Insufficient information to permit judgement of low or high risk (e.g. number randomised not stated, no reasons for missing data provided; number of dropouts not reported for each group)
8. Selective reporting (reporting bias)	Low risk	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 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)

(*Continued*)

	High risk	Not all of the study's prespecified primary outcomes have been reported One or more primary outcomes is/are reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not prespecified One or more reported primary outcomes were not prespecified (unless clear justification for their reporting is provided, such as an unexpected adverse effect) One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis The study report fails to include results for a key outcome that would be expected to have been reported for such a study
	Unclear risk	Insufficient information to permit judgement of 'yes' or 'no'
9. Free of other bias: comparability of cohorts for baseline characteristics and outcome measures on the basis of the design or analysis	Low risk	Exposed and non-exposed individuals were matched in the design for most important confounding factors Authors demonstrated balance between group for the confounders Analysis are adjusted for most important confounding factors and imbalance Randomised controlled trial
	High risk	No matching or no adjustment for most important confounding factor
	Unclear risk	No information about comparability of cohort
10. 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 derivation of the non-exposed cohort
11. Free of other bias: protection against contamination	Low risk	Allocation was by community, institution or practice and it is unlikely that the control group received the intervention
	High risk	It is likely that the control group received the intervention
	Unclear risk	It is possible that communication between intervention and control groups could have occurred
10. 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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None known.

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