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Alcoholics Anonymous and other 12-step programs for alcohol use disorder

Cochrane Systematic Review - **Intervention - Protocol** | Version published: 21 November 2017

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Abstract

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

The primary objective of this review is to evaluate the efficacy of Alcoholics Anonymous mutual help groups, operated by peers, and TSF interventions, operated by professionals. Both will be evaluated relative to other interventions for AUD by examining their effects on abstinence, drinking intensity, and drinking-related consequences. The secondary objective is to examine the healthcare utilization cost impact of Alcoholics Anonymous attendance and of TSF.

In this review, Alcoholics Anonymous attendance and TSFs will be compared with the following interventions.

1) Other clinical interventions (e.g. motivational enhancement therapy (MET), cognitive-behavioral therapies (CBT), etc.).

2) Other 12-step program variants (e.g. studies comparing different types of 12-step interventions).

3) No treatment (e.g. wait list control).

Background

Description of the condition

Alcohol use disorder (AUD) confers a prodigious burden of disease, disability, and premature mortality, particularly in high-income countries (Stahre 2014). With 3.3 million attributable deaths each year globally, alcohol is responsible for approximately 10 times the mortality rate for all illicit drugs combined, as well as 5.1% of the total global burden of disease (WHO 2014). Alcohol misuse is the leading risk factor for death and disability among 15- to 19-year-olds worldwide (Lim 2012) and, on average, moderate-to-severe AUD shortens the life-span by 20 to 30 years (Rosenbaum 2015). The financial burden associated with alcohol misuse is also staggering - amounting to approximately USD 250 billion annually in the USA due to lost productivity, criminal justice, and healthcare costs (Sacks 2015). The response to these problems is multipronged, and includes a broad array of specific professional treatment services in diverse settings. In addition, a number of low-cost or free recovery support services have emerged to prevent relapse and aid recovery (e.g. mutual-help organizations, sober living environments). The oldest and by far the largest of these AUD recovery supports is Alcoholics Anonymous (AA).

Description of the intervention

Consisting of more than 5 million members in 181 countries (Humphreys 2004), Alcoholics Anonymous is a worldwide nonprofessional, peer-to-peer support organization intended to help those suffering from AUD achieve abstinence from alcohol, facilitate full remission, and increase quality of life (AA 2001). In many world regions, Alcoholics Anonymous is widely accessed. In North America, for example, it is the most commonly sought source of help for AUD (Caetano 1998; Room 2006; Hedden 2015). As such, Alcoholics Anonymous is part of the de facto system of care for AUD. Given that AUD is highly prevalent worldwide, especially in middle- and high-income countries, and is susceptible to relapse and reinstatement over the long term, the free and widespread availability of Alcoholics Anonymous means that the organization has the potential to serve as an easily accessible long-term recovery management service. Alcoholics Anonymous holds meetings in local community, rented accommodations (e.g. churches, hospitals, community centers, colleges). Group meetings typically last 60 to 90 minutes during which members share stories of their alcohol addiction and recovery experiences, and help one another practice the principles encompassed in a 12-step program that is intended to increase psychological well-being and the ability to cope successfully with the adaptation to abstinence and a sober lifestyle. The freely available nature and widespread adoption of Alcoholics Anonymous has drawn increasing efforts to rigorously evaluate its clinical and public health impact.

In addition to Alcoholics Anonymous community groups, researchers have also evaluated clinical interventions that have adapted the methodology and concepts of Alcoholics Anonymous. These '12-step facilitation' (TSF) interventions include extended counselling, adopting some of the techniques and principles of Alcoholics Anonymous, as well as brief interventions designed to link individuals to community Alcoholics Anonymous groups (Humphreys 1999). TSF interventions have been studied to determine whether they succeed at linking individuals with this free community resource and whether this in turn results in better alcohol-related and other outcomes (Ducharme 2006; Mann 2006a; Mann 2006b; Kelly 2013a; Kelly 2017; Knudsen 2016).

How the intervention might work

The intervention is purported to work via its social fellowship and its 12-step program (AA 2001). The social components operate through peer support and role modeling of successful AUD recovery, and through providing close mentoring and recovery management oversight through 'sponsorship'. As is the case in some forms of group psychotherapy theory (Yalom 2008), the common suffering of Alcoholics Anonymous group members may provide a sense of belonging or universality that can help to diminish stigma, shame, and guilt. Further, observations of successful recovery can instill hope and enhance a positive psychological future orientation. Members are strongly encouraged to obtain a sponsor who is well established in sobriety and who can offer guidance, daily support, and accountability to help new members stay sober. The 12-step program is intended to facilitate the internal psychological, emotional, and spiritual changes deemed necessary to sustain abstinence and lead to enhanced psychological well-being that can compete with the more immediate rewards provided by alcohol use (AA 2001; Kelly 2013b). Despite having an ostensibly 'spiritual' emphasis and orientation, rigorous reviews of the mechanisms of behavior change through which Alcoholics Anonymous enhances recovery have found that Alcoholics Anonymous typically confers benefits by mobilizing multiple therapeutic factors simultaneously, mostly through facilitating adaptive changes in the social networks of participants and by boosting members' recovery coping skills, recovery motivation, abstinence self-efficacy, and psychological well-being, and by reducing impulsivity and craving (Kelly 2009; Kelly 2017). Spiritual factors are considered central to Alcoholics Anonymous by a minority of participants (Humphreys 2004).

Why it is important to do this review

Because Alcoholics Anonymous is not controlled or standardized by professionals, it has historically been harder to study than professionally designed and delivered treatments for which manuals are written, doses can be randomly assigned, and length of contact can be standardized and predetermined (Humphreys 2004; Kelly 2017). However, over the past two decades, Alcoholics Anonymous researchers have become increasingly sophisticated at finding methods to study Alcoholics Anonymous in a rigorous fashion. Reviews of this research have been conducted, including a prior Cochrane Review (Ferri 2006a; Ferri 2006b; Kaskutas

2009; Kelly 2009), but a flurry of additional empirical investigations since these reviews were conducted signifies a need for major update. Consequently, an additional rigorous, high-quality systematic review is needed that includes more recent studies to inform the field of the clinical and public health utility, and effectiveness and cost-effectiveness of, AA and TSF. Consequently, this review updates and supercedes the previously conducted Cochrane Review, on which one of the present coauthors participated (Ferri 2006b).

Objectives

The primary objective of this review is to evaluate the efficacy of Alcoholics Anonymous mutual help groups, operated by peers, and TSF interventions, operated by professionals. Both will be evaluated relative to other interventions for AUD by examining their effects on abstinence, drinking intensity, and drinking-related consequences. The secondary objective is to examine the healthcare utilization cost impact of Alcoholics Anonymous attendance and of TSF.

In this review, Alcoholics Anonymous attendance and TSFs will be compared with the following interventions.

1) Other clinical interventions (e.g. motivational enhancement therapy (MET), cognitive-behavioral therapies (CBT), etc.).

2) Other 12-step program variants (e.g. studies comparing different types of 12-step interventions).

3) No treatment (e.g. wait list control).

Methods

Criteria for considering studies for this review

Types of studies

We will include randomized controlled trials (RCTs) and quasi-experimental studies that compare Alcoholics Anonymous or treatments designed to facilitate engagement in Alcoholics Anonymous with other interventions such as MET or CBT, 12-step program variants, or no treatment. Given the potential healthcare cost savings of using freely available community-based recovery resources such as Alcoholics Anonymous and TSF/12-step treatments, we will consider cost-effectiveness studies that use controlled clinical trial (CCT), quasi-experimental, or observational designs as well as RCTs.

Types of participants

We will include adults (18 years or older) with AUD, alcohol abuse, or alcohol dependence, as defined using commonly used standardized criteria (i.e. the *Diagnostic and Statistical Manual of Mental Disorders*, 4th and 5th editions (APA 1994; APA 2013); the 9th and 10th revisions of the *International Statistical Classification of Diseases and Related Health Problems* (WHO 2010); validated screening or diagnostic tools), attending Alcoholics Anonymous meetings and/or participating in TSF/12-step treatments. We will exclude studies involving participants coerced to attend Alcoholics Anonymous meetings by legal order.

Types of interventions

Experimental interventions will include Alcoholics Anonymous participation and TSF. Control interventions will include other psychological clinical interventions (e.g. MET, CBT, etc.), other 12-step program variants (e.g. studies comparing different 12-step interventions), and no treatment (e.g. wait list control).

Types of outcome measures

We will describe variations in outcome measures of the same domain (e.g. in the time window assessed) in the narrative, as appropriate, along with any potential limitations to inferences and generalizability that may result from such variation.

Primary outcomes

1) Abstinence, as measured by: proportion of individuals who are continuously abstinent; longest period of abstinence; and percent days abstinent (PDA)

2) Drinking intensity, as measured by: percent days of heavy drinking and grams of pure alcohol consumed

3) Alcohol-related consequences, as measured by: self-reports of physical, social, and psychological sequelae resulting from alcohol use (e.g. Drinker Inventory of Consequences (Miller 1995), Short Inventory of Problems (Miller 1995), or similar measures)

The above-mentioned outcomes will be measured through self-report and, when available and appropriate, confirmed via bioassay.

Secondary outcomes

1) Healthcare cost offsets, as measured by: changes in addiction and mental health-related service utilization and related monetary impacts

2) Indices reflecting quality of life and/or psychological well-being

Search methods for identification of studies

We will impose no language, publication year or publication status restrictions.

Electronic searches

We will identify published, unpublished, and ongoing studies by searching the following databases from their inception.

- Cochrane Drugs and Alcohol Group Specialised Register.
- Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library.
- MEDLINE PubMed (from 1946 onwards).
- Embase Ovid (from 1974 onwards).
- CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature; from 1982 onwards).
- PsycINFO (from 1880s onwards).

We will model the subject strategies for databases on the search strategy designed for CENTRAL (Appendix 1).

We will search the following trial registries.

- World Health Organization International Clinical Trials Registry Platform (www.who.int/trialsearch).
- ClinicalTrials.gov (www.clinicaltrials.gov).

We will also search the above databases for health economics evidence.

Searching other resources

We will attempt to identify other potentially eligible studies by searching the reference lists of retrieved included studies, systematic reviews, and meta-analyses.

Data collection and analysis

Selection of studies

Two review authors (JK, KH) will independently scan the abstract, title, or both, of every record retrieved to determine which studies should be further evaluated for inclusion. We will investigate all potentially relevant articles as full text, and resolve any discrepancies between the two review authors through consultation and discussion with the third author (MF). We will add studies that remain questionable for review inclusion even after discussion among the authors to the list of articles awaiting assessment. We will contact study authors for clarification when necessary. We will delineate the study selection process in a PRISMA flow chart (Liberati 2009; Moher 2009).

Data extraction and management

Using a standardized data extraction form, two authors (JK and KH) will independently abstract the relevant elements of the study, including study design, sample characteristics, description of the experimental and control interventions, outcomes, study funding, and conflicts of interest. Any disagreements regarding these details will be resolved among all review authors by discussion. We will contact study authors for clarification when necessary.

Assessment of risk of bias in included studies

Two review authors (JK and MF) will independently assess the risk of bias in the included studies using the criteria recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). The recommended approach for assessing risk of bias in studies comprises the assessment of seven domains: sequence generation, 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 assessment process involves describing what was reported to have happened in the study. The second part involves assigning a judgment relating to the risk of bias for that entry, in terms of low, high, or unclear risk. To make these judgments we will use the criteria indicated by the *Cochrane Handbook for Systematic Reviews of Interventions* adapted to the addiction field (Higgins 2011b) (see Appendix 2 for details).

We will address the domains of sequence generation and allocation concealment (avoidance of selection bias) using a single entry for each study.

We will consider the blinding of participants, personnel, and outcome assessor (avoidance of performance bias and detection bias) separately for objective outcomes (e.g. drop out from treatment, use of substance measured by urinalysis, participants relapsed at the end of follow-up, participants engaged in further treatments) and subjective outcomes (e.g. duration and severity of signs and symptoms of withdrawal, participant self-reported use of substance, side effects, social functioning as integration at school or at work, family relationship).

We will consider incomplete outcome data (while also taking due note of any observed attrition bias) for all outcomes except for drop-out from treatment, which is very often the primary outcome measure in trials on addiction.

We will operationalize 'Risk of bias' tables 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).

We will evaluate any cost-effectiveness studies using the appropriate Cochrane 'Risk of bias' criteria, according to the specific design of each study (e.g. if the cost-effectiveness study is conducted using an RCT or CCT design, then we will use the appropriate 'Risk of bias' criteria).

Measures of treatment effect

Where applicable, we will calculate the standardized mean difference for continuous variables (e.g. percent days abstinent) or the relative risk for dichotomous variables (e.g. proportion of participants completely abstinent) with the uncertainty of the estimate expressed using 95% confidence intervals. If the degree of heterogeneity across studies is such that it precludes us from conducting a meta-analysis, we will describe the findings and effects using a narrative review. Where applicable (e.g. in multiarm studies), we will report outcomes separately.

Unit of analysis issues

If we include multiarm studies, wherein there are more than two intervention conditions being compared, we will combine all the relevant experimental groups into a single group where appropriate and compare this with the control group to avoid double-counting participants in the control groups.

Dealing with missing data

All the review authors will appraise the presence and impact of missing data on study findings and detail in the narrative as appropriate. If necessary, we will contact the original study authors to attempt to obtain any missing data and information on their potential impact.

Assessment of heterogeneity

We will analyse heterogeneity by means of the I^2 statistic and the Chi^2 test. We will regard heterogeneity as substantial if the I^2 statistic is greater than 50% or the P value lower than 0.10 for the Chi^2 test for heterogeneity. Following the guidance in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) we will consider the following values to denote no important, moderate, substantial, or

considerable heterogeneity, respectively: 0% to 40%, 30% to 60%, 50% to 90%, and 75% to 100%. If we find considerable levels of heterogeneity (i.e. ≥ 75%), we will explore possible reasons by visually inspecting the forest plot to identify studies that might be contributing to heterogeneity.

Assessment of reporting biases

We will report whether studies obtained ethical approval, or were registered, or both, where applicable (e.g. for RCTs). We will obtain and extract the registered outcomes and compare them with the reported outcomes to assess reporting bias. We also will visually inspect funnel plots (plots of the effect estimate from each study against the sample size or effect standard error) to identify possible publication bias. We acknowledge that the funnel plot should be seen as a generic means of displaying small-study effects (the tendency for the intervention effects estimated in smaller studies to differ from those estimated in larger studies, so that asymmetry could be due to publication bias), but small-study effects may be due to reasons other than publication bias, such as a greater risk of bias in smaller studies, and the inclusion of a more-restricted and thus more-responsive population, or merely due to the role of chance. We will inspect funnel plot symmetry when there are at least 10 studies included in a meta-analysis.

Data synthesis

We will combine the outcomes from individual trials through meta-analysis where possible (comparability of intervention and outcomes between trials) using a random-effects model because we expect a certain degree of heterogeneity among trials.

As detailed in the *Cochrane Handbook for Systematic Reviews of Interventions* (section 15.6.3; Higgins 2011c) there is currently no consensus regarding the appropriate methods for pooling combined estimates of cost-effectiveness studies, as well as potential issues concerning the validity of such methods when combining metrics across cost-effectiveness studies. For these reasons, rather than conduct a meta-analysis, we plan to summarize results from any cost-effectiveness studies in the narrative.

Subgroup analysis and investigation of heterogeneity

We will perform subgroup analyses according to AUD severity, where appropriate (e.g. according to the DSM IV criteria 'abuse' versus 'dependence').

Sensitivity analysis

We will perform sensitivity analyses to assess the robustness of the results, including examining how the pattern of findings is affected by excluding studies at high risk of selection or attrition bias. We will also conduct sensitivity analyses across types of study designs, as appropriate (e.g. RCTs versus quasi-experimental studies).

Grading of evidence

We will assess the overall quality of the evidence for the primary outcomes using the GRADE system (Schunemann 2013), which takes into account issues related to internal and external validity, such as directness, consistency, imprecision of results, and publication bias. We will use 'Summary of findings' tables to present the main findings of the review in a transparent and simple tabular format. These tables will provide key information concerning the quality of evidence, the magnitude of effect of the interventions examined, and the sum of available data on the main outcomes.

The GRADE system uses the following criteria for assigning grades of evidence.

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

Grading can be decreased for any of the following reasons.

- Serious (-1 grade) or very serious (-2) study limitation for risk of bias.
- Serious (-1) or very serious (-2) inconsistency between study results.
- Some (-1) or major (-2) uncertainty about directness (the correspondence between the population, the intervention, or the outcomes measured in the studies actually found and those under consideration in our systematic review).
- Serious (-1) or very serious (-2) imprecision of the pooled estimate.
- Publication bias strongly suspected (-1).

Grading can be increased for any of the following reasons.

- Strong evidence of association - significant relative risk of > 2 (< 0.5) based on consistent evidence from two or more observational studies, with no plausible confounders (+1).
- Very strong evidence of association - significant relative risk of > 5 (< 0.2) based on direct evidence with no major threats to validity (+2).
- Evidence of a dose response gradient (+1).

The presence of all plausible confounders will reduce the effect (+1).

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Contributions of authors

JK: Drafting protocol; writing and editing review drafts; data searching and extraction; rating risk of bias; data analysis and synthesis

KH: Drafting protocol; writing and editing review drafts; data searching and extraction; rating risk of bias; data analysis and synthesis

MF: Drafting protocol; writing and editing review drafts; data searching and extraction; rating risk of bias; data analysis and synthesis

Declarations of interest

JK: None known.

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MF: None known.

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Appendices

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor: [Alcohol-Related Disorders] explode all trees

#2 MeSH descriptor: [Drinking Behavior] explode all trees

#3 alcoholism:ti,ab,kw (Word variations have been searched)

#4 alcohol:ti,ab,kw (Word variations have been searched)

#5 #1 or #2 or #3 or #4

#6 MeSH descriptor: [Self-Help Groups] explode all trees

#7 self next help next group*

#8 alcoholic* near/2 anonymou*

#9 mutual next help

#10 mutual next aid

#11 twelve next step*

#12 #6 or #7 or #8 or #9 or #10 or #11

#13 #5 and #12

Appendix 2. Criteria for 'Risk of bias' assessment of randomized controlled trials (RCTs), quasi-RCTs, and 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 to permit judgment of low or high risk
2. Allocation concealment (selection bias)	Low risk	Investigators enroling 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 enroling 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 judgment 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 judgment
3. Blinding of participants and providers (performance bias) Objective outcomes	Low risk	No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken
	High risk	No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding
	Unclear risk	Insufficient information to permit judgment of low or high risk
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 judgment 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
	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 judgment of low or high risk
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
	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 judgment of low or high risk

7. Incomplete outcome data (attrition bias) For all outcomes except retention in treatment or drop out	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; f or 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; m issing data have been imputed using appropriate methods; all randomized participants are reported/analyzed in the group they were allocated to by randomization irrespective of noncompliance 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; f or dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; f or 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 information to permit judgment of low or high risk (e.g. number randomized not stated, no reasons for missing data provided; number of drop outs 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)
	High risk	Not all of the study's prespecified primary outcomes have been reported; one or more primary outcomes is 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 judgment of low or high risk

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 nonexposed individuals are 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; randomized 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 nonexposed 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 nonexposed 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