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Strategies for enhancing the implementation of school-based policies or practices targeting risk factors for chronic disease (Protocol)

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[Intervention Protocol]

Strategies for enhancing the implementation of school-based policies or practices targeting risk factors for chronic disease

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The primary aims of the review are to examine the effectiveness of strategies aiming to improve the implementation of school-based policies, programs or practices that aim to promote healthy or reduce unhealthy behaviours relating to child diet, physical activity, obesity, or tobacco or alcohol use.

Secondary objectives of the review are to:

- examine the effectiveness of implementation strategies on health behavioural (e.g. fruit and vegetable consumption) and anthropometric outcomes (e.g. BMI, weight);
- describe the impact of such strategies on the knowledge, skills or attitudes of stakeholders involved in implementing health promoting policies, programs or practices;
- describe the cost or cost effectiveness of such strategies;
- describe any unintended adverse effects of strategies on schools, school staff or children.

BACKGROUND

Description of the condition

Five health behavioural risks: physical inactivity, poor diet, tobacco smoking, risky alcohol consumption and obesity, are the most common modifiable causes of chronic disease (Lim 2012). These risk factors, all among the top 20 risk factors contributing

to global death and disability, each account for a significant proportion of the total global disease burden: dietary risks (9.24%), tobacco smoking (5.49%), alcohol use (3.9%), high body-mass index (BMI) (3.76%) and physical inactivity (2.78%) (IHME 2013). Together, they were estimated to result in more than 580 million years lived with disability and 24 million deaths in 2010 (IHME 2013). As a consequence, reducing the impact of these modifiable health risks in the community has been identified as a public health priority (WHO 2011).

Targeting health risk behaviours in children is an important aspect of chronic disease prevention, as heath behaviours established in childhood are likely to track into adulthood (Swinburn 2011). Schools are an attractive setting for the implementation of child focused chronic disease prevention initiatives, as they offer continuous and intensive contact with children (WHO 2012). Furthermore, evidence from systematic reviews support a range of benefits from the implementation of school-based health programs (Dobbins 2013; Dusenbury 2003; Foxcroft 2002; Jaime 2009; Kahn 2002; Thomas 2013; Waters 2011). For instance, a comprehensive approach to promoting physical activity, including break time opportunities for activity and structured physical education, improves school time activity, movement skills and knowledge for lifetime physical activity (Kahn 2002). A more recent Cochrane review found school-based physical activity interventions led to a more than two-fold improvement (odds ratio 2.74, 95%CI 2.01 to 3.75) in the proportion of children engaging in moderate to vigorous physical activity during school hours (Dobbins 2013). A Cochrane review of school-based programmes for smoking, found interventions (>1 years in duration) that aimed to prevent smoking uptake reduced smoking rates by up to 12% (Thomas 2013). Similarly, Cochrane reviews obesity programs and alcohol prevention programs detail evidence that school-based programs can have positive effects on BMI and alcohol misuse, when the fidelity of these programs is optimised (Dusenbury 2003; Foxcroft 2002; Waters 2011). Regarding healthy diet, a systematic review by Jamie and colleagues found school policies when implemented where generally effective in improving the food environment and dietary intake in schools (Jaime 2009)

Despite evidence supporting the reduction in health risks through school-based programs the actual implementation of polices, programs and recommended practices is poor. Research conducted in Brazil, Canada and Australia for example, suggests that less than 10% of schools are compliant with legislation, policy or nutrition guidelines regarding the sale and promotion of healthy foods in schools (de Silva-Sanigorski 2011; Downs 2012; Gabriel 2009). In Australia, a recent report highlighted that around 30% of schools did not provide recommended planned physical activity to children (Audit Office of New South Wales 2012). In the United States, while most states and districts have adopted policy stating that schools will teach physical education, less than 8% of elementary schools provided this (Lee 2007). Regarding substance misuse prevention programs in the United States, including tobacco and alcohol, it was reported that less than 17% of schools implemented programs effectively (Ennett 2003).

Description of the intervention

The translation of research findings, which is characterised by the transition of evidence regarding an intervention to its application in the real world, is an important aspect of health research, because research about a treatment or intervention cannot lead to health outcomes if health systems, organisations, or professionals do not use interventions with known health benefits (Eccles 2009). The process of research translation, is however complex. To guide the process, the National Institute of Health in the United States have described four phases of the translation process from research discovery to population health impact (Glasgow 2012; Khoury 2010). Earlier phases focus on basic science, epidemiology and testing the efficacy of health interventions. Interventions known to provide health gains are recommended for use in the real world, often in the context of a guideline, policy, practice or program. Phase 3, known as 'T3', is dedicated to research designed to increase the implementation of evidence-based 'interventions', practices, polices or programs (Glasgow 2012). 'Implementation' itself is concerned with the uptake, adoption, use and/or integration of an intervention, policy, program or practice. 'Implmentation strategies' are techniques designed to change practice patterns within specific settings to improve the 'implementation' of evidence-based health interventions (Glasgow 2012; Rabin 2008). Implementation research specifically is the study of the 'implementation strategies' designed to promote and integrate the recommended intervention or practice; the outcome being the success of it's 'implementation' (Eccles 2009; Schillinger 2010). Implemenation research is fundamental to the process of translating research to practice, where the assessment and comparison of 'implementation strategies' is essential in understanding how best to improve the use of recommended 'interventions' which lead to health gains.

Why it is important to do this review

Studying the effectiveness of 'implementation strategies', and why these strategies succeed or fail, provides critical information for future implementation. Identifying factors that positively or negatively affect the delivery of a health intervention, and how these changes impact intended outcomes, informs real world application aiming to achieve the best possible health gains; in scale up or redesign. While a number of systematic reviews have been conducted describing the effectiveness of strategies to implement practice guidelines and improve professional practice of clinicians in clinical settings, such as audit and feedback (Ivers 2012), reminders (Arditi 2012), education meetings and workshops (Forsetlund 2009), and incentives (Scott 2011), implemen-

tation research in non-clinical community settings has largely been overlooked (Buller 2010). To our knowledge only one systematic review concerning implementation of community interventions has been conducted (Rabin 2010). This review included studies investigating cancer prevention strategies and only identified nine school-based implementation strategies. Other studies conducted in schools targeting a variety of health risk factors, with implementation as the primary focus, were likely omitted. Moreover, the review only included studies published until the start of 2008. More recently, other school-based implementation studies have been published (Nathan 2012). To guide optimal implementation of school-based health initiatives further synthesis of evidence is warranted to ensure the inclusion of all relevant studies within the schools setting. By doing so, this review aims to provide evidence for how health promotion practitioners and education systems can design and optimally implement polices, programmes and practices in the schools to promote healthy behaviours of children.

OBJECTIVES

The primary aims of the review are to examine the effectiveness of strategies aiming to improve the implementation of school-based policies, programs or practices that aim to promote healthy or reduce unhealthy behaviours relating to child diet, physical activity, obesity, or tobacco or alcohol use.

Secondary objectives of the review are to:

- examine the effectiveness of implementation strategies on health behavioural (e.g. fruit and vegetable consumption) and anthropometric outcomes (e.g. BMI, weight);
- describe the impact of such strategies on the knowledge, skills or attitudes of stakeholders involved in implementing health promoting policies, programs or practices;
- describe the cost or cost effectiveness of such strategies;
- describe any unintended adverse effects of strategies on schools, school staff or children.

METHODS

Criteria for considering studies for this review

Types of studies

Strategies to improve the implementation of policies, programs or practices are often complex in nature and have been evaluated with a wide variety of methods and designs. While results of randomised controlled trials (RCTs) are considered more robust, using this study design is often impractical or inappropriate for complex public health interventions (Glasgow 1999). We are aware of ongoing RCTs evaluating implementation strategies in schools; however, we envisage there will be a paucity of completed trials of this kind. To overcome this, we will consider any trial (randomised or non-randomised) with a parallel control group published in any language including the following trial designs:

- RCTs and cluster-RCTs;
- quasi-RCTs and cluster quasi-RCTs;
- controlled before and after studies (CBAs), cluster-CBAs.

We will exclude other trial designs.

We will consider studies assessing any strategy aiming to improve the implementation of policies, programs or practices in a school setting which target healthy eating, physical activity or obesity, or tobacco or alcohol prevention (or combination of). While the interventions policies, programs and practices) being implemented are school-based (or target school children) the strategies to promote their implementation may not be wholly or exclusively school-based. Studies that do not specifically aim (primary or secondary) to examine 'implementation' (i.e. there intended difference between intervention and controls groups is a different approach to implementation) will be excluded.

Types of participants

We will include studies set in elementary, primary, secondary, middle, high and central schools. We will include studies set in these institutions with a mean age of students between 5 and 18. Study participants could be any stakeholders who may influence the uptake, implementation or sustainability of the target health promoting interventions including teachers, managers, cooks or other staff of schools and education departments including administrators, officials, representatives of school services, or other health, education, government or non-government personnel responsible for encouraging or enforcing the implementation of health promoting programs, policies or practices in schools. Participants maybe individuals, classes or whole schools.

Types of interventions

We will include studies that compared school-based strategies with the primary intent of improving the implementation of a health promoting policies, programs or practices for physical activity, healthy eating, obesity prevention, tobacco use prevention or alcohol use prevention with either:

- other implementation strategies; or
- no implementation strategy or 'usual' practice.

To be eligible for inclusion, implementation strategies must seek to improve implementation by stakeholders involved in the delivery, uptake or use of policies, programs or practices. Strategies may

include quality improvement initiatives, education and training, performance feedback, prompts and reminders, implementation resources (e.g. manuals), financial incentives, penalties, communication and social marketing strategies, professional networking, the use of opinion leaders or implementation consensus processes. Strategies could be singular or multi component and could be directed at individuals, classes or whole schools.

While there are many other health risk factors (e.g. road safety, sexual health, immunisation etc) for which schools are encouraged to implement health promotion strategies for, we chose to focus on physical activity, healthy eating, obesity, tobacco and alcohol for several reasons. First, these risks are the major contributors to chronic diseases and are therefore of major interest to advancing public health. Second, by including all risk factors contributing to chronic disease the review would not be manageable. Finally, the review aims to answer how to optimally encourage schools, school systems and school staff to accept, adopt, and correctly and sustainability deliver health policies and programs. The focus is on the setting rather than any one condition, and we therefore expect the findings to generalise to other health promotion interventions.

Types of outcome measures

Our review will examine a range of primary and secondary outcomes of interest. We will include studies in the review if they report be any measure of school policy, program or practice implementation (e.g. proportion of schools implementing canteen service consistent with dietary guidelines or mean number of lessons of teaching curricula implemented).

Primary outcomes

- Any objectively or subjectively (self-reported) measure of school policy, program or practice implementation intervention and control groups.

We will consider a range of measures relating to successful implementation including uptake, partial/complete uptake (e.g. consistent with protocol/design), routine use, adaptation as a condition of uptake, repeated delivery (i.e. sustainability over time), reach, adoption. Such data may be obtained from audits of school records, questionnaires or surveys of staff, direct observation or recordings, examination of routine collected information from government departments (such as compliance with food standards or breaches of department regulations) or other sources.

Secondary outcomes

- Measures of other health behaviours or risk factor relevant to polices, programs, or practices being implemented (i.e. sedentary behaviour; dietary patterns; tobacco or alcohol use; BMI; energy expenditure; other anthropometric data)
- Any measure of school staff knowledge, skills or attitudes related to the implementation of policies, programs or practices supportive of diet, physical activity, or healthy weight, or tobacco or alcohol use prevention
- Estimates of absolute costs or any assessment of the cost-effectiveness of strategies to improve implementation of policies, programs or practices in schools
- Any reported unintended adverse consequences of a strategy to improve implementation of policies, programs or practices in schools
    - These could include impact on child health (unintended changes in other risk factors, injury), school operation or staff attitudes (e.g. impacts on staff motivation or cohesion following implementation), or the displacement of other key programs, curricula or practice

These may be measured objectively or subjectively (self-reported).

Search methods for identification of studies

We will perform a comprehensive search for both published and unpublished research studies across a broad range of information sources to reflect the cross-disciplinary nature of the topic. We will consider articles in all languages, and no restrictions will be made regarding article publication dates.

Electronic searches

We will search the following electronic databases:

- Cochrane Central Register of Controlled trials (CENTRAL) (*Cochrane Library*);
- MEDLINE (1950-2014);
- EMBASE (1947 to 2014);
- PsycINFO (1950-2014);
- Education Resource Information Center (ERIC) (up to 2014);
- CINAHL (up to 2014); and
- Applied Social Sciences Index and Abstracts (ASSIA).

We will adapt the MEDLINE search strategy for each database using database-specific subject headings, where available (Appendix 1). We will include filters used in other systematic reviews for research design (Waters 2011), population (Guerra 2014), physical activity and healthy eating (Dobbins 2013; Guerra 2014; Jaime 2009), obesity (Waters 2011), tobacco use prevention (Thomas 2013), and alcohol misuse (Foxcroft 2002). A search filter for intervention (implementation strategies) will be based on previous reviews (Rabin 2010), and common terms in implementation and dissemination research (Rabin 2008).

Searching other resources

We will search the Healthcare Management Information Consortium (HMIC) for grey literature. We will screen reference lists of all included trials for citations of other potentially relevant trials. We will also conduct forward citation searches of included studies using Web of Science. We will handsearch all publications for the past five years in the journals *Implementation Science* and *Journal of Translational Behavioural Medicine*. We will also conduct searches of the WHO International Clinical Trials Registry Platform (ICTRP) Search Portal (http://apps.who.int/trialsearch/). Studies identified in such searches which have not yet been published will be listed in the 'Characteristics of ongoing studies' table. We will consult with experts in the field to identify other relevant research missed and any unpublished research.

Data collection and analysis

Selection of studies

Initially, one author (CW) will screen the titles and abstracts retrieved from our literature search to exclude duplicate records and clearly-ineligible articles (i.e. studies of non-humans or inappropriate settings). We will take an inclusive approach whereby if there is any uncertainty on whether records are potentially relevant, we will retain them for further screening.

The remaining titles and abstracts will then be screened by two independent authors (NN, LW, TD, RS, RW, or SY). We will obtain full texts of all remaining potentially relevant or unclear articles and review these against our inclusion criteria, in duplicate, by two independent authors (NN, LW, TD, RS, RW, or SY). At each stage, disagreements will be resolved by discussion between the two authors and, where required, by consulting a third author (CW). We will record reasons for exclusion of studies in the 'Characteristics of excluded studies' table.

Data extraction and management

Two authors (CW, NN, RS, RW, SY, or TD) will independently extract data, in duplicate, using a data extraction form adapted from the Cochrane Public Health Group Methods Manual (CPHG 2011). Any disagreements in data extraction will be resolved by discussion or by consulting a third author (LW) if required.

If key data are missing from the study reports, we will attempt to contact the investigators to obtain the information. Where multiple reports of the same study are published, we will use the most recent peer-reviewed article reporting outcomes of interest (or most recent report date for studies available only as unpublished literature) as the primary reference. We will extract data comprehensively to cover all relevant outcomes and methods reported across the studies.

We will collect and report the following study characteristics.

- Information regarding study eligibility as well as the study design, date of publication, school type, country, participant/school demographic/socioeconomic characteristics, number of experimental conditions, as well as information to allow assessment of risk of study bias.
- Information describing the characteristics of the implementation strategy, including the duration, number of contacts, and intervention (policy, program, practice), the theoretical underpinning of the strategy (if noted in the study), information to allow classification against the Cochrane Effective Practice and Organisation of Care (EPOC) Group 'Taxonomy of Interventions' as well as data describing consistency of the execution of the strategy with a planned delivery protocol (EPOC 2002).
- Information on trial primary and secondary outcomes, including the data collection method, validity of measures used, effect size and measures of outcome variability, costs and adverse outcomes.
- Information on the source(s) of research funding and potential conflicts of interest.

Assessment of risk of bias in included studies

For RCTs, we will use the Cochrane Collaboration's tool for assessing risk of bias, which includes assessments based on six domains (selection bias, performance bias, detection bias, attrition bias, reporting bias, and other sources of bias) (Higgins 2011). For analysis of non-RCTs, we will follow the advice from both the *Cochrane Handbook for Systematic Reviews of Interventions* and the Cochrane EPOC Group 'Risk of bias tool', which incorporates the standard Cochrane Collaboration's tool for assessing risk of bias as well as additional considerations (EPOC 2002; Higgins 2011). We will assess studies as having 'low', 'high', or 'unclear' risk of bias.

Two authors (CW, NN) will assess risk of bias independently for each study and any disagreement will be resolved by discussion, or by involving an additional author (LW).

Overall risk of bias

For all included studies, we will summarise the overall risk of bias. Studies at high risk of bias will be those with high or unclear risk of bias in the following domains: allocation concealment, similarity of baseline outcome measurements, completeness of outcome data, and other risks of bias. Judgements will also take into account the likely magnitude and direction of bias, and whether it is likely to impact on the findings of the study.

Measures of treatment effect

We will report continuous outcomes as they were found in the primary research. If outcomes were combined from different scales, these will be standardised for effect size and we will calculate the

standardised mean differences (SMDs) with their 95% confidence intervals (CIs). Where appropriate, we will present dichotomous outcomes as risk ratios (RRs) with 95% CIs. For statistically significant results, we will create a 'Summary of findings' table to calculate the number needed to treat to benefit (NNTB) or the number needed to treat to harm (NNTH) with their 95% CIs.
If sufficient data are available to calculate missing information from the study, we will use these to impute the missing data. However, where this is not possible, the data may be re-analysed using a best-worst and worst-best scenario sensitivity analysis (Higgins 2011).
If we do not find enough studies, or the studies cannot be pooled, we will summarise the results in narrative form.

Dichotomous data

For dichotomous data, we will present proportions and, for two-group comparisons, results as average RRs or odds ratios (ORs) with 95% CIs.

Continuous data

We will report results for continuous outcomes as mean differences (MDs) with 95% CIs, if outcomes were measured in the same way between trials. Where some studies have reported endpoint data and others have reported change from baseline data (with errors), we will combine these in the meta-analysis if the outcomes have been reported using the same scale. We will use SMDs with 95% CIs to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

Cluster studies

We will examine cluster trials for unit of analysis errors. If analyses of cluster-randomised trials have been performed at a different level to that of allocation, and have not accounted appropriately for the cluster design in their analyses, we will calculate trials' effective sample size to account for the effect of clustering in data. We will utilise the intracluster correlation coefficient (intracluster correlation) derived from the trial (if available), or from another source (e.g. using the intracluster correlations derived from other, similar trials). We will calculate design effect using the formula provided in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). If this approach is used, we will report this and undertake sensitivity analysis to investigate the effect of variations in intra-cluster correlation.
Where possible, we will re-analyse studies that randomly or non-randomly allocated strategies to schools (clusters) but did not account for the correlated nature of the data; standard errors will be inflated. If this is not possible, we will report only the point estimate and adjust the 'other risk of bias' to account for the likely impact of not accounting for the clustering.

Multiple time points per outcome

We will define and summarise outcomes at both short (<12 months of follow-up) and long-term (12 month follow-up) time points for studies that report multiple time points.

Studies with more than two treatment groups

If we identify studies with more than two strategies groups (multi-arm studies) for meta-analysis, we will combine groups, where possible, to create a single pair-wise comparison (Higgins 2011). If this is not possible, we will use alternate methods as set out in the *Cochrane Handbook for Systematic Reviews of Interventions* to avoid double counting study participants (Higgins 2011).

Dealing with missing data

When outcomes, methods, or results of the studies are missing or unclear, we will contact the study authors to supply the data. We will record details of selective or incomplete reporting of outcome data in the 'Risk of bias' table. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing. We will contact lead study authors for clarification of missing summary data, or, if possible, we will estimate missing summary data using other statistical information (e.g. standard errors) provided in the primary paper and impute the standard deviations either from other studies in the same systematic review, or from studies in another systematic review. We will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.
Our analyses will be conducted using the intention-to-treat principle, that is, we will include all participants randomised to each group in the analyses, and analyse them in the group to which they were allocated regardless of whether or not they received the allocated strategy.

Assessment of heterogeneity

We will assess study heterogeneity by examining the similarities and differences in the characteristics of the study designs, settings, populations, implementation strategies, comparison groups, and outcome measures as specified in Criteria for considering studies for this review. We will only consider conducting a meta-analysis if studies are sufficiently similar so to provide a meaningful summary when their findings are pooled.
We will assess statistical heterogeneity using the I^2 statistic, with findings summarised in a forest plot. We will exercise caution in

the interpretation of those results with high levels of unexplained heterogeneity.

Assessment of reporting biases

Where we suspect reporting bias (Assessment of risk of bias in included studies), we will attempt to contact study authors and ask them to provide missing outcome data. Where this is not possible, and the missing data are thought to introduce serious bias, we will explore the impact of including such studies in the overall assessment of results by a sensitivity analysis. Where we pool studies in meta-analysis, we will order studies in terms of weight (size of trial), so that a visual examination of forest plots may allow us to assess whether the results from smaller and larger studies are similar, or if there are any apparent differences (i.e. we will check that the effect size is similar in smaller and larger studies).

If sufficient studies are found reporting the same outcome (at least 10), we will use funnel plots to test for publication bias. We will visually assess the asymmetry of any plot generated and will test the plot for asymmetry (Egger 1997).

Data synthesis

We will carry out meta-analysis to provide an overall estimate of treatment effect when more than one study examines the same strategy, provided that studies use similar methods, and measure the same outcome in similar ways in all populations. We will not combine results from randomised and non-randomised trials together in a meta-analysis, nor will we present pooled estimates for non-randomised studies with different types of study designs. Evidence about different outcomes may be available from different types of studies (for example, it is likely that data on less common adverse events will be reported in larger non-randomised studies). Where there is evidence about a particular outcome from both randomised trials and non-randomised studies, we will use the evidence from trials that are at a lower risk of bias to estimate treatment effect. We will use a random-effects model for meta-analysis, as we anticipate that there may be natural heterogeneity between studies, that is attributable to the different doses, durations, populations and implementation or delivery strategies.

In the absence of meta-analysis, we will consider several type of synthesis of evidence including narrative synthesis (Ivers 2012), tables and harvest plots. Synthesis, in this case, will be guided by the available data, in terms of the ways in which studies may be grouped and summarised in this review to describe the outcomes, and describe the impact of strategies, where this information is available.

We will create a 'Summary of findings' table for the primary outcomes where available (Primary outcomes). We will assess quality of evidence for each individual outcome using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. We will consider the following issues:

- risk of bias among the included studies;
- directness of the evidence;
- heterogeneity;
- precision of the effect estimates;
- risk of publication bias;
- potential for dose-response relationships;
- absence of confounders;
- magnitude of effect.

We will grade quality of the body of evidence for each individual outcome from 'High' to 'Very Low' in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Subgroup analysis and investigation of heterogeneity

We will examine the impact of strategies according to the intervention taxonomy developed by the Cochrane EPOC Group (EPOC 2002).

If heterogeneity is high (I^2>75%), we will split included trials into subgroups based on implementation strategy characteristics in an effort to improve homogeneity. We will visually inspect the data and remove outlying studies to see if homogeneity is restored. Should this occur with no more than 10% of the data being excluded, we will present the data. If not, we will not pool the data but discuss these issues. There are no apparent characteristics of studies that may be associated with heterogeneity except 'risk of bias'. However, should another characteristic of the studies be highlighted by the investigation of heterogeneity, we will discuss these post-hoc reasons and the data will be analysed and presented. Should no reasons for the heterogeneity be clear, we will present the final data without a meta-analysis.

Sensitivity analysis

If a sufficient number of studies with a low, moderate or unclear risk of bias are identified, we will carry out a sensitivity analysis by removing studies with a high risk of bias from the meta-analysis. If cluster trials are included, we will consider a sensitivity analysis using a range of intracluster correlation values.

Quality of evidence

We will use considerations recommended by GRADE (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome, and to draw conclusions about the quality of evidence within the text of the review.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

#	Search terms
1	Schools/
2	((primary or elementary or middle or junior or high or secondary) adj (school* or student*)).mp
3	kinder*.mp.
4	1 or 2 or 3
5	implement*.mp.
6	dissemination.mp.
7	adopt*.mp.
8	practice.mp.
9	organi?ational change.mp.
10	diffusion.mp.
11	systems change.mp.
12	quality improvement.mp.
13	transformation.mp.
14	translation.mp.
15	transfer.mp.
16	uptake.mp.
17	sustainab*.mp.
18	institutionali*.mp.
19	rountin*.mp.
20	maintenance.mp.
21	capacity.mp.

(*Continued*)

22	incorporation.mp.
23	adherence.mp.
24	program.mp.
25	integration.mp.
26	scal*.mp.
27	/or 5-26
28	exp Obesity/
29	Weight Gain/
30	exp Weight Loss/
31	obes*.af.
32	(weight gain or weight loss).af.
33	(overweight or over weight or overeat* or over eat*).af.
34	weight change*.af.
35	((bmi or body mass index) adj2 (gain or loss or change)).af.
36	exp Primary Prevention/
37	(primary prevention or secondary prevention).af.
38	(preventive measure* or preventative measure*).af.
39	(preventive care or preventative care).af.
40	(obesity adj2 (prevent* or treat*)).af.
41	/or 28-40
42	exp Exercise/
43	physical inactivity.mp.
44	physical activity.mp.
45	exp Motor Activity/

(*Continued*)

46	(physical education and training).mp.
47	exp "Physical Education and Training"/
48	Physical Fitness/
49	sedentary.tw.
50	exp Life Style/
51	exp Leisure Activities/
52	exp Sports/
53	Dancing/
54	dancing.mp.
55	(exercise* adj aerobic*).tw.
56	sport*.tw.
57	((life style or life style) adj5 activ*).tw.
58	/or 42-57
59	exp Diet/
60	nutrition*.mp.
61	healthy eating.mp.
62	Child Nutrition Sciences/
63	fruit*.tw.
64	vegetable*.tw.
65	canteen.mp.
66	food service.tw.
67	menu.tw.
68	(calorie or calories).tw.
69	energy intake.tw.

(*Continued*)

70	energy density.tw.
71	eating.tw.
72	(feeding behavior or feeding behaviour).tw.
73	dietary intake.tw.
74	food habits.tw.
75	food.tw.
76	soft drink*.tw.
77	soda.tw.
78	sweetened drink*.tw.
79	fat.tw.
80	confectionary.tw.
81	school lunch*.tw.
82	school meal*.tw.
83	menu planning.tw.
84	feeding program*.tw.
85	food program*.tw.
86	nutrition program*.tw.
87	nutritional program*.tw.
88	cafeteria*.tw.
89	nutritional status.tw.
90	/or 59-89
91	exp Smoking/
92	exp "Tobacco Use Cessation"/
93	smok*.mp.

(*Continued*)

94	nicotine.mp.
95	tobacco use*.tw.
96	tobacco.mp.
97	exp tobacco/
98	/or 91-97
99	cessation.tw
100	prevent*
101	stop*
102	quit*.tw
103	abstin*
104	abstain*
105	reduc*
106	"tobacco use disorder".mp
107	ex-smoker.mp
108	anti-smok*.mp
109	/or 99-108
110	98 and 109
111	exp Alcohol/
112	exp Alcohol Drinking/
113	exp Alcohol Abuse/
114	exp Alcohol, Ethyl/ae
115	alcohol*.mp.
116	Drink*.mp
117	liquor*.mp.

(*Continued*)

118	beer*.mp.
119	wine*.mp.
120	spirit*.mp.
121	drunk*.mp.
122	intoxicat*.mp.
123	binge.mp.
124	/or 111-123
125	41 or 58 or 90 or 110 or 124
127	randomi?ed controlled trial.pt.
128	controlled clinical trial.pt.
129	Random Allocation/
130	Double-Blind Method/
131	Single-Blind Method/
132	Placebos/
133	*Research Design/
134	Intervention Studies/
135	Evaluation Studies/
136	Comparative Study/
137	exp Longitudinal Studies/
138	Cross-Over Studies/
139	clinical trial.tw.
140	clinical trial.pt.
141	latin square.tw.
142	(time adj series).tw.

(*Continued*)

143	(before adj2 after adj3 (stud* or trial* or design*)).tw.
144	((singl* or doubl* or trebl* or tripl*) adj5 (blind* or mark)).tw
145	placebo*.tw.
146	random*.tw.
147	(matched adj (communit* or school* or population*)).tw.
148	control*.tw.
149	(comparison group* or control group*).tw.
150	matched pairs.tw.
151	outcome stud*.tw.
152	(quasiexperimental or quasi experimental or pseudo experimental).tw
153	(nonrandomi?ed or non randomi?ed or pseudo randomi?ed or quasi randomi?ed).tw
154	prospectiv*.tw.
155	volunteer*.tw.
156	/or 127-155
157	4 and 27 and 125 and 156
158	limit 157 to ("child (6 to 12 years)" or "adolescent (13 to 18 years)")
159	4 and 27 and 125
160	limit 159 to ("child (6 to 12 years)" or "adolescent (13 to 18 years)")

Appendix 2. Risk of bias assessment tool

RANDOM SEQUENCE GENERATION **Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence**	
Criteria for a judgement of 'Low risk' of bias.	The investigators describe a random component in the sequence generation process such as: • Referring to a random number table; • Using a computer random number generator;

(*Continued*)

	• Coin tossing; • Shuffling cards or envelopes; • Throwing dice; • Drawing of lots; • Minimization*. *Minimization may be implemented without a random element, and this is considered to be equivalent to being random
Criteria for the judgement of 'High risk' of bias.	The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: • Sequence generated by odd or even date of birth; • Sequence generated by some rule based on date (or day) of admission; • Sequence generated by some rule based on hospital or clinic record number. Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example: • Allocation by judgement of the clinician; • Allocation by preference of the participant; • Allocation based on the results of a laboratory test or a series of tests; • Allocation by availability of the intervention.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information about the sequence generation process to permit judgement of 'Low risk' or 'High risk'
ALLOCATION CONCEALMENT **Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment**	
Criteria for a judgement of 'Low risk' of bias.	Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: • Central allocation (including telephone, web-based and pharmacy-controlled randomization); • Sequentially numbered drug containers of identical appearance; • Sequentially numbered, opaque, sealed envelopes.
Criteria for the judgement of 'High risk' of bias.	Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: • Using an open random allocation schedule (e.g. a list of random numbers); • Assignment envelopes were used without appropriate

(*Continued*)

	safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered); • Alternation or rotation; • Date of birth; • Case record number; • Any other explicitly unconcealed procedure.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement - for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed
BLINDING OF PARTICIPANTS AND PERSONNEL **Performance bias due to knowledge of the allocated interventions by participants and personnel during the study**	
Criteria for a judgement of 'Low risk' of bias.	Any one of the following: • No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; • Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; • Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.
Criteria for the judgement of 'Unclear risk' of bias.	Any one of the following: • Insufficient information to permit judgement of 'Low risk' or 'High risk'; • The study did not address this outcome.
BLINDING OF OUTCOME ASSESSMENT **Detection bias due to knowledge of the allocated interventions by outcome assessors**	
Criteria for a judgement of 'Low risk' of bias.	Any one of the following: • No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; • Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding;

(*Continued*)

	• Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding.
Criteria for the judgement of 'Unclear risk' of bias.	Any one of the following: • Insufficient information to permit judgement of 'Low risk' or 'High risk'; • The study did not address this outcome.
INCOMPLETE OUTCOME DATA **Attrition bias due to amount, nature or handling of incomplete outcome data**	
Criteria for a judgement of 'Low risk' of bias.	Any one of the following: • No missing outcome data; • Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); • Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; • Missing data have been imputed using appropriate methods.
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; • 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization; • Potentially inappropriate application of simple imputation.
Criteria for the judgement of 'Unclear risk' of bias.	Any one of the following: • Insufficient reporting of attrition/exclusions to permit judgement of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided);

(*Continued*)

	• The study did not address this outcome.
SELECTIVE REPORTING **Reporting bias due to selective outcome reporting**	
Criteria for a judgement of 'Low risk' of bias.	Any of the following: • The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; • The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • Not all of the study's pre-specified primary outcomes have been reported; • One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; • One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); • One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; • The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. It is likely that the majority of studies will fall into this category
OTHER BIAS **Bias due to problems not covered elsewhere in the table**	
Criteria for a judgement of 'Low risk' of bias.	The study appears to be free of other sources of bias.
Criteria for the judgement of 'High risk' of bias.	There is at least one important risk of bias. For example, the study: • Had a potential source of bias related to the specific study design used; or • Has been claimed to have been fraudulent; or • Had some other problem.
Criteria for the judgement of 'Unclear risk' of bias.	There may be a risk of bias, but there is either: • Insufficient information to assess whether an important risk of bias exists; or • Insufficient rationale or evidence that an identified problem will introduce bias.

CONTRIBUTIONS OF AUTHORS

All authors contributed to the design and development of the protocol.

CMW drafted the protocol.

All authors approved the final version of the protocol.

DECLARATIONS OF INTEREST

There are no conflicts of interest.

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