

# Dietary advice for reducing cardiovascular risk (Review)

Brunner EJ, Thorogood M, Rees K, Hewitt G



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## ABSTRACT

### Background

Changes in population diet are likely to reduce cardiovascular disease and cancer, but the effect of dietary advice is uncertain.

### Objectives

To assess the effects of providing dietary advice to achieve sustained dietary changes or improved cardiovascular risk profile among healthy adults.

### Search strategy

We searched the Cochrane Controlled Trials Register on The Cochrane Library (Issue 2 2000), MEDLINE (January 1966 to December 2000), EMBASE (January 1985 to December 2000), DARE (December 2000), CAB Health (December 1999), dissertation abstracts, and reference lists of articles. We contacted researchers in the field.

### Selection criteria

Randomised studies with no more than 20% loss to follow-up, lasting at least three months involving healthy adults comparing dietary advice with no advice or less intensive advice. Trials involving children, trials to reduce weight or those involving supplementation were excluded.

### Data collection and analysis

Two reviewers independently assessed trial quality and extracted data. Study authors were contacted for additional information.

### Main results

Twenty-three trials with 29 intervention arms (comparisons) comparing dietary advice with no advice were included in the review. Dietary advice reduced total serum cholesterol by 0.13 mmol/l (95% CI 0.03 to 0.23) and LDL cholesterol by 0.13 mmol/l (95% CI 0.01 to 0.25) after 3-12 months. Mean HDL cholesterol levels were unchanged. Dietary advice reduced blood pressure by 2.10 mmHg systolic (95% CI 1.37 to 2.83) and 1.63 mmHg diastolic (95% CI 0.56 to 2.71) and 24-hour urinary sodium excretion by 44.2 mmol (95% CI 33.6 to 54.7) after 3-36 months. Plasma triglycerides,  $\beta$ -carotene and red cell folate were each measured in one small study which suggested no significant effect. Self-reported dietary intake may be subject to reporting bias, and there was significant heterogeneity in all the following analyses. Compared to no advice, dietary advice increased fruit and vegetable intake by 1.24 servings/day (95% CI 0.43 to 2.05). Dietary fibre intake increased with advice by 7.22 g/day (95% CI 2.84 to 11.60), while total dietary fat as a percentage of total energy intake fell by 6.18 % (95% CI 4.00 to 8.36) with dietary advice and saturated fat intake fell by 3.28 % (95% CI 1.92 to 4.64).

### Authors' conclusions

Dietary advice appears to be effective in bringing about modest beneficial changes in diet and cardiovascular risk factors over approximately 9 months but longer term effects are not known.

## PLAIN LANGUAGE SUMMARY

Dietary advice to encourage healthy people to make beneficial changes in diet and cardiovascular risk factors.

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**Dietary advice for reducing cardiovascular risk (Review)**

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Diet is an important determinant of chronic disease risk, particularly heart disease. This review assessed the effects of providing dietary advice to healthy adults in order to produce sustained improvements in their diets. Whether dietary improvement would reduce the risk factors associated with heart disease was also examined. We found 23 trials in which healthy adults were randomly assigned to receive dietary advice or no dietary advice. The dietary improvements recommended to the people in the intervention groups centred largely on the reduction of salt and fat intake and an increase in the intake of fruits, vegetables, and fibre. Advice was delivered in a variety of ways, including one-to-one contact, group sessions, and written materials. There were variations in intensity of intervention, ranging from one contact per study participant to 50 hours of counseling over four years. The duration of the trials ranged from three months to four years, with a median follow-up period of nine months. There was some evidence of greater effectiveness in people told that they were at risk of heart disease or cancer. Modest improvements were shown in cardiovascular risk factors, such as blood pressure and total and LDL-cholesterol levels. In the trials that separated effects by gender, women tended to make larger reductions in fat intake, but there was insufficient evidence to show whether this translated to a larger reduction in total cholesterol levels. The trials did not last long enough to answer the question of whether the beneficial changes in cardiovascular risk factors resulted in a reduced incidence of heart disease, stroke, or heart attack.

## BACKGROUND

### Dietary factors in risk of cardiovascular disease

Dietary pattern is an important determinant of chronic disease risk and overall mortality (Knoops 2004; Trichopoulou 2005). Although drug treatment, such as lipid-lowering with statins, may be appropriate among individuals at high risk of cardiovascular disease (CVD) (Hunninghake 1993), adoption of a healthy diet is preferable to long-term medication in the general population in order to prevent or delay the onset of disease and to reduce the burden on health services.

### Dietary advice to reduce risk of cardiovascular disease

Advice that encourages consumption of a diet relatively lower in any one or more of: fat, saturated fatty acids, cholesterol, sodium; or relatively higher in any one of: fruit, vegetables, polyunsaturated fatty acids, monounsaturated fatty acids, fish, fibre, potassium is likely to reduce the risk of cardiovascular disease and certain cancers (COMA 1994; DOH 2004; HSS 2005; WHO 2003). Dietary advice can take many forms: verbal or written, single or multiple contacts with individuals or groups, and may be delivered by health professionals or other agencies such as fitness consultants, trade unions or commercial organisations. The present review is concerned with trials of the effect of such advice in healthy European, North American and Australasian populations.

### How dietary advice might work

Dietary change has been shown to modify risk. For example, changes in the quantity and quality of dietary fat improve the lipid profile (Mensink 1992), and blood pressure is lowered by reducing sodium intake (Hooper 2004a) and increasing potassium intake (Cappuccio 1991). These findings are based on trials involving well-motivated individuals, often in metabolic wards (Mensink 1992), living in institutions (Dayton 1969; Frantz 1989; Turpeinen 1979), or receiving treatment in a hospital clinic (Watts 1992).

### Why this review is important

Public health policy in the UK and elsewhere advocates dietary change as a means to improve population health (DOH 2004). There remains some uncertainty about whether dietary advice given to healthy individuals is effective in achieving change (FHSG 1994; Hooper 2004a; Hooper 2004b; Kelly 2004; Ramsay 1991). In this review we aim to quantify the impact of dietary advice given to healthy free living adults and to identify factors that influence the effectiveness of dietary advice. We have excluded weight reduction trials because although obesity is a risk factor for cardiovascular disease and a major public health problem, other systematic reviews which address obesity are registered with the Cochrane Heart Group (Campbell 2002; Campbell 2003; Pirozzo 2002) and other health technology research organisations (Avenell 2004). We have also excluded trials involving supplementation, free foods or drinks, or financial inducements, because we are interested in the effects of advice rather than other interventions.

## OBJECTIVES

To assess the effects of providing dietary advice for obtaining sustained desirable dietary changes or improvement in cardiovascular risk profile among healthy adults.

## CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

### Types of studies

We have included randomised controlled trials (RCT) or quasi-randomised trials involving parallel group design, with allocation at either individual or group level. All trials involved dietary advice designed to reduce chronic disease risk and had at least 3 months of follow-up from recruitment. Trials were excluded if there was more than 20% loss to follow-up, unless there was an intention-to-treat analysis.

### Types of participants

Participants were healthy community-dwelling adults aged 18 years or older. Less than 25% of the participants in any trial had diagnosed cardiovascular disease at recruitment. Reported use of pharmacological therapy (e.g. statins or diuretics), during the trial was no greater than 10% of participants in any arm of the trial.

### Types of intervention

Dietary interventions involve verbal or written advice delivered in person or over the phone to individuals or small groups. The advice could include a combination of such approaches, and be given by health professionals or other personnel. Trials could include additional interventions such as posters in a works canteen. We considered trials involving advice to decrease consumption of one or more of fat, saturated fatty acids, cholesterol, salt, and/or increase consumption of one or more of fruit, vegetables, polyunsaturated fatty acids, monounsaturated fatty acids, fish, fibre, and potassium. We have restricted this review to interventions involving only advice on diet, to minimise confounding. Multiple interventions, such as those involving advice on physical activity, are excluded. Trials of weight reducing diets are excluded. The control group received no or minimal dietary advice.

### Types of outcome measures

For all outcome measures the preferred measure of effect was the estimated mean net change in the outcome variable over the duration of the trial. The net change is the change in the outcome measure in the intervention group minus the change in the control group.

### Primary outcomes

Cardiovascular risk factors: resting blood pressure, blood lipids and lipoproteins (cholesterol), and blood or red cell folate and/or homocysteine.

Bio-markers of dietary intake: urinary sodium, urinary potassium and blood diet-derived antioxidants such as  $\beta$ -carotene.

### Secondary outcomes

Self-reported measures of dietary intake, including fat, fat fractions, dietary fibre, fish, fruit and vegetables, vitamin C (ascorbic acid), vitamin E (tocopherols), carotenoids, flavonoids, and folic acid.

### Follow-up

Trials were included if they had at least three months follow-up from baseline. The longest follow-up duration was used provided loss to follow-up was less than 20% for the outcome measure of interest, unless there was an intention-to-treat analysis.

## SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

### Electronic searches

We searched The Cochrane Controlled Trials Register and other databases of The Cochrane Library (Issue 2 2000) including DARE and HTA (Issue 4 2000). We searched MEDLINE (January 1966 to December 2000), EMBASE (January 1985 to December 2000), CAB Health (January 1972 to December 1999), CVRCT Registry (December 2000), INST ED-Bibliomap and INST ED-EPPI-Centre (December 2000), Current Controlled Trials (December 2000) and SIGLE (January 1980 to June 2000).

The MEDLINE search used the following terms.

#### *Diet-related terms*

explode "Diet-Atherogenic"/ all subheadings  
explode "Diet-Fat-Restricted"/ all subheadings  
explode "Diet-Sodium-Restricted"/ all subheadings  
explode "Dietary-Fats"/ all subheadings  
explode "Dietary-Fiber"/ all subheadings  
explode "Potassium-Dietary"/ all subheadings  
explode "Sodium-Dietary"/ all subheadings  
explode "Ascorbic-Acid"/ all subheadings  
explode "Beta-Carotene"/ all subheadings  
explode "Folic-Acid"/ all subheadings  
explode "Vitamin-E"/ all subheadings  
explode "Fish-Oils"/ all subheadings  
explode "Plant-Oils"/ all subheadings  
explode "Dairy-Products"/ all subheadings  
explode "Fruit"/ all subheadings  
explode "Meat"/ all subheadings  
explode "Vegetables"/ all subheadings  
explode "Fats-Unsaturated"/ all subheadings  
explode "Fatty-Acids-Unsaturated"/ all subheadings  
explode "Food-Habits"/ all subheadings  
"Diet"/ all subheadings  
"Diet-Therapy"/ all subheadings

diet\* in ti,ab  
food\* in ti,ab  
mediterranean\* in ti,ab  
lipid\* near (low\* or reduc\* or modifi\*)  
poly?unsaturat\*  
mono?unsaturat\*  
omega\*  
n?3  
n?6  
marg?rine\* in ti,ab,nm  
butter\* in ti,ab,nm  
meat\* in ti,ab  
fish in ti,ab  
vegetable\* in ti,ab  
fruit\* in ti,ab  
legum\* in ti,ab  
soy\* in ti,ab  
bean\* in ti,ab

oat\* in ti,ab  
 grain\* in ti,ab  
 starch\* in ti,ab  
 carbohydrate\* in ti,ab  
 roughage in ti,ab  
 non?starch adj (poly?saccharide\* in ti,ab)  
 nut in ti,ab  
 nuts in ti,ab  
 lard\* in ti,ab  
 salt\* in ti,ab  
 anti?oxidant\* in ti,ab,nm  
 folic in ti,ab,nm  
 folate\* in ti,ab,nm  
 ascorb\* in ti,ab,nm  
 tocopherol\* in ti,ab,nm  
 alpha?tocopherol\* in ti,ab,nm

(vitamin adj c) or (vitamin adj e) or beta?carotene or carotenoid\*  
 sodium\* near (diet\* or intake\* or food\*)  
 potassium\* near (diet\* or intake\* or food\*)  
 (fibre or fiber) not (“nerve fibre” or “nerve fiber” or “muscle  
 fibre” or “muscle fiber” or “fib?? bundle\*” or “fiber?optic\*” or  
 “fibre?optic\*” or “Fiber-Optics”/ all subheadings)  
 fat\* near (low\* or modifi\* or animal\* or vegetable\* or acid\* or  
 saturat\* or unsaturat\*)  
 oil\* near (vegetable\* or olive\* or rape\* or sunflow\* or linseed\* or  
 saturat\* or unsaturat\*)

*Diet-related terms were combined with the <or> operator*

*Intervention-related terms*

explode “Communication”/ all subheadings  
 explode “Practice-Guidelines”/ all subheadings  
 explode “Counseling” tree: 3/ all subheadings  
 explode “Diet-Therapy”/ all subheadings  
 explode “Health-Education”/ all subheadings  
 explode “Life-Style”/ all subheadings

diet\* adj (therap\* or educat\* or counsel\* or intervention\* or  
 treatment\*)  
 nutriti\* adj (therap\* or educat\* or counsel\* or intervention\*)  
 health adj (therap\* or counsel\* or educat\*)  
 group adj counsel\*  
 brief adj intervention\*  
 health adj behav\* adj intervention\*  
 advice  
 leaflet\*  
 video\*  
 guideline\*  
 lifestyle\* near chang\*  
 diet\* near chang\*  
 intake\* near (increas\* or decreas\* or reduc\* or rais\* or low\* or  
 chang\* or restrict\* or high\*)  
 consumption near (increas\* or decreas\* or reduc\* or rais\* or low\*  
 or chang\* or restrict\* or high\*)

(salt or sodium) near (decreas\* or reduc\* or low\* or chang\* or  
 restrict\*)  
 (fat\* or cholesterol) near (decreas\* or reduc\* or low\* or chang\* or  
 restrict\*)  
 (fish or fruit\* or vegetable\*) near (increas\* or rais\* or chang\* or  
 high\*)

*Intervention-related terms were combined with the <or> operator*

explode “Child”/ all subheadings  
 explode “Adult”/ all subheadings

*Diet-related and intervention-related terms were combined with the  
 <AND> operator. The search excluded studies containing “Child”  
 terms but not “Adult” terms.*

*MEDLINE search terms for randomised trials*

A standard search filter was used (Dickersin 1994).

### **Handsearching and other sources**

Bibliographies of systematic reviews addressing food based  
 dietary interventions relevant to cardiovascular disease were  
 checked as a source of RCTs. Cochrane Review Groups in areas  
 related to this review include the Diabetes Group, Stroke Group,  
 Renal Group, Hypertension Group and Peripheral Vascular  
 Disease Group. The groups were contacted and asked to search  
 their trial registers for relevant trials.

Experts in the field were contacted for references to studies  
 not yet identified by the search process. Experts are defined as  
 members of the Cochrane Heart Group, persons who served as  
 author (not necessarily the primary author) on more than one  
 trial meeting inclusion criteria for the review; or the contact  
 author for any relevant trial; or the contact author for any  
 relevant systematic review. No language restrictions were applied  
 and evaluations of all relevant non-English articles were obtained.

## **METHODS OF THE REVIEW**

### **Data collection and analysis**

#### *Selection of Studies*

For each paper identified by the searches, the titles and then the  
 abstracts of potentially relevant references were read independently  
 by two reviewers. Articles were rejected only if both reviewers  
 determined from the title or abstract that the article was not a  
 report of a randomised controlled trial; or the trial did not address  
 food based dietary advice relevant to cardiovascular disease; or the  
 trial was of less than 3 months duration; or the intervention was  
 multi-factorial.

When a title/abstract could not be rejected with certainty, the  
 full text of the article was obtained for further evaluation. Two  
 reviewers (EB, MT) independently selected trials to be included in  
 the review using the predetermined inclusion criteria. A proforma

was used to determine study inclusion status. Disagreements were resolved by discussion.

### **Data extraction and management**

Data on participants, interventions, outcomes and trial quality were extracted independently by two reviewers (EB, MT) using a proforma. Disagreements were resolved by discussion. Chief investigators were contacted to provide additional relevant information. Data on potential effect modifiers were abstracted, including the setting of the trial (work site, community, home or health care facility), duration of the intervention and the follow-up, intensity of advice giving (number of scheduled contacts), and proportion of participants who were women.

### **Assessment of methodological quality of included studies**

Quality assessment was based on reporting of the randomisation procedure, allocation concealment, and blinding of outcome assessment. Allocation concealment (concealing group assignment) was considered adequate if participants were randomised individually after recruitment was complete. Allocation concealment was considered inadequate in cluster randomised trials where all participants at a given location were assigned to the same intervention or control group. Trial personnel and participants in trials of dietary advice, as with other behavioural interventions, cannot be blinded to the nature of the intervention. Where report of the trial method indicated that outcome measures were determined without knowledge of group assignment, blinding of outcome assessment was considered adequate.

### **Measures of intervention effect**

All outcomes were continuously distributed. We compared net differences between baseline and follow-up measurements and calculated the difference in means and 95% confidence interval for each outcome measure (Deeks 2004). We combined net differences across studies using random effects meta-analysis. Where standard deviation differences were not reported in the source papers, we made allowance for within participant correlation from baseline to follow-up measurements by using the correlation coefficient between the two (see Cochrane Heart Groupweb site for details and Follmann 1992).

### **Unit of analysis issues**

#### ***Studies with multiple intervention groups***

Data for the control group were used for each intervention group comparison. The weight assigned to the control group was reduced by dividing the control group N by the number of intervention groups.

#### ***Cross-over trials***

Data for the two periods were combined only if the study design ensured minimal carryover effects.

#### ***Cluster randomised trials***

Cluster randomised trials were analysed using the unit of randomisation (cluster) as the number of observations. Where

necessary, individual-level means and standard deviations adjusted for clustering were utilised together with the number of clusters in the denominator, in order to weight the trials appropriately.

### ***Missing Data***

If a trial collected an outcome measure at more than one time point the longest period of follow-up with 20% or fewer dropouts was utilised.

### ***Assessment of reporting biases***

The primary outcome measurements, apart from blood pressure, depend on laboratory analysis. Potential reporting bias is likely to be important only in the case of trial personnel involved in blood pressure measurement. Secondary outcomes in this review are the self-reported measures of dietary intake. Measures of diet are considered to be, at best, weak estimates of actual behaviour and behaviour change.

### **Subgroup analysis and investigation of heterogeneity**

For each outcome, a test of heterogeneity was carried out. If we detected substantial heterogeneity ( $P < 0.1$ ), we looked for possible explanations (e.g. participants and intervention). Regardless of the magnitude of heterogeneity, where six or more trials provided data for a given outcome, results were grouped according to five potential effect-modifying factors:

- gender: women, men, mixed;
- disease risk group: general population, high cardiovascular disease risk, high cancer risk;
- intervention setting: healthcare, community/workplace/home;
- intervention intensity: low, high (more than three scheduled personal contacts with participants enrolled in the intervention arm(s) of a trial);
- trial duration: short, long (follow-up at 12 months or more).

## **DESCRIPTION OF STUDIES**

### **Results of search**

The searches generated 36,600 hits. Screening of titles and abstracts identified 192 papers for formal inclusion or exclusion. Of these, 151 papers were excluded and 42 went forward to the data extraction stage. Twenty-three trials (29 papers) met the inclusion criteria and 13 papers were excluded.

### **Excluded studies**

Of the 13 studies we excluded, eight provided insufficient data for analysis despite contact or attempted contact with investigators, three had greater than 20% missing outcome data at follow-up and were not analysed on an intention-to-treat basis, one had more than 10% of participants on lipid lowering medication, and one had weight loss as the main objective (see excluded studies table).

### **Included studies**



Details of methods, participants, interventions and outcome measures are presented in the included studies table. A total of 24,443 participants were randomised. Six trials utilised a cluster design (Beresford 1997; Buller 1999; Havas 1998; Keyserling 1997; Sorensen worksite; Tilley 1999) and the units of randomisation (individually randomised participants and clusters) total 11723 (see Unit of analysis issues below). The number of participants/clusters contributing outcome data was in the range 29 - 4328 respectively for plasma  $\beta$ -carotene and reported dietary fat intake. Seventeen of the 23 included trials were conducted in the USA. Five of these recruited a total of 11,427 participants on low incomes, receiving welfare benefits or in blue collar occupations (Buller 1999; Coates WHT MP 1999; Cox 1996; Havas 1998; Tilley 1999).

### **Weight change**

Nine of the 17 individually randomised trials provided information on initial weight and/or weight loss during follow-up. Baseline body mass index (BMI) was approximately 30 kg/m<sup>2</sup> in one trial (Cox 1996) while other trials involved participants with lower BMI. Net mean weight loss in the intervention groups during follow-up was 1 kg or less in 7 trials (Anderson high fibre; Anderson low fibre; Baron men 1990; Baron women 1990; Bloemberg 1991; Hellenius 1993; Maskarinec 1999; Neil dietitian 1995; Neil nurse 1995; Smith-Warner 2000), 1.1 kg in one (Schatzkin 2000) and 1.8 kg in one (Henderson WHTV 1990).

### **Gender**

15 trials enrolled men and women, and of these one presented the findings by gender (Baron men 1990; Baron women 1990). Five trials enrolled women only, three men only.

### **Disease risk group**

Nine trials enrolled participants without screening, of which three involved American women with high prevalence of food poverty (Coates WHT MP 1999; Cox 1996; Havas 1998), two involved clients of American health maintenance organisations (Kristal 2000; Lutz non-tailored) and one US community health centre workers (Sorensen worksite). Nine trials enrolled participants on the basis of cardiovascular disease risk factor screening, of which four involved cholesterol screening (Anderson high fibre; Bloemberg 1991; Hellenius 1993; Keyserling 1997; Neil dietitian 1995), three blood pressure screening (Koopman 1990; TOHP II 1997; TOHP I) and one plasma homocysteine screening (Riddell 2000). Four trials enrolled people who were at increased risk of breast cancer (Henderson WHTV 1990; Maskarinec 1999) or colorectal cancer (Schatzkin 2000; Smith-Warner 2000) and one trial enrolled car workers being screened for colorectal cancer (Tilley 1999).

### **Intervention setting**

Most studies involved interventions in healthcare settings (15 studies), while others were set in the work place (3 trials), community centres (3 trials) or exclusively in the home (2 trials) using

telephone and mail (Kristal 2000; Lutz non-tailored; Lutz tailored 1999; Lutz tailored & goals).

### **Intervention intensity**

Ten trials involved an intervention design with between one and three scheduled contacts. Thirteen trials involved a design with between four brief interventions and 50 hours of individual counselling over four years (Schatzkin 2000).

### **Trial duration**

The modal duration of follow-up was six months (8 studies). There were 4 short duration trials: three of 3 months (Baron men 1990; Baron women 1990; Koopman 1990; Riddell 2000) and one of 4 months (Keyserling 1997). Nine studies contributed results for 12-48 months of follow-up.

Six or more trials provide results for serum total cholesterol, total dietary fat and fruit and vegetable intake and five subgroup analyses, as above, are displayed to explore effect modification.

## **METHODOLOGICAL QUALITY**

In general, details of the methods utilised in the included studies in this review were not well reported (Moher 2001). The methodological quality of the included studies as reported in the source papers is summarised in Table 01.

### **Randomisation**

All trials involved randomisation, but the methods were poorly described.

### **Allocation concealment**

Two of the 17 individually randomised trials appeared to have used an adequate allocation concealment method (Schatzkin 2000; TOHP II 1997). Six studies involved cluster randomisation and allocation concealment was considered adequate in one case (Buller 1999).

### **Blinding of outcome assessment**

Blinding of participants to the intervention is not possible in trials of behavioural advice, however outcome assessment can be conducted by trial personnel without knowledge of group allocation. Primary outcomes in this review are cardiovascular disease risk factors and biomarkers of dietary intake. With the exception of blood pressure, these outcomes are relatively free of the risk of information bias. There was some indication of blinding in the reports of 11 trials (Anderson high fibre; Anderson low fibre; Beresford 1997; Bloemberg 1991; Coates WHT MP 1999; Hellenius 1993; Keyserling 1997; Maskarinec 1999; Neil dietitian 1995; Neil nurse 1995; Riddell 2000; Smith-Warner 2000; TOHP I 1992). The secondary outcomes are self-reported measures of dietary intake, commonly based on a food frequency questionnaire. In no case was there adequate description of the procedures used to blind the assessors of dietary intake during data collection or analysis.

### **Unit of analysis issues**

Six trials were cluster randomised. In one community trial a cross-over design was used such that each site acted as its own control and site was the unit of analysis (Havas 1998). In a work place trial 41 pairs of employee cliques (informal social networks) were the unit of randomisation and analysis (Buller 1999). In two further work place trials, worksite was the unit of randomisation, but data were analysed at the level of the individual. We used worksite as the denominator for the meta-analysis (TOHP I 1992; Tilley 1999). Two trials based in clinics used physician practice as the unit of randomisation but analysed at individual level. Analysis allowed for random effects of clinic and physician practice, with physician nested within clinic. We used physician as the denominator for the meta-analysis (Beresford 1997; Keyserling 1997).

#### **Loss to follow-up**

Our inclusion criteria specified that loss to follow-up was no more than 20%. Six trials involved two or more outcome assessment phases. We used the longest reported follow-up data for two trials (Tilley 1999; TOHP II 1997), otherwise the longest duration of follow-up meeting our inclusion criteria. Drop-out rose to more than 20% at longer follow-up in three trials (Baron men 1990; Baron women 1990; Coates WHT MP 1999; TOHP I 1992) and the proportion taking lipid-lowering medication exceeded 10% after 4 months in another (Keyserling 1997).

## **RESULTS**

For the variables fruit and vegetable consumption, dietary fibre, high density lipoprotein (HDL) cholesterol,  $\beta$ -carotene and red cell folate, an increase in value from baseline to follow-up indicates improvement with the dietary intervention. Summary statistics are based on a random effects model.

#### **Any dietary advice versus no dietary advice (Comparison 01)**

##### ***Blood pressure and urinary sodium (outcomes 01, 02, 03)***

Systolic blood pressure and diastolic blood pressure were reported in four studies (1846 participants randomised). Two trials focused on salt reduction (TOHP II 1997, TOHP I), one on salt reduction plus increased dietary fibre and polyunsaturated fatty acid intakes (Koopman 1990) and the other more broadly on healthy eating advice (Hellenius 1993). Initial mean BP in the control group of these studies was in the range 125/84 to 144/95 mmHg (Table 02).

Systolic blood pressure was reduced by 2.10 mmHg (difference in means, 95% CI -2.83 to -1.37), and diastolic blood pressure by 1.63 mmHg (difference in means, 95% CI -2.71 to 0.56) with dietary advice. Twenty-four hour urinary sodium output was reported in the 3 trials of salt reduction (1533 participants randomised). Urinary sodium output was reduced by 44.2 mmol/24 hr (difference in means, 95% CI -54.7 to 33.6).

##### ***Blood lipids (outcomes 04, 05, 06, 07)***

Total blood cholesterol was reported in 7 studies (10 trial arms, 1042 participants/clusters randomised). All trials involved healthy eating advice designed to lower cholesterol, except one that focused on increasing fruit and vegetable intake (Maskarinec 1999). Fibre intake was emphasised in three trial arms (Anderson high fibre; Baron men 1990; Baron women 1990). Initial mean total cholesterol in the control group of the trials was in the range 4.8 to 7.4 mmol/l (Table 02).

There was a small but significant reduction in total cholesterol with advice of 0.13 mmol/l (difference in means, 95% CI -0.23 to 0.03). There was a similar reduction in low density lipoprotein (LDL) cholesterol in 5 studies (8 trial arms, 899 participants/clusters randomised) of 0.13 mmol/l (difference in means, 95% CI -0.25 to 0.01). There was no effect of advice on HDL cholesterol in 5 trials (8 trial arms, 956 participants randomised). Triglyceride levels were reported in one study (Hellenius 1993). Dietary advice had no effect.

##### ***Other biomarkers (outcomes 08, 09)***

Plasma  $\beta$ -carotene and red cell folate were reported in two separate trials (29 and 30 participants randomised respectively) which focused on increasing fruit and vegetable intake (Maskarinec 1999) or folate-rich foods (Riddell 2000). The effects were in the expected direction, but neither was statistically significant.

##### ***Dietary fat and dietary saturated fatty acids (outcomes 10, 11)***

Total dietary fat intake was reported in 10 studies (11 trial arms, 4328 participants/clusters randomised). Dietary advice reflected consensus healthy eating guidelines in six trial arms (Anderson low fibre; Beresford 1997; Bloemberg 1991; Cox 1996; Tilley 1999; Hellenius 1993). Three trials aimed to reduce fat intake to 20% or less of calories (Henderson WHTV 1990; Coates WHT MP 1999; Schatzkin 2000). One trial focused on increasing fruit and vegetable intake (Schatzkin 2000).

Total dietary fat intake expressed as a percentage of total calories fell by 6.18% with intervention overall (difference in means -6.18%; 95%CI -8.36 to 4.00). There was substantial heterogeneity ( $P < 0.00001$ ) in the trial effects, with the largest effects seen in the 3 trials that aimed to reduce fat intake to 20% or less of calories. Saturated fatty acid intake was reported in a subset of 5 of these trials (6 trial arms, 2381 participants randomised). The Women's Health Trial Minority Populations study, based in Georgia, Alabama and Florida (Coates WHT MP 1999), obtained a large reduction in total fat intake (10.8%) whereas another trial among US low income women (Cox 1996) was less effective (5.1% reduction). A trial among predominantly male US car workers (Tilley 1999) obtained a non-significant reduction in fat intake (1.2%).

Saturated fatty acid intake was reduced by 3.28% with dietary advice (difference in means -3.28%; 95% CI -4.64 to 1.92). There was heterogeneity ( $P < 0.00001$ ) in the trial effects, with a large effect seen in a trial that recruited women with increased risk of breast cancer (Henderson WHTV 1990).

### ***Fruit and vegetables (outcomes 12, 13, 14)***

Eight studies (12 trial arms, 3952 participants/clusters randomised) reported the combined outcome of servings of fruit and vegetables per day. All trials aimed to increase the number of fruit and vegetable servings eaten. Three trials also aimed to reduce fat intake (Kristal 2000; Schatzkin 2000; Tilley 1999). For one study (Schatzkin 2000), servings of fruit and vegetables were expressed as intake per 1000 calories rather than servings per day. The data provided for this study have been multiplied by the mean number of calories consumed per day as reported.

Fruit and vegetable intake in those given dietary intervention increased by 1.24 servings (difference in means) (95% CI 0.43 to 2.05). There was heterogeneity ( $P < 0.00001$ ) in the trial effects, with a large effect seen in a trial of men and women at increased risk of colorectal cancer (Smith-Warner 2000). Three US trials with low income and blue collar participants (Buller 1999; Havas 1998; Tilley 1999) obtained small increases in mean fruit and vegetable intake (range 0.24–0.43 servings per day).

Intakes of fruit and vegetables were reported separately in 5 trials (2125 participants/clusters randomised). There was no significant overall effect of intervention on fruit intake alone (difference in means 0.34, 95% CI -1.24, 1.92), but there was a beneficial effect of intervention on vegetable intake alone (difference in means 0.82; 95% CI 0.19 to 1.45).

There was heterogeneity ( $P < 0.00001$ ) in both sets of trials.

### ***Dietary fibre (outcome 15)***

Dietary fibre intake was reported in 4 studies (6 trial arms, 2313 participants randomised). Participants in these trials were given dietary advice that included fat reduction as well as fibre advice, with the exception of one that focused on increasing fruit and vegetable intake (Maskarinec 1999). For one study (Schatzkin 2000), fibre intake was expressed per 1000 calories rather than servings per day. The data provided for this study were multiplied by the mean number of calories consumed per day as reported.

People given the dietary intervention increased dietary fibre intake by 7.22 grams per day (difference in means) compared to those on control treatment (95% CI 2.84 to 11.60). There was heterogeneity ( $P < 0.00001$ ) in the trial effects, with a large effect seen in a 4-year trial of individuals at increased risk of colorectal cancer (Schatzkin 2000).

### ***Subgroup analyses (Comparison 02)***

Six or more trials provide results for total blood cholesterol, total dietary fat and fruit and vegetable intake. We present subgroup analyses of these outcomes, for gender, disease risk group, intervention setting, intervention intensity and trial duration. These sub-group findings should be treated with caution as self-report outcomes are subject to reporting bias and sub-group analyses in aggregated data without formal statistical interaction tests may generate spurious false positive and false negative findings.

### ***Gender***

In general, women were more likely than men to report reduced dietary fat intake, increased fruit and vegetable intakes, but no gender difference in total blood cholesterol levels was found. There were large intervention effects on fat intake in the two Women's Health Trial pilot studies (Coates WHT MP 1999; Henderson WHTV 1990).

### ***Disease risk group***

Participants at higher risk of cardiovascular disease did not report greater reductions in dietary fat intake or blood cholesterol level, but those at high cancer risk had a substantially greater reported intake of fruit and vegetables. One trial with participants at increased risk of colorectal cancer obtained a mean net increase in consumption of 5.1 servings per day (Smith-Warner 2000).

### ***Intervention setting***

Trials conducted in health care settings tended to show greater reporting of reduced dietary fat and increased fruit and vegetable consumption than workplace/community settings. However, no differences in blood cholesterol reductions were found.

### ***Intervention intensity***

Overall, high intensity interventions, involving more than three scheduled personal contacts with participants enrolled in the intervention arm(s) of a trial, tended to be associated with larger effects than low intensity interventions. The difference in effect size between subgroups was statistically significant for dietary fat and fruit and vegetables, however there was heterogeneity in the effects within these high intensity subgroups. However, no differences in blood cholesterol reductions were found.

### ***Trial duration***

The trial duration used in these analyses is the maximum trial follow-up period where non-participation at that follow-up was less than 20% for the outcome of interest (see Loss to follow-up above). Overall, there was no evidence that longer duration trials, with follow up at 12 months or more, obtained smaller reported dietary changes or blood cholesterol changes.

## **DISCUSSION**

The aim of this review is to evaluate the evidence for the sustained effectiveness of dietary advice in adults free of disease.

### ***Summary of main results***

The review shows that dietary advice promotes modestly beneficial changes in reported dietary intake (lower salt and fat, higher fibre and fruit and vegetables) and in some cardiovascular risk factors (blood pressure, total cholesterol, LDL cholesterol). The trial participants were healthy adults studied for at least three months and up to four years (median duration 9 months). There was some evidence that dietary advice was more effective when individuals were recruited on the basis of increased risk of cardiovascular disease or cancer, but beneficial changes were obtained when individuals were not screened at recruitment.

Advice to reduce fat intake (total and saturated fatty acids), and to increase dietary fibre, fruit and vegetable consumption was associated with a reduction over 3-12 months of follow-up for blood total and LDL cholesterol of 0.13 mmol/l cholesterol. Advice to reduce salt intake over 3-36 months of follow-up was associated with a reduction in blood pressure of 2.1 mmHg systolic and 1.6 mmHg diastolic and with a reduced 24-hour urinary sodium excretion of 44.2 mmol.

Reported fruit and vegetable intake increased by 1.2 servings per day with dietary intervention over 6 to 48 months of follow-up. Dietary fibre intake increased with intervention over 3 to 48 months by 7.2 grams per day. Reported total dietary fat intake expressed as a percentage of total calorie intake fell by 6.2% with intervention over 6-48 months. The corresponding reduction in saturated fatty acid intake was 3.3%.

### Overall completeness and applicability of evidence

More than 1000 randomised individuals/clusters contributed data to most of the outcomes discussed in this review, including the 'objective' outcomes blood cholesterol, blood pressure and urinary sodium output. For total dietary fat and fruit and vegetable intake this number was approximately 4000. There was a lack of evidence in relation to plasma triglycerides, carotenes and folate. No trials met the inclusion criteria for plasma vitamin C and urinary potassium. However, the literature searches for this study were completed in 2001, and studies published after the year 2000 remain to be identified and included in the review.

Dietary changes are effective in modifying risk when adherence is high, but there has been uncertainty about the effects of giving advice to healthy adults. Trials involving well-motivated individuals being fed controlled diets in metabolic wards (Mensink 1992), institutions (Dayton 1969; Frantz 1989; Turpeinen 1979), or the community (Appel 1997) do not assess the real-world effect of dietary advice. This review assembles the evidence that dietary advice is effective in less selected participants drawn from communities and work places.

A number of gaps in the evidence of the effects of dietary advice are apparent in the studies identified to date. There is a lack of high quality trials of cholesterol-lowering by diet among unscreened healthy adults. In addition, we found no evidence from countries other than the USA of the effect of cholesterol-lowering dietary interventions provided outside healthcare settings. This is surprising, given the importance of population cholesterol levels for cardiovascular disease prevention, but in part reflects the narrow inclusion criteria used in this review. Speculatively, it may be more efficient to provide dietary advice together with other forms of healthy eating promotion in the community or work place.

Five US trials (11,427 participants) provide evidence of the effect of dietary advice, limited to dietary fat and fruit and vegetable intake, among low income women (Coates WHT MP 1999; Cox 1996; Havas 1998) and blue collar workers (Buller 1999; Tilley

1999). One trial showed a large reduction in fat intake at 6 months among minority ethnic group and low socioeconomic class women (Coates WHT MP 1999). The two trials involving American, predominantly male, blue collar workers were not effective in increasing fruit and vegetable intake at 6 months (Buller 1999) or 2 years (Tilley 1999).

Although there are five trials of advice to increase fruit and vegetable intake among unscreened healthy adults, we did not identify any outside the USA up to the end of our literature search period.

### Overall quality, strength and consistency of evidence

The majority of trials were conducted in the USA (17 trials). Most trials involved individual randomisation (17). There were six cluster-randomised trials, all based in the USA, three in work places, two in healthcare settings and one in community centres. To limit selection bias we restricted loss to follow-up to 20% and in consequence data from shorter follow-up periods often had to be utilised for the longer duration trials. Descriptions of the trials, including methods used in randomisation, allocation concealment and blinding of outcome assessment, were in general poor, in comparison with the CONSORT recommendations (Moher 2001). Only two of the individually randomised trials and one of the six cluster-randomised trials showed evidence of adequate allocation concealment.

The primary outcomes (BP, urinary sodium output, lipids and other biomarkers) used in this review are broadly free of information bias but this is not the case with the secondary outcome measures, based on self-reported dietary intakes. Some of the intervention effects assessed by self-report were substantial, but may in part reflect information (reporting) bias, either on the part of participants or the trial personnel responsible for coding and analysing diet questionnaires. A particular weakness of the trial reports in this review is the absent or poor description of blinding of assessors to group allocation.

Weight loss during the trials may potentially confound changes in dietary composition indexed by BP and blood cholesterol. We excluded studies that had weight loss as a main aim; however weight loss as a consequence of the recommended dietary alteration could add to the apparent effect of dietary change by causing temporary reductions in BP and cholesterol. Nine of the 17 individually randomised trial reports provided information on initial weight and weight loss and this was reassuring. Net mean weight loss in these intervention groups during the trials was in the range 0-1.8 kg.

Interventions varied considerably in terms of the nature of the dietary advice. Two main groups are evident: those giving broad healthy eating advice that followed consensus guidelines (COMA 1994; HSS 2005) on fat, fibre, fruit and vegetables (Anderson high fibre; Anderson low fibre; Baron men 1990; Baron women 1990; Beresford 1997; Bloemberg 1991; Cox 1996; Hellenius 1993; Henderson WHTV 1990; Keyserling 1997; Kristal 2000; Neil

dietitian 1995; Neil nurse 1995; Schatzkin 2000; Tilley 1999) and those focused on increasing fruit and vegetable consumption along the lines of '5-a-day' campaigns (Buller 1999; Havas 1998; Lutz non-tailored; Lutz tailored 1999; Lutz tailored & goals; Maskarinec 1999; Sorensen work+family; Sorensen worksite; Smith-Warner 2000). In addition, three trials emphasised salt restriction (Koopman 1990; TOHP II 1997; TOHP I), another aimed to reduce fat consumption to 20% of energy or less among low income women (Coates WHT MP 1999) and another aimed to increase folate-rich food consumption (Riddell 2000). The trials involving broad healthy eating advice were consistent in their modest effects on blood total cholesterol reduction. The two Women's Health Trials (Coates WHT MP 1999; Henderson WHTV 1990) achieved very large reductions in dietary fat intake, but blood cholesterol was not measured. Trial interventions that advised an increase in fruit and vegetable consumption obtained similar increases in intake, with the exception of two that obtained much larger reported effects among participants presumably motivated by awareness of their increased risk of colorectal cancer (Schatzkin 2000; Smith-Warner 2000). The three trials with both BP and urinary sodium measures showed inconsistent effects, in that larger reductions in sodium output (TOHP II 1997; TOHP I) were not associated with larger reductions in BP, however the third trial (Koopman 1990) was small and of short (3 months) duration.

The intervention varied considerably among the included trials in terms of the mode of delivery of the dietary advice. Our subgroup analysis of the effect of intensity, based on the frequency of scheduled contacts, provides inconsistent evidence that higher intensity intervention is associated with larger dietary changes. Lower intensity interventions are more likely to be adopted in routine health care. There was heterogeneity in the effects within the subgroup of high intensity trials largely due to those with participants at increased cancer risk (Henderson WHTV 1990; Schatzkin 2000; Smith-Warner 2000). We expected to find that the effect of intervention would decline with duration of the trial. There was no evidence that this was the case, comparing longer duration trials with follow up at 12 months or more with those of shorter duration.

Of the 23 trials with 29 intervention arms meeting the inclusion criteria, ten (14 intervention arms, 5113 participants/clusters randomised) recruited participants without some form of screening to identify people at elevated risk of disease, compared to the general population. By design, participants were predominantly free of diagnosed chronic disease and not taking lipid-lowering or hypotensive medication, but there was evidence of a greater effect of advice in the trials with increased cancer risk participants. This may be a sign of greater motivation among these participants compared with those in healthy population trials, and it may be that some of the effects reported here would be smaller for dietary advice offered to a healthy population.

### Potential biases in the review process

Two aspects of selection bias are relevant to this review. First, our decision was to restrict the review to trials of dietary intervention alone to avoid the potential confounding effects due to other behavioural interventions, such as exercise advice, on our primary outcomes. The effect of this restriction may also be to overestimate the effectiveness of dietary advice if in practice it is given simultaneously with other health promotion interventions. Second, we decided to limit dropout to 20% or less to avoid selection bias in effect estimation, rather than to perform sensitivity analysis to examine the consequences of varying dropout rates. The effect of this restriction has been to exclude a number of well-known trials with a relatively high dropout rate (e.g. Boyd 1990; HPTR 1990). In addition, we may be biasing our findings by limiting our evidence to trials with conscientious participants.

### Agreements and disagreements with other studies or reviews

Two Cochrane reviews have examined interventions to reduce blood pressure in normotensive people. One studied the efficacy of reduced sodium intake rather than the effectiveness of advice to reduce sodium intake, and hence selected only trials that showed a reduction in sodium excretion of at least 40 mmol/24 hours (He 2004). The authors found a median reduction in normotensive people of 74 mmol/24 hours that was associated with a fall of 2.03 mmHg (95% CI -2.56 to 1.50) in systolic and 0.99 mmHg (95% CI -1.40 to 0.57) in diastolic pressure. Another Cochrane review included trials of interventions aimed at sodium reduction of at least 6 months duration (Hooper 2004a). Three trials in normotensives were identified giving a mean reduction in sodium excretion of 35 mmol/24 hours (95% CI -47.2 to 23.9) and a mean reduction of systolic pressure of 1.1 mmHg (95% CI -1.8 to 0.4) and of diastolic pressure of 0.6 mmHg (95% CI -1.5 to 0.3). The fall in sodium excretion is compatible with our findings of a fall in sodium excretion of 44.2 mmol/24 hours (95% CI -57.7 to 33.6). However, we have found a slightly larger effect on blood pressure with a fall in systolic pressure of 2.10 mmHg (95% CI -2.83 to 1.37) and diastolic pressure of 1.63 mmHg (95% CI -2.71 to 0.56). Hooper et al concluded that 'resulting falls of 1.1 mmHg systolic and 0.6 mmHg in diastolic blood pressure may be useful at a population level; however the intensity of intervention applied to individuals required to achieve this is not realistic for community control of high blood pressure'. In our review the two largest studies (TOHP I 1992; TOHP II 1997) involved intensive interventions while the two smaller studies were limited to three contacts with a health professional. Evidence of the effectiveness of low intensity interventions is limited and in the absence of such evidence, and given the importance of processed food as a source of sodium, we agree with Hooper et al that 'changes in food production and catering practices' are needed (Hooper 2004a).

A further Cochrane review (Hooper 2000) examined the effectiveness of interventions to reduce dietary fat, but has only reported on mortality and cardiovascular events and not changes in lipid levels although these were included as secondary outcomes. Within healthcare, a Cochrane review has assessed the effects of

dietary advice given by a dietitian compared with other health professionals, (Thompson 2004) concluding that dietitians were better than doctors at lowering blood cholesterol, but not other diet-related outcomes, in the short to medium term.

## AUTHORS' CONCLUSIONS

### Implications for practice

We made estimates, corrected for regression dilution bias, of the effects of reductions in serum cholesterol, and diastolic BP on the incidence of coronary heart disease and stroke. Based on randomised controlled trials in primary prevention, a reduction of 0.6 mmol/l (10%) in serum cholesterol will reduce coronary heart disease by 25%. (Law 1994) The estimated effect of a 5 mmHg reduction of diastolic BP, based on cohort studies, is a 21% reduction in coronary heart disease and a 34% reduction in stroke. (MacMahon 1994) Applying these estimates to our summary effects the dietary intervention may reduce coronary heart disease incidence by 12% (5% due to cholesterol lowering) and stroke by 11%. The estimates assume the observed changes in dietary habits would be sustained, and that the reductions in risk attributable to the changes in cholesterol and diastolic BP can be combined additively.

Our review suggests that the average changes in individual nutrients and related risk factors obtained through dietary advice are likely to be relatively small. When aggregated across the entire dietary pattern, however, several small changes in food habits may lead to greater health gains than the above estimates would suggest. In support of this view, the Lyon Diet Heart trial of a Mediterranean-type obtained a reduction of more than 50%, compared to the control group, in the recurrence of fatal and nonfatal cardiovascular disease over 4 years of study (De Lorgeril 1999).

The public health significance of national dietary patterns is not disputed. Here we have assembled the evidence on the effectiveness of dietary advice given to individuals and small groups in a variety of settings. The review shows that brief interventions are modestly effective in reducing blood lipid levels, blood pressure and dietary fat intake, and increasing fruit and vegetable intake. We were unable to identify evidence of effectiveness for plasma  $\beta$ -carotene and red cell folate levels. Variation in the nature and combination of the messages given across the included studies meant that it was not possible to identify 'best advice'. The extent of dietary change is influenced by the intensity and duration of intervention, and by perceived disease risk. There appears to be little if any gain in effectiveness by locating health promotion in primary care in contrast to work places and other non-healthcare

settings. Brief dietary interventions aimed at the whole population are likely to produce health gain; however the workload and cost to the UK National Health Service and other healthcare systems requires careful assessment.

### Implications for research

Questions remain about the most effective way to promote dietary change among healthy adults. Systematic research is needed on the effectiveness of non-individualised modes of dietary health promotion at population and community level. There is a shortage of evidence on the effectiveness of minimal interventions, and their specific components, to promote dietary change in UK healthcare and other settings. High quality trials with follow-up for one year or more are notably sparse. If health promotion is targeted in deprived areas (DOH 2004) with a high proportion of minority ethnic groups, it may be that dietary change will depend as much on wider determinants, particularly access and availability of healthy foods (Morris 2004) as it will on information and motivation.

## POTENTIAL CONFLICT OF INTEREST

None

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**T A B L E S****Characteristics of included studies**

| Study         | Anderson high fibre   |
|---------------|---|
| Methods       | RCT of parallel group design. The control group N is halved to take account of the 2 intervention arms.   |
| Participants  | High risk - total cholesterol 5.2-7.8 mmol/l on 2 screenings 2 weeks apart. Recruited from major employers, churches and shopping centres in the USA. 177 participants randomised, 59.6% men, mean age 40.6 years.  |
| Interventions | Two interventions - both AHA-type cholesterol lowering diets. This trial arm included a high-carbohydrate fibre diet (50 grams/day). Both arms included a 10 week diet education seminar series (1 hour/week) followed by 30 minute individual counselling sessions, plus 4 home visits from dietitians. Comparison group received no intervention. Follow-up at 12 months. |

### Characteristics of included studies (Continued)

Outcomes Dietary fibre, total dietary fat and saturated fatty acids (% Kcal), total, HDL and LDL cholesterol.

Notes

Allocation concealment B – Unclear

#### Study **Anderson low fibre**

Methods RCT of parallel group design.

Participants High risk - total cholesterol 5.2-7.8 mmol/l on 2 screenings 2 weeks apart. Recruited from major employers, churches and shopping centres in the USA. 177 participants randomised, 59.6% men, mean age 40.6 years.

Interventions Two interventions - both AHA-type cholesterol lowering diets. This trial arm included a recommended approximately. 15 grams/day fibre diet. See 'Anderson high fibre' for further details of intervention. Follow-up at 12 months.

Outcomes Dietary fibre, total dietary fat and saturated fatty acids (% Kcal), total, HDL and LDL cholesterol.

Notes

Allocation concealment B – Unclear

#### Study **Baron men 1990**

Methods RCT of parallel group design.

Participants Healthy individuals recruited from GP lists in Abingdon, Oxfordshire. 437 subjects randomised, 51% men with mean age 41.9 years. Men and women have been analysed separately.

Interventions Intervention administered by practice nurse. Individual or group session lasting 30 minutes on dietary advice to decrease total fat intake to 30-35% of calories and increase dietary fibre. A booklet was also given to participants on basic ideas of diet, recipes and advice concerning local restaurants. There was a brief follow-up session at 1 and 3 months. The comparison group were told they were part of a nutrition survey but were offered no dietary advice. Follow-up at 3 and 12 months (3 month data used as follow-up less than 80% at 12 months).

Outcomes Total cholesterol, HDL and LDL cholesterol, dietary fibre.

Notes

Allocation concealment B – Unclear

#### Study **Baron women 1990**

Methods RCT of parallel group design.

Participants Healthy individuals recruited from GP lists in Abingdon, Oxfordshire. 437 subjects randomised, 49% women with mean age 41.5 years. Men and women have been analysed separately.

Interventions See Baron 1990 for details of intervention. Follow-up at 3 and 12 months (3 month data used as follow-up less than 80% at 12 months).

Outcomes Total cholesterol, HDL and LDL cholesterol, dietary fibre.

Notes

Allocation concealment B – Unclear

#### Study **Beresford 1997**

Methods Cluster RCT. Physician practice was unit of randomisation. Analysis was at individual level, allowing for random effects of clinic and physician practice, with physician nested within clinic. The denominator used in this review is the physician.

Participants 28 GP practices in 6 primary care clinics in the USA. Participants attending routine visits without major illness were recruited. 2111 participants, 32% men, 25.5% greater than 65 years.

### Characteristics of included studies (Continued)

|               |  |
|---------------|--|
| Interventions | Low intensity dietary intervention to increase fibre and reduce fat intake. Self help booklet developed by the authors based on behavioural change principles from social learning theory and a brief motivational message from the physician. The control group received no intervention. Follow-up at 12 months. |
|---------------|--|

|          |                             |
|----------|-----------------------------|
| Outcomes | Total dietary fat (% Kcal). |
|----------|-----------------------------|

|       |  |
|-------|--|
| Notes |  |
|-------|--|

|                        |             |
|------------------------|-------------|
| Allocation concealment | B – Unclear |
|------------------------|-------------|

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|              |                       |
|--------------|-----------------------|
| <b>Study</b> | <b>Bloemberg 1991</b> |
|--------------|-----------------------|

|         |                               |
|---------|-------------------------------|
| Methods | RCT of parallel group design. |
|---------|-------------------------------|

|              |  |
|--------------|--|
| Participants | High risk - total cholesterol 6.5-10.0 mmol/l. 80 Dutch men randomised, mean age 47 years. |
|--------------|--|

|               |   |
|---------------|---|
| Interventions | Individualised dietary advice from a dietitian with the aim to lower plasma cholesterol by 1mmol/l. After one week, advice reinforced by 2 follow-up calls. Information on healthy diet also mailed to participants on 5 occasions. Intervention lasted 6 months. No details regarding the comparison group. Follow-up at 6 months. |
|---------------|---|

|          |  |
|----------|--|
| Outcomes | Total dietary fat and saturated fat (% Kcal), total cholesterol. |
|----------|--|

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|-------|--|
| Notes |  |
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|------------------------|-------------|
| Allocation concealment | B – Unclear |
|------------------------|-------------|

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|              |                    |
|--------------|--------------------|
| <b>Study</b> | <b>Buller 1999</b> |
|--------------|--------------------|

|         |   |
|---------|---|
| Methods | Cluster RCT. Employee cliques (informal social networks) were paired on several factors including mean fruit and vegetable consumption at baseline, ethnicity, sex composition, and size. One clique of each pair was randomly assigned to the intervention. Clique was the unit of analysis. |
|---------|---|

|              |   |
|--------------|---|
| Participants | 41 cluster pairs of cliques (informal social networks) of blue collar workers recruited from 10 public employers in Arizona. Clusters include 905 workers of low socioeconomic class, 75% men, mean age 42.1 years. |
|--------------|---|

|               |  |
|---------------|--|
| Interventions | Peer education intervention to increase fruit and vegetable consumption. One employee from each clique was recruited as a peer educator. In addition there was a 5-a-day program using worksite mail, cafeteria promotions and speakers. The comparison group received this 5-a-day program but no peer education intervention. Follow-up was at 6 months. |
|---------------|--|

|          |                                       |
|----------|---------------------------------------|
| Outcomes | Fruit and vegetable servings per day. |
|----------|---------------------------------------|

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| Notes |  |
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|------------------------|--------------|
| Allocation concealment | A – Adequate |
|------------------------|--------------|

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|              |                           |
|--------------|---------------------------|
| <b>Study</b> | <b>Coates WHT MP 1999</b> |
|--------------|---------------------------|

|         |                               |
|---------|-------------------------------|
| Methods | RCT of parallel group design. |
|---------|-------------------------------|

|              |  |
|--------------|--|
| Participants | Post-menopausal women from minority and low socioeconomic class populations consuming at least 35% of energy from fat. Women recruited from clinics in Georgia, Alabama and Florida. Women had no major chronic disease and were not on lipid-lowering medication. 2208 women randomised (60% to the intervention), mean age 60 years. |
|--------------|--|

|               |   |
|---------------|---|
| Interventions | Intervention to reduce fat intake to 20% energy or less. A nutritionalist assigned fat gram goals to each participant. Group sessions were held weekly for 6 weeks, fortnightly for 6 weeks, and monthly for 9 months and then quarterly. Sessions included nutritional information and behavioural change strategies. Elements of the program were enhanced or added to meet the needs of a diverse population. The comparison group received “dietary guidelines for Americans” but were not counselled. Intervention lasted for 2 years, with follow-up at 6, 12 and 18 months. Data abstracted for 6 months follow-up as thereafter follow-up was poor. |
|---------------|---|

|          |   |
|----------|---|
| Outcomes | Total dietary fat and saturated fat (% Kcal), fruit servings per day, vegetable servings per day. |
|----------|---|

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|-------|--|
| Notes |  |
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## Characteristics of included studies (Continued)

Allocation concealment B – Unclear

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| <b>Study</b>           | <b>Cox 1996</b>   |
|------------------------|---|
| Methods                | RCT of parallel group design.   |
| Participants           | Women with poor diet with high fat content from low income families in USA. 150 women randomised, mean age 29 years, 69% black.   |
| Interventions          | Education series emphasising the prevention of cardiovascular disease and cancer by dietary and lifestyle changes. Encouraged to decrease total and saturated fat intake, decrease salt intake, and increase consumption of low fat milk products, fruit and vegetables, soluble fibre, complex carbohydrates, antioxidant nutrients, calcium and potassium. Comparison group were taught about money management but received no information on health or nutrition. Follow-up at 6 months. |
| Outcomes               | Total dietary fat and saturated fat (% Kcal), fruit servings per day, vegetable servings per day.   |
| Notes                  |   |
| Allocation concealment | B – Unclear   |

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| <b>Study</b>           | <b>Havas 1998</b>   |
|------------------------|---|
| Methods                | Cluster RCT of cross-over design. Sites were switched 4 months after completion of phase 1. Each site acted as own control, using intention to treat analysis. Phase 1 participants were not eligible to enrol in phase 2. Specially employed peer educators conducted the intervention.  |
| Participants           | Women on low incomes recruited from a government funded special supplemental nutrition program for women infants and children in Baltimore City. 16 sites where this program was carried out were randomised, involving 3122 women, of whom 40.5% were aged between 18-24, 26.5% between 25-29 and 33% 30 years or more.  |
| Interventions          | Five a day promotional program where the goal was to increase fruit and vegetable consumption by at least half a serving per day. Peer educators delivered 2 types of nutrition education - brief messages regarding increasing fruit and vegetable consumption at enrolment, and 3 group discussions of 45 minutes during the 6 month intervention period which included personal goal setting, overcoming perceived barriers and maintenance strategies. Printed materials, visual aids and booklets with recipes were distributed. Four individually tailored letters were sent over the 6 month period. Comparison group received no intervention. Follow-up at 8 months. |
| Outcomes               | Fruit and vegetable servings per day.   |
| Notes                  |   |
| Allocation concealment | B – Unclear   |

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| <b>Study</b>  | <b>Hellenius 1993</b>   |
|---------------|---|
| Methods       | RCT of parallel group design.   |
| Participants  | Moderate/high risk - total cholesterol 5.2-7.8 mmol/l, DBP less than or equal to 100 mmHg, fasting triglycerides less than or equal to 5.6 mmol/l, fasting blood glucose less than or equal to 6.7 mmol/l, recruited from an ongoing prevention program in Sweden. 160 men randomised, mean age 46.2 years.   |
| Interventions | Three interventions - dietary advice alone, exercise alone and diet plus exercise. This review is concerned only with the dietary intervention alone (40 men randomised). Physician provided individual verbal and written information about diet in accordance with consensus documents, and participants also met with a dietitian 2 weeks later for further advice concerning low fat diets. Compliance with the intervention was checked at 3 months. The comparison group were told to continue with their lifestyle as previously. Follow-up at 6 months. |
| Outcomes      | Total dietary fat (% Kcal), total HDL and LDL cholesterol, triglycerides, SBP, DBP.   |
| Notes         |   |

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## Characteristics of included studies (Continued)

Allocation concealment B – Unclear

| Study                  | Henderson WHTV 1990   |
|------------------------|---|
| Methods                | Multicentre RCT of parallel group design.   |
| Participants           | High risk - women recruited from clinical units in USA at increased risk of breast cancer (one or more of the following - female first or second degree relative with breast cancer, one or more benign breast biopsies, first birth after the age of 30 or nulliparous, or history of breast biopsy with atypical epithelial hyperplasia. 303 women randomised, mean age 54.8 years.   |
| Interventions          | Intervention to decrease fat intake to 20% of total calories and increase complex carbohydrate intake to ensure adequate levels of vitamins and minerals. Nutritionalist led group sessions providing information and behavioural skills to make lifestyle changes. Group sessions once a week for 8 weeks, twice a month for the next 6 months and then monthly for 12 months. Individual sessions at 2 and 12 weeks. No details regarding the comparison group. Follow-up at 2 years. |
| Outcomes               | Total dietary fat (% Kcal).   |
| Notes                  |   |
| Allocation concealment | B – Unclear   |

| Study                  | Keyserling 1997  |
|------------------------|--|
| Methods                | Cluster RCT. Data were analysed at the level of the individual, allowing for the effect of physician clusters. The denominator used in this review is the physician.   |
| Participants           | 42 primary care physicians from 21 community and rural health centres in North Carolina and Virginia were randomised. High risk patients with elevated LDL cholesterol (greater than 4.1 mmol/l or between 3.4 -4.1 mmol/l plus 2 more risk factors or known CHD) were identified during routine appointments. The number of participants was 372, 67% were female, mean age 56 years.   |
| Interventions          | Food for heart program dietary intervention administered by physicians. All underwent a 90 minute training session. The intervention included a brief dietary assessment and three 5-10 minute dietary counselling sessions including referral to a dietitian if LDL remained elevated at 4 months, and a prompt to consider lipid lowering drugs at 7 months if LDL remained elevated still. The comparison group was usual care. Follow-up was at 4, 7 and 12 months. Four month data were abstracted as greater than 10% of participants were taking lipid lowering medication after this time. |
| Outcomes               | Total cholesterol and LDL cholesterol.   |
| Notes                  |  |
| Allocation concealment | B – Unclear  |

| Study                  | Koopman 1990   |
|------------------------|--|
| Methods                | RCT of parallel group design.  |
| Participants           | High risk - mild to moderate hypertension (DBP 90-110 mmHg on 3 separate occasions). Participants recruited from a Dutch GP surgery - 35 randomised, 46% men, mean age 45 years.   |
| Interventions          | Pilot intervention of intensive dietary counselling by a dietitian in general practice. Participants visited 3 times and goals were to have a daily intake of 80-100 mmol sodium, 30 grams of fibre, 10-12% of polyunsaturated fatty acids. Comparison group told they would see the dietitian in 3 months. Follow-up at 3 months. |
| Outcomes               | SBP, DBP, urinary sodium.  |
| Notes                  |  |
| Allocation concealment | B – Unclear  |

| Study   | Kristal 2000  |
|---------|---|
| Methods | RCT of parallel group design, individual randomisation stratified by age and sex. |

### Characteristics of included studies (Continued)

|                        |  |
|------------------------|--|
| Participants           | Participants were selected at random from enrollees from an American health maintenance organisation. 1459 subjects randomised, 50% men, mean age 45.8 years.  |
| Interventions          | Self-help manual of dietary change based on social learning theory designed to promote lower fat and higher fruit and vegetable consumption. Manual included dietary information, dietary analysis with behavioural feedback. Subjects also received a motivational phone call by a trained health educator and newsletters. No details regarding the control group. Follow-up at 12 months. |
| Outcomes               | Fruit and vegetable servings per day.  |
| Notes                  |  |
| Allocation concealment | B – Unclear  |

#### **Study**                      **Lutz non-tailored**

|                        |  |
|------------------------|--|
| Methods                | RCT of parallel group design. The control group N is divided by 3 to take account of the 3 intervention arms.  |
| Participants           | Healthy adults recruited from subscribers to an American health maintenance organisation. 710 participants randomised, 35.6% men, mean age 39.3 years.   |
| Interventions          | Three interventions to increase fruit and vegetable consumption. The 3 interventions were non-tailored newsletters, computer tailored newsletters taking into consideration individual baseline survey dietary information, and tailored newsletters with goal setting - to increase fruit and vegetable consumption to 5 or more servings per day. The control group did not receive a newsletter. Newsletters were posted each month for 4 months to participants in the intervention groups. Follow-up was at 6 months. |
| Outcomes               | Fruit and vegetable servings per day.  |
| Notes                  |  |
| Allocation concealment | B – Unclear  |

#### **Study**                      **Lutz tailored&goals**

|                        |  |
|------------------------|--|
| Methods                | RCT of parallel group design. The control group N is divided by 3 to take account of the 3 intervention arms.                                |
| Participants           | Healthy adults recruited from subscribers to a health maintenance organisation. 710 participants randomised, 35.6% men, mean age 39.3 years. |
| Interventions          | See 'Lutz non-tailored' for details of intervention. Follow-up was at 6 months.  |
| Outcomes               | Fruit and vegetable servings per day.  |
| Notes                  |  |
| Allocation concealment | B – Unclear  |

#### **Study**                      **Lutz tailored 1999**

|                        |  |
|------------------------|--|
| Methods                | RCT of parallel group design. The control group N is divided by 3 to take account of the 3 intervention arms.                                |
| Participants           | Healthy adults recruited from subscribers to a health maintenance organisation. 710 participants randomised, 35.6% men, mean age 39.3 years. |
| Interventions          | See 'Lutz non-tailored' for details of intervention. Follow-up was at 6 months.  |
| Outcomes               | Fruit and vegetable servings per day.  |
| Notes                  |  |
| Allocation concealment | B – Unclear  |

#### **Study**                      **Maskarinec 1999**

|         |                               |
|---------|-------------------------------|
| Methods | RCT of parallel group design. |
|---------|-------------------------------|

### Characteristics of included studies (Continued)

|                        |  |
|------------------------|--|
| Participants           | High risk - at increased risk of breast cancer (greater than 50% mammographic densities) and less than 5-a-day. 33 women randomised, mean age 48.9 years, mostly of Asian decent. Based in Hawaii.   |
| Interventions          | Individualised dietary counselling program with dietitian - goal to incorporate 9 servings of fruit and vegetables in daily diet. Group meetings monthly for 6 months for cooking instructions and demonstrations. Participants logged their daily intake of fruit and vegetables. The comparison group received nutritional counselling on how to maintain a healthy diet. Follow-up at 6 months. |
| Outcomes               | Total dietary fat (%Kcal), total cholesterol, fruit and vegetable servings per day, beta carotene.   |
| Notes                  |  |
| Allocation concealment | B – Unclear  |

#### Study **Neil dietitian1995**

|                        |   |
|------------------------|---|
| Methods                | RCT of parallel group design. The control group N is halved to take account of the two intervention arms.   |
| Participants           | High risk - total cholesterol 6 - 8.5 mmol/l on repeat screening at a general practice in Oxfordshire. 309 subjects randomised, 53% men, median age 55 years.   |
| Interventions          | Three interventions all containing advice to decrease total daily fat consumption to 30% or less. Participants were either randomised to receive advice from a dietitian or a nurse or to receive a leaflet containing dietary information by post. Those randomised to see the dietitian received an individual appointment of 30 minutes to discuss dietary habits and weight and offer advice to decrease fat consumption. At 8 weeks participants had a further 10 minute appointment. Those randomised to see the nurse also had an individual 30 minute appointment using a structure food frequency questionnaire and offered similar advice to the dietitian with a further 10 minute appointment at 8 weeks. The comparison group to these 2 interventions was the leaflet. Follow-up was at 6 months. |
| Outcomes               | Total cholesterol, HDL and LDL cholesterol.   |
| Notes                  |   |
| Allocation concealment | B – Unclear   |

#### Study **Neil nurse 1995**

|                        |   |
|------------------------|---|
| Methods                | RCT of parallel group design. The control group N is halved to take account of the two intervention arms.   |
| Participants           | High risk - total cholesterol 6 - 8.5 mmol/l on repeat screening at a general practice in Oxfordshire. 309 subjects randomised, 53% men, median age 55 years. |
| Interventions          | See ' Neil 1995 dietitian' for details of intervention. Follow-up was at 6 months.  |
| Outcomes               | Total cholesterol, HDL and LDL cholesterol.   |
| Notes                  |   |
| Allocation concealment | B – Unclear   |

#### Study **Riddell 2000**

|               |  |
|---------------|--|
| Methods       | RCT of parallel group design, individual randomisation stratified by sex.  |
| Participants  | High risk - men and women with elevated plasma total homocysteine (greater than or equal to 9 micromol/l). Sixty six subjects randomised aged 36-71 years (61% men) recruited from advertisements in local newspapers. Fifteen subjects were randomised to the intervention of interest to this review - increasing the consumption of folate rich foods, and 15 to the control group. Based in New Zealand.   |
| Interventions | Three interventions for decreasing homocysteine levels by increasing intake of folic acid - the first was supplementation, the second was consumption of fortified breakfast cereals and the third was increased consumption of folate rich foods. This review is concerned only with the third intervention. Subjects were asked to increase their intake of folate rich foods to 600 micrograms per day. Subjects were provided with a list of folate rich foods and were given detailed dietary information by a dietitian at recruitment and randomisation and reinforced advice by fortnightly phone calls. Additional encouragement was given by |



### Characteristics of included studies (Continued)

phone when required. The control group continued to follow a fat modified diet which was also used as a run in before randomisation in the intervention groups. The intervention lasted for 12 weeks and follow-up was 12 weeks.

|                        |                  |
|------------------------|------------------|
| Outcomes               | Red cell folate. |
| Notes                  |                  |
| Allocation concealment | B – Unclear      |

#### Study **Schatzkin 2000**

|                        |  |
|------------------------|--|
| Methods                | RCT of parallel group design.  |
| Participants           | High risk - one or more colorectal adenomas removed within 6 months before recruitment. Referrals from endoscopists. 2079 randomised, 64.5% men, mean age 61 years. American multicentre study.  |
| Interventions          | Intensive counselling to follow a low fat (less than 20% calories), high fibre (18 gram/1000 cauls.) diet and to increase fruit and vegetable consumption to 3.5 servings /1000 cauls. Nutritional information and behavioural modification techniques. More than 50 hours counselling sessions over 4 years. Comparison group were given a standard brochure on healthy eating. Follow-up at 4 years. |
| Outcomes               | Total dietary fat (% Kcals), dietary fibre, fruit and vegetable servings per day.  |
| Notes                  |  |
| Allocation concealment | A – Adequate   |

#### Study **Smith-Warner 2000**

|                        |  |
|------------------------|--|
| Methods                | RCT of parallel group design, individual randomisation stratified by sex.  |
| Participants           | High risk - men and women with recent history (previous 5 years) of colorectal adenomas recruited from a gastroenterology clinic in Minnesota. 201 participants randomised, 71% men, mean age 59.3 years.  |
| Interventions          | Participants were asked to increase fruit and vegetable consumption to at least 8 servings per day. Clinic visits at 3, 6, 9 and 12 months to reinforce this plus 4 additional individual diet intervention appointments. Intervention used behaviour modification strategies derived from social learning theory and nutritional counselling focused on goal setting. The control group continued their usual diet and were seen at 3, 6, 9 and 12 month clinic visits. Follow-up at 12 months. |
| Outcomes               | Fruit and vegetable servings per day.  |
| Notes                  |  |
| Allocation concealment | B – Unclear  |

#### Study **Sorensen work+family**

|               |  |
|---------------|--|
| Methods       | Cluster RCT. Data were analysed at the level of the individual, allowing for clustering within worksites. The denominator used in this review is the worksite. The control group N is halved to take account of the two intervention arms.   |
| Participants  | 22 worksites in USA randomised including 1359 employees at community health centres. 84% women, participants described as healthy and from racially and ethnically diverse backgrounds. No details regarding age.  |
| Interventions | Two interventions to increase fruit and vegetable consumption - one based at the worksite only, where workers participated in program planning whose aims were to change individual behaviour and make changes in the worksite environment. The other intervention included the worksite intervention plus a family intervention involving a written learn at home program, an annual newsletter, annual family festival and periodic mailings. The comparison group received a minimal intervention comprising exposure to national media campaigns and a 1 hour general nutrition presentation. This minimal intervention was received also by both intervention groups. Follow-up was at 19.5 months. |

### Characteristics of included studies (Continued)

|                        |                                       |
|------------------------|---------------------------------------|
| Outcomes               | Fruit and vegetable servings per day. |
| Notes                  |                                       |
| Allocation concealment | B – Unclear                           |

#### Study **Sorensen worksite**

|                        |  |
|------------------------|--|
| Methods                | Cluster RCT. Data were analysed at the level of the individual, allowing for clustering within worksites. The denominator used in this review is the worksite. The control group N is halved to take account of the two intervention arms. |
| Participants           | 22 worksites in USA randomised including 1359 employees at community health centres. 84% women, participants described as healthy and from racially and ethnically diverse backgrounds. No details regarding age.                          |
| Interventions          | See 'Sorensen work+family' for details of intervention. Follow-up was at 19.5 months.  |
| Outcomes               | Fruit and vegetable servings per day.  |
| Notes                  |  |
| Allocation concealment | B – Unclear  |

#### Study **TOHP I 1992**

|                        |   |
|------------------------|---|
| Methods                | Multicentre RCT of parallel group design.   |
| Participants           | High risk - DBP 80-89 mmHg not on antihypertensive medication recruited from 10 medical centres in the USA. 2182 participants randomised overall, 744 to the sodium reduction trial. 71.3% were men, age range 30-54 years.   |
| Interventions          | Several non-pharmacological interventions aimed at reducing blood pressure. This review is concerned only with the intervention to reduce sodium. Intervention administered by trained professionals and involved participant education and motivation, skills to change behaviour, goal setting and problem solving. The objective was to decrease urinary sodium to less than 80 mmol/24 hours. The intervention included 8 group and 2 individual sessions in the first 3 months with less frequent counselling thereafter but a minimum contact of 1 individual meeting every 2 months. No details given regarding the comparison group. Follow-up at 6, 12 and 18 months. Data abstracted for 12 months for urinary sodium and 18 months for blood pressure. |
| Outcomes               | SBP, DBP, urinary sodium.   |
| Notes                  |   |
| Allocation concealment | B – Unclear   |

#### Study **TOHP II 1997**

|                        |   |
|------------------------|---|
| Methods                | Multicentre RCT of parallel group design.   |
| Participants           | High risk - moderately overweight with high normal DBP - 83-89 mmHg recruited from 9 medical centres in the USA. 2382 participants randomised, 66.6% men, mean age 43.7 years.  |
| Interventions          | Two interventions - one to promote weight loss, the other to reduce sodium intake. This review is concerned only with the latter. Goal was to reduce sodium intake to 80 mmol/day. Group sessions and counselling weekly for 10 weeks, then 4 monthly sessions followed by 1 or 2 monthly contacts and refresher sessions offered. Sessions provided core knowledge and behavioural skills to reduce sodium intake. Intervention administered by trained dietitians, psychologists and health counsellors. Comparison group received no active intervention. Follow-up was at 6, 18 and 36 months. The 3 year follow-up was used in the analysis. |
| Outcomes               | SBP, DBP, urinary sodium.   |
| Notes                  |   |
| Allocation concealment | A – Adequate  |

| <b>Study</b>           | <b>Tilley 1999</b>   |
|------------------------|--|
| Methods                | Cluster RCT. Data were analysed at the level of the individual, allowing for difference in covariates between control and treatment worksites. The denominator used in this review is the worksite.  |
| Participants           | 28 car industry worksites in USA randomised. 5042 automobile employees believed to be at increased risk of colorectal cancer. 96% men, mean age 55.5 years.  |
| Interventions          | Screening programme for colorectal cancer plus nutritional intervention and educational booklet. Nutritional intervention included worksite classes encouraging increased fruit and vegetable and fibre and reduced fat consumption, self help materials and feedback from food frequency questionnaires. Newsletters were mailed quarterly. The intervention was repeated in year 2 of the trial. The control group received the screening program only. Follow-up at 12 months and 2 years. 2 year follow-up was used in the analysis. |
| Outcomes               | Total dietary fat (% Kcal), fruit and vegetable servings per day.  |
| Notes                  |  |
| Allocation concealment | B – Unclear  |

### Characteristics of excluded studies

| <b>Study</b>    | <b>Reason for exclusion</b>  |
|-----------------|--|
| Boyd 1990       | Outcomes are reported in only 70% of those participants randomised.  |
| Braeckman 1999  | Additional data were provided by the authors to allow analysis in meta-view but unfortunately the numbers of participants followed up for the outcomes of interest were poor at approximately 60% of those randomised.   |
| Chalmers 1986   | Data available in the published report could not be used as the baseline data and changes in DBP with the intervention relative to baseline were missing. The authors were contacted, but unfortunately these data could not be retrieved given the age of this study.                                     |
| Fehily 1983     | Data available in the published report could not be used as the baseline data and changes in total, HDL and LDL cholesterol with the intervention relative to baseline were missing. This additional data was requested from the authors but there was no response after several attempts to contact them. |
| HPTR 1990       | Data available in the published report could not be used as the variance at baseline for SBP, DBP and urinary sodium was missing. This additional data was requested from the authors but there was no response after several attempts to contact them.  |
| Hyman 1998      | Data available in the published report on total cholesterol could not be used as the variance at follow-up was missing. Authors were contacted but they were unable to provide missing data.   |
| Leduc 1994      | Study published in abstract form only. No information regarding the participation rate or nature of the intervention. We were unable to contact the authors for further information.   |
| Ni Mhurchu 1998 | Greater than 20% of participants were lost to follow up.   |
| Ockene 1999     | Variance of outcome variables not available at follow-up. More than 10% of the control group were taking lipid lowering medication during the trial.   |
| Simon 1997      | Greater than 20% of participants were lost to follow up.   |
| Smith 1997      | Data available in the published report on dietary fat as a percentage of energy could not be used as there were missing variances at baseline and follow-up. Authors were contacted but they were unable to provide missing data.  |
| Sorensen 1992   | Data available in the published report on dietary fat as a percentage of energy and dietary fibre could not be used as there were missing variances at baseline and follow-up. Authors were contacted but they were unable to provide missing data due to the age of the study.                            |
| Torjesen 1997   | Participants were selected to be overweight or obese, and the primary aim of the trial was weight loss.  |

**Characteristics of excluded studies** (*Continued*)

**ADDITIONAL TABLES**

**Table 01. Methodological quality of included studies**

| <b>Study ID</b> | <b>Randomisation</b>                             | <b>Alloc. concealment</b>      | <b>Blinding?</b>                                       | <b>Loss to follow-up</b>   |
|-----------------|--|--------------------------------|--|--|
| Anderson        | Stratified systematic random procedure           | Unclear                        | Unclear  | 17.5% loss to follow-up over 12 months   |
| Baron           | Unclear  | Unclear                        | Unclear  | 18% loss to follow-up at 3 months  |
| Beresford       | Random numbers                                   | Unclear.                       | Interviewer and participants blind to group allocation | 14% of individuals lost to follow-up over 12 months  |
| Bloemberg       | Unclear  | Unclear                        | Outcome assessors                                      | 1% loss to follow-up over 6 months   |
| Buller          | Unclear  | Adequate. Project statistician | Unclear  | Clusters analysed, but response rate to follow-up surveys for individuals only 64% at 6 months.                      |
| Coates WHR MP   | Unclear  | Unclear                        | Unclear  | 19% of the intervention group lost to follow-up at 6 months, at 12 months loss to follow-up was 33%, at 2 years 76%. |
| Cox             | Lottery method                                   | Unclear                        | Unclear  | None reported from the CVD arm of the trial  |
| Havas           | Unclear  | Unclear                        | Unclear  | 1 of 16 sites excluded - 6.25%   |
| Hellenius       | Unclear  | Unclear                        | Unclear  | 2% loss to follow-up over 6 months   |
| Henderson WHT V | Unclear  | Unclear                        | Unclear  | 5.3% loss to follow-up over 24 months  |
| Keyserling      | Unclear  | Unclear                        | Unclear  | 8% loss to follow-up for blood analyses  |
| Koopman         | Unclear  | Unclear                        | Unclear  | 14% loss to follow-up over 3 months  |
| Kristal         | Unclear  | Unclear                        | Unclear  | 13.5% loss to follow-up over 12 months   |
| Lutz            | Unclear  | Unclear                        | Unclear  | 19% loss to follow-up at 6 months  |
| Maskarinec      | Unclear  | Unclear                        | Unclear  | 12% loss to follow-up over 6 months  |
| Neil            | List of consecutive random treatment assignments | Unclear                        | Outcome assessors                                      | 9.7% loss to follow-up   |
| Riddell         | Unclear  | Unclear                        | Unclear  | 4.5% loss to follow-up at 12 weeks   |

**Table 01. Methodological quality of included studies (Continued)**

| Study ID       | Randomisation                      | Alloc. concealment  | Blinding?         | Loss to follow-up   |
|----------------|------------------------------------|---|-------------------|---|
| Schatzkin      | Computer program of random numbers | Adequate. Telephone coordinating centre                     | Unclear           | 8.4% loss to follow-up over 4 years                                 |
| Smith-Warner   | Unclear                            | Unclear   | Unclear           | 8% loss to follow-up at 12 months                                   |
| Sorensen       | Unclear                            | Unclear   | Unclear           | 3.9% individuals lost to follow-up at 19.5 months                   |
| Tilley         | Random number table                | Unclear   | Unclear           | 1.6% individuals lost to follow-up at 12 months, 3.5% at 24 months. |
| TOHP II        | Unclear                            | Adequate. Telephone coordinating centre or opaque envelopes | Outcome assessors | 7.5% loss to follow-up at 18 months                                 |
| Whelton TOHP I | Unclear                            | Unclear   | Outcome assessors | 20% loss to follow-up over 12 months                                |

**Table 02. Initial mean level of risk factors in control group of included studies**

| Study ID            | Cholesterol mmol/l | Blood pressure mmHg |
|---------------------|--------------------|---------------------|
| Anderson 1992       | 5.9                | not available       |
| Baron 1990 men      | 4.8                | not available       |
| Baron 1990 women    | 4.9                | not available       |
| Bloemberg 1991      | 7.0                | not available       |
| Coates 1999 HT MP   | 5.7                | not available       |
| Hellenius 1993      | 6.0                | 130/82              |
| Keyserling 1997     | 6.5                | not available       |
| Koopman 1990        | not available      | 144/95              |
| Neil 1995           | 7.4                | not available       |
| TOHP II 1997        | not available      | 127/86              |
| Whelton 1997 TOHP I | not available      | 125/84              |

## ANALYSES

### Comparison 01. Any dietary intervention versus no intervention

| Outcome title  | No. of studies | No. of participants | Statistical method                       | Effect size          |
|--|----------------|---------------------|--|----------------------|
| 01 Systolic blood pressure, change from baseline (mmHg)  | 4              | 1846                | Weighted Mean Difference (Random) 95% CI | -2.10 [-2.83, -1.37] |
| 02 Diastolic blood pressure, change from baseline (mmHg) | 4              | 1846                | Weighted Mean Difference (Random) 95% CI | -1.63 [-2.71, -0.56] |

|  |    |      |  |                          |
|--|----|------|--|--------------------------|
| 03 Urinary sodium output (mmol/24 hr) Change from baseline | 3  | 1533 | Weighted Mean Difference (Random) 95% CI | -44.18 [-54.74, -33.62]  |
| 04 Total cholesterol (mmol/l) Change from baseline         | 10 | 1042 | Weighted Mean Difference (Random) 95% CI | -0.13 [-0.23, -0.03]     |
| 05 LDL cholesterol (mmol/l), change from baseline          | 8  | 899  | Weighted Mean Difference (Random) 95% CI | -0.13 [-0.25, -0.01]     |
| 06 HDL cholesterol (mmol/l), change from baseline          | 8  | 956  | Weighted Mean Difference (Random) 95% CI | 0.01 [-0.02, 0.04]       |
| 07 Triglycerides (mmol/l), change from baseline            | 1  | 79   | Weighted Mean Difference (Random) 95% CI | -0.03 [-0.21, 0.15]      |
| 08 Plasma $\beta$ -carotene (ng/ml), change from baseline  | 1  | 29   | Weighted Mean Difference (Random) 95% CI | -65.00 [-263.40, 133.40] |
| 09 Red cell folate (nmol/l), change from baseline          | 1  | 30   | Weighted Mean Difference (Random) 95% CI | -74.00 [-192.16, 44.16]  |
| 10 Total dietary fat (% Kcal), change from baseline        | 11 | 4328 | Weighted Mean Difference (Random) 95% CI | -6.18 [-8.36, -2.00]     |
| 11 Dietary saturated fatty acids (% Kcal)                  | 6  | 2381 | Weighted Mean Difference (Random) 95% CI | -3.28 [-4.64, -1.92]     |
| 12 Fruit and vegetable (servings per day)                  | 12 | 3952 | Weighted Mean Difference (Random) 95% CI | 1.24 [0.43, 2.05]        |
| 13 Fruit (servings per day)                                | 5  | 2125 | Weighted Mean Difference (Random) 95% CI | 0.34 [-1.24, 1.92]       |
| 14 Vegetable (servings per day)                            | 5  | 2125 | Weighted Mean Difference (Random) 95% CI | 0.82 [0.19, 1.45]        |
| 15 Dietary fibre (grams per day)                           | 6  | 2313 | Weighted Mean Difference (Random) 95% CI | 7.22 [2.84, 11.60]       |

## Comparison 02. Subgroup analyses

| Outcome title                                  | No. of studies | No. of participants | Statistical method                       | Effect size          |
|--|----------------|---------------------|--|----------------------|
| 01 Total cholesterol (gender)                  | 10             | 1042                | Weighted Mean Difference (Random) 95% CI | -0.13 [-0.23, -0.03] |
| 02 Total dietary fat (gender)                  | 11             | 4328                | Weighted Mean Difference (Random) 95% CI | -6.18 [-8.36, -2.00] |
| 03 Fruit & vegetable servings/day (gender)     | 12             | 3952                | Weighted Mean Difference (Random) 95% CI | -1.24 [-2.05, -0.43] |
| 04 Total cholesterol (risk group)              | 10             | 1042                | Weighted Mean Difference (Random) 95% CI | -0.13 [-0.23, -0.03] |
| 05 Total dietary fat (risk group)              | 11             | 4328                | Weighted Mean Difference (Random) 95% CI | -6.18 [-8.36, -2.00] |
| 06 Fruit & vegetable servings/day (risk group) | 12             | 3952                | Weighted Mean Difference (Random) 95% CI | -1.24 [-2.05, -0.43] |
| 07 Total cholesterol (setting)                 | 10             | 1042                | Weighted Mean Difference (Random) 95% CI | -0.13 [-0.23, -0.03] |
| 08 Total dietary fat (setting)                 | 11             | 4328                | Weighted Mean Difference (Random) 95% CI | -6.18 [-8.36, -2.00] |
| 09 Fruit & vegetable servings/day (setting)    | 12             | 3952                | Weighted Mean Difference (Random) 95% CI | -1.24 [-2.05, -0.43] |
| 10 Total cholesterol (intensity)               | 10             | 1042                | Weighted Mean Difference (Random) 95% CI | -0.13 [-0.23, -0.03] |
| 11 Total dietary fat (intensity)               | 11             | 4328                | Weighted Mean Difference (Random) 95% CI | -6.18 [-8.36, -2.00] |
| 12 Fruit & vegetable servings/day (intensity)  | 12             | 3952                | Weighted Mean Difference (Random) 95% CI | -1.24 [-2.05, -0.43] |
| 13 Total cholesterol (duration)                | 10             | 1042                | Weighted Mean Difference (Random) 95% CI | -0.13 [-0.23, -0.03] |
| 14 Total dietary fat (duration)                | 11             | 4328                | Weighted Mean Difference (Random) 95% CI | -6.18 [-8.36, -2.00] |
| 15 Fruit & vegetable servings/day (duration)   | 12             | 3952                | Weighted Mean Difference (Random) 95% CI | -1.24 [-2.05, -0.43] |

## INDEX TERMS

### Medical Subject Headings (MeSH)

Cardiovascular Diseases [\*prevention & control]; Cholesterol [blood]; \*Diet; Diet, Fat-Restricted; Dietetics [\*methods]; Randomized Controlled Trials

### MeSH check words

Humans

## COVER SHEET

|   |   |
|---|---|
| <b>Title</b>  | Dietary advice for reducing cardiovascular risk   |
| <b>Authors</b>  | Brunner EJ, Thorogood M, Rees K, Hewitt G   |
| <b>Contribution of author(s)</b>                            | Eric Brunner<br>Preparation of protocol, advice, writing, preparation of selection materials. Reading and selecting abstracts and papers.<br>Margaret Thorogood<br>Preparation of protocol, advice, writing, preparation of selection materials. Reading and selecting abstracts and papers.<br>Karen Rees<br>Data abstraction, contacting authors, data analysis, writing.<br>Gillian Hewitt<br>Literature searches, library research, appraisal of abstracts. |
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| <b>Date new studies found and included/excluded</b>         | Information not supplied by author  |
| <b>Date authors' conclusions section amended</b>            | Information not supplied by author  |
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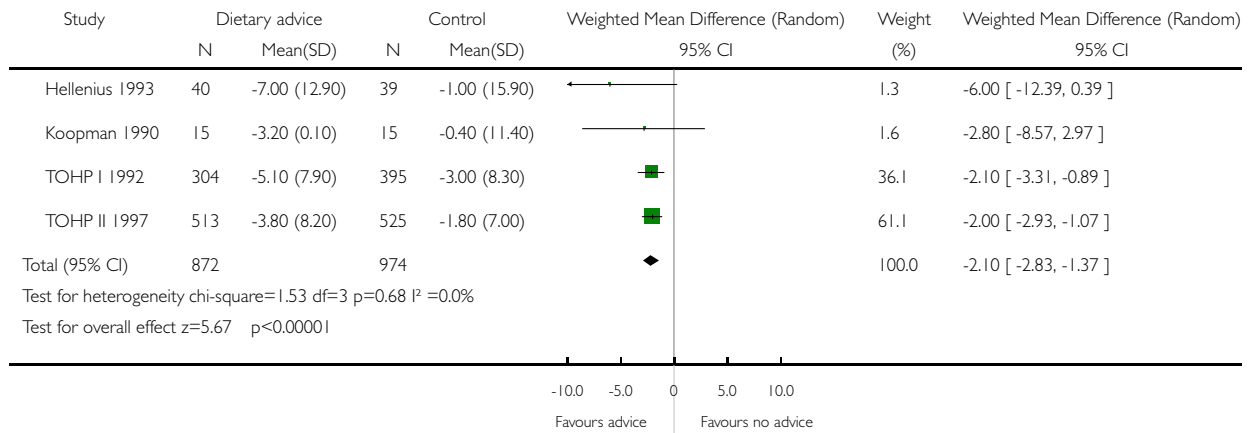
### GRAPHS AND OTHER TABLES

#### Analysis 01.01. Comparison 01 Any dietary intervention versus no intervention, Outcome 01 Systolic blood pressure, change from baseline (mmHg)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 01 Any dietary intervention versus no intervention

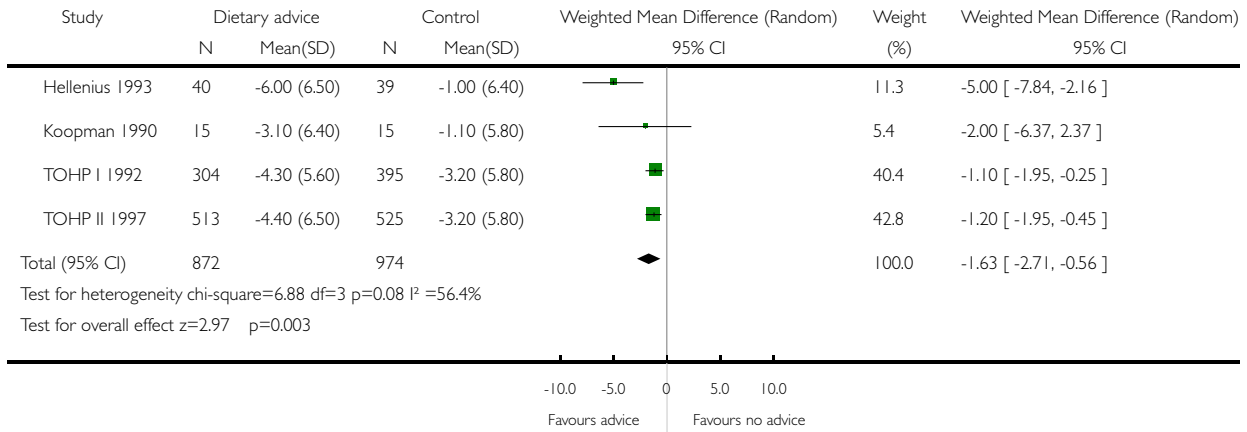
Outcome: 01 Systolic blood pressure, change from baseline (mmHg)





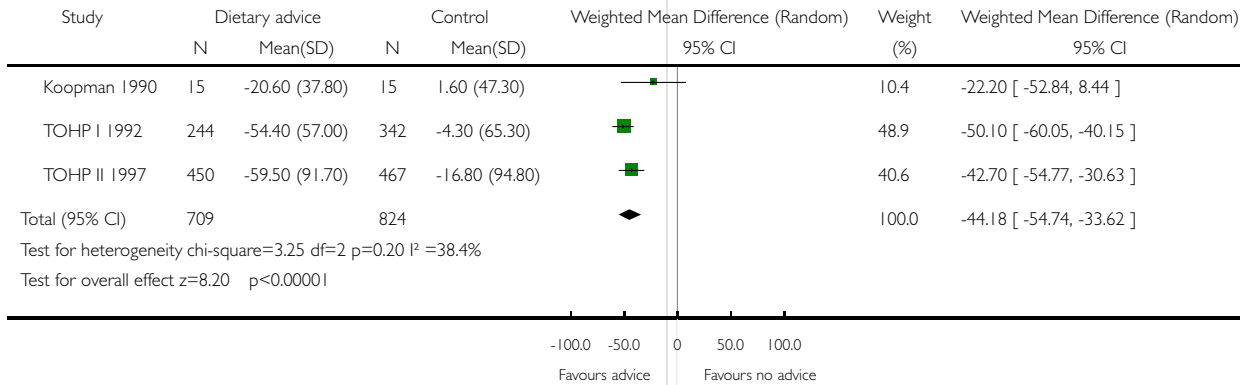
**Analysis 01.02. Comparison 01 Any dietary intervention versus no intervention, Outcome 02 Diastolic blood pressure, change from baseline (mmHg)**

Review: Dietary advice for reducing cardiovascular risk  
 Comparison: 01 Any dietary intervention versus no intervention  
 Outcome: 02 Diastolic blood pressure, change from baseline (mmHg)



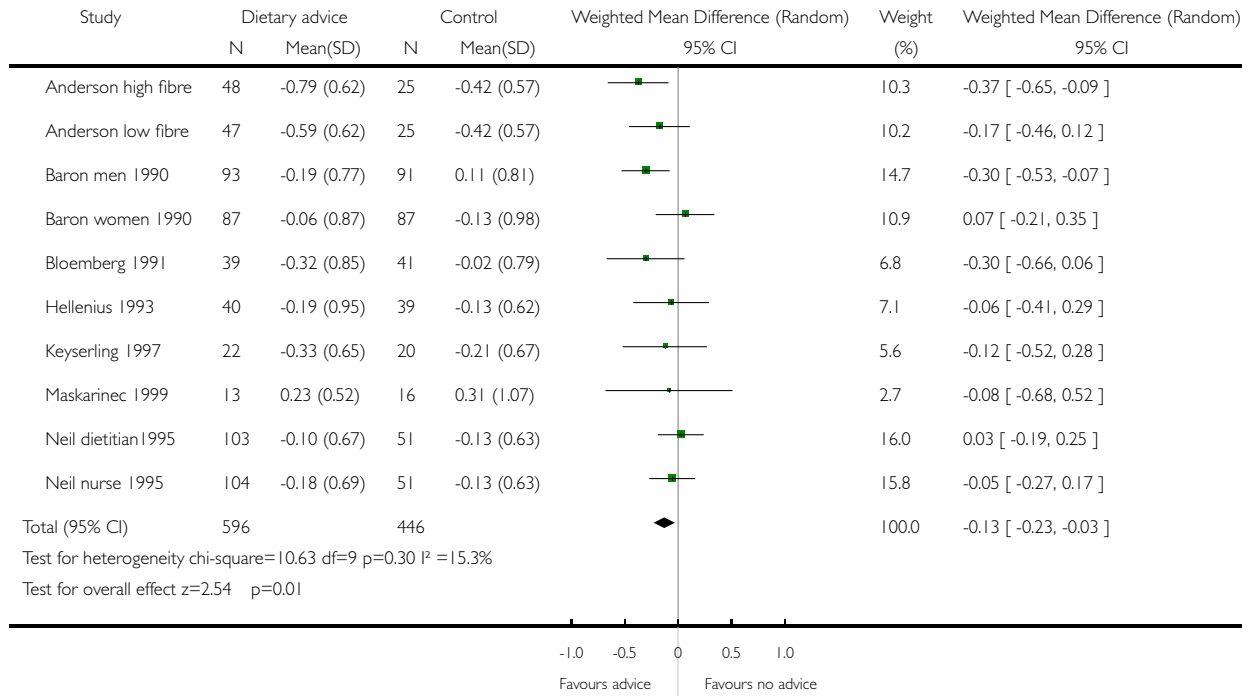
**Analysis 01.03. Comparison 01 Any dietary intervention versus no intervention, Outcome 03 Urinary sodium output (mmol/24 hr) Change from baseline**

Review: Dietary advice for reducing cardiovascular risk  
 Comparison: 01 Any dietary intervention versus no intervention  
 Outcome: 03 Urinary sodium output (mmol/24 hr) Change from baseline



**Analysis 01.04. Comparison 01 Any dietary intervention versus no intervention, Outcome 04 Total cholesterol (mmol/l) Change from baseline**

Review: Dietary advice for reducing cardiovascular risk  
 Comparison: 01 Any dietary intervention versus no intervention  
 Outcome: 04 Total cholesterol (mmol/l) Change from baseline

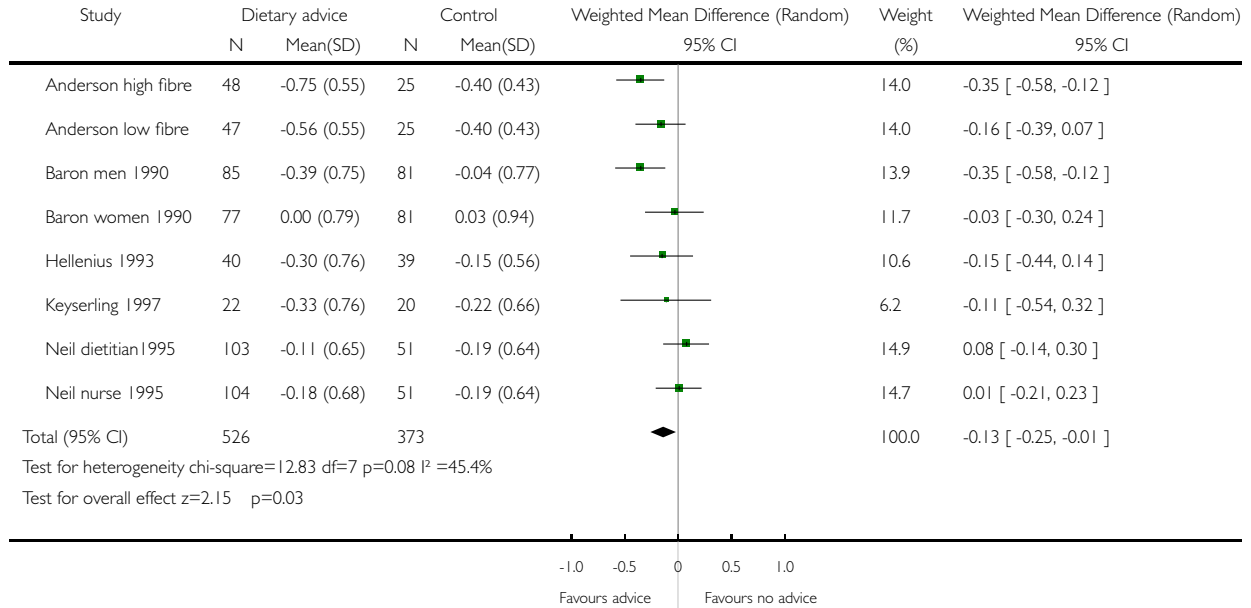


**Analysis 01.05. Comparison 01 Any dietary intervention versus no intervention, Outcome 05 LDL cholesterol (mmol/l), change from baseline**

Review: Dietary advice for reducing cardiovascular risk

Comparison: 01 Any dietary intervention versus no intervention

Outcome: 05 LDL cholesterol (mmol/l), change from baseline

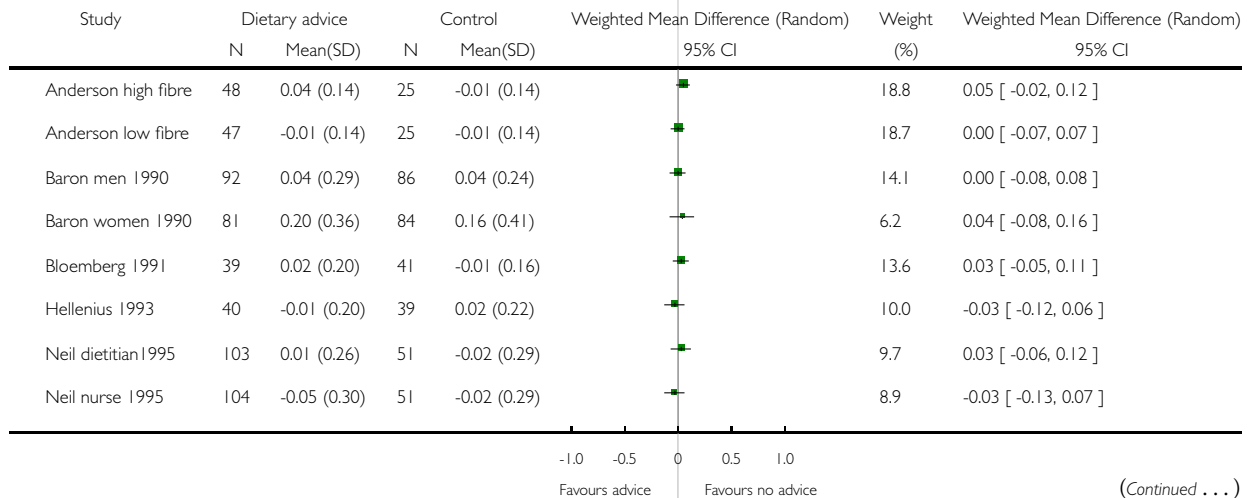


**Analysis 01.06. Comparison 01 Any dietary intervention versus no intervention, Outcome 06 HDL cholesterol (mmol/l), change from baseline**

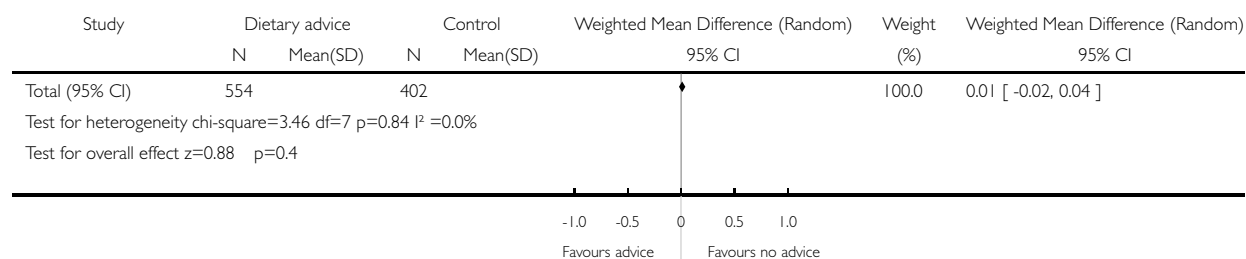
Review: Dietary advice for reducing cardiovascular risk

Comparison: 01 Any dietary intervention versus no intervention

Outcome: 06 HDL cholesterol (mmol/l), change from baseline

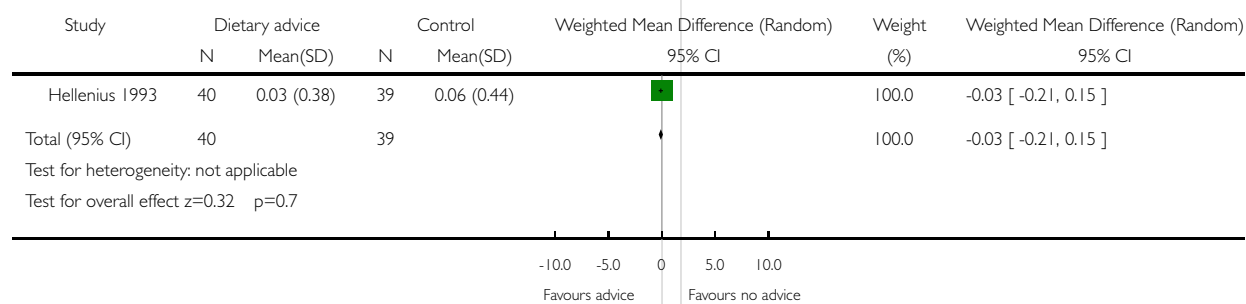


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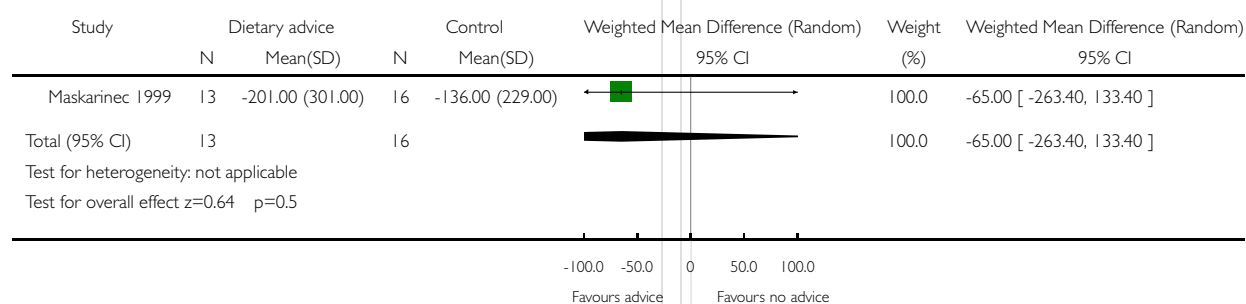
**Analysis 01.07. Comparison 01 Any dietary intervention versus no intervention, Outcome 07 Triglycerides (mmol/l), change from baseline**

Review: Dietary advice for reducing cardiovascular risk  
Comparison: 01 Any dietary intervention versus no intervention  
Outcome: 07 Triglycerides (mmol/l), change from baseline



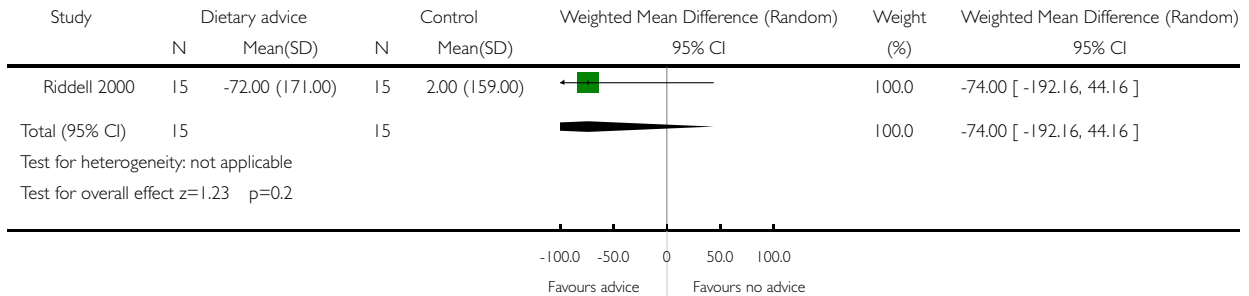
**Analysis 01.08. Comparison 01 Any dietary intervention versus no intervention, Outcome 08 Plasma β-carotene (ng/ml), change from baseline**

Review: Dietary advice for reducing cardiovascular risk  
Comparison: 01 Any dietary intervention versus no intervention  
Outcome: 08 Plasma β-carotene (ng/ml), change from baseline



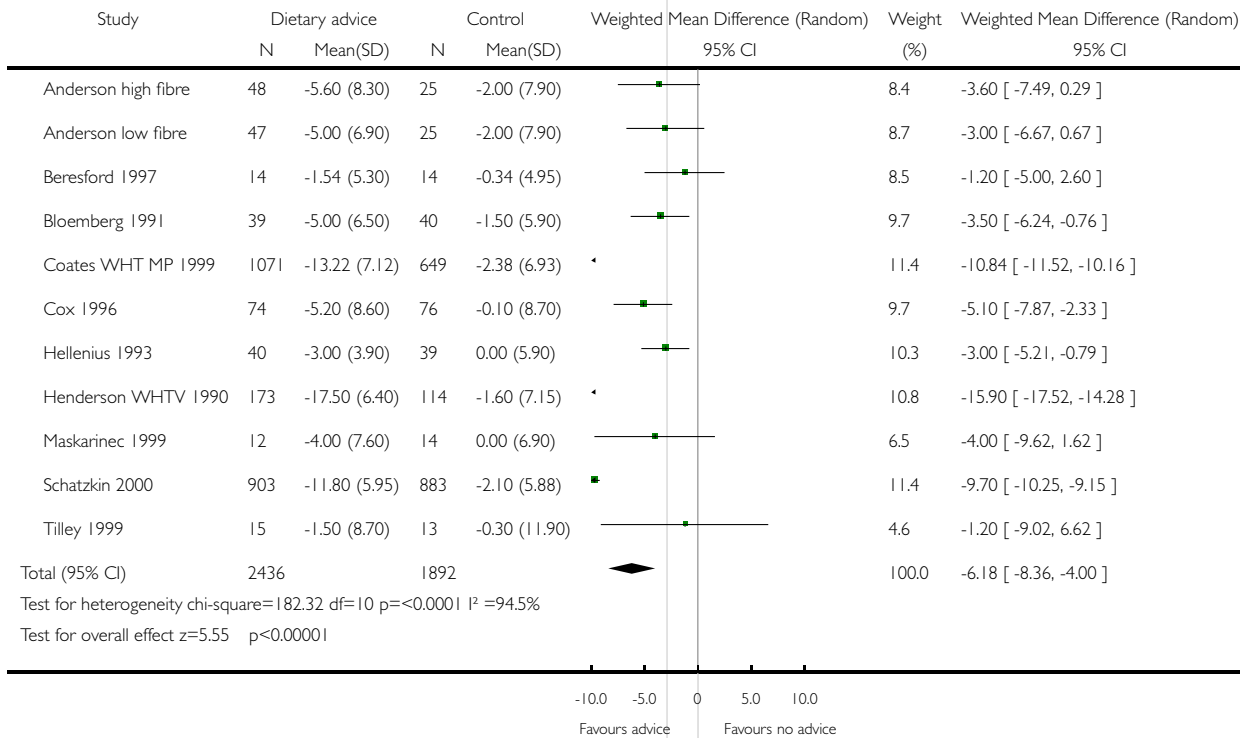
**Analysis 01.09. Comparison 01 Any dietary intervention versus no intervention, Outcome 09 Red cell folate (nmol/l), change from baseline**

Review: Dietary advice for reducing cardiovascular risk  
 Comparison: 01 Any dietary intervention versus no intervention  
 Outcome: 09 Red cell folate (nmol/l), change from baseline



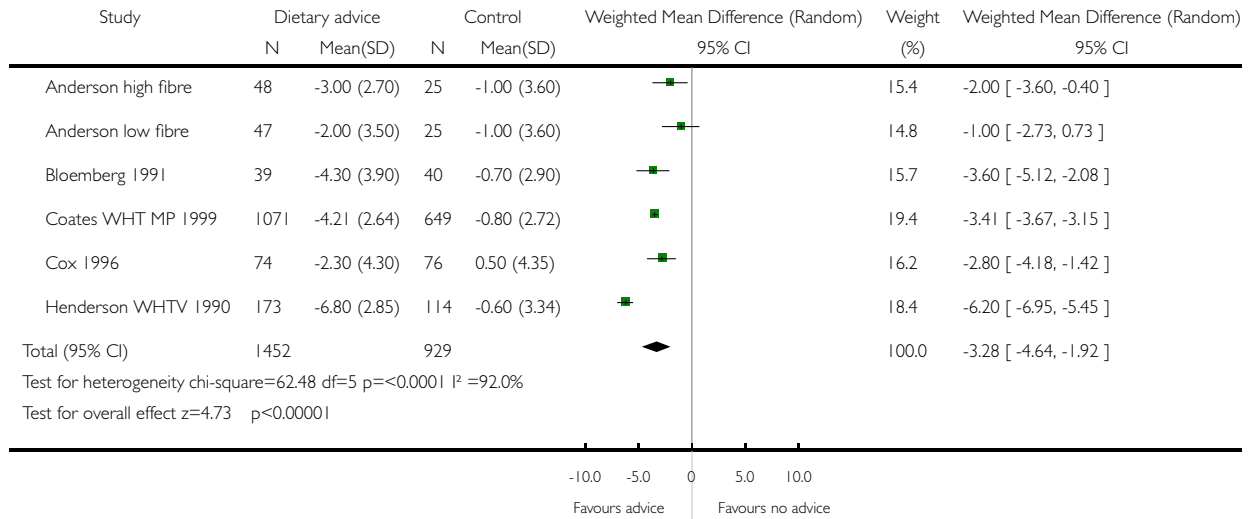
**Analysis 01.10. Comparison 01 Any dietary intervention versus no intervention, Outcome 10 Total dietary fat (% Kcal), change from baseline**

Review: Dietary advice for reducing cardiovascular risk  
 Comparison: 01 Any dietary intervention versus no intervention  
 Outcome: 10 Total dietary fat (% Kcal), change from baseline



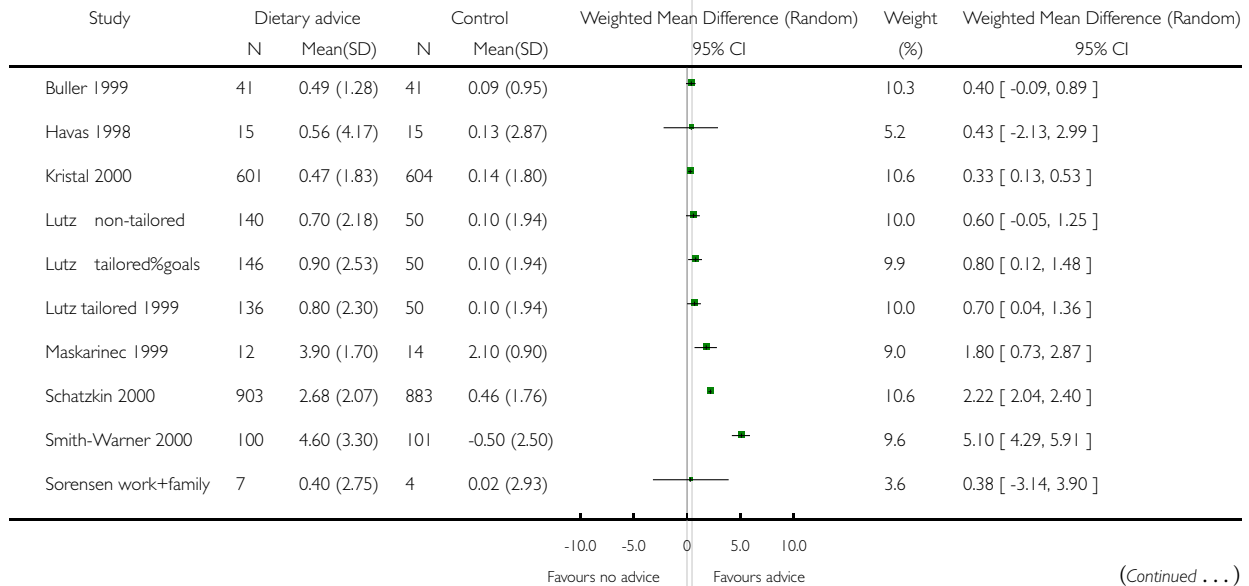
**Analysis 01.11. Comparison 01 Any dietary intervention versus no intervention, Outcome 11 Dietary saturated fatty acids (% Kcal)**

Review: Dietary advice for reducing cardiovascular risk  
 Comparison: 01 Any dietary intervention versus no intervention  
 Outcome: 11 Dietary saturated fatty acids (% Kcal)

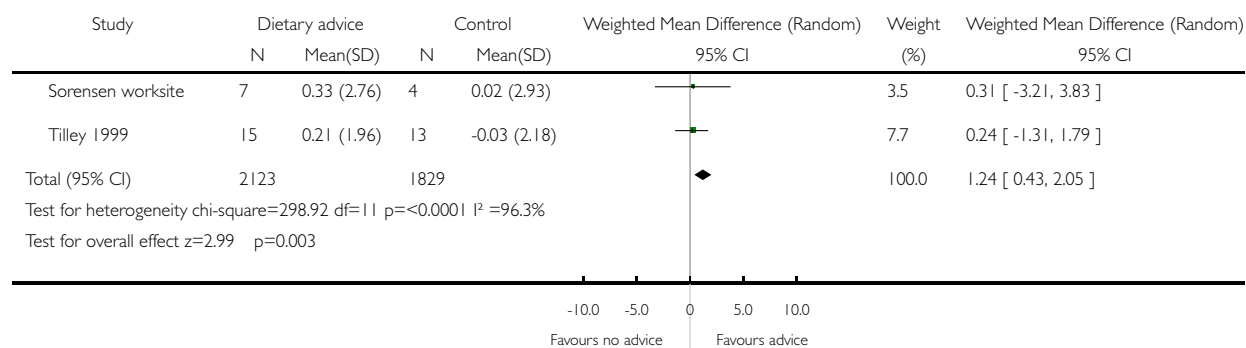


**Analysis 01.12. Comparison 01 Any dietary intervention versus no intervention, Outcome 12 Fruit and vegetable (servings per day)**

Review: Dietary advice for reducing cardiovascular risk  
 Comparison: 01 Any dietary intervention versus no intervention  
 Outcome: 12 Fruit and vegetable (servings per day)



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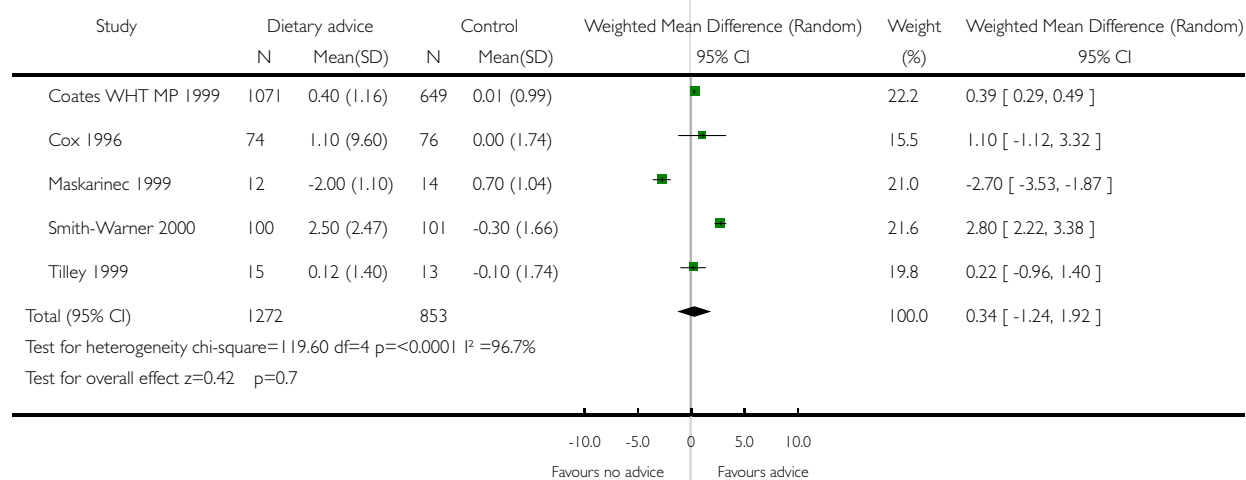


### Analysis 01.13. Comparison 01 Any dietary intervention versus no intervention, Outcome 13 Fruit (servings per day)

Review: Dietary advice for reducing cardiovascular risk

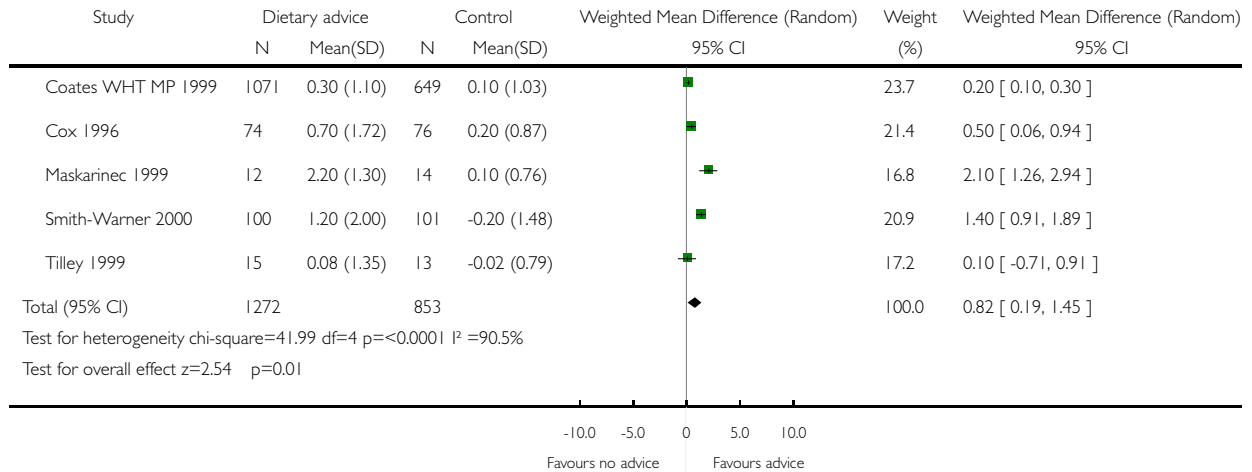
Comparison: 01 Any dietary intervention versus no intervention

Outcome: 13 Fruit (servings per day)



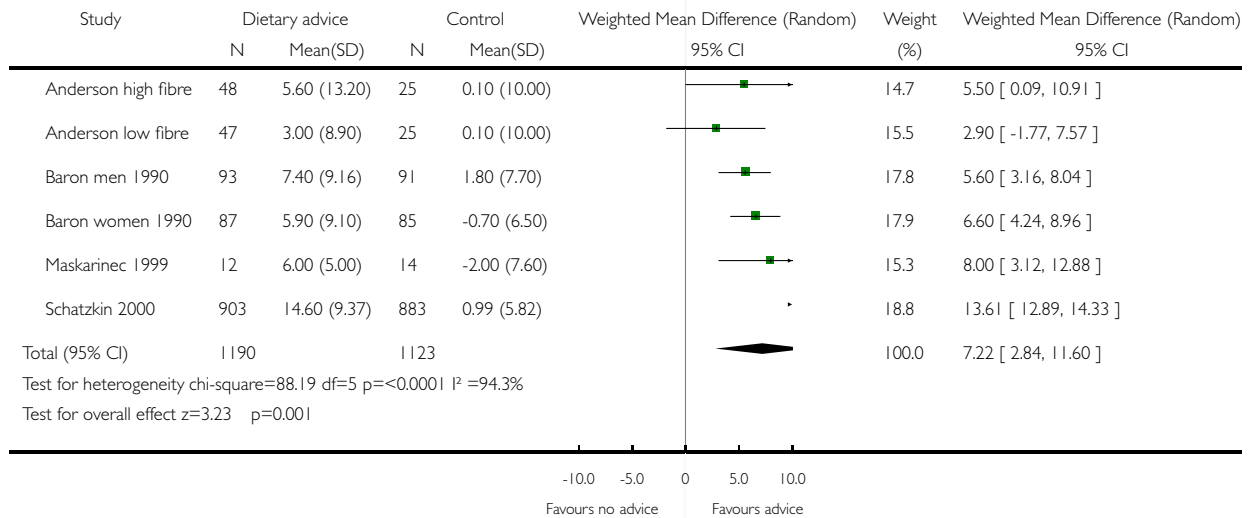
**Analysis 01.14. Comparison 01 Any dietary intervention versus no intervention, Outcome 14 Vegetable (servings per day)**

Review: Dietary advice for reducing cardiovascular risk  
 Comparison: 01 Any dietary intervention versus no intervention  
 Outcome: 14 Vegetable (servings per day)



**Analysis 01.15. Comparison 01 Any dietary intervention versus no intervention, Outcome 15 Dietary fibre (grams per day)**

Review: Dietary advice for reducing cardiovascular risk  
 Comparison: 01 Any dietary intervention versus no intervention  
 Outcome: 15 Dietary fibre (grams per day)



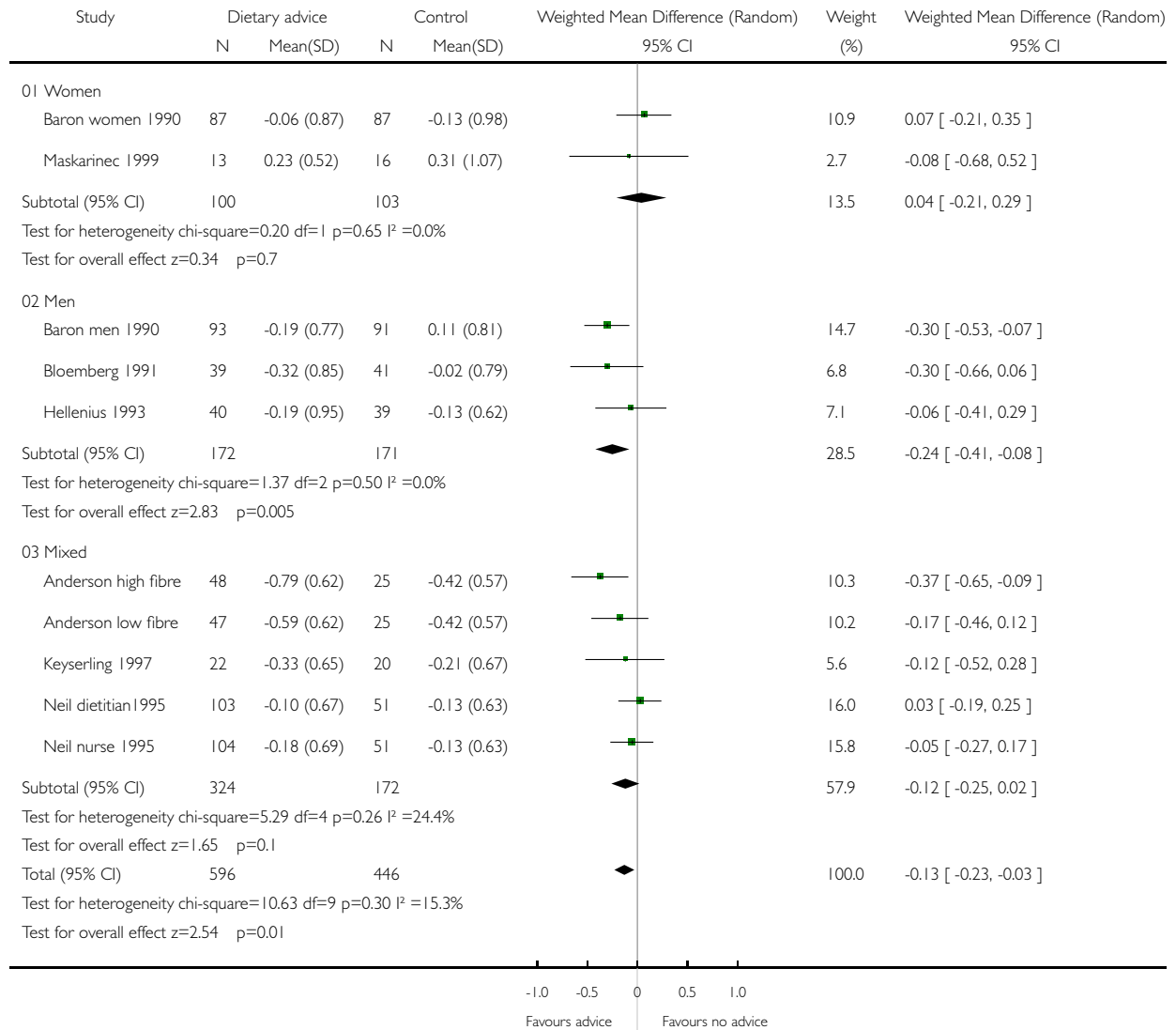


### Analysis 02.01. Comparison 02 Subgroup analyses, Outcome 01 Total cholesterol (gender)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 02 Subgroup analyses

Outcome: 01 Total cholesterol (gender)

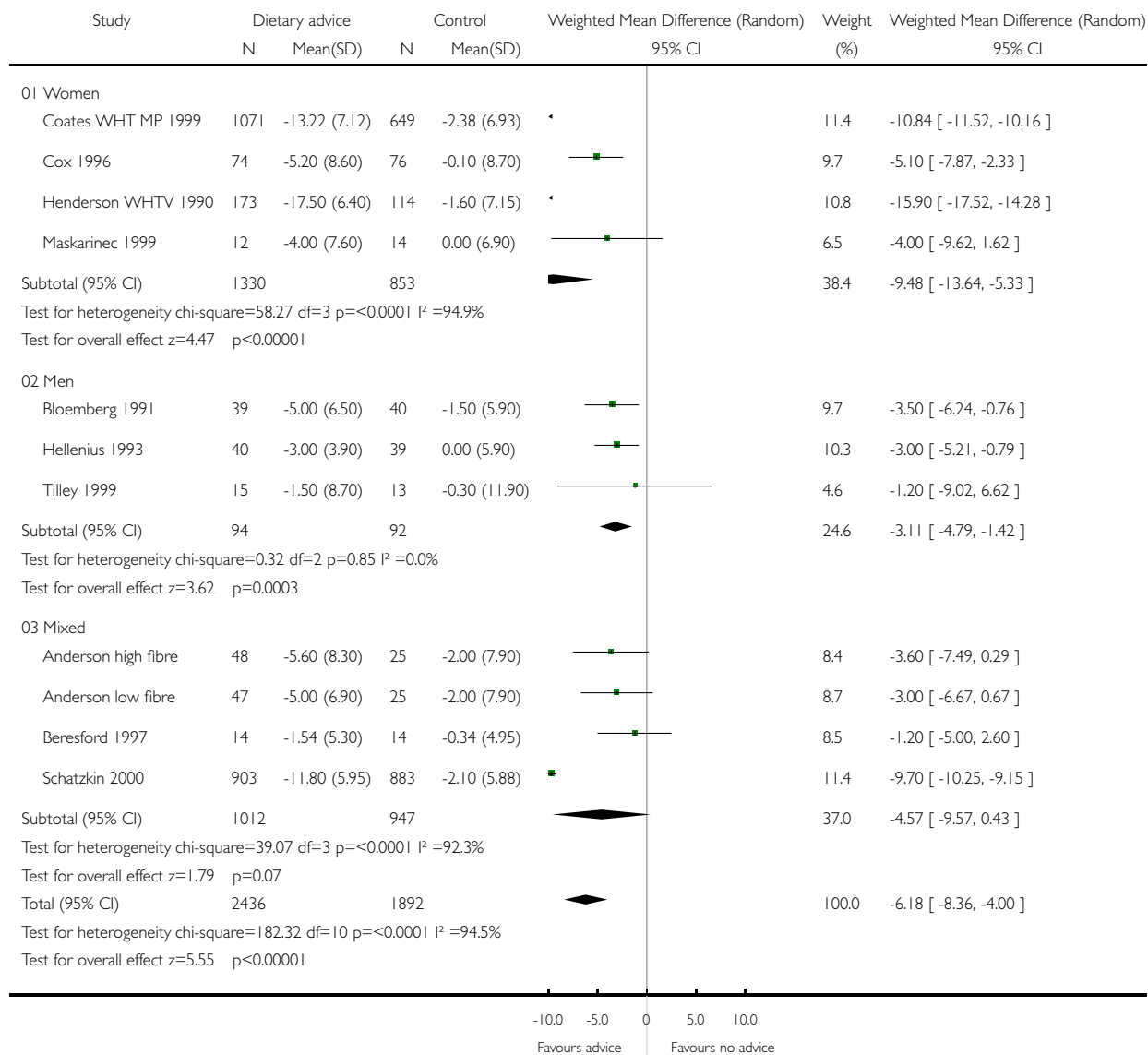


## Analysis 02.02. Comparison 02 Subgroup analyses, Outcome 02 Total dietary fat (gender)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 02 Subgroup analyses

Outcome: 02 Total dietary fat (gender)

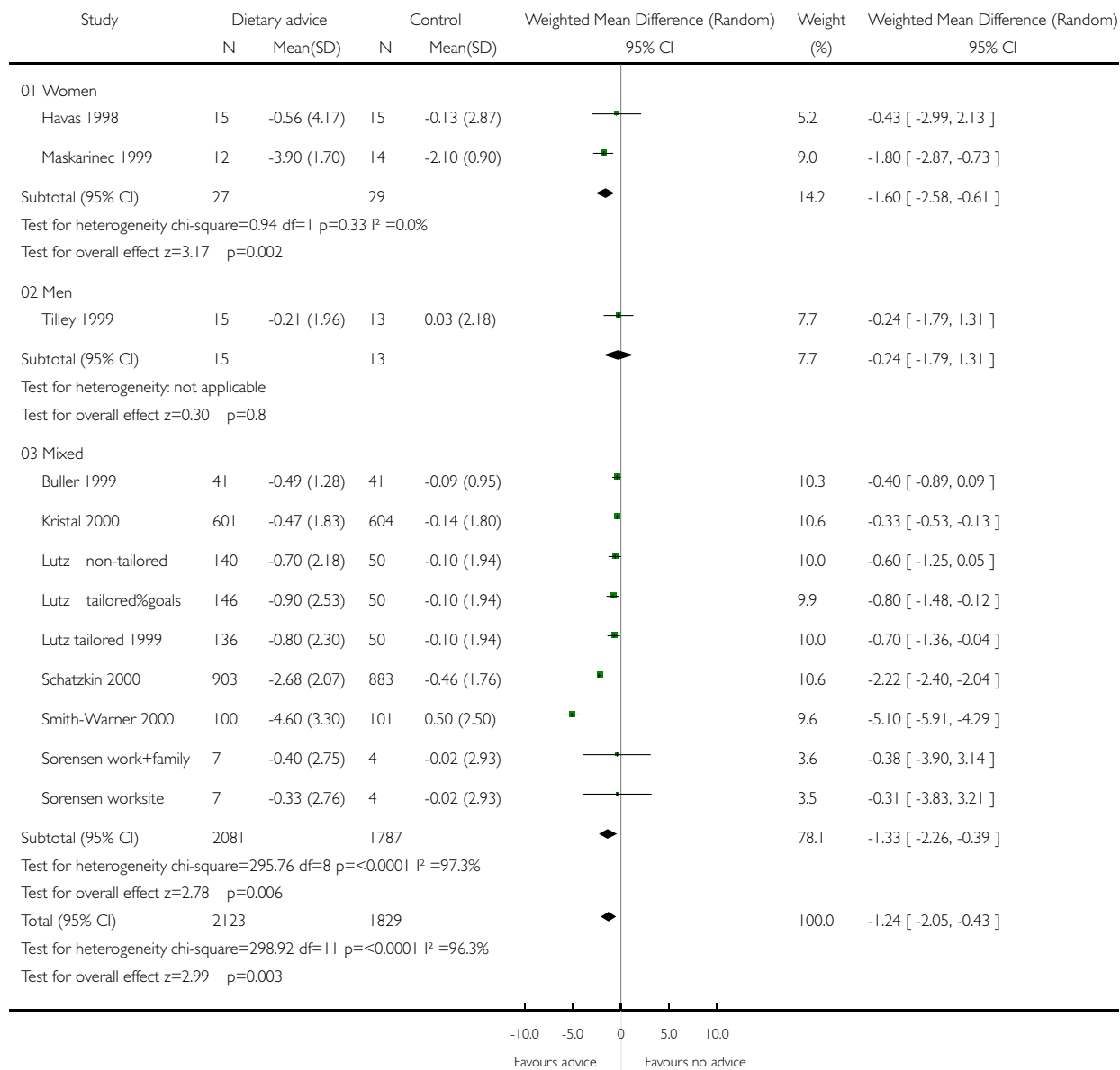


### Analysis 02.03. Comparison 02 Subgroup analyses, Outcome 03 Fruit & vegetable servings/day (gender)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 02 Subgroup analyses

Outcome: 03 Fruit % vegetable servings/day (gender)

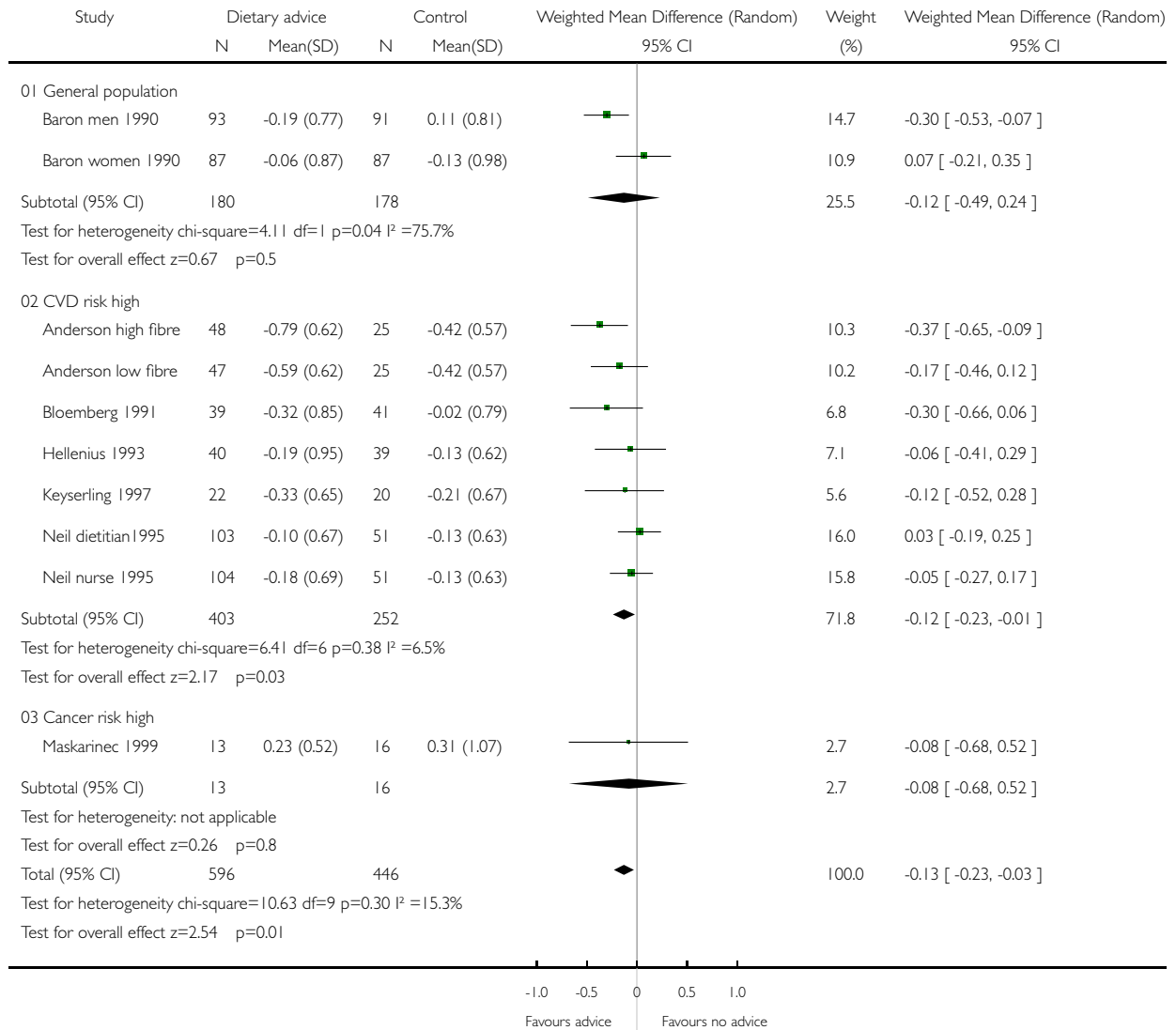


### Analysis 02.04. Comparison 02 Subgroup analyses, Outcome 04 Total cholesterol (risk group)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 02 Subgroup analyses

Outcome: 04 Total cholesterol (risk group)

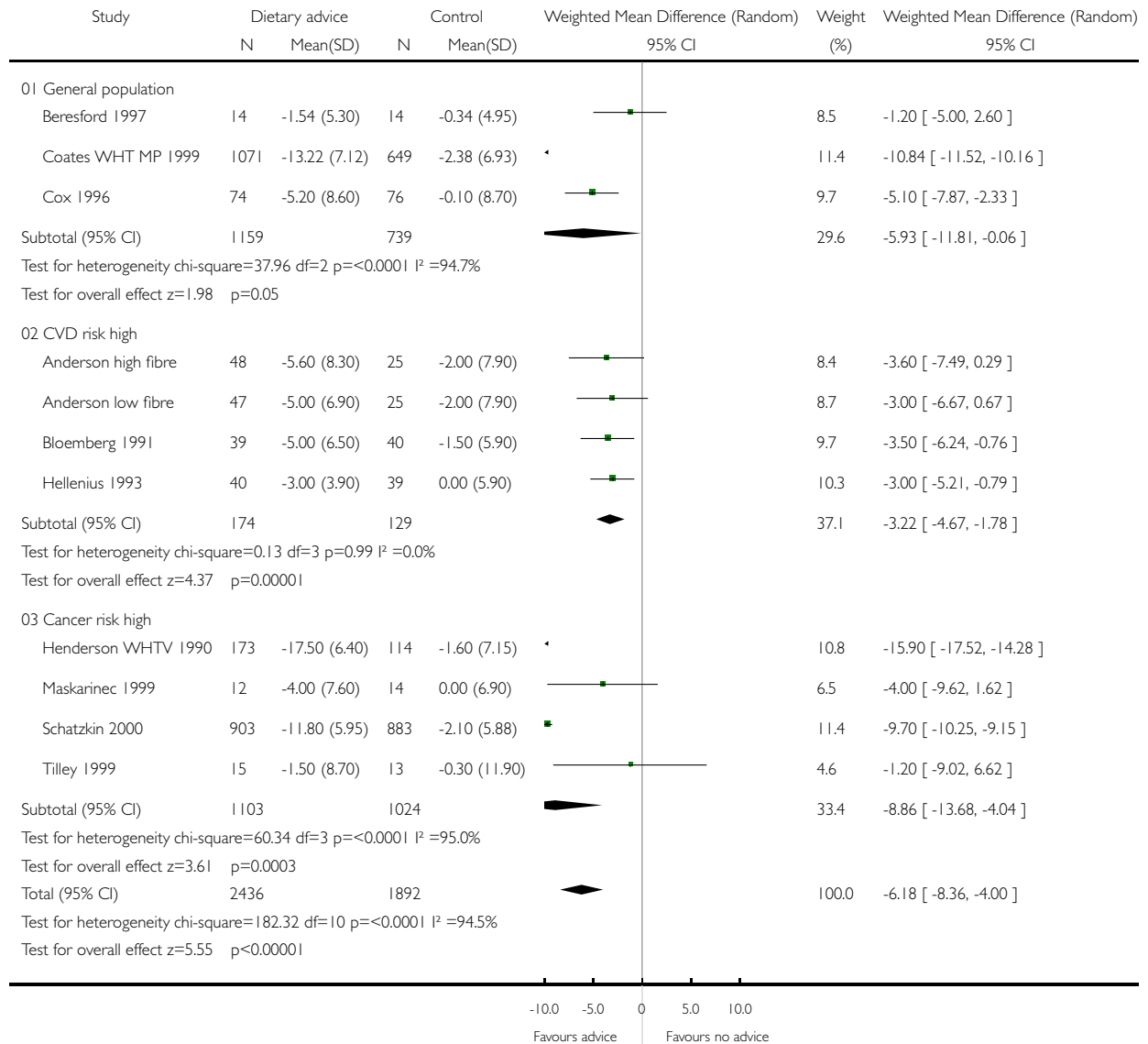


### Analysis 02.05. Comparison 02 Subgroup analyses, Outcome 05 Total dietary fat (risk group)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 02 Subgroup analyses

Outcome: 05 Total dietary fat (risk group)

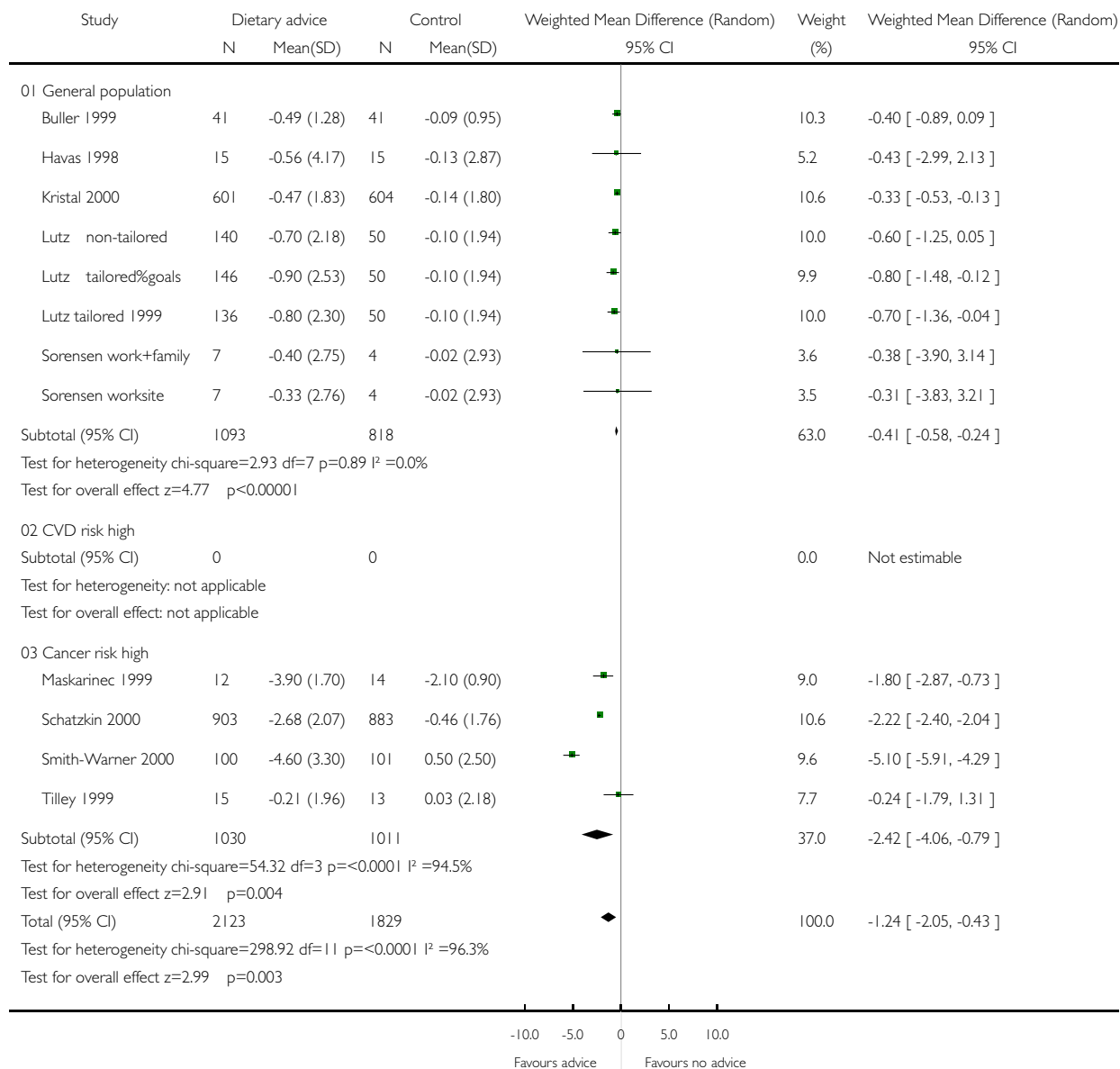


## Analysis 02.06. Comparison 02 Subgroup analyses, Outcome 06 Fruit & vegetable servings/day (risk group)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 02 Subgroup analyses

Outcome: 06 Fruit % vegetable servings/day (risk group)

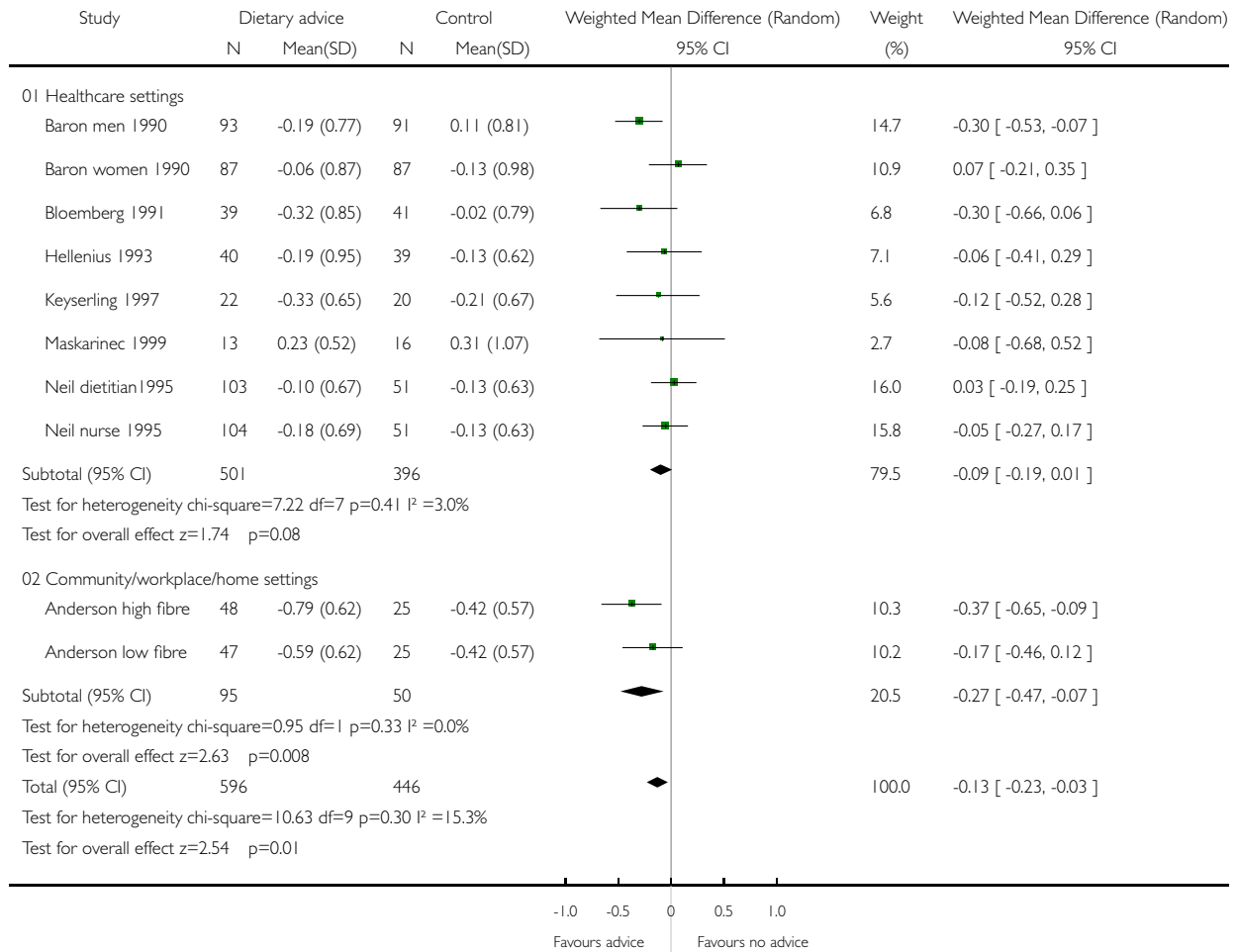


### Analysis 02.07. Comparison 02 Subgroup analyses, Outcome 07 Total cholesterol (setting)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 02 Subgroup analyses

Outcome: 07 Total cholesterol (setting)

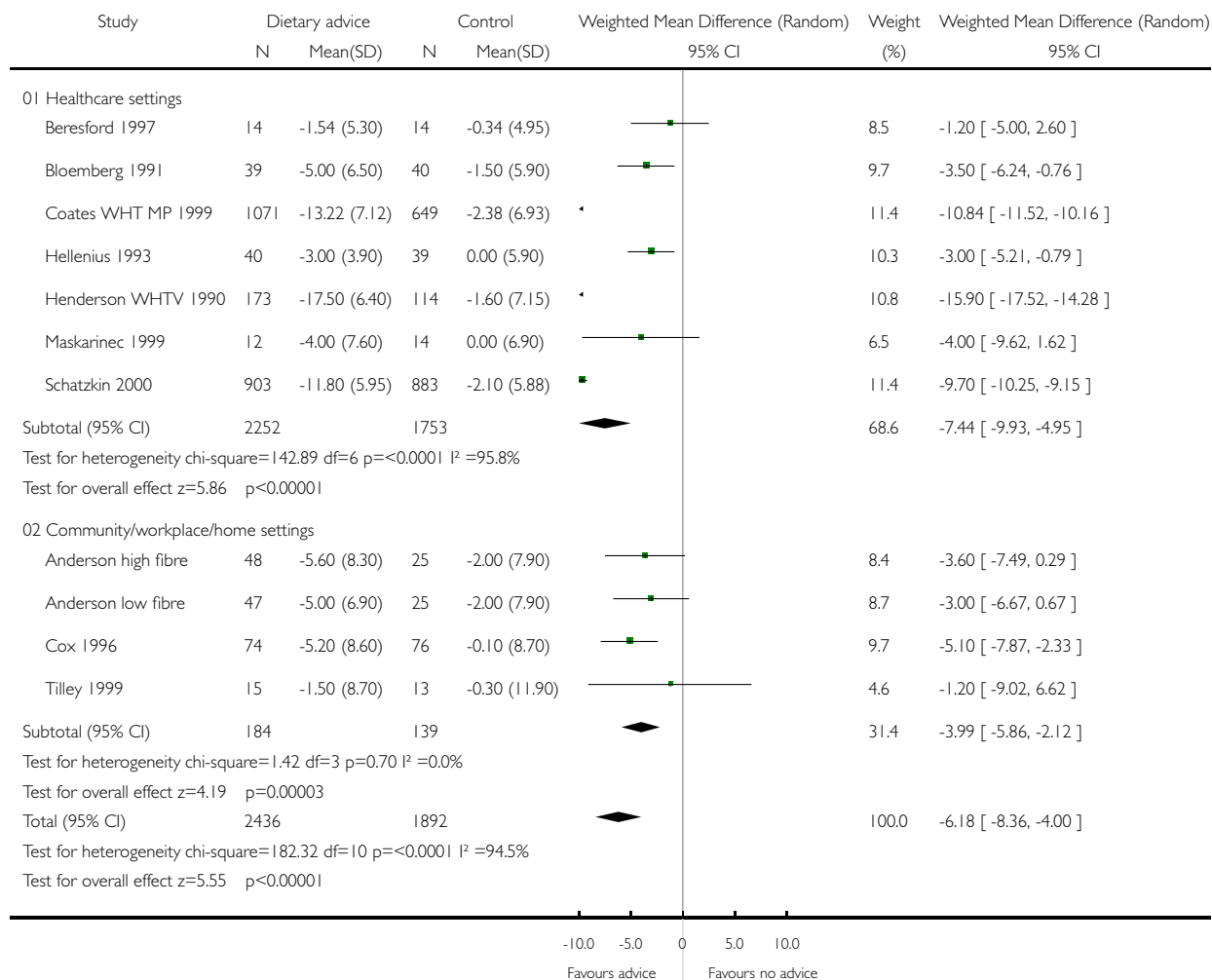


### Analysis 02.08. Comparison 02 Subgroup analyses, Outcome 08 Total dietary fat (setting)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 02 Subgroup analyses

Outcome: 08 Total dietary fat (setting)



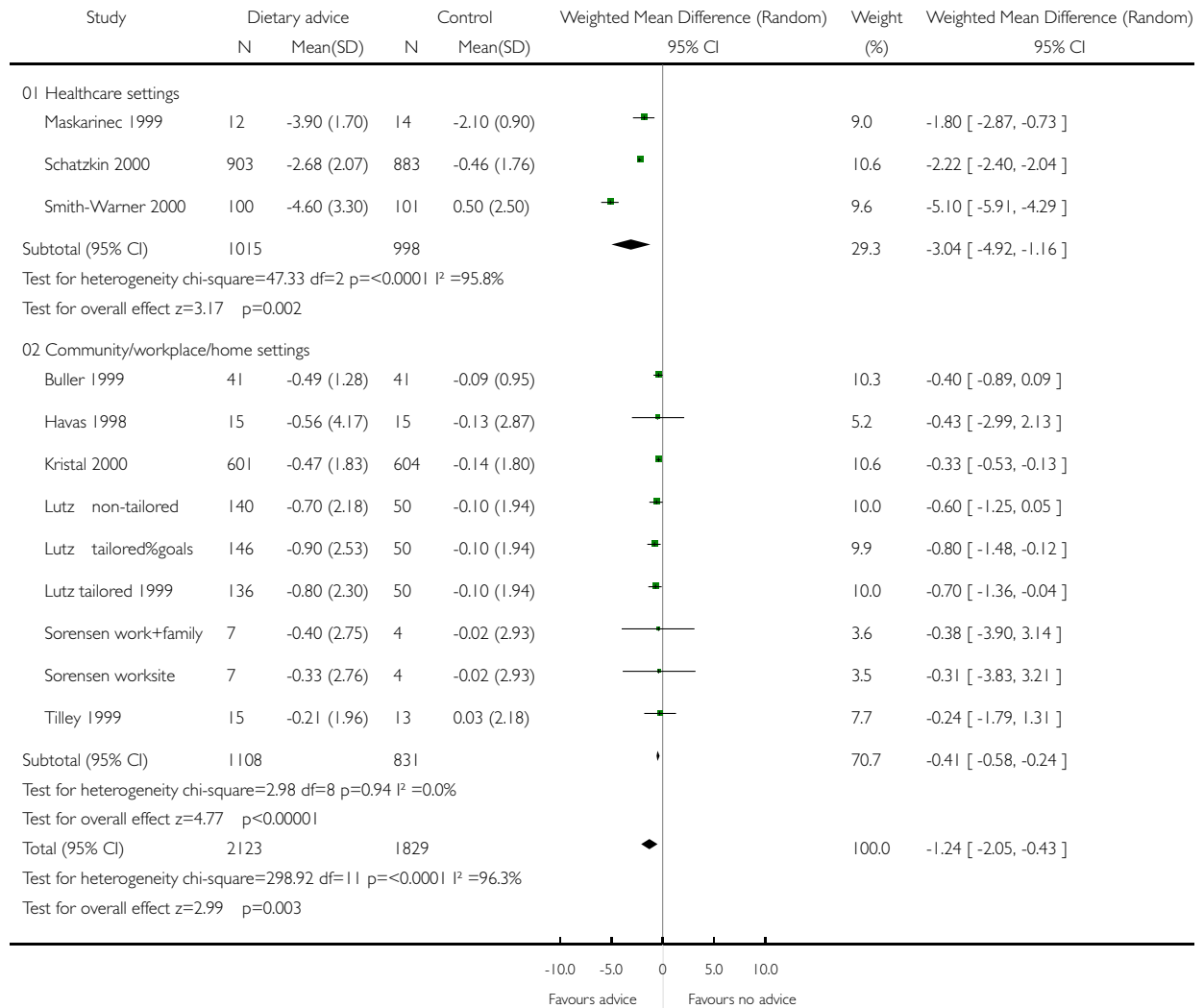


### Analysis 02.09. Comparison 02 Subgroup analyses, Outcome 09 Fruit & vegetable servings/day (setting)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 02 Subgroup analyses

Outcome: 09 Fruit % vegetable servings/day (setting)

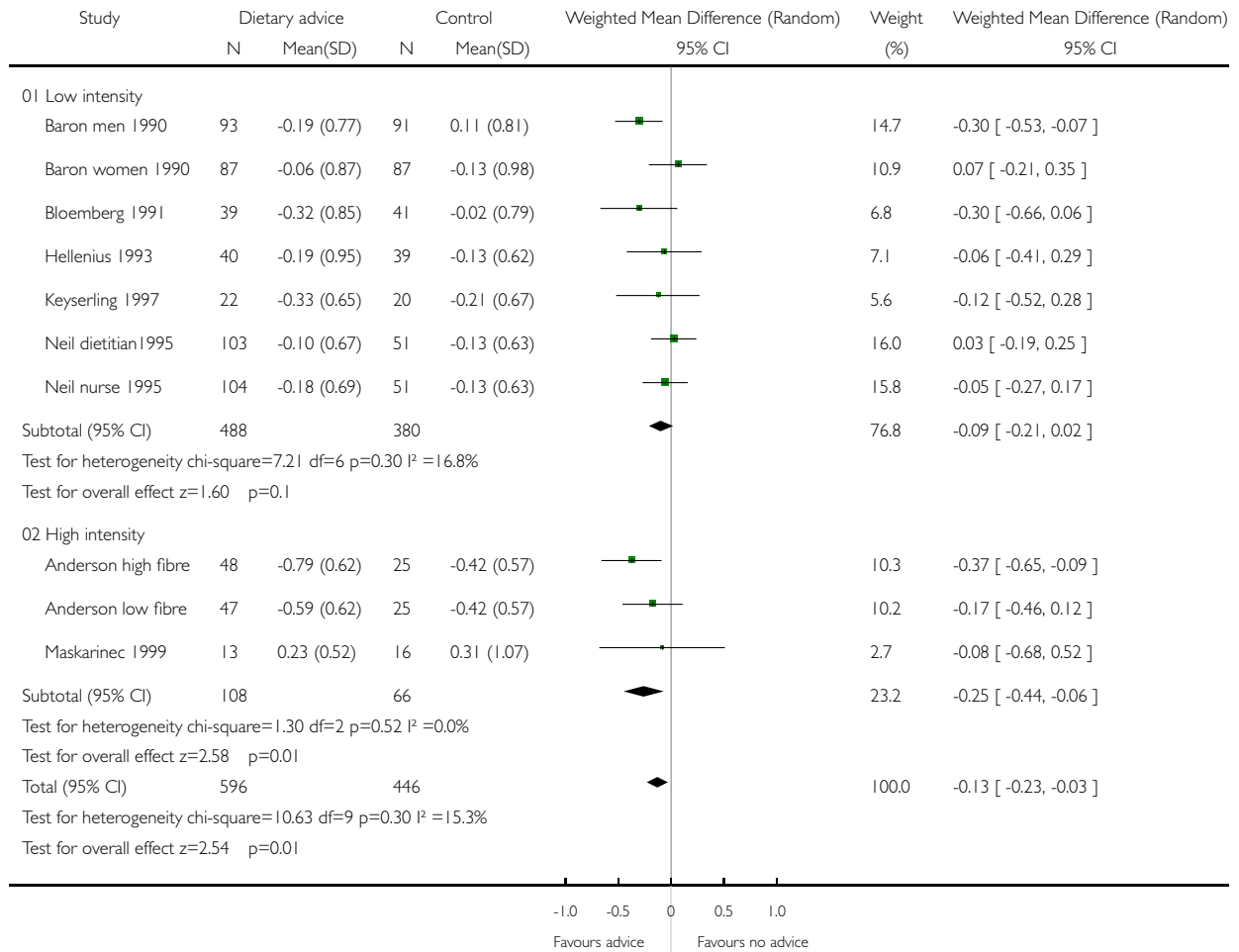


### Analysis 02.10. Comparison 02 Subgroup analyses, Outcome 10 Total cholesterol (intensity)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 02 Subgroup analyses

Outcome: 10 Total cholesterol (intensity)

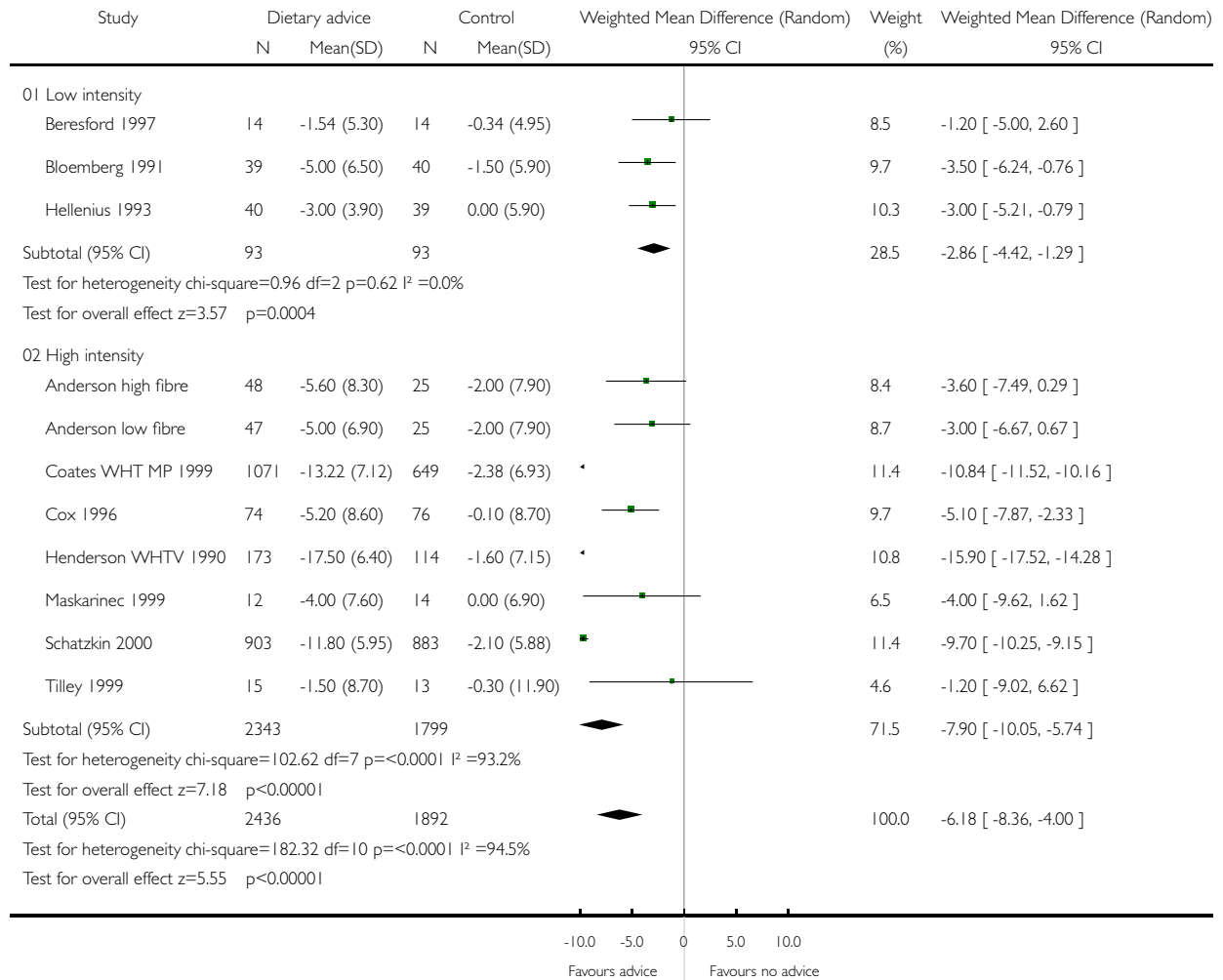


### Analysis 02.11. Comparison 02 Subgroup analyses, Outcome 11 Total dietary fat (intensity)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 02 Subgroup analyses

Outcome: 11 Total dietary fat (intensity)

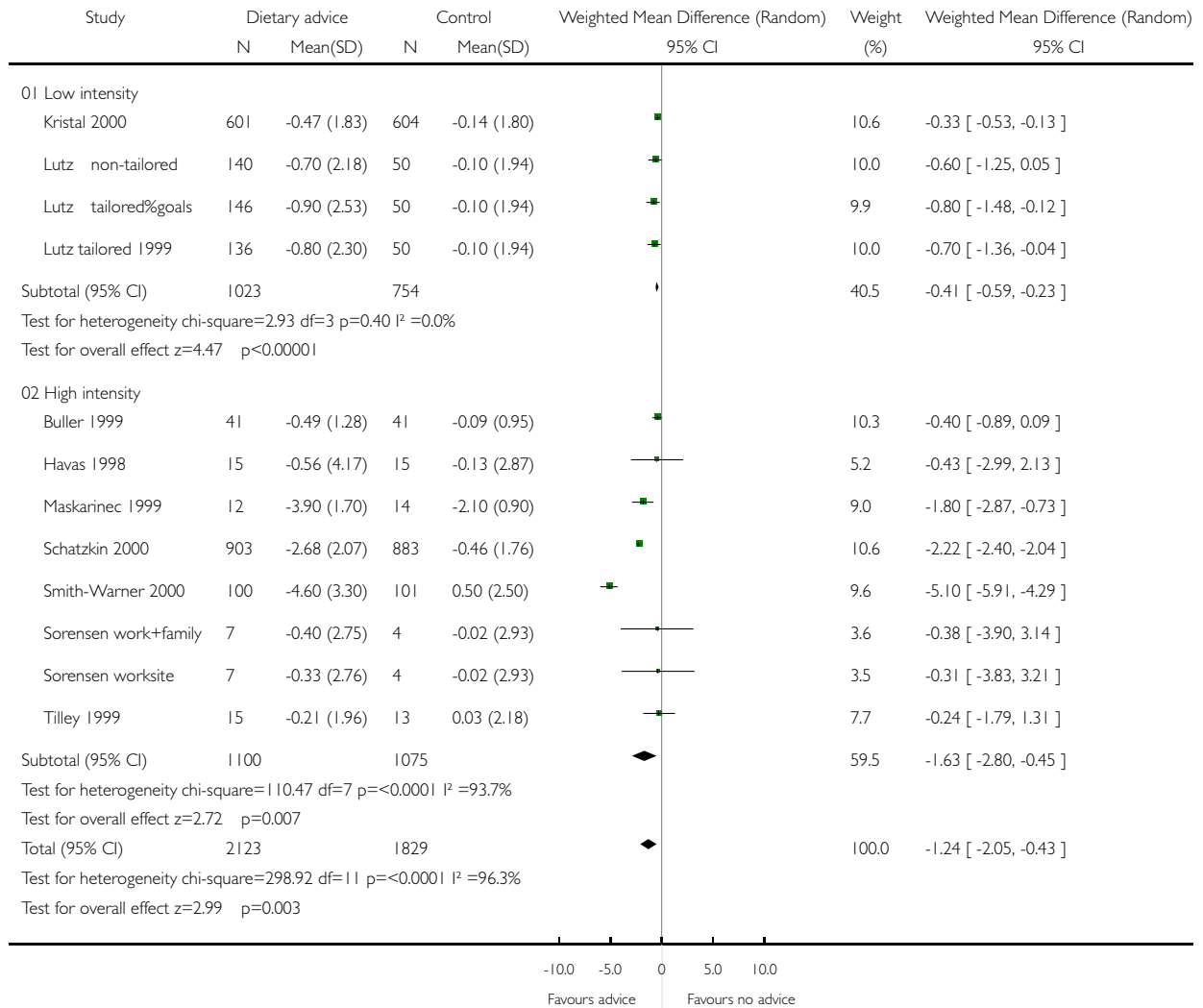


## Analysis 02.12. Comparison 02 Subgroup analyses, Outcome 12 Fruit & vegetable servings/day (intensity)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 02 Subgroup analyses

Outcome: 12 Fruit % vegetable servings/day (intensity)

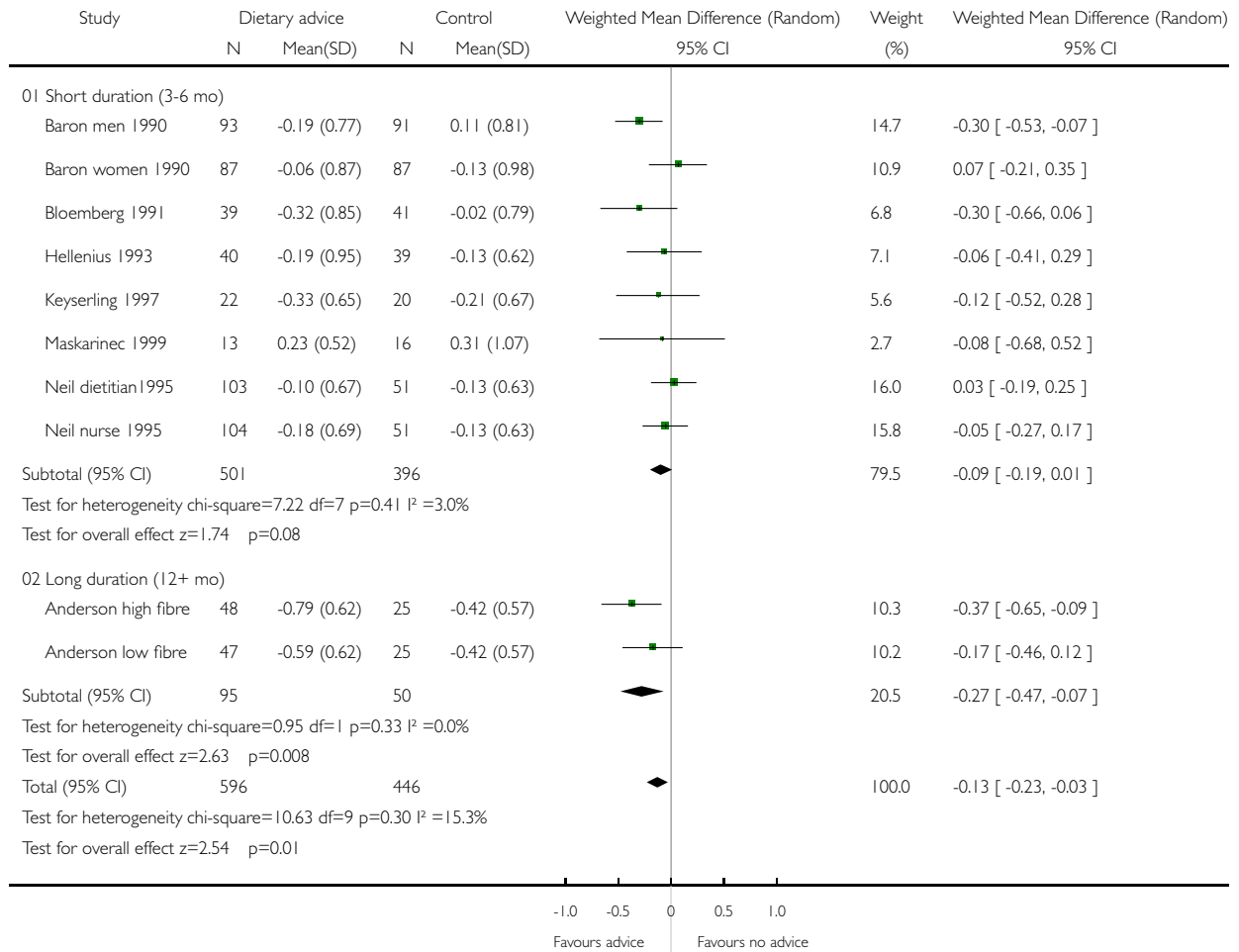


### Analysis 02.13. Comparison 02 Subgroup analyses, Outcome 13 Total cholesterol (duration)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 02 Subgroup analyses

Outcome: 13 Total cholesterol (duration)

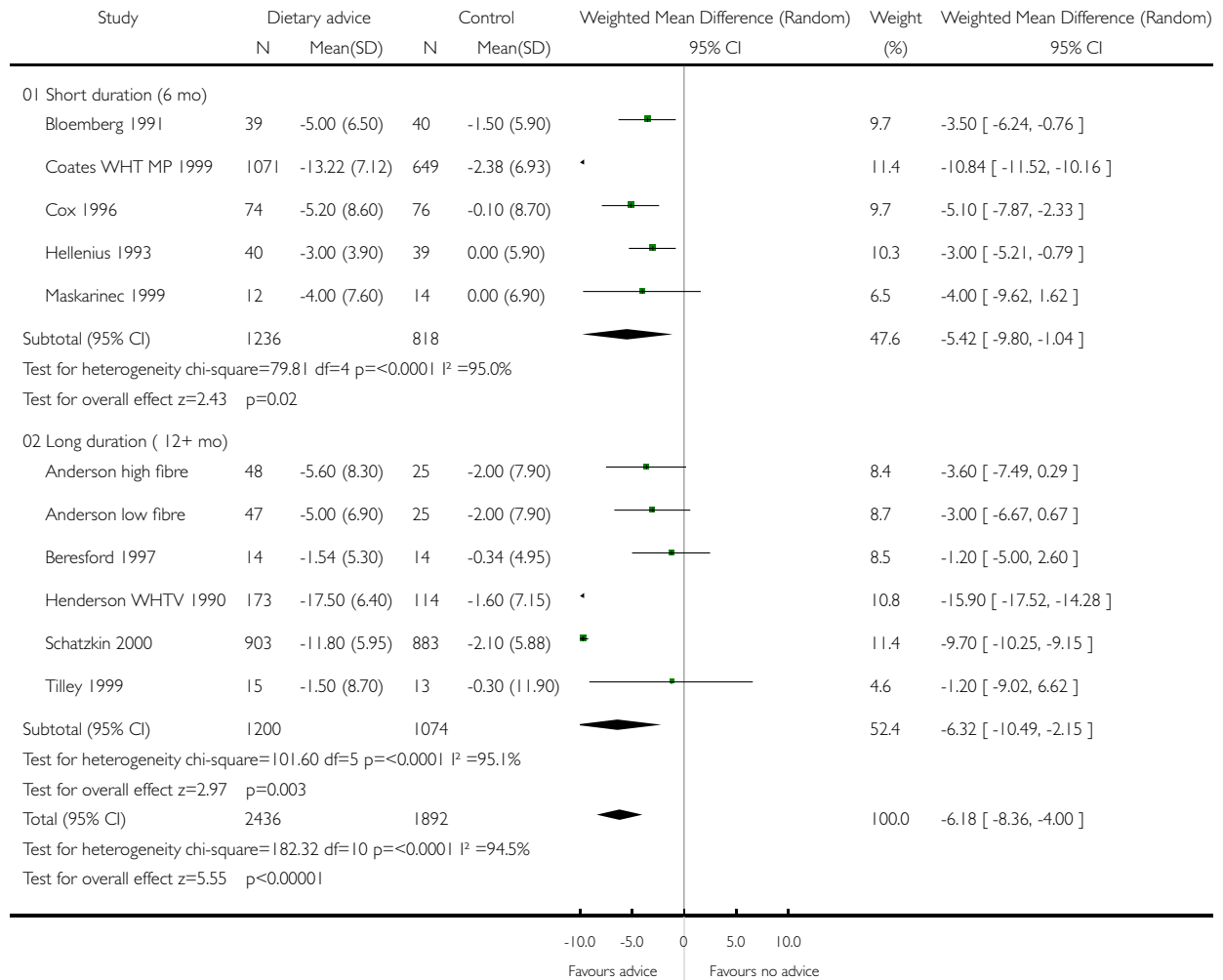


### Analysis 02.14. Comparison 02 Subgroup analyses, Outcome 14 Total dietary fat (duration)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 02 Subgroup analyses

Outcome: 14 Total dietary fat (duration)



## Analysis 02.15. Comparison 02 Subgroup analyses, Outcome 15 Fruit & vegetable servings/day (duration)

Review: Dietary advice for reducing cardiovascular risk

Comparison: 02 Subgroup analyses

Outcome: 15 Fruit % vegetable servings/day (duration)

