

**HLTH 4511: Introduction to Problematic Substance Use and  
Approaches for its Prevention and Treatment**

**Universal family-based prevention programs for  
alcohol misuse in young people**

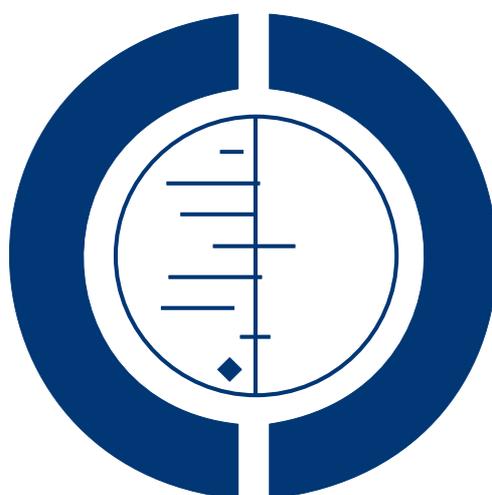
**By**

**David R Foxcroft & Alexander Tsertsvadze**

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# Universal family-based prevention programs for alcohol misuse in young people (Review)

Foxcroft DR, Tsertsvadze A



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## TABLE OF CONTENTS

HEADER . . . . .	1
ABSTRACT . . . . .	1
PLAIN LANGUAGE SUMMARY . . . . .	2
BACKGROUND . . . . .	2
OBJECTIVES . . . . .	3
METHODS . . . . .	3
Figure 1. . . . .	5
Figure 2. . . . .	6
Figure 3. . . . .	7
RESULTS . . . . .	8
DISCUSSION . . . . .	11
AUTHORS' CONCLUSIONS . . . . .	13
ACKNOWLEDGEMENTS . . . . .	14
REFERENCES . . . . .	14
CHARACTERISTICS OF STUDIES . . . . .	19
DATA AND ANALYSES . . . . .	47
ADDITIONAL TABLES . . . . .	47
APPENDICES . . . . .	48
HISTORY . . . . .	51
CONTRIBUTIONS OF AUTHORS . . . . .	51
DECLARATIONS OF INTEREST . . . . .	51
SOURCES OF SUPPORT . . . . .	51
NOTES . . . . .	52
INDEX TERMS . . . . .	52

[Intervention Review]

# Universal family-based prevention programs for alcohol misuse in young people

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## ABSTRACT

### Background

Alcohol misuse in young people is a cause of concern for health services, policy makers, prevention workers, and criminal justice system, youth workers, teachers, and parents.

### Objectives

To systematically review evidence on the effectiveness of universal family-based prevention programs in preventing alcohol misuse in school-aged children up to 18 years of age. To update a part of a previously published Cochrane systematic review.

### Search methods

Relevant evidence (up to 2002) was selected from the previous Cochrane review. Later studies, to July 2010, were identified from MEDLINE, Cochrane Central Register of Controlled Trials, EMBASE, Project CORK, and PsycINFO.

### Selection criteria

Randomized trials evaluating universal family-based prevention programs and reporting outcomes for alcohol use in students 18 years of age or younger were included. Two reviewers screened titles/abstracts and full text of identified records.

### Data collection and analysis

Two reviewers extracted relevant data independently using an *a priori* defined extraction form. Risk of bias was assessed.

### Main results

12 parallel-group trials were included. The reporting quality of trials was poor, only 20% of them reporting adequate method of randomisation and program allocation concealment. Incomplete data was adequately addressed in about half of the trials and this information was unclear for about 30% of the trials. Due to extensive heterogeneity across interventions, populations, and outcomes, the results were summarized only qualitatively.

9 of the 12 trials showed some evidence of effectiveness compared to a control or other intervention group, with persistence of effects over the medium and longer-term. Four of these effective interventions were gender-specific, focusing on young females. One study with a small sample size showed positive effects that were not statistically significant, and two studies with larger sample sizes reported no significant effects of the family-based intervention for reducing alcohol misuse.

## Authors' conclusions

In conclusion, in this Cochrane systematic review we found that the effects of family-based prevention interventions are small but generally consistent and also persistent into the medium- to longer-term.

## PLAIN LANGUAGE SUMMARY

### Family-based alcohol misuse prevention for young people can be effective

We conducted a Cochrane systematic review of 12 randomised controlled trials that examined the effectiveness of family-based universal programs for the prevention of alcohol misuse in young people. In family settings, universal prevention typically takes the form of supporting the development of parenting skills including parental support, nurturing behaviours, establishing clear boundaries or rules, and parental monitoring. Social and peer resistance skills, the development of behavioural norms and positive peer affiliations can also be addressed with a universal family-based preventive program.

Most of the studies included in this review reported positive effects of family-based universal programs for the prevention of alcohol misuse in young people. Two studies, each with a large sample size, reported no effects. In conclusion, in this Cochrane systematic review we found that the effects of family-based prevention interventions are small but generally consistent and also persistent into the medium- to longer-term.

## BACKGROUND

### Description of the condition

Alcohol misuse is defined as drinking levels of alcohol that can cause physical, psychological and social problems - both in the short term and the long term. Worldwide, alcohol misuse causes 1.8 million deaths (3.2% of total deaths) and 58.3 million Disability-Adjusted Life Years (DALYs) (4% of total). Accidental injuries are responsible for about one third of the 1.8 million deaths, while neuro-psychiatric conditions are responsible for nearly 40% of the 58.3 million DALYs (WHO 2008).

The European Union (EU) is the heaviest drinking region of the world, drinking 11 litres of pure alcohol per adult each year (Anderson 2006). More than 1 in 4 deaths among men (aged 15-29 years) and 1 in every 10 deaths among young women in the EU is alcohol related (Rehm 2005). Young people (aged 15-24 years) are responsible for a high proportion of this burden, with over 25% of youth male mortality and approximately 10% of young female mortality being due to alcohol (Anderson 2006). Sparse information exists on the extent of social harm in young people, despite the fact that a third of a million (6%) 15-16 year old school students in the EU report engaging in fights, and 200,000 (4%) report unprotected sex, due to their own drinking (Anderson 2006).

In many countries heavy episodic or binge drinking is prevalent amongst young people and presents an increased risk for accidents, violence, criminal activity, poorer health and social outcomes. Alcohol consumption is also limited by legislated age-related restrictions, and much alcohol use by young people under the age of 21 (e.g. United States) or 18 (e.g. United Kingdom and some other European countries) is therefore illegal.

Amongst young people, early initiation of alcohol use has been shown to be linked to later binge drinking, heavy drinking and alcohol-related problems, in both prospective longitudinal studies (Pitkanen 2005; Warner 2003; Zakrajsek 2006) and large scale cross-sectional epidemiological studies from the United States (Dawson 2008; Hingson 2006; Hingson 2003a; Hingson 2003b). There is some evidence that early consumption may lead to neurological development problems and impairment (AMA 2004), and the Chief Medical Officer for England has recently advised that young people below the age of 15 should not be allowed to drink alcohol (CMO 2009).

### Description of the intervention

The United States Institute of Medicine (Mrazek 1994) proposed a framework for classifying prevention into universal or selective prevention interventions, as a replacement for the previous concepts of primary or secondary prevention. Universal prevention strategies address the entire population within a particular set-

ting (schools, colleges, families, community). The aim of universal prevention is to deter or to delay the onset of a disorder or problem by providing all individuals the information and skills necessary to prevent the problem. Universal prevention programs are delivered to large groups without any prior screening for risk factors, so all members of the population share the same general risk, although the risk may vary greatly among individuals and sub-groups (EMCDDA 2010). In family settings, universal prevention typically takes the form of supporting the development of parenting skills including parental support, nurturing behaviours, establishing clear boundaries or rules, and parental monitoring. Social and peer resistance skills, the development of behavioural norms and positive peer affiliations can also be addressed with a universal family-based preventive program.

### How the intervention might work

Parents and carers play an important role in the socialization of young people. We know that positive parental supportive and controlling behaviours, and adequate parental monitoring, can promote the development of pro-social behaviour and reduce affiliation with, and influence from, deviant peer groups. If young people have a positive family environment and develop social and peer resistance skills then they are more likely to develop and adopt behavioural norms associated with their family life and to be resilient against external influences, either from peers or advertisers. Family-based prevention programmes differ from school-based prevention programmes in an important characteristic: the mechanism of effect is indirect, via parents and family, rather than an intervention program delivered direct to the target population, ie young people.

Universal prevention interventions are best when the risk factors for development of a problem are not easy to identify, are diffuse in the population, and are not easily targeted by an intervention. Another indication for universal, as opposed to selective prevention, is when the prevention paradox operates, i.e. more problems within a population arise from those at lower levels of risk than those at higher levels of risk. Several studies indicate that the prevention paradox is relevant to youth drinking.

In a robust cost-benefit model (Caulkins 2004) it was estimated that even small effect sizes in universal prevention interventions, in terms of delaying initiation into substance use for a few years, could lead to important savings to society over an individual's lifetime. Similarly, the United Kingdom National Institute for Health and Clinical Excellence (NICE 2010) has estimated that a national alcohol misuse prevention program in schools would be a cost effective use of public money if it cost £75 million and achieved at least a 1.4% absolute reduction in alcohol consumption amongst young people, a very small effect size.

Both economic models assumed that delaying onset of alcohol misuse and use would avert some of the long-term adverse health outcomes associated with alcohol consumption. Therefore, an im-

portant consideration when evaluating the effectiveness of alcohol misuse prevention programs is how long a program's effects persist, i.e. a program's duration of impact. Those interventions that show persistence of effects over several years are more useful than those interventions that show some immediate or short-term effects but no evidence of any longer-term duration of impact over several years.

### Why it is important to do this review

A previous Cochrane systematic review (Foxcroft 2002) covered the primary prevention of alcohol misuse amongst young people, with 55 studies included for the period to January 2002. This review was broad in scope, extending across different intervention settings (e.g. schools, families, community, health clinics), age groups (up to age 25 years-old), population focus (universal and selective primary prevention programmes), and study designs (randomised controlled trials, matched comparison studies, interrupted times series studies). In updating the search for this previous Cochrane review, we found a large number of records (n=153, to July 2010) reporting new randomised trials and new results from existing randomised trials.

We therefore decided to narrow the scope of the Cochrane review and produce an updated review of randomised trials evaluating the effectiveness of universal family-based prevention programs for alcohol misuse amongst youth 18 years or younger, alongside a separate review focusing on universal school-based prevention programs for alcohol misuse amongst youth 18 years or younger. This is consistent with other reviews produced by the Cochrane Drugs and Alcohol Group, for example universal school-based prevention of drug misuse (Faggiano 2005).

Two other, more focused, reviews have also been produced: one covers universal school-based prevention (Foxcroft 2011), and the other universal multi-component prevention (Foxcroft 2011 a).

Other Cochrane reviews, begun or published since 2002, have also focused on the prevention of alcohol misuse in young people, though typically in young adults including college student populations (Coombes 2008; Moreira 2009).

## OBJECTIVES

To systematically review evidence on the effectiveness of universal family-based prevention programs in preventing alcohol misuse in school-aged children up to 18 years of age. The specific aim of this review was to determine if family-based psychosocial and educational prevention programs prevent alcohol misuse compared to other types of interventions or no intervention.

## METHODS

## Criteria for considering studies for this review

### Types of studies

Randomized controlled trials (individual or cluster design).

### Types of participants

Young people up to 18 years attending school. For this review, young people are defined as children and adolescents.

### Types of interventions

**Experimental** - any universal family-based psychosocial or educational prevention program. Psychosocial intervention is defined as one that specifically aims to develop psychological and social attributes and skills in young people (e.g., behavioural norms, peer resistance), via parental socialization and influence, so that young people are less likely to misuse alcohol. Educational intervention is defined as one that specifically aims to raise awareness amongst parents and / or carers of how to positively influence young people, or of the potential dangers of alcohol misuse, so that young people are less likely to misuse alcohol. Studies that evaluated interventions aiming specifically at preventing and reducing alcohol misuse as well as generic interventions (e.g., drug education programs), or other types of interventions (e.g., screening for alcohol consumption) were eligible for inclusion in the review.

**Control** - any alternative prevention program (e.g., school-, family-, office-based, multi-component, other) or no program.

### Types of outcome measures

#### Primary outcomes

1. Any direct self-reported or objective measures of alcohol consumption or problem drinking. Outcome measures related to psychological perception/attitudes or awareness were deemed as indirect and therefore were not considered in this review. As an example, the following outcomes were included and considered as relevant:

2. Alcohol use (yes/no)
3. Alcohol use (quantity, frequency)
4. Drinking 5+ drinks at any one occasion (yes/no)
5. Incidence of drunkenness

#### Secondary outcomes

1. Alcohol initiation (age)
2. drunkenness initiation (age)

## Search methods for identification of studies

All relevant studies published up to 2002 inclusively, evaluating the effectiveness of universal family-based prevention programs in reducing/preventing alcohol use or misuse in students 18 years of age or younger were identified and selected from the previously published Cochrane review (Foxcroft 2002). The selection was not restricted by language or status of publication.

### Electronic searches

Update searches were conducted to identify new relevant evidence for the period of 2002 January to 2010 July. No language restrictions were applied. The following electronic databases were searched:

- MEDLINE (2002 January - July Week 1 2010)
- Cochrane Central Register of Controlled Trials (*The Cochrane Library* 2009, issue 4)
- EMBASE (2002 January - July Week 1 2010)
- Project CORK (2002 January - 2009 December)
- PsycINFO (up to July Week 1 2010)

Details of search terms are given in [Appendix 1](#), [Appendix 2](#) and [Appendix 3](#)

### Searching other resources

The references of topic-related systematic reviews and included studies were hand searched in order to identify potentially relevant citations. Unpublished reports, abstracts, dissertations, brief and preliminary reports were eligible for inclusion.

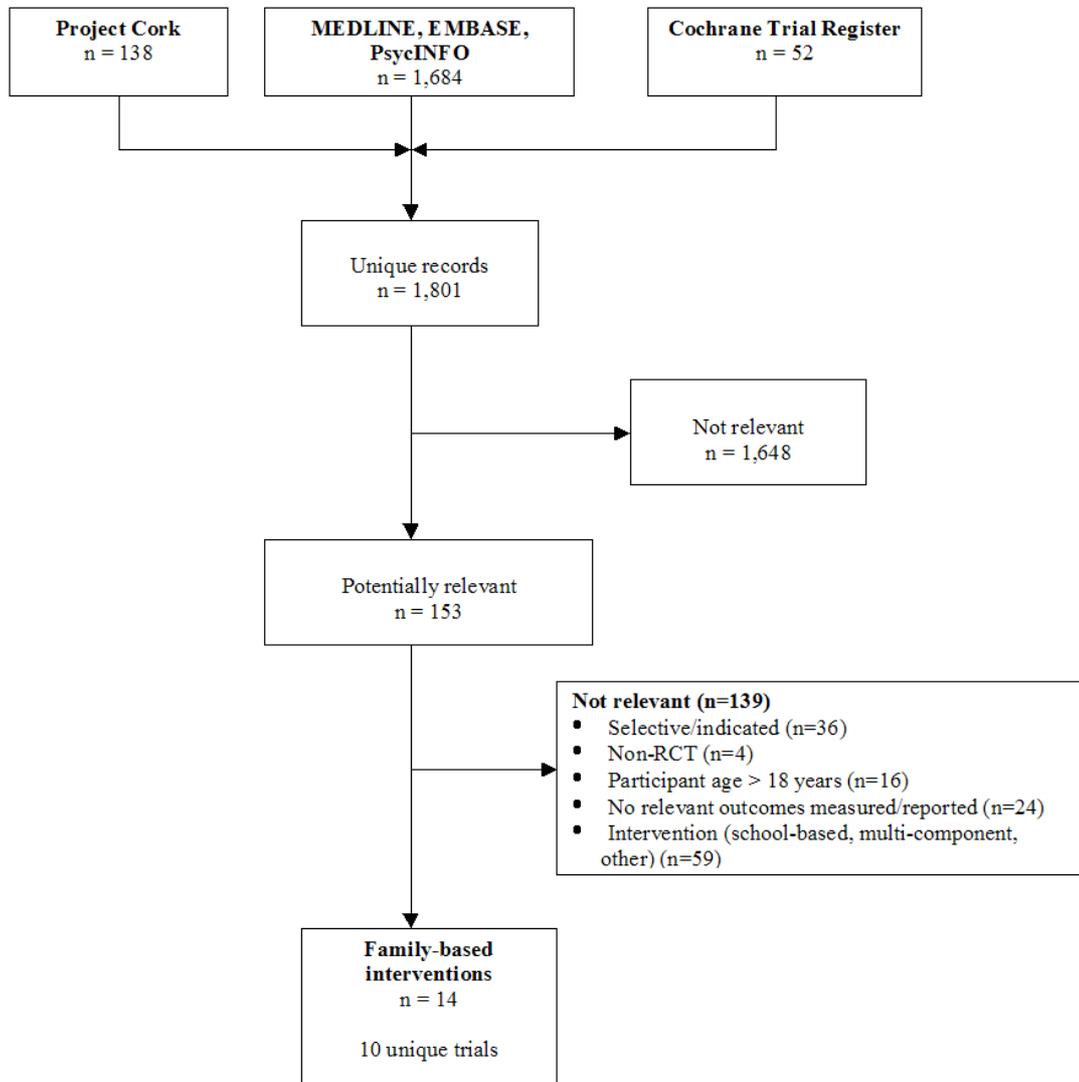
## Data collection and analysis

### Selection of studies

Two independent reviewers (D.F. and A.T.) completed broad screening of titles and abstracts of all identified records (screening level 1). Afterwards, the same reviewers independently assessed full-text reports of all potentially relevant for inclusion records that passed the initial screening level. Differences in opinion arising at both screening levels were resolved through discussions. After bibliographic searches were completed, all the retrieved records were assembled in a database and were de-duplicated (i.e., duplicate records identified and removed). The amount of evidence was maximized by using all companion publications reporting relevant outcomes for any given study. The study flow diagram of records identified from update search conducted in electronic databases is presented in [Figure 1](#).

Figure 1.

Study Flow Diagram



## Data extraction and management

Two reviewers (D.F. and A.T.) extracted relevant data independently using *a priori* defined extraction form and entered data into RevMan 5.0.24 (RevMan 2010). Differences in opinion arising during data extraction were resolved through discussions.

## Assessment of risk of bias in included studies

For each study included in the review, two authors (D.F. and A.T.) independently assessed the risk of bias using the Cochrane Collaboration's tool (Higgins 2009, section 8.5.1.) The risk of bias assessment was based on the recommended 6 methodological domains of validity:

1. Adequate sequence generation (High, Low, Unclear risk)
2. Adequate allocation concealment (High, Low, Unclear risk)
3. Blinding of personnel/outcome assessors (High, Low, Unclear risk)
4. Addressing incomplete outcome data (High, Low, Unclear risk)
5. Free of selective outcome reporting (High, Low, Unclear risk)
6. Free of other bias (High, Low, Unclear risk)

Each item was rated with one of three possible responses: high, low, or unclear. For each response, an explanation was provided.

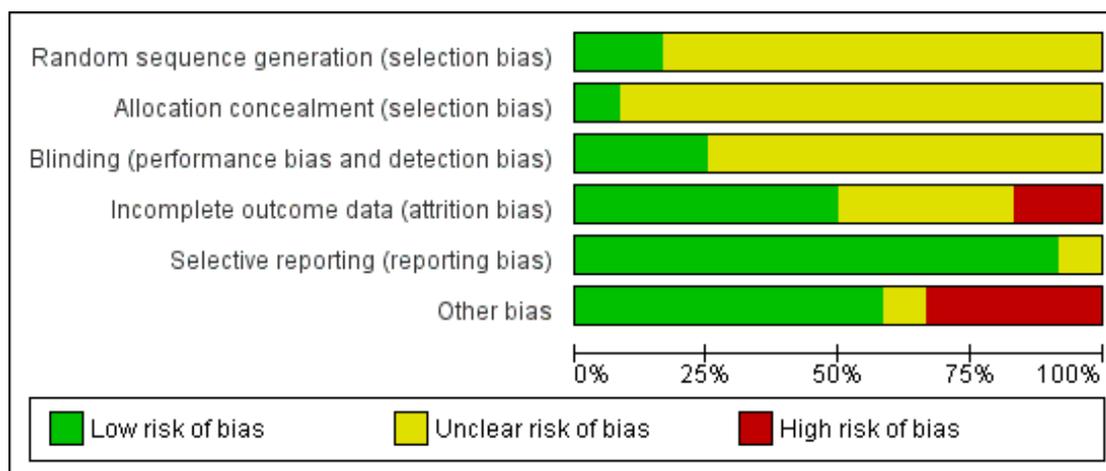
Blinding of participants and program deliverers (item #3) is not achievable for these sort of interventions, so our assessment of blinding focused on whether outcome assessors were blinded to study condition.

For addressing incomplete outcome data (item #4), a cut-off value of 20% for attrition rate (Fewtrell 2008) and reporting of intention to treat (ITT) analysis were considered. For example, studies with higher attrition rates (> 20%) not reporting ITT analysis were classified as 'High risk'. Studies with lower attrition rates ( $\leq$  20%) reporting ITT analysis were classified as 'Low risk'. If only either of the two criteria was met (e.g.,  $\leq$  20% attrition but no ITT analysis reported), the study was classified as 'Unclear'.

For item #5, we classified a study as 'Low risk' of outcome reporting bias if all outcome measures listed in the study methodology were reported in detail in the results section. If all outcome measures were not reported then the study was classified as 'High risk'. If only less relevant and less used outcomes were reported in the study methodology and results sections, we classified the risk of selective outcome reporting as 'unclear'.

For the purpose of this review, Item # 6 was assessed for possibility of confounding (i.e., baseline between study group imbalance in important covariate such as gender and alcohol use) and contamination of program effects (e.g., if clusters of students were randomised to the experimental or control program within one school). The risk of bias data for included trials was summarized in Figure 2 (risk of bias graph) and Figure 3 (risk of bias summary).

**Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.**



**Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.**

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bauman 2002	?	?	+	+	+	-
Brody 2006	?	?	+	?	+	-
Haggerty 2007	?	?	?	+	+	+
Koning 2009	?	+	?	?	+	+
Loveland-Cherry 1999	?	?	?	?	+	?
O'Donnell 2010	?	?	+	+	+	-
Schinke 2009a	?	?	?	+	+	+
Schinke 2009b	?	?	?	+	?	-
Schinke 2009c	?	?	?	+	+	+
Spoth 1999a	+	?	?	-	+	+
Stevens 2002	+	?	?	-	+	+
Werch 2008	?	?	?	?	+	+

### Unit of analysis issues

Additional validity threats were ascertained regarding appropriate unit of analysis depending whether the randomisation was implemented at individual- or cluster-level (see Tables of Characteristics of included studies).

### Dealing with missing data

If important data was missing, attempts were made to contact the authors of included studies.

### Assessment of reporting biases

The extent of publication bias was to be assessed through visual inspection of asymmetry and running the regression-based method for a funnel plot (Egger 1997; Peters 2008).

### Data synthesis

The statistical pooling of results of individual studies was planned conditional on the absence of heterogeneity with respect to study populations (e.g., baseline characteristics, gender), interventions (e.g., type, differences in target/focus), and outcome measures (e.g., different tools, instruments, scales) as well as the methodology of conduct (e.g., units of randomisation and analysis, cluster vs. individual trials).

### Subgroup analysis and investigation of heterogeneity

The extent of heterogeneity was planned through examination of forest plots (Chi square statistic and p-value;  $I^2$  statistic) and qualitative subgroup analysis. The subgroup analyses would explore whether or not the effects of universal family-based prevention programs differed in certain subgroups of study participants. The following *a priori* determined participant-level subgroups were based on age, race (Caucasians vs. Blacks, Hispanics), gender, and levels of alcohol use/consumption (at baseline).

### Sensitivity analysis

These analyses were planned, if data allowed, to investigate whether the effects of universal family-based prevention programs in reducing alcohol misuse were different in the following trial-level defined groups:

1. Cluster (ones appropriately analysed)- vs. individually randomised trials.
2. Cluster-randomized trial appropriately analysed (i.e., units of randomisation and analysis are matching) vs. cluster-

randomised trial inappropriately analysed (i.e., units of randomisation and analysis not matching).

3. Trials with attrition > 20% (1<sup>st</sup> follow-up) vs. trials with attrition ≤ 20% (1<sup>st</sup> follow-up)

## RESULTS

### Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

See: [Characteristics of included studies](#) and [Characteristics of excluded studies](#).

### Results of the search

Initially, we examined the previously published Cochrane review (Foxcroft 2002) to identify trials published up to 2002 January inclusively by applying our eligibility criteria (see the Methods section). Only two trials were eligible for inclusion in the review (Loveland-Cherry 1999; Spoth 1999a).

The updated electronic searches (2002 January - 2010 July) identified 1,874 bibliographic records (1,684 through MEDLINE, EMBASE, and PsycINFO; 138 through Project Cork; 52 through the Cochrane Trial Register). The process of de-duplication resulted in 1,801 unique bibliographic records. Through the screening of titles and abstracts, 1,648 records were excluded as obviously irrelevant. The full text reports of the remaining 153 records were examined of whom 139 were excluded due to ineligibility of intervention (n=95; selective, indicated, school-based, multi-component, other), design (n=4; non-randomised study), study participants age (n=16; age > 18 years), and outcomes (n=24; non-alcohol related). The screening process left 14 records representing 10 unique trials, which were also included in this review (Bauman 2002; Brody 2006; Haggerty 2007; Koning 2009; O'Donnell 2010; Schinke 2009a; Schinke 2009b; Schinke 2009c; Stevens 2002; Werch 2008). The study flow diagram of the update search is depicted in Figure 1.

In total, 12 trials evaluating universal family-based alcohol misuse prevention programs in young people were included in the review (Bauman 2002; Brody 2006; Haggerty 2007; Koning 2009; Loveland-Cherry 1999; O'Donnell 2010; Schinke 2009a; Schinke 2009b; Schinke 2009c; Spoth 1999a; Stevens 2002; Werch 2008). The following 4 trials were reported in multiple companion publications: Brody 2006 (Gerrard 2006; Brody 2010), Koning 2009 (Koning 2010), Spoth 1999a (Spoth 1999b; Park 2000; Spoth 2001; Spoth 2004; Gyll 2004; Spoth 2006; Spoth 2009; Mason 2009), and Stevens 2002 (Jones 2005).

All 12 trials were published in peer-reviewed journals.

### Included studies

All 12 included studies were parallel-group randomised controlled trials. The unit of randomisation in 4 trials was a cluster (e.g., county, school, clinic) (Brody 2006; Koning 2009; Spoth 1999a; Stevens 2002), in 3 trials - an adolescent-family pair (Haggerty 2007; Loveland-Cherry 1999; O'Donnell 2010), in 4 trials - an adolescent-parent pair (Bauman 2002; Schinke 2009a; Schinke 2009b; Schinke 2009c), and in one trial an individual adolescent (Werch 2008).

The total number of students randomised across 12 trials ranged from 202 (Schinke 2009a) to 3,496 (Stevens 2002).

**Countries:** Eleven of the 12 trials were conducted in the US and one trial was conducted in the Netherlands (Koning 2009).

**Participants:** The study participants' mean age at baseline in the included trials ranged from 11 years (Brody 2006; Spoth 1999a; Stevens 2002) to 15 years (Werch 2008). Authors of one trial failed to report the age of study participants at baseline (Loveland-Cherry 1999). In 4 trials only female adolescent participants were enrolled (O'Donnell 2010; Schinke 2009a; Schinke 2009b; Schinke 2009c). The proportion of males amongst the remaining trials ranged from 44% (Werch 2008) to 54% (Stevens 2002). The distribution of gender was not reported for one trial (Brody 2006). The distribution of ethnic background of study participants varied across trials. Half of the trials conducted in the US included mixtures of Caucasian, Black American, Asian, and Hispanic students (Haggerty 2007; O'Donnell 2010; Schinke 2009a; Schinke 2009b; Schinke 2009c; Werch 2008). One trial included only African-American participants (Brody 2006) and in three trials - the majority (> 75%) of participants were Caucasians (Bauman 2002; Loveland-Cherry 1999; Spoth 1999a). The data on ethnic composition were not reported for two trials (Koning 2009; Stevens 2002).

**Interventions:** In all 12 trials, universal family-based prevention programs were implemented. In 6 trials, at least two different intervention programs were compared (Haggerty 2007; Koning 2009; O'Donnell 2010; Spoth 1999a; Stevens 2002; Werch 2008). For example, in one trial (Spoth 1999a), two family-based intervention programs Iowa Strengthening Families Program (ISFP) and Preparing for the Drug-Free Years Program (PDFY) were evaluated. In another trial (Koning 2009), three programs for alcohol use were compared: family-based, school-based, and the combination of the two interventions. In one trial (Haggerty 2007), two self- and parent/adolescent-administered social development model-based programs were evaluated. Stevens and colleagues compared two family-based programs one that targeted alcohol/tobacco use, and the other program - gun safety, seatbelt use, bicycle and helmet use (Stevens 2002). Comparator arms used in the reviewed trials were 'no program' (Bauman 2002; Haggerty 2007; Koning 2009; Loveland-Cherry 1999; O'Donnell 2010; Schinke

2009a; Schinke 2009b; Schinke 2009c) and mailed leaflets (Brody 2006; Spoth 1999a). In two trials there were no comparator arms (Stevens 2002; Werch 2008).

The components of the evaluated intervention programs in the majority of trials were the promotion of awareness in parents and adolescents (e.g., benefits, consequences, risks), resilient behaviour, change in normative beliefs/attitudes, self-esteem, social networking, peer resistance, as well as the development of problem solving, refusal, and/or decision-making skills. Other features were development of parental rules, monitoring and supervision, support, communication between parents and their children, time spent together, attachment, and conflict reduction.

The **duration of intervention** programs across the included trials ranged from 3 weeks (Schinke 2009a; Werch 2008) to 36 months (Stevens 2002).

**Outcomes:** The outcome measures of alcohol use differed greatly across the trials. For example, the outcomes varied with respect to their definition (e.g., lifetime alcohol use, frequency of drinking, heavy weekly drinking, mean number of drinks, proportion of alcohol users, weekly drinking, frequency of alcohol use, alcohol initiation, lifetime drunkenness, alcohol composite index), and the period to which they pertained (e.g., past month, past 7 days, past year, ever).

### Risk of bias in included studies

The assessment results of risk of bias for the included trials are presented in Figure 2 and Figure 3. All trials were randomised.

#### Allocation

The adequate method of randomisation and program allocation concealment was reported only for about 20% of the trials. It was unclear whether 80%-85% of the trials utilized adequate methods for randomisation or program allocation concealment.

#### Blinding

No blinding of study participants was carried out and it was unclear for 80% of the trials whether or not the outcome assessors were blinded; this information was not explicitly reported.

#### Incomplete outcome data

Incomplete data was adequately addressed in about half of the trials and this information was unclear for about 30% of the trials. It was also unclear whether differential attrition and lack of ITT analysis was a significant concern in one study where analysed sample sizes differed markedly between intervention and control groups (Loveland-Cherry 1999). The attrition rates (at first follow-up) for 10 trials were acceptable ( $\leq 20\%$ ) and for 2 trials (Stevens 2002;

[Spoth 1999a](#)) not acceptable (> 20%). Attrition over subsequent follow-ups was between 32% and 36% in one trial ([Spoth 1999a](#)).

### Selective reporting

The majority of the trials (> 85%) were free of selective outcome reporting

### Other potential sources of bias

About 60% of the trials were found free of other bias (i.e., confounding, contamination), whereas results in 30% of the trials were deemed to be prone to confounding, contamination, or both. It was unclear for 10% of the trials whether or not their results may have been biased due to confounding and/or contamination. For all 4 cluster-randomised trials ([Brody 2006](#); [Koning 2009](#); [Spoth 1999a](#); [Stevens 2002](#)), the intervention effect estimates were adjusted for clustering effects. The results based on ITT analysis were carried out for only 4 out of 12 trials ([Brody 2006](#); [Haggerty 2007](#); [O'Donnell 2010](#); [Schinke 2009b](#)). For one trial, it was unclear whether or not the reported results were ITT-based ([Schinke 2009a](#)).

The instruments or questionnaires used for measurement of alcohol misuse/consumption were validated only for 8 trials ([Brody 2006](#); [Loveland-Cherry 1999](#); [Schinke 2009a](#); [Schinke 2009b](#); [Schinke 2009c](#); [Spoth 1999a](#); [Stevens 2002](#); [Werch 2008](#)). It was unclear whether or not the outcome measures reported in the remaining 4 trials had been validated ([Bauman 2002](#); [Haggerty 2007](#); [Koning 2009](#); [O'Donnell 2010](#)).

### Effects of interventions

See [Characteristics of included studies](#) and [Table 1](#), Summary of Findings

In general, results from 9 trials indicated statistically significantly greater reductions in alcohol use (e.g., alcohol use initiation, mean composite index, frequency/quantity score of alcohol use, alcohol use or being drunk in past year, proportion of youth reporting lifetime alcohol use, alcohol use occasions, initiation and frequency of drunkenness) for the family-based intervention alone groups compared to the control groups ([Bauman 2002](#); [Brody 2006](#); [Loveland-Cherry 1999](#); [O'Donnell 2010](#); [Schinke 2009a](#); [Schinke 2009b](#); [Schinke 2009c](#); [Spoth 1999a](#); [Werch 2008](#)). The follow-up for these trials at which the alcohol use outcomes were ascertained ranged from 2 months to 8 years. The duration of post-intervention impact (i.e., difference between the duration of intervention and last follow-up to which positive result persisted) for the 5 trials ranged from 2 months ([Schinke 2009a](#)) to 8 years ([Spoth 1999a](#)).

For example, in one long-term trial ([Spoth 1999a](#)), the effectiveness of two family-based intervention programs (Iowa Strengthening Families Program and Preparing for the Drug-Free Years

Program) were compared to the control intervention (4 mailed leaflets) through a 10-year follow-up for different alcohol use measures (e.g., lifetime use, past year use, past month use, lifetime drunkenness, past month frequency of drinking, alcohol use composite index, or alcohol use initiation growth curve parameters). The long-term results of this trial indicated that both family-based interventions significantly reduced the proportion of new alcohol users, past month mean frequency of drinking, and alcohol use composite index. In general, the positive effect of the Iowa Strengthening Families Program (ISFP) relative to the control intervention was more pronounced than that of the Preparing for the Drug-Free Years Program (PDFY) for reducing several alcohol use outcome measures (e.g., lifetime use, past year use, past month use, lifetime drunkenness, ever drinking alcohol, and growth curves for lifetime alcohol use, lifetime drunkenness, and initiation of drunkenness). In head-to-head comparison, the two intervention programs (ISFP and PDFY) did not significantly differ in a number of alcohol use outcome measures (past month frequency of drinking, alcohol use composite index). Moreover, in the same trial, the effect of PDFY on the rate of alcohol abuse was modified by gender (at 10-year follow-up point). Specifically, the proportion of youth reporting alcohol abuse was significantly lower in the PDFY vs. the mailed leaflets group in women (6% vs. 16%,  $p < 0.05$ ), but not in men (29% vs. 25%,  $p > 0.05$ ). In another trial ([Brody 2006](#)), the proportion of children, who initiated alcohol use was significantly lower in the family-based intervention group (Strong African American families; SAAF) compared to the control group (mailed leaflets) two years after the end of intervention (data was not reported). Similarly, in one trial ([Bauman 2002](#)), one year after treatment, the group assigned to the family-based intervention (Family Matters) had a significantly reduced proportion of adolescents reporting lifetime alcohol use compared to the group assigned to 'no intervention' study arm (Control vs. Intervention; OR = 1.34, 95% CI's lower bound 1.06).

In another trial ([Werch 2008](#)), the intervention effect was modified by the drug use status at baseline. For example, in drug users at baseline after 4 months follow-up, mailed parental postcards with brief image-based message were significantly better in reducing rates of alcohol initiation ( $4.86 \pm 0.32$  vs.  $5.97 \pm 0.36$ ,  $p = 0.004$ ) and 30-day alcohol use frequency ( $1.03 \pm 0.16$  vs.  $1.73 \pm 0.17$ ,  $p = 0.01$ ) compared to mailed fliers that included similar but shorter messages with commercial quality images, although these subgroups analyses may have been post-hoc and there were many statistical tests, leading to concerns about a multiple testing problem. There was no significant difference in the same outcome measures between the two intervention groups amongst adolescents not using drugs at baseline (alcohol initiation;  $3.11 \pm 0.18$  vs.  $2.92 \pm 0.16$ ,  $p > 0.05$ ). Similarly, in another trial ([Loveland-Cherry 1999](#)), a family-based intervention significantly reduced alcohol misuse compared to 'no intervention' but only in youth with prior use of alcohol. The effect of intervention was not significant amongst youth with no prior use of alcohol.

In two trials (O'Donnell 2010; Schinke 2009a), gender-specific computer-mediated programs were significantly more effective in reducing alcohol use/consumption in past year than 'no treatment' three months post-baseline. In two other trials with a longer-follow-up (Schinke 2009b; Schinke 2009c), female adolescents assigned to two gender-specific intervention programs experienced significantly reduced mean number of alcohol use occasions compared to their counterparts in 'no intervention' groups one year ( $0.17 \pm 0.32$  vs.  $0.31 \pm 0.61$ ,  $p < 0.05$ ) and two years ( $0.17 \pm 0.3$  vs.  $0.33 \pm 0.7$ ,  $p = 0.006$ ) after the intervention.

Although in their trial (Haggerty 2007), Haggerty and colleagues observed reduced proportion of African-American adolescents who reported ever having alcohol in the self-administered Parents Who Care intervention (PWC-SA) group compared to those in the parent-administered intervention (PWC-PA) or 'no intervention' group, these differences were not statistically significant (12.1% vs. 22.0% vs. 24.2%,  $p > 0.05$ ). The statistically non-significant results may have been due to the relatively small sample size of this trial (331 randomised adolescents). For Caucasian Americans, the proportion of adolescents who reported ever having alcohol did not differ across the two intervention (PWC-SA and PWC-PA) and 'no treatment' groups (45.9% vs. 36.4% vs. 41.0%,  $p > 0.05$ ). In two trials (Koning 2009; Stevens 2002), family-based intervention alone either did not significantly reduce alcohol use compared to 'no intervention' (Koning 2009) or significantly increased alcohol use compared to the control but non-family-based intervention (Stevens 2002). For example, in the first trial (Koning 2009), the parent or school-based intervention alone did not significantly differ from 'no intervention' for weekly drinking (at 10 months follow-up) or frequency of drinking (at 10 and 22 months after baseline). Instead, the combination of parent and school-based interventions was associated with a significantly reduced rate compared to 'no intervention' for the above-mentioned outcome measures. In the other trial (Stevens 2002), there was a negative effect of the intervention at three years follow-up after randomisation, indicating significantly greater proportion of 'ever drinker' subjects in the group assigned to the intervention targeting alcohol use compared with the group assigned to the intervention targeting safety behaviour such as helmet use, seatbelt use, and gun safety (OR=1.30, 95% CI: 1.07, 1.57).

### Quantitative data synthesis

The reviewers could not pool the results from individual trials due to heterogeneity in study populations (baseline characteristics), interventions (differences in target/focus), and the outcome measures of alcohol misuse (different tools, instruments, scales, outcome definitions). Therefore, the main results are presented in tabular form and compared in the style of a narrative systematic review.

### Subgroup analysis

Given the fact that studies could not be pooled in this review, the extent of between-study statistical heterogeneity in the intervention effects (e.g., forest plots; Chi square statistic and p-value;  $I^2$  statistic) could not be assessed quantitatively.

The study-level subgroup analysis qualitatively exploring whether or not the effect of any given universal family-based prevention program differed across the subgroups defined by age, gender, ethnicity, or prior alcohol use of study participants could not be carried out due to insufficient variability in study results, unavailability, and non-comparability of relevant data. For example, there were four trials that included only females (O'Donnell 2010; Schinke 2009a; Schinke 2009b; Schinke 2009c), one trial that included only Black Americans (Brody 2006) and one trial that included only Caucasian Americans (Spath 1999a). The interventions evaluated in these trials differed.

Within-study subgroup effects of the interventions (if reported that such effects existed) are qualitatively summarized in the Results section (see 'the effects of interventions' sub-section) and presented in [Characteristics of included studies](#).

### Sensitivity analysis

The study-level sensitivity analysis qualitatively exploring whether or not the effect of any given universal family-based prevention program differed across methodological aspect defined by unit of randomisation (individual vs. cluster), the appropriateness of analysis (matching units of randomisation and analysis), and attrition rates ( $> 20\%$  vs.  $\leq 20\%$ ) was attempted but could not reveal any specific methodological aspect(s) that would potentially account for differences in the study results; the reason being that the studies evaluated different intervention program(s) and insufficient variability in study results (the majority of them showing positive results in favour of intervention programs).

### Publication bias

We were not able to estimate publication bias for the same reason we did not undertake a meta-analysis, heterogeneity. Any asymmetry in a funnel plot may arise not due to publication bias but from essential differences between smaller and larger studies, for example in terms of the level of risk in the population group studied (e.g. age or gender characteristics), length of follow up, or date of study. Simulation studies have shown that bias may be incorrectly inferred if studies are heterogeneous (Lau 2006; Macaskill 2001).

## DISCUSSION

### Summary of main results

In this systematic review we have found that 9 of the 12 included studies (Bauman 2002; Brody 2006; Loveland-Cherry 1999; O'Donnell 2010; Schinke 2009a; Schinke 2009b; Schinke 2009c; Spoth 1999a; Werch 2008) demonstrated statistically significant effects across a range of outcome measures for the prevention of alcohol misuse amongst young people, in the short-term and also over the longer-term. One study suggested a positive, though not statistically significant effect (Bauman 2002) which may have been due to the small sample size. Two studies (Koning 2009; Stevens 2002) with sufficient sample sizes found no significant positive effect of the family-based prevention program. There was no discernible pattern in characteristics (e.g., sample size, appropriate analysis, attrition rates, subgroups, intervention duration, unit of randomisation) that would distinguish trials with positive results from those with negative results. One of these studies (Koning 2009) found that the family-based intervention was effective when combined with a school-based intervention.

There is evidence that gender-specific interventions between daughters and parents, typically mothers (O'Donnell 2010; Schinke 2009a; Schinke 2009b; Schinke 2009c) can be effective in the short- to medium-term. Some trials observed a subgroup effects differentiated by baseline alcohol (Loveland-Cherry 1999) or drug-use (Werch 2008) status. It is not clear if these were planned subgroup analyses, so such analyses should perhaps be regarded as hypothesis generating. It is also possible that some studies that looked only at main effects, without adjusting for potential confounders or effect modifiers, may have concealed possible subgroup effects (e.g. stronger effects in males). Characteristics such as gender and baseline alcohol use are potential effect moderators, so by not accounting for them in the analysis, subgroup effects may be missed.

One study (Stevens 2002) reported unexpected effects, in that the intervention seemed to increase the risk of alcohol misuse. However, before any attribution of iatrogenic effects of particular interventions can be made, it is important to rule out the possibility that such occasional unexpected results did not arise by chance, differential attrition or confounding.

Family-based prevention programs do not focus exclusively on the prevention of one behaviour, for example alcohol misuse, as they have a psychosocial developmental orientation that is designed to impact on a range of health and lifestyle behaviours amongst young people. Such programs offer an advantage over alcohol-specific prevention programs by potentially impacting on a broader set of problem behaviours, for example cannabis, tobacco, harder drugs, antisocial behaviour. Overall, we conclude that the evidence supports the effectiveness of certain family-based programs for alcohol misuse prevention amongst young people, with effect sizes that are often small but potentially important based on economic models (Caulkins 2004; NICE 2010).

Most studies showing some effect and remaining studies showing no effect may be a reflection of the reality that family-based alcohol prevention programs do not work, i.e., they are ineffective,

and that there is simply a variation of individual study (and subgroup analysis) effect size estimates around an actual zero effect, with some achieving statistical significance by chance or as a result of a prevailing methodological bias (Ioannidis 2005). However, we regard this as unlikely given the proportion and sample size of studies that found statistically significant effects coupled with the likelihood that at least one study was underpowered to find small effects. A more likely interpretation of the overall picture is that some family-based psychosocial and developmental prevention interventions are effective in particular settings for reducing alcohol misuse amongst young people. However, in this systematic review, we have also found that some prevention interventions were not effective (e.g. Koning 2009; Stevens 2002).

### **Content and Context: further considerations**

The content or ingredients of effective prevention programs, as distinct from the content of ineffective prevention programs, needs to be more clearly understood. For example, components of family-based programs may or may not vary importantly across different programs. Unfortunately, standard scientific reporting of prevention trials does not include sufficient information about the content detail of prevention interventions to make an analysis of effective ingredients straightforward. Rather, program manuals and unpublished reports have to be scrutinised, coded for different ingredients, and then analysed, which is a labour-intensive and costly approach. Some early review work that has taken this approach had analysed the contribution of different ingredients of prevention programs and these studies have highlighted a number of methodological and analytical challenges (Hansen 2007; Abraham 2008).

Alternatively, it may be that program content is less important than context in discriminating effective from ineffective interventions. It may be that characteristics of program delivery, including program setting, key personnel, or target age are important moderators of program effects. For example, a prevention program which has been shown to be effective in a low prevalence adolescent alcohol misuse setting or country may be ineffective where adolescent drinking is the norm and social and cultural pressures to drink are more powerful.

In order to better understand the importance of content and context for effective prevention, replication studies and more systematic reporting of program content details and delivery contexts are needed. Meta-analysis, via subgroup analysis or using meta-regression techniques, could then be used to illuminate the important aspects of content and context for effective prevention interventions.

### **Overall completeness and applicability of evidence**

Twelve trials with 14,595 participants randomised met the inclusion criteria for the review. However, eleven trials were from the continental United States, with the other from Europe (Netherlands) so the external validity of this evidence is limited to a western, developed world setting. Four trials were specific to females only, reporting gender-specific interventions. The included study settings and family-based programs were consistent with those found in prevention settings in the United States and Europe.

### Quality of the evidence

In previous systematic reviews of alcohol misuse prevention for young people (Foxcroft 1997; Foxcroft 2002) we have pointed to methodological limitations in included studies. Over this period, consensus statements have been published providing guidance on reporting of randomised controlled trials generally (CONSORT 2010) or more specifically for prevention trials (Flay 2005). Cochrane reviews have also become better at systematically identifying methodological limitations through the risk of bias analysis. Our assessment is that the methodological quality of trials of alcohol misuse prevention for young people has improved over time, between 1997, 2002 and 2010. However, despite these improvements, there remain important methodological limitations and reporting problems. The failure of some studies to account for clustering effects in design or analysis is a significant limitation in studies of universal alcohol misuse prevention programs, given the need for large studies that have sufficient statistical power to detect small effect sizes.

Most included studies reported acceptable rates of attrition at first follow-up. High attrition rates remain a challenge over the longer-term, with one study (Spath 1999a) reporting quite high attrition. Higher attrition limits study power to detect pre-specified between-group differences and/or the extent of applicability of study results (Fewtrell 2008). More importantly, in case of differential attrition, study results may be seriously biased due to selection bias/confounding. Alongside this, few studies reported using more advanced techniques for missing data imputation and analysis within an intention to treat approach (Brown 2008). Moreover, in this review over 30% of the studies included were deemed to be susceptible to other bias in the form of confounding or contamination.

Reporting of salient features of RCTs (CONSORT 2010) was also poor in some aspects, notably allocation concealment, randomisation technique, and blinding of outcome assessors.

Overall, although the quality of the evidence has improved, there remain methodological and reporting weaknesses that make it difficult to absolutely rule out the possibility that individual trial results, and the results of the review, are susceptible to prevailing bias problems (Ioannidis 2005).

### Potential biases in the review process

It is possible that we missed relevant trials, although we believe that this is unlikely because of our systematic search efforts. Further information was sought for four of the included studies by contacting the lead or corresponding author, although only one responded (Spath 1999a). We were not able to estimate publication bias because of heterogeneity in the included studies. Our inclusion criteria were sufficiently broad to allow inclusion of all family-based alcohol misuse prevention programs with different population groups, in different settings and with a range of outcome measures.

In our qualitative synthesis we were not able to weigh the evidence from individual studies, so our assessment may give more or less weight to individual studies than is merited.

### Agreements and disagreements with other studies or reviews

Smit 2008 undertook a meta-analysis of RCTs of family intervention effects on adolescent alcohol use in general populations. They identified eight RCTs, of which six were included in this review (Bauman 2002; Brody 2006; Loveland-Cherry 1999; Spath 1999a (both ISFP and PDFY); Stevens 2002; and Werch 2008). Two RCTs included by Smit 2008 but not included in this review were Schinke 2004 and Spath 2002a; Spath 2002b; Spath 2002c. The reasons they did not meet our inclusion criteria is that these two studies did not have a family-based arm independent of other interventions. For example, in the Schinke 2004 study the parenting intervention was combined with a CD-ROM curriculum intervention for young people alone, and similarly with Spath 2002a; Spath 2002b; Spath 2002c the SFP10-14 intervention was combined with a life skills training curriculum. The combination of the family-based intervention with other interventions makes it impossible to directly assess the effects of the family-based intervention alone. The Smit 2008 meta-analysis reported a significant overall effect of family interventions in reducing alcohol initiation (OR:0.71; 95% CI:0.54,0.94) and frequency of alcohol use (d:-0.25; 95%CI: -0.37, -0.12) but with marked between study heterogeneity (p-heterogeneity:  $p < 0.001$ ;  $I^2$ : 78.6%). The significant and high level of heterogeneity suggests caution in using and interpreting the meta-analysis. The overall conclusion from the Smit 2008 meta-analysis is consistent with the results of this review: that the effects of family-based prevention interventions are small but consistent and persistent into the medium- to longer-term.

## AUTHORS' CONCLUSIONS

### Implications for practice

Current evidence suggests that certain family-based prevention

programs can be effective and could be considered as policy and practice options. However, given variability in effect sizes and persistence of effects between studies it is recommended that particular attention is paid to program content and delivery context, ideally through conducting further evaluation studies alongside any further implementation in different settings.

## Implications for research

As small effects could provide important cost-benefits for prevention programs, it is important to undertake studies with sufficient statistical power to detect small effects. Such small effects may vary in size and importance between subgroups, so further research should also be powered to detect hypothesized subgroup effects.

The relevance of content and context of prevention program delivery for program effects is poorly understood, so studies should undertake more rigorous process evaluations alongside outcome evaluations. Reporting of program content and context should be more detailed and systematic to enable comparison of these aspects across studies. Further improvement to study design, analysis and reporting, in line with accepted guidance is required (Flay 2005; CONSORT 2010).

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\* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

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

#### Bauman 2002

Methods	<p>Design: RCT  FU: 12 mo (post-intervention)  Attrition: 19%  ITT: no  Unit of randomisation: pairs of adolescent and parent (90% mothers)  Clustering effect adjusted: NA</p>
Participants	<p><u>N of Clusters (subjects) randomised</u>  Int: NR (NR)  Ctrl: NR (NR)  Total N: 1316 (1316)  <u>N of Clusters (subjects) participated</u>  Int: 531 (531)  Ctrl: 604 (604)  Total N: 1135 (1135)  <u>Analyzed sample N of clusters (subjects)</u>  Int: 531 (531)  Ctrl: 604 (604)  Total N: 1135 (1135)  Age: mean 13.9 (SD=0.9) range: 12-14 yrs  Sex (male): 49.3%  Ethnicity: non-Hispanic White (78%)  Alcohol users: 63.4%  Country: US</p>
Interventions	<p><u>Intervention</u>: Family Matters involving successive mailings of 4 booklets to families and telephone discussions between health educators and family members  <u>Focus/target</u>: substance use  <u>Components</u>: <b>booklet-1</b> (identify and discuss possible consequences of tobacco/alcohol use), <b>booklet-2</b> (considers non-specific family characteristics known to influence adolescents such as supervision, support, communication skills, time spent together, attachment, conflict reduction), <b>booklet-3</b> (based on social learning theory; consideration of tobacco/alcohol-specific variables such as agreement on rules and sanctions for substance use), <b>booklet-4</b> (based on social inoculation theory; considers variables outside of family that may influence substance use)  <u>Fidelity</u>: NR, but 34% completed the program  <u>Duration/frequency</u>: ave. 6 mo  <u>Control</u>: No program</p>
Outcomes	<p>FU - 3 and 12 mo (post-intervention)  % of youth reporting lifetime alcohol use (over both FUs): OR (Ctrl vs. Int) =1.34 (p=0.02, 95% CI's lower bound 1.06)  % of baseline non-users who began use: OR= 1.26, p=0.1</p>

**Bauman 2002** (Continued)

Notes	<p><b>Family Matters</b> One-tailed statistical tests were used; baseline differences (NR) controlled in the analyses, 12 mo effects appear to be much smaller than 3 mo effects, though these were not tested statistically</p> <p><u>Abbreviations</u> FU=follow-up; RCT=randomised controlled trial; N=number; Int=intervention; Ctrl=control; ITT=intention to treat (analysis); yr(s)=year(s); mo=month(s); wk(s)=week(s); NR=not reported; NA=not applicable; 95% CI=ninety-five percent confidence interval; OR=odds ratio</p>
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<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Low risk	Data collection was blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition < 20%
Selective reporting (reporting bias)	Low risk	Outcomes specified in Methods section also reported in Results section
Other bias	High risk	No adjustment for clustering effect

**Brody 2006**

Methods	<p>Design: RCT FU: 9, 18, 29, 53, and 65 mo (post-baseline) Attrition: 15% ITT: yes Unit of randomisation: county Clustering effect adjusted: yes</p>
Participants	<p><u>Cohort 1: FU at 29 mo only (separate report)</u> <u>Cohort 1+2: FU at all points</u> <u>N of Clusters (subjects) randomised (Cohort 1)</u> Int: 4 (307) Ctrl: 4 (214) Total N: 8 (521) <u>N of Clusters (subjects) participated (Cohort 1)</u> Int: 4 (181)</p>

Brody 2006 (Continued)

	<p>Ctrl: 4 (149)  Total N: 8 (330)  <u>Analyzed sample N of clusters (subjects) (Cohort 1)</u>  Int: 4 (172)  Ctrl: 4 (133)  Total N: 8 (305)  <u>N of Clusters (subjects) randomised (Cohort 1+2)</u>  Int: 4 (638)  Ctrl: 4 (462)  Total N: 8 (1100)  <u>N of Clusters (subjects) participated (Cohort 1+2)</u>  Int: 4 (369)  Ctrl: 4 (298)  Total N: 8 (667)  <u>Analyzed sample N of clusters (subjects) (Cohort 1+2)</u>  Int: 4 (326)  Ctrl: 4 (245)  Total N: 8 (571)  Age: 11 (10-12) yrs  Sex (male): NR  Ethnicity: 100% African Americans  Alcohol users: alcohol composite index (score: 0-3), Int vs Ctrl: 0.3 (0.71) vs. 0.17 (0.5), n.s. (Cohort 1)  Country: US</p>
Interventions	<p><u>Intervention</u>: SAAF is a prevention program modelled after existing family skills training interventions, notably SFP and based on the social development model  <u>Focus/target</u>: alcohol use, substance use and early sexual activity  <u>Components</u>: 7 weekly meetings with separate parent and child skill building curricula, and a family curriculum; concurrent training sessions for parents and children followed by a joint parent-child session during which families practice newly learned skills  <u>Fidelity</u>: mean coverage of the components that comprised the program was &gt;80%  <u>Duration/frequency</u>: 7 wks  <u>Control</u>: mailed 3 leaflets on aspects of early adolescence development, stress management, encouraging exercise for children</p>
Outcomes	<p><u>FU - 29 mo (Cohort 1 only)</u>  Proportion of children who initiated alcohol use was significantly lower in Int vs. Ctrl (data not given)  Alcohol composite index (score: 0-3): Int had a slower rate of increase in alcohol use than Ctrl (<math>\beta=-0.18</math>, <math>p &lt; 0.05</math>)  <u>FU - 65 mo (Cohorts 1+2)</u>  SAAF had a slower rate of increase in alcohol use from first to final FU (<math>\beta=-0.23</math>, <math>p &lt; 0.05</math>)  SAAF group drank half as often as Ctrl group: ave. weekly drinking occasions 0.68 (1.76) vs. 1.41 (7.99)</p>
Notes	<p>No differential attrition detected. Gender as an effect modifier was not significant  <u>Abbreviations</u></p>

**Brody 2006** (Continued)

FU=follow-up; RCT=randomised controlled trial; N=number; Int=intervention; Ctrl=control; ITT=intention to treat (analysis); yr(s)=year(s); mo=month(s); wk(s)=week(s); NR=not reported; NA=not applicable; SAAF=strong African American families		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Children's lists were numbered and their order was permuted randomly
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Low risk	Field interviewers were blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Yes; ITT analysis and low attrition
Selective reporting (reporting bias)	Low risk	Outcomes specified in Methods section also reported in Results section
Other bias	High risk	Some baseline imbalances in covariates (Cohort 1)

**Haggerty 2007**

Methods	Design: RCT FU: 24 mo (post-intervention) Attrition: 5.3% (yr 1), 8% (yr 2) ITT: yes Unit of randomisation: family Clustering effect adjusted: NA
Participants	<u>N of Clusters (subjects) randomised</u> Int-1: 107 (107) Int-2: 118 (118) Ctrl: 106 (106) Total N: 331 (331) <u>N of Clusters (subjects) participated</u> Int-1: NR (NR) Int-2: NR (NR) Ctrl: NR (NR) Total N: NR (NR) <u>Analyzed sample</u> Int-1: 73 (73) Int-2: 84 (84)

Haggerty 2007 (Continued)

	<p>Ctrl: 79 (79)          Total N: 236 (236)          Age: 13.7 yrs (8<sup>th</sup> grade)          Sex (male): 51%          Ethnicity: 49.2% (African American), 51% (White)          Alcohol users: NR          Country: US</p>	
Interventions	<p><u>Intervention-1</u>: PWC-SA is a program based on social development model which includes parenting, youth, and family components  <u>Components</u>: video, workbook, checklist of activities, contact by phone  <u>Focus/target</u>: substance use and other problem behaviours  <u>Intervention-2</u>: PWC-PA is a program based on social development model which includes parenting, youth, and family components  <u>Components</u>: families met for 7 sessions, viewing video, practice specific skills  <u>Focus/target</u>: substance use and other problem behaviours  <u>Fidelity</u>: 81%  <u>Duration/frequency</u>: 7-10 wks  <u>Control</u>: no program</p>	
Outcomes	<p><u>FU - 24 mo (post-intervention)</u>          Ever had alcohol (African Americans): PWC-SA (12.1%) vs. PWC-PA (22%) vs. Ctrl (24.2%), p&gt;0.05          Ever had alcohol (European Americans): PWC-SA (45.9%) vs. PWC-PA (36.4%) vs. Ctrl (41.0%), p&gt;0.05</p>	
Notes	<p>PWC          No significant baseline differences by condition; gender as an effect modifier was not significant  <u>Abbreviations</u>:          FU=follow-up; RCT=randomised controlled trial; N=number; Int=intervention; Ctrl=control; ITT=intention to treat (analysis); yr(s)=year(s); mo=month(s); wk(s)=week(s); NR=not reported; NA=not applicable; PWC=parents who care; SA=self-administered; PA=parent and adolescent-administered</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described

**Haggerty 2007** (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT analysis; low attrition rate
Selective reporting (reporting bias)	Low risk	Outcomes specified in Methods section also reported in Results section
Other bias	Low risk	No other important sources of bias could be identified

**Koning 2009**

Methods	<p><u>Design</u>: RCT</p> <p><u>FU</u>: 22 mo (post-randomisation)</p> <p><u>Attrition</u>: 12.5% (2570/2937); dropouts differed from completers in being older, drinking more, and having parents with lower level of education</p> <p><u>ITT</u>: No</p> <p><u>Unit of randomisation</u>: school</p> <p><u>Clustering effect adjusted</u>: Yes</p>
Participants	<p><u>N of Clusters (subjects) randomised</u></p> <p>Int 1: NR (801)</p> <p>Int 2: NR (942)</p> <p>Int 3: NR (812)</p> <p>Ctrl: NR (935)</p> <p>Total N: 20 (3490)</p> <p><u>N of Clusters (subjects) participated</u></p> <p>Int 1: NR (608)</p> <p>Int 2: NR (675)</p> <p>Int 3: NR (588)</p> <p>Ctrl: NR (699)</p> <p>Total N: 19 (2570)</p> <p><u>N of Clusters (subjects) analysed</u></p> <p>Int 1: NR (689)</p> <p>Int 2: NR (771)</p> <p>Int 3: NR (698)</p> <p>Ctrl: NR (779)</p> <p>Total N: 19 (2937)</p> <p>Age: 12.7 yrs (1<sup>st</sup> and 2<sup>nd</sup> yr high school students)</p> <p>Sex (male): 51%</p> <p>Ethnicity: NR</p> <p>Alcohol use: Not heavy drinkers</p> <p>Country: Netherlands</p>
Interventions	<p><u>Intervention 1</u>: PI</p> <p><u>Focus/target</u>: parental rules for their children's alcohol use</p> <p><u>Components</u>: 1) 20 min presentation about adverse effects of alcohol use at young age; 2) parents meet with the class mentor to discuss rules and reach a consensus; 3) Information leaflet with summary information sent to parents' home addresses as reminder of rules</p>

**Koning 2009** (Continued)

	<p>and consensus reached</p> <p><u>Intervention 2: SI</u></p> <p><u>Focus/target:</u> Based on HSD prevention program</p> <p><u>Components:</u> 1) coordinating committee; 2) 3 series of educational lessons about tobacco, alcohol, cannabis, ecstasy, games; 3) school regulations on drug use; 4) system of detection of drug problems; and 5) parental involvement</p> <p><u>Intervention 3: PI + SI combined</u></p> <p><u>Fidelity:</u> NR</p> <p><u>Duration/frequency:</u> 2 mo</p> <p><u>Control:</u> Standard curriculum</p>
<p>Outcomes</p>	<p><u>FU-10 mo</u></p> <p><u>Heavy weekly drinking</u></p> <p>Int 1 (3.5%) vs. Int 2 (3.4%) vs. Int 3 (1.2%) vs. Ctrl (3.2%), <math>P &lt; 0.05</math> (Int 3 vs. Ctrl)</p> <p><u>Weekly drinking</u></p> <p>Int 1 (12.6%) vs. Int 2 (16.1%) vs. Int 3 (11.8%) vs. Ctrl (16.6%), <math>P &lt; 0.05</math> (Int 3 vs. Ctrl)</p> <p><u>Frequency of drinking</u></p> <p>Students in Int 3 (combined intervention: PI + SI) drank significantly less frequently than students in the Ctrl arm</p> <p><u>FU-22 mo</u></p> <p><u>Heavy weekly drinking</u></p> <p>Int 1 (10.5%) vs. Int 2 (8.2%) vs. Int 3 (7.6%) vs. Ctrl (9.9%), NS</p> <p>- OR=1.13, 95% CI: 0.73, 1.73 (adjusted; Int 1 vs. Ctrl), NNT = 48.9</p> <p>- OR=0.85, 95% CI: 0.56, 1.29 (adjusted; Int 2 vs. Ctrl), NNT = 84.4</p> <p>- OR=0.80, 95% CI: 0.48, 1.32 (adjusted; Int 3 vs. Ctrl), NNT = 58.7</p> <p><u>Weekly drinking</u></p> <p>Int 1 (33.2%) vs. Int 2 (36.1%) vs. Int 3 (31.5%) vs. Ctrl (41.5%), NS</p> <p>- OR=0.86, 95% CI: 0.63, 1.16 (adjusted; Int 1 vs. Ctrl), NNT = 181.8</p> <p>- OR=0.92, 95% CI: 0.71, 1.19 (adjusted; Int 2 vs. Ctrl), NNT = 67.9</p> <p>- OR=0.71, 95% CI: 0.53, 0.94 (adjusted; Int 3 vs. Ctrl), NNT = 17.2</p> <p><u>Frequency of drinking</u></p> <p>Students in Int 3 (combined intervention: PI + SI) drank significantly less frequently than students in the Ctrl arm</p> <p>The delaying effect of the combined intervention (PI + SI) on the onset of weekly drinking was mediated through adolescents' perceived rules, self-control, and parental attitudes</p>
<p>Notes</p>	<p>Even though the authors reported to have used ITT analysis (based on 2937 students) with imputations, they had already excluded 431 (baseline drinkers) + 122 (refusals/not present) students from the initial sample of 3490 students</p> <p><u>Abbreviations</u></p> <p>FU=follow-up; RCT=randomised controlled trial; N=number; Int=intervention; Ctrl=control; yr(s)=year(s); NR=not reported; wk(s)=week(s); mo=months; NA=not applicable; min(s)=minute(s); NS=statistically non-significant; PI=parent intervention; SI=student intervention; HSD=healthy school and drugs; NNT=number needed to treat; OR=odds ratio; 95% CI=ninety-five percent confidence interval; ITT=intention to treat (analysis)</p>

**Koning 2009** (Continued)

<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Low risk	Central randomisation
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT was done but not on the original/initial sample
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	Yes, baseline differences adjusted

**Loveland-Cherry 1999**

Methods	Design: RCT FU: 4 yrs (post-randomisation) Attrition: 19% ITT: no Unit of randomisation: family Clustering effect adjusted: NA
Participants	<u>N of Clusters (subjects) randomised</u> Int: NR (NR) Ctrl: NR (NR) Total N: 892 (892) <u>N of Clusters (subjects) participated</u> Int: NR (NR) Ctrl: NR (NR) Total N: 723 (723) <u>Analyzed sample N of clusters (subjects)</u> Int: 90 (90) Ctrl: 338 (338) Total N: 428 (428) Age: NR yrs (4 <sup>th</sup> grade) Sex (male): 46% Ethnicity: 86% (White) Alcohol users: 15% Country: US

Loveland-Cherry 1999 (Continued)

Interventions	<p><u>Intervention</u>: general parenting skills and family functioning: Children and Parent Relations (CAPR)</p> <p><u>Focus/target</u>: alcohol</p> <p><u>Components</u>: Program (4<sup>th</sup> grade) carried out in 3 in home sessions each 1 hr long, family meetings, and follow-up tel calls</p> <p>Booster was added (in 7<sup>th</sup> grade)</p> <p><u>Fidelity</u>: NR</p> <p><u>Duration/frequency</u>: 3 sessions in 3 mo</p> <p><u>Control</u>: no program</p>
Outcomes	<p><b>Int vs. Ctrl</b></p> <p><u>Total frequency/quantity score for alcohol use/misuse per wk over the last 12 mo</u></p> <p>Quantity [0=haven't drunk, 6= drank 10 or more];</p> <p>Frequency [0=haven't drunk, 1=had a drink few times a yr or less, 2=about once a mo, 3=once a wk, 4=3-4 d/wk, everyday]</p> <p><u>Alcohol use (total: prior + no prior)</u></p> <p>0.1 ± 0.33 vs. 0.2 ± 0.5 (yr 1 posttest)</p> <p>0.2 ± 0.46 vs. 0.2 ± 0.52 (yr 2 posttest)</p> <p>0.4 ± 1.07 vs. 0.4 ± 0.89 (yr 3 posttest)</p> <p>0.7 ± 1.58 vs. 0.8 ± 1.44 (yr 4 posttest)</p> <p>No between-group difference</p> <p><u>Alcohol misuse</u></p> <p>0.0 ± 0.15 vs. 0.1 ± 0.56 (yr 1 posttest)</p> <p>0.2 ± 0.68 vs. 0.1 ± 0.59 (yr 2 posttest)</p> <p>0.3 ± 1.01 vs. 0.3 ± 1.02 (yr 3 posttest)</p> <p>0.6 ± 1.53 vs. 0.7 ± 1.48 (yr 4 posttest)</p> <p>No between-group difference</p> <p><b>Sub-group analysis by prior use status:</b></p> <p><u>Alcohol use (no prior use)</u>: No between-group difference</p> <p><u>Alcohol use (prior use)</u>: Alcohol use was lower in Int vs. Ctrl (F=5.16, p &lt; 0.01)</p> <p><u>Alcohol misuse (no prior use)</u>: No between-group difference</p> <p><u>Alcohol misuse (prior use)</u>: Alcohol misuse was lower in Int vs. Ctrl (F=3.08, p &lt; 0.05)</p>
Notes	<p>CAPR</p> <p>Differential attrition and lack of ITT analysis may have biased the study results</p> <p><u>Abbreviations</u></p> <p>FU=follow-up; RCT=randomised controlled trial; N=number; Int=intervention; Ctrl=control; ITT=intention to treat (analysis); yr(s)=year(s); mo=month(s); wk(s)=week(s); NR=not reported; NA=not applicable; CAPR=child and parent relations</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described

**Loveland-Cherry 1999** (Continued)

Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Possible differential attrition; no ITT analysis
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Unclear risk	Not enough detail reported

**O'Donnell 2010**

Methods	Design: RCT FU: 9 mo (post-randomisation) Attrition: 17% ITT: yes Unit of randomization: family Clustering effect adjusted: NA
Participants	<u>N of Clusters (subjects) randomized</u> Int-1: NR (NR) Int-2: NR (NR) Ctrl: NR (NR) Total N: 268 (268) <u>N of Clusters (subjects) participated</u> Int-1: NR (NR) Int-2: NR (NR) Ctrl: NR (NR) Total N: 222 (222) <u>Analyzed sample N of clusters (subjects)</u> Int-1: NR (NR) Int-2: NR (NR) Ctrl: NR (NR) Total N: NR (NR) Age: 11-13 yrs (6 <sup>th</sup> grade) Sex (male): 0% (all girls) Ethnicity: Latina (34.3%) Alcohol users: 14.6% (had a drink in the past yr), 3.4% (gotten drunk) Country: US
Interventions	<u>Intervention-1</u> : gender-specific culturally relevant parent education program, based on social development model, delivered through a set of 4 audio CDs <u>Focus/target</u> : delaying sex and alcohol use <u>Components</u> : 4 CDs contain stories of lives of 4 fictional families (Latino and African American); each story aims to increase parents' awareness of the risks their daughters may face <u>Intervention-2</u> : an attention controlled condition

	<p><u>Focus/target:</u> delaying sex and alcohol use  <u>Components:</u> 4 booklet set of visually appealing print materials covering similar topics  <u>Fidelity:</u> 93% parents had listened to CDs, &gt; 80% reported having listened with the child participant; all parents requested the Especially for Daughters CDs at the end of study  <u>Duration/frequency:</u> 24 wks (each CD or booklet mailed every 6 wks)  <u>Control:</u> no program</p>	
Outcomes	<p><b>FU - 3 mo (post-intervention)</b>  <u>Alcohol use or being drunk in past yr</u>  OR = 0.38, 95% CI: 0.15, 0.97  Adjusted for school [int-1 vs. Ctrl]</p> <p><b>FU - 9 mo (post-intervention)</b>  <u>Alcohol use or being drunk in past yr</u>  OR = 0.49, 95% CI: 0.20, 1.19  Adjusted for school [int-2 vs. Ctrl]</p>	
Notes	<p><b>Especially for Daughters</b>  Contamination possible (assigned within schools)  Not applicable to boys, Caucasians, and youth from affluent families  Adjusted only for school, so some confounding maybe present  Baseline characteristics by arms not presented  <u>Abbreviations:</u>  FU=follow-up; RCT=randomised controlled trial; N=number; Int=intervention; Ctrl=control; ITT=intention to treat (analysis); yr(s)=year(s); mo=month(s); wk(s)=week(s); NR=not reported; NA=not applicable</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Low risk	Assessors blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition; ITT analysis
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	High risk	Confounding; contamination

Schinke 2009a

Methods	<p>Design: RCT  FU: 3 wks (post-randomisation) or immediately post-test, 11 wks (post-randomisation) or 2 mo (post-treatment)  Attrition: 1%-2%  ITT: NR  Unit of randomisation: daughter-mother dyad / pair  Clustering effect adjusted: NA</p>
Participants	<p><u>N of Clusters (subjects) randomised</u>  Int: NR (NR)  Ctrl: NR (NR)  Total N: 202 (202)  <u>N of Clusters (subjects) participated</u>  Int: NR (NR)  Ctrl: NR (NR)  Total N: 202 (202)  <u>Analyzed sample N of clusters (subjects)</u>  Int: NR (NR)  Ctrl: NR (NR)  Total N: NR (NR)  Age (mean): 12.2 (SD=0.95) yrs  Sex (male): 0% (female only)  Ethnicity: 67.8% (White), 14.1% (Latina), 9.5% (Black), 0.5% (Asian), 8% (Other)  <u>Alcohol users (Int vs. Ctrl):</u>  30-d: 0.33 (0.47) vs. 0.30 (0.46)  7-d: 0.17 (0.38) vs. 0.10 (0.30)  1-yr: 0.47 (0.50) vs. 0.35 (0.48)  Country: US</p>
Interventions	<p><u>Intervention:</u> computer-mediated gender-specific program based on family interaction theory aims to a) enhance quality of daughters' relationship with their mothers and b) teach girls cognitive-behavioral skills. Exercises taught girls and mothers about value of listening to each other, spending time together, negotiation during arguments, giving compliments, and personal favors  <u>Focus/target:</u> alcohol use  <u>Components:</u> completion by mothers 14 computer-mediated intervention modules; modules 1-5 (rapport and respect building between daughters and mothers), modules 6-10 (conflict management, ground rules for negotiating arguments, emphatic listening), and modules 11-14 (help participants analyze media portrayal of drinking)  <u>Fidelity:</u> NR  <u>Duration/frequency:</u> 3 wks  <u>Control:</u> No program</p>
Outcomes	<p>FU - 3 wks post-randomisation or immediately post-test (Int vs. Ctrl)  N of alcohol drinks consumed (e.g., glasses of wine or mixed drinks; cans or bottles of beer; shots of spirits)  30-d: 0.18 (0.39) vs. 0.31 (0.47)  7-d: 0.08 (0.27) vs. 0.12 (0.32)  FU - 11 wks post-randomisation or 2 mo post-treatment (Int vs. Ctrl)  N of alcohol drinks consumed (e.g., glasses of wine or mixed drinks; cans or bottles of</p>

**Schinke 2009a** (Continued)

	<p>beer; shots of spirits)            30-d: 0.26 (0.44) vs. 0.30 (0.46), F=0.37            7-d: 0.08 (0.27) vs. 0.16 (0.37), F=1.4</p> <p><u>Intervention by time interaction</u>            Less 30-d (F=3.96, p&lt;0.05), 7-d (F=4.74, p&lt;0.01), and 1 yr (F=6.18, p&lt;0.01) alcohol consumption in Int vs. Ctrl</p>
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Notes	<p>None; baseline covariates were balanced between the program and control groups</p> <p><u>Abbreviations</u>            FU=follow-up; RCT=randomised controlled trial; N=number; Int=intervention; Ctrl=control; ITT=intention to treat (analysis); yr(s)=year(s); mo=month(s); wk(s)=week(s); NR=not reported; NA=not applicable; SD=standard deviation</p>
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**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	Small attrition but ITT not clear
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	Baseline covariates balanced; no other source of bias is evident

**Schinke 2009b**

Methods	<p>Design: RCT            FU: 1 yr and 2 yrs post-randomisation            Attrition: 5.7% (yr 1 post-randomisation); 4.2% (between yr 1 and yr 2 post-randomisation); 9% overall at yr 2            ITT: yes            Unit of randomisation: daughter-mother dyad / pair            Clustering effect adjusted: NA</p>
Participants	<p><u>N of Clusters (subjects) randomised</u>            Int: 458 (458)            Ctrl: 458 (458)</p>

Schinke 2009b (Continued)

	<p>Total N: 916 (916)  <u>N of Clusters (subjects) participated</u>            Int: 434 (434)            Ctrl: 430 (430)            Total N: 864 (864)  <u>Analyzed sample N of clusters (subjects) - yr 1</u>            Int: 458 (458)            Ctrl: 458 (458)            Total N: 916 (916)  <u>Analyzed sample N of clusters (subjects) - yr 2</u>            Int: 415 (415)            Ctrl: 413 (413)            Total N: 828 (828)            Age (mean): 12.7 (SD=1.0) yrs            Sex (male): 0% (female only)            Ethnicity: 23.2% (White), 23.1% (Latina), 40.6% (Black), 10.8% (Asian), 1.7% (Other)            Alcohol users: NR            Country: US</p>
Interventions	<p><u>Intervention</u>: computer-mediated gender-specific program based on family interaction theory. Mothers learnt to better communicate with their daughters, monitor their daughters' activities, build their daughters' self-image and self-esteem, establish rules and consequences for substance abuse, create family rituals, refrain from placing unrealistic expectations on their daughters. Girls learnt to manage stress, conflict/mood, refuse peer pressure, and enhance their body esteem. Program exercises taught girls and mothers about value of listening to each other, spending time together, negotiation during arguments, giving compliments, and personal favours  <u>Focus/target</u>: substance use  <u>Components</u>: 9 sessions (45 min each per week) and 2 annual booster sessions (review)  <u>Fidelity</u>: NR  <u>Duration/frequency</u>: 9 wks (9 sessions 45 min each per week)  <u>Control</u>: No program</p>
Outcomes	<p><u>FU-1yr post-randomisation (Int vs. Ctrl)</u>            Alcohol use occasions in the past 30 d: 0.15 (0.2) vs. 0.25 (0.5), p=NR  <u>FU-2 yrs post-randomisation (Int vs. Ctrl)</u>            Alcohol use occasions in the past 30 d: 0.17 (0.3) vs. 0.33 (0.7), F=5.2, p=0.006</p>
Notes	<p>Lost to follow-up did not differ from those who remained in the study            Baseline differences in depression and positive patterns of communication, being more frequent in Int group (p&lt;0.05)  <u>Abbreviations</u>            FU=follow-up; RCT=randomised controlled trial; N=number; Int=intervention; Ctrl=control; ITT=intention to treat (analysis); yr(s)=year(s); mo=month(s); wk(s)=week(s); NR=not reported; NA=not applicable; SD=standard deviation</p>
<b>Risk of bias</b>	
<b>Bias</b>	<b>Authors' judgement</b>
	<b>Support for judgement</b>

**Schinke 2009b** (Continued)

Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT analysis and low attrition
Selective reporting (reporting bias)	Unclear risk	All outcomes reported
Other bias	High risk	Baseline covariates (depression, positive communication patterns) imbalanced between the study groups; confounding possible

**Schinke 2009c**

Methods	<p>Design: RCT  FU: immediate and 1 yr post-intervention  Attrition: 1.5% (post-test), 10% (1 yr post-randomisation)  ITT: no  Unit of randomisation: pair of daughter-mother  Clustering effect adjusted: NA</p>
Participants	<p><u>N of Clusters (subjects) randomised</u>  Int: 252 (252)  Ctrl: 339 (339)  Total N: 591 (591)  <u>N of Clusters (subjects) participated</u>  Int: 244 (244)  Ctrl: 338 (338)  Total N: 582 (582)  <u>Analyzed sample (immediate post-intervention) N of clusters (subjects)</u>  Int: 244 (244)  Ctrl: 338 (338)  Total N: 582 (582)  <u>Analyzed sample (1 yr post-intervention)</u>  Int: 205 (205)  Ctrl: 327 (327)  Total N: 532 (532)  Age: 12.7 (SD=1.0) yrs  Sex (male): 0% (female only)  Ethnicity: 39% vs. 17% (White), 22% vs. 26% (Latina), 39% vs. 56% (Black)  Alcohol users: 34% (lifetime use)</p>

Schinke 2009c (Continued)

	Country: US	
Interventions	<p><u>Intervention:</u> computer-mediated gender-specific program based on family interaction theory. Mothers learnt to better communicate with their daughters, monitor their daughters' activities, build their daughters' self-image and self-esteem, establish rules and consequences for substance abuse, create family rituals, refrain from placing unrealistic expectations on their daughters. Girls learnt to manage stress, conflict/mood. Through animated vignettes and video demonstrations, girls and mothers learnt how depression can result from stress and pressure to succeed. Session interactive activity showed the importance of valuing personal character and accomplishments. Program aim was enhance emotional closeness between girls and mothers</p> <p><u>Focus/target:</u> substance use</p> <p><u>Components:</u> 9 sessions (45 min each per week)</p> <p><u>Fidelity:</u> participants could only advance to the next session if each separately answered correctly questions on the prior session; participants could access post-intervention and follow-up measures unless they finished all program sessions</p> <p><u>Duration/frequency:</u> 9 wks (9 sessions 45 min each per week)</p> <p><u>Control:</u> No program</p>	
Outcomes	<p><u>FU-immediate post-intervention (Int vs. Ctrl)</u> Alcohol use occasions in the past 30 d: 0.14 (0.18) vs. 0.23 (0.50), Wald chi-square=1.88, p&gt;0.05</p> <p><u>FU-1 yr post-intervention (Int vs. Ctrl)</u> Alcohol use occasions in the past 30 d: 0.17 (0.32) vs. 0.31 (0.61), Wald chi-square=6.11, p&lt;0.05</p>	
Notes	<p>At baseline, more White participants in Int vs. Ctrl group (39% vs. 17%, p&lt;0.05), but the analysis adjusted for these and other differences</p> <p>Attrition sample did not differ from the remaining sample</p> <p><u>Abbreviations</u> FU=follow-up; RCT=randomised controlled trial; N=number; Int=intervention; Ctrl=control; ITT=intention to treat (analysis); yr(s)=year(s); mo=month(s); wk(s)=week(s); NR=not reported; NA=not applicable; SD=standard deviation</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described

**Schinke 2009c** (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	No ITT analysis was done, however there was a small (<10%) and non-differential attrition
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other apparent source of bias

**Spoth 1999a**

Methods	<p>Design: RCT  FU: 18, 30, 48, 72, 120 mo (post-randomisation)  Attrition: 32-36% across different FU points  ITT: no  Unit of randomisation: school  Clustering effect adjusted: yes</p>
Participants	<p><u>N of Clusters (subjects) randomised</u>  Int-1: 11 (437)  Int-2: 11 (463)  Ctrl: 11 (409)  Total N: 33 (1309)  <u>N of Clusters (subjects) pre-tested</u>  Int-1: 11 (238)  Int-2: 11 (221)  Ctrl: 11 (208)  Total N: 33 (667)  <u>N of Clusters (subjects) participants</u>  Int-1: 11 (117)  Int-2: 11 (124)  Ctrl: 11 (208)  Total N: 33 (449)  <u>Analyzed sample N of clusters (subjects) - 18 mo FU</u>  Int-1: NR (161)  Int-2: NR (156)  Ctrl: NR (155)  Total N: 33 (472)  <u>Analyzed sample N of clusters (subjects) - 30 mo FU</u>  Int-1: NR (152)  Int-2: NR (141)  Ctrl: NR (145)  Total N: NR (438)  <u>Analyzed sample N of clusters (subjects) - 48 mo FU</u>  Int-1: NR (151)  Int-2: NR (151)  Ctrl: NR (144)  Total N: NR (446)</p>

Spoth 1999a (Continued)

	<p><u>Analyzed sample N of clusters (subjects) - 72 mo FU</u>            Int-1: 7 (151)            Int-2: 8 (157)            Ctrl: 8 (149)            Total N: 23 (457)</p> <p><u>Analyzed sample N of clusters (subjects) - 120 mo FU</u>            Int-1: NR (170)            Int-2: NR (161)            Ctrl: NR (152)            Total N: NR (483)            Age (mean): 11.3 (SD=0.03) yrs            Sex (male): 46%            Ethnicity: 99% White            Alcohol users: NR            Country: US</p>
Interventions	<p><u>Intervention-1</u>: ISFP based on biopsychosocial model and other empirically based family risk and protective factor models including the resiliency and the social ecology models of adolescent substance use  <u>Focus/target</u>: substance use  <u>Components</u>: 7 weekly sessions including 6 separate but concurrent parent and child curricula 1 hour each, followed by six 1 hour joint family session where parents and children practice skills that they learnt; the 7<sup>th</sup> session includes only 1 hour family session. Parents are taught to clarify expectations, use appropriate disciplinary practices, manage strong emotions of children, and effective communication with children; children additionally are given peer resistance and peer relationships skill training; use of videotapes</p> <p><u>Intervention-2</u>: PDFY based on Social Development Model to enhance protective parent-child interactions and to reduce family-based risk factors for early substance use initiation. The program goals were: a) increase the frequency of opportunities for prosocial involvement in the family, b) strengthening the child's skills for prosocial involvements and resistance to anti-social influence, c) increasing recognitions and rewards for child behavior that conforms to family rules and expectations  <u>Focus/target</u>: substance use  <u>Components</u>: 5 weekly sessions 2 hours duration each; Children attended only one session and parents attended all sessions. Parents were instructed on risk factors for substance use, developing clear guidelines on substance-related behavior, enhancing parent-child bonding, monitoring compliance with guidelines, managing anger and family conflict. Children were instructed on peer resistance skills; use of videotapes</p> <p><u>Fidelity</u>: For ISFP, 83%-89% of group leaders' component tasks were covered; For PDFY, 69% of group leaders' component tasks were covered</p> <p><u>Duration/frequency</u>: ISFP (7 sessions in 7 wks) and PDFY (5 sessions in 5 wks)  <u>Control</u>: minimal contact (mailed 4 leaflets describing different aspects of adolescent development such as physical and emotional changes)</p>
Outcomes	<p><b>FU - 18 mo post-randomisation (ISFP vs. PDFY vs. Ctrl)</b>            % Reporting lifetime alcohol use: 26.2% (42/160) vs. 39.3% (61/155) vs. 35.8% (56/156), p=NR            % Reporting past month alcohol use: 5.6% (9/160) vs. 11.6% (18/155) vs. 10.2% (16/156), p=NR</p>

	<p>% Reporting past year alcohol use: 10.0% (16/160) vs. 22.6% (35/155) vs. 22.4% (35/156), p=NR</p> <p>% Reporting lifetime drunkenness: 6.8% (11/160) vs. 8.4% (13/155) vs. 9.0% (14/156), p=NR</p> <p><b>FU - 30 mo post-randomisation (ISFP vs. PDFY vs. Ctrl)</b></p> <p>% Reporting lifetime alcohol use: 34.8% (53/152) vs. 49.6% (72/145) vs. 56.0% (79/141), p=NR</p> <p>% Reporting past month alcohol use: 11.2% (17/152) vs. 20.6% (30/145) vs. 27.6% (39/141), p=NR</p> <p>% Reporting past year alcohol use: 25.6% (39/152) vs. 40.0% (58/145) vs. 48.2% (68/141), p=NR</p> <p>% Reporting lifetime drunkenness: 9.2% (14/152) vs. 17.9% (26/145) vs. 19.1% (27/141), p=NR</p> <p><b>FU - 48 mo post-randomisation (ISFP vs. PDFY vs. Ctrl)</b></p> <p>% Reporting lifetime alcohol use: 60.3% (91/151) vs. 66.0% (95/144) vs. 72.8% (110/151), p=NR</p> <p>% Reporting past month alcohol use: 30.4% (46/151) vs. 23.6% (34/144) vs. 39.7% (60/151), p=NR</p> <p>% Reporting past year alcohol use: 45.7% (69/151) vs. 48.6% (70/144) vs. 60.2% (91/151), p=NR</p> <p>% Reporting lifetime drunkenness: 31.1% (47/151) vs. 36.3% (52/143) vs. 44.3% (67/151), p=NR</p> <p><u>% of new alcohol users</u></p> <p>Ever drank alcohol: 50% (65/131) vs. 60% (73/122) vs. 68% (85/126), p&lt;0.05 (ISFP vs. Ctrl)</p> <p>Ever drunkenness: 26% (39/148) vs. 36% (50/141) vs. 44% (66/150), p&lt;0.05 (ISFP, PDFY vs. Ctrl)</p> <p><u>Relative reduction in % of new alcohol behaviours</u></p> <p>Ever drank alcohol (ISFP vs. Ctrl): 26.4, p&lt;0.01</p> <p>Ever drank alcohol (PDFY vs. Ctrl): 11.3, p&gt;0.05</p> <p>Ever drunkenness (ISFP vs. Ctrl): 40.1, p&lt;0.01</p> <p>Ever drunkenness (PDFY vs. Ctrl): 19.4, p&gt;0.05</p> <p><u>% of alcohol users in the past month</u></p> <p>In ISFP group reduced compared to Ctrl (relative reduction in ISFP was 30%, z=2.19, p&lt;0.05)</p> <p>In PDFY group reduced compared to Ctrl (relative reduction in PDFY was 40.6%, z=2.97, p&lt;0.05)</p> <p><u>Past month mean frequency of drinking</u></p> <p>1.0 (0.15) vs. 0.96 (0.15) vs. 1.47 (0.15), p&lt;0.05 for ISFP &amp; PDFY vs. Ctrl; p&gt;0.05 for ISFP vs. PDFY</p> <p><u>Alcohol use composite index (0=no use, 1=use)</u></p> <p>1.51 (0.14) vs. 1.78 (0.13) vs. 2.16 (0.14), p&lt;0.05 for ISFP &amp; PDFY vs. Ctrl; p&gt;0.05 for ISFP vs. PDFY</p> <p><u>Effect size (Alcohol use composite index; 0=no use, 1=use)</u></p> <p>0.38 (ISFP) vs. 0.27 (PDFY)</p> <p><b>FU - 72 mo post-randomisation (ISFP vs. PDFY vs. Ctrl)</b></p> <p>% Reporting lifetime alcohol use: 80.6% (121/150) vs. 84.6% (126/149) vs. 81.4% (127/156), p=NR</p>
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% Reporting past month alcohol use: 48.6% (72/148) vs. 45.9% (68/148) vs. 53.9% (83/154), p=NR  
 % Reporting past year alcohol use: 67.3% (101/150) vs. 70.4% (105/149) vs. 73.0% (114/156), p=NR  
 % Reporting lifetime drunkenness: 55.3% (83/150) vs. 59.4% (88/148) vs. 68.0% (106/156), p=NR

Parameters for growth curves

*ISFP vs. Ctrl*  
 Alcohol composite use index (0=no use, 1=use):  $\gamma_1 = 0.001$  (p>0.05)  
 Lifetime alcohol use:  $\gamma_1 = -0.023$  (p<0.05) significantly slower growth rate in use for ISFP compared to Ctrl  
 Lifetime drunkenness:  $\gamma_1 = -0.013$  (p>0.05)

*PDFY vs. Ctrl*  
 Alcohol composite use index (0=no use, 1=use):  $\gamma_1 = -0.011$  (p>0.05)  
 Lifetime alcohol use:  $\gamma_1 = -0.019$  (p>0.05)  
 Lifetime drunkenness:  $\gamma_1 = -0.003$  (p>0.05)

**FU - 120 mo post-randomisation (ISFP vs. PDFY vs. Ctrl)**

Drunkenness frequency: 1.45 (1.34) vs 1.66 (1.50) vs 1.68 (1.43)  
Alcohol problem frequency: 0.27 (0.36) vs 0.23 (0.36) vs 0.31 (0.48)

Intervention effects on initiation growth factors

*Average level of initiation drunkenness*  
 ISFP vs. Ctrl: -0.15 (t=-3.68, p<0.01)  
 PDFY vs. Ctrl: -0.09 (t=-1.94, p>0.05)

*Rate of increase in drunkenness frequency*  
 ISFP vs. Ctrl: -0.25 (t=-3.99, p<0.01)  
 PDFY vs. Ctrl: -0.11 (t=-1.94, p>0.05)

*Average level of initiation alcohol problems*  
 ISFP vs. Ctrl: -0.15 (t=-3.54, p<0.01)  
 PDFY vs. Ctrl: -0.09 (t=-1.94, p>0.05)

*Rate of increase in alcohol problem frequency*  
 ISFP vs. Ctrl: -0.25 (t=-3.98, p<0.01)  
 PDFY vs. Ctrl: -0.11 (t=-1.96, p>0.05)

Indirect effect on drunkenness  
 ISFP vs. Ctrl: -0.09 (t=-3.16, p<0.01), RRR=19% (ISFP)  
 PDFY vs. Ctrl: -0.04 (t=-1.97, p<0.05), RRR=9% (PDFY)

Direct effect on drunkenness  
 ISFP vs. Ctrl (p<0.05)  
 PDFY vs. Ctrl (p>0.05)

Indirect effect on alcohol problems  
 ISFP vs. Ctrl: -0.08 (t=-3.34, p<0.01), RRR=23% (ISFP)  
 PDFY vs. Ctrl: -0.03 (t=-1.64, p>0.05), RRR=11% (PDFY)

Direct effect on alcohol problems  
 ISFP vs. Ctrl (p<0.05)  
 PDFY vs. Ctrl (p>0.05)

The rate of alcohol abuse (PDFY vs. Ctrl)  
 Men: 29% vs. 25%, p>0.05  
 Women: 6% vs. 16%, p<0.05  
 There was a significant Indirect effect of PDFY on the rate of alcohol abuse in women through the mediation of prosocial skills (B=-0.41, SE=0.17, p<0.05;  $\beta = -0.19$ )

**Spoth 1999a** (Continued)

Notes	<p><b>ISFP and PDFY</b></p> <p>No evidence of between-group differences in covariates at baseline          No evidence of differential attrition was found; lower parental education, younger parental age, and higher child alcohol initiation score were related to higher chance for attrition between 6<sup>th</sup> grade pre-test and 10<sup>th</sup> grade follow-up assessments.  <math>\gamma</math> = test of differences in slopes of the growth curves          The effect of PDFY on the rate of alcohol abuse was moderated by gender, i.e., no significant difference between PDFY and Ctrl in men, but a significantly lower rate of alcohol abuse in PDFY than Ctrl in women</p> <p><u>Abbreviations</u>          FU=follow-up; RCT=randomised controlled trial; N=number; Int=intervention; Ctrl=control; ITT=intention to treat (analysis); yr(s)=year(s); mo=month(s); wk(s)=week(s); NR=not reported; NA=not applicable; ISFP=Iowa strengthening families program; PDFY=preparing for the drug-free years program; SD=standard deviation; RRR=rate relative reduction</p>
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**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	randomised block design was used
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	High risk	No ITT, large attrition though no evidence found for differential attrition, no imputation for missing data
Selective reporting (reporting bias)	Low risk	all outcomes reported
Other bias	Low risk	No other apparent source of bias

**Stevens 2002**

Methods	<p>Design: RCT          FU: 12, 24, 36 mo post-randomisation          Attrition: 22% [2741/3496] (at 12 mo FU post-baseline)          ITT: no          Unit of randomisation: paediatric clinic          Clustering effect adjusted: yes</p>
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<p>Participants</p>	<p><u>N of Clusters (subjects) randomised</u>            Int-1: 6 (NR)            Int-2: 6 (NR)            Total N: 12 (3496)  <u>N of Clusters (subjects) participated</u>            Int-1: 6 (NR)            Int-2: 6 (NR)            Total N: 12 (3145)  <u>Analyzed sample N of clusters (subjects)</u>            Int-1: 6 (NR)            Int-2: 6 (NR)            Total N: 12 (2183)            Age (mean): 11 (SD=0.8) yrs            Sex (male): 50%-54%            Ethnicity: NR            Alcohol users: 7.6%            Country: US</p>
<p>Interventions</p>	<p><u>Intervention-1: family based program mediated through paediatric primary care clinician</u>  <u>Focus/target: alcohol and tobacco</u>  <u>Components: signing a contract with a clinician and engaging child and parent in discussions and communication about alcohol and tobacco smoking; later components were clinician's letter, newsletters of reinforcement, bi-annual telephone calls</u>  <u>Intervention-2: family based program mediated through paediatric primary care clinician</u>  <u>Focus/target: gun safety, seatbelt use, bicycle helmet use</u>  <u>Components: signing a contract with a clinician and engaging child and parent in discussions and communication about gun safety, seatbelt use, bicycle helmet use; later components were clinician's letter, newsletters of reinforcement, bi-annual telephone calls</u>  <u>Fidelity: Int-1 (50%-97%) vs. Int-2 (46%-90%)</u>  <u>Duration/frequency: 36 mo</u>  <u>Control: NA</u></p>
<p>Outcomes</p>	<p><u>FU - 12 mo post-randomisation</u>            Alcohol ever drinker (Int-1 vs. Int-2): OR*=1.17, 95% CI: 0.92, 1.48  <u>FU - 24 mo post-randomisation</u>            Alcohol ever drinker (Int-1 vs. Int-2): OR*=1.27, 95% CI: 1.03, 1.55 (negative intervention effect)  <u>FU - 36 mo post-randomisation</u>            Alcohol ever drinker (Int-1 vs. Int-2): OR*=1.30, 95% CI: 1.07, 1.57 (negative intervention effect)            * OR adjusted for child's age, child's gender, parent education, family income, parent marital status, child having drinking friend, parental high stress and low self esteem, parent with drinking problems</p>
<p>Notes</p>	<p><b>Dartmouth Prevention Project (DPP)</b>            Negative effect of the intervention was observed at 24 and 36 mo FU after baseline  <u>Abbreviations</u>            FU=follow-up; RCT=randomised controlled trial; N=number; Int=intervention; Ctrl=control; ITT=intention to treat (analysis); yr(s)=year(s); mo=month(s); wk(s)=week(s)</p>

Stevens 2002 (Continued)

; NR=not reported; NA=not applicable; SD=standard deviation; OR=odds ratio; 95% CI=ninety-five percent confidence interval		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Computer-generated
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	High risk	High attrition (> 20%) and no ITT analysis
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	Possible contamination

Werch 2008

Methods	Design: RCT FU: 4 mo (post-intervention) or 19 wks post-randomisation Attrition: 5%-8% (4 mo post-intervention) ITT: no Unit of randomisation: student Clustering effect adjusted: NA
Participants	<u>N of Clusters (subjects) randomised</u> Int-1: NA (NR) Int-2: NA (NR) Ctrl: NA (NA) Total N: NA (684) <u>N of Clusters (subjects) participated</u> Int-1: NA (NR) Int-2: NA (NR) Ctrl: NA (NA) Total N: NA (NR) <u>Analyzed sample N of clusters (subjects)</u> Int-1: NA (182) Int-2: NA (202) Ctrl: NA (NA) Total N: NA (384) Age (mean): 15.24 (SD=1.09) yrs

	<p>Sex (male): 44%</p> <p>Ethnicity: 49.6% (White), 21.2% (African American), 29.3% (Others)</p> <p>Alcohol users: NR</p> <p>Country: US</p>
Interventions	<p><u>Intervention-1</u>: 8.5 x 11 inch one sided parent postcard (adopted from Project Sport consultation); a brief image-based print-mediated parent/caregiver message about communication on fitness promotion and avoidance of alcohol</p> <p><u>Focus/target</u>: alcohol use</p> <p><u>Components</u>: a series of 3 postcards were mailed</p> <p><u>Intervention-2</u>: 8.5 x 11 inch two-sided adolescent flier integrating physical activity and other health-promoting behaviors</p> <p><u>Focus/target</u>: alcohol use</p> <p><u>Components</u>: a series of 3 fliers were mailed with similar but shorter messages than those in parental postcard but with commercial quality images of healthy and active youth with brief fitness and alcohol avoidance messages</p> <p><u>Fidelity</u>: 65% of parents received at least one postcard and 53% of them received all three postcards; corresponding proportions of adolescents receiving fliers were 70% and 59%, respectively; 95% of the parents talked to their children about the postcard and 91% of the teens liked the fliers</p> <p><u>Duration/frequency</u>: 3 wks (one postcard or flier mailed per week)</p> <p>Control: NA</p>
Outcomes	<p><b>FU - 4 mo post-intervention (19 wks after baseline) int-1 vs. int-2, means (standard errors)</b></p> <p>Alcohol initiation: 3.52 (0.17) vs. 3.47 (0.17), p=0.29</p> <p>30-d alcohol frequency: 0.55 (0.08) vs. 0.68 (0.08), p=0.01</p> <p>30-d alcohol quantity: 0.90 (0.12) vs. 1.00 (0.11), p=0.07</p> <p>30-d alcohol heavy use (5 or more drinks in a row): 0.21 (0.06) vs. 0.30 (0.05), p=0.17</p> <p>Alcohol problems: 1.40 (0.20) vs. 1.72 (0.19), p=0.009</p> <p>Length of alcohol use (&lt;30 d to 6 months or longer): 2.10 (0.11) vs. 2.08 (0.10), p=0.61</p> <p><u>Intervention effect modification by 'drug use' at baseline (group x drug use status x time)</u></p> <p>Alcohol initiation (drug users at baseline): 4.86 (0.32) vs. 5.97 (0.36),</p> <p>Alcohol initiation (drug non-users at baseline): 3.11 (0.18) vs. 2.92 (0.16), p=0.004</p> <p>30-d alcohol frequency (drug users at baseline): 1.03 (0.16) vs. 1.73 (0.17),</p> <p>30-d alcohol frequency (drug non-users at baseline): 0.39 (0.09) vs. 0.46 (0.08), p=0.001</p> <p>30-d alcohol quantity (drug users at baseline): 2.10 (0.23) vs. 2.36 (0.24),</p> <p>30-d alcohol quantity (drug non-users at baseline): 0.50 (0.13) vs. 0.69 (0.11), p=0.29</p> <p>30-d alcohol heavy use (drug users at baseline): 0.63 (0.11) vs. 0.85 (0.12),</p> <p>30-d alcohol heavy use (drug non-users at baseline): 0.06 (0.06) vs. 0.18 (0.06), p=0.31</p> <p>Alcohol problems (drug users at baseline): 3.03 (0.39) vs. 3.97 (0.42),</p> <p>Alcohol problems (drug non-users at baseline): 0.87 (0.22) vs. 1.21 (0.19), p=0.31</p> <p>Length of alcohol use (drug users at baseline): 2.97 (0.20) vs. 3.41 (0.23),</p> <p>Length of alcohol use (drug non-users at baseline): 3.11 (0.18) vs. 2.92 (0.16), p=0.004</p>
Notes	<p>No baseline differences in important covariates between the two intervention groups</p> <p>Attrition was not significantly different (p&gt;0.05) with respect to alcohol/drug use and</p>

**Werch 2008** (Continued)

exercise behaviours between the participants bringing all three postcards or fliers and those returning less than three postcards or fliers; non-compliers tended to have greater smoking and drinking problems than those who returned with all three fliers/postcards (p=0.04)

The reduction of 30-d alcohol frequency and alcohol initiation in the parent postcard group compared to the adolescent flier group was even greater in drug users vs. drug non-users at baseline. However, it is not clear if these were post-hoc tests and there is multiple statistical testing, so some chance findings are possibly more likely

Drug use at baseline was measured as past 30-day use of cigarettes or marijuana

Abbreviation  
 FU=follow-up; RCT=randomised controlled trial; N=number; Int=intervention; Ctrl=control; ITT=intention to treat (analysis); yr(s)=year(s); mo=month(s); wk(s)=week(s); NR=not reported; NA=not applicable

<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Small attrition but no ITT analysis
Selective reporting (reporting bias)	Low risk	All data reported
Other bias	Low risk	No evidence of other source of bias

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

Study	Reason for exclusion
Ackermann 2008	Participant age > 18 years old
Allison 1990	School-based
Amaro 2009	Selective/indicated prevention
Anderson 2004	No relevant outcomes

(Continued)

Bailey 2004	Community-based intervention
Beaulieu 1998	School-based
Bell 2005	No relevant outcomes
Benner 2008	No relevant outcomes
Bersamin 2007	Participant age > 18 years old
Boekeloo 2004	Office-based intervention
Bond 2004	School-based
Botvin 2006	School-based
Brody 2004	No relevant outcomes
Brody 2005	No relevant outcomes
Brody 2008	No relevant outcomes
Brown 2005	Multi-component intervention
Brown 2007	Meta-analysis
Bryan 2009	Selective/indicated prevention
Castellanos 2006	No relevant outcomes
Caudill 2007	Selective/indicated prevention
Connell 2007	Family/multi-component intervention
Conrod 2006	Selective/indicated prevention
Conrod 2008	Selective/indicated prevention
Croom 2009	Participant age > 18 years old
D'Amico 2008	Selective/indicated prevention
DeGarmo 2009	Multi-component intervention
Dembo 2002	Selective/indicated prevention
Donohue 2004	Participant age > 18 years old

(Continued)

Eddy 2003	Multi-component intervention
Elder 2002	Selective/indicated prevention
Elliot 2004	No relevant outcomes
Friedman 2002	Selective/indicated prevention
Fromme 2004	Participant age > 18 years old
Griffin 2003	Selective/indicated prevention
Griffin 2004	No relevant outcomes
Haggerty 2006	Combination (family+school)
Haggerty 2008	Selective/indicated prevention
Hembroff 2007	Participant age > 18 years old
Jemmott 2005	Participant age > 18 years old
Kellam 2008	School-based
Kitzman 2010	No relevant outcomes
Komro 2006	No relevant outcomes
Martinez 2005	Selective/indicated prevention
Poduska 2008	No relevant outcomes
Simons-Morton 2005	Multi-component intervention
Sussman 2002	Not randomised trial
Wagenaar 2005	Not randomised trial
Wolchik 2002	Selective/indicated prevention

## DATA AND ANALYSES

This review has no analyses.

## ADDITIONAL TABLES

Table 1. Narrative Summary of Findings

Study	Follow-up (months)	Narrative summary: effect of the intervention	Comments
<a href="#">Bauman 2002</a>	3 and 12, combined	Lower lifetime alcohol use	1-tailed tests; small effect
<a href="#">Brody 2006</a>	29, 65	Lower rates of alcohol initiation, and lower rate of increase in alcohol use across time	Small N (at cluster level); appropriate analysis
<a href="#">Haggerty 2007</a>	24	No effects	No effects by ethnicity in planned subgroup analysis
<a href="#">Koning 2009</a>	22	No effects of parenting intervention alone	Brief parenting intervention; sig. effects when combined with school intervention
<a href="#">Loveland-Cherry 1999</a>	48	Significant effects in prior drinkers, but not in lifetime non-drinkers	Sub-group analysis was pre-planned
<a href="#">O'Donnell 2010</a>	3,9	Significant effects at 3 months but not 9 months.	Females only, small sample size
<a href="#">Schinke 2009a</a>	2	Lower alcohol consumption	Females only. This result reported from an intervention x time analysis
<a href="#">Schinke 2009b</a>	12, 24	Less 30-day alcohol use	Females only
<a href="#">Schinke 2009c</a>	12	Less 30-day alcohol use	Females only
<a href="#">Spoth 1999a</a>	18, 30, 48, 72, 120	Lower levels of alcohol use and drunkenness at 18, 30, 48 months. 72 month analysis showed significantly slower growth rate in alcohol use compared to controls. 120 month analysis showed effects of intervention on drunkenness and alcohol problems	Two family-based interventions compared: ISFP and PDFY. ISFP seemed to have stronger effects
<a href="#">Stevens 2002</a>	12, 24, 36	No effects at 12 months. Negative effect at 24 and 36 months, for "ever used alcohol"	Possible iatrogenic effect, although cannot rule out chance or prevailing bias

**Table 1. Narrative Summary of Findings** (Continued)

Werch 2008	4	Effects on 30-day quantity, frequency and alcohol problem measures	Multiple statistical testing
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## APPENDICES

### Appendix I. Medline Search Strategy

1 RANDOMIZED CONTROLLED TRIAL.pt.  
2 CONTROLLED CLINICAL TRIAL.pt.  
3 RANDOMIZED CONTROLLED TRIALS.sh.  
4 RANDOM ALLOCATION.sh.  
5 DOUBLE BLIND METHOD.sh.  
6 SINGLE BLIND METHOD.sh.  
7 or/1-6  
8 CLINICAL TRIAL.pt.  
9 exp CLINICAL TRIALS/  
10 (clin\$ adj25 trial\$).ti,ab.  
11 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab.  
12 PLACEBOS.sh.  
13 placebo\$.ti,ab.  
14 random\$.ti,ab.  
15 RESEARCH DESIGN.sh.  
16 or/8-15  
17 7 or 16  
18 (ANIMALS not HUMAN).sh.  
19 17 not 18  
20 exp ALCOHOLS/ad, ae  
21 exp Alcohol Drinking/  
22 exp Alcohol Abuse/  
23 exp Alcohol, Ethyl/ae  
24 exp Alcohol Abuse/mo, pc, rh, th  
25 alcohol\$.ti,ab.  
26 drink\$.ti,ab.  
27 drunk\$.ti,ab.  
28 intoxicat\$.ti,ab.  
29 or/20-28  
30 adolescen\$.ti,ab. 31.31 teenage\$.ti,ab.32.(young adj2 people).ti,ab.  
33 (early adj2 adult\$).ti,ab.  
34 (young adj2 adult\$).ti,ab.  
35 youth\$.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]  
36 exp adolescent/ or exp child/ or exp infant/ or exp students/  
37 exp youth/  
38 or/30-37  
39 intervention\$.ti,ab.  
40 educat\$.ti,ab.

41 promot\$.ti,ab.  
 42 adverti\$.ti,ab.  
 43 campaign\$.ti,ab.  
 44 (mass adj2 media).ti,ab.  
 45 (primary adj5 prevention).ti,ab.  
 46 (secondary adj5 prevention).ti,ab.  
 47 (universal adj5 prevention).ti,ab.  
 48 (selective adj5 prevention).ti,ab.  
 49 (target\$ adj5 prevention).ti,ab.  
 50 exp education/  
 51 or/39-50  
 52 19 and 29 and 38 and 51  
 53 limit 52 to yr="2002 -Current"

## Appendix 2. EMBASE Search Strategy

1 random\$.ab,ti.  
 2 placebo.ab,ti.  
 3 ((singl\$ or doubl\$ or trebl\$ or tripl\$) and (blind\$ or mask\$)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]  
 4 (cross-over\$ or crossover\$).tw.  
 5 randomized controlled trial/  
 6 phase-2-clinical-trial/  
 7 phase-3-clinical-trial/  
 8 double blind procedure/  
 9 single blind procedure/  
 10 crossover procedure/  
 11 Latin square design/  
 12 exp PLACEBOS/  
 13 multicenter study/  
 14 or/1-13  
 15 limit 14 to human  
 16 exp alcohol/  
 17 Drinking Behavior/  
 18 Alcoholism/  
 19 exp alcohol abuse/  
 20 exp Alcohol Drinking/  
 21 drink\$.ti,ab.  
 22 drunk\$.ti,ab.  
 23 intoxicat\$.ti,ab.  
 24 alcohol\$.ti,ab.  
 25 or/16-24  
 26 adolescen\$.ti,ab.  
 27 teenage\$.ti,ab.  
 28 (young adj2 people).ti,ab.  
 29 (early adj2 adult\$).ti,ab.  
 30 (young adj2 adult\$).ti,ab.  
 31 youth\$.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]  
 32 exp adolescent/ or exp child/ or exp infant/ or exp students/  
 33 exp youth/  
 34 or/26-33

35 intervention\$.ti,ab.  
 36 educat\$.ti,ab.  
 37 promot\$.ti,ab.  
 38 adverti\$.ti,ab.  
 39 campaign\$.ti,ab.  
 40 (mass adj2 media).ti,ab.  
 41 (primary adj5 prevention).ti,ab.  
 42 (secondary adj5 prevention).ti,ab.  
 43 (universal adj5 prevention).ti,ab.  
 44 (selective adj5 prevention).ti,ab.  
 45 (target\$ adj5 prevention).ti,ab.  
 46 exp education/  
 47 or/35-46  
 48 15 and 25 and 34 and 47  
 49 limit 48 to yr="2002 -Current"

### Appendix 3. PsycInfo Search Strategy

1 clinical trials.sh.  
 2 placebo.sh.  
 3 (Single adj blind\*).ab,ti.  
 4 (Single adj dumm\*).ab,ti.  
 5 (Single adj mask\*).ab,ti.  
 6 (Double adj blind\*).ab,ti.  
 7 (Double adj dumm\*).ab,ti.  
 8 (Double adj mask\*).ab,ti.  
 9 (triple adj blind\*).ab,ti.  
 10 (triple adj dumm\*).ab,ti.  
 11 (triple adj mask\*).ab,ti.  
 12 (treble adj blind\*).ab,ti.  
 13 (treble adj dumm\*).ab,ti.  
 14 (treble adj mask\*).ab,ti.  
 15 (control\* adj study).ab,ti.  
 16 (control\* adj studies).ab,ti.  
 17 (control\* adj trial\*).ab,ti.  
 18 (Random\* or sham or shams or placebo\* or RCT\*).ab,ti.  
 19 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18  
 20 alcohol\$.ti,ab.  
 21 drink\$.ti,ab.  
 22 drunk\$.ti,ab.  
 23 intoxicat\$.ti,ab.  
 24 exp sobriety/ or exp alcohol withdrawal/ or exp alcohol intoxication/ or exp alcoholism/ or exp alcohols/ or exp blood alcohol concentration/ or exp binge drinking/ or exp driving under the influence/ or exp alcohol abuse/ or exp alcoholic psychosis/ or exp alcohol rehabilitation/ or exp alcohol drinking patterns/  
 25 or/20-24  
 26 adolescen\$.ti,ab.  
 27 teenage\$.ti,ab.  
 28 (young adj2 people).ti,ab.  
 29 (early adj2 adult\$).ti,ab.  
 30 (young adj2 adult\$).ti,ab.  
 31 youth\$.mp. [mp=title, abstract, heading word, table of contents, key concepts]  
 32 exp adolescent/ or exp child/ or exp students/

33 exp youth/  
 34 or/26-33  
 35 intervention\$.ti,ab.  
 36 educat\$.ti,ab.  
 37 promot\$.ti,ab.  
 38 adverti\$.ti,ab.  
 39 campaign\$.ti,ab.  
 40 (mass adj2 media).ti,ab.  
 41 (primary adj5 prevention).ti,ab.  
 42 (secondary adj5 prevention).ti,ab.  
 43 (universal adj5 prevention).ti,ab.  
 44 (selective adj5 prevention).ti,ab.  
 45 (target\$ adj5 prevention).ti,ab.  
 46 exp education/  
 47 or/35-46  
 48 19 and 25 and 34 and 47  
 49 limit 48 to yr="2002 -Current"

## HISTORY

Review first published: Issue 9, 2011

Date	Event	Description
22 November 2010	New search has been performed	This review represents a substantial update of the review "Primary prevention for alcohol misuse in young people" that has been split into three reviews. This represents one of the three. The other two reviews focus on universal school-based prevention and on universal multi-component prevention

## CONTRIBUTIONS OF AUTHORS

DF conceived and led on the scope and design of the review. DF and AW both undertook searches, screening and data extraction. AW led on data analysis. Both DF and AW contributed to drafting and writing the review.

## DECLARATIONS OF INTEREST

DFs Department has received funding from the alcohol industry for adapting and evaluating a family based prevention program, the ISFP. The adapted version is being evaluated in large scale randomised controlled trials in Wales, funded by the UK Medical Research Council, and Poland, funded by the Polish National Bureau for Drug Prevention.

## SOURCES OF SUPPORT

### Internal sources

- Oxford Brookes University, UK.  
Funding to employ co-reviewer

### External sources

- NIHR, UK.  
Small grant to update previous review

## NOTES

This review represents a substantial update of the review "Primary prevention for alcohol misuse in young people" that has been split into three reviews. This represents one of the three. The other two reviews focus on universal school-based prevention and on universal multi-component prevention.

## INDEX TERMS

### Medical Subject Headings (MeSH)

\*Family Health; Alcohol Drinking [\*prevention & control]; Alcohol-Related Disorders [\*prevention & control]; Primary Prevention [\*methods]; Program Evaluation; Randomized Controlled Trials as Topic; Sex Factors

### MeSH check words

Adolescent; Child; Female; Humans; Male