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# Family-based programmes for preventing smoking by children and adolescents (Protocol)

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# Family-based programmes for preventing smoking by children and adolescents (Protocol)

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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 effectiveness of interventions to help family members strengthen non-smoking attitudes and promote non-smoking by children and other family members by identifying and assessing RCT's that provide training, skills and support to family members to prevent smoking initiation.

Hypothesis: This is an exploratory review, and only one hypothesis based on the literature review will be tested: "Interventions to help family members strengthen non-smoking attitudes and promote non-smoking by children and other family members are more effective in preventing children starting smoking than no intervention."

## BACKGROUND

The importance of smoking for subsequent health

Tobacco use is the single major preventable cause of morbidity and mortality for adolescents (Bricker 2003). A study of 2,227 6th through 8th graders in North Carolina measured 16 risky behaviours such as violence, carrying weapons, substance use, not using a bike helmet, in-line skating or skateboarding, not wearing a seat-belt, riding with a driver who had been drinking, and suicidal plans) and found that smoking at age 11 was the best predictor of these risky behaviours and explained 22% of the variance and the next seven variables (gender, early marijuana or cocaine use, older age, lower academic rank, being white, and living in a one-parent family) explained a further 19% of the variance (DuRant 1999).

The natural history of smoking by adolescents

Mayhew reviewed four types of studies of stages in children's acquisition of smoking (Mayhew 2000). Eleven cross-sectional studies identified several factors correlated with adolescent smoking: individual factors (male, Caucasian, positive attitudes to smoking, concerns with body weight, affect regulation, and cigarette availability); family factors (number of family members who smoke, perceptions of parental permissiveness about smoking, and parental

approval of smoking); and the number of friends in the adolescent's network who smoked. However, these cross-sectional studies are methodologically weak in assessing a developmental process. Prospective studies were of two kinds: those which aggregated the stages of adolescent smokers, and those which kept the stages discrete. Nineteen prospective studies which aggregated the experimenting, regular and established smokers into one group identified individual factors (number of cigarette offers, beliefs about the positive functions of smoking, minimisation of risks, intentions to smoke, tolerance for deviance and drug use, and high estimates of smoking prevalence); family factors (parents and siblings who smoked, and the level of parental involvement and support); and non-family factors (number of friends who smoked, approval of smoking by friends, low academic expectations by friends, and a commitment to part-time work while in school). Nine prospective studies that identified discrete stages of smoking found that smoking by parents, family, and best friend, and school performance were factors that predicted moving from non-smoking to experimenting; and positive intentions to smoke and lack of commitment not to smoke were related to the transitions between non-smoking and experimenting and experimenting and regular use. Seven developmental studies which specifically tried to study the development of smoking stages found that for individual factors

positive attitudes to smoking predicted high initial rates of smoking and faster rates of smoking; high estimates of the prevalence of tobacco use and alcohol use predicted the transition from trying to experimenting; and marijuana use predicted transitions from non-smoking to trying, trying to experimenting, and experimenting to regular use. For family factors, having smoking parents predicted the transition from non-smoking to experimenting; and parental divorce predicted the transition from non-smoking to regular smoking. For non-family factors the number of peers who smoked predicted the transitions from never to trying and trying to experimenting.

Chassin and colleagues followed a cohort of 4,035 students from grade 12 to an average age of 29, with a retention rate of 73% (Chassin 1984; Chassin 1996). This found a significant increase in smoking prevalence between adolescence and adulthood, and little reduction between early adulthood and the late 20's. Education and family smoking were important predictors of adult smoking: 17% of those with some education post high school were adult smokers, compared to 42% of those without education after high school; and 12.5% among those whose parents had never smoked compared to 27% of those with a family history of smoking. The assumption of adult roles was associated with quitting: those who got married were more likely to quit (38%) than those who did not (28%,  $p < .02$ ) and those who became employed were more likely to quit (35%) than those who remained unemployed (6%,  $p < .001$ ).

**Adolescent Smoking: The relationship to smoking by parents and siblings**

Avenevoli and Merikangas (Avenevoli 2003) noted that research on familial influences on smoking has focussed on two main themes: risk and protective factors, and genetic factors. This review identified 87 studies of the relationship between adolescent and parental or sibling smoking, of which 43 assessed smoking by both parents and siblings. Most studies were of Caucasian students in the US. They exhibited a lack of standardised instruments, failed to measure important confounding and mediating variables, and relied on cross-sectional designs. Avenevoli was able to identify only five methodologically rigorous studies. Avenevoli noted that when effects of parental smoking are found the odds ratios are generally less than 2.0, and the effects are often eliminated when other variables are included in models. The inconsistencies between studies may be due to methodological issues, because most studies are large-scale questionnaire studies which use a few questions about current or life-time smoking (whereas parental influence may be related more to regular use or nicotine dependence); failure to assess moderators (gender and ethnicity may be important); and use of a limited number of mediators and models such as exposure, availability and role-modelling (whereas smoking-specific socialization practices, and the influences of parents on their children's health beliefs, choice of peers, susceptibility to peer pressure, values, and association with peers who smoke may be more impor-

tant). Avenevoli concluded that further research is needed to identify the possible effects of parental smoking. Although there are fewer studies of the effects of smoking by siblings, most are predictive of current and life-time smoking by adolescents.

An important publication of the Hutchinson RCT in Washington State (Bricker 2003) which was published in the same edition of *Addiction* 2003 and was not included in Avenevoli's review followed a cohort of 3,012 children over a 9 year period and found that 24% smoked daily in the 12th grade. When both parents never smoked the children's odds of daily smoking were 14% (a reduction of 71% (95%CI = 62%,78%); when both parents smoked the odds were 37%; and when both smoking parents quit the children's odds of daily smoking were 26% (a reduction of 39% [95%CI = 15%,56%] compared to if both parents were current smokers). This RCT corrects most of the errors of previous research: it uses a prospective design that spans the important ages of risk for smoking initiation; directly measured parental smoking rather than relying on adolescents' reports; used a large sample with 95% retention over 9 years; and used bioassay validation of smoking status. It demonstrates the importance of cessation by parents (Chassin 2003). Swan pointed out that the study showed that the children of parents who never smoked had lower rates of daily smoking than those whose parents quit, and hypothesised that aunts, uncles, friends and neighbours may have continued to smoke (Swan 2003).

The British National Child Development Study followed 18,000 children born during one week in March 1958. By age 23, 33% were smokers, which declined to 24% by age 33. Stopping smoking was more likely if there were no other smokers in the household (39%) than if there were other smokers (14%); and if the individual was affluent (35%) rather than poor (14%) (Jarvis 1997).

Darling notes that the focus in the literature on predicting the risk of adolescent smoking (which is a continuous process of change) from stable family characteristics such as structure, may be one reason why understanding of the developmental processes involved in tobacco initiation is limited (Darling 2003).

**Adolescent Smoking: The relationship to parental attitudes to smoking**

Advice by parents not to smoke is associated with less smoking. In a study of 735 students in grades 7-12 in the U.S. midwest on the effects of parental advice to children, if parents who did not smoke told their children not to smoke, 69% of their children never smoked; whereas if the parents did not say they disapproved, 53% of their children never smoked. If parents who smoked told their children not to smoke, 55% of their children never smoked; but if they did not tell their children they disapproved, 24% of their children never smoked. Sixty-eight per cent of the non-smokers said their parents would be upset if they smoked, and 56% of the smokers ( $p < .009$ ) (Newman 1989). In a study of 10,579 pupils aged 11-16 years in 10 comprehensive schools in Bristol, U.K.,

whether children were non-smokers was more strongly related to parental opposition to smoking than whether the parents smoked. The authors reported their data in the form of a path analysis, with parental smoking correlated 0.153 and parental opposition to smoking correlated - 0.380 with whether their child smoked, and the child's current smoking status was correlated 0.498 with future intentions to smoke (Eisner 1989).

In the Harvard Youth Health Promotion Project study of 847 11 and 14 year olds, parental attitudes against smoking reduced the probability that a child would start smoking. The authors reported their results in the form of maximum likelihood parameter estimates. For the 11 year olds the maximum likelihood parameter estimates to predict smoking were 1.581 for parental attitudes, 0.624 for peer smoking, and 0.003 for parental smoking. For the 14 year olds the predictors of smoking were peer smoking 1.579, parental attitude 0.438, and parental smoking 0.211. (Krosnick 1982).

In a study of unmarried pregnant teenagers in Seattle the best predictor that they would not smoke during pregnancy was if their parents disapproved. In addition, the pregnant teenagers were less likely to smoke if they were enrolled in school and had high educational aspirations (Hussey 1992).

**Adolescent Smoking: The relationship to parental restrictions about smoking in the home**

In the Full Court Press Project study of 8,886 middle and high school students in a southwestern U.S. city, for middle school students trying smoking was associated with ethnicity (OR = 1.60), grade level (OR = 1.39), permissive home smoking policies (OR = 1.32) and parents being former smokers (OR = 1.45). For high school students trying smoking was associated with ethnicity (OR = 1.39), home smoking policy (OR = 1.25), and parents currently smoking (OR = 1.38) (Proescholdbell 2000).

**Adolescent Smoking: The relationship to parenting style and family relationships**

Two studies in North Carolina examined the effects of parenting style on adolescent smoking. Authoritative parenting was defined as setting and enforcing clear standards of behaviour, actively monitoring and supervising a child's activities, maintaining structure and regimen in a child's daily life, and making maturity demands consistent with the developmental phase of a child. Responsive behaviours by parents were being affectionate and accepting, providing comfort and support, being involved in children's academic and social development, and recognizing children's achievements. Indulgent parenting was defined as responsive but undemanding, authoritarian as demanding but relatively unresponsive, and neglectful as both undemanding and unresponsive. The Authoritative Parenting Index (API) had 9 items about responsiveness with a reliability of 0.85 and 7 items about being demanding with a reliability of 0.71. A study of substance abuse in North Carolina of 1,236 4th and 6th graders examined smoking and family structure

over four years: the odds ratios for never using tobacco were 1.0 for authoritative families; 2.04 for authoritarian; 2.24 for indulgent; and 3.65 for neglectful. Another study of anger, alienation and conflict resolution in 305 8th graders found that the odds ratios were 1.0 for authoritative; 2.29 for indulgent; 3.97 for authoritarian; and 4.36 for neglectful families (Jackson 1998).

Mounts studied 300 9th graders in a small city in the mid-western US and assessed parental management of their children's relationships with a Parental Management of Peers Inventory with 9 items for guiding friendships, 5 items for neutrality, 6 items for prohibiting friendships and 5 items for supporting friendships. Drug use was defined as alcohol, marijuana, and "other drugs" in the last three months but substances were not separated, levels of use were not indicated, and it was not reported if tobacco use was included. Adolescents who reported higher levels of monitoring, supporting and guiding by parents reported lower levels of "drug use," whereas those who reported higher levels of prohibiting reported higher levels of "drug use." Higher levels of guiding in authoritative homes were associated with lower levels of drug use, but there was no relationship for guiding in authoritarian and indulgent homes. For children with authoritative parents, higher levels of monitoring were associated with having friends with lower levels of "drug use," but there was no association with friends' drug use for authoritarian, indulgent or uninvolved parents (Mounts 2002)

Simons-Morton studied 1,081 middle school students in a school district in Maryland, US. Smoking initiation was associated with having friends who showed problem behaviours (OR = 0.44) and perceived prevalence of smoking (OR = 2.29); and negatively associated with perceived social competence (OR = 0.58) and parental monitoring (OR = 0.55). Among teens with friends with problem behaviours only those with uninvolved parents were at increased risk of smoking initiation. There were no effects of depressive symptoms, school adjustment, parental expectations and parental involvement (Simons-Morton 2002).

Some family characteristics which are not modifiable affect the likelihood of adolescent smoking but need to be kept in mind in assessing research results. Living in an intact two-parent family is associated with less smoking by children (Isohanni 1991; Covey 1990; Turner 1991; Borvin 1993). In the study by Isohanni the rate of experimental or regular smoking for 14 year olds was 65% in the two-parent families (with 6% smoking daily), and 76% in those with one parent (daily smoking 12%). Compared to two-parent families the odds ratios of children smoking were 1.62 if a single parent was present throughout childhood; 1.65 if the father had died; 1.85 if the mother had died; and 2.00 if both parents had died. Parental socio-economic status and education are generally inversely correlated with smoking by children (Tyas 1998).

**Summary of the Background on Family Influences and Adolescent Smoking:**

If parents encourage non-smoking, have policies against anyone smoking at home, have positive authoritative and nurturing parenting styles, and if parents and siblings do not smoke, children are less likely to smoke. Smoking by age 11 is a predictor of other risky adolescent behaviours, but it is not known if it is a gateway to other risky behaviours. If RCT interventions can encourage and provide skills to family members to keep their children as never-smokers, they may be able to make an important contribution to their children's health. Further background on adolescent smoking is available in the Cochrane review "School based-interventions to prevent smoking" by R. Thomas.

## OBJECTIVES

To assess the effectiveness of interventions to help family members strengthen non-smoking attitudes and promote non-smoking by children and other family members by identifying and assessing RCT's that provide training, skills and support to family members to prevent smoking initiation.

Hypothesis: This is an exploratory review, and only one hypothesis based on the literature review will be tested: "Interventions to help family members strengthen non-smoking attitudes and promote non-smoking by children and other family members are more effective in preventing children starting smoking than no intervention."

## CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

### Types of studies

Studies will be included in which students and/or family members were randomised to receive interventions or be in the control group, and will be excluded if they did not state that allocation to intervention and control groups was randomised. We will assess whether studies used analytic methods appropriate to both the level of allocation and the level of measurement of the outcomes. We will exclude those studies that presented only cross-sectional data that permit neither individuals nor clusters nor cohorts to be followed to the conclusion of the study.

### Types of participants

Children (aged 5-12) and adolescents (aged 13-18) and family members. The search strategy chosen will also located studies that follow these children beyond age 18.

### Types of intervention

Interventions with children and family members intended to deter the use of tobacco. Those with school- or community-based components will be included provided the effect of the family-based intervention can clearly be measured and separated from the wider

school- or community-based interventions. Interventions that focus on preventing drug or alcohol use will be included if outcomes for tobacco use are reported. The family-based intervention may include any components to change parenting behaviour, parental smoking behaviour, or family communication and interaction.

For each study we will determine whether during the study the participants received any co-interventions such as the standard health or tobacco education curriculum taught in the school, or interventions that occurred in their community; and whether the control group received any interventions.

### Types of outcome measures

The primary outcome will be the effect of the intervention on the smoking status of children who reported no use of tobacco at baseline. Secondary outcomes are change in tobacco use by children already reporting some tobacco use at baseline; the smoking behaviour of parents and other family members; and intermediate variables such as changes in attitudes toward smoking by the child or family members, parenting behaviour, and family interactional patterns. Intermediate outcomes will be reported because if the intervention does not change the presumed intermediate variables it may explain why persistence in nonsmoking is not achieved. We will record whether the effects of the interventions were found at the conclusion of the programme, at six months after intervention, and long-term (defined as two years after the end of the programme). We will exclude studies that do not assess baseline smoking status in the pre-test survey.

Any measure of smoking behaviour will be considered. Studies may use different measures of tobacco use, either frequency (monthly, weekly, daily), or the number of cigarettes smoked, or an index constructed from multiple measures. These measures attempt to capture the trajectories of smoking uptake in which there is a progression from initial experimentation to becoming a regular smoker. Not all experimenters make the transition to regular smoking, and interventions that reduce the likelihood of progression may be as useful as those that deter any experimentation. Previous reviews have noted that few studies use biochemical validation (by saliva thiocyanate or cotinine or expired air carbon monoxide levels) of self-reported tobacco use for inclusion, and we will not require such validation here but will record its use.

## SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

1. Electronic Bibliographic Databases
2. Grey Literature Databases
3. Searching reference lists of key articles
4. Targeted Internet searching of organization websites
5. Free-text Internet searching
6. Hand-searching of key journals

## 7. Consultation with experts

### 1. Electronic Bibliographic Databases

CBCA Fulltext Education Index

CINAHL

Cochrane Controlled Trials Register

Cochrane Tobacco Addictions Group Register

DARE Database of Reviews of Effectiveness

EBSCO Sociological Collection

EMBASE

ERIC (also a grey literature source)

Medline

PsychInfo

Social Sciences Abstracts

Sociological Abstracts

Web of Science (Science & Social Science Citation Indexes)

Wilson Education Fulltext

[OvidHealthStar\* will not be searched as it is no longer maintained by the U.S. National Library of Medicine. Articles in HealthStar are also in Medline, and books in NLM's LocatorPlus database, and these sources will be searched instead].

### Medline Terms & Searches

A similar search strategy will be used in other data bases. Terms designated as Mesh will vary between databases; asterisks denote term truncation

#### Term Set #1

adolescen\*[Text Word] OR child[Text Word] OR children[Text Word] OR childhood[Text Word] OR juvenile\*[Text Word] OR teen\*[Text Word] OR youth\*[Text Word] OR Adolescent[MESH:NOEXP] OR child[MESH:NOEXP]

#### Term Set #2

Parents[Mesh] OR parent\*[Text Word] OR "family member"[Text Phrase] OR father\*[Text Word] OR mother\*[Text Word] OR classroom\*[Text Word] OR "elementary school"[Text Phrase] OR "high school"[Text Phrase] OR community[Text Word] OR communities[Text Word] OR school\*[Text Word] OR home[Text Word] OR "home based"[Text Phrase] OR family[Text Word] OR families[Text Word] OR "community based"[Text Phrase] OR "family based"[Text Phrase] OR family[MESH] OR family therapy[MESH] OR family health[MESH] OR schools[MESH]

#### Term Set #3

((cigarette\* OR smoking OR tobacco[Text Words]) AND (cessation OR quit\* OR stop\* OR prevent OR preventing OR prevention OR intervention\*[Text Words])) OR Tobacco Use Cessation[MESH] OR tobacco use disorder/prevention and control[Mesh] OR Smoking Cessation[MESH] OR smoking/prevention and control[MESH:NOEXP]

#### Term Set #4

single blind method[Mesh] OR random allocation[Mesh] OR ((double OR single OR triple OR treble[Text Words]) AND (blind\* OR mask\*[Text Words])) OR rct\*[Text Word] OR (random\*[Text Word] AND (trial OR trials OR allocat\* OR assign\* OR control[Text Words])) OR randomized controlled trials[Mesh] OR double blind method[Mesh] OR randomized controlled trial[Publication Type]

### 2. Grey Literature Databases

Australian Policy Online: <http://www.apo.org.au/>

BioMed Central (online peer reviewed journal articles, incl rcts):

<http://www.biomedcentral.com/rct/>

BioMedNet (conferences reporter):

<http://news.bmn.com/conferences>

Campbell Collaboration (systematic reviews of social, psychological and educational interventions):

<http://www.campbellcollaboration.org/>

Canadian Research Index (Government policy & research reports and theses)

CABOT Canadian Health Research Database:

<http://www.mycabot.ca/cgi-bin/WebObjects/cabot>

CenterWatch Clinical Trials Listing Service:

<http://www.centerwatch.com/>

Clinicaltrials.gov: <http://clinicaltrials.gov/ct/gui/c/b>

Current Controlled Trials: <http://www.controlled-trials.com/>

Digital Dissertations (Doctoral dissertations and master's theses worldwide)

EDResearch Online (Australian educational database): <http://cunningham.acer.edu.au/dbtw-wpd/sample/edresearch.htm>

GrayLit Network (database of U.S. Federal gray literature documents): <http://www.osti.gov/graylit/>

Health Promotion and Education Database (National Center for Chronic Disease Prevention and Health Promotion):

<http://outside.cdc.gov:8085/BASIS/ccdchid/web/hes/sf>

HealthPromis (health promotion database that includes both published and grey literature: <http://healthpromis.hda-online.org.uk/>

Health Technology Assessment Database - Univ of York:

<http://nhscrd.york.ac.uk/>

Index to Theses (Grey literature doctoral/masters theses from British and Irish universities)

Moving Ideas Electronic Policy Network (Database of policy reports produced by research agencies in the U.S.:

<http://movingideas.org/ideas/subjects/environment-1.html>

National Library of Medicine LocatorPlus (Catalogue of books & reports held by the National Library of Medicine:

<http://gateway.nlm.nih.gov/gw/Command>

Papers First (Indexes papers given at congresses, conferences, symposia, and meetings)

Policy Library (Database of international healthcare,

public health and health systems policy reports:



<http://www.policylibrary.com/health/>  
Proceedings First (Tables of contents of proceedings from congresses, conferences, expositions, workshops, symposia, and meetings.  
Social Science Research Network: <http://www.SSRN.Com/>  
Trials Central: <http://www.trialscentral.org/>  
UK National Research Register. Clinical Trials Directory: <http://www.update-software.com/National/>  
University of Laval E-Watch Bulletin & database on knowledge utilization: <http://kuuc.chair.ulaval.ca/english/index.php>  
U.S. Grey Literature Report: <http://www.nyam.org/library/greylit/>  
U.S. National Technical Information Service (a major source of U.S. grey literature): <http://www.ntis.gov/>  
TRIP Evidence Based Medicine Database: <http://www.tripdatabase.com/index.cfm>  
World Health Organization Library Catalogue: <http://www.who.int/dsa/>  
WorldCat (Joint catalogue of materials held by libraries worldwide)

3. Searching reference lists of key articles. When all articles have been retrieved, the references lists will be searched.

#### 4. Targeted Internet Searching of Specific Organizations

Canadian Organizations:  
The Alberta Consortium for Health Promotion Research and Education: <http://www.health-in-action.org/new/Consort/consort.shtml>  
Atlantic Health Promotion Research Centre: <http://www.medicine.dal.ca/ahprc/>  
Canadian Consortium for Health Promotion Research: <http://www.utoronto.ca/chp/chp/consort/introe.htm>  
Canadian Institutes of Health Research: <http://www.cihr-irsc.gc.ca/>  
Canadian Provincial/Territorial Ministries of Health  
Canadian Public Health Association  
<http://www.cpha.ca/>  
Health Canada. Health Promotion Online  
[http://www.hc-sc.gc.ca/english/for\\_you/hpo/index.html](http://www.hc-sc.gc.ca/english/for_you/hpo/index.html)  
Institute of Health Promotion Research, University of B.C.  
<http://www.ihpr.ubc.ca/>  
National Clearinghouse on Tobacco and Health  
<http://www.ncth.ca/NCTHweb.nsf>  
Prairie Region Health Promotion Research Centre, University of Saskatchewan  
<http://www.usask.ca/healthsci/che/prhprc/>

International Organizations:  
American Public Health Association <http://www.apha.org/>  
Centers for Disease Control and Prevention <http://www.cdc.gov/>  
Centre for Health Program Evaluation (AU)  
<http://chpe.buseco.monash.edu.au/>

Global Tobacco Prevention and Control  
<http://www.cdc.gov/tobacco/global/>

International Department of Health Web Sites:  
Health Promotion HotLinks  
<http://www.web.net/~stirling/#anchor69179>  
International Health Promotion Research Links  
<http://www.phs.ki.se/hprin/>  
International Institute for Health Promotion  
<http://www.american.edu/academic.depts/cas/health/iihp/iihpabout.html>  
Monash University Health Promotion Unit  
<http://www.med.monash.edu.au/healthpromotion/>  
National Centre for Social Research <http://www.scpr.ac.uk/>  
Stanford Center for Research in Disease Prevention  
<http://prevention.stanford.edu/>  
World Health Organization <http://www.who.int/en/>

5. Free-text Internet searching. The Internet will be searched using the key MEDLINE Mesh terms

6. Hand Searching of Key Journals (if not already completed by the Cochrane hand-searching groups, by review of contents pages).

American Journal of Health Promotion: AJHP  
American Journal of Public Health

Canadian Journal of Public Health. *Revue canadienne de santé publique*.  
Health Education & Behavior (Former Title: Health Education)  
Health Education Research.  
Health Promotion International

7. Consultation with Experts. The Tobacco Review Group editor and experts identified through the literature search will be consulted.

## METHODS OF THE REVIEW

The review will have three stages:

(1). All studies from the literature searches will be reviewed to determine whether they were randomised controlled trials.

(2). All studies will be assessed to determine whether formal meta-analysis is possible. If there is considerable heterogeneity in study design, type of outcome measure and statistical reporting, quantitative synthesis is not appropriate and a narrative systematic review will be used.

(3) Studies will be categorised into three groups according to methodological strength. In synthesizing the results, conclusions will be based on those in Category 1.

In evaluating study quality, six sources of bias that might threaten the validity of a study will be considered:

(I) Selection bias (systematic differences in comparison groups, assessed by adequacy of randomisation);

(II) Performance bias problems with the implementation of the intervention, for example through contamination of the control group);

(III) Attrition bias (systematic differences in withdrawals from groups). Attrition bias will be considered likely if attrition is >20% and the effects of attrition are not adjusted for in the analysis;

(IV) Ascertainment bias;

(V) Inadequate sample size (if either there is no power computation or the post-hoc power computation shows risk of Type II error);

(VI) Whether conclusions for individual studies were based on analytical methods appropriate to the unit of randomisation. Studies that randomise by cluster (school or classroom) but analyse at the level of the individual, are at risk of drawing false positive conclusions. Clustering typically inflates the required sample size.

Based on our assessment of the probability of bias and of appropriate statistical methods, studies will be assigned to three categories: Category 1 studies are those with minimal likelihood of bias, adequate power and appropriate statistical analysis. Category 2 studies contain one or more problems in design or conduct that could threaten the validity of their conclusions. Category 3 studies are those with serious problems in design or conduct that preclude drawing any conclusions.

## POTENTIAL CONFLICT OF INTEREST

None

## SOURCES OF SUPPORT

### External sources of support

- No sources of support supplied

### Internal sources of support

- No sources of support supplied

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