SYSTEMATIC REVIEW

ASSESSING THE COST-EFFECTIVENESS OF PUBLIC HEALTH INTERVENTIONS TO PREVENT OBESITY: A SYSTEMATIC REVIEW OF THE EFFECTIVENESS OF 16 OBESITY PREVENTION INTERVENTIONS

April 2010

Health Research Council of New Zealand Partnership Programme

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We would also like to thank the stakeholder reference group for their advice throughout this research project.

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EXECUTIVE SUMMARY

Obesity and overweight constitute a significant, and increasing, public health issue in New Zealand. The ultimate purpose of this research was to provide evidence on the relative cost-effectiveness of selected population-based initiatives aimed at preventing obesity and obesity-related chronic health problems in New Zealand. This research was commissioned by the Health Research Council of New Zealand and the Ministry of Health. The research was undertaken by a collaborative group of researchers from the Health Services Research Centre at Victoria University of Wellington, Health Technology Analysts (a consultancy group based in Sydney, Australia), and Canterbury University. The research team was supported by a stakeholder reference group (SRG), which provided input throughout the project. The research took place between September 2009 and October 2010.

The first phase of this research, described in this report, was a wide ranging scoping search of the literature to identify population-based obesity-prevention interventions. The scoping search involved a broad search of existing interventions designed to prevent obesity using literature databases, searching of reference lists of relevant studies and contacting both academic and government experts in the fields of education, nutrition and physical activity.

All identified interventions were tabulated by region and key information including study type, population type, intervention type and results were extracted. A total of 95 relevant primary prevention interventions were found: 22 in New Zealand, 16 in Australia, 31 in the United States or Canada, and 26 from the United Kingdom, Europe or elsewhere in the world. From these, the SRG selected the 16 individual interventions or settings to undergo full systematic review. In order to be considered for full systematic review, interventions generally had to have been found to be effective using a weight-based outcome including BMI, weight, waist circumference, percentage body fat or incidence or prevalence of obesity. These interventions were then subject to full systematic review. Those selected covered both nutrition and physical activity interventions in a variety of age groups and settings (pre-school, school, tertiary education, community, primary care and workplace). The aim of the systematic review was to formally assess the evidence on the effectiveness of the selected interventions.

Each included study was assigned a level of evidence in accordance with the NHMRC (2005) levels of evidence. In addition, each study was assessed for its methodological quality, statistical precision, the size of the effect and the relevance of the evidence.

Interventions selected for systematic review

Setting	**Intervention**	**Example studies from scoping search**
Pre-school	Nutrition/activity program specifically targeting pre-school	Hip hop to health junior
Primary school	Activity co-ordinators	APPLE
Primary school	Physical activity/behaviour modification through structured activity	Switch-play
Primary school	Education nutrition, nutrition policy	School Nutrition Policy Initiative
Primary school	Reducing the consumption of carbonated beverages	CHOPPS, Muckelbauer
Primary school	Health promotion targeting low SES/overweight children	KOPS
Primary school	Multifaceted intervention- diet and physical activity lessons, family involvement	CATCH
Secondary school	Any secondary school based intervention studies	Lionis
Community kids	Child and family involvement (Nutrition, activity, behaviour modification)	Be Active Eat Well
Community kids	Increasing PA options and availability of foods	Shape up Somerville
Community Adults	Dietary modification in post menopausal women	Women's dietary modification trial
Community Adults	Dietary behaviour and physical activity program	Women's healthy lifestyle project
Primary care	Green prescription	Green prescription
Primary care	General health screening	Denmark general health screen
Workplace	Targeted workplace interventions	NASA and DOW [a]
College	Health promotion/behavioural intervention	Hivert

When the systematic review was completed, the research team and SRG met again to consider the evidence and select 10 obesity-prevention scenarios to undergo cost-effectiveness analysis. A scenario is a particular obesity prevention intervention in a specific population or sub-population. In making their selection, the group considered relevance to the New Zealand population (including Māori and Pacific peoples) and policy setting; feasibility for implementation in New Zealand; the effectiveness of the intervention in preventing obesity; ability to produce population benefits; and a balance of intervention types, settings and ages. The 10 scenarios selected for cost-effectiveness modelling are shown in the table below.

Interventions selected for cost-effectiveness modelling following systematic review

Scenario Number	Study	Country in which Evidence was Collected	Setting	Intervention Type	Proposed Population for Modelling
1	APPLE (children)	New Zealand	Community	Activity/Education	General population
2, 3, 4	Be Active Eat Well (children)	Australia	Community	Nutrition/Activity/ Behaviour modification	General population, Māori, Pacific
5, 6, 7	General Health Screening (adults)	Denmark	General Practice	Education	General population, Māori, Pacific
8	Green Prescriptions (adults)	New Zealand	General Practice	Activity	General population
9	SNPI (School Nutrition Policy Initiative) (children)	USA	Primary school	Education (nutrition)/ Nutrition	General population
10	Switch-Play (children)	Australia	Primary school	Activity/Behaviour modification	General population

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1 BACKGROUND

1.1 PURPOSE OF THIS DOCUMENT

The purpose of this research is to provide evidence to assist decision making and cost-effective investment in population-based public health interventions designed to prevent obesity and obesity-related health problems in New Zealand. This research will involve systematic literature reviews, data collection and analysis, and health-economic modeling, with the ultimate aim being to rank up to 10 selected intervention scenarios in terms of their cost-effectiveness in the New Zealand setting. The findings of this research will inform policy makers about the relative merits of different investments, with a view to reducing the prevalence of a range of chronic health problems including diabetes, arthritis, cancer and obesity. This in turn will result in improved quality of life for New Zealanders and better value for money in health-care expenditure in New Zealand. The research has been commissioned by the Health Research Council (HRC) of New Zealand.

This systematic review has been prepared for the consideration of the Stakeholder Reference Group (SRG). The primary aim of the systematic review is to present the results of an assessment of the effectiveness of 15 selected obesity prevention interventions the processes that will be used to aid in identifying 10 scenarios that may be further assessed for cost-effectiveness in the New Zealand setting.

1.2 CLINICAL NEED FOR THE RESEARCH

1.2.1 Obesity

Obesity and overweight constitute a significant, and increasing, public health issue in New Zealand (NZ). Premature mortality, morbidity, and poorer quality of life are all associated with higher body mass index (BMI). In the past two decades the average level of obesity in OECD countries has risen 8 percent (Bleich *et al.* 2008), with considerable variation among countries. New Zealand compares poorly, with an increase of more than 100% in obesity prevalence between 1977 and 2003 (MOH 2004).

Currently NZ is ranked in the top five OECD countries for adult obesity (OECD 2006). Between 1977 and 2003, prevalence increased from 11% to 22% among females and from 9% to 20% among males, which gives an average annual percent change of approximately 3% for both genders (MOH 2004). Recent data show that about one in four (27%) adults meet the criterion for obesity (BMI>30), with a further 36% being classified as overweight (MOH 2008). Māori and Pacific men and women are more likely than the general population to be classified as obese, as are those, particularly women, living in areas of highest neighbourhood deprivation (MOH 2008).

While there was no increase in childhood obesity from 2002 to 2007, the reported rate of 8-10% for young males and females remains a significant concern, particularly given that early onset of obesity is associated with increased likelihood of obesity in later life and an increased prevalence of obesity-related disorders (Summerbell *et al.* 2005; Kopelman 2000). The ethnic disparities seen in adults are also apparent among children, with Māori boys and girls being 1.5 times more likely to be obese than those in the total population, and Pacific girls and boys 2.5 times more likely (MOH 2008). More concerning still, in a representative sample of NZ school children, Goulding *et al.* (2007) reported a 2.7% prevalence of extreme obesity, with considerable ethnic differences: 0.8% among New Zealand European; 5.1% among Māori; and 10.9% among Pacific children.

1.2.2 Population-based prevention strategies

Existing reviews of the obesity prevention literature have reported mixed results from a diverse range of studies. Doak *et al.* (2005), reviewing 25 school-based interventions, reported that 65% (17 of 25) of the interventions reviewed were effective based on a statistically significant reduction in BMI or measurement of skin-folds. Four of the studies reviewed were reported to be effective based on both of these measures. The studies reviewed typically involved mixed interventions including diet and activity components (and in three cases an emphasis on reduced television viewing). Gender differences in effectiveness were evident in some studies but with no consistency of direction. One effective intervention involved the simple provision of a clear message to reduce consumption of carbonated beverages, and increase fruit intake and consumption of water (James *et al.* 2004).

Another review conducted by The Cochrane Collaboration examined interventions for preventing obesity in children (Summerbell *et al.* 2005). Twenty-two studies were included; 10 long-term (at least 12 months) and 12 short-term (12 weeks to 12 months). Nineteen were school-based interventions, one was a community-based intervention targeting low-income families, and two were family-based interventions targeting non-obese children of obese or overweight parents. Six of the 10 long-term studies combined dietary education and physical activity interventions; five resulted in no difference in overweight status between groups and one resulted in improvements for girls receiving the intervention, but not boys. Two studies focused on physical activity alone. Of these, a multi-media approach appeared to be effective in preventing obesity. Two studies focused on nutrition education alone, but neither was effective in preventing obesity. Four of the twelve short-term studies focused on interventions to increase physical activity levels, and two of these studies resulted in minor reductions in overweight status in favour of the intervention. The other eight studies combined advice on diet and physical activity, but none had a significant impact.

To date it is unclear which specific aspects of particular intervention programs (e.g. various approaches to reducing intake of energy-dense foods: school-based programs, television or other social marketing campaigns; promotion of increased physical activity through structured programs, environmental change (cycle ways), or education) are the most effective and cost-effective in obesity prevention. A better understanding of the effectiveness and cost-effectiveness of intervention approaches will allow evidence-based decision making on the most efficient allocation of heath resources to reduce unhealthy weight gain in New Zealand

2 OBJECTIVE

The objective of the systematic review is to assess the effectiveness of 16 selected public health obesity prevention interventions. The effectiveness of the selected obesity-prevention interventions will then be summarised so that the stakeholder reference group can select up to 10 scenarios to undergo cost-effectiveness analysis.

3 GENERAL METHODS

3.1 SELECTION OF INTERVENTIONS FOR FULL SYSTEMATIC REVIEW

The 16 interventions/settings selected for full systematic review were identified via a scoping search, conducted as the first stage of this research. The scoping search involved a broad search of existing interventions designed to prevent obesity using literature databases, searching of reference lists of relevant studies and contacting both academic and government experts in the fields of education, nutrition and physical activity.

All identified interventions were tabulated by region and key information including study type, population type, intervention type and results were extracted. From these tables, the SRG selected the 16 individual interventions or settings to undergo full systematic review. In order to be considered for full systematic review, interventions generally had to have been found to be effective using a weight-based outcome including BMI, weight, waist circumference, percentage body fat or incidence or prevalence of obesity. A full list of the interventions considered for inclusion in this systematic review can be found in **Appendix 1**.

It should be noted that the original objective was to systematically review specific individual interventions. However, the small number of interventions identified during the scoping search in some settings (including high school, university/college and workplace) necessitated that these broader settings be further searched in order to identify any additional interventions in these settings. Following the systematic search of the setting, any interventions that met the inclusion criteria defined during the scoping search (ie, at least 1 year of follow-up, presents data for a weight-related outcome and was shown to be effective based on a weight-related outcome) were eligible for systematic review.

The interventions/settings to be systematically reviewed are shown in **Table 1**.

Table 1 Interventions/settings selected for systematic review following scoping search

Number	Setting	Intervention	Location
1	Pre-school	Hip Hop to Health Junior	USA
2	Pre-school/primary school	Be Active Eat Well	Australia
3	Primary school/community	KOPS (Kiel Obesity Prevention Study)	Germany
4	Primary school	APPLE (A Pilot Programme for Lifestyle and Exercise)	New Zealand
5	Primary school	Changing drinking behaviours	-
6	Primary school/community	Shape up Somerville	Germany
7	Primary school	CATCH (Child and Adolescent Trial for Cardiovascular Health	USA
8	Primary school	Switch-Play	Australia
9	Primary school	SNPI (School Nutrition Policy Initiative)	USA
10	High school	-	-
11	University/college	-	-
12	Workplace	-	-
13	Community (women)	Women's Health Initiative Dietary Modification Trial	USA
14	Community (women)	Women's Healthy Lifestyle project	USA
15	General Practice	Green Prescription	New Zealand
16	General Practice	General Health Screening	Denmark

Note: Settings/interventions shown in shading were searched broadly for additional interventions.

3.2 DEFINING THE RESEARCH QUESTIONS

It is important to define the research question that the systematic review seeks to address. As there were 16 interventions to be systematically assessed for effectiveness, multiple research questions were defined for this review.

These questions were defined according to the PICO (or PICOT) criteria:

1. Population
2. Intervention
3. Comparator
4. Outcomes
5. Time consideration (should be considered with regard to all of the above domains)

In the context of performing a systematic review of a public health intervention, the following should be taken into consideration when defining the components of the research question (CRD, 2009):

- The *population* of interest is often represented by groups of people, or entire communities, such as young people in schools or particular geographical regions. This is in contrast to reviews of clinical topics where individuals are usually the focus, for example patients undergoing a particular procedure or with a particular disease.

- Public health *interventions and comparators* are often characterised as a package of components, for example, the inclusion of diet, exercise and education in obesity prevention programs. These types of interventions are often referred to as 'complex' due to the fact that the constituent parts may act both independently and inter-dependently.
- In terms of *outcomes*, the outcomes for this review are those related to weight (ie, BMI, weight, waist circumference, incidence of obesity/overweight). Although public health interventions have the potential to improve population health overall, improvements (in terms of the total number who benefit from the intervention) may mask differences between groups (eg, male vs. female). For example, a review of healthy eating interventions in schoolchildren found differences between males and females in knowledge and consumption of healthy foods. As such, where applicable the results will be explored in terms of population characteristics including gender and ethnicity. Ethnicity is particularly important in this review as the effect of interventions on preventing obesity in Māori and Pacific Islander populations is relevant to the New Zealand setting.

For systematic reviews of public health interventions, it is also suggested that the *context* of an intervention be considered. Consideration of the context is important because if an intervention is found to be effective it is useful to be able to assess whether context was a contributor.

The individual research questions for each included intervention/setting are included in each relevant section.

3.3 NATURE OF THE EVIDENCE INCLUDED

In addition to the criteria above which will determine the nature of the interventions to be sourced, it is also important to identify what types of studies are eligible to be included. The levels of evidence based on NHMRC guidelines are defined as follows:

- **Level I:** A systematic review of level II studies.
- **Level II:** A randomised controlled trial
- **Level III-1:** A pseudorandomised controlled trial (ie, alternate allocation or some other method)

- **Level III-2:** A comparative study with concurrent controls: (i) non-randomised, experimental trial; (ii) cohort study; (iii) case-control study; or (iv) interrupted time series with a control group
- **Level III-3:** A comparative study without concurrent controls: (i) historical control study; (ii) two or more single arm studies; (iii) interrupted time series without a parallel control group
- **Level IV:** Case series with either post-test or pre-test/post-test outcomes.

For a systematic review, all levels of evidence are potentially relevant for inclusion. In the case of this review, inclusion of studies does not have to be based on any particular study type. It is possible that the prevention studies identified for this review will use a wide range of study methodologies.

3.4 SEARCHING THE LITERATURE

The published peer-reviewed medical literature will be searched using the Cochrane, Medline, EMBASE and CINAHL databases. In addition the Healthy Eating Healthy Action Knowledge Library will be searched. Other databases/websites which may be searched include the following:

- NICE: http://www.nice.org.uk
- AHRQ/USPSTF: http://www.ahrq.gov
- INAHTA: http://www.inahta.org/Search2/?pub=1

The following clinical practice guideline clearing house will be searched in order to identify any recent clinical practice guidelines that have been underpinned by full systematic reviews that have not been captured elsewhere.

- National Guideline Clearing House Database: http://www.guideline.gov

Hand searching of specific journals or conferences will not be undertaken, although the reference lists of key papers will be searched to identify any peer-reviewed evidence that may have been missed in the literature searches.

3.5 ASSESSING ELIGIBILITY

In a systematic review, the eligibility of identified citations should be determined using criteria based on the elements of the clinical question being answered.

In the case of this review, the following exclusion criteria were defined:

1. Not a relevant study: Excludes non-systematic reviews, case reports, animal studies, short notes, letters, editorials, conference abstracts, in-vitro studies.

2. Wrong population/intervention: does not assess one of the selected public health obesity-prevention interventions.

3. Wrong outcomes: does not measure one of the defined outcomes (eg, change in BMI).

4. Not in English: due to resource constraints non-English publications will not be included.

3.6 ASSESSING THE EVIDENCE

The evidence will be assessed according to the dimensions outlined in **Table 2**. Information regarding these dimensions as well as the results data will be extracted into a specifically designed data extraction sheet.

Table 2 Dimensions of evidence

Dimension	Definition
Strength of evidence	
Level	The study design used, as an indicator of the degree to which bias has been eliminated by design
Quality	The methods used by the investigators to minimise bias within a study design
Statistical precision	The P-value or alternatively, the precision of the estimate of the effect (as indicated by the confidence interval). It reflects the degree of certainty about the existence of a true effect.
Size of effect	The distance of the study estimate from the 'null' value and the inclusion of only clinically important effects in the confidence interval.
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.

Source: NHMRC 2000b.

Each study will be assigned a level of evidence in accordance with the NHMRC (2005) levels of evidence. The levels of evidence vary according to the nature of the research question. Importantly, the level of evidence is assigned at the individual study level, rather than to the body of evidence. In addition to determining the level of evidence, each study will be assessed for its methodological quality.

4 RESULTS

The following section includes a full systematic review of the evidence for each of the selected obesity prevention interventions. Each section will include a description of the characteristics of the intervention, as well as a description of the study which assesses the intervention. While the primary aim of this review is to identify the effect of the intervention on prevention of obesity via a reduction or prevention of increase in BMI, data from other weight-based outcomes including weight (in kg), waist circumference and incidence and prevalence of overweight/obesity will also be extracted. BMI z score was also presented in some included studies so has been reported where possible. Where available, physical activity results will also be briefly described.

4.1 INTERVENTION 1: HIP HOP TO HEALTH JUNIOR

The Hip-Hop to Health Junior curriculum was developed for low-income minority pre-school children. The intervention is designed to be effective for both overweight children and children who are at-risk for becoming obese. It has been implemented in Chicago in the US.

This intervention was identified during the scoping search via a search of online databases, grey literature and content experts.

4.1.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of Hip Hop to Health Junior in terms of the prevention of obesity. The specific research question to be answered is as follows:

Does the obesity prevention intervention Hip Hop to Health Junior prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

In order to answer this research question, an extensive literature search was conducted.

4.1.2 Literature search

In order to identify studies relevant to the assessment of the Hip Hop to Health Junior intervention, searches of Embase.com (covering the Embase and Medline databases) and the Cochrane Library were conducted. Search terms used included those relating to the intervention (ie 'Hip-Hop to Health') and two of the lead authors identified during the scoping search. In addition, a search of grey literature was conducted. The reference lists of identified studies were also checked for additional studies. Details of the search and search results are presented in **Table 3**.

Table 3 Literature search for Hip-Hop to Health Junior: Embase.com and Cochrane Library

Search location	Search string	Citations
Embase.com (EMBASE and Medline) 04/02/2010	#1 'fitzgibbon m.l.'/au #2 'hip-hop to health':ab,ti '#3 'stolley m.r.'/au #4 (#1 OR #3 OR #4)	57
Cochrane Library (Trials Register) 04/02/2010	#1 'fitzgibbon m.l.'/au #2 'hip-hop to health':ab,ti '#3 'stolley m.r.'/au #4 #1 OR #3 OR #4	7
Other databases and grey literature search	"Hip-Hop to Health"	1
Subtotal		*65*
Manual searching of reference lists	"Hip-Hop to Health"	0
TOTAL		*65*

The following exclusion criteria were applied to the 65 identified citations:

1. Duplicate citation – excludes multiple citations for the same publication

2. Not a clinical study – excludes publications which do not report the results of an original study conducted in humans (ie, excludes animal studies, in vitro studies, narrative reviews)

3. Wrong population/intervention – excludes studies which do not describe and/or assess the Hip Hop to Health Junior Project.

4. Wrong outcomes- does not report a relevant weight-based outcome

Applying the exclusion criteria resulted in the identification of four publications relating to the Hip Hop to Health Junior Project. All four of these citations were identified via the search of Embase.com and Cochrane Library. The results of the application of exclusion criteria are presented in **Table 4**.

Table 4 Exclusion of citations for Hip Hop to Health Junior

Criterion	Citations
TOTAL IDENTIFIED	65
Duplicate citation	7
Not a clinical study	15
Wrong population/intervention	39
Wrong outcomes	0
TOTAL REMAINING	4

Details of the four identified citations are presented in **Table 5**. It should be noted that two of these citations (Fitzgibbon *et al* (2002) and Stolley *et al* (2003)) provide background information on the study rationale, design and baseline characteristics but do not present results. The remaining two citations (Fitzgibbon *et al* (2005) and Fitzgibbon *et al* (2006)) provide data regarding the results of the Hip Hop to Health Junior programme in two different populations (African American children and Latino children, respectively).

Table 5 Included citations: Hip Hop to Health Junior

Citation details	Included
Fitzgibbon ML, Stolley MR, Dyer AR, VanHorn L, and KauferChristoffel K. (2002) A community-based obesity prevention program for minority children: Rationale and study design for Hip-Hop to Health Jr. Preventive Medicine 34:289-297.	
Stolley MR, Fitzgibbon ML, Dyer A, Van Horn L, KauferChristoffel K, and Schiffer L. (2003) Hip-Hop to Health Jr., an obesity prevention program for minority preschool children: Baseline characteristics of participants. Preventive Medicine 36:320-329.	
Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, KauferChristoffel K, and Dyer A. (2005) Two-year follow-up results for Hip-Hop to Health Jr.: A randomized controlled trial for overweight prevention in preschool minority children. Journal of Pediatrics 146:618-625.	✓
Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, KauferChristoffel K, and Dyer A. (2006) Hip-Hop to Health Jr. for Latino preschool children. Obesity 14:1616-1625.	✓

4.1.3 Results

The following section provides details of the characteristics of the intervention, the included studies, the baseline characteristics of the intervention and control groups and two sets of results: (i) results of the weight-related outcomes from the study of African-American children; and (ii) results of the weight-related outcomes from the study of Latino children.

While the results of all weight-based analyses will be presented, this section will focus on the Fitzgibbon *et al* (2005) study of African American children where the intervention was shown to be effective. Less detail will be provided for the Fitzgibbon *et al* (2006) study in Latino children.

4.1.3.1 Intervention characteristics

Hip Hop to Health Junior was developed based on Hip-Hop to Health, a community-based cardiovascular risk reduction program that was conducted with 6 to 10-year-old African-American children and their families. The primary aim of Hip-Hop to Health Junior is to alter the trajectory toward overweight/obesity in African-American and Latino preschool children. The 14-week intervention presents a developmentally, culturally, and linguistically appropriate integrated dietary/physical activity curriculum that targets preschoolers, while also including a parent component that addresses the dietary and physical activity patterns of the family (Fitzgibbon *et al*, 2002).

The program occurs three times a week in 45-minute sessions for a total of 14 weeks. In each class, children first learn about a healthy eating habit or exercise activity for about 20 minutes. Then, children participate in an intense physical activity session for about 20 minutes. This activity session involves games, songs, and dancing. Each child's parent also receives a weekly newsletter which contains information on what children are learning in their sessions, homework activities they can do with their child and coupons for healthy food options. Two aerobics classes are offered each week to program parents (Fitzgibbon *et al*, 2002).

A summary of the programme components and their timing is presented in **Table 6**.

Table 6 Components and timing of the Hip Hop to Health Junior intervention

Week	Concept
1	Introduction to program and go grow foods
2	Food pyramid
3	Portions
4	Grains
5	Fruits
6	Vegetables A to Z
7	Milk: Making the switch to 1%
8	Protein
9	Heart healthy exercise- Fitness part 1
10	Instead of TV, I could…...Fitness part II
11	Grooving moving– Fitness part III
12	Health snacks
13	Healthy me– Part I
14	Healthy me–Part 2

Source: Fitzgibbon *et al* (2002), page 294.

4.1.3.2 Study characteristics

The programme has been designed as an ongoing, 5-year cluster-randomised intervention study that targets 3 to 5-year old children from minority populations. Twelve of the sites were randomly assigned to receive the intensive intervention and 12 were assigned to the general health intervention. During the first year of the active intervention, 12 sites that serviced primarily African-American communities were selected. During the second year of the active intervention, 12 sites that service primarily Latino communities were selected.

The main characteristics of the two studies assessing the Hip Hop to Health Junior intervention are summarised in **Table 7**. The Hip Hop to Health Junior study was a group randomised controlled trial conducted in two separate minority populations in Chicago in consecutive years. The populations consisted of pre-school age children (approximately 4-5 years). Various anthropomorphic, physical activity and dietary outcomes were assessed at different time points, as shown in **Table 7**. It is important to note that only two-year follow-up results were found in the literature.

Table 7 Study characteristics: Hip Hop to Health Junior

Citation	Study type	Population		Intervention/ comparator	Outcomes
		Intervention	Control		
Fitzgibbon *et al* (2005)	Paired school cluster-randomised controlled trial Pre-school based 6 intervention schools/6 control schools 5 years duration	N= 197 Age: 48.6±7.6 months Gender (% female): 49.7% Ethnicity (%): African-American 99%, other-1% BMI ≥85th percentile[a]: 62 (31.5%)	N=212 Age: 50.8±6.4 months Gender (% female): 50.5% Ethnicity (%):African-American 80.7%, Latino-12.7%, other-6.6% BMI ≥85th percentile[a]: 77 (36.3%)	Hip Hop to Health Junior vs. General health intervention Hip Hop to Health Junior consisted of a 14 week intervention including education on nutrition, physical activity and general well being	1 and 2 year follow-up Weight (kg) Height (cm) *BMI (kg/m²)* *BMI z score* Total fat (% kcal) Saturated fatty acids (% kcal) Fibre (g/1000 kcal) TV viewing Exercise frequency (% ≥7 x /wk) Exercise intensity (Borg scale)
Fitzgibbon *et al* (2006)	Group randomised controlled trial Pre-school based 6 intervention schools/6 control schools 5 years duration	N=202 Age: 50.8±7.3 Gender (% female): 47.5% Ethnicity (%): African-American 15.8%, Latino-73.3%, Multi-racial/other-10.9% BMI: 17.0±2.8 kg/m² BMI ≥85th percentile[a]: 202 (39.6%)	N=199 Age: 51.0±7.0 Gender (% female): 51.3% Ethnicity (%):African-American 6.5%, Latino- 89.4%, Multi-racial/other-4.0% BMI: 17.5±2.2 kg/m² BMI ≥85th percentile[a]: 199 (51.3%)	Hip Hop to Health Junior vs. General health intervention Hip Hop to Health Junior consisted of a 14 week intervention including education on nutrition, physical activity and general well being	1 and 2 year follow-up Weight (kg) Height (cm) *BMI (kg/m²)* *BMI z score* Total fat (% kcal) Saturated fatty acids (% kcal) Fibre (g/1000 kcal) TV viewing Exercise frequency (% ≥7 x /wk) Exercise intensity (Borg scale)

Source: Fitzgibbon *et al* (2005), Table 1 page 621; Fitzgibbon *et al* (2006), Table 1, page 1620.
Abbreviations: BMI = body mass index
Note: Outcomes which are considered relevant to this review, and which are described in the results section, are shown in italics.
[a] Overweight or at risk for overweight is defined as BMI >85th percentile for age and sex.

4.1.3.3 Baseline participant characteristics

Table 8 summarises the baseline characteristics of participants in the Hip Hop to Health Junior studies, as presented in the two included citations. Baseline measurements were made on up to 409 children during the Fitzgibbon *et al* (2005) study; however, a lesser proportion of children had repeat measurements at post-intervention (362), Year 1 (289) and Year 2 (300) follow-up. Similarly in the Fitzgibbon *et al* (2006) study, 401 children had measurements taken at baseline, compared to 383 post-intervention, 336 at Year 1 and 331 at Year 2 follow-up.

The majority of children included in the Fitzgibbon *et al* (2005) study were African American (~99% and ~81% for the intervention and control group, respectively) whereas the majority of children in the Fitzgibbon *et al* (2006) study were Latino (~73% and ~89% for the intervention and control group, respectively). In both studies of the Hip Hop to Health Junior program, children were in pre-school and around 4-5 years of age. There were similar proportions of males and females in the intervention and control groups of both studies. Approximately one third of participants in each arm of the Fitzgibbon *et al* (2005) study had a BMI score greater than the 85th percentile for their age and sex. In the Fitzgibbon *et al* (2006) study, 39.6% of participants in the intervention and 51.3% of participants in the control group had a BMI score greater than the 85th percentile for their age and sex. In both studies analyses were adjusted for group randomisation. Analyses in the Fitzgibbon *et al* (2006) study were also adjusted for months from baseline.

Table 8 Baseline characteristics: Hip Hop to Health Junior

Citation	Characteristic	Unit	Intervention		Control		P value [a]
Fitzgibbon *et al* (2005)	**Children**						
	Age (months)	Mean ± SD	n=197	48.6 ± 7.6	n=212	50.8 ± 6.4	NR
	Gender (% female)	Mean ± SD	n=197	49.7	n=212	50.5	NR
	Ethnicity (%)		n=197		n=212		NR
	African-American	%		99.0		80.7	
	Latino	%		0.0		12.7	
	Multiracial/Other	%		1.0		6.6	
	BMI (kg/m²)	Mean ± SD	n=197	16.5 ± 1.5	n=212	16.7 ± 2.0	NR
	BMI <85th percentile [b]	Mean ± SD	n=135	15.7 ± 0.7	n=135	15.6 ± 0.9	NR
	BMI ≥85th percentile [b]	Mean ± SD	n=62	18.2 ± 1.3	n=77	18.5 ± 2.0	NR
	BMI Z-score for age and sex [c]	Mean ± SD	n=197	0.62 ± 0.90	n=212	0.67 ± 1.11	NR
	Weight (kg)	Mean ± SD	n=197	17.6 ± 2.9	n=212	18.3 ± 3.4	NR
	Height (cm)	Mean ± SD	n=197	102.8 ± 6.4	n=212	104.6 ± 5.9	NR
	BMI ≥85th percentile (%) [b]	%	n=197	31.5	n=212	36.3	NR
	Total fat (% kcal) [d]	Mean ± SD	n=175	33.6 ± 7.6	n=183	33.4 ± 8.3	NR
	Saturated fatty acids (% kcal) [b, d]	Mean ± SD	n=175	12.1 ± 3.9	n=183	11.9 ± 3.8	NR
	Dietary fibre (% kcal) [d]	Mean ± SD	n=175	6.4 ± 2.9	n=183	6.6 ± 3.6	NR
	TV viewing (hours/day)	Mean ± SD	n=174	3.4 ± 1.9	n=182	3.1 ± 1.6	NR
	Exercise frequency (% ≥7 x /wk)	%	n=174	43.7	n=182	54.4	NR
	Exercise intensity (Borg scale)	Mean ± SD	n=174	5.3 ± 2.2	n=182	5.2 ± 2.1	NR
	Parents [e]						
	Age (years)	Mean ± SD	n=137	30.0 ± 9.7	n=152	30.8 ± 9.5	NR
	BMI (kg/m²)	Mean ± SD	n=122	30.6 ± 8.6	n=148	31.5 ± 8.5	NR
	Education (years)	Mean ± SD	n=136	12.4 ± 1.8	n=152	12.7 ±1.7	NR
	Married/living as married (%)	%	n=136	19.9	n=152	21.7	NR
Fitzgibbon *et al* (2006)	**Children**						
	Age (months)	Mean ± SD	N=202	50.8 ± 7.3	N=199	51.0 ± 7.0	0.71

Citation	Characteristic	Unit	Intervention		Control		P value [a]
	Gender (% female)	Mean ± SD	N=202	47.5	N=199	51.3	0.45
	Ethnicity (%)		N=202		N=199		<0.001
	African American	%		15.8		6.5	
	Latino	%		73.3		89.4	
	Multiracial/Other	%		10.9		4.0	
	Height (cm)	Mean ± SD	N=202	104.0 ± 5.9	N=199	103.3 ± 6.1	0.21
	Weight (kg)	Mean ± SD	N=202	18.6 ± 4.1	N=199	18.8 ± 3.8	0.59
	BMI (kg/m^2)	Mean ± SD	N=202	17.0 ± 2.8	N=199	17.5 ± 2.2	0.10
	BMI Z-score for age and sex [c]	Mean ± SD	N=202	0.87 ± 1.24	N=199	1.13 ± 1.06	0.023
	BMI ≥85th percentile [b]	%	N=202	39.6	N=199		0.019
	BMI ≥95th percentile [b]	%	N=202	21.8	N=199		0.033
	Total fat (% kcal) [d]	Mean ± SD	N=188	30.0 ± 8.7	N=174		0.59
	Saturated fatty acids (% kcal) [b, d]	Mean ± SD	N=188	11.3 ± 3.8	N=174		0.37
	Dietary fibre (% kcal) [d]	Mean ± SD	N=188	8.5 ± 4.6	N=174		0.96
	TV viewing (hours/day)	Mean ± SD	N=180	2.8 ± 1.6	N=170		0.46
	Exercise frequency (% ≥7 x /wk)	%	N=180	26.7	N=170		0.35
	Exercise intensity (Borg scale)	Mean ± SD	N=180	3.7 ± 2.9	N=169		0.30
	Parents [e]						
	Age (years)	Mean ± SD	N=155	31.5 ± 8.6	N=155		0.38
	BMI (kg/m^2)	Mean ± SD	N=136	28.5 ± 5.9	N=136		0.018
	Education (years)	Mean ± SD	N=140	11.3 ± 3.6	N=138		0.10
	Married/living as married (%)	%	N=140	67.9	N=138		0.73
	Acculturation score [f]		N=107	2.0 ± 1.2	N=121		0.80

Abbreviations*:* BMI = body mass index; NR = not reported; SD = standard deviation; TV = television.

[a] From $\chi 2$ tests for categorical variables and two-sample Student's t tests for continuous variables.

[b] Overweight or at risk for overweight is defined as BMI ≥85th percentile for age and sex. Overweight is defined as BMI ≥95th percentile for age and sex.

[c] Deviation from the mean BMI for age and sex for the reference population divided by the age- and sex-specific standard deviation for the reference population.

[d] If the child was in school the previous day, the parent completed a recall for the child's time at home; otherwise, the parent completed a 24-hour recall for the child.

[e] Female parents with some baseline data only.

[f] Mean score for four questions about language used in thinking, reading, and speaking at home and with friends. Possible scores for each question range from 1 (uses only Spanish) to 5 (uses only English). Latina parents only.

4.1.3.4 Weight-related results

The results of the analysis of weight-related outcomes for three time-points (post intervention, 1 year, 2 years follow-up) for each study are presented in **Table 9**. Only the results presented in each publication which had been adjusted for the most variables are included here, as these tended to provide the most conservative results.

In the Fitzgibbon *et al* (2005) study, which included predominantly African American children, the increase in adjusted mean BMI in intervention children was 0.06 kg/m^2, whereas mean BMI increased by 0.59 kg/m^2 in control children (P = 0.012) one year post-intervention. Change in BMI z score also differed significantly between groups (–0.08 vs. 0.16, P = 0.006). Two years post-intervention, the adjusted mean increase in BMI was 0.54 kg/m^2 higher in control children than intervention children (P = 0.022), whereas the difference in change in adjusted BMI z score was 0.18 (P = 0.015). The mean increases in weight over this period were 7.95 kg for control children and 6.84 kg for children receiving the Hip Hop to Health Junior intervention.

In the Fitzgibbon *et al* (2006) study, which included predominantly Latino children, there was a trend towards less weight gain in the intervention group compared to the control group, however, post-intervention changes in adjusted BMI and adjusted BMI z score did not differ significantly between the intervention and control children at any follow-up time point (**Table 9**). The authors have suggested that this may have been due to several factors. Firstly, the parental component of the intervention may not have been intensive enough. The intervention may not have targeted ethnic foods and the cultural aspects of eating and physical activity in a way most appropriate for low-acculturated Latinos. Also, children who attended predominantly Latino centres had higher BMIs at baseline than children from African American centres. The authors have suggested this may have contributed to the lack of impact of the intervention in this population. Whether or not ethnicity was a contributing factor to the different results seen in each study is uncertain and was not discussed.

Table 9 Weight-related results: Hip Hop to Health Junior

Citation	Follow-up	Adjustments	Intervention		Control		Difference (WCI–GHI) (95% CI)	p-value
			N	Mean (SE)	N	Mean (SE)		
Fitzgibbon *et al* (2005)	**Post-intervention**							
	Adjusted BMI (kg/m2) [a]	Adjusted for baseline age quartile, baseline value, and Head Start site.	179	0.06± 0.05	183	0.13 ± 0.05	–0.07 (-0.23 to 0.09)	0.373
	Adjusted BMI z score [a,b]	Adjusted for baseline age quartile, baseline value, and Head Start site.	179	0.05 ± 0.04	183	0.08 ± 0.04	–0.03 (–0.14 to 0.09)	0.606
	Year 1							
	Adjusted BMI (kg/m2) [a]	Adjusted for baseline age quartile, baseline value, and Head Start site.	143	0.06 ± 0.12	146	0.59 ± 0.12	–0.53 (–0.91 to –0.14)	*0.012*
	Adjusted BMI z score [a,b]	Adjusted for baseline age quartile, baseline value, and Head Start site.	143	-0.08 ± 0.05	146	0.16 ± 0.05	-0.23 (–0.38 to –0.09)	*0.006*
	Year 2							
	Adjusted BMI (kg/m2) [a]	Adjusted for baseline age quartile, baseline value, and Head Start site.	146	0.54 ± 0.14	154	1.08 ± 0.14	-0.54 (–0.98 to –0.10)	*0.022*
	Adjusted BMI z score [a,b]	Adjusted for baseline age quartile, baseline value, and Head Start site.	146	0.00 ± 0.04	154	0.17 ± 0.04	–0.18 (–0.31 to –0.04)	*0.015*
Fitzgibbon *et al* (2006)	**Post-intervention**							
	Adjusted BMI (kg/m2) [a]	Adjusted for baseline age quartile, baseline value, and Head Start site.	196	0.12 ± 0.11	187	0.12 ± 0.11	0.00 (–0.36 to 0.36)	1.0
	Adjusted BMI z score [a,b]	Adjusted for baseline age quartile, baseline value, and Head Start site.	196	0.07 ± 0.06	187	0.07 ± 0.06	0.01 (–0.19 to 0.20)	0.94
	Year 1							
	Adjusted BMI (kg/m2) [a]	Adjusted for baseline age quartile, baseline value, and Head Start site.	176	0.31 ± 0.16	160	0.44 ± 0.17	–0.13 (–0.65 to 0.39)	0.60
	Adjusted BMI z score [a,b]	Adjusted for baseline age quartile, baseline value, and Head Start site.	176	–0.01 ± 0.07	160	0.11 ± 0.07	–0.11 (–0.34 to 0.11)	0.29
	Year 2							
	Adjusted BMI (kg/m2) [a]	Adjusted for baseline age quartile, baseline value, and Head Start site.	171	0.46 ± 0.19	160	0.66 ± 0.20	–0.20 (–0.82 to 0.42)	0.49
	Adjusted BMI z score [a,b]	Adjusted for baseline age quartile, baseline value, and Head Start site.	171	–0.13 ± 0.07	160	0.02 ± 0.07	–0.15 (–0.38 to 0.09)	0.19

Source: Fitzgibbon *et al* (2005), Table II, page 622; Fitzgibbon *et al* (2006), Table II, page 1621

Abbreviations: BMI = body mass index; CI = confidence interval; GHI = general health intervention; SE = standard error; WCI = weight control intervention

[a] Adjusted for baseline age quartile, baseline value, and Head Start site. The baseline age quartiles were <3.715, 3.715-<4.178, 4.178-<4.602, and≥4.602 years. Quartiles were coded as indicator variables.

[b] Deviation from the mean BMI for age and sex for the reference population divided by the age- and sex-specific standard deviation for the reference population.

4.1.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for the Hip Hop to Health Junior intervention is provided in **Table 10**.

Table 10 Dimensions of evidence for the Hip Hop to Health Junior studies

Dimension	Definition
Strength of evidence	
Level	The primary studies were Level II cluster-randomised controlled trials.
Quality	The studies were high quality controlled trials with standardised assessment.
Statistical precision	Weight measures were adjusted for baseline demographic and study characteristics. In the Fitzgibbon *et al* (2005) study the p-value for adjusted mean difference in BMI was p=0.022. In Fitzgibbon *et al* (2006), for the same outcome, the p value was p=0.49.
Size of effect	There was a significant difference in adjusted mean BMI and adjusted BMI z score in the study of African American children at 1 and 2 years follow-up. There was no significant difference in these measures between the control and intervention group at any follow-up time point in the study of predominantly Latino children.
Relevance of evidence	The study presents adjusted mean BMI and BMI z score, which are both clinically relevant outcomes. The studies were conducted in African-American and Latino populations, whether or not these are applicable to NZ is uncertain.

Source: NHMRC 2000b.

4.1.5 Translation of results for economic analysis

The results of these two studies suggest that the Hip Hop to Health Junior programme may be effective in African American pre-school children but not in Latino pre-school children, as shown in **Table 11**. As this study provides results in terms of BMI, the results can be transferred for use in an economic model.

Table 11 BMI results for Intervention 1: Hip Hop to Health Junior

Country	Setting	Category	Age (years)	Ethnicity	Mean difference in change in BMI Intervention – control (kg/m²)		Mean difference in change in BMI z score Intervention – control	
					1 year	2 years	1 year	2 years
USA	Pre-school	PA/N	3-5	African American (~95%)	**-0.5**	**-0.5**	**-0.2**	**-0.2**
				Latino (~81%)	-0.1	-0.2	-0.1	-0.2

Note: statistically significant results are shown in bold.
Abbreviations: BMI=body mass index; N=nutrition; PA=physical activity.

4.2 INTERVENTION 2: BE ACTIVE EAT WELL

The Be Active Eat Well (BAEW) project aimed to increase the community's capacity to promote healthy eating and physical activity and prevent unhealthy weight gain in children aged 4-12 years. The study was conducted in Victoria, Australia.

This intervention was identified during the scoping search via a search of the medical literature and advice from content experts.

4.2.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of Be Active Eat Well in terms of the prevention of obesity. The specific research question to be answered is as follows:

Does the obesity prevention intervention 'Be Active Eat Well' prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

In order to answer this research question, an extensive literature search was conducted.

4.2.2 Literature search

In order to identify studies relevant to the assessment of the Be Active Eat Well intervention, searches of Embase.com (covering the EMBASE and Medline databases) and the Cochrane Library were conducted. Search terms used included those relating to the intervention (ie 'Be Active Eat Well') and the primary author identified for the published article (Sanigorski). In addition, the reference lists of identified studies were checked for additional studies and a grey literature search was conducted to identify further reports. Details of the search and search results are presented in **Table 12**.

Table 12 Literature search for Be Active Eat Well: Embase.com and Cochrane Library

Search location	Search string	Citations
Embase.com (EMBASE and Medline) 26/03/2010	1. 'Be Active Eat Well':ab,ti or 'BAEW':ab;ti or 'Colac':ab,ti 2. Sanigorski A.M/au	11
Cochrane Library (Trials Register) 26/03/2010	1. 'Be Active Eat Well':ab,ti or 'BAEW':ab;ti	0
Other databases and grey literature search	1. Be Active Eat Well	6
Subtotal		*17*
Manual searching of reference lists	Be Active Eat Well	0
TOTAL		*17*

The following exclusion criteria were applied to the 17 identified citations:

1. Duplicate citation – excludes multiple citations for the same publication
2. Not a clinical study – excludes publications which do not report the results of an original study conducted in humans (ie, excludes animal studies, in vitro studies, narrative reviews)
3. Wrong population/intervention – excludes studies which do not describe and/or assess the Be Active Eat Well programme
4. Wrong outcomes- does not report a relevant weight-based outcome

Applying the exclusion criteria resulted in the identification of seven publications relating to the Be Active Eat Well project. One of these was identified via the search of Embase.com and six were identified via a search of the grey literature. The results of the application of exclusion criteria are presented in **Table 13**.

Table 13 Exclusion of citations for Be Active Eat Well

Criterion	Citations
TOTAL IDENTIFIED	17
Duplicate citation	0
Not a clinical study	1
Wrong population/intervention	9
Wrong outcomes	0
TOTAL REMAINING	7

Details of the seven identified citations are presented in **Table 14**. It should be noted that five of the citations provide background information and demographic characteristics while the remaining two citations (Sanigorski *et al* 2008a and Simmons *et al* 2008) provided data regarding the results of the programme.

Table 14 Included citations: Be Active Eat Well

Citation details	Included
Kremer P,Malakellis M,Sanigorski A,Swinburn BA. Nutrition and Physical Activity in Children and Adolescents. Barwon-South Western Region. Sentinel Site Series. Report 4: Physical Activity Patterns. 2008. Victoria, Department of Human Services.	
Mathews L, Mathews L.,Kremer P,Sanigorski A.,Simmons A.,Nichols M.,Moodie M,Swinburn BA. Nutrition and Physical Activity in Children and Adolescents. Barwon-South Western Region. Sentinel Site Series. Report 1: Methods and Tools. 2008. Victoria, Department of Human Services.	
Sanigorski AM, Bell AC, Kremer PJ, Cuttler R, and Swinburn BA. Reducing unhealthy weight gain in children through community capacity-building: Results of a quasi-experimental intervention program, Be Active Eat Well. International Journal of Obesity 2008a 32:1060-1067.	✓
Sanigorski AM, Malakellis M,Kremer P,Swinburn BA. Nutrition and Physical Activity in Children and Adolescents. Barwon-South Western Region, Sentinel Site Series. Report 2: Anthropometry. 2008b. Victoria, Department of Human Services.	
Sanigorski AM,Malakellis M,Azadi L,Kremer P,Swinburn BA. Nutrition and Physical Activity in Children and Adolescents. Barwon-South Western Region Sentinel Site Series. Report 3: Dietary Patterns. 2008c. Victoria, Department of Human Services.	
Mathews,L.,Malakellis M.,Sanigorski,A.M,Kremer,P.Swinburn,B..A. Nutrition and Physical Activity in Children and Adolescents. Barwon-South Western Region. Sentinel Site Series. Report 5: Obesogenic Environments. 2008. Victoria, Department of Human Services	
Simmons A., Sanigorski AM,Cuttler R,Brennan M,Kremer P,Mathews L,& Swinburn BA. Nutrition and Physical Activity in Children and Adolescents. Barwon-South Western Region. Sentinel Site Series. Report 6: Lessons learned from Colac's Be Active Eat Well project (2002-6). 2008. Victoria, Department of Human Services.	✓

4.2.3 Results

The following section provides details of the characteristics of the intervention, the included studies, baseline characteristics of the intervention and control groups and two sets of results: (i) results of the pivotal weight-related outcomes for this review; and (ii) results of the supportive physical activity-related outcomes.

4.2.3.1 Intervention characteristics

Be Active Eat Well was a community based project that aimed to promote healthy eating and physical activity behaviours and reduce weight gain in children aged 4–12 years in the rural Australian town of Colac in Victoria. It used a multi-setting, multi-strategy approach and was based on community capacity building principles. The capacity-building objective included broad actions around governance, partnerships, coordination, training and resource allocation. Five objectives targeted evidence-based behaviour changes:

- reducing television viewing
- reducing sugar drinks and increasing water consumption

- reducing energy dense snacks and increasing fruit intake
- increasing active play after school and weekends and
- increasing active transport to school.

Each objective had a variety of strategies (such as social marketing, programs and policies). A more detailed overview of the intervention is provided in **Figure 1**.

Figure 1 Overview of the Be Active Eat Well intervention strategies

Nutrition strategies[a]
- School-appointed dietitian for support
- School nutrition policies (including policies around water, fruit breaks, canteens, fundraising)
- Training for canteen staff
- Canteen menu changes
- Lunch pack (healthy combos in designed packaging; 549 sold during the pilot period and remaining packs, about 4000, provided to schools for ongoing use)
- Professional development for teachers about healthy eating curriculum
- One-off class sessions conducted by dietitians
- Taste tests of new canteen menu items
- Fresh taste program (Melbourne Markets)
- Healthy breakfast days
- Interactive, glossy, children's newsletters (set of four 1600 copies of each newsletter distributed through the schools)
- Teacher fliers (linking to children's newsletters)
- Promotional materials (for example, balloons, stickers)
- Happy healthy families program (small groups, 6 weeks)
- Parent tips sheets (set of 10)
- Healthy lunchbox tip sheets
- Community garden
- Choice chips program (7 hot chip outlets in Colac)
- Fruit shop displays (3 shops involved)

Physical activity strategies[b]
- After-school activities program
- Be Active Arts program
- Walking school buses
- Walk to school days
- Promotional materials (for example, balloons, stickers)
- Sporting club coach training
- Sporting club equipment
- Two class sets of pedometers for rotation between schools

Screen time[c]
- TV power-down week, including a 2-week curriculum
- Interactive, glossy, children's newsletters (series of five 1600 copies of each distributed thorough the schools)
- Teacher fliers (linking to children's newsletters)

Across all strategies
- Sponsorship of the Colac Kana festival 2004
- Sponsorship of kids day out 2003
- Broad media coverage over 4 years (57 newspaper articles, 21 paid adverts)
- Incorporation of BAEW strategies on Municipal Early Years Plan (Colac Otway Shire)
- Incorporation of BAEW strategies into Integrated Health Promotion Plan (Colac Area Health)
- Incorporation of BAEW strategies into Municipal Public Health Plan (Colac Otway Shire)
- Social marketing training
- Obesity-prevention training

Source: Sanigorski *et al* (2008a), Table 1, page 1061

4.2.3.2 Study characteristics

The main study characteristics of the Be Active Eat Well program are shown in **Table 15**. The study was a quasi-experimental, non-randomised longitudinal study with anthropometric data collected on children in four preschools and six primary schools at baseline (n=1001) and follow-up (n= 844). The comparison sample was a stratified random selection of preschools (n=4) and primary schools (n=12) from the rest of the Barwon South Western region of Victoria. The area is considered socioeconomically disadvantaged compared with state-wide averages. Baseline measures were assessed in 2003/2004 and again in 2006.

Table 15 Study characteristics: Be Active Eat Well

<table>
<tr><th>Citation</th><th>Study type</th><th>Population</th><th>Intervention/
comparator</th><th>Outcomes</th></tr>
<tr><td>Sanigorski et al (2008a)</td><td rowspan="2">Quasi-experimental, non-randomised longitudinal study

Community-based

10 intervention schools/16 control schools

3 years duration</td><td rowspan="2">N= up to 1001
4-12 year-old children
Mean age: ~8 years
Gender (female): ~52%
Ethnicity: NR
Prevalence of overweight: ~19%
Prevalence of obesity: 7%</td><td rowspan="2">Be Active Eat Well vs. no intervention

Be Active Eat Well was a community-based intervention targeting nutrition, physical activity and reducing sedentary behaviours.</td><td rowspan="2">Body weight
BM (kg/m²)
BMI z score
Waist circumference (cm)
Waist-for-height
Overweight (%)
Obese (%)</td></tr>
<tr><td>Simmons et al (2008)</td></tr>
</table>

Abbreviations: BMI = body mass index; NR = not reported
Note: Outcomes which are considered relevant to this review, and which are described in the results section, are shown in italics.

4.2.3.3 Baseline participant characteristics

Table 16 summarises the baseline characteristics of participants in the Be Active Eat Well study, as presented in the two included citations. There were no significant differences in age, weight, waist circumference, BMI, BMI-z score or proportion of overweight and obese children between the two groups at baseline, although height was significantly lower in the intervention group (P=0.01). The proportion of children whose parents were born overseas is higher in the comparison group (12%) than the intervention group (6%), although both groups still have only a low level of cultural diversity and represent a predominately Anglo-Saxon Australian population.

Table 16 Characteristics of the study population at baseline

	Intervention	Control
n	1001	1183
Age, years (SD)	8.21 (2.26)	8.34 (2.22)
Female (%)	53.6	50.2
Height (cm)	128.9 (14.2)	130.5 (13.9)a
Weight (kg)	30.7(10.4)	31.4 (10.4)
BMI, kg/m^2	18.0 (3.0)	17.9 (2.9)
BMI-z score	0.63 (0.93)	0.60 (0.88)
Waist circumference (cm)	63.4 (8.9)	63.5 (9.1)
Waist-for-height (SD)	0.49 (0.05)	0.49 (0.05)
Thinness, grades 1-3 (%)	3.11	2.20
Overweight (%)	18.76	19.73
Obese (%)	8.53	6.77

Source: Sanigorski et al (2008a) Table 2, page 1065
Abbreviations: BMI= Body mass index; SD = standard deviation

4.2.3.4 Weight-related results

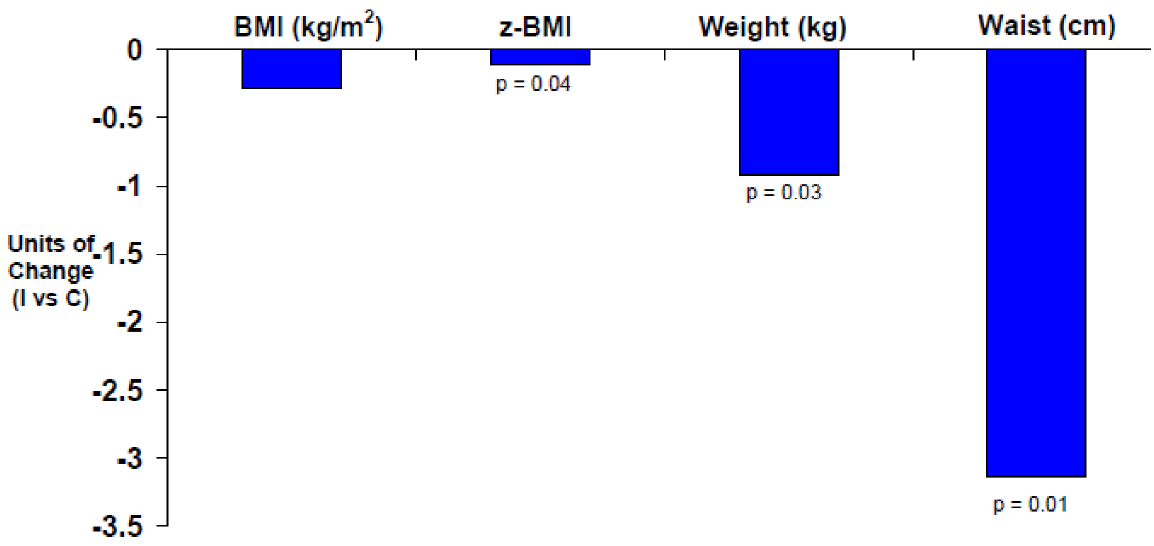
The results of the analysis of weight-related outcomes are presented in **Table 17** and **Figure 2**. Regression models were adjusted for baseline variables, age and height at follow-up, gender, duration between measurements and clustering by school. Children in the intervention group gained less weight (–0.92 kg), showed significantly lower increases in waist circumference (–3.14 cm), BMI-z score (–0.11) and waist/height ratio (–0.02), compared with the control group. However, the prevalence of overweight and obesity increased in both groups, and the incidence of overweight/obesity was not significantly different between the intervention and control group (incidence rate ratio: 0.91 (95% CI: 0.65–1.28)). The socio-economic gradient with unhealthy weight gain seemed to flatten out in the intervention group whereas in the comparison group, the expected pattern of the lower SES children gaining more weight than the higher SES children was seen.

Table 17 Adjusted differences in outcome measures between control and intervention children at follow-up

Variable	Difference	Robust standard error	P	95% CI
Body weight (kg)	–0.92	0.41	0.03	–1.74 to –0.11
Waist circumference (cm)	–3.14	0.96	0.01	–5.07 to –1.22
BMI (kg/m^2)	–0.28	0.21	0.20	–0.7 to 0.15
Waist/height [a]	–0.02	0.01	0.01	–0.03 to 0.004
BMI-z score	–0.11	0.05	0.04	–0.21 to –0.01

Source: Sanigorski *et al* (2008a), Table 3, page 1065
Abbreviations: BMI= body mass index; CI = confidence interval
[a] Height excluded from this model

Figure 2 **Anthropometric outcomes of the Be Active Eat Well Intervention**

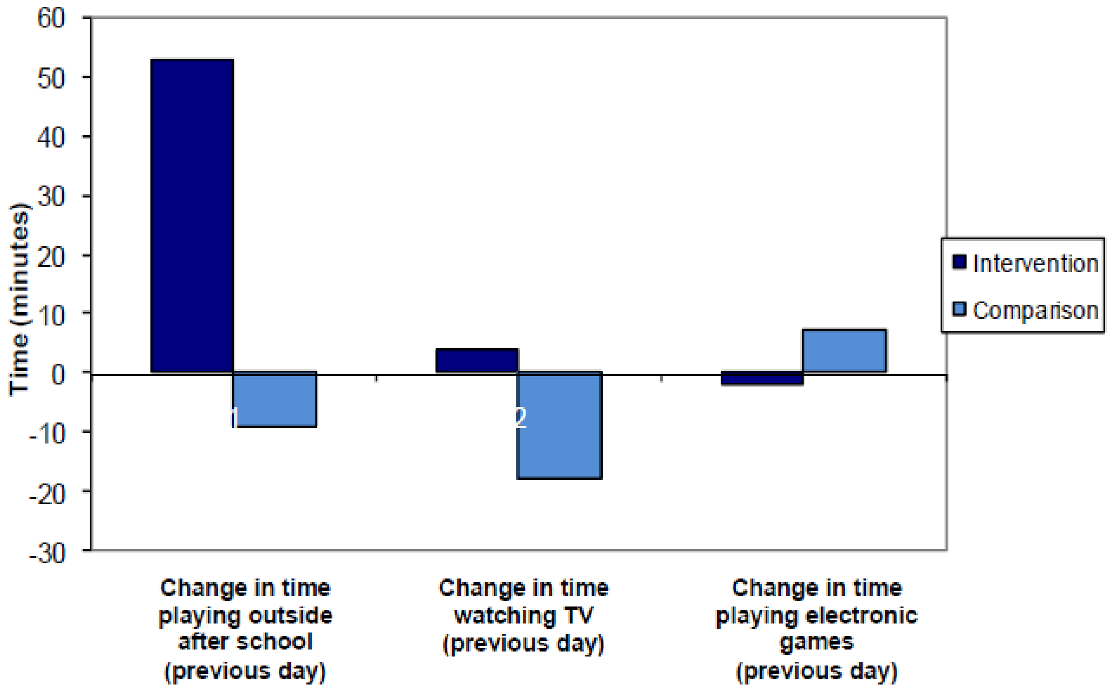


Source: Simmons *et al* (2008), Figure 4, page 44.

4.2.3.5 Physical activity-related results

A summary of the change in outside play, television viewing and playing electronic games between the intervention and control group is shown in **Figure 3**. There was an increase in time spent playing outside after school for the intervention group while the control group showed a slight decrease. For TV watching, the intervention sample showed a possible slight increase while the comparison sample reduced slightly. Trends for time playing computer games showed an opposite pattern, however none of these changes were statistically significant. Similarly there was no change in active transport to and from school. (Simmons *et al* 2008).

Figure 3 Summary of (adjusted) change in outside play, watching TV and playing electronic games for intervention and comparison samples



Source: Simmons *et al* (2008), Figure 8, page 49

4.2.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for the Be Active Eat Well intervention is provided in **Table 18**.

Table 18 Dimensions of evidence for the Be Active Eat Well study

Dimension	Definition
Strength of evidence	
Level	The primary study was a Level III-2 non-randomised, controlled trial.
Quality	The study was a good quality, quasi-experimental study. There was a difference in duration of follow-up between the intervention and control group which may have influenced results, although this was adjusted for in statistical analysis. Group allocation was not blinded. Response rates were moderate (~50%).
Statistical precision	The confidence intervals around the mean difference between the intervention and control group for weight related outcomes were narrow.
Size of effect	Children in the intervention group gained less weight (–0.92 kg), showed significantly lower increases in waist circumference (–3.14 cm), BMI-z score (–0.11) and waist/height ratio (–0.02), compared with the control group. However, the prevalence of overweight and obesity increased in both groups, and the incidence of overweight/obesity was not significantly different between the intervention and control group (incidence rate ratio: 0.91 (95% CI: 0.65–1.28)). Nor was the difference in BMI (–0.28kg/m^2) significant.
Relevance of evidence	The study presents relevant weight-based outcomes. It was conducted in Victoria, Australia, and therefore demographic characteristics of the population are likely to be similar to NZ. The study results are likely to be generalisable to NZ.

Source: NHMRC 2000b.
Abbreviations: BMI = body mass index; CI = confidence interval; NZ = New Zealand

4.2.5 Translation of results for economic analysis

While this study does provide results in terms of BMI, the difference in effect (–0.28 kg/m^2) between the intervention and control group was not significant (**Table 19**). The study did, however, find children in the intervention group gained less weight (–0.92 kg), showed significantly lower increases in waist circumference (–3.14 cm), BMI-z score (–0.11) and waist/height ratio (–0.02), compared with the control group. The difference in BMI, although not statistically significant, could be used in an economic evaluation.

Table 19 BMI results for Intervention 2: Be Active Eat Well

Country	Setting	Category	Age (years)	Ethnicity	Mean difference in change in BMI Intervention – control (kg/m^2)	Mean difference in change in BMI z score Intervention – control
					3 years	3 years
Australia	Pre- to primary school	PA/N	4-12 years	Predominantly Anglo-Saxon	-0.3	**-0.1**

Note: statistically significant results are shown in bold.
Abbreviations: BMI=body mass index; N=nutrition; PA=physical activity.

4.3 INTERVENTION 3: KOPS (KIEL OBESITY PREVENTION STUDY)

The Kiel Obesity Prevention Study (KOPS) was conducted in Germany amongst children 5-7 years, 9-11 years and 13-15 years. The intervention involved a behaviour and education programme targeting nutrition, physical activity and reduced television viewing.

This intervention was identified during the scoping search via a search of medical databases, the grey literature and content experts.

4.3.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of the KOPS in terms of the prevention of obesity. The specific research question to be answered is as follows:

Does the obesity prevention intervention 'KOPS' prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

In order to answer this research question, an extensive literature search was conducted.

4.3.2 Literature search

In order to identify studies relevant to the assessment of the KOPS, searches of Embase.com (covering the EMBASE and Medline databases) and the Cochrane Library were conducted. Search terms used included those relating to the intervention (e.g. KOPS), obesity ('obesity', 'BMI') and four of the lead authors. In addition, the reference lists of identified studies were checked for additional studies. Details of the search and search results are presented in **Table 20**.

Table 20 Literature search for KOPS: Embase.com and Cochrane Library

Search location	Search string	Citations
Embase.com (EMBASE and Medline) 12/03/2010	1. 'KOPS' OR 'kiel obesity prevention study' 2. Danielzik S 3. Pust S 4. Landsberg B 5. Muller M.J 6. 'obesity':ab,ti OR 'BMI':ab,ti or 'body mass index':ab,ti 7. #5 AND #6 8. #1 OR #2 OR #3 OR #4 OR #7	282
Cochrane Library (Trials Register) 12/03/2010	9. 'KOPS' OR 'kiel obesity prevention study' in clinical trials.	3
Subtotal		*285*
Manual searching of reference lists	'KOPS' or 'Kiel Obesity Prevention Study'	0
TOTAL		*285*

The following exclusion criteria were applied to the 285 identified citations:

1. Duplicate citation – excludes multiple citations for the same publication
2. Not a clinical study – excludes publications which do not report the results of an original study conducted in humans (ie, excludes animal studies, in vitro studies, narrative reviews)
3. Wrong population/intervention – excludes studies which do not describe and/or assess the KOPS
4. Wrong outcomes- does not report a relevant weight-based outcome

Applying the exclusion criteria resulted in the identification of five publications relating to the KOPS. All of these citations were identified via the search of Embase.com. The results of the application of exclusion criteria are presented in **Table 21**.

Table 21 Exclusion of citations for the KOPS

Criterion	Citations
TOTAL IDENTIFIED	285
Duplicate citation	10
Not a clinical study	51
Wrong population/intervention	211
Wrong outcomes	8
TOTAL REMAINING	5

Details of the five identified citations are presented in **Table 22**. It should be noted that one citation (Danielzik *et al* 2004) provides only background information or baseline data on how the KOPS was developed, while four citations (Muller *et al* 2001; Danielzik *et al* 2005, Danielzik *et al* 2007; and Platcha-Danielzik *et al* 2007) provide data regarding the results of the programme at various follow-up time points.

Table 22 Included citations: the KOPS

Citation details	Included
Danielzik S, Czerwinski-Mast M, Langnase K, Dilba B, and Muller MJ. (2004) Parental overweight, socioeconomic status and high birth weight are the major determinants of overweight and obesity in 5-7 y-old children: Baseline data of the Kiel Obesity Prevention Study (KOPS). International Journal of Obesity 28:1494-1502.	
Danielzik S, Pust S, Landsberg B, and Muller MJ. (2005) First lessons from the Kiel Obesity Prevention Study (KOPS). International Journal of Obesity 29:S78-S83.	✓
Danielzik S, Pust S, and Muller MJ. (2007) School-based interventions to prevent overweight and obesity in prepubertal children: Process and 4-years outcome evaluation of the Kiel Obesity Prevention Study (KOPS). Acta Paediatrica, International Journal of Paediatrics 96:19-25.	✓
Muller MJ, Asbeckl I, Mast M, Langnase K, and Grund A. (2001) Prevention of obesity - More than an intention. Concept and first results of the Kiel obesity prevention study (KOPS). International Journal of Obesity 25:S66-S74.	✓
Plachta-Danielzik S, Pust S, Asbeck I, Czerwinski-Mast M, Langnase K, Fischer C, Bosy-Westphal A, Kriwy P, and Muller MJ. (2007) Four-year follow-up of school-based intervention on overweight children: The KOPS study. Obesity 15:3159-3169.	✓

4.3.3 Results

The following section provides details of the intervention, study characteristics, including the baseline characteristics of the intervention and control groups, and results at various time points over the course of the longitudinal study.

4.3.3.1 Intervention characteristics

The Kiel Obesity Prevention Study (KOPS) was a longitudinal study conducted in Germany that intended to characterise the determinants of childhood overweight and the effect of preventive measures within schools as well as within families (Danielzik *et al*, 2005). Within the KOPS, the same behavioural and educational messages were given to all children and their parents (Muller *et al*, 2001). These messages were:

- eat fruit and vegetables each day
- reduce the intake of high fat foods
- keep active at least one hour per day, and
- decrease TV consumption to less than one hour a day.

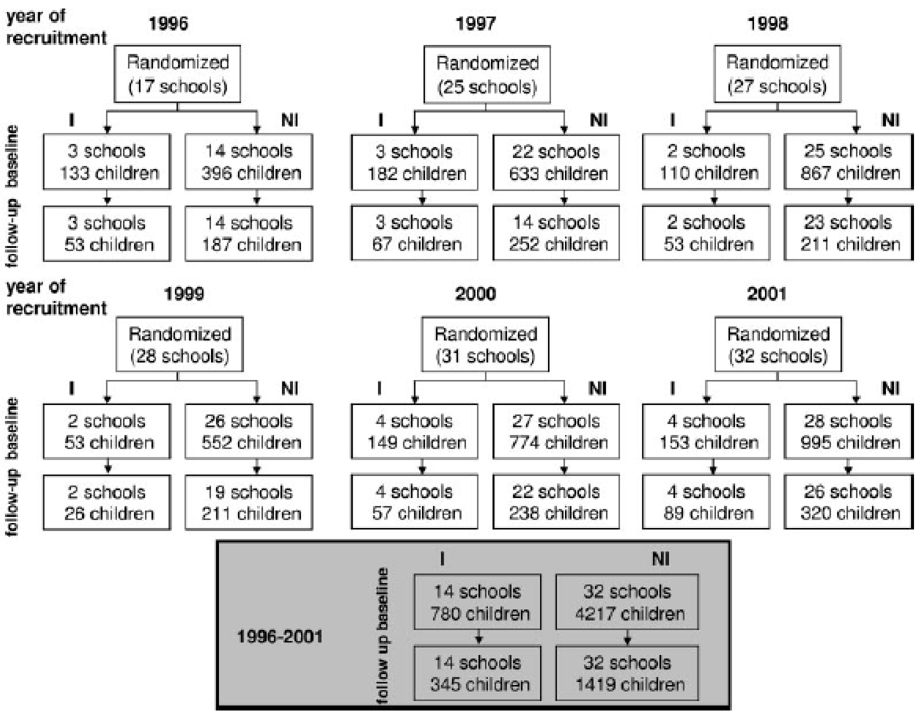
These messages were delivered to all primary school children within their first year in three representative schools in Kiel. A course of nutrition education was offered by a nutritionist together with a teacher to both children and their parents via a school meeting. In addition to school-based interventions for all children, parents and teachers, families with overweight and obese children were offered a face-to-face counselling and support programme within the family environment (three to five home visits organised by a nutritionist) (Danielzik *et al*, 2005).

The aims of the KOPS is (i) to characterise the prevalence and incidence of overweight and obesity in children and adolescence; (ii) to describe determinants and risk factors of childhood overweight and (iii) to assess the long-term effects of a 'low-level intervention at school for all children and in families who are at risk of obesity (Danielzik *et al*, 2005).

4.3.3.2 Study characteristics

The KOPS includes three cross-sectional studies: (i) 5–7 year old children (KOPS cohort T0: recruited between 1996 and 2001); (ii) 9–11 year old children (KOPS cohort T1: recruited between 2000 and 2005) and (iii) 13–15 year old children (KOPS cohort T2: recruiting between 2004 and 2009). One part of the KOPS assesses the long-term effect of interventions (1) at school for all children and (2) within 'overweight families' for overweight children. The school-based intervention was performed in 18 schools in Kiel (Danielzik *et al,* 2005). **Figure 4** shows the number of schools and children per year recruited at baseline (T0) and at the 4-year follow-up (T1).

Figure 4 The number of children and schools (cluster) in every year of recruitment (T0) and at 4-year follow-up (T1)



Source: Platcha-Danielzik *et al* (2007): Figure 1, page 3161

The main characteristics of the studies assessing the KOPS are summarised in **Table 23**. Between 1996 and 2001, 4997 5–7 year old children (2503 boys, 2494 girls) were recruited (KOPS cohort T0) (Danielzik *et al* 2004).

Table 23 Study characteristics: the KOPS

Citation	Study type	Population	Intervention/ comparator	Outcomes
Muller *et al* (2001) Danielzik *et al* (2004) Danielzik *et al* (2005) Danielzik *et al* (2007) Platcha-Danielzik *et al* (2007)	Longitudinal cohort study School and family-based 14 intervention schools/32 control schools 8 years duration	N= up to 4997 5-7 year-old children 13–15 year old children 9–11 year old children Characteristics of the 5-7 year old children at baseline: N=2631, gender (female): 50.6%, mean weight (kg): 22.1 (20.4-24.6) kg, mean BMI: 15.5 (14.6-16.5) kg/m2 , obese: 4.0%, overweight: 6.1%.	KOPS intervention vs. no intervention KOPS consisted of a multi-dimensional nutritional, physical activity and lifestyle educational intervention targeted at children and their families.	Height Weight *BMI* *Total skin fold* *Triceps skinfold* *Waist circumference* *Prevalence of overweight and obesity* *Cumulative incidence* *Fat mass* Nutrition habits

Abbreviations: BMI=body mass index; DBP=diastolic blood pressure; SBP=systolic blood pressure.
Note: Outcomes which are considered relevant to this review, and which are described in the results section, are shown in italics.
[a] Follow-up occurred at a mean of ~ 3.2 years.

4.3.3.3 Baseline participant characteristics

Each publication has examined different aspects of the KOPS, including different sub-populations and different outcomes. The publication by Muller *et al* (2001) describes an initial cohort of 2,440 5-7 year old children recruited between 1996 and 1999, from which they had full data on 1,640 children. Of these children 340 (20.7%) were considered overweight and obese, 1108 children (67.6%) normal weight and 192 children (11.7%) underweight (Muller *et al*, 2001). There were no sex differences in the prevalence of overweight or in the different risk groups.

The Danielzik *et al* (2004) publication examined the data of the KOPS subcohort T0. The characteristics of the KOPS study population (median/interquartile range) are shown in **Table 24**. Boys were heavier and taller than girls, but girls had a higher fat mass than boys. When compared with high SES children, children from low SES families were more frequently overweight. The SES distribution was different between overweight and obese boys and girls; 42% of overweight girls were considered low SES when compared to 24% of overweight boys. According to the publication by Danielzik *et al* (2005), the KOPS cohort T0 consisted of 4997 children (2,503 boys, 2,494 girls). In total, 4487 children (2,228 boys, 2,259 girls) were examined at the age of 9–11 y (KOPS cohort T1). Up to when this study was published, 1,251 children had been measured twice (ie at the age of 5–7 years and at the age of 9–11 years).

Table 24 Characteristics of the KOPS study population (median/interquartile range) of children

	KOPS population		
	All	**Boys**	**Girls**
N	2631	1301	1330
Age (years)	6.2 (5.9-6.5)	6.2[a] (6.0–6.5)	6.2[a] (5.9–6.5)
Weight (kg)	22.1 (20.4–24.6)	22.5[a] (20.7–24.7)	22.0[a] (20.0–24.5)
Height (m)	1.20 (1.16–1.24)	1.21[a] (1.17–1.24)	1.19[a] (1.16–1.23)
BMI (kg/m²)	15.5 (14.6–16.5)	15.5 (14.7–16.4)	15.5 (14.5–16.6)
Sum of 4 SF (mm)	28.3 (23.0–35.3)	26.3[a] (22.0–32.3)	30.2[a] (24.7–38.3)
FM (%)	28.4 (25.2–31.9)	27.2[a] (24.1–30.1)	29.7[a] (26.3–33.2)
Obese (%)	4.0	3.7	4.4
Overweight (%)	6.1	5.5	6.8
Normal weight (%)	82.8	83.5	82.1
Under weight (%)	7.1	7.4	6.8

Source: Danielzik *et al* (2004), Table 1, page 1496
Abbreviations: SF = skinfolds, FM= fat mass.
[a] Significant differences between boys and girls (Mann–Whitney U-test, $P<0.05$)

More detailed participant characteristics were provided in the Platcha-Danielzik *et al* (2007) publication, compared by intervention and control group. The characteristics of the study population before and after the four year observation period are shown in **Table 25**. There was a significant difference in BMI and BMI standard deviation score between the two groups at baseline, which was adjusted for in analysis. It is important to note the high drop-out rate over the four-year follow-up (55.8% in the intervention group and 66.4% in the control group). The prevalence of overweight and percentage of children of low SES were significantly higher in dropouts compared with participants in both the intervention and control group. Dropout at the school level was seen in control schools only (the range of dropouts was zero to eight schools).

Table 25 Characterisation of the study population before (T0) and after the 4-year observation (T1) period: data are given as median (interquartile range)

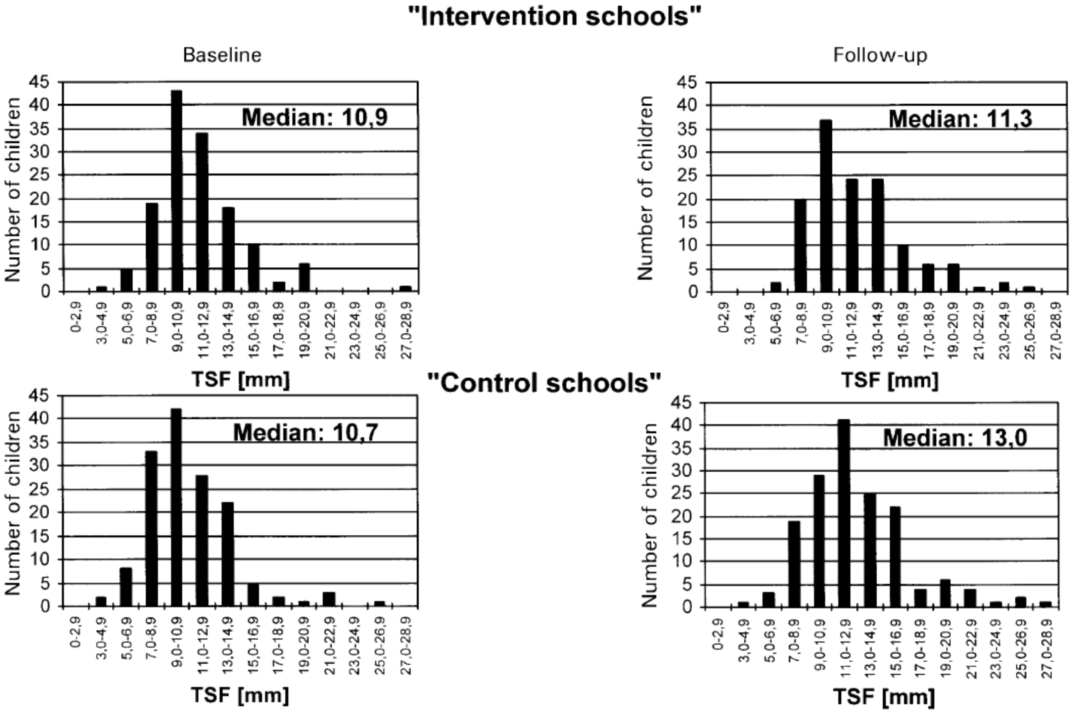
	Control group (n=1419)			Intervention group (n=345)		
	T0	T1	Δ (T1–T0)	T0	T1	Δ (T1–T0)
Boys/girls (%)	48.8/51.2			50.3/49.7		
SES:low/middle/high (%)	26.6/30.2/43.2			26.7/26.5/46.8		
Overweight and obese mothers (%)	30.2			23.2		
Age (yrs)	6.3 (6.0 to 6.5)	10.2 (10.0 to 10.5)	4.0 (0)	6.3 (5.9 to 6.5)	10.3 (9.9 to 10.5)	4.0 (0)
Height (m)	1.20 (1.17 to 1.24)	1.44 (1.39 to 1.49)	0.24 (0.22 to 0.26)	1.20 (1.16 to 1.23)	1.44 (1.40 to 1.48)	0.24 (0.22 to 0.26)
Weight (kg)	22.0 (20.4 to 24.5)	35.7 (31.7 to 42.0)	13.2 (10.7 to 17.5)	22.5 (20.5 to 24.5)	36.1 (31.7 to 41.2)	13.5 (10.7 to 17.1)
BMI (kg/m^2)	15.4[a] (14.6 to 16.4)	17.2 (15.8 to 19.6)	1.8 (0.9 to 3.3)	15.6 (14.8 to 16.7)	17.5 (16.0 to 19.1)	1.7 (0.7 to 3.1)
BMI-SDS	0.03[a] (–0.59 to 0.55)	0.13 (–0.54 to 0.98)	0.15[a] (–0.28 to 0.61)	0.11 (–0.43 to 0.70)	0.26 (–0.41 to 0.83)	0.07 (–0.42 to 0.57)
TSF (mm)	10.3 (9.0 to 13.0)	14.3 (10.1 to 19.4)	3.6 (0.0 to 7.3)	10.7 (9.0 to 13.9)	13.7 (10.2 to 18.5)	2.9 (–0.5 to 7.2)
Sum of four skinfolds (mm)	27.7[a] (22.7 to 35.6)	36.6 (25.9 to 55.8)	8.3 (–0.5 to 22.4)	29.0 (24.0 to 38.2)	38.0 (26.9 to 55.6)	8.7 (–1.7 to 21.1)
FM (%)	20.6[a] (16.1 to 25.3)	20.6 (15.7 to 27.2)	0.54 (–3.9 to 5.4)	21.06 (16.7 to 24.9)	20.8 (16.1 to 27.0)	0.24 (–5.2 to 4.7)
WC (cm)	54.0 (52.0 to 57.6)	62.7 (58.7 to 68.3)	8.1 (5.0 to 12.3)	55.0 (52.0 to 58.0)	63.1 (59.5 to 67.8)	8.3 (4.7 to 12.4)

Source: Plachta-Danielzik *et al* (2007), Table 1, page 3162
[a] Significant difference between the non-intervention and intervention group; Mann-Whitney test ($p<0.05$)
Abbreviations: BMI = body mass index; FM=fat mass; SES = socioeconomic status; SDS=standard deviation score; TSF=triceps skinfolds; WC=waist circumference

4.3.3.4 Weight-related results

In the Muller *et al* (2001) study, results of the KOPS after one year of follow-up were reported. **Figure 5** shows distribution of triceps skinfold (TSF) in 297 children (136 in the intervention group and 161 in the control group) at baseline and after one year with or without the intervention. When compared with the control group there was a significant shift in the distribution of TSF one year after intervention (median TSF: 13.0 vs. 11.3., respectively; P <0.01); whereas no group differences in the distribution of TSF were observed at baseline (Muller *et al* 2001).

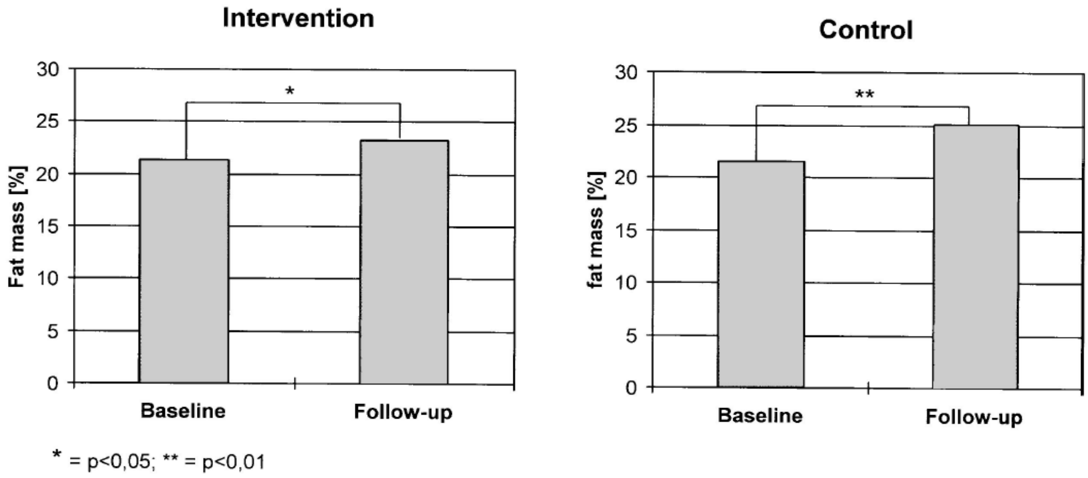
Figure 5 **Total skin folds at baseline and one year follow-up for intervention and control schools**



Source: Muller *et al* (2001): Figure 4, page S72

Figure 6 shows the one year changes in fat mass in overweight children in the intervention and control schools. After one year there was a significant change in fat mass in both groups. When compared with children in intervention schools, children in control schools showed disproportionate increases in median TSF (mean values of 13.0 vs. 11.3 mm at one year follow-up, $P<0.01$) as well as in percentage fat mass of overweight children (increase by 3.6 vs. 0.4%, $P<0.05$) (Muller *et al* 2001).

Figure 6 Percentage fat mass in overweight and obese children before and one year after intervention



Source: Muller *et al* (2001): Figure 5, page S72

According to the Danielzik *et al* (2005) publication, the prevalence of overweight and obesity was 12.8% and 17.6% (according to 90th percentile of BMI) and 23% and 39% (according to 90th percentile of TSF) in 5–7 and 9–11 year old children in the KOPS cohorts T0 and T1, respectively, at baseline. The four year follow-up data showed that 77.4% of children who were overweight at the age of 5–7 years remained overweight at the age of 10–11 years. The spontaneous incidence and remission of overweight were 7.9% and 5.3% per year, respectively.

Table 26 shows characteristics and net differences of prevalence, four year incidence and four year remission between children in the intervention and control group. There was no difference in BMI or TSF between the intervention and control groups in T1. However, a difference between the groups was seen in the upper distribution of BMI and TSF at T1. There was a smaller increase in the prevalence of overweight in the intervention group compared to the control group (a factor of 2.2 and 2.0, respectively). The four year incidence of overweight was reduced in the intervention group (36.5% vs. 41.7% in T0 and T1, respectively). However, the effect was only seen in girls. The remission of overweight was higher in the intervention than control group, with a larger effect observed in boys (Danielzik *et al* 2005).

Table 26 Characteristics and outcome of KOPS[a]

	School intervention group		Control group	
	T0	T1	T0	T1
N	257		257	
Age (y)	6.3 (0.4)	10.1 (0.5)	6.3 (0.4)	10.1 (0.5)
Weight (kg)	23.3 (3.9)	37.7 (8.2)	23.2 (3.9)	37.9 (8.0)
Height (m)	1.20 (0.1)	1.43 (0.1)	1.21 (0.1)	1.44 (0.1)
BMI (kg/m2)	16.0 (1.9)	18.3 (3.1)	15.9 (1.9)	18.3 (2.6)
BMI-SDS	0.21 (0.9)	0.34 (1.0)	0.13 (0.9)	0.39 (0.9)
TSF (mm)	11.0 (3.9)	15.5 (6.1)	11.3 (4.0)	15.5 (6.6)
Prevalence of overweight (%)				
Boys	18.9	40.9	19.7	40.2
Girls	25.4	46.2	25.4	60.0
Net differences (I-C)				
Prevalence (%) at T1				
Boys	+0.8			
Girls	-13.2			
4 year incidence (%)				
Boys	+2.8			
Girls	-13.4			
4 year remission (%)				
Boys	+12.0			
Girls	+5.2			

Source: Danielzik *et al* (2005), Table 3, page S81
Abbreviations: BMI= body mass index; C= control; SI= school intervention
[a] Data analysis of the first 5 years; 1 year is still missing.

The family-based intervention also showed some positive effects. Within the one year observation period, family intervention was capable of normalising increases in the BMI of overweight children. In addition, similar increases in fat mass were observed in children of the reference as well as in the control group (+ 27 vs. +32%). In contrast, the increase in fat mass was +10% in children in the intervention group. However, a low socio-economic status was shown to act as a barrier against intervention measures (Danielzik *et al* 2005).

The publication by Danielzik *et al* (2007) reported the four-year outcome among 6-10 year old children (**Table 27**). The data came from 344 children in the KOPS at age 6, compared with 1,420 control children. The T0-T1 longitudinal data (6-10 year follow-up data) are presented here. The four-year increase in prevalence of overweight was higher in the control group when compared with the intervention; however this difference was not significant. The effect of interventions on the four-year increase of overweight was stronger in girls, particularly when defined by waist circumference. Cumulative four-year incidence was lower in the intervention group when compared with the control group, however this was not significant. The difference in incidence between the control group and intervention group was similar according to triceps skinfold and waist circumference but higher when compared with that of BMI. Cumulative four-year remission was higher in the intervention group when compared with control and reached significance for TSF (Adjusted OR: 2.09, 1.20-3.62) (Danielzik *et al* 2007).

Table 27 Cumulative 4-year incidence and remission of overweight + obesity with crude and adjusted odds ratios

Incidence		Control (%)	Intervention (%)	I-C (%)	Crude OR (95% CI), p-value	Adjusted OR (95% CI), p-value
All	BMI	10.0	8.8	–1.2	0.87 (0.56–1.34) p=0.05255	0.76 (0.47–1.23) p=0.2722
	TSF	33.3	30.4	–2.9	0.88 (0.65–1.17) p=0.3707	0.92 (0.68–1.25) p=0.5957
	WC	18.3	15.5	−2.8	0.82 (0.57–1.17) p=0.2734	0.76 (0.52–1.11) p=0.1561
Boys	BMI	10.6	9.7	−0.9	0.90 (0.50–1.63) p=0.7337	0.63 (0.32–1.25) p=0.1793
	TSF	32.6	31.6	−1.0	0.96(0.64–1.44) p=0.8283	1.00(0.65–1.54) p=0.9899
	WC	18.1	14.4	−3.7	0.76(0.46–1.27) p=0.2967	0.61(0.35–1.04) p=0.0705
Girls	BMI	9.4	7.9	−1.5	0.83 (0.43–1.58) p=0.5660	0.88 (0.44–1.76) p=0.7183
	TSF	34.0	29.1	−4.9	0.80 (0.53-1.22) p=0.2950	0.81 (0.52-1.27) p=0.3596
	WC	18.5	16.7	−1.8	0.88(0.53–1.46) p=0.6261	1.01 (0.58–1.75) p=0.9739
Remission (all)	BMI	20.9	29.7	+8.8	1.60 (0.70–3.64) p=0.2640	1.84 (0.77–4.38) p=0.1686
	TSF	**22.6**	**39.3**	**+16.7**	**2.21[a] (1.32–3.71) p=0.0027**	**2.09[a] (1.20–3.62) p=0.0087**
	WC	31.9	40.0	+8.1	1.42 (0.81–2.49) p=0.2190	1.54 (0.83–2.87) p=0.1707
Boys	BMI	25.0	27.8	+2.8	1.15(0.35–3.86) p=0.8163	1.34 (0.34–5.23) p=0.6750
	TSF	23.1	37.5	+12.5	1.99 (0.94–4.24) p=0.0735	1.89 (0.84–4.28) p=0.1266
	WC	35.3	25.9	−9.4	0.64 (0.25–1.64) p=0.3531	0.78 (0.26–2.36) p=0.6584
Girls	BMI	18.2	31.6	+13.4	2.08 (0.67–6.41) p=0.2039	2.46 (0.76–8.08) p=0.1350
	TSF	**22.2**	**40.9**	**+18.7**	**2.42[a] (1.19–4.94) p=0.0148**	**2.27[a] (1.06–4.85) p=0.0339**
	WC	**29.3**	**50.0**	**+20.7**	**2.42[a] (1.17–5.01) p=0.0175**	**2.45[a] (1.13–5.32) p=0.0235**

Source: Danielzik *et al* (2007), Table 3, page 23
Abbreviations: BMI=body mass index; TSF=triceps skinfolds; WC=waist circumference
[a] Statistically significant difference between intervention and control group

The Plachta-Danielzik *et al* (2007) publication also reported the four-year results from the KOPS. At T1, there was no significant difference in prevalence of overweight and obesity (**Table 28**). The effect of intervention increased with SES, resulting in a lower prevalence of overweight in children of high SES (adjusted OR 0.35, 0.14 to 0.91; p=0.03). The effect almost reached significance in children of normal-weight mothers (adjusted OR 0.57; 0.33 to 1.00; p=0.05). No effect was seen in children of overweight mothers.

Similar cumulative four-year incidence rates of overweight were seen in the intervention and control groups (**Table 29**). Sex and mother's weight had no effect. A significant effect was seen only in children from families of high SES (adjusted OR 0.26; 0.07 to 0.87; p=0.03). The intervention and control groups showed similar cumulative four-year remission rates of overweight. A significant effect was seen in children of normal-weight mothers only (adjusted OR 5.43; 1.28 to 23.01; p = 0.02). A non-significant effect on remission of overweight was seen for all children (adjusted OR 2.52; 0.88 to 7.16; p=0.08) and in girls (adjusted OR 4.52; 0.86 to 23.65; p=0.07), whereas no effect was seen in boys.

Table 28 Characterization of weight status at T0 (6-year-old children) and T1 (10-year-old children) and adjusted ORs (95% CI) for prevalence of overweight and obesity after intervention at T1

					SES				
		All	**Boys**	**Girls**	**Low**	**Middle**	**High**	**O wt mother**	**N wt mother**
Prevalence at T0									
Intervention	Obese (%)	3.8	4.0	3.5	7.6	2.2	2.5	6.3	3.1
	Overweight (%)	7.0	6.4	7.6	10.9	7.7	4.3	12.7	5.0
	Normal-weight (%)	83.7	86.1	81.3	79.3	84.6	85.7	79.7	85.1
	Underweight (%)	5.8	3.5	7.6	2.2	5.5	7.5	1.3	6.9
Control	Obese (%)	3.9	3.3	4.4	7.4	3.3	2.1	8.1	2.1
	Overweight (%)	5.2	4.2	6.2	6.6	5.4	4.2	7.1	4.3
	Normal-weight (%)	83.7	84.7	82.8	76.9	85.1	86.9	79.1	85.7
	Underweight (%)	7.2	7.8	6.6	9.0	6.3	6.7	5.7	7.9
Prevalence at T1									
Intervention	Obese (%)	5.2	5.8	4.7	7.6	4.4	4.3	11.4	3.4
	Overweight (%)	10.2	10.4	9.9	17.4	14.3	3.7	19.0	7.3
	Normal-weight (%)	78.8	78.6	78.9	71.7	72.5	86.3	67.1	82.4
	Underweight (%)	5.8	5.2	6.4	3.3	8.8	5.6	2.5	6.9
Control	Obese (%)	5.1	4.9	5.4	9.5	4.7	2.8	10.7	2.8
	Overweight (%)	11.1	10.5	11.7	13.3	13.3	8.3	14.7	9.4
	Normal-weight (%)	76.9	77.8	76.1	69.8	76.9	81.2	69.1	80.2
	Underweight (%)	6.8	6.8	6.9	7.4	5.1	7.7	5.5	7.6
Prevalence (T1) of overweight	Adjusted OR [a]	0.87	0.88	0.86	1.31	1.03	**0.35**[a]	1.31	0.57
	95% CI	(0.57 to 1.31)	(0.48 to 1.64)	(0.48 to 1.53)	(0.69 to 2.46)	(0.51 to 2.07)	**(0.14 to 0.91)**	(0.69 to 2.47)	(0.33 to 1.00)
	P value	p=0.497	p=0.697	p=0.602	p=0.406	p=0.935	**p=0.031**	p=0.411	p=0.051
Prevalence (T1) of obesity	Adjusted OR	0.83	0.87	0.90	0.52	1.18	1.23	1.02	0.69
	95% CI	(0.40 to 1.74)	(0.32 to 2.32)	(0.32 to 2.52)	(0.17 to 1.62)	(0.27 to 5.22)	(0.28 to 5.39)	(0.39 to 2.66)	(0.22 to 2.17)
	P value	p=0.628	p=0.778	p=0.848	p=0.258	p=0.824	p=0.786	p= 0.972	p=0.528

Source: Plachta-Danielzik *et al* (2007), Table 3, page 3165
Abbreviations: CI = confidence interval; N wt = normal weight; O wt = overweight; OR = odds ratio; SES = socioeconomic status
[a] Adjusted for baseline BMI of the children, sex, SES, and BMI of the mother, as well as clustering effect among schools (OR of NI was taken as 1)

Table 29 Four-year cumulative incidence and remission of overweight and obesity and adjusted ORs (95% CI)

Four year cumulative incidence		Gender			SES			Mothers weight status	
		All	Boys	Girls	Low	Middle	High	O wt mother	N wt mother
Incidence of overweight	Intervention	7.6	8.1	7.2	13.7	11.7	**2.2**	14.3	5.9
	Control	9.2	9.2	9.1	11.0	11.2	**6.8**	12.9	7.4
	Adjusted OR[a]	0.72	0.67	0.76	1.20	0.85	**0.26[b]**	0.99	0.60
	(95% CI)	(0.43 to 1.19)	(0.33 to 1.35)	(0.36 to 1.59)	(0.54 to 2.67)	(0.36 to 1.98)	**(0.07 to 0.87)**	(0.43 to 2.26)	(0.62 to 1.15)
	p value	p=0.198	p =0.260	p=0.468	p=0.655	p=0.698	**p=0.030**	p=0.974	p=0.127
Incidence of obesity	Intervention	2.9	3.2	2.6	3.6	2.4	2.8	8.2	1.3
	Control	3.1	3.1	3.1	5.0	3.3	1.8	5.8	2.0
	Adjusted OR[a]	0.58	0.56	0.62	0.29	0.67	1.00	1.04	0.40
	(95% CI)	(0.24 to 1.45)	(0.16 to 1.97)	(0.17 to 2.30)	(0.06 to 1.40)	(0.12 to 3.87)	(0.18 to 5.73)	(0.36 to 3.07)	(0.09 to 1.79)
	p value	p=0.244	p=0.366	p=0.475	p=0.123	p=0.658	p=0.999	p=0.939	p=0.230
Remission of overweight	Intervention	41.7	45.5	38.5	40.0	42.9	42.9	20.0	**61.5[b]**
	Control	27.0	37.9	20.0	20.0	21.7	38.5	23.3	**26.2[b]**
	Adjusted OR[a]	2.52	1.79	4.52	9.75	3.55	1.22	0.40	**5.43[b]**
	(95% CI)	(0.88 to 7.16)	(0.37 to 8.62)	(0.86 to 23.65)	(0.95 to 100.3)	(0.46 to 27.11)	(0.17 to 8.50)	(0.05 to 3.26)	**(1.28 to 23.01)**
	p value	p=0.084	p=0.468	p=0.074	p=0.056	p=0.223	p=0.842	p=0.389	**p=0.022**
Remission of obesity	Intervention	30.8	28.6	33.4	42.9	0.0	25.0	40.0	25.0
	Control	38.2	34.8	40.6	28.6	50.0	46.2	29.4	55.0
	Adjusted OR[a]	1.71	7.74	1.80	0.66	—	7.10	1.01	4.99
	(95% CI)	(0.42 to 6.91)	(0.39 to 152.0)	(0.26 to 12.50)	(0.11 to 4.09)	—	(0.22 to 232.1)	(0.10 to 9.85)	(0.48 to 51.61)
	p value	p =0.449	p=0.178	p=0.552	p=0.653	—	p=0.271	p=0.993	p=0.178

Source: Plachta-Danielzik *et al* (2007), Table 4, page 3166
Abbreviations: CI = confidence interval; N wt = normal weight; O wt = overweight; OR = odds ratio; SES = socioeconomic status
[a] Adjusted for baseline BMI of the children, sex, SES, and BMI of the mother, as well as clustering effect among schools (OR of NI was taken as 1)
[b] Significant difference between I and NI (χ^2 test, $p < 0.05$)

4.3.3.5 Physical activity-related results

Regular sport activities (low: not a member in a sports club; medium: 0 to 1 hour per week; high: ≥1 hour per week) was assessed in all participants. Compared with no intervention, four-year changes in physical activity tended to improve in the intervention group (**Table 30**).

Table 30 Four-year changes in prevalence of physical activity

	No intervention	Intervention		No intervention	Intervention
High	n=240 (39.3%)	n=69 (42.1%)	High	80.4	81.2
			Medium	8.8	11.6
			Low	10.8	7.2
Medium	n = 160 (26.2%)	n = 52 (31.7%)	High	70.0	69.2
			Medium	14.4	13.5
			Low	15.6	17.3
Low	n = 211 (34.5%)	n= 43 (26.2%)	High	51.7	51.2
			Medium	9.3	9.5
			Low	38.9	39.5

Source: Plachta-Danielzik *et al* (2007), Table 5, page 3167

4.3.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for the KOPS is provided in **Table 31**.

Table 31 Dimensions of evidence for the KOPS

Dimension	Definition
Strength of evidence	
Level	The primary study was a Level III-II cluster-sampled, quasi-randomised controlled trial.
Quality	The study was a controlled trial with standardised assessment of weight-related outcomes. Investigators were blinded to the allocation of children. However, there was significant loss to follow-up. Prevalence of overweight and children of low SES families were higher in dropout rate compared with participants. The higher prevalence of overweight mothers in the control group may have caused selection bias.
Statistical precision	The confidence intervals around the adjusted OR for four-year cumulative incidence of obesity and remission of obesity were (OR: 0.58 (95% CI 0.24 to 1.45) p=0.244) and (OR: 1.71 (0.42 to 6.91) p =0.449), respectively. The confidence intervals around the adjusted OR of prevalence for overweight and obesity were moderate (OR: 0.83 (95% CI: 0.40 to 1.74) p=0.628).
Size of effect	At four-year follow-up, there was no significant difference in overall prevalence of overweight and obesity. There was significantly lower prevalence and cumulative incidence in intervention children from high SES (OR 0.26; p=0.03). A significant difference in remission of overweight was also seen in children of normal-weight mothers (OR: 5.43; p=0.022).
Relevance of evidence	The study uses measures of TSF, waist circumference and BMI to determine the prevalence, cumulative incidence and remission of overweight and obesity. These are all relevant outcomes. The study was conducted in Germany, therefore the generalisability in terms of participant demographics is uncertain.

Source: NHMRC 2000b.

4.3.5 Translation of results for economic analysis

The BMI result identified for this intervention is shown in **Table 32** and show no significant difference in mean change in BMI between intervention and control groups at year 4.

Table 32 BMI results for Intervention 3: KOPS

Country	Setting	Category	Age (years)	Ethnicity	Mean difference in change in BMI Intervention – control (kg/m^2)
					4 years
Germany	Primary school/community	PA/N	5-7 years	Not stated	-0.1

Note: statistically significant results are shown in bold.
Abbreviations: BMI=body mass index; N=nutrition; PA=physical activity.

When compared with children in intervention schools, children in control schools showed disproportionate increases in median TSF (mean values of 13.0 vs. 11.3 mm at one year follow-up, P<0.01) as well as in percentage fat mass of overweight children (increase by 3.6% vs. 0.4%, P<0.05). At four-year follow-up, there was no significant difference in overall prevalence, cumulative incidence or remission of overweight and obesity. However, there was significantly lower prevalence of overweight in children of high SES (adjusted OR 0.35, 0.14 to 0.91; p=0.03). Similarly, there was a significant difference observed in cumulative incidence in intervention children from families of high SES (adjusted OR 0.26; 0.07 to 0.87; p=0.03). A significant difference in remission of overweight was also seen in children of normal-weight mothers (adjusted OR 5.43; 1.28 to 23.01; p = 0.02). A non-significant effect on remission of overweight was seen for all children (adjusted OR 2.52; 0.88 to 7.16; p=0.08) and in girls (adjusted OR 4.52; 0.86 to 23.65; p=0.07), whereas no effect was seen in boys.

These data suggested that the KOPS had long term effects on overweight, but these effects were selective in children with high SES and children with normal-weight mothers. In addition, girls appeared to receive more benefit from the program than boys.

4.4 INTERVENTION 4: APPLE (A PILOT PROGRAMME FOR LIFESTYLE AND EXERCISE)

A Pilot Programme for Lifestyle and Exercise (APPLE) is a complex community-based intervention that focuses on physical activity and nutrition intervention components to change attitude and behaviours in children. The study was conducted in Dunedin, NZ.

This intervention was identified during the scoping search via a search of the grey literature and content experts.

4.4.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of APPLE in terms of the prevention of obesity. The specific research question to be answered is as follows:

Does the obesity prevention intervention APPLE prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

In order to answer this research question, an extensive literature search was conducted.

4.4.2 Literature search

In order to identify studies relevant to the assessment of the APPLE Project intervention, searches of Embase.com (covering the EMBASE and Medline databases) and the Cochrane Library were conducted. Search terms used included those relating to the intervention, obesity and two of the lead authors. In addition, the reference lists of identified studies were checked for additional studies. Details of the search and search results are presented in **Table 33**.

Table 33 Literature search for APPLE: EMBASE.com and Cochrane Library

Search location	Search string	Citations
Embase.com (EMBASE and Medline) 10/11/2009	1. 'apple project' OR 'pilot programme for lifestyle and exercise' 2. Taylor r.w. 3. Mann j.i. 4. 'obesity'/exp OR obesity 5. (#2 OR #3) AND #4 6. #1 OR #5	64
Cochrane Library (Trials Register) 10/11/2009	7. 'apple project' OR 'pilot programme for lifestyle and exercise' 8. Taylor r.w. 9. Mann j.i. 10. 'obesity'/exp OR obesity 11. (#2 OR #3) AND #4 12. #1 OR #5	4
Subtotal		*68*
Manual searching of reference lists	'apple' OR 'pilot programme'	1
TOTAL		*69*

The following exclusion criteria were applied to the 69 identified citations:

1. Duplicate citation – excludes multiple citations for the same publication

2. Not a clinical study – excludes publications which do not report the results of an original study conducted in humans (ie, excludes animal studies, in vitro studies, narrative reviews)

3. Wrong population/intervention – excludes studies which do not describe and/or assess the APPLE Project.

4. Wrong outcomes- does not report a relevant weight-based outcome

Applying the exclusion criteria resulted in the identification of four publications relating to the APPLE Project. Three of these citations were identified via the search of EMBASE.com and one was identified via the reference list search. The results of the application of exclusion criteria are presented in **Table 34**.

Table 34 Exclusion of citations for APPLE

Criterion	Citations
TOTAL IDENTIFIED	69
Duplicate citation	5
Not a clinical study	7
Wrong population/intervention	43
Wrong outcomes	0
TOTAL REMAINING	4

Details of the four identified citations are presented in **Table 35**. It should be noted that one citation (Williden *et al*, 2006) provides background information on how the APPLE programme was developed, while the remaining three citations (Taylor *et al* 2006; 2007; 2008) provide data regarding the results of the programme at various timepoints during the intervention and at follow-up.

Table 35 Included citations: APPLE

Citation details	Included
Williden M, Taylor RW, McAuley KA, Simpson JC, Oakley M, and Mann JI. 2006. The APPLE project: An investigation of the barriers and promoters of healthy eating and physical activity in New Zealand children aged 5-12 years. Health Educ J 65:135-148.	
Taylor RW, McAuley KA, Williams SM, Barbezat W, Nielsen G, and Mann JI. 2006. Reducing weight gain in children through enhancing physical activity and nutrition: the APPLE project. Int J Pediatr Obes 1:146-152.	✓
Taylor RW, McAuley KA, Barbezat W, Strong A, Williams SM, and Mann JI. 2007. APPLE Project: 2-y findings of a community-based obesity prevention program in primary school-age children. Am J Clin Nutr 86:735-742.	✓
Taylor RW, McAuley KA, Barbezat W, Farmer VL, Williams SM, and Mann JI. 2008. Two-year follow-up of an obesity prevention initiative in children: The APPLE project. Am J Clin Nutr 88:1371-1377.	✓

4.4.3 Results

The following section provides details of the characteristics of the included studies, the baseline characteristics of the intervention and control groups and two sets of results: (i) results of the pivotal weight-related outcomes for this review; and (ii) results of the supportive physical activity-related outcomes.

While the results of all weight-based analyses will be presented, this section will focus on the primary outcome defined for this review, BMI. In this study, BMI has been measured using the BMI z score. The standard deviation of BMI increases with age so z scores have been used (from Centers for Disease Control and Prevention tables) which take into account age and sex and thus standardises the outcome for children of different ages and gender.

4.4.3.1 Intervention characteristics

APPLE was developed based on the results of a qualitative study carried out by Williden *et al* (2006) which aimed to determine the barriers and promoters to healthy eating and physical activity in children aged 5-12 in the location chosen to receive the obesity prevention programme.

The intervention involves many components including:

- Community Activity Coordinators
- Increased availability of equipment and services
- Implementation of school policies regarding drinks and 'snacktivity' breaks
- Community activity days
- School walking buses
- Educational activities

The resulting programme assessed in these studies was a collection of several physical activity and nutritional initiatives to be introduced at various stages during the two-year duration of the programme. A summary of the programme components and their timing is presented in **Table 36**. The overall aim of the programme was to increase opportunities for physical activity and reinforce dietary messages. While some of the programme was conducted within the school, the aim was to also involve the wider community.

Table 36 Components and timing of the APPLE intervention

Year introduced	Physical	Nutritional
Year 1	Provision of Community Activity Co-ordinators (ACs) who developed a community based activity programme which included extra-curricular activities at recess, lunch and after school. These activities often involved other community members as well. The activities included: Golf Taekwondo Community walks Beach hikes School triathlons Line dancing Household chores Gardening Children's games from other countries Parent and child team sports	-
Year 2	Increased promotion and availability of a variety of sport and play equipment	Science lessons highlighting the health effects of sugary drinks
	The GoTri interactive card game which simulated competition in a triathlon	A healthy eating resource was developed and made available to all members of the intervention community

4.4.3.2 Study characteristics

The main characteristics of the three studies assessing the APPLE intervention are summarised in **Table 37**. The APPLE study was a non-randomised controlled trial conducted in two geographically separate intervention and control regions in Dunedin, NZ. The population consisted of 5-12 year-old children from four intervention and three control schools; up to 730 children provided data for the study. Various anthropomorphic, physical activity and dietary outcomes were assessed at different timepoints, as shown in **Table 37**.

Table 37 Study characteristics: APPLE

Citation	Study type	Population	Intervention/ comparator	Outcomes
Taylor *et al* 2006	Cluster non-randomised controlled trial Community-based 4 intervention schools/3 control schools 2 years duration	N= up to 730 5-12 year-old children Mean age: 7-8 years Gender (female): 184 (47.9%) Ethnicity: Caucasian: ~82%; Māori: ~17%; Pacific islanders: <1% Prevalence of overweight/obese: intervention 24%	APPLE vs no APPLE	*1-year change in BMI z score* *1-year change in waist circumference* 1-year change in pulse rate 1-year change in SBP 1-year change in DBP *1-year change in physical activity* TV viewing
Taylor *et al* 2007				*1 and 2-year change in BMI z score* 1 and 2-year change in height 1 and 2-year change in weight *1 and 2-year change in waist circumference* 1 and 2-year change in SBP 1 and 2-year change in DBP 1 and 2-year change in pulse rate Dietary intake *2-year change in physical activity*
Taylor *et al* 2008				*2-year and follow-up[a] change in BMI z score* 2-year and follow-up change in height 2-year and follow-up change in weight *2-year and follow-up change in prevalence of overweight/obese*

Abbreviations: BMI = body mass index; DBP = diastolic blood pressure; SBP = systolic blood pressure.
Note: Outcomes which are considered relevant to this review, and which are described in the results section, are shown in italics.
[a] Follow-up occurred at a mean of ~ 3.2 years.

4.4.3.3 Baseline participant characteristics

The majority of children included in the APPLE study were Caucasian (~82%), while ~17% were Māori and < 1% were Pacific Islanders, and children were considered to predominantly come from middle class backgrounds (Ministry of Education 2003 School Decile ratings of 3-7).

Table 38 summarises the baseline characteristics of participants in the APPLE study, as presented in the three included citations. It should be noted that there are differences in the baseline values reported in each citation as each analysed a slightly different population. Measurements were made on up to 730 children during the study; however, a lesser proportion of children had repeat measurements at baseline and/or Year 1, Year 2 or follow-up.

In the Taylor *et al* (2006) publication which describes the 1-year results, 513 children had baseline measurements and 384 children had 1-year measurements. The majority of children who did not have 1-year measurements had left the school to attend high school (84%). In the Taylor *et al* (2007) publication which describes the 2-year measurements in addition to 1-year measurements, at least one measurement was available for 730 children. A total of 470 children provided data measured at either baseline and 1 year, or baseline and 2-years. Of the 260 children missing from the analysis, the majority had left to attend high school. Children who were not included in the analysis were older than those who were, but did not differ on other baseline characteristics including z-scores for height, weight or BMI. In the Taylor *et al* (2008) publication which describes follow-up measurements as well as 2-year measurements, the most complete dataset provides baseline data for 554 children who had at least one measurement during the intervention; ie, at baseline and 1 or 2 years and follow-up. The majority of children who did not participate in follow-up had moved from the area (92%). The authors note that children who did not provide follow-up data were of similar age, sex distribution and had similar BMI than those who did provide follow-up data. It should be noted that the data presented in **Table 38** for this publication represents the population of children who provided data at baseline, 2 years and follow-up.

As can be seen in **Table 38**, baseline characteristics were similar for the different populations assessed in the three publications. There were statistically significant differences between the intervention and control children with respect to a number of baseline characteristics including the weight-related variables BMI z-score, waist circumference and prevalence of overweight, as well as the physical activity-related variable accelerometry. In order to account for these differences, analyses were conducted adjusting for baseline variables in addition factors.

Table 38 Baseline characteristics: APPLE

Citation	Characteristic	Unit	Intervention		Control		P value
Taylor *et al* 2006	Age (years)	Mean ± SD	n=207[a]	8.0 ± 1.7	n=177[a]	7.9 ± 1.5	0.655
	Gender (female)	%	n=207	45.9	n=177	50.3	0.391
	BMI Z-score	*Mean ± SD*	*n=207*	*0.58 ± 0.82*	*n=177*	*0.83 ± 0.89*	*0.004*
	Prevalence of overweight/obese	*%*	*n=207*	*24*	*n=177*	*37*	*0.010*
	Waist circumference (cm)	*Mean ± SD*	*n=207*	*59.3 ± 7.6*	*n=177*	*62.1 ± 9.7*	*0.002*
	Pulse rate (counts/min)	Mean ± SD	n=205	89 ± 12	n=177	88 ± 12	0.366
	SBP (mmHg)	Mean ± SD	n=205	104 ± 14	n=177	103 ± 14	0.579
	DBP (mmHg)	Mean ± SD	n=205	59 ± 8	n=177	58 ± 8	0.122
	Average accelerometer (counts/min)	*Mean ± SD*	*n=162*	*1165 ± 505*	*n=141*	*976 ± 467*	*0.001*
	Television (hours/day)	Mean ± SD	n=163	1.5 ± 0.8	n=153	1.6 ± 0.9	0.338
Taylor *et al* 2007	Age (years)	Mean ± SD	n=250	7.7 ± 1.8	n=219	7.7 ± 1.6	-
	Gender (female)	%	n=250	44.4	n=219	49.3	-
	BMI Z-score	*Mean ± SD*	*n=250*	*0.61 ± 0.82*	*n=219*	*0.80 ± 0.87*	*<0.05*
	Prevalence of overweight/obese	%	n=250	32.4	n=219	42.5	-
	Waist circumference (cm)	*Mean ± SD*	*n=250*	*58.9 ± 7.5*	*n=219*	*61.4 ± 9.6*	*<0.05*
	Pulse rate (counts/min)	Mean ± SD	n=250	90 ± 12	n=219	88 ± 12	-
	SBP (mmHg)	Mean ± SD	n=250	103 ± 14	n=219	102 ± 14	-
	DBP (mmHg)	Mean ± SD	n=250	59 ± 8	n=219	58 ± 8	-
	Average accelerometer (counts/min)	*Mean ± SD*	*n=250*	*1165*	*n=219*	*944*	*0.001*
	Television (hours/day)	Mean ± SD	n=250	nr	n=219	nr	NS
Taylor *et al* 2008	Age (years)	Mean ± SD	n=131[a]	7.5 ± 1.6	n=125[a]	7.5 ± 1.3	-
	Gender (female)	%	n=131	nr	n=125	nr	-
	BMI Z-score	Mean ± SD	n=131	0.62 ± 0.83	n=125	0.79 ± 0.86	NS
	Prevalence of overweight/obese	%	n=131	31	n=125	44	<0.05
	Waist circumference (cm)	Mean ± SD	n=131	nr	n=125	nr	-

Abbreviations: BMI = body mass index; DBP = diastolic blood pressure; min = minute; NS = not significant; SBP = systolic blood pressure.

[a] Includes participants with repeat measures only (ie, baseline and Year 1).

[b] Includes participants with at least one repeat measure (ie baseline and Year 1 or Year 2).

[c] Includes only children who participated at baseline, 2 years and follow-up. Baseline results of these participants were similar to those for intervention and control children who provided at least one year of follow up (n=201 and 188 children respectively) and those who provided at least one measurement during the intervention (1-year or 2-year) who participated in the follow-up (n=280 and 274 respectively).

4.4.3.4 Weight-related results

The results of the analysis of weight-related outcomes for three time-points (1 year, 2 years and follow-up) are presented in **Table 39**. Only the results presented in each publication which had been adjusted for the most variables are included here, as these tended to provide the most conservative results. The results for BMI z-score are represented graphically in **Figure 7**. All analyses presented in this review were those that were adjusted for various variables including baseline measures.

These results suggest that the APPLE intervention was successful in preventing weight gain. In particular, based on the results of the analysis of changes in height and weight z scores, it was shown that the lower BMI z score in intervention children compared with control children is a result of greater reductions in weight in the intervention group and not greater increases in height. Taylor *et al* (2007) showed that the reduction in BMI z score in intervention children is driven solely by the results in children who were of normal weight to begin with (-0.29; -0.38, -0.21 at 2 years). Children who were already classified as overweight (based on a BMI z score of ≥ 85% percentile) showed no difference in change in BMI between the intervention and control groups (-0.02; -0.16, 0.12 at 2 years).

Table 39 Weight-related results: APPLE

Citation	Outcomes	Adjustments	Risk estimate (95% CI)		
			1 year	2 years	Follow-up
Taylor *et al* 2006	Change in BMI z score	Age, sex, baseline value, school, TV, baseline physical activity	RD -0.12 (-0.21, -0.02)	-	-
	Change in waist circumference	Age, sex, baseline value, school, TV, baseline physical activity	RD -0.1 (-1.1, 0.9)	-	-
Taylor *et al* 2007	Change in BMI z score	Age, sex, activity rating, television viewing, baseline value and clustering	RD -0.09 (-0.18, -0.01)[b]	RD -0.26 (-0.32, -0.21)[b]	-
	Change in weight z score	Age, sex, activity rating, television viewing, baseline value and clustering	RD -0.04 (-0.12, 0.03)[b]	RD -0.18 (-0.22, -0.13)[b]	-
	Change in waist circumference	Age, sex, activity rating, television viewing, baseline value and clustering	RD 0.1 (-1.0, 1.0)[b]	RD -1.0 (-2.0, -0.0)[b]	-
Taylor *et al* 2008	Change in BMI z-score	Age, sex, baseline values, clustering, time in study, whether still attending an intervention school	-	RD -0.30 (-0.36, -0.25)[c] RD -0.22 (-0.28, -0.16)[d]	RD -0.21 (-0.29, -0.14)[c] RD -0.19 (-0.24, -0.13)[d] RD -0.17 (-0.25, -0.08)[e]
	Change in weight z score	Age, sex, baseline values, clustering, time in study, whether still attending an intervention school	-	RD -0.20 (-0.26, -0.14)[c] RD -0.14 (-0.18, -0.10)[d]	RD -0.17 (-0.23, -0.11)[c] RD -0.14 (-0.17, -0.10)[d] RD -0.08 (-0.14, -0.02)[e]
	Overweight prevalence	Age, sex, baseline values, clustering, time in study, whether still attending an intervention school	-	RR 0.70 (0.54, 0.90)[c] RR 0.82 (0.70, 0.96)[d]	RR 0.81 (0.69, 0.94)[c] RR 0.88 (0.76, 1.03)[d] RR 0.85 (0.71, 1.01)[e]

Abbreviations: BMI = body mass index; DBP = diastolic blood pressure; RD = risk difference; RR = relative risk; SBP = systolic blood pressure.

[a] Includes intervention and control children with at 1 year of follow-up (n=207 and 177 respectively).

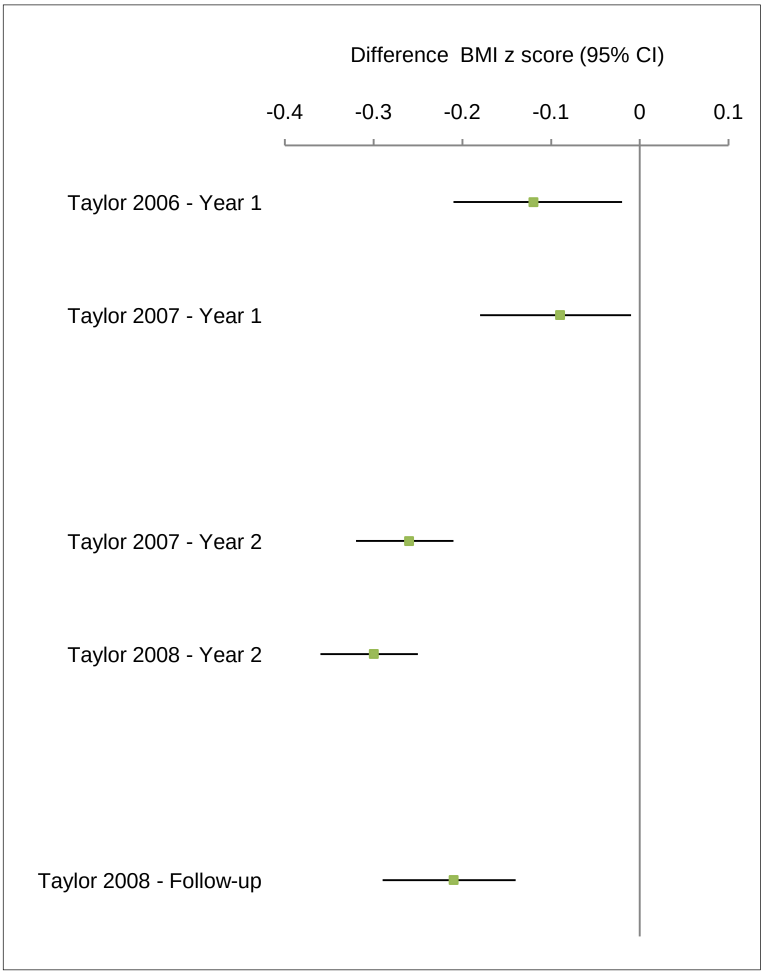
[b] Includes intervention and control children with at least 1 year of follow-up (n=246 and 217 respectively for year 1 and 151 and 136 respectively for year 2).

[c] Includes only children in the intervention and control groups who participated at baseline, 2 years and follow-up (N=131 and 125 respectively).

[d] Includes children in the intervention and control groups who were present for at least the 1-year measurement and follow-up (N=201 and 188 respectively).

[e] Includes children in the intervention and control groups who were present for either the 1 or 2-year measurement and follow-up (N=280 and 274 respectively).

Figure 7 Difference in BMI z-score between intervention and control



Abbreviations: BMI=body mass index

4.4.3.5 Physical activity-related results

The results of the analysis of physical activity-related outcomes are presented in **Table 40**. These results were only available for the Year 1 timepoint (Taylor *et al*, 2006). The results showed that after adjusting for high baseline activity rates, physical activity was greater in intervention compared with control children based on average accelerometry (difference in mean change counts/minute: 1.28; 95% CI: 1.11, 1.47) and time spent in moderate activity (ratio: 1.07; 95% CI: 1.03, 1.12).

Table 40 Physical activity results: APPLE

Citation	Outcomes	Adjustments	Ratio I:C (95% CI)		
			1 year	2 years	Follow-up
Taylor *et al* 2006	*Average accelerometry count*	*Age, sex, baseline difference and school*	*1.28 (1.11, 1.47)*	-	-
	Time in sedentary activity	Age, sex, baseline difference and school	0.91 (0.85, 0.97)	-	-
	Time in light activity	Age, sex, baseline difference and school	1.14 (0.99, 1.32)	-	-
	Time in moderate activity	*Age, sex, baseline difference and school*	*1.07 (1.03, 1.12)*	-	-
	Time in vigorous activity	Age, sex, baseline difference and school	1.42 (0.87, 2.31)	-	-
	Time in moderate/vigorous activity	*Age, sex, baseline difference and school*	*1.10 (1.02, 1.18)*	-	-

Abbreviations: C = control; CI = confidence interval; I = intervention
Note: Statistically significant results in favour of the intervention are shown in italics.

4.4.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for the APPLE intervention is provided in **Table 41**.

Table 41 Dimensions of evidence for the APPLE study

Dimension	Definition
Strength of evidence	
Level	The primary studies were Level III-1cluster non-randomised controlled trials.
Quality	The studies were high quality controlled trials with standardised assessment
Statistical precision	The confidence intervals around the estimates of risk difference for weight related outcomes were narrow.
Size of effect	There was a significant difference in change in BMI z score in the intervention group. The risk difference for one, two and three-year follow-up was RD -0.09 (-0.18, -0.01), RD -0.26 (-0.32, -0.21) and RD -0.17 (-0.25, -0.08).
Relevance of evidence	The study presents BMI z score rather than BMI; however BMI z score is still clinically relevant. The studies were conducted in NZ and therefore are applicable in terms of population characteristics and implementation.

Source: NHMRC 2000b.

4.4.5 Translation of results for economic analysis

This study does not provide results in terms of absolute BMI; results are presented as z scores and thus cannot be simply transferred for use in an economic model. As noted in Taylor *et al* (2007), translating from BMI z score to BMI is difficult due to variations in age and heights of children. However, they state that if an assumption is made that a child is of median height, the difference of

0.26 BMI z score seen in their analysis would equate to approximately a difference of 0.5 BMI for a 7-year-old child and 0.7 BMI for an 11-year-old child. The BMI z-score results are presented in **Table 42**. Corresponding changes in BMI have been estimated based on the abovementioned approximation.

Table 42 BMI results for Intervention 4: APPLE

Country	Setting	Category	Age (years)	Ethnicity	Mean difference in change in BMI Intervention – control (kg/m²)		Mean difference in change in BMI z-score Intervention – control	
					1 year	2 years	1 year	2 years
New Zealand	Primary school/community	PA/N	5-12 years	Caucasian: ~82% Māori: ~17% Pacific islanders: <1%	-0.2	-0.4	-0.1	-0.2

Note: statistically significant results are shown in bold.
Abbreviations: BMI=body mass index; N=nutrition; PA=physical activity.

4.5 INTERVENTION 5: CHANGING DRINKING BEHAVIOURS IN PRIMARY SCHOOL CHILDREN

The consumption of carbonated beverages has been identified as a contributing factor to excess weight gain in children (James *et al*, 2004). In the US, children who drink one regular carbonated drink a day have been found to average 10% more total energy intake than those children who don't (Hamack et al, 1999). Consequently, the increased consumption of water and reduced consumption of carbonated beverages has become a public health goal.

During the scoping search two interventions were identified which addressed this issue. A study by James *et al* (2004), titled the Christchurch Obesity Prevention Program in Schools (CHOPPS) study, and a study by Muckelbauer *et al* (2009) which examined the promotion of drinking water in schools for overweight prevention.

4.5.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of public health obesity programs that examine changing drinking behaviours in primary school children. The specific research question to be answered is as follows:

Does a change in drinking behaviour in primary school children prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

In order to answer this research question, an extensive literature search was conducted.

4.5.2 Literature search

In order to identify studies relevant to changing drinking behaviour in primary school children, searches of Embase.com (covering the EMBASE and Medline databases) and the Cochrane Library were conducted. The focus was on the reduction of carbonated beverage consumption and increased water intake. Search terms used included those relating to the intervention (e.g. 'carbonated beverage', 'soda'), obesity ('obesity', 'bmi') and two of the lead authors of the relevant papers identified during the scoping search. In addition, the reference lists of identified studies were checked for additional studies. Details of the search and search results are presented in **Table 43**.

Table 43 Literature search for changing drinking behaviour of primary school children: Embase.com and Cochrane Library

Search location	Search string	Citations
Embase.com (EMBASE and Medline) 25/02/2010	1. 'muckelbauer r.'/au 2. 'carbonated beverage':ab,ti OR 'soda':ab,ti OR 'soft drink':ab,ti OR 'sugar-sweetened':ab,ti 3. 'obesity':ab,ti OR 'bmi':ab,ti OR 'body mass index':ab,ti OR 'weight gain':ab,ti 4. #2 AND #3 5. 'james j.'/au 6. #3 AND #5 7. #1 OR #4 OR #6	311
Cochrane Library (Trials Register) 25/02/2010	1. 'carbonated beverage' OR 'soda' OR 'soft drink' OR 'sugar sweetened':ti:ab:kw 2. 'obesity' OR 'BMI' OR 'Body mass index' OR 'weight gain':ti,ab,kw 3. #1 AND #2 4. Muckelbauer R:au 5. James J:au 6. #5 AND #2 7. #3 OR #4 OR #6	28
Subtotal		*339*
Manual searching of reference lists	'carbonated beverage' OR 'soda' OR 'soft drink'	0
TOTAL		*339*

Abbreviations: BMI = body mass index.

The following exclusion criteria were applied to the 339 identified citations:

1. Duplicate citation – excludes multiple citations for the same publication
2. Not a clinical study – excludes publications which do not report the results of an original study conducted in humans (ie, excludes animal studies, in vitro studies, narrative reviews)
3. Wrong population/intervention – excludes studies which do not describe and/or assess the a study examining an intervention for reduction in carbonated beverages
4. Wrong outcomes- does not report a relevant weight-based outcome

Applying the exclusion criteria resulted in the identification of six publications relating to changing drinking behaviour in primary school children. All of these citations were identified via the search of Embase.com and Cochrane Library databases. The results of the application of exclusion criteria are presented in **Table 44**.

Table 44 Exclusion of citations for changing drinking behaviour of primary school children

Criterion	Citations
TOTAL IDENTIFIED	339
Duplicate citation	50
Not a clinical study	79
Wrong population/intervention	200
Wrong outcomes	4
TOTAL REMAINING	6

Details of the six identified citations are presented in **Table 45** . It should be noted that two citations by James *et al* (2004 and 2007) relate to the same study, and three citations by Muckelbauer *et al* (2009) relate to the same study. The publication by James *et al* (2004) presents results at one year follow-up, whereas the study by James *et al* (2007) presents results at three years follow-up. One of the studies by Muckelbauer *et al* (2009b) describes the process evaluation of the study and the other two describe the results of the study.

The study by Sichieri *et al* (2008) was a cluster randomised trial on prevention of excessive weight gain by discouraging students from drinking sodas. Participants were 1140, 9–12-year-old fourth grade students (N=1043). The main outcome was the change in BMI (BMI=weight (kg)/height (m^2)), measured at the beginning and at the end of the school year. There was a decrease in the daily consumption of carbonated drinks in the intervention compared to control however no significant difference in reduction of BMI (p=0.33). Among those students overweight at baseline, the intervention group showed greater BMI reduction (0.4kg/m^2 compared with 0.2kg/m^2 in the control group (P=0.11). The only statistically significant difference was among girls overweight at baseline (P=0.009). This study will not be discussed further in the results.

Table 45 Included citations:

Citation details	Included
James J, Thomas P, Cavan D, and Kerr D. (2004) Preventing childhood obesity by reducing consumption of carbonated drinks: Cluster randomised controlled trial. British Medical Journal 328:1237-1239.	✓
James J, Thomas P, and Kerr D. (2007) Preventing childhood obesity: two year follow-up results from the Christchurch obesity prevention programme in schools (CHOPPS). BMJ (Clinical research ed.) 335:762.	✓
Muckelbauer R, Libuda L, Clausen K, Toschke AM, Reinehr T, and Kersting M. (2009a) Promotion and provision of drinking water in schools for overweight prevention: randomized, controlled cluster trial. Pediatrics 123:e661-e667.	✓
Muckelbauer R, Libuda L, Clausen K, and Kersting M. (2009b) Long-term process evaluation of a school-based programme for overweight prevention. Child: Care, Health and Development 35:851-857.	
Muckelbauer R, Libuda L, Clausen K, Reinehr T, and Kersting M. (2009c) A simple dietary intervention in the school setting decreased incidence of overweight in children. Obesity Facts 2:282-285.	✓
Sichieri R, Paula TA, de Souza RA, and Veiga GV. (2008) School randomised trial on prevention of excessive weight gain by discouraging students from drinking sodas. Public health nutrition 12:197-202.	

4.5.3 Results

The following section provides details of the two interventions, characteristics of the included studies, the baseline characteristics of the intervention and control groups, and results. As the interventions were different, with one examining an education programme to reduce carbonated beverage consumption, and the other investigating the promotion of drinking water through environmental change, they will be discussed independently.

4.5.3.1 Intervention characteristics

CHOPPS

The Christchurch Obesity Prevention Project in Schools (CHOPPS) took place between 2001 and 2002 over one school year. The study took place in six junior schools in children aged 7 to 11 years. The main objective was to discourage the consumption of soft drink and encourage a healthy balanced diet. Teachers assisted in a delivering a one hour session each class of each term. The initial session focused on the balance of good health and promotion of drinking water. This included giving each class a tooth immersed in a carbonated beverage to assess its effect on dentition. The second and third sessions comprised a music competition; with students challenged to produce a song or a rap with a healthy message. The final session involved presentations of art and a classroom quiz.

Muckelbauer *et al* 2009

The other primary study was the promotion and provision of drinking water in primary schools to prevent overweight in Germany (Muckelbauer *et al* 2009a). The study was conducted between 2006 and 2007 and involved second and third grade children from 32 elementary schools. Water fountains were installed and teachers presented four prepared classroom lessons in the intervention schools to promote water consumption. Control groups did not receive any intervention.

4.5.3.2 Study characteristics

The main characteristics of the two studies assessing changing drinking behaviours in primary school children are summarised in **Table 46**.

CHOPPS

The CHOPPS study was a cluster, randomised controlled trial conducted in Christchurch, England. Clusters were randomised according to a random number table, with blinding to schools or classes. The population consisted of 644 children aged 7-11 years, from 29 classes, 15 in the intervention and 14 in the control group.

Muckelbauer *et al* 2009

The Muckelbauer *et al* (2009a) study was also a randomised, cluster controlled trial. The study population comprised children attending the second and third grades of elementary schools in deprived neighbourhoods of two neighbouring cities, Dortmund and Essen, in Germany. Data was collected and analysed on up to 2950 children. The prevalence of overweight and BMI SD scores were determined before and after the intervention.

Table 46 Study characteristics: changing drinking behaviour in primary school children

Citation	Study type	Population	Intervention/ comparator	Outcomes
James *et al* (2004) James *et al* (2007)	Cluster, randomised controlled trial Primary-school setting 6 schools, 29 classes 1 and 3 year follow-up	N=644 7-11 year-old children Mean age: 8.7 ±0.9 years Gender (%): Male: 324 (50.3); Female: 320 (48.2) Overweight (%): 52 (8.1); Obese (%): 29 (4.5%)	Intervention classes received education sessions on reducing carbonated beverage consumption and changing dietary habits Control classes did not receive any intervention	Drink consumption *Weight* *Waist circumference z score* *BMI z score* *Prevalence of overweight and obese children at 1 and 3 years follow-up*
Muckelbauer *et al* (2009a) Muckelbauer *et al* (2009b) Muckelbauer *et al* (2009c)	Randomised, controlled-cluster trial Primary-school setting 32 schools 1 year intervention	N= 2950 Mean age: 8.3±0.7 years Male gender (%): 1482 (50.2) With migration background (%): 1306 (44.3) Overweight (%):723 (24.5)	Intervention schools had water fountains installed and teachers presented four classroom lessons Control schools did not receive any intervention	*Prevalence of overweight* Beverage consumption (number of glasses) *BMI z scores (SDS)* Daily water flow

Abbreviations: BMI = body mass index; SDS = standard deviation score
Note: Outcomes which are considered relevant to this review, and which are described in the results section, are shown in italics.

4.5.3.3 Baseline participant characteristics

CHOPPS

Both the intervention and control groups in the CHOPPS study were similar at baseline for distributions of age, sex, consumption of carbonated drinks, and percentage overweight or obese (**Table 47**). Body mass index was measured in 602 (93.5%) children at six months and 574 (89.1%) children at 12 months. No further information on baseline characteristics was provided.

Table 47 Baseline characteristics in the CHOPPS study

Characteristic	Girls		Boys	
	Control group (n=164)	Study group (n=156)	Control group (n=155)	Study group (n=169)
Mean (SD) age (years)	8.7 (0.9)	8.7 (1.0)	8.6 (0.9)	8.7 (0.8)
No (%) overweight	13 (20	13 (19)	13 (18)	13 (21)
No (%) obese	8 (12)	7 (10)	7 (10)	7 (11)
Mean (SD) consumption of carbonated drinks: No of glasses in three days	1.7 (2.0) (N=5)	2.2 (2.6) (N=77)	1.8 (2.0) (N=89)	1.6 (2.0) (N=91)

Source: James *et al* (2004), Table 2
Abbreviations: SD = standard deviation

<u>Muckelbauer *et al* 2009</u>

In the water promotion and provision study, the intervention group and control group did not differ in baseline characteristics regarding gender, age, migration background, prevalence of overweight, or BMI SDS (**Table 48**). The mean age in the intervention and control group was 8.26 ± 0.73 and 8.34 ± 0.76, respectively. There were 23.4% and 25.9% of participants classified as overweight at baseline, in the intervention and control group, respectively. Follow-up measurements were conducted 250 ± 8 days after baseline assessment, on average. The follow-up periods did not differ between groups (Muckelbauer *et al* 2009a).

Table 48 Baseline characteristics and outcome variables for analysed participants in the intervention and control groups

Characteristic	Intervention	Control	*P*
Participants, *N*	1641	1309	
Schools, *N*	17	15	
Classes, *N*	85	75	
Participants per school, mean ± SD	97 ± 29	87 ± 34	
Age, mean ± SD, y	8.26 ± 0.73	8.34 ± 0.76	0.050
Male, *n* (%)	824 (50.2)	658 (50.3)	0.405
With migrational background, n (%)	691 (42.1)	615 (47.0)	0.596
Body weight status			
Overweight, n (%)	384 (23.4)	339 (25.9)	0.209
BMI SDS, mean ± SD	0.23 ± 1.06	0.30 ± 1.13	0.137
Beverage consumption, mean ± SD			
glasses per day			
Water	3.0 ± 2.7	3.4 ± 2.7	0.064
Juice	1.5 ± 1.8	2.71 ± 31.6	0.032
Soft drinks	1.3 ± 1.7	1.31 ± 31.7	0.771

Source: Muckelbauer *et al* (2009) Table 1, page e664
Abbreviations: BMI = body mass index; IG = intervention group; CG = control group; SD = standard deviation

4.5.3.4 Weight-related results

<u>CHOPPS</u>

Table 49 shows the change in prevalence of overweight and obesity in the CHOPPS study according to 1990 British centile charts, with children above the 91st centile classed as overweight. At 12 months follow-up, the mean percentage of overweight and obese children increased in the control

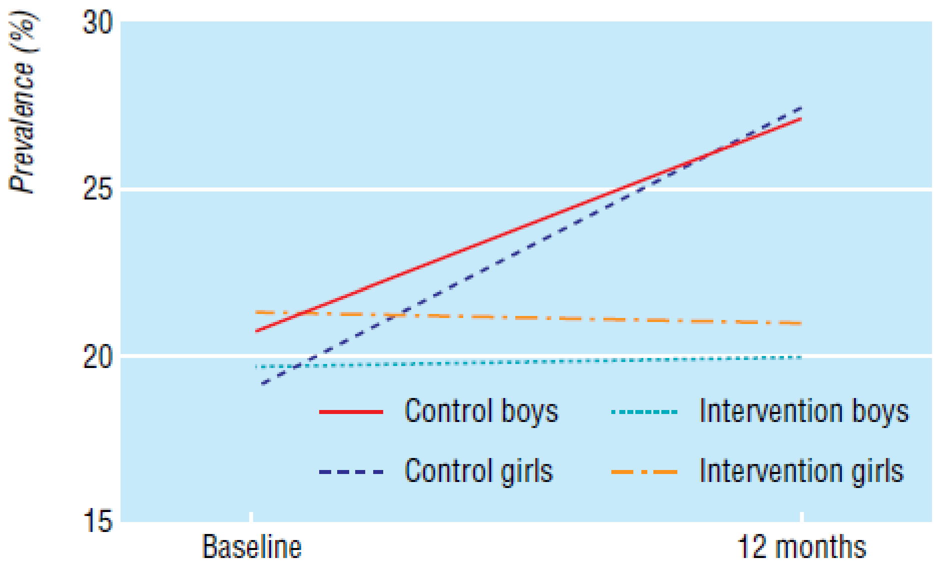
clusters by 7.5%, compared with a decrease in the intervention group of 0.2% (mean difference 7.7%, 2.2% to 13.1%; risk difference 9.8%, 1.83% to 17.8%) (James *et al* 2004; James *et al* 2007). However, three years after baseline the difference between groups was smaller and no longer significant (mean difference not reported; risk difference 4.6%, -4.3% to 13.5%). The mean change in prevalence of overweight and obese children from baseline to follow-up at 12 months according to clusters is also presented in **Figure 8**.

Table 49 Prevalence of overweight at 12 months and 3 years after baseline

	Control (%)	**Intervention (%)**	**Odds ratio (95% CI)**	**P value**	**Risk difference[a] (95% CI)**
Baseline (n=486)	20.6	17.4	0.79 (0.50 to 1.26)	P=0.33	3.2% (-4.23% to 10.6%)
After 12 months (n=474)	28.5	18.7	0.58 (0.37 to 0.89)	P=0.01	9.8% (1.83% to 17.8%)
After 3 years (n=434)	30.2	25.6	0.79 (0.52 to 1.21)	P=0.28	4.6% (-4.3% to 13.5%)

Source: James *et al* (2007) Table 2, page 3
Abbreviations: CI, confidence interval

Figure 8 Mean change in prevalence of overweight and obese children from baseline to follow-up at 12 months according to clusters



Source: James *et al* (2004), Figure 2

Table 50 shows the body mass indices, z scores (SDS), and percentage of children above the 91% centile at baseline and 12 months and change in anthropometric measurements over 12 months. The intra-cluster correlation coefficient for BMI was 0.01 (95% confidence interval − 0.01 to 0.06). After 12 months there was no significant change in the difference in body mass index (mean difference 0.13, 95% CI −0.08 to 0.34) or z score (mean difference 0.04, 95% CI: −0.04 to 0.12).

Table 50 Body mass indices, z scores (standard deviations scores), and mean percentages >91st centile at baseline and 12 months

Characteristic	Control clusters (n=14)	Intervention clusters (n=15)	Mean difference (95% CI)
Baseline [a]			
Mean (SD) BMI	17.6 (0.7)	17.4 (0.6)	0.0 (−0.5 to 0.5)
Mean (SDS) z score [b]	0.47 (0.2)	0.50 (0.23)	−0.03 (−0.2 to 0.13)
Mean percentage >91st centile (z score >1.34)	19.4 (8.4)	20.3 (6.3)	−0.9 (−6.6 to 4.8)
12 months [a]			
Mean (SD) BMI	18.3 (0.8)	17.9 (0.7)	0.4 (−0.2 to 1.0)
Mean (SDS) z score	0.60 (0.19)	0.48 (0.23)	0.12 (−0.04 to 0.28)
Mean percentage >91st centile (z score >1.34)	26.9 (12.3)	20.1 (6.7)	6.8 (−0.7 to 14.3)
Change over 12 months [c]			
Mean (SD) BMI	0.8 (0.3)	0.7 (0.2)	0.1 (−0.1 to 0.3)
Mean (SDS) z score	0.08 (0.13)	0.04 (0.07)	0.04 (−0.04 to 0.12)
Mean percentage >91st centile	7.5 (8.0)	−0.2 (6.3)	7.7 (2.2 to 13.1)

Source: James *et al* (2004), Table 3
Abbreviations: BMI, body mass index; CI, confidence interval; SD, standard deviation
[a]Based on maximum number of children in each cluster.
[b]Age and sex specific body mass index converted to standard deviation score using revised 1990 reference standards.
[c] Based on children with data at baseline and 12 months.

Muckelbauer *et al* 2009

In the water provision and promotion study (Muckelbauer *et al* 2009a), the prevalence of overweight at the follow-up assessment was 23.5% in the intervention group and 27.8% in the control group (**Table 51**). The risk of overweight at the follow-up assessment was significantly reduced in the intervention group compared with the control group, as indicated by an odds ratio of 0.69 (95% CI: 0.48-0.98). The intracluster correlation coefficient for the prevalence of overweight was 0.011, indicating more clustering of final results than expected. BMI SDS changes from baseline to the follow-up assessment were 0.005 ± 0.289 in the intervention group and 0.007 ± 0.295 in the control group. The estimated group difference in BMI SDS, adjusted for BMI SDS at baseline, was not significant -0.004 (P=0 .829).

Table 51 Intervention effect on the prevalence of overweight at follow-up assessment

Group	Crude change, n (percentage points) [a]	Adjusted Risk, Odds Ratio (95%CI)[b]	*P*
Intervention	1 (0.06)	0.69 (0.48-0.98)	.04
Control	25 (1.91)	1.00 (reference)	

Overweight was defined according to the recommendations of the International Obesity Task Force.[23]
[a]Unadjusted change from baseline to the follow-up assessment in the prevalence of overweight on an individual level.
[b]Risk of overweight at the follow-up assessment, with adjustment for the prevalence of overweight at baseline and clustering according to school.

4.5.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for the two included studies examining interventions aimed at changing drinking behaviour in primary school children is provided in **Table 52**.

Table 52 Dimensions of evidence for changing drinking behaviour in primary school children

Dimension	Definition
Strength of evidence	
Level	Both studies were Level II cluster randomised controlled trials.
Quality	The studies were high quality controlled trials with standardised assessment measures of obesity. Blinding was not possible given the nature of the interventions. There was some (~33%) loss to follow-up three years after baseline in the CHOPPS study.
Statistical precision	In the CHOPPS study, for the prevalence of overweight, the confidence intervals around the odds ratio and risk difference were moderate at one year follow-up 0.58 (0.37 to 0.89) and wide at three year follow-up 0.79 (0.52 to 1.21). In the Muckelbauer *et al* (2009a) study, the confidence intervals around the odds ratio estimates for weight related outcomes were narrow. The p-value for the adjusted risk odds ratio was p=0.04. Baseline variables were generally comparable between the control and intervention groups in both studies, and were adjusted for in both analyses.
Size of effect	In the CHOPPS study, there was a significant difference in the mean percentage of overweight and obese children at 12 months follow-up (mean difference 7.7%, 95% CI 2.2% to 13.1%), but not at three years follow-up (risk difference 4.6%, -4.3% to 13.5%). In the Muckelbauer *et al* (2009[a]) study, the risk of overweight at the follow-up assessment was significantly reduced in the intervention group, compared with the control group, as indicated by an odds ratio of 0.69 (95% CI: 0.48-0.98).
Relevance of evidence	The primary weight-based outcome in the CHOPPS study was the number of overweight and obese children. The prevalence of overweight and BMI SD scores were both assessed in the Muckelbauer *et al* (2009a) study. The CHOPPS study was conducted in the UK and the Muckelbauer study in Germany. Whether or not these populations are generalisable to NZ is uncertain.

Source: NHMRC 2000b.

4.5.5 Translation of results for economic analysis

Result in terms of BMI were available only for the CHOPPS study. These showed no significant difference between intervention and control and are presented in **Table 53**.

The primary results from the CHOPPPS study were presented as the mean difference in percentage of overweight and obese children in the intervention and control group. There was a statistically significant difference between the two groups at 12 months (mean difference 7.7%; 95% CI: 2.2% to 13.1%), but the effect appeared to diminish over time and was no longer significant at three years follow-up (mean difference 4.6%; 95% CI: –4.3% to 13.5%).

Prevalence of overweight was the primary outcome in the Muckelbauer *et al* (2009) study. There was a significant reduction in the risk of being overweight in the intervention group compared to the control group (adjusted OR: 0.69; 95%CI: 0.48-0.98; p<0.04).

Table 53 BMI results for Intervention 5: CHOPPS

Country	Setting	Category	Age (years)	Ethnicity	Mean difference in change in BMI Intervention – control (kg/m²)	Mean difference in change in BMI z-score Intervention – control
					1 year	1 year
UK	Primary school	N	7-11 years	Not stated	-0.1	-0.04

Note: statistically significant results are shown in bold.
Abbreviations: BMI=body mass index; N=nutrition; PA=physical activity.

4.6 INTERVENTION 6: SHAPE UP SOMERVILLE

'Shape up Somerville' was an obesity prevention project aimed at increasing physical activity and healthy food availability for children in the community. The study was conducted in Massachusetts, US.

This intervention was identified during the scoping search via a search of the medical literature and through advice from content experts.

4.6.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of Shape up Somerville in terms of the prevention of obesity. The specific research question to be answered is as follows:

Does the obesity prevention intervention 'Shape up Somerville' prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

In order to answer this research question, an extensive literature search was conducted.

4.6.2 Literature search

In order to identify studies relevant to the assessment of the Shape up Somerville intervention, searches of Embase.com (covering the EMBASE and Medline databases) and the Cochrane Library were conducted. Search terms used included those relating to the intervention (ie 'Shape up Somerville') and two of the lead authors identified during the scoping search. In addition, the grey literature and reference lists of identified studies were checked for additional studies. Details of the search and search results are presented in **Table 54**.

Table 54 Literature search for Shape up Somerville: Embase.com and Cochrane Library

Search location	Search string	Citations
Emabse.com (EMBASE and Medline) 26/03/2010	1. 'Shape up Somerville' 2. 'Economos C.D'/au 3. 'Goldberg J.P'/au 4. 'obesity'/exp OR 'obesity' OR 'body mass index'/exp OR 'body mass index' OR 'bmi' OR 'weight gain'/exp OR 'weight gain' 5. #3 AND #4 6. #1 OR #2 OR #5	36
Cochrane Library (Trials Register) 26/03/2010	1. Shape up Somerville in Clinical Trials 2. Economos C.D:au in Clinical Trials 3. Goldberg J.P:au in Clinical Trials	2
Subtotal		*38*
Grey literature search		0
Manual searching of reference lists		1
TOTAL		*39*

The following exclusion criteria were applied to the 39 identified citations:

1. Duplicate citation – excludes multiple citations for the same publication

2. Not a clinical study – excludes publications which do not report the results of an original study conducted in humans (ie, excludes animal studies, in vitro studies, narrative reviews)

3. Wrong population/intervention – excludes studies which do not describe and/or assess the Shape up Somerville project in children

4. Wrong outcomes- does not report a relevant weight-based outcome

Applying the exclusion criteria resulted in the identification of two publications relating to the Shape up Somerville project. One of these citations was identified via the search of Embase.com and one was identified via the reference list search. The results of the application of exclusion criteria are presented in **Table 55**.

Table 55 Exclusion of citations for Shape up Somerville

Criterion	Citations
TOTAL IDENTIFIED	39
Duplicate citation	1
Not a clinical study	7
Wrong population/intervention	27
Wrong outcomes	2
TOTAL REMAINING	2

Details of the two identified citations are presented in **Table 56**. It should be noted that one citation (Economos and Curtatone 2010) provides background information on how the Shape up Somerville programme was developed, while the remaining citation (Economos *et al* 2007) provides data regarding the results of the programme during the first year. It is important to note that although the study was conducted over a three-year period, only the results relating to the first year of the programme (which were obtained at 8 months) were found during this review.

Table 56 Included citations: Shape up Somerville

Citation details	Included
Economos CD, Hyatt RR, Goldberg JP, Must A, Naumova EN, Collins JJ, and Nelson ME. (2007) A community intervention reduces BMI z-score in children: Shape up Somerville first year results. Public Health Public Policy 15:1325-1336.	✓
Economos CD and Curtatone JA. (2010) Shaping up Somerville: A community initiative in Massachusetts. Preventive Medicine 50:S97-S98.	

4.6.3 Results

The following section provides details of the characteristics of the intervention, the included study, the baseline characteristics of the intervention and control groups and two sets of results: (i) results of the pivotal weight-related outcomes for this review; and (ii) results of the supportive physical activity-related outcomes.

4.6.3.1 Intervention characteristics

Figure 9 shows a summary of the components of the Shape up Somerville intervention. Many groups and individuals within the community (including children, parents, teachers, school food service providers, city departments, policy makers, healthcare providers, before- and after-school programs, restaurants, and the media) were engaged in the intervention. The intervention activities were developed to influence every part of the child's day. The aim of the intervention was to increase energy expenditure up to 125 kcal/day beyond the increases in energy expenditure that normally accompany growth.

Figure 9 Components of the Shape up Somerville intervention

Before school	After school
Breakfast program	SUS after-school curriculum
Increase fresh fruits, low-fat milk, whole grains	Increase physical activity
Taste tests	Cooking lessons
Adult monitors	Promote healthy snacks
Walk to School Campaign	Farm trips
Walking to school bus	Professional development for program staff
Traffic calming tactics	Walk from school campaign (see Walk to school campaign)
Walking contests	
International Walk to School Day	**Home**
Safe routes to school maps	Parent outreach and education
During school	Bi-monthly newsletter
Professional development (nutrition and physical activity) for all school staff	Free and reduced coupons
	Family events
School health office	Parent nutrition forums
Anthropometric equipment	Child's "Health Report Card" mailed each year
Height/weight data collection	**Community**
School food service	SUS Community Advisory Council
Increase whole grains, fruits and vegetables, low-fat dairy	Ethnic-minority group collaborations
Healthier a la carte snacks	Support from local "community champions"
Monthly taste tests	Walking/pedestrian trainings
New vegetarian recipes	City Employee Wellness Campaign
Ice cream sold only one day/wk	"Farmers Market" initiative
New equipment to enhance food presentation	Local physician and clinic staff training
SUS classroom curriculum	SUS "approved" restaurants
10-minute daily "Cool Moves"	City ordinances on walkability/bikeability
30-minute nutrition and physical activity lesson (~1 week)	Annual SUS 5 K Family Fitness Fair
Fun and healthy giveaways	Regular local media placement
Enhanced recess	Monthly SUS column in the *Somerville Journal*
New play equipment/game cards	Collaborated on City of Somerville health events
School "wellness" policy development	Resource guides
School food service	Physical Activity Guide
Classroom environment	Healthy Meeting Guide
Physical education environment	Health Message Translations Booklet
Structured day environment	
After-school environment	
School health environment	
To/from school environment	

Source: Economos et al (2007), Table 1, page 1328
Abbreviations: SUS = Shape up Somerville.

4.6.3.2 Study characteristics

The main characteristics of the included study assessing the Shape up Somerville intervention are summarised in **Table 57**. Shape up Somerville was a non-randomised controlled trial conducted over 3-years (2002-2005) in three culturally diverse urban cities in Massachusetts, US. Somerville was the intervention community and two socio-demographically-matched cities were control communities. Children (n = 1178) in grades one to three attending public primary schools participated in the intervention which was designed to bring the energy equation into balance by increasing physical activity options and the availability of healthy foods within the before-, during-, afterschool, home, and community environments. Change in BMI z-score was the primary health outcome of the study.

Table 57 Study characteristics of the Shape up Somerville Intervention

Citation	Study type	Population	Intervention/ comparator	Outcomes
Economos *et al* 2007	Non-randomised controlled trial Community and school-based 3 urban cities in Massachusetts 1 intervention city (Massachusetts), 2 control cities (location not reported) 3 years duration (NB: published results only available for one year)	N= up to 1178 Mean age: 7.6 ± 1.0 years Gender (female): 605 (51.4%) Ethnicity (%): Caucasian: 523 (44.4); African-American: 186 (15.8); Hispanic: 152 (12.9); Asian: 65 (5.5); Other: 215 (18.3) Over one third (36% to 49%) of children were either at risk for overweight or overweight at pre-intervention.	Shape up Somerville vs. no intervention Shape up Somerville involved multiple physical activity and nutrition-based activities and promotions in the school and community environment.	Height (cm) Weight (lbs) *BMI-z score*

Abbreviations: BMI = body mass index
Note: Outcomes which are considered relevant to this review, and which are described in the results section, are shown in italics.

4.6.3.3 Baseline participant characteristics

As can be seen in **Table 58**, most baseline characteristics were similar for the intervention and control populations. The children included in the Shape up Somerville study were from culturally diverse backgrounds with the majority being Caucasian (~44%), while ~16% were African-American and ~13% Hispanic. Children were considered to predominantly come from middle to lower class backgrounds (Economos *et al* 2007). Most children were 7-9 years of age and all were attending grade 1, 2 or 3. In the intervention group, 24.4% of children were classified as having a BMI >95th percentile, compared to 20% in control group one and 25.4% in control group two. It is important to note that parent education was higher, on average, in the intervention community than in either of the control communities. In addition, a significantly higher percentage of children in the control groups had televisions in their bedrooms and consumed less than two pieces of fruit per day at baseline.

Table 58 Baseline characteristics: Shape up Somerville

	Intervention	Control 1	Control 2
n	385	561 [a]	232
Age (years)			
Mean (±SD)	7.92 (1.061)	7.34 (0.944) [a]	7.8 (1.047)
Grade (%)			
1	32.2	47.4 [a]	43.5 [a]
2	29.6	23.7 [a]	25.4
3	38.2	28.9 [a]	31
Ethnicity (%)			
White	49.6	37.8 [a]	51.7
African American	7.5	25.1 [a]	6.9
Hispanic	18.2	11.8 [a]	22.8
Asian	9.1	2.3 [a]	7.3
Other	15.6	23 [a]	11.2
Non-English primary home language (%)	33	15.9 [a]	35.3
Weight-category (%)			
<85th percentile BMI	55.6	63.6 [a]	56.9
85th to 95th percentile BMI	20.0	16.4	17.7
>95th percentile BMI	24.4	20.0	25.4

Source: Economos *et al* (2007), Table 2, page 1330
Abbreviations: BMI= body mass index; SD = standard deviation;
[a] Significantly different from intervention by t test (age) and χ^2 (all others)

4.6.3.4 Weight-related results

The pre and post intervention BMI z-score measures and the mean change over the intervention period are shown in **Table 59**. **Table 60** presents the impact of the intervention on the change in BMI z-score in the intervention and control communities. The average change in BMI z-score in the intervention community was –0.1307 [95% confidence interval (CI), –0.1836 to –0.0778; p= 0.02] compared with Control 1 and –0.1048 (95% CI, –0.1541 to –0.0555; p =0.02) compared with Control 2 after controlling for baseline BMI z-score, sex, grade, age, ethnicity, primary language spoken at home, school, and community. When the controls were pooled, the average change in BMI z-score was –0.1005 (95% CI, –0.1151 to –0.0859; p = 0.001) in the intervention community compared with the control communities, after controlling for the same covariates as above.

Authors reported that baseline BMI z-score was included in the regression for two reasons. Firstly, subjects with larger positive baseline BMI z-scores are likely to experience greater weight change than those who have normal, average, or low BMI z-score. Second, there is a general statistical problem with regression to the mean in a pre-post study design. Even if the intervention is not effective, a second measurement of BMI among a large group is likely to show some post intervention change toward the mean score (i.e., lower post score among children with higher initial weight). The study found no significant effects due to sex, grade, age, ethnicity, and primary language spoken at home after adjusting for baseline BMI z-score.

Table 59 Unadjusted pre- and post-intervention BMI z-score by community and sex

	Intervention (n=385)		Control 1 (n=561)		Control 2 (n=232)	
	Female	Male	Female	Male	Female	Male
n	190	195	298	263	117	115
Pre BMI z-score						
Mean years (±SD)	0.782 (1.100)	0.918 (1.021)	0.617 (1.060)	0.777(0.999)	0.679(1.055)	1.132 (0.903)
Post BMI z-score						
Mean (±SD)	0.755 (1.070)	0.882 (1.022)	0.615 (1.065)	0.768 (0.995)	0.688 (1.055)	1.113 (0.926)
Change in BMI z-score						
Mean (±SD)	–0.027(0.356)	–0.036 (0.284)	–0.002 (0.265)	–0.009 (0.289)	–0.009 (0.294)	–0.018 (0.253)

Source: Economos et al (2007), Table 5, page 1331
Abbreviations: BMI = body mass index; SD = standard deviation

Table 60 Results of multiple regression model of change in BMI z-score pre- and post-intervention (N=1178)

Variable	Control 1	Control 2	Control 1 + 2
Intervention (Somerville vs.)	– 0.1307 (0.0203)	– 0.1048(0.0235)	– 0.1005(0.0011)
Baseline BMI z-score	–0.0328 (0.3466)	–0.0448 (0.2204)	–0.031 (0.1516)
Sex	0.00003 (0.9963)	–0.0058 (0.4323)	–0.0022 (0.6475)
Grade	–0.0304 (0.3389)	–0.0228 (0.5026)	–0.0208 (0.3249)
Age (months)	0.0013 (0.5409)	0.0011(0.6276)	0.0007 (0.6510)
Ethnicity	0.0009 (0.0251)	0.0052 (0.5024)	0.0027 (0.3540)
Primary language spoken at home	0.0079 (0.6279)	0.0076 (0.6837)	0.0129 (0.3255)
Constant	–0.0099 (0.8986)	–0.0322 (0.6862)	–0.0136 (0.8277)

Source: Economos *et al* (2007), Table 6, page 1332
Abbreviations: BMI = body mass index

4.6.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for the Shape up Somerville intervention is provided in **Table 61**.

Table 61 Dimensions of evidence for the Shape up Somerville study

Dimension	Definition
Strength of evidence	
Level	The primary study was a Level III-2 non-randomized controlled trial with one intervention city (Massachusetts) matched to two socio-demographically similar control cities (not reported).
Quality	The study was a high quality controlled trial with standardised assessment measures
Statistical precision	The confidence interval was narrow and p-values small and significant for the change in BMI z-score (for intervention vs. pooled controls, 95% CI: –0.1151 to –0.0859; p=0.001).
Size of effect	There was a small but significant difference in change in BMI z score between the intervention and control group 1 (–0.1307), control group 2 (–0.1048) and the pooled control groups (–0.1005).
Relevance of evidence	The study presents BMI z score rather than BMI, however BMI z score is still clinically relevant. The intervention was conducted in a culturally diverse population in the US. Whether or not the results can be generalised to the NZ population is uncertain.

Source: NHMRC 2000b.
Abbreviations: BMI = body mass index; CI = confidence interval; NZ = New Zealand; US = United States

4.6.5 Translation of results for economic analysis

While this study does provide results in terms of BMI, these are presented as z scores and thus cannot be simply transferred for use in an economic model. As such, an approximate BMI has been estimated, as shown in **Table 62**.

Table 62 BMI results for Intervention 6: Shape up Somerville

Country	Setting	Category	Age (years)	Ethnicity	Mean difference in change in BMI Intervention – control (kg/m^2)	Mean difference in change in BMI z-score Intervention – control
					1 year	1 year
USA	Primary school	N/PA	7-9 years	Caucasian (~45%)	**-0.05**	**-0.1**

Note: statistically significant results are shown in bold.
Abbreviations: BMI=body mass index; N=nutrition; PA=physical activity.

4.7 INTERVENTION 7 : CHILD AND ADOLESCENT TRIAL FOR CARDIOVASCULAR HEALTH (CATCH)

The Child and Adolescent Trial for Cardiovascular Health (CATCH) was a study that involved the promotion of nutrition, physical activity and discouraged tobacco use by elementary children approximately 8-9 years. The study was conducted in various regions within the US.

This intervention was identified during the scoping search via a search of the medical and grey literature and content experts.

4.7.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of the CATCH in terms of the prevention of obesity. The specific research question to be answered is as follows:

Does the obesity prevention intervention 'CATCH' prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

In order to answer this research question, an extensive literature search was conducted.

4.7.2 Literature search

In order to identify studies relevant to the assessment of the CATCH, searches of Embase.com (covering the EMBASE and Medline databases) and the Cochrane Library were conducted. Search terms used included those relating to the intervention (i.e. 'CATCH') and study terms (i.e. 'study', 'program', 'trial'). In addition, a grey literature search was conducted of internet search engines and HTA websites. A CATCH publication list, updated to 2006, was identified on the University of Texas website. Subsequently, all these references were searched for using Embase.com and the citations and abstracts were added to the potentially included studies database. Details of the search and search results are presented in **Table 63**.

Table 63 Literature search for the CATCH: Embase.com and Cochrane Library

Search location	Search string	Citations
Embase.com (EMBASE and Medline) 17/03/2010	1. 'CATCH':ti OR 'child and adolescent trial for cardiovascular health':ti 2. 'study':ti OR 'program':ti OR 'programme':ti OR 'trial' 3. #1 AND #2	104
Cochrane Library (Trials Register) 17/03/2010	4. 'CATCH' OR "child and adolescent trial for cardiovascular health'	38
Subtotal		*142*
Additional citations retrieved based on CATCH publications list	-	37
TOTAL		*179*

The following exclusion criteria were applied to the 179 identified citations:

1. Duplicate citation – excludes multiple citations for the same publication
2. Not a clinical study – excludes publications which do not report the results of an original study conducted in humans (ie, excludes animal studies, in vitro studies, narrative reviews)
3. Wrong population/intervention – excludes studies which do not describe and/or assess the CATCH
4. Wrong outcomes- does not report a relevant weight-based outcome

Applying the exclusion criteria to the title and abstract resulted in the identification of seven publications that appeared to present weight-related outcomes of CATCH. Another four citations were identified that presented background information on the project, baseline participant characteristics or statistical considerations of the trial. The results of the application of exclusion criteria are presented in **Table 64**.

Table 64 Exclusion of citations for CATCH

Criterion	Citations
TOTAL IDENTIFIED	179
Duplicate citation	47
Not a clinical study	9
Wrong population/intervention	56
Wrong outcomes	56
TOTAL REMAINING	11

Details of the 11 identified citations are presented in **Table 65**. Although 11 publications were identified as potentially relevant for inclusion, after further examination of the full text papers, it became clear that only one study had reported a benefit in a weight-based outcome, and hence qualified for further discussion. Therefore only the Coleman *et al* (2005) study is discussed in the results section below. The remaining studies included background information, presented the wrong outcomes or showed no benefit.

Table 65 Included citations: CATCH

Citation details	Included
Coleman KJ, Tiller CL, Sanchez J, Heath EM, Sy O, Milliken G, and Dzewaltowski DA. (2005) Prevention of the epidemic increase in child risk of overweight in low-income schools: The El Paso coordinated approach to child health. Archives of Pediatrics and Adolescent Medicine 159:217-224.	✓
Dwyer JT, Stone EJ, Yang M, Webber LS, Must A, Feldman HA, Nader PR, Perry CL, and Parcel GS. (2000) Prevalence of marked overweight and obesity in a multiethnic pediatric population: findings from the Child and Adolescent Trial for Cardiovascular Health (CATCH) study. Journal of the American Dietetic Association 100:1149-1156.	
Heath EM and Coleman KJ. (2002) Evaluation of the institutionalization of the coordinated approach to child health (CATCH) in a U.S./Mexico border community. Health education & behavior : the official publication of the Society for Public Health Education 29:444-460.	
Heath EM and Coleman KJ. (2003) Adoption and institutionalization of the Child and Adolescent Trial for Cardiovascular Health (CATCH) in El Paso, Texas. Health promotion practice 4:157-164.	
Kelder SH, Osganian SK, Feldman HA, Webber LS, Parcel GS, Leupker RV, Wu MC, and Nader PR. (2002) Tracking of physical and physiological risk variables among ethnic subgroups from third to eighth grade: The Child and Adolescent Trial for Cardiovascular Health cohort study. Preventive Medicine 34:324-333.	
Kelder SH, Mitchell PD, McKenzie TL, Derby C, Strikmiller PK, Luepker RV, and Stone EJ. (2003) Long-term implementation of the CATCH physical education program. Health education & behavior: the official publication of the Society for Public Health Education 30:463-475.	
Luepker RV, Perry CL, McKinlay SM, Nader PR, Parcel GS, Stone EJ, Webber LS, Elder JP, Feldman HA, Johnson CC, Kelder SH, and Wu M. (1996) Outcomes of a field trial to improve children's dietary patterns and physical activity: The Child and Adolescent Trial for Cardiovascular Health (CATCH). Journal of the American Medical Association 275:768-776.	
Luepker RV, Perry CL, Osganian V, Nader PR, Parcel GS, Stone EJ, and Webber LS. (1998) The child and adolescent trial for cardiovascular health (CATCH). Journal of Nutritional Biochemistry 9:525-534.	
Nader PR, Stone EJ, Lytle LA, Perry CL, Osganian SK, Kelder S, Webber LS, Elder JP, Montgomery D, Feldman HA, Wu M, Johnson C, Parcel GS, and Luepker RV. (1999) Three-year maintenance of improved diet and physical activity: The CATCH cohort. Archives of Pediatrics and Adolescent Medicine 153:695-704.	
Webber LS, Osganian SK, Feldman HA, Wu M, McKenzie TL, Nichaman M, Lytle LA, Edmundson E, Cutler J, Nader PR, and Luepker RV. (1996) Cardiovascular risk factors among children after a 2 1/2-year intervention-The CATCH Study. Preventive Medicine 25:432-441.	
Zucker DM, Lakatos E, Webber LS, Murray DM, McKinlay SM, Feldman HA, Kelder SH, and Nader PR. (1995) Statistical design of the Child and Adolescent Trial for Cardiovascular Health (CATCH): implications of cluster randomization. Controlled Clinical Trials 16:96-118.	

4.7.3 Results

The following section provides details of the characteristics of the intervention, the included study, the baseline characteristics of the intervention and control groups and two sets of results: (i) results of the pivotal weight-related outcomes for this review; and (ii) results of the supportive physical activity-related outcomes.

4.7.3.1 Intervention characteristics

The original CATCH was a multicenter, school-based intervention study promoting healthy eating, physical activity, and non tobacco use by elementary school children. A summary of the components of the intervention program is shown in **Table 66**. Both behavioural and risk factor goals were identified. The primary physiologic goal was to reduce serum total cholesterol levels. Behavioural goals included reduction of dietary fat (total, saturated) and sodium intake, increased physical activity, and prevention of the onset of smoking.

Table 66 CATCH Phase II Intervention Programs

Grade Level	Type of program	Title/reference	Description
3	Classroom curricula	The adventures of hearty heart and friends	**Eating and exercise program**; 15 sessions over five weeks, skills training, modelling by cartoon characters, food preparations, teacher-led
4-5	Classroom curricula	GO for health	**Eating and exercise program; 24 sessions over 12 weeks per grade level**; monitoring, goal setting, skills training, GO foods and activities; teacher-led
5	Classroom curricula	F.A.C.T.S for 5	**Tobacco-use prevention**; 4 sessions in four weeks; aversive aspects of tobacco use, benefits of non-use, social skills training, teacher and peer-led
3-5	Family based	The Home Team Programs	**Eating, exercise and tobacco-use prevention**; four to six activity packets per program for home-based skills development complement curricula
3-4	Family based	Family fun nights	**Eating, exercise and tobacco-use prevention**; two-hour evening activity; health booths healthy snacks, aerobic routines
3-5	School environmental change	Eat smart school nutrition program	**Low-fat and sodium food in school lunch program**; changes in menus, food purchasing, recipe modification, food preparation and production, promotion
3-5	School environmental change	CATCH PE	**Increase moderate to vigorous physical activities in PE program**; greater involvement new fitness activities, warm-up and cool-down
3-5	School environmental change	Smart Choices	**Establishment of non-tobacco use in CATCH schools**; developing school-wide policies

Source: Perry *et al* (1990), Table 1

Since then, the intervention methods implemented in CATCH have been adopted for use in other populations. One such adaptation has been the El Paso CATCH, which has since become the Coordinated Approach to Child Health (Coleman *et al* 2005). The CATCH intervention in this population had four main components, all of which were culturally specific:

- CATCH PE: physical activity interventions
- CATCH EAT SMART: implemented during school meals
- GO for health: a classroom educational curriculum implemented in 3rd-5th grade
- HOME TEAM: implemented in the classroom and at home

This approach differed substantially from the original CATCH in that schools were encouraged to change the program to fit their specific needs.

4.7.3.2 Study characteristics

The main characteristics of the included study assessing the CATCH intervention is summarised in **Table 67**. The Coleman *et al* (1995) study was an untreated, matched control group design with repeated pre-test and post-test samples used. The study was conducted in four El Paso CATCH and four control elementary schools in Texas, along the US-Mexico border region. There were 896 children included in the study, all in third-grade, 93% of whom were Hispanic. The primary weight-based outcomes were risk of overweight or obesity, BMI and waist-to-hip ratio.

Table 67 Study characteristics: CATCH

Citation	Study type	Population	Intervention/ comparator	Outcomes
Coleman *et al* (2005)	Pre-test-post-test matched control, quasi experimental design 4 intervention schools 4 control schools 2 year follow-up US	N= 896 Mean age= 8.8 years Male gender (%)=473 (52.8) Hispanic: 93%	Community-based implementation of the national CATCH program Standard curriculum	*BMI (kg/m²)* *Weight (kg)* *Risk of overweight (%)* *Overweight (%)* *Time spent in moderate to vigorous physical activity*

Abbreviations: BMI = body mass index; US = United States
Note: Outcomes which are considered relevant to this review, and which are described in the results section, are shown in italics.
[a] Follow-up occurred at a mean of ~ 3.2 years.

4.7.3.3 Baseline participant characteristics

In the Coleman *et al* (2005) study of the CATCH, the majority of participants were Hispanic (93%). There were 896 participants (224 girls and 249 boys), all of whom were recruited from third grade in schools in Texas. Schools examined were low-income elementary schools. Mean weight at baseline was approximately 32 kg and mean BMI 18 kg/m^2. Twenty-three percent of boys in the control group and 22% of boys in the intervention group were overweight at baseline. For girls, there were 17% and 13% classified as overweight at baseline, in the control and intervention group respectively. The baseline characteristics reported in Coleman *et al* (2005) are presented in **Table 68**.

Table 68 Sample characteristics at third grade

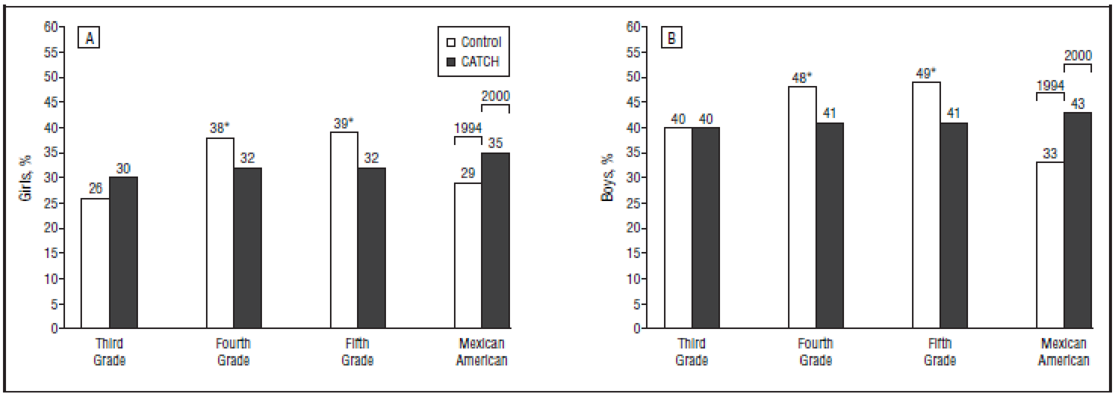
Characteristics	Control		Intervention	
	Boys (n=211)	Girls (n=189)	Boys (n=175)	Girls (n=169)
Age, mean (SD), years	8.3 (0.5)	8.3 (0.5)	8.3 (.0.5)	8.2 (0.45)
Height, mean (SD), cm	132.13 (5.94)	131.88 (5.92)	131.88 (6.30)	131.19 (6.68)
Weight, mean (SD), kg	32.90 (9.21)	31.52 (8.16)	32.30 (9.13)	30.78 (8.81)
BMI, mean (SD)	18.66 (4.08)	18.10 (3.62)	18.44 (3.99)	17.82 (3.50)
Passing, %	60	55	59	54
Risk of overweight, %	17	8	17	17
Overweight, %	23	17	22	13

Source: Coleman *et al* (2005), table 1, page 220
Abbreviations: BMI= body mass index; SD =standard deviation

4.7.3.4 Weight-related results

Results for percentage of risk of overweight or obese are shown in **Figure 10**. Girls in intervention schools had significantly lower increases in percentage of risk of overweight or overweight from third to fifth grades (2% for CATCH vs. 13% in control girls). A similar pattern was seen for boys, with a rate of increase for boys in CATCH schools of 1% compared with 9% for control boys. For the third, fourth, and fifth grades, the percentage of overweight in girls did not change for CATCH and control groups (control, 17%, 18%, and 18%, and CATCH, 13%, 14%, and 15%, respectively), but it significantly increased in boys for both CATCH and control groups (control, 23%, 29%, and 31%, and CATCH, 22%, 27%, and 27%, respectively). The rate of increase was 8% in two years for boys in control schools and 5% in two years for boys in CATCH schools, with no difference between CATCH and control school boys (Coleman *et al* 2005). There was no effect of CATCH on height, weight, waist-to-hip ratio, or BMI for any children in the study. All children had increases in height, weight, and BMI and decreases in waist-to-hip ratio from year to year.

Figure 10 Risk of overweight or overweight in control and CATCH girls (A) and boys (B) as defined by BMI in the 85th percentile or higher on CDC growth charts across third to fifth grades



Source: Coleman *et al* (2005), Figure 2, page 221
Abbreviations: BMI = body mass index; CDC = centre for disease control
* significant change

4.7.3.5 Physical activity-related results

The results of the analysis of physical activity-related outcomes are presented in **Table 69**. In the spring semester of the third grade and the autumn semester of the fourth grade, CATCH schools had higher moderate to vigorous physical activity (MVPA) compared with control schools. However, control and CATCH schools had similar values for MVPA by the end of the fourth grade. A similar trend was observed for the fifth grade, with CATCH schools having higher MVPA at the beginning of the fifth grade, and control and CATCH schools having similar MVPA by the end of the fifth grade. Vigorous physical activity (VPA) was somewhat different, with CATCH schools having higher VPA than control schools in the autumn of the fourth grade and for both the autumn and spring semesters of the fifth grade (Coleman *et al* 2005).

Table 69 Physical activity results: CATCH

Outcome	Third grade		Fourth grade		Fifth grade	
	Autumn	Spring	Autumn	Spring	Autumn	Spring
Time spent in moderate to vigorous physical activity (goal ≥ 50%), %						
Control	38	43	53[a]	54[a]	44	63[a]
CATCH	30	52	56[b]	57[a]	55[b]	60[a]
Time spent in vigorous physical activity (goal ≥ 20%), %						
Control	11	15[a]	13	12	6[a]	10
CATCH	10	16[a]	16[b]	13[a]	12[b]	12[b]

Source: Coleman *et al* (2005), Table 3, page 221
Abbreviations: CATCH = Child and adolescent trial of cardiovascular health
[a] Significant changes from autumn semester of third grade
[b] Significant changes from autumn semester of third grade and El Paso CATCH schools significantly different from control schools

4.7.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for the CATCH intervention is provided in **Table 70**.

Table 70 Dimensions of evidence for the CATCH study

Dimension	Definition
Strength of evidence	
Level	The primary study was a Level III-I pseudo-randomised, cluster controlled trial
Quality	The study was a controlled trial with controls matched to intervention schools. There did not appear to be selection bias. There was some loss to follow-up (~17%). There was limited information regarding confidence intervals and p-values.
Statistical precision	Confidence intervals around the differences in risk of overweight and overweight were not reported. P-values were not reported.
Size of effect	There was a significantly lower increase in risk of overweight and overweight in boys (difference ~8%) and girls (difference ~11%) in the CATCH schools compared to controls from third to fifth grade.
Relevance of evidence	The study assessed the risk of overweight and overweight. The study was conducted in a low-income, Hispanic population. Generalisability to NZ is uncertain.

Source: NHMRC 2000b.
Abbreviations: CATCH = child and adolescent trial of cardiovascular health; NZ = New Zealand

4.7.5 Translation of results for economic analysis

No BMI results are presented in this study.

The CATCH intervention successfully slowed the increase in risk of overweight or overweight seen in control school children. Girls in control schools had significant lower increases in percentage of risk of overweight or overweight from third to fifth grades (2% for CATCH vs. 13% in control girls). A similar pattern was seen for boys, with a rate of increase for boys in CATCH schools of 1% compared with 9% for control boys. There was no effect on waist-to-hip ratio or BMI for any children in the study. Given that this study was conducted in a low-income, Hispanic population, the generalisability to NZ is uncertain.

4.8 INTERVENTION 8: SWITCH-PLAY

'Switch-Play' was a school-based intervention aimed at maintaining healthy weight among 10-year-old children through reducing the time spent in sedentary behaviours and increasing physical activity. The intervention was implemented in Victoria, Australia.

This intervention was identified during the scoping search via a search of medical literature databases and consultation with content experts.

4.8.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of Switch-Play in terms of the prevention of obesity. The specific research question to be answered is as follows:

Does the obesity prevention intervention 'Switch-Play' prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

In order to answer this research question, an extensive literature search was conducted.

4.8.2 Literature search

In order to identify studies relevant to the assessment of the Switch-Play intervention, searches of Embase.com (covering the EMBASE and Medline databases) and the Cochrane Library were conducted. Search terms used included those relating to the intervention (e.g. 'Switch-Play'), obesity (e.g. 'body mass index') and three of the lead authors on a 'Switch-Play' publication identified during the scoping search (e.g. Salmon J). The reference lists of identified papers were checked for additional studies of relevance. Details of the search and search results are presented in **Table 71**.

Table 71 Literature search for 'Switch-Play': Embase.com and Cochrane Library

Search location	Search string	Citations
Embase.com (EMBASE and Medline) 19/02/2010	1. 'Salmon J' 2. 'Ball K' 3. 'Crawford D' 4. 'obesity':ab,ti OR 'bmi:ab,ti OR 'body mass index':ab,ti' 5. (#1 OR #2 OR #3) AND #4 6. 'Switch Play' OR 'Switch-Play' 7. #5 OR #6	81
Cochrane Library (Trials Register) 19/02/2010	1. 'Switch Play' OR 'Switch-Play'	41
Subtotal		*122*
Manual searching of reference lists	'Switch-Play'	1
TOTAL		*123*

The following exclusion criteria were applied to the 123 identified citations:

1. Duplicate citation – excludes multiple citations for the same publication

2. Not a clinical study – excludes publications which do not report the results of an original study conducted in humans (ie, excludes animal studies, in vitro studies, narrative reviews)

3. Wrong population/intervention – excludes studies which do not describe and/or assess the 'Switch-Play' intervention.

4. Wrong outcomes- does not report a relevant weight-based outcome

Applying the exclusion criteria resulted in the identification of three publications relating to the 'Switch-Play' intervention. All of these citations were identified through the search of Embase.com and the Cochrane library. The results of the application of exclusion criteria are presented in **Table 72**.

Table 72 Exclusion of citations for 'Switch-Play'

Criterion	Citations
TOTAL IDENTIFIED	123
Duplicate citation	8
Not a clinical study	17
Wrong population/intervention	95
Wrong outcomes	0
TOTAL REMAINING	3

Details of the three identified citations are presented in **Table 73**. It should be noted that one citation (Salmon *et al*, 2005) provides background information on how the 'Switch-Play' programme was developed, one citation (Salmon *et al*, 2006) investigated which factors differentiated changes in TV viewing during the course of the intervention, while the remaining citation (Salmon *et al*, 2008) provides data regarding the pivotal results of the programme.

Table 73 Included citations: Switch-Play

Citation details	Included
Salmon J, Ball K, Crawford D, Booth M, Telford A, Hume C, Jolley D, and Worsley A. (2005) Reducing sedentary behaviour and increasing physical activity among 10-year-old children: Overview and process evaluation of the 'Switch-Play' intervention. *Health Promotion International* 20:7-17.	
Salmon J, Hume C, Ball K, Booth M, and Crawford D. (2006) Individual, social and home environment determinants of change in children's television viewing: The Switch-Play intervention. Journal of Science and Medicine in Sport 9:378-387.	
Salmon J, Ball K, Hume C, Booth M, and Crawford D. (2008) Outcomes of a group-randomized trial to prevent excess weight gain, reduce screen behaviours and promote physical activity in 10-year-old children: Switch-Play. International Journal of Obesity 32:601-612.	✓

4.8.3 Results

The following section provides details of the characteristics of the intervention, the included study, the baseline characteristics of the intervention and control groups and two sets of results: (i) results of the pivotal weight-related outcomes for this review divided by intervention group; and (ii) results of the BMI and physical activity outcomes among girls.

While the results of all weight-based analyses will be presented, this section will focus on the primary outcome defined for this review, BMI. In this study, unadjusted and adjusted BMI has been presented for the whole cohort and for girls separately, because of significant differences in BMI by intervention group among girls at baseline.

4.8.3.1 Intervention characteristics

The primary goal of the intervention was to develop and test three approaches towards the achievement of healthy weight maintenance (Salmon *et al*, 2005):

1. through reducing the time spent in sedentary behaviours (e.g. TV viewing, playing electronic games and recreational computer use);

2. through increasing skills and enjoyment of physical activity; and

3. through a combination of these two strategies.

Components of the intervention program were developed by the study team, while others were adapted from previous interventions; SPARK (Faucette *et al.* 1995; Hovell *et al.* 1999), from concepts outlined in Robinson's study (Robinson 1999), from Planet Health (Gortmaker *et al.*, 1999) and from the Victorian Fundamental Motor Skills program (Department of Education Victoria (DOE), 1998). **Table 74** outlines the content of the intervention conditions.

Table 74 Components and timing of the 'Switch-Play' intervention

Lesson	Behaviour modification	Fundamental movement skills
1	Introduction to 'Switch-Play'	Run and throw
2	Patterns of sedentary behaviour (SB)[a]	Throw and dodge
3	Self-monitoring SB	Run and strike
4	Physical activity and health	Vertical jump and throw
5	Patterns of physical activity behaviour	Dodge and kick
6	The home environment	Run and strike
7	The community environment	Throw and dodge
8	Decision-making	Kick and vertical jump
9	Identifying alternative activities	Dodge and throw
10	Increasing physical activity	Throw and kick
11	Intelligent viewing and decreasing SB[b]	Throw and strike
12	Intelligent viewing[c] and TV advertising	Throw and vertical jump
13	Advocacy of decreased SB—role plays[d]	Run and kick
14	Perform advocacy plays[e]	Dodge and strike
15	Advocacy of decreased SB—posters	Vertical jump and strike
16	Complete advocacy posters	Throw and run
17	Increasing physical activity—pedometers	Kick and dodge
18	'Switch-Play' games	Vertical jump, run and kick
19	Present posters to younger grades	Dodge, run, strike and kick

Source: Salmon *et al* (2005) Table 1, page 10
[a]Sedentary behaviour comprises TV viewing, computer use, electronic game use
[b,c,d,e]'Switch-Off challenge' from one TV programme in lesson 11 to four programmes in lesson 14

4.8.3.2 Study Characteristics

The main characteristics of the 'Switch-Play' study are summarised in **Table 75**. 'Switch-Play' was a cluster-randomised trial using a two-by-two factorial design. Assessment was conducted at baseline and immediately post-intervention as well as at 6 and 12 months post-intervention, to assess longer-term effects of the programme. A total of 397 children (51% boys; mean age 10.1 ± 0.4 years) enrolled in grade 5 at three government primary schools across four campuses in low socio-economic status suburbs in metropolitan Melbourne, Australia, were recruited to the study. However, only 311 consented and were randomised into treatment or control conditions. While some of the programme was conducted within the school, the aim was to also involve the wider community (Salmon *et al*, 2005).

Each grade five class within each school was randomly allocated to one of four conditions: a behavioural modification condition (BM; baseline n = 66); a fundamental movement skills (FMS) condition (baseline n = 74); a combined BM/FMS (baseline n = 93) condition; or a control/comparison condition (C; baseline n = 62). The BM and BM/FMS programmes focused on reducing the time spent in sedentary behaviours, and also focused on physical activity alternatives students could undertake in a variety of settings. The focus for children in the FMS and BM/FMS conditions was mastery of six FMS that are important for a broad range of lifestyle and organised physical activities. Children in the control condition participated in the usual school curriculum.

Table 75 Study characteristics: 'Switch-Play'

Citation	Study type	Population	Intervention/ comparator	Outcomes
Salmon *et al* (2008) Salmon *et al* (2006)	Cluster-randomised controlled trial School-based 3 schools, 17 classes 9 months duration with 6 and 12 month post-intervention follow-up	N= 311 10 year-old children Gender (female): 156 (51%) Ethnicity: Not reported Overweight/obese: Boys: 46.9% (38.6–55.4%) Girls: 37.6% (29.8–45.9)	Four conditions: Behavioural Modification condition (BM); Fundamental Motor Skills condition (FMS); combined BM/FMS condition; and comparison usual curriculum condition (C)	*Odds ratios of overweight/obese (adjusted and unadjusted) at 12 months follow-up* *BMI (adjusted and unadjusted) at 12 months follow-up* TV viewing (min/week) Computer use (min/week) Electronic games (min/week) Counts per day (x 10^3) Moderate PA (min/day) Vigorous PA (min/day) PA enjoyment FMS z-scores

Abbreviations: BMI = body mass index; FMS = fundamental movement skills; PA = physical activity; TV = television
Note: Outcomes which are considered relevant to this review, and which are described in the results section, are shown in italics.

4.8.3.3 Baseline participant characteristics

Informed consent was received from 311 children (78% response rate). Data were unavailable for one child (left the school) and incomplete for five children, resulting in a final baseline sample size of N = 306. The sample included 150 boys (mean age 10 years 8±5 months) and 156 girls (mean age 10 years 8±4 months). Complete BMI data were available for 295 children at baseline, 278 children at post intervention, 246 children at 6-month follow-up and 268 children at 12-month follow-up (12% attrition from baseline).

Table 76 shows baseline means data by gender and by intervention group within gender. Compared with girls, boys spent significantly more time engaged in moderate- and vigorous-intensity physical activities and playing electronic games, had significantly higher accelerometer movement counts and FMS z-scores. There were significant differences between intervention groups at baseline in age and sex-adjusted BMI among girls; however, these differences were taken into account with the inclusion of baseline data in all General Estimating Equation analyses. There were no data provided on ethnicity, or level of education; however, the study was aimed at schools within low socioeconomic status areas.

Table 76 Baseline characteristics: Switch-Play

Characteristic	Total	Controls	BM	FMS	BM/FMS
BMI[a] (mean, SD)					
Boys	3.4 ± 3.6	4.5 ± 3.3	3.3 ± 3.8	3.3 ± 3.2	2.8 ± 4.0
Girls	2.6 ± 3.5	2.8 ± 4.1	3.1 ± 3.3	3.0 ± 3.7	1.8 ± 3.1[b]
Overweight/obese[c] (%, 95% CI)					
Boys	46.9 (38.6–55.4)	56.3 (37.7–73.6)	43.8 (26.4–62.3)	50.0 (32.9–67.1)	40.0 (25.7–55.7)
Girls	37.6 (29.8–45.9)	43.3 (25.5–62.6)	44.1 (27.2–62.1)	36.8 (21.8–54.0)	29.8 (17.3–44.9)
TV viewing (min/week) (mean, SD)					
Boys	959.8 ± 650.4	823.8 ± 676.2	1037.7 ± 778.3	976.2 ± 618.1	988.2 ± 548.7
Girls	866.7 ± 543.4	730.0 ± 520.0	977.3 ± 530.6	892.5 ± 583.8	849.8 ± 530.2
Computer use (min/week) (mean SD)					
Boys	143.3 (218.1)	125.0 (153.7)	200.0 (263.1)	110.4 (164.2)	141.2 (255.0)
Girls	164.2 (255.4)	161.4 (274.4)	147.3 (183.5)	155.4 (266.8)	186.6 (286.7)
Electronic games use (min/week) (mean, SD)					
Boys	583.5 (645.5)[d]	520.6 (595.6)	585.8 (620.0)	758.5 (740.0)	480.5 (604.4)
Girls	197.3 (354.1)	256.8 (447.3)	206.4 (362.9)	108.6 (149.4)	227.3 (398.7)
Counts per day (x 10^3) (mean, SD)					
Boys	543.1 (235.7)[d]	481.1 (127.3)	543.3 (268.6)	594.7 (354.7)	551.7 (150.1)
Girls	425.3 (138.4)	397.8 (101.7)	433.4 (129.6)	453.6 (153.1)	414.9 (151.4)
Moderate PA (mins/day) (mean, SD)					
Boys	131.2 (35.9)[e]	124.1 (27.8)	123.1 (34.1)	133.9 (43.9)	140.4 (34.8)
Girls	112.5 (33.5)	107.1 (27.6)	118.3 (28.9)	118.4 (42.0)	107.1 (31.9)
Vigorous PA (mins/day) (mean, SD)					
Boys	25.4 (22.8)[d]	19.9 (11.0)	24.2 (18.5)	33.6 (39.5)	24.4 (13.6)
Girls	14.2 (8.9)	12.2 (7.1)	13.8 (9.4)	16.1 (8.2)	14.2 (10.0)
PA enjoyment (mean, SD)					
Boys	0.63 (0.54)[e]	0.56 (0.59)	0.57 (0.54)	0.84 (0.43)	0.55 (0.54)
Girls	0.78 (0.45)	0.79 (0.33)	0.75 (0.51)	0.88 (0.46)	0.72 (0.46)
FMS z-scores (mean, SD)					
Boys	0.52 (0.83)[f]	0.28 (0.83)	0.66 (0.68)	0.51 (0.78)	0.59 (0.93)
Girls	-0.50 (0.89)	-0.95 (0.60)	-0.28 (0.89)	-0.27 (0.94)	-0.60 (0.91)

Source: Salmon *et al* (2008), Table 2, page 607
Abbreviations: BM, behaviour modification; BMI, body mass index; CI, confidence interval; FMS, fundamental movement skills, NS, not significant; PA, physical activity; SD= standard deviation
[a]BMI/sex–age population median
[b]$P<0.05$ significant difference by intervention group within gender (adjusting for clustering)
[c]Age- and sex-specific internationally accepted cut points
[d]$P<0.001$ significant differences by gender across intervention groups (adjusting for clustering)
[e]$P<0.05$, significant differences by gender across intervention groups (adjusting for clustering)
[f]$P<0.01$, significant differences by gender across intervention groups (adjusting for clustering)

4.8.3.4 Weight-related results

The results of the analysis of weight-related outcomes for baseline to post intervention and baseline to 12-month follow-up are presented in **Table 77**. After adjusting for food frequency and moderate to vigorous physical activity, the BM/FMS group recorded on average -1.53 BMI units (kg/m^2) less than the control group. These effects were maintained with the inclusion of 6- and 12-month follow-up data. In addition, after adjusting for food frequency and moderate to vigorous physical activity, compared with children in the control group, those in the combined BM/FMS group were over 60% less likely to be overweight or obese on average between baseline and post intervention and over the four time points of the study.

There were significant differences in BMI by intervention group among girls at baseline. Consequently, separate analyses were performed by gender adjusting for baseline BMI. There were no significant intervention effects on boys' or girls' unadjusted or adjusted BMI from baseline to post intervention. However, with the inclusion of 6- and 12-month follow-up data, there were significant intervention effects on unadjusted BMI among girls in the FMS and BM/FMS groups compared with the control group. After adjusting for food frequency and moderate-to-vigorous intensity physical activity, girls in the BM/FMS group recorded on average -0.15 BMI units less than the control group.

Table 77 Intervention and maintenance effects on body mass index and weight status

Outcomes	BM		FMS		BM/FMS	
	Baseline to post intervention[a]	Baseline to 12-month follow-up[b]	Baseline to post intervention[a]	Baseline to 12-month follow-up[b]	Baseline to post intervention[a]	Baseline to 12-month follow-up[b]
Odds ratios (95% CI)[c]						
Overweight/obese (unadjusted)	0.78 (0.39 to 1.57)	0.78 (0.39 to1 .57)	0.76 (0.38 to 1.50)	0.76 (0.39 to 1.50)	0.53 (0.28 to 1.03)	0.53 (0.28 to 1.03)
Overweight/obese (adjusted)[d]	0.88 (0.36 to 2.15)	0.65 (0.35 to 2.10)	0.62 (0.26 to 1.48)	0.66 (0.28 to 1.56)	**0.36 (0.15 to 0.86)[e]**	**0.38 (0.16 to 0.89)[e]**
Overall results β-coefficients (95% CI)						
BMI (unadjusted)	-0.40 (-1.11 to 0.30)	-0.42 (-1.07 to 0.23)	-0.50 (-1.25 to 0.25)	-0.45 (-1.19 to 0.29)	**-1.30 (-2.29 to -0.31)[e]**	**-1.30 (-2.24 to -0.35)[g]**
BMI (adjusted)[f]	-0.06 (-1.23 to 1.12)	-0.15 (-1.29 to 0.99)	-0.86 (-1.94 to 0.23)	-0.77 (-1.80 to 0.26)	**-1.88 (-3.22 to -0.53)[g]**	**-1.53 (-2.82 to -0.24)[e]**
Results for Girls (β-coefficients (95% CI))						
BMI (unadjusted)[c]	-0.01 (-0.05 to 0.03)	-0.01 (-0.07 to 0.04)	-0.02 (-0.07 to 0.03)	**-0.07 (-1.12 to 0.02)[g]**	**-0.03 (-0.08 to 0.02)**	**-0.07 (-0.13 to -0.01)[e]**
BMI (adjusted)[f]	-0.07 (-0.03 to 0.17)	-0.01 (-0.14 to 0.12)	0.13 (-0.02 to 0.29)	-0.08 (-0.22 to 0.05)	0.01 (-0.50 to 0.13)	**-0.15 (-0.31 to -0.00)[e]**

Abbreviations: BM, behaviour modification; BMI, body mass index; CI, confidence interval; FMS, fundamental movement skills; PA, physical activity
Bold values denote statistical significance
[a]Generalized estimating equation (GEE) coefficient at baseline and post intervention, adjusted for clustering by school class
[b]GEE coefficient at baseline and post intervention, 6- and 12-month follow-up periods, adjusted for clustering by school class
[c]Referent category: not overweight/obese
[d]Adjusted for food-frequency intake (high energy drinks, sweet and savoury snacks, confectionery and fast food) and MVPA
[e]P<0.05
[f]BMI units of difference from US sex- and age-adjusted population median
[g]P<0.01
[h]P<0.001

4.8.3.5 Physical activity-related results

Physical activity-related results are shown in **Table 78**. Between baseline and post intervention, there were significant average effects over time between the control and BM groups and between the control and FMS groups in movement counts per day and in vigorous-intensity physical activity (min/day). Gender was a significant moderator of the intervention for movement counts per day, moderate-intensity physical activity and vigorous-intensity physical activity min day (P<0.001). Between baseline and post-intervention, there were significant positive average differences over time between the BM and control groups in movement counts per day and moderate physical activity in girls, and between the BM and control and the FMS and control groups in movement counts per day and in vigorous-intensity physical activity among boys.

Table 78 Intervention and maintenance effects on physical activity

Outcomes	BM		FMS		BM/FMS	
	Baseline to post intervention[a]	**Baseline to 12-month follow-up[b]**	**Baseline to post intervention[a]**	**Baseline to 12-month follow-up[b]**	**Baseline to post intervention[a]**	**Baseline to 12-month follow-up[b]**
Counts per day ($x10^3$)	**47.0 (24.2 to 69.8)[c]**	**47.5 (24.6 to 70.4)[c]**	**76.6 (35.2 to 118.0)[c]**	**76.1 (33.4 to 118.9)[c]**	40.8 (-9.9 to 91.4)	40.1 (-9.8 to 90.1)
Moderate PA (min day)	5.3 (-2.0 to 12.6)	4.3 (-3.6 to 12.2)	**10.4 (2.8 to 18.1)[d]**	**9.5 (1.4 to 17.6)[e]**	7.7 (-5.1 to 20.6)	6.7 (-6.4 to 19.8)
Vigorous PA (min day)	**2.8 (0.3 to 5.4)[e]**	**2.8 (0.2 to 5.4)[e]**	**7.8 (3.4 to 12.3)[d]**	**7.7 (3.2 to 12.2)[d]**	3.1 (-0.58 to 6.7)	3.0 (-0.59 to 6.6)
Results for Girls (β-coefficients (95% CI))						
Counts per day ($x10^3$)[g]	**36.5 (0.29 to 72.7)[e]**	**39.3 (9.4 to 69.1)[e]**	56.2 (-18.6 to 131.0)	58.0 (-11.8 to 127.8)	180.3 (-17.3 to 53.3)	21.6 (-10.3 to 53.5)
Moderate PA (min day)	**12.1 (3.9 to 20.3)[d]**	**11.1 (3.8 to 18.4)[d]**	11.4 (-4.5 to 27.3)	10.2 (-4.7 to 25.1)	1.1 (-7.5 to 9.8)	0.3 (-7.7 to 8.3)
Results for Boys (β-coefficients (95% CI))						
Counts per day ($x10^3$)[g]	**61.5 (21.7 to 101.4)[d]**	**61.6 (12.4 to 110.9)[e]**	**112.8 (59.1 to 166.5)[c]**	**114.0 (52.8 to 175.2)[c]**	72.1 (–7.7 to 151.9)	66.2 (–20.7 to 153.0)
Vigorous PA (min day)	**4.5 (0.91 to 8.0)[e]**	**4.4 (0.44 to 8.4)[e]**	**13.8 (8.7 to 18.9)[c]**	**13.8 (8.4 to 19.1)[c]**	**5.7 (0.21 to 11.2)[e]**	4.8 (–1.2 to 10.7)

Source: Salmon *et al* (2008), Table 3, Table 4, Table 5
Abbreviations: BM, behaviour modification; BMI, body mass index; CI, confidence interval; FMS, fundamental movement skills; PA, physical activity
Bold values denote statistical significance
[a]Generalized estimating equation (GEE) coefficient at baseline and post intervention, adjusted for clustering by school class
[b]GEE coefficient at baseline and post intervention, 6- and 12-month follow-up periods, adjusted for clustering by school class
[c]P<0.001
[d]P<0.01
[e] P<0.05

4.8.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for the intervention is provided in **Table 79**.

Table 79 Dimensions of evidence for the Switch-Play study

Dimension	Definition
Strength of evidence	
Level	The study was a Level II cluster randomised controlled trial.
Quality	The study used objective measurement and children's FMS were evaluated by specialist staff blinded to the intervention group. With the intervention groups being randomised by class, there was potential for contamination between intervention and control groups.
Statistical precision	The confidence intervals around the odds ratio estimates of overweight/obesity and around the mean BMI estimates were moderate.
Size of effect	Children in the BM/FMS group recorded significantly lower adjusted BMI compared to children in the control group 12 months after follow-up (β-coefficients, 95% CI;1.53 (-2.82 to -0.24))
Relevance of evidence	The study presents BMI and prevalence of overweight/obesity, both of which are clinically relevant outcomes. The study was conducted in Australia and therefore the study population is likely to be applicable to NZ.

Source: NHMRC 2000b.

4.8.5 Translation of results for economic analysis

This study found, on average, between baseline and post-intervention, and including 6- and 12-month follow-up data, children in the combined BM/FMS group recorded significantly lower BMI compared with children in the control (**Table 80**). The adjusted estimate of BMI indicated that participants in the BM/FMS had an average change in BMI of -1.53kg/m^2.

Table 80 BMI results for Intervention 6: Switch-Play

Country	Setting	Category	Age (years)	Ethnicity	Mean difference in change in BMI Intervention – control (kg/m^2)
					1 year
Australia	Primary school	E	10 years	Not stated	-0.2
		PA	10 years	Not stated	-0.8
		E/PA	10 years	Not stated	**-1.5**

Note: statistically significant results are shown in bold.
Abbreviations: BMI = body mass index; E = education; N = nutrition; PA = physical activity.

4.9 INTERVENTION 9: SCHOOL NUTRITION POLICY INITIATIVE (SNPI)

The School Nutrition Policy Initiative (SNPI) focused on improving nutrition education and nutrition policy in primary schools in Philadelphia, US. The children targeted were grades four to six (mean age ~11 years).

This intervention was identified during the scoping search via a search of the medical literature and consultation with content experts.

4.9.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of the SNPI in terms of the prevention of overweight and obesity. The specific research question to be answered is as follows:

Does the obesity prevention intervention 'SNPI' prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

In order to answer this research question, an extensive literature search was conducted.

4.9.2 Literature search

In order to identify studies relevant to the assessment of the SNPI, searches of Embase.com (covering the EMBASE and Medline databases) and the Cochrane Library were conducted. Search terms used included those relating to the intervention (ie 'School Nutrition Policy Initiative'), and three of the lead authors cited on the publication identified for this intervention during the scoping search. In addition, the reference lists of identified studies were checked for additional studies. Details of the search and search results are presented in **Table 81**.

Table 81 Literature search for SNPI: Embase.com and Cochrane Library

Search location	Search string	Citations
Embase.com (EMBASE and Medline) 23/02/2010	1. 'school nutrition policy initiative':ab,ti OR 'SNPI':ab,ti 2. Foster G.D 3. Sherman S 4. Shults J 5. 'Obesity':ab,ti OR 'Body mass index':ab,ti OR 'BMI':ab,ti OR 'weight gain':ab,ti 6. (#2 OR #3 OR #4) AND #5 7. #1 OR #6	90
Cochrane Library (Trials Register) 23/02/2010	8. 'school nutrition policy initiative':ab,ti OR 'SNPI':ab,ti 9. Foster GD OR Sherman S OR Shults J):au and (Obesity):ti,ab,kw in Clinical Trials Taylor r.w. 10. (#8 OR #9)	29
Subtotal		*119*
Manual searching of reference lists	'School Nutrition Policy Initiative'	0
TOTAL		*119*

The following exclusion criteria were applied to the 119 identified citations:

1. Duplicate citation – excludes multiple citations for the same publication

2. Not a clinical study – excludes publications which do not report the results of an original study conducted in humans (ie, excludes animal studies, in vitro studies, narrative reviews)

3. Wrong population/intervention – excludes studies which do not describe and/or assess the SNPI.

4. Wrong outcomes- does not report a relevant weight-based outcome

Applying the exclusion criteria resulted in the identification of one publication relating to the SNPI. This was the same publication that had already been identified during the scoping search. The results of the application of exclusion criteria are presented in **Table 82**.

Table 82 Exclusion of citations for SNPI

Criterion	Citations
TOTAL IDENTIFIED	119
Duplicate citation	21
Not a clinical study	22
Wrong population/intervention	75
Wrong outcomes	0
TOTAL REMAINING	**1**

The included citation is presented in **Table 83**.

Table 83 Included citations: SNPI

Citation details	Included
Foster GD, Sherman S, Borradaile KE, Grundy KM, Vander Veur SS, Nachmani J, Karpyn A, Kumanyika S, and Shults J. (2008) A policy-based school intervention to prevent overweight and obesity. Pediatrics 121:e794-e802.	✓

4.9.3 Results

The following section provides details of the characteristics of the intervention, the included study, the baseline characteristics of the intervention and control groups and two sets of results: (i) results of the weight-related outcomes; and (ii) results of the physical activity outcomes.

While the results of all weight-based analyses will be presented, this section will focus on the primary outcome defined for this review, incidence of overweight and obesity. In this study, body mass was also assessed using both BMI and the BMI z score. The standard deviation of BMI increases with age so z scores have been used (from Centers for Disease Control and Prevention tables) which take into account age and sex and thus standardises the outcome for children of different ages and gender.

4.9.3.1 Intervention characteristics

Detail on each of the components of the intervention is provided in **Table 84**. The SNPI was developed based on the Centre for Disease Control and Prevention (CDC) Guidelines to Promote Lifelong Healthy Eating and Physical Activity (Foster *et al* 2008).

The purpose of the intervention was the prevention of overweight and obesity among children. Given the disproportionately high rates of obesity among children in lower socioeconomic status groups, the study was implemented in schools that had ≥50% of children eligible for federally subsidised, free, or reduced-price meals. Schools were matched on school size and type of food service and randomly assigned to intervention or control.

Table 84 Components of the SNPI

Intervention component	Description
Self-assessment	Schools assessed their environments by using the CDC School Health Index. Each school formed a Nutrition Advisory Group to guide the assessment. Teams included administrators, teachers, nurses, coaches, and parents. After completing ratings on healthy eating and physical activity, schools developed an action plan for change. Schools proposed various strategies, such as limiting the use of food as reward, punishment, or for fundraising; promoting active recess; and serving breakfast in classrooms to increase the number of students eating a healthy breakfast.
Nutritional education	The goal was to provide 50 hours of food and nutrition education per student per school year, which was based on the National Center for Education Statistics guidelines. The educational component was designed to be integrative and interdisciplinary. Its purpose was to show how food choices and physical activity are tied to personal behaviour, individual health, and the environment. Nutrition was integrated into various classroom subjects. For example, students used food labels to practice fractions and nutrition topics for writing assignments.
Nutrition policy	In each of the intervention schools, all of the foods sold and served were changed to meet the following nutritional standards, which were based on the Dietary Guidelines for Americans and converted from the percentage of calories to grams per serving, which is in alignment with information shown on nutrition labels: all of the beverages were limited to 100% juice (recommended 6-oz serving size), water (no portion limits), and low-fat milk (recommended 8-oz serving size). Snack standards allowed ≤7 g of total fat, 2 g of saturated fat, 360 mg of sodium, and 15 g of sugar per serving. Before these changes, soda, chips, and other drinks and snacks had been sold in vending machines and a la carte in the cafeteria of schools with full-service kitchens. Schools without full-service kitchens did not sell a la carte food items or have vending machines. Schools were matched by type of food service to control for differences in the sales of vending and a la carte items.
Social marketing	The SNPI used several social marketing techniques. To increase meal participation and consumption of healthy snack and beverage items, students who purchased healthy snacks and beverages or who brought in snack items that met the nutritional standards from home or local stores received raffle tickets. Raffle winners received prizes for healthy eating, such as bicycles, indoor basketball hoops, jump ropes, and calculators. The message "Want Strength?. . .Eat Healthy Foods," paired with an easily recognisable character, reinforced healthy messages through incentives and frequent exposure. Both the slogan and the character were developed through focus groups with students who were not in the study schools but were of similar age, ethnicity, and socioeconomic status.
Family Outreach	Nutrition educators reached family members through home and school association meetings, report card nights, parent education meetings, and weekly nutrition workshops. They encouraged parents and students, on the way to and from school, to purchase healthy snacks. Students participated in the 2-1-5 challenge to be less sedentary (≤2 hours per day of television and video games), to be more physically active (≥1 hour per day), and to eat more fruits and vegetables (≥5 per day). Intervention schools reduced the amount of unhealthy foods sold at parent fundraisers and discouraged parents from sending sweets to teachers at holiday time. One school chose to have a weekly breakfast club with female athletes from a local university.

Source: Foster *et al* (2008), page e795-e796

4.9.3.2 Study characteristics

The main characteristics of the Foster *et al* (2008) study assessing the SNPI are summarised in **Table 85**. The SNPI study was a cluster randomised controlled trial conducted in 10 separate schools in Philadelphia, USA. The population consisted of children in grades 4 through 6 (~11 years old) from 5 intervention and 5 control schools. Among the 1349 students assessed at baseline, 921 (68.3%) (510 intervention and 411 control) were reassessed at year one and 844 (62.6%; 479 intervention and 365 control) were reassessed at year two. There was no attrition at the school level. Various anthropomorphic, physical activity and dietary outcomes were assessed at baseline and again at one and two-year follow-up.

Table 85 Study characteristics: SNPI

Citation	Study type	Population	Intervention/ comparator	Outcomes
Foster *et al* (2008)	Cluster quasi-randomised controlled trial Community-based 5 intervention schools/5 control schools 2 years duration	N= up to 1349 4th to 6th grade children Mean age: ~11 years Gender (female): ~53% Ethnicity: African American: 45.4%; Asian: 21.8%; Caucasian: 11.5%; Hispanic: 15.0%; Other: 5.5%. Prevalence of overweight/obese: intervention: 42.6%; control: 38.3% Mean BMI: ~21 kg/m²	SNPI (school self-assessment, nutrition education, nutrition policy, social marketing, and parent outreach) Vs. Usual curriculum	*Incidence of overweight, obesity* *Prevalence of overweight, obesity* *Remission of overweight, obesity* *Change in BMI (kg/m²)* *Change in BMI z score* Change in total energy (kJ/d) Change in total fat (g/d) Change in fruits and vegetables (n per day) *Change in total activity (h/wk)* Change in body dissatisfaction (raw) *Total inactivity (hrs/wk)* Total television (hrs/weekday) Total television (hrs/weekend)

Source: Foster *et al* (2008), Table 1, e797
Abbreviations: BMI = body mass index; SNPI = school nutrition policy initiative
Note: Outcomes which are considered relevant to this review, and which are described in the results section, are shown in italics.

4.9.3.3 Baseline participant characteristics

The baseline participant characteristics are shown in **Table 86**. Among the 1388 students who provided consent, 1349 were assessed at baseline. The sample consisted of 53.7% females. Participants had a mean (± SD) age of 11.2 ± 1.0 years and BMI of 20.9 ± 5.1 kg/m². Approximately 40% were overweight or obese (≥85th percentile), and nearly a quarter (23.8%) were obese (≥95th percentile). African American children composed nearly half of the sample and Asian children almost a quarter. There were no significant differences between control and intervention groups on any variable at baseline except for ethnicity. There were more Hispanic students in the intervention group than there were in the control group (22.4% and 5.8%, respectively; P<0.001). To account for these differences at baseline, ethnicity was controlled for in subsequent analyses.

Table 86 Baseline characteristics: SNPI

Variable	Control (n=600)	Intervention (n=749)	P value
Female, n (%)	313 (52.17)	412 (55.01)	0.30
Age, mean ± SD, years	11.20 ± 1.0	11.13 ± 1.0	0.20
Ethnicity, n (%)			<0.001
African American	281 (46.83)	332 (44.33)	
Asian	166 (27.67)	128 (17.09)	
Hispanic	35 (5.83)	168 (22.43)	
Other	33 (5.50)	41 (5.47)	
White	85 (14.17)	80 (10.68)	
Weight status, n (%)			0.08
Underweight	18 (3.00)	10 (1.34)	
Normal weight	352 (58.67)	420 (56.07)	
Overweight	99 (16.50)	129 (17.22)	
Obese	131 (21.83)	190 (25.37)	
BMI, mean ± SD, kg/m²	20.71 ± 5.0	20.98 ± 5.1	0.33
BMI z score, mean ± SD	0.65 ± 1.1	0.71 ± 1.1	0.35
Fruit and vegetable, mean ± SD, n per day	5.64 ± 4.2	5.32 ± 3.9	0.16
Total energy, mean ± SD, kJ/day	13979.41 ± 8170.68	14029.85 ± 8112.72	0.91
Total Fat, mean ± SD, g/day	118.46 ± 72.2	119.18 ± 71.0	0.86
Activity, mean ± SD, hours/week	26.18 ± 19.3	25.85 ± 19.8	0.77
Inactivity, mean ± SD, hours/week	108.77 ± 44.5	113.91 ± 50.1	0.14
Television, mean ± SD, hours/weekday	2.80 ± 1.5	2.87 ± 1.6	0.49
Television, mean ± SD, hours/weekend	3.34 ± 1.57	3.31 ± 1.6	0.75
Body dissatisfaction, mean ± SD, raw score	9.19 ± 7.8	9.04 ± 7.6	0.74

Source: Foster *et al* (2008), Table 1, page e797
Abbreviations: BMI = body mass index

4.9.3.4 Weight-related results

Body weight

The results for BMI and BMI z score are shown in **Table 87**. There were no differences between groups with respect to changes in BMI (P =0 .71) or BMI z score (P=0 .80). The study suggested the lack of an effect on BMI z score was not surprising given a reduction in BMI z score is not desired among those in the normal or underweight categories who composed ~60% of the sample at baseline.

Table 87 Secondary outcomes at two years: SNPI

Measure	Sample, N	Baseline	Follow-up	Unadjusted change	Adjusted difference	P
BMI						
Control	364	20.76	22.86	2.10	-0.04 (-0.27 to 0.19)	0.71
Intervention	479	21.07	23.06	1.99		
BMI z score						
Control	364	0.66	0.76	0.10	-0.01 (-0.08 to 0.06)	0.80
Intervention	479	0.73	0.80	0.07		

Source: Foster *et al* (2008), Table 3, page e800
Abbreviations: BMI = body mass index

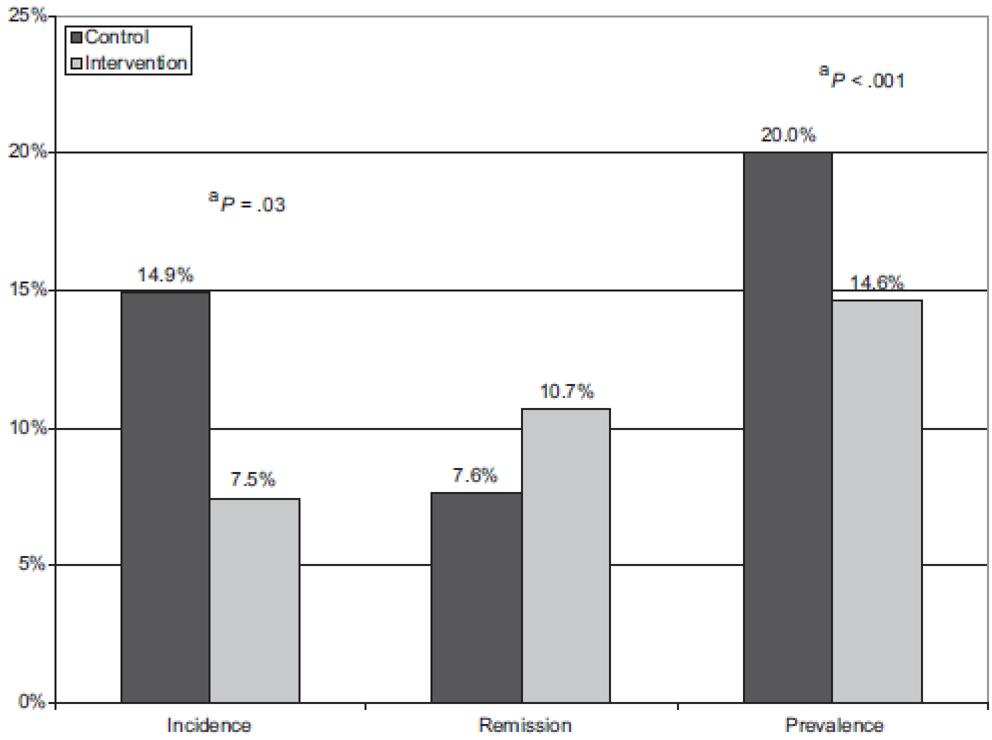
Incidence, remission and prevalence of overweight

The unadjusted incidence, remission, and prevalence of overweight (85.0th–94.9th percentiles) at two year follow-up are shown in **Figure 11**. The primary outcome of the study was the incidence of overweight and obesity. Significantly fewer children in the intervention schools (7.5%) than in the control schools (14.9%) became overweight after two years. After controlling for gender, ethnicity, and age, the predicted odds of incidence of overweight were ~33% lower for the intervention group (OR: 0.67; 95% CI: 0.47 to 0.96; P<0.05). By contrast, there were no differences between intervention and controls schools in the incidence of obesity. After two years, there were no interaction effects between the intervention and ethnicity, gender, or age on obesity incidence. After collapsing the overweight and obese weight categories (≥85th percentile), the predicted odds of incidence of overweight or obesity were ~15% lower for the intervention group (OR: 0.85; 95% CI: 0.74 to 0.99; P <0.05).

After two years, the unadjusted prevalence of overweight had decreased by 10.3% in intervention schools and had increased by 25.9% in control schools. After adjustments for baseline variables, the predicted odds of overweight prevalence were 35% lower for the intervention group (OR: 0.65; 95% CI: 0.54 to 0.79; P<0.0001). The intervention's effect on the prevalence of overweight was particularly effective for African American students with students in the intervention schools 41% less likely to be overweight than those in the control schools after two years. There were no interaction effects between the intervention and gender or age on the prevalence of overweight. After two years, there were no differences between intervention and control schools in the prevalence of obesity. After collapsing the overweight and obese weight categories (≥85th percentile), there was no statistically significant difference between the intervention and control schools in the prevalence of overweight or obesity (P=0.07).

There were no differences between intervention and control schools with respect to the remission of overweight or obesity (P =0.40 and P=0.50, respectively). However, after collapsing the overweight and obese weight categories (≥85th percentile), the predicted odds of remission of overweight or obesity were ~32% higher for the intervention group (OR: 1.32; 95% CI: 1.09 to 1.60; P<0.01). Independent of any intervention effect, there was a main effect of age for the prevalence (OR: 0.73; 95% CI: 0.56 to 0.94; P<0 .05), the incidence (OR: 0.73; 95% CI: 0.54 to 0.99; P<0 .05), and the remission (OR: 1.46; 95% CI: 1.07 to 1.99; P<0 .05) of obesity over two years. Thus, older children were less likely to be obese or become obese and more likely to remit after two years. There were no main effects for the prevalence, incidence, and remission of overweight.

Figure 11 Unadjusted incidence, remission, and prevalence of overweight (85.0th–94.9th percentiles) at two years



Source: Foster *et al* (2008), Figure 1, page e799
[a] Statistically significant differences between the intervention and control schools after controlling for ethnicity, gender, age, and baseline prevalence for the prevalence outcome.

4.9.3.5 Physical activity-relayed results

Decreases in self-reported amounts of physical activity were reported by students at intervention and control schools, also with no differences between the two groups (p=0.40). After two years, the unadjusted hours of total inactivity increased by ~3% in the control group and decreased by ~11% in the intervention group. After controlling for gender, ethnicity, age, and baseline inactivity, inactivity was 4% lower in the intervention group than in the control group (OR: 0.96; 95% CI: 0.94 to 0.99; P <.01). There were no interaction effects between the intervention and ethnicity, gender, or age on the level of inactivity.

Table 88 Secondary outcomes at two years: SNPI

Measure	Sample, N	Baseline	Follow-up	Unadjusted change	Adjusted difference	P
Total activity (h/wk)						
Control	335	25.17	20.62	-4.55	0.30 (-0.40 to 1.00)	0.40
Intervention	416	25.03	21.28	-3.75		
Total inactivity (hrs/wk)						
Control	210	105.45	108.93	3.48	1.00	
Intervention	269	115.21	104.42	-10.79	0.96 (0.94 to 0.99)	0.005

Source: Foster *et al* (2008), Table 3, page e800
Abbreviations: BMI, body mass index

4.9.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for the SNPI is provided in **Table 89**. Overall the study was a high quality, Level III-1 trial with pseudo-randomisation. However, despite the randomised nature of the study, the small sample limited the studies ability to create homogenous groups. Although the groups only differed with respect to ethnicity, which was included in all of the statistical analyses, it is possible that the intervention and control schools differed on unmeasured characteristics that were related to the outcome.

Table 89 Dimensions of evidence for the SNPI

Dimension	Definition
Strength of evidence	
Level	The study was a Level III-1 pseudo-randomised, cluster controlled trial.
Quality	The study was high quality with standardised assessment measures of obesity. Blinding was not possible given the nature of the intervention. There was a significant difference in ethnicity between the intervention and control schools at baseline; however this was adjusted for in statistical analyses.
Statistical precision	The 95% confidence interval around the odds ratio estimate for the primary outcome (incidence of overweight, obesity) was 0.74 to 0.99. The p-value was P<0.05.
Size of effect	Significantly fewer children in the intervention schools than in the control schools became overweight after two years (OR: 0.67; 95% CI: 0.47-0.96). There were no differences between intervention and controls schools in the incidence of obesity. For the two categories combined, there incidence was ~15% lower for the intervention group (OR: 0.85; 95% CI: 0.74 to 0.99; P <0.05).
Relevance of evidence	The primary outcome was incidence of overweight and obesity. This is a clinically relevant outcome. Prevalence and remission of overweight and obesity, change in mean BMI, and change in mean BMI z score were also measured. The study was conducted in the US in a low SES population, the generalisation to the NZ population is therefore uncertain.

Source: NHMRC 2000b.
Abbreviations: BMI = body mass index; NZ= New Zealand; SES= socioeconomic status; SNPI = school nutrition policy initiative

4.9.5 Translation of results for economic analysis

The study showed no significant difference in mean BMI between the intervention and control group at two-years follow-up, as shown in **Table 90**. However, the authors' argue that a significant change would not be expected given that ~60% of the cohort were not overweight or obese at baseline.

This study provides results in terms of the incidence of overweight and obesity over two years, as separate measures, and as a collapsed category of overweight and obesity (≥85th percentile). On this outcome, the predicted odds of incidence of overweight or obesity were ~15% lower for the intervention group compared to the control group (OR: 0.85; 95% CI: 0.74 to 0.99; P <0.05).

Table 90 BMI results for Intervention 9: School Nutrition Policy Initiative

Country	Setting	Category	Age (years)	Ethnicity	Mean difference in change in BMI Intervention – control (kg/m²)	Mean difference in change in BMI z-score Intervention – control
					2 years	2 years
USA	Primary school	N	11 years	African American (~45%)	-0.04	-0.01

Note: statistically significant results are shown in bold.
Abbreviations: BMI=body mass index; N=nutrition; PA=physical activity.

4.10 INTERVENTION 10: A HEALTH EDUCATION INTERVENTION PROGRAM AMONG CRETAN ADOLESCENTS

An educational and screening intervention program was developed in Greece which aimed to motivate high school students to attain and maintain lifestyles that would reduce their risk of developing heart disease and cancer.

This intervention was identified during the scoping search via a search of medical literature databases and consultation with content experts.

4.10.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of the educational program in the prevention of obesity in high school students. The specific research question to be answered is as follows:

Does an educational obesity prevention program conducted in Cretan adolescents prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

In order to answer this research question, an extensive literature search was conducted.

4.10.2 Literature search

During the initial scoping search, only one study was identified that examined an obesity prevention intervention in a high school setting, and met the inclusion criteria (ie, measured a weight-related outcome, was effective in terms of one of these measures, and had follow-up >12 months) for systematic review. Consequently, it was decided a more extensive search would be conducted to determine whether there were any other interventions that focused on obesity prevention amongst individuals in this setting.

In order to identify studies relevant to the assessment of obesity prevention in the high school setting, searches of Embase.com (covering the EMBASE and Medline databases) and the Cochrane Library were conducted. Search terms used included those relating to obesity, the high school setting and the lead author of the study identified during the scoping search. In addition, the reference lists of identified studies were checked for additional studies. Details of the search and search results are presented in **Table 91**.

Table 91 Literature search for obesity prevention programmes in the high school setting

Search location	Search string	Citations
Embase.com (EMBASE and Medline) 15/02/2010	1. 'Lionis C' 2. 'high school'/exp OR 'high school student'/exp 3. 'obesity':ab,ti OR 'bmi':ab,ti OR 'body mass index':ab,ti OR 'weight gain':ab,ti 4. (#2 OR #3) 5. #1 OR #4 AND [humans]/lim AND [English]/lim AND [1990–2010]	348
Cochrane Library (Trials Register) 15/02/2010	6. 'Lionis C' 7. 'high school' OR 'high school student'	1
Subtotal		*349*
Manual searching of reference lists	Any high school obesity prevention programme	0
TOTAL		**349**

The following exclusion criteria were applied to the 349 identified citations:

1. Duplicate citation – excludes multiple citations for the same publication
2. Not a clinical study – excludes publications which do not report the results of an original study conducted in humans (ie, excludes correlation studies with no intervention, animal studies, in vitro studies, narrative reviews)
3. Wrong population/intervention – excludes studies which do not describe and/or assess an obesity prevention programme implemented in the high school setting
4. Wrong outcomes- does not report a relevant weight-based outcome

Applying the exclusion criteria to the title and abstract of citations resulted in the identification of eight publications examining obesity prevention programmes in high school students. However, only one of these studies had follow-up greater than 12 months. This was the Lionis *et al* (1991) study which had already been identified during the scoping search phase of the project. This publication was identified in both the search of Embase.com and the Cochrane library. The results of the application of exclusion criteria are presented in **Table 92**.

Table 92 Exclusion of citations for obesity prevention programmes in high school

Criterion	Citations
TOTAL IDENTIFIED	349
Duplicate citation	7
Not a clinical study	164
Wrong population/intervention	166
Wrong outcomes	11
TOTAL REMAINING	**1**

The Lionis *et al* (1991) study examined a health education intervention program among Cretan adolescents. This is the intervention which has been reviewed in full in the results section. Details of this citation are presented in **Table 93**.

Table 93 Included citation: Health education intervention among Cretan adolescents

Citation details	Included
Lionis C, Kafatos A, Vlachonikolis J, Vakaki M, Tzortzi M, and Petraki A. (1991) The effects of a health education intervention program among Cretan adolescents. Preventive Medicine 20:685-699.	✓

4.10.3 Results

The following section provides details of the characteristics of the intervention, the characteristics of the included study, the baseline characteristics of the intervention and control groups; a comparison of those who participated at baseline and follow-up and students who were lost to follow-up; and the results of weight-related outcomes after one year of intervention.

4.10.3.1 Intervention characteristics

The health education intervention developed for Crete adolescents was created because of the steady increase in incidence of cardiovascular disease observed in Greece over the last few decades (Lionis *et al*, 1991). The study was a one year intervention program with two treatment conditions. All schools in two neighbouring provinces were included, with students from one province (Agios Vassilios) assigned to the intervention group and students attending schools in the other province (Amari) assigned to the control group.

The programme was based on the American Health Foundation's 'Know Your Body' program. Although various forms of this program have been implemented in other countries, this study was the first to assess such a program in high school students. The main aim was to enable students to recognise risk factors and resist the negative influences of the surrounding environment. The intervention also recognised the importance of participation among teachers, students' parents, and health workers from the local community. The education curriculum focused on nutrition, physical fitness, and prevention of cigarette smoking. Ten sessions of two hours each were spread out over the academic year (approximately 9 months) in each of the three high schools in the Agios Vassilios province. The students' progress in understanding the concepts being taught was assessed using a standardised questionnaire at the end of each session. The intervention group parents were invited to attend meetings in each village within the area health centre, where they were lectured on the prevention of chronic diseases, with the aid of selected audiovisual material.

4.10.3.2 Study characteristics

The main characteristics of the study assessing the health education intervention in high school students is summarised in **Table 94**. The study was a non-randomised controlled trial conducted in two geographically separate intervention and control regions in Crete, Greece. The population consisted of 13-14 year-old children from 3 intervention and 2 control schools; up to 171 children provided data for the study. Various anthropomorphic, cardiovascular and dietary outcomes were assessed, as shown in **Table 94**.

Table 94 Study characteristics: health education intervention among Cretan adolescents

Citation	Study type	Population	Intervention/ comparator	Outcomes
Lionis *et al* 1991	Cluster non-randomised controlled trial High school and community-based 3 intervention schools/2 control schools 1 year duration	N= up to 171 13-14 year-old children Gender (male): N=84 (49%) Majority of students from rural, farming families	Health education intervention versus no intervention Health intervention programme involved nutrition, physical activity and smoking education.	Height (cm) *Weight (kg)* Arm circumference (cm) *Skinfold triceps (mm)* *BMI (kg/m²)* SBP (mm Hg) DBP fourth and fifth phase (mm Hg) Serum total cholesterol (mg/dL) HDL, LDL cholesterol (mg/dL) Various nutrition components

Abbreviations: BMI = body mass index; DBP = diastolic blood pressure; SBP = systolic blood pressure.
Note: Outcomes which are considered relevant to this review, and which are described in the results section, are shown in italics.

4.10.3.3 Baseline participant characteristics

There was limited information on the demographic characteristics of the study cohort. The historical and socio-cultural backgrounds of both the intervention and control provinces are similar. The children in the study were from rural areas of Crete, with the majority having parents who were farmers or breeders of livestock. However, there were significantly more civil servants and merchants among the parents in the intervention group than among the parents in the control group. Students were 13–14 years old and attending high school. Approximately half (49%) of participants were male and half (51%) female.

Table 95 shows the mean values of targeted variables at baseline in the subjects reexamined at follow-up compared to the mean values of those subjects who had only one value (at baseline). Importantly, there was a significant difference between the groups in weight-related measures, with those students who were lost to follow-up having significantly higher mean (±SD) BMI and triceps skinfolds than those students with follow-up data.

Table 95 Comparison between mean levels of targeted variables among the students who participated at baseline and at follow-up, and students who were lost to follow-up

Variable	Students with follow-up data		Students lost to follow-up		P [a]
	N	Mean value (SD)	N	Mean value (SD)	
BMI (kg/m^2)	147	20.0 ± 2.7	20	22.0 ± 3.8	*P<0.05*
Skinfold triceps (mm)	145	14.0 ± 5.4	21	18.4 ± 7.4	*P<0.05*
Systolic blood pressure (mm Hg)	146	109.1 ± 10.0	21	115.0 ± 14.7	ns
Diastolic blood pressure/fourth phase (mm Hg)	146	80.7 ± 6.8	21	79.9 ± 6.4	ns
Diastolic blood pressure/fifth phase (mm Hg)	146	63.9 ± 7.1	21	62.3 ± 6.3	ns
Serum total cholesterol (mg/dL)	134	163.3 ± 28.4	22	169.8 ± 26.3	ns

Source: Lionis *et al* (1991), Table 1, page 691.
Abbreviations: BMI = body mass index; SD = standard deviation
[a] Two-tailed t test

4.10.3.4 Weight-related results

The results of the analysis of outcomes are presented in **Table 96**. Results show the mean value of each outcome at baseline and the mean change from baseline at one year follow-up. Only those outcomes related to obesity have been included.

Body mass index increased, on average, by 0.22 kg/m^2 in the intervention students and by 0.71 kg/m^2 in the control students (P<0.05) resulting in a difference in change of ~0.5 kg/m^2. This result remained statistically significant even after adjustment for baseline BMI value, sex, and age. Triceps skinfold thickness decreased in both groups, but to a greater extent in the control subjects (1.30 mm) than in the interventions subjects (0.13 mm) (P<0.05). This difference was no longer significant when an analysis of covariance was carried out using the values at baseline, age, and sex as covariates. The percentage of students with a BMI greater or equal to 21 kg/m² increased from 23.1% at baseline to 25.3% at follow-up in the intervention group, and from 26.3% at baseline to 35.1% at follow-up in the control group. Arm circumference increased by 1.05 cm in the intervention group and by 1.16 cm in the control group, but the difference was not significant.

Table 96 Weight-related results: health education intervention in high school students

Outcomes	Adjustments	Intervention group (n=91)	Control group (n=57)	ANOVA [a] ANCOVA [b]
Weight (kg)				
Value at baseline	-	49.92 ± 9.45	50.48 ± 10.10	NS
Change	-	4.03 ± 4.58	5.10 ± 13.15	NS
Body mass index (kg/m²)				
Value at baseline	-	19.99 ± 2.69	19.96 ± 2.63	NS
Adjusted change	Baseline value, age, sex.	0.21 ± 1.43	0.72 ± 0.97	*P<0.05*
Skinfold (mm)				
Value at baseline	-	13.82 ± 5.24	14.43 ± 5.99	NS
Adjusted change	Baseline value, age, sex.	–0.40 ± 2.77	–1.02 ± 2.72	NS
Arm circumference				
Value at baseline	-	23.20 ± 2.74	23.16 ± 2.75	NS
Adjusted change	Baseline value, age, sex.	1.06 ± 1.12	1.15 ± 0.96	NS

Source: Lionis *et al* (1991), Table 2, page 692
Abbreviations: BMI = body mass index; NS = not significant
[a] ANOVA, analysis of variance
[b] ANCOVA, analysis of covariance; covariates: value at baseline, age, sex

As expected, the group of students who received the health education intervention gained weight, however they gained less weight than the control students (P<0.05). It is important to note that participants lost to follow-up had significantly higher BMI and triceps skinfold values than those who completed the study. How this may influence the results is uncertain as baseline values of BMI were not available by treatment arm and the number of patients lost to follow-up by treatment arms not described.

4.10.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for the health education intervention in high school students in Greece is provided in **Table 97**.

Table 97 Dimensions of evidence for the health education intervention in high school students

Dimension	Definition
Strength of evidence	
Level	The study was a Level III-II, non-randomised, cluster, controlled trial.
Quality	The study was not randomised; however two geographically separate, but demographically similar regions were compared. There was a significant difference in BMI and triceps skinfolds for those participants lost to follow-up compared with those with follow-up. Whether this would have introduced bias is uncertain.
Statistical precision	There were no confidence intervals reported. The p-value for the difference in adjusted change in mean BMI between groups was $p<0.05$.
Size of effect	There was a significant difference in change in mean BMI between the intervention and control group (~0.5 kg/m^2). There were no other significant differences in weight-based outcomes between the groups.
Relevance of evidence	The study presents BMI and triceps skinfolds, both clinically relevant outcomes. The study was conducted in Greece, in Cretan adolescents. Whether or not NZ adolescents are sufficiently similar for generalisability is unclear.

Source: NHMRC 2000b.

4.10.5 Translation of results for economic analysis

This study provides results in terms of mean weight change, BMI, triceps skinfold and arm circumference. Students in both the intervention and control group were shown to have increases in mean BMI over time; however the intervention group gained less weight than those in the control group. The difference in change in mean BMI between groups at one year follow-up was 0.51 kg/m^2 (**Table 98**).

Table 98 BMI results for Intervention 10: Health education among Cretan adolescents

Country	Setting	Category	Age (years)	Ethnicity	Mean difference in change in BMI Intervention – control (kg/m^2)
					1 year
Greece	High School	N/PA	13-14 years	Not stated	**-0.5**

Note: statistically significant results are shown in bold.
Abbreviations: BMI=body mass index; N=nutrition; PA=physical activity.

4.11 INTERVENTION 11: A SEMINAR-BASED OBESITY PREVENTION PROGRAM FOR UNIVERSITY STUDENTS

It has been suggested that adoption of healthy lifestyles during the first years of university or college could prevent the onset of weight gain associated with this period of acquired independence and eventually decrease the incidence of overweight and obesity.

The university/college intervention setting was identified during the scoping search via a search of the grey literature and content experts.

A study by Hivert *el at* (2007) examined the effects of a small group, seminar-based educational and behavioural program on weight gain in young university students in Quebec, Canada. The Hivert *et al* (2007) study was identified during the scoping search via a search of the grey literature and content experts. However, as it was the only study identified, a broader search for additional university-based interventions was conducted.

4.11.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of interventions conducted in the university/college setting in terms of the prevention of obesity. The specific research question to be answered is as follows:

Do obesity prevention interventions conducted in the university/college setting prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

In order to answer this research question, an extensive literature search was conducted.

4.11.2 Literature search

To identify studies relevant to the assessment of obesity prevention interventions conducted in the university/college setting, searches of Embase.com (covering the EMBASE and Medline databases) and the Cochrane Library were conducted. Search terms used included those relating to obesity (eg 'obesity' and 'bmi'), the setting (eg, 'university' and 'student'), and general program terms such as 'intervention' and 'monitoring'. In addition, the reference lists of identified studies were checked for additional studies. Details of the search and search results are presented in **Table 99**.

Table 99 Literature search for university/college interventions: Embase.com and Cochrane library

Search location	Search string	Citations
Embase.com (Embase and Medline) 29/01/2010	1. 'obesity':ab,ti OR 'bmi':ab,ti OR 'weight gain':ab,ti ' 2. young adult':ab,ti OR 'young adults':ab,ti OR 'college':ab,ti OR 'community college':ab,ti OR 'university':ab,ti OR 'student':ab,ti OR 'students':ab,ti OR 'freshman':ab,ti 3. intervention:ab,ti OR monitoring:ab,ti 4. #1 AND #2 AND #3 5. #1 AND #2 AND #3 AND [english]/lim AND [humans]/lim AND [1990-2010]/py	699
Cochrane Library (Trials Register) 29/01/2010	1. (obesity):ti,ab,kw or (BMI):ti,ab,kw or (weight gain):ti,ab,kw 2. (young adult OR young adults):ti,ab,kw or (college OR community college):ti,ab,kw or (university):ti,ab,kw or (student OR students):ti,ab,kw or (freshman):ti,ab,kw 3. (intervention):ti,ab,kw or (monitoring):ti,ab,kw 4. (#1 AND #2 AND #3), from 1990 to 2010	376
Subtotal		*1075*
Manual searching of reference lists	Any university/college interventions	0
TOTAL		*1075*

The following exclusion criteria were applied to the 1075 identified citations:

1. Duplicate citation – excludes multiple citations for the same publication

2. Not a clinical study – excludes publications which do not report the results of an original study (ie, in vitro studies, narrative reviews)

3. Wrong population/intervention – excludes studies which do not describe and/or assess an obesity prevention intervention in the university/college setting

4. Wrong outcomes- does not report a relevant weight-based outcome

Applying the exclusion criteria to the titles and, where available, abstracts, resulted in the identification of five publications relating to obesity prevention programmes in the university/college setting.

All of these citations were identified via the search of Embase.com and Cochrane library databases. No further studies were identified via the reference list search. The results of the application of exclusion criteria are presented in **Table 100.**

Table 100 Exclusion of citations for university/college interventions

Criterion	Citations
TOTAL IDENTIFIED	1075
Duplicate citation	110
Not a clinical study	73
Wrong population/intervention	882
Wrong outcomes	5
TOTAL REMAINING	5

The full text papers for these five studies were retrieved and a summary of each study has been provided in **Table 101**. Only the Hivert *et al* (2007) trial met the inclusion criteria for this part of the review. Three studies [Levitsky *et al* (2006); Gow, Trace and Mazzeo (2010); and Cholewa and Irwin (2008)] were excluded because of insufficient follow-up (ie, <1 year). The Matvienko, Lewis and Schafer (2001) study found that mean weight and BMI were unchanged in both groups during the 4-month intervention, and 12 months following the intervention.

Table 101 Identified university/college-based interventions

Citation	Study type	Intervention	Population		Follow-up	Outcomes	Considered effective	Included
			Control	Intervention				
Hivert *et al* (2007) Prevention of weight gain in young adults through a seminar-based intervention program. Int J Obes 31:1262–1269	RCT	Small-group interactive seminars designed to educate students and modify behaviour in relation to diet and exercise.	N=57 Age: 19.5±0.2 years Gender: 47 female Caucasian: 93%	N=58 Age: 19.9±0.2 years Gender: 47 female Caucasian: 93%	2 years	Weight (kg), BMI	Yes	✓
Levitsky *et al* (2006) Monitoring weight daily blocks the freshman weight gain: a model for combating the epidemic of obesity. Int J Obes 30:1003–1010	Cohort study	Participants were asked to weigh themselves each day. Using a tissue monitoring system, researchers provided feedback to participants on whether they were gaining or losing body tissue.	N=34 Age: 18–21 years Mean weight at baseline: 62.5±10.2 kg		4 months	Weight (kg)	Yes	
Matvienko, Lewis and Schafer (2001) A college nutrition science course as an intervention to prevent weight gain in female college freshman. JNE 33:95–101	RCT	A college course composed of lectures and laboratory exercisers where students were taught principles related to dietary and body sources of biologic energy.	N=19 All female Age: 19.5±1.1 years Weight: 65.7±12.7 kg BMI: 23.7±4.6 kg/m²	N=21 All female Age: 19.3±0.8 years Weight: 67.7±12.9 kg BMI: 24.6±4.7 kg/m²	16 months	Weight (kg), BMI, nutrient intake and knowledge.	No	
Gow, Trace and Mazzeo (2010) Preventing weight gain in first year college students: an online intervention to prevent the 'freshman fifteen'. Eating behaviours 11:33–39.	Randomised pre-test post-test controlled study	Feedback group: weighed themselves and reported back once per week. Internet group: weekly health education sessions delivered online Combined feedback and intervention group.	N=159 Male: 41 (25.8%); Female: 118 (74.2%) Caucasian: 53.8%; African American: 22.2%; Asian 10.8%; Hispanic: 2.5%; 'Other': 10.8% Mean BMI: 24.38 kg/ m²		3 months	BMI	Yes, for combined intervention group only	
Cholewa and Irwin (2008) Brief report on a Pilot Programme promoting Physical Activity among University Students. J Health Psychol 13;1207–1212	Pre-test post-test study	A buddy system was used to pair same sex individuals who worked together to increase their physical activity. Participants recorded exercise in a log book.	N=71 N=51 completed 9 weeks Full time students at the University of Western Ontario No. with BMI<25: 76.5%		9 weeks	BMI, physical activity level	No	

Source: Cholewa and Irwin (2008); Gow *et al* (2010); Hivert *et al* (2007); Levitsky *et al* (2006); Matvienko *et al* (2001)
Abbreviations: BMI= body mass index; RCT = randomised controlled trial

4.11.3 Results

The following section provides further details of the intervention and the characteristics of the included Hivert *et al* (2007) study. The baseline characteristics of the intervention and control groups are described as well as two sets of results: (i) results of the pivotal weight-related outcomes; and (ii) results of other supportive outcomes.

4.11.3.1 Intervention characteristics

The components and timing of various aspects of the intervention is shown in **Figure 12**. Small-group interactive seminars were offered every two weeks for the first two months of the semester and every month thereafter for the remaining two years (a total of 23 seminars over two years). The seminars were initially aimed at increasing knowledge on weight gain, dietary recommendations and exercise. The remaining seminars were designed to introduce behavioural modification methods. Some focused on behavioural strategies to maintain a healthy lifestyle during specific periods such as final exams, holidays, winter and vacations.

Figure 12 Components and timing of the seminar-based intervention

T=0	T=3	T=6	T=12
Fall #1 Seminars every 2 weeks 1-Obesity: epidemiology and health consequences 2-Physical activity, types and benefits 3-Balanced nutrition 4-Exercise and motivation, how do you do it? 5-Food, concept of "volumetric" 6-School studies and exercise 7-Christmas holidays: how to deal with it?	Winter #2 Seminars once a month 8-Reducing sedentarity 9-Testimony of people who study hard but still find time to perform highly in competitive sports 10-Demystifying diets, weight loss programs and products	Spring #1 Seminars once a month 11-How to keep good resolutions and stay motivated 12-Alcohol and tobacco: relations to global health and weight 13-Plan your summer	Summer #1 No seminar

T=12		T=18	T=24
Fall #2 Seminars once a month 14-Back to school: review of the last year and objectives for the coming one 15-How to modify your lifestyle 16-Meet the dietician: all you always wanted to ask 17-Metabolism of physical activity	Winter #2 Seminars once a month 18-Reading food labels: let's go to the supermarket 19-Testimony: people health professionals who still find time to exercise 20-Recipes: quick, easy and healthy	Spring #2 Seminars once a month 21-How to build your training program 22-Restaurants and fast foods 23-Lifestyle and family: what you got from your parents and what impact you will have on your own family later	Summer #1 No seminar

Source: Hivert *et al* (2007), Figure 1, page 1263

4.11.3.2 Study characteristics

The main characteristics of the Hivert *et al* (2007) study are summarised in **Table 102**. It was designed as a randomised, prospective, controlled trial, conducted over two years in a Quebec University. The population consisted of 115 predominantly female students, with a mean age of 19 years. Various anthropomorphic, physiological and dietary outcomes were assessed at different time points.

Table 102 Study characteristics: University-based intervention

Citation	Study type	Population	Intervention/ comparator	Outcomes
Hivert *et al* 2007	Randomised controlled trial University-based 1 intervention and 1 control group 2 years duration	N= 115 Mean age: 19 years Gender (female):94 (81.7%) Ethnicity: Caucasian: 93% Majority had a BMI in the healthy range (only 15/115 had a BMI between 25 and 30 kg/m²)	Seminars vs. no Seminars The seminars consisted of a series of educational sessions relating to exercise, nutrition and other aspects of maintaining a healthy lifestyle	*Weight (kg)* Height (cm) *BMI (kg/m²)* *Waist circumference (cm)* *Lean mass (kg)* *Non-lean mass (kg)* VO_2 max Physical activity (kcal/kg/year) Total caloric intake (kcal/d) % carbohydrates % proteins % of lipids % of alcohol Total cholesterol Triglycerides (mmol/l) HDL (mmol/l) LDL (mmol/l) Cholesterol total/HDL SBP DBP

Abbreviations: BMI, body mass index; DBP = diastolic blood pressure; systolic blood pressure
Note: Outcomes which are considered relevant to this review, and which are described in the results section, are shown in italics.

4.11.3.3Baseline participant characteristics

Table 103 summarises the mean baseline characteristics of participants in the Hivert *et al* (2007) study, as presented in the publication. The majority of participants included in the study were female (~82%), Caucasian (~93%), and 19-20 years of age. Participants were recruited from health care courses within the university. At baseline, most individuals had a BMI in the healthy range (only 15 out of the 115 participants had a BMI between 25 and 30 kg/m²). Food intake, physical activity level and fitness levels were similar in both groups. Similarly, there were no significant differences at baseline in the lipid profile or blood pressure of the control and intervention group.

Table 103 Baseline characteristics of Hivert *et al* (2007) study

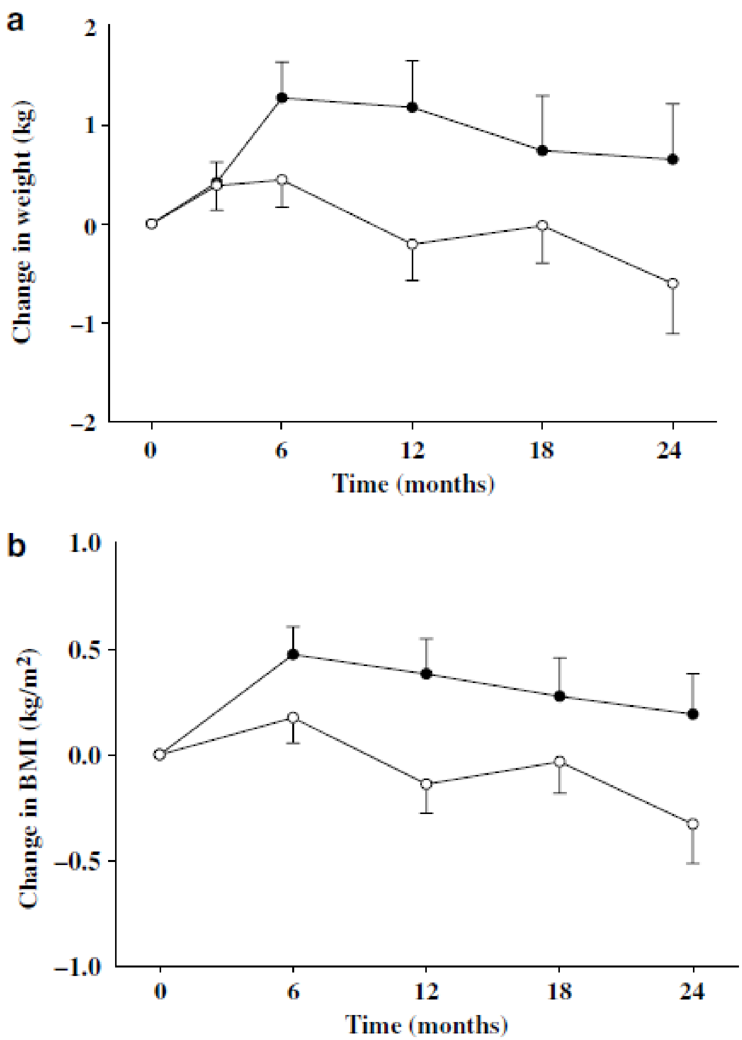
	Control group (n=57)	Intervention group (n=58)
Age (year)	19.5 (0.2)	19.9 (0.2)
Gender (female/male)	47/10	47/11
Caucasian (%)	93	93
Family history		
BMI – father (kg/m²)	26.5 (0.5)	26.7 (0.4)
BMI – mother (kg/m²)	25.4 (0.7)	24.5 (0.5)
Anthropometric data		
Weight (kg)	63.5 (1.3)	62.9 (1.4)
Height (m)	1.680 (0.109)	1.672 (0.093)
BMI (kg/m2)	22.4 (0.3)	22.4 (0.4)
Waist circumference (cm)	72 (1)	72 (1)
Lean mass (kg)	48.5 (1.0)	48.0 (1.1)
Non-lean mass (kg)	15.0 (0.6)	15.0 (0.5)
Physical activity (kcal/kg/year)	1378 (145)	1216 (112)
VO_2 max (ml/kg/min)	38.8 (0.6)	39.0 (0.6)
Food intake		
Average caloric intake (kcal/day)	2016 (77)	2051 (77)
% carbohydrates	52.4 (0.9)	52.6 (1.0)
% proteins	16.6 (0.4)	16.5 (0.4)
% lipids	30.1 (0.8)	29.5 (0.8)
% alcohol	0.9 (0.2)	1.5 (0.4
Lipid profile		
Total cholesterol (mmol/l)	4.33 (0.10)	4.55 (0.12)
Triglycerides (mmol/l)	1.11 (0.05)	1.24 (0.08)
HDL (mmol/l)	1.31 (0.04)	1.30 (0.03)
LDL (mmol/l)	2.52 (0.08)	2.68 (0.10)
Total cholesterol/HDL ratio	3.4 (0.1)	3.6 (0.1)
Blood pressure		
Systolic (mm Hg)	110 (2)	111 (1)
Diastolic (mm Hg)	71 (1)	70 (1)

Source: Hivert *et al* (2007), Table 1, page 1265
Abbreviations: BMI = body mass index; HDL – high density lipoprotein; LDL = low density lipoprotein

4.11.3.4 Weight-related results

The results of the analyses of change in weight and BMI from baseline to 24 months are presented in **Figure 13.** As expected, the control group gained weight over the two year follow-up period. By contrast, the intervention group did not gain weight and, on average, exhibited a slight weight loss. The difference in weight change between the two groups was most prominent in the first six months of the study, with the difference maintained over 24 months. Change in BMI showed a similar trend and became significantly lower in the intervention group over the follow-up period (P=0.01). These results suggest that the university, seminar-based intervention was successful in preventing weight gain.

Figure 13 **(a) Change in weight (kg) over the 24-month follow-up period in the intervention (open circles) vs. control (closed circles) groups; (b) Change in BMI (kg/m^2) over the 24-month follow-up period in the intervention (open circles) vs. control (closed circles) groups**



Source: Hivert *et al* (2007), Figure2, page 1265

The changes in other outcome parameters over time is shown in **Table 104**. Only those related to weight have been included. There was no difference in height over time or between the groups. Secondary analysis with the last observation carried forward (LOCF) method showed similar results, although the difference of weight gain between the two groups was of borderline statistical significance for weight (P=0.06 for weight, P=0.01 for BMI). However, the latter analysis assumed that dropouts did not gain weight and therefore can be considered conservative. The ANOVAs were also performed with adjustment for weight at baseline and it did not change results. Waist circumference and lean body mass did not change significantly over the follow-up period. Non-lean mass (weight minus lean mass) increased in the control group, especially at 12 months, whereas it decreased in the intervention group (P=0.07).

Table 104 Change in outcome parameters over time

	Change at 12 months (mean±s.e.m)	Change at 24 months (mean±s.e.m)	ANOVA P-value for group effect
Weight (kg)			
Control	1.2±0.5	+0.7±0.6	0.04
Intervention	-0.2±0.4	-0.6±0.5	
BMI (kg/m²)			
Control	+0.4±0.2	+0.2±0.2	0.01
Intervention	-0.1±0.1	-0.3±0.2	
Waist circumference (cm)			
Control	0±0	0±1	0.11
Intervention	-1±0	-1±1	
Lean mass (kg)			
Control	0.0±0.2	+0.2±0.2	0.13
Intervention	-0.4±0.2	-0.2±0.4	
Non-lean mass (kg)			
Control	+1.3±0.2	+0.4±0.2	0.07
Intervention	+0.2±0.2	-0.3±0.2	

Source: Hivert *et al* (2007), Table 2, page 1266
Abbreviations: ANOVA = analysis of variance; s.e.m = standard error of the mean

4.11.3.5Physical activity-related results

There were small, but not statistically significant differences in self-reported levels of physical activity between the control and intervention groups (**Table 105**). At 24 months, the average level of physical activity was still considered 'high' in the intervention group (3.18 kcal/kg/day), whereas it had decreased to 'moderate' (defined as 1.5–2.9 kcal/kg/day) in the control group (2.88 kcal/kg/day).

Table 105 Change in outcome parameters over time

	Change at 12 months (mean±s.e.m)	Change at 24 months (mean±s.e.m)	ANOVA P-value for group effect
Physical activity (kcal/kg/year)			
Control	-260±111	-292±110	0.15
Intervention	-81±92	-89±127	
VO_2 max (ml/kg/min)			
Control	–0.96 ± 0.46	+0.31 ± 0.42	0.37
Intervention	–0.31 ± 0.34	+0.28 ± 0.34	

Source: Hivert *et al* (2007), Table 2, page 1266
Abbreviations: ANOVA = analysis of variance; VO_2 max: =estimated maximal oxygen consumption

In addition, the study examined correlations between change in weight and other outcome measures at 24 months (**Table 106**). Change in weight correlated very strongly with changes in waist circumference, non-lean mass and moderately with change in lean mass. No significant correlation was detected between body weight change and change in physical activity level measured by questionnaire. However, baseline self-reported activity level was negatively correlated to weight gain (r=–0.32; P=0.005). Baseline total caloric intake was positively correlated with weight gain (r=0.27; P=0.008) but increase in food intake was not associated with increase in body weight.

Table 106 Correlations between change in weight and other outcome measurements over 24 months

	Pearson coefficient	P-value
Height	0.03	0.80
Waist circumference	0.75	<0.001
Lean mass	0.45	<0.001
Non-lean mass	0.83	<0.001
Physical activity	0.13	0.25

Source: Hivert *et al* (2007), Table 3, page 1267
Abbreviations: VO_2 max = estimated maximal oxygen consumption

The Hivert *et al* (2007) study demonstrates the effectiveness of a seminar-based educational and behavioural program to prevent weight gain in young healthy adults in a university setting. One limitation of the study is that university students, particularly in health care disciplines, may be more health conscious than the young adult population in general. Therefore the generalisability of the results to other populations is uncertain. Nevertheless, if maintained over a prolonged period, such a degree of prevention in weight gain could translate into substantial public health benefits.

4.11.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for the university-based, obesity prevention intervention is provided in **Table 107**.

Table 107 Dimensions of evidence for the university-based, obesity prevention study

Dimension	Definition
Strength of evidence	
Level	The study was a Level II randomised controlled trial.
Quality	The study was a high quality controlled trials with standardised assessment
Statistical precision	The variation around the estimates of weight related outcomes were small. The study was sufficiently powered to detect a significant difference between the control and intervention group.
Size of effect	There was a significant difference in change in BMI over 24 months between the control and intervention group (mean difference: 0.5kg/m^2, p= 0.01). The control group, on average, gained weight, whereas the intervention group, on average, lost weight over the two year follow-up period.
Relevance of evidence	The study presents weight change and BMI, both clinically relevant outcomes when examining obesity prevention programs. Whether or not these results, found in a population of health science university students, are generalisable to other college/university settings, is uncertain.

Source: NHMRC 2000b.

4.11.5 Translation of results for economic analysis

This study showed a statistically significant difference in BMI between the intervention and control group (mean difference: 0.5 kg/m^2, p=0.01) at both 1 and 2 years (**Table 108**).

Table 108 BMI results for Intervention 10: Health education among Cretan adolescents

Country	Setting	Category	Age (years)	Ethnicity	Mean difference in change in BMI Intervention – control (kg/m²)	
					1 year	2 years
USA	University	N/PA	~19 years	Caucasian (~93%)	**-0.5**	**-0.5**

Note: statistically significant results are shown in bold.
Abbreviations: BMI=body mass index; N=nutrition; PA=physical activity.

4.12 INTERVENTION 12: WORKPLACE INTERVENTIONS

Workplaces are a sedentary setting for many people, and also a place where access to energy dense food and beverage is widespread (Anderson *et al*, 2009). As a result, a variety of obesity prevention interventions have been targeted at individuals in the workplace setting. These interventions focus on increasing the proportion of adults who are at a healthy weight and reducing the proportion of adults who are overweight or obese.

Two obesity prevention interventions implemented in the workplace were identified during the scoping search via a search of online databases, grey literature and content experts. However, due to the small number of appropriate interventions identified that met the inclusion criteria for potential review, a full systematic search of workplace interventions was undertaken to ensure all possible workplace interventions were identified and reviewed.

4.12.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of workplace interventions in terms of the prevention of obesity. The specific research question to be answered is as follows:

Do workplace obesity prevention interventions prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

In order to answer this research question, an extensive literature search was conducted.

4.12.2 Literature search

In order to identify studies relevant to the assessment of workplace obesity prevention programs, searches of Embase.com (covering the EMBASE and Medline databases) and the Cochrane Library were conducted. Search terms used included those relating to obesity ('obesity' and 'BMI'), the setting ('workplace', 'work environment', 'employee' and 'employer') and two of the lead authors for two workplace interventions identified during the scoping literature search. Details of the search and search results are presented in **Table 109**.

Table 109 Literature search for workplace interventions: Embase.com and Cochrane Library

Search location	Search string	Citations
Embase.com (EMBASE and Medline) 13/01/2010	1. 'goetzel r.z'/au 2. 'wier l.t'/au 3. 'obesity':ab,ti OR 'bmi':ab,ti 4. 'workplace':ab,ti OR 'work environment':ab,ti OR 'employee':ab,ti OR 'employer':ab,ti 5. #3 AND #4 6. #1 OR #2 OR #5	397
Cochrane Library (Trials Register and economic evaluations) 13/01/2010	1. 'goetzel r.z'/au 2. 'wier l.t'/au 3. 'obesity':ab,ti OR 'bmi':ab,ti 4. 'workplace':ab,ti OR 'work environment':ab,ti OR 'employee':ab,ti OR 'employer':ab,ti 5. #3 AND #4 6. #1 OR #2 OR #5	65
Subtotal		*462*
Manual searching of reference lists		0
TOTAL		*462*

The following exclusion criteria were applied to the 462 identified citations:

1. Duplicate citation – excludes multiple citations for the same publication
2. Not a clinical study – excludes publications which do not report the results of an original study conducted in humans (ie, excludes animal studies, in vitro studies, narrative reviews)
3. Wrong population/intervention – excludes studies which do not describe and/or assess a relevant workplace intervention with relevant outcomes and sufficient follow-up
4. Wrong outcomes- does not report a relevant weight-based outcome
5. Not in English language.

Applying the exclusion criteria resulted in the identification of 14 citations potentially relevant for inclusion, one of which was a large systematic review conducted by Anderson *et al* (2009). The results of the application of exclusion criteria are presented in **Table 110**.

Table 110 Exclusion of citations for workplace interventions

Criterion	Citations
TOTAL IDENTIFIED	462
Duplicate citation	49
Not a clinical study	240
Wrong population/intervention	158
Not in English language	1
TOTAL REMAINING	14

As mentioned previously, one of the studies identified was a large systematic review (Anderson *et al* 2009). Summaries of all the studies included in the systematic review, as well as those more recent studies found in the updated literature search were presented to the SRG. From this, the SRG selected two studies for full review. Details of the two included citations are presented in **Table 111**.

Table 111 Included citations: Workplace interventions

Citation details	Included
Gemson DH, Commisso R, Fuente J, Newman J, and Benson S. (2008) Promoting weight loss and blood pressure control at work: Impact of an education and intervention program. Journal of Occupational and Environmental Medicine 50:272-281.	✓
Gomel M, Oldenburg B, Simpson JM, and Owen N. (1993) Work-site cardiovascular risk reduction: A randomized trial of health risk assessment, education, counseling, and incentives. American Journal of Public Health 83:1231-1238.	✓

4.12.3 Results

Gomel and colleagues (1993) conducted a work-site cardiovascular risk reduction study that assessed the effectiveness of four different work-site health promotion programs primarily concerned with behavioural counselling and education. The study was conducted in Sydney, Australia amongst 431 ambulance service employees. Gemson *et al* (2008) assessed the impact of a multi-faceted intervention, primarily focusing on encouraging physical activity, on hypertensive Merrill Lynch employees in the US. The study will be referred to as the Education and Intervention Program.

4.12.3.1 Intervention characteristics

Gomel *et al* (1993)

Participants were randomly allocated to one of four workplace intervention conditions. These included health risk assessment (HRA), risk factor education (RFE), behaviour counselling (BC) and behaviour counselling plus incentives (BCI). For risk assessment, major risk factors for cardiovascular disease were assessed and feedback provided to each participant on his or her risk factor profile. No other information or advice was given to participants in this condition. Risk factor education involved participants receiving the same health assessment as those in the health risk assessment condition and, in addition, standardised advice on lifestyle modifications to reduce cardiovascular disease risk. Participants in the behaviour counselling group received the same components as those in the risk factor education condition. If risk factors were identified, participants were offered up to six life-style counselling sessions over a 10-week period following the baseline assessment. Behavioural counselling plus incentives involved the same components as risk factor education plus they were provided with a life-style change manual and were offered a goal-setting and follow-up counselling session, as well as a range of incentives. Incentives were lottery tickets and money for achieving goals.

Gemson *et al* (2008)

Gemson *et al* (2008) aimed to assess the impact of a multi-faceted intervention on BMI and blood pressure among hypertensive Merrill Lynch employees participating in an employer-based screening program. All participants, in both the experimental and control group, shared the following components of the intervention:

- A hypertension screening program
- Tables staffed by registered nurses to communicate with employees about the study
- A questionnaire and a blood pressure reading
- Being weighed on scales
- Receiving a wallet sized health information card with blood pressure, weight, BMI, and five lifestyle modifications to improve blood pressure control
- Educational brochures promoting physical activity and blood pressure awareness

In addition, employees in the experimental group received or were exposed to the following components of the intervention:

- Pedometers
- A poster placed in each blood pressure screening station stating health messages
- A wallet sized health information card exactly the same as in the control group except with two additional messages regarding increasing physical activity on the back
- Registered nurses were instructed to verbally state three brief health messages
- Each employee had body fat measured by bioelectrical impedance method

- An environmental intervention with fresh fruits displayed at the cafeteria

4.12.3.2 Study characteristics

Gomel *et al* (1993)

The Gomel *et al* (2003) study was conducted in the Sydney metropolitan area of the Ambulance Service in New South Wales, Australia. Twenty-eight stations with 12 or more employees were randomly selected for inclusion. A cluster randomisation procedure, in which ambulance stations rather than individuals were assigned to each of the four conditions, was used to limit potential contamination between the conditions. Once a station was randomised to a condition, all staff within that station received that intervention. There was no control group in the study. Participants were assessed at baseline and at 3, 6, and 12 months following the baseline assessment. Various anthropometric measures were recorded and blood pressure and cholesterol measures were taken at each assessment.

Gemson *et al* (2008)

This study was conducted in the US among Merrill Lynch employees. A quasi experimental study design was used in which five sites (consisting of 6, 319 employees) served as the potential control group and two sites (consisting of 9, 534 employees) served as the potential experimental group. The sites were selected to represent similar numbers of participants in the two groups and without regard to demographic or employment characteristics. Eligibility required employees to undergo baseline blood pressure screening in May 2004 and to have a systolic blood pressure ≥140 mm Hg and/or a diastolic blood pressure ≥90 mm Hg, this resulted in the inclusion of 298 in the experimental group and 255 in the control group. Outcome measures included BMI, blood pressure, self-reported physical activity, self-reported diet and nutrition behaviours, and a series of attitudinal questions about weight, blood pressure, and motivation to change health behaviour. Changes were assessed at one year follow-up.

It is important to note there was significant dropout from the original study population. Employees who were eligible at baseline and completed the 1-year follow-up evaluation included just 47 of 298 (15.8%) of the experimental group and 94 of 255 (36.9%) of the control group. There were no data reported for non-completers.

4.12.3.3 Baseline participant characteristics

Gomel *et al* (1993)

A summary of the demographic characteristics of participants at baseline are presented in **Table 112**. Participants were approximately 30 years of age, with 80-85% being male. There was a small but statistically significant baseline difference between groups for age and job description. However, age was not used as a covariate because the differences between groups were small and unlikely to interact with interventions over time. The majority of participants were married or living with a partner and had been educated to at least high school level. Most participants were working as ambulance officers.

Table 112 Baseline demographic characteristics of participants

Demographics	Health risk assessment	Risk factor education	Behaviour counselling	Behaviour counselling plus incentives
N	*130*	*82*	*124*	*95*
Mean age, years	31	33	33	31
Sex, %				
Male	85	82	81	85
Female	15	18	19	15
Marital status, %				
Never married	32	28	27	26
Married or living together	58	55	61	61
Other (separated, divorced or widowed)	10	17	13	13
Education level, %				
Some high school (7–12 years)	20	18	18	20
High school (12 years)	53	51	56	55
Further education	27	31	27	25
Job title, %				
Ambulance officer	79	76	73	59
Paramedic	18	18	18	30
Manager/administrator	3	6	9	11

Source: Gomel *et al* (1993): Table 1, page 1232

Gemson *et al* (2008)

Baseline demographic characteristics, BMI, and blood pressure values are shown in **Table 113**. It is important to note that this study was only conducted in patients who had high blood pressure at baseline screening measurements. There was no statistically significant difference between the experimental and control groups with respect to gender, mean age, ethnicity, blood pressure, or BMI. Mean (SD) age in the experimental group was 45.4 (9.4) years and in the control group was 47.7 (11.9) years. There were slightly more men in the experimental group (46.8%) versus the control group (51.1%). Approximately half of both populations were Caucasian (48.9%, experimental group; 46.8%, control group). The experimental group consisted of fewer African-Americans and Hispanic (21.3% vs. 29.8% and 4.3% vs. 7.4%, respectively) versus the control group, but both groups had a comparable proportion of Asian/Pacific Islanders employees (14.9% and 14.9%, respectively).

Table 113 Baseline demographic characteristics

Characteristic	Experimental	Control	p
N	*47*	*94*	
Male, n (%)	22 (46.8)	48 (51.1)	0.63
Age (yr), mean ± SD	45.4 ± 9.4	47.7 ± 11.9	0.21
Ethnicity, n (%)			0.21
Caucasian	23 (48.9)	44 (46.8)	
African American	10 (21.3)	28 (29.8)	
Asian/Pacific islander	7 (14.9)	14 (14.9)	
Hispanic	2 (4.3)	7 (7.4)	
Other	5 (10.6)	1 (1.1)	
SBP (mm Hg), mean ± SD	138.5 ± 11.7	140.6 ± 10.4	0.29
DBP (kg/m²), mean ± SD	90.7 ± 6.4	89.0 ± 7.0	0.14
BMI (kg/m²), mean ± SD	28.0 ± 4.2	29.7 ± 7.0	0.10
Use pedometer, n (%) ('always or sometimes')	4 (8.5)	7 (7.4)	0.77

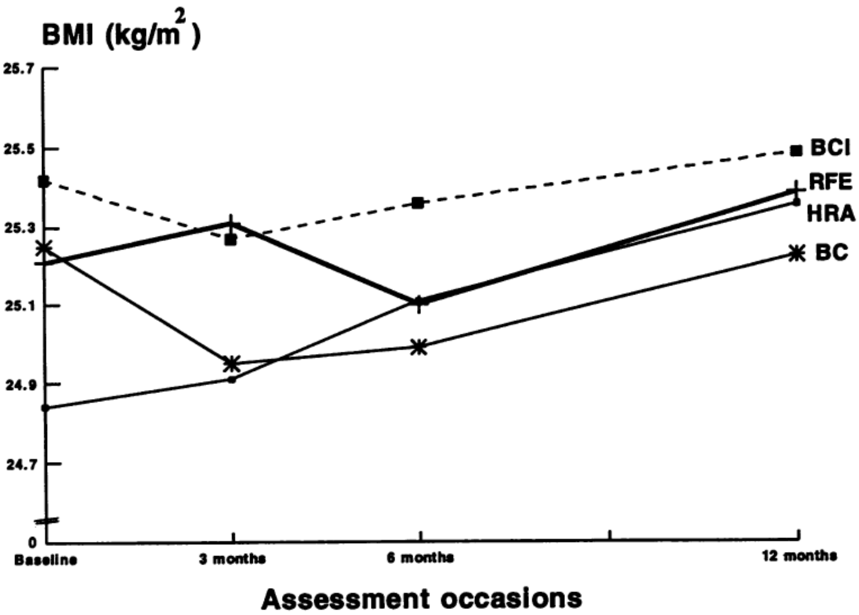
Source: Gemson *et al* (2008) Table 1, page 276
Abbreviations: BMI = body mass index; DBP = diastolic blood pressure; SBP = systolic blood pressure

4.12.3.4 Weight-related results

Gomel *et al* (1993)

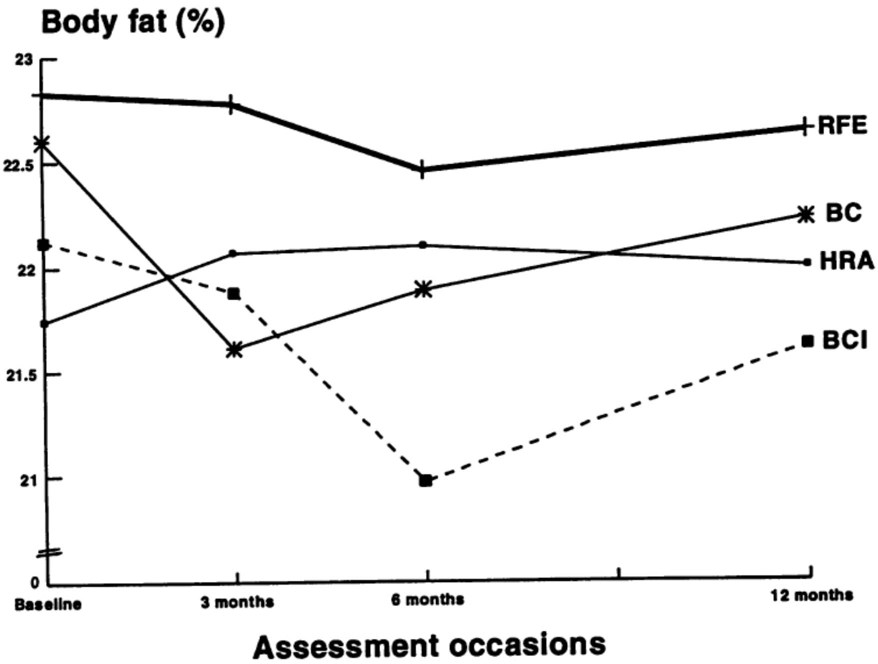
The change in BMI by intervention group across the 12 month study period is shown in **Figure 14**. The HRA group had a mean BMI at baseline of ~24.85 kg/m², which increased to ~25.35 kg/m² at 12 months follow-up (+0.5 kg/m²). The RFE group had a mean BMI at baseline of ~25.2 kg/m² which increased to ~25.4 kg/m² at 12 months follow-up (+0.2 kg/m²). The BC intervention group had a mean BMI at baseline of 25.28 kg/m² which decreased to ~25.2 kg/m² at 12 months follow-up (–0.08 kg/m²). The BCI group had a mean BMI at baseline of ~25.42 kg/m² which increased to ~25.49 kg/m² at 12 months follow-up (+0.07 kg/m²). Although BMI increased significantly overall over the four assessment occasions (p = 0.04), the increase was significantly greater for the average of the HRA and RFE groups than for the average of the BC and BCI groups (p=0 .04). The increase in BMI from baseline to the 12-month follow-up for the average of the HRA and the risk factor education groups was ~4% higher than the average increase in the behavioural counselling and behavioural counselling plus incentives groups.

Figure 14 Change in BMI



Change in percentage body fat over the 12 month study period is presented in **Figure 15**. The HRA group had a mean % body fat at baseline of ~21.75%, which increased to ~22% at 12 months follow-up (+0.25%). The RFE group had a mean % body fat at baseline of ~22.8% which decreased to ~22.6% at 12 months follow-up (–0.2%). The BC intervention group had a mean % body fat at baseline of 22.6% which decreased to ~22.25% at 12 months follow-up (–0.35%). The BCI group had a mean % body fat at baseline of ~22.1% which decreased to ~21.6% at 12 months follow-up (–5%). There were no significant changes between groups for estimated percentage of body fat from baseline to 12 months. However, there was a significant decrease in body fat, followed by a return to baseline levels over the 12 months, for the average of the BC and BCI groups compared with the average of the HRA and RFE groups (P =0.02).

Figure 15 Change in percentage of body fat



Gemson *et al* (2008)

The weight and BMI change at one-year follow-up is shown in **Table 114**. After one year follow-up, the experimental groups' BMI had declined, on average, by 1.0 kg/m^2 compared with the control group, whose BMI increased, on average, by 0.2 kg/m^2 (difference of 1.2 kg/m^2; P<0.01). Although the results indicate a statistically significant difference in BMI between the intervention and control, there are a number of factors that limit the results. Firstly, the groups were not randomly assigned and participants may have significantly differed in ways that the investigators were unable to assess. Secondly, as employees chose to participate there may have been some 'volunteer bias'. There were also a large number of participants screened at baseline who were lost to follow-up (~84% in the intervention group and ~64% in the control group) which could have substantially influenced the results.

Table 114 Weight and BMI change at one year follow-up

Characteristic (Mean ± SD)	Experimental (n=47)	Control (n=94)	P
Weight (kg)[a]	3.7 ± 4.6	1.1 ± 5.7	<0.01
BMI (kg/m^2)	–1.0 ± 1.6	+0.2 ± 1.2	<0.01

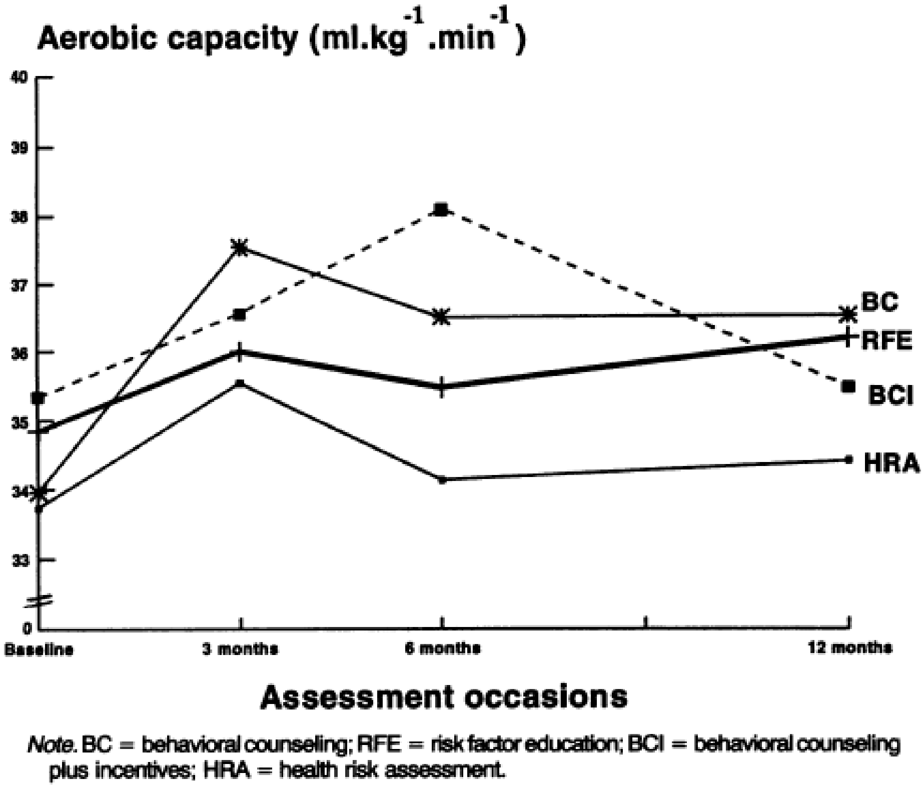
Source: Gemson *et al* (2008) Table 2, page 276
[a] The pounds presented in report were converted to kg

4.12.3.5 Physical activity related results

Gomel *et al* (1993)

The only outcome measure in the study relating to physical activity was aerobic capacity. Changes in aerobic capacity are shown in **Figure 16**. The HRA group had a mean aerobic capacity at baseline of ~33.9 $ml.kg^{-1}.min^{-1}$, which increased to ~34.2 $ml.kg^{-1}.min^{-1}$ at 12 months follow-up (+0.3 $ml.kg^{-1}.min^{-1}$). The RFE group had a mean aerobic capacity at baseline of ~34.9 $ml.kg^{-1}.min^{-1}$ which increased to ~36.0 $ml.kg^{-1}.min^{-1}$ at 12 months follow-up (+1.1 $ml.kg^{-1}.min^{-1}$). The BC intervention group had a mean aerobic capacity at baseline of 34.0 $ml.kg^{-1}.min^{-1}$ which increased to ~36.5 $ml.kg^{-1}.min^{-1}$ at 12 months follow-up (+2.5 $ml.kg^{-1}.min^{-1}$). The BCI group had a mean aerobic capacity at baseline of ~35.2 $ml.kg^{-1}.min^{-1}$ which increased to ~35.5 $ml.kg^{-1}.min^{-1}$ at 12 months follow-up (+0.3 $ml.kg^{-1}.min^{-1}$). Aerobic capacity increased significantly for all groups, but this increase was not maintained at 12 months. The short-term improvement in aerobic capacity was similar across all intervention groups.

Figure 16 Change in aerobic capacity over time



Gemson *et al* (2008)

At baseline, 19.1% of the experimental group and 22.3% of the control group reported undertaking vigorous physical activity (≥3 x/wk); a difference that was not statistically significant. At one-year follow-up, 38.3% of the experimental group and 27.7% of the control group reported undertaking vigorous physical activity. This represents a 100% increase in those undertaking vigorous physical activity in the experimental group and a 23.8% increase in the control group. There was also a statistically significant increase in pedometer use in the experimental group from 8.5% to 27.7% ($P < 0.05$). Use in the control group, who did not receive a pedometer, remained—not unexpectedly—unchanged, highlighting the willingness of engaged participants to use a free tool to monitor their physical activity.

Table 115 Physical activity and pedometer self-reported change at one-year follow-up

Characteristic	Experimental (Baseline; n=47), %	Experimental (Follow-up; n=47), %	Control (Baseline; n=94), %	Control (Follow-up; n=94), %
Vigorous physical activity (≥3 x wk)	19.1	38.3	22.3	27.7
Use pedometer ('always or sometimes'	8.5	27.7	7.4	5.3

4.12.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for each study is provided in **Table 116**.

Table 116 Dimensions of evidence for workplace intervention studies

Study	**Gomel *et al* (1993)**	**Gemson *et al* (2008)**
Dimension	**Definition**	
Strength of evidence		
Level	The study was a Level II cluster randomised trial	The study was a Level III-2 non-randomised controlled trial
Quality	The study was a high quality randomised trial but with no control group. There was 12 months follow-up and minimal loss to follow-up. Recruitment may have introduced some selection bias.	There was no randomisation and substantial attrition over the course of the study. There was no reporting of differences between those who were followed-up and those who weren't. Selection bias may have also been an issue.
Statistical precision	The p value for difference in BMI increase between the average of the health risk assessment and risk factor education groups compared to behavioural counseling plus incentive groups was small (p=0.04)	The p value for the difference in change in BMI between the intervention and control group at one-year follow-up was <0.01.
Size of effect	BMI increased significantly in all four groups at one year follow-up. However, the increase in BMI from baseline to the 12-month follow-up for the average of the health risk assessment and the risk factor education groups was 4% higher than the average increase in the behavioral counseling and behavioral counselling plus incentives groups.	The mean difference in BMI between the intervention and control group was 1.2 kg/m^2 at one year follow-up.
Relevance of evidence	This study was conducted in Australia amongst ambulance service workers. Standard measures of obesity assessment were used. Results could be applied however minimal change was observed.	The study was conducted in the US amongst Merrill Lynch employees who were hypertensive. Therefore, whether or not these results for such a specific population are applicable to NZ is uncertain.

Source: NHMRC 2000b.

4.12.5 Translation of results for economic analysis

In the Gomel *et al* (1993) study, changes from baseline in weight-related outcomes were minimal with little difference in BMI and no significant change in percentage body fat at 12 months-follow up. The only significant finding was that the increase in BMI from baseline to 12-month follow-up for the average of the health risk assessment and the risk factor education groups was 4% higher than the average increase in the behavioral counseling and behavioral counselling plus incentives groups. The Gemson *et al* (2008) study reported a significant mean difference in BMI between the intervention and control group of 1.2 kg/m^2 at one year follow-up.

Table 117 BMI results for Intervention 12: Workplace interventions

Country	Setting	Category	Age (years)	Ethnicity	Mean difference in change in BMI Intervention – control (kg/m²)
					1 year
Australia	Workplace: Ambulance Service	RFE - HRA	Adult	NR	–0.30 [a]
		BC - HRA	Adult	NR	–0.58 [a]
		BCI-HRA	Adult	NR	–0.43 [a]
USA	Workplace: Merrill Lynch	E/PA	Adult	Caucasian (~48%); African-American (~27%)Asian/Pacific Islander (~15%)	**–1.2**

Note: statistically significant results are shown in bold.
Abbreviations: BC = behaviour counselling; BCI = behaviour counselling plus incentive; BMI=body mass index; E = education; HRA= health risk assessment; NR=not reported; PA = physical activity; RFE = risk factor education
[a] Calculated post-hoc from Gomel *et al* (1993): Figure 1, page 1235.

4.13 INTERVENTION 13: THE WOMEN'S HEALTH INITIATIVE DIETARY MODIFICATION TRIAL

The Women's Health Initiative Dietary Modification Trial was a long term intervention study examining the effect of educational sessions to promote a decrease in fat intake and increases in vegetable, fruit, and grain consumption amongst post-menopausal women. The study was conducted in the US.

This intervention was identified during the scoping search via a search of medical literature databases and content experts.

4.13.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of The Women's Health Initiative Dietary Modification Trial in terms of the prevention of obesity. The specific research question to be answered is as follows:

Does the obesity prevention intervention 'The Women's Health Initiative Dietary Modification Trial' prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

In order to answer this research question, an extensive literature search was conducted.

4.13.2 Literature search

In order to identify studies relevant to the assessment of the The Women's Health Initiative Dietary Modification Trial, searches of Embase.com (covering the EMBASE and Medline databases) and the Cochrane Library were conducted. Search terms used included those relating to the intervention and two of the lead authors. In addition, the grey literature was searched and reference lists of identified studies were checked for additional studies. Details of the search and search results are presented in **Table 118**.

Table 118 Literature search for The Women's Health Initiative Dietary Modification Trial: Embase.com and Cochrane Library

Search location	Search string	Citations
Embase.com (EMBASE and Medline) 29/03/2010	1. 'women health initiative' OR 'womens health initiative' OR 2. 'Dietary modification trial'	80
Cochrane Library (Trials Register) 29/03/2010	1. (women's health initiative dietary modification trial):ti,ab,kw in Clinical Trials	21
Subtotal		*101*
Grey literature search	'The Women's Health Initiative Dietary Modification Trial'	0
Manual searching of reference lists	'The Women's Health Initiative Dietary Modification Trial'	0
TOTAL		*101*

The following exclusion criteria were applied to the 101 identified citations:

1. Duplicate citation – excludes multiple citations for the same publication

2. Not a clinical study – excludes publications which do not report the results of an original study conducted in humans (ie, excludes animal studies, in vitro studies, narrative reviews)

3. Wrong population/intervention – excludes studies which do not describe and/or assess the The Women's Health Initiative Dietary Modification Trial

4. Wrong outcomes- does not report a relevant weight-based outcome

Applying the exclusion criteria resulted in the identification of four publications relating to The Women's Health Initiative Dietary Modification Trial. All of these citations were identified via the search of Embase.com. The results of the application of exclusion criteria are presented in **Table 119**.

Table 119 Exclusion of citations for The Women's Health Initiative Dietary Modification Trial

Criterion	Citations
TOTAL IDENTIFIED	101
Duplicate citation	14
Not a clinical study	28
Wrong population/intervention	21
Wrong outcomes	34
TOTAL REMAINING	4

Details of the four identified citations are presented in **Table 120**. It should be noted that two of these citations (The Women's Health Initiative Study Group 1998 and Ritenbaugh *et al* (2003) provided background information and demographic characteristics for the trial. The two remaining publications, both authored by Howard and colleagues (2006a and 2006b), report key results from the trial. Although Howard *et al* (2006b) reports some weight-based outcomes at 8.1 years follow-up, the primary focus of the article is on cardiovascular risk factors such as blood pressure and cholesterol. The Howard *et al* (2006a) publication concentrates on weight-based outcomes only and reports these at up to nine years follow-up. Significantly more detail is provided in this article particularly in relation to differences in weight-based outcomes for different sub-groups. Therefore the evidence for this review will be extracted from Howard *et al* (2006a).

Table 120 Included citations: The Women's Health Initiative Dietary Modification Trial.

Citation details	Included
The Women's Health Initiative Study Group (1998) Design of the Women's Health Initiative clinical trial and observational study. The Women's Health Initiative Study Group. Controlled clinical trials 19:61-109.	
Ritenbaugh C, Patterson RE, Chlebowski RT, Caan B, Fels-Tinker L, Howard B, and Ockene J. (2003) The Women's Health Initiative dietary modification trial: Overview and baseline characteristics of participants. Annals of Epidemiology 13:S87-S97	
Howard BV, Manson JE, Stefanick ML, Beresford SA, Frank G, Jones B, Rodabough RJ, Snetselaar L, Thomson C, Tinker L, Vitolins M, and Prentice R. (2006a) Low-fat dietary pattern and weight change over 7 years: The Women's Health Initiative Dietary Modification Trial. Journal of the American Medical Association 295:39-49.	✓
Howard BV, Van Horn L, Hsia J *et al.* (2006b) Low-fat dietary pattern and risk of cardiovascular disease: The Women's Health Initiative randomized controlled dietary modification trial. Journal of the American Medical Association 295:655-666.	

4.13.3 Results

The following section provides details of the characteristics of the intervention, the included study, the baseline characteristics of the intervention and control groups and two sets of results: (i) results of the pivotal weight-related outcomes for this review; and (ii) results of the supportive physical activity-related outcomes.

4.13.3.1 Intervention characteristics

The Women's Health Initiative Dietary Modification Trial was one component of the larger Women's Health Initiative. It was designed to examine the long term benefits and risks of a dietary pattern low in fat, with increased vegetable, fruit and grain intake on a number of risk factors and diseases, one of which was weight gain. Women assigned to the control group received a copy of the Dietary Guidelines for Americans as well as other diet and health-related educational materials, but otherwise had no contact with study dietitians.

Women randomised to the intervention were assigned to groups of 8 to 15 participants for a series of educational sessions promoting diet and behaviour changes that would result in reducing total dietary fat to 20% and increasing intake of fruit and vegetables to five or more servings and grains to six or more servings daily. Eighteen group sessions were scheduled during the first 12 months, after which the frequency of sessions was reduced to four per year for the duration of the trial.

4.13.3.2 Study characteristics

The main characteristics of The Women's Health Initiative Dietary Modification Trial are summarised in **Table 121**. The study was a randomised controlled trial in 48 835 post-menopausal women in the United States. There were 19 541 (40%) participants randomised to the intervention group and 29 294 (60%) to the control group between 1993 and 1998. This analysis included a mean follow-up of 7.5 years, although some patients have been measured at 9 years follow-up.

Table 121 Study characteristics: The Women's Health Initiative Dietary Modification Trial

Citation	Study type	Population	Intervention/ comparator	Outcomes
Howard *et al* (2006a)	Randomised controlled trial Community-based 40 US clinical centres 7.5 years mean duration	N= 48 835 50-79 years old Mean age: 62.3 ± 6.9 years Gender (female): 100% Ethnicity: Caucasian ~81%; African-American: ~11%; Hispanic: ~4%; Asian/Pacific Islander: ~2%	Dietary modification group vs. control Dietary modification consisted of group and individual sessions to promote a decrease in fat intake and increases in vegetable, fruit, and grain consumption	*Change in body weight (kg)* *BMI (kg/m²)* *Waist circumference (cm)* *Waist-hip-ratio*

Abbreviations: BMI = body mass index
Note: Outcomes which are considered relevant to this review, and which are described in the results section, are shown in italics.

4.13.3.3 Baseline participant characteristics

The baseline characteristics if participants in the Women's Health Initiative Dietary Modification Trial are summarized in **Table 122**. The majority of women in the study were Caucasian (~81%), with nearly 20% from other ethnic minorities including African-American, Hispanic, Asian/Pacific Islander and American Indian. Participants were between the ages of 50 and 79 years, with the mean age 62.3 ± 6.9 years. Forty-four percent of the women were taking postmenopausal hormone therapy at baseline, and the proportion decreased during the years of follow-up. The majority of the women were educated at a level above high school (~78%) with approximately half of these with college degrees or higher. Mean BMI at baseline was 29.1±5.1kg/m^2, indicating that, on average, and according to WHO criteria, participants were overweight. There were no statistically significant differences in baseline variables between the intervention and control group.

Table 122 Baseline characteristics: The Women's Health Initiative Dietary Modification Trial

Characteristic	Number (%)		P value
	Intervention	Control	
N	19 541	29 294	0.99
Age, mean (SD), years	62.3 (6.9)	62.3 (6.9)	
Ethnicity			
Caucasian	15 869 (81.2)	23 890 (81.6)	0.76
African-American	2137 (10.9)	3129 (10.7)	
Hispanic	755 (3.9)	1099 (3.8)	
American Indian	88 (0.5)	115 (0.4)	
Asian/Pacific Islander	433 (2.2)	674 (2.3)	
Unknown	259 (1.3)	387 (1.3)	
Education			
Grade school	210 (1.1)	366 (1.3)	0.27
Some high school	632 (3.3)	1007 (3.5)	
High school diploma/GED	3425 (17.6)	5093 (17.5)	
School after high school	7711 (39.7)	11 597 (39.8)	
College degree or higher	7445 (38.3)	11 042 (37.9)	
Family income, $			
< 10 000	683 (3.7)	1100 (4.0)	0.40
10 000 – 19 999	2091 (11.4)	3203 (11.6)	
20 000 – 34 999	4501 (24.4)	6814 (24.7)	
35 000 – 49 999	3954 (21.5)	5868 (21.3)	
50 000 – 74 999	3887 (21.1	5662 (20.5)	
≥75 000	3293 (17.9)	4948 (17.9)	
Height, mean (SD), cm	162.2 (6.4)	162.1 (6.6)	0.12
Weight, mean (SD), kg [a]	76.8 (16.7)	76.7 (16.5)	0.38
BMI, mean (SD)	29.1 (5.9)	29.1 (5.9)	0.58
Waist circumference, mean (SD)	89.0 (13.9)	89.0 (13.7)	0.84
Current smoker	1273 (6.6)	1977 (6.8)	0.33
History of diabetes	1165 (6.0)	1783 (6.1)	0.57
History of cancer	853 (4.4)	1286 (4.4)	0.89
Current hormone therapy use at baseline	8640 (44.2)	12 972 (44.3)	0.86

Source: Howard *et al* (2006a): Table 1, page 42
Abbreviations: BMI = body mass index; GED = General equivalency diploma
[a] Tested on the log scale

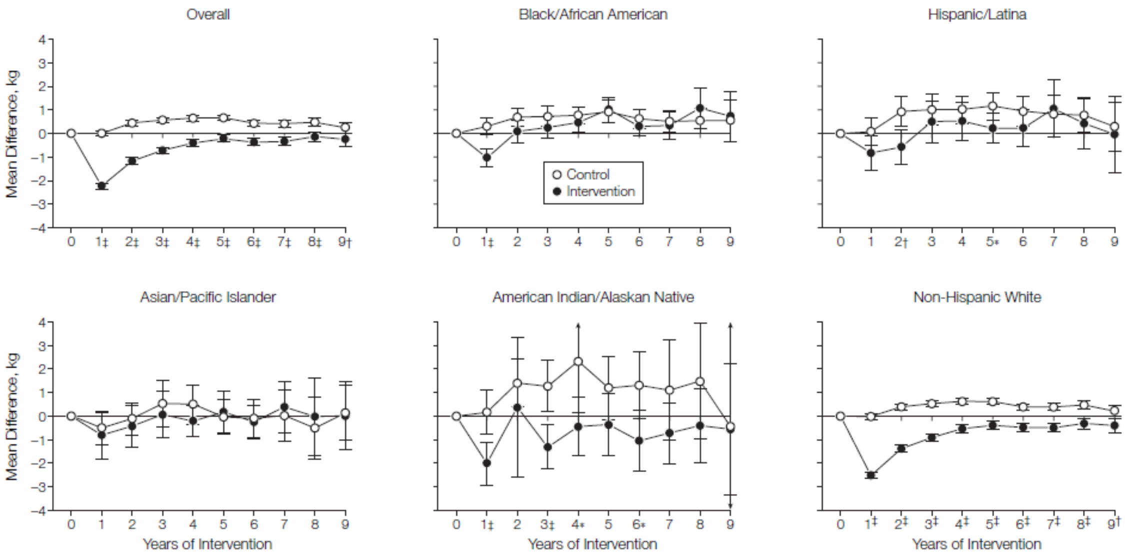
4.13.3.4 Weight-related results

At the follow-up assessment time for this study, 2092 (4.3% control and 4.3% intervention) participants were deceased, 1309 had stopped follow-up (2.5% control and 2.9% intervention), and 670 (1.2% control and 1.6% intervention) were lost to follow-up. Mean follow-up was 7.5 years. Dropout rates were slightly higher in younger (50-59 years) women (4.7%) and in non Caucasian women (6.1%).

Figure 17 shows change in body weight by group and ethnicity. All anthropometric data for each ethnic group and the total cohort are included in **Table 123**. Overall, mean weight decreased significantly in the intervention group from baseline to year one (2.2 kg; $p<0.001$) and was 2.2 kg less than the control group, which did not change from baseline. The difference between the control and intervention groups diminished over time, but a significant difference in weight was still observed nine years after initiation of the study (0.5 kg, $p=0.01$). For mean BMI, there was a difference at follow-up between the intervention and control group of 0.3 kg/m^2 ($p<0.001$). Slight increases occurred in both the intervention group and the control group in waist circumference, although waist increases were less in the intervention group (0.3cm; $P=0.04$).

In all racial and ethnic groups, initial weight loss occurred in the intervention group. Decreases in weight from baseline in the intervention versus control group during the course of the study remained significantly different in all years for Caucasian women, in year one for African-American women, in years two and five for Hispanic women, and in years one, three, four, and six for American Indian women. In Asian/Pacific Islander women, there was no significant difference between groups.

Figure 17 Change in Body Weight by Group and Ethnicity



Error bars indicate 95% confidence intervals.
*$P \leq .05$ and $> .01$ for control group minus intervention group difference.
†$P \leq .01$ and $> .001$ for control group minus intervention group difference.
‡$P \leq .001$ for control group minus intervention group difference.

Source: Howard *et al* (2006a): Figure 2, page 44

Table 123 Anthropometric measures by Ethnicity

	Intervention		Control		Difference (SE)	P Value	Intervention		Control		Difference (SE)	P Value
	No.	Mean (SD)	No.	Mean (SD)			No.	Mean (SD)	No.	Mean (SD)		
	Non-Hispanic White						Black/African American					
Weight, kg												
Baseline	15855	76.1 (16.1)	23868	76.1 (15.9)	−0.03 (0.2)	>.99	2136	85.2 (18.1)	3129	85.1 (18.4)	−0.2 (0.5)	.66
Follow-up	13400	74.8 (16.5)	20650	75.4 (16.4)	0.6 (0.2)	<.001	1697	85.0 (19.3)	2523	85.0 (18.7)	−0.1 (0.6)	.91
Change	13400	−1.0 (10.0)	20650	−0.2 (10.1)	0.8 (0.1)	<.001	1697	0.2 (11.3)	2523	0.2 (11.2)	0.1 (0.4)	.85
BMI												
Baseline	15805	28.8 (5.7)	23782	28.8 (5.7)	0.01 (0.1)	.78	2124	32.1 (6.4)	3118	32.0 (6.5)	−0.1 (0.2)	.70
Follow-up	13350	28.6 (5.9)	20564	28.8 (5.7)	0.2 (0.1)	<.001	1684	32.2 (6.7)	2507	32.3 (6.7)	0.03 (0.2)	.77
Change	13350	−0.01 (3.2)	20564	0.3 (3.1)	0.3 (0.03)	<.001	1684	0.2 (3.4)	2507	0.4 (3.3)	0.2 (0.1)	.12
Waist circumference, cm												
Baseline	15830	88.6 (13.8)	23823	88.7 (13.6)	0.1 (0.1)	.38	2130	93.6 (13.8)	3121	93.5 (13.7)	−0.1 (0.4)	.93
Follow-up	4541	89.7 (14.4)	7045	90.2 (14.1)	0.5 (0.3)	.03	879	94.4 (14.1)	1261	94.7 (14.4)	0.3 (0.6)	.65
Change	4541	1.6 (8.6)	7045	1.9 (8.8)	0.3 (0.2)	.06	879	1.5 (9.9)	1261	2.0 (9.4)	0.5 (0.4)	.27
WHR												
Baseline	15824	0.82 (0.1)	23812	0.82 (0.1)	0 (0.001)	.53	2128	0.83 (0.1)	3117	0.82 (0.1)	−0.002 (0.002)	.51
Follow-up	4519	0.83 (0.1)	7022	0.83 (0.1)	0.001 (0.002)	.44	873	0.84 (0.1)	1257	0.84 (0.1)	−0.003 (0.004)	.35
Change	4519	0.02 (0.1)	7022	0.02 (0.1)	0.001 (0.002)	.48	873	0.02 (0.1)	1257	0.02 (0.1)	−0.0002 (0.003)	.96
	Hispanic/Latina						American Indian/Alaskan Native					
Weight, kg												
Baseline	754	75.2 (16.0)	1099	73.6 (15.2)	−1.5 (0.7)	.04	87	77.8 (14.4)	115	80.8 (16.9)	2.9 (2.3)	.23
Follow-up	560	75.4 (16.6)	870	73.4 (15.0)	−2.0 (0.8)	.03	66	75.5 (14.4)	88	84.0 (16.9)	8.5 (2.6)	<.001
Change	560	0.2 (9.8)	870	0.5 (8.9)	0.3 (0.5)	.57	66	−0.9 (5.4)	88	0.6 (8.4)	1.5 (1.2)	.19
BMI												
Baseline	749	30.1 (5.7)	1094	29.6 (5.6)	−0.5 (0.3)	.08	87	29.9 (5.5)	115	30.7 (6.2)	0.8 (0.8)	.37
Follow-up	557	30.5 (6.1)	864	29.8 (5.5)	−0.7 (0.3)	.06	65	29.2 (5.3)	88	32.2 (6.2)	3.0 (1.0)	.002
Change	557	0.4 (2.8)	864	0.4 (2.9)	−0.001 (0.2)	>.99	65	−0.1 (2.1)	88	0.7 (3.4)	0.8 (0.5)	.09
Waist circumference, cm												
Baseline	748	89.2 (13.3)	1097	88.3 (13.5)	−0.9 (0.6)	.11	87	92.5 (14.5)	115	94.6 (16.8)	2.1 (2.3)	.37
Follow-up	302	90.6 (12.6)	502	90.1 (12.4)	−0.5 (0.9)	.62	30	90.5 (11.3)	41	96.0 (15.8)	5.5 (3.4)	.13
Change	302	2.0 (7.5)	502	1.2 (9.7)	−0.7 (0.7)	.24	30	0.6 (7.6)	41	4.2 (7.5)	3.5 (1.8)	.06
WHR												
Baseline	747	0.82 (0.1)	1097	0.82 (0.1)	0.001 (0.004)	.81	87	0.84 (0.1)	115	0.86 (0.1)	0.02 (0.02)	.25
Follow-up	300	0.84 (0.1)	500	0.84 (0.1)	−0.01 (0.01)	.17	30	0.83 (0.1)	41	0.85 (0.1)	0.02 (0.02)	.43
Change	300	0.02 (0.1)	500	0.01 (0.1)	−0.01 (0.01)	.01	30	0.01 (0.04)	41	0.02 (0.1)	0.002 (0.01)	.87
	Asian/Pacific Islander						Total					
Weight, kg												
Baseline	433	63.4 (13.2)	674	63.3 (14.3)	−0.1 (0.9)	.76	19524	76.8 (16.6)	29272	76.7 (16.5)	−0.1 (0.2)	.36
Follow-up	380	63.0 (13.5)	609	62.9 (13.1)	−0.1 (0.9)	.99	16297	75.7 (17.1)	25056	76.1 (16.9)	0.4 (0.2)	.01
Change	380	−0.2 (8.6)	609	−0.4 (10.4)	−0.3 (0.6)	.67	16297	−0.8 (10.1)	25056	−0.1 (10.1)	0.7 (0.1)	<.001
BMI												
Baseline	433	26.2 (4.9)	670	26.0 (4.9)	−0.2 (0.3)	.50	19457	29.1 (5.9)	29164	29.1 (5.9)	−0.03 (0.1)	.57
Follow-up	380	26.1 (4.8)	605	26.1 (4.8)	−0.04 (0.3)	.94	16230	29.0 (6.1)	24943	29.2 (5.9)	0.2 (0.1)	<.001
Change	380	0.1 (2.8)	605	0.1 (2.9)	0.1 (0.2)	.67	16230	0.03 (3.2)	24943	0.3 (3.1)	0.3 (0.03)	<.001
Waist circumference, cm												
Baseline	431	81.5 (10.9)	673	81.0 (11.1)	−0.4 (0.7)	.51	19485	89.0 (13.9)	29216	89.0 (13.7)	0.003 (0.1)	.85
Follow-up	303	83.4 (12.3)	493	82.8 (11.9)	−0.6 (0.9)	.51	6154	90.1 (14.4)	9517	90.4 (14.2)	0.3 (0.2)	.12
Change	303	1.5 (5.9)	493	1.8 (6.1)	0.2 (0.4)	.58	6154	1.6 (8.6)	9517	1.9 (8.8)	0.3 (0.1)	.04
WHR												
Baseline	431	0.82 (0.1)	673	0.82 (0.1)	−0.001 (0.004)	.82	19475	0.82 (0.1)	29200	0.82 (0.1)	0.0002 (0.001)	.67
Follow-up	303	0.84 (0.1)	492	0.84 (0.1)	−0.01 (0.01)	.31	6123	0.83 (0.1)	9487	0.83 (0.1)	−0.0003 (0.002)	.98
Change	303	0.01 (0.1)	492	0.01 (0.1)	−0.0002 (0.004)	.97	6123	0.02 (0.1)	9487	0.02 (0.1)	0.0003 (0.001)	.85

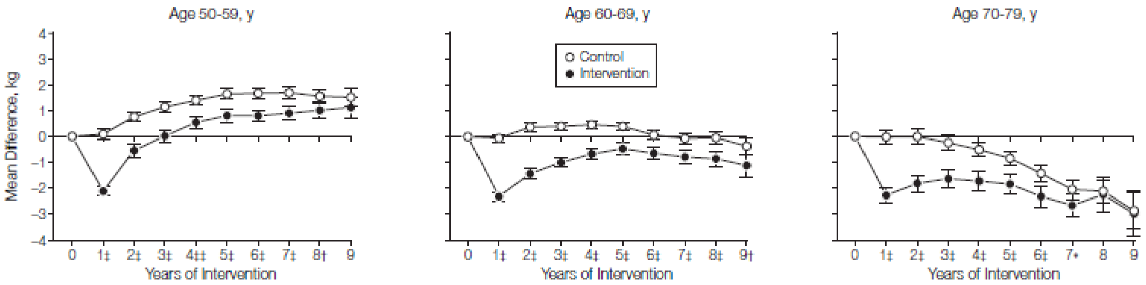
Abbreviations: BMI, body mass index, measured as weight in kilograms divided by height in meters squared; WHR, waist-hip ratio.
* Difference = control − intervention. Change = follow-up − baseline.

Source: Howard *et al* (2006a): Table 3, page 45

Differences from baseline in body weight by group and age at screening is presented in **Figure 18**. More weight gain was demonstrated among women aged 50 to 59 years (mean=1.2 kg), relative to those aged 60 to 69 years at baseline (mean = −0.4 kg) and a tendency toward weight loss in those aged 70 to 79 years (mean =−2.2 kg). Mean weight change from baseline was significantly lower in the intervention group than in the control group through year seven for women aged 70 to 79 years and through year eighty for the two younger age strata.

Results were also presented showing change in body weight stratified by baseline BMI (**Figure 19**). Results showed that although the normal-weight (BMI <25 kg/m²) women in the control group tended to gain more weight (mean =1.4 kg) than the obese women (BMI ≥30), the differences in weight change between the intervention and control groups were similar across BMI groups.

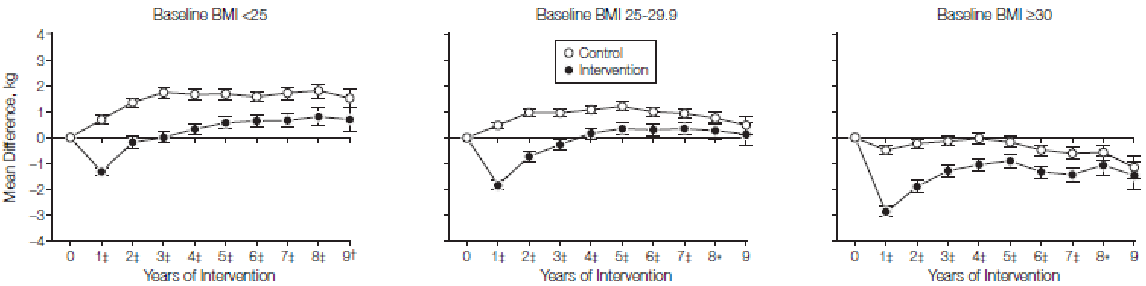
Figure 18 Differences (from baseline) in body weight by group and age at screening



Error bars indicate 95% confidence intervals. Numbers at baseline for intervention and control were 50-59 years, 7206 and 10797; 60-69 years, 9086 and 13626; 70-79 years, 3249 and 4871.
**P*≤.05 and ≥.01 for control group minus intervention group difference.
†*P*≤.01 and >.001 for control group minus intervention group difference.
‡*P*≤.001 for control group minus intervention group difference.

Source: Howard *et al* (2006a): Figure 3, page 46

Figure 19 Difference (from baseline) in body weight by group and body mass index (BMI) at screening



Error bars indicate 95% confidence intervals. Numbers at baseline for intervention and control were BMI <25, 5072 and 7585; BMI 25-29.9, 6940 and 10446; and BMI ≥30, 7442 and 11126, respectively. BMI was calculated as weight in kilograms divided by height in meters squared.
**P*≤.05 and ≥.01 for control group minus intervention group difference.
†*P*≤.01 and >.001 for control group minus intervention group difference.
‡*P*≤.001 for control group minus intervention group difference.

Source: Howard *et al* (2006a): Figure 4, page 46

4.13.3.5 Physical activity-related results

Limited information was provided on changes in physical activity. The authors stated that self-report data were available for one third of the participants. At one year follow-up, there were no significant changes in physical activity in the control or intervention group. When change in physical activity was included in the multivariate model, weight-change differences between the intervention and control groups during the study period remained significant (P=0.001).

4.13.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for The Women's Health Initiative Dietary Modification Trial intervention is provided in **Table 124**.

Table 124 Dimensions of evidence for The Women's Health Initiative Dietary Modification Trial

Dimension	Definition
Strength of evidence	
Level	The primary study was a Level II randomised controlled trial
Quality	The study was a high quality controlled trial with standardised assessment of weight outcomes. Clinical staff responsible for anthropometric assessments were blinded to treatment assignments to the extent practical.
Statistical precision	P-values were small for estimates of difference in weight change between the intervention and control group at one year ($P<0.001$) and at 7.5 years ($P=0.01$) follow-up.
Size of effect	Women in the intervention group lost weight in the first year (mean of 2.2 kg) and maintained lower weight than control women during an average 7.5 years of follow-up (difference, 1.9 kg, at 1 year and 0.4 kg at 7.5 years). For mean BMI, there was a difference at follow-up between the intervention and control group of 0.3 kg/m^2 ($p<0.001$).
Relevance of evidence	The study presents change in weight in kg and BMI, both clinically relevant outcomes. The study was a large RCT conducted in the US. It is likely the results are generalisable to the NZ population.

Source: NHMRC 2000b.

4.13.5 Translation of results for economic analysis

This study provides results in terms of change in body weight and change in BMI (**Table 125**). For mean BMI, there was a difference at follow-up between the intervention and control group of 0.3 kg/m^2 ($p<0.001$). Women in the intervention group lost weight in the first year (mean of 2.2 kg) and maintained lower weight than control women during an average 7.5 years of follow-up (difference, 1.9 kg, at 1 year and 0.4 kg at 7.5 years).

Table 125 BMI results for Intervention 10: Women's Health Initiative Dietary Intervention

Country	Setting	Category	Age (years)	Ethnicity	Mean difference in change in BMI Intervention – control (kg/m^2)
					1 year
USA	Community	N	Adult	Caucasian (~81%)	**-0.3**

Note: statistically significant results are shown in bold.
Abbreviations: BMI=body mass index; N=nutrition; PA=physical activity.

4.14 INTERVENTION 14: WOMEN'S HEALTHY LIFESTYLE PROJECT

The Women's Healthy Lifestyle intervention was an education based program, comprising cognitive-behavioural therapy, aimed at preventing cardiovascular risk factors including weight gain. The study was conducted in women between 44 and 50 years of age in the US.

This intervention was identified during the scoping search via a search of the medical literature databases, grey literature and content experts.

4.14.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of The Women's Healthy Lifestyle Project in terms of the prevention of obesity. The specific research question to be answered is as follows:

Does the obesity prevention intervention 'The Women's Healthy Lifestyle Project' prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

In order to answer this research question, an extensive literature search was conducted.

4.14.2 Literature search

In order to identify studies relevant to the assessment of the Women's Healthy Lifestyle Project, searches of Embase.com (covering the EMBASE and Medline databases) and the Cochrane Library were conducted. Search terms used included those relating to the intervention and three of the lead authors. In addition, the reference lists of identified studies were checked for additional studies. Details of the search and search results are presented in **Table 126**.

Table 126 Literature search for The Women's Healthy Lifestyle Project: Embase.com and Cochrane Library

Search location	Search string	Citations
Embase.com (EMBASE and Medline) 30/03/2010	1. 'kuller l.h.'/au 2. 'simkin-silverman l.r.'/au 3. 'ives d.g.'/au 4. women* AND 'healthy lifestyle project' 5. 'clinical trial':ab,ti 6. 'women'/exp 7. #1 AND #5 AND #6 8. #2 OR #3 OR #4 OR #7	109
Cochrane Library (Trials Register) 30/03/2010	1. women's healthy lifestyle project):ti,ab,kw	11
Subtotal		*120*
Manual searching of reference lists		1
TOTAL		*121*

The following exclusion criteria were applied to the 121 identified citations:

1. Duplicate citation – excludes multiple citations for the same publication
2. Not a clinical study – excludes publications which do not report the results of an original study conducted in humans (ie, excludes animal studies, in vitro studies, narrative reviews)
3. Wrong population/intervention – excludes studies which do not describe and/or assess the Women's Healthy Lifestyle Project
4. Wrong outcomes- does not report a relevant weight-based outcome

Applying the exclusion criteria resulted in the identification of four publications relating to the Women's Healthy Lifestyle Project. Three of these citations were identified via the search of Embase.com and one was identified after a manual search of the included studies reference lists. The results of the application of exclusion criteria are presented in **Table 127**.

Table 127 Exclusion of citations for the Women's Healthy Lifestyle Project

Criterion	Citations
TOTAL IDENTIFIED	121
Duplicate citation	15
Not a clinical study	2
Wrong population/intervention	93
Wrong outcomes	7
TOTAL REMAINING	4

Details of the four identified citations are presented in **Table 128**. It should be noted that one citation (Simkin-Silverman et al 1995) provides results of the study at six months, one study (Simkin-Silverman *et al* 1998) provides results of the study at 18 months, whilst the remaining two citations (Kuller *et al* 2001 and Simkin-Silverman *et al* 2003) provide data at 54 months, with Simkin-Silverman *et al* (2003) focusing more on the prevention of weight gain rather than changes in cardiovascular biochemistry and blood variables.

Table 128 Included citations: Women's Healthy Lifestyle Project

Citation details	Included
Kuller LH, Simkin-Silverman LR, Wing RR, Meilahn EN, and Ives DG. (2001) Women's healthy lifestyle project: A randomized clinical trial: Results at 54 months. Circulation 103:32-37.	✓
Simkin-Silverman L, Wing RR, Hansen DH, et al.(1995) Prevention of cardiovascular risk factor elevations in healthy premenopausal women. Prev Med. 24:509 –517.	
Simkin-Silverman LR, Wing RR, Boraz MA, Meilahn EN, and Kuller LH. (1998) Maintenance of cardiovascular risk factor changes among middle-aged women in a lifestyle intervention trial. 's health (Hillsdale, N. J.) 4:255-271.	
Simkin-Silverman LR, Wing RR, Boraz MA, and Kuller LH. (2003) Lifestyle Intervention Can Prevent Weight Gain during Menopause: Results from a 5-Year Randomized Clinical Trial. Annals of Behavioral Medicine 26:212-220.	✓

4.14.3 Results

The following section provides details of the intervention, characteristics of the included studies, the baseline characteristics of the intervention and control groups and two sets of results: (i) results of the pivotal weight-related outcomes for this review; and (ii) results of the supportive physical activity-related outcomes.

4.14.3.1 Intervention characteristics

The Women's Healthy Lifestyle Project was a five-year cognitive-behavioural program aimed at preventing the increase in LDL cholesterol levels, preventing weight gain, and increasing leisure-time physical activity (Kuller *et al*, 2001). Participants were asked to lower their dietary fat intake to 25% of daily calories, their saturated fat intake to 7% of calories, and their dietary cholesterol to 100 mg daily. All women were given a modest weight loss goal, depending on baseline weight status, and they were asked to reduce daily caloric intake to 1300 kcal until the weight goal was achieved. Lifestyle changes were advised to facilitate weight control. The intervention included an intensive group program during the first 6 months and follow-up individual/group sessions from 6 through 54 months.

4.14.3.2 Study characteristics

The main characteristics of the included study assessing the Women's Healthy Lifestyle Project intervention are summarised in **Table 129**. The study was a randomised controlled trial conducted in Pennsylvania in the US with recruitment between 1992 and 1994. The population consisted of 44 to

50 year-old women who by self-report were premenopausal and not taking hormone replacement therapy. After the screening and baseline data were completed, participants were randomly assigned to either an assessment-only control group (n = 275) or a lifestyle intervention group (n = 260). Those involved with baseline data collection and participant randomisation did not collect follow-up data. All follow-up data were collected by trained interviewers or nurses who were blinded to group assignment. Various anthropomorphic, physical activity and cardiovascular outcomes were assessed at different follow-up time points (6, 18, 30, 42, and 54 months after randomisation) as shown in **Table 129**.

Table 129 Study characteristics: Women's Healthy Lifestyle Project

Citation	Study type	Population	Intervention/ comparator	Outcomes
Kuller *et al* (2001) Simkin-Silverman *et al* (1995) Simkin-Silverman *et al* (1998)[a] Simkin-Silverman *et al* (2003)	Randomised controlled trial Community-based Single blinded 5 years duration	N= up to 535 44-50 year-old women Mean age: 47 ± 1.6 years Ethnicity: Majority Caucasian: % not reported Mean BMI: 25.1 kg/m^2	Women's lifestyle intervention versus standard assessment with no intervention	LDL cholesterol (mg/dL) HDL cholesterol (mg/dL) Triglycerides (mg/dL) Glucose (mg/dL) DBP and SBP (mm Hg) *Weight (lb)* *Waist circumference (cm)* *BMI (kg/m^2)* *Body fat (%)* *Fat-free mass (%)* Caloric intake (kcal/day) *Physical activity (motion counts/hour)* Dietary fat (%) Dietary saturated fat (%)

Abbreviations: BMI = body mass index; DBP = diastolic blood pressure; SBP = systolic blood pressure.
Note: Outcomes which are considered relevant to this review, and which are described in the results section, are shown in italics.
[a] Follow-up only to 18 months

4.14.3.3 Baseline participant characteristics

The majority of women included in the Women's Healthy Lifestyle Project were Caucasian (percentage not reported), married (74%), educated beyond high school (85%), and employed for wages (86%). The mean age of study participants was 47 years. Eligibility criteria required that BMI was 20 to 34 kg/m^2, fasting total cholesterol was 140 to 260 mg/dl, fasting LDL-cwas 80 to 160 mg/dl, fasting glucose levels were less than 140 mg/dl, and diastolic blood pressure (DBP) was less than 95 mm Hg. **Table 130** summarises selected baseline characteristics for the lifestyle intervention and control groups. No significant differences were found between groups on any of the variables.

Table 130 Comparison of baseline characteristics of intervention and assessment groups

Variable	Assessment group (n=275)		Intervention Group (n=260)	
	Mean	**SD**	**Mean**	**SD**
Baseline age, y	47	2	47	2
Systolic BP, mm Hg	110	13	110	12
Diastolic BP mm Hg	68	9	68	8
Baseline total HDL, mg/dL	59	13	60	13
Baseline cholesterol, mg/dL	190	24	190	24
Baseline LDL cholesterol, mg/dL	116	22	115	22
Baseline triglycerides, mg/dL	79	42	81	38
Baseline BMI	25	3	25	3
Weight, kg	67.27	10.00	67.73	9.55
Baseline WHR, cm	0.768	0.059	0.773	0.056
Fasting glucose, mg/dL	98	8	98	8
Physical activity, kcal/wk	1412	1386	1248	1064

Source: Kuller *et al* (2001): Table 1, page 33
Abbreviations: BMI = body mass index; HDL = high-density lipoprotein; LDL = low-density lipoprotein; SD = standard deviation; WHR = waist-to-hip ratio

4.14.3.4 Weight-related results

The results of the analysis of weight-related outcomes were reported in the Simkin-Silverman *et al* (1998) publication for two time-points: 6 months and 18 months. Long-term results (ie, 30 months, 42 months and 54 months) were presented in Simkin-Silverman *et al* (2003). The Kuller *et al* (2001) publication reported change from baseline in weight and waist circumference at all of the above time-points.

The change from baseline in weight, waist circumference, BMI, body fat and fat free mass by study group is shown in **Table 131**. In terms of weight gain prevention, 55% (136/246) of the lifestyle intervention participants were at or below baseline weight compared with 26% (68/261) of controls at the 54-month visit ($p<0.001$). There was an approximate 2.5 kg difference in weight between groups at 54 months, with the mean weight change in the intervention group being just below baseline (–0.08 kg) and the control group gaining on average 2.36 kg. Waist circumference also decreased more in the intervention group compared with the control group at 54 months follow-up (mean change: –2.90 cm vs. –0.46 cm, $p<0.001$).

On average, there was a mean increase in BMI in both the intervention and control group after 54 months. However, the mean increase in the intervention group (0.05 kg/m^2) was significantly lower than the mean increase in the control group (0.96 kg/m^2; $p<0.001$). Furthermore, up until 42 months follow-up, the mean BMI in the intervention group had shown an average decrease (-0.34 kg/m^2). The intervention group showed a greater loss of percentage of body fat than the control group at 30, 42, and 54 months ($P<0.001$). The control group averaged greater increases in FFM at 30 and 54 months compared with the intervention group. The intervention group, however, did not show a decline in FFM.

Table 131 Mean change from baseline in risk factor levels by group

Variable	Change from baseline									
	6 months		18 months		30 months [a]		42 months [b]		54 months [c]	
	I	C	I	C	I	C	I	C	I	C
Weight (kg) [d]	–4.86[e]	–0.22	–3.05[e]	–0.26	–2.14[e]	0.95	–1.00[e]	1.64	0.08[e]	2.36
Waist circumference (cm)	–4.20[e]	–0.36	–3.50[e]	–0.68	–3.00[e]	–0.21	–2.50[e]	–0.17	–2.90[e]	–0.46
BMI	-	-	-	-	–0.67 ± 1.8 [f]	0.44 ± 1.6	–0.34 ± 1.9 [f]	0.67 ± 1.7	0.05 ± 2.0 [f]	0.96 ± 1.8
Body fat (%)	-	-	-	-	–2.2 ± 3.8 [f]	–0.3 ± 3.6	–1.6 ± 4.1 [e]	0.2 ± 3.6	–0.5 ± 4.1[e]	1.1 ± 3.9
Fat-free mass (kg)	-	-	-	-	0.1 ± 1.6[e]	0.8 ± 1.4	0.2 ± 1.6	0.6 ± 1.9	0.0 ± 1.9 [g]	0.5 ± 2.1

Source: Kuller *et al* (2001): Table 2, page 34; Simkin-Silverman *et al* (2003): Table 2, page 217
Abbreviations: BMI= body mass index; C = control; I = intervention
[a] n= 475; [b] n=479; [c] n=509
[d] Converted from pounds
[e] P<0.01; [f] P<0.001; [g] P<0.05

Mean change from baseline in body weight by baseline weight status is presented in **Table 132**. Weight status was defined according to WHO criteria. Women in the intervention group who were initially of normal weight lost more weight than women in the control group who were initially of normal weight at all follow-up assessments (p<0.001). The same treatment effect was observed for women who were overweight and obese, except at 54 months. A similar trend was observed for percentage of initial body weight lost. There was no difference, however, in the percentage of intervention participants who were at or below baseline weight at 54 months by weight status: normal weight = 56.2%, overweight = 57.3%, and obese = 40.0%, p=0.352.

Table 132 Mean change in weight by baseline weight status

Weight status	6 months			18 months			30 months			42 months			54 months		
	Mean	SD	%	Mean	SD	%	Mean	SD	%	Mean	SD	%	Mean	SD	%
Normal weight															
Intervention	–4.1	3.1	–6.7[a]	–2.3	3.4	–3.7[a]	–1.5	3.6	–2.3[a]	–0.6	4.2	–0.89[a]	–0.2	4.3	–0.29[a]
Control	0.1	2.0	0.12	0.6	2.7	0.95	0.9	3.0	1.5	1.7	3.3	2.8	2.8	3.6	4.6
Overweight															
Intervention	–5.3	4.9	–7.4[a]	–3.5	5.8	–4.6[a]	–2.7	5.4	–3.5[a]	–1.4	5.7	–1.7[b]	0.1	6.1	0.31
Control	–0.5	3.3	–0.87	0.1	4.0	0.07	0.3	5.1	0.41	1.3	5.5	1.9	1.5	5.2	2.2
Obese															
Intervention	–7.4	7.2	–9.1[b]	–6.6	8.4	–7.7[b]	–4.3	6.7	–5.0[b]	–2.0	6.4	–2.3[c]	–0.2	6.9	–0.17
Control	–0.6	5.1	–0.63	–0.5	4.5	–0.36	2.9	5.4	3.5	1.9	5.7	2.5	3.1	7.7	3.7

Source: Simkin-Silverman *et al* (2003): Table 3, page 217
Note: Baseline sample size: normal weight (intervention n = 143, control n = 144), overweight (intervention n = 95, control n = 95), and obese (intervention n = 22, control n = 36). Percentages are the percentage of initial weight lost, t tests were used to compare change scores between groups from baseline to each follow-up.
[a] p<0.001
[b] p<0.01
[c] p<0.05

4.14.3.5 Physical activity-related results

The results of the analysis of physical activity-related outcomes are presented in **Table 133**. The lifestyle intervention group remained more active than controls at 30, 42, and 54-month follow-up assessments ($p<0.001$). This increase was primarily attributed to walking, which was emphasised throughout the trial, although an increase in sport and recreational activity was also observed between groups at 30 and 42 months. Flights of stairs climbed did not differ between groups at any point. The intervention group continued to show an increase in motion counts per hour at both 18 months (3.5, $p<0.001$) and 54 months (2.3, $p<0.01$).

Table 133 Physical activity results: Women's Health Lifestyle trial

Variable and group	30 months [a]		42 months [a]		54 months [a]	
	Mean	SD	Mean	SD	Mean	SD
Physical activity (kcal)						
Intervention	406.4	1,199.5[b]	473.3	1,384.9[b]	274.9	1,172.9[b]
Control	–61.3	1,203.1	–105.6	1,127.4	–113.3	1,261.0
Blocks walked (kcal)						
Intervention	159.4	631.3[b]	186.8	645.3[b]	187.8	615.0[b]
Control	–104.0	557.3	–104.5	542.4	–83.1	610.6
Sport and Recreational activity (kcal)						
Intervention	234.4	1,118.1[c]	243.1	1,203.7[c]	56.6	1,023.0
Control	17.2	1,035.3	–16.7	1,015.2	–47.2	1,104.4
Activity monitor (counts/hour) [a]						
Intervention	-	-	-	-	2.3	9.1[d]
Control	-	-	-	-	–0.26	7.8

Source: Simkin-Silverman *et al* (2003)
[a] 30 months: n=475; 42 months: n=479; 54 months: n=509; activity monitor: n=313 due to missing data
[b] $p<0.001$
[c] $p<0.05$
[d] $p<0.01$

4.14.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for the Women's Healthy Lifestyle project is provided in **Table 134**.

Table 134 Dimensions of evidence for the Women's Healthy Lifestyle project

Dimension	Definition
Strength of evidence	
Level	The primary study was a Level II randomised controlled trial
Quality	The study was a high quality controlled trial with standardised assessment measures of weight, and blinding of outcome assessors to minimise the chance of bias. Participants were volunteers, how this may have affected motivation and response is uncertain.
Statistical precision	The p-values for the comparison of mean change from baseline in BMI between the intervention and control group were small ($p<0.001$) at 30, 42 and 54 months.
Size of effect	There was a significant difference in change in mean BMI in the intervention group compared to the control group (~0.9 kg/m^2) at 54 months follow-up. However, on average, at 54 months, the intervention group had an increase in BMI of 0.05 kg/m^2.
Relevance of evidence	The study presents weight-related outcomes including BMI for a population of premenopausal women in the US. It is likely that results are generalisable to women in NZ.

Source: NHMRC 2000b.

4.14.5 Translation of results for economic analysis

The BMI results for the Women's Healthy Lifestyle project are presented in **Table 135**. The results show that there was a substantial difference in change in mean BMI for the intervention versus the control group over a long time-frame. There were also substantial differences in the change in weight between the intervention and control groups (-3 kg, -2.6 kg and -2.3 kg at 30, 42 and 54 months, respectively).

Table 135 BMI results for Intervention 14: Women's Healthy Lifestyle Project

Country	Setting	Category	Age (years)	Ethnicity	Mean difference in change in BMI Intervention – control (kg/m^2)		
					3 years[a]	4 years[b]	5 years[c]
USA	Community	N	Adult	Caucasian (majority)	-1.1	-1.0	-0.9

Note: statistically significant results are shown in bold.
Abbreviations: BMI=body mass index; N=nutrition; PA=physical activity.
[a] 30 months.
[b] 42 months
[c] 54 months.

4.15 INTERVENTION 15: GREEN PRESCRIPTION

The 'Green Prescription' is a physical activity initiative which involves clinicians providing individuals with written physical activity advice during typical general practice consultations. It is targeted at sedentary individuals and has been implemented in NZ.

This intervention was identified during the scoping search via a search of online medical databases, grey literature and content experts.

4.15.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of the Green Prescription intervention in terms of preventing obesity. The specific research question to be answered is as follows:

Does the obesity prevention intervention 'Green Prescription' prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

In order to answer this research question, an extensive literature search was conducted.

4.15.2 Literature search

In order to identify studies relevant to the assessment of the Green Prescription intervention, a search of Embase.com (covering the EMBASE and Medline databases) and the Cochrane Library were conducted. Two separate searches were conducted. The first search included search terms relating specifically to the Green Prescription intervention. This included a search of the two primary authors of key Green Prescription studies identified through an initial scoping search. The second search of Embase.com only, was a more general search including terms relating to the intervention, obesity, and the setting. The reference lists of identified studies were checked for additional studies. A grey literature search was also undertaken to ensure no studies of relevance had been missed. Details of the searches and search results are presented in **Table 136**.

Table 136 Literature search for Green Prescription: EMBASE.com and Cochrane Library

Search location	Search string	Citations
EMBASE.com (EMBASE and Medline) 11/12/2009	#1'Green Prescription' OR 'Green Prescriptions' #2'elley c.r' #3'lawton b.a' #4(#1 OR #2 OR #3)	78
EMBASE.com (EMBASE and Medline) 11/12/2009	#1'exercise' ab.ti #2'physical activity' ab,ti #3'obesity' ab,ti #4'prescription' OR 'prescribe' ab,ti #5(#1 OR #2) AND (#3) AND (#4) #6'general practice' OR 'GP' OR 'primary care' #7(#1 OR #2) AND (#3) AND (#6) #8(#5 OR #7)	345
Cochrane Library (Trials Register) 11/12/2009	#1'Green Prescription' OR 'Green Prescriptions' #2'elley c.r' #3'lawton b.a' (#1 OR #2 OR 3#)	12
Subtotal		*435*
Manual searching of grey literature and reference lists	'Green Prescription'	2
TOTAL		**437**

The following exclusion criteria were applied to the 437 citations identified through the literature search:

1. Duplicate citation – excludes multiple citations for the same publication

2. Not a clinical study – excludes publications which do not report the results of an original study conducted in humans (ie, excludes animal studies, in vitro studies, narrative reviews)

3. Wrong population/intervention – excludes studies which do not describe and/or assess Green Prescription or a comparable intervention for obesity prevention

4. Wrong outcomes- does not report a relevant weight-based outcome

Applying the exclusion criteria resulted in the identification of 10 publications relating to the Green Prescription intervention. All of these citations were identified via the search of EMBASE.com and the Cochrane library. The results of the application of exclusion criteria are presented in **Table 137**.

Table 137 Exclusion of citations for Green Prescription

Criterion	Citations
TOTAL IDENTIFIED	437
Duplicate citation	46
Not a clinical study	133
Wrong population/intervention	248
Wrong outcomes	0
TOTAL REMAINING	10

Of the 10 studies relating to the Green Prescription intervention, only two were original studies that measured changes in weight-based outcomes for participants at follow-up. The remaining studies included background information, the extent of program use by general practitioners, economic evaluations of the intervention, and studies of behaviour change outcomes only. Details of the identified citations are presented in **Table 138**.

Table 138 Included citations: Green Prescription

Citation details	**Included**
Croteau K, Schofield G, and McLean G. (2006) Physical activity advice in the primary care setting: Results of a population study in New Zealand. *Australian and New Zealand Journal of Public Health* 30:262-267.	
Elley CR, Kerse N, Arroll B, and Robinson E. (2003) Effectiveness of counselling patients on physical activity in general practice: Cluster randomised controlled trial. British Medical Journal 326:793-796.	✓
Elley CR, Kerse N, Arroll B, Swinburn B, Ashton T, and Robinson E. (2004) Cost-effectiveness of physical activity counselling in general practice. *New Zealand Medical Journal* 117.	
Gribben B, Goodyear-Smith F, Grobbelaar M, O'Neill D, and Walker S. (2000) The early experience of general practitioners using Green Prescription. *The New Zealand medical journal* 113:372-373.	
Kerse N, Elley CR, Robinson E, and Arroll B. (2005) Is physical activity counseling effective for older people? A cluster randomized, controlled trial in primary care. *Journal of the American Geriatrics Society* 53:1951-1956.	
Lawton BA, Rose SB, Elley CR, Dowell AC, Fenton A, and Moyes SA. (2008) Exercise on prescription for women aged 40-74 recruited through primary care: Two year randomised controlled trial. BMJ 338:88-91.	✓
Pfeiffer BA, Clay SW, and Conatser J. (2001) A green prescription study: Does written exercise prescribed by a physician result in increased physical activity among older adults? *Journal of Aging and Health* 13:527-538.	
Swinburn BA, Walter LG, Arroll B, Tilyard MW, and Russell DG. (1997) Green prescriptions: Attitudes and perceptions of general practitioners towards prescribing exercise. *British Journal of General Practice* 47:567-569.	
Swinburn B and McLennan J. (1998) The green prescription: A novel way of increasing uptake of physical activity. *New Zealand Public Health Report* 5:1-2.	
Swinburn BA, Walter LG, Arroll B, Tilyard MW, and Russell DG. (1998) The green prescription study: A randomized controlled trial of written exercise advice provided by general practitioners. *American Journal of Public Health* 88:288-291.	

4.15.3 Results

The following section provides details of the characteristics of the included studies, the baseline characteristics of the intervention and control groups and two sets of results: (i) results of the pivotal weight-related outcomes for this review; and (ii) results of the supportive physical activity-related outcomes.

Although BMI is the focus of this review, only the study by Elley *et al* (2003) reported BMI as an outcome. The study by Lawton *et al* (2009) measured mean weight and waist circumference but not BMI.

4.15.3.1 Intervention characteristics

The Green Prescription was conceived in the late 1990s as a response to increasing levels of obesity in New Zealand. General practice was considered an ideal setting to identify sedentary individuals and deliver interventions because more than 80% of individuals visit their physician at least once a year (NZ MoH, 1998).

Initial reports on the Green Prescription reported anecdotal success in terms of improving physician attitude towards 'prescribing' exercise and changing physical activity habits of patients (Swinburn *et al* 1997; 1998). It wasn't until 2003, however, that a randomised controlled trial set out to determine the effectiveness of the Green Prescription in terms of weight-based outcomes (Elley *et al* 2003). The effectiveness of exercise on prescription was re-evaluated in 2008 by another RCT conducted in 40-74 year old women (Lawton *et al* 2008).

The overall aim of the intervention was to increase patients' physical activity level. A comprehensive summary of the intervention as evaluated in Elley *et al* (2003) is presented in **Figure 20**. In brief, the physician provided the participant with a 'prescription' for exercise, which was forwarded to a recreation centre, who would take responsibility for following up with the patient over a three month period. The intervention evaluated by Lawton *et al* (2008) built on the Green Prescription, however, the intervention was delivered by a primary care nurse and follow-up was extended to include phone calls over a nine month period.

Figure 20 The Green Prescription intervention

- Primary care clinicians are offered four hours of training in how to use motivational interviewing techniques to give advice on physical activity and the green prescription.
- Patients who have been identified as "less active" through screening at the reception desk, and who agree to participate, receive a prompt card from the researcher to give to the general practitioner during consultation.
- In the consultation, the primary care professional discusses increasing physical activity and decides on appropriate goals with the patient. These goals, usually home-based physical activity or walking, are written on a standard green prescription and given to the patient.
- A copy of the green prescription is faxed to the local sports foundation with the patient's consent. Relevant details such as age, weight, and particular health conditions are often included.
- Exercise specialists from the sports foundation make at least three telephone calls (lasting 10-20 minutes) to the patient over the next three months to encourage and support them. Motivational interviewing techniques are used. Specific advice about exercise or community groups is provided if appropriate.
- Quarterly newsletters from the sports foundations about physical activity initiatives in the community and motivational material are sent to participants. Other mailed materials, such as specific exercise programmes, are sent to interested participants.
- Staff of the general practice are encouraged to provide feedback to the participant on subsequent visits to the practice.

Source: Elley2003, page 794.

4.15.3.2 Study characteristics

The main characteristics of the two studies assessing the Green Prescription intervention are summarised in **Table 139**. The Elley *et al* (2003) study was an RCT conducted in 42 rural and urban general practices in the Waikato area of New Zealand. The population consisted of 40-79 year-old sedentary adults; with 750 completing the 12 month follow-up assessment. The Lawton *et al* (2008) study assessed 40-74 year-old women not undertaking 30 minutes of moderate intensity physical activity on at least five days of the week. There were 974 patients who completed the 24 months follow-up assessment. Various measures of physical activity, body mass and co-morbidity were assessed, as shown in **Table 139**.

Table 139 Study characteristics: Green Prescription

Citation	Study type	Population	Intervention/ comparator	Outcomes
Elley *et al* (2003)	Cluster randomised controlled trial Primary care, community-based 42 rural and urban practices in eastern Waikato, NZ 1 year duration	N: 878 40-79 year-old sedentary patients 66.3% female Ethnicity: European 77.2% Māori/Pacific Islanders: NR Mean BMI: ~30kg/m^2	Green prescription vs. 'usual care' delivered by GP Green prescription consisted of a physical activity regimen written as a 'prescription' by the GP	*1-year change in BMI (kg/m^2)* *Total energy expenditure (kcal/kg/wk)* *Leisure physical activity(kcal/kg/wk)* *Leisure exercise (mins/wk)* 1-year change in SBP 1-year change in DBP 4 year risk of CHD 1-year change in cholesterol 1-year change in SF-36
Lawton *et al* (2008)	Randomised controlled trial Primary care, community-based 17 primary care practices in Wellington, NZ 2 year duration	N: 1089 40-74 year-old women Ethnicity: European 77.7% Māori/Pacific Islanders: 13.1% Mean BMI:~29kg/m^2	Green prescription vs. 'usual care' delivered by their primary care practice Green prescription consisted of physical activity regimen written as a 'prescription' by the primary care nurse	*Mean weight (kg)* *Mean waist circumference (cm)* *No (%) completing ≥150 mins physical activity/wk* *Median (IR) mins physical activity/wk* Mean SBP Mean DBP Cholesterol HbA_{1c} Insulin Glucose

Abbreviations: CHD = coronary heart disease; GP = general practitioner; HbA1c = glycosylated haemoglobin; IR = inter-quartile range; NZ = New Zealand; Wk = week.
Note: Outcomes which are considered relevant to this review, and which are described in the results section, are shown in italics.

4.15.3.3 Baseline participant characteristics

Table 140 summarises the baseline characteristics of participants in the Green Prescription studies, as presented in the two included studies. The majority of participants in both the Elley *et al* (2003) and Lawton *et al* (2008) studies were of European origin (77.2% and 77.7%, respectively). While the proportion of Māori and Pacific Islanders was not reported in the Elley *et al* (2003) study, there were 13.1% Māori and Pacific Islander participants in the Lawton *et al* (2008) study.

Both studies examined the Green Prescription in adult populations with the mean age (±SD) for the Elley *et al* (2003) and Lawton *et al* (2008) intervention groups being 57.2±10.8 years and 59.1±6.8 years, respectively. Study arms were well balanced in terms of patient characteristics with the mean age (±SD) in the control groups being 58.6 ± 11.5 years and 58.7 ± 6.9 years, respectively.

In the Elley *et al* (2003) study, 66.3% of participants were female. At baseline, the intervention group had a mean BMI (± SD) of 30.0 ± 6.7kg/m^2 and the control group a mean BMI (± SD) of 29.9 ± 6.4 kg/m^2, indicating that the majority of patients were overweight or obese, according to World Health Organisation definitions (WHO, 2000). In the Lawton *et al* (2008) study, baseline BMIs for the intervention and control group were both 29.2 kg/m^2, indicating a similar level of obesity between the two Green Prescription studies. All participants in the Lawton *et al* (2008) study were female.

Based on these baseline patient characteristics, it appears that the Green Prescription was primarily used in those who were already overweight or obese. While the primary aim of the intervention was to increase physical activity levels in sedentary patients, one potential outcome of this is the prevention of further weight gain or promotion of weight loss amongst patients.

Table 140 Baseline characteristics: Green Prescription

Citation	Characteristic	Unit	Intervention	Control
Elley *et al* (2003)	Number of participants:		N=451	N=427
	Female	N (%)	301 (67)	281 (66)
	Lower socioeconomic status	N (%)	205 (45)	211 (49)
	With post-high school qualification	N (%)	106 (24)	121 (28)
	European origin	N (%)	354 (78)	324 (76)
	Smokers	N (%)	78 (17)	76 (18)
	Diabetic	N (%)	46 (10)	46 (11)
	Hypertensive	N (%)	240 (53)	220 (52)
	Previous cardiovascular disease	N (%)	93 (21)	74 (17)
	Obese (BMI>30)	N (%)	198 (44)	176 (41)
	Taking leisure exercise ≥ 2.5 hrs/wk	N (%)	80 (18)	91 (21)
	Age (years)	Mean ± SD	57.2 ± 10.8	58.6 ± 11.5
	Systolic blood pressure (mm Hg)	Mean ± SD	135.1 ± 19.6	135.4 ± 17.9
	Diastolic blood pressure (mm Hg)	Mean ± SD	82.4 ± 12.2	81.8 ± 12.1
	BMI (kg/m^2)	Mean ± SD	30.0 ± 6.7	29.9 ± 6.4
	Cholesterol concentration (mmol/L)	Mean ± SD	5.78 ± 1.0	5.64 ± 1.0
	HDL concentration (mmol/L)	Mean ± SD	1.33 ± 0.4	1.34 ± 0.4
	Four year risk of CHD (%)	Mean ± SD	5.7 ± 6.2	5.5 ± 5.8
	Total energy expenditure (kcal/kg/wk)	Mean ± SD	237.5 ± 42.2	235.7 ± 45.3
	Leisure physical activity (kcal/kg/wk)	Mean ± SD	6.0 ± 12.2	6.5 ± 11.1
	Leisure exercise (minutes/day)	Mean ± SD	11.3 ± 21.7	12.0 ± 20.5
	No of medical drugs taken	Mean ± SD	2.6 ± 2.5	2.4 ± 2.4
	SF-36 QoL scores (out of 100):			
	Physical functioning	Mean ± SD	71.3 ± 23.9	70.9 ± 24.6
	Role physical	Mean ± SD	57.9 ± 41.7	60.4 ± 41.4
	Bodily pain	Mean ± SD	61.1 ± 25.7	63.9 ± 26.9
	General health	Mean ± SD	62.7 ± 20.7	66.1 ± 20.6
	Vitality	Mean ± SD	53.8 ± 20.6	56.0 ± 21.2
	Social functioning	Mean ± SD	77.9 ± 24.6	77.6 ± 25.2
	Role emotional	Mean ± SD	69.6 ± 41.3	68.7 ± 40.6
	Mental health	Mean ± SD	74.5 ± 17.3	74.0 ± 18.2
	Rural or semirural practices	N (%)	12 (52)	9 (47)
	Female general practitioners	N (%)	17 (28)	18 (31)
Lawton *et al* (2008)	Number of participants:		N=544	N=545
	Current smokers	N (%)	67 (12)	70 (13)
	Lower socioeconomic status	N (%)	87 (16)	75 (14)
	With tertiary education	N (%)	230 (42)	246 (45)
	European	N (%)	411 (76)	435 (80)
	Māori or Pacific Islander	N (%)	79 (15)	64 (12)
	Age (years)	Mean ± SD	59.1 ± 6.8	58.7 ± 6.9
	Body mass index	Mean ± SD	29.2 ± 5.8	29.2 ± 6.1
	Leisure exercise/week (mins)	Mean ± SD	58 ± 84	60 ± 91
	QoL (SF-36):			
	Role physical	Mean ± SD	90.4 ± 18.7	89.8 ± 14.4
	Bodily pain	Mean ± SD	72.0 ± 23.0	74.2 ± 23.3
	Vitality	Mean ± SD	59.0 ± 14.2	59.5± 13.5
	Social functioning	Mean ± SD	89.2 ± 18.2	89.2 ± 18.3
	Role emotional	Mean ± SD	92.2 ± 16.5	93.4 ± 14.3
	Mental health	Mean ± SD	71.2 ± 11.9	71.7 ± 10.6
	General health	Mean ± SD	76.4 ± 17.9	78.0 ± 17.9

Source: Elley *et al* (2003), table 1 page 796; Lawton *et al* (2008), table 1 page 2511
Abbreviations: BMI=body mass index; CHD = coronary heart disease; HDL = high density lipoprotein; QoL = quality of life; SF = short form

4.15.3.4 Weight-related results

The results of the analysis of weight-related outcomes for the two Green Prescription studies are presented in **Table 141**. All analyses presented were adjusted for a number of variables including baseline measures.

Although there was a larger reduction in BMI in the intervention group in the Elley *et al* (2003) study, the difference between the intervention and control groups was not significant (mean change: -0.06; 95% CI: -0.24, 0.12; p=0.5). Similarly, in the Lawton *et al* (2008) study, there was no significant difference in mean (±SD) weight between the intervention and control group at 24 months follow-up (72.6±0.6kg, 72.5±0.6kg, respectively; p=0.6). Furthermore, mean (±SD) waist circumference was the same in both the intervention and control group at 24 months follow-up (88.7±0.6cm; p=0.7). However, it should be noted that both studies were powered to detect a difference between groups in a target level of physical activity (the primary outcome), but not a difference in BMI (a secondary outcome).

Table 141 Weight-related results: Green Prescription

Citation	Outcomes	Time point	Intervention [a]	Control [a]	Difference between groups [b]	P value [c]
Elley *et al* (2003)	Mean (95% CI) change in BMI (kg/m^2)	12 months	-0.11 (-0.25, 0.02)	-0.05 (-0.18, 0.07)	-0.06 (-0.24, 0.12)	0.5
Lawton *et al* (2008)	Mean (±SD) weight (kg)	Baseline	73.2 (±0.6)	72.7 (±0.6)	-	0.60
		12 months	72.6 (±0.6)	72.7 (±0.6)	-	
		24 months	72.6 (±0.6)	72.5 (±0.6)	-	
	Mean (±SD) waist circumference (cm)	Baseline	86.7 (±0.6)	86.2 (±0.6)	-	0.70
		12 months	87.3 (±0.5)	87.3 (±0.5)	-	
		24 months	88.7 (±0.6)	88.7 (±0.6)	-	

Source: Elley *et al* (2003), Table 2 page 797; Lawton *et al* (2008), Table 2 page 2512
Abbreviations: BMI = body mass index; CI = confidence interval; SD = standard deviation.
[a] For the Elley *et al* (2003) study, unadjusted for clustering
[b] For the Elley *et al* (2003) study, adjusted for clustering by medical practice
[c] For the Lawton *et al* (2008) study, analyses took into account repeated measures and adjusted for baseline values. Data that were not normally distributed were log transformed.

4.15.3.5 Physical activity-related results

The results of the analysis of physical activity-related outcomes are presented in **Table 142.** For the Elley *et al* (2003) study, the results showed that leisure physical activity, leisure exercise and total energy expenditure were significantly greater at 12 months follow-up in the intervention group compared to the control group (p=0.02, p=0.04 and p=0.001, respectively). The proportion of participants in the intervention who achieved 2.5 hours of moderate or vigorous leisure physical activity per week increased by 66/451(14.6%) compared with 21/427 (4.9%) in the control group

(P=0.003). In the Lawton *et al* (2008) study, the number of participants completing at least 150 minutes physical activity per week at 24 months was significantly higher in the intervention group compared to the control group (214 ± 39 versus 179 ± 33, p=0.001). Similarly, the median minutes of physical activity per week at 24 months follow-up was significantly higher in the intervention group compared to the control group (105 minutes and 90 minutes, respectively; p=0.01).

Table 142 Physical activity results: Green Prescription

Citation	Outcomes	Time point	Intervention [a]	Control [a]	Difference between groups [b]	P value [c]
Elley *et al* (2003)	Total energy expenditure (kcal/kg/wk)	12 months	9.76 (5.85, 13.68)	0.37 (-3.39, 4.14)	9.38 (3.96, 14.81) (975 kcal/wk)	0.001
	Leisure physical activity (kcal/kg/wk)	12 months	4.32 (3.26, 5.38)	1.29 (0.11, 2.47)	2.67 (0.48, 4.86) (247 kcal/wk)	0.02
	Leisure exercise	12 months	54.6 (41.4, 68.4)	16.8 (6.0, 32.4)	33.6 (2.4, 64.2)	0.04
Lawton *et al* (2008)	No (%) completing at least 150 minutes physical activity/wk)	Baseline	56 (10)	62 (11)	-	0.001
		12 months	233 (43)	165 (30)	-	
		24 months	214 (39)	179 (33)	-	
	Median (IR) minutes physical/wk	Baseline	30 (0, 90)	30 (0, 90)	-	0.01
		12 months	120 (0, 210)	75 (0, 170)	-	
		24 months	105 (0, 205)	90 (0, 190)	-	

Source: Elley *et al* (2003), Table 2 page 797; Lawton *et al* (2008), Table 2 page 2512
Abbreviations: BMI = body mass index; CI = confidence interval; SD = standard deviation.
[a] For the Elley *et al* (2003) study, unadjusted for clustering
[b] For the Elley *et al* (2003) study, adjusted for clustering by medical practice
[c] For the Lawton *et al* (2008) study, analyses took into account repeated measures and adjusted for baseline values. Data that were not normally distributed were log transformed.

4.15.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for the Green Prescription intervention is provided in **Table 143**.

Table 143 Dimensions of evidence for Green Prescription

Dimension	Definition
Strength of evidence	
Level	The studies were Level II evidence, randomised controlled trials
Quality	The studies were high quality with randomisation and 1 and 2 year follow-up
Statistical precision	The p-values were non-significant for weight-based outcomes, but significant for physical activity outcomes.
Size of effect	There was no significant difference between the intervention and control group for weight-based outcomes. The difference in mean change in BMI was 0.06kg/m^2 in favour of the intervention group in the Elley *et al* (2003) study. There were significant differences between the intervention and control group, in favour of the intervention group, for physical activity outcomes. This is not surprising given the study was powered to detect a difference in physical activity (the primary outcome) and not BMI (a secondary outcome).
Relevance of evidence	The weight-based outcomes were mean change in BMI, mean weight and mean waist circumference, which are all clinically relevant outcomes. The Green Prescription intervention has been implemented in NZ and is therefore applicable.

Source: NHMRC 2000b.
Abbreviations: BMI = body mass index; NZ = New Zealand

4.15.5 Translation of results for economic analysis

Whilst the study by Elley *et al (*2003) presents mean change in BMI at 12 months follow-up, the difference between the intervention and control group was not significant (mean change in BMI: –0.06kg/m^2; p=0.5), as shown in **Table 144**. In the Lawton *et al* (2008) study, BMI was not measured at follow-up. There was a trend towards less weight gain in the intervention group compared to the control group for weight and waist circumference, however, the difference between groups was not significant (p=0.6 and p=0.7, respectively). It is important to note that neither study was powered to detect a significant difference in weight related-outcomes, as these were secondary outcomes of the study.

There were significant differences between the intervention and control groups in measures of physical activity (the primary outcome of the study), in favour of the Green Prescription group. In the Elley *et al* (2003) study, leisure physical activity, leisure exercise, total energy expenditure and the number of participants achieving 2.5 hours of moderate or vigorous leisure physical activity per week was significantly greater in the intervention group compared to the control group. In the Lawton *et al* (2008) study, the number of participants completing at least 150 minutes physical activity per week and the median minutes of physical activity per week was significantly greater in the Green Prescription group.

Table 144 BMI results for Intervention 12: Green Prescription

Country	Setting	Category	Age (years)	Ethnicity	Mean difference in change in BMI Intervention – control(kg/m^2)
					1 year
NZ	General practice	PA	Adult	Caucasian (~75%)	-0.06

Note: statistically significant results are shown in bold.
Abbreviations: BMI=body mass index; N=nutrition; PA=physical activity.

4.16 INTERVENTION 16: GENERAL HEALTH SCREENING

Various forms of 'General Health Screening' can be implemented by physicians in primary health care. Screening interventions are used to prevent general health problems using lifestyle changes as the primary prevention tool. Thus far, most studies examining general health screening as an intervention have focused on improving the cardiovascular risk profile of patients. However, obesity and cardiovascular health are closely linked with reductions in obesity conferring benefits for cardiovascular health.

General health screening interventions were identified during the scoping search via a search of the EMBASE.com and Cochrane library databases.

4.16.1 Objective

The objective of this research is to systematically review the evidence regarding the effectiveness of General Health Screening interventions, carried out through primary health care, in terms of preventing obesity. The specific research question to be answered is as follows:

Does the obesity prevention interventions 'general health screening', prevent obesity (via a reduction in a weight-related outcome or prevention of an increase in a weight-related outcome) over a period of at least 12 months compared with no intervention?

This section of the systematic review is not concerned with reviewing a single intervention, rather a class of interventions which would be classified as General Health Screening.

4.16.2 Literature search

In order to identify studies relevant to the assessment of the General Health Screening intervention, a search of Embase.com (covering the EMBASE and Medline databases) and the Cochrane Library were conducted. The search included terms relating to the intervention, such as 'general health screening' and 'screening', terms relating to the setting, such as 'primary health care' and 'general practice', and terms relating to obesity prevention such as 'obesity' and 'BMI'. A grey literature search was also undertaken to ensure no studies of relevance had been missed. Details of the searches and search results are presented in **Table 145**.

Table 145 Literature search for General Health Screening: Embase.com and Cochrane Library

Search location	Search string	Citations
Embase.com (EMBASE and Medline) 05/01/2010	#1 'obesity'/exp OR 'bmi' #2 ''general health screening' OR 'general health screenings' OR 'screening'/exp OR screening #3 'primary health care'/exp OR 'primary health care' OR 'general practice' #4 (#1 AND #2 AND #3)	303
Cochrane Library (Clinical trials) 05/01/2010	#1 'obesity' OR 'bmi' #2 'general health screening' OR ''general health screenings' OR 'screening' #3 (#1 AND #2) limit to 'Clinical trials database only'	211
Subtotal		*514*
Manual searching of grey literature and reference lists	'General health screening'	1
TOTAL		**515**

Abbreviations: BMI = body mass index

The following exclusion criteria were applied to the 515 citations identified through the literature search:

1. Duplicate citation – excludes multiple citations for the same publication

2. Not a clinical study – excludes publications which do not report the results of an original study conducted in humans (ie, excludes animal studies, in vitro studies, narrative reviews)

3. Wrong population/intervention – excludes studies which do not describe and/or assess a General Health Screening programme or comparable intervention for obesity prevention.

4. Wrong outcomes- does not report a relevant weight-based outcome

Applying the exclusion criteria to the titles and/or abstracts of the identified citations resulted in the inclusion of six publications for full paper review relating to General Health Screening. Five of these citations were identified via the search of Embase.com and the Cochrane library and one was identified via a manual search of the included studies' reference lists. The results of the application of exclusion criteria are presented in **Table 146**.

Table 146 Exclusion of citations for General Health Screening

Criterion	Citations
TOTAL IDENTIFIED	515
Duplicate citation	23
Not a clinical study	208
Wrong population/intervention	278
TOTAL REMAINING	6

Of the six papers which appeared to relate to general health screening, only three original studies were included after full text review. Two studies were found to discuss the wrong intervention for this particular research question and one was not in English. Three papers describing two studies were selected for inclusion. Of these three papers, two provided study results and one methodological information and baseline data. Details of the citations are presented in **Table 147**.

Table 147 Included citations: General Health Screening

Citation details	**Included**
Engberg M, Christensen B, Karlsmose B, Lous J, and Lauritzen T. (2002) General health screenings to improve cardiovascular risk profiles: A randomised controlled trial in general practice with a 5-year follow-up. Journal of Family Practice; 51(6):546–552.	✓
Engberg M, Christensen B, Karlsmose B, Lous J, and Lauritzen T. (2002) [Can systematic general health screening and patient-physician health discussions improve the cardiovascular profile of the population? A randomized controlled trial in general practice with a 5-year follow-up]. *Ugeskrift for Laeger* 164:3354-3360.	
Hellenius ML, Johansson J, De Faire U, Elofsson S, and Krakau I. (1999) Four years experience of a cardiovascular opportunistic screening and prevention programme in the primary health care in Sollentuna, Sweden. *Scandinavian Journal of* 17:111-115.	
Laws R and -Counterweight-Project-Team. (2004) A new evidence-based model for weight management in primary care: the Counterweight Programme. *Journal of human nutrition and dietetics : the official journal of the British Dietetic Association* 17:191-208.	
Muir J, Lancaster T, Jones L, Yudkin P. Effectiveness of health checks conducted by nurses in primary care: final results of the OXCHECK study. (1995) BMJ 310:1099-1104.	✓
Muir J, Neil A, Roe L, Rusted N, Thorogood M, Mant D. Prevalence of risk factors for heart disease in OXCHECK trial: implications for screening in primary care. (1991) Imperial Cancer Research Fund OXCHECK Study Group. BMJ 302:1057-1060.	✓

4.16.3 Results

The following section provides details of the characteristics of the Engberg *et al* (2002) and OXCHECK study, which both describe a General Health Screening intervention. The intervention, study and baseline participant characteristics, and two sets of results are presented: (i) results of the Engberg *et al* (2002) study, and (ii) results of the OXCHECK study.

For the Engberg *et al* (2002) study, obesity prevention was not the primary objective of the intervention; however, BMI was measured at baseline and at 5 years follow-up. Furthermore, the study reported that the majority of physician advice during screening was related to weight (63%). The OXCHECK study examined a series of health outcomes for patients which included, but did not focus on, measurements of obesity.

4.16.3.1 Intervention characteristics

Various forms of General Health Screening have been applied in primary care in the past; however, few studies have attempted to quantify the health benefit of screening for patients as an 'intervention', *per se*, through a controlled trial.

Engberg *et al* (2002)

In this study, participants were given a multiphase, broad spectrum screening at baseline. This included various measurements of cardiovascular disease, body mass and other co-morbidity assessment. Baseline health screenings were performed by three laboratory assistants in the central clinic which five of the general practitioners shared. A few weeks after screening, all participants tested received written feedback from their general practitioners. Where values fell outside the normal range, the feedback included advice relating primarily to lifestyle changes. In the one to five years after the baseline screening measurement, an annual 45 minute consultation with the participants own general practitioner was also offered to those in the 'screening plus discussion' group. The control group was promised further health screening and a health discussion at the end of the study period.

OXCHECK (1995)

In OXCHECK, practice nurses performed health checks which included a medical history, lifestyle questionnaire, and structured dietary assessment. They measured height, weight and blood pressure and drew blood for determination of serum cholesterol concentration. Initial health checks took 45-60 minutes, and follow up visits 10-20 minutes. Nurses were instructed in the importance of identifying and following up patients with multiple risk factors and in the use of a patient centred communication model. Results are presented both for those who attended for re-examination and for all patients scheduled to attend on the assumption that non-attenders showed no change from their initial visit or last recheck (intent to treat analysis).

4.16.3.2 Study characteristics

Engberg *et al* (2002)

The Engberg *et al* (2002) study took place in Ebeltoft, a rural region of Denmark. The main characteristics summarised in **Table 148**. There were nine general practitioners in the region who participated. Of 3,464 inhabitants aged 30 to 49 years, and registered with a local general practitioner, a random sample of 2000 (57.7%) were invited to participate. Participants were randomly assigned to one of three groups by proportional, stratified randomisation based on the general practitioner with whom they were registered, their sex, age, cohabitation status, and BMI. Health screenings were offered to two of the groups and follow-up health discussions with physicians in one of the intervention groups.

OXCHECK (1995)

The OXCHECK study was a randomised controlled trial undertaken in the United Kingdom that also examined the impact of General Health Screening. The main study characteristics are summarised in **Table 148**. This intervention was administered in five general practices, with nurses assessing patients. A total of 11,090 patients were randomised to either health checks during one of the four years from 1989 to 1993, or to the control group, who attended only one health check in 1993. To assess the effectiveness of the intervention the two groups were compared at one time point only (ie 1994), which was three years of follow-up.

Table 148 Study characteristics: General Health Screening

Study	Study type	Population	Intervention/ comparator	Outcomes
Engberg *et al* (2002)	Randomised controlled trial Primary care, community-based 9 rural practices in Aarhus country, Denmark 5 years duration	30–49 year-old patients N: 1507 Gender: males: 48.6%	Health Screening, Health Screening + Discussion vs. Control Health Screening was performed for all participants at baseline and annually for those in the two intervention groups. Controls were screened at baseline and 5 year follow-up only. Screening involved an assessment of multiple health indicators.	Cardiovascular risk score at 5 year follow-up *Mean BMI at 5-year follow up* *5-year change in mean BMI from baseline*[a] Mean systolic BP at 5-year follow-up Mean diastolic BP at 5-year follow-up Mean serum cholesterol
OXCHECK (1995)	Randomised controlled trial Primary care, community-based 5 general practices in Bedfordshire 3 years duration	35–64 years old N: 5,559 randomised; N=4,121 with data Gender: Males: 44.8%	Health screening vs. control (no health checks) In year 1, after randomisation, health screening was performed on intervention group. Both intervention and control group were assessed at Year 4 and compared.	Serum total cholesterol concentration Blood pressure *Body mass index* Smoking prevalence Self reported dietary, exercise, and alcohol habits.

Source: Engberg *et al* (2002), Page 447-448; Muir *et al* (1995), page 1099-1100
Abbreviations: CHD = coronary heart disease; GP = general practitioner; HbA1c = Glycosylated haemoglobin; IR = inter-quartile range; NZ = New Zealand; Wk = week.
Note: Outcomes which are considered relevant to this review, and which are described in the results section, are shown in italics.
[a] Calculated post-hoc by the reviewer

4.16.3.3 Baseline participant characteristics

Table 149 summarises the baseline characteristics of participants in the Engberg *et al* (2002) and OXCHECK study. Only limited baseline participant information was available for the OXCHECK study, which came from a report published prior to the release of the publication containing the final study results.

Engberg *et al* (2002)

The baseline participant characteristics in the Engberg *et al* (2002) study were comparable between groups. The mean age in the control, health screening, and health screening plus discussion groups was approximately 40 years old. There were also a similar proportion of male participants in each group (48.3%, 48.6% and 49.0%, respectively). The percentage of patients who were living in co-habitation and the proportion of smokers were also comparable. Mean BMI (kg/m^2) was approximately 24 kg/m^2 in each group indicating participants were, on average, according to WHO classifications, borderline overweight.

OXCHECK (1995)

In the OXCHECK study, the publication reporting patient baseline health characteristics described the cohort in *toto*, prior to randomisation into separate study arms (ie, screening and no screening). There were 987 (44.8%) men and 1218 (46.2%) women who participated in the study. Of the men, 320 (32.4%) were between 35 and 44 years, 332 (33.6%) between 45 and 54 years, and 335 (33.9%) between 55 and 64 years. Of the women, 414 (34.0%) were between 35 and 44 years, 424 (34.8%) between 45 and 54 years and 380 (31.2%) between 55 and 64 years. For men, the mean prevalence (95% CI) across age groups of BMI ≥30 kg/m^2 (obese) was 10% (8% to 12%) and the mean prevalence (95% CI) of males with BMI between 25 and 29.9 kg/m^2 (overweight) was 45% (42% to 48%). For women, the mean prevalence (95% CI) across age groups of BMI ≥30 kg/m^2 was 16% (14% to 185) and the mean prevalence (95% CI) of males with BMI between 25 and 29.9 kg/m^2 was 32% (29% to 35%). Generally, 35% of men were current smokers, 31% had a high fat diet. The corresponding figures for women were 24% and 18%.

Table 149 Baseline characteristics: General Health Screening

Study	Characteristic	Unit	Intervention		Control
			Health screening	Health screening plus discussion	
Engberg *et al* (2002)			N=502	N=504	N=501
	Age (years)	Mean ± SD	40.4 ± 5.6	40.6 ± 5.7	40.4 ± 5.8
	Males	(%)	48.6	49.0	48.3
	Cohabitating	(%)	82.3	83.8	81.7
	Smokers	(%)	51.4	53.9	51.4
	BMI (kg/m²)	Mean ± SD	24.1 ± 3.6	24.6 ± 4.2	24.4 ± 4.0
OXCHECK [a]			N=2205		N=1916
	Age (years)	Range	35–64		35–64
	Males	N (%)	987 (44.8%)		885 (46.2%)
	Cohabitating		NR		NR
	Smokers		NR		NR
	BMI (kg/m²)		NR		NR

Source: Engberg *et al* (2002), table 1, page 4; Muir *et al* (1995), page 1099-1100
Abbreviations: BMI = body mass index; SD = standard deviation.
[a] Baseline characteristics reported in the study were limited and not split into intervention and control groups

4.16.3.4 Weight-related results

The results of the analyses of weight-related outcomes for the two General Health Screening studies are presented in **Table 150**. Both studies reported mean BMI at one follow-up time point and made statistical comparisons between groups based on these measurements. In order to provide some additional information, the reviewer has calculated mean change from baseline as a crude, *post-hoc* analysis for the Engberg *et al* (2002) study. This was not possible for the OXCHECK study because baseline BMI was not reported for each group.

Engberg *et al* (2002)

The Engberg *et al* (2002) study reported a mean BMI for participants in the control group of 26.5 ± 4.4 kg/m² at five years follow-up compared to a mean BMI of 25.9 ± 4.1 kg/m² in the intervention group (including both health screening and health screening plus discussion programs). The difference between the two groups was statistically significant ($p<0.05$). The mean increase from baseline in BMI in the control group was 2.1 kg/m², compared to a mean increase in BMI in the intervention group of 1.5 kg/m² resulting in a difference of 0.6 kg/m².[1] Both the intervention and control group gained weight, although the intervention group, on average, gained less.

OXCHECK (1995)

The OXCHECK study reported the mean BMI and difference in BMI between the control and intervention group after three years. The intervention group results were split into an intent-to-treat (ITT) population (ie, inclusive of participants who dropped out), and a non-ITT population (ie,

[1] The mean change for the intervention group was calculated by taking a crude, weighted average of the means for the health screening and health screening plus discussion groups at baseline, and calculating the difference between this and the mean BMI of the combined intervention group at follow-up.

attendees only). The results of both analyses are presented in **Table 150**. Patients in the control group had a mean BMI of 26.26 ± 4.31 kg/m^2 compared with those in the ITT intervention group who had a mean BMI of 25.88 ± 4.21kg/ m^2 three years post-intervention (difference 0.38; 0.12 to 0.64). The number of participants who were classified as obese (ie, BMI ≥30 kg/m^2) at three years follow-up was also assessed for each group and the results indicated no significant difference between the intervention and control group. It is difficult to interpret the results of this study because control participants were not assessed at baseline.

Table 150 Weight-related results: General Health Screening

Citation	**Outcomes**	**Time point**	**Control**	**Intervention**	
Engberg *et al* (2002)	Mean BMI (kg/m^2)	Baseline	24.4 kg/m^2 [a]	24.4 kg/ m^2	
	Mean (SD) BMI (kg/m^2)	5 years	26.5 (±4.4)	25.9 (±4.1) [b]	
	Change from baseline (kg/m^2) [a]	5 years	+2.1 kg/m^2	+1.5 kg/m^2	
Citation	**Outcomes**	**Time point**	**Control**	**Attenders only**	**All participants**
OXCHECK study Muir *et al* 1995	Mean (SD) BMI (kg/m^2)	3 years	26.26 (±4.31)	25.89 (±4.14)	25.88 (±4.21)
	Difference from control (95% CI)	3 years		0.37 (0.09 to 0.65)	0.38 (0.12 to 0.64)
	N (%) BMI ≥ 30 kg/m^2	3 years	304 (±15.9)	220 (±13.5)	310 (±14.3)

Source:Engberg *et al* (2002), Table 1page 4 and Table 2 page 6; Muir *et al* (1995)
Abbreviations: BMI, body mass index;; CI, confidence interval; SD, standard deviation.
[a] Calculated post-hoc by reviewer. A crude weighted average was calculated combining the two intervention groups at baseline
[b] $p<0.05$, significantly different from control group at this time point

4.16.3.5 Physical activity-related results

There were no physical activity-related results reported in the Engberg *et al* (2007) study. Self-reported exercise in the OXCHECK study is shown in **Table 151**. The proportion of patients reporting taking vigorous exercise less than once a month was significantly lower in the intervention group (difference 3.3%, 95% CI: 0 5 % to 6.1%).

Table 151 Reported exercise in control group after three years of intervention. Values are numbers (percentages) of patients

		Intervention group		Difference from control (95% confidence interval)	
	Control group	Attenders only	All participants	Attenders only	All participants
Men and Women					
No of participants	1916	1660	2205		
Exercise < once per month	1354 (70.9)	1094 (66.5)	1478 (67.6)	4.5 (1.4–7.5)	3.3 (0.5–6.1)
Men					
No of participants	885	738	987		
Exercise < once per month	635 (71.8)	479 (65.4)	648 (66.2)	6.4 (1.9 – 10.9)	5.6 (1.5 – 9.8)
Women					
No of participants	1031	922	1218		
Exercise < once per month	719 (70.1)	615 (67.3)	830 (68.8)	2.9 (–1.3 – 7.0)	1.4 (–2.5 – 5.2)

Source: Muir *et al* (1995), Table III, page 1102

4.16.4 Summary of dimensions of evidence

A summary of the dimensions of evidence for the General Health Screening intervention is provided in **Table 152**. The two studies were sufficiently different to warrant separate assessment.

Table 152 Dimensions of evidence for General Health Screening

Study	**Engberg *et al* (2002)**	**OXCHECK**
Dimension	**Definition**	
Strength of evidence		
Level	The study was Level II evidence, a randomised controlled trial	The study was Level II evidence, a randomised controlled trial
Quality	The study was good quality RCT with 5 years follow-up. Stratified randomisation based on the GP with whom they registered their sex, age, cohabitation status, and BMI. There was some (~30%) loss-to-follow up which may have biased results.	The study was an RCT with three year follow-up. Insufficient information on baseline characteristics was provided to assess bias in the study. Comparison between study arms was cross-sectional, assessed at one time point only.
Statistical precision	There was a significantly difference between groups in mean BMI ($p<0.05$) in favour of the intervention. The difference in mean change of BMI from baseline was 0.6 kg/m^2.	In the ITT analysis, body mass index was 0.38 kg/m^2 (0.12 to 0.64) or 1.4% lower in the intervention group at follow-up ($p<0.005$).
Size of effect	There was a small but significant difference between the intervention and control group for BMI.	There was a small but significant difference between the intervention and control group for BMI at 3 year follow-up but baseline BMI was not reported by group.
Relevance of evidence	The outcomes were mean BMI, mean BMI change from baseline, both relevant weight outcomes.	Difference in BMI and the proportion of patients with BMI ≥ 30 kg/m^2 at follow-up are relevant outcomes.

Source: NHMRC 2000b.
Abbreviations: BMI, body mass index; GP, general practitioner; RCT, randomised controlled trial

4.16.5 Translation of results for economic analysis

Evidence from the Engberg *et al* (2002) study suggested that patients who were subject to health screening, although still gaining weight, gained less weight, on average, than those who did not receive the intervention. The difference in mean BMI at 5-years follow-up (0.6kg/m^2) was statistically significant ($p<0.05$) (**Table 153**).

In the OXCHECK study, patients in the control group had a mean BMI of 26.26 ± 4.31 kg/m^2 compared with those in the ITT intervention group who had a mean BMI of 25.89 ± 4.21kg/ m^2 (mean difference: 0.38, 95% CI:0.12 to 0.64). However, a difference in the mean change could not be calculated.

Table 153 BMI results for Intervention 13: General Health Screening

Country	Setting	Category	Age (years)	Ethnicity	Mean difference in change in BMI Intervention – control(kg/m^2)	
					3 years	5 years
Denmark	General practice	Screening	Adult	Not stated	-0.4	**-0.6**

Note: statistically significant results are shown in bold.
Abbreviations: BMI=body mass index; N=nutrition; PA=physical activity.

5 SELECTION OF SCENARIOS TO UNDERGO ECONOMIC EVALUATION

A summary of the (i) BMI and (ii) incidence and prevalence of overweight/obesity results for the included interventions is shown in **Table 154** and **Table 155**, respectively.

After a meeting of the SRG, the following scenarios were selected for economic evaluation:

1. APPLE: General population
2. Switch-Play: General population
3. Green Prescription: General population
4. General Health Screening: General population
5. General Health Screening: Māori
6. General Health Screening: Pacific
7. Be Active Eat Well: General population
8. Be Active Eat Well: Māori
9. Be Active Eat Well: Pacific
10. SNPI: General population

Table 154 Summary of BMI results across the included interventions

No.	Intervention	Country	Setting	Category	Age	Ethnicity	Mean difference in change in BMI Intervention – control (kg/m²)					Mean difference in change in BMI z-score Intervention – control (kg/m²)				
							1 year	2 years	3 years	4 years	5 years	1 year	2 years	3 years	4 years	5 years
1	Hip Hop to Health Jnr	USA	Pre-school	Activity/ nutrition	3-5 years	African-American (95%)	**-0.5**	**-0.5**	-	-	-	**-0.2**	**-0.2**	-	-	-
						Latino (81%)	-0.1	-0.2	-	-	-	-0.1	-0.2	-	-	-
2	Be Active Eat Well	Australia	Pre-school/ primary school	Activity/ nutrition	4-12 years	Not stated	-	-	-0.3	-	-	-	-	**-0.1**	-	-
3	KOPS	Germany	Primary school/community	Education	5-7 years	Not stated	-	-	-	-0.1	-	-	-	-	-	-
4	APPLE	NZ	School/ community	Activity/ nutrition	5-12 years	Caucasian (82%)	**-0.2**	**-0.4**	**-**	-	**-**	**-0.1**	**-0.2**	-	-	-
5a	CHOPPS	UK	Primary school	Education/ nutrition	7-11 years	Not stated	0.1	-	-	-	-	-0.04	-	-	-	-
5b	Drinking water provision	Germany	Primary school	Policy	Mean 8 years	Not stated	-	-	-	-	-	-	-	-	-	-
6	Shape Up Somerville	USA	Primary school/ community	Activity/ education/ nutrition/ policy	Mean 8 years	Caucasian (44%)	-	-	-	-	-	**-0.1**	-	-	-	-
7	CATCH	USA	Primary school	Activity/ education/ nutrition	8-9 years	Hispanic (93%)	-	-	-	-	-	-	-	-	-	-
8	Switch-Play	Australia	Primary school	Education	10 years	Not stated	-0.2	-	-	-	-	-	-	-	-	-
				Activity	10 years	Not stated	-0.8	-	-	-	-	-	-	-	-	-
				Education/activity	10 years	Not stated	**-1.53**	-	-	-	-	-	-	-	-	-
9	SNPI	USA	Primary school	Education/policy	11 years	African-American (45%)	-	-0.04	-	-	-	-	-0.01	-	-	-
10	Health education	Crete	High school	Education	13-14 years	Not stated	**-0.5**	**-**	-	-	-	-	-	-	-	-

11	Seminar-based	USA	University	Education	Mean 19 years	Caucasian (93%)	**-0.5**	**-0.5**	-	-	-	-	-	-	-	-
12a	Work-site cardiovascular risk reduction	Australia	Workplace	Screening	Mean 32 years	Not stated	**-**	-	-	-	-	-	-	-	-	-
				Education	Mean 32 years	Not stated	-0.3[a]	-	-	-	-	-	-	-	-	-
				Counselling	Mean 32 years	Not stated	-0.58[a]	-	-	-	-	-	-	-	-	-
				Education and incentives	Mean 32 years	Not stated	-0.43[a]	-	-	-	-	-	-	-	-	-
12b	Multi-faceted intervention for weight loss and blood pressure control	USA	Workplace	Education/ screening/ activity	Mean age ~46 years	Caucasian (48%); African-American (27%)	**-1.2**	-	-	-	-	-	-	-	-	-
13	Women's Health Initiative	USA	Community	Nutrition	Post-menopausal women	Caucasian (81%)	**-0.3**	-	-	-	-	-	-	-	-	-
14	Women's healthy Lifestyle	USA	Community	Nutrition	Pre-menopausal women	Caucasian (majority)	**-**	-	-1.1	-1.0	-1.9					
15	Green Prescription	NZ	General Practice	Activity	Adult	Caucasian (77%)	0.05	**-**	**-**	**-**	**-**	-	-	-	-	-
16	General Health Screening	Denmark	General Practice	Screening	Adult	Not stated	-	**-**	-0.4	**-**	**-0.6**	-	-	-	-	-

Note: BMIs estimated from BMI z-scores are shown in italics.
[a] Calculated *post hoc* by reviewer

Table 155 Summary of incidence and prevalence or overweight/obesity results across the included interventions

No.	Intervention	Country	Setting	Category	Age	Ethnicity	Incidence overweight or obese Intervention/control Risk estimate (95% CI)			Prevalence overweight or obese Intervention/control Risk estimate (95% CI)	
							1 year	2 years	4 years	1 year	3 years
1	Hip Hop to Health Jnr	USA	Pre-school	Activity/ nutrition	3-5 years	African-American (95%)	-	-	-	-	-
						Latino (81%)	-	-	-	-	-
2	Be Active eat Well	Australia	Pre-school/ primary school	Activity/ nutrition	4-12 years	Not stated	-	-	-	-	-
3	KOPS	Germany	Primary school/community	Education	5-7 years	Not stated	-	-	OR 0.76 (0.47, 1.23)	-	-
4	APPLE	NZ	School/ community	Activity/ nutrition	5-12 years	Caucasian (82%)	-	-	-	-	-
5a	CHOPPS	UK	Primary school	Education/ nutrition	7-11 years	Not stated	-	**-**	-	**OR 0.58 (0.37, 0.89)**	OR 0.79 (0.52, 1.21)
5b	Drinking water provision	Germany	Primary school	Policy	Mean 8 years	Not stated	-	**-**	-	**OR 0.69 (0.48, 0.98)**	-
6	Shape Up Somerville	USA	Primary school/ community	Activity/ education/ nutrition/ policy	Mean 8 years	Caucasian (44%)	-	-	-	-	-
7	CATCH	USA	Primary school	Activity/ education/ nutrition	8-9 years	Hispanic (93%)	-	-	-	-	-
8	Switch-Play	Australia	Primary school	Education	10 years	Not stated	OR 0.65 (0.35, 2.10)	-	-	-	-
				Activity	10 years	Not stated	OR 0.66 (0.28, 1.56)	-	-	-	-
				Education/activity	10 years	Not stated	**OR 0.38 (0.16, 0.89)**	-	-	-	-

No.	Intervention	Country	Setting	Category	Age	Ethnicity	Incidence overweight or obese Intervention/control Risk estimate (95% CI)			Prevalence overweight or obese Intervention/control Risk estimate (95% CI)	
							1 year	2 years	4 years	1 year	3 years
9	SNPI	USA	Primary school	Education/policy	11 years	African-American (45%)	-	**OR 0.73 (0.54, 0.99)**	-	-	-
10	Health education	Crete	High school	Education	13-14 years	Not stated	-	-	-	-	-
11	Seminar-based	USA	University	Education	Mean 19 years	Caucasian (93%)	-	-	-	-	-
12a	Work-site cardiovascular risk reduction	Australia	Workplace	Screening	Mean 32 years	Not stated	-	-	-	-	-
				Education	Mean 32 years	Not stated	-	-	-	-	-
				Counselling	Mean 32 years	Not stated	-	-	-	-	-
				Education and incentives	Mean 32 years	Not stated	-	-	-	-	-
12b	Multi-faceted intervention for weight loss and blood pressure control	USA	Workplace	Education/ screening/ activity	Mean age ~46 years	Caucasian (48%); African-American (27%)	-	-	-	-	-
13	Women's Health Initiative	USA	Community	Nutrition	Adult	Caucasian (81%)	-	-	-	-	-
14	Women's healthy Lifestyle	USA	Community	Nutrition	Pre-menopausal women	Caucasian (majority)	-	-	-	-	-
15	Green Prescription	NZ	General Practice	Activity	Adult	Caucasian (77%)	-	-	-	-	-
16	General Health Screening	UK	General Practice	Screening	Adult	Not stated	-	-	-	-	-

REFERENCES

(1991) Prevalence of risk factors for heart disease in OXCHECK trial: implications for screening in primary care. Imperial Cancer Research Fund OXCHECK Study Group. BMJ (Clinical research ed.) 302:1057-1060.

Bleich S, Cutler DM, Murray CJ, and Adams A. (2008) Why is the developed world obese? Annual Review of Public Health 29.

Centre for Reviews and Dissemination. Systematic reviews: CRD's guidance for undertaking reviews in health care. 2009. University of York, CRD.

Cholewa S and Irwin JD. (2008) Project IMPACT: Brief report on a pilot programme promoting physical activity among university students. Journal of Health Psychology 13:1207-1212.

Coleman KJ, Tiller CL, Sanchez J, Heath EM, Sy O, Milliken G, and Dzewaltowski DA. (2005) Prevention of the epidemic increase in child risk of overweight in low-income schools: The El Paso coordinated approach to child health. Archives of Pediatrics and Adolescent Medicine 159:217-224.

Croteau K, Schofield G, and McLean G. (2006) Physical activity advice in the primary care setting: Results of a population study in New Zealand. Australian and New Zealand Journal of Public Health 30:262-267.

Danielzik S, Czerwinski-Mast M, Langnase K, Dilba B, and Muller MJ. (2004) Parental overweight, socioeconomic status and high birth weight are the major determinants of overweight and obesity in 5-7 y-old children: Baseline data of the Kiel Obesity Prevention Study (KOPS). International Journal of Obesity 28:1494-1502.

Danielzik S, Pust S, Landsberg B, and Muller MJ. (2005) First lessons from the Kiel Obesity Prevention Study (KOPS). International Journal of Obesity 29:S78-S83.

Danielzik S, Pust S, and Muller MJ. (2007) School-based interventions to prevent overweight and obesity in prepubertal children: Process and 4-years outcome evaluation of the Kiel Obesity Prevention Study (KOPS). Acta Paediatrica, International Journal of Paediatrics 96:19-25.

Department of Education,V. Fundamental Motor Skills: An Activities Resource for Classroom Teachers. 1998. Victoria, Department of Education, Victoria.

Doak CM, Adair LS, Bentley M, Monteiro C, and Popkin BM. (2005) The dual burden household and the nutrition transition paradox. International Journal of Obesity 29:129-136.

Dwyer JT, Stone EJ, Yang M, Webber LS, Must A, Feldman HA, Nader PR, Perry CL, and Parcel GS. (2000) Prevalence of marked overweight and obesity in a multiethnic pediatric population: findings from the Child and Adolescent Trial for Cardiovascular Health (CATCH) study. Journal of the American Dietetic Association 100:1149-1156.

Economos CD, Hyatt RR, Goldberg JP, Must A, Naumova EN, Collins JJ, and Nelson ME. (2007) A community intervention reduces BMI z-score in children: Shape up somerville first year results. Public Health Public Policy 15:1325-1336.

Economos CD and Curtatone JA. (2010) Shaping up Somerville: A community initiative in Massachusetts. Preventive Medicine 50:S97-S98.

Elley CR, Kerse N, Arroll B, and Robinson E. (2003) Effectiveness of counselling patients on physical activity in general practice: Cluster randomised controlled trial. British Medical Journal 326:793-796.

Elley CR, Kerse N, Arroll B, Swinburn B, Ashton T, and Robinson E. (2004) Cost-effectiveness of physical activity counselling in general practice. New Zealand Medical Journal 117.

Engberg M, Christensen B, Karlsmose B, Lous J, and Lauritzen T. (2002) General health screenings to improve cardiovascular risk profiles: A randomised controlled trial in general practice with a 5-year follow-up. Ugeskrift for Laeger 164:3354-3360.

Faucette N, Sallis J, McKenzie T, Alcaraz J, Kolody B, and Nugent P. (1995) Comparison of fourth grade students' out-of-school physical activity levels and choices by gender: Project SPARK. Journal of Health Education Supplement 26:S82-S90.

Fitzgibbon ML, Stolley MR, Dyer AR, VanHorn L, and KauferChristoffel K. (2002) A community-based obesity prevention program for minority children: Rationale and study design for Hip-Hop to Health Jr. Preventive Medicine 34:289-297.

Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, KauferChristoffel K, and Dyer A. (2005) Two-year follow-up results for Hip-Hop to Health Jr.: A randomized controlled trial for overweight prevention in preschool minority children. Journal of Pediatrics 146:618-625.

Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, KauferChristoffel K, and Dyer A. (2006) Hip-Hop to Health Jr. for Latino preschool children. Obesity 14:1616-1625.

Foster GD, Sherman S, Borradaile KE, Grundy KM, Vander Veur SS, Nachmani J, Karpyn A, Kumanyika S, and Shults J. (2008) A policy-based school intervention to prevent overweight and obesity. Pediatrics 121:e794-e802.

Gomel M, Oldenburg B, Simpson JM, and Owen N. (1993) Work-site cardiovascular risk reduction: A randomized trial of health risk assessment, education, counseling, and incentives. American Journal of Public Health 83:1231-1238.

Gortmaker S, Peterson K, Wiecha J, *et al.* (1999) Reducing obesity via a school-based interdisciplinary intervention among youth. Archives of Pediatric and Adolescent Medicine 153:409-418.

Gortmaker SL, Cheung LWY, Peterson KE, Chomitz G, Cradle JH, Dart H, Fox MK, Bullock RB, Sobol AM, Colditz G, Field AE, and Laird N. (1999) Impact of a school-based interdisciplinary intervention on diet and physical activity among urban primary school children: Eat well and keep moving. Archives of Pediatrics and Adolescent Medicine 153:975-983.

Goulding A, Grant AM., Taylor RW., Williams SM., Parnell WR., Wilson N, and Mann J. (2007) Ethnic Differences in Extreme Obesity. The Journal of Pediatrics 151:542-544.

Gow RW, Trace SE, and Mazzeo SE. (2010) Preventing weight gain in first year college students: An online intervention to prevent the "freshman fifteen". Eating behaviors 11:33-39.

Gribben B, Goodyear-Smith F, Grobbelaar M, O'Neill D, and Walker S. (2000) The early experience of general practitioners using Green Prescription. The New Zealand medical journal 113:372-373.

Heath EM and Coleman KJ. (2002) Evaluation of the institutionalization of the coordinated approach to child health (CATCH) in a U.S./Mexico border community. Health education & behavior : the official publication of the Society for Public Health Education 29:444-460.

Heath EM and Coleman KJ. (2003) Adoption and institutionalization of the Child and Adolescent Trial for Cardiovascular Health (CATCH) in El Paso, Texas. Health promotion practice 4:157-164.

Hivert MF, Langlois MF, Bérard P, Cuerrier JP, and Carpentier AC. (2007) Prevention of weight gain in young adults through a seminar-based intervention program. International Journal of Obesity 31:1262-1269.

Hovell M, Sallis J, Kolody B, and McKenzie T. (1999) Children's physical activity choices: a developmental analysis of gender intensity levels, and time. Pediatric Exercise Science 11:158-168.

Howard BV, Manson JE, Stefanick ML, Beresford SA, Frank G, Jones B, Rodabough RJ, Snetselaar L, Thomson C, Tinker L, Vitolins M, and Prentice R. (2006) Low-fat dietary pattern and weight change over 7 years: The Women's Health Initiative Dietary Modification Trial. Journal of the American Medical Association 295:39-49.

Howard BV, Van Horn L, Hsia J, Manson JE, Stefanick ML, Wassertheil-Smoller S, *et al.* (2006) Low-fat dietary pattern and risk of cardiovascular disease: The Women's Health Initiative randomized controlled dietary modification trial. Journal of the American Medical Association 295:655-666.

Imperial Cancer Research Fund OXCHECK Study Group. (1995) Effectiveness of health checks conducted by nurses in primary care: final results of the OXCHECK study. BMJ (Clinical research ed.) 310:1099-1104.

James J, Thomas P, Cavan D, and Kerr D. (2004) Preventing childhood obesity by reducing consumption of carbonated drinks: cluster randomised controlled trial. BMJ (Clinical research ed.) 328:1237.

James J, Thomas P, Cavan D, and Kerr D. (2004) Preventing childhood obesity by reducing consumption of carbonated drinks: Cluster randomised controlled trial. British Medical Journal 328:1237-1239.

James J, Thomas P, and Kerr D. (2007) Preventing childhood obesity: two year follow-up results from the Christchurch obesity prevention programme in schools (CHOPPS). BMJ (Clinical research ed.) 335:762.

Kelder SH, Osganian SK, Feldman HA, Webber LS, Parcel GS, Leupker RV, Wu MC, and Nader PR. (2002) Tracking of physical and physiological risk variables among ethnic subgroups from third to eighth grade: The Child and Adolescent Trial for Cardiovascular Health cohort study. Preventive Medicine 34:324-333.

Kelder SH, Mitchell PD, McKenzie TL, Derby C, Strikmiller PK, Luepker RV, and Stone EJ. (2003) Long-term implementation of the CATCH physical education program. Health education & behavior : the official publication of the Society for Public Health Education 30:463-475.

Kerse N, Elley CR, Robinson E, and Arroll B. (2005) Is physical activity counseling effective for older people? A cluster randomized, controlled trial in primary care. Journal of the American Geriatrics Society 53:1951-1956.

Kopelman PG. (2000) Obesity as a medical problem. Nature 404:635-643.

Kremer P,MMSASB. Nutrition and Physical Activity in Children and Adolescents. Barwon-South Western Region. Sentinel Site Series. Report 4: Physical Activity Patterns. 2008. Victoria, Department of Human Services.

Kuller LH, Simkin-Silverman LR, Wing RR, Meilahn EN, and Ives DG. (2001) Women's healthy lifestyle project: A randomized clinical trial: Results at 54 months. Circulation 103:32-37.

Lawton BA, Rose SB, Elley CR, Dowell AC, Fenton A, and Moyes SA. (2008) Exercise on prescription for women aged 40-74 recruited through primary care: Two year randomised controlled trial. BMJ (Clinical research ed.) 338:88-91.

Levitsky DA, Garay J, Nausbaum M, Neighbors L, and Dellavalle DM. (2006) Monitoring weight daily blocks the freshman weight gain: a model for combating the epidemic of obesity. International Journal of Obesity 30:1003-1010.

Lionis C, Kafatos A, Vlachonikolis J, Vakaki M, Tzortzi M, and Petraki A. (1991) The effects of a health education intervention program among Cretan adolescents. Preventive Medicine 20:685-699.

Luepker RV, Perry CL, McKinlay SM, Nader PR, Parcel GS, Stone EJ, Webber LS, Elder JP, Feldman HA, Johnson CC, Kelder SH, and Wu M. (1996) Outcomes of a field trial to improve children's dietary patterns and physical activity: The Child and Adolescent Trial for Cardiovascular Health (CATCH). Journal of the American Medical Association 275:768-776.

Luepker RV, Perry CL, Osganian V, Nader PR, Parcel GS, Stone EJ, and Webber LS. (1998) The child and adolescent trial for cardiovascular health (CATCH). Journal of Nutritional Biochemistry 9:525-534.

Mathews L.,KPSASANMMMSB. Nutrition and Physical Activity in Children and Adolescents. Barwon-South Western Region. Sentinel Site Series. Report 1: Methods and Tools. 2008. Victoria, Department of Human Services.

Mathews,LMMSAMKPSBA. Nutrition and Physical Activity in Children and Adolescents. Barwon-South Western Region. Sentinel Site Series. Report 5: Obesogenic Environments. 2008. Victoria, Department of Human Services.

Matvienko O, Lewis DS, and Schafer E. (2001) A college nutrition science course as an intervention to prevent weight gain in female college freshmen. Journal of nutrition education 33:95-101.

Ministry of Health. Taking the pulse- 1996-97 New Zealand Health Survey. 1998. Wellington, MOH.

Ministry of Health. Tracking the Obesity Epidemic: New Zealand 1977-2003. 2004. Ministry of Health.

Ministry of Health. A Portrait of Health: Key results from the 2006/07 New Zealand Health Survey. 2008. Ministry of Health.

Muckelbauer R, Libuda L, Clausen K, Toschke AM, Reinehr T, and Kersting M. (2009) Promotion and provision of drinking water in schools for overweight prevention: randomized, controlled cluster trial. Pediatrics 123:e661-e667.

Muckelbauer R, Libuda L, Clausen K, Reinehr T, and Kersting M. (2009) A simple dietary intervention in the school setting decreased incidence of overweight in children. Obesity Facts 2:282-285.

Muckelbauer R, Libuda L, Clausen K, and Kersting M. (2009) Long-term process evaluation of a school-based programme for overweight prevention. Child: Care, Health and Development 35:851-857.

Muller MJ, Asbeckl I, Mast M, Langnase K, and Grund A. (2001) Prevention of obesity - More than an intention. Concept and first results of the kiel obesity prevention study (KOPS). International Journal of Obesity 25:S66-S74.

Nader PR, Stone EJ, Lytle LA, Perry CL, Osganian SK, Kelder S, Webber LS, Elder JP, Montgomery D, Feldman HA, Wu M, Johnson C, Parcel GS, and Luepker RV. (1999) Three-year maintenance of improved diet and physical activity: The CATCH cohort. Archives of Pediatrics and Adolescent Medicine 153:695-704.

NHMRC. How to use the evidence: assessment and application of scientific evidence . 2000. Canberra, National Health and Medical Research Council.

NHMRC. NHMRC levels of evidence. 2005. National Health and Medical Research Council .

OECD. OECD Health Data 2009. 2009. Paris, OECD.

Pfeiffer BA, Clay SW, and Conatser J. (2001) A green prescription study: Does written exercise prescribed by a physician result in increased physical activity among older adults? Journal of Aging and Health 13:527-538.

Plachta-Danielzik S, Pust S, Asbeck I, Czerwinski-Mast M, Langnase K, Fischer C, Bosy-Westphal A, Kriwy P, and Muller MJ. (2007) Four-year follow-up of school-based intervention on overweight children: The KOPS study. Obesity 15:3159-3169.

Ritenbaugh C, Patterson RE, Chlebowski RT, Caan B, Fels-Tinker L, Howard B, and Ockene J. (2003) The Women's Health Initiative dietary modification trial: Overview and baseline characteristics of participants. Annals of Epidemiology 13:S87-S97.

Robinson T. (1999) Reducing children's television viewing to prevent obesity. Journal of the American Medical Association 282:1561-1566.

Robinson TN. (1999) Reducing children's television viewing to prevent obesity: A randomized controlled trial. Journal of the American Medical Association 282:1561-1567.

Salmon J, Ball K, Crawford D, Booth M, Telford A, Hume C, Jolley D, and Worsley A. (2005) Reducing sedentary behaviour and increasing physical activity among 10-year-old children: Overview and process evaluation of the 'Switch-Play' intervention. Health Promotion International 20:7-17.

Salmon J, Ball K, Crawford D, Booth M, Telford A, Hume C, Jolley D, and Worsley A. (2005) Reducing sedentary behaviour and increasing physical activity among 10-year-old children: Overview and process evaluation of the 'Switch-Play' intervention. Health Promotion International 20:7-17.

Salmon J, Hume C, Ball K, Booth M, and Crawford D. (2006) Individual, social and home environment determinants of change in children's television viewing: The Switch-Play intervention. Journal of Science and Medicine in Sport 9:378-387.

Salmon J, Hume C, Ball K, Booth M, and Crawford D. (2006) Individual, social and home environment determinants of change in children's television viewing: The Switch-Play intervention. Journal of Science and Medicine in Sport 9:378-387.

Salmon J, Ball K, Hume C, Booth M, and Crawford D. (2008) Outcomes of a group-randomized trial to prevent excess weight gain, reduce screen behaviours and promote physical activity in 10-year-old children: Switch-Play. International Journal of Obesity 32:601-612.

Salmon J, Ball K, Hume C, Booth M, and Crawford D. (2008) Outcomes of a group-randomized trial to prevent excess weight gain, reduce screen behaviours and promote physical activity in 10-year-old children: Switch-Play. International Journal of Obesity 32:601-612.

Sanigorski AM,MMKPSB. Nutrition and Physical Activity in Children and Adolescents. Barwon-South Western Region, Sentinel Site Series. Report 2: Anthropometry. 2008. Victoria, Department of Human Services.

Sanigorski AM,MMALKPSB. Nutrition and Physical Activity in Children and Adolescents. Barwon-South Western Region Sentinel Site Series. Report 3: Dietary Patterns. 2008. Victoria, Department of Human Services.

Sanigorski AM, Bell AC, Kremer PJ, Cuttler R, and Swinburn BA. (2008) Reducing unhealthy weight gain in children through community capacity-building: Results of a quasi-experimental intervention program, Be Active Eat Well. International Journal of Obesity 32:1060-1067.

Sichieri R, Paula TA, de Souza RA, and Veiga GV. (2009) School randomised trial on prevention of excessive weight gain by discouraging students from drinking sodas. Public health nutrition 12:197-202.

Simkin-Silverman L WRHDea. (1995) Prevention of cardiovascular risk factor elevations in healthy premenopausal women. Prev Med 24:509-517.

Simkin-Silverman LR, Wing RR, Boraz MA, Meilahn EN, and Kuller LH. (1998) Maintenance of cardiovascular risk factor changes among middle-aged women in a lifestyle intervention trial. 's health (Hillsdale, N. J.) 4:255-271.

Simkin-Silverman LR, Wing RR, Boraz MA, and Kuller LH. (2003) Lifestyle Intervention Can Prevent Weight Gain during Menopause: Results from a 5-Year Randomized Clinical Trial. Annals of Behavioral Medicine 26:212-220.

Simmons A.,SACRBMKPML&SB. Nutrition and Physical Activity in Children and Adolescents. Barwon-South Western Region. Sentinel Site Series. Report 6: Lessons learned from Colac's Be Active Eat Well project (2002-6). 2008. Victoria, Department of Human Services.

Stolley MR, Fitzgibbon ML, Dyer A, Van Horn L, KauferChristoffel K, and Schiffer L. (2003) Hip-Hop to Health Jr., an obesity prevention program for minority preschool children: Baseline characteristics of participants. Preventive Medicine 36:320-329.

Summerbell CD, Waters E, Edmunds LD, Kelly S, Brown T, and Campbell KJ. (2005) Interventions for preventing obesity in children. Cochrane database of systematic reviews (Online) -:CD001871.

Swinburn B and McLennan J. (1998) The green prescription: A novel way of increasing uptake of physical activity. New Zealand Public Health Report 5:1-2.

Swinburn BA, Walter LG, Arroll B, Tilyard MW, and Russell DG. (1997) Green prescriptions: Attitudes and perceptions of general practitioners towards prescribing exercise. British Journal of General Practice 47:567-569.

Swinburn BA, Walter LG, Arroll B, Tilyard MW, and Russell DG. (1998) The green prescription study: A randomized controlled trial of written exercise advice provided by general practitioners. American Journal of Public Health 88:288-291.

Taylor RW, McAuley KA, Williams SM, Barbezat W, Nielsen G, and Mann JI. (2006) Reducing weight gain in children through enhancing physical activity and nutrition: the APPLE project. Int J Pediatr Obes 1:146-152.

Taylor RW, McAuley KA, Barbezat W, Strong A, Williams SM, and Mann JI. (2007) APPLE Project: 2-y findings of a community-based obesity prevention program in primary school-age children. American Journal of Clinical Nutrition 86:735-742.

Taylor RW, McAuley KA, Barbezat W, Farmer VL, Williams SM, and Mann JI. (2008) Two-year follow-up of an obesity prevention initiative in children: The APPLE project. American Journal of Clinical Nutrition 88:1371-1377.

The Women's Health Initiative Study Group. (1998) Design of the Women's Health Initiative clinical trial and observational study. The Women's Health Initiative Study Group. Controlled Clinical Trials 19:61-109.

Webber LS, Osganian SK, Feldman HA, Wu M, McKenzie TL, Nichaman M, Lytle LA, Edmundson E, Cutler J, Nader PR, and Luepker RV. (1996) Cardiovascular risk factors among children after a 2 1/2-year intervention-The CATCH Study. Preventive Medicine 25:432-441.

Williden M, Taylor RW, McAuley KA, Simpson JC, Oakley M, and Mann JI. (2006) The APPLE project: An investigation of the barriers and promoters of healthy eating and physical activity in New Zealand children aged 5-12 years. Health Education Journal 65:135-148.

World Health Organisation. Obesity: preventing and managing the global epidemic. Report of a WHO Consultation. 2000. Geneva: World Health Organization. WHO Technical Report Series 894.

Zucker DM, Lakatos E, Webber LS, Murray DM, McKinlay SM, Feldman HA, Kelder SH, and Nader PR. (1995) Statistical design of the Child and Adolescent Trial for Cardiovascular Health (CATCH): implications of cluster randomization. Controlled Clinical Trials 16:96-118

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APPENDIX 1: SCOPING PROTOCOL

BACKGROUND

PURPOSE OF THIS DOCUMENT

The purpose of this research is to provide evidence to assist decision making and cost-effective investment in population-based public health interventions designed to prevent obesity and obesity-related health problems in New Zealand. This research will involve systematic literature reviews, data collection and analysis, and health-economic modelling, with the aim being to rank up to 10 selected intervention scenarios in terms of their cost-effectiveness. The findings of this research will inform policy makers about the relative merits of different investments, with a view to reducing the prevalence of a range of chronic health problems including diabetes, arthritis, cancer and obesity. This in turn will result in improved quality of life for New Zealanders and better value for money in health-care expenditure in New Zealand. The research has been commissioned by the Health Research Council (HRC) of New Zealand.

The Health Services Research Centre (HSRC) at Victoria University of Wellington has been contracted to undertake this research in conjunction with Health Technology Analysts (HTanalysts) and the University of Canterbury. The research, including the initial scoping search, full systematic review of up to 15 selected interventions and economic evaluation of up to 10 scenarios, will be conducted by a research team which is comprised of experts in a number of different fields. The members of the research team include Dr Jacqueline Cumming (Principal Investigator), Dr Lynne Pere and Dr Ausaga Fa'asalele from the HRSC, Dr Terri Green from the Department of Management at the University of Canterbury, Dr Adele Weston, Mr Paul Mernagh and Dr Kristina Coleman from HTanalysts and Ms Kirsten McLachlan from the Department of Community and Public Health at the Canterbury District Health Board.

This Scoping Protocol has been prepared for the consideration of the Stakeholder Reference Group (SRG). The primary aims of the Scoping Protocol are (i) to outline the processes that will be used for this evaluation, (ii) to present the results of the initial scoping search to aid in the selection of up to 15 obesity-prevention interventions that will undergo full-systematic review; (iii) to present a summary of the results of the full systematic review to aid in the selection of up to 10 scenarios which will undergo cost-effectiveness analysis; and (iii) to confirm the methodology to be used in the systematic review and economic analysis.

This *initial* version of the Scoping Protocol will focus on the scoping search and the identification of the selected obesity-prevention interventions to undergo systematic review and cost-effectiveness analysis. Subsequent versions will focus of the systematic review and economic analysis methodology. **Thus, in this initial version of the Scoping Protocol Section 1 (scoping search) is complete; Section 2 (systematic review) and Section 3 (cost-effectiveness analysis) will be completed in subsequent versions.**

CLINICAL NEED FOR THE RESEARCH

Obesity

Obesity and overweight constitute a significant, and increasing, public health issue in New Zealand (NZ). Premature mortality, morbidity, and poorer quality of life are all associated with higher body mass index (BMI). In the past two decades the average level of obesity in OECD countries has risen 8 percent (Bleich *et al.* 2008), with considerable variation among countries. New Zealand compares poorly, with an increase of more than 100% in obesity prevalence between 1977 and 2003 (MOH 2004).

Currently NZ is ranked in the top five OECD countries for adult obesity (OECD 2006). Between 1977 and 2003, prevalence increased from 11% to 22% among females and from 9% to 20% among males, which gives an average annual percent change of approximately 3% for both genders (MOH 2004). Recent data show that about one in four (27%) adults meet the criterion for obesity (BMI>30), with a further 36% being classified as overweight (MOH 2008). Māori and Pacific men and women are more likely than the general population to be classified as obese, as are those, particularly women, living in areas of highest neighbourhood deprivation (MOH 2008).

While there was no increase in childhood obesity from 2002 to 2007, the reported rate of 8-10% for young males and females remains a significant concern, particularly given that early onset of obesity is associated with increased likelihood of obesity in later life and an increased prevalence of obesity-related disorders (Summerbell *et al.* 2005; Kopelman 2000). The ethnic disparities seen in adults are also apparent among children, with Māori boys and girls being 1.5 times more likely to be obese than those in the total population, and Pacific girls and boys 2.5 times more likely (MOH 2008). More concerning still, in a representative sample of NZ school children, Goulding *et al.* (2007) reported a 2.7% prevalence of extreme obesity, with considerable ethnic differences: 0.8% among New Zealand European; 5.1% among Māori; and 10.9% among Pacific children.

Population-based prevention strategies

Existing reviews of the obesity prevention literature have reported mixed results from a diverse range of studies. Doak *et al.* (2005), reviewing 25 school-based interventions, reported that 65% (17 of 25) of the interventions reviewed were effective based on a statistically significant reduction in BMI or measurement of skin-folds. Four of the studies reviewed were reported to be effective based on both of these measures. The studies reviewed typically involved mixed interventions including diet and activity components (and in three cases emphasis on reduced television viewing). Gender differences in effectiveness were evident in some studies but with no consistency of direction. One effective study involved the simple provision of a clear message to reduce consumption of carbonated beverages, and increase fruit intake and consumption of water (James *et al.* 2004).

Another review conducted by The Cochrane Collaboration examined interventions for preventing obesity in children (Summerbell *et al.* 2005). Twenty-two studies were included; 10 long-term (at least 12 months) and 12 short-term (12 weeks to 12 months). Nineteen were school-based interventions, one was a community-based intervention targeting low-income families, and two were family-based interventions targeting non-obese children of obese or overweight parents. Six of the 10 long-term studies combined dietary education and physical activity interventions; five resulted in no difference in overweight status between groups and one resulted in improvements for girls receiving the intervention, but not boys. Two studies focused on physical activity alone. Of these, a multi-media approach appeared to be effective in preventing obesity. Two studies focused on nutrition education alone, but neither was effective in preventing obesity. Four of the twelve short-term studies focused on interventions to increase physical activity levels, and two of these studies resulted in minor reductions in overweight status in favour of the intervention. The other eight studies combined advice on diet and physical activity, but none had a significant impact.

To date it is unclear which specific aspects of particular intervention programmes (e.g. various approaches to reducing intake of energy-dense foods: school-based programmes, television or other social marketing campaigns; promotion of increased physical activity through structured programmes, environmental change (cycle ways), or education) are the most effective and cost-effective in obesity prevention. A better understanding of the effectiveness and cost-effectiveness of intervention approaches will allow evidence-based decision making on the most efficient allocation of heath resources to reduce unhealthy weight gain in New Zealand

SUMMARY OF THE REVIEW PROCESS

This research will be conducted in a number of stages as follows:

1. Scoping search
   The scoping search will be a wide ranging search designed to identify a large number of population-based obesity-prevention interventions. The identified obesity-prevention interventions will then be summarised so that the HRC and stakeholder reference group can select up to 15 interventions to undergo full systematic review of effectiveness.

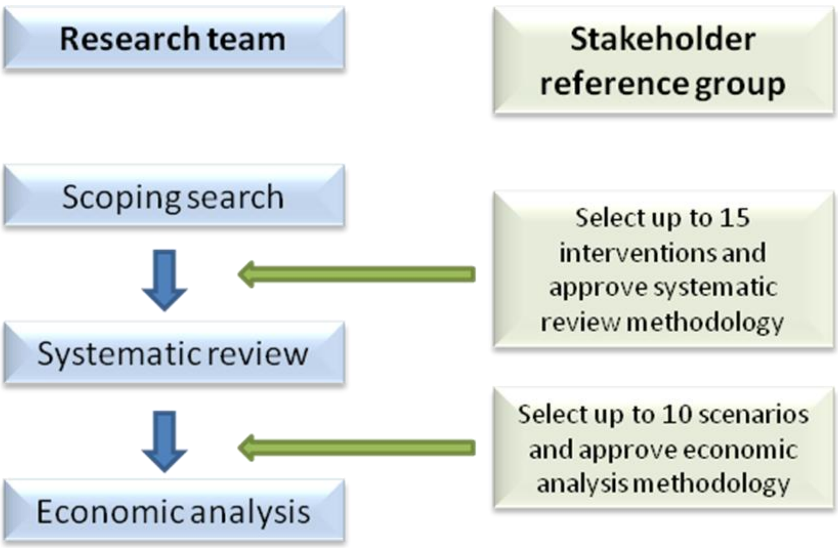
2. Systematic review

The systematic review of the 15 selected obesity-prevention interventions will involve the following steps: (i) a comprehensive search of the literature for evidence of the effectiveness of the selected obesity-prevention interventions; (ii) identification of all relevant evidence; (iii) assessment of the quality of the identified evidence; and (iv) assessment of the results of the identified evidence for each of the selected interventions. Based on this evidence, the HRC and stakeholder reference group can select up to 10 obesity-prevention scenarios to undergo cost-effectiveness analysis.

3. <u>Cost-effectiveness analysis</u>
   The cost-effectiveness analysis of up to 10 selected obesity-prevention scenarios will follow the systematic review stage. It should be noted that each scenario will comprise a single intervention, a single comparator and a single population. Therefore, if the same intervention was assessed in two different priority population groups with different baseline risk or intervention efficacy results, this would equate to two different scenarios, producing two different cost-effectiveness results.

   Progression to each of the stages of the research will require sign-off by the SRG as outlined in **Figure 21**.

Figure 21 **Stages of the research and required sign-off by the SRG**



1 SCOPING SEARCH

1.1 OBJECTIVE

The objective of the scoping search was to identify a large number of population-based obesity-prevention interventions. The identified obesity-prevention interventions will then be summarised so that the HRC and stakeholder reference group can select up to 15 interventions to undergo full systematic review of effectiveness.

It should be noted that the list of studies presented here is not exhaustive, but represents those studies identified via the literature search which are considered most likely to be potentially beneficial in the prevention of obesity. **SRG members are invited to suggest other programmes if they feel they may also be appropriate.**

1.2 METHODS

1.2.1 Research question

The research question to be answered for this stage of the review was the following: what public-health prevention interventions are available for the prevention of obesity? To identify studies relevant to this question, the population was not limited (ie, prevention strategies aimed at both children and adults were included) and any prevention interventions were included as long as they were aimed at the wider population level and not at the individual level. In addition, interventions had to be aimed at the *prevention of obesity* and not the *treatment of obesity in already obese patients*. Thus, the PICO criteria related to this clinical question were as follows:

- Population: General (not specifically overweight or obese)
- Intervention: Any intervention aimed at prevention of weight gain at the population level (not interventions aimed specifically at treating obesity by decreasing weight).
- Comparator: Any (not restricted to any particular comparator)
- Outcome: body mass index (BMI), weight, incidence of overweight or obese.

1.2.2 Literature search

A literature search encompassing both published and unpublished evidence was conducted. The search for published evidence was conducted using literature databases, while an internet search for published and unpublished evidence was also conducted. Finally, the reference lists of relevant studies were hand searched for additional relevant evidence. It should be noted that this was an iterative search process, with the initial database search leading to additional database, internet and reference list searches.

1.2.2.1 Database search

The search for published literature was conducted using the EMBASE and Medline databases (via EMBASE.com) and the Cochrane Library. The search terms and results of the searches are shown in **Table 156**. The results of the EMBASE.com and Cochrane Library searches were downloaded into a Reference Manager (RefMan) database. A total of 790 non-duplicate citations were identified. The results of this literature search were examined and all relevant systematic reviews and original studies were identified.

Table 156 Database search strategy and results (obesity search)

Database (date searched)	No.	Search terms	Results
EMBASE.com[a] 20 July 2009	1	Obesity:ti	35,780
	2	'prevention':ti,ab OR 'preventive':ti,ab OR 'preventative':ti,ab OR 'prevent':ti,ab	536,596
	3	'population based' OR ('public health'/exp OR 'public health')	367,044
	4	#1 AND #2 AND #3	721
	5	#4 AND [english]/lim AND [humans]/lim	611
Cochrane Library[b] 20 July 2009	#1	(obesity):ti AND (prevent*):ti,ab,kw	214

[a] EMBASE.com searches both the EMBASE and Medline databases.
[b] The Cochrane Library searches the Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Cochrane Central Register of Controlled Trials, Cochrane Methodology Register, Health Technology Assessment Database, NHS Economic Evaluation Database and Cochrane Groups.

The database and internet obesity search (**Table 156**) identified 18 systematic reviews which assessed programmes aimed at preventing obesity. A summary of these reviews is provided in **Table 157**. Of the identified reviews, the majority assessed prevention strategies in children and adolescent, while two assessed programmes in younger children (Saunders et al, 2007; Small et al, 2007) and one included an assessment of programmes in adults (SBU, 2005). All relevant studies included in the identified systematic reviews that had not been identified via the literature search were entered into the RefMan database.

Table 157 Summary of identified systematic reviews

Citation	Population	Outcomes[a]	No. included studies
Kamath 2008	Children and adolescents	Indices of overweight and obesity Other	29
Lemmens 2008	Adults	BMI of body weight	9
Katz 2008	Children and adolescents	Indices of overweight and obesity	21
Klesges 2008	Children and adolescents	Indices of overweight and obesity Other	19
Connelly 2007	Children and adolescents	Indices of overweight and obesity	28
DeMattia 2007	Children and adolescents	Indices of overweight and obesity	12
Saunders 2007	Pre-school children aged < 5	Indices of overweight and obesity Other	6
Small 2007	Young children aged 4-7	Indices of overweight and obesity Other	6
Budd 2006	Children and adolescents	Indices of overweight and obesity Other	12
Doak 2006	Children and adolescents	Indices of overweight and obesity	25
Flynn 2006	Children and adolescents	Indices of overweight and obesity Adverse effects	147
Stice 2006	Children and adolescents	Indices of overweight and obesity Other	46
Ng 2005	Children and adolescents	Indices of overweight and obesity Other	21
Summerbell 2005	Children and adolescents	Indices of overweight and obesity Other	21
Swedish Council on Technology Assessment in Health Care (SBU) 2005	Children, adolescents and adults	Indices of overweight and obesity Other	70
Bautista-Castano 2004	Children and adolescents	Indices of overweight and obesity	14
Clemmens 2004	Girls aged 12-19	Indices of overweight and obesity Other	7
Thomas 2004/2006	Children and adolescents	Indices of overweight and obesity Other	365

Note: Systematic reviews shown in shading will form the basis of the identification of obesity prevention programmes relevant to this project.
[a] Outcomes relevant to this current review. Indices of overweight or obesity include BMI, proportion overweight or obese, % body fat etc.

It should be noted that the scoping literature search aimed to identify programmes specifically targeted to preventing obesity. However, programmes targeted at other issues (eg, improving overall health and fitness, preventing diabetes, preventing cardiovascular disease) could also impact on obesity. A search of the reference lists of identified systematic reviews was also undertaken to identify these additional studies not identified via the database and internet searches.

The majority of studies identified via the systematic reviews were not found during the initial literature search because they were not specifically targeted at preventing obesity, and were instead targeted at other outcomes such as improving physical fitness or cardiovascular health. However, as many of these studies included an outcome measure relevant to obesity prevention, they were also considered relevant to this project. Therefore, an additional database search was designed to identify these types of studies published subsequent to those identified via the systematic reviews. The systematic review by Flynn et al (2006) provides the most recent and comprehensive data on prevention of obesity in children and adolescents, while the systematic review conducted by the Swedish Council on Technology Assessment in Healthcare (SBU, 2005) is the only systematic review which assessed obesity prevention programmes in adults. Thus, the additional literature search was conducted from 2003 onwards.

Table 158 Database search strategy and results (additional search)

Database (date searched)	No.	Search terms	Results
EMBASE.com[a] 2 September 2009	1	'obesity'/exp AND ('prevention':ab,ti OR 'preventive':ab,ti OR 'preventative':ab,ti OR 'prevent':ab,ti) AND ('population based' OR 'public health'/exp OR 'public health') AND (bmi:ab OR 'body mass index':ab OR weight:ab OR anthropomorphic:ab) AND [english]/lim AND [humans]/lim AND [2003-2010]/py	916

[a] EMBASE.com searches both the EMBASE and Medline databases.

In total, 1914 non-duplicate citations were included in the RefMan database.

1.2.2.2 Internet search

In addition, a search of government and non-government health websites in Australia and New Zealand was conducted to identify potentially unpublished public health obesity programmes. Many of these appear to be ongoing and therefore have not been formally evaluated.

In particular, a database of nutrition and physical activity programmes and providers was identified for New Zealand through the Agencies for Nutrition Action (ANA) website (www.ana.org.nz/napad.php). While this has not been updated since July 2009 due to lack of funding, it appears to include all programmes and providers in New Zealand.

1.2.3 Inclusion/exclusion criteria

Citations were eligible for inclusion in the list of potentially relevant public health interventions for obesity prevention is they met the following inclusion criteria:

1. The intervention was related to the prevention of obesity (not treatment)

2. The intervention was applied at the population level (not at the individual level)

It should be noted that the purpose of the scoping search was to identify as many different types of obesity-prevention interventions as possible, in order to identify those that may subsequently undergo formal systematic review. Thus, the studies identified by this scoping search may not meet all of the inclusion criteria which will be used for the full systematic review.

If a citation was identified which was considered to be potentially relevant to this research, the main characteristics of the intervention/study were extracted and tabulated. Relevant information extracted from each citation included name of the programme, description of the intervention, study type, type of population, population number, duration, setting, whether it had been evaluated, and if so, the comparator and outcomes assessed.

As priority will be given to interventions already implemented or under development in NZ, and those that address the particular needs of NZ priority populations, emphasis was placed on identifying NZ-based interventions. Interventions were tabulated by country/region as follows: NZ, Australia, US and UK, Europe and other locations. In addition, priority was given to interventions which have been assessed using the highest levels of evidence. Therefore, a tentative level of evidence for each intervention was applied using the NHMRC criteria and interventions have been ordered according to that level of evidence.

1.3 RESULTS

The following tables provide a summary of the main characteristics of identified studies which outlined and/or assessed public health intervention to prevent obesity. Each of the interventions has been classified based on the description of the intervention into four categories: activity, advertising, education or nutrition. Interventions that specifically related to physical activity or nutrition (eg, exercise programmes or changes to availability of foods at school canteen) were classified as Activity and Nutrition, respectively. Interventions in which education was provided regarding increasing psychical activity or improving diet were classified as Education (activity) or Education (nutrition), respectively. Many interventions included a combination of different types of intervention (eg, Activity/Nutrition or Activity/Education (nutrition). Each of the studies has also been classified according to their location into the following categories: New Zealand, Australia, US/Canada and UK/Europe/other. We have only included interventions assessed in the US/Canada and UK/Europe/other if they are (i) ≥ 1 year duration, (ii) provide an outcome measure relevant to obesity prevention (including BMI, weight, % body fat, skin fold and incidence of obesity or overweight) and (iii) have been evaluated. We have been more inclusive for interventions assessed in New Zealand and Australia, and the tables for these locations show interventions that may not yet have been evaluated.

For each intervention identified, it has been noted whether each of three criteria have been met (✓). The three criteria are: (1) is the study duration ≥ 1 year; (2) does the study include a relevant outcome; and (3) has the intervention been shown to be effective using this outcome?

Interventions for which all three criteria have been met are considered to be those which should receive further consideration for inclusion in the systematic review of this project. These interventions are shaded. New interventions identified since the original version of the scoping protocol was circulated have been included in the tables and highlighted.

The majority of identified studies related to pre-school, school and workplace interventions designed either specifically to reduce overweight or obesity, or to achieve other outcomes including improved physical fitness or reduced cardiovascular risk. Only one intervention study relating to breastfeeding and obesity was identified. However, the scoping literature search identified a number of studies on the correlation between breastfeeding and obesity. Two large cross sectional correlation studies conducted in the US and four similarly designed studies were identified from the UK/Europe/other. Ultimately these were excluded because they did not meet the eligibility criteria (i.e. they were cross-sectional correlation studies rather than intervention studies) but they are described briefly here. The results of these studies varied substantially. One study from the US found that the duration of breastfeeding showed a dose-response, protective relationship with the risk of overweight only among non-Hispanic whites (Grummer-Strawn *et al* 2004). Another concluded that having been breastfed was not associated with women's likelihood of becoming overweight or obese throughout life course (Michels *et al* 2007).

Study results from the UK and Europe were also mixed. One study conducted in Scotland found the prevalence of obesity was significantly lower in breastfed children (Armstrong 2002). Another large correlation study conducted in Holland found that compared with non-breastfed children, children breastfed for >16 weeks had a lower BMI at 1 year of age. However, the association between breastfeeding and BMI between 1 and 7 years of age was negligible.

One large RCT was identified that assessed whether an intervention designed to promote exclusive and prolonged breast-feeding affected children’s height, weight, adiposity, and blood pressure at age 6.5 years. No significant intervention effects were observed on height, BMI, adiposity measures, or blood pressure. The breast-feeding promotion intervention resulted in substantial increases in the duration and exclusivity of breast-feeding yet did not reduce measures of adiposity at age 6.5 years (Kramer *et al* 2009).

Citation and abstracts for most of the identified publications can be found in **Appendix 2**.

1.3.1.1 New Zealand

The majority of primary prevention obesity intervention programmes identified in New Zealand were found through a grey literature search. Unfortunately, many of these interventions do not appear to have been evaluated or have been evaluated for outcomes that are not related to weight. As shown in **Table 159**, of the 22 interventions identified, only four have been formally evaluated for relevant outcomes. These include a cluster randomised controlled trial (RCT) assessing Green Prescriptions (NHMRC Level II evidence), a non-randomised controlled trial assessing APPLE (A Pilot Programme for Lifestyle and Exercise) and a non-randomised workplace intervention for men. Each of the three evaluated programs included a proportion of Māori and Pacific Islander participants. The remaining evaluated intervention (Let's beat Diabetes – Community Nutrition Project) showed a significant benefit in terms of BMI but was only of 6 months duration.

Table 159 Population-based obesity prevention programs in New Zealand

Number	Name of program *Citation*	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated for a weight-related outcome [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
NHMRC Level II evidence														
1	Green prescription (GRx) *Lawton 2008*	Cluster RCT	2 years	General practice	Women aged 40-74 (including ~ 13% Māori and Pacific Islander women)	1089	**Activity** A health professionals written advice to a patient to be physically active, as part of patient health management.	Yes	Physical activity, QoL, weight, waist circumference, cardiovascular risk factors	Increased activity and QoL but no change in clinical outcomes	✓	✓		
2	Green prescription (GRx) *Elley 2003*	Cluster RCT	1 year	General practice	40–79 year olds (assumed to be ~25% Māori and Pacific Islander participants)	878	**Activity** A health professionals written advice to a patient to be physically active, as part of patient health management.	No	Change in total expenditure of energy and leisure time expenditure of energy, cardiovascular risk and quality of life.	Increase in total energy expenditure in intervention group.	✓			
NHMRC Level III-I evidence														
3	A Pilot Programme for Lifestyle and Exercise (APPLE) *Taylor 2007*	Non-randomised controlled trial	2 years	School and community	5–12 year olds (15% Māori and < 1% Pacific Islander)	730	**Activity/Education** Intervention components included nutrition education that targeted reductions in sweetened drinks and increased fruit and vegetable intake and activity coordinators who managed an activity program that focused on noncurricular lifestyle-based activities (eg, community walks).	Yes	BMI, waist circumference, blood pressure	BMI z-score reduced in normal-weight but not overweight intervention children relative to controls	✓	✓	✓	✓
4	Project Energize	Controlled, comparative trial	2 years	Schools	School children (% Māori and Pacific Islander unknown)	-	**Education** The project aims to improve activity and nutrition in children. The two-year programme involves 130 schools – 65 will have an intensive programme of healthy lifestyles support and coaching, compared with 65 in the control group.	No	-	-				

Number	**Name of program** *Citation*	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated for a weight-related outcome [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
5	Health promotion programme *Cook 2001*	Non-randomised controlled trial	1 year	Workplace	Male workers (including 21% Māori and 43% Pacific Islander)	253	**Education (nutrition/activity)** Nutritional displays in the cafeteria and monthly 30 minute workshops for 6 months	Yes	BMI, self reported diet and exercise	Reduced fat intake, increased vegetable intake and PA, improved nutrition knowledge and reduced systolic BP. No difference in change in mean BMI or waist circumference.	✓	✓		
6	Fruit in Schools	Non-randomised controlled trial	-	High deprivation schools	School children (% Māori and Pacific Islander unknown)	2000	**Nutrition** The Ministry has established a 'Fruit in Schools' (FIS) programme that is offered to high-needs primary schools that are prepared to commit to being sun smart and smoke-free and promoting both increased physical activity and healthy food.	No	Children eating fruit	Early results of pilot study showed 66% ate fruit every day and 20% eating fruit 3-4 times a week				

Number	Name of program *Citation*	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated for a weight-related outcome [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
NHMRC Level IV evidence														
7	Green Prescription Active Families Program	Uncontrolled intervention	Up to 12 months	Community	Children aged 5-18 with a BMI > 25 and their families (including 47% Māori families and 17% Pacific Islander families)	90	**Activity** A health professionals written advice to a patient to be physically active, as part of patient health management.	Yes	Changes in health and fitness, increased exercise in children and household	93% of respondents to survey said they had noticed changes in child's health or fitness	✓			
8	Active Schools	Uncontrolled intervention	Ongoing	Schools	School children (% Māori and Pacific Islander unknown)	-	**Education** Active schools toolkit provided to encourage teachers to include more physical activity across the curriculum. A series of resources provided in Phase 1. Phase 2 active schools facilitators. Phase 3- active mark.	No	-	-				
9	The Mangere Healthy Kai Programme	Uncontrolled intervention	-	Community	General (% Māori and Pacific Islander unknown)	-	**Nutrition** Increase the availability and consumption of healthy food choices through retailers selling ready to eat healthy food, point of purchase advertising.	No	Awareness of programme and food sales	Moderate effects on encouraging customers to make healthy choices				
10	Fuelled for School	Uncontrolled intervention	-	High School	High school students (% Māori and Pacific Islander unknown)	-	**Education/Activity/Nutrition** Pilot program to allow students to become actively involved in learning about nutrition and promoting healthy food options	No	Students asked if they considered the program was effective	> 70% of students considered it to be fairly successful and ~ 14% considered it to be very successful				

Number	Name of program *Citation*	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated for a weight-related outcome [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
11	Let's Beat Diabetes	Uncontrolled intervention	-	Community	Diabetics and general population (% Māori and Pacific Islander unknown)	-	**Education/Activity/Nutrition** A range of interventions are proposed in order to prevent diabetes. PA and nutrition changes and activities.	No	Changes in attitudes, diet	-				
12	**New entry** Let's Beat Diabetes (Swap2Win)	Uncontrolled intervention	-	Community	As above	-	**Social marketing campaign**	No	Recall of campaign	-				
13	**New entry** Let's Beat Diabetes (McDonalds Low Sugar Drinks)	Uncontrolled intervention	-	Community	As above	-	**Nutrition** Sprite replaced with Sprite Zero at 21 McDonalds restaurants	No	Awareness of trial, consumer reaction and impact on sales	-				
14	**New entry** Let's Beat Diabetes (Community Nutrition Project)	Uncontrolled intervention	6 months	Primary care	Overweight	-	**Education (Nutrition/Activity)** 6 education sessions	Yes	Weight, BMI, others	Statistically significant change in BMI of ~ 1 (p=0.008)	✓	✓	✓	
15	**New entry** Let's Beat Diabetes (Fresh for Less)	Uncontrolled intervention	-	Primary care	Overweight	-	**Environmental** Education, promotions and price reductions for featured fruit and vegetables	No	Sales	-				
16	Push Play * Report due Nov/Dec 2009	Uncontrolled intervention	-	Population	Adult New Zealanders (% Māori and Pacific Islander unknown)	-	**Media** Television commercials	Yes	Awareness of campaign, intention/behaviour change	Campaign increased awareness and intention to become physically active. No sustained changes in physical activity				

Number	Name of program *Citation*	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated for a weight-related outcome [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
17	**New entry** Vibrant Living Project	Uncontrolled intervention	9 weeks	Community	Low income families	11	**Education** Positive parenting, healthy eating and practical cooking, healthy activity, growing a garden, relationship skills	No	Participant and facilitator feedback	-				
18	**New entry** Kitchen Garden Project	Uncontrolled intervention	5 years	School	General	-	**Education/Nutrition** Establishment and maintenance of a kitchen garden	No	Stakeholder interviews	-				
19	**New entry** HeaVen	Uncontrolled intervention	12 months	Workplace	Workforce	-	**Education** Development of Guidelines to improve nutritional quality of foods sold in vending machines	No	Interviews and sales	-				
20	**New entry** Grab a bite that's right	Uncontrolled intervention	12 months	Community/schools	General	-	**Activity/Nutrition/Education** Support community and schools to develop physical and nutritional programmes	No	Interviews	-				
21	**New entry** Mission-On (Upball campaign)	Uncontrolled intervention	-	School	5-12 years olds with > 2 hours screen time per day (focus on Māori and Pacific Islander children)	-	**Activity** Ball and game book aimed at encouraging health activity alternatives to computer use and TV viewing	No	Uptake, behaviour change	-				
22	**New entry** Mission-On (Weird World of Sports campaign)	Uncontrolled intervention	-	Community	18-24 year olds	-	**Social Marketing** Nine week campaign which invited participants to invent a new sport.	No	Awareness and participation	-				

Abbreviations: 1 = is the intervention ≥ 1 year duration?; 2 = does the study assess a relevant outcome (ie, BMI, weight, % body fat, incidence overweight or obese?; 3 = has the intervention been shown to be effective using one of the relevant outcomes?; BM = behaviour modification; BMI = body mass index; BP = blood pressure; FMS = fundamental movement skills; POS = point of sale; RCT = randomised controlled trial; SF = skin fold; SR? = should the study be considered for further systematic review?; PWC = physical work capacity.

[a] In order to be classified as 'Yes' for the evaluation criterion, the program had to have undergone formal evaluation using an objective measure of weight, not just evaluated with a questionnaire of attitude or behaviour change.

1.3.1.2 Australia

There were 16 primary prevention interventions identified from Australia. One study (Active Nutrition Script) was excluded because it was a targeted intervention for overweight individuals attending general practice clinics and therefore was not considered primary prevention (Booth 2006). The 15 included studies consisted of four RCTs or clustered RCTs, two of which (Switch-Play and Daily Physical Activity Programme), met all three criteria that would deem them strong candidates for systematic review. In the Physical Activity and Nutrition Programme for couples, the difference in BMI at follow-up between the intervention and control groups was not significant. Although the HELP-her mother study was deemed effective, participants had only been followed-up for 4 months.

There was also two programmes identified as NHMRC Level III-3 and nine primary prevention programmes identified as NHMRC Level IV evidence. Similar to programmes found for New Zealand, these programmes were generally large scale public health interventions that appeared to lack evidence of evaluation. The majority were school-based interventions. One of the Level III-3 interventions (Be Active Eat Well) was shown to be beneficial in terms of a number of weight-related outcomes.

Table 160 Population-based obesity prevention programs in Australia

Number	Name of program	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
NHMRC Level II evidence														
1	Switch-Play *Salmon 2008*	Cluster RCT	1 year	School	Children, low SES, Mean: 10 years 8 months	311	**Activity/Behaviour modification** Four groups: behavioural modification group, fundamental movement skills group, a combined BM/FMS group and control.	Yes	BMI	Yes, significant reduction in age and sex-adjusted BMI in intervention group at 6 and 12 months.	✓	✓	✓	✓
2	Daily physical activity program *Dwyer 1983*	Cluster RCT	2 years	School	Children, 10 years old	216	**Activity** Endurance fitness program for 1.25 hours per day.	Yes	SF, physical work capacity, body fat	Yes, smaller SF and greater PWC, with lower BP reaching significance for boys.	✓	✓	✓	✓
3	Physical activity and nutrition programme for couples *Burke 2003*	RCT	1 year	Community	Adult couples	137	**Education (activity/nutrition)** Six modules, after an initial group session mailed to low intervention group, in high intervention, half were mailed and half delivered through interactive sessions	Yes	BMI	At follow-up, BMI increased in all groups with a trend to a smaller increase in the high-level group, but these differences were not significant (P=.28).	✓	✓		
4	HELP-her *Lombard 2009*	Cluster RCT	4 months	Community	Mothers with young children	250	**Education (activity/nutrition)** Intervention group received four interactive group sessions over 4 months, comparator received one session non-interactive.	Yes	Mean weight	Mean measured weight decreased significantly in the intervention group (-0.78 kg 95% CI; -1.22 to -0.34, p < 0.001). More women lost or maintained weight in the intervention group.		✓	✓	
NHMRC Level III-3 evidence														

5	**New entry** Nutrition and physical activity in children and adolescents (Romp and Chomp) *Mathews et al (2008) - Report*	Historical controlled trial	2 years	Community	Pre-school children	~12,000	**Nutrition/Activity/Behaviour modification** Decrease high sugar drinks and promote water and milk, decrease energy dense snacks and increase fruit and vegetables, increase active play and decrease TV viewing	Yes but not in this report	Prevalence of overweight and obese	?				
6	**New entry** Nutrition and physical activity in children and adolescents (Be Active Eat Well) *Mathews et al (2008) - Report*	Historical controlled trial	2 years	Community	Children 4-12 and their families	~1000	**Nutrition/Activity/Behaviour modification** Decrease high sugar drinks and promote water and milk, decrease energy dense snacks and increase fruit and vegetables, increase active play and decrease TV viewing, increase the proportion who walk/cycle to school	Yes	BMI, z-BMI, weight, waist circumference	No significant difference in change in BMI, significant difference in changes in z-BMI (p=0.04), weight (p=0.03) and waist circumference (p=0.01)	✓	✓	✓	✓
NHMRC Level IV evidence														
7	Reduction in TV advertising	Cross-sectional	-	Media	Children ≤14 years	-	**Advertising** Alter regulatory framework to restrict advertising of fast food to children up to age 14	Unclear	-	-				
8	Kids - 'Go for your life'	Uncontrolled intervention	-	Primary school	Primary school children	-	**Education (activity/nutrition)** Encourages healthy eating and physical activity in children through primary schools and early childhood services through various promotional activities. 6 key health messages.	Unclear	-	-				
9	Go for 2 & 5	Uncontrolled intervention	-	Media/POS	General population	-	**Education (nutrition)** Encouraging increased fruit and veg consumption through various promotional activities	Unclear	-	-				
10	Find 30	Uncontrolled intervention	-	Media	General population	-	**Education (activity)** Encourages people to be sufficiently active for good health. 30 minutes of moderate-intensity physical activity on most days of the week.	Unclear	-	-				

11	Walking School Bus (WSB)	Uncontrolled intervention	-	School	School children	-	**Activity** Aims to increase the number of primary school children walking to school. Children are accompanied by 2 adult 'conductors' and travel a set route picking up kids.	No	-	-				
12	Travelsmart Schools (TSS)	Uncontrolled intervention	-	School	School children	-	**Education (activity)** Engage whole school community through meeting and info sessions about program. Classroom activities (20 hours over 4 weeks). Encourage active transport.	No	-	-				
13	Active after-school community program	Uncontrolled intervention	-	School	School children	-	**Activity** Implemented by the ASC, eight week after school sports program each term.	No	-	-				
14	'Get moving'	Uncontrolled intervention	-	Media	Children and parents	-	**Education (activity)** Advertising campaign promoting physical activity	No	-	-				
15	**New entry** Nutrition and physical activity in children and adolescents (It's Your Move) Mathews et al (2008) - Report	Uncontrolled intervention	3 years	Community	Adolescents aged 12-18	~3000	**Nutrition/Activity/Behaviour modification** Decrease high sugar drinks and promote water, increase the proportion of young people eating breakfast, increase fruit and vegetable consumption, increase the healthiness of school food	Yes but not in this report	BMI, z-BMI, % body fat					

Abbreviations: 1 = is the intervention ≥ 1 year duration?; 2 = does the study assess a relevant outcome (ie, BMI, weight, % body fat, incidence overweight or obese?; 3 = has the intervention been shown to be effective using one of the relevant outcomes?; BM = behaviour modification; BMI = body mass index; BP = blood pressure; FMS = fundamental movement skills; POS = point of sale; RCT = randomised controlled trial; SF = skin fold; SR? = should the study be considered for further systematic review?; PWC = physical work capacity.

[a] In order to be classified as 'Yes' for the evaluation criterion, the program had to have undergone formal evaluation using an objective measure of weight, not just evaluated with a questionnaire of attitude or behaviour change.

1.3.1.3 US and Canada

As mentioned previously, in order to qualify for inclusion, studies from the US and Canada must have been evaluated with follow-up greater than one year, using an objective measure of weight (e.g. BMI, weight, % body fat, skin fold and/or incidence of obesity or overweight). There were 29 publications from the scoping literature search that met these criteria. There was some overlap between studies with similarly named intervention programmes being applied in different sized populations, adapted interventions being administered in different locations, and the same program being evaluated over different follow-up periods.

There were 24 studies classified as NHMRC Level II evidence, two classified as NHMRC Level III-1 evidence, four classified as NHMRC Level III-2 evidence and one classified as NHMRC Level IV evidence. Of these, 14 studies were evaluated over a period greater than one year, used an objective measure of weight, and were considered to be effective. These have been highlighted in grey in **Table 161**.

Table 161 Population-based obesity prevention programs in US and Canada

Number	Name of program	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
NHMRC Level II evidence														
1	A policy-based school intervention to prevent overweight and obesity *Foster 2008*	Cluster RCT	2 years	School	Grade 4–6	1349	**Education (nutrition)/Nutrition** School self-assessment, nutrition education, nutrition policy (eg reduced priced health food), social marketing and parent outreach.	Yes	Incidence and prevalence of overweight and obesity, BMI	Yes, intervention resulted in a 50% reduction in the incidence of overweight. Significantly fewer children in the intervention schools (7.5%) than in the control schools (14.9%) became overweight after 2 years.	✓	✓	✓	✓
2	Planet Health/5-2-1 Go! *Gortmaker 1999*	Cluster RCT	18 months	School	Grade 6–8	1295	**Education (activity/lifestyle/nutrition)** Sessions focused on decreasing television viewing, decreasing consumption of high-fat foods, increasing fruit and vegetable intake, and increasing moderate and vigorous physical activity.	Yes	BMI, skin folds	Somewhat, the prevalence of obesity among girls in intervention schools was reduced compared with controls, with no differences found among boys. There was greater remission of obesity among intervention girls vs. control girls.	✓	✓		
3	Planet Health/5-2-1 Go! *Chavarro 2005*	Cluster RCT	2 years	School	Grade 6–8	508	**Education (activity/lifestyle/nutrition)** Sessions focused on decreasing television viewing, decreasing consumption of high-fat foods, increasing fruit and vegetable intake, and increasing moderate and vigorous physical activity.	Yes	BMI, skin folds	Yes, attending an intervention school was associated with lower increase in BMI (p = 0.003).	✓	✓	✓	✓

Number	Name of program	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
4	Pathways *Caballero 2003*	Cluster RCT	3 years	School	American Indian children grade 3–5	1704	**Activity/Education/Nutrition** I: Changed diet. Increased physical activity. Health education. Family involvement. C: Reference schools. 12 weeks/year including four components: classroom lectures. Support school kitchen staff. Exercise+recess activities+freetime. Family involvement	Yes	% body fat, BMI	The intervention resulted in no significant reduction in percentage body fat. However, a significant reduction in the percentage of energy from fat was observed in the intervention schools.	✓	✓		
5	SPARK (Sports, Play and Active Recreation for Kids) *Sallis 1993*	Cluster RCT	2 years	School	School children, mean age; 9.5 years	740	**Activity** Incorporating physical education and self-management into the school curriculum. Two intervention schools, led by either 1) certified physical education specialists or 2) classroom teachers evaluated against a control. Controls received usual PE curriculum.	Yes	BMI	No, there was a trend for the children exposed to the PE intervention to have lower levels of body fat, but the differences were not significant.	✓	✓		
6	SPARK (Sports, Play and Active Recreation for Kids) *Sallis 2003*	Cluster RCT	2 years	School	Age 11–14 years	1109	**Activity** Incorporating physical education and self-management into the school curriculum. Two intervention schools, led by either 1) certified physical education specialists or 2) classroom teachers evaluated against a control. Controls received usual PE curriculum.	Yes	BMI	The intervention was not effective for total fat (p <0.91) or saturated fat (p <0.79).	✓	✓		

Number	Name of program	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
7	CATCH *Leupker 1996*	Cluster RCT	3 years	School	3rd to 5th grade	5106	**Activity/Education/Nutrition** Diet and PA lessons, PA intervention, family involvement; school food service intervention	Yes	BMI, skin folds	Blood pressure, body size, and cholesterol measures did not differ significantly between treatment groups	✓	✓		
8	CATCH *Coleman 2005*	Cluster RCT	2 years	School	3rd grade	896	**Activity/Education/Nutrition** As above	Yes	BMI, skin folds	The rate of increase for overweight and obesity in the CATCH schools was significantly lower compared with the rate of increase for control schools.	✓	✓	✓	✓
9	CATCH *Nader 1999*	Cluster RCT	3 years	School	Grade 6, 7 and 8	3714	**Activity/Education/Nutrition** As above	Yes	BMI, cholesterol, BP	No significant differences were noted among BMI, BP, or serum lipid and cholesterol levels.	✓	✓		
10	CATCH *Webber 1996*	Cluster RCT	2 years	School	Grade 3 to 5	4019	**Activity/Education/Nutrition** As above	Yes	BMI	Overall, changes in obesity, BP, and serum lipids in the intervention group, compared with the control group, were not statistically significant.	✓	✓		

Number	Name of program	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
11	Know Your Body Program *Bush 1989*	Cluster RCT	1 year	School	African American school children	1041	**Activity/Education/Nutrition** 30-45 minute weekly health education curriculum; school food service intervention; Poster and essay contests, student aerobics, and special health lectures	Yes	BP, SF	Favourable changes in diastolic blood pressure and serum thiocyanate were observed at all re-examinations.	✓			
12	Know Your Body Program *Renicow 1992*	Cluster RCT	3 years	School	1st to 6th grades	1209	**Activity/Education/Nutrition** As above	Yes	BMI, cholesterol, BP	No significant difference in BMI.	✓	✓		
13	Medical College of Georgia Fit Kid Project *Yin 2005*	Cluster RCT	1 year	School	3rd grade children	1187	**Activity** 2-hour after school programme, 128 school days	Yes	BMI	Youths in the intervention group showed a relative reduction of % body fat, a greater relative gain in bone mineral density, and a greater relative reduction in heart rate response to the step test	✓	✓	✓	✓
14	Education to reduce soda drinking *Sichieri 2009*	Cluster RCT	1 year	School	9-12 years, 4th grade	1140	**Education (nutrition)** Educational programme aimed at discouraging students from drinking sugar-sweetened beverages	Yes	BMI	Non-significant overall reduction in BMI. Among those students overweight at baseline, the intervention group showed greater BMI reduction compared with the control group.	✓	✓	✓	✓

Number	Name of program	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
15	The Women's Health Initiative Dietary Modification Trial *Howard 2006*	RCT	7.5 years	Community	Postmenopausal women	48835	**Education** Group and individual sessions to promote reduced fat intake and increased fruit and vegetables, control received diet-related educational material.	Yes	Change in body weight	Yes, women in the intervention group lost weight in the first year (mean of 2.2 kg, P<.001) and maintained lower weight than control women during an average 7.5 years of follow-up.	✓	✓	✓	✓
16	Family based obesity prevention programme *Epstein 2001*	RCT	1 year	Family	Children 6 to 11 years	26	**Education (nutrition)** Families with obese parents and non-obese children were randomized to groups in which parents were provided a comprehensive behavioural weight-control program and were encouraged to increase fruit and vegetable intake. Comparison groups were encouraged to decrease intake of high fat/high sugar foods.	Yes	% overweight	Parents in the increased fruit and vegetable group showed significantly greater decreases in percentage of overweight than parents in the decreased high-fat/high-sugar group.	✓	✓	✓	✓
17	Obesity prevention program *Donnelly 1996*	RCT	2 years	School	3rd to 5th grade (8-11 years)	108	**Activity/Education/Nutrition** Nutrition education: grade-specific curriculum "Physical best" activity program: 3 weekly sessions 30-40 minutes, focused on individual, non-competitive activities; "Lunch Power!"	Yes	BMI, fitness test	No, body weight and body fat were not different between schools for normal weight or obese children.	✓	✓		
18	Hip Hop to Health Junior *Fitzgibbon 2005*	RCT	2 years	Preschool	Minority preschool children	Unknown	**Nutrition/Activity** Culturally proficient dietary and physical activity program.	Yes	BMI	Yes, intervention children had significantly smaller increases in BMI compared with control children.	✓	✓	✓	✓

Number	Name of program	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
19	Dietary intervention study in children (DISC) *Obarzanek 2001*	RCT	3 years	School	Children with elevated LDL cholesterol, 8-10 years	663	**Nutrition** Cholesterol lowering dietary intervention	Yes	BMI, cholesterol	No, there was no significant difference between groups at any time point	✓	✓		
20	Seminar based intervention program to prevent obesity [b] *Hivert 2007*	RCT	2 years	College	Young adults, mean age: 19.7 years	115	**Education (nutrition/activity)** Educational/behavioural intervention designed to help maintain a healthy lifestyle	Yes	BMI	Yes, statistically significant difference in mean BMI at 12 and 24 months.	✓	✓	✓	✓
21	Type 2 diabetes prevention program	RCT	1 year	School	High risk children, mean age: 12.6 years	41	**Education (nutrition/activity)** Nutrition education and exercise training, the experimental group also received coping skills training.	Yes	Glucose, insulin, BMI	No, no significant difference in BMI	✓	✓		
22	Weight gain prevention among women *Levine 2007*	RCT	3 years	Community	25-44 year old women	284	**Education (nutrition/behaviour)** A clinic based group, a correspondence course, or an information only control.	Yes	Body weight, height and BMI	There was a non-significant trend favouring the clinic intervention group.	✓	✓		
23	Women's healthy lifestyle project *Simkin-Silverman 2003/Kuller 2001*	RCT	4.5 years	Community	44 to 50 years	535	**Activity/Nutrition** Participants were randomly assigned to either a lifestyle intervention group receiving a 5-year behavioural dietary and physical activity program or assessment only control group	Yes	Weight, waist circumference, cholesterol	Yes, intervention group had significantly lower BMI, % body fat at follow-up	✓	✓	✓	✓
24	Two year educational program	RCT	2 years	Community	Premenopausal women	277	**Education (nutrition)** Participants were randomly assigned to treatment (six months of lectures and six months of personal contact) or control.	Yes	CVD risk factors, BMI	No, between group differences were not significantly different at any follow-up point.	✓	✓		

Number	Name of program	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
NHMRC Level III-I evidence														
25	Wise Mind Project *Williamson 2007*	Controlled trial/active control arm	2 years	School	Grade 2 to 6	670	**Education (activity/nutrition)** Intervention: Environmental approach- modification of eating habits and physical activity through education and improved cafeteria; Comparator: education on substance abuse	Yes	BMI	No significant differences between the groups in BMI. There were also no significant changes in secondary endpoints, including body fat percentage.	✓	✓		
26	Eat well and keep moving *Gortmaker 1999*	Quasi-experimental study, controlled	2 years	School	Grade 4 and 5 African American children	2103	**Education (nutrition/lifestyle)** Materials provided links to school food services and families and provided training and wellness programs for teachers and other members	No	Total energy use, fruit and vegetable intake	The percentages of total energy from fat and saturated fat were reduced among students in intervention compared with control schools.	✓			
NHMRC Level III-II evidence														
27	Shape up Somerville *Economos 2007*	Non-randomised controlled trial	1 year	Community	Mean age: 7.6 years (grade 1 to 3)	1178	**Education/Activity/Nutrition** Program designed to increase PA options and availability of health foods.	Yes	BMI	Yes, intervention decreased BMI z-score in children at high risk for obesity.	✓	✓	✓	✓
28	NASA Health Related Fitness Program *Wier 1989*	Non-randomised controlled trial	2 years	Workplace	NASA employees	258	**Activity** A 12-week educational component and quarterly fitness retests.	Yes	VO_2, body composition	Yes, changes in physical activity were related to program completion, % body fat, body weight.	✓	✓	✓	✓

Number	Name of program	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
29	**New entry** Obesity prevention program at Dow Chemical Company *Goetzel 2009*	Non-randomised controlled trial	1 year	Workplace	Dow employees	10,282	**Education/Activity/Nutrition** Individual intervention including health education material, leadership training, physical activity, weight management programs, reimbursement for participating	Yes	BMI	Yes for BMI but not for proportion at risk for overweight and obesity	✓	✓	✓	✓
30	**New entry** Education program for premenopausal women *Miller 2001*	Non-randomised controlled trial	2 years	Community?	Rural, premenopausal women	277	**Education** 6 monthly 45-50 minute sessions (topics covered not described but mostly likely nutritional) followed by 6 monthly personal or mail contacts	Yes	CVD risk (including BMI), dietary intakes	No difference in BMI, waist/hip ration or % body fat; significant difference in % calories from fat	✓	✓		
NHMRC Level IV evidence														
31	Obesity prevention for children from kindergarten to 8 *Gombosi 2007*	Uncontrolled intervention programme	5 years	School /Community / Family	Children aged 5-14 years	Unclear	**Education/Activity** School, family, community, and industry-based primary intervention- education, activities.	Yes	Incidence of overweight and obesity	Somewhat, although overweight and obesity incidence increasing over time.	✓	✓	✓	✓

Abbreviations: 1 = is the intervention ≥ 1 year duration?; 2 = does the study assess a relevant outcome (ie, BMI, weight, % body fat, incidence overweight or obese?; 3 = has the intervention been shown to be effective using one of the relevant outcomes?; BMI = body mass index; BP = blood pressure; NASA = national aeronautics and space administration; RCT = randomised controlled trial; SF = skin folds; SR? = should the study be considered for further systematic review?

[a] In order to be classified as 'Yes' for the evaluation criterion, the program had to have undergone formal evaluation using an objective measure of weight, not just evaluated with a questionnaire of attitude or behaviour change.

[b] Canadian study

1.3.1.4 UK/Europe/Other

There were approximately 50 primary prevention programme studies identified in the scoping literature search from the UK, Europe or elsewhere in the world. In order to narrow down the potential programmes for inclusion in the systematic review, the same eligibility criteria were applied as was the case for studies from the US and Canada (ie, have been evaluated with follow-up greater than one year, using an objective measure of weight). There were 27 studies which met these inclusion criteria, eight of which came from the UK.

There were 21 studies which were designed as RCTs or clustered RCTs. Of these, 11 studies were evaluated over a period greater than 1 year using an objective measure of weight and were considered to be effective. Two studies were semi-randomised or controlled comparative trials that examined how education programmes influenced weight. Both interventions were considered effective in terms of BMI. According to the NHMRC levels of evidence, two level III-2, one level III-3 and one level IV study were also identified.

Table 162 Population-based obesity prevention programs in the UK, Europe and other locations

Number	Name of program	Location	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
NHMRC Level II evidence															
1	APPLES-Reduce risk factors for obesity *Sahota 2001*	UK	Cluster RCT	1 year	School	7 to 11 years	636	**Activity/Education/ Nutrition** Teacher training, modification of school meals, and the development of school action plans targeting the curriculum, physical education, tuck shops, and playground activities.	Yes	BMI, diet, physical activity	No, there was no difference in body mass index, other psychological measures, or dieting behaviour between the groups.	✓	✓		
2	Christchurch obesity prevention programme (CHOPPS) *James 2004/James 2007*	UK	Cluster RCT	3 years	School	Children aged 7 to 11 years	644	**Education (nutrition)** Various education and games associated with reducing carbonated beverage consumption	Yes	Waist circumference, BMI.	Age and sex specific BMI z scores increased in the control group by 0.10 (SD 0.53) but decreased in the intervention group by -0.01 (SD 0.58), with a mean difference of 0.10 (P=0.06).	✓	✓	✓	✓
3	School and family-based interventions in UK schools *Warren 2003*	UK	Cluster RCT	14 months	School	Ages 5-7 years	218	**Activity/Education (nutrition)** Intervention 1: 'Eat Smart': Dietary education. Intervention 2: 'Play smart': Physical activity program. Intervention 3: Combination of 'Eat Smart' and 'Play Smart'. Comparator: Education on food without nutritional perspective.	Yes	BMI, skin folds	No significant changes in the rates of overweight and obesity were seen as a result of the intervention.	✓	✓		

Number	Name of program	Location	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
4	Pre-school physical activity program to prevent obesity *Reilly 2006*	UK	Cluster RCT	1 year	Preschool	Mean age: 4.2 years	545	**Activity** Enhanced physical activity programme in nursery (3 x 30 min sessions/week)	Yes	BMI, Physical activity	Group allocation had no significant effect on BMI at 6 and 12 months.	✓	✓		
5	The pound of prevention study *Jeffrey 1999*	UK	RCT	3 years	Community	Adults	1226	**Education** 1) no-contact control, 2) education through monthly newsletters, 3) education plus incentives for participation	Yes	Weight	Weight gain over 3 years did not differ significantly by treatment group.	✓	✓		
6	Lay-led walking programme versus PA advice *Lamb 2002*	UK	RCT	1 year	Community	High risk middle aged men and women, 40-70 years	260	**Activity** Lay-led walking scheme versus advice on PA	Yes	Attitude, BMI, cholesterol	There was no statistically significant difference in BMI.	✓	✓		
7	Dutch obesity prevention in teenagers *Singh 2009*	Netherlands	Cluster RCT	20 months	Secondary school	12 – 14 years	1108	**Education (activity)** An interdisciplinary program with an adapted curriculum for 11 lessons in biology and physical education and environmental change options	Yes	Skin folds	Effective in preventing increases in measures of body composition in girls (biceps SF and sum of 4 skinfolds) and boys (triceps, biceps, and subscapular SF).	✓	✓	✓	✓

Number	Name of program	Location	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
8	General health screening *Engberg 2002*	Denmark	RCT	5 years	Family practice clinics	30 to 50 years	1507	**Education** Health screening or health screening plus 2 follow-up consultations versus no health screening	Yes	Cardiovascular risk score, BMI, BP	After 5 years, the CRS, BMI, and serum cholesterol levels were lower in the intervention groups compared with the control group.	✓	✓	✓	✓
9	CHILT project *Graf 2008*	Germany	Cluster RCT	4 years	School	5 to 14 years	547	**Education** Teachers asked to give one extra health education lesson per week (20-30 min) plus additional 5 min activity breaks and teacher training	Yes	Anthropometric, incidence of overweight/obesity	No difference in the prevalence and incidence of overweight and obesity in the intervention and control schools before and after intervention. Remission of overweight was higher in the intervention schools.	✓	✓		
10	Promotion of drinking water for overweight prevention *Muckelbauer 2009*	Germany	Cluster RCT	1 year	School	Children, Mean age: 8.3 years	2950	**Nutrition** Water fountains were installed and 4 sessions presented by teachers	Yes	BMI, water consumption	The prevalence of overweight at the follow-up assessment was 23.5% in the IG and 27.8% in the CG. No for BMI.	✓	✓		

Number	Name of program	Location	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
11	KOPS study *Muller 2001*	Germany	Cluster RCT	1 year	School	Children 5-7 years	297	**Education (nutrition)** Nutrition education and health promotion for students, parents, and teachers. Repeated information sessions for 3 months.	Yes	BMI, skin folds	Significant effects on the age-dependent increases in median triceps skinfolds of the whole group as well as in percentage fat mass of overweight children.	✓	✓	✓	✓
12	KOPS study *Danielzik 2005*	Germany	Cluster RCT	4 years	School	1st and 4th grade	9484	**Education (nutrition)/ Activity** Nutrition education and active school breaks.	Yes	Nutritional status, health habits and risk factors of disease	Obesity prevention was possible, but there were limited success rates in boys and children from low social class.	✓	✓	✓	✓
13	Tiger Kids *Bayer 2009*	Germany	Cluster RCT	12-20 months	Kindergarten	Age 5-6 years	1329	**Activity/Nutrition** Tiger Kids- behavioural intervention, enhance physical activity and to modify habits of food and drink consumption	Yes	Food survey, drink consumption, overweight/obesity.	Prevalence of overweight and obesity were not statistically different between intervention and control groups.	✓	✓		
14	Overweight prevention through physical activity *Simon 2008*	France	Cluster RCT	4 years	School	12 years old, 6th grade	954	**Education (activity)** Integrating environmental change to induce sustained changes in physical activity.	Yes	BMI	Yes, intervention students had a lower increase in BMI and age- and gender-adjusted BMI over time than controls.	✓	✓	✓	✓

Number	Name of program	Location	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
15	Israeli version of Know Your Body *Tamir 1990*	Israel	RCT	2 years	School	7-9 year olds	8 school classes	**Education** Health education and promotion program	Yes	BMI, lipids, cholesterol	A significant decrease in serum total cholesterol and BMI.	✓	✓	✓	✓
16	Health education intervention program *Lionis 1991*	Greece	Cluster RCT	1 year	School	13 and 14 years	171	**Education** 10 sessions and practical instruction on health issues in the classroom	Yes	Cholesterol, BP, BMI	Significant reductions were observed in BMI.	✓	✓	✓	✓
17	Health education intervention programme *Manios 1998*	Greece	Cluster RCT	3 years	School	First grade	393	**Education** Health education intervention directed at kids and parents	Yes	Knowledge, fitness, SF, BMI	Statistically smaller increases in the intervention as opposed to the control group were observed in suprailiac skinfold and BMI.	✓	✓	✓	✓
18	Health education intervention programme *Manios 2003*	Greece	Cluster RCT	6 years	School	First grade	1046	**Education** Health education intervention directed at kids and parents	Yes	BMI, SF	Yes, changes observed in the anthropometric variables in the two groups were in favour of the intervention.	✓	✓	✓	✓
19	Breastfeeding promotion programme *Kramer 2009*	Belarus	Cluster RCT	6.5 years	Hospital/clinic	Healthy breast fed infants	17046	**Education (breastfeeding)** Baby-friendly hospital initiative comprising 10 steps to help mothers to succeed at breast feeding and to feed for a longer duration	Yes	BMI, exclusive breast feeding rates	No significant intervention effects were observed on height, BMI, adiposity measures, or BP.	✓	✓		

Number	Name of program	Location	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
20	Obesity prevention programme *Jiang 2007*	China	Cluster RCT	3 years	School	Children grade 1-4 and their parents	2425	**Activity/Education (nutrition)** Intervention: programme of nutrition education and physical activity for children and their parents; Comparator: usual health and physical education	Yes	BMI, incidence & prevalence of overweight and obesity	Yes, there was a significant difference in BMI between intervention and control schools after intervention.	✓	✓	✓	✓
NHMRC Level III-I evidence															
21	School based obesity prevention intervention *Simonetti D'Arca 1986*	Italy	Semi-randomised controlled trial	1 year	School	4 to 9 year olds	1321	**Education** A multi-media education program, a written education program and a control group	Yes	BMI	Yes, for the multi-media intervention group.	✓	✓	✓	✓
22	Health Hunters *Eiben 2006*	Sweden	Controlled, comparative trial	1 year	Community	18-28 year olds with at least one severely obese parent	40	**Education (activity/lifestyle/nutrition)** Behavioural program focusing on food choice, physical activity and other lifestyle factors.	Yes	Body weight, BMI	Compared to the control group (which gained weight), the intervention group displayed significant improvements in body weight, BMI.	✓	✓	✓	✓
NHMRC Level III-2 evidence															
23	Community intervention program *Giampaoli 1997*	Italy	Non-randomised controlled trial	10 years	Community	Adults	2064	**Education (nutrition/smoking)** Mass health education, nutrition education, anti-smoking material.	Yes	Blood glucose, cholesterol, BMI	No, only small differences in BMI.	✓	✓		

Number	Name of program	Location	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated [a]	Primary outcome(s)	Considered effective?	1	2	3	SR?
24	Primary prevention program *Alexandrov 1988*	Russia	Controlled, non-randomised, comparative	3 years	School	11 years	4213	**Education (nutrition/smoking)** Round-table discussions, lectures, and the distribution of health-education materials relating to dietary habits and smoking.	Yes	Body mass, SF, BP	Non-significant decline in the age-specific increase in body mass compared to the reference group.	✓	✓	✓	✓
NHMRC Level III-3 evidence															
25	School-based physical activity and changes in adiposity *Wardle 2007*	UK	Longitudinal intervention study	5 years	School	11-12 years	2727	**Activity** School-based PA vs. low PA at school	Yes	Weight, height, waist circumference	There were no differences in BMI changes or the percentage of students classified as obese.	✓	✓		
NHMRC Level IV evidence															
26	National mass media campaign to prevent weight gain *Wammes 2005*	Netherlands	Uncontrolled intervention	5 years	Media	25-35 years	1949	**Education** Mass media campaign to increase awareness of weight gain	Yes	Self reported awareness and BMI	No, higher self-reported BMI associated with intervention.	✓	✓		

Abbreviations: 1 = is the intervention ≥ 1 year duration?; 2 = does the study assess a relevant outcome (ie, BMI, weight, % body fat, incidence overweight or obese?; 3 = has the intervention been shown to be effective using one of the relevant outcomes?; BMI = body mass index; BP = blood pressure; CRS = cardiovascular risk score; RCT = randomised controlled trial; SR? = should the study be considered for further systematic review?; UK = United Kingdom.

[a] In order to be classified as 'Yes' for the evaluation criterion, the program had to have undergone formal evaluation using an objective measure of weight, not just evaluated with a questionnaire of attitude or behaviour change.

1.4 CONCLUSIONS

Obesity and overweight is an increasing public health concern and primary prevention strategies form an important component of the multi-faceted approach required to address this issue. It is clear from the results of the scoping literature search that there are numerous programmes in NZ, Australia and overseas that have attempted to implement educational, activity-based and nutrition-based obesity prevention programmes. Many of these appear to have been administered, but either not formally evaluated, or not evaluated at all. This is particularly evident with programmes conducted in NZ and Australia, as many of these were identified through a grey literature search, rather than through the formal search of published evidence databases. It is important to note, therefore, that the list of identified obesity prevention programmes for NZ and Australia is not exhaustive. If the SRG feel there are other programmes that would be appropriate for systematic review and subsequent economic evaluation, the research team are more than happy to consider these.

It will be extremely important for the SRG to consider programs for full systematic review and economic evaluation that have been formally evaluated using an objective weight measure (eg, BMI, weight, % overweight or obese). Without formal evaluation using an objective weight measure, more assumptions and proxy measures will be required, adding to the uncertainty of the economic evaluation. Undoubtedly, this will need to be considered alongside the relevance of the patient population in the identified studies. Many of the studies highlighted in grey in the results tables have been conducted in other countries throughout the world and the demographic similarity and therefore generalisability of these studies to the NZ population must be taken into account.

Although the scope of this project includes public health interventions aimed at all age groups, the majority of obesity prevention interventions are targeted at children. As a result, many of the programmes are implemented in a school environment. There are some exceptions with community and workplace-based programmes targeted at adults, however for the most part 'prevention' implies instilling healthy lifestyle habits at an early age to avoid the development of overweight, obesity and their associated co-morbidities during adulthood. The SRG needs to consider whether they would like to evaluate obesity interventions that are targeted at a range of different age groups, or whether they would like the focus to be on children.

Selected Interventions

The interventions for systematic review were selected in a meeting of the SRG. They are outlined in **Table 163**.

Table 163 Selected interventions for systematic review

Setting	Intervention	Example studies from scoping search
Pre-school	Nutrition/activity program specifically targeting pre-school	Hip hop to health junior
Primary school	Activity co-ordinators	APPLE
Primary school	Physical activity/behaviour modification through structured activity	Switch-play
Primary school	Education nutrition, nutrition policy	School Nutrition Policy Initiative
Primary school	Reducing the consumption of carbonated beverages	CHOPPS, Muckelbauer
Primary school	Health promotion targeting low SES/overweight children	KOPS
Primary school	Multifaceted intervention- diet and physical activity lessons, family involvement	CATCH
Secondary school	Any secondary school based intervention studies	Lionis
Community kids	Child and family involvement (Nutrition, activity, behaviour modification)	Be Active Eat Well
Community kids	Increasing PA options and availability of foods	Shape up Somerville
Community Adults	Dietary modification in post menopausal women	Women's dietary modification trial
Community Adults	Dietary behaviour and physical activity program	Women's healthy lifestyle project
Primary care	Green prescription	Green prescription
Primary care	General health screening	Denmark general health screen
Workplace	Targeted workplace interventions	NASA and DOW [a]
College	Health promotion/behavioural intervention	Hivert

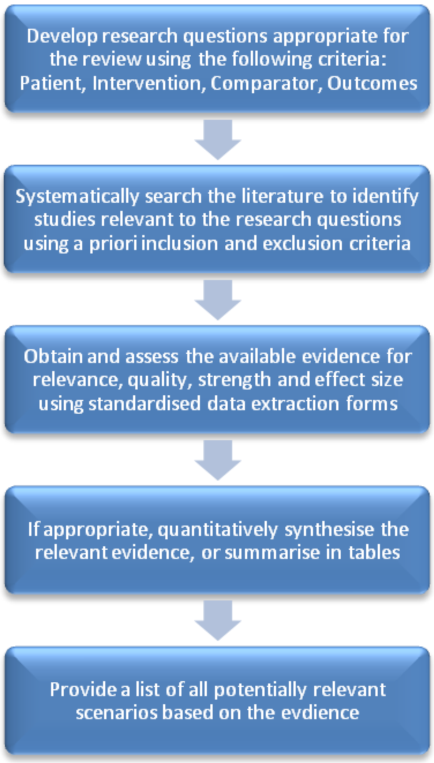
a

2 SYSTEMATIC REVIEW

While the previous section has provided a general outline of the proposed scope of the review, this section outlines the review methodology which will be used and provides specific information on the types of population-based, obesity prevention interventions which have been identified through an initial scoping search. Program specific information has been provided such that the reference group can select up to 15 interventions which will undergo systematic review and economic evaluation.

The review methodology is broadly based upon guidelines published by the National Health and Medical Research Council (NHMRC) (2000ab, 2005). The flowchart in **Figure 22** outlines the major steps involved in a systematic review.

Figure 22 The systematic review process



2.1 OBJECTIVE

The objective of the systematic review is to assess the effectiveness of up to 15 selected public health obesity prevention interventions. The effectiveness of the selected obesity-prevention interventions will then be summarised so that the stakeholder reference group can select up to 10 scenarios to undergo cost-effectiveness analysis.

2.2 METHODS

2.2.1 Selection of interventions for full systematic review

After careful consideration the SRG selected a range of obesity prevention interventions which had been implemented and evaluated in a variety of settings. The interventions selected for systematic review are shown in **Table 164**. Six of these interventions had been applied to children of primary school age. Interventions evaluated in pre-school, secondary school, at a general community level, in primary care, the workplace, and college settings were also selected.

Table 164 Interventions selected for full systematic review

Setting	Intervention	Example studies from scoping search
Pre-school	Nutrition/activity program specifically targeting pre-school	Hip hop to health junior
Primary school	Activity co-ordinators	APPLE
Primary school	Physical activity/behaviour modification through structured activity	Switch-play
Primary school	Education nutrition, nutrition policy	A policy-based multi-faceted intervention
Primary school	Reducing the consumption of carbonated beverages	CHOPPS, Muckelbauer
Primary school	Health promotion targeting low SES/overweight children	KOPS
Primary school	Multifaceted intervention- diet and physical activity lessons, family involvement	CATCH
Secondary school	Any secondary school based intervention studies	Lionis
Community kids	Child and family involvement (Nutrition, activity, behaviour modification)	Be Active Eat Well
Community kids	Increasing PA options and availability of foods	Shape up Somerville
Community Adults	Dietary modification in post menopausal women	Women's dietary modification trial
Community Adults	Dietary behaviour and physical activity program	Women's healthy lifestyle project
Primary care	Green prescription	Green prescription
Primary care	General health screening	Denmark general health screen
Workplace	Targeted workplace interventions	NASA and DOW
College	Health promotion/behavioural intervention	Hivert

Further details on the interventions for systematic review and associated studies from which the interventions were selected are provided in **Table 165**.

Table 165

Number	Name of program *Citation*	Location	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated for a weight-related outcome [a]	Primary outcome(s)	Considered effective?
Pre-school											
US18	Hip Hop to Health Junior *Fitzgibbon 2005*	US	RCT	2 years	Preschool	Minority preschool children	Unknown	**Nutrition/Activity** Culturally proficient dietary and physical activity program.	Yes	BMI	Yes, intervention children had significantly smaller increases in BMI compared with control children.
Primary school											
NZ3	A Pilot Programme for Lifestyle and Exercise (APPLE) *Taylor 2007*	NZ	Non-randomised controlled trial	2 years	School and community	5–12 year olds (15% Māori and < 1% Pacific Islander)	730	**Activity/Education** Intervention components included nutrition education that targeted reductions in sweetened drinks and increased fruit and vegetable intake and activity coordinators who managed an activity program that focused on noncurricular lifestyle-based activities (eg, community walks).	Yes	BMI, waist circumference, blood pressure	BMI z-score reduced in normal-weight but not overweight intervention children relative to controls
A1	Switch-Play *Salmon 2008*	AUS	Cluster RCT	1 year	School	Children, low SES, Mean: 10 years 8 months	311	**Activity/Behaviour modification** Four groups: behavioural modification group, fundamental movement skills group, a combined BM/FMS group and control.	Yes	BMI	Yes, significant reduction in age and sex-adjusted BMI in intervention group at 6 and 12 months.
US1	A policy-based school intervention to prevent overweight and obesity *Foster 2008*	US	Cluster RCT	2 years	School	Grade 4–6	1349	**Education (nutrition)/Nutrition** School self-assessment, nutrition education, nutrition policy (eg reduced priced health food), social marketing and parent outreach.	Yes	Incidence and prevalence of overweight and obesity, BMI	Yes, intervention resulted in a 50% reduction in the incidence of overweight. Significantly fewer children in the intervention schools (7.5%) than in the control schools (14.9%) became overweight after 2 years.

Number	Name of program *Citation*	Location	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated for a weight-related outcome [a]	Primary outcome(s)	Considered effective?
UK2	Christchurch obesity prevention programme (CHOPPS) *James 2004/James 2007*	UK	Cluster RCT	3 years	School	Children aged 7 to 11 years	644	**Education (nutrition)** Various education and games associated with reducing carbonated beverage consumption	Yes	Waist circumference, BMI.	Age and sex specific BMI z scores increased in the control group by 0.10 (SD 0.53) but decreased in the intervention group by -0.01 (SD 0.58), with a mean difference of 0.10 (P=0.06).
UK10	Promotion of drinking water for overweight prevention *Muckelbauer 2009*	Germany	Cluster RCT	1 year	School	Children, Mean age: 8.3 years	2950	**Nutrition** Water fountains were installed and 4 sessions presented by teachers	Yes	BMI, water consumption	The prevalence of overweight at the follow-up assessment was 23.5% in the IG and 27.8% in the CG. No for BMI.
UK12	KOPS study *Danielzik 2005*	Germany	Cluster RCT	4 years	School	1st and 4th grade	9484	**Education (nutrition)/ Activity** Nutrition education and active school breaks.	Yes	Nutritional status, health habits and risk factors of disease	Obesity prevention was possible, but there were limited success rates in boys and children from low social class.
US7	CATCH *Leupker 1996*	US	Cluster RCT	3 years	School	3rd to 5th grade	5106	**Activity/Education/Nutrition** Diet and PA lessons, PA intervention, family involvement; school food service intervention	Yes	BMI, skin folds	Blood pressure, body size, and cholesterol measures did not differ significantly between treatment groups

Number	Name of program *Citation*	Location	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated for a weight-related outcome [a]	Primary outcome(s)	Considered effective?
US8	CATCH *Coleman 2005*	US	Cluster RCT	2 years	School	3rd grade	896	**Activity/Education/Nutrition** As above	Yes	BMI, skin folds	The rate of increase for overweight and obesity in the CATCH schools was significantly lower compared with the rate of increase for control schools.
US9	CATCH *Nader 1999*	US	Cluster RCT	3 years	School	Grade 6, 7 and 8	3714	**Activity/Education/Nutrition** As above	Yes	BMI, cholesterol, BP	No significant differences were noted among BMI, BP, or serum lipid and cholesterol levels.
US10	CATCH *Webber 1996*	US	Cluster RCT	2 years	School	Grade 3 to 5	4019	**Activity/Education/Nutrition** As above	Yes	BMI	Overall, changes in obesity, BP, and serum lipids in the intervention group, compared with the control group, were not statistically significant.
US11	CATCH *Webber 1996*	US	Cluster RCT	2 years	School	Grade 3 to 5	4019	**Activity/Education/Nutrition** As above	Yes	BMI	Overall, changes in obesity, BP, and serum lipids in the intervention group, compared with the control group, were not statistically significant.
Secondary school											
UK16	Health education intervention program *Lionis 1991*	Greece	Cluster RCT	1 year	School	13 and 14 years	171	**Education** 10 sessions and practical instruction on health issues in the classroom	Yes	Cholesterol, BP, BMI	Significant reductions were observed in BMI.
Community kids											

Number	Name of program *Citation*	Location	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated for a weight-related outcome [a]	Primary outcome(s)	Considered effective?
A6	Nutrition and physical activity in children and adolescents (Be Active Eat Well) *Mathews et al (2008) - Report*	Aus	Historical controlled trial	2 years	Community	Children 4-12 and their families	~1000	**Nutrition/Activity/Behaviour modification** Decrease high sugar drinks and promote water and milk, decrease energy dense snacks and increase fruit and vegetables, increase active play and decrease TV viewing, increase the proportion who walk/cycle to school	Yes	BMI, z-BMI, weight, waist circumference	No significant difference in change in BMI, significant difference in changes in z-BMI (p=0.04), weight (p=0.03) and waist circumference (p=0.01)
US27	Shape up Somerville *Economos 2007*	US	Non-randomised controlled trial	1 year	Community	Mean age: 7.6 years (grade 1 to 3)	1178	**Education/Activity/Nutrition** Program designed to increase PA options and availability of health foods.	Yes	BMI	Yes, intervention decreased BMI z-score in children at high risk for obesity.
Community adults											
US15	The Women's Health Initiative Dietary Modification Trial *Howard 2006*	US	RCT	7.5 years	Community	Postmenopausal women	48835	**Education** Group and individual sessions to promote reduced fat intake and increased fruit and vegetables, control received diet-related educational material.	Yes	Change in body weight	Yes, women in the intervention group lost weight in the first year (mean of 2.2 kg, P<.001) and maintained lower weight than control women during an average 7.5 years of follow-up.
US23	Women's healthy lifestyle project *Simkin-Silverman 2003/Kuller 2001*	US	RCT	4.5 years	Community	44 to 50 years	535	**Activity/Nutrition** Participants were randomly assigned to either a lifestyle intervention group receiving a 5-year behavioural dietary and physical activity program or assessment only control group	Yes	Weight, waist circumference, cholesterol	Yes, intervention group had significantly lower BMI, % body fat at follow-up

Number	Name of program *Citation*	Location	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated for a weight-related outcome [a]	Primary outcome(s)	Considered effective?
Primary care											
NZ1	Green prescription (GRx) *Lawton 2008*	NZ	Cluster RCT	2 years	General practice	Women aged 40-74 (including ~ 13% Māori and Pacific Islander women)	1089	**Activity** A health professionals written advice to a patient to be physically active, as part of patient health management.	Yes	Physical activity, QoL, weight, waist circumference, cardiovascular risk factors	Increased activity and QoL but no change in clinical outcomes
NZ2	Green prescription (GRx) *Elley 2003*	NZ	Cluster RCT	1 year	General practice	40–79 year olds (assumed to be ~25% Māori and Pacific Islander participants)	878	**Activity** A health professionals written advice to a patient to be physically active, as part of patient health management.	No	Change in total expenditure of energy and leisure time expenditure of energy, cardiovascular risk and quality of life.	Increase in total energy expenditure in intervention group.
NZ7	Green Prescription Active Families Program	NZ	Uncontrolled intervention	Up to 12 months	Community	Children aged 5-18 with a BMI > 25 and their families (including 47% Māori families and 17% Pacific Islander families)	90	**Activity** A health professionals written advice to a patient to be physically active, as part of patient health management.	Yes	Changes in health and fitness, increased exercise in children and household	93% of respondents to survey said they had noticed changes in child's health or fitness
UK8	General health screening *Engberg 2002*	Denmark	RCT	5 years	Family practice clinics	30 to 50 years	1507	**Education** Health screening or health screening plus 2 follow-up consultations versus no health screening	Yes	Cardiovascular risk score, BMI, BP	After 5 years, the CRS, BMI, and serum cholesterol levels were lower in the intervention groups compared with the control group.
Workplace											

Number	Name of program *Citation*	Location	Study type	Duration	Setting	Population	N	Description of intervention	Evaluated for a weight-related outcome [a]	Primary outcome(s)	Considered effective?
US28	NASA Health Related Fitness Program *Wier 1989*	US	Non-randomised controlled trial	2 years	Workplace	NASA employees	258	**Activity** A 12-week educational component and quarterly fitness retests.	Yes	VO_2, body composition	Yes, changes in physical activity were related to program completion, % body fat, body weight.
US29	Obesity prevention program at Dow Chemical Company *Goetzel 2009*	US	Non-randomised controlled trial	1 year	Workplace	Dow employees	10,282	**Education/Activity/Nutrition** Individual intervention including health education material, leadership training, physical activity, weight management programs, reimbursement for participating	Yes	BMI	Yes for BMI but not for proportion at risk for overweight and obesity
NZ5	Health promotion programme *Cook 2001*	NZ	Non-randomised controlled trial	1 year	Workplace	Male workers (including 21% Māori and 43% Pacific Islander)	253	**Education (nutrition/activity)** Nutritional displays in the cafeteria and monthly 30 minute workshops for 6 months	Yes	BMI, self reported diet and exercise	Reduced fat intake, increased vegetable intake and PA, improved nutrition knowledge and reduced systolic BP. No difference in change in mean BMI or waist circumference.
College											
US20	Seminar based intervention program to prevent obesity *Hivert 2007*	US	RCT	2 years	College	Young adults, mean age: 19.7 years	115	**Education (nutrition/activity)** Educational/behavioural intervention designed to help maintain a healthy lifestyle	Yes	BMI	Yes, statistically significant difference in mean BMI at 12 and 24 months.

2.2.2 Defining the research questions

It is important to define the research question that the systematic review seeks to address. As there are up to 15 interventions to be systematically assessed for effectiveness, there will be multiple research questions to be defined for this review.

These questions are defined according to the PICO (or PICOT) criteria:

6. Population
7. Intervention
8. Comparator
9. Outcomes
10. Time consideration (should be considered with regard to all of the above domains)

In the context of performing a systematic review of a public health intervention, the following should be taken into consideration when defining the components of the research question (CRD, 2009)[2]:

- The *population* of interest is often represented by groups of people, or entire communities, such as young people in schools or particular geographical regions. This is in contrast to reviews of clinical topics where individuals are usually the focus, for example patients undergoing a particular procedure or with a particular disease.
- Public health *interventions and comparators* are often characterised as a package of components, for example, the inclusion of diet, exercise and education in obesity prevention programs. These types of interventions are often referred to as 'complex' due to the fact that the constituent parts may act both independently and inter-dependently.
- In terms of *outcomes*, the outcomes for this review will be those related to weight (ie, BMI, weight, waist circumference, incidence of obesity/overweight). Although public health interventions have the potential to improve population health overall, improvements (in terms of the total number who benefit from the intervention) may mask differences between groups (eg, male vs female). For example, a review of healthy eating interventions in schoolchildren found differences between males and females in knowledge and consumption of healthy foods. As such, it may be necessary to explore the results in terms of population characteristics including gender and ethnicity. Ethnicity is particularly important in this review as the effect of interventions on preventing obesity in Māori and Pacific Islander populations is relevant to the New Zealand setting.

[2] Centre for Reviews and Dissemination (2009) Systematic reviews: CRD's guidance for undertaking reviews in health care. CRD, University of York.

For systematic reviews of public health interventions, it is also suggested that the *context* of an intervention be considered. Consideration of the context is important because if an intervention is found to be effective it is useful to be able to assess whether context was a contributor.

2.2.3 Nature of the evidence included

In addition to the criteria above which will determine the nature of the interventions to be sourced, it is also important to identify what types of studies are eligible to be included. The levels of evidence based on NHMRC guidelines are defined as follows:

- **Level I:** A systematic review of level II studies.
- **Level II:** A randomised controlled trial
- **Level III-1:** A pseudorandomised controlled trial (ie, alternate allocation or some other method)
- **Level III-2:** A comparative study with concurrent controls: (i) non-randomised, experimental trial; (ii) cohort study; (iii) case-control study; or (iv) interrupted time series with a control group
- **Level III-3:** A comparative study without concurrent controls: (i) historical control study; (ii) two or more single arm studies; (iii) interrupted time series without a parallel control group
- **Level IV:** Case series with either post-test or pre-test/post-test outcomes.

Once the requestor has confirmed the prevention interventions for evaluation, a full systematic review of the interventions selected will be performed. For a systematic review, all levels of evidence are potentially relevant for inclusion. In the case of this review, inclusion of studies does not have to be based on any particular study type. It is possible that the prevention studies identified for this review will use a wide range of study methodologies.

2.2.4 Searching the literature

The published peer-reviewed medical literature will be searched using the Cochrane, Medline, EMBASE and CINAHL databases. In addition the Healthy Eating Healthy Action Knowledge Library will be searched. Other databases/websites which may be searched include the following:

- NICE: http://www.nice.org.uk/

- AHRQ/USPSTF: http://www.ahrq.gov/
- INAHTA: http://www.inahta.org/Search2/?pub=1

The following clinical practice guideline clearing house will be searched in order to identify any recent clinical practice guidelines that have been underpinned by full systematic reviews that have not been captured elsewhere.

- National Guideline Clearing House Database: http://www.guideline.gov/

Hand searching of specific journals or conferences will not be undertaken, although the reference lists of key papers will be searched to identify any peer-reviewed evidence that may have been missed in the literature searches.

2.2.5 Assessing eligibility

In a systematic review, the eligibility of identified citations should be determined using criteria based on the elements of the clinical question being answered.

In the case of this review, the following exclusion criteria were defined:

1. Not a relevant study: Excludes non-systematic reviews, case reports, animal studies, short notes, letters, editorials, conference abstracts, in-vitro studies.
2. Wrong intervention: does not assess one of the selected public health obesity-prevention interventions.
3. Wrong outcomes: does not measure one of the defined outcomes (eg, change in BMI).
4. Not in English: due to resource constraints non-English publications will not be included.

A full list of excluded citations annotated by the key reason for exclusion will be provided in the review. Double-checking of eligibility of a random sample of citations by a second reviewer will be undertaken.

2.2.6 Assessing the evidence

The evidence will be assessed according to the dimensions outlined in **Table 2**. Information regarding these dimensions as well as the results data will be extracted into a specifically designed data extraction sheet.

Table 166 Dimensions of evidence

Dimension	Definition
Strength of evidence	
Level	The study design used, as an indicator of the degree to which bias has been eliminated by design
Quality	The methods used by the investigators to minimise bias within a study design (see Table 3)
Statistical precision	The P-value or alternatively, the precision of the estimate of the effect (as indicated by the confidence interval). It reflects the degree of certainty about the existence of a true effect.
Size of effect	The distance of the study estimate from the 'null' value and the inclusion of only clinically important effects in the confidence interval.
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.

Source: NHMRC 2000b.

Each study will be assigned a level of evidence in accordance with the NHMRC (2005) levels of evidence. The levels of evidence vary according to the nature of the research question. Importantly, the level of evidence is assigned at the individual study level, rather than to the body of evidence.

In addition to determining the level of evidence, each study will be assessed for its methodological quality. The criteria used to assess quality will most likely be based on those shown in **Table 167**, however, alternative quality assessment criteria may be required if other study types are included. Quality criteria will be tabulated and discussed in the data extraction form (see below), rather than used to formulate a numeric score. However, if statistical meta-analysis is appropriate, a post-hoc meta-analysis of just the higher quality studies may be undertaken, with the cut-off criteria clearly enunciated.

Table 167 Quality criteria for different levels of evidence

Study type	Quality criteria
Systematic review	Was an adequate search strategy used? Were the inclusion criteria appropriate and applied in an unbiased way? Was a quality assessment of included studies undertaken? Were the characteristics and results of the individual studies appropriately summarised? Were the methods for pooling the data appropriate? Were sources of heterogeneity explored?
RCT	Was the study double-blinded? Was allocation to treatment groups concealed from those responsible for recruiting subjects? Were all randomised participants included in the analysis?
Cohort	How were subjects selected for the 'new' intervention? How were subjects selected for the comparison or control group? Does the study adequately control for demographic characteristics, clinical features and other potential confounding variables in the study design or analysis? Was the measurement of outcomes unbiased (i.e., blinded to treatment group and comparable across groups)? Was follow-up long enough for outcomes to occur? Was follow-up complete and were their exclusions from analysis?
Case-control	How were cases defined and selected? How were controls defined and selected? Does the study adequately control for demographic characteristics and important potential confounders in the study design or analysis? Was measurement of exposure to the factor of interest (e.g., the new intervention) adequate and kept blinded to case/control status? Were all selected subjects included in the analysis?

Source: NHMRC (2000b).

2.2.7 Data extraction

Data will be extracted and entered into a data extraction table. Double data extraction will not be undertaken. No attempt will be made to contact authors.

2.2.8 Data synthesis

For systematic reviews with analyses involving evidence from RCTs, a meta-analysis may be performed when appropriate using the methodology of the Cochrane Collaboration (Mulrow and Oxman, 1997).

APPENDIX 2: RELEVANT PUBLICATIONS IDENTIFIED BY SCOPING SEARCH

Alexandrov A, Isakova G, Maslennikova G, Shugaeva E, Prokhorov A, Olferiev A, and Kulikov S. 1988. Prevention of atherosclerosis among 11-year-old schoolchildren in two Moscow administrative districts. Health Psychol 7 Suppl:247-252.
Abstract: A total of 4,213 boys and girls 11 years of age were screened in two Moscow administrative districts. Preventive measures were conducted in one district and were directed at excess body mass, systolic blood pressure, blood lipids (only among boys), cigarette smoking, and physical inactivity. A reference group of peers, who did not receive advice on prevention, was selected from another district. The intervention was targeted to three groups--schoolchildren, their parents, and teaching staff. It included round-table discussions, lectures, and the distribution of health-education materials relating to dietary habits and smoking. Over a 3-year period, these measures resulted in nonsignificant decline in the age-specific increase in body mass compared to the reference group. The intervention group had smaller subscapular skinfold thickness measurements than the reference group. These differences were significant. Mean systolic blood pressure increased with age in both groups. The increase was less in the intervention group than in the reference group and affected boys less than girls. A significant decrease in lipids (cholesterol and triglycerides) was observed in the intervention district. We conclude that additional study is needed to evaluate more precisely the effectiveness of such prevention efforts

Bayer O, Von Kries R, Strauss A, Mitschek C, Toschke AM, Hose A, and Koletzko BV. 2009. Short- and mid-term effects of a setting based prevention program to reduce obesityrisk factors in children: A cluster-randomized trial. Clin Nutr 28:122-128.
Abstract: Background & aims: To assess the effects of a low cost behavioral prevention program in a preschool setting. Methods: 64 Kindergartens in 4 Bavarian regions were randomly assigned as intervention or controls in a 2:1 ratio. Samples of 1318 and 1340 children examined in the school entrance health examination at 5.7 (plus or minus) 2.6 and 17.6 (plus or minus) 2.3 months (mean (plus or minus) standard deviation for first and second sample) after the start of the program were analysed. Measurements: Main outcome measures were the prevalence of high fruit and vegetable consumption, low consumption of high caloric drinks assessed in parental questionnaires, overweight and obesity, and secondary, further dietary habits and results of motoric testing. Results: The program led to an increased proportion of children with high fruit and vegetable consumption already after 6 months, which was sustainable with adjusted odds ratios of 1.59 (1.26: 2.01) and 1.48 (1.08: 2.03) after 18 months. Subgroup analyses by gender, overweight and parental education, performed in order to assess consistency of effects, showed similar results. Prevalence of overweight and obesity as well as motoric testing results were not statistically different between intervention and control groups. Conclusion: This low cost setting based behavioral intervention achieved sustainable effects on fruit and vegetable consumption in young children 18 months after the start of the intervention and showed effects also in the high risk groups of children from families with lower education levels, and children already overweight. (copyright) 2009 Elsevier Ltd and European Society for Clinical Nutrition and Metabolism

Burke V, Giangiulio N, Gillam HF, Beilin LJ, and Houghton S. 2003. Physical activity and nutrition programs for couples: A randomized controlled trial. J Clin Epidemiol 56:421-432.
Abstract: Diet and physical activity habits may deteriorate after cohabitation, leading to weight gain and increased risk of lifestyle diseases. We carried out a 4-month, randomized controlled trial of a diet and physical activity program for couples with a 1-year follow-up, comparing two methods of delivery. The program used six modules, which, after an initial group session, were mailed to the low-level intervention group. In the high-level intervention group, half of the modules were mailed, and the others were delivered at interactive group sessions. A control group received no intervention. Postintervention and at follow-up, physical fitness improved in the high-level group, saturated fat intake decreased in both intervention groups, and low-density lipoprotein cholesterol fell in the high-level group. Fewer participants in the high-level group became overweight or obese. Health promotion for couples can improve health behaviors and potentially lower the risk of lifestyle diseases in participants and their future families. (copyright) 2003 Elsevier Inc. All rights reserved

Bush PJ, Zuckerman AE, Taggart VS, Theiss PK, Peleg EO, and Smith SA. 1989. Cardiovascular risk factor prevention in african American school children: the "Know Your Body" evaluation project. Health Educ Q 16:215-227.
Abstract: A longitudinal study of the effectiveness of the "Know Your Body" (KYB) program in reducing coronary heart disease risk factors was begun among african American students in the District of Columbia in

1983. Subjects were in grades four through six at nine schools stratified on socioeconomic status and randomized into one control and two intervention groups. At baseline, 1,041 students were measured for systolic and diastolic blood pressure, ponderosity, triceps skinfold thickness, postexercise pulse recovery rate, serum thiocyanate, serum total cholesterol, and serum HDL cholesterol. Significant net changes in individual values occurred in the favorable direction at one or all four annual follow-up reexaminations for systolic blood pressure, diastolic blood pressure, HDL cholesterol, HDL/total cholesterol ratio, serum thiocyanate, and fitness. Favorable changes in diastolic blood pressure and serum thiocyanate were observed at all reexaminations, and these were substantiated by analyses that used the school grade as the unit of analysis. Intervention students who were judged to have had the best KYB teachers showed significant favorable net changes in total serum cholesterol after one year. Results are consistent with other evaluations of the Know Your Body program suggesting that KYB may reduce chronic disease risk in diverse school populations, and that increased efforts should be made to improve implementation methods

Caballero B, Clay T, Davis SM, Ethelbah B, Rock BH, Lohman T, Norman J, Story M, Stone EJ, Stephenson L, and Stevens J. 2003. Pathways: a school-based, randomized controlled trial for the prevention of obesity in American Indian schoolchildren. Am J Clin Nutr 78:1030-1038.
Abstract: BACKGROUND: Childhood obesity is a major public health problem in the United States, particularly among American Indian communities. OBJECTIVE: The objective was to evaluate the effectiveness of a school-based, multicomponent intervention for reducing percentage body fat in American Indian schoolchildren. DESIGN: This study was a randomized, controlled, school-based trial involving 1704 children in 41 schools and was conducted over 3 consecutive years, from 3rd to 5th grades, in schools serving American Indian communities in Arizona, New Mexico, and South Dakota. The intervention had 4 components: 1) change in dietary intake, 2) increase in physical activity, 3) a classroom curriculum focused on healthy eating and lifestyle, and 4) a family-involvement program. The main outcome was percentage body fat; other outcomes included dietary intake, physical activity, and knowledge, attitudes, and behaviors. RESULTS: The intervention resulted in no significant reduction in percentage body fat. However, a significant reduction in the percentage of energy from fat was observed in the intervention schools. Total energy intake (by 24-h dietary recall) was significantly reduced in the intervention schools but energy intake (by direct observation) was not. Motion sensor data showed similar activity levels in both the intervention and control schools. Several components of knowledge, attitudes, and behaviors were also positively and significantly changed by the intervention. CONCLUSIONS: These results document the feasibility of implementing a multicomponent program for obesity prevention in elementary schools serving American Indian communities. The program produced significant positive changes in fat intake and in food- and health-related knowledge and behaviors. More intense or longer interventions may be needed to significantly reduce adiposity in this population

Chavarro JE, Peterson KE, Sobol AM, Wiecha JL, and Gortmaker SL. 2005. Effects of a school-based obesity-prevention intervention on menarche (United States). Cancer Causes Control 16:1245-1252.
Abstract: Objective: Early menarche is a risk factor for breast cancer. Since body composition influences age at menarche we decided to estimate the effects of a school-based intervention for the prevention of obesity on the initiation of menses in young girls. Methods: Ten schools were randomized to a modified curriculum or no curricular changes for 2 school-years. Data of 508 pre-menarcheal girls at baseline (age range: 10-13 years) were analyzed. Results: Girls attending an intervention school experienced menarche less frequently than girls attending control schools during the intervention period (intervention schools = 54%, control schools = 59%; RR = 0.76; 95% CI [0.66, 0.87]). Attending an intervention school was also associated with lower increase in BMI (-0.3 kg/m2; p = 0.003), lower gains in triceps skinfold thickness (-1.5 mm;/ p = 0.007), decreased television viewing (-0.6 h/day; p <0.0001) and increased physical activity (3.1 MET-h/week; p = 0.032). Including these changes as predictors of menarche incidence attenuated the intervention effect (RR = 0.94; 95% CI [0.80, 1.10]). Conclusions: The intervention delayed menarche in this group of girls. The delay was produced by increased physical activity, reduced television viewing and changes in BMI and fat distribution. These findings may have implications for the primary prevention of breast cancer. (copyright) Springer 2005

Coleman KJ, Tiller CL, Sanchez J, Heath EM, Sy O, Milliken G, and Dzewaltowski DA. 2005. Prevention of the epidemic increase in child risk of overweight in low-income schools: The El Paso coordinated approach to child health. Arch Pediatr Adolesc Med 159:217-224.
Abstract: Objective: To assess the impact on children's health of translating an evidence-based national intervention trial (Child and Adolescent Trial for Cardiovascular Health [CATCH]) to low-income elementary schools with primarily Hispanic students. Design: An untreated, matched control group design with repeated dependent pretest and posttest samples was used. Setting: Four El Paso CATCH and 4 control elementary schools in El Paso, Tex, along the US-Mexico border region. All had Title I status (most were low-income students). Participants: Participants were 896 third-grade children (473 control schools [224 girls and 249 boys] and 423 CATCH schools [199 girls and 224 boys]); 93% were Hispanic. Intervention: Community-based

implementation of the national CATCH program. Main Outcome Measures: Risk of overweight or overweight, body mass index, waist-to-hip ratio, yards run in 9 minutes, passing rates for Fitnessgram national mile standards, moderate to vigorous physical activity and vigorous physical activity in physical education class, and percentage of fat and sodium in school lunches. Results: Girls in control schools had significant increases in percentage of risk of overweight or overweight from third (26%) to fifth (39%) grades, as did girls in CATCH schools (30%-32%); however, the rate of increase for girls in the CATCH schools was significantly lower (2%) compared with the rate for control girls (13%). A similar pattern was seen for boys, with a rate of increase for boys in CATCH schools of 1% (40%-41%), which was significantly less than the 9% increase (40% to 49%) for control boys. Conclusions: The translation of the national CATCH program to low-income schools with Hispanic students successfully slowed the epidemic increase in risk of overweight or overweight seen in control school children. An emphasis should be placed on community organizing and evaluation feedback when implementing evidence-based school health programs in low-income Hispanic communities

Cook C, Simmons G, Swinburn B, and Stewart J. 2001. Changing risk behaviours for non-communicable disease in New Zealand working men--is workplace intervention effective? N Z Med J 114:175-178.
Abstract: AIMS: To evaluate the effectiveness of a health promotion programme targeting dietary behaviours and physical activity among male hourly-paid workers and to explore demographic and attitudinal influences on dietary patterns at baseline. METHODS: A controlled field trial compared workers at one intervention and one control worksite. The intervention comprised nutrition displays in the cafeteria and monthly 30-minute workshops for six months. Key outcome measures at six and twelve-months were self-reported dietary and lifestyle behaviours, nutrition knowledge, body mass index (BMI), waist circumference and blood pressure. RESULTS: 132 men at the intervention site and 121 men at the control site participated in the study and a high retention rate (94% at 6-months and 89% at 12-months) was achieved. At baseline, 40% of the total sample (253) were obese, 30% had elevated blood pressure, 59% indicated an excessive fat intake and 92% did not meet the recommended vegetable and fruit intake. The intervention reduced fat intake, increased vegetable intake and physical activity, improved nutrition knowledge and reduced systolic blood pressure when compared to the control site. There was no difference in change in mean BMI or waist circumference. Reduction in BMI was associated with reduction in fat intake. DISCUSSION: Low intensity workplace intervention can significantly improve reported health behaviours and nutrition knowledge although the impact on more objective measures of risk was variable. A longer duration or more intensive intervention may be required to achieve further reduction in risk factors

Danielzik S, Pust S, Landsberg B, and Muller MJ. 2005. First lessons from the Kiel Obesity Prevention Study (KOPS). Int J Obes 29:S78-S83.
Abstract: AIMS: Prevention of obesity is a public health agenda. There are only few longitudinal studies on prevention of overweight in children. The Kiel Obesity Prevention Study (KOPS) intends to characterise the determinants of childhood overweight and the effect of preventive measures within schools as well as within families. METHODS: Between 1996 and 2005, KOPS investigated 4997 German 5-7 and 4487 9-11-y-old children or 41 and 37% of the total population of all first and fourth graders in 32 primary schools in Kiel (248 000 inhabitants), northwest Germany. Main outcome measures were nutritional status, health habits and risk factors of disease. In addition, health promotion was performed each year in three schools for all first graders and their teachers (nutrition education and active school breaks) together with a family-oriented approach in families with obese and preobese children. Up to now, the children were followed for 4 y and were reinvestigated at age 10 y. RESULTS: The KOPS population was representative for all 5-7 and 9-11-y-old children in Kiel. The prevalence of overweight/obesity ((greater-than or equal to)90th/97th BMI reference percentile) was 7.0/5.8 and 11.3/6.3% in 5-7 and 9-11-y-old children, respectively. Parental overweight, a low socio-economic status and a high birth weight were identified as main risk factors for overweight in prepubertal children. The first results of the interventions show that obesity prevention was possible, but there were limited success rates in boys and children from low social class. CONCLUSION: Faced with the environmental contributors to the obesity problem societal rather than individual responsibilities are evident. This idea suggests that dissecting and tackling the obesogenic environment is necessary to complement school- and family-based interventions. (copyright) 2005 Nature Publishing Group All rights reserved

Donnelly JE, Jacobsen DJ, Whatley JE, Hill JO, Swift LL, Cherrington A, Polk B, Tran ZV, and Reed G. 1996. Nutrition and physical activity program to attenuate obesity and promote physical and metabolic fitness in elementary school children. Obes Res 4:229-243.
Abstract: Obesity and low levels of physical and metabolic fitness are risk factors for cardiovascular disease and diabetes. The purpose of this investigation was to attenuate obesity and improve physical and metabolic fitness in elementary school children. Schools have the opportunity, mechanisms, and personnel in place to deliver nutrition education, fitness activities, and a school food service that is nutritious and healthy. Cohorts from grades 3 to 5 in two school districts in rural Nebraska (Intervention/Control) participated in a 2-year study of

physical activity and modified school lunch program. Data collection for aerobic capacity, body composition, blood chemistry, nutrition knowledge, energy intake, and physical activity was at the beginning and end of each year. Int received enhanced physical activity, grade specific nutrition education, and a lower fat and sodium school lunch program. Con continued with a regular school lunch and team sports activity program. At year 2, Int lunches had significantly less energy (9%), fat (25%), sodium (21%), and more fiber (17%). However, measures of 24-hour energy intake for Int and Con showed significant differences for sodium only. Physical activity in the classroom was 6% greater for Int compared to Con ($p < 0.05$) but physical activity outside of school was approximately 16% less for Int compared to Con ($p < 0.05$). Body weight and body fat were not different between schools for normal weight or obese children. No differences were found for cholesterol, insulin, and glucose; however, HDL cholesterol was significantly greater and cholesterol/HDL was significantly less for Int compared to Con ($p < 0.05$). It appears that compensation in both energy intake and physical activity outside of school may be responsible for the lack of differences between Int and Con

Dwyer T, Coonan WE, Leitch DR, Hetzel BS, and Baghurst RA. 1983. An investigation of the effects of daily physical activity on the health of primary school students in South Australia. Int J Epidemiol 12:308-313.
Abstract: Studies of the health effects of a daily physical activity programme have been carried out in 10-year-old school children in Adelaide, South Australia. In the first phase (1978) observations on endurance fitness, four skin folds, blood pressure and blood lipids were made before and after a randomized trial over a period of 14 weeks. Comparisons were made on over 500 children drawn from classes in seven Primary schools involved in an endurance fitness programme (1 1/4 hours per day), a skill programme and the previous physical education programme (controls). The fitness group experienced significant gains in physical work capacity (PWC) and showed significant decreases in body fat compared to the other two groups. No significant differences were observed in plasma cholesterol, triglycerides and HDL cholesterol. Subsequently in the second phase (1980) observations were made on a group of 216 10-year-old children who had already experienced two years of the physical activity programme adopted after phase one. Comparison with the observations in the 10-year-old children in 1978 made prior to the intervention revealed significantly smaller skin folds and greater PWC, with lower blood pressure reaching statistical significance for diastolic pressure in boys. The findings suggest beneficial effects on health of daily physical activity programmes within existing primary school curricula. There was no evidence of any loss of academic performance as measured by arithmetic and reading tests in spite of 45-60 minutes' loss of formal teaching time each day

Economos CD, Hyatt RR, Goldberg JP, Must A, Naumova EN, Collins JJ, and Nelson ME. 2007. A community intervention reduces BMI z-score in children: Shape up somerville first year results. Obesity 15:1325-1336.
Abstract: Objective: The objective was to test the hypothesis that a community-based environmental change intervention could preventweight gain in young children (7.6 (plus or minus) 1.0 years). Research Methods and Procedures: A non-randomized controlled trial was conducted in three culturally diverse urban cities in Massachusetts. Somerville was the intervention community; two socio-demographically-matched cities were control communities. Children (n = 1178) in grades 1 to 3 attending public elementary schools participated in an intervention designed to bring the energy equation into balance by increasing physical activity options and availability of healthful foods within the before-, during-, after-school, home, and community environments. Many groups and individuals within the community (including children, parents, teachers, school food service providers, city departments, policy makers, healthcare providers, before- and after-school programs, restaurants, and the media) were engaged in the intervention. The main outcome measure was change in BMI z-score. Results: At baseline, 44% (n = 385), 36% (n = 561), and 43% (n = 232) of children were above the 85th percentile for BMI z-score in the intervention and the two control communities, respectively. In the intervention community, BMI z-score decreased by -0.1005 (p = 0.001, 95% confidence interval, -0.1151 to -0.0859) compared with children in the control communities after controlling for base-line covariates. Discussion: A community-based environmental change intervention decreased BMI z-score in children at high risk for obesity. These results are significant given the obesigenic environmental backdrop against which the intervention occurred. This model demonstrates promise for communities throughout the country confronted with escalating childhood obesity rates. Copyright (copyright) 2007 NAASO

Eiben G and Lissner L. 2006. Health Hunters--an intervention to prevent overweight and obesity in young high-risk women. Int J Obes 30:691-696.
Abstract: AIM: The aim of the study was to develop and implement an obesity and weight gain prevention program targeted to a high-risk group. METHOD: Women, 18-28 years old, with at least one severely obese parent, were randomized to the intervention or control group of the 'Health Hunters' program. During 1 year of follow-up, the intervention group received an individualized behavioral program focusing on food choice, physical activity and other lifestyle factors. Anthropometric measures, DXA-based body composition and fitness levels were measured at baseline and after 1 year. Self-reported changes in obesity-related behaviors were

also assessed. RESULTS: Baseline examinations were conducted in 40 women, of whom 30 completed follow-up examinations 1 year later. Pregnancy was the most common reason for failure to complete the study. Compared to the control group (which gained weight), the intervention group displayed significant improvements in body weight, body mass index, waist circumference, waist-to-hip ratio and self-reported physical activity. Changes in body composition, although not significant, suggested that the intervention tended to be associated with improved body composition. Further analysis of changes in diet and fitness in relation to concurrent weight changes indicated that the strongest 'protective' associations were for energy percent protein, fiber density and fitness. CONCLUSION: Pilot data from the Health Hunters obesity prevention program indicates that it is effective in high-risk young women with familial predisposition for obesity

Engberg M, Christensen B, Karlsmose B, Lous J, and Lauritzen T. 2002. General health screenings to improve cardiovascular risk profiles: A randomized controlled trial in general practice with 5-year follow-up. J Fam Pract 51:546-552.
Abstract: OBJECTIVES: To investigate the impact of general health screenings and discussions with general practitioners on the cardiovascular risk profile of a random population of patients. STUDY DESIGN: A population-based, randomized, controlled, 5-year follow-up trial conducted in a primary care setting. POPULATION The study group consisted of 2000 patients, randomly selected middle-aged men and women aged 30 to 50 years, from family practices in the district of Ebeltoft, Denmark. Of these patients, 1507 (75.4%) agreed to participate. Patients were randomized into (1) a control group that received no health screenings, (2) an intervention group that received 2 health screenings, (3) an intervention group that received both the 2 screenings and a 45-minute follow-up consultation annually. OUTCOMES MEASURED: Cardiovascular risk score (CRS), body mass index (BMI), blood pressure, serum cholesterol, carbon monoxide in expiratory air, and tobacco use. RESULTS: After 5 years, the CRS, BMI, and serum cholesterol levels were lower in the intervention groups compared with the control group. The improved outcome was greater in the baseline risk groups. The number of patients with elevated CRS in the intervention groups was appropriately half the number of patients with elevated CRS in the control group. The difference was not a result of medication use. There was no difference between the group that received consultations after the screenings and the group that had health screenings alone. CONCLUSIONS: Health screenings reduced the CRS in the intervention groups. After 5 years of follow-up, the number of persons at elevated cardiovascular risk was about half that expected, based on the prevalence/proportion in a population not receiving the health checks (the control group). The impact of intervention was higher among at-risk individuals. Consultations about health did not appear to improve the cardiovascular profile of the study population

Epstein LH, Gordy CC, Raynor HA, Beddome M, Kilanowski CK, and Paluch R. 2001. Increasing fruit and vegetable intake and decreasing fat and sugar intake in families at risk for childhood obesity. Obes Res 9:171-178.
Abstract: OBJECTIVE: The goal of this study was to evaluate the effect of a parent-focused behavioral intervention on parent and child eating changes and on percentage of overweight changes in families that contain at least one obese parent and a non-obese child. RESEARCH METHODS AND PROCEDURES: Families with obese parents and non-obese children were randomized to groups in which parents were provided a comprehensive behavioral weight-control program and were encouraged to increase fruit and vegetable intake or decrease intake of high-fat/high-sugar foods. Child materials targeted the same dietary changes as their parents without caloric restriction. RESULTS: Changes over 1 year showed that treatment influenced targeted parent and child fruit and vegetable intake and high-fat/high-sugar intake, with the Increase Fruit and Vegetable group also decreasing their consumption of high-fat/high-sugar foods. Parents in the increased fruit and vegetable group showed significantly greater decreases in percentage of overweight than parents in the decreased high-fat/high-sugar group. DISCUSSION: These results suggest that focusing on increasing intake of healthy foods may be a useful approach for nutritional change in obese parents and their children

Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, KauferChristoffel K, and Dyer A. 2005. Two-year follow-up results for Hip-Hop to Health Jr.: A randomized controlled trial for overweight prevention in preschool minority children. Journal of Pediatrics 146:618-625.
Abstract: Objectives: To assess the impact of a culturally proficient dietary/physical activity intervention on changes in body mass index (BMI) (kg/m2). Study design: Randomized controlled trial (Hip-Hop to Health Jr.) conducted between September 1999 and June 2002 in 12 Head Start preschool programs in Chicago, Illinois. Results: Intervention children had significantly smaller increases in BMI compared with control children at 1-year follow-up, 0.06 vs 0.59 kg/m2; difference -0.53 kg/m2 (95% CI -0.91 to -0.14), P =. 01; and at 2-year follow-up, 0.54 vs 1.08 kg/m2; difference -0.54 kg/m2 (95% CI -0.98 to -0.10), P =. 02, with adjustment for baseline age and BMI. The only significant difference between intervention and control children in food intake/physical activity was the Year 1 difference in percent of calories from saturated fat, 11.6% vs 12.8% (P

=. 002). Conclusions: Hip-Hop to Health Jr. was effective in reducing subsequent increases in BMI in preschool children. This represents a promising approach to prevention of overweight among minority children in the preschool years. Copyright (copyright) 2005 Elsevier Inc. All rights reserved

Foster GD, Sherman S, Borradaile KE, Grundy KM, Vander Veur SS, Nachmani J, Karpyn A, Kumanyika S, and Shults J. 2008. A policy-based school intervention to prevent overweight and obesity. Pediatrics 121:e794-e802.
Abstract: BACKGROUND: The prevalence and seriousness of childhood obesity has prompted calls for broad public health solutions that reach beyond clinic settings. Schools are ideal settings for population-based interventions to address obesity. OBJECTIVE: The purpose of this work was to examine the effects of a multicomponent, School Nutrition Policy Initiative on the prevention of overweight (85.0th to 94.9th percentile) and obesity (> 95.0th percentile) among children in grades 4 through 6 over a 2-year period. METHODS: Participants were 1349 students in grades 4 through 6 from 10 schools in a US city in the Mid-Atlantic region with > or = 50% of students eligible for free or reduced-price meals. Schools were matched on school size and type of food service and randomly assigned to intervention or control. Students were assessed at baseline and again after 2 years. The School Nutrition Policy Initiative included the following components: school self-assessment, nutrition education, nutrition policy, social marketing, and parent outreach. RESULTS: The incidences of overweight and obesity after 2 years were primary outcomes. The prevalence and remission of overweight and obesity, BMI z score, total energy and fat intake, fruit and vegetable consumption, body dissatisfaction, and hours of activity and inactivity were secondary outcomes. The intervention resulted in a 50% reduction in the incidence of overweight. Significantly fewer children in the intervention schools (7.5%) than in the control schools (14.9%) became overweight after 2 years. The prevalence of overweight was lower in the intervention schools. No differences were observed in the incidence or prevalence of obesity or in the remission of overweight or obesity at 2 years. CONCLUSION: A multicomponent school-based intervention can be effective in preventing the development of overweight among children in grades 4 through 6 in urban public schools with a high proportion of children eligible for free and reduced-priced school meals

Giampaoli S, Poce A, Sciarra F, Lo Noce C, Dima F, Minoprio A, Santaquilani A, Caiola De Sanctis P, Volpe R, Menditto A, Menotti A, and Urbinati GC. 1997. Change in cardiovascular risk factors during a 10-year community intervention program. Acta Cardiol 52:411-422.
Abstract: The study describes changes in cardiovascular risk factors during 10 years of a community intervention program conducted in a rural area in Central Italy. Two areas were involved, one for treatment and one for reference. In 1983-84, 739 men and 859 women in the treatment area and 942 men and 1045 women in the control area, aged 20-69 years, were screened; total and HDL cholesterol, systolic and diastolic blood pressure, fasting blood glucose, smoking habit, weight and height were measured. Between 1983 and 1993 several intervention activities based on community medicine were carried out in the treatment area. They were based on interaction with the local socio-sanitary institutions and school system in order to influence individual persons, small groups and entire community. Major effort was addressed to mass health education, nutrition education, antismoking-propaganda and detection and treatment of hypertension, diabetes and hyperlipidemia. In 1993-96 a new independent sample was examined including 307 men and 305 women in the treatment area and 704 men and 748 women in the control area. Risk factor levels of base-line and of later examination were compared to assess the effectiveness of intervention. The results obtained were not as positive as expected: in men fasting blood glucose reduced of 3.4 mg/dl, diastolic blood pressure of 1.1 mm Hg and body mass index of 0.1 Kg/m2 in the treatment compared to the control area. HDL cholesterol increased of 0.4 mg/dl and prevalence of hypertensives under treatment increased of 15.6% in the treatment compared to the control area. In women body mass index decreased of 1.2 kg/m2, prevalence of smokers decreased of 6.6%, diastolic blood pressure decreased of 0.2 mm Hg in the treatment compared to the control area while the prevalence of hypertensives under treatment increased of 5%

Goetzel RZ, Baker KM, Short ME, Pei X, Ozminkowski RJ, Wang S, Bowen JD, Roemer EC, Craun BA, Tully KJ, Baase CM, DeJoy DM, and Wilson MG. 2009. First-year results of an obesity prevention program at The Dow Chemical Company. J Occup Environ Med 51:125-138.
Abstract: OBJECTIVE: To examine first-year results from a workplace environmental obesity prevention program at The Dow Chemical Company. METHODS: A quasi-experimental cohort study was conducted among employees at nine treatment worksites (n = 8013) who received environmental weight management interventions and three control worksites (n = 2269). Changes in employees' weight, body mass index (BMI), and other health risks were examined using chi2 and t-tests. RESULTS: After 1 year, a modest treatment effect was observed for weight and BMI largely because the control group subjects gained weight; however, no effect was observed for overweight and obesity prevalence. Other risk factors (tobacco use, high blood pressure, and systolic and diastolic blood pressure values) decreased significantly, although blood glucose (high risk

prevalence and values) increased. CONCLUSIONS: Environmental changes to the workplace can achieve modest improvements in employees' health risks, including weight and BMI measures, in 1 year

Gombosi RL, Olasin RM, and Bittle JL. 2007. Tioga County Fit for Life: A primary obesity prevention project. Clin Pediatr 46:592-600.
Abstract: Pediatric obesity, which has reached epidemic proportions in the United States in the past 10 years, translates directly into rising rates of adult obesity. This study assessed the impact of a school, family, community, and industry-based primary intervention project on the rates of overweight and obesity in a rural countywide cohort of children in grades kindergarten through 8. It included classroom education, student/family wellness booklets, point source healthy menus, occupational health analyses, and community health fairs. A 5-year longitudinal analysis of grade-specific rates of overweight and obesity of the participating children showed that overweight and obesity rates increased for all cohorts. Key elements contribute to increasing rates of pediatric obesity. Inadequate penetration of education/information dissemination and lag time represent 2 explanations for the lack of obesity reduction during the program implementation period. Strategies for successful engagement of multiple groups are essential to effectively reverse the pediatric obesity epidemic. (copyright) 2007 Sage Publications

Gortmaker SL, Cheung LWY, Peterson KE, Chomitz G, Cradle JH, Dart H, Fox MK, Bullock RB, Sobol AM, Colditz G, Field AE, and Laird N. 1999. Impact of a school-based interdisciplinary intervention on diet and physical activity among urban primary school children: Eat well and keep moving. Arch Pediatr Adolesc Med 153:975-983.
Abstract: Objective: To evaluate the impact of a school-based interdisciplinary health behavior intervention on diet and physical activity among children in grades 4 and 5. Design: A quasiexperimental field trial with 6 intervention and 8 matched control schools. Outcomes were assessed longitudinally using preintervention (fall 1995) and follow-up (spring 1997) student survey food frequency and activity measures and follow-up 24-hour recall measures of diet and activity. Change was also assessed using yearly repeated cross-sectional surveys of all grade 5 students from 1995 through 1997. Participants: Longitudinal data were collected from 479 students initially in grade 4 in Baltimore, Md, public schools; 91% were African American. Repeated 24-hour recall measures in 1997 were collected for a random subsample of 336 students. Cross-sectional survey data were collected from all grade 5 students in 1995, 1996, and 1997 (n = 2103). Intervention: The Eat Well and Keep Moving Program was taught by classroom teachers over 2 years in math, science, language arts, and social studies classes. Materials provided links to school food services and families and provided training and wellness programs for teachers and other staff members. Intervention materials focused on decreasing consumption of foods high in total and saturated fat and increasing fruit and vegetable intake, as well as reducing television viewing and increasing physical activity. Main Outcome Measures: Dietary intake and physical activity measured via repeated 24-hour recall were primary end points, with additional food frequency and activity measures. Results: The 24-hour recall measures indicated that, after controlling for baseline covariates, the percentages of total energy from fat and saturated fat were reduced among students in intervention compared with control schools (-1.4%; 95% confidence interval [CI], -2.8 to -0.04; P = .04 and -0.60%; 95% CI, -1.2 to -0.01; P = .05). There was an increase in fruit and vegetable intake (0.36 servings/4184 kJ; 95% CI, 0.10-0.62; P = .01), in vitamin C intake (8.8 mg/4184 kJ; 95% CI, 2.0-16; P = .01), and in fiber consumption (0.7 g/4184 kJ; 95% CI, 0.0-1.4; P = .05). Television viewing was marginally reduced (- 0.55 h/d; 95% CI, -1.04 to 0.04; P = .06). Analysis of longitudinal and repeated cross-sectional food frequency data indicated similar significant decreases in the percentages of total energy from fat and saturated fat. Conclusion: Evaluation of the Eat Well and Keep Moving Program indicates effectiveness in improving dietary intake of students and reducing television viewing

Graf C, Koch B, Falkowski G, Jouck S, Christ H, Staudenmaier K, Tokarski W, Gerber A, Predel HG, and Dordel S. 2008. School-based prevention: effects on obesity and physical performance after 4 years. Journal of sports sciences 26:987-994.
Abstract: Juvenile obesity is increasing worldwide. Preventive strategies are warranted. The school-based Children's Health Interventional Trial (the CHILT Project) combines health education and physical activity for children. The effect on obesity and physical performance was studied after four years in 12 primary schools compared with five control schools. Anthropometric data were recorded. Physical performance was measured by a coordination test for children (balancing backwards, one-legged obstacle jumping, lateral jumping, sideways movements) and a 6-min run (endurance). No difference in the prevalence and incidence of overweight and obesity was found between the intervention and control schools before and after the intervention. Remission of overweight was higher in the intervention schools (23.2 vs. 19.2%), but not significant. An increase in coordination related to lateral jumping and balancing backwards was apparent in the intervention schools (30.6, s = 10.8 vs. 26.1, s = 10.8, P = 0.005; 21.8, s = 11.8 vs. 19.4, s = 11.7, P = 0.007), and the increase in endurance performance tended to be higher in intervention schools (100.8, s = 122.7 vs. 92.8, s = 126.0, P = 0.055), adjusted for age, sex, baseline test result, and body mass index at final examination. Therefore, preventive

intervention in primary school offers the possibility to improve physical performance in children. The prevalence and incidence of obesity were not affected

Hivert MF, Langlois MF, Berard P, Cuerrier JP, and Carpentier AC. 2007. Preventionof weight gain in young adults through a seminar-based intervention program. Int J Obes 31:1262-1269.
Abstract: Objective: Prevention would be the ideal public health strategy to face the current obesity epidemic. Adoption of healthy lifestyles during the first years of college or university could prevent the onset of weight gain associated with this period of acquired independence and eventually decrease the incidence of obesity. Design: Randomized-controlled trial over a period of 2 years. The subjects received an educational/behavioral intervention (small group seminars) designed to help maintain a healthy lifestyle or no specific intervention (control group). Subjects: One-hundred and fifteen non-obese freshmen in a Faculty of Medicine. Measurements: Anthropometric measurements, physical activity level, fitness level, food intake and lipid profile were recorded at predetermined intervals. Results: The control group gained weight, whereas the intervention group lost a slight amount of weight over 2 years. The difference between the two groups was 1.3 kg at the end of the follow-up, the trend of weight gain differing between the two groups during the 2-year intervention period (P=0.04). There was no detectable difference in fitness, physical activity level or total caloric intake between the two groups during follow-up. However, plasma triglyceride levels increased in the control group and decreased in the intervention group (P=0.04). Conclusion: In this randomized-controlled trial, a small-group seminar educational/behavioral intervention successfully prevents weight gain in normal weight young healthy university students. Such small absolute changes in body composition and lipid profile, if maintained over a prolonged period, could result in significant long-term health benefits for the general population (ClinicalTrial.gov registration number: NCT00306449). (copyright) 2007 Nature Publishing Group All rights reserved

Howard BV, Manson JE, Stefanick ML, Beresford SA, Frank G, Jones B, Rodabough RJ, Snetselaar L, Thomson C, Tinker L, Vitolins M, and Prentice R. 2006. Low-fat dietary pattern and weight change over 7 years: The Women's Health Initiative Dietary Modification Trial. J Am Med Assoc 295:39-49.
Abstract: Context: Obesity in the United States has increased dramatically during the past several decades. There is debate about optimum calorie balance for prevention of weight gain, and proponents of some low-carbohydrate diet regimens have suggested that the increasing obesity may be attributed, in part, to low-fat, high-carbohydrate diets. Objectives: To report data on body weight in a long-term, low-fat diet trial for which the primary end points were breast and colorectal cancer and to examine the relationships between weight changes and changes in dietary components. Design, Setting, and Participants: Randomized intervention trial of 48 835 postmenopausal women in the United States who were of diverse backgrounds and ethnicities and participated in the Women's Health Initiative Dietary Modification Trial; 40% (19 541) were randomized to the intervention and 60% (29 294) to a control group. Study enrollment was between 1993 and 1998, and this analysis includes a mean follow-up of 7.5 years (through August 31, 2004). Interventions: The intervention included group and individual sessions to promote a decrease in fat intake and increases in vegetable, fruit, and grain consumption and did not include weight loss or caloric restriction goals. The control group received diet-related education materials. Main Outcome Measure: Change in body weight from baseline to follow-up. Results: Women in the intervention group lost weight in the first year (mean of 2.2 kg, P<.001) and maintained lower weight than control women during an average 7.5 years of follow-up (difference, 1.9 kg, P<.001 at 1 year and 0.4 kg, P=.01 at 7.5 years). No tendency toward weight gain was observed in intervention group women overall or when stratified by age, ethnicity, or body mass index. Weight loss was greatest among women in either group who decreased their percentage of energy from fat. A similar but lesser trend was observed with increases in vegetable and fruit servings, and a nonsignificant trend toward weight loss occurred with increasing intake of fiber. Conclusion: A low-fat eating pattern does not result in weight gain in postmenopausal women. (copyright)2006 American Medical Association. All rights reserved

James J, Thomas P, Cavan D, and Kerr D. 2004. Preventing childhood obesity by reducing consumption of carbonated drinks: cluster randomised controlled trial. BMJ 328:1237.
Abstract: OBJECTIVE: To determine if a school based educational programme aimed at reducing consumption of carbonated drinks can prevent excessive weight gain in children. DESIGN: Cluster randomised controlled trial. SETTING: Six primary schools in southwest England. PARTICIPANTS: 644 children aged 7-11 years. INTERVENTION: Focused educational programme on nutrition over one school year. MAIN OUTCOME MEASURES: Drink consumption and number of overweight and obese children. RESULTS: Consumption of carbonated drinks over three days decreased by 0.6 glasses (average glass size 250 ml) in the intervention group but increased by 0.2 glasses in the control group (mean difference 0.7, 95% confidence interval 0.1 to 1.3). At 12 months the percentage of overweight and obese children increased in the control group by 7.5%, compared with a decrease in the intervention group of 0.2% (mean difference 7.7%, 2.2% to 13.1%). CONCLUSION: A targeted, school based education programme produced a modest reduction in the

number of carbonated drinks consumed, which was associated with a reduction in the number of overweight and obese children

James J, Thomas P, and Kerr D. 2007. Preventing childhood obesity: two year follow-up results from the Christchurch obesity prevention programme in schools (CHOPPS). BMJ 335:762.
Abstract: OBJECTIVE: To assess the long term effects of an obesity prevention programme in schools. DESIGN: Longitudinal results after a cluster randomised controlled trial. SETTING: Schools in southwest England. PARTICIPANTS: Of the original sample of 644 children aged 7-11, 511 children were tracked and measurements were obtained from 434 children three years after baseline. INTERVENTION: The intervention was conducted over one school year, with four sessions of focused education promoting a healthy diet and discouraging the consumption of carbonated drinks. MAIN OUTCOME MEASURES: Anthropometric measures of height, weight, and waist circumference. Body mass index (BMI) converted to z scores (SD scores) and to centile values with growth reference curves. Waist circumference was also converted to z scores (SD scores). RESULTS: At three years after baseline the age and sex specific BMI z scores (SD scores) had increased in the control group by 0.10 (SD 0.53) but decreased in the intervention group by -0.01 (SD 0.58), with a mean difference of 0.10 (95% confidence interval -0.00 to 0.21, P=0.06). The prevalence of overweight increased in both the intervention and control group at three years and the significant difference between the groups seen at 12 months was no longer evident. The BMI increased in the control group by 2.14 (SD 1.64) and the intervention group by 1.88 (SD 1.71), with mean difference of 0.26 (-0.07 to 0.58, P= 0.12). The waist circumference increased in both groups after three years with a mean difference of 0.09 (-0.06 to 0.26, P=0.25). CONCLUSIONS: These longitudinal results show that after a simple year long intervention the difference in prevalence of overweight in children seen at 12 months was not sustained at three years

Jeffery RW and French SA. 1999. Preventing weight gain in adults: The pound of prevention study. Am J Public Health 89:747-751.
Abstract: Objectives. This study examined whether weight gain with age could be prevented through the use of a low-intensity intervention. Methods. Participants, 228 men and 998 women recruited from diverse sources, were randomized to one of the following groups: (1) no-contact control, (2) education through monthly newsletters, or (3) education plus incentives for participation. All participants were weighed and completed questionnaires about behaviors and attitudes related to weight at baseline and annually for 3 years thereafter. Results. Individuals in intervention groups reported favorable changes over time in frequency of weighing and healthy dieting practices relative to those in the control group. These behavior changes were in turn related to a reduced rate of weight gain over time. However, weight gain over 3 years did not differ significantly by treatment group. Conclusions. This low-intensity educational approach to weight gain prevention sustained interest over a lengthy time period and was associated positively with behavior change, but it was not strong enough to significantly reduce weight gain with age

Jiang J, Xia X, Greiner T, Wu G, Lian G, and Rosenqvist U. 2007. The effects of a 3-year obesity intervention in schoolchildren in Beijing. Child: care, health and development 33:641-646.
Abstract: BACKGROUND: Childhood obesity has become a health problem in urban areas in China. Intervention to reduce childhood obesity should be of high priority. School-based intervention programmes are needed to deal with the growing prevalence of childhood obesity in China. METHODS: Five primary schools were selected randomly for this study in the Beijing urban area in China; two were allocated to the intervention group and three to the control group. A total of 2425 children (1029 children in intervention schools and 1396 children in control schools) took part in the study for 3 years. In the intervention group, children and their parents were involved in a programme of nutrition education and physical activity. Control school students followed their usual health and physical education curriculum with no extra intervention. RESULTS: After the 3-year intervention, the prevalence of overweight and obesity were significantly lower in the intervention schools than in the control schools (overweight: 9.8% vs. 14.4%, P < 0.01; obesity: 7.9% vs. 13.3%, P < 0.01). The prevalence of overweight and obesity decreased by 26.3% and 32.5% in intervention schools respectively after intervention. The prevalence of overweight and obesity increased in control schools. There was also significant difference in body mass index between intervention and control schools (18.2 +/- 2.6 vs. 20.3 +/- 3.4, P < 0.01) after intervention. More non-obese children became obese in the control schools (7.0%) than in the intervention schools (2.4%) at end line (P < 0.01). Among the children who were obese at baseline, 49.2% remained obese at end line in intervention schools while 61.9% remained obese in control schools (P < 0.01). CONCLUSIONS: Our study showed that an intervention programme could be feasible in schools in Beijing, China. The prevalence of overweight and obesity was reduced in schoolchildren in Beijing through an intervention focused on nutrition education and physical activity. Overweight and obesity children as well as normal weight children and their parents should be involved in such an intervention programme

Kramer MS, Matush L, Vanilovich I, Platt RW, Bogdanovich N, Sevkovskaya Z, Dzikovich I, Shishko G, Collet JP, Martin RM, Smith GD, Gillman MW, Chalmers B, Hodnett E, and Shapiro S. 2009. A randomized breast-feeding promotion intervention did not reduce child obesity in Belarus. The Journal of nutrition 139:417S-421S.
Abstract: The evidence that breast-feeding protects against obesity is based on observational studies, with potential for confounding and selection bias. This article summarizes a previously published study in which we assessed whether an intervention designed to promote exclusive and prolonged breast-feeding affects children's height, weight, adiposity, and blood pressure (BP) at age 6.5 y. The Promotion of Breastfeeding Intervention Trial (PROBIT) is a cluster-randomized trial of a breast-feeding promotion intervention based on the WHO/UNICEF Baby-Friendly Hospital Initiative. A total of 17,046 healthy breast-fed infants were enrolled from 31 Belarussian maternity hospitals and affiliated clinics, of whom 13,889 (81.5%) were followed up at 6.5 y with duplicate measurements of height, weight, waist circumference, triceps and subscapular skinfold thicknesses, systolic and diastolic BP. Analysis was based on intention to treat, with statistical adjustment for clustering within hospitals/clinics to permit inferences at the individual level. The experimental intervention led to a large increase in exclusive breast-feeding at 3 mo (43.3% vs. 6.4%, $P < 0.001$) and a significantly higher prevalence of any breast-feeding throughout infancy. No significant intervention effects were observed on height, BMI, adiposity measures, or BP. The breast-feeding promotion intervention resulted in substantial increases in the duration and exclusivity of breast-feeding yet did not reduce measures of adiposity at age 6.5 y. Previous reports of protective effects against obesity may reflect uncontrolled bias caused by confounding and selection

Kuller LH, Simkin-Silverman LR, Wing RR, Meilahn EN, and Ives DG. 2001. Women's healthy lifestyle project: A randomized clinical trial: Results at 54 months. Circulation 103:32-37.
Abstract: Background - The Women's Healthy Lifestyle Project Clinical Trial tested the hypothesis that reducing saturated fat and cholesterol consumption and preventing weight gain by decreased caloric and fat intake and increased physical activity would prevent the rise in LDL cholesterol and weight gain in women during perimenopause to postmenopause. Methods and Results - There were 275 premenopausal women randomized into the assessment only group and 260 women into the intervention group. The mean age of participants at baseline was 47 years, and 92% of the women were white. The mean LDL cholesterol was 115 mg/dL at baseline, and mean body mass index was 25 kg/m2. The follow-up through 54 months was excellent. By 54 months, 35% of the women had become postmenopausal. At the 54-month examination, there was a 3.5-mg/dL increase in LDL cholesterol in the intervention group and an 8.9-mg/dL increase in the assessment-only group (P=0.009). Weight decreased 0.2 lb in the intervention and increased 5.2 lb in the assessment-only group (P=0.000). Triglycerides and glucose also increased significantly more in the assessment-only group than in the intervention group. Waist circumference decreased 2.9 cm in the intervention compared with 0.5 cm in the assessment-only group (P=0.000). Conclusions - The trial was successful in reducing the rise in LDL cholesterol during perimenopause to postmenopause but could not completely eliminate the rise in LDL cholesterol. The trial was also successful in preventing the increase in weight from premenopause to perimenopause to postmenopause. The difference in LDL cholesterol between the assessment and intervention groups was most pronounced among postmenopausal women and occurred among hormone users and nonusers

Lamb SE, Bartlett HP, Ashley A, and Bird W. 2002. Can lay-led walking programmes increase physical activity in middle aged adults? A randomised controlled trial. J Epidemiol Community Health 56:246-252.
Abstract: Study objective: To compare health walks, a community based lay-led walking scheme versus advice only on physical activity and cardiovascular health status in middle aged adults. Design: Randomised controlled trial with one year follow up. Physical activity was measured by questionnaire. Other measures included attitudes to exercise, body mass index, cholesterol, aerobic capacity, and blood pressure. Setting: Primary care and community. Participants: 260 men and women aged 40-70 years, taking less than 120 minutes of moderate intensity activity per week. Main results: Seventy three per cent of people completed the trial. Of these, the proportion increasing their activity above 120 minutes of moderate intensity activity per week was 22.6% in the advice only and 35.7% in the health walks group at 12 months (between group difference = 13% (95% Cl 0.003% to 25.9%) p = 0.05). Intention to treat analysis, using the last known value for missing cases, demonstrated smaller differences between the groups (between group difference = 6% (95% Cl -5% to 16.4%)) with the trend in favour of health walks. There were improvements in the total time spent and number of occasions of moderate intensity activity, and aerobic capacity, but no statistically significant differences between the groups. Other cardiovascular risk factors remained unchanged. Conclusions: There were no significant between group differences in self reported physical activity at 12 month follow up when the analysis was by intention to treat. In people who completed the trial, health walks was more effective than giving advice only in increasing moderate intensity activity above 120 minutes per week

Lawton BA, Rose SD, Elley CR, Dowell AC, Fenton A, and Moyes SA. 2008. Exercise on prescription for women aged 40-74 recruited through primary care: two year randomised controlled trial. BMJ 337.

Levine MD, Klem ML, Kalarchian MA, Wing RR, Weissfeld L, Li Q, and Marcus MD. 2007. Weight gain prevention among women. Obesity 15:1267-1277.
Abstract: Objective: Women 25 to 45 years old are at risk for weight gain and future obesity. This trial was designed to evaluate the efficacy of two interventions relative to a control group in preventing weight gain among normal or overweight women and to identify demographic, behavioral, and psychosocial factors related to weight gain prevention. Research Methods and Procedures: Healthy women (N = 284), ages 25 to 44, with BMI < 30 were randomized to one of three intervention conditions: a clinic-based group, a correspondence course, or an information-only control. Intervention was provided over 2 years, with a follow-up at Year 3. BMI and factors related to eating and weight were assessed yearly. Results: Over the 3-year study period, 40% (n = 114) of the women remained at or below baseline body weight ((plus or minus)2 lbs), and 60% gained weight (>2 lbs). Intervention had no effect on weight over time. Independently of intervention, women who were older, not actively dieting to lose weight, and who reported less perceived hunger at baseline were more likely to be successful at weight maintenance. Weight maintenance also was associated with increasing dietary restraint (conscious thoughts and purposeful behaviors to control calorie intake) and decreasing dietary disinhibition (the tendency to lose control over eating) over time. Discussion: This study raises concern about the feasibility and efficacy of weight gain prevention interventions because most women were interested in weight loss, rather than weight gain prevention, and the interventions had no effect on weight stability. Novel approaches to the prevention of weight gain are needed. Copyright (copyright) 2007 NAASO

Lionis C, Kafatos A, Vlachonikolis J, Vakaki M, Tzortzi M, and Petraki A. 1991. The effects of a health education intervention program among Cretan adolescents. Prev Med 20:685-699.
Abstract: Background. An educational intervention program for the prevention of cardiovascular disease among 171 Cretan school students (13- and 14-year- olds) is assessed. Three schools from the province of Agios Vassilios acted as the intervention group while two schools from a neighboring province (Amari) formed the control group. Methods. Variables measured included: systolic and diastolic blood pressures, body mass index, triceps skinfold thickness, serum total and high-density lipoprotein cholesterol, triglycerides, and smoking habits. The intervention, based upon social learning theory, consisted of 10 sessions of theoretical and practical instruction on health issues in the classroom, supplemented with discussion, in the classroom, of the issues raised by different sessions. Results. At the end of 1 academic year of intervention the results showed, after adjusting for age, sex, baseline value, height, and weight, an increase in total serum cholesterol of 0.70 mg/dl in the intervention group and 17.91 mg/dl in the control group (P < 0.0001). Diastolic blood pressure (fourth phase) decreased by 2.95 mm Hg in the intervention group and by 0.48 mm Hg in the control group (P < 0.05). Similar changes were observed in the body mass index (P < 0.05). The proportion of school children starting smoking was significantly lower in the intervention group (6%) than in the control (20%) (P < 0.01). The results indicate that this health education program in schools is effective in decreasing some of the major CVD risk factors. The long-term effect remains to be evaluated

Lombard CB, Deeks AA, Ball K, Jolley D, and Teede HJ. 2009. Weight, physical activity and dietary behavior change in young mothers: short term results of the HeLP-her cluster randomized controlled trial. Nutr J 8:17.
Abstract: BACKGROUND: Preventing weight gain rather than treating established obesity is an important economic and public health response to the rapidly increasing rates of obesity worldwide. Treatment of established obesity is complex and costly requiring multiple resources. Preventing weight gain potentially requires fewer resources to reach broad population groups, yet there is little evidence for successful interventions to preventweight gain in the community. Women with children are an important target group because of high rates of weight gain and the potential to influence the health behaviors in family members. METHODS: The aim of this cluster randomized controlled trial was to evaluate the short term effect of a community-based self-management intervention to preventweight gain. Two hundred and fifty mothers of young children (mean age 40 years +/- 4.5, BMI 27.9 kg/m2 +/- 5.6) were recruited from the community in Melbourne, Australia. The intervention group (n = 127) attended four interactive group sessions over 4 months, held in 12 local primary schools in 2006, and was compared to a group (n = 123) receiving a single, non-interactive, health education session. Data collection included self-reported weight (both groups), measured weight (intervention only), self-efficacy, dietary intake and physical activity. RESULTS: Mean measured weight decreased significantly in the intervention group (-0.78 kg 95% CI; -1.22 to -0.34, p < 0.001). Comparing groups using self-reported weight, both the intervention and comparison groups decreased weight, -0.75 kg (95% CI; -1.57 to 0.07, p = 0.07) and -0.72 kg (95% CI; -1.59 to 0.14 p = 0.10) respectively with no significant difference between groups (-0.03 kg, 95% CI; -1.32 to 1.26, p = 0.95). More women lost or maintained weight in the intervention group. The intervention group tended to have the greatest effect in those who were overweight at baseline and in those who weighed themselves regularly. Intervention women who

rarely self-weighed gained weight (+0.07 kg) and regular self-weighers lost weight (-1.66 kg) a difference of -1.73 kg (95% CI; -3.35 to -0.11 p = 0.04). The intervention reported increased physical activity although the difference between groups did not reach significance. Both groups reported replacing high fat foods with low fat alternatives and self-efficacy deteriorated in the comparison group only. CONCLUSION: Both a single health education session and interactive behavioral intervention will result in a similar weight loss in the short term, although more participants in the interactive intervention lost or maintained weight. There were small non-significant changes to physical activity and changes to fat intake specifically replacing high fat foods with low fat alternatives such as fruit and vegetables. Self-monitoring appears to enhance weight loss when part of an intervention. TRIAL REGISTRATION: ACTRN12608000110381

Luepker RV, Perry CL, McKinlay SM, Nader PR, Parcel GS, Stone EJ, Webber LS, Elder JP, Feldman HA, Johnson CC, Kelder SH, and Wu M. 1996. Outcomes of a field trial to improve children's dietary patterns and physical activity: The Child and Adolescent Trial for Cardiovascular Health (CATCH). J Am Med Assoc 275:768-776.
Abstract: Objective. - To assess the outcomes of health behavior interventions, focusing on the elementary school environment, classroom curricula, and home programs, for the primary prevention of cardiovascular disease. Design. - A randomized, controlled field trial at four sites with 56 intervention and 40 control elementary schools. Outcomes were assessed using prerandomization measures (fall 1991) and follow-up measures (spring 1994). Participants. - A total of 5106 initially third-grade students from ethnically diverse backgrounds in public schools located in California, Louisiana, Minnesota, and Texas. Intervention. - Twenty-eight schools participated in a third- grade through fifth-grade intervention including school food service modifications, enhanced physical education (PE), and classroom health curricula. Twenty-eight additional schools received these components plus family education. Main Outcome Measures. - At the school level, the two primary end points were changes in the fat content of food service lunch offerings and the amount of moderate-to-vigorous physical activity in the PE programs. At the level of the individual student, serum cholesterol change was the primary end point and was used for power calculations for the study. Individual level secondary end points included psychosocial factors, recall measures of eating and physical activity patterns, and other physiologic measures. Results. - In intervention school lunches, the percentage of energy intake from fat fell significantly more (from 38.7% to 31.9%) than in control lunches (from 38.9% to 36.2%)(P<.001). The intensity of physical activity in PE classes during the Child and Adolescent Trial for Cardiovascular Health (CATCH) intervention increased significantly in the intervention schools compared with the control schools (P<.02). Self-reported daily energy intake from fat among students in the intervention schools was significantly reduced (from 32.7% to 30.3%) compared with that among students in the control schools (from 32.6% to 32.2%) (P<.001). Intervention students reported significantly more daily vigorous activity than controls (58.6 minutes vs 46.5 minutes; P<.003). Blood pressure, body size, add cholesterol measures did not differ significantly between treatment groups. No evidence of deleterious effects of this intervention on growth or development was observed. Conclusion. - The CATCH intervention was able to modify the fat content of school lunches, increase moderate-to-vigorous physical activity in PE, and improve eating and physical activity behaviors in children during 3 school years

Manios Y, Kafatos A, and Mamalakis G. 1998. The effects of a health education intervention initiated at first grade over a 3 year period: Physical activity and fitness indices. Health Educ Res 13:593-606.
Abstract: A health education intervention was carried out for three consecutive years on primary school Cretan children. Baseline measures were obtained from 962 pupils (509 boys and 453 girls) registered in first grade in 1992. The health education intervention programme was directed at both the children of the intervention group and their parents, and has a projected duration of 6 years. After the completion of the 3 years of intervention and while pupils were in fourth grade, measures were obtained for evaluation purposes on a random subsample of 393 pupils of the original cohort. Statistically greater improvements in the intervention, as opposed to the control group, were observed for both children's and parents' health knowledge, and children's standing broad jump, sit-ups (SUP), sit-and-reach, handgrip and endurance run test (ERT). Furthermore, time spent on moderate to vigorous physical activities out of school significantly increased for intervention group children compared to the control group. Statistically smaller increases in the intervention as opposed to the control group were observed in suprailiac skinfold and body mass index. The degree of improvement in both SUP and ERT related positively to parent's baseline physical activity score. Finally, the parental attitude of health-related hedonism related negatively to SUP improvement

Manios Y, Moschandreas J, Hatzis C, and Kafatos A. 2002. Health and nutrition education in primary schools of Crete: Changes in chronic disease risk factors following a 6-year intervention programme. Br J Nutr 88:315-324.
Abstract: The effectiveness of a health and nutrition education programme, in changing certain chronic disease risk factors, was assessed after the 6 years intervention period was completed. The school-based intervention

programme was applied to all children registered in the first grade (age 5.5-6.5 years) in 1992 in two countries of Crete, while the children from a third county served as a control group. In order to assess the effectiveness of the intervention, a variety of biological and behavioural parameters were measured before and following completion of the intervention in a randomly selected school-based sample of 602 intervention group (IG) and 444 control group (CG) pupils. At the end of the 6-year period, it was found that biochemical indices generally improved significantly more in the IG compared with the CG (mean change for IG v. CG was -0.27 v. -0.12 mmol/l for total cholesterol (TC); -0.07 v. +0.24 for TC:HDL and -0.13 v. +0.14 for LDL:HDL). Similarly, the changes observed in the anthropometric variables in the two groups were in favour of the IG (+3.68 v. +4.28 kg/m2 for BMI; +2.97 v. +4.47 mm for biceps skinfold). Total energy intake and consumption of total fat and saturated fat increased significantly less in the IG compared with the CG (+747.7 v. 1534.7 kJ (+178.7 v. +366.8 kcal); +5.9 v. +18.8 and +0.8 v. +5.1 g respectively), while time devoted to leisure time physical activity and cardiovascular run test performance increased significantly more in the IG (+281 v. +174 min/week and +2.5 v. +1.2 stages respectively). The findings of the present study underline the importance of such programmes in health promotion and disease prevention. Although the long-term effects of these programmes can only be assessed by tracking this population through to adolescence and adulthood, these programmes seem to have the potential to lead to a healthier lifestyle and thus a reduction in risk factor levels

Miller SL, Reber RJ, and Chapman-Novakofski K. 2001. Prevalence of CVD risk factors and impact of a two-year education program for premenopausal women. Women's Health Issues 11:486-493.
Abstract: Indicators of cardiovascular disease risk in premenopausal women before, during, and after a 2-year educational intervention measured prevalence of risk and program effectiveness. Women (n = 277) were assigned to either treatment/education (n = 174) or control (n = 103) group. Many had at least one cardiovascular disease risk factor: high BMI (n = 123); high-fat diet (n = 160); and/or high body fat percent (n = 136). The treatment group was significant for change in calories from fat (P < .01). This study shows that premenopausal women have cardiovascular disease risks that should be addressed, and that nutrition education can successfully change dietary behavior. Copyright (copyright) 2001 Elsevier Science Inc

Muckelbauer R, Libuda L, Clausen K, Toschke AM, Reinehr T, and Kersting M. 2009. Promotion and provision of drinking water in schools for overweight prevention: Randomized, controlled cluster trial. Pediatrics 123:e661-e667.
Abstract: OBJECTIVE. The study tested whether a combined environmental and educational intervention solely promoting water consumption was effective in preventing overweight among children in elementary school. METHODS. The participants in this randomized, controlled cluster trial were second- and third-graders from 32 elementary schools in socially deprived areas of 2 German cities. Water fountains were installed and teachers presented 4 prepared classroom lessons in the intervention group schools (N = 17) to promote water consumption. Control group schools (N = 15) did not receive any intervention. The prevalence of overweight (defined according to the International Obesity Task Force criteria), BMI SD scores, and beverage consumption (in glasses per day; 1 glass was defined as 200 mL) self-reported in 24-hour recall questionnaires, were determined before (baseline) and after the intervention. In addition, the water flow of the fountains was measured during the intervention period of 1 school year (August 2006 to June 2007). RESULTS. Data on 2950 children (intervention group: N = 1641; control group: N = 1309; age, mean (plus or minus) SD: 8.3 (plus or minus) 0.7 years) were analyzed. After the intervention, the risk of overweight was reduced by 31% in the intervention group, compared with the control group, with adjustment for baseline prevalence of overweight and clustering according to school. Changes in BMI SD scores did not differ between the intervention group and the control group. Water consumption after the intervention was 1.1 glasses per day greater in the intervention group. No intervention effect on juice and soft drink consumption was found. Daily water flow of the fountains indicated lasting use during the entire intervention period, but to varying extent. CONCLUSION. Our environmental and educational, school-based intervention proved to be effective in the prevention of overweight among children in elementary school, even in a population from socially deprived areas. Copyright (copyright) 2009 by the American Academy of Pediatrics

Muller MJ, Asbeckl I, Mast M, Langnase K, and Grund A. 2001. Prevention of obesity - More than an intention. Concept and first results of the kiel obesity prevention study (KOPS). Int J Obes 25:S66-S74.
Abstract: OBJECTIVE: Obesity prevention is necessary to address the steady rise in the prevalence of obesity. Although all experts agree that obesity prevention has high priority there is almost no research in this area. The effectiveness of different intervention strategies is not well documented. There is also no structured framework for obesity prevention. DESIGN: Based on (i) our current and limited knowledge and (ii) the idea that prevention of childhood obesity is an effective treatment of adult obesity, the Kiel Obesity Prevention Study (KOPS) was started in 1996. Concept, intervention strategies and first results of KOPS are reported in this paper. KOPS is an ongoing 8 y follow-up study. We first enrolled a large scale cohort of 5 to 7-y-old children, providing sufficient baseline data. KOPS allows further analyses of the role of individual risk factors as well as

of long-term effectiveness of different intervention strategies. RESULTS: From 1996 to 1999 a representative group of 2440 5 to 7-y-old children was recruited (ie 30.2% of the total population of 5 to 7-y-old children examined by the school physicians) and a full data set was obtained from 1640 children. Of the children, 340 (20.7%) were considered as overweight and obese, 1108 children (67.6%) were normal weight, and underweight was found in 192 children (11.7%). Of the normal-weight children, 31% or 346 (21.1 % of the total population) were considered to have a risk of becoming obese. Cross-sectional data provided evidence that (i) there is an inverse social gradient in childhood overweight as well as health-related behaviours and (ii) parental fatness had a strong influence on childhood overweight. We observed considerable changes in health-related behaviours within 1 y after combined 'school-' and 'family-based' interventions. Interventions aimed to improve health-related behaviours had significant effects on the age-dependent increases in median triceps skinfolds of the whole group (from 10.9 to 11.3 mm in 'intervention schools' vs from 10.7 to 1 3.0 mm in 'control schools', P < 0.01) as well as in percentage fat mass of overweight children (increase by 3.6 vs 0.4% per year without and with intervention, respectively; P < 0.05). CONCLUSION: First results of KOPS are promising. Besides health promotion, a better school education and social support seem to be promising strategies for future interventions

Nader PR, Stone EJ, Lytle LA, Perry CL, Osganian SK, Kelder S, Webber LS, Elder JP, Montgomery D, Feldman HA, Wu M, Johnson C, Parcel GS, and Luepker RV. 1999. Three-year maintenance of improved diet and physical activity: The CATCH cohort. Arch Pediatr Adolesc Med 153:695-704.
Abstract: Objective: To assess differences through grade 8 in diet, physical activity, and related health indicators of students who participated in the Child and Adolescent Trial for Cardiovascular Health (CATCH) school and family intervention from grades 3 through 5. Design: Follow-up of the 4- center, randomized, controlled field trial with 56 intervention and 40 control elementary schools. Participants: We studied 3714 (73%) of the initial CATCH cohort of 5106 students from ethnically diverse backgrounds in California, Louisiana, Minnesota, and Texas at grades 6, 7, and 8. Results: Self-reported daily energy intake from fat at baseline was virtually identical in the control (32.7%) and intervention (32.6%) groups. At grade 5, the intake for controls remained at 32.2%, while the intake for the intervention group declined to 30.3% (P<.001). At grade 8, the between-group differential was maintained (31.6% vs 30.6%, P = .01). Intervention students maintained significantly higher self-reported daily vigorous activity than control students (P = .001), although the difference declined from 13.6 minutes in grade 5 to 11.2, 10.8, and 8.8 minutes in grades 6, 7, and 8, respectively. Significant differences in favor of the intervention students also persisted at grade 8 for dietary knowledge and dietary intentions, but not for social support for physical activity. No impact on smoking behavior or stages of contemplating smoking was detected at grade 8. No significant differences were noted among physiologic indicators of body mass index, blood pressure, or serum lipid and cholesterol levels. Conclusion: The original CATCH results demonstrated that school-level interventions could modify school lunch and school physical education programs as well as influence student behaviors. This 3-year follow-up without further intervention suggests that the behavioral changes initiated during the elementary school years persisted to early adolescence for self-reported dietary and physical activity behaviors

Obarzanek E, Kimm SYS, Barton BA, Van Horn L, Kwiterovich J, Simons-Morton DG, Hunsberger SA, Lasser NL, Robson AM, Franklin J, Lauer RM, Stevens VJ, Friedman LA, Dorgan JF, and Greenlick MR. 2001. Long-term safety and efficacy of a cholesterol-lowering diet in children with elevated low-density lipoprotein cholesterol: Seven-year results of the dietary intervention study in children (DISC). Pediatrics 107:256-264.
Abstract: Objective. Diets reduced in fat and cholesterol are recommended for children over 2 years of age, yet long-term safety and efficacy are unknown. This study tests the long-term efficacy and safety of a cholesterol-lowering dietary intervention in children. Methods. Six hundred sixty-three children 8 to 10 years of age with elevated low-density lipoprotein cholesterol (LDL-C) were randomized to a dietary intervention or usual care group, with a mean of 7.4 years' follow-up. The dietary behavioral intervention promoted adherence to a diet with 28% of energy from total fat, <8% from saturated fat, up to 9% from polyunsaturated fat, and <75 mg/1000 kcal cholesterol per day. Serum LDL-C, height, and serum ferritin were primary efficacy and safety outcomes. Results. Reductions in dietary total fat, saturated fat, and cholesterol were greater in the intervention than in the usual care group throughout the intervention period. At 1 year, 3 years, and at the last visit, the intervention compared with the usual care group had 4.8 mg/dL (.13 mmol/L), 3.3 mg/dL (.09 mmol/L), and 2.0 mg/dL (.05 mmol/L) lower LDL-C, respectively. There were no differences at any data collection point in height or serum ferritin or any differences in an adverse direction in red blood cell folate, serum retinol and zinc, sexual maturation, or body mass index. Conclusion. Dietary fat modification can be achieved and safely sustained in actively growing children with elevated LDL-C, and elevated LDL-C levels can be improved significantly up to 3 years. Changes in the usual care group's diet suggest that pediatric practices and societal and environmental forces are having positive public health effects on dietary behavior during adolescence

Reilly JJ, Kelly L, Montgomery C, Williamson A, Fisher A, McColl JH, Lo CR, Paton JY, and Grant S. 2006. Physical activity to prevent obesity in young children: cluster randomised controlled trial. BMJ 333:1041.
Abstract: OBJECTIVE: To assess whether a physical activity intervention reduces body mass index in young children. DESIGN: Cluster randomised controlled single blinded trial over 12 months. SETTING: Thirty six nurseries in Glasgow, Scotland. PARTICIPANTS: 545 children in their preschool year, mean age 4.2 years (SD 0.2) at baseline. INTERVENTION: Enhanced physical activity programme in nursery (three 30 minute sessions a week over 24 weeks) plus home based health education aimed at increasing physical activity through play and reducing sedentary behaviour. MAIN OUTCOME MEASURE: Body mass index, expressed as a standard deviation score relative to UK 1990 reference data. Secondary measures were objectively measured physical activity and sedentary behaviour; fundamental movement skills; and evaluation of the process. RESULTS: Group allocation had no significant effect on the primary outcome measure at six and 12 months or on measures of physical activity and sedentary behaviour by accelerometry. Children in the intervention group had significantly higher performance in movement skills tests than control children at six month follow-up (P=0.0027; 95% confidence interval 0.3 to 1.3) after adjustment for sex and baseline performance. CONCLUSIONS: Physical activity can significantly improve motor skills but did not reduce body mass index in young children in this trial. TRIAL REGISTRATION: Current Controlled Trials ISRCTN36363490

Resnicow K, Cohn L, Reinhardt J, Cross D, Futterman R, Kirschner E, Wynder EL, and Allegrante JP. 1992. A three-year evaluation of the know your body program in inner-city schoolchildren. Health Educ Q 19:463-480.
Abstract: The impact of the Know Your Body (KYB) comprehensive school health education program was evaluated in a sample of first through sixth-grade students from New York City, using two analytic strategies: a longitudinal cohort and a "posttest only" cohort. In both cohorts, program impact was examined between condition (i.e., KYB vs. no-treatment comparison group) as well as within condition (i.e., low, moderate, and high student exposure). Students in the longitudinal cohort (n = 1,209) who were exposed to high implementation teachers had significantly (p < .05) lower total plasma cholesterol and systolic blood pressure at 3-year posttest than comparison students. Students in the posttest only cohort (n = 3,066) who had high implementation teachers showed significantly (p < .05) lower total plasma cholesterol, systolic blood pressure, self-reported intake of meat and desserts, as well as higher health knowledge and self-reported intake of "heart healthy" foods and vegetables than comparison students. In both cohorts, program effects for several outcome variables were linearly related to level of student exposure to the curriculum, suggesting a dose-response effect. While several methodologic limitations may have influenced study outcomes, these data nonetheless appear to confirm that the KYB program can have a significant positive impact on the knowledge, behavior, and selected risk factors of students in primary grades and that efforts to disseminate and evaluate school health education programs should include strategies to monitor and enhance teacher implementation

Sahota P, Rudolf MC, Dixey R, Hill AJ, Barth JH, and Cade J. 2001. Randomised controlled trial of primary school based intervention to reduce risk factors for obesity. BMJ 323:1029-1032.
Abstract: OBJECTIVE: To assess if a school based intervention was effective in reducing risk factors for obesity. DESIGN: Group randomised controlled trial. SETTING: 10 primary schools in Leeds. PARTICIPANTS: 634 children aged 7-11 years. INTERVENTION: Teacher training, modification of school meals, and the development of school action plans targeting the curriculum, physical education, tuck shops, and playground activities. MAIN OUTCOME MEASURES: Body mass index, diet, physical activity, and psychological state. RESULTS: Vegetable consumption by 24 hour recall was higher in children in the intervention group than the control group (weighted mean difference 0.3 portions/day, 95% confidence interval 0.2 to 0.4), representing a difference equivalent to 50% of baseline consumption. Fruit consumption was lower in obese children in the intervention group (-1.0, -1.8 to -0.2) than those in the control group. The three day diary showed higher consumption of high sugar foods (0.8, 0.1 to 1.6)) among overweight children in the intervention group than the control group. Sedentary behaviour was higher in overweight children in the intervention group (0.3, 0.0 to 0.7). Global self worth was higher in obese children in the intervention group (0.3, 0.3 to 0.6). There was no difference in body mass index, other psychological measures, or dieting behaviour between the groups. Focus groups indicated higher levels of self reported behaviour change, understanding, and knowledge among children who had received the intervention. CONCLUSION: Although it was successful in producing changes at school level, the programme had little effect on children's behaviour other than a modest increase in consumption of vegetables

Sallis JF, McKenzie TL, Alcaraz JE, Kolody B, Hovell MF, and Nader PR. 1993. Project SPARK. Effects of physical education on adiposity in childdren. ANN NEW YORK ACAD SCI 699:127-136.
Abstract: Project SPARK evaluates multiple effects of a health-related physical education (PE) program for elementary school students. Seven schools were randomly assigned to one of three conditions: usual PE or control, trained classroom teachers, or PE specialists. The intervention was implemented throughout the fourth and fifth grades. Data are available from one cohort of 550 children who were measured in the fall and spring

of both grades. Adiposity was assessed by triceps and calf skinfolds, and body mass index (BMI) was also measured. Data at each measurement point were analyzed by ANOVAs, covarying for baseline values. At no measurement point were there significant group differences in total skinfold. At both fifth grade measurement points for boys and girls, however, there was a trend for the control group to have higher skinfold values than the two intervention groups. At the final measure, the difference between the highest and lowest groups was about 3 mm for girls and 2 mm for boys. BMIs were significantly lower at some measurement points for boys and girls, but this could be due to increased lean body mass in intervention students. After two years, there was a trend for the children exposed to the PE intervention to have lower levels of body fat, but the differences were not significant

Sallis JF, McKenzie TL, Conway TL, Elder JP, Prochaska JJ, Brown M, Zive MM, Marshall SJ, and Alcaraz JE. 2003. Environmental interventions for eating and physical activity: A randomized controlled trial in middle schools. Am J Prev Med 24:209-217.
Abstract: Background: Our objective was to evaluate the effects of environmental, policy, and social marketing interventions on physical activity and fat intake of middle school students on campus. Design: Twenty-four middle schools were randomly assigned to intervention or control conditions. Baseline measures were collected in spring 1997, and interventions were conducted during the 1997-1998 and 1998-1999 school years. Setting/participants: The schools had mean enrollments of 1109, with 44.5% nonwhite students. Intervention: Over 2 years, physical activity interventions were designed to increase physical activity in physical education classes and throughout the school day. Nutrition interventions were designed to provide and market low-fat foods at all school food sources, including cafeteria breakfasts and lunches, a la carte sources, school stores, and bag lunches. School staff and students were engaged in policy change efforts, but there was no classroom health education. Main outcome measures: Primary outcomes were measured by direct observation and existing records. Results: Randomized regression models (N =24 schools) revealed a significant intervention effect for physical activity for the total group ($p <0.009$) and boys ($p <0.001$), but not girls ($p <0.40$). The intervention was not effective for total fat ($p <0.91$) or saturated fat ($p <0.79$). Survey data indicated that the interventions reduced reported body mass index for boys ($p <0.05$). Conclusions: Environmental and policy interventions were effective in increasing physical activity at school among boys but not girls. The interventions were not effective in reducing fat intake at school. School environmental and policy interventions have the potential to improve health behavior of the student population, but barriers to full implementation need to be better understood and overcome. (copyright) 2003 American Journal of Preventive Medicine

Salmon J, Ball K, Hume C, Booth M, and Crawford D. 2008. Outcomes of a group-randomized trial to prevent excess weight gain, reduce screen behaviours and promote physical activity in 10-year-old children: Switch-Play. Int J Obes 32:601-612.
Abstract: Objectives: To evaluate the effectiveness of an intervention to prevent excess weight gain, reduce time spent in screen behaviours, promote participation in and enjoyment of physical activity (PA), and improve fundamental movement skills among children. Participants: In 2002, 311 children (78% response; 49% boys), average age 10 years 8 months, were recruited from three government schools in low socioeconomic areas of Melbourne, Australia. Design: Group-randomized controlled trial. Children were randomized by class to one of the four conditions: a behavioural modification group (BM; n=66); a fundamental movement skills group (FMS; n=74); a combined BM/FMS group (BM/FMS; n=93); and a control (usual curriculum) group (n=62). Data were collected at baseline, post intervention, 6- and 12-month follow-up periods. Results: BMI data were available for 295 children at baseline and 268 at 12-month follow-up. After adjusting for food intake and PA, there was a significant intervention effect from baseline to post intervention on age- and sex-adjusted BMI in the BM/FMS group compared with controls (-1.88 kg m-2, $P<0.01$), which was maintained at 6- and 12-month follow-up periods (-1.53 kg m-2, $P<0.05$). Children in the BM/FMS group were less likely than controls to be overweight/obese between baseline and post intervention (adjusted odds ratio (AOR)=0.36, $P<0.05$); also maintained at 12-month follow-up (AOR=0.38, $P<0.05$). Compared with controls, FMS group children recorded higher levels and greater enjoyment of PA; and BM children recorded higher levels of PA and TV viewing across all four time points. Gender moderated the intervention effects for participation in and enjoyment of PA, and fundamental movement skills. Conclusion: This programme represents a promising approach to preventing excess weight gain and promoting participation in and enjoyment of PA. Examination of the mediators of this intervention and further tailoring of the programme to suit both genders is required. (copyright) 2008 Nature Publishing Group All rights reserved

Sichieri R, Paula Trotte A, de Souza RA, and Veiga GV. 2009. School randomised trial on prevention of excessive weight gain by discouraging students from drinking sodas. Nutr 12:197-202.
Abstract: OBJECTIVE: To determine whether an educational programme aimed at discouraging students from drinking sugar-sweetened beverages could prevent excessive weight gain. DESIGN: Forty-seven classes in twenty-two schools were randomised as intervention or control. SUBJECTS: Participants were 1140, 9-12-year-

old fourth graders (435 in the intervention group and 608 in the control group). Sugar-sweetened beverages and juice intake were measured through one 24 h recall at baseline and another at the end of the trial. The main outcome was the change in BMI (BMI = weight (kg)/height (m2)), measured at the beginning and at the end of the school year. Intention-to-treat analysis was performed taking into account the cluster (classes) effect. RESULTS: A statistically significant decrease in the daily consumption of carbonated drinks in the intervention compared to control (mean difference = -56 ml; 95 % CI -119, -7 ml) was followed by a non-significant overall reduction in BMI, P = 0.33. However, among those students overweight at baseline, the intervention group showed greater BMI reduction (-0.4 kg/m2 compared with -0.2 kg/m2 in the control group (P = 0.11)), and this difference was statistically significant among girls (P = 0.009). Fruit juice consumption was slightly increased in the intervention group (P = 0.08), but not among girls. CONCLUSION: Decreasing sugar-sweetened beverages intake significantly reduced BMI among overweight children, and mainly among girls. Efforts to reduce energy intake through liquids need to emphasise overall sweetened beverages and addition of sugar on juices

Simkin-Silverman LR, Wing RR, Boraz MA, and Kuller LH. 2003. Lifestyle Intervention Can Prevent Weight Gain during Menopause: Results from a 5-Year Randomized Clinical Trial. ANN BEHAV MED 26:212-220.
Abstract: Context: Menopausal-related weight gain and increased waist circumference have major cardiovascular health implications for older women. The efficacy of a dietary and physical activity lifestyle intervention to prevent weight gain and elevations in cardiovascular disease (CVD) risk factors from the peri- to postmenopause is unknown. Objective: To report the 54-month results of a lifestyle dietary and physical activity program on weight, body composition, physical activity, diet, and other CVD risk factors. Design: Data are from a 5-year randomized clinical trial known as the Women's Healthy Lifestyle Project, conducted from 1992 to 1999. Participants: 535 healthy, premenopausal women ages 44 to 50 at study entry enrolled into the trial. Intervention: Participants were randomly assigned to either a lifestyle intervention group receiving a 5-year behavioral dietary and physical activity program or to an assessment-only control group. The lifestyle intervention group was given modest weight loss goals (5-15 lb, or approximately 2.3-6.8 kg) to prevent subsequent gain above baseline weight by the end of the trial. To achieve weight loss and lower low-density lipoprotein cholesterol levels, intervention participants followed an eating pattern consisting of 1,300 kcal/day (25% total fat, 7% saturated fat, 100 mg of dietary cholesterol) and increased their physical activity expenditure (1,000-1,500 kcal/week). Main Outcome Measures: Regarding weight gain prevention, 55% (136/246) of intervention participants were at or below baseline weight compared with 26% (68/261) of controls after 4.5 years, X2(2, N = 507) = 45.0, p < .001. The mean weight change in the intervention group was 0.1 kg below baseline (SD = 5.2 kg) compared with an average gain of 2.4 kg (SD = 4.9 kg) observed in the control group. Waist circumference also significantly decreased more in the intervention group compared with controls (M = -2.9 cm, SD = 5.3 vs. M = -0.5 cm, SD = 5.6, p < .001). Moreover, participants in the lifestyle intervention group were consistently more physically active and reported eating fewer calories and less fat than controls. Long-term adherence to physical activity and a low-fat eating pattern was associated with better weight maintenance. Conclusions: In healthy women, weight gain and increased waist circumference during the peri- to postmenopause can be prevented with a long-term lifestyle dietary and physical activity intervention

Simon C, Schweitzer B, Oujaa M, Wagner A, Arveiler D, Triby E, Copin N, Blanc S, and Platat C. 2008. Successful overweight prevention in adolescents by increasing physical activity: A 4-year randomized controlled intervention. Int J Obes 32:1489-1498.
Abstract: Background: Population-based studies directed at promoting physical activity in youth have shown limited success in obesity prevention. Objective: To assess whether an intervention integrating environmental changes to induce sustained changes in physical activity, prevents overweight in adolescents. Design: Four-year randomized trial started in 2002 in eight middle schools of Eastern France. The intervention, randomized at school level, was designed to promote physical activity by changing attitudes through debates and attractive activities, and by providing social support and environmental changes encouraging physical activity. Subjects: Nine hundred and fifty four 12-year-old six-graders. Measurements: Body mass index (BMI), body composition, physical activity by questionnaire, plasma lipids and glucose, insulin resistance. Results: Intervention students had a lower increase in BMI (P=0.01) and age- and gender-adjusted BMI (P<0.02) over time than controls. The differences across groups of the age- and gender-adjusted BMI changes (95% confidence interval (CI)) were -0.29 (-0.51; -0.07) kg/m2 at 3 years, -0.25 (-0.51; 0.01) kg/m2 at 4 years. An interaction with baseline weight status was noted. The intervention had a significant effect throughout the study in initially non-overweight adolescents (-0.36 (-0.60;-0.11) kg/m2 for adjusted BMI at 4 years), corresponding to a lower increase in fat mass index (P<0.001). In initially overweight adolescents, the differences observed across groups at 2 years (-0.40 (-0.94; 0.13) kg/m2 for adjusted BMI) did not persist over time. At 4 years, 4.2% of the initially non-overweight adolescents were overweight in the intervention schools, 9.8% in the controls (odds ratio=0.41 (0.22; 0.75); P<0.01). Independent of initial weight status, compared with controls, intervention adolescents had an increase in supervised physical activity (P<0.0001), a decrease of TV/video viewing

(P<0.01) and an increase of high-density cholesterol concentrations (P<0.0001). Conclusion: Enhancing physical activity with a multilevel program prevents excessive weight gain in non-overweight adolescents. Our study provides evidence that prevention of obesity in youth is feasible. (copyright) 2008 Macmillan Publishers Limited All rights reserved

Simonetti D'Arca A, Tarsitani G, and Cairella M. 1986. Prevention of obesity in elementary and nursery school children. Public Health 100:166-173.

Singh AS, Chin AP-M, Brug J, and Van Mechelen W. 2009. Dutch obesity intervention in teenagers: effectiveness of a school-based program on body composition and behavior. Archives of pediatrics & adolescent medicine 163:309-317.
Abstract: OBJECTIVE: To determine whether a multicomponent health promotion intervention for Dutch adolescents (defined as persons between 12 and 14 years of age) would be successful in influencing body composition and dietary and physical activity behavior in both the short and long terms. DESIGN: Randomized controlled trial. SETTING: Ten intervention and 8 control prevocational secondary schools. PARTICIPANTS: A total of 1108 adolescents (mean age, 12.7 years). Intervention An interdisciplinary program with an adapted curriculum for 11 lessons in biology and physical education and environmental change options. MAIN OUTCOME MEASURES: Body height and weight, waist circumference, 4 skinfold thickness measurements, and dietary and physical activity behavior data. RESULTS: Multilevel analyses showed that the intervention remained effective in preventing unfavorable increases in important measures of body composition after 20-month follow-up in girls (biceps skinfold and sum of 4 skinfolds) and boys (triceps, biceps, and subscapular skinfolds). Consumption of sugar-containing beverages was significantly lower in intervention schools both after intervention (boys: -287 mL/d; 95% confidence interval [CI], -527 to -47; girls: -249; -400 to -98) and at 12-month follow-up (boys: -233; -371 to -95; girls: -271; -390 to -153). For boys, screen-viewing behavior was significantly lower in the intervention group after 20 months (-25 min/d; 95% CI, -50 to -0.3). No significant intervention effects on consumption of snacks or active commuting to school were found. CONCLUSION: The Dutch Obesity Intervention in Teenagers program resulted in beneficial effects on the sum of skinfold thickness measurements in girls and consumption of sugar-containing beverages in both boys and girls in both the short and long terms

Tamir D, Feurstein A, Brunner S, Halfon ST, Reshef A, and Palti H. 1990. Primary prevention of cardiovascular diseases in childhood: Changes in serum total cholesterol, high density lipoprotein, and body mass index after 2 years of intervention in Jerusalem schoolchildren age 7-9 years. Prev Med 19:22-30.
Abstract: A school health education and promotion program, the Israeli version of the American Health Foundation's 'Know Your Body' program, was developed by the Department of Public Health of the Municipality of Jerusalem in 1983. Eight experimental and eight control schools participated in this cohort study of Arab and Jewish first-grade children. After the first 2 years of intervention, comparison of experimental and control groups showed a significant increase in serum high density lipoproteins among Jewish children and a decrease in serum total cholesterol and body mass index among both Jewish and Arab children. These results indicate that changes in cardiovascular disease risk factors such as blood total cholesterol, high density lipoproteins, and body mass index are possible after a health education program is introduced to first-grade students for a relatively short period of time

Wammes B, Breedveld B, Looman C, and Brug J. 2005. The impact of a national mass media campaign in The Netherlands on the prevention of weight gain. Nutr 8:1250-1257.
Abstract: Objective: A 5-year nationwide mass media campaign aimed at prevention of overweight was organised from 2002 onwards. The present study evaluates the first campaign, which was aimed primarily at increasing awareness of weight gain. Design and subjects: Data were collected by telephone interview in four independent cross-sectional surveys among non-obese Dutch adults aged 25-35 years (total n = 1949) for statistical analyses. Awareness of personal body-weight status, overweight-related risk perceptions, attitudes towards weight-gain prevention, motivation to preventweight gain and self-reported body mass index (BMI) were measured in each survey. Campaign exposure was assessed in the post-intervention surveys. To identify intervention effects over time multiple linear and logistic regression analyses were used, adjusted for secular time effects and age. Results: After the campaign about 65% of the respondents knew about the campaign. The campaign was associated with more positive attitudes towards the prevention of weight gain ((beta) = 0.16; P < 0.01) and higher self-reported BMI ((beta) = 0.14; P < 0.01). Conclusions: The results suggest that the first campaign reached a large proportion of the population and initiated some positive change in attitudes, but did not achieve significant improvements in other determinants of weight-gain prevention among non-obese young adults. (copyright) The Authors 2005

Wardle J, Brodersen NH, and Boniface D. 2007. School-based physical activity and changes in adiposity. Int J Obes 31:1464-1468.
Abstract: Objective: School-based physical education (PE) is often proposed as a strategy for obesity prevention, but many trials have found non-significant effects on body mass index (BMI). We examined the impact of school PE on adiposity in adolescents, using an ecological analysis to relate the number of PE sessions to changes in BMI and waist circumference. Research methods and procedures: Five-year, longitudinal, school-based study involving 34 secondary schools in London, England. Students were aged 11-12 years at baseline. Twenty-five schools reported one weekly session of PE, seven schools reported two sessions and two boys' schools reported three sessions. Weights, heights and waist circumferences were measured annually, and complete data from the first and fifth years of the study were available on 2727 students. Analyses compared anthropometric changes between students in schools with higher or lower amounts of PE time. In boys, the comparisons were between those receiving 1, 2 or 3 weekly sessions. In girls, comparisons were between those receiving one and two sessions. Results: There were no differences in BMI changes or the percentage of students classified as obese between schools of higher and lower frequency of PE. However, using unadjusted data, there were lower gains in waist circumference in boys and girls from the higher PE schools. Controlling for baseline demographic and anthropometric characteristics, boys in schools providing 3 weekly PE sessions gained on average approximately 3 cm less than boys in schools providing one or two sessions ($P<0.001$). Differences in girls were in the same direction but not significant. Discussion: Higher levels of school PE were associated with lower gains in adiposity in boys. This strengthens the case for including recommendations on school PE time as part of population strategies to control adolescent obesity. (copyright) 2007 Nature Publishing Group All rights reserved

Warren JM, Henry CJ, Lightowler HJ, Bradshaw SM, and Perwaiz S. 2003. Evaluation of a pilot school programme aimed at the prevention of obesity in children. Health promotion international 18:287-296.
Abstract: This paper describes the development, implementation and evaluation of a school- and family-based intervention to prevent obesity in children aged 5-7 years. In addition, the efficacy of three different intervention programmes was compared. Children aged 5-7 years (n=213) were recruited from three primary schools in Oxford and randomly allocated to a control group or one of three intervention groups: nutrition group, physical activity group, and combined nutrition and physical activity group. The setting for the interventions was lunchtime clubs, where an interactive and age-appropriate nutrition and/or physical activity curriculum was delivered. The intervention lasted for 20 weeks over four school terms (approximately 14 months). Children's growth, nutrition knowledge, diet and physical activity were assessed at baseline and at the end of the intervention. Significant improvements in nutrition knowledge were seen in all children ($p<0.01$) between baseline and post-intervention, and results were highly significant in the nutrition and combined group ($p<0.001$). Overall, fruit and vegetable intake increased significantly ($p<0.01$ and <0.05, respectively), with changes seen in fruit consumption in the nutrition group ($p<0.05$) and the control group ($p<0.05$) in particular. No significant changes in the rates of overweight and obesity were seen as a result of the intervention. Gender differences were not detected in the majority of assessments and there was no clear effect of programme type per se. This pilot study has demonstrated that school may be a suitable setting for the promotion of healthy lifestyles in children, but requires replication in other social settings. Future initiatives should be long-lasting, multi-faceted and sustainable, involving all children in a school, and should target the whole environment and be behaviourally focused. The ultimate goal of any such programme is to lead to positive behaviour change which will have a beneficial effect on long-term health. Successful targeting of the family remains a challenge to such interventions

Webber LS, Osganian SK, Feldman HA, Wu M, McKenzie TL, Nichaman M, Lytle LA, Edmundson E, Cutler J, Nader PR, and Luepker RV. 1996. Cardiovascular risk factors among children after a 2 1/4 -year intervention - The CATCH study. Prev Med 25:432-441.
Abstract: Background. Cardiovascular risk factors and related behaviors begin during youth. Methods. As part of the Child and Adolescent Trial for Cardiovascular Health, 4,019 children from four states and representing multiple ethnic groups were measured for selected risk factors both at baseline and after 2 1/4 years of intervention. Common protocols were used for both examinations at the four sites. Results. Overall, changes in obesity, blood pressure, and serum lipids in the intervention group, compared with the control group, were not statistically significant. Total cholesterol, the primary physiologic outcome measure, decreased by 1.3 mg/dl over time in the intervention group and by 0.9 mg/dl ($P > 0.05$) in the control group. Different risk factor patterns for boys and girls and among three ethnic groups were noted. Conclusions. Although the school-based program effected significant institutional changes in food service and physical education class and although the children made significant changes in eating and physical activity behaviors, these did not translate to significant changes in risk factors at these ages. These behavioral changes, however, if sustained into adulthood, have the potential to influence cardiovascular risk reduction

Wier LT, Jackson AS, and Pinkerton MB. 1989. Evaluation of the Nasa/JSC Health Related Fitness Program. Aviat Space Environ Med 60:438-444.
Abstract: This study evaluated the long-term effects of the NASA/Johnson Space Center Health Related Fitness Program (HRFP) which includes a 12-week educational component (EC) and quarterly fitness retests (RT). The groups studied were: Compliers (completed EC and (greater-than or equal to)75% of RT, N = 64); Non-compliers (completed EC but <75% of RT, N = 106); Drop-outs (disenrolled from EC, N = 36) and Controls (randomly selected from eligible program pool, N = 52). Pretest medical examination and maximum stress test data showed the groups did not differ on age, % fat, weight, blood lipids, and VO2max (p>0.05). Multivariate analysis of pre- and posttest change data (greater-than or equal to)2 years from start showed group differences in blood lipids, body composition and VO2max. Results showed that changes in physical activity were related to program completion and periodic fitness reevaluations, and that these group-related changes were associated with changes in VO2max, percent body fat, body weight, and blood lipids

Yin Z, Gutin B, Johnson MH, Hanes J, Moore JB, Cavnar M, Thornburg J, Moore D, and Barbeau P. 2005. An environmental approach to obesity prevention in children: Medical College of Georgia FitKid Project year 1 results. Obes Res 13:2153-2161.
Abstract: OBJECTIVE: To test the hypothesis that third grade children (mean age = 8.7, SD = 0.5) who attended an 8-month after-school program would exhibit favorable changes in body composition, cardiovascular fitness, blood pressure, total cholesterol, and high-density lipoprotein-cholesterol compared with children in control condition. RESEARCH METHODS AND PROCEDURES: Subjects were 61% African-American, 31% white, and 8% other racial background from 18 public schools. Sixty-eight percent were eligible for free or reduced price lunch. Percentage body fat and bone mineral density were assessed by DXA, cardiovascular fitness by heart rate response to a step test, resting blood pressure with a Dinamap, and non-fasting total cholesterol and high-density lipoprotein-cholesterol by finger stick. Data pre- and post-intervention were available for 447 children. Children in the nine intervention schools who attended at least 40% of the after-school sessions were compared with control subjects. RESULTS: Compared with the control subjects and after controlling for ethnicity, sex, free/reduced price lunch status, and school-level covariates, [-4.4 (95% CI, -8.2, 0.6)]. The other outcome variables showed non-significant trends in favor of the intervention subjects. DISCUSSION: These results are promising in light of the potential impact on the emerging childhood obesity epidemic. The Medical College of Georgia FitKid Project has the potential to be institutionalized because it is built on the existing infrastructure in most public schools in the U.S