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[Intervention Review]

Interventions for tobacco use prevention in Indigenous youth

Kristin V Carson¹, Malcolm P Brinn¹, Nadina A Labiszewski¹, Matthew Peters², Anne B Chang³, Antony Veale⁴, Adrian J Esterman⁵, Brian J Smith⁶

¹Clinical Practice Unit, The Queen Elizabeth Hospital, Adelaide, Australia. ²Medicine, Concord Clinical School, The University of Sydney, Sydney, Australia. ³Menzies School of Health Research, Charles Darwin University, Casuarina, Australia. ⁴Respiratory Medicine, The Queen Elizabeth Hospital, Adelaide, Australia. ⁵University of South Australia, Adelaide, Australia. ⁶Department of Medicine, University of Adelaide, The Queen Elizabeth Hospital, Adelaide, Australia

Contact address: Kristin V Carson, Clinical Practice Unit, The Queen Elizabeth Hospital, 4A Main Building, 28 Woodville Road Woodville South, Adelaide, South Australia, 5011, Australia. kristin.carson@health.sa.gov.au.

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ABSTRACT

Background

Tobacco use in Indigenous populations (people who have inhabited a country for thousands of years) is often double that in the non-Indigenous population. Addiction to nicotine usually begins during early adolescence and young people who reach the age of 18 as non-smokers are unlikely to become smokers thereafter. Indigenous youth in particular commence smoking at an early age, and a disproportionate burden of substance-related morbidity and mortality exists as a result.

Objectives

To evaluate the effectiveness of intervention programmes to prevent tobacco use initiation or progression to regular smoking amongst young Indigenous populations and to summarise these approaches for future prevention programmes and research.

Search methods

The Cochrane Tobacco Addiction Group Specialised Register was searched in November 2011, with additional searches run in MEDLINE. Online clinical trial databases and publication references were also searched for potential studies.

Selection criteria

We included randomized and non-randomized controlled trials aiming to prevent tobacco use initiation or progression from experimentation to regular tobacco use in Indigenous youth. Interventions could include school-based initiatives, mass media, multi-component community level interventions, family-based programmes or public policy.

Data collection and analysis

Data pertaining to methodology, participants, interventions and outcomes were extracted by one reviewer and checked by a second, whilst information on risk of bias was extracted independently by a combination of two reviewers. Studies were assessed by qualitative narrative synthesis, as insufficient data were available to conduct a meta-analysis. The review process was examined by an Indigenous (Aboriginal) Australian for applicability, acceptability and content.

Main results

Two studies met all of the eligibility criteria for inclusion within the review and a third was identified as ongoing. The two included studies employed multi-component community-based interventions tailored to the specific cultural aspects of the population and were based in Native American populations (1505 subjects in total). No difference was observed in weekly smoking at 42 months follow-up in the one study assessing this outcome (skills-community group versus control: risk ratio [RR] 0.95, 95% CI 0.78 to 1.14; skills-only group versus control: RR 0.86, 95% CI 0.71 to 1.05). For smokeless tobacco use, no difference was found between the skills-community arm and the control group at 42 weeks (RR 0.93, 95% CI 0.67 to 1.30), though a significant difference was observed between the skills-only arm and the control group (RR 0.57, 95% CI 0.39 to 0.85). Whilst the second study found positive changes for tobacco use in the intervention arm at post test ($p < 0.05$), this was not maintained at six month follow-up (change score -0.11 for intervention and 0.07 for control). Both studies were rated as high or unclear risk of bias in seven or more domains (out of a total of 10).

Authors' conclusions

Based on the available evidence, a conclusion cannot be drawn as to the efficacy of tobacco prevention initiatives tailored for Indigenous youth. This review highlights the paucity of data and the need for more research in this area. Smoking prevalence in Indigenous youth is twice that of the non-Indigenous population, with tobacco experimentation commencing at an early age. As such, a significant health disparity exists where Indigenous populations, a minority, are over-represented in the burden of smoking-related morbidity and mortality. Methodologically rigorous trials are needed to investigate interventions aimed at preventing the uptake of tobacco use amongst Indigenous youth and to assist in bridging the gap between tobacco-related health disparities in Indigenous and non-Indigenous populations.

PLAIN LANGUAGE SUMMARY

Can smoking prevention interventions targeted at Indigenous youth prevent Indigenous youth from starting to smoke or use other tobacco products?

In Indigenous populations, the number of people who smoke has not fallen as it has in the wider communities around them. Young people remain at particular risk of taking up smoking. The associated harms to health are unacceptable. This review found that there is not enough published research evaluating programmes aiming to prevent Indigenous youth from starting to use tobacco. Information from the two included studies in this review (1505 participants in total, in Native American communities) does not allow a conclusion to be drawn as to whether tobacco prevention programmes in Indigenous populations prevent Indigenous youth from smoking or using smokeless tobacco. The review highlights the absence of data and need for more research.

BACKGROUND

Specific definitions for 'Indigenous' vary between regions and populations. These terms remain highly contested and are not always accepted or used ([Nettelton 2007](#)). Such examples include 'Australian Aboriginal' or 'Torres Strait Islanders' for the Australian Indigenous, 'First Nations' to describe the Indian populations indigenous to Canada, 'Native Hawaiians' for Hawaii's Indigenous and 'Tangata Whenua' or 'People of the land' for the Māori of New Zealand ([Cunningham 2003](#)). In an attempt to create consistency, though cognisant of the preferential syntax for populations, the term 'Indigenous' has been chosen to encompass participants within this review as it reflects "the experiences shared by a group of people who have inhabited a country for thousands of years, which often contrast with those of other groups of people who reside in the same country for a few hundred years" ([Cunningham 2003](#)). No offence is meant to any group for whom their preferred descriptor is not used.

Description of the condition

Throughout the world, Indigenous populations bear a disproportionate burden of substance-related morbidity and mortality when compared to non-Indigenous populations. Prevalence of tobacco use amongst the Indigenous population is often double that of the relevant non-Indigenous population, with estimates of 51 to 59 per cent in Canada ([Health Canada 2003](#); [CEITC 2005](#)), 47 to 53 per cent in Australia ([CEITC 2005](#); [ABS 2009](#)), 45 per cent in New Zealand ([Ministry of Health 2009](#)) and 44 per cent in the United States for Alaskan natives ([First Nations Center 2005](#); [Alaska Department of Health 2006](#)). In all populations, addiction to nicotine usually begins during early adolescence, with only 10 per cent of new smokers initiating the habit after the age of 18 years ([US Dept Health and Human Services 1998](#)). In the recent US Surgeon General's Report, authors state that almost no one in the US will commence smoking after the age of 25, with nearly nine out of 10 smokers initiating tobacco use by the age of 18, and 99 per cent starting by age 26 ([Surgeon General's Report 2012](#)). The report also found that if the success in reducing youth tobacco use that was made between 1997 and 2003 had been maintained, there could potentially be three million fewer smokers in the US currently. A similar reduction in tobacco use was also observed in Australian youth between 1996 and 2005, which included a cohort of Indigenous youth ([White 2009](#)). Authors report that this reduction in smoking prevalence coincided with a period of increased tobacco control activity, including the funding of local Indigenous tobacco control programmes that were culturally appropriate and tailored for individual communities.

For Indigenous youth there is an added social context to tobacco use. An increased rate of tobacco use in Indigenous youth has been documented in many populations. An Australian report suggests the added social context has resulted in almost half of Indigenous youth aged 14 years and older reporting smoking on a daily basis, compared to approximately 20 per cent in non-Indigenous Australians ([AIHW 2002](#)). Despite some reductions in tobacco use following increased tobacco control programmes in Australia, the gap in smoking prevalence between Indigenous and non-Indigenous populations has remained consistent ([White 2009](#)). An evaluation of British Columbian youth estimates the prevalence of smoking in their Indigenous population to be 41 per cent for adolescents aged 12 to 18 years and 61 per cent for youth aged 19 to 24 years, whilst non-Indigenous youth have prevalence estimates of

18 per cent and 31 per cent respectively ([Reading 1999](#)). A Canadian survey of Indigenous youth reports smoking initiation peaking at 13 years of age ([First Nations Center 2005](#)). The First Nations regional longitudinal health survey, conducted in 2002 and 2003, found 38 per cent of youth reporting current smoking, double the rate of that of the relevant non-Indigenous population ([Reading 2009](#)). Use of smokeless tobacco, pipe tobacco, roll your own cigarettes and flavoured cigarettes is also reported to be twice as prevalent in Indigenous populations compared to the non-Indigenous ([Elton-Marshall 2011](#)).

The 'normalisation' of tobacco use in Indigenous populations has resulted in a disproportionate burden of disease, with subsequent effects on social interactions and relationship building amongst Indigenous youth. The primary social influences resulting in youth initiation of smoking are relevant for all youth, Indigenous and non-Indigenous alike, and include peer group pressure, positive attitudes toward smoking and the observation of adult smoking. For Indigenous youth this is amplified by the increase in adult smoking prevalence and the normalisation of tobacco use as part of the usual Indigenous landscape ([Lindorff 2002](#); [Scollo 2008](#); [Leavy 2010](#)). Parental behaviours and best friend smoking status in particular have been identified as key determinants of smoking among Indigenous adolescents ([Scragg 2007](#)). Furthermore, reports suggest that substandard and overcrowded living conditions increase tobacco exposure in young people in Indigenous Australian communities ([Johnston 1997](#); [Eades 1999](#); [Ivers 2001](#); [Penman 2006](#); [Johnston 2008](#)). A recent Australian survey of tobacco exposure in Aboriginal and Torres Strait Islander households reported that 21 per cent of children aged 0 to 14 years were exposed to indoor tobacco smoke in 2008, which was a decrease from reports of 29 per cent in 2004 to 2005 ([ABS 2011](#)). However, a 2012 report on tobacco use among youth in the US found that rates of decline for cigarette smoking have slowed in the past decade and that rates of decline for smokeless tobacco use have stalled completely ([Surgeon General's Report 2012](#)).

Description of the intervention

Interventions considered in this review aim to prevent tobacco use initiation or progression from experimentation to regular tobacco use in Indigenous youth. Tobacco use prevention initiatives targeted at young people are known to prevent the uptake of smoking in youth ([Brinn 2010](#); [Carson 2011a](#)). Interventions aiming to prevent youth smoking can include: school-based initiatives that involve classroom lessons (e.g., school-based curriculum delivered by classroom teachers); mass media such as television, radio, billboards or posters (e.g. community or nation-wide media campaigns directed at adolescents or adults through highlighting the health effects of tobacco use); multi-component community level interventions (e.g. combined tobacco use prevention campaigns involving peer role models, school curriculums, anti-smoking messages at local sporting or community events, combined into one intervention); family-based programmes (e.g., anti-smoking messages involving parent and child communication and activities including games, workbooks, discussions or written information); or public policy interventions (e.g. plain packaging of cigarettes or policies for a smoking ban in public places or where children are present, which is enforced by the community). A recent Cochrane review of such interventions in Indigenous populations found evidence of some success in smoking cessation, with significant reductions in tobacco use

reported in Indigenous populations (Carson 2012a). However, the review included only four studies and highlighted a paucity of data with which to determine the effectiveness of cessation initiatives specifically tailored to Indigenous populations.

How the intervention might work

Public health programmes have the potential to prevent the uptake of smoking and progression of regular smoking in youth, which may subsequently reduce health inequalities (Hill 2005). A significant amount of social science research has been conducted to establish motivational theories that can address smoking among young people, including the health beliefs model (Stretcher 1997), protection motivation theory (Floyd 2000), social cognitive theory (Bandura 1998), social development model (Fleming 2008) and behavioural change theory (Glanz 2008). Many of these are hinged on interpersonal traits such as self-esteem and self-efficacy as well as social and environmental influences, including peers, family and the school and community environment. Programmes to influence smoking behaviour based exclusively on one theoretical concept alone have been criticised (Bauman 1996; De Vries 2003a), with suggestions that indirect peer pressure may be just as effective in the prevention of smoking. Indeed, the smoking status of parents and peers have been identified as predictors of smoking onset (De Vries 2003b) and as such are believed to be important mediators to target for prevention initiatives. Evidence from other meta-analyses suggest that underpinning a prevention initiative with an established research theory that addresses social and cognitive influences of tobacco use may influence the uptake of smoking by youth (Brinn 2010; Carson 2011a). This has been performed through the provision of 'knowledge' about the health effects of tobacco use and through addressing 'attitudes' toward tobacco and 'perceptions' around peer use and acceptability, combined with support and structured lessons (Carson 2011a).

Why it is important to do this review

Smoking prevalence in the Indigenous population still remains twice that in the non-Indigenous, suggesting that existing mainstream tobacco prevention initiatives are producing little benefit in reducing the uptake of tobacco use amongst this high risk population. Some research has found that smoking prevalence may be decreasing as a result of increased tobacco control activities (White 2009), however more recent reports have found that rates of decline for smoking in the past decade have now slowed (Surgeon General's Report 2012). This 2012 report from the US also found that for each person that dies because of a smoking related illness (more than 1200 per day), at least two youths or young adults are becoming regular smokers (Surgeon General's Report 2012). Indigenous populations bear a disproportionate burden of tobacco-related illnesses in comparison to the non-Indigenous (Reading 2010). As a result, tobacco prevention in youth has been identified as key to reducing long term morbidity and mortality (Fiore 2004). However, a systematic consolidation of interventions and sub-components for those within this high-risk population has not occurred to date. A review of current literature is required to identify features of effective programmes that can be translated into policy to guide future prevention initiatives and research. As such, this review aims to consolidate this evidence to identify features of any effective programmes for Indigenous populations so that they can be pursued (US Dept Health and Human Services 1998), and to identify ineffective programmes so that they can be altered or abandoned.

OBJECTIVES

To evaluate the effectiveness of intervention programmes to prevent tobacco use initiation or progression to regular smoking amongst young Indigenous populations and to summarise these approaches for future prevention programmes and research.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized controlled trials (RCT) or quasi-randomized controlled trials (CCT).

Types of participants

Young people aged 25 years or less, of either gender, who are members of Indigenous populations, using 'Indigenous' in the sense described earlier, that participated in a study to prevent tobacco use initiation. Interventions could target groups of individuals (e.g. school classes), some of whom had already used tobacco. Trial participants were not required to be selected according to their susceptibility or suitability for particular interventions.

No attempts were made to re-define Indigenous status for the purpose of including a study in this review. If meaningful data was found which referred to an Indigenous subpopulation in a larger study, it was considered for inclusion in this review.

Types of interventions

We included interventions to prevent tobacco use initiation or progression from experimentation to regular tobacco use. Interventions were grouped by type and setting based on the following categories:

1. School only (including class lessons etc.), e.g. school-based curriculum delivered by classroom teachers.
2. Mass media (including television, radio, billboards, posters etc.), e.g. community- or nation-wide media campaigns highlighting the health effects of tobacco use and directed at adolescents.
3. Multi-component (i.e. more than one) community-based intervention targeting large areas (including school, specialised community groups, health care professionals, mass media etc.), e.g. combined tobacco use prevention campaigns involving peer role models, school curriculums, anti-smoking messages at local sporting or community events, combined into one intervention.
4. Family-based programmes, e.g. anti-smoking messages involving parent and child communication and activities including games, workbooks, discussions or written information.
5. Public policy (including legislative interventions, retailer restrictions etc.), e.g. policy for smoking bans in public places or where children are present, which are enforced by the community.

Controls could be usual practice, no intervention, co-interventions or reduced intervention. Control participants receiving reduced interventions could be offered brief tobacco use prevention advice,

but support had to be of a lower intensity than that given to the intervention participants in order to be included.

Types of outcome measures

Primary outcomes

The primary outcome was tobacco use status as defined by self-report or objectively through bio-chemical validation (e.g. saliva thiocyanate levels, alveolar carbon monoxide), at the longest follow-up point reported in the study (minimum of six months). No included studies reported tobacco use prevention data excluding baseline tobacco users (i.e., examining a cohort of only non-smokers at baseline). Had this non-smoking baseline cohort occurred, results would have been reported separately from those including baseline smokers within the reported cohort.

We recorded the definition of smoking or tobacco use used by each study. This could be reported as any smoking/tobacco use since the intervention, or as used within a particular period.

We considered the sustainability of change (whether the effect at longest follow-up is larger or smaller than that at earlier follow-ups) in tobacco use behaviour after the intervention (less than versus longer than one year).

Secondary outcomes

Secondary outcomes that were considered for extraction included:

1. whether the intervention had an effect on intentions to use tobacco, attitudes toward tobacco use, knowledge about tobacco use, decision making, refusal skills, self-efficacy and tobacco use perception/norms;
2. levels of implementation for process measures (e.g. measuring the amount of exposure to the intervention that the participants actually received, including details of implementation) as given in each included study, for example: cigarette purchases by minors, membership of anti-smoking clubs for young people, media reach and level of exposure to each component of an intervention;
3. costs of interventions.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Tobacco Addiction Group Specialised Register in November 2011. The Specialised Register is generated through regular searches of The Cochrane Library, EMBASE, MEDLINE, PsycINFO and Science Citation Index for trials of tobacco use prevention and cessation interventions. No language restrictions were applied. The following free text search terms were used to identify records relevant to the topic:

- 'aborig*' OR 'Indig*' OR 'inuit' OR 'maori' OR 'native american' OR 'american indian' OR 'tribe*' OR 'tribal', AND
- 'young people' OR 'teen*' OR 'adolesce*' OR 'juveniles' OR 'child*' OR 'boy*' OR 'girl*'

Since the Specialised Register is limited to studies of smoking and other tobacco use behaviour, no smoking related terms were used.

We also searched MEDLINE using the search strategy used for the Specialised Register, which combines terms for smoking and

terms to identify controlled trials, combined with MeSH terms for Indigenous populations, and age related limits. The MEDLINE search strategy is reported in full in [Appendix 1](#).

Online clinical trial registers were searched for ongoing and recently completed studies. We searched Controlled Clinical Trials (www.controlled-trials.com), the National Research Register (www.nrr.nhs.uk), government registries (clinicaltrials.gov), and WHO registries (www.who.int/trialsearch/).

Searching other resources

We reviewed reference lists of reviews and all included studies to identify potentially relevant citations. In addition, we made enquiries regarding other published or unpublished studies known to the authors of the included studies.

Data collection and analysis

Selection of studies

From the title, abstract, or descriptors, KC independently reviewed the literature searches to identify potentially relevant trials. All studies that clearly did not meet the inclusion criteria in terms of study design, population or interventions, were excluded. KC extracted the data, which was checked by a second reviewer (MB). Both KC and either NL or MB independently extracted information on risk of bias for all included studies. We did not exclude trials with high levels of attrition, however this was documented within the Risk of Bias tables and discussed.

Data extraction and management

KC extracted data for the trials using a standardised data extraction form prior to entry into The Cochrane Collaboration software programme, Review Manager 5.1.6. KC also corresponded with authors to obtain any missing or raw data as required. Risk of bias for each included study was extracted by two independent authors (KC and either NL or MB).

The following information was extracted:

- Methods: country/setting of trial; design; objectives; study site; methods of participant recruitment; methods of analysis
- Participants: age; gender; ethnicity; socio-economic status; n-values for eligibility, recruitment and completion
- Interventions: descriptions of interventions and controls; duration; intervention delivery; type/duration of behavioural support and control group components
- Outcomes: method of outcome collection; pre-specified outcome data; validation; follow-up period; other follow-ups and definitions of abstinence; outcome data as defined under '[Types of outcome measures](#)' in this review.
- Risk of bias: methods of sequence generation; allocation concealment; blinding; incomplete outcome data; selective outcome reporting; imbalance of outcome measures at baseline; comparability of intervention and control group characteristics at baseline; protection against contamination; selective recruitment of participants and other potential threats to validity.

Assessment of risk of bias in included studies

Information on risk of bias was evaluated by two independent reviewers, KC and either NL or MB, in line with recommendations

made in the Cochrane Handbook (Higgins 2011) and additional criteria developed by the Cochrane EPOC Group (EPOC 2009). Risk of bias was assessed based on allocation sequence, allocation concealment, blinding of participants and outcome assessors, incomplete outcome data, selective outcome reporting and other potential threats to validity. Three additional domains recommended by the Cochrane EPOC group were used to assess design-specific threats to validity: imbalance of outcome measures at baseline; comparability of intervention and control group characteristics at baseline and protection against contamination (EPOC 2009). Finally, for cluster study designs, an assessment of risk of bias associated with an additional domain of selective recruitment of participants was performed. Risk of bias for each domain was assessed as low, high or unclear as per the guidelines from table 8.5.d of the Cochrane Handbook (Higgins 2011). Conflicts in the assessments were resolved through consensus or by referring to a third party (either BS or AV).

Measures of treatment effect

Data was reported through narrative synthesis. Due to the small number of included studies it was not possible to meta-analyse data and make all of the comparisons as detailed in the protocol (Carson 2011b). Methods specified in the protocol but not used due to an insufficient number of studies are detailed in Appendix 2. Where possible, we used a risk ratio (RR) to describe the primary outcome defined as (number of subjects using tobacco in the intervention group/ total number randomized to the intervention group) / (number of subjects using tobacco in the control group/ total number randomized to the control group). An RR less than 1 indicates that the intervention was effective, and more subjects remained non-smokers in the intervention group than in the control group. Data were tabulated using Review Manager 5.1.6.

Unit of analysis issues

In the presence of cluster controlled trials, the analysis has been performed at the level of individual whilst accounting for the clustering in the data. For studies that did not include adjustments for clustering, the size of the trial was reduced to the effective sample size (Rao 1992) using the original sample size from each study, divided by a design effect of 1.2, which is consistent with other tobacco use intervention trials (Gail 1992) and as per recommendations in the Cochrane Handbook, section 16.3.4 (Higgins 2011). Whether or not an author has made adjustments for clustering effects has been reported under 'methods' in the *Characteristics of included studies* tables.

Dealing with missing data

Missing data regarding participants were evaluated on an available case analysis basis as described in chapter 16.2.2 of the Cochrane Handbook (Higgins 2011). Where statistics essential for analysis

were missing (e.g. group means and standard deviations for both groups were not reported) and could not be calculated from other data, we attempted to contact the authors to obtain data. Losses of participants that occurred prior to performance of baseline measurements were assumed to have no effect on the eventual outcome data of the study. We assessed and discussed any losses after the baseline measurement. We considered both differential losses between intervention and control conditions, and differential losses within conditions according to baseline characteristics.

Assessment of reporting biases

Reporting biases in individual studies were extrapolated within the risk of bias tables. Due to the limited number of studies it was not possible to assess reporting biases further.

Sensitivity analysis

Due to the small number of included studies we were not able to conduct sensitivity analyses. Were sufficient data available, sensitivity analyses would have been conducted on studies with a high risk of bias for sequence generation and allocation concealment.

Indigenous engagement in the review process

A recent short report by McDonald 2010 outlines the results of a taskforce conducted between the public health group within the Cochrane Collaboration and Indigenous health researchers, to discuss the issues and challenges of systematic reviews in Indigenous health. It highlights the complexities involved in the synthesis of evidence in such populations, for whom the social determinants of health are important factors underlying health inequalities. An important outcome of this review was to engage Indigenous people, organisations and communities to improve health translation. For this reason, the review was examined by two independent Indigenous representatives for consideration of applicability and content. At least one of these reviewers was an Indigenous researcher or health care worker.

RESULTS

Description of studies

Results of the search

The literature search identified 142 references, of which 92 were obtained from screening electronic clinical trial registries, five through bibliographic screening and one through author contact. Thirteen references were identified from this search for retrieval and possible inclusion in the review, producing a total of two included studies and one ongoing study (nine citations in total) which met all of the inclusion criteria (see Figure 1).

Figure 1. Study flow diagram.

Included studies

The two studies included in this review were published in 1987 and 1994. They were both randomized controlled trials and used multi-component community-based interventions targeting large areas and involving school forums for message delivery. [Gilchrist 1987](#) had two study arms (three intervention sites, one urban and two rural, and four control sites, one urban and three rural). The intervention in [Gilchrist 1987](#) consisted of a 10-session skills-enhancement programme delivered through school curriculum, group discussions, and invitations to adult from tribal programmes to be guest speakers. This intervention was compared to a test-only control group. The [Schinke 1994](#) study (reservation sites and tribal schools) had three study arms: 'skills-only' (including 15 classroom group interventions and booster sessions six months after initial intervention); 'skills-community' (same as 'skills-only' with the addition of an annual intervention designed to involve the community with various activities in which students modelled the skills they had learned in classrooms to their parents and other community members); and a no intervention control arm.

A total of 1505 subjects were included from these two studies and both were based in the Native American population. Follow-up time periods ranged from six months to three and a half years post baseline data collection, although intermediate data collection also occurred, ranging from three months to two years post intervention commencement for the [Gilchrist 1987](#) and [Schinke 1994](#) studies

respectively. Intervention durations varied between approximately three and six months, with school-based delivery of between 10 ([Gilchrist 1987](#)) and 15 ([Schinke 1994](#)) classroom sessions. Sample sizes were moderate for both studies with 109 participants in the [Gilchrist 1987](#) study and 1,396 in the [Schinke 1994](#) study.

In the [Gilchrist 1987](#) study, multiple outcomes were assessed at six month follow-up including drug knowledge scales, attitude scales, interpersonal behaviour tests and amount of alcohol, marijuana, tobacco and inhalants used (if any). Multiple follow-up periods were assessed in [Schinke 1994](#) (6, 12, 24 and 36 months post baseline) for outcomes related to tobacco use (use rates and intentions to use smoked and smokeless tobacco).

For full details of the trials see [Characteristics of included studies](#).

Excluded studies

Three relevant studies were excluded as they did not meet the inclusion criteria as defined for this review due to absence of a control comparison. See [Characteristics of excluded studies](#) for further details.

Ongoing studies

One study was assessed as ongoing at the time of review completion ([Glover 2009](#)). The primary outcome publication for this study was in construction at the time of this review completion;

as such, not all trial information was available. For detailed study design information see the [Characteristics of ongoing studies](#) table.

Risk of bias in included studies

The key features for risk of bias in the two included studies are summarised in [Figure 2](#), and are detailed in the 'risk of bias' tables

at the end of each [Characteristics of included studies](#) table. Overall, methodological biases were unclear, although each study had at least two categories marked as a high risk of bias.

Figure 2. 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 of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Imbalance of outcome measures at baseline	Comparability of intervention and control group characteristics at baseline	Protection against contamination	Selective recruitment of participants	Other bias
Gilchrist 1987	?	?	-	?	-	?	+	?	?	?	
Schinke 1994	+	-	-	?	?	?	+	+	?	?	

Selection bias

Sequence generation was rated as unclear risk in [Gilchrist 1987](#) and low risk in the [Schinke 1994](#) study, which employed a random numbers table using a spreadsheet. Allocation concealment was at high risk of bias in the [Schinke 1994](#) study, with allocation reported as not being concealed, and unclear in [Gilchrist 1987](#). Selective

recruitment of participants was unclear for both studies as authors did not report the methods for individual participant recruitment.

Performance and detection bias

Due to the nature of the community level interventions in both studies, it was not possible to blind participants to the

interventions. However, it is possible that participants were not aware that they were taking part in a research trial and as such were not aware of their group allocation, i.e. to intervention or control. There was no mention of attempted blinding of outcome assessors in either study.

Attrition bias

Incomplete outcome data was assessed as a high risk of bias in [Gilchrist 1987](#), which reported attrition but did not specify reasons for attrition and did not discuss how missing outcome data was addressed within analyses. [Schinke 1994](#) was unclear for this outcome as insufficient information was provided to permit a judgement.

Reporting bias

Reporting biases were unclear in both studies as there was insufficient information to permit a judgement and neither study had a published clinical trial protocol prior to study commencement.

Baseline measures

Both studies adequately addressed imbalances of outcome measures at baseline. One study reported no imbalances at baseline ([Gilchrist 1987](#)) and the [Schinke 1994](#) study adjusted for differences using an analysis of covariance approach. [Schinke 1994](#) also adjusted for baseline differences in participant characteristics using an analysis of covariance. [Gilchrist 1987](#) did not report sufficient information to judge differences in participant characteristics at baseline.

Protection against contamination

Potential contamination was unclear for both studies. The [Schinke 1994](#) study authors report that the likelihood of contamination between and among intervention and control arms is small, although it could not be completely ruled out.

No other biases were identified for either of the included studies.

Effects of interventions

Tobacco use

Two multi-component community-based trials were available for evaluation of tobacco prevention strategies for Indigenous youth. At final follow-up, neither study detected statistically significant changes between intervention and control groups ([Table 1](#)). As the two included studies reported outcomes that were not comparable, we were unable to pool results or compare them side to side.

[Gilchrist 1987](#) detected positive changes in tobacco use at post-test ($p < 0.05$; change score of -0.15 for intervention and -0.01 for control). However, these were not maintained at six month follow-up (change score of -0.11 for intervention and 0.07 for control).

In the [Schinke 1994](#) study, no significant differences in weekly smoking between the intervention and control groups were observed at any follow-up. However, weekly tobacco use more than trebled to 35 to 40 per cent over the three and a half year study period. No effect estimates were provided for any 12 month outcomes. At 12 months a non-significant increase in daily smoking, disproportionate to the rest of the sample, was observed in both control conditions and all females. The skills-community

condition reported the greatest increase in weekly smoking at 12 months, however smoked tobacco use did rise across the entire sample. During the previous month, an uptake of smoking was shown across all conditions, whilst smokeless tobacco use in the past year increased for skills-community males and skills-only females. Control females showed an increase in smokeless tobacco use, though it was not as high as that observed in the skills-only males. By 42 month follow-up, weekly smoking in the control group had increased over that of the skills-community group and the skills-only group, however the difference was not statistically significant for either group when compared to control (skills-community: RR 0.95, 95% CI 0.78 to 1.14; skills-only: RR 0.86, 95% CI 0.71 to 1.05; [Analysis 1.1](#)). Smokeless tobacco use at the 30 and 42 month follow-ups was lower for subjects in the skills-only arm compared to subjects in the control (at 42 months, RR 0.57, 95% CI 0.39 to 0.85; [Analysis 1.2](#)), whereas the difference between smokeless tobacco use in the skills-community arm when compared to the control arm was not statistically significant at 42 months (RR 0.93, 95% CI 0.67 to 1.30).

Results from the ongoing [Glover 2009](#) study have not been adjusted by ethnicity, and as authors report that more Indigenous youth were present in the intervention arm and Indigenous youth were more likely to take up smoking during the study period, results need to be interpreted with caution. Unpublished results from [Glover 2009](#) detected no difference between intervention and control groups at follow-up for the unmatched cohort (see [Table 1](#)). Māori and Pacific Islander students were more likely to initiate smoking by follow-up compared to other ethnicities (Māori: OR 4.60, 95% CI 3.24 to 6.52; Pacific Islander: OR 2.75, 95% CI 1.92 to 3.82). For the matched cohort (never smokers at baseline that completed both baseline and follow-up assessments), there was a statistically significant difference in favour of the control, with a greater proportion of students in the intervention group having tried smoking by the time of follow-up ($p < 0.001$) ([Glover 2012](#)).

Sustainability of change

Both included studies reported multiple follow-up periods. The interim follow-up for the [Gilchrist 1987](#) study (immediately post intervention, i.e. three months) produced statistically significant changes in tobacco use in favour of the intervention, however these findings were not maintained at final follow-up (six months). For the [Schinke 1994](#) study, there were no significant differences in weekly smoking between the intervention and control groups at any of the reported follow-ups. At the 30 to 42 month follow-ups, smokeless tobacco use was lower for subjects in the skills-only arm compared to subjects in both the control and skills-community arms of the study at 30 month ($p < 0.0001$) and 42 month ($p < 0.001$) follow-ups.

Secondary outcomes

Only the [Gilchrist 1987](#) study reported on participant level outcomes. Attitudes toward drugs and self-esteem were assessed in both intervention and control groups at post-test and six months follow-up. No statistically significant differences were found at post-test or six month follow-up between groups for changes in attitudes toward drugs (intervention change score 0.83, control change score 0.52) or changes in self-esteem (intervention change score 0.47, control change score 0.24). Comparisons of changes in knowledge at both post-test (intervention change score 0.03, control change score -0.01) and six months (intervention change score 0.17, control change score -0.08) follow-up produced a

statistically significant benefit in favour of the intervention ($p < 0.01$ for both).

No studies reported process measures for intervention implementation or reported the costs of interventions as an outcome.

DISCUSSION

Summary of main results

Two completed studies in Native American populations assessed the benefits of smoking prevention interventions for Indigenous youth among 1505 participants. Whilst some methodological variations occurred between studies in relation to intervention characteristics, delivery and duration, they both incorporated multi-component community-based interventions aimed at preventing tobacco use in Indigenous youth. No statistically significant differences were observed between intervention and control groups at final follow-up in either study. One study found a statistically significant difference in favour of the intervention for weekly smoking at post-intervention follow-up, but this was not maintained at the six month follow-up. The same study examined secondary outcomes including changes in attitudes, self-esteem and knowledge, and no differences were observed between groups for changes in attitudes toward drugs or changes in self-esteem. However, a statistically significant benefit in favour of the intervention was observed for changes in knowledge at both post-test and six month follow-up. Neither study reported information on process measures or the cost effectiveness of the interventions.

Overall completeness and applicability of evidence

In the context of current practice, this review should provide readers with an outline of what prevention initiatives have been conducted to date, and indicate where resources need to be directed for future investigations. However, this review highlights the paucity of data with which to evaluate tobacco prevention interventions for Indigenous youth from around the world. Only two multi-component community level trials were identified for inclusion in this review, despite the search for multiple intervention types, including prevention programmes as a component of adult initiatives and non-tailored initiatives. Types of prevention interventions that have been examined in non-Indigenous specific populations include school-based (Thomas 2006), mass media (Brinn 2010), community level (Carson 2011a), family-based (Thomas 2008) and public policy (Ross 2006; Richardson 2009).

The lack of published trials available for inclusion in this review reflects the need for research to be performed alongside tobacco prevention programmes in Indigenous populations. Significant amounts of government and private funding are being invested into tobacco cessation and prevention programmes (Ministry of Health 2004; COAG 2009; SA Department of Health 2010; US Dept of Health and Human Services 2010), many of which specifically target Indigenous youth. However, effective evaluation procedures that run alongside them are lacking. These policies (which can include mass media campaigns, access to free nicotine replacement therapies, school-based interventions etc.) require considerable resources. Their subsequent ability to increase long-term smoking abstinence following implementation is, however, unknown. The use of resources for programmes with unproven effectiveness in the Indigenous context can have a harmful result,

as resources provided for the delivery of ineffective interventions means an opportunity cost for other interventions (Ivers 2004). Without these accompanying analyses, the true effectiveness of these interventions cannot be ascertained and, importantly, the translation of evidence both nationally and internationally is being hindered as a result. Based on available evidence (through published exploratory qualitative analyses) and the results of the two included studies, the following should be incorporated into the design of future initiatives to ensure intervention effectiveness and methodological rigour:

- Use culturally appropriate interventions tailored for the population being targeted; consider the views and incorporate the suggestions of key members from the population (develop the intervention with community members); provide sufficient intervention exposure, duration and training; where possible involve Indigenous health care workers or project officers for intervention delivery and outcome collection
- Ensure an adequate control group which mirrors the demographic characteristics of the intervention population; consider potential sources of contamination where the intervention may reach the control population and incorporate strategies to minimise this risk
- Collect data (including smoking status) pre-intervention and post-intervention in the same cohort of subjects; provide meaningful follow-up periods (i.e. minimum six months post-baseline data collection); pre-specify outcome data and methods of analysis (publish in an online clinical trial registry such as clinicaltrials.gov to reduce *post hoc* amendments and additions which can introduce bias); calculate a target sample size prior to recruitment which has sufficient power to determine intervention effectiveness.

Dichotomy has been emerging in the uptake of smoking between genders with current reports indicating that smoking behaviour among adolescent girls is increasing over that of boys (Mackay 2006; Warren 2009). At 12 month follow-up in the included Schinke 1994 study, all females reported a disproportionate increase in weekly smoking, though this was not statistically significant. In Schinke 1994, smoking in the previous month was also correlated with a slight increase in smokeless tobacco use in the past year for skills-community males and skills-only females. Control females also demonstrated an increase in smokeless tobacco use, although it was not as high as that observed in the skills-only males. This trend should continue to be examined in future evaluations of prevention initiatives.

Quality of the evidence

Due to the lack of published evidence available with which to evaluate the effectiveness of tobacco use prevention initiatives targeted at Indigenous populations, the external validity of this review is limited, as is the ability to draw any reliable conclusion from the results.

A significant health disparity exists whereby Indigenous populations, a minority, are over-represented in the burden of smoking-related morbidity and mortality (Bramley 2005; ABS 2006; Wood 2008; ABS 2011). Despite the significant health disparity, a paucity of evidence incorporating methodologically rigorous evaluations to assess tobacco prevention and cessation interventions has been identified for the Indigenous population, which has been confirmed by many researchers (Gohdes 2002; Ivers

2003; Clifford 2009). As a result, this review is limited by a lack of published investigations on which to draw a conclusion. Not only is there a lack of evidence examining the different types of interventions (e.g. mass media, school-based, public policy etc.), but there is also a lack of investigation within the various sub-sets of Indigenous populations (e.g. Native Alaskan, Māori, Aboriginal Australian, Native American etc.). Of the available data, risk of bias is a potential issue in this review, with each study having at least seven out of the 10 risk of bias categories assessed as unclear or high risk. No studies evaluated the cost-effectiveness of the prevention initiatives, or assessed any process measures to determine exactly how much of the intervention was received by the population being studied. The gap in this evidence has also been identified in other recent studies (Sanson-Fisher 2006; Clifford 2009), and is of concern due to the health disparities between Indigenous and non-Indigenous populations, which are further exacerbated by the delay between intervention research efforts and implementation of cost-effective dissemination strategies (Berwick 2003).

Potential biases in the review process

A potential bias in the review process is the exclusion of studies examining Indigenous-specific interventions that are of questionable methodological design. This review does sacrifice inclusion of some relevant information, however the trade-off is an analysis of higher quality evidence (and lower risk of bias) on which future investigations can be based. One key strength of the review process to address potential biases is the use of two experienced and independent review authors who assess study risk of bias. However, this can do little to account for biases occurring in the methodological designs of included studies.

This review does not take into account the social construct of smoking in Indigenous communities and how this differs from the mainstream dominant culture's views of tobacco use. It is difficult to separate addiction from social determinants of tobacco use, especially for the studies predominantly reporting intervention outcomes. A theoretical model titled 'the four sided house' (Te Whare Tapa Wha) was used in the ongoing Glover 2009 study as the model to underpin the prevention initiative. This design was Indigenous-specific to the Māori and Pacific Islander population being targeted and comprised four interdependent elements (the physical body, the mental realm, family and social relationships and the spiritual realm). In this sense, the prevention initiative was holistic in nature, targeting the 'physical' addiction to nicotine and the attitudes of parents, incorporating spiritual acknowledgement in the processes such as through prayers to open events and meetings, and acknowledging environmental effects proposed by Glover 2005, including the impact of the broader political and economic context such as tobacco industry influences. Although preliminary results of this trial were not statistically significant, the concept is perhaps worthy of further consideration as it incorporates the social constructs of the Indigenous communities as well as broader aspects of tobacco use at the environmental level that are relevant to all youth. Strategies encompassing multiple areas have also been examined in an Aboriginal Canadian context: McKennitt 2007 identifies four aspects of health (physical, mental, emotional and spiritual), and argues that future initiatives should consider a holistic approach coupled with the involvement of Aboriginal healthcare professionals to increase the effectiveness of smoking prevention programmes.

The utilisation of healthcare professionals to intervene as part of tobacco interventions has been successfully implemented as part of mainstream smoking cessation programmes (Carson 2012b). The success of these studies can partly be attributed to the perceptions around healthcare professionals, particularly doctors and dentists, being viewed as influential sources of information (WHO 2005; Zwar 2009). Moreover, they consult millions of people a year and as such mass dissemination opportunities for intervention messages exist (Mullins 1999; Richmond 1999; Zwar 2009). Based on the success of these studies for smoking cessation, perhaps healthcare professionals could be utilised for future tobacco prevention interventions among youth.

Agreements and disagreements with other studies or reviews

A review of smoking, nutrition, alcohol and physical activity interventions targeting Indigenous Australians found twenty studies with few employing methodologically rigorous designs and most omitting important details (Clifford 2011). The authors' conclusions are identical to those found in this review: there is a need for more rigorous evaluations to establish the reliability and validity of any effect. The concept of SNAP (smoking, nutrition, alcohol and physical activity) combines interventions to address each of these issues in a multi-faceted approach and is certainly worthy of further research, since it is often difficult to separate out the use of tobacco, alcohol and other drugs. Moreover, research has found that Indigenous youth in particular are more likely to smoke tobacco, try marijuana and other illicit drugs and engage in binge drinking in comparison to non-Indigenous youth (Elton-Marshall 2011). A systematic review of the American National Cancer Institute's adolescent smoking prevention programmes identified five interventions aimed at preventing smoking in youth. They suggested that future programmes should target specific high-risk demographic groups, use professional health educators and/or trained community members and build in methods of updating material to improve the chances of success (Sherman 2009). Although none of the intervention programmes identified were targeted specifically at Indigenous youth, the implied outcome is that future programmes should target Indigenous populations as they are a high-risk demographic. Moreover, the primary conclusion, that programmes are still needed to address current issues in tobacco control, appears universal.

AUTHORS' CONCLUSIONS

Implications for practice

The findings from this review highlight the paucity of data to evaluate tobacco prevention initiatives in Indigenous youth. More evidence is needed to clearly ascertain what interventions and components of interventions are effective for preventing tobacco use in this population. Based on published qualitative data and recommendations by study authors referenced in this review, pilot work including evaluations such as focus groups should be considered within Indigenous populations prior to intervention delivery to identify potential programmes and components of programmes that are most likely to be effective. This will also produce an assessment of the potential barriers to implementation and facilitators if executed correctly. Interventions should be of a reasonable duration and intensity to produce an effect and should consider process measures for the amount of intervention exposure an individual is likely to receive. It

is important to consider conducting assessments alongside any future practices to determine if an intervention is truly effective and investments are appropriately directed. When considering strategies for intervention implementation it is also important to consider 'who' will deliver the intervention.

Implications for research

There is an urgent need for research to assess interventions being funded to prevent tobacco use in Indigenous populations, as there is limited evidence to date for proven intervention effectiveness. This includes classroom lessons, mass media, multi-component community level interventions, family-based programmes and public policy interventions. Based on published qualitative data and recommendations by study authors referenced in this review, researchers should:

- Ensure the appropriateness of these interventions and tailor the programmes to the specific requirements of the population being tested
- Provide adequate intervention exposure, duration and training through the use of Indigenous project officers wherever possible to enhance the uptake of prevention messages and collect process measures to quantify the degree of implementation
- Select an appropriately matched control population to compare results
- Collect data both pre- and post-intervention at meaningful time points (i.e. follow-up of a minimum of six months post-baseline assessment)
- Ensure collected data is pre-specified (through the use of a published online clinical trial registry) and includes meaningful

information pre- and post-intervention (such as tobacco use, baseline characteristics (specifically gender differences), existing initiatives underway in the community and secondary outcomes as mentioned in the methods of this review)

- Conduct an evaluation of the cost effectiveness of the intervention using predictive models for disease avoidance
- Be explicit and comprehensive when describing the limitations and barriers of implementation, as lessons can be learnt from past experiences which can be translated into new investigations.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Gilchrist 1987

Methods	<p><i>Country:</i> United States of America</p> <p><i>Design:</i> Randomized controlled trial, cluster, nested</p> <p><i>Objective/s:</i> To determine the effectiveness of a skills enhancement model for preventing substance abuse with American Indian adolescents</p> <p><i>Study Site:</i> Reservation and non-reservation settings in the Pacific Northwest; Three intervention sites (one urban and two rural) and four control sites (one urban and three rural)</p> <p><i>Programme name:</i> Not reported</p> <p><i>Methods of analysis:</i> Not reported</p> <p><i>Cluster adjustment made:</i> No</p>
Participants	<p><i>Eligible for study (n-value):</i> Not reported</p> <p><i>Recruited:</i></p> <p><u>Clusters:</u> n = 3 intervention sites (one urban and two rural); n = 4 control sites (one urban and three rural)</p> <p><u>Individuals:</u> n = 109</p> <p><i>Completed:</i> n = 39 intervention; n = 58 control</p> <p><i>Age:</i> Intervention mean = 11.22 $\pm$ 1.15; Control mean = 11.46 $\pm$ 1.43</p> <p><i>Gender:</i> Intervention = 52% female; Control = 46% female</p> <p><i>Ethnicity:</i> Native American</p> <p><i>Socio-economic status:</i> Not reported</p> <p><i>Recruitment means:</i> Not reported however intervention occurred in schools</p>
Interventions	<p><i>Theoretical basis:</i> Skills enhancement approaches; SODAS (Stop, Options, Decide, Act/communication skills, Self-praise) problem solving model</p>

Gilchrist 1987 (Continued)

Intervention description/s: Ten session skills enhancement programme through school curriculum delivered by two people, one a Native American research staff member and the other an Indigenous community leader; Intervention included: discussion of myths concerning Native American drug use, impact of stereotypes on behaviour, provision of health education information through games, handouts, films and posters, group discussions and peer guest speakers sharing personal reasons for rejecting drug use, discussions around SODAS problem solving model, opportunities for skills practice, creation of videotape and adult guest speaker invited from tribal alcohol treatment programme

Control description/s: Test only control subjects

Duration of intervention: Ten, 60- minute classroom sessions

Intervention delivered by: Two person team consisting of one Native American research staff member and one Indigenous community leader (e.g., Native American teachers, school counsellors and alcohol and drug treatment staff members whom subjects knew well and respected; All professional personnel received 10 hours of training about how to deliver the prevention curriculum

Outcomes

Method of outcome collection: Not reported

Pre-specified outcome data: Demographics, drug knowledge scales, attitude scales, interpersonal behaviour tests and if any/amount of alcohol, marijuana, tobacco and inhalants used

Validation: None reported

Follow-up period: Six months

Number of follow-up periods reported: Two; post-test and 6 months

Process measures: Attendance rates for the intervention condition indicated that 83% of subjects completed the 10 session programme, bulk of remaining subjects attended at least 8 sessions

Definition of tobacco use: Not reported

Notes
Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomization mentioned however methods not described
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the intervention it is not possible to blind participants
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No mention of blinding for outcome assessors
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition reported however reasons not specified and no mention of any missing outcome data or how it was addressed
Selective reporting (reporting bias)	Unclear risk	Baseline outcomes reported and similar between groups

Gilchrist 1987 (Continued)

Imbalance of outcome measures at baseline	Low risk	Baseline characteristics reported and similar between groups
Comparability of intervention and control group characteristics at baseline	Unclear risk	Insufficient information to permit judgement of yes or no
Protection against contamination	Unclear risk	Insufficient information to permit judgement of yes or no
Selective recruitment of participants	Unclear risk	Insufficient information to permit judgement of yes or no

Schinke 1994

Methods	<p><i>Country:</i> United States of America</p> <p><i>Design:</i> Randomized controlled trial</p> <p><i>Objective/s:</i> To investigate an intervention outcome study of a prevention strategy developed for Native American youth at risk for adopting habitual and lifelong habits of tobacco use</p> <p><i>Study Site:</i> Fourth and fifth grade youths from both reservation sites and tribal schools; n = 27 tribal or public schools on 10 reservations in 5 states across western United States</p> <p><i>Programme name:</i> Not reported</p> <p><i>Methods of analysis:</i> Chi² tests used to detect differences between genders, ANOVA, no correction for intra-class correlation. Scheffe <i>post-hoc</i> multiple comparison tests</p> <p><i>Cluster adjustment made:</i> No</p>
Participants	<p><i>Eligible for study (n-value):</i> Clusters: n = 10 reservations in North and South Dakota; n = 27 tribal and public schools</p> <p><i>Recruited:</i></p> <p><u>Clusters:</u> n = 10 reservations in North and South Dakota; n = 27 tribal and public schools</p> <p><u>Individuals:</u> n = 1396</p> <p><i>Completed:</i> 18% attrition; Total population only - Individuals: T1 n = 1396; T2 n = 1374; T3 n = 1329; T4 n = 1268; T5 n = 1199</p> <p><i>Age:</i> Mean 10 years at baseline</p> <p><i>Gender:</i> At follow-up 49% female</p> <p><i>Ethnicity:</i> Native American</p> <p><i>Socio-economic status:</i> Not reported</p> <p><i>Recruitment means:</i> Reservation sites and tribal schools</p>
Interventions	<p><i>Theoretical basis:</i> Life skills and social influence models of prevention</p> <p><i>Intervention description/s:</i></p> <p><u>Skills-only:</u> Fifteen classroom group interventions and booster sessions six months after initial intervention; Interventions included material on bicultural competence, tobacco use knowledge, cognitive and behavioural techniques for problem solving, communication and resistance and stress and coping;</p>

Interventions for tobacco use prevention in Indigenous youth (Review)

Schinke 1994 (Continued)

Interactive classroom work was used with participation in rehearsals of techniques to avoid tobacco use

Skills-community: As above plus an annual intervention designed to involve the community including various activities in which students modelled the skills they had learned in classrooms to their parents and other community members; Publications and posters were produced to further educate parents and other community members about the nature and purpose of the intervention; Media was used to enhance participation using traditional Native American legends and puppets to initiate and enhance classroom discussion; Group leaders and group discussions were employed to encourage students to discuss their learning experiences at home and in the community

Control description/s: Not described, assumed no intervention control

Duration of intervention: Fifteen x 50 minute classroom lessons plus booster sessions at six months

Intervention delivered by: Health professionals who had participated in week-long training workshops run by study investigators

Outcomes

Method of outcome collection: Questionnaires (no further details)

Pre-specified outcome data: Demographics, use rates, intentions to use smoked and smokeless tobacco, plus numerous other structural, environmental, social and psychological factors likely to predict future risk for use of tobacco substances

Validation: Thiocyanate and cotinine were administered to every client at each measurement occasion, only a small proportion analysed; Correlation only 0.53 but no information about levels of misreporting

Follow-up period: Three years post-intervention (or 3.5-years post recruitment)

Number of follow-up periods reported: Four after baseline: T1 baseline/ T2 six months/ T3 one year/ T4 two years/ T5 three years

Process measures: Not reported

Definition of tobacco use: Weekly: number of cigarettes smoked during the 7 days prior to test administration; Monthly: month prior to test administration; Yearly: Used during the year subsequent to initial follow-up

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomized using a random numbers table on a spreadsheet - data obtained from contact with authors
Allocation concealment (selection bias)	High risk	Allocation was not concealed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the intervention it is not possible to blind participants
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No mention of attempted blinding for assessors
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to permit judgement of yes or no; Cotinine measurements collected but not all were tested, however those that were tested were

Schinke 1994 (Continued)

		not reported in this paper; Subject survey missing data were removed from analysis
Selective reporting (reporting bias)	Unclear risk	'Post-hoc' analysis for self-reported substance use was conducted to assess differences by study arm using the Scheffe multiple comparison test; It is unclear if this method of testing was pre-determined at the protocol stage
Imbalance of outcome measures at baseline	Low risk	Differences were present between conditions for smokeless tobacco use with control subjects reporting ever use and used in the past month significantly more than those in the skills-only condition, however ANOVA analysis performed; Students did not differ among the 3-arms for 'subject's use of cigarettes'
Comparability of intervention and control group characteristics at baseline	Low risk	Slight but significant demographic differences were observed between the skills-only condition for both age and gender which were higher compared to the other conditions; Analysis of covariance occurred for imbalances
Protection against contamination	Unclear risk	Authors state the likelihood of contamination between and among intervention and control arms is small; However this can not be ruled out
Selective recruitment of participants	Unclear risk	Eligible individuals prior to recruitment not stated; Methods of recruitment not stated

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Davis 1995	No control group
Dixon 2007	No control group
Vogeltanz-Holm 2009	Not a RCT/CCT intervention of tobacco prevention; No control group

Characteristics of ongoing studies [ordered by study ID]

Glover 2009

Trial name or title	The Keeping Kids Smokefree study
Methods	<p><i>Country:</i> New Zealand</p> <p><i>Design:</i> Controlled Clinical Trial</p> <p><i>Objective/s:</i> To investigate whether changing parental smoking behaviour and attitudes via a community-partnership approach with parents, school and local health providers can reduce smoking initiation by 11-13 year olds</p> <p><i>Study Site:</i> Four South Auckland 'intermediate' schools in an urban area of high social deprivation with large numbers of Māori and Pacific Islands families</p> <p><i>Methods of analysis:</i> Not reported – raw data obtained</p> <p><i>Cluster adjustment made:</i> Not reported – raw data obtained</p>
Participants	<i>Eligible for study (n-value):</i> Not reported

Interventions for tobacco use prevention in Indigenous youth (Review)

Glover 2009 (Continued)

Recruited: Intervention n = 1938, Control n = 2570

Completed: 2007: Intervention n = 1320, Control n = 1650; 2008: Intervention n = 1250, Control n = 1575; 2009: Intervention n = 1147, Control n = 1590

Age: Children aged 11-13 years

Gender: Intervention 51.1% female, control 51.1% female

Ethnicity: Māori: Intervention 38.9%, Control 19.3%; Pacific Islanders: Intervention 44.0%, Control 44.8%

Socio-economic status: High social deprivation

Recruitment means: One school was recruited through a local newspaper article about the proposed study, whilst the remaining three schools were invited to participate by the investigators

Interventions

Theoretical basis: An Indigenous model Te Whare Tapa Wha (the four-sided house), comprising the physical body, the mental realm family and social relationships and the spiritual realm

Intervention description/s: Community level intervention including: non-government tobacco control action organisation, regional public health providers, regional tribal Māori health provider organisation, sport and recreation association, schools, parents, local businesses and the New Zealand Health Sponsorship Council. The intervention included:

The promotion of smoking cessation to parents and school staff through two 'Quit and Win' contests and material sent to parents identified as smokers throughout the year

Promotion of protective parental behaviour to reduce child uptake of smoking through a DVD given to each child titled 'Our Choice, Their Future'

Attempts to reduce the social supply of tobacco to minors through controlled purchase operations (CPO) visits every two months and through the display of posters developed by a student with the message 'Don't sell or offer cigarettes to children' and 'Report under 18 sales'

A smoke-free art competition with winning pieces displayed on wallet cards for parents, posters for community displays and advertising on buses

Communication with parents was conducted through newsletters, personal letters, a web site and face-to-face contact through presentations to school staff, parents and community groups, and showings of the DVD at community libraries during the school holidays

Health promotion events included stalls at locally run sports or smoke-free days in the community (e.g. at a local marae: traditional Māori meeting place), a family fun day, sponsored school events with prize giveaways, celebrity appearances, class-based fun activities, cultural dance and music performances by students, enrolment with Māori cessation support services with quit-cards, distribution of sample nicotine lozenges at events; Intervention staff set up stalls in local shopping malls to promote a 'Quit and Win' contest

Control description/s: Not reported, assumed no intervention control

Duration of intervention: Approximately 9 months, commencing at the beginning of each school year and waning mid-term 4

Intervention delivered by: Study investigators

Outcomes

Method of outcome collection: Surveyed in class using self-administered questionnaires

Pre-specified outcome data: Student smoking, parental smoking, smoking inside homes and cars

Validation: For children whose parents consented, saliva-cotinine and exhaled carbon monoxide were collected at baseline and follow-up

Follow-up period: Twelve months

Glover 2009 (Continued)

Number of follow-up periods reported: One at 12 months

Process measures: None reported

Definition of tobacco use: Not reported

Starting date	2007 for baseline surveys
Contact information	Dr Marewa Glover e-mail: m.glover@auckland.ac.nz
Notes	The primary outcome publication for this study was in construction at the time of this review completion, as such not all trial information was available.

DATA AND ANALYSES

Comparison 1. Reported tobacco use

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Smoking - Weekly at 42 months follow-up	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
1.1 Skills and community	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
1.2 Skills only	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
2 Smokeless tobacco use - Weekly at 42 months follow-up	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.1 Skills and community	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.2 Skills only	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 1.1. Comparison 1 Reported tobacco use, Outcome 1 Smoking - Weekly at 42 months follow-up.

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
1.1.1 Skills and community				
Schinke 1994	125/325	139/342		0.95[0.78,1.14]
1.1.2 Skills only				
Schinke 1994	117/333	139/342		0.86[0.71,1.05]
			Favours experimental 0.2 0.5 1 2 5 Favours control	

Analysis 1.2. Comparison 1 Reported tobacco use, Outcome 2 Smokeless tobacco use - Weekly at 42 months follow-up.

ADDITIONAL TABLES

Table 1. Narrative synthesis of intervention effectiveness

Study ID/sub-headings:	Detailed synthesis of intervention effectiveness:
Gilchrist 1987 Tobacco use	Positive changes in tobacco use found at post-test ($p < 0.05$; change score of -0.15 for intervention and -0.01 for control) were not maintained at 6 months follow-up ($p = \text{NS}$, change score of -0.11 for intervention and 0.07 for control). No intervention effects were observed in subjects' self-identification as tobacco users.
Intermediate outcome data	No differences were found in attitudes toward drugs or self-esteem, however a statistically significant difference in favour of the intervention was observed for change in knowledge at both post test and six month follow-up ($p < 0.01$ for both).
Glover 2009 (ongoing study) Tobacco use	Authors report no difference between intervention and control at follow-up (OR 1.30, 95% CI 0.24 to 7.08) as a whole, however Māori (OR 4.60, 95% CI 3.24 to 6.52) and Pacific Islander (OR 2.75, 95% CI 1.92 to 3.82) students were more likely to initiate smoking by follow-up compared to other ethnicities. For the matched cohort (never smokers at baseline that completed both baseline and follow-up assessments), there was a statistically significant difference in favour of the control, with a greater proportion of students in the intervention group having tried smoking by the time of follow-up (21.2% and 14.3% for intervention and control group respectively; $p < 0.001$). However, these results have not been adjusted by ethnicity, and as authors report that more Indigenous youth were present in the intervention arm and Indigenous youth were more likely to take up smoking during the study period, these results need to be interpreted with caution.
Intermediate outcome data	None reported.
Schinke 1994 Tobacco use	<p>There were no significant differences in weekly smoking between the intervention and control groups at any follow-up, though all rates more than trebled to 35 to 40% over 3.5-years.</p> <p><u>12 months:</u> Both control conditions and all females reported an increase in daily smoking disproportionate to the rest of the sample at 12 months, however this was not significant. For weekly smoking, the skills-community condition reported the greatest increases, however smoked tobacco use did rise across the entire sample. During the previous month, a slight uptake of smoking was shown across all conditions, whilst smokeless tobacco use in the past year increased for skills-community males and skills-only females. Control females did show a gain in smokeless tobacco use, however it was not as high as that observed in the skills-only males. No effect estimates were provided for 12 month outcomes.</p> <p><u>30-42 months:</u> By 42 month follow-up, weekly smoking in the control group increased over that of the skills-community group, however this was not significant. Smokeless tobacco use was lower for subjects in the skills-only arm compared to subjects in both the control and skills-community arms of the study at 30 months ($p < 0.0001$) and 42 months ($p < 0.001$) follow-ups. Smokeless tobacco at 42 months follow-up has been presented in the meta-analysis for this review, however the p-values</p>

Table 1. Narrative synthesis of intervention effectiveness *(Continued)*

are slightly lower though still significant as adjustments for potential clustering effects were incorporated.

Intermediate outcome data	None reported.
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APPENDICES

Appendix 1. MEDLINE search strategy

Database: Ovid MEDLINE(R) without Revisions <1996 to November Week 1 2011>

Search Strategy:

- 1 RANDOMIZED-CONTROLLED-TRIAL.pt. (216874)
- 2 CONTROLLED-CLINICAL-TRIAL.pt. (37532)
- 3 CLINICAL-TRIAL.pt. (263281)
- 4 Meta analysis.pt. (27635)
- 5 exp Clinical Trial/ (444975)
- 6 Random-Allocation/ (37521)
- 7 randomized-controlled trials/ (67037)
- 8 double-blind-method/ (66942)
- 9 single-blind-method/ (12743)
- 10 placebos/ (12010)
- 11 Research-Design/ (42253)
- 12 ((clin\$ adj5 trial\$) or placebo\$ or random\$).ti,ab. (513639)
- 13 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj5 (blind\$ or mask\$)).ti,ab. (65581)
- 14 (volunteer\$ or prospectiv\$).ti,ab. (329833)
- 15 exp Follow-Up-Studies/ (261406)
- 16 exp Retrospective-Studies/ (302980)
- 17 exp Prospective-Studies/ (226194)
- 18 exp Evaluation-Studies/ or Program-Evaluation.mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier] (181432)
- 19 exp Cross-Sectional-Studies/ (109522)
- 20 exp Behavior-therapy/ (24238)
- 21 exp Health-Promotion/ (32843)
- 22 exp Community-Health-Services/ (239136)
- 23 exp Health-Education/ (67524)
- 24 exp Health-Behavior/ (57938)
- 25 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 or 19 or 20 or 21 or 22 or 23 or 24 (1932357)
- 26 smoking cessation.mp. or exp Smoking Cessation/ (16988)
- 27 "Tobacco-Use-Cessation"/ (528)
- 28 "Tobacco-Use-Disorder"/ (5409)
- 29 Tobacco-Smokeless/ (1419)
- 30 exp Tobacco-Smoke-Pollution/ (6325)
- 31 exp Tobacco-/ (13526)
- 32 exp Nicotine-/ (10034)
- 33 ((quit\$ or stop\$ or ceas\$ or giv\$) adj5 smoking).ti,ab. (6274)
- 34 exp Smoking/pc, th [Prevention & Control, Therapy] (8520)
- 35 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 [A category smoking terms] (48931)
- 36 exp Smoking/ not 35 [B category smoking terms] (40119)
- 37 1 or 2 or 3 [Likely CT design terms; RCTs, CCTs, Clinical trials] (374329)
- 38 35 and 25 [A category smoking+all design terms] (17340)
- 39 35 and 37 [A category smoking terms+likely CT design terms] (3184)
- 40 (animals not humans).sh. [used with 'not' to exclude animal studies for each subset] (1486040)
- 41 ((26 or 27 or 28 or 29) and REVIEW.pt.) not 38 [Set 4: Core smoking related reviews only] (2162)
- 42 36 and 25 [B category smoking+all design terms] (17271)
- 43 (42 and 37) not 40 [Set 3: B smoking terms, likely CT design terms, human only] (1919)
- 44 38 not 39 not 40 [Set 2: A smoking terms, not core CT terms, human only] (13847)

45 (35 and 37) not 40 [Set 1: A smoking terms, likely CT design terms, human only] (3181)
 46 exp Smoking Cessation/ not (44 or 45) [Smoking cessation only, no design terms] (5583)
 47 indigenous.mp. or Health Services, Indigenous/ or Ethnic Groups/ (30757)
 48 Population Groups/ (1862)
 49 culture/ or minority groups/ (19244)
 50 cultural characteristics/ (7966)
 51 Smoking Cessation/eh [Ethnology] (338)
 52 Smoking/eh [Ethnology] (1342)
 53 47 or 48 or 49 or 50 or 51 or 52 (57199)
 54 45 and 53 (96)
 55 44 and 53 (613)
 56 43 and 53 (24)
 57 54 or 55 or 56 (733)
 58 limit 57 to (humans and ("all child (0 to 18 years)" or "adolescent (13 to 18 years)")) (348)

Appendix 2. Differences between protocol and review

During protocol development we were expecting to identify several types and a considerable number of studies. As such, we described the methods for including and analysing them. The limitations we experienced in applying our protocol are described below:

Measures of treatment effect:

An estimated pooled weighted average for RRs would have been calculated using the Mantel-Hetzel fixed-effect model, with 95% confidence intervals, in the presence of low levels of heterogeneity. Had data been available through a combination of continuous and dichotomous data for the same outcome, we would have combined them using the generic inverse variance (GIV) approach as per section 9.4.6 of the Cochrane Handbook ([Higgins 2011](#)) and as outlined in our published protocol ([Carson 2011b](#)). We expect secondary outcomes to be presented in different formats, as such we pre-specified that data would be presented as either dichotomous, continuous or combine the two if available in different formats for the same outcome, using GIV. We would have conducted an intention-to-treat analysis, including participants enrolled at baseline, whether or not they receive the intended intervention.

Unit of analysis issues:

As trials were predicted to use a variety of statistical methods to investigate or compensate for clustering, we would have recorded whether studies used these and whether the significance of any effect was altered. Had there been meta-analysable data available for multi-arm trials we would have included each pair-wise comparison separately, but with shared intervention groups divided out approximately evenly among the comparators. However, for those with intervention groups deemed similar enough to be pooled, the groups were combined using appropriate formulas in the Cochrane Handbook (table 7.7.a for continuous data and chapter 16.5.4 for dichotomous data) ([Higgins 2011](#)).

Assessment of reporting biases:

Had there been more than ten included studies, potential reporting biases would have been assessed using a funnel plot. Asymmetry in the plot could be attributed to publication bias, but may well be due to true heterogeneity, poor methodological design or artefact. In case of asymmetry, we would have included contour lines corresponding to perceived milestones of statistical significance ($p=0.01, 0.05, 0.1$ etc.) in funnel plots, which may help to differentiate between asymmetry due to publication bias from that due to other factors ([Higgins 2011](#)).

Sub-group analysis and investigations of heterogeneity:

We attempted to categorise trials according to the subgroups listed in [Types of interventions](#) above. However, there were insufficient numbers of included studies available for meta-analysis. Had more studies been available for assessment consideration would have been given to pooling trials within these subgroups, however we would not attempt to pool trials of different intensities of behavioural interventions, or different types of population based interventions. Further heterogeneity could have been contributed by factors such as baseline tobacco use status, participant and community characteristics, (e.g. age, physical state, cultural and educational differences), time of measurement of results and varying measurement tools used to assess outcomes.

The chi square and I^2 statistic, in addition to visual inspection of the data ([Higgins 2011](#)), would have been used to quantify inconsistencies across studies. In groups of trials where meta-analysis was judged potentially appropriate, extracted data would have been pooled using the fixed-effect model. In the presence of substantial heterogeneity (based on visual inspection of study data, I^2 statistic, and consideration of study design and methodology), the use of a random-effects model would have been considered. However this would have been performed with caution taking into account the possible influence of smaller studies, which could over or under estimate the true treatment effect.

Ideally we aimed to conduct subgroup analyses for each population (e.g. Australian Aborigines, Alaskan native etc.), however, due to insufficient numbers of included studies this was not possible. Also within each population, tobacco use prevalence was predicted to vary widely between dispersed community groups, further adding to potential heterogeneity of results. As each Indigenous population is unique

and each has specific characteristics (such as remoteness) that could influence the effectiveness of tobacco use cessation interventions, subgroup analysis would have provided the most relevant results for a particular population. However, as anticipated, insufficient numbers of studies were available for any populations to be analysed as subgroups. Subgroup analysis of remote versus urban dwelling and isolated versus integrated populations would also have been considered.

We predicted that for studies of long duration, results may be presented for several periods of follow-up including short-term (≤ 26 weeks), medium-term (27 to 52 weeks) and long-term (≥ 53 weeks). Had data permitted, extended follow-up would have also been collated for studies presenting data over two years. For studies with more than one follow-up, we would have considered whether the effect at longest follow-up is larger or smaller than at earlier follow-ups.

CONTRIBUTIONS OF AUTHORS

Protocol conceived and prepared by Kristin V Carson, reviewed by Antony Veale, Adrian J Esterman and Brian J Smith.

Literature sorting, data extraction, data entry, data analysis and production of the manuscript completed by Kristin V Carson (as part of post-graduate studies at The University of Adelaide).

Second author risk of bias extraction by Malcolm P Brinn and Nadina A Labiszewski.

Review of draft manuscript by Matthew Peters, Anne Chang, Antony Veale, Adrian J Esterman and Brian J Smith.

Supervision of review by Brian J Smith.

DECLARATIONS OF INTEREST

ABC has received a grant provided by GSK which is unrelated to this topic. She is also the principal investigator on a study examining azithromycin for bronchiolitis in Indigenous children. MJP has received honoraria in relation to attendance at a Smoking Cessation Advisory Board from Pfizer Ltd. No other conflicts of interest are known.

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- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

There are a number of differences between the protocol and this review. The changes mainly relate to data analysis and collection, and are a result of the small number and type of included studies (see [Appendix 2](#)). Future updates of the review may need to incorporate these methods if new studies are included.

INDEX TERMS

Medical Subject Headings (MeSH)

*Indians, North American; *Smoking Prevention; *Tobacco, Smokeless; Randomized Controlled Trials as Topic; Smoking [epidemiology] [ethnology]

MeSH check words

Adolescent; Humans