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

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[Intervention Review]

Family-based programmes for preventing smoking by children and adolescents

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ABSTRACT

Background

There is evidence that children's decisions to smoke are influenced by family and friends.

Objectives

To assess the effectiveness of interventions to help family members to strengthen non-smoking attitudes and promote non-smoking by children and other family members.

Search strategy

We searched 14 electronic bibliographic databases, including the Cochrane Tobacco Addiction Group specialized register, MEDLINE, EMBASE, PsycINFO and CINAHL. We also searched unpublished material, and the reference lists of key articles. We performed both free-text Internet searches and targeted searches of appropriate web sites, and we hand-searched key journals not available electronically. We also consulted authors and experts in the field. The most recent search was performed in November 2007.

Selection criteria

Randomized controlled trials (RCTs) of interventions with children (aged 5-12) or adolescents (aged 13-18) and family members to deter the use of tobacco. The primary outcome was the effect of the intervention on the smoking status of children who reported no use of tobacco at baseline. Included trials had to report outcomes measured at least six months from the start of the intervention.

Data collection and analysis

We reviewed all potentially relevant citations and retrieved the full text to determine whether the study was an RCT and matched our inclusion criteria. Two authors independently extracted study data and assessed them for methodological quality. The studies were too limited in number and quality to undertake a formal meta-analysis, and we present a narrative synthesis.

Main results

We identified 22 RCTs of family interventions to prevent smoking. We identified six RCTs in Category 1 (minimal risk of bias on all counts); ten in Category 2 (a risk of bias in one or more areas); and six in Category 3 (risks of bias in design and execution such that reliable conclusions cannot be drawn from the study).

Considering the sixteen Category 1 and 2 studies together: (1) four of the nine that tested a family intervention against a control group had significant positive effects, but one showed significant negative effects; (2) one of the five RCTs that tested a family intervention against a school intervention had significant positive effects; (3) none of the seven that compared the incremental effects of a family plus a school programme to a school programme alone had significant positive effects; (4) the one RCT that tested a family tobacco intervention against a family non-tobacco safety intervention showed no effects; and (5) the trial that used general risk reduction interventions found the group which received the parent and teen interventions had less smoking than the one that received only the teen intervention, and in the trial of CD-ROMs to reduce alcohol use, both groups which received the alcohol reduction intervention had less smoking than the control. In neither trial was there a tobacco intervention, but tobacco outcomes were measured.

For the included trials the amount of implementer training and the fidelity of implementation are related to positive outcomes, but the number of sessions is not.

Authors' conclusions

Some well-executed RCTs show family interventions may prevent adolescent smoking, but RCTs which were less well executed had mostly neutral or negative results. There is thus a need for well-designed and executed RCTs in this area.

PLAIN LANGUAGE SUMMARY

Does preventing children from starting to smoke reduce the number of people damaging their health by smoking

Children and adolescents' likelihood of starting to smoke may be influenced by the behaviour of their families, and it may be possible to help family members strengthen non-smoking attitudes and promote non-smoking in children and other family members. Some high quality studies show that family interventions may help to prevent adolescent smoking, but less well-conducted trials had mostly neutral or negative findings. How well the programme staff are trained and how well they deliver the programme may be related to effectiveness, but the number of sessions in the programme does not seem to make a difference.

BACKGROUND

The WHO Health Behaviour in School-aged Children 1997-8 survey of 11-, 13- and 15-year-olds in 29 countries (Europe, Canada and the USA) found that for the 15-year-olds in 14 countries more than 20% of females smoked daily (Greenland 56%, Austria 26%, Germany 25%, France 25%, England 24%, Scotland 24% and Northern Ireland 24%). In 11 countries more than 20% of males smoked daily (Greenland 45%, Hungary 29%, Latvia 27%, Germany 22%, Poland 22% and Flemish-speaking Belgium 21%) (WHO 2000). Smoking in adolescence continues to rise in many countries, with 23% of American high school students smoking in 2000, up from 18.5% in 1991 (Johnston 2000). Adult smoking begins in adolescence: In US studies 89% of adult smokers began regular tobacco use by the age of 18 (Bricker 2003). Intervening to prevent smoking uptake during adolescence is critical to slowing or halting the trend towards increased tobacco-related illness (USDHHS 1994).

A number of reviews, surveys and cohort studies have identified three broad classes of influences for smoking in adolescence: individual characteristics (e.g. gender, ethnicity, concerns with body weight, attitudes to smoking), family factors (parental smoking, number of smokers in the family, parental permissiveness and approval) and peer-group or friends (number who smoke, academic expectations by friends) (Mayhew 2000). Ethnicity (Proescholdbell 2000), levels of affluence (Jarvis 1997) and level of

education also affect smoking, with tertiary education being associated with lower rates of smoking (Chassin 1984; Chassin 1996). Jarvis 1997 in a long-term cohort study found that as adolescent smokers moved into young adulthood they were more likely to quit if they assumed adult responsibilities such as marriage and employment.

Parental behaviour emerges as a significant determinant of adolescent smoking in a number of studies (Mounts 2002). A cohort study nested within the Hutchinson Smoking Prevention Project (Bricker 2003) found that the children of parents both of whom had never smoked were the least likely to smoke (odds reduced by 71% compared with both parents currently smoking), while children of parents who had quit smoking also had reduced odds of smoking themselves (reduced by 39%). Several studies reported that parental advice not to smoke or explicit disapproval of smoking could be effective in young teens (Eisner 1989; Krosnick 1982; Newman 1989; Huver 2007) and in unmarried pregnant teenagers (Hussey 1992).

Parenting style and parental restrictions on smoking at home also appeared to have an impact, with permissive home policies increasing the likelihood of experimentation, while authoritative parenting (combining demanding and responsive management of children's behaviour) was the least likely to prompt uptake of smoking (Jackson 1998; Proescholdbell 2000).

The influence of friends and peers has also been shown to be associated with smoking behaviour (Krosnick 1982; Simons-Morton 2002), but smoking uptake is negatively related to perceived social competence and parental monitoring. Smoking is associated with other risk behaviours (DuRant 1999).

There are some non-modifiable family characteristics that affect the likelihood of smoking. Living in an intact two-parent family is associated with less smoking by children (Botvin 1993: Covey 1990; Isohanni 1991; Turner 1991) while parental socio-economic status and education are generally inversely correlated with children's smoking (Tyas 1998). However, Darling 2003 has pointed out that the focus of 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.

Further background and theoretical issues concerning adolescent smoking initiation are covered in a companion review of school-based interventions (Thomas 2006).

The literature search in November 2007 for the second edition of this review identified a systematic review (Petrie 2007). They identified 16 RCTs, three controlled before and after (CBA) studies and one controlled trial about parenting programmes to prevent tobacco, alcohol or drugs misuse by children under 18 years. They included only six of the RCTs we identified (Bauman 2001; Jackson 2006; Jøsendal 1998; Spoth 2001; Spoth 2002; Storr 2002), and our review excluded four of the RCTs they included Lochman 2002 (because there was no tobacco intervention) and Johnson 1990, Perry 2003 and Severson 1991 (because the effects of the family intervention could not be separated from those of the school intervention). They included one RCT we located but did not include in the first edition (Forman 1990).

OBJECTIVES

To assess the effectiveness of interventions to help family members to strengthen non-smoking attitudes and promote non-smoking by children or adolescents or their family members.

METHODS

Criteria for considering studies for this review

Types of studies

Studies were included in which students and/or family members were randomized to receive interventions or be in the control group, and were excluded if they did not state that allocation to intervention and control groups was randomized. We assessed whether studies used analytic methods appropriate to both the level of allocation and the level of measurement of the outcomes. We excluded those studies that presented only cross-sectional data that permitted 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 also located studies that follow these children beyond age 18.

Types of interventions

Interventions with children and family members intended to deter the use of tobacco. Those with school- or community-based components were included provided the effect of the family-based intervention could clearly be measured and separated from the wider school- or community-based interventions. Interventions that focus on preventing drug or alcohol use were included if outcomes for tobacco use were reported. The family-based intervention could include any components to change parenting behaviour, parental or sibling smoking behaviour, or family communication and interaction.

For each study we determined 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 is the effect of the intervention on the smoking status of children who reported no use of tobacco at baseline.

Secondary outcomes are:

- the smoking behaviour of parents and other family members;
- intermediate variables such as changes in attitudes toward smoking by the child or family members, parenting behaviour, and family interactional patterns.

Intermediate outcomes were reported because if the intervention does not change the presumed intermediate variables it may explain why persistence in nonsmoking is not achieved. We recorded 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 **excluded** studies that:

- do not assess baseline smoking status in the pre-test survey
- measure attitudes and intentions to smoke, and do not measure smoking behaviour
- do not allow us to separate the effects of the family intervention from those of other co-interventions
- the primary focus is cessation rather than prevention
- do not follow up participants for at least six months from the start of the intervention.

Any measure of smoking behaviour was 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 (e.g. once a month in a younger child) 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 did not require such validation here but recorded its use.

Search methods for identification of studies

We searched the Cochrane Tobacco Addiction Group Specialized Register (compiled by regular searching of electronic databases and specialist conference proceedings), and the Cochrane Central Register of Controlled Trials (CENTRAL). We also performed ad hoc searches of the main electronic databases, including MEDLINE, EMBASE, PsycINFO, CINAHL, Web of Science, and ERIC. The MEDLINE search terms are given as an example in Additional Table 1 ('Search Strategy'). We also searched the 'grey' literature (unpublished reports and conference proceedings), the web sites of relevant organizations, and the reference lists of key articles. Full details of the search terms, databases searched and web sites are given in the 'Search Strategy' table (Additional Table 1). The most recent search was performed in November 2007 and identified 365 potential citations: 30 were reviewed in full text, and two RCTs (Connell 2007, a Category three study; and Forman 1990, a Category two study) were included for this update.

Table 1. Search Strategy

Medline search terms	Grey lit databases	Internet websites	Electronic databases
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]	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://	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/	CBCA Fulltext Education Index CINAHL Cochrane Controlled Trials Register Cochrane Tobacco Addictions Group Register DARE Database of Reviews of Effectiveness EBSCO Sociological Collection EMBASE

Table 1. Search Strategy (*Continued*)

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 ran-	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 pol-	chp/consort/introe.htm Canadian Institutes of Health Research: http://www.cihr-irsc.gc.ca/ Canadian Provinical/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 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	ERIC (also a grey literature source) MEDLINE PsycINFO Social Sciences Abstracts Sociological Abstracts Web of Science (Science & Social Science Citation Indexes) Wilson Education Fulltext

Table 1. Search Strategy (*Continued*)

domized controlled trial[Publication Type]	icy 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/Cmd 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	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/	

Table 1. Search Strategy (*Continued*)

	World Health Organization Library Catalogue: http://www.who.int/dsa/ World- Cat (Joint catalogue of materials held by libraries worldwide)		

Data collection and analysis

The review had four stages:

1. **Review of Studies:** We reviewed all the studies retrieved from the literature searches to determine whether they were RCTs, and whether they matched our inclusion criteria. Details of those studies which did not meet the criteria are given in the Table of Excluded Studies, with the reason for their exclusion.

2. **Data Extraction:** One reviewer (RT) extracted data from the included studies, and the second reviewer (PB) independently checked them. We corresponded with authors to clarify study details. Any disagreements were resolved by discussion and consensus. The Co-ordinating Editor of the Tobacco Addiction Group was available to assist with persistent disagreements.

3. **Quality of studies** was independently assessed by RT and PB. For this process, we judged the likelihood of four sources of bias that the Cochrane Collaboration Reviewers' Handbook identifies as potential threats to validity, and two additional statistical measures of study quality. These were the extent to which the studies minimized the following sources of bias:

(a) Selection bias: systematic differences in comparison groups, due to imperfect randomization.

(b) Performance bias: problems with the implementation of the intervention, often due to incomplete intervention or contamination of the control group.

(c) Attrition bias: losses to follow up or systematic differences in rate of loss to follow up among different groups. We considered studies with an overall attrition rate of greater than 20% to be at significant risk from attrition bias. Where there was differential attrition between groups, we considered bias more likely if there was no sensitivity analysis of the effect of this attrition on outcomes.

(d) Detection bias: significant differences in outcome assessment.

We also applied the following statistical criteria:

(e) A reported power calculation with attainment of the desired sample size.

(f) The statistical analysis was deemed appropriate to the unit of randomization. Intra-class correlations (ICCs) in smoking behaviour vary by school grade, frequency of smoking, gender, ethnicity, and time of school year. ICCs typically inflate the required sample size, and failure to take account of these may lead to inadequate sample size and the risk of drawing false negative conclusions (Type II error) (Dielman 1994; Murray 1990; Murray 1997; Palmer 1998). We considered statistical analysis to be appropriate if the analysis used the same unit as randomization (for example, if the intervention was delivered at the level of the school then the school was the unit of analysis), or if other methods were used to account for cluster effects, such as multi-level modelling.

We assigned studies to three quality categories: Category 1 (minimal risk of bias on all counts); Category 2 (a risk of bias in one or more areas); and Category 3 (risks of bias in design and execution such that reliable conclusions cannot be drawn from the study).

(4) **Data Synthesis:** Data were extracted from randomized controlled trials that reported smoking prevention (number or percentage of non-smoking children at baseline that remained non-smokers at follow up) and a minimum follow-up time of six months. The outcomes used were the proportion prevented from smoking at short term (less than or equal to 18 months) and long term (more than 18 months). We used the longest available follow-up time for the analysis.

In the first version of this review, we used odds ratios where available. In line with the Tobacco Addiction Group's recent change of

policy, we are now expressing these data as relative risks. Risk ratios were obtained from individual randomized trials with the control group as comparator. Adjusted risk ratios from cluster-randomized trials were obtained directly from those trials that reported them. We assessed all studies to determine whether formal meta-analysis was possible. Where appropriate we computed pooled risk ratios where numerical data were available. If there was considerable heterogeneity in study design, type of outcome measure and statistical reporting, quantitative synthesis was not appropriate and we used narrative synthesis.

We include the Cochrane Tobacco Addiction Group's glossary of tobacco-specific terms (Table 2).

Table 2. Glossary of terms

Term	Definition
Abstinence	A period of being quit, i.e. stopping the use of cigarettes or other tobacco products, May be defined in various ways; see also: point prevalence abstinence; prolonged abstinence; continuous/sustained abstinence
Biochemical verification	Also called 'biochemical validation' or 'biochemical confirmation': A procedure for checking a tobacco user's report that he or she has not smoked or used tobacco. It can be measured by testing levels of nicotine or cotinine or other chemicals in blood, urine, or saliva, or by measuring levels of carbon monoxide in exhaled breath or in blood.
Bupropion	A pharmaceutical drug originally developed as an antidepressant, but now also licensed for smoking cessation; trade names Zyban, Wellbutrin (when prescribed as an antidepressant)
Carbon monoxide (CO)	A colourless, odourless highly poisonous gas found in tobacco smoke and in the lungs of people who have recently smoked, or (in smaller amounts) in people who have been exposed to tobacco smoke. May be used for biochemical verification of abstinence.
Cessation	Also called 'quitting' The goal of treatment to help people achieve abstinence from smoking or other tobacco use, also used to describe the process of changing the behaviour
Continuous abstinence	Also called 'sustained abstinence' A measure of cessation often used in clinical trials involving avoidance of all tobacco use since the quit day until the time the assessment is made. The definition occasionally allows for lapses. This is the most rigorous measure of abstinence
'Cold Turkey'	Quitting abruptly, and/or quitting without behavioural or pharmaceutical support.
Craving	A very intense urge or desire [to smoke]. See: Shiffman et al 'Recommendations for the assessment of tobacco craving and withdrawal in smoking cessation trials' Nicotine & Tobacco Research 2004: 6(4): 599-614

Table 2. Glossary of terms (*Continued*)

Dopamine	A neurotransmitter in the brain which regulates mood, attention, pleasure, reward, motivation and movement
Efficacy	Also called 'treatment effect' or 'effect size': The difference in outcome between the experimental and control groups
Harm reduction	Strategies to reduce harm caused by continued tobacco/nicotine use, such as reducing the number of cigarettes smoked, or switching to different brands or products, e.g. potentially reduced exposure products (PREPs), smokeless tobacco.
Lapse/slip	Terms sometimes used for a return to tobacco use after a period of abstinence. A lapse or slip might be defined as a puff or two on a cigarette. This may proceed to relapse, or abstinence may be regained. Some definitions of continuous, sustained or prolonged abstinence require complete abstinence, but some allow for a limited number or duration of slips. People who lapse are very likely to relapse, but some treatments may have their effect by helping people recover from a lapse.
nAChR	[neural nicotinic acetylcholine receptors]: Areas in the brain which are thought to respond to nicotine, forming the basis of nicotine addiction by stimulating the overflow of dopamine
Nicotine	An alkaloid derived from tobacco, responsible for the psychoactive and addictive effects of smoking.
Nicotine Replacement Therapy (NRT)	A smoking cessation treatment in which nicotine from tobacco is replaced for a limited period by pharmaceutical nicotine. This reduces the craving and withdrawal experienced during the initial period of abstinence while users are learning to be tobacco-free The nicotine dose can be taken through the skin, using patches, by inhaling a spray, or by mouth using gum or lozenges.
Outcome	Often used to describe the result being measured in trials that is of relevance to the review. For example smoking cessation is the outcome used in reviews of ways to help smokers quit. The exact outcome in terms of the definition of abstinence and the length of time that has elapsed since the quit attempt was made may vary from trial to trial.
Pharmacotherapy	A treatment using pharmaceutical drugs, e.g. NRT, bupropion
Point prevalence abstinence (PPA)	A measure of cessation based on behaviour at a particular point in time, or during a relatively brief specified period, e.g. 24 hours, 7 days. It may include a mixture of recent and long-term quitters. cf. prolonged abstinence, continuous abstinence
Prolonged abstinence	A measure of cessation which typically allows a 'grace period' following the quit date (usually of about two weeks), to allow for slips/lapses during the first few days when the effect of treatment may still be emerging. See: Hughes et al 'Measures of abstinence in clinical trials: issues and recommendations'; Nicotine & Tobacco Research, 2003: 5 (1); 13-25
Relapse	A return to regular smoking after a period of abstinence

Table 2. Glossary of terms (*Continued*)

Secondhand smoke	Also called passive smoking or environmental tobacco smoke [ETS] A mixture of smoke exhaled by smokers and smoke released from smouldering cigarettes, cigars, pipes, bidis, etc. The smoke mixture contains gases and particulates, including nicotine, carcinogens and toxins.
Self-efficacy	The belief that one will be able to change one's behaviour, e.g. to quit smoking
SPC [Summary of Product Characteristics]	Advice from the manufacturers of a drug, agreed with the relevant licensing authority, to enable health professionals to prescribe and use the treatment safely and effectively.
Tapering	A gradual decrease in dose at the end of treatment, as an alternative to abruptly stopping treatment
Tar	The toxic chemicals found in cigarettes. In solid form, it is the brown, tacky residue visible in a cigarette filter and deposited in the lungs of smokers.
Titration	A technique of dosing at low levels at the beginning of treatment, and gradually increasing to full dose over a few days, to allow the body to get used to the drug. It is designed to limit side effects.
Withdrawal	A variety of behavioural, affective, cognitive and physiological symptoms, usually transient, which occur after use of an addictive drug is reduced or stopped. See: Shiffman et al 'Recommendations for the assessment of tobacco craving and withdrawal in smoking cessation trials' Nicotine & Tobacco Research 2004: 6(4): 599-614

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

We identified 22 randomized controlled trials (RCTs) which met our inclusion criteria. Full details of these are given in the Included Studies Table

Sixteen trials were conducted in the USA, two in Norway, and one each in Australia, Finland, India and the UK.

All RCTs had a family intervention. The interventions were varied, with five focusing exclusively on preventing smoking; four on the prevention of smoking and other addictions; one on alcohol and tobacco with a control intervention about gun safety and the use of bicycle helmets and car seatbelts; one on safe sex to reduce HIV risk, drugs, alcohol, drug selling, parental monitoring and communicating; three on cardiovascular disease risk, exercise and tobacco; one on counselling high risk fathers about risk factors for coronary heart disease, smoking and exercise; four on parenting without a focus on tobacco control but tobacco use was measured after the intervention; and one on classroom management compared to a family-school partnership.

Follow up varied from one year (eight trials), to twenty months (one trial); two years (two trials); three years (six trials); and one trial each at 6, 7, 15, and 27 to 29 years.

Risk of bias in included studies

Based on the four key Cochrane assessments for bias (selection; performance, attrition, and detection) we rated six trials (Bauman 2001; Curry 2003; Schinke 2004; Spoth 2001; Spoth 2002; Storr 2002) as Category 1 (minimal risk of bias); ten trials (Ary 1990; Biglan 1987; Cullen 1996; Elder 1996; Forman 1990; Jackson

2006, Jøsendal 1998; Nutbeam 1993; Stevens 2002; Wu 2003) as Category 2 (one or more risks of bias); and six trials (Connell 2007; Dishion 1995; Knutsen 1991; Olds 1998; Reddy 2002; Salminen 2005) as Category 3 (multiple risks of bias).
Two studies concealed allocation from interviewers (Bauman 2001; Jackson 2006) and one study used an intention-to-treat analysis (Jackson 2006).

Effects of interventions

The outcome of interest is the percentage of children who were never-smokers at baseline who remained never-smokers at the final assessment point of the trial. Detailed results for each trial are given in the Comparison and Data tables.
We structured five comparisons:
(Question 1) Are family interventions better than no intervention or 'usual care'? *[Comparison 01.01]*:
Four Category 1 (minimal risk of bias) randomized controlled trials (RCTs) (Bauman 2001; Curry 2003; Spoth 2001; Storr 2002), and five Category 2 (moderate risk of bias) (Biglan 1987; Cullen 1996; Jackson 2006; Jøsendal 1998; Nutbeam 1993) provided evidence. The family intervention in two trials (Cullen 1996; Olds 1998) did not include a tobacco intervention, but tobacco outcomes were measured.
Four RCTs found more baseline nonsmokers remained nonsmokers with a family intervention compared to control: Jackson 2006 compared printed activity guides, parenting tips sheets, child newsletters and incentives to no intervention and after three years found the control group was more likely to initiate smoking (19.3%) than the experimental group (11.9%) (Odds ratio (OR) 2.16; 95% confidence interval (CI) 1.39 to 3.37; P < 0.001). Jøsendal 1998 found the group who received the parents' programme had fewer new smokers than the control (we computed OR 0.48; 95% CI 0.39 to 0.59). Spoth 2001after six years found that lifetime cigarette use was significantly lower in the Iowa Strengthening Families Program [ISFP] group than control using growth curve analysis (P < 0.01). Storr 2002 after seven years found that the Family-School Partnership (OR with covariate adjustments 0.55; 95% CI 0.34 to 0.88; P = 0.013) retained more baseline nonsmokers than control.
Four RCTs found no difference: Bauman 2001 compared manuals giving advice to parents and supportive telephone calls to no intervention and at one year found that the odds of nonsmokers in the intervention group remaining nonsmokers compared to control were 1.30 (P = 0.037), but 1.27 corrected for design effect (P = 0.059). There were 16.4% fewer new smokers in the intervention group. Biglan 1987 found no differences between the group whose parents received messages compared to control. Curry 2003 compared a mailed parental smoking prevention kit, telephone calls, child education materials and cues to physicians to deliver prevention messages to no intervention, and at 20 months follow up found no statistically significantly differences in initiation of smoking as measured by ever smoking (13.6% in the intervention group and 12.1% in the control; OR 1.14; ns), or smoking in the past 30 days (2.4% in the intervention group and 2.3% in the control; OR 1.07; ns). Cullen 1996 compared interviews with mothers of newborns over four years by a GP encouraging gentle positive interactions with their child to no intervention, and after 27 to 29 years follow up found no significant differences in smoking between the intervention (22.8%) and the control groups (33.6%; P = 0.081; we computed an OR of 0.60; 95% CI 0.33 to 1.08).
One RCT found fewer nonsmokers remained in the family intervention group: Nutbeam 1993 found the percentage of nonsmokers in the Family Smoking Education Project group declined more over two years (from 77.6% to 53.8%) than in the control group (from 79.6% to 62%; P < 0.05; we computed an OR of 1.40; 95% CI 1.61 to 1.70).

There were four Category 3 RCTs (high risk of bias) (Knutsen 1991; Olds 1998; Reddy 2002; Salminen 2005) which made this comparison, but no reliable conclusions can be drawn from them.
(Question 2) Are family interventions better than school interventions? *[Comparison 01.02]*:
Two Category 1 RCTs (Spoth 2001; Storr 2002) and three Category 2 RCTs (Biglan 1987; Jøsendal 1998; Nutbeam 1993) directly compared a family and a school intervention.
One RCT found a family intervention superior to a school intervention. Spoth 2001 after six years found time to initiation of smoking was 54.9 months in the Iowa Strengthening Families Program (ISFP) compared to 31.0 months in control (P < 0.05) and 31.8 months in the Preparing for the Drug Free Years Programme (PDFY; n.s. compared to control). Although the ISFP and PDFY were not compared statistically, because the months to initiation are identical for the PDFY and control it would be reasonable to conclude that the ISFP has statistically significantly longer times to initiation than the PDFY (P < 0.05)
Four RCTs found no differences between a family and a school intervention. Biglan 1987 did not find any significant differences between the group whose parents received messages and the group which received the schools refusal skills program. Jøsendal 1998 did not find significant differences between the classroom with parents programme and the classroom with teachers programme (we computed an OR of 0.82; 95% CI 0.66 to 1.02). Nutbeam 1993 after two years found the Family Smoking Education Project group retained fewer baseline nonsmokers than the Smoking and Me Project (P < 0.05; but we computed a non-significant OR of 1.08; 95% CI 0.89 to 1.32). Storr 2002 did not find significant differences between the Family-School Partnership and the Classroom-Centered intervention (we computed an OR of 1.08; 95% CI 0.71 to 1.64), but both were significantly better than control.

(Question 3) Are combined family plus school interventions better than school interventions? *[Comparison 01.03]*:

One category 1 (Spoth 2002) and six Category 2 RCTs provided evidence (Ary 1990; Biglan 1987; Elder 1996; Forman 1990; Jøsendal 1998; Nutbeam 1993).

None of the seven RCTs found incremental effects of a family-plus-school intervention compared to a family intervention alone: Ary 1990 compared a school social influences PATH programme to control and a PATH programme-plus-messages to parents to control,and at one year found no effects for either the family or school interventions. Biglan 1987 after one year found no significant differences between groups which received messages to parents and a schools intervention compared to a social influences schools intervention. Elder 1996 after three years found no significant differences in smoking by adding a family programme (the "Unpuffables") to the CATCH school smoking prevention intervention. Forman 1990 asked teachers to refer 14 year olds with two or more of: experimental alcohol or drug use, a high number of disciplinary incidents, unexcused absences, friends and family members who used drugs or alcohol, low social esteem, or social withdrawal and found that 29% had never smoked. He compared Botvin's ten-session Life Skills Training Intervention in schools with the same intervention plus a five session parent intervention and found no differences in smoking. The negative result of this study may partly have been due to ceiling effects. Jøsendal 1998 at the three-year follow up found 68.5% nonsmokers in the classroom-plus-parents-plus teachers intervention group and 68.3% in the classroom-plus-teacher training intervention (n.s.) [although the classroom-plus-parents-plus-teachers intervention group compared to control had significantly fewer new smokers: fewer daily (OR 0.69; 95% CI 0.48 to 0.99), weekly (OR 0.65; 95% CI 0.46 to 0.91) or any time smokers (OR 0.74; 95% CI 0.55 to 0.98)]. Nutbeam 1993 found a non-significant difference between the percentage of baseline nonsmokers remaining smoke-free in the family-plus-school intervention (69%) compared to the family intervention (65%; n.s.). Spoth 2002 found no differences for the Strengthening Families Program plus the Life Skills Training programme compared to the Life Skills Training programme (we computed an OR of 0.85; 95% CI 0.60 to 1.20).

There was one Category 3 RCT (Reddy 2002), from which no reliable conclusions could be drawn.

(Question 4) Are family interventions which target tobacco better than family interventions which do not target tobacco? *[Comparison 01.04]:*

One Category 2 RCT provided evidence: Stevens 2002 found at three-year follow up that there was no change in tobacco usage in the intervention group which received the alcohol and tobacco messages at their paediatricians compared to the other intervention group which received the gun, bicycle helmet and seat belt safety intervention (OR 0.97; 95% CI 0.79 to 1.20; P = 0.78).

(Question 5) Are family plus peer interventions to reduce risks better than peer interventions to reduce risks? *[comparison 01.05]:*

There was one category 1 (Schinke 2004) and one Category 2 trial (Wu 2003) which provided evidence. Schinke 2004 at three years found that both the group which received a CD-ROM intervention to reduce alcohol use, and the group which received the CD-ROM plus parental intervention had less smoking than control (P <.001). Wu 2003 at two years found less smoking in the group which received both the Focus on Kids (FOK) and the Informed Parents and Children Together (ImPACT) risk reduction interventions (12.5%), compared to those who received only the FOK intervention (22.7%; P = 0.003). There was one Category 3 RCT (Dishion 1995) from which no conclusion could be drawn. The family intervention in both trials was oriented towards general risk reduction and did not include a tobacco intervention, but tobacco outcomes were measured.

DISCUSSION

Of the six randomized controlled trials (RCTs) rated as Category 1 (minimal risk of bias), three found positive effects of family interventions (Schinke 2004; Spoth 2001; Storr 2002), and of the ten Category 2 RCTs (moderate risk of bias) three found positive effects (Jackson 2006; Jøsendal 1998; Wu 2003) and one found some negative effects (Nutbeam 1993).

We sought possible reasons for these modest findings.

One possibility is that the period of follow up was long enough for any findings to attenuate. However, the positive studies had longer follow ups: Wu 2003 (two years). Jackson 2006, Jøsendal 1998 and Schinke 2004 (three years), Spoth 2001 (six years) and Storr 2002 (seven years).

Another possibility is that comparing a family intervention with a no-intervention control group is more likely to produce positive significant findings (Jackson 2006; Jøsendal 1998; Schinke 2004; Spoth 2001; Storr 2002) than comparing one active intervention with another (Spoth 2001), or an intervention with an incremental intervention and control (Wu 2003).

Another limitation may have been combining interventions with differing aims (e.g. tobacco, bicycle helmet, gun and seatbelt safety and) and that these unrelated aims caused 'noise' which masked the basic message to prevent smoking. It is possible that some of the combination studies might have shown larger effects if they had limited themselves to a strong tobacco intervention.

We were unable to test whether socio-economic characteristics may have confounded the results, as there were too few studies and details within the studies to determine whether the effects of the intervention were related to socio-economic characteristics. However, randomization should have prevented differential confounding.

Unrecorded co-interventions may have occurred during the study, reducing the apparent effect of the family intervention. Possible co-interventions could include other mandated school anti-smoking programmes, social marketing campaigns using mass media, restriction of smoking locations, enforcement of legislation to prohibit the sale and supply of tobacco to those under 18, increasing taxation and cost of cigarettes, and changes in tobacco promotion by tobacco companies. Another possible confounder was the selection of schools because the teachers were enthusiastic, and although the schools may later have been randomized (as in Biglan 1987) the co-intervention of teacher enthusiasm could augment the effect of the school component. Most of the studies do not report co-interventions, and if these operated effectively during the study an incremental effect of the family intervention may not have been perceptible.

Minimal interventions (e.g. Bauman 2001, with four booklets posted to parents) did not appear to be a determinant of success, as they were used in both the positive and in the no-effect RCTs.

We explored whether or not the number of sessions was related to positive outcomes. Of those Category 1 and 2 RCTs that had positive results Bauman 2001 used four mailed booklets and a phone call; Jackson 2006 mailed six printed activity guides and five to the control group; Jøsendal 1998 eight sessions; Schinke 2004 ten 45-minute sessions with a CD-ROM; Spoth 2001 seven lessons compared with five; Storr 2002 an average of four workshops; Wu 2003 eight sessions). Of the Category 1 and 2 RCTs that had no effect or a negative effect, the number of sessions varied greatly, with no clearly discernible relationship between efficacy and programme duration (Ary 1990 25 sessions; Biglan 1987 six sessions; Cullen 1996 12 interviews; Curry 2003 a handbook, video, two phone calls; Elder 1996 eight tobacco sessions [FACTS programme] compared with a four-session Unpuffables programme; Nutbeam 1993 a five-session compared with a three-session programme; Spoth 2002 a seven-session compared with a fifteen-session programme; Stevens 2002 at least one visit to a pediatrician, brochures and 12 quarterly newsletters).

We also examined the effects of intensity of training and/or fidelity of implementation by those who presented the interventions. Among the Category 1 and 2 trials with positive outcomes: in Forman 1990 the average completion rate of intervention activities in all coping skills sessions was 74%, with two-thirds of the students completing 9 or 10 of the 10 planned intervention sessions, although only 44% had a parent participate in the parent training intervention. In Jackson 2006 the interviewers had two years of experience working with children and received an additional 30 hours of training; in Jøsendal 1998 two days of training plus manual and evaluation questionnaire; in Spoth 2001 high levels of coverage of key concepts in both interventions; in Storr 2002 60 hours of training, with feedback on compliance and coverage from teachers and parents [although Schinke 2004 did not describe any training for the research staff, and Wu 2003 provided no process analysis], there tended to be more hours of training, higher levels of compliance with the programme and more detailed programme evaluation by teachers and by parents than among those trials which delivered negative or no-effect results (Ary 1990 two to three hours training; Curry 2003 low levels [3-22%] of discussion of tobacco use; Elder 1996 variable levels of programme fidelity; Nutbeam 1993 one day of training; Spoth 2002 relatively high levels of compliance; Stevens 2002 47-51% fidelity to programme delivery; Biglan 1987 and Cullen 1996 did not report on training or programme fidelity). Unlike the number of sessions, intensity of training and fidelity of implementation seemed to be associated with more positive outcomes.

For those studies at high risk of bias (e.g. no description of method of randomization or allocation concealment, inadequate delivery of the intervention, no attrition analysis), it is not appropriate to place confidence in their conclusions. The results of some of the trials were also compromised by lack of power computations and on occasion by disparities between the units of allocation and analysis.

One study, Hahn 2007, compared the BABES Plus and BABES interventions to improve the family environment of five year olds, assuming that improvement would be related to less ssubstance-abuse later on. We have not included this study in the systematic review as it does not have tobacco outcomes for the children, but it may be a promising line of research for the neglected field of tobacco prevention aimed at very young children.

Previous reviews have identified the contribution of family, individual and social factors in adolescent smoking, and have also identified several problems in studying how families influence adolescent smoking.

Darling 2003 noted three problems in identifying the causes of adolescent smoking: the transitional nature of adolescent smoking, the multiple forms of family structure and influences, and the relationship of families to other developmental processes.

Avenevoli 2003 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 US Caucasian students. The studies lacked standardized instruments, did not measure important confounding and mediating variables (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), and used cross-sectional designs. Avenevoli was able to identify only five methodologically rigorous studies, and 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. Most studies of siblings predict current and life-time smoking by adolescents.

Mayhew 2000 identified 11 cross-sectional studies and found

that adolescent smoking was associated with 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 and approval of smoking); and the number of friends in the adolescent's network who smoked, but these cross-sectional studies are methodologically weak in assessing a developmental process. Mayhew identified 19 prospective studies which aggregated the experimenting, regular and established smokers into one group and identified individual factors (number of cigarette offers, beliefs about the positive functions of smoking, minimization 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 parents who smoked 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 from trying to experimenting.

Tyas 1998 found that adolescent smokers who begin at younger ages are more likely to become regular smokers and less likely to quit; parental indifference, lack of supervision and lack of knowledge about their children's friends increases the risk of smoking, as does the perception that friends smoke. Participating in sports is associated with lower rates of smoking.

Although parents are important in influencing smoking by children and adolescents, most interventions have focused directly on youth in schools, and the family component in the few studies that included one tended to be small. This may reflect the difficulties of conducting interventions in families.

This review identified only six RCTs at minimal risk of bias and ten at moderate risk of bias, and the conclusions drawn are thus based on a deliberately limited group of studies compared to previous reviews.

AUTHORS' CONCLUSIONS

Implications for practice

Considering only those trials at minimal or moderate risk of bias, four of the nine that tested a family intervention against a control group had significant positive effects, but one showed significant negative effects. One of the five RCTs that tested a family intervention against a school intervention detected significant positive effects. None of the seven RCTs that compared the incremental effect of a family + school intervention to a school intervention, nor the RCT that compared a family tobacco to a family non-tobacco intervention detected significant effects. However, two programmes which did not use tobacco interventions found positive outcomes: a parent-plus-teens general risk reduction intervention showed less tobacco use compared to a teen intervention or control, and an RCT to reduce alcohol found both the family + teen and the teen interventions resulted in less tobacco usage. Across all the included studies, the number of sessions was not related to positive outcomes, but the extent of implementer training and the fidelity of implementation appeared to be higher in those studies with positive outcomes.

It is not possible to draw firm conclusions from the current evidence base about the efficacy of family interventions to prevent adolescent smoking, or whether the interventions are intense enough to produce a sustained effect.

Implications for research

There is a need for more well-designed and executed randomized controlled trials in this area, building on previous successful designs.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Ary 1990

Methods	Country: USA Site: 22 middle/elementary & 15 high schools from 13 districts in Oregon Focus: tobacco, alcohol and marijuana prevention Design: Schools matched on urban/rural status, level of tobacco use, ethnicity and school size, then randomized (with the exception of one middle school assigned to the treatment condition as it had earlier served as a pilot school for programme development). In the 12 intervention schools, parents randomized to receive or not receive parent messages Analysis: ANCOVA.
Participants	Number at pre-test: 7837 Age; 1943 6th graders; 1890 7th graders; 698 8th graders; 1364 9th graders; 205 10th graders; 163 11th graders 9.9% weekly smoking Gender: not stated; Ethnicity : White 89%, 4.9% Black, 2.2% Asian, 1.8% Latin American, 1.2% Hispanic Only results for grades 6-9 given in Ary 1990 Attrition: 24.4 % (I) and 24.6% (C) schools; no differential attrition on pretest use by gender, grade, CO level, number of peers who smoked, offers of cigarettes, parental smoking.
Interventions	(1) Intervention: Project PATH (Programs to Advance Teen Health) Components: At each grade level (a) awareness of social influences to engage in substance use (b) refusal skills training (c) health facts, and (d) contracting not to use cigarettes and other substances. Information was provided about the short- and long-term health effects of tobacco; social, family and advertising influences to use substances; students analyzed advertisements and edited them to make them honest; learned social skills to deal with using substances: identified personal situations where they would want to say 'no' to an offer to use substances; 6 ways to say 'no'; practiced refusal skills in situations that the students said were likely to happen to them; saw videos which modelled refusal skills and modelled supporting friends refusing; made commitments not to smoke. Sessions taught by classroom teachers (who received 2 to 3 hours of training), and in grades 7 and 9 by peers nominated by their classmates. Program different for each grade. (2) PATH + Parent messages: also mailed 3 brochures: to support the classroom messages about refusal skills, information about the health effects of smoking, and commitments not to smoke or chew, and encouraged parents to discuss their views about tobacco use with their children and set clear rules about non-smoking. Duration: 25 classroom sessions (5 in each of grades 6 through 10), typically taught over a 1 week period ('focused most heavily on cigarette smoking and smokeless tobacco use, it was designed to deter the use of marijuana and alcohol'). (3) Control: typically received 10 classroom sessions of standard tobacco/drug use education.
Outcomes	Smoking: Pechacek's self-reported smoking index to yield an estimate of the no. cigs smoked in last month (composite of no. in last 6m, last month, last week, and last 24 hours): Dichotomised on >1 cig in previous month. Expired air CO tested before survey completion Follow up: 9-12m after pre-test.

Ary 1990 (*Continued*)

Notes	Study Category 2: 1. Randomization bias: minimal risk. 2. Performance bias: minimal risk: Surveys of teachers indicated that the control group received 10 sessions of standard tobacco and drug education (with 97% recognizing peer pressures, 97% short-term effects on the body and brain, 96% long-term health consequences, 84% decision-making skills, 72% media pressures, and 67% refusal skills practice), and the intervention schools received a median of 5 sessions of other drug education in addition to PATH; 3. Attrition bias: 24%; no differential attrition. 4. Detection bias: minimal risk. 5. Power computation: not performed. 6. Statistical quality: moderate: ANCOVA, no adjustment for clustering.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Bauman 2001

Methods	Country: USA Site: National telephone survey Focus: tobacco and alcohol prevention Design: 64,811 telephone numbers representative of all telephone numbers in the US; then by random digit dialing found 2,395 (3.7%) where there was a household with an eligible adolescent age 12-14 and parent pair; then randomized to intervention or control; Analysis: GEE
Participants	Of 2395 eligibles, 1,326 (55%) completed a baseline interview, and of these 549 (46%) began the program, and 407 (34%) completed it; Follow up: of the 1316 baseline pairs, 1135 (86%) completed either 1st or 2nd follow-up interviews, and 1014 (77.1%) completed both; Baseline demographics not reported in detail, but no sig diffs between groups except fewer non-Hispanic Whites (70.6%) in intervention than in control group (76.1%, P=0.05)
Interventions	(1) The Family Matters intervention: 4 booklets mailed to participants: (a) booklet 1 from expectancy theory asked families to discuss the consequences to the family if the adolescent used tobacco or alcohol; (b) booklet 2 asked family members to list normal adolescent behaviours, and understand the importance of supervision, support, communication skills, attachment and conflict resolution, and practise communication skills and plan special times to be together with the adolescent; (c) booklet 3 from social learning theory asked adults to list their own behaviours that might encourage substance abuse, identify rules that could influence their child's substance use, monitor use, and agree on rules and sanctions for substance use; (d) booklet 4 from social innoculation theory asked adults and adolescents to consider what the adolescent could do to resist peer and media pressures to use substances, to practise refusals of tobacco and alcohol, and to watch favourite TV shows together to discuss the messages of the programmes about alcohol and tobacco use. 2 wks after each booklet was posted, a health educator telephoned a parent, encouraged the participation of all family members in the programme, and answered questions; (2) Control; No active programme, only data collection

Bauman 2001 (*Continued*)

Outcomes	One question: 'How much have you ever smoked cigarettes in your life?': Likert-scale responses collapsed to never-smoked or had smoked even a puff. Smokeless tobacco determined by 'Have you ever tried chewing tobacco (such as Redman, Levi Garrett, or Beechnut) or snuff (such as Skoal, Skoal Bandits, or Copenhagen)?'. Follow up at 3m and 12m.
Notes	Study Category 1: 1. Randomization bias: minimal risk; method not reported 2. Performance bias: minimal risk. 3. Attrition bias: minimal risk: respondents lost to follow up were more likely to be users at baseline but no differential attrition across groups. 4. Detection bias: minimal risk. 5. Power computation: not performed. 6. Statistical quality: adequate: GEE used to analyze programme effects and allow for the effect of confounders.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Biglan 1987

Methods	Country: USA Site: 13 middle, junior & high schools, Oregon Focus: Preventing and reducing smoking Design: In one school district whole schools assigned to conditions. In 2 districts classes of teachers willing to use curriculum were randomized. In an additional component students in 6 schools randomized individually Analysis: classroom unit of analysis, factorial analysis of covariance
Participants	Number at pre-test: 3387 in 135 classrooms (4.9% weekly smokers); age: 7-10th grades; 51% F; majority white
Interventions	(1) Intervention 1: Information about health effects and short-term effects of tobacco; sensitization to pressures to smoke; training in refusal skills including modelling, rehearsal, reinforcement, practice, video practice, and supporting peers in refusals. (2) Intervention 2 (additional): 7th graders in 6 schools randomized to have 4 messages mailed to their parents following the programme to encourage parents to discuss their views of smoking with their child and set clear rules about smoking. Duration: 5 sessions; 4 on consecutive days + booster at 2 wks. Providers: regular science or health teachers, trained for 2-3 hrs (3) Control: no intervention
Outcomes	Weighted index of self-reported smoking (Pechacek) based on no. smoked in previous week and yesterday. Nonsmoking=no cigs in previous week. Expired CO measured and saliva collected prior to questionnaire completion.

Biglan 1987 (*Continued*)

	Follow up: 9m and 1 yr.
Notes	Study Category 2: 1. Randomization bias: minimal risk; allocation method not stated. 2. Performance bias: moderate risk: no process analysis 3. Attrition bias: minimal risk: 18.7%; no differential attrition; 4. Detection bias: minimal risk; 5. Power Computation: no power computation for the main study. 6. Statistical quality: adequate: separate analyses for those reporting smoking in previous week at baseline and others. A combined within- and between- schools design was used to investigate contamination effects

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Connell 2007

Methods	Country: USA Site: 3 middle schools in a NW metropolitan area Focus: Preventing and reducing smoking Design: 998 6th graders randomized to either control or 'universal intervention' classrooms Analysis: To control for the effect of noncompliance, used Complier Average Causal Effect with mixture model using MPlus software to identify from the control group the optimum comparison group to compare to those compliant with treatment.
Participants	All 6th graders in the three middle schools (1110) were invited to participate, 998 agreed, 498 allocated to control, 500 to experimental (of whom 115 received an additional family intervention); 794 (80%) remained by age 18-19
Interventions	1. Intervention: A. schools were provided with a Family Resource Center (a) brief consultations with parents; (b) telephone consultations; (c) feedback to parents on their childrens' behaviour at school; (d) access to videotapes and books; (e) SHAPe Curriculum for students with 6 lessons (school success, health decisions, building positive peer groups, cycle of respect, coping with stress and anger, and solving problems peacefully); B. 115 of these students and parents participated in the Family Check Up (interview exploring parent concerns, assessment including videotaping family at home, feedback by the therapist using motivational interviewing strategies and exploring interventional services the family could use, which were delivered over two years by therapists) 2. Control: no intervention.
Outcomes	Tobacco from 1 (never) to 6 (more than 20 times)
Notes	New for 2008 update. Study Category 3: 1. Randomization bias: (a) for allocation to intervention or control: minimal risk, but allocation method not stated; (b) to Family Check Up within the intervention group: high risk as adolescents self-selected themselves

	2. Performance bias: moderate risk: no process analysis 3. Attrition bias: moderate risk: 21% by age 18; no analysis if differential attrition occurred; 4. Detection bias: minimal risk; 5. Power Computation: no power computation. 6. Statistical quality: CACE analysis is intended to control for non-compliance; minimal details are provided; results for tobacco are stated as "significant" but no levels of significance are given or n's

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Cullen 1996

Methods	Country: Australia Site: alternate births in Busselton Hospital, Busselton, WA. Focus: prevention of behaviour disorders Design: 246 newborns 1964-7 stratified by gender and birth order in their family, then allocated by alternate births to either intervention or control; Analysis: tests of proportions using normal appoximation to the binomial distribution;
Participants	Baseline: cohort of 246 (124 (I), 122 (C)) newborns 1964-7 Follow up in 1993: 209 (90%) adults aged 27-29 years; 105 (I), 104 (C).
Interventions	(1) Intervention: 20-30 min interviews by GP(4 per yr in 1st yr, 2 per yr for next 4 yrs) with mothers to enhance self-worth, self-acceptance, foster gentle physical interaction with child, and adopt a positive attitude to modifying child's behaviour; (2) Control: the study secretary maintained contact with the parents; No contact with either group 1975-1993 'other than sporadic visits' to one author as their GP.
Outcomes	Current smoking (not further defined); Personality, language and learning ability tests at 6 yrs of age.
Notes	Study Category 2: 1. Randomization bias: minimal risk: alternate allocation is usually a weak method, but alternate allocation of births may not involve bias as there are no intrinsic characteristics that would cause newborns with specific characteristics to alternate time of birth; 2. Performance bias: moderate risk: no statement or process analysis if all GP interviews were conducted and all according to protocol; 3. Attrition bias: moderate risk: 10% attrition; no attrition analysis; 4. Detection bias: minimal risk: 5. Power computation: not performed: 6. Statistical quality: adequate.

Risk of bias

Item	Authors' judgement	Description

Cullen 1996 (*Continued*)

Allocation concealment?	No	C - Inadequate

Curry 2003

Methods	Country: USA Site: Portland, Seattle; Focus: smoking prevention; Design: families stratified by child's age, site, and subcohort (assessment or only follow up) then randomized to intervention or control; Analysis: Chi squared to compare nominal data; t-tests to compare means on ordinal and interval data; logistic regression for comparisons adjusting for parent baseline survey data, and to test for effect modification using treatment interaction terms;
Participants	7,337 families with a child 10-12 yrs identified in the membership files of 2 HMOs in Seattle and Portland. 4,026 [55%] gave consent and 3,563 (88% of enrolled) completed the 20m follow up; at the 20m assessment the response rate was 86% (I) and 90% (C) (P<0.001);
Interventions	'Steering Clear Project: (1) intervention: described as 'minimal intensity'. (a) a 12-chapter parent handbook; a videotape on the experiences of a former tobacco model; a CDC videotape; and a comic book, pen and stickers for the child; (b) two calls from a counsellor; (c) a 6-page newsletter 14m later; (d) access to a website; and (e) physicians were prompted during appointments to encourage families to use the videos and website and talk about staying smoke-free; (2) Control: 'usual care'. Exposure to school-based tobacco prevention curricula; tobacco marketing; and media-based tobacco prevention messages was assessed at baseline, 6m, 12m, and 20 month follow ups.
Outcomes	Ever smoking and smoking in the past 30 days. Follow up at 20m.
Notes	Study Category 1: 1. Randomization bias: minimal risk: method of randomization not stated; groups were similar at baseline; 2. Performance bias: minimal risk: at 6m 83% (I) parents said they had read handbook, completed one or more activities and spoken with a counsellor; 51% reported they had watched model video and 42% CDC video. 47% (I) and 45% (C) children had visited physician in previous 6m. However, of these only 22% (I) and 15% (C) said tobacco use was discussed with the child; 17% (I) and 3% (C) said the 'Steering Clear' project was discussed. 3. Attrition bias: minimal risk: at 20m assessment response rate was 86% (I) and 90% (C) (P<0.001); but no dfferential attrition analysis 4. Detection bias: minimal risk: 5. Power computation: not performed: 6. Statistical quality: adequate.

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	No	C - Inadequate

Dishion 1995

Methods	Country: USA Site: Eugene, Oregon Focus: parent management of family interaction; teen self-management and pro-social interactions; Design: self-recruitment through advertisements, then randomly assigned to intervention or control; Analysis: MANCOVA;
Participants	Sample recruited by newspaper advertisements, flyers, and referrals from counsellors. Half the respondents eliminated after exploratory phone call because of low adolescent risk scores; 158 families remained after screening, 147 children at termination of study. Gender: 63% M; av age: 12
Interventions	All 4 interventions were 12 x 90-min counselling sessions based on scripted materials and videotapes: (1) Parent focus: the parent's family management practices and communication skills (monitoring, positive reinforcement, limit setting, and problem solving, with discussion of home practices and demonstration of the skills, with exercises, role-plays, and discussions); (2) Teen focus: teen self-regulation and pro-social behaviour in parental and peer environments (self-monitoring and tracking, pro-social goal setting, developing peer environments supportive of pro-social behaviour; setting limits with friends; and problem solving and communication skills with parents and peers); (3) combined parent and teen intervention; (4) self directed change (the 6 newsletters and 5 brief videos that accompanied the parent- and teen-interventions); (5) Control: separately recruited by advertisements, no intervention offered.
Outcomes	(1) Tobacco use over previous 3m; (2) expired CO; (3) parent-child problem solving; (4) parent reports of family conflict; (5) parent reports of child behaviour. Follow up at 1 yr.
Notes	Study Category 3: 1. Randomization bias: minimal risk: method of randomization not stated; 2. Performance bias: moderate risk: av attendance by 69% of parents and 71% of adolescents; 3. Attrition bias: moderate risk: a small sample of 199; no attrition analysis; 147 at 3 yrs; 4. Detection bias: moderate risk: 93% of the post-intervention child assessments completed; 89% of the Child Behavior Check Lists assessed by the mother; 91% of the teacher ratings completed; 86% agreement on parent-child problem solving during 2 10 min videos as assessed by the Family Process Code; 73% agreement on the affective valence between 2 independent assessors, combined kappa of .69 [however, wide range .37 to .78]); low correlations for the parent's reports of the child's behaviour using the Child Behavior Check List [the children's and mother's scores on the Externalising scale agreed r = .43 at baseline and r = .41 at 1 yr; and reports by the mother and father agreed r = .65]; correlations of expired CO with tobacco use were low [r = .47 at baseline; r = .58 at completion of the programme; and r= .65 at the 1 yr follow up]; 5. Power computation: not performed: 6. Statistical quality: adequate.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Elder 1996

Methods	Country: USA Sites: 96 schools in Texas, California, Louisiana and Minnesota. Focus: CATCH trial (Child and Adolescent Trial for Cardiovascular Health). Design: 10 schools at each site randomized to control, 7 to school-based intervention, 7 to school and family Analysis: % in (I) and (C) groups; multiple logistic regression. Study was not designed to find a difference in smoking prevalence.
Participants	7827 children at end of 5th grade, of whom 6527 gave complete information. 51% F ; Ethnicity: 71% white, 16% hispanic; 14% African-Americans. Differential characteristics at baseline or differential attrition from baseline: not stated.
Interventions	Interventions: (1) SCHOOL intervention, 15 sessions in 3rd grade about diets healthy for hearts and exercise, 12 in 4th grade about exercise, and 16 about exercise in 5th grade plus 8 about tobacco. The tobacco intervention, only offered in 5th grade, was 'F.A.C.T.S. for 5' (Facts and Activities about Chewing Tobacco and Smoking). 4 x 50 min sessions: Session 1: short- and long-term effects of tobacco use; Session 2: motivations and fallacies about tobacco use; Session 3: economic costs of tobacco use and the efforts of the tobacco companies to promote use; Session 4: dangers of passive smoking and being supportive of those who want to quit; (2) SCHOOL + FAMILY intervention: as above, plus: (a) Home-based programme, using 'The Unpuffables' from the ALA: 4 sessions with stories about adolescents who combat tobacco use, and games to play with parents; and (b) Policy component, encouraging the adoption of policies for the school to be tobacco-free (Minnesota schools already had a policy of 100% smoke-free schools at all time periods). Teachers received 1 or 1 1/2 sessions of training; (3) Control
Outcomes	% of schools with smoke-free policies; Smoking prevalence. Duration of follow up: 3 yrs.
Notes	Study Category 2: 1. Randomization bias: minimal risk: 2. Performance bias: minimal risk: All the schools participated during the entire 3 yr intervention period; of the children who began in a school which offered the school + family intervention, 47% attended such a school for the entire period. The process analysis for the FACTS tobacco curriculum showed that 87% of teachers participated in the classroom sessions; checklists were returned for 96% of classroom sessions; 96% completed the entire lesson; and 87% were implemented without modification. For the Family Intervention for tobacco 97% of session-specific activities were completed; 78% of adults participated in the home activities; however, only 48% of home team activity cards were returned; 40% of schools participated in 'Great American Smokeout' activities; 33% of schools held assemblies about tobacco; and 25% sponsored anti-tobacco or anti-drug clubs; 3. Attrition bias: minimal risk: 100% of 3rd grade teachers and 67% of students attended Family Fun Nights; All schools remained in the study; however, there was no attrition analysis; 4. Detection bias: minimal risk: 5. Power computation: not performed: 6. Statistical quality: adequate; Analysis was by multiple logistical regression (including a school random effect), but school effects were not stated.

Risk of bias

Elder 1996 (*Continued*)

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Forman 1990

Methods	Country: USA Site: all 30 secondary schools in a SE metropolitan area Focus: tobacco, alcohol and marijuana prevention Design: Schools matched on level (middle vs. high school) ethnic composition, % of students receiving free lunches, and school size, and within each cluster randomized to the school intervention, school plus parent intervention or comparison group. Analysis: Repeated measures multivariate ANOVA, analysed separately with the school and the individual as unit of analysis (results showed no differences by unit of allocation).
Participants	327 students average age 15 yrs; referred by teachers if had two or more of: high number of disciplinary incidents, low grades, high number of unexcused absences, drug or alchol use by most friends, drug or alcohol use by family members, low self-esteem, social withdrawal, or experimental alcohol or drug use
Interventions	Intervention 1: School intervention (10 session small groups with Botvin's Life Skills Training, with 2 hr booster 1 year later) Intervention 2: School plus Parent intervention: same as 1, plus parents participated in 5 weekly 2-hr sessions to teach parents the coping skills their children were learning in the student groups, teach parents behaviour management skills, and develop small group support system for parents. Control: 10x2-hr sessions in structured small groups with substance abuse programme adapted from that provided by the state drug and alcohol commission
Outcomes	Lifetime, monthly, weekly and 24-hr tobacco use; saliva samples were collected but not analysed
Notes	New for 2008 update. Study Category 2: 1. Randomization bias: moderate risk, method not described; unequal numbers in groups at baseline (school intervention n = 91; school and parent intervention n = 86; control n = 102). 2. Performance bias: minimal risk: All sessions tape recorded and independent raters achieved intercoder agreement > 90%; In coping skills training group half of the sessions covered > 80% of the planned activities, and average completion rate across all coping sessions = 74%; 2/3 of the students completed 9 or 10 of the intervention sessions, and 92% completed at least 7; 44% of the students in the School Plus Parent intervention had at least one parent participate in the parent training sessions, and of the parents who attended 74% attended at least 4 meetings; 3. Attrition bias: moderate; 15%; 279 of 327 students completed the 20 hour training and pre-and post-treatment assessment sessions, and of these 200 (72%) completed the booster one year later; no differential attrition analysis; 4. Detection bias: minimal risk. 5. Power computation: not performed. 6. Statistical quality: Multiple measures ANOVA, adjustment for clustering (no differences in results for individual and school as unit of analysis).
Risk of bias		

Forman 1990 (*Continued*)

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Jackson 2006

Methods	Country: USA Sites: 28 school districts in N Carolina, S Carolina and Colorado Focus: tobacco prevention Design: parent-child dyads randomized to experimental or control group Analysis: X2 to test for attrition bias; logistic regression to test whether the progam affected initiation of smoking
Participants	1147 parents submitted consent forms; 135 not contactable; 125 not eligible; 887 parent-child (3rd grader) dyads completed baseline assessment
Interventions	(1) "Smoke Free" program: 6 guides mailed to home (5 at 2 week intervals, one after 1 year) with tips on parenting skills; newsletters; gifts to participating children (yo-yos, wrist bands, cameras); (2) Control: 5 fact sheets about tobacco mailed to home
Outcomes	Ever having puffed on a cigarette
Notes	Study Category: 2 1. Randomization bias: Minimal. At baseline groups equivalent except in the intervention group 68% had parent who had attended college vs 60% for control group (p <.03); 2: Performance bias: moderate - no process analysis whether parents received, read and discussed tip sheets, or if control group received and read the fact sheets; 3. Attrition bias: Minimal: 11% attrition, no differential attrition 4. Detection bias: minimal: few logic errors in childrens' reporting of smoking status 5. Power computation: not performed 6. Statistical quality: minimal risk of bias: intention to treat analysis; analysis adjusted for covariates

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Jøsendal 1998

Methods	Country: Norway Site: nationwide sample of 4441 students in 195 classes in 99 schools. Focus: smoking prevention. Design: From a zipcode-ordered listing of all Norwegian secondary schools a school was randomly chosen, then the next three schools with a similar number of students, yielding clusters of 4 schools. Analysis: Pearson chi squared for differences across groups; McNemar's test for significance of changes and multiple logistic regression for changes in smoking rates.
Participants	4441 students, of whom 4215 provided written consent. Programme administered by classroom teachers. Parents received a brochure, teachers involved parents in discussions, and students signed a contract of non-smoking with parents.
Interventions	8-session intervention focused on personal freedom, the freedom to choose, freedom from addiction, making one's own decisions, tobacco-resistance skills, and the short-term consequences of smoking. The classroom teachers received 2 days training, detailed programme manuals to secure fidelity, and filled in a questionnaire after each lesson to evaluate programme fidelity. Students brought 2 brochures home; teachers involved parents in discussions on 'appropriate occasions', and students and parents signed non-smoking contracts. (1) classroom programme with involvement of parents and teachers; (2) classroom programme with involvement of parents; (3) classroom programme with involvement of teachers. (4) Control; no information on whether control group received any intervention
Outcomes	Daily, weekly, <weekly smoking, and non-smoking. Follow up at 6m, 18m, 30m. Only 6m follow-up data reported here.
Notes	Study Category 2: 1. Randomization bias: minimal risk: by random numbers; 2. Performance bias: moderate risk: process analysis conducted but results not stated; also, the programme was varied and no process analysis of the variations as time progressed: Verbal assurances of compliance from Grade 8 pupils and teachers and Grade 9 pupils. 3. Attrition bias: minimal risk: after 4 yrs attrition 11% (I) and 5.8% (C); 4. Detection bias: minimal risk: 5. Power computation: power 80% alpha = 0.05 required n = 757 in each group, with sample sizes achieved; 6. Statistical quality: adequate: no adjustment for clustering in Josendal (1998), but multilevel modeling allowed for clustering for 3 yr follow up (Josendal 2005)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Knutsen 1991

Methods	Country: Norway. Site: Tromsø. Focus: cardiovascular disease in male adults. Design: in 1986/7 re-interviewed a sample from the 1979/80 Tromsø study and randomly allocated men at high risk for cardiovascular disease (lowest quintile of HDL cholesterol and/or highest decile of triglycerides), and their family members intervention or control groups. Analysis: ANOVA
Participants	1373 men 30-54 years at high risk for cardiovascular disease, and family members (1143 wives and 2838 children); of these 1060 males, 935 women and 1103 children participated in the survey.
Interventions	(1) Intervention: baseline survey; 2 home visits 1-2 yrs after 1979/80 survey with counselling by a physician about risk factors for coronary heart disease with special emphasis on diet, and mention of smoking and exercise. Measured height, weight, non-fasting blood samples all aged 12+ yrs, BP for aged 7+. Family received dietary advice. Contact maintained through quarterly newsletters, and 2 personal phone calls to high risk adult males, + new lipid analysis offered 1-2 years post-intervention; (2) Control: data collection only.
Outcomes	Current daily smoking (not further defined). Follow up at 6 yrs.
Notes	Study Category 3: 1. Randomization bias: minimal risk: method of randomization not stated; 2. Performance bias: high risk: no anti-smoking intervention directed to the children; no process analysis; 3. Attrition bias: high risk: 77% of the eligible men participated, 82 % of the wives, but only 39% of children; no analysis of differential attrition. 4. Detection bias: minimal risk: 5. Power computation: not performed: 6. Statistical quality: inadequate: no baseline survey data from 1986/1987 for the children;

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Nutbeam 1993

Methods	Country: U.K. Study site: 39 secondary schools in 4 different educational authorities in Wales and England Focus: smoking prevention and changes in attitudes, knowledge, and values toward smoking. Programme type: 2 projects, lasting 3 months, integrated into classroom settings: (i) FSE, adapted from Norwegian family smoking education project; (ii) SAM, derived from Minnesota smoking prevention programme [Smoking and Me]. In 2 districts schools were randomly selected from school lists, while in remaining 2 districts schools were approached based upon previous response to health education; schools matched by size and catchment area and assigned to one of 4 groups. Statistical analysis: ANOVA, chi squared,and logistic regression, with analyses taking account of clustering.
Participants	5078 eligible students at pre-test were eligible, with 4562 (89.8%) completing the pretest; Age: 11-12 yrs: 52% M; Ethnicity not stated; .
Interventions	(1) 'Smoking and Me Project' (SAM) (9 schools, n=1021): 5 lessons, with pupil-led discussion groups about the social consequences of smoking, peer, family and media influences on smoking, and practising tobacco refusal skills. One teacher from each school was encouraged to attend a 1-day training session; (2) 'Family Smoking Education Project' (FSE) (10 schools, n=1127): 3 lessons on the immediate health impact of smoking on children, a pupil booklet, and a parent booklet which encourages parents to reinforce the messages from school and show disapproval of smoking. All teachers were required to attend a 1-day training seminar (3) both programmes (10 schools, n=1161) (4) control group: no formal interventions (10 schools, n=1229)
Outcomes	Self-reported smoking (never; tried once or twice; < 1 cig/week; 1-6 cigs/week; > 6 cigs/week) Saliva for thiocyanate levels collected but not analysed Follow-up: immediate post-test following programmes and 1 yr, on 89.4% cases valid for analysis.
Notes	Study Category 2: 1. Randomization bias: moderate risk: cards chosen from a hat, but also non-random assignment. Significant baseline differences between % of never-smokers in the FSE/SAM and SAM groups. 2. Performance bias: moderate risk. 3. Attrition bias: minimal risk: 4. Detection bias: minimal risk: 5. Power computation: not performed: 6. Statistical quality: adequate; logistic regression takes account of clustering.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Olds 1998

Methods	Country: USA. Site: semi-rural community (Chemung Country) in NY state; Focus: Effect of prenatal and early childhood nurse visits on children's antisocial behaviour. Design: 3x2x2 factorial structure, with 6 covariates (maternal age, maternal education, locus of control, support from partner, maternal employment status, paternal public assistance status); random assignment to one of four interventions or control; Analysis: intention to treat; general linear model and adjustment for covariates;
Participants	315 adolescents followed up at 15 yrs of age, children of participants in a randomized trial of 400 consecutive primiparous pregnant women, 85% <19, or unmarried or low SES. 89% white.
Interventions	(1) (n=94): Free sensory and developmental screening at 12m and 24m, with referrals for further evaluation and treatment where necessary; (2) (n=90): As (1), + free taxi transport for pre-natal and well-child care until child was 2; (3) (n=100): as (2), + nurse home visits during the pregnancy; (4) (n=116) as (3), + nurse home visits until child's 2nd birthday. The nurses taught positive health-related behaviours; competent care of the child, and personal development for the mother (family planning, educational achievement, and return to the workforce).
Outcomes	Cigarettes smoked/day in the preceding 6m. Groups 1 and 2 combined as comparison, since no differences between them. Follow up at 15 yrs.
Notes	Study Category 3: 1. Randomization bias: minimal risk: Participants randomized by selecting treatment assignment from decks of cards composed to ensure proportional treatment assignment within stratification blocks based upon women's race, marital status, and geographic region of residence at registration. To ensure balanced subclasses during the 2.5-yr recruitment phases, card decks were periodically reconstituted to over-represent treatment conditions that had smaller numbers of subjects; groups were similar at baseline and at 15 yrs; 2. Performance bias: high risk: wide ranges in the number of visits (families visited at home received an average of 9 (range 0 -16) visits during pregnancy and 23 (range 0 - 59) from birth through child's 2nd birthday); no process analysis of the content of the visits; 3. Attrition bias: moderate risk: From 500 eligible pregnant women 400 were enrolled and 315 offspring participated at 15 yr follow up; no attrition analysis; 4. Detection bias: minimal risk: 5. Power computation: moderate risk: based on estimates of program impact for prenatal and infancy outcomes identified at much earlier phases of the study and therefore has little bearing on the adolescent smoking outcome reported; 6. Statistical quality: adequate.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Reddy 2002

Methods	Country: India Site: 30 elementary schools in New Delhi Focus: Project HRIDAY: reduction in cardiovascular risk factors (diet, physical activity, tobacco use) Design: schools blocked on type (private, government) and gender (males only, females only, and co-educational) and randomized by coin toss. Analysis: Mixed effects regression with the school specified as the nested effect.
Participants	At baseline: 5752 students aged 12 (7th grade); 5043 (88%) provided consent, 4776 (83%) participated in the baseline survey Present after 1 year: 4452 (77%). 50.5% M
Interventions	Project HRIDAY [Health-Related Information and Dissemination Among Youth]: 1. School Intervention (10 schools, n=1439): (a) 10 posters in schools on cardiovascular health, (b) distribution of the HRIDAY project booklet with information on heart health, (c) classroom activities selected by teachers from a list of 20 [including 3 on influences to smoke, ways to refuse offers to smoke, and passive smoke], (d) round table discussions on food policy and nutrition, (e) invitation to sign a petition requesting a ban on tobacco advertising to be presented to the Prime Minister of India. (2) School/Family intervention (10 schools, n= 1863): as (1), + 6 booklets (1 on tobacco use, the rest on dietary patterns and exercise) taken home by pupils, and brought back parents' signed opinions about the booklets. (3) Control (10 schools, n=1474): Usual curriculum Intervention lasted for 1 school yr (September-June); teachers and selected peer leaders received training (duration not stated).
Outcomes	Ever use of cigarette or bidi, and likelihood of tobacco use when adult. Knowledge of and attitudes to smoking also surveyed. Follow up 1-8m post-intervention.
Notes	Study Category 3: 1. Randomization bias: minimal risk: randomization by coin toss (personal communication from authors]; groups were equivalent at baseline; 2. Performance bias: moderate risk: no process analysis; 2/30 schools had shorter follow up; 14/20 schools displayed all 10 posters, 6 displayed 7-9; 6/20 schools implemented all 20 activities from the teachers' manual; 8/10 schools in Family intervention group distributed at least 5 of the 6 booklets. 3. Attrition bias: moderate risk: no attrition analysis; no linkage of pre- and post student responses. [an e-mail from Dr. Cheryl Perry states there was adjustment for clustering, but insufficient funding for process evaluation and attrition]; 4. Detection bias: minimal risk: 5. Power computation: not performed: 6. Statistical quality: moderate; Individual student survey data could not be matched from pre-to post-test, but school populations 'fairly stable during the study period'.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Salminen 2005

Methods	Country: Finland Site: Kainuu, 10 municipalities in eastern Finland Focus: diet, exercise and tobacco Design: adults with early onset myocardial infarction, coronary heart disease, stroke, or family history of cholesterolemia were identified from hospital discharge registers; and invited to participate and provide names of their children and grandchildren ages 6-17 living in Kainuu; a random sample of children 6-17 was taken; Control Group 1 = children 6-17 belonging to high risk families; Control Group 2 = children not belonging to high risk families; Analysis: generalized estimating equations for correlation between repeated measurements; cumulative logistic model for ordinal data
Participants	600 adults with early onset myocardial infarction, coronary heart disease, stroke or family hypercholesterolemia were identifed from hospital registers, and 515 children (86%) from these families participated 1997-8 in the intervention; of 1609 in the control group 768 (48%) participated in the follow up, with 245 from high risk and 523 not from high risk families; avg age 10.8 years;
Interventions	Family-oriented health education September 1997-June 2000 consisted of 2 individual counseling sessions at school for children about diet, nutrition, smoking, drugs and alcohol; and 3 sessions for children and family members at home about diet, exercise, smoking, drugs, alcohol, stress, leisure time, fatigue, and social relations; family members identified their own risk factors and made plans to control them; goals were evaluated and progress towards the goals discussed; throughout the intervention period reading materials from voluntary organisations especially the Heart Association of Finland about nutrition cholesterol, alcohol, smoking and exercise were handed out; Control group received no counseling or intervention
Outcomes	Number of cigarettes, pipes or cigars smoked daily
Notes	Study Category: 3 1. Randomization bias: high. Ethics commitee thought that it would be unethical to randomize the high risk families into an intervention and control group, and the authors recognise the effect of the quasi-randomized design. 2. Performance bias: minimal. No process analysis, but all counseling was with individual children and families by 2 trained nurses; 3. Attrition bias: moderate: 432 (84% of baseline participants) children in intervention group; 200 (82%) in high risk control group; 423 (55%) in non high risk control group; no differential attrition analysis; 4. Detection bias: minimal: ascertained in interview by 2 trained nurses 5. Power calculation: not performed 6. Statistical quality: minimal bias: generalised estimating equations controlled for repeated observations; and cumulative logistical models for ordinal data.

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	No	C - Inadequate

Schinke 2004

Methods	Country: USA Site: New York City, New Jersey and Delaware Focus: Alcohol reduction Design: Youths were recruited from 43 community agencies in NY City, New Jersey and Delaware, and sites were stratified by geography and ethnicity, then randomly assigned to the CD-ROM intervention, CD -ROM + parent intervention, or control. Analysis: MANOVA
Participants	Baseline: 514 Age: avg 11.5 y Gender: 51.4% f
Interventions	(1) Social learning and Problem solving using CD-ROM: ten 45 minute sessions on goal setting, coping, peer pressure, refusal skills, norm correcting, self-efficacy, problem-solving (Stop, Options, Decide, Act, Self-praise), decison-making, effective communciation, and time management, (2) CD-ROM + Parent intervention: (a) parents received a 30 minute videotape with printed materials on the goals of the youth intervention, showed how parents could help avoid problems with alcohol, and the importance of family rituals, rules and bonding (b) 2 hour parent workshop; (c) parent CD-ROM how to reduce youth alcohol use (3) Control: (no further description)
Outcomes	No of cigarettes in the last 30 days
Notes	Study Category 1; 1. Randomization bias: minimal risk: groups equivalent at baseline; 2. Performance bias: minimal risk: usage of CD-ROMs was recorded by a code; 95% of youths completed the CD-ROM in the CD-ROM intervention group, and 91% in the CD-ROM + parent intervention group; 83% of parents watched the videotape; 67 % attended the workshop, and 79% completed the parent CD-ROM. 3: Attrition bias: minimal risk: 7.9% attrition in the CD-ROM group, 11.8% in the CD-ROM + parent group, and 6.7% in control; no differential attrition; 4. Detection bias: minimal risk: research assistants administered questionnaires individually by phone; 5: Power computation: no power computation; Statistical quality: MANOVA, youths did the CD-ROMs individually so no adjustment for clustering needed

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	No	C - Inadequate

Spoth 2001

Methods	Country: USA Site: 33 rural schools in 19 contiguous counties in a midwestern US state [Iowa]. Focus: tobacco, alcohol, marijuana prevention Design: Schools blocked on size and proportion in lower income households, then randomly assigned to one of 3 groups. Analysis: multilevel mixed model ANCOVA; dichotomous outcomes by z tests; for 4 and 6 yr follow up growth curve analysis was used;
Participants	Baseline: 1,309 eligible families (index child in 6th grade), of whom 667 (51%) completed the pretest; 10th grade follow up, at age 15: 447 (67%); and 373 families (56%) completed all 5 data assessments across 4 years; Age: 6th graders, age 11, 55% F.
Interventions	(1) Iowa Strengthening Families Program (ISFP) (11 schools, n=117): 7-session programme, with concurrent 1-hr sessions for parents and children: parents taught to clarify expectations, use appropriate discipline, manage strong emotions regarding their child, effectively communicate with their child; Children's sessions paralleled the parents' , + peer resistance and peer relationship skills training; in family sessions family members practised conflict resolution and communication skills and engaged in activities to increase family cohesiveness and positive involvement of the child in the family; (2): Preparing for the Drug-Free Years Program (PDFY) (11 schools, n=124): 5-session programme, with 4 parents only sessions: parents instructed on risk factors for substance abuse, developing clear guidelines on substance-related behaviours, enhancing parent-child bonding, monitoring compliance with their guidelines and providing appropriate consequences, managing anger and family conflict; and enhancing positive child involvement in family tasks; 1 child session on peer resistance skills. (3) Control (11 schools, n=208): 4 mailed booklets (physical and emotional changes in adolescence, and parent-child relationships).
Outcomes	Ever smoked, ever used chewing tobacco, cigarettes/day, and no. of times chewed tobacco in the past month. Follow up at 4 yrs and 6 yrs.
Notes	Study Category 1: 1. Randomization bias: minimal risk: schools randomly assigned by computer; 2. Performance bias: minimal risk: (a) for ISFP programme, 94% of attending families were represented by 1 family member in 5 or more sessions, and all key programme concepts were covered; (b) for PDFY programme all teams covered all key concepts, and completed 69% of the detailed tasks in the group leaders' manual. 93% of families attended at least 4/5 sessions. 87% of activities covered in the family sessions, 83% in the parent sessions, and 89% in the youth sessions; 3. Attrition bias: minimal risk: 447 remained at 4 years, but no differential attrition across groups; a multiple imputation Monte Carlo software programme (NORM) showed that attrition did not affect the findings; there was also no differential attrition after 6 yrs; 4. Detection bias: minimal risk; 5. Power computation: no power computation; 6. Statistical quality: adequate: the groups were equivalent at baseline and multilevel analyses with logistic growth curve techniques controlled for the effects of clustering; multilevel mixed model ANCOVA; dichotomous outcomes by z tests.
Risk of bias	

Spoth 2001 (*Continued*)

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Spoth 2002

Methods	Country: USA Site: 36 rural schools in 22 contiguous counties in a midwestern US state [Iowa]. Focus: family- and school-based competency training to prevent uptake of alcohol, tobacco and marijuana. Design: cluster-randomized trial, randomized block design. Analysis: multilevel analyses of covariance, with school incorporated as a random effect and dual biological parent families as a covariate (only significant difference between groups at baseline). Post-test measures used as baseline.
Participants	1664 7th graders in selected schools completed pretest. 53% M, 96% white.
Interventions	(1): Strengthening Families Program for Parents and Youth 10-14 (SFP 10-14): revision of the Iowa Strengthening Families Program; 7 1-hr weekly sessions for parents and children: parents' strengthened parental skills in nurturing, setting limits and communication about substances; children's strengthened prosocial and peer resistance skills. 4 booster sessions offered 1 yr later; (2): Life Skills Training (LST): 15 x 45-min classes + homework to provide knowledge about substance abuse, and promote youth skills in social resistance, self-management and general social skills, using coaching, facilitating, role modeling, feedback and reinforcement. 5 booster sessions in 8th grade. 12 schools received LST (n=621), 12 received LST + SFP 10-14 (n=549). (3) Control (n= 494): no statement if received any anti-tobacco intervention.
Outcomes	Self-reported never smoking at 1 yr after post-test assessment; 'bogus pipeline' CO monitoring at all assessments (i.e data collected but not assessed, to encourage honest reporting)
Notes	Study Category 1: 1. Randomization bias: minimal risk 2. Performance bias: minimal risk: adherence to the SFP programme was 92%, and to the LST programme 85%. Of the students who participated, the percentages attending 50% or more of the lessons were 100% for the LST programme + 100% for the boosters; 90% for the SFP 10-14 programme + 89% for the boosters. 3. Attrition bias: minimal risk: 18% no differential drop-out between groups; 4. Detection bias: minimal risk; expired CO samples were collected but not analysed; 5. Power computation: no power computation; 6. Statistical quality: adequate; allocation was at the school level and multilevel analysis controlled for the effects of clustering;

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Stevens 2002

Methods	Country: USA Site: 12 primary care pediatric practices in Massachusetts, New Hampshire and Vermont Focus: Dartmouth Prevention Cohort Study: prevention of risky adolescent behaviours by office-based pediatric interventions. Design: Cluster-randomized trial. Practices matched by size and randomized within each pair using computer-generated random numbers. Two intervention arms, no usual-care control group. Analysis: Chi squared and t tests to check for baseline differences, controlled for by logistic regression analyses.
Participants	4096 families approached by participating primary care physicians; 3525 (86%) agreed to participate; 3094 (77%) 5th and 6th graders and their parents completed the baseline assessment ; av child age 11, 48% F, 5% ever smokers at baseline.
Interventions	(1) Clinician advice about alcohol and tobacco. (2) Clinician advice about gun safety, bicycle helmets and car seatbelts. Pediatricians and nurse practitioners received 3 hr training session. All the practice staff encouraged family communication and rule setting about the issues. Families received a brochure on effective communication and pends, card games or fridge magnets to reinforce the message; children and parents each received 12 quarterly newsletters to reinforce the messages. The practices received a monthly message based on chart audits, phone calls and visits from the research co-ordinator. Pediatrician, parent and child signed a contract committing family to discuss the issues at home and to develop a policy about the relevant behaviours. Families received a follow-up signed letter from clinician, and a fridge magnet to 'post' the policy document.
Outcomes	Ever smoking at 12m, 24m, 36m follow up, on 2183 child-parent pairs.
Notes	Study Category 2: 1. Randomization bias: minimal risk: 2. Performance bias: minimal risk: High level of process evaluation by research staff. After the initial intervention visits 95% of children were seen for subsequent visits, during which prevention messages were delivered in only 47% of the practices allocated to the safety intervention and 51% of those allocated to the alcohol/tobacco intervention. 3. Attrition bias: minimal risk: 4. Detection bias: minimal risk: 5. Power computation: not performed: 6. Statistical quality: adequate

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Storr 2002

Methods	Country: USA Site: 9 public primary schools in Baltimore. MD. Focus: classroom management Design: Randomized controlled trial, with pupils randomly assigned within each school. Classroom was unit of randomization. Analysis: Chi squared and ANOVA to analyse pre-intervention equivalence of groups; logistic regression to assess attrition; multilevel logistic regression models; intention to treat analysis, with GEEs with a multivariate response profile approach. intention to treat analysis
Participants	Baseline: 678 first graders; Av age 5.7 yrs; 53% M, 86% African-American.
Interventions	(1) Classroom-Centered (CC) Intervention (n=230): (a) language and mathematics curricula enhanced to encourage skills in critical thinking, composition, listening and comprehension; (b) whole-class strategies to encourage problem solving by children in group contexts, decrease aggressive behaviour, and encourage time on task; (c) strategies for children not performing adequately. Teams of children received points for good behaviour and lost points for behaviours such as starting fights; the points could be exchanged for classroom activities, game periods and stickers. (2) Family-School Partnership (FSP) intervention (n=229): (a) the 'Parents on Your Side Program' trained teachers to communicate with parents and build partnerships, with 3-day workshop, training manual and follow-up supervisory visits; (b) weekly home-school learning and communicating activities; (c) 9 workshops for parents. (3) Control group (n=219): usual curriculum and parent-teacher communications.
Outcomes	Self-reported time to initiation of smoking, at 5, 6 and 7 yrs.
Notes	Study Category 1: 1. Randomization bias: minimal risk; SAS computer programme generated class lists and randomly assigned students. There was balancing for gender and kindergarten teacher ratings of aggressive disruptive behaviour and academic readiness [author's personal communication]. 2. Performance bias: minimal risk: implementation scores for the CC intervention averaged 60%, and parents in the FSP intervention attended an average of 4/7 sessions; high level of process evaluation throughout. 3. Attrition bias: minimal risk: 84% assessed 7 yrs later; with no differential attrition. 4. Detection bias: minimal risk; 5. Power computation: Estimated that 150 children per group would be needed. With an average 30% cumulative risk of initiating smoking, between-group relative risk of initiating smoking is 1.75; and alpha 0.05, 2-tailed for 80% power. 6. Statistical quality: adequate

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Wu 2003

Methods	Country: USA Site: 35 housing developments, community and recreatiuon centres in Baltimore, MD Focus: Effect of adding parental monitoring and booster sessions to small-group risk reduction interventions for adolescents. Design: Longitudinal randomized community-based cohort study, randomized at level of site. Analysis: Chi squared and Student t tests for differences in characteristics at baseline; general linear modeling with adjustment for clustering;
Participants	817 African-American youths 12-16 years, 42% M.
Interventions	(1) Focus on Kids (FOK): 8 session HIV small-group risk reduction programme on decision making, goal setting, communication, negotiating, and consensual relationships and information regarding safe sex, drugs, alcohol and drug selling. Conducted in small groups (5-10), led by 2 older peers. (2) FOK + ImPACT (Informed Parents and Children Together): 20-min video about parental monitoring and communicating with 2 instructor-led role-playing vignettes in the child's home). (3) FOK + ImPACT + booster sessions at 6m and 10m
Outcomes	Sexual intercourse; unprotected sex; self-reported smoking in last 6m (not further defined), alcohol, drugs, selling or delivering drugs; carrying a knife, fighting, beating someone up, or intention to take a risk. Assessment on Parent Adolescent Communication Scale Follow up at 6m,12m, 24m.
Notes	Study Category 2: 1. Randomization bias: minimal risk: method of randomisation not described. 2. Performance bias: moderate risk: no process analysis; 3. Attrition bias: minimal risk: 58% attrition by 24m follow up, no differential attrition on smoking status by group; 4. Detection bias: minimal risk: 5. Power computation: not performed: 6. Statistical quality: adequate

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

ALA: American Lung Association
CDC: Centers for Disease Control
CO: carbon monoxide
C: control
F: female
GEE: Generalized Estimating Equations
GP: general practitioner
HDL: high density lipid
HMO: Health Maintenance Organization
I: intervention
m: month

M: male
no.: number
SES: socio-economic status
Study Category 1: minimal risk of systematic bias
Study Category 2: moderate risk of systematic bias
Study Category 3: significant risk of systematic bias

Characteristics of excluded studies *[ordered by study ID]*

Abdullah 2004	RCT; but intervention is to help parents of young children stop smoking; no asssment of childrens' smoking
Albrecht 2006	RCT; tobacco outcomes; no prevention, only cessation. New for 2008 update.
Allendorf 1985	RCT; parent intervention, but no outcome data on tobacco
Biglan 2000	Family intervention not separately analysable
Cohen 1989	Effects of parental interventions cannot be separated from school interventions
Cohen 1995	RCT; Only 6% of families began the intervention
Ellickson 2003	Effects of parental interventions cannot be separated from school interventions
Flay 1988	Family intervention not separately analysable
Hahn 2007	No tobacco outcomes. New for 2008 update.
Hansen 1987	Family intervention not separately analysable
Hansen 1991	Cannot separate effects of parent interview homework from schools intervention
Hawkins 1999	Not RCT (CCT). New for 2008 update.
Horn 2007	RCT; smoking cessation. New for 2008 update.
Jackson 1994	Survey, not RCT
Johnson 1990	RCT; tobacco outcomes; cannot separate effects of family intervention from school intervention. New for 2008 update.
Krohn 1983	Survey, not RCT
Litrownik 2000	RCT; pre- and post -assessment at 8 weeks. Follow up not long enough
Lochman 2002	RCT; family intervention; no tobacco outcomes. New for 2008 update.
Moncher 1994	RCT; cannot separate outcomes of family from community intervention

(*Continued*)

O'Byrne 2002	Survey, not RCT
Patten 2006	RCT, cessation. New for 2008 update.
Pentz 1989	Not RCT (CBA). New for 2008 update.
Perry 1990	Not an RCT. New for 2008 update.
Perry 2003	RCT; D.A.R.E. Plus program consists of: (a) 4 session classroom program "On the Verge," (b) home team activities with parents, (c) theatre productions in classrooms, (d) 3 postcards to students, and (e) 10 postcards to parents. Cannot separate effects of parental from school components.
Piper 2000	No parental intervention
Ramchand 2006	Not RCT (follow up of cohort); tobacco outcomes; no family intervention. New for 2008 update.
Rohrbach 1994	RCT; Cannot separate out effect of parental intervention from school intervention
Rohrbach 2002	Parents not randomly assigned to experimental control groups
Schinke 1988	RCT; cannot separate outcomes of family from community intervention
Schinke 2000	RCT; cannot separate outcomes of family from community intervention
Severson 1991	Effects of quiz given to parents by students, and messages mailed to parents cannot be separated from the school intervention
Simons-Morton 2005	RCT; but cannot separate effects of parent component
Spoth 2007	RCT; tobacco outcomes; cannot separate effects of family from school interventions. New for 2008 update.
Stevens 1993	Not RCT (CBA). New for 2008 update.
Tang 1997	Not RCT (CBA). New for 2008 update.
Tingen 2006	Not an RCT; cannot separate effects of family component from Georgia Quit Line telephone help line
Vartiainen 2007	RCT; cannot separate effects of family intervention from schools intervention. New for 2008 update.
Werch 1991	RCT; did not measure children's smoking behaviour, only intentions to smoke
Werch 2005	RCT; but no family intervention: the flyer mailed to the home did not involve the parents or other family members explicitly, and the effects of the flyer cannot be separated from the individual counselling in school
Young 1996	RCT; did not measure children's smoking behaviour, only intentions to smoke

(*Continued*)

Zavela 2004	Not an RCT; cannot separate effect of family intervention

CBA: controlled before and after

DATA AND ANALYSES

Comparison 1. Summary of results of studies at minimal or moderate risk of bias

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Are family interventions better than no intervention or 'usual care'?			Other data	No numeric data
2 Are family interventions better than school interventions?			Other data	No numeric data
3 Are combined family plus school interventions better than school interventions?			Other data	No numeric data
4 Are family interventions which target tobacco better than family interventions which do not target tobacco?			Other data	No numeric data
5 Are combined family plus peer risk reduction interventions better than peer risk reduction interventions?			Other data	No numeric data

Analysis 1.1. Comparison 1 Summary of results of studies at minimal or moderate risk of bias, Outcome 1 Are family interventions better than no intervention or 'usual care'?.

Are family interventions better than no intervention or 'usual care'?

Bauman 2001	1,326 completed a base- line interview and of these 407 (34%) completed the pro-gramme; Follow-up: of the 1316 baseline pairs, 1135 (86%) com-pleted either the first or second follow-up interviews, and 1014 (77.1%) completed both		At year 1: there were 16.4% fewer new smokers in the intervention group than control, and they were less likely to begin smok-ing (OR = 1.27; 95% CI lower bound = 0.99; p corrected for design effect = .059) than the control. There were 25% fewer new smokers among non-His-panic Whites, attributed to stricter parental supervision and less parental smoking.	Minimal risk of bias	
Biglan 1987	Pre-test: 3387; at one year 2391		At 1 year there were no ef-fects of the messages to par-ents and no difference from control.	Moderate risk of bias	

Are family interventions better than no intervention or 'usual care'? (*Continued*)

Cullen 1996	Baseline: 246 newborns 1964-7; Follow-up in 1993: 209 adults aged 27-29 years (90%)		After 27-29 years: No significant differences in smoking for intervention (22.8%) compared to controls (33.6%, P=0.081; we computed OR = 0.60; 95%CI = 0.33 to 1.08)	Moderate risk of bias	
Curry 2003	Baseline: 7,337 families with a child 10-12 years; 20 month follow-up (88% of enrolled)		After 20 months: no statistically significant difference from participating in a family programme for adolescents as measured by ever smoking (12.1% control; 13.6% intervention; ns) or in the past 30 days (2.3% control, 2.4% intervention; ns)	Minimal risk of bias	
Jackson 2006	Of the 887 parent and child dyads who completed the baseline questionnaire, 776 (87%) were followed for 3 years		After 3 years control group more likely to initiate smoking than experimental group (OR = 2.16; 95%CI = 1.39 to 3.37; p <.001).	Moderate risk of bias	
Jøsendal 1998	Baseline: 4,441 students, of whom 4,215 provided written consent.; At 3 years: attrition in experimental groups 11.2% and control 5.8% (n's not stated)		After 3 years 68.3% nonsmokers in group which received the classroom-plus-parents intervention, and 58.3% in the control (p <.05; we computed OR = 0.48; 95%CI = 0.39 to 0.59). Average number of cigarettes smoked/week 12.8 for the parents + classroom group, 17.8 for the control, but no statistical analysis was presented because the authors state that no software is appropriate for their skewed data and design effect.	Moderate risk of bias	
Nutbeam 1993	Pre-test: 5078 students aged 11 and 12 eligible, and 4562		The percentage of nonsmokers in the Family Smoking Education Project	Moderate risk of bias	

Are family interventions better than no intervention or 'usual care'? (*Continued*)

	(89.8%) completed the pretest; Follow-up: 4538 (89.4%) valid cases for analyses.		group declined more over two years (from 77.6% to 53.8%) than in the control group (from 79.6% to 62%; p < 0.05; we computed OR = 1.40; 95%CI = 1.61 to 1.70).		
Spoth 2001	Baseline: 1,309 eligible families, of whom 667 (51%) completed the pretest; 10th grade Follow-up at 1 year: 447 (67%); and 373 families (56%) completed all five data assessments across 4 years.		After 1 year: 13.9% new smokers in the Iowa Strengthening Families Program and 16.7% in the control (a 27.5% relative difference; n.s.). After 4 years 67% in ISFP, 50% in control were never smokers; (relative reduction for ISFP vs. control 34.8% (p <.01); After 6 years: by growth curve analysis lifetime cigarette use was lower in the ISFP than control (p <.01).	Minimal risk of bias	
Storr 2002	Baseline: 678 first graders; Follow up in 6th, 7th, and 8th grades: 566 (84%)		As measured by time to initiation of smoking, lower risk of starting smoking for the Family-School Partnership (RR = 0.62; 95% CI = 0.39, 0.98; P = 0.041) compared to the control group.	Minimal risk of bias	

Analysis 1.2. Comparison 1 Summary of results of studies at minimal or moderate risk of bias, Outcome 2 Are family interventions better than school interventions?.

Are family interventions better than school interventions?

Biglan 1987	Pre-test: 3387; at one year 2391		At 1 year there were no effects of either the messages to parents or the school refusal skills programme	Moderate risk of bias	
Jøsendal 1998	Baseline: 4,441 students, of whom 4,215 provided written consent.; At 3 years: attrition in experimen-		At 3 years the percentage of non-smokers was, 68.3% in the group which received the classroom-plus-parents intervention and 62.7% in the classroom programme-	Moderate risk of bias	

Are family interventions better than school interventions? (*Continued*)

	tal groups 11.2% and control 5.8% (n's not stated)		plus-teacher training intervention (n.s.). The average number of cigarettes smoked per week was 12.8 for the school + parents group and 14.3 for the school + teacher group but no statistical analysis was presented because the authors state that no software is appropriate for their skewed data and design effect.		
Nutbeam 1993	Pre-test: 5078 students aged 11 and 12 eligible, and 4562 (89.8%) completed the pretest; Follow-up: 4538 (89.4%) valid cases for analyses.		After 2 years the Family Smoking Education project group retained fewer baseline non smokers as non-smokers than the Smoking and Me Project (p <.05; we computed OR = 1.08; 95%CI = 0.89 to 1.32).	Moderate risk of bias	
Spoth 2001	Baseline: 1,309 eligible families, of whom 667 (51%) completed the pretest; 10th grade Follow-up at 1 year: 447 (67%); and 373 families (56%) completed all five data assessments across 4 years.		After 6 years time to initiation of smoking was 54.9 months in the Iowa Strengthening Families Program compared to 31.0 months in control (p <.05) and 31.8 months in the Preparing for the Drug Free Years Programme (n.s. compared to control). Although the ISFP and PDFY were not compared statistically, because the months to initiation are identical for the PDFY and control it is reasonable to conclude that the ISFP has statistically significantly longer times to initiation than the PDFY (p <.05)	Minimal risk of bias	
Storr 2002	Baseline: 678 first graders; Follow up in 6th, 7th, and 8th grades: 566 (84%)		As measured by time to initiation of smoking there was a lower risk of starting smoking for both the Classroom-Centered group (RR	Minimal risk of bias	

			adjusted = 0.55; 95% CI = 0.34, 0.88; P = 0.013) and the Family-School Partnership (RR = 0.62; 95% CI = 0.39, 0.98; P = 0.041) compared to the control group, The CC and FSP interventions were not compared statistically, but we computed OR = 1.08; 95%CI = 0.71 to 1.64		

Analysis 1.3. Comparison 1 Summary of results of studies at minimal or moderate risk of bias, Outcome 3 Are combined family plus school interventions better than school interventions?.

Are combined family plus school interventions better than school interventions?

Ary 1990	Pre-test: 7,837 1 year: 6263 completed asessments at baseline and one year		After 1 year there were no effects of the messages to parents. For grades 6 to 9, no significant differences in proportions remaining non-smokers, but the baseline smokers in the experimental group smoked fewer cigarettes a month (77) than those in the control (111; p < 0.05). Thus no incremental effect of a family + school compared to school programme.	Moderate risk of bias	
Biglan 1987	Pre-test:3387; at one year 2391		At one year there were no effects of the messages to parents, and (a) for female non-smokers there were no effects of the school refusal skills intervention on smoking behaviour and (b) for males smoking rates in the intervention group were higher than control (p < 0.04) [but expired air carbon dioxide levels were not significantly different] so it can be concluded for both females and males the combined intervention was not	Moderate risk of bias	

Are combined family plus school interventions better than school interventions? (*Continued*)

		better than the schools intervention.		
Elder 1996	Baseline: 7,827; At 36 months, at end of 5th grade: 6,527 gave complete information);	At 3 years no significant differences in the percentages in the experimental (4.7%) and control groups (5%) stating that they had ever smoked (OR = 1.01, 95% CI 0.79-1.30). No effect of adding the family "Unpuffables" intervention to the school intervention.	Moderate risk of bias	
Forman 1990	Eligibles: 327 Baseline: 279 students in 30 schools completed 20 hour training programme and pre and post-treatment assessment sessions 1 year: 201 completed booster and 1 year assessment (drop-outs: 20 students had moved school, 24 voluntarily wirhdrew; 4 prohibited from participation due to very disruptive behaviour)	1 year: no significant differences	Moderate risk of bias	
Jøsendal 1998	Baseline: 4,441 students, of whom 4,215 provided written consent.; At 3 years: attrition in experimental groups 11.2% and control 5.8% (n's not stated)	At 3 years the percentage of non-smokers was 68.5% in the group which received the classroom-plus-parents-plus teacher-training intervention and 68.3% for the classroom programme-plus-parent intervention (n.s.) The average number of cigarettes smoked per week was 10.9 for the full intervention group and 12.82 for the school + parents group, but no statistical analysis was	Moderate risk of bias	

Are combined family plus school interventions better than school interventions? (*Continued*)

			presented because the authors state that no software is appropriate for their skewed data and design effect.		
Nutbeam 1993	Pre-test: 5078 students aged 11 and 12 eligible, and 4562 (89.8%) completed the pretest; Follow-up: 4538 (89.4%) valid cases for analyses.		After 2 years for never smokers, the percentage remaining never smokers was 69% in the combined Family Smoking Education Project plus Smoking and Me group and 70% in the Smoking and Me Project group (n.s).	Moderate risk of bias	
Spoth 2002	Pretest: LST 621; LST + SFP 549; control 494; Follow-up at 1 year: LST 503; LST + SFP 453; control 416.		At 1 year the % of new smokers was 12.1 in the combined Life Skills Training (LST) + Strengthening Families Project, 13.9% in the LST, and 16.7% in the control (n.s.; we computed OR = 0.85; 95%CI = 0.60 to 1.20)	Minimal risk of bias	

Analysis 1.4. Comparison 1 Summary of results of studies at minimal or moderate risk of bias, Outcome 4 Are family interventions which target tobacco better than family interventions which do not target tobacco?.

Are family interventions which target tobacco better than family interventions which do not target tobacco?

Stevens 2002	The families of 4,096 5th and 6th graders in the practices of primary care physicians were approached to participate, of whom 3094 (77%) completed both the parent's and children's baseline survey; 36 month follow-up: 2183 parent-child pairs (53%)		At 3 years there was no change in tobacco usage in the intervention group which received the alcohol and tobacco messages compared to the other intervention group which received the gun, bicycle helmet and seat belt safety intervention.	Moderate risk of bias	Heterogeneous combination of intervention strategies with different aims

Analysis 1.5. Comparison 1 Summary of results of studies at minimal or moderate risk of bias, Outcome 5 Are combined family plus peer risk reduction interventions better than peer risk reduction interventions?.

Are combined family plus peer risk reduction interventions better than peer risk reduction interventions?

Schinke 2004	Baseline: 514 After 3 years: 469 (91%)	At 1,2, and 3 years lower cigarette use in both intervention groups than control (p <.001)		
Wu 2003	Baseline: 817 youths 12-16 years, 24 year follow-up: 346 (42%)	At 2 years less smoking in the group which received both the Focus on Kids (FOK) and the Informed Parents and Children Together (ImPACT) interventions (12.5%), compared to those who received only the FOK intervention (22.7%; p<.05).	Moderate risk of bias	Incremental, and with comparison against a control.

WHAT'S NEW

Last assessed as up-to-date: 15 December 2007.

16 April 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 4, 2003

Review first published: Issue 1, 2007

18 December 2007	New search has been performed	Updated for 2008 issue 2, with two new included studies (Forman 1990 and Connell 2007) and 14 new excluded trials. Conclusions strengthened but unchanged.

CONTRIBUTIONS OF AUTHORS

RT conceived and wrote the review; RT and PB checked retrieved studies, extracted data and worked on tables. DL performed multiple searches. All authors read and contributed to the scope, content and style of the review.

DECLARATIONS OF INTEREST

None known.

INDEX TERMS

Medical Subject Headings (MeSH)

*Family; Adolescent; Randomized Controlled Trials as Topic; Smoking [*prevention & control; psychology]

MeSH check words

Child; Humans