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[Intervention Protocol]

Interventions for increasing fruit and vegetable consumption in preschool aged children

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effectiveness, cost-effectiveness and associated adverse events of interventions designed to increase the consumption of fruit and/or vegetables amongst children aged five years and under.

BACKGROUND

Description of the condition

Insufficient consumption of fruits and vegetables is associated with micronutrient deficiencies and a range of chronic diseases such as cancer and cardiovascular disease (World Health Organization 2003). Globally, 1.8% of the total burden of disease, and over 2.5 million deaths each year are attributable to inadequate fruit and vegetable intake (Lock 2005). Consumption of at least 400 grams per day of fruit and vegetables is recommended to reduce the risk of chronic diseases (World Health Organization 1997). Nationally representative surveys, however, indicate that throughout most regions of the globe, daily consumption of fruits and vegetables is well below such recommendations (Lock 2005).

Population surveys of children indicate the need to increase the intake of fruits and vegetables (Lock 2005; World Health Organization 2004; Yngve 2005). For example, less than a third of school aged children from European nations report daily consumption of vegetables (World Health Organization 2004). While the mean intake of fruit and vegetables is below the WHO recommendations across all WHO regions, South American, African, and South East Asian nations report the lowest quantities of child fruit and vegetable consumption (Lock 2005).

Longitudinal studies suggest that eating behaviours established in childhood are likely to persist into adulthood (Lien 2001). Encouraging healthy eating among children may therefore represent a particularly effective primary prevention strategy for reducing the risk of chronic diseases (Maynard 2003; Ness 2005). In addition, adequate fruit and vegetable intake during childhood may have a number of immediate beneficial impacts, including reducing the risk of excessive weight gain (Lin 2002; Rolls 2004) and a number of respiratory illnesses (Antova 2003; Forastiere 2005).

Description of the intervention

The etiology of fruit and vegetable consumption is complex, involving the dynamic interaction of a variety of factors. Given such complexity, a number of frameworks have been utilised to guide the development of interventions to increase fruit and vegetable intake (Klepp 2005; Miller 2000; World Health Organization 2004b). The conceptual framework developed for the international Pro Children Project suggests that interventions targeting a variety of cultural, physical and social environment factors, as well as those targeting personal factors may be effective in positively influencing fruit and vegetable intake among children (Klepp 2005).

Despite the range of potential intervention targets, previous trials have tended to focus on those determinants more amenable to intervention, such as nutrition knowledge and skills, or the food environment of settings such as schools (Hector 2008). Among school aged children, systematic reviews suggest that the strongest evidence exists for the efficacy of interventions specifically targeting fruit and vegetable consumption rather than broader healthy eating interventions, multicomponent school based interventions, and interventions incorporating a parent or family element (Blanchette 2005; Burchett 2003; Ciliska 2000; French 2003; Knai 2006). While similar strategies would be hypothesised to be effective for preschool aged children, previous systematic reviews have not focused on the efficacy

of interventions targeting children of this age (Blanchette 2005; Burchett 2003; Ciliska 2000; French 2003; Knai 2006).

How the intervention might work

A number of theories have been used to explain a mechanism by which interventions may be able to influence fruit and vegetable consumption of children (Rasmussen 2006). In most instances, psychosocial theories such as Social Cognitive Theory (Bandura 1986), the Theory of Planned Behaviour (Ajzen 1991), and the Stages of Change Trans-theoretical Model (Prochaska 1984) have been used to explain possible causal pathways to fruit and vegetable consumption (Rasmussen 2006). Collectively, such theories assert that changes to attitudes, knowledge and skills and perceived norms and expectancies are required for behavioural change. The international Pro Children Project incorporated Social-Ecological Theory in its conceptual theoretical framework of determinants of children's fruit and vegetable consumption (Klepp 2005). Interventions derived from Social-Ecological Theory recognise the importance of more structural influences on fruit and vegetable consumption of children, for example, the availability or accessibility of fruit and vegetables in the home or at settings such as schools which children frequent.

Why it is important to do this review

Previous reviews have identified a number of determinants of fruit and vegetable consumption among children (Rasmussen 2006; van der Horst 2007). While such reviews provide important information for the development of interventions, only systematic reviews of randomised controlled trials are able to determine the efficacy of strategies to increase child fruit and vegetable consumption. A number of such reviews have been published (Burchett 2003; Ciliska 2000; French 2003; Knai 2006), however, few of these reviews included trials of preschool aged children, and most lacked important information relevant to practice such as the effectiveness of interventions for various subpopulations (such as minority groups), the cost effectiveness of interventions, or the presence of any unintended adverse effects of the intervention. A comprehensive systematic review on this issue is therefore required to provide guidance for practitioners and policy makers interested in implementing strategies to promote the consumption of fruits and vegetables in early childhood.

OBJECTIVES

To assess the effectiveness, cost-effectiveness and associated adverse events of interventions designed to increase the consumption of fruit and/or vegetables amongst children aged five years and under.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs), including cluster-randomised controlled trials, will be included that:

1. compare two or more alternative intervention programmes to increase the consumption of fruit and/or vegetables of children aged five years and under; or

2. compare an intervention programme to increase the consumption of fruit and/or vegetables of children aged five years and under with a standard care or no intervention control group.

Randomised trials must explicitly state fruit or vegetable intake as a primary or secondary outcome of the trial outcome.

Types of participants

Participants may include:

1. Children aged 5 years and under
2. Parents, guardians and families responsible for the care of children aged 5

years and under

3. Professionals responsible for the care of children aged 5 years and under

including childcare staff and health professionals.

Types of interventions

We will consider any educational, experiential, health promotion and/or psychological/family/ behavioural therapy/counselling/ management/structural/policy/legislative reform interventions designed to increase fruit and/or vegetable consumption in children aged 5 years and under, as defined in types of participants. Interventions can be conducted in any setting and may include interventions conducted in the home, childcare/ preschool services, health services, or community settings.

Comparison: Any alternate intervention to encourage fruit and vegetable consumption as described above, or a no intervention control or attention control or wait-list control.

Types of outcome measures

We will include studies with evaluated outcomes measuring biomedical and/or dietary indices.

Primary outcomes

a) Change in the number of portions or serves of daily fruit and/or vegetable intakes at follow-up as measured by diet recalls, food diaries, food frequency questionnaires or diet records completed by an adult on behalf of the child. We will include both short-term effects (3 to <12 months post-intervention), and long-term effects (at least 12 months post-intervention).

b) Change in grams of daily fruit and/or vegetable intakes during follow-up as measured by diet recalls, food diaries, food frequency questionnaires or diet records completed by an adult on behalf of the child. We will include both short-term effects (3 to <12 months post-intervention), and long-term effects (at least 12 months post-intervention).

c) Changes in biomedical markers of fruit and/or vegetable consumption, such as α -carotene, β -carotene, cryptoxanthin, lycopene and lutein. We will include both short-term effects (3 to <12 months post-intervention), and long-term effects (at least 12 months post-intervention).

Secondary outcomes

a) Estimates of absolute costs and cost-effectiveness of interventions to increase the consumption of fruits and/or vegetables reported in identified studies

b) Any reported adverse event of an intervention to increase the consumption of fruits and vegetables reported in identified studies. This may include any physical, behavioural, psychological or financial impact on the child, parent or family, or the service or facility where an intervention may have been implemented.

Search methods for identification of studies

We will obtain relevant trials published in any language via searches of electronic bibliographic databases, dissertations, hand searching of relevant journals, and following direct communication with relevant study authors and professional organisations.

Electronic searches

We will search electronic databases including the Cochrane Central Register of Controlled Trials (CENTRAL) on *The Cochrane Library*, MEDLINE, EMBASE, CINAHL and PsycINFO. We will search the metaRegister of controlled trials, including the International Randomised Controlled Trial Number Register and the National Institutes of Health Randomised Trial Records. The search strategy for CENTRAL is in [Appendix 1](#).

Searching other resources

We will search the reference lists of relevant articles. We will identify the three most relevant journals and hand search them for the past five years. We will search the database of published dissertations and identify and contact key authors and relevant professional organisations in an attempt to obtain unpublished trials and ongoing trials. We will describe ongoing studies, where available, detailing the primary author, research question(s), methods and outcome measures together with an estimate of the reporting date.

Data collection and analysis

Selection of studies

Two review authors will independently screen titles and abstracts of identified papers. Review authors will not be blind to the details of the study author or journal. Review authors will apply a standardised screening tool to assess eligibility. Based on the paper title and abstract, we will exclude papers which clearly do not meet the eligibility criteria of the review. Two review authors will independently examine the full text of all remaining papers. We will record information regarding the reason for ineligibility on review eligibility forms and document this information in the 'Characteristics of Excluded Studies' table accompanying the review. We will consult a third review author with expertise in review methodology in order to resolve any disagreement between review authors regarding study eligibility. For papers which do not provide sufficient information to determine eligibility, we will contact the study authors for clarification.

Data extraction and management

Two review authors will independently extract data from included trials. Review authors will not be blind to the details of the study author or journal. We will record data on data extraction forms designed specifically for this review. The review authors will pilot

test the data extraction forms. We will consult a third review author with expertise in review methodology to resolve any discrepancies between review authors in data extraction. We will attempt to contact authors of included papers in instances where information for data extraction is not available from the published report or is unclear. One review author will transcribe data into the systematic review software 'Review Manager'. We will extract the following information:

1. Information on the study, research design and methods such as the study authors; date of publication; date of study initiation; study duration; setting; number of participants; participants age, gender, indigenous status, ethnicity, and socioeconomic position; sequence generation; allocation concealment; blinding of participants, personnel and outcome assessors; and other concerns regarding bias.
2. Information on experimental conditions of the trial such as the number of experimental conditions; and intervention and comparator components, duration, number of contacts, modalities, interventionist and integrity.
3. Information on the trial outcomes and results such as rates of recruitment and attrition; sample size; number of participants per experimental condition; mean and standard deviation of the primary or secondary outcomes described above; any subgroup analyses by gender, population group or intervention characteristics; and incomplete outcome data.

Assessment of risk of bias in included studies

Two review authors will independently assess the risk of bias in included studies. We will consult a third review author with expertise in review methodology to resolve any disagreements between review authors. We will use the tool outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2009) to assess risk of bias. The tool requires an explicit judgment by review authors, based on trial information, regarding the risk of bias attributable to the generation of random sequence, allocation concealment, completeness of outcome data, selective reporting and other potential threats to validity. We will record the judgments regarding the risk of bias for each trial in the 'Risk of Bias' table to accompany the review. Based on such assessments, we will make an overall risk of bias assessment for each included trial and report these assessments in the text of the review.

Measures of treatment effect

We will report mean and standard deviation information for each arm of included trials. Intervention effect will be expressed as a mean difference should outcomes be reported using a standard metric. Alternatively, intervention effect will be expressed as a standardised mean difference where outcomes are reported using different methods.

Unit of analysis issues

We anticipate including cluster randomised trials in the review. We will carefully assess these for unit of analysis error. Where unit of analysis error has occurred, we will calculate a corrected assessment of intervention effect if the number of clusters per group, or mean size of cluster; the outcome data (ignoring the cluster design) for the total number of participants; and an estimate

of the intraclass correlation coefficient is available within the published paper or following contact with the study authors.

Dealing with missing data

We will attempt to contact the authors of any included paper with missing data. When available, we will use outcomes of trials reporting an intention-to-treat analysis. We will use sensitivity analyses to explore the impact on the overall assessment of treatment effects of inclusion of trials which do not report an intention-to-treat analysis, with high rates of participant attrition or with other missing data.

Assessment of heterogeneity

We will examine statistical heterogeneity via visual inspection of forest plots of included trials and using the I^2 statistic. Where the percentage of the variability in effect estimates is greater than 50% ($I^2 > 50\%$) we will consider carefully the appropriateness of conducting meta-analysis. Examination of the trial characteristics (participants, design, interventions, outcomes and risk of bias) through sub-group analysis will attempt to identify the source of heterogeneity.

Assessment of reporting biases

The comprehensive search strategy of this review, which will include both published and unpublished trials, will help reduce the risk of reporting bias. We will inspect the funnel plots of included studies to assess reporting bias.

Data synthesis

We anticipate that trial outcomes will be assessed using a variety of dietary assessment tools and be reported in various metrics, including scale scores, fruit or vegetable portions, serves, or grams (Knai 2006). As such, meta-analyses of trials will be conducted in strata of similar outcome measures, such as those trials reporting β -carotene, or those reporting a serve based measure of fruit or vegetables as the trial outcome.

We will use fixed-effect models to perform meta-analysis for the primary outcomes where a sufficient number of trials with suitable data and homogeneity are identified. For the primary review outcomes, we will perform separate meta-analyses for trials providing short-term (3 to <12 months) and long-term (at least 12 months) follow-up data. We will perform meta-analysis using the 'Review Manager' software. We will not conduct meta-analysis where a high level of heterogeneity is evident. We will perform sensitivity analyses, if appropriate, with trials considered at risk of introducing bias; with trials which do not report an intention-to-treat analysis, with high rates of participant attrition or other missing data. If data cannot be combined in a meta-analysis, we will provide a narrative summary of the trial findings according to the review objectives. We will give a narrative description of the secondary outcome measures of the review.

Subgroup analysis and investigation of heterogeneity

The review will attempt to conduct the following subgroup analyses:

1. Interventions targeting boys and girls.
2. Interventions targeting minority groups including indigenous populations.

3. Interventions delivered in various settings including health and children's services.
4. Interventions of varying intensities defined in terms of the number and duration of intervention contacts or components.
5. Interventions delivered in different delivery modes such as via telephone, the internet or face to face.

Sensitivity analysis

We will use sensitivity analyses (such as age of trial, location of trial) to explore the impact of the inclusion of trials which are considered likely to introduce bias.

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We would like to acknowledge the contribution of health promotion practitioners, community dieticians, Children's Services staff and parent members of the *Good for Kids. Good for Life* Children's Services Advisory Group, who provided comment on the scope and focus of the review protocol.

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Knai 2006

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APPENDICES**Appendix 1. Search strategies**

CENTRAL on The Cochrane Library

- #1 MeSH descriptor Fruit explode all trees
- #2 MeSH descriptor Citrus explode all trees
- #3 MeSH descriptor Vegetables explode all trees
- #4 fruit* in All Text
- #5 vegetable* in All Text
- #6 orange* in All Text
- #7 apple* in All Text
- #8 (pear in All Text or pears in All Text)
- #9 (grape in All Text or grapes in All Text)
- #10 banana* in All Text
- #11 (berry in Title, Abstract or Keywords or berries in Title, Abstract or Keywords)
- #12 citrus in All Text
- #13 carrot* in All Text
- #14 "greens" in All Text
- #15 cabbage* in All Text
- #16 brassica* in All Text
- #17 blackberr* in All Text
- #18 blueberr* in All Text
- #19 cranberr* in All Text
- #20 kiwi in All Text
- #21 guava in All Text
- #22 lingonberr* in All Text
- #23 mango* in All Text
- #24 melon* in All Text
- #25 papaya* in All Text
- #26 pineapple* in All Text
- #27 raspberr* in All Text
- #28 strawberr* in All Text
- #29 tomato* in All Text
- #30 grapefruit* in All Text
- #31 mandarin* in All Text
- #32 satsuma* in All Text
- #33 tangerine* in All Text
- #34 (plum in All Text or plums in All Text)
- #35 apricot* in All Text
- #36 (cherry in All Text or cherries in All Text)
- #37 nectarine* in All Text

#38 (peach in All Text or peaches in All Text)
#39 celery in All Text
#40 spinach in All Text
#41 (salad in All Text or salads in All Text)
#42 (pea in All Text or peas in All Text)
#43 (bean in All Text or beans in All Text)
#44 broccoli in All Text
#45 cauliflower* in All Text
#46 beetroot* in All Text
#47 turnip* in All Text
#48 rhubarb in All Text
#49 MeSH descriptor Food Habits this term only
#50 MeSH descriptor Food Preferences this term only
#51 healthy next eating in All Text 208
#52 (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10)
#53 (#11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20)
#54 (#21 or #12 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30)
#55 (#31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40)
#56 (#41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51)
#57 (#52 or #53 or #54 or #55 or #56)
#58 MeSH descriptor Health Education explode all trees
#59 MeSH descriptor Health Promotion explode all trees
#60 MeSH descriptor behavior therapy explode all trees
#61 MeSH descriptor counseling explode all trees
#62 MeSH descriptor organizational policy this term only
#63 (public in All Text and policy in All Text)
#64 MeSH descriptor public policy this term only
#65 MeSH descriptor health policy explode all trees
#66 MeSH descriptor inservice training explode all trees
#67 promot* in All Text
#68 educat* in All Text
#69 program* in All Text
#70 (policy in All Text or policies in All Text)
#71 train* in All Text
#72 (diet* in All Text near/6 intervention* in All Text)
#73 (behavi* in All Text near/6 intervention* in All Text)
#74 (#58 or #59 or #60 or #61 or #62 or #63 or #64 or #65 or #66 or #67)
#75 (#68 or #69 or #70 or #71 or #72 or #73 or #74)
#76 (#74 or #75)
#77 MeSH check word Infant
#78 MeSH descriptor Child, Preschool this term only
#79 (child in All Text or children in All Text)
#80 (pre-school* in All Text or preschool* in All Text)
#81 (infant in All Text or infants in All Text)
#82 (nursery in All Text or nurseries in All Text)
#83 MeSH descriptor Parents explode all trees
#84 (parent in All Text or parents in All Text)
#85 toddler* in All Text
#86 MeSH descriptor Nurseries this term only
#87 nurseries in All Text
#88 (#77 or #78 or #79 or #80 or #81 or #82 or #83 or #84 or #85 or #86 or #87)
#89 (#57 and #76 and #88)

CONTRIBUTIONS OF AUTHORS

Luke Wolfenden will lead the development of the review. All authors have contributed to the conception of the research and will be involved in the preparation of the review including providing critical comment on drafts. Luke Wolfenden, Fiona Stacey and Rebecca Hodder will screen titles and abstracts and determine study eligibility. Erica James, Ben Britton and Rebecca Wyse will extract data from eligible trials, and assess heterogeneity and risk of bias. Patrick McElduff and Luke Wolfenden will conduct meta-analyses.

DECLARATIONS OF INTEREST

Luke Wolfenden, Rebecca Wyse and Karen Campbell are currently undertaking a randomised trial of an intervention to increase fruit and vegetable consumption which may be included in this review. The authors have not received any benefit, in cash or kind, any hospitality, or any subsidy derived from the food industry or any other source perceived to have an interest in the outcome of the review.

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Internal sources

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- Cancer Institute NSW, Australia.
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External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

*Eating; *Feeding Behavior; *Fruit; *Vegetables; Conditioning (Psychology); House Calls; Randomized Controlled Trials as Topic; Reward

MeSH check words

Child, Preschool; Humans; Infant