

Dietary advice for reducing cardiovascular risk (Review)

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[Intervention Review]

Dietary advice for reducing cardiovascular risk

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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 methods

We searched the Cochrane Central Register of Controlled Trials, DARE and HTA databases on *The Cochrane Library* (Issue 4 2006), MEDLINE (1966 to December 2000, 2004 to November 2006) and EMBASE (1985 to December 2000, 2005 to November 2006). Additional searches were done on CAB Health (1972 to December 1999), CVRCT registry (2000), CCT (2000) and SIGLE (1980 to 2000). Dissertation abstracts and reference lists of articles were checked and researchers were contacted.

Selection criteria

Randomised studies with no more than 20% loss to follow-up, lasting at least 3 months involving healthy adults comparing dietary advice with no advice or minimal 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

Thirty-eight trials with 46 intervention arms (comparisons) comparing dietary advice with no advice were included in the review. 17,871 participants/clusters were randomised. Twenty-six of the 38 included trials were conducted in the USA. Dietary advice reduced total serum cholesterol by 0.16 mmol/L (95% CI 0.06 to 0.25) and LDL cholesterol by 0.18 mmol/L (95% CI 0.1 to 0.27) after 3-24 months. Mean HDL cholesterol levels and triglyceride levels were unchanged. Dietary advice reduced blood pressure by 2.07 mmHg systolic (95% CI 0.95 to 3.19) and 1.15 mmHg diastolic (95% CI 0.48 to 1.85) and 24-hour urinary sodium excretion by 44.2 mmol (95% CI 33.6 to 54.7) after 3-36 months. Three trials reported plasma antioxidants where small increases were seen in lutein and β -

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cryptoxanthin, but there was heterogeneity in the trial effects. 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 1.25 servings/day (95% CI 0.7 to 1.81). Dietary fibre intake increased with advice by 5.99 g/day (95% CI 1.12 to 10.86), while total dietary fat as a percentage of total energy intake fell by 4.49 % (95% CI 2.31 to 6.66) with dietary advice and saturated fat intake fell by 2.36 % (95% CI 1.32 to 3.39).

Authors' conclusions

Dietary advice appears to be effective in bringing about modest beneficial changes in diet and cardiovascular risk factors over approximately 10 months but longer term effects are not known.

PLAIN LANGUAGE SUMMARY

Dietary advice for reducing cardiovascular risk

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 38 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 fruit, 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 counselling over 4 years. The duration of the trials ranged from 3 months to 4 years, with a median follow-up period of 10 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

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.

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, Australasian and Japanese 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).

OBJECTIVES

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

METHODS

Criteria for considering studies for this review

Types of studies

We have included randomised controlled trials (RCTs) 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. Trials involving pregnant women or children, trials to reduce weight or those involving supplementation were excluded.

Types of interventions

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

1. Cardiovascular risk factors: resting blood pressure, blood lipids and lipoproteins (cholesterol), and blood or red cell folate and/or homocysteine.
2. Bio-markers of dietary intake: urinary sodium, urinary potassium and blood diet-derived antioxidants such as β -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 3 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

Electronic searches

We searched the Cochrane Central Register of Controlled Trials, the Database of Abstracts of Reviews of Effects (DARE) and the HTA database on *The Cochrane Library* (Issue 4 2006). We searched MEDLINE (January 1966 to December 2000, 2004 to November 2006) and EMBASE (January 1985 to December 2000, 2005 to November 2006). The updated searches were run from the years 2004 (MEDLINE) and 2005 (EMBASE) as central searches of these databases mean that identified RCTs have previously been added to CENTRAL.

Additional searches were done on 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 search strategy used for *The Cochrane Library* is below, see additional Table 1 and Table 2 for details of MEDLINE and EMBASE searches. A filter for finding RCTs was used on MEDLINE (Dickersin 1994) and EMBASE (Lefebvre 1996).

- #1 MeSH descriptor Diet, Atherogenic explode all trees
- #2 MeSH descriptor Diet, Fat-Restricted this term only
- #3 MeSH descriptor Diet, Sodium-Restricted this term only
- #4 MeSH descriptor Dietary Fats explode all trees
- #5 MeSH descriptor Dietary Fiber this term only
- #6 MeSH descriptor Potassium, Dietary this term only
- #7 MeSH descriptor Sodium, Dietary explode all trees
- #8 MeSH descriptor Ascorbic Acid explode all trees
- #9 MeSH descriptor beta Carotene this term only
- #10 MeSH descriptor FOLIC ACID explode all trees
- #11 MeSH descriptor VITAMIN E explode all trees
- #12 MeSH descriptor FISH OILS explode all trees
- #13 MeSH descriptor PLANT OILS explode all trees
- #14 MeSH descriptor DAIRY PRODUCTS explode all trees
- #15 MeSH descriptor FRUIT explode all trees
- #16 MeSH descriptor MEAT explode all trees
- #17 MeSH descriptor VEGETABLES explode all trees
- #18 MeSH descriptor Fats, Unsaturated explode all trees
- #19 MeSH descriptor Fatty Acids, Unsaturated explode all trees
- #20 (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10)
- #21 (#11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19)
- #22 diet*
- #23 food*
- #24 (lipid near/6 modifi*)
- #25 (lipid* near/6 low*)
- #26 (lipid* near/6 reduc*)
- #27 (fat* near/6 low*)
- #28 (fat* near/6 modifi*)
- #29 (fat* near/6 animal)
- #30 (fat* near/6 acid*)
- #31 (fat* near/6 saturat*)
- #32 (fat* near/6 unsaturat*)
- #33 (oil* near/6 olive)
- #34 (oil* near/6 rape*)
- #35 (oil* near/6 sunflower*)
- #36 (oil* near/6 linseed*)
- #37 (oil* near/6 saturat*)
- #38 (oil* near/6 unsaturat*)
- #39 polyunsaturate*
- #40 monounsaturate*
- #41 omega*
- #42 (fat or fats or oil*)

- #43 omega3*
- #44 omega-3*
- #45 (omega* near/6 fat*)
- #46 (diet* or food*)
- #47 margarine*
- #48 butter
- #49 meat
- #50 fish
- #51 vegetable*
- #52 fruit*
- #53 legum*
- #54 soy*
- #55 (#22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30)
- #56 (#31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40)
- #57 (#41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50)
- #58 (#51 or #52 or #53 or #54)
- #59 (#55 or #56 or #57 or #58)
- #60 (#20 or #21 or #59)
- #61 MeSH descriptor HEALTH EDUCATION explode all trees
- #62 MeSH descriptor COUNSELING explode all trees
- #63 MeSH descriptor COMMUNICATION explode all trees
- #64 MeSH descriptor PRACTICE GUIDELINES this term only
- #65 MeSH descriptor BEHAVIOR THERAPY explode all trees
- #66 (#61 or #62 or #63 or #64 or #65)
- #67 (#60 and #66)
- #68 counsel*
- #69 advice
- #70 leaflet*
- #71 video*
- #72 (poster or posters)
- #73 (educate* or educational)
- #74 MeSH descriptor Life Style explode all trees
- #75 MeSH descriptor Risk Reduction Behavior this term only
- #76 (lifestyle near/6 change*)
- #77 (lifestyle near/6 program*)
- #78 (diet* near/6 change*)
- #79 (#61 or #62 or #63 or #64 or #65 or #66 or #67 or #68 or #69 or #70)
- #80 (#71 or #72 or #73 or #74 or #75 or #76 or #77)
- #81 (#80 and #60)
- #82 (health next behavi* near/6 intervention*)
- #83 guideline*
- #84 brief next intervention*
- #85 diet* next therap* in Abstract
- #86 MeSH descriptor diet therapy this term only
- #87 (diet near/6 plan)
- #88 diet* next therap* in Record Title
- #89 diet* next intervention*
- #90 diet* next treatment*

#91 MeSH descriptor food habits this term only
#92 (behavi* near/3 change*)
#93 motivat*
#94 MeSH descriptor motivation this term only
#95 (#82 or #83 or #84 or #85 or #86 or #87 or #88 or #89 or #90 or #91 or #92 or #93 or #94)
#96 (#95 and #60)
#97 (#96 or #81)

Handsearching and other sources

In the original review, 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. These groups were contacted and asked to search their trials 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.

Data collection and analysis

Selection of studies

For the original search 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.

The results of the updated search were checked by one reviewer to eliminate those studies that were definitely not relevant to the review. Remaining records were checked by two reviewers independently. All papers that were thought to be of relevance were obtained and read by two reviewers independently. Two reviewers 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 or by consultation with a third reviewer.

Data extraction and management

Data on participants, interventions, outcomes and trial quality were extracted independently by two reviewers 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 ([Cochrane Handbook](#)). We combined net differences across studies using a random-effects model. 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 Handbook](#) 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 carry-over 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); and
- Trial duration: short, long (follow up at 12 months or more).

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of ongoing studies](#).

Results of search

The searches generated 45,100 hits. Screening of titles and abstracts identified 299 papers for formal inclusion or exclusion. Of these 38 trials met the inclusion criteria. Fifteen new trials were included following the updated search, a substantial increase on the 23 included in the original review.

Details of the studies included in the review are shown in the table of characteristics of included studies. Reasons for exclusion for the majority of studies included greater than 20% missing outcome data at follow up without an intention-to-treat analysis, the control group did not receive minimal intervention or no intervention and insufficient data for analysis despite contact or attempted contact with investigators. Details and reasons for exclusion for the studies which most closely missed the strict inclusion criteria are presented in the table of excluded studies.

Included studies

Details of methods, participants, interventions and outcome measures are presented in the included studies table. Thirty-eight trials with 46 trial arms were included with 17871 participants/clusters randomised. Twenty-six of the 38 included trials were conducted in the USA.

Weight change

Twenty-one of the 29 individually randomised trials provided information on initial weight and/or weight loss during follow-up.

Baseline body mass index (BMI) was approximately 30 kg/m² in two trials ([Cheng 2004](#); [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 13 trials ([Anderson high fibre](#); [Anderson low fibre](#); [Baron men 1990](#); [Baron women 1990](#); [Bloemberg 1991](#); [Brekke 2005](#); [Cheng 2004](#); [Hellenius 1993](#); [John 2002](#); [Maskarinec 1999](#); [Neil dietitian 1995](#); [Neil nurse 1995](#); [Sacerdote 2006](#); [Smith-Warner 2000](#); [Takahashi 2006](#); [van der Veen 2002](#)), 1.1 kg in one ([Schatzkin 2000](#)) and 1.8 kg in one ([Henderson WHTV 1990](#)).

Gender

Twenty-five trials enrolled men and women, and of these one presented the findings by gender ([Baron men 1990](#); [Baron women 1990](#)). Ten trials enrolled women only, three men only.

Disease risk group

Seventeen 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 recruited American women through direct contact and mailings ([Elder promotora](#); [Elder tailored](#); [Gann 2003](#)), three involved clients of American health maintenance organisations ([Kristal 2000](#); [Lutz non-tailored](#); [Stevens 2003](#)), two recruited from healthcare settings in Italy and the UK ([John 2002](#); [Sacerdote 2006](#)), one recruited from Black American churches ([Fuemmeler 2006](#)) and three from US worksites ([Beresford 2006](#); [Buller 1999](#); [Sorensen worksite](#)).

Thirteen trials enrolled participants on the basis of cardiovascular disease risk factor screening, of which six involved cholesterol screening ([Anderson high fibre](#); [Bloemberg 1991](#); [Cheng 2004](#); [Hellenius 1993](#); [Keyserling 1997](#); [Neil dietitian 1995](#); [van der Veen 2002](#)), four blood pressure screening ([Koopman 1990](#); [Little 2004](#); [TOHP II 1997](#); [TOHP I 1992](#)) and one plasma homocysteine screening ([Riddell 2000](#)). One trial enrolled siblings of CHD patients diagnosed before 60 years of age with at least one other risk factor (eg. high cholesterol or blood pressure levels) ([Moy 2001](#)), and one recruited first degree relatives of type-2 diabetic patients ([Brekke 2005](#)).

Three trials enrolled people who were at increased risk of breast cancer ([Djuric combination](#); [Djuric high F&V](#); [Henderson WHTV 1990](#); [Maskarinec 1999](#)), one trial enrolled people at increased risk of cervical cancer ([Rock 2001](#)), two trials enrolled people at increased risk of 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 (25 studies), while others were set in the work place (four studies), community centres (six studies) or exclusively in the home (three studies) using telephone and mail ([Kristal 2000](#); [Lutz non-tailored](#); [Lutz tailored 1999](#); [Lutz tailored&goals](#); [Rock 2001](#)).

Intervention intensity

Fifteen trials involved an intervention design with between one

and three scheduled contacts. Twenty-three 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 12 months (12 studies). There were six short duration trials: three of 3 months (Baron men 1990; Baron women 1990; Elder promotora; Elder tailored; Koopman 1990; Riddell 2000) and two of 4 months (Cheng 2004; Keyserling 1997). Nineteen studies contributed results for 12-48 months of follow-up.

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

Risk of bias in included studies

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 3.

Randomisation

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

Allocation concealment

Three of the 29 individually randomised trials appeared to have used an adequate allocation concealment method (Little 2004; Schatzkin 2000; TOHP II 1997). Nine 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 12 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; Sacerdote 2006; 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

Nine 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 (Tilley 1999; TOHP I 1992). Another worksite trial analysed data at the level of the cluster (Beresford 2006). Three 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; van der Veen 2002). One trial was based in Black American churches where data were analysed the individual level taking account of clustering (Fuemmeler 2006). We used churches as the denominator in the meta-analysis.

Loss to follow up

Our inclusion criteria specified that loss to follow up was no more than 20%. We used the longest reported follow-up data for each trial meeting our inclusion criteria. Drop out rose to more than 20% at longer follow up in several trials (Baron men 1990; Baron women 1990; Coates WHT MP 1999; Djuric combination; Djuric high F&V; Elder promotora; Elder tailored; TOHP I 1992) and the proportion taking lipid-lowering medication exceeded 10% after 4 months in another (Keyserling 1997).

Effects of interventions

For the variables fruit and vegetable consumption, dietary fibre, high density lipoprotein (HDL) cholesterol, and micronutrients, 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 eight studies (6223 participants randomised). Two trials focused on salt reduction (TOHP I 1992; TOHP II 1997), one on salt reduction plus increased dietary fibre and polyunsaturated fatty acid intakes (Koopman 1990), and one on sodium reduction and increased intake of vitamin C and carotene by increasing fruit and vegetable intake (Takahashi 2006). One trial focused on increasing fruit and vegetable intake (John 2002), and the others more broadly on healthy eating advice (Hellenius 1993; Little 2004; Sacerdote 2006). Initial mean BP in the control group of these studies was in the range 125/84 to 154/93 mmHg (Table 4).

Systolic blood pressure was reduced by 2.06 mmHg (difference in means -2.06, 95% CI -3.19 to -0.92), and diastolic blood pressure by 1.15 mmHg (difference in means -1.15, 95% CI -1.85 to -0.46) with dietary advice. Twenty-four hour urinary sodium output was reported in three trials of salt reduction (Koopman 1990; TOHP I 1992; TOHP II 1997; 1533 participants randomised). Urinary sodium output was reduced by 44.18 mmol/24 hr (difference in means -44.18, 95% CI -54.74 to -33.62).

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

Total blood cholesterol was reported in 13 studies (17 trial arms, 2124 participants/clusters randomised). All trials involved healthy eating advice designed to lower cholesterol, except one trial and one trial arm that focused on increasing fruit and vegetable intake (Djuric high F&V; 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 4.4 to 7.4 mmol/L (Table 4).

There was a small but significant reduction in total cholesterol with advice of 0.16 mmol/l (difference in means -0.16, 95% CI -0.25 to -0.06). There was a similar reduction in low density lipoprotein (LDL) cholesterol in 10 studies (14 trial arms, 1484 participants/clusters randomised) of 0.18 mmol/L (difference in means -0.18, 95% CI -0.27 to -0.10). There was no effect of advice on HDL cholesterol in nine studies (13 trial arms, 1481 participants randomised). Triglyceride levels were reported in four studies (five trial arms, 429 participants randomised) where dietary advice had no effect.

Other biomarkers (outcomes 08, 09, 10, 11, 12, 13, 14, 15, 16, 17)

Plasma α -carotene and β -carotene were reported in three trials (four trial arms, 779 and 765 participants randomised respectively) all of which focused on increasing fruit and vegetable intake (Djuric combination; Djuric high F&V; John 2002; Rock 2001). There was heterogeneity in the trial effects and changes with the dietary intervention were in the expected direction but did not reach statistical significance. These trials also reported plasma lutein, lycopene and β -cryptoxanthin. Similarly, there was heterogeneity in the trial effects but small increases in both lutein (difference in means 0.02 μ mol/L (95% CI 0.01 to 0.04)) and β -cryptoxanthin (difference in means 0.07 μ mol/L (95% CI 0.02 to 0.11)) with the dietary intervention which were statistically significant. There was no effect of dietary advice on plasma lycopene.

Plasma α -tocopherol, γ -tocopherol and plasma ascorbic acid were reported in two trials (three trial arms, 750 participants randomised). There was no effect of dietary advice on α -tocopherol or γ -tocopherol. There was an increase in plasma ascorbic acid with dietary advice but this did not reach statistical significance. Total plasma carotenoids were measured in two trials (113 participants randomised) where the effect of dietary advice was in the expected direction but was not statistically significant.

Red cell folate was measured in one trial (Riddell 2000) which focused on increasing intake of folate rich foods. The effect was in the expected direction but was not statistically significant.

Dietary fat and dietary saturated fatty acids (outcomes 18, 19)

Total dietary fat intake was reported in 18 studies (20 trial arms, 6170 participants/clusters randomised). All data are presented as changes from baseline with the exception of one trial (Elder promotora, Elder tailored) where only final follow-up data were available. Dietary advice reflected consensus healthy eating guidelines in ten trial arms (Anderson low fibre; Beresford 1997;

Bloemberg 1991; Brekke 2005; Cox 1996; Hellenius 1993; Little 2004; Stevens 2003; Tilley 1999; van der Veen 2002). Five trials aimed to reduce fat intake to 20% or less of calories (Coates WHT MP 1999; Gann 2003; Henderson WHTV 1990; Moy 2001; Schatzkin 2000). One trial focused on increasing fruit and vegetable intake (Schatzkin 2000), and one on reducing salt and increasing fruit and vegetable intake (Takahashi 2006).

Total dietary fat intake expressed as a percentage of total calories fell by 4.49% with intervention overall (difference in means -4.49%; 95% CI -6.66 to -2.31). There was substantial heterogeneity ($P < 0.00001$) in the trial effects, with the largest effects seen in four of the five trials that aimed to reduce fat intake to 20% or less of calories. 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 reported in a subset of 10 of these trials (12 trial arms, 3157 participants randomised). Saturated fatty acid intake was reduced by 2.36% with dietary advice (difference in means -2.36%; 95% CI -3.39 to -1.32). 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 20, 21, 22)

Fifteen studies (18 trial arms, 8416 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. Five trials also aimed to reduce fat intake (Kristal 2000; Sacerdote 2006; Schatzkin 2000; Stevens 2003; 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 1.25 servings (difference in means) (95% CI 0.70 to 1.81). 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) and in women at increased risk of cervical cancer (Rock 2001). 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 eight trials (nine trial arms, 4439 participants/clusters randomised) for fruit and in seven trials (eight trial arms, 4412 participants/clusters randomised) for vegetables. There was an increase in both fruit intake alone (difference in means 0.67, 95% CI 0.07 to 1.28), and vegetable intake alone (difference in means 0.92; 95% CI

0.34 to 1.49) with the intervention. There was heterogeneity ($P < 0.00001$) in both sets of trials.

Dietary fibre (outcome 23)

Dietary fibre intake was reported in seven studies (nine trial arms, 2981 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 5.99 grams per day (difference in means) compared to those on control treatment (95% CI 1.12 to 10.86). 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).

Dietary intake of micronutrients (outcomes 24, 25)

Three trials (five trial arms, 2335 participants randomised) report dietary intake of vitamin C (ascorbic acid). Dietary intake of vitamin C increased by 53.39 mg/day with dietary advice (difference in means, 95% CI 31.97 to 74.80) but there was significant heterogeneity in trial effects.

Dietary intake of β -carotene was reported in two trials (three trial arms, 542 participants randomised). There was an increase of 3.39mg/day (difference in means, 95% CI 1.20 to 5.59) but again there was heterogeneity in the trial effects.

One trial (Lanza men 2001; Lanza women 2001) reports also dietary intake of folate and vitamin E, where the authors found a statistically significant increase in dietary folate with the intervention, but no change in vitamin E intake. Similarly, no intervention effect was seen on dietary intake of α and δ -tocopherol in another trial (Djuric combination; Djuric high F&V).

Subgroup analyses (Comparison 02)

Eight or more trials provide results for total blood cholesterol, blood pressure, 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 subgroup 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. Men, unlike women, achieved modest but significant cholesterol-lowering. 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 but there was a tendency for greater reductions in total cholesterol. Reductions in total dietary fat intake were reported more frequently in those at high risk of cancer and there was a statistically significantly greater reported intake of fruit and vegetables in this group (2.69 servings/day, 95% CI 1.53 to 3.85) compared to the general population (0.62 servings/day, 95% CI 0.32 to 0.93). 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). There were no differences in SBP or DBP between the general population and those at high risk of CVD.

Intervention setting

Trials conducted in healthcare 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 total dietary fat (high intensity, difference in means -5.72%, 95% CI -7.75 to -3.69, low intensity, difference in means -1.68% (-3.13 to -0.23)). However there was heterogeneity in the effects within the high intensity subgroup. A similar pattern was seen for reported fruit and vegetable intake. However, no differences in blood cholesterol or blood pressure 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 and blood pressure 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 3 months and

up to 4 years (median duration 10 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 3-24 months of follow up for blood total cholesterol of 0.16 mmol/L and for LDL cholesterol 0.18mmol/L. Advice to reduce salt intake and/or reduce fat and increase fruit and vegetable and fibre consumption over 3-36 months of follow up was associated with a reduction in blood pressure of 2.07 mmHg systolic and 1.15 mmHg diastolic. Advice to reduce salt intake was associated with a reduced 24-hour urinary sodium excretion of 44.2 mmol.

Reported fruit and vegetable intake increased by 1.25 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 5.99 g per day. Reported total dietary fat intake expressed as a percentage of total calorie intake fell by 4.49% with intervention over 3-48 months. The corresponding reduction in saturated fatty acid intake was 2.36%.

Overall completeness and applicability of evidence

More than 10,000 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 14,300. There was a lack of evidence in relation to plasma triglycerides and folate. Since the search for the original review to the year 2000, three new trials measuring plasma antioxidants have been included, with over 700 participants randomised (Djuric combination; Djuric high F&V; John 2002; Rock 2001). Small changes were seen with the intervention for lutein and β -cryptoxanthin but there was heterogeneity in the trial effects. With the advent of new trials, evidence for changes in plasma antioxidants with dietary advice will be more complete.

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. In the original review (searching to year 2000) it was noted that there was a lack of high

quality trials of cholesterol lowering by diet among unscreened healthy adults. Since this time, two trials have been published and included in the review, one based in the UK showing no effect of the intervention on cholesterol levels (John 2002), and one based in the US showing effects in the desirable direction but not statistically significant (Stevens 2003). 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 (Thorogood 2007). We did not identify trials meeting the inclusion criteria that used quality of life outcomes or economic evaluation.

Five US trials (11,427 participants) provided 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 11 trials of advice to increase fruit and vegetable intake among unscreened healthy adults, only two were based outside the USA (John 2002; Sacerdote 2006).

Overall quality, strength and consistency of evidence

The majority of trials were conducted in the USA (26 trials). Most trials involved individual randomisation (29). There were nine cluster-randomised trials, eight were based in the USA, three in work places, two in healthcare settings and one in community centres, and one was based in a healthcare setting in the Netherlands (van der Veen 2002). 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 (blood pressure, lipids and other biomarkers) used in this review are broadly free of information bias. For urinary sodium output, short-term salt restriction, or over-compliance bias, before the follow-up urine sample may have been

large enough to contribute to the large observed intervention effect. The three trials with both blood pressure and urinary sodium measures showed some evidence of inconsistency, in that large reductions in sodium output (TOHP I 1992; TOHP II 1997) were not associated with large reductions in blood pressure. The third trial (Koopman 1990) was small and of short (3 months) duration.

The secondary outcome measures were based on self-reported dietary intakes. Some of the intervention effects assessed by self-report were substantial, and 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. Information bias may explain in part the discrepant findings for vitamin C, the only outcome measured both by self-report and biomarker. Intake assessed by self-report was found to increase substantially in response to intervention, whereas the corresponding effect assessed by plasma ascorbate assay was not significant.

Weight loss during the trials may potentially confound changes in dietary composition indexed by blood pressure 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 blood pressure and cholesterol. Twenty-one of the 29 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; Brekke 2005; Cheng 2004; Cox 1996; Djuric combination; Djuric high F&V; Elder promotora; Elder tailored; Fuemmeler 2006; Gann 2003; Hellenius 1993; Henderson WHTV 1990; Keyserling 1997; Kristal 2000; Little 2004; Moy 2001; Neil dietitian 1995; Neil nurse 1995; Sacerdote 2006; Schatzkin 2000; Stevens 2003; Takahashi 2006; Tilley 1999; van der Veen 2002) and those focused on increasing fruit and vegetable consumption along the lines of "5-a-day" campaigns (Beresford 2006; Buller 1999; Havas 1998; John 2002; Lutz non-tailored; Lutz tailored 1999; Lutz tailored&goals; Maskarinec 1999; Rock 2001; Smith-Warner 2000; Sorensen work+family; Sorensen worksite). In addition, three trials emphasised salt restriction (Koopman 1990; TOHP I 1992; TOHP II 1997), 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 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, provide some evidence that higher intensity intervention is associated with larger dietary changes, particularly for dietary fat intake. 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 38 trials with 46 intervention arms meeting the inclusion criteria, 20 (23 intervention arms, 8795 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 2.07 mmHg (95% CI -3.19 to 0.95) and diastolic pressure of 1.15 mmHg (95% CI -1.85 to 0.48). 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, two large studies targeting salt reduction (TOHP I 1992; TOHP II 1997) involved intensive interventions whereas the remaining six studies involved low intensity interventions. In subgroup analysis there was no evidence of an effect of intervention intensity on outcome although there was heterogeneity in the trial effects in the low intensity group, possibly reflecting the different intervention types, with three targeting salt reduction as well as general healthy eating advice, and three targeting reductions in fat and/or increasing fruit, vegetable and fibre consumption. Given the evidence of effectiveness of low intensity interventions is limited, 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 2003), 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. 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 (Brunner 2006).

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 (Thorogood 2007). 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 1 year or more are notably sparse. Trials utilising quality of life outcomes or cost-effectiveness evaluation are lacking. 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.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

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 g/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	
Outcomes	Dietary fibre, total dietary fat and saturated fatty acids (% Kcal), total, HDL and LDL cholesterol	
Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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 g/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		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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. Followup 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	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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
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	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Beresford 2006

Methods	Cluster RCT. Worksite was the unit of randomisation. Blocking criteria included baseline survey response rates, type and size of worksite and % of female employees. Analysis was at the level of the cluster
Participants	28 worksites (educational, medical and other) were randomised. All worksites with food serving cafeterias and with between 250 and 2000 employees within the greater metropolitan area of Seattle, USA were eligible
Interventions	The Special Intervention developed around the stages of change model addressing both the work environment and individual behaviour change. Each worksite had an employee advisory board (EAB) using a protocol specifying minimum activities required at each worksite and general structure for organising and implementing the intervention activities. The EAB met with a member of the research group approximately every 2 weeks, who provided materials, assisted with activities and participated in EAB meetings. The EABs took responsibility for tailoring the intervention. Intervention messages included increasing awareness about 5 a day and introducing the idea of eating more F&V in the workplace. The intervention targeted transition points from precontemplation to contemplation, contemplation to preparation, preparation to action and action to maintenance. The control group received a minimal intervention which encouraged eating more F&V using posters and brochures, newsletters, food demonstrations and a self help manual. Follow up was at 24 months
Outcomes	Fruit and vegetable servings/day
Notes	

Risk of bias

Beresford 2006 (Continued)

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Bloemberg 1991

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
Notes	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Brekke 2005

Methods	RCT of parallel group design.
Participants	Non-diabetic first degree relatives of type 2 diabetic patients aged 25-55 with a medical history free of CHD recruited from outpatients clinics from questionnaires concerning family history of diabetes and advertisements in newspapers in the Goteborg area, Sweden. Exclusion criteria were diabetes (fasting blood glucose >6.1 mmol/L or 2 hour blood glucose >11.1 mmol/L or both), BMI>35, diseases or medications affecting glucose or lipid metabolism. 77 participants randomised, 60% men, mean age 43 years
Interventions	Two intervention arms - diet and diet plus exercise and control group. This review is concerned only with the diet intervention. Dietary advice aimed to decrease saturated fat (goal 10% of energy), increase monosaturated fat (goal 10-15% of energy) and n-3 fatty acids (goal 1% energy) from fatty fish and vegetable origin and for vegetables to take up one third of the lunch or dinner plate, increasing fruit and soluble fibre consumption as much as possible and increasing the intake of low GI foods. Dietician performed group counselling (3-11 participants/group with members of household who prepare food), sessions lasted 1-2 hours. There were 2 dietary education sessions 1-2 weeks apart at the beginning of the study. During the 16 week intervention period there was intensive follow-up with unannounced phone calls every 10 days (8 calls per person). Control group participants received a letter informing them to continue with their usual lifestyle. Follow-up was at 2 years. For ethical reasons after 1 year the control group began the intervention and were followed for a further 2 years. This review uses the follow-up data at 12 months

Brekke 2005 (Continued)

Outcomes	Plasma total cholesterol, LDL and HDL cholesterol and triglycerides (mmol/L), total fat %Kcal and saturated fat %Kcal, dietary fibre (g/1000Kcal - converted to g/day by assuming Kcal intake of 2000)	
Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Buller 1999

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.	
Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Cheng 2004

Methods	RCT of parallel group design.	
Participants	Participants with hypercholesterolaemia recruited from an urban academic primary care practice in Philadelphia. Participants were either referred by physicians or referred themselves from posters in the practice. None of the participants were on lipid lowering medications and none had prior formal nutritional counselling. 208 participants randomised, 28.6% men, mean age 53.8 years (range 25-101)	

Cheng 2004 (Continued)

Interventions	The intervention used the Food for Heart Programme, a core component of which is the dietary risk assessment - a food frequency questionnaire based on the 20 foods highest in saturated fat and cholesterol in the American diet. The dietary risk assessment has 4 categories (meats, side dishes/desserts/snacks, dairy/eggs, fats/oils) each of which formed the basis of a brief focused visit to the practice. The intervention was administered by a research assistant with no background in nutrition. Problem foods were identified and advice sheets with suggestions for more healthy substitutes were given as well as a cook book with low fat recipes. The control group received no intervention. Follow-up was at 4 months	
Outcomes	Plasma total cholesterol, LDL and HDL cholesterol (mmol/L)	
Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Coates WHT MP 1999

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 nutritionist 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	
Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Cox 1996

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		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Djuric combination

Methods	RCT of parallel group design. The control group N is halved to take account of the two intervention arms	
Participants	Premenopausal women with at least one first degree relative with breast cancer, and consuming >25% fat of total energy and < 5/day F&V. The study was based in the USA. Women were required to be in good general health with no expected changes lifestyle or the use of oral contraceptives. Women taking supplements were excluded. Women were recruited through community advertising for the Nutrition and Breast Health Study. 127 women were randomised to 3 intervention arms (high F&V, low fat and a combination of low fat and high F&V) and a control. Mean age was 37 years (range 21-50)	
Interventions	2x2 factorial trial design - 3 intervention arms, high F&V intake, low fat and a combination of high F&V and low fat. The low fat arm was excluded from our analyses due to high loss to follow-up (leaving 82 participants randomised). The other intervention arms received individualised counselling every 2 weeks initially by a trained dietician, then monthly, and monthly group meetings for the intervention period of 12 months. The goal for the high F&V arm was to increase F&V to 9 servings/day in a specified variety to increase carotenoid intake. The goal for the combination arm was to decrease fat to 15% total energy from fat and increase F&V to 9 servings/day. Monthly meetings provided additional education on a variety of topics consistent with their dietary assignment. The control group received no dietary counselling and were told they should continue their usual diet. They received a one page daily food guide pyramid as a guide for healthy eating but this was not discussed. Follow-up was at 12 months. Longer term follow-up (2 years) was reported by the authors (Radakovich 2006) but loss to follow-up was greater than 20%	
Outcomes	Plasma total cholesterol, LDL and HDL cholesterol and triglycerides (mg/dL converted to mmol/l). Plasma alpha and beta carotene, lutein, lycopene, beta-cryptoxanthin, alpha and gamma-tocopherol and ascorbic acid (micrograms/ml converted to micromol/l). Dietary intake of beta-carotene, ascorbic acid and alpha and gamma-tocopherol (micrograms/1000kcal/day)	

Djuric combination (Continued)

Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Djuric high F&V

Methods	RCT of parallel group design. The control group N is halved to take account of the two intervention arms	
Participants	Premenopausal women with at least one first degree relative with breast cancer, and consuming >25% fat of total energy and < 5/day F&V. The study was based in the USA. Women were required to be in good general health with no expected changes lifestyle or the use of oral contraceptives. Women taking supplements were excluded. Women were recruited through community advertising for the Nutrition and Breast Health Study. 127 women were randomised to 3 intervention arms (high F&V, low fat and a combination of low fat and high F&V) and a control. Mean age was 37 years (range 21-50)	
Interventions	see Djuric combination for details	
Outcomes	Plasma total cholesterol, LDL and HDL cholesterol and triglycerides (mg/dL converted to mmol/l). Plasma alpha and beta carotene, lutein, lycopene, beta-cryptoxanthin, alpha and gamma-tocopherol and ascorbic acid (micrograms/mL converted to micromol/L). Dietary intake of beta-carotene, ascorbic acid and alpha and gamma-tocopherol (micrograms/1000kcal/day)	
Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Elder promotora

Methods	RCT of parallel group design. The control group N is halved to take account of the two intervention arms	
Participants	Spanish dominant latinas from central and southern regions of San Diego county. Women were recruited and assessed for eligibility using random digit dialing using a telephone list of Hispanic surname households. 357 women randomised, mean age 40 years	
Interventions	Two intervention arms to decrease dietary fat and increase fibre - promotora and tailored. In the promotora arm participants recieved weekly visits or phone calls from promotoras (lay health advisors) over a 14 week period and 12 tailored newsletters with homework assignments mailed weekly. Promotoras worked with individuals to negotiate behaviour change and provide support and encouragement and the weekly newsletters were used to guide discussions. The tailored arm recieved the 12 weekly newsletters and	

Elder promotora (Continued)

	homework assignments created by using baseline assessments for each individual. They provided feedback on assessments as well as personalised goal setting and dealing with identified barriers. The last newsletter contained information from the 12 week assessment and included changes achieved and steps to continue or maintain the change process. The control group received newsletters in Spanish covering the same content area, but they were off the shelf materials readily available to the public. Follow-up was at 12 months but data for this review were taken at 12 weeks due to the high loss to follow-up at 6 and 12 months
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Outcomes	Total dietary fat and saturated fat (grams, converted to % energy from fat by using Kcal intakes provided in the report). Only follow-up data were provided for these outcomes
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Notes	
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Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Elder tailored

Methods	RCT of parallel group design. The control group N is halved to take account of the two intervention arms
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Participants	Spanish dominant latinas from central and southern regions of San Diego county. Women were recruited and assessed for eligibility using random digit dialing using a telephone list of Hispanic surname households. 357 women randomised, mean age 40 years
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Interventions	see Elder promotora for details.
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Outcomes	Total dietary fat and saturated fat (grams, converted to % energy from fat by using Kcal intakes provided in the report). Only follow-up data were provided for these outcomes
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Notes	
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Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Fuemmeler 2006

Methods	Cluster RCT. Churches were paired according to size and socioeconomic status of congregants and urban or rural geography and then each pair was randomised to intervention or control. Churches were the unit of analysis
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Fuemmeler 2006 (Continued)

Participants	14 black American churches with at least 200 congregants located near cancer society offices in California, Georgia, North and South Carolina, Delaware and Virginia, USA. Clusters contained 1020 individuals, 26.6% men, mean age 49.7 years	
Interventions	The Body and Soul intervention designed to increase F&V consumption included a set of core churchwide activities (e.g. serving F&V after church services, food demonstrations and taster tests, invited speakers, messages in pastors sermons), self help materials (cook book and video containing spiritual and secular motivational messages targeting F&V intake) and peer counselling based on the principles and techniques of motivational interviewing. Congregations nominated members to be part of an oversight committee responsible for implementing the Body and Soul intervention. The committee liaised with the research team and members of the committee and peer counsellors were given training. The control group received the delayed intervention at 6 months. Follow-up was at 6 months	
Outcomes	F&V (servings/day)	
Notes		
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Gann 2003

Methods	RCT of parallel group design.	
Participants	Healthy women aged 20-40 years recruited by direct mailings and advertising in downtown Chicago. Women who were on diets, were pregnant or planning pregnancy and those on oral contraceptives were excluded. 213 women randomised, mean age 33 years	
Interventions	Low fat high fibre dietary intervention. Goals were to reduce total fat intake to <20%, increase total fibre intake to 25-30g, increase F&V intake to >8 servings/day, to eat more complex carbohydrates (carbohydrate intake 60-65% Kcal/day) and protein intake 15-20% Kcal/day. Women were not encouraged to reduce calorie intake. Intervention included classroom nutrition education (18 group classes) plus individual counselling (2 individual meetings in 12 months) to provide women with the knowledge and behavioural skills necessary to make a permanent lifestyle change. To maximise the impact of the intervention sessions, appropriate food was prepared and served. Sessions included practice shopping, label reading, meal preparation techniques and eating out and convenience foods were discussed. The control group were told to follow their usual diet and received a leaflet on healthy eating. After 12 month intervention period they received some of the materials given to the intervention group. Follow-up was at 12 months	
Outcomes	Total fat %Kcal, saturated fat (g - converted to %Kcal by using Kcal intake as reported), total dietary fibre (g/day)	
Notes		

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Havas 1998

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	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Hellenius 1993

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

Hellenius 1993 (Continued)

	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		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

John 2002

Methods	RCT of parallel group design.	
Participants	Participants recruited from primary health care centres in Oxfordshire, UK. Participants aged between 25 and 64 years with no chronic diseases were eligible. Those who were pregnant or attempting to conceive or on dietary supplements were excluded. 729 participants randomised, 49% men, mean age 46 (SD 10.1) years	

Interventions	Brief negotiation method to increase F&V consumption to at least 5 portions/day. A trained research nurse discussed the benefits of eating more F&V and presented a pictorial portion guide. The brief negotiation method was used to encourage participants to identify specific and practical ways consistent with their habits and preferences of eating more F&V. Participants attended the health centre for 2 appointments 6 months apart and were phoned 2 weeks after the first appointment to reinforce the message and discuss any problems. At 3 months participants were sent a letter reinforcing the 5 a day message and a booklet with seasonal recipes and strategy check list of ways to increase additional portions of F&V. Participants were given a copy of their individualised action plan, a fridge magnet with the 5 a day logo, a portion guide and a 2 week self monitoring record book. The control group were asked to continue their usual diet and received the intervention after 6 months. Follow-up was at 6 months	
Outcomes	SBP and DBP (mmHg), plasma total cholesterol (mmol/L), plasma alpha and beta-carotene, lutein, lycopene, beta-cryptoxanthin, alpha and gamma-tocopherol and ascorbic acid (all micromols/L) and F&V (servings/day)	
Notes		
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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		
Risk of bias		
Item	Authors' judgement	Description

Keyserling 1997 (Continued)

Allocation concealment?	Unclear	B - Unclear
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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 g 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	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Kristal 2000

Methods	RCT of parallel group design, individual randomisation stratified by age and sex
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	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Lanza men 2001

Methods	See Schatzkin 2000 for details.
Participants	See Schatzkin 2000 for details. Data in this publication are analysed separately for men and women
Interventions	See Schatzkin 2000 for details.
Outcomes	Unlike Schatzkin 2000, data are reported separately for men and women. Additional outcomes reported in this publication are fruit (g/day), vegetables (g/day) and dietary intake of vitamin C (mg/day), vitamin E (mg/day) and total carotenoids (micrograms/day)
Notes	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Lanza women 2001

Methods	See Schatzkin 2000 for details.
Participants	See Schatzkin 2000 for details. Data in this publication are analysed separately for men and women
Interventions	See Schatzkin 2000 for details.
Outcomes	Unlike Schatzkin 2000, data are reported separately for men and women. Additional outcomes reported in this publication are fruit (g/day), vegetables (g/day) and dietary intake of vitamin C (mg/day), vitamin E (mg/day) and total carotenoids (micrograms/day)
Notes	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Little 2004

Methods	RCT of parallel group design (2x2x2 factorial trial).
Participants	Participants were recruited during the "watchful waiting" period for hypertension from 6 clinics in Southampton, UK. Inclusion criteria were one BP reading of >160/90 and not on antihypertensive treatment. Exclusion criteria were established hypertension and participants who were very ill or less able to change diet. 33 participants randomised to the prompts plus low salt intervention, 37 to the control (no intervention). Mean age was 55 (10) years, 56% were male

Little 2004 (Continued)

Interventions	2x2x2 factorial design: no booklet or booklet, no advice to use low salt or advice to use low salt, no use of prompts or use of healthy lifestyle prompts. We excluded the booklet intervention as it was multifactorial (advice to reduce smoking, alcohol and weight as appropriate and exercise regularly). We also excluded the healthy lifestyle prompts alone as loss to follow-up was >20% for this intervention. Our analysis focused on the prompts plus low salt intervention with no intervention as the comparison group. Participants were given a pot of low sodium salt and asked to use it in cooking and on food in place of normal salt. The healthy lifestyle prompts included a fatty food swap sheet where participants were asked to swap foods listed in one column with lower fat foods from the other column. Participants were asked to take the sheet with them when shopping and place it in a prominent position at home such as the fridge door. Fruit, vegetable and fibre daily prompt sheets gave options to increase consumption of these. The intervention (s) were administered by research nurses in GP surgeries. Interventions were reinforced at 4 weeks and 6 months. Control participants received no intervention. Follow-up was at 6 months
Outcomes	SBP and DBP (mmHg), Total cholesterol, LDL cholesterol and HDL cholesterol (mmol/L), total plasma carotenoids (mmol/L - converted to micromol/L) and % energy from fat
Notes	F&V (g/day) were also measured in this trial, but we were unable to verify the data with the authors and have therefore excluded this outcome

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

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	

Risk of bias

Item	Authors' judgement	Description
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Lutz non-tailored (Continued)

Allocation concealment?	Unclear	B - Unclear
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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	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Maskarinec 1999

Methods	RCT of parallel group design.	
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		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Moy 2001

Methods	RCT of parallel group design. Randomisation was by family.	
Participants	Healthy 30-59 year old brothers and sisters of patients with documented CHD diagnosed before the age of 60. Siblings with at least one of the following risk factors were eligible: LDL cholesterol ≥ 3.4 mmol/L, BP $\geq 140/90$ or current use of antihypertensives or current smoking. 235 individuals were randomised, 52% men, mean age 46 (SD 7) years. This study was based in the USA	
Interventions	Intervention focused primarily on decreasing total fat consumption and daily monitoring. Nurse counselling followed the National Cholesterol Education Programme Adult Treatment Panel II Guidelines which recommend dietary intervention as the first line approach in the treatment of hypercholesterolaemia. Participants were seen individually and with family members every 6-8 weeks by trained nurse counsellors (approximately 40 hours training by PI and dietician). Participants were given a "fat allowance" based on intake at baseline, current lifestyle and willingness to change. Participants were taught how to read food labels and use a fat counter to monitor and record total daily fat intake and negotiated their fat intake up or down with the nurse in counselling sessions. Physicians of siblings in the intervention group were asked explicitly not to manage dietary interventions. Participants in the usual care group were referred to physicians for dietary management. Physicians received specific detailed recommendations for risk factor management at baseline, 1 year and 2 years. Follow-up was at 2 years	
Outcomes	Plasma total cholesterol, LDL and HDL cholesterol and triglycerides (mmol/L), %Kcal from total fat and % Kcal from saturated fat	
Notes		
<i>Risk of bias</i>		

Moy 2001 (Continued)

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Neil dietitian 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	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		

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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		

Risk of bias

Item	Authors' judgement	Description
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Neil nurse 1995 (Continued)

Allocation concealment?	Unclear	B - Unclear
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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 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		

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Rock 2001

Methods	RCT of parallel group design.	
Participants	Premenopausal women with cervical intraepithelial neoplasia (a precancerous condition) recruited from primary care and gynecology medical practices in the USA. Women who were pregnant, lactating, were post menopausal, had a previous history of cancer or a current diagnosis of any malignancies were excluded. 56 women were randomised with a mean age of 27.8 (SD 6) years	
Interventions	Aim was to increase F&V consumption to 8-10 servings/day. Specific strategies and food choices were identified and targeted through individualised counselling and guidance utilising a self management approach based on social cognitive behavioural theories. A dietitian administered the intervention where counselling was by phone or internet with a minimum of weekly contact or more frequent if problems arose. The counselling protocol was supplemented by monthly newsletters and incentives to promote retention. The control group were provided with newsletters and incentives of a more general nature without specific nutrition information or dietary guidance. Follow-up was at 12 months but data are	

Rock 2001 (Continued)

	presented only for 6 months follow-up
Outcomes	Plasma alpha and beta-carotene, beta-cryptoxanthin, leutin, lycopene and total carotenoids (micromol/L) . F&V servings/day
Notes	Table 1 in the paper provides dietary intake of micronutrients also but these are expressed only as medians and ranges. Contact authors to see if these data are available as means and SDs - for a future update

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Sacerdote 2006

Methods	RCT of parallel group design.
Participants	Healthy 18-65 year olds recruited from GP clinics in Italy. Inclusion criteria were BMI<30 and no chronic or severe diseases. Those visiting the GP for GI complaint or with dietary restrictions were excluded. 3179 participants randomised (1592 intervention, 1587 control), mean age 44.5(12.4) years, 50% male
Interventions	Personalised nutritional education intervention administered by a GP using a brochure based on Italian guidelines for correct nutrition, 1998. Intervention focused on the importance of increasing consumption of F&V (goal >5/day), fish (goal >1/week) and olive oil (goal - use in place of other fats) and decreasing meat (goal - <3/week), snacks and sweets. Participants randomised to the intervention visited the GP surgery 3 times over the 12 month intervention period - interviews lasted 15 minutes each. Control participants recieved a "sham" intervention where they met the GP for a simpler non-personalised conversation without the use of the brochure. Each GP took part in a 4 day training course on nutrition carried out by clinical nutritionalists. Follow-up was at 12 months
Outcomes	SBP and DBP (mmHg) and fruit and vegetable servings/week (converted to servings/day)
Notes	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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 g/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		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

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		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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	
Outcomes	Fruit and vegetable servings per day.	
Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Stevens 2003

Methods	RCT of parallel group design	
Participants	Healthy women - members of a HMO in Oregon, USA. Women aged 40-70 (mean 53.8) years who had a negative result on a recent screening mammogram. Women were only included if their total cholesterol level was 5.2mmol/L or greater (authors chose the top half of the cholesterol distribution to increase the probability of detecting dietary change), and were willing to change dietary patterns and were willing to consider regular breast self-exam (control condition - recruitment emphasised cancer prevention and control). Women were excluded if they were taking statins or had treatment for cancer in the previous year. 616 women were randomised (308 intervention, 308 control)	
Interventions	The dietary intervention combined strategies from motivational interviewing, problem solving and social cognitive theory. Experienced masters degree level counsellors provided individual counselling based in a research clinic. The first individual counselling session (45 mins) focused on decreasing fat and increasing fruit and vegetables and wholegrains. Participants were provided feedback from a baseline questionnaire and asked to select one of two goals (decreasing fat or increasing fruit and vegetables). The second counselling session (45 mins) 2-3 weeks later focused on the goal participants had not chosen at the first session. Telephone support was given 2-3 weeks after the second session and again 2-3 weeks later (5-10 mins each). Participants randomised to the control arm received an intervention focused on breast self examination where individuals received one counselling session and 2 follow-up phone calls but no dietary recommendations. Follow-up was at 12 months	
Outcomes	Total cholesterol (mg/dL converted to mmol/L), % energy from fat and F&V (servings/day)	
Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Takahashi 2006

Methods	RCT of crossover design but data analysed and presented as a parallel group design at time of cross-over at 12 months	
Participants	Participants from 2 rural villages in Japan recruited through public magazines and posters. Individuals were eligible if they were aged between 40 and 69 and had physician permission to participate if under medical treatment or dietary control. 550 participants randomised, 32% men, mean age 56 years. Of the participants in the control group at baseline, 9.6% had hypertension, 2.9% had diabetes and 9.6% had hyperlipidaemia	
Interventions	Tailored dietary intervention to encourage a decrease in sodium intake and an increase in vitamin C and carotene intake via increasing F&V consumption. Dietary goals were to decrease salt to less than 8 and 10g/day in women and men respectively and increase carotene intake to more than 5000 micrograms/day and vitamin C intake to more than 200mg/day. The intervention consisted of 2 individualised dietary counselling sessions at baseline and 5 months (15 minutes each), a group lecture half way through the intervention, and 2 newsletters. Control subjects received the intervention at 12 months (cross-over period). Follow-up data were presented at 12 months	

Takahashi 2006 (Continued)

Outcomes	SBP and DBP (mmHg), fruit and vegetable intake (g/day converted to servings/day using a typical 80g serving), dietary fibre (g/day), dietary intake of vitamin C (mg/day), alpha and beta-carotene (micrograms/day)	
Notes		
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Tilley 1999

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		
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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	

TOHP I 1992 (Continued)

	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		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

van der Veen 2002

Methods	Cluster RCT. Data were analysed at the level of the individual, allowing for clustering within GP practices. The denominator used in this review is the GP practice	
Participants	Participants at elevated risk of CVD recruited from 9 GP practices joining the Nijmegen Monitoring Project, University Medical Centre St Radboud, Netherlands. Eligibility criteria included a dietary fat	

	intake of >37% or saturated fat intake of >12%, hypertension, diabetes, total cholesterol >or=6.2mmol/L but no manifest CVD. 89% of control participants had hypertension at baseline, and 7% had diabetes. The 9 GP practices included 143 individuals, 26.5% men, mean age 58 years	
Interventions	Stage matched nutrition counselling performed by GPs with selective referral to dieticians if patients reached the action stage (stages of change model). In precontemplation counselling is aimed at raising consciousness about dietary behaviour and on motivation to change dietary behaviour in the contemplation stage. Individuals met with the GP on 3 occasions 2 weeks apart for approximately 10 minutes. If participants reached the action stage and were referred to the dietician there were 3 appointments - the first was 30-40 minutes, the other 2 were 10-15 minutes, appointments were 2-8 weeks apart. Counselling focused on decreasing saturated fat intake and was tailored to the individual. Participants in the control group received usual care. Follow-up was at 12 months	
Outcomes	Plasma total cholesterol (mg/dl converted to mmol/l), total fat %Kcal and saturated fat %Kcal	
Notes		
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

F&V = fruit and vegetables

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Ammerman 2003	Greater than 20% of participants were lost to follow up.
Anderson 2001	Greater than 20% of participants were lost to follow up.
Bhargava 2004	Greater than 20% of participants were lost to follow up.
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
Burke 2005	Greater than 25% of participants had a history of CVD.
Cappuccio 2006	Control group did not receive minimal intervention or no intervention

(Continued)

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
Colombo 2005	Control group did not receive minimal intervention or no intervention
Eid 2006	Greater than 25% of participants had verified CVD at baseline
Estruch 2006	Greater than 50% of participants had Type 2 diabetes at baseline
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
Fitzgibbon 2004	Greater than 20% of participants were lost to follow up.
Fries 2005	Greater than 20% of participants were lost to follow up.
Havas 2003	20% of participants were pregnant during the trial. Pregnancy was an exclusion criteria
Henkin 2000	RCT of effect of dietitian advice over and above physician advice. Control group did not receive minimal intervention or no intervention
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
Hunt 2001	Data available in the published report on F&V could not be used as the variance at baseline and follow-up were missing. Authors were contacted but they were unable to provide missing data
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
Iso 2002	Control group did not receive minimal intervention or no intervention
Korhonen 2003	RCT of weight loss, alcohol reduction and exercise.
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
Marcus 2001	Greater than 20% of participants were lost to follow up.
Martin 2006	Greater than 20% of participants were lost to follow up.
Ni Mhurchu 1998	Greater than 20% of participants were lost to follow up.

(Continued)

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
Resnicow 2001	Data available in the published report on F&V consumption could not be used as the variance at baseline and follow-up and the number of individuals available at follow-up were missing. Authors were contacted but they were unable to provide missing data
Richards 2006	Greater than 20% of participants were lost to follow up.
Sartorelli 2005	Intervention included advice to increase exercise (multifactorial intervention). The exercise advice tended to increase walking for 30min/day (42% intervention group v. 24% control group, p=0.15 at 1 year)
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.
WHI 2006	There was extensive use of medications (estrogens, statins, diabetic medications, aspirin) during the trial
Willaing 2004	Control group did not receive minimal intervention or no intervention
Williams-Piehota	Greater than 20% of participants were lost to follow up.

Characteristics of ongoing studies *[ordered by study ID]*

Bowen 2004

Trial name or title	The "Eating for a Healthy Life (EHL)" project
Methods	
Participants	Members of religious organisations (cluster RCT where 40 religious organisations were randomised - 2175 individuals)
Interventions	Intervention package of self-help books and motivational messages and social interactions designed to change dietary behaviours (lowering fat and increasing F&V consumption)

Bowen 2004 (Continued)

Outcomes	Primary outcomes were fat and F&V related behaviours using the Fat and Fibre Behaviour (FFB) Questionnaire
Starting date	Unclear - intervention was 9 months with 12 months follow-up. Final outcome data collected in 2003 so likely start date 2002
Contact information	Dr Bowen - dbowen@fhcrc.org
Notes	

DATA AND ANALYSES

Comparison 1. Any dietary intervention versus no intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Systolic blood pressure, change from baseline (mmHg)	8	6223	Mean Difference (IV, Random, 95% CI)	-2.07 [-3.19, -0.95]
2 Diastolic blood pressure, change from baseline (mmHg)	8	6223	Mean Difference (IV, Random, 95% CI)	-1.15 [-1.85, -0.46]
3 Urinary sodium output (mmol/24 hr), change from baseline	3	1533	Mean Difference (IV, Random, 95% CI)	-44.18 [-54.74, -33.62]
4 Total cholesterol (mmol/l), change from baseline	17	2124	Mean Difference (IV, Random, 95% CI)	-0.16 [-0.25, -0.06]
5 LDL cholesterol (mmol/l), change from baseline	14	1484	Mean Difference (IV, Random, 95% CI)	-0.18 [-0.27, -0.10]
6 HDL cholesterol (mmol/l), change from baseline	13	1481	Mean Difference (IV, Random, 95% CI)	Not estimable
7 Triglycerides (mmol/l), change from baseline	5	429	Mean Difference (IV, Random, 95% CI)	0.00 [-0.13, 0.13]
8 Plasma alpha-carotene (nanomol/L), change from baseline	4	779	Mean Difference (IV, Random, 95% CI)	368.29 [-125.86, 862.44]
9 Plasma β-carotene (nanomol/L), change from baseline	4	765	Mean Difference (IV, Random, 95% CI)	272.05 [-52.03, 596.14]
10 Plasma alpha-tocopherol (micromol/L), change from baseline	3	750	Mean Difference (IV, Random, 95% CI)	-3.11 [-8.87, 2.65]
11 Plasma gamma-tocopherol (micromol/L), change from baseline	3	750	Mean Difference (IV, Random, 95% CI)	-0.33 [-1.07, 0.41]
12 Plasma lycopene (micromol/L), change from baseline	4	807	Mean Difference (IV, Random, 95% CI)	-0.01 [-0.04, 0.01]
13 Plasma lutein (micromol/L), change from baseline	4	798	Mean Difference (IV, Random, 95% CI)	0.02 [0.00, 0.04]
14 Plasma beta-cryptoxanthin (micromol/L), change from baseline	4	772	Mean Difference (IV, Random, 95% CI)	0.07 [0.02, 0.11]
15 Plasma total carotenoids (micromol/L), change from baseline	2	113	Mean Difference (IV, Random, 95% CI)	0.97 [-0.84, 2.78]
16 Plasma ascorbic acid (micromol/L), change from baseline	3	750	Mean Difference (IV, Random, 95% CI)	12.47 [-18.81, 43.75]
17 Red cell folate (nanomol/L), change from baseline	1	30	Mean Difference (IV, Random, 95% CI)	74.0 [-44.16, 192.16]
18 Total dietary fat (% Kcal)	20	6170	Mean Difference (IV, Random, 95% CI)	-4.49 [-6.66, -2.31]

19 Dietary saturated fatty acids (% Kcal)	12	3157	Mean Difference (IV, Random, 95% CI)	-2.36 [-3.39, -1.32]
20 Fruit and vegetable (servings per day), change from baseline	18	8416	Mean Difference (IV, Random, 95% CI)	1.25 [0.70, 1.81]
21 Fruit (servings per day), change from baseline	9	4439	Mean Difference (IV, Random, 95% CI)	0.67 [0.07, 1.28]
22 Vegetable (servings per day), change from baseline	8	4412	Mean Difference (IV, Random, 95% CI)	0.92 [0.34, 1.49]
23 Dietary fibre (grams per day), change from baseline	9	2981	Mean Difference (IV, Random, 95% CI)	5.99 [1.12, 10.86]
24 Dietary intake of ascorbic acid (mg/day), change from baseline	5	2335	Mean Difference (IV, Random, 95% CI)	53.39 [31.97, 74.80]
25 Dietary intake of beta-carotene (mg/day), change from baseline	3	542	Mean Difference (IV, Random, 95% CI)	3.39 [1.20, 5.59]

Comparison 2. Subgroup analyses

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Total cholesterol (gender)	17	1858	Mean Difference (IV, Random, 95% CI)	-0.18 [-0.28, -0.08]
1.1 Women	5	557	Mean Difference (IV, Random, 95% CI)	-0.02 [-0.23, 0.19]
1.2 Men	3	343	Mean Difference (IV, Random, 95% CI)	-0.24 [-0.41, -0.08]
1.3 Mixed	9	958	Mean Difference (IV, Random, 95% CI)	-0.21 [-0.36, -0.05]
2 Total dietary fat (gender)	20	6170	Mean Difference (IV, Random, 95% CI)	-4.49 [-6.66, -2.31]
2.1 Women	8	3208	Mean Difference (IV, Random, 95% CI)	-6.77 [-10.01, -3.53]
2.2 Men	3	186	Mean Difference (IV, Random, 95% CI)	-3.11 [-4.79, -1.42]
2.3 Mixed	9	2776	Mean Difference (IV, Random, 95% CI)	-2.90 [-6.83, 1.04]
3 Fruit & vegetable servings/day (gender)	19	8469	Mean Difference (IV, Random, 95% CI)	1.27 [0.72, 1.82]
3.1 Women	5	1298	Mean Difference (IV, Random, 95% CI)	1.98 [0.96, 2.99]
3.2 Men	2	1214	Mean Difference (IV, Random, 95% CI)	1.43 [-0.60, 3.47]
3.3 Mixed	12	5957	Mean Difference (IV, Random, 95% CI)	0.91 [0.33, 1.48]
4 Total cholesterol (risk group)	17	2124	Mean Difference (IV, Random, 95% CI)	-0.16 [-0.25, -0.06]
4.1 General population	3	906	Mean Difference (IV, Random, 95% CI)	-0.09 [-0.28, 0.10]
4.2 CVD risk high	11	1117	Mean Difference (IV, Random, 95% CI)	-0.20 [-0.33, -0.07]
4.3 Cancer risk high	3	101	Mean Difference (IV, Random, 95% CI)	-0.13 [-0.46, 0.20]
5 Total dietary fat (risk group)	20	6170	Mean Difference (IV, Random, 95% CI)	-4.49 [-6.66, -2.31]
5.1 General population	8	3393	Mean Difference (IV, Random, 95% CI)	-4.26 [-8.09, -0.43]
5.2 CVD risk high	8	650	Mean Difference (IV, Random, 95% CI)	-2.91 [-3.97, -1.85]
5.3 Cancer risk high	4	2127	Mean Difference (IV, Random, 95% CI)	-8.86 [-13.68, -4.04]
6 Fruit & vegetable servings/day (risk group)	18	8416	Mean Difference (IV, Random, 95% CI)	1.25 [0.70, 1.81]
6.1 General population	13	6322	Mean Difference (IV, Random, 95% CI)	0.62 [0.32, 0.93]
6.2 CVD risk high	0	0	Mean Difference (IV, Random, 95% CI)	Not estimable
6.3 Cancer risk high	5	2094	Mean Difference (IV, Random, 95% CI)	2.69 [1.53, 3.85]
7 SBP mmHg (risk group)	8	6223	Mean Difference (IV, Random, 95% CI)	-2.07 [-3.19, -0.95]
7.1 General population	3	4317	Mean Difference (IV, Random, 95% CI)	-2.18 [-4.47, 0.11]
7.2 CVD high risk	5	1906	Mean Difference (IV, Random, 95% CI)	-1.96 [-3.41, -0.51]

8 DBP mmHg (risk group)	8	6223	Mean Difference (IV, Random, 95% CI)	-1.15 [-1.85, -0.46]
8.1 General population	3	4317	Mean Difference (IV, Random, 95% CI)	-0.84 [-1.74, 0.07]
8.2 CVD high risk	5	1906	Mean Difference (IV, Random, 95% CI)	-1.46 [-2.62, -0.31]
9 Total cholesterol (setting)	17	2124	Mean Difference (IV, Random, 95% CI)	-0.16 [-0.25, -0.06]
9.1 Healthcare settings	15	1979	Mean Difference (IV, Random, 95% CI)	-0.14 [-0.25, -0.04]
9.2 Community/workplace/home settings	2	145	Mean Difference (IV, Random, 95% CI)	-0.27 [-0.47, -0.07]
10 Total dietary fat (setting)	20	6170	Mean Difference (IV, Random, 95% CI)	-4.49 [-6.66, -2.31]
10.1 Healthcare settings	14	5535	Mean Difference (IV, Random, 95% CI)	-5.22 [-7.80, -2.64]
10.2 Community/workplace/home settings	6	635	Mean Difference (IV, Random, 95% CI)	-3.15 [-4.73, -1.56]
11 Fruit & vegetable servings/day (setting)	18	8416	Mean Difference (IV, Random, 95% CI)	1.25 [0.70, 1.81]
11.1 Healthcare settings	6	6383	Mean Difference (IV, Random, 95% CI)	1.88 [1.07, 2.70]
11.2 Community/workplace/home settings	12	2033	Mean Difference (IV, Random, 95% CI)	0.83 [0.20, 1.47]
12 Total cholesterol (intensity)	17	2124	Mean Difference (IV, Random, 95% CI)	-0.16 [-0.25, -0.06]
12.1 Low intensity	8	877	Mean Difference (IV, Random, 95% CI)	-0.09 [-0.20, 0.01]
12.2 High intensity	9	1247	Mean Difference (IV, Random, 95% CI)	-0.23 [-0.39, -0.07]
13 Total dietary fat (intensity)	20	6170	Mean Difference (IV, Random, 95% CI)	-4.49 [-6.66, -2.31]
13.1 Low intensity	6	725	Mean Difference (IV, Random, 95% CI)	-1.68 [-3.13, -0.23]
13.2 High intensity	14	5445	Mean Difference (IV, Random, 95% CI)	-5.72 [-7.75, -3.69]
14 Fruit & vegetable servings/day (intensity)	18	8416	Mean Difference (IV, Random, 95% CI)	1.25 [0.70, 1.81]
14.1 Low intensity	7	5625	Mean Difference (IV, Random, 95% CI)	0.66 [0.20, 1.11]
14.2 High intensity	11	2791	Mean Difference (IV, Random, 95% CI)	1.64 [0.78, 2.51]
15 SBP mmHg (intensity)	8	6223	Mean Difference (IV, Random, 95% CI)	-2.07 [-3.19, -0.95]
15.1 Low intensity	6	4486	Mean Difference (IV, Random, 95% CI)	-1.87 [-4.30, 0.57]
15.2 High intensity	2	1737	Mean Difference (IV, Random, 95% CI)	-2.04 [-2.77, -1.30]
16 DBP mmHg (intensity)	8	6223	Mean Difference (IV, Random, 95% CI)	-1.15 [-1.85, -0.46]
16.1 Low intensity	6	4486	Mean Difference (IV, Random, 95% CI)	-1.22 [-2.62, 0.19]
16.2 High intensity	2	1737	Mean Difference (IV, Random, 95% CI)	-1.16 [-1.72, -0.59]
17 Total cholesterol (duration)	17	2124	Mean Difference (IV, Random, 95% CI)	-0.16 [-0.25, -0.06]
17.1 Short duration (3-6 months)	9	1072	Mean Difference (IV, Random, 95% CI)	-0.14 [-0.26, -0.02]
17.2 Long duration (12+ months)	8	1052	Mean Difference (IV, Random, 95% CI)	-0.22 [-0.40, -0.03]
18 Total dietary fat (duration)	20	6170	Mean Difference (IV, Random, 95% CI)	-4.49 [-6.66, -2.31]
18.1 Short duration (3-6 months)	8	2426	Mean Difference (IV, Random, 95% CI)	-3.76 [-7.56, 0.05]
18.2 Long duration (12+ months)	12	3744	Mean Difference (IV, Random, 95% CI)	-4.90 [-8.02, -1.78]
19 Fruit & vegetable servings/day (duration)	18	8416	Mean Difference (IV, Random, 95% CI)	1.25 [0.70, 1.81]
19.1 Short duration (6-8 months)	9	1432	Mean Difference (IV, Random, 95% CI)	1.24 [0.49, 1.99]
19.2 Long duration (12+ months)	9	6984	Mean Difference (IV, Random, 95% CI)	1.26 [0.40, 2.12]

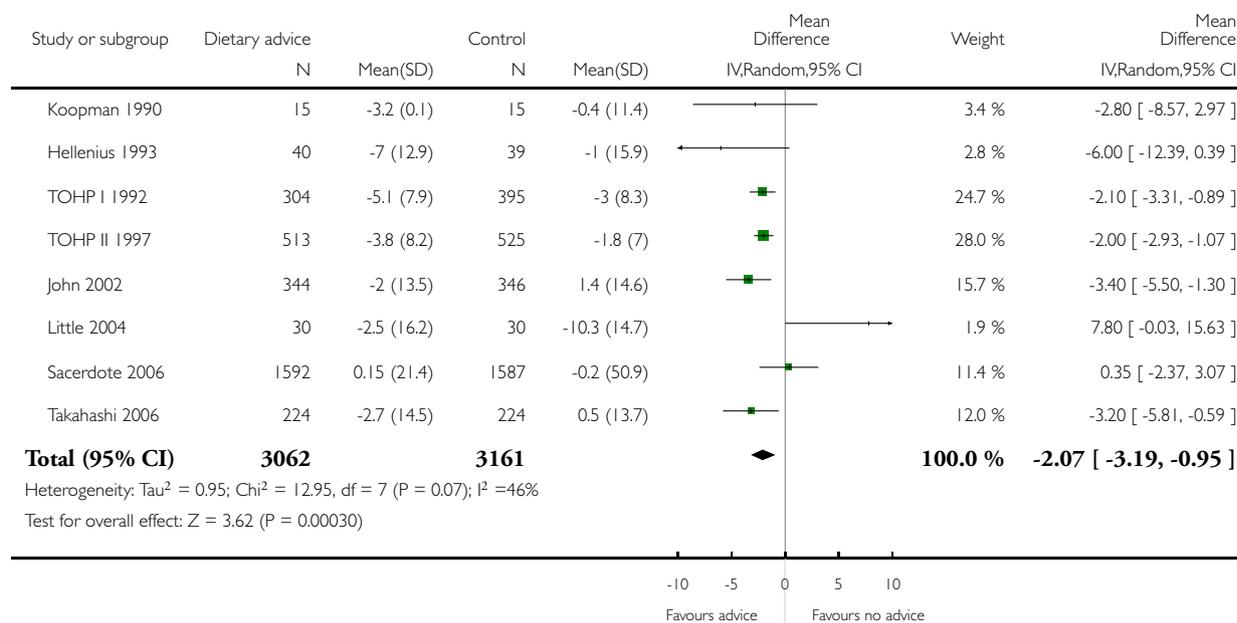
20 SBP mmHg (duration)	8	6223	Mean Difference (IV, Random, 95% CI)	-2.07 [-3.19, -0.95]
20.1 Short duration (3-6 months)	4	859	Mean Difference (IV, Random, 95% CI)	-1.87 [-6.16, 2.41]
20.2 Long duration 12+ months	4	5364	Mean Difference (IV, Random, 95% CI)	-1.94 [-2.77, -1.11]
21 DBP mmHg (duration)	8	6223	Mean Difference (IV, Random, 95% CI)	-1.15 [-1.85, -0.46]
21.1 Short duration (3-6 months)	4	859	Mean Difference (IV, Random, 95% CI)	-1.77 [-4.29, 0.75]
21.2 Long duration (12+ months)	4	5364	Mean Difference (IV, Random, 95% CI)	-1.03 [-1.55, -0.52]

Analysis 1.1. Comparison 1 Any dietary intervention versus no intervention, Outcome 1 Systolic blood pressure, change from baseline (mmHg).

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 1 Systolic blood pressure, change from baseline (mmHg)

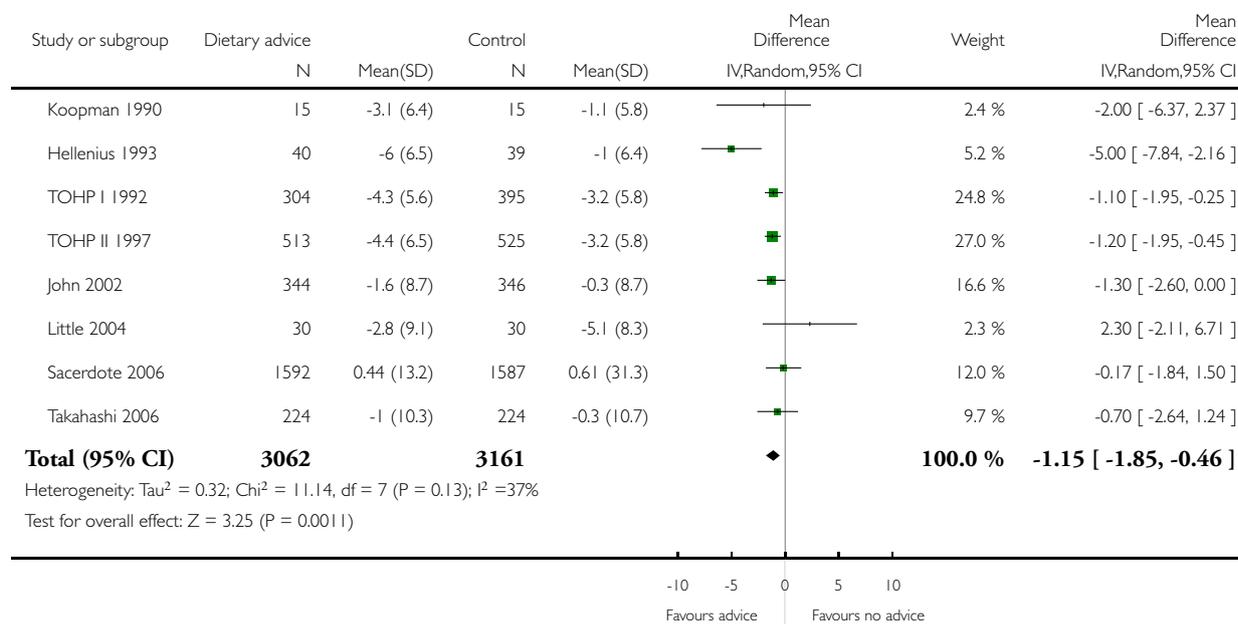


Analysis 1.2. Comparison 1 Any dietary intervention versus no intervention, Outcome 2 Diastolic blood pressure, change from baseline (mmHg).

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 2 Diastolic blood pressure, change from baseline (mmHg)

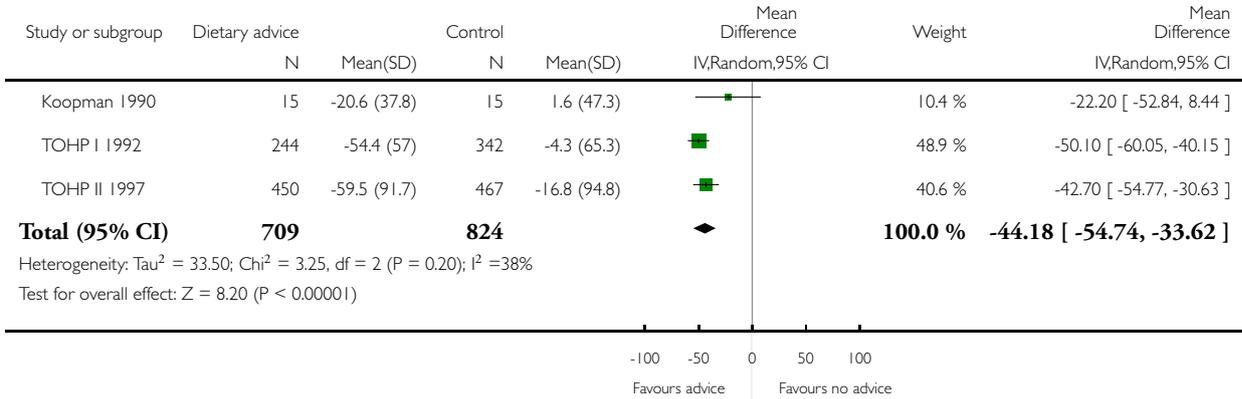


Analysis 1.3. Comparison 1 Any dietary intervention versus no intervention, Outcome 3 Urinary sodium output (mmol/24 hr), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 3 Urinary sodium output (mmol/24 hr), change from baseline

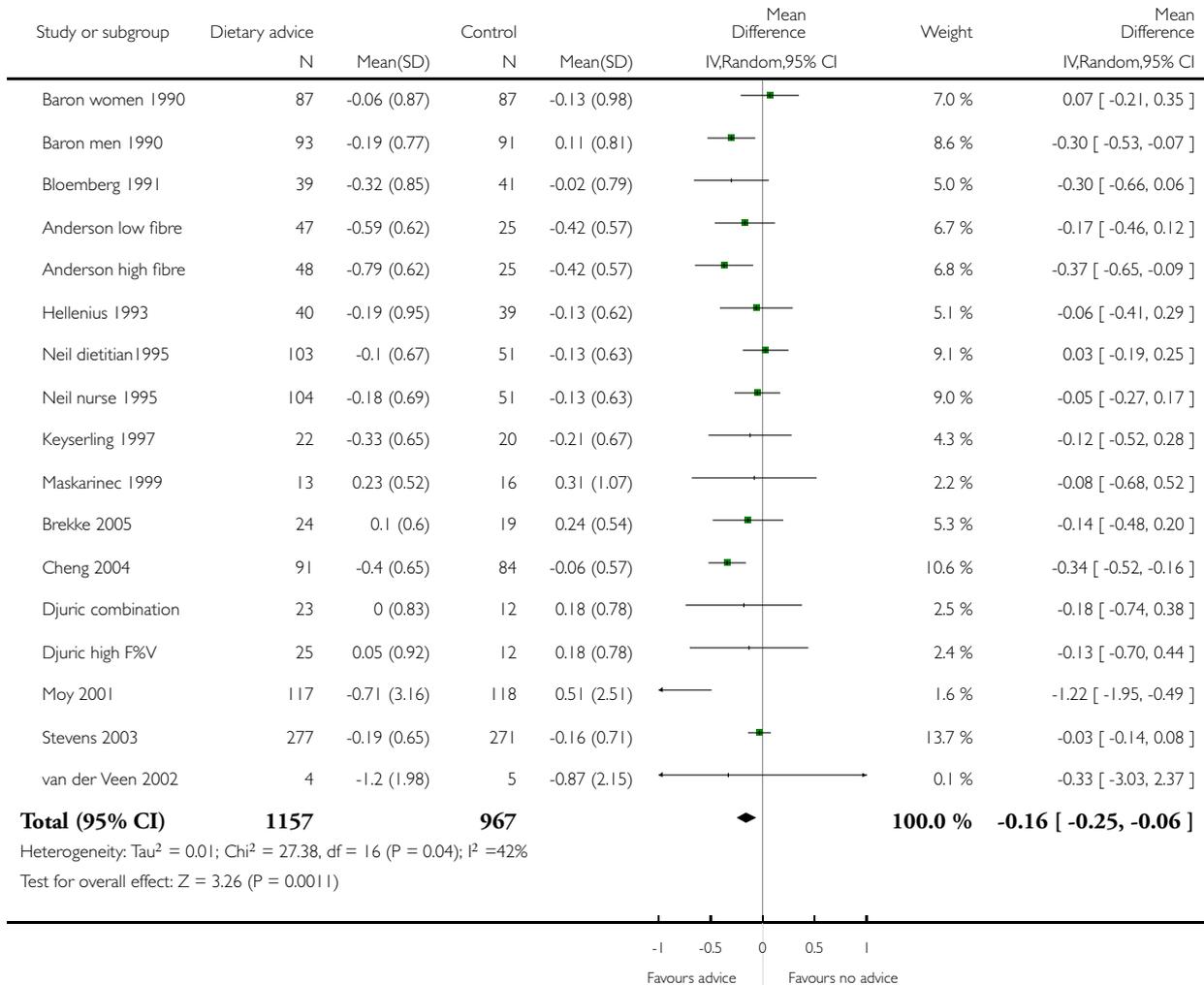


Analysis 1.4. Comparison 1 Any dietary intervention versus no intervention, Outcome 4 Total cholesterol (mmol/l), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 4 Total cholesterol (mmol/l), change from baseline

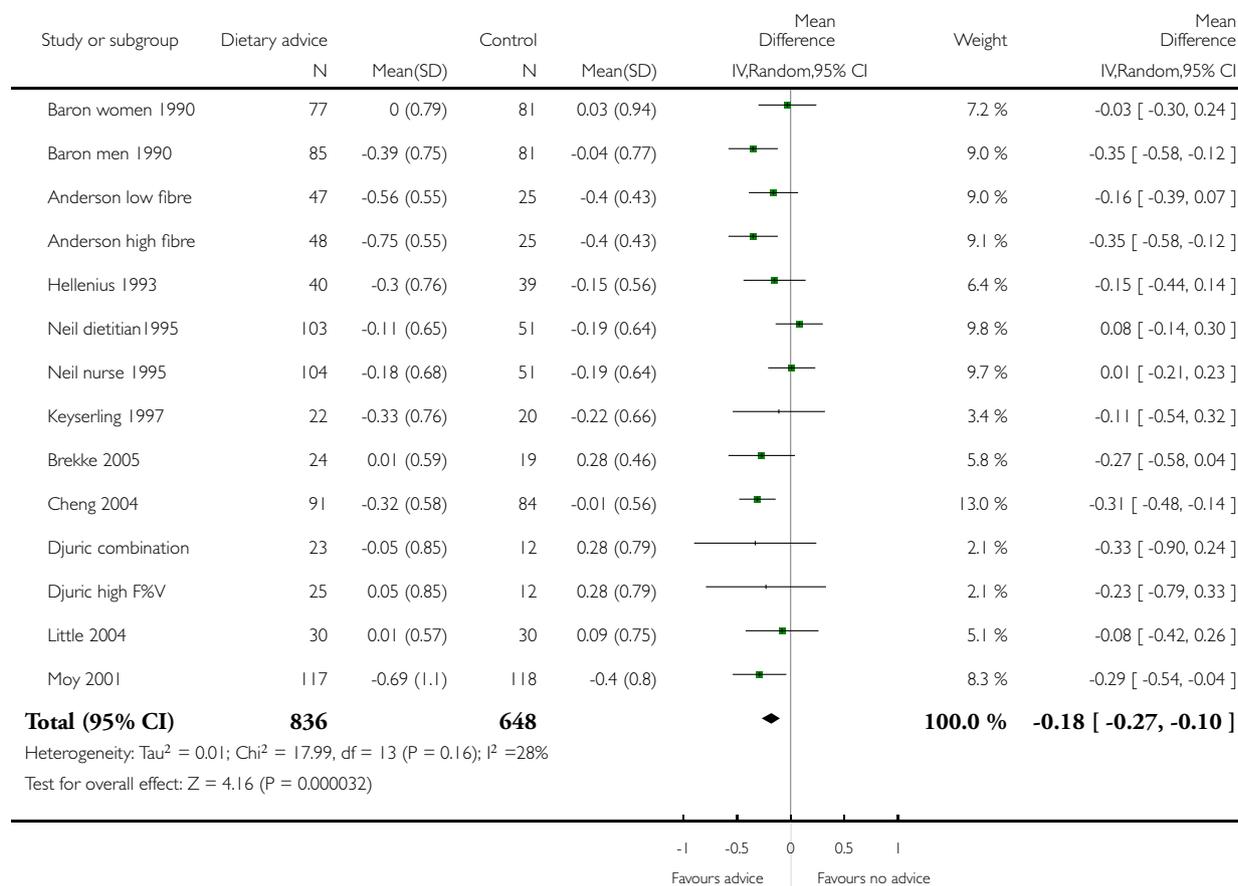


Analysis 1.5. Comparison 1 Any dietary intervention versus no intervention, Outcome 5 LDL cholesterol (mmol/l), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 5 LDL cholesterol (mmol/l), change from baseline

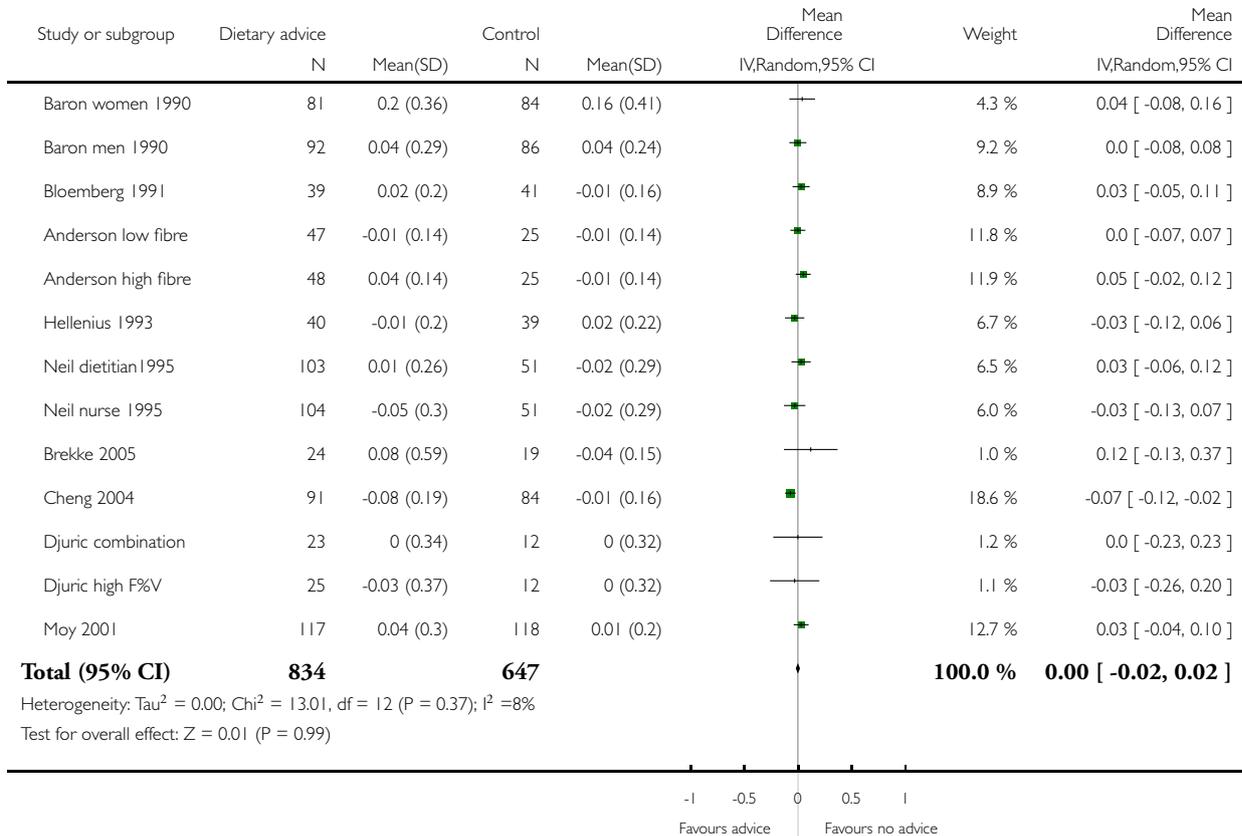


Analysis 1.6. Comparison 1 Any dietary intervention versus no intervention, Outcome 6 HDL cholesterol (mmol/l), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 6 HDL cholesterol (mmol/l), change from baseline

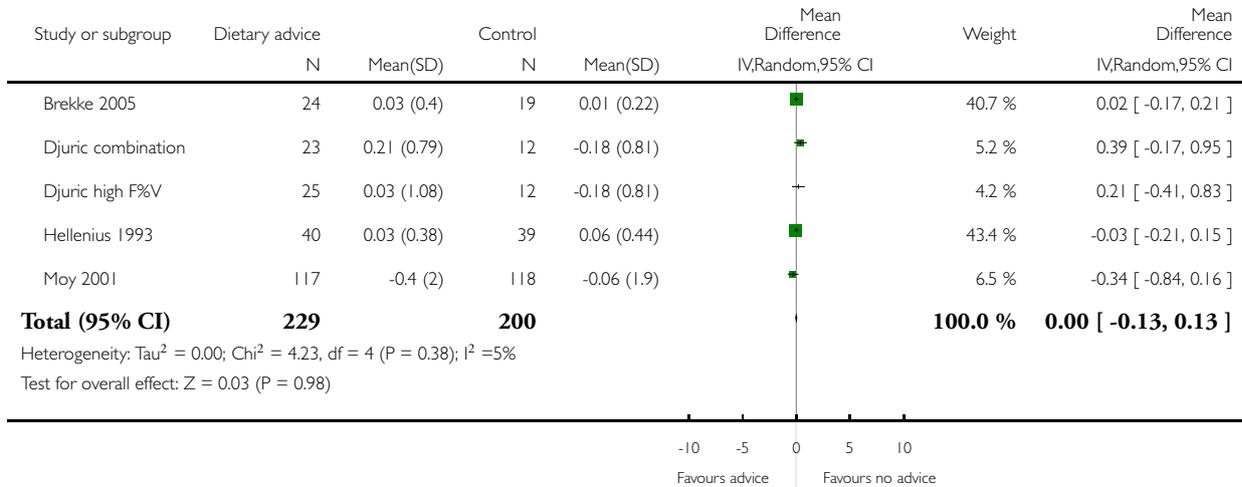


Analysis 1.7. Comparison 1 Any dietary intervention versus no intervention, Outcome 7 Triglycerides (mmol/l), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 7 Triglycerides (mmol/l), change from baseline

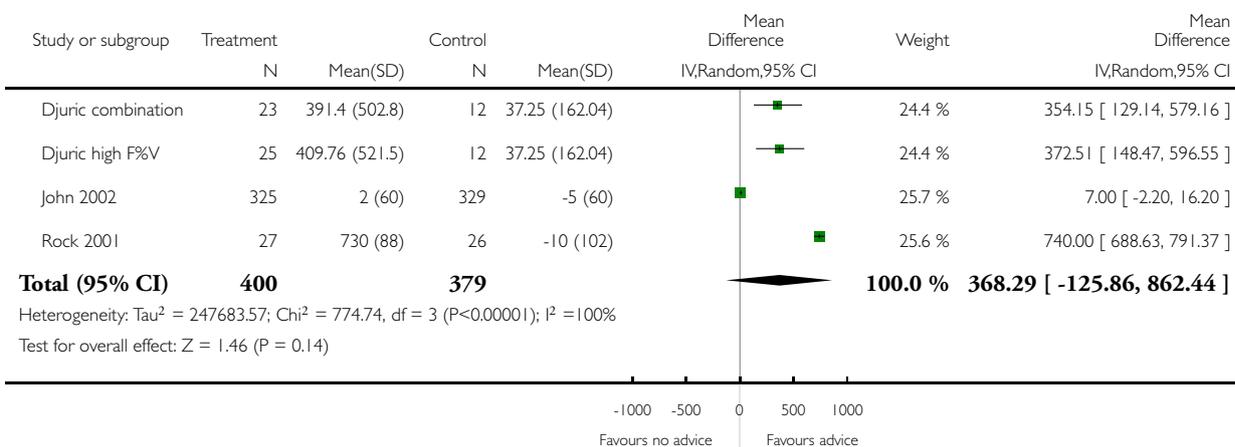


Analysis 1.8. Comparison 1 Any dietary intervention versus no intervention, Outcome 8 Plasma alpha-carotene (nanomol/L), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 8 Plasma alpha-carotene (nanomol/L), change from baseline

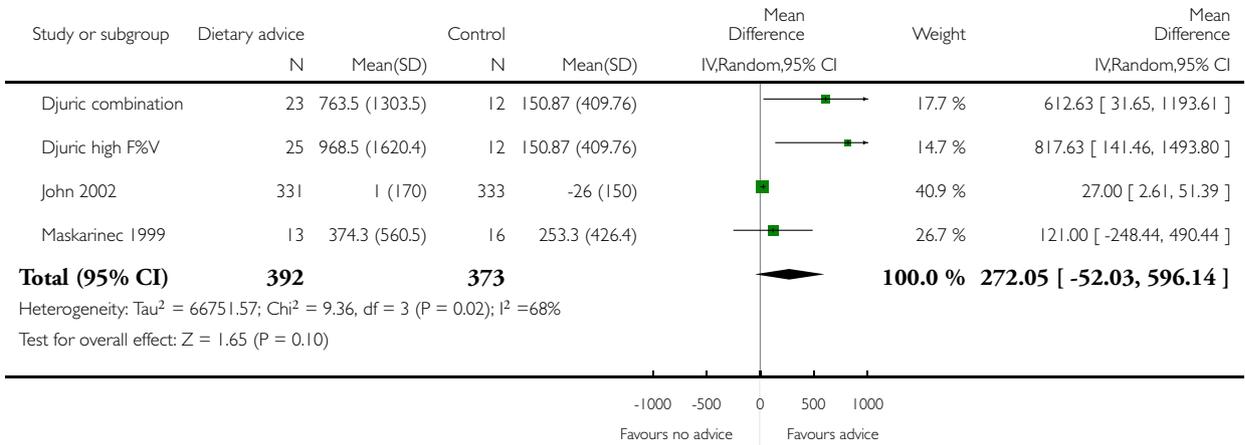


Analysis 1.9. Comparison 1 Any dietary intervention versus no intervention, Outcome 9 Plasma β -carotene (nanomol/L), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 9 Plasma β -carotene (nanomol/L), change from baseline

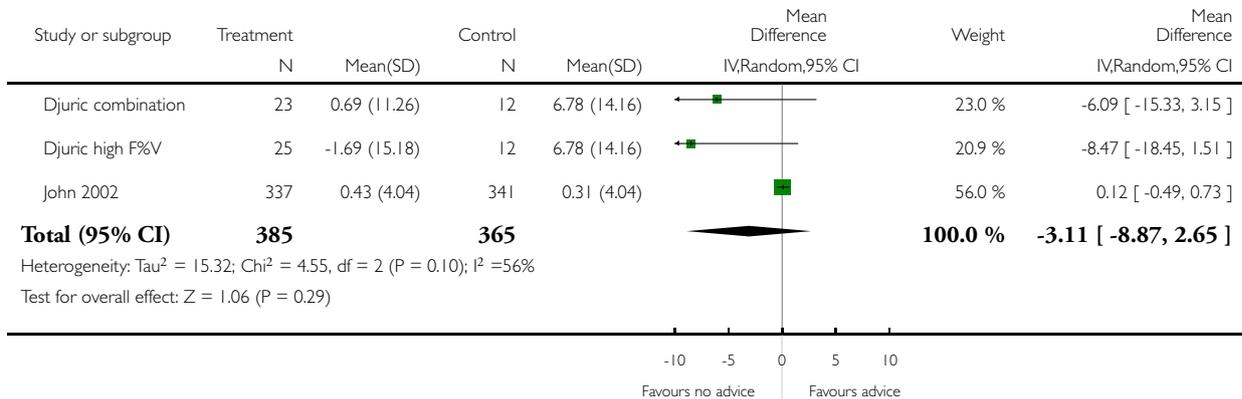


Analysis 1.10. Comparison 1 Any dietary intervention versus no intervention, Outcome 10 Plasma alpha-tocopherol (micromol/L), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 10 Plasma alpha-tocopherol (micromol/L), change from baseline

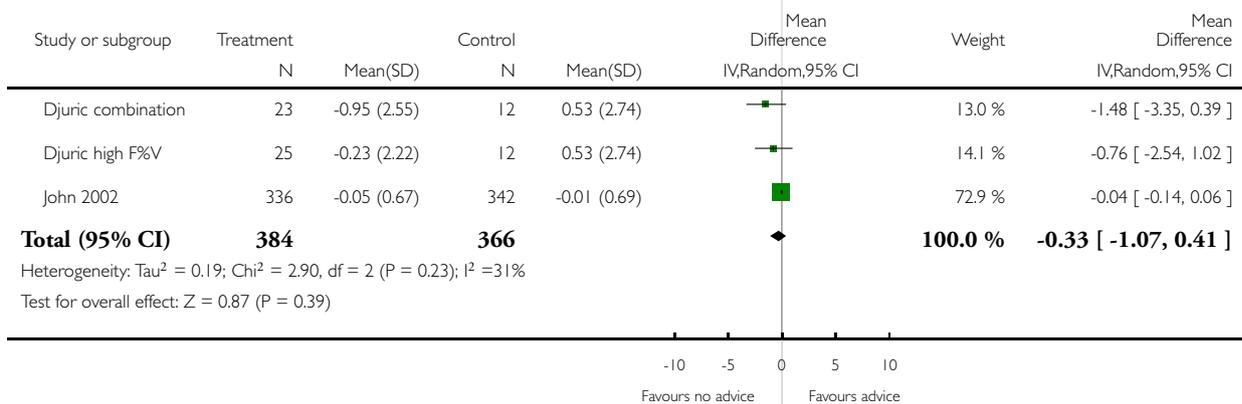


Analysis 1.11. Comparison 1 Any dietary intervention versus no intervention, Outcome 11 Plasma gamma-tocopherol (micromol/L), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 11 Plasma gamma-tocopherol (micromol/L), change from baseline

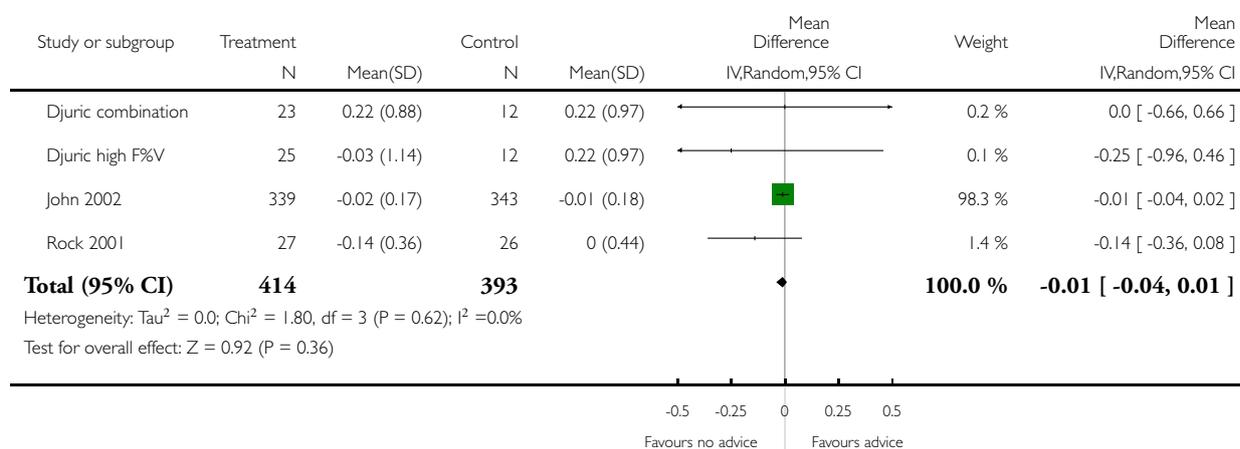


Analysis 1.12. Comparison 1 Any dietary intervention versus no intervention, Outcome 12 Plasma lycopene (micromol/L), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 12 Plasma lycopene (micromol/L), change from baseline

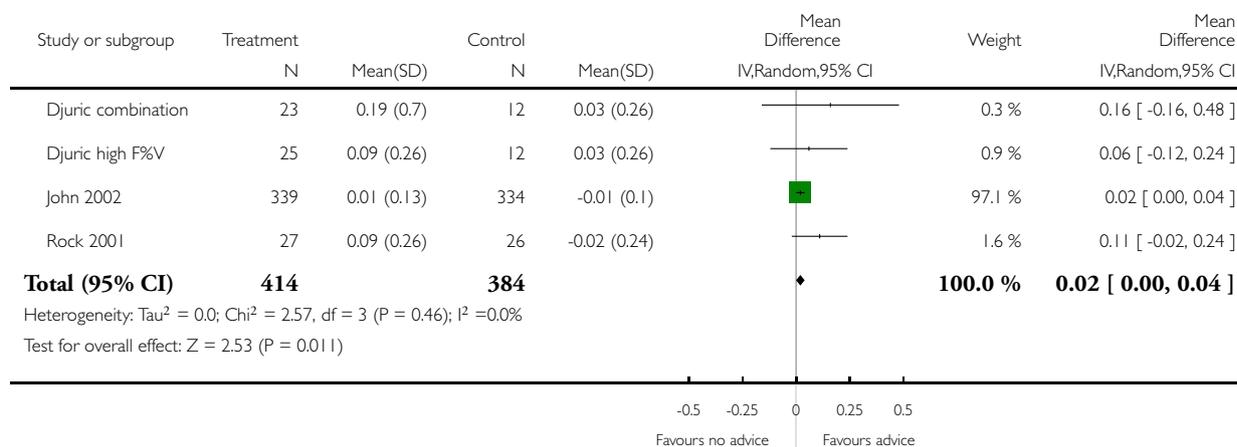


Analysis 1.13. Comparison 1 Any dietary intervention versus no intervention, Outcome 13 Plasma lutein (micromol/L), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 13 Plasma lutein (micromol/L), change from baseline

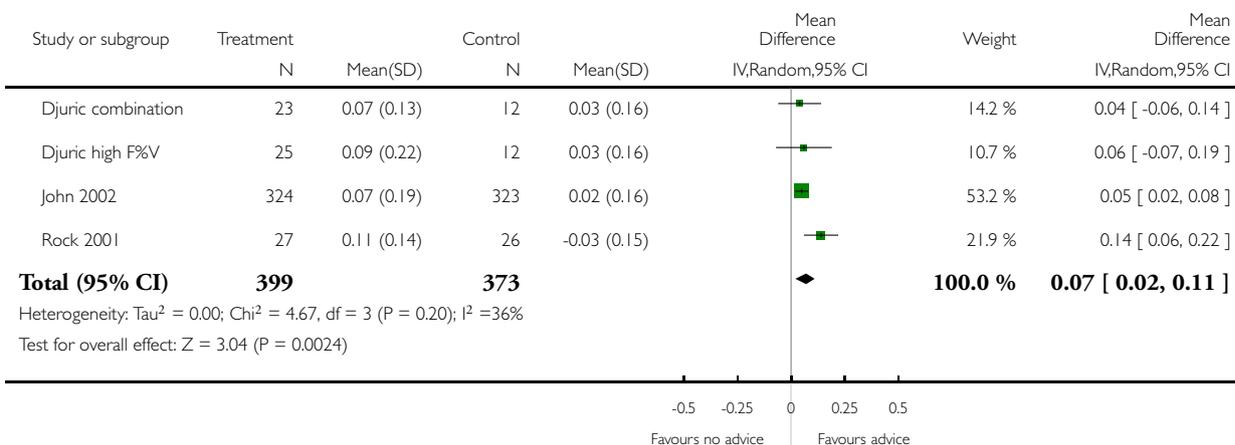


Analysis 1.14. Comparison 1 Any dietary intervention versus no intervention, Outcome 14 Plasma beta-cryptoxanthin (micromol/L), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 14 Plasma beta-cryptoxanthin (micromol/L), change from baseline

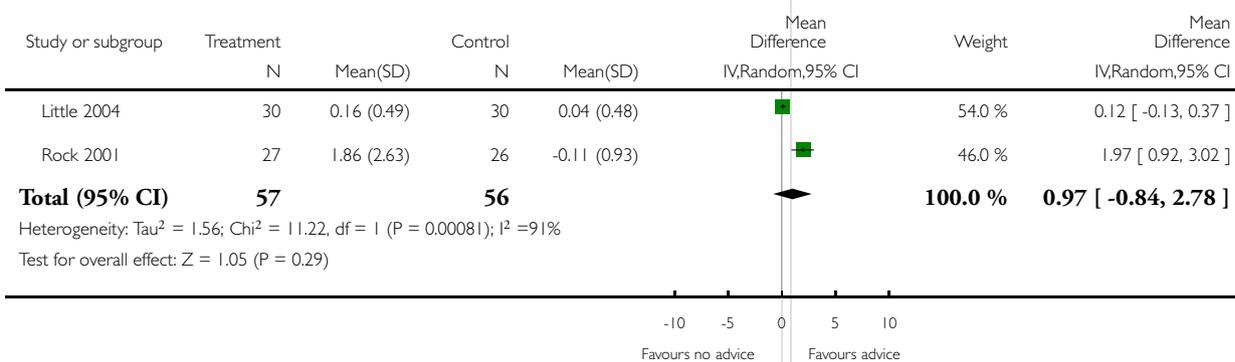


Analysis 1.15. Comparison 1 Any dietary intervention versus no intervention, Outcome 15 Plasma total carotenoids (micromol/L), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 15 Plasma total carotenoids (micromol/L), change from baseline

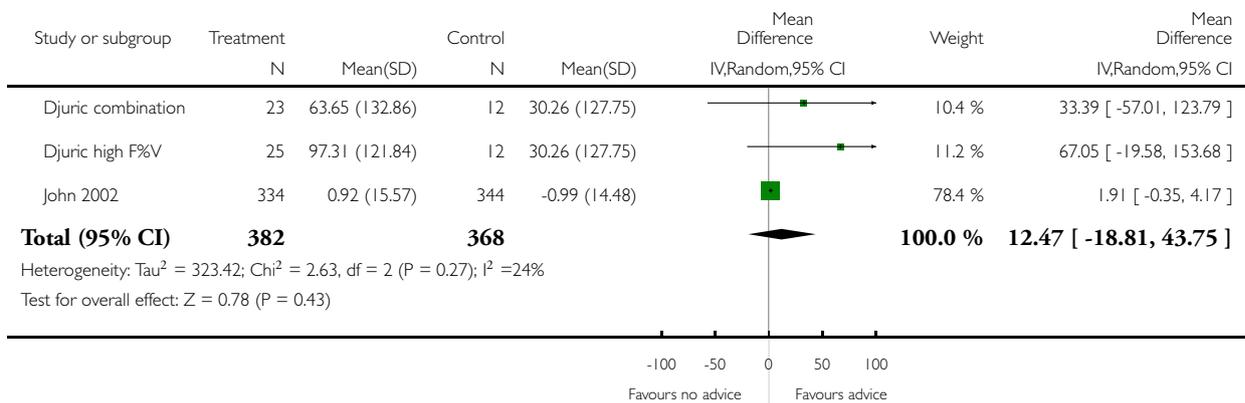


Analysis 1.16. Comparison 1 Any dietary intervention versus no intervention, Outcome 16 Plasma ascorbic acid (micromol/L), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 16 Plasma ascorbic acid (micromol/L), change from baseline

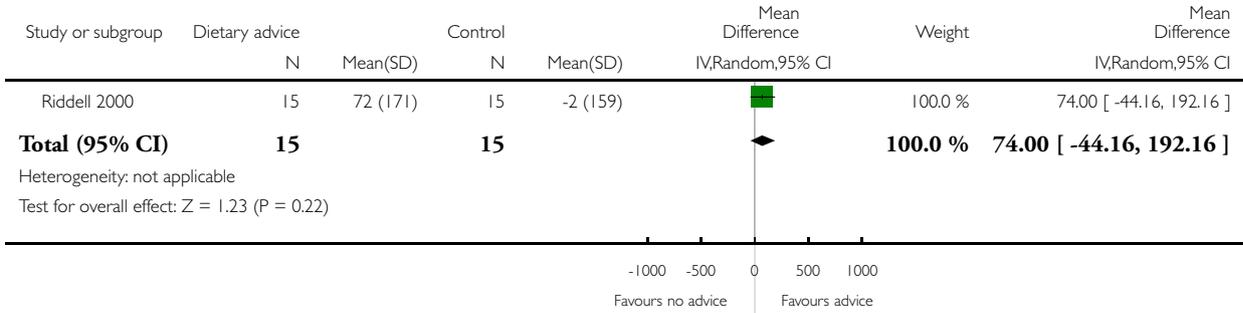


Analysis 1.17. Comparison 1 Any dietary intervention versus no intervention, Outcome 17 Red cell folate (nanomol/L), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 17 Red cell folate (nanomol/L), change from baseline

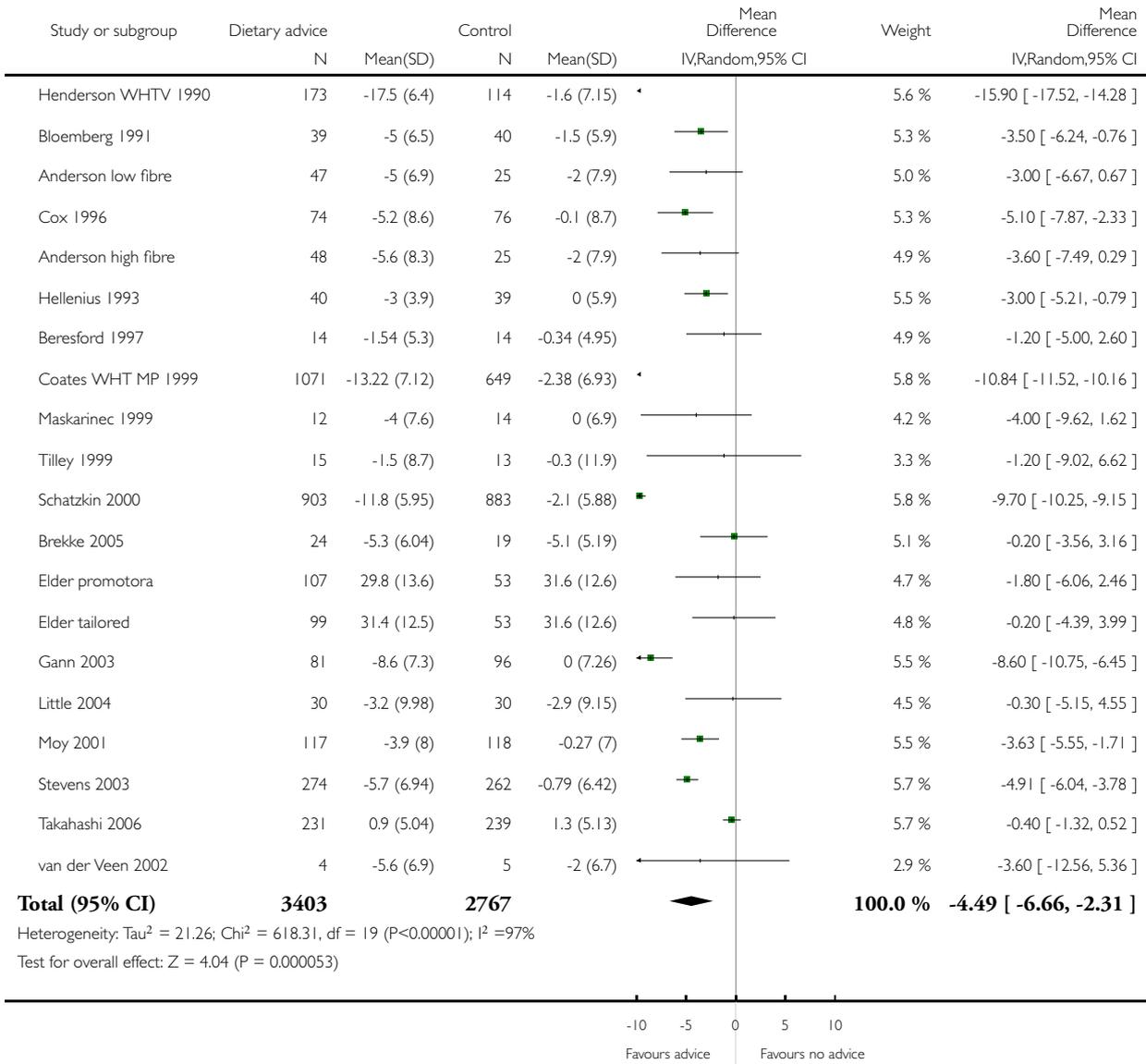


Analysis 1.18. Comparison 1 Any dietary intervention versus no intervention, Outcome 18 Total dietary fat (% Kcal).

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 18 Total dietary fat (% Kcal)

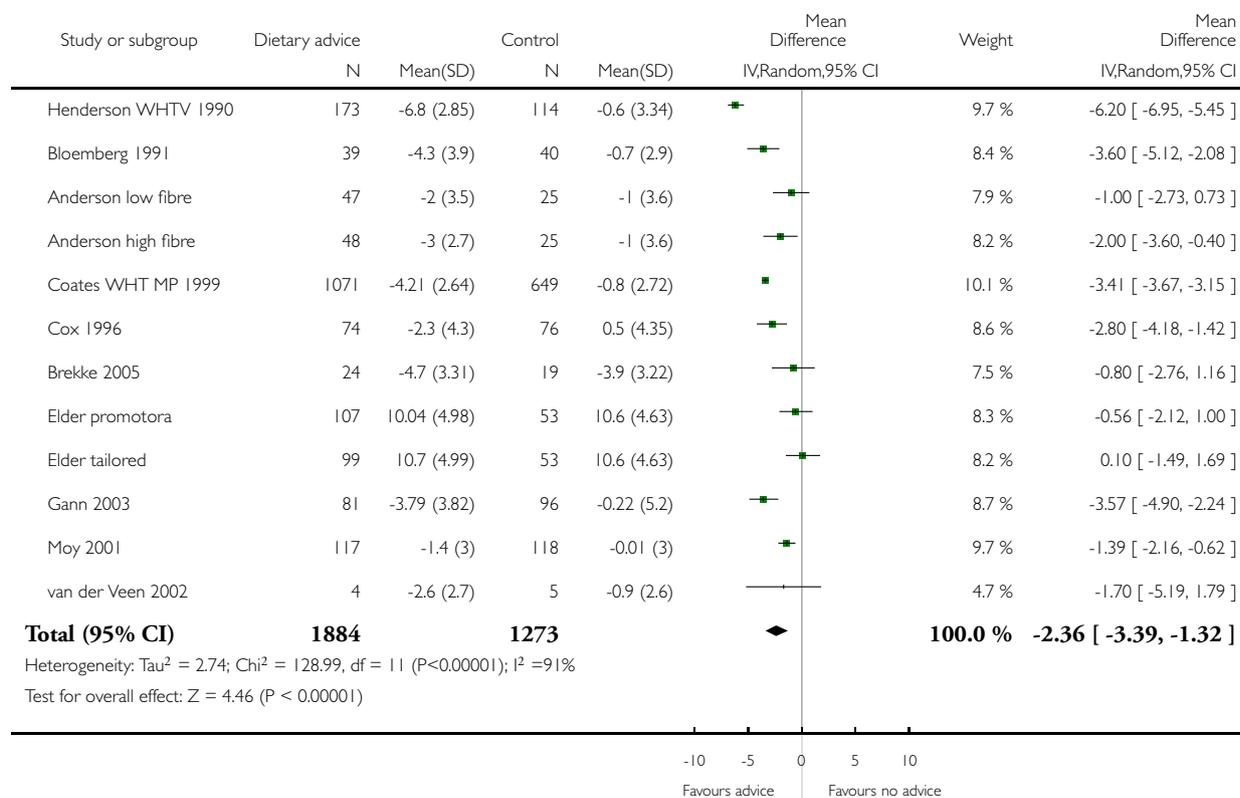


Analysis 1.19. Comparison 1 Any dietary intervention versus no intervention, Outcome 19 Dietary saturated fatty acids (% Kcal).

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 19 Dietary saturated fatty acids (% Kcal)

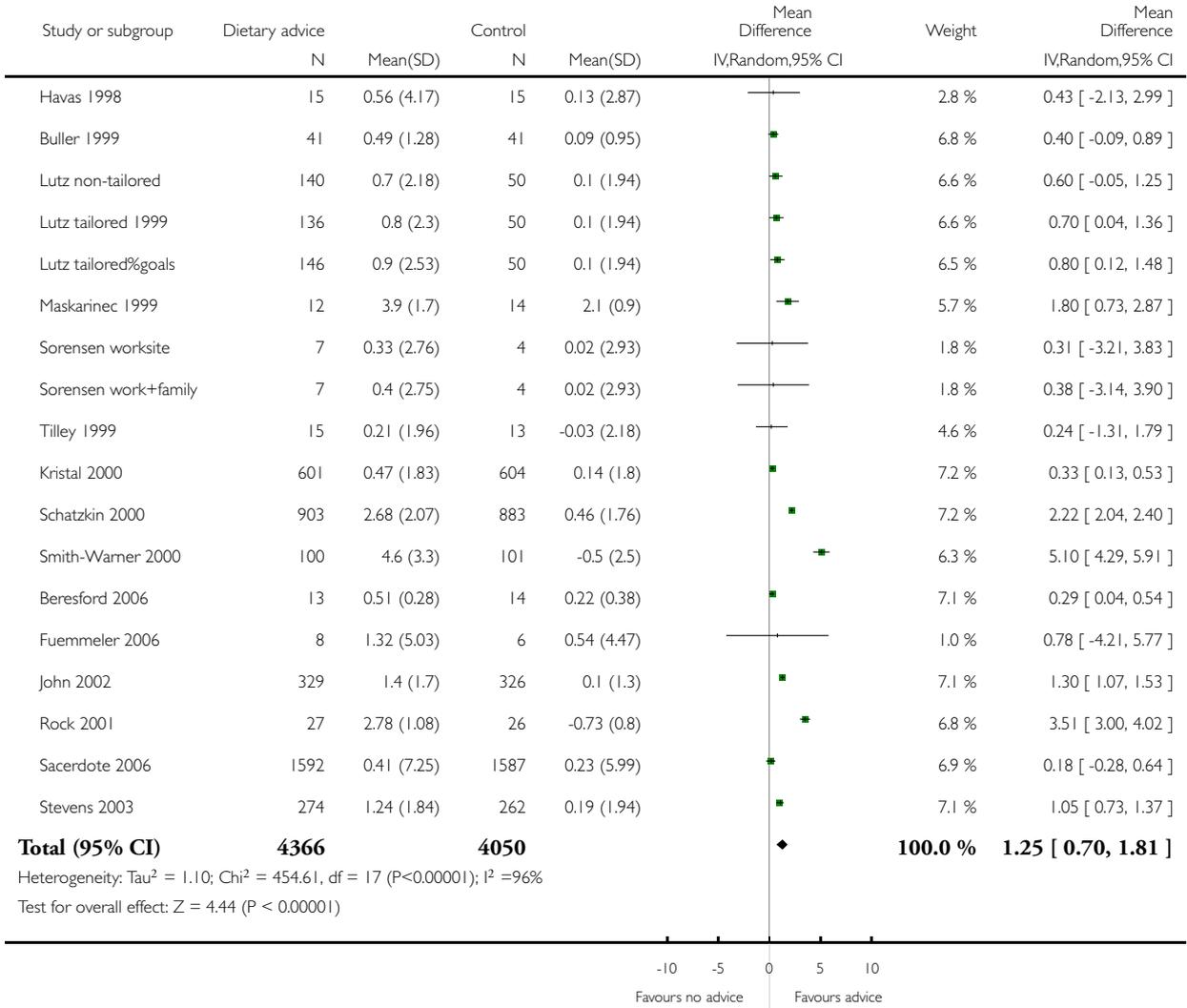


Analysis 1.20. Comparison 1 Any dietary intervention versus no intervention, Outcome 20 Fruit and vegetable (servings per day), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 20 Fruit and vegetable (servings per day), change from baseline

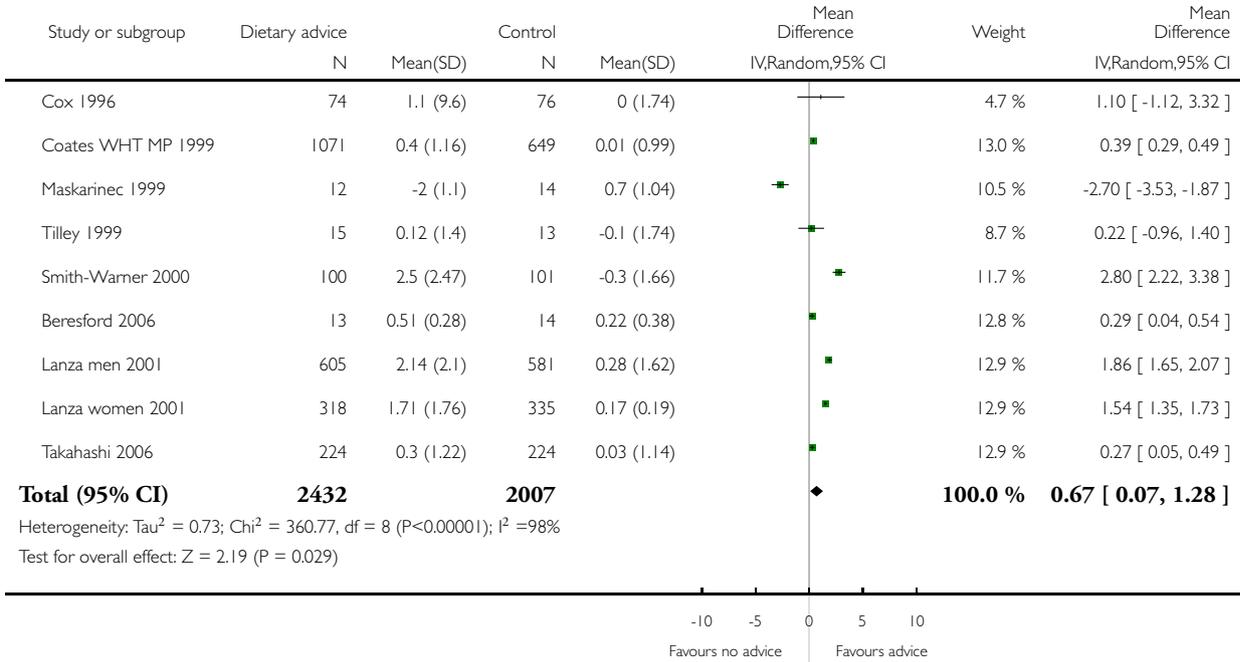


Analysis 1.21. Comparison 1 Any dietary intervention versus no intervention, Outcome 21 Fruit (servings per day), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 21 Fruit (servings per day), change from baseline

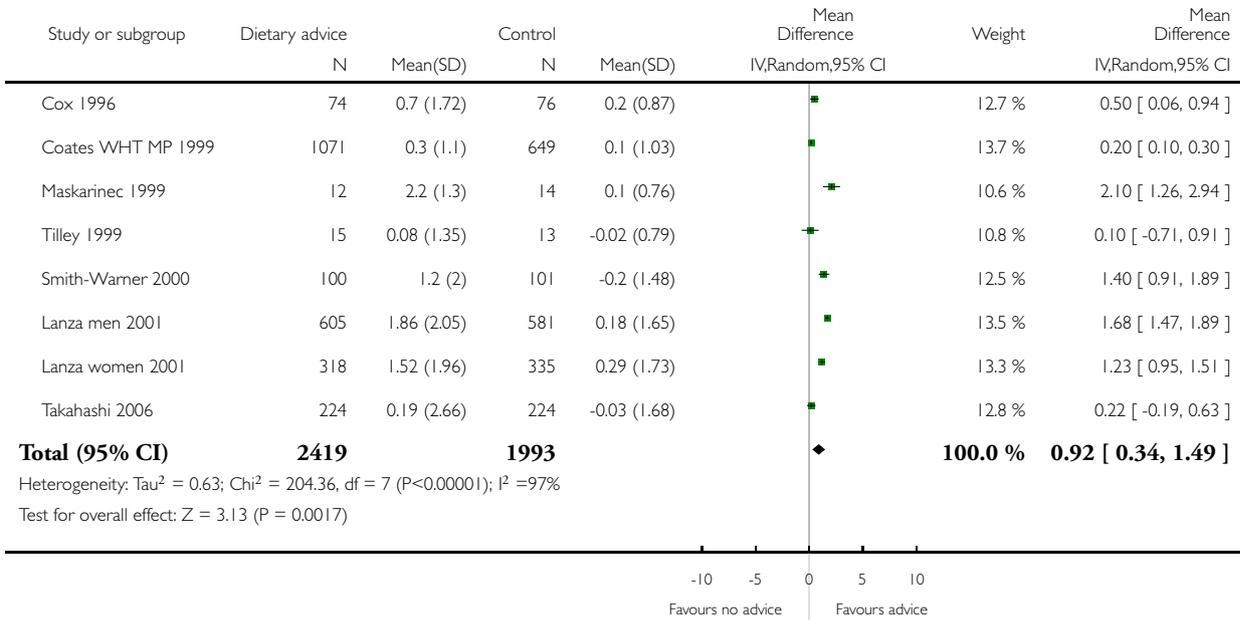


Analysis 1.22. Comparison 1 Any dietary intervention versus no intervention, Outcome 22 Vegetable (servings per day), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 22 Vegetable (servings per day), change from baseline

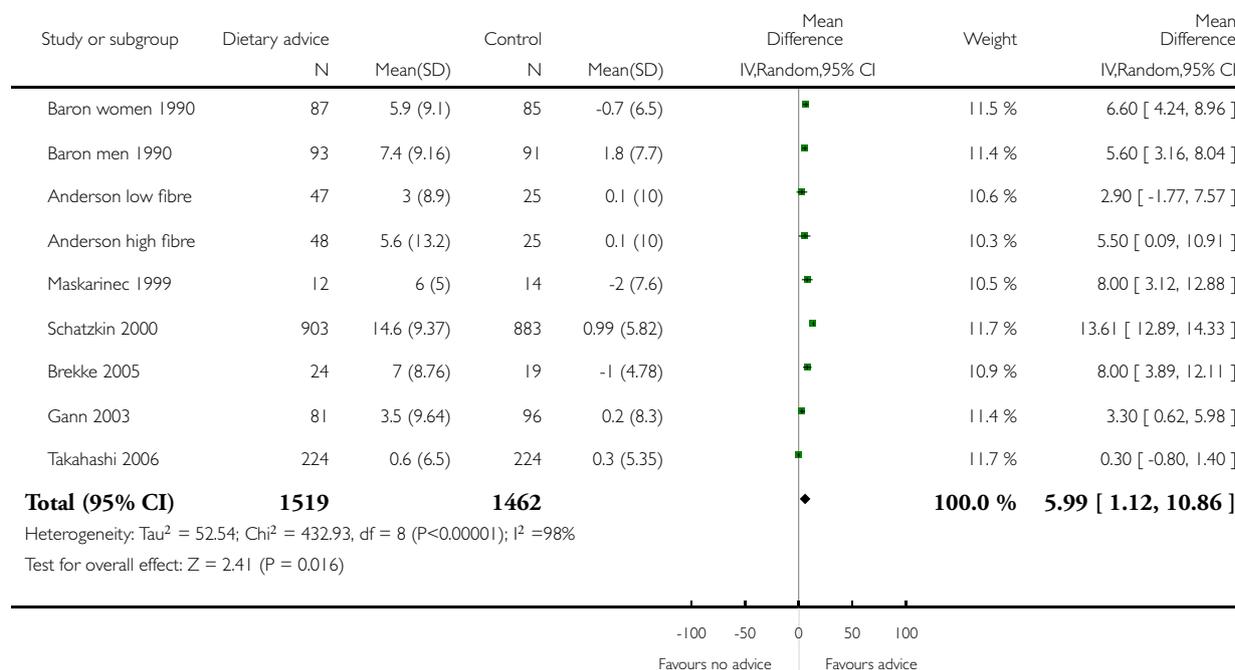


Analysis 1.23. Comparison 1 Any dietary intervention versus no intervention, Outcome 23 Dietary fibre (grams per day), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 23 Dietary fibre (grams per day), change from baseline

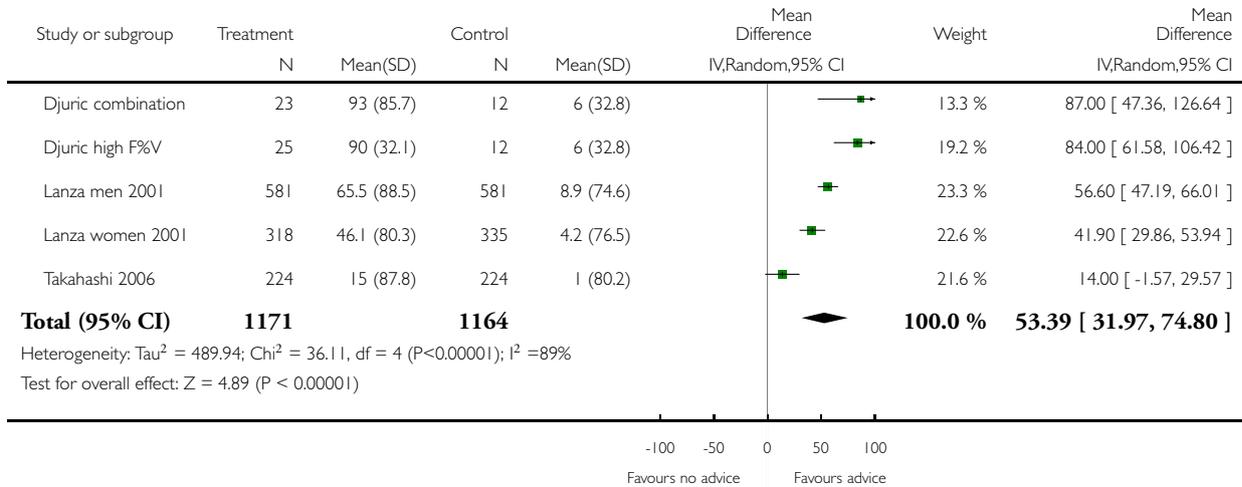


Analysis 1.24. Comparison 1 Any dietary intervention versus no intervention, Outcome 24 Dietary intake of ascorbic acid (mg/day), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 24 Dietary intake of ascorbic acid (mg/day), change from baseline

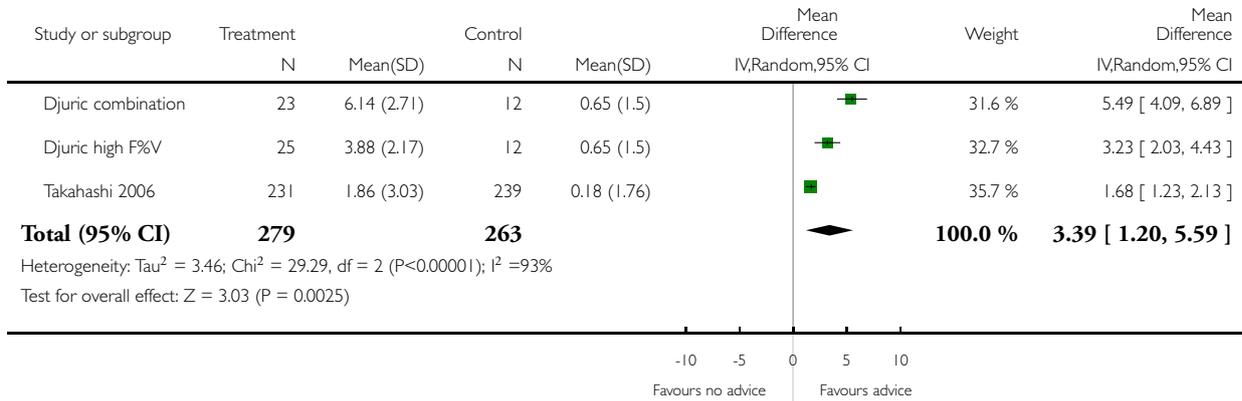


Analysis 1.25. Comparison 1 Any dietary intervention versus no intervention, Outcome 25 Dietary intake of beta-carotene (mg/day), change from baseline.

Review: Dietary advice for reducing cardiovascular risk

Comparison: 1 Any dietary intervention versus no intervention

Outcome: 25 Dietary intake of beta-carotene (mg/day), change from baseline

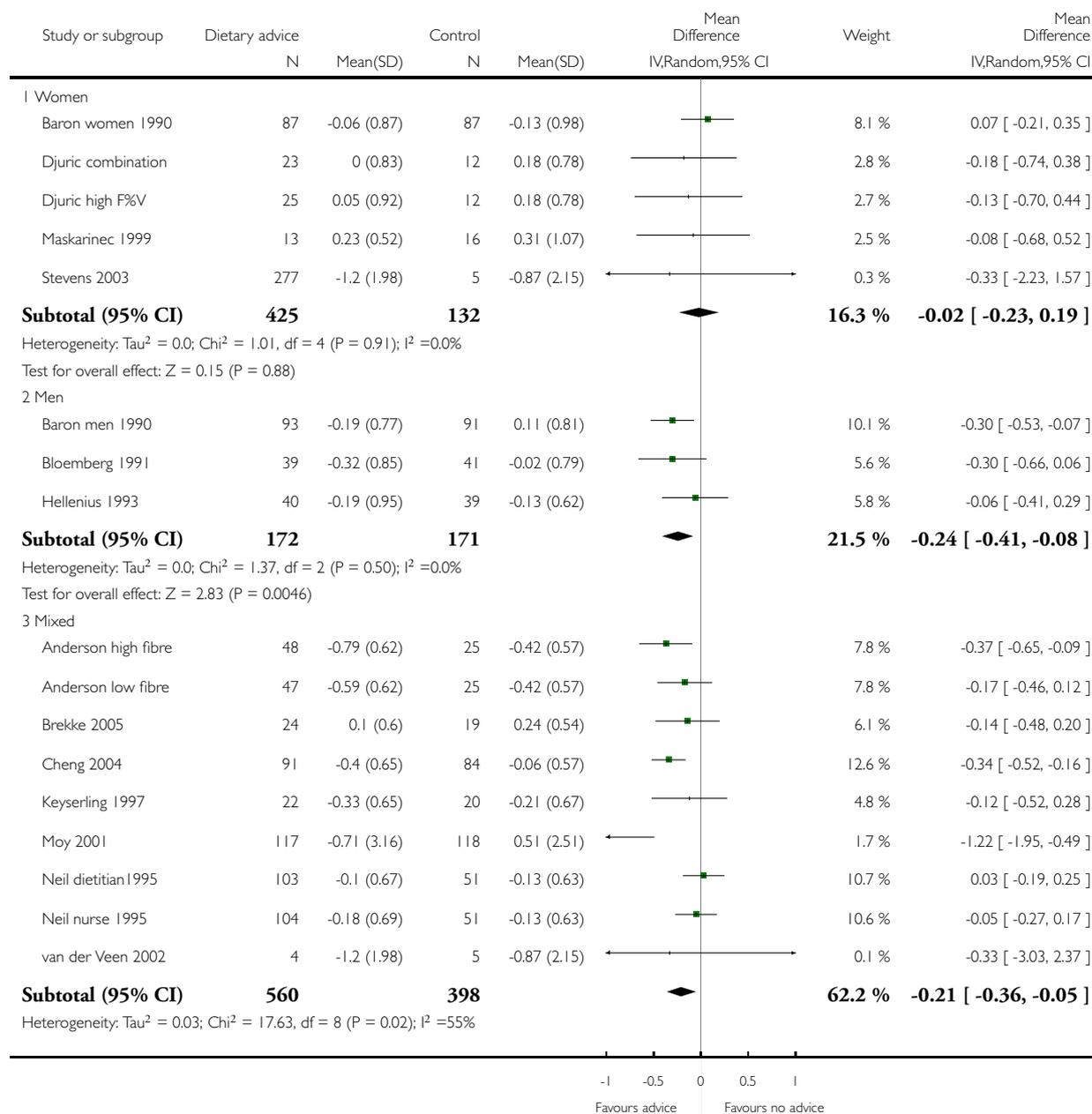


Analysis 2.1. Comparison 2 Subgroup analyses, Outcome 1 Total cholesterol (gender).

Review: Dietary advice for reducing cardiovascular risk

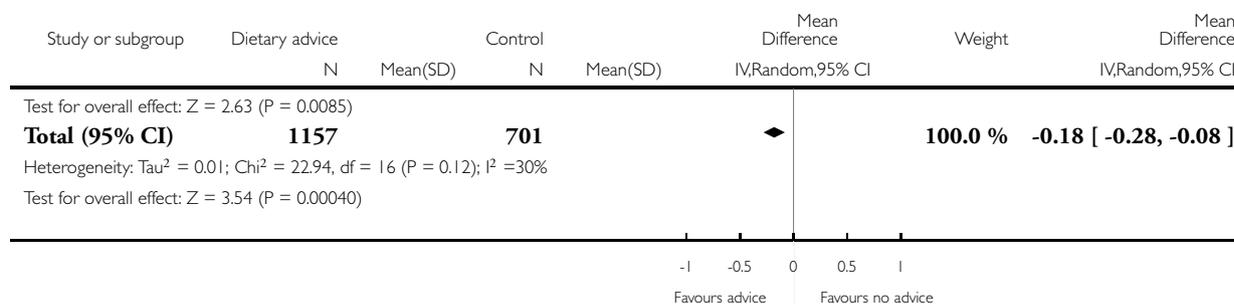
Comparison: 2 Subgroup analyses

Outcome: 1 Total cholesterol (gender)



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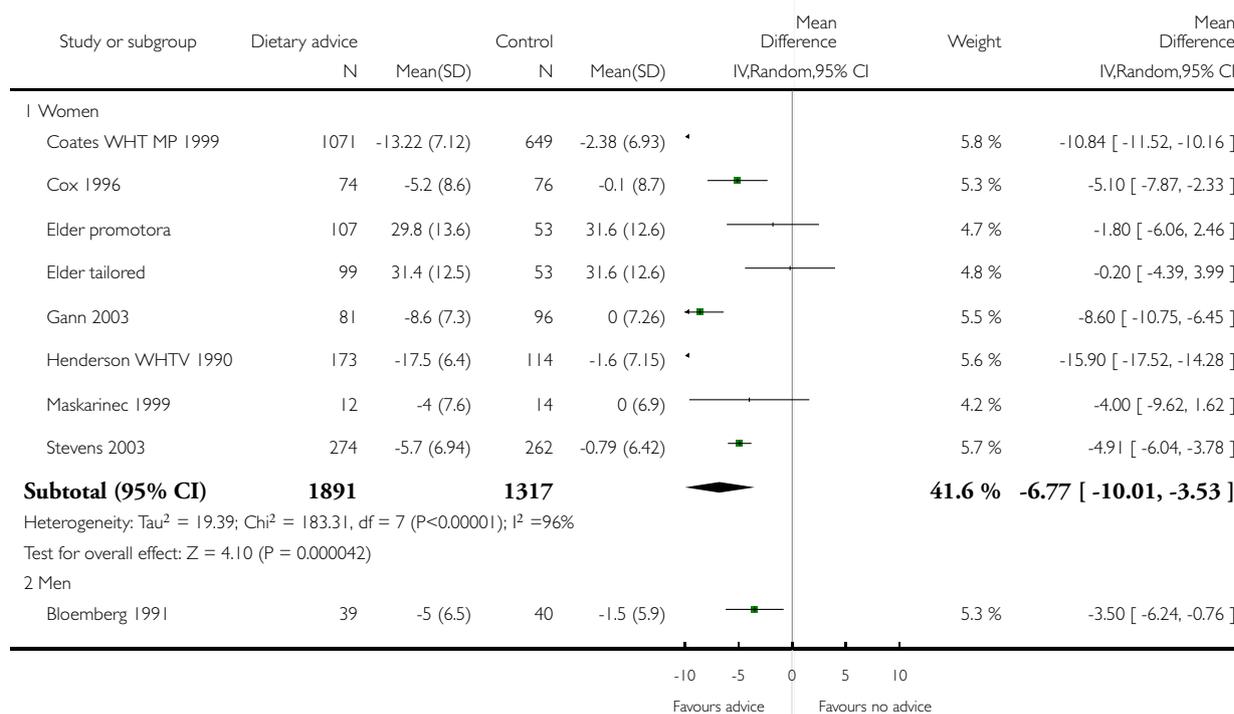


Analysis 2.2. Comparison 2 Subgroup analyses, Outcome 2 Total dietary fat (gender).

Review: Dietary advice for reducing cardiovascular risk

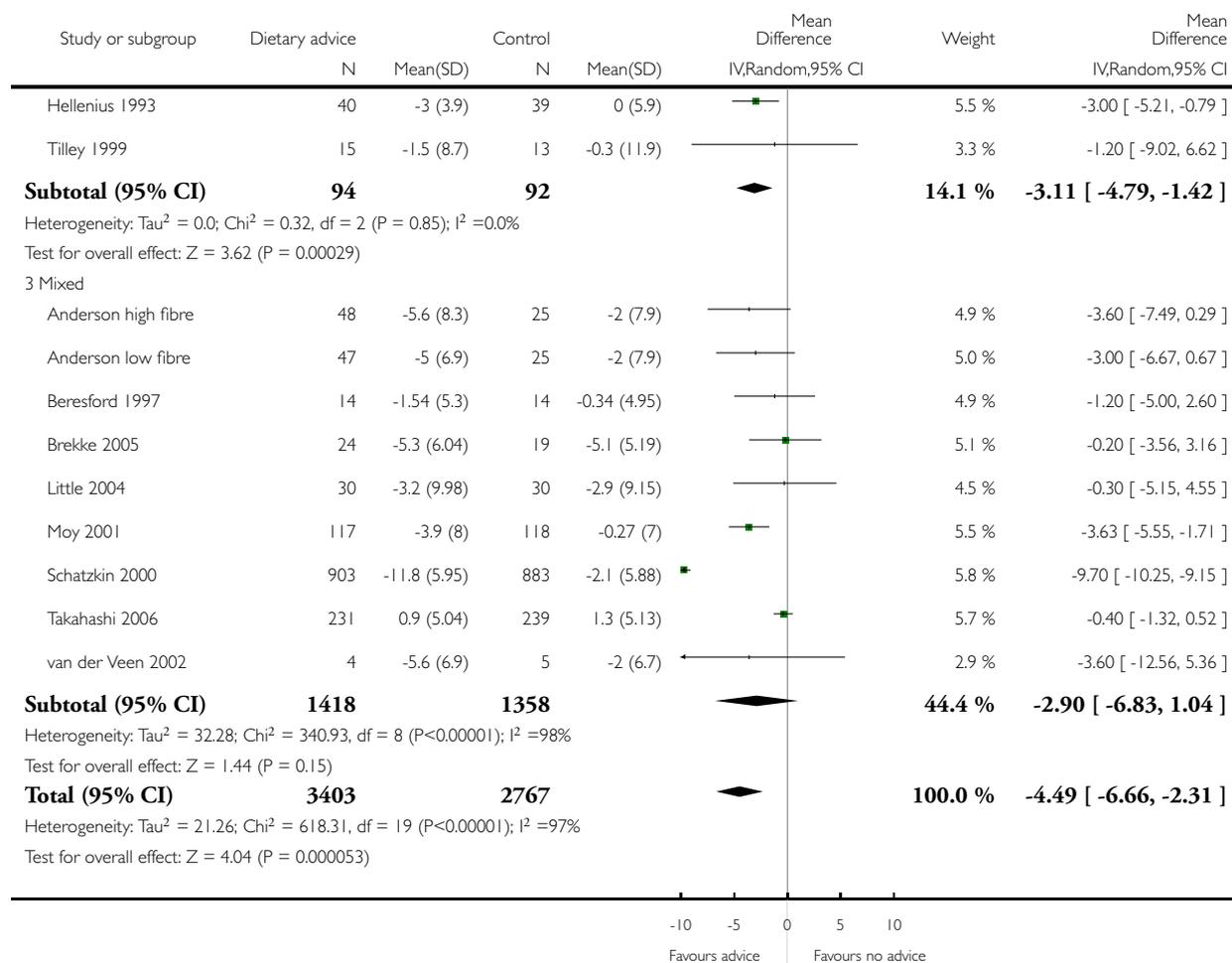
Comparison: 2 Subgroup analyses

Outcome: 2 Total dietary fat (gender)



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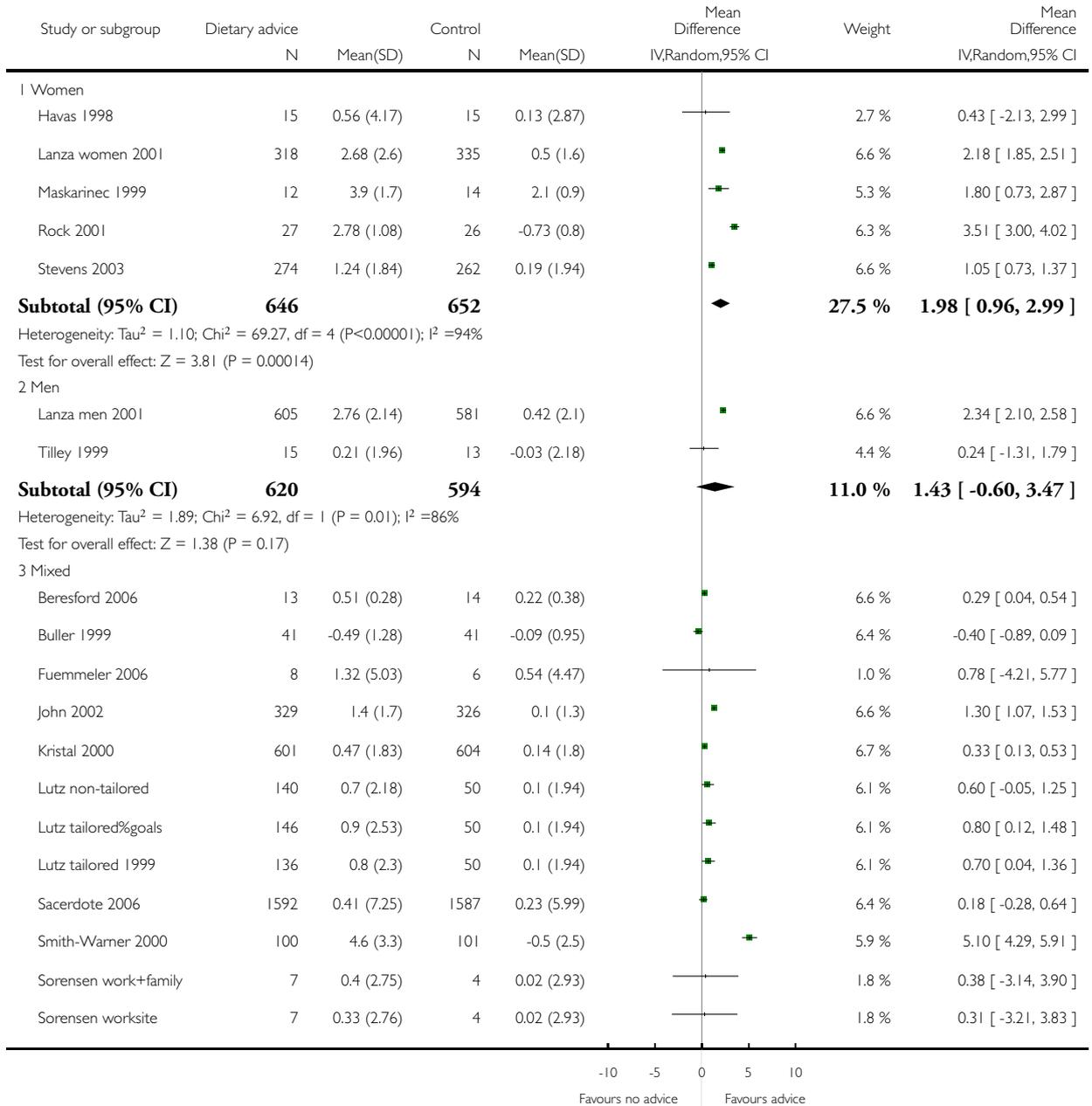


Analysis 2.3. Comparison 2 Subgroup analyses, Outcome 3 Fruit & vegetable servings/day (gender).

Review: Dietary advice for reducing cardiovascular risk

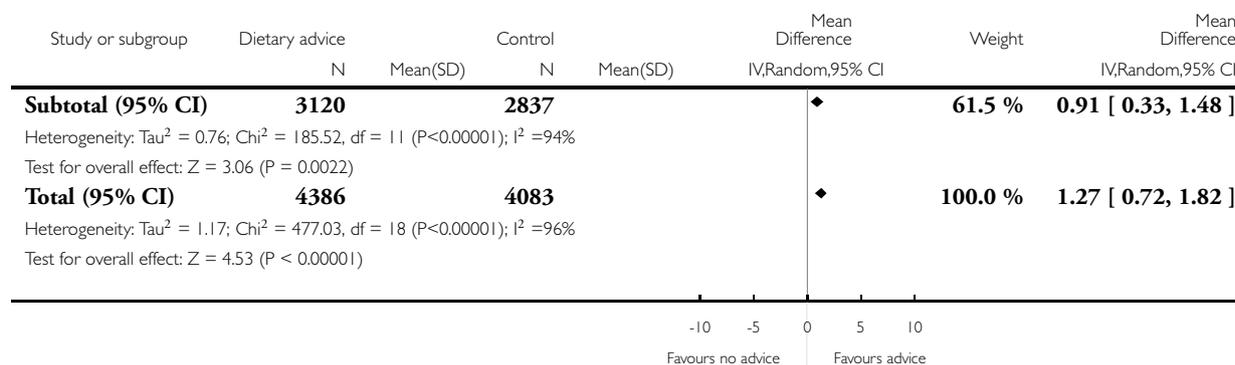
Comparison: 2 Subgroup analyses

Outcome: 3 Fruit % vegetable servings/day (gender)



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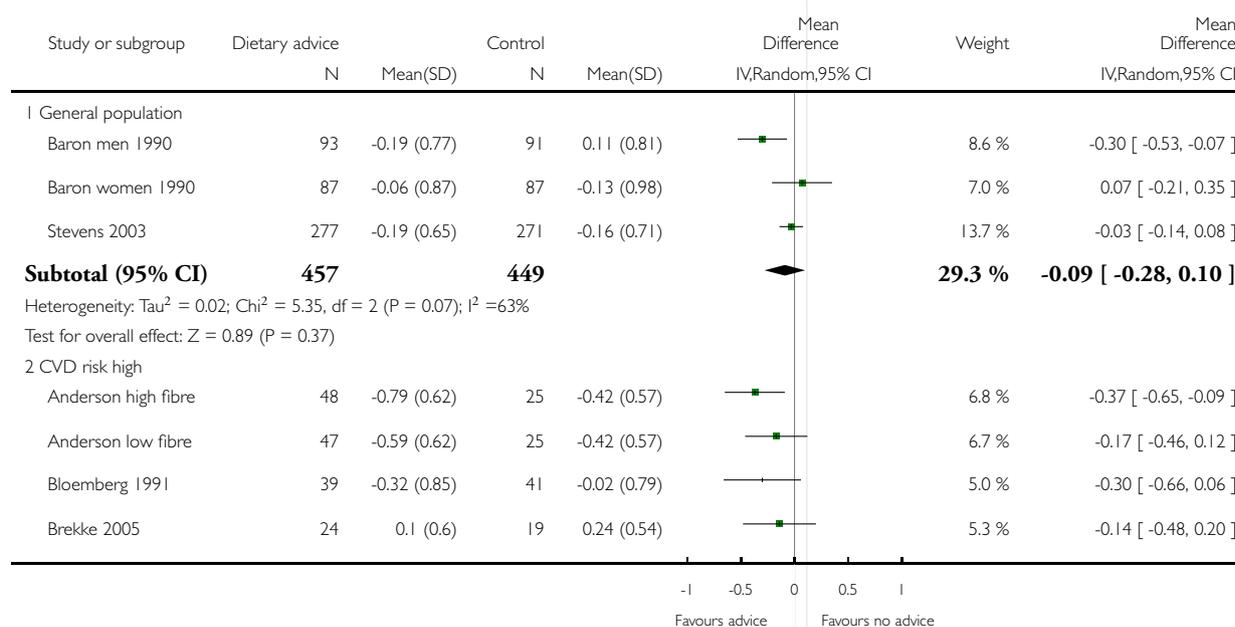


Analysis 2.4. Comparison 2 Subgroup analyses, Outcome 4 Total cholesterol (risk group).

Review: Dietary advice for reducing cardiovascular risk

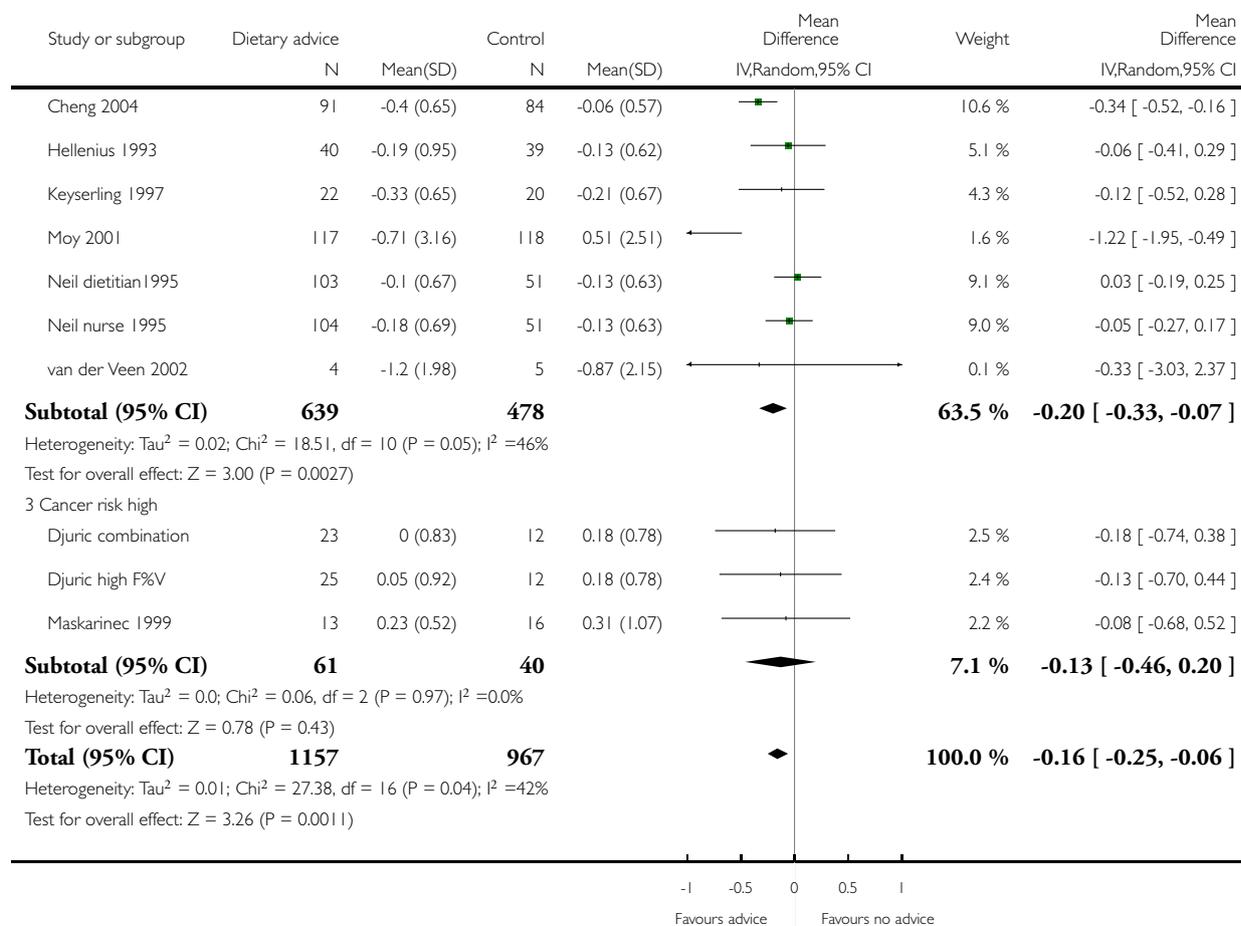
Comparison: 2 Subgroup analyses

Outcome: 4 Total cholesterol (risk group)



(Continued ...)

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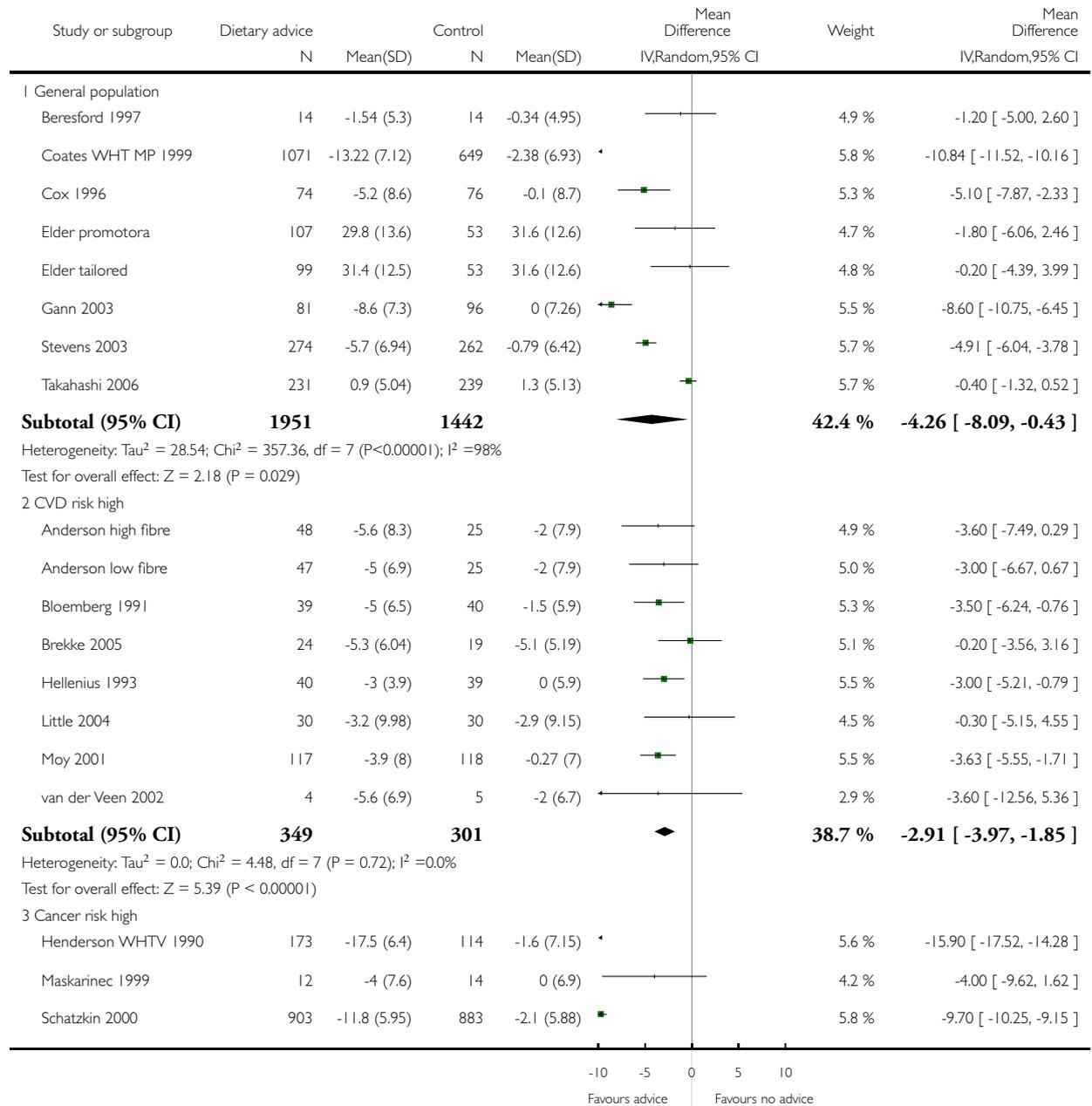


Analysis 2.5. Comparison 2 Subgroup analyses, Outcome 5 Total dietary fat (risk group).

Review: Dietary advice for reducing cardiovascular risk

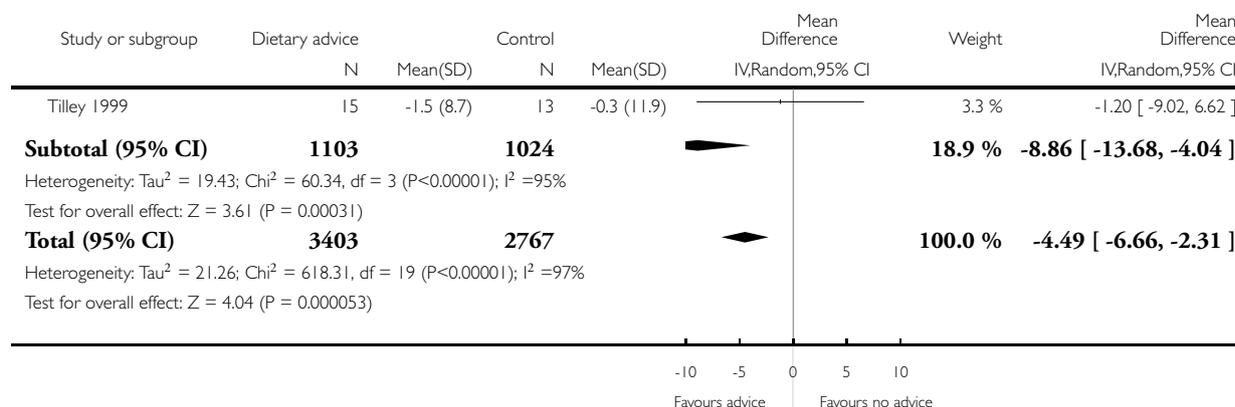
Comparison: 2 Subgroup analyses

Outcome: 5 Total dietary fat (risk group)



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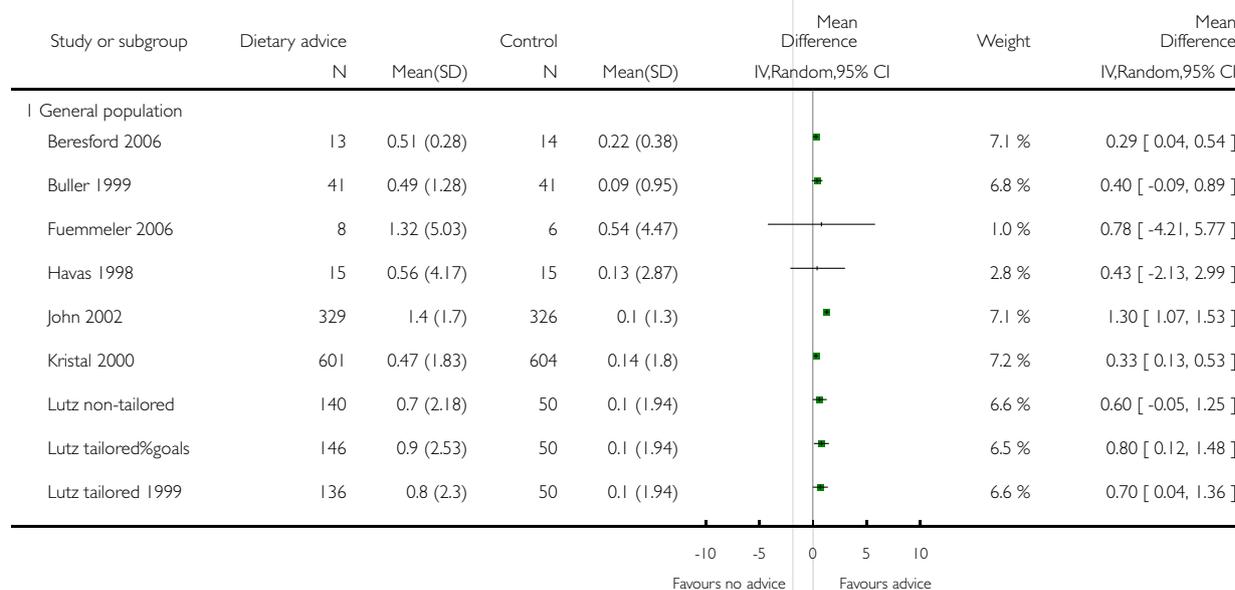


Analysis 2.6. Comparison 2 Subgroup analyses, Outcome 6 Fruit & vegetable servings/day (risk group).

Review: Dietary advice for reducing cardiovascular risk

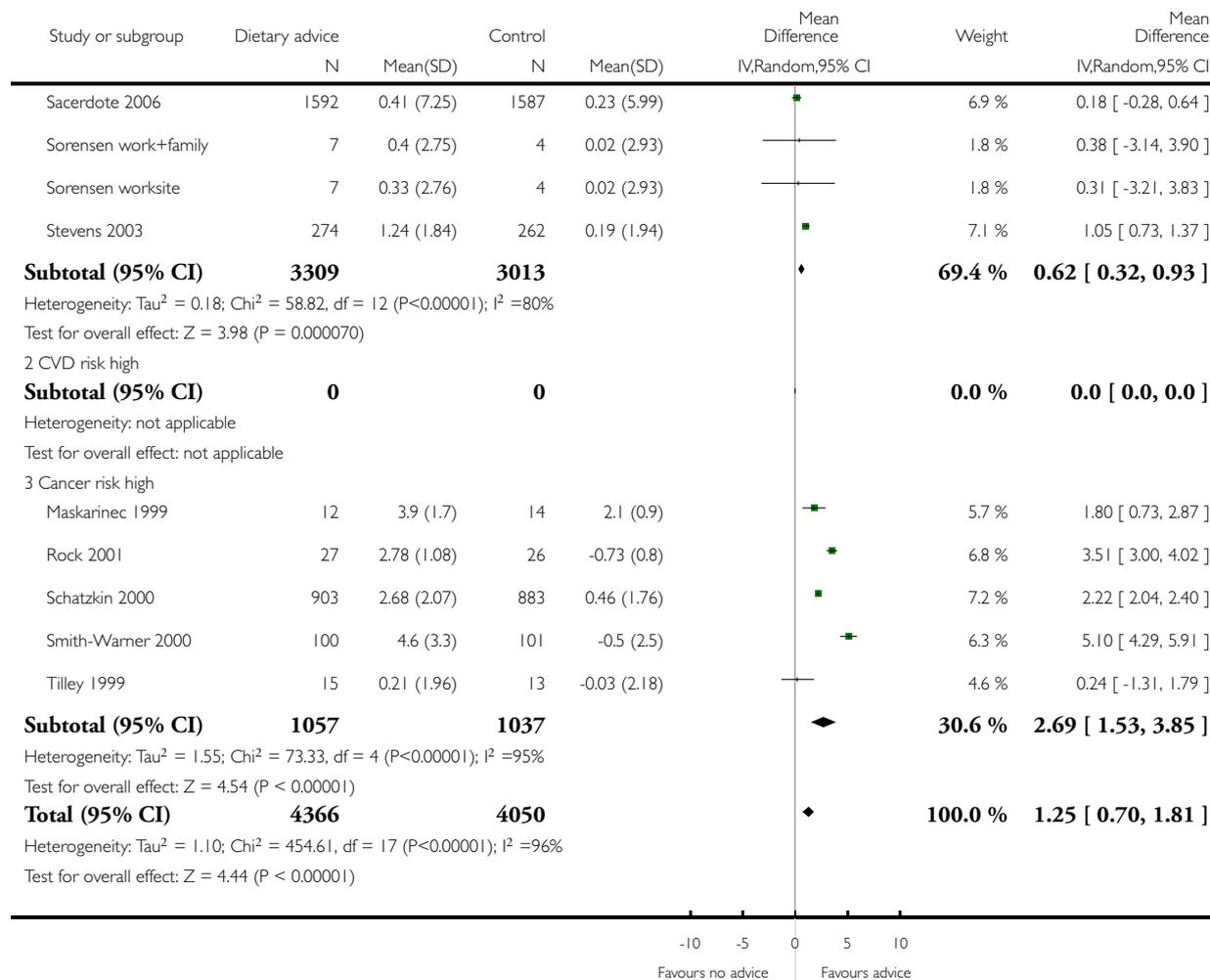
Comparison: 2 Subgroup analyses

Outcome: 6 Fruit % vegetable servings/day (risk group)



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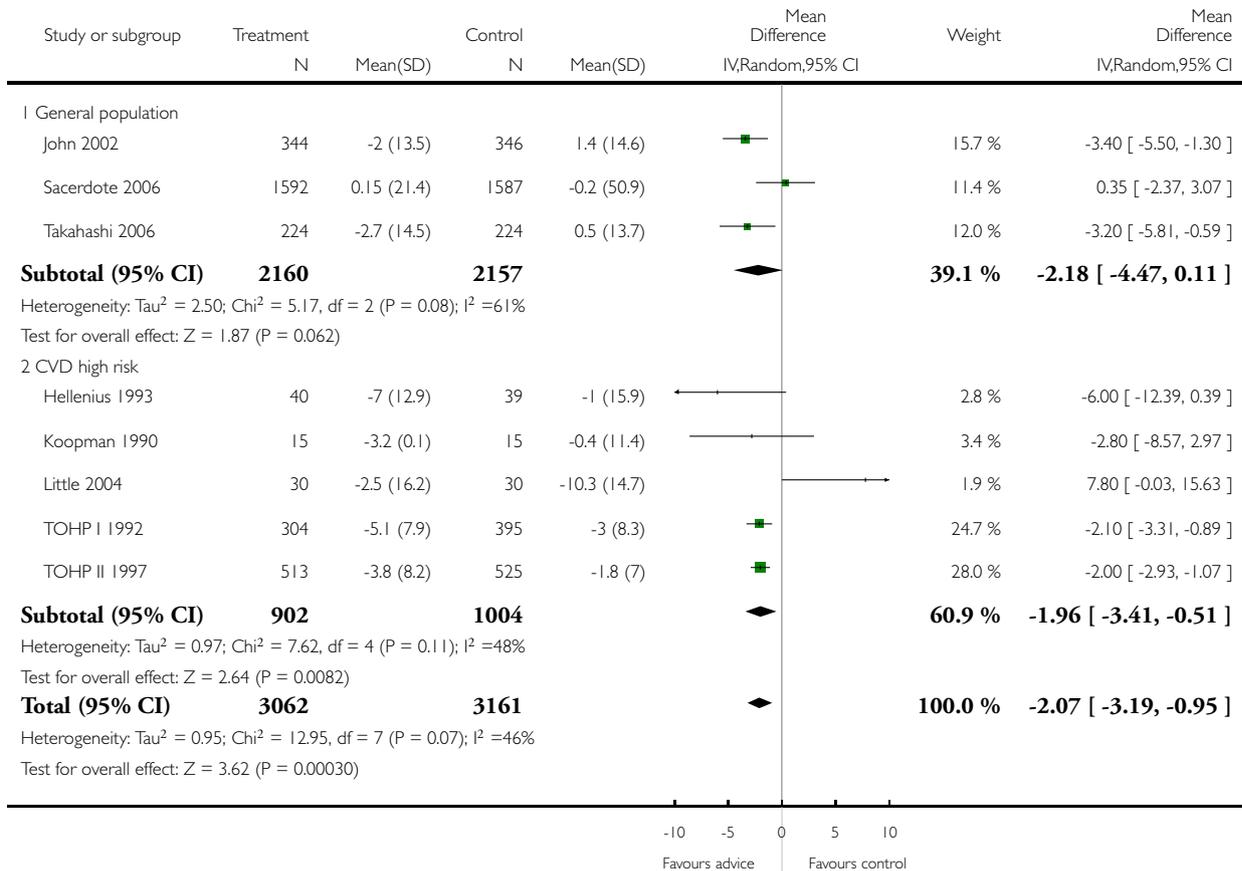


Analysis 2.7. Comparison 2 Subgroup analyses, Outcome 7 SBP mmHg (risk group).

Review: Dietary advice for reducing cardiovascular risk

Comparison: 2 Subgroup analyses

Outcome: 7 SBP mmHg (risk group)

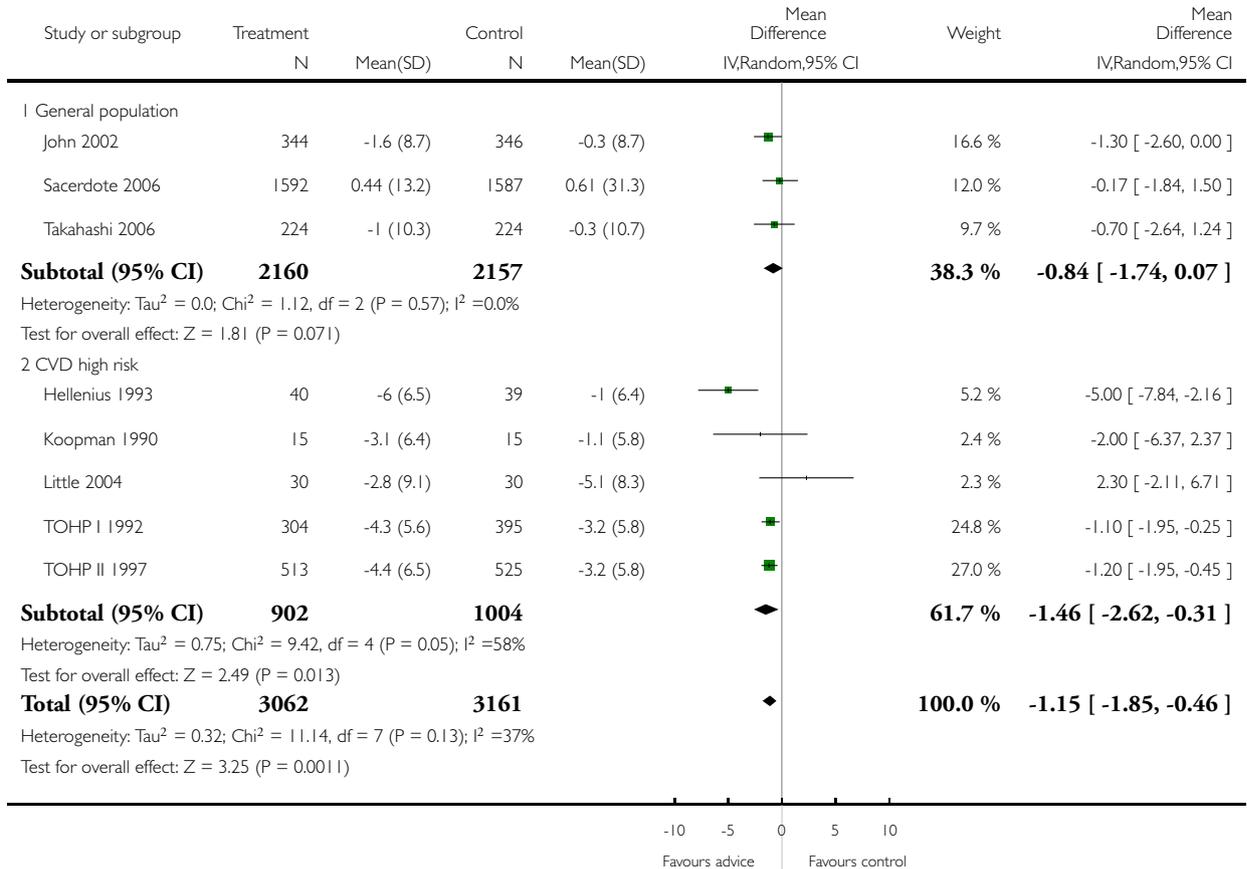


Analysis 2.8. Comparison 2 Subgroup analyses, Outcome 8 DBP mmHg (risk group).

Review: Dietary advice for reducing cardiovascular risk

Comparison: 2 Subgroup analyses

Outcome: 8 DBP mmHg (risk group)

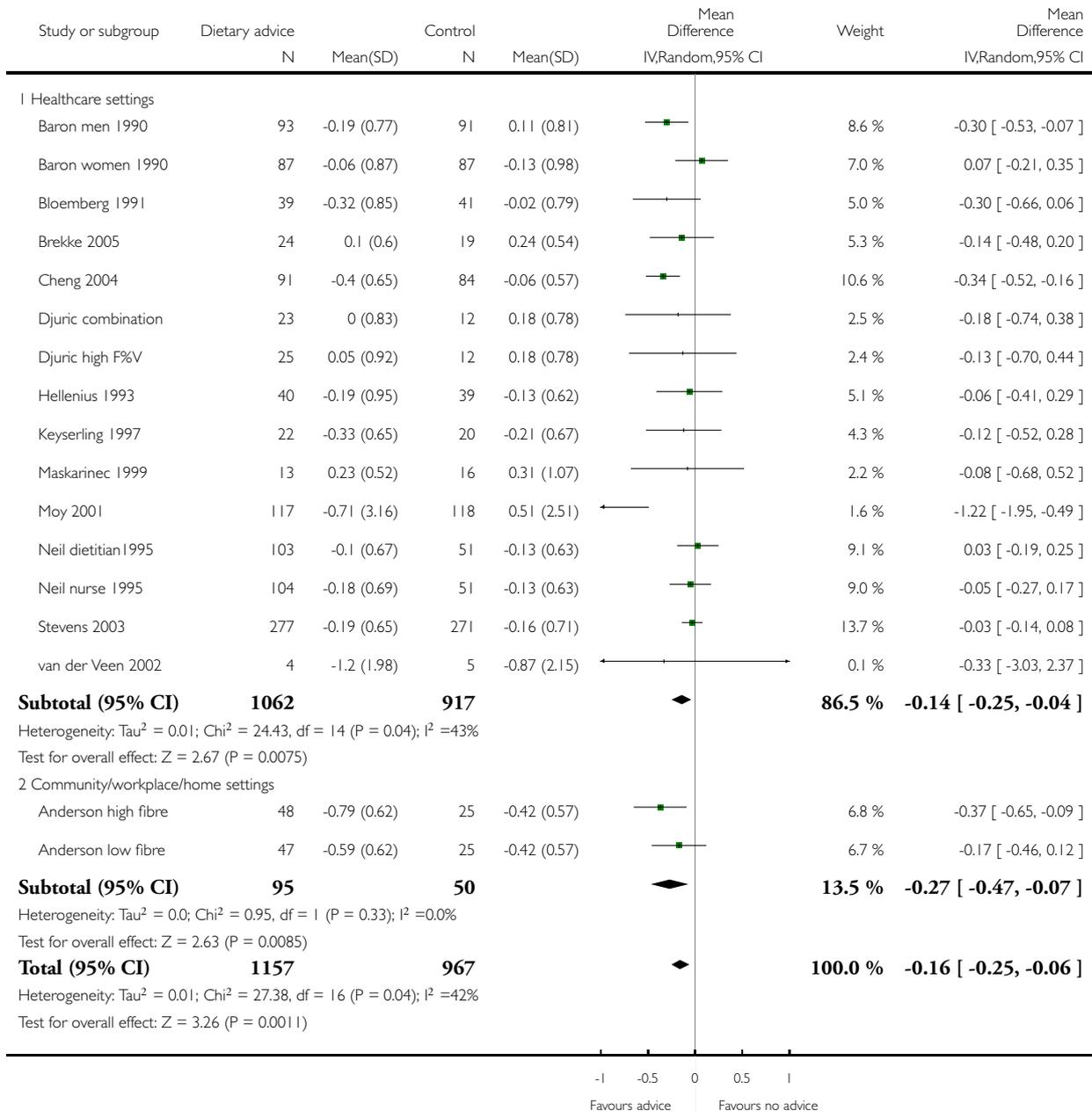


Analysis 2.9. Comparison 2 Subgroup analyses, Outcome 9 Total cholesterol (setting).

Review: Dietary advice for reducing cardiovascular risk

Comparison: 2 Subgroup analyses

Outcome: 9 Total cholesterol (setting)

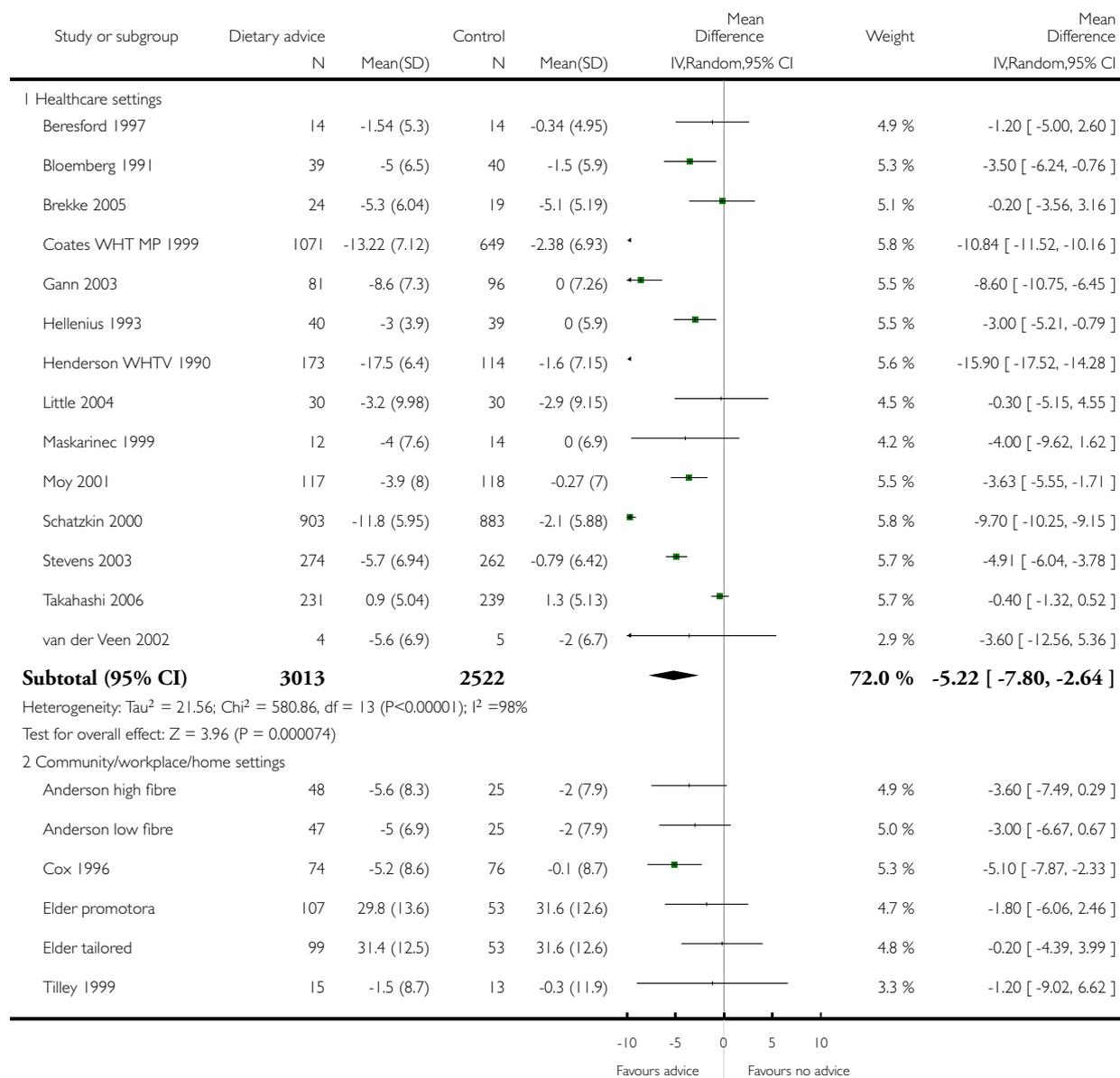


Analysis 2.10. Comparison 2 Subgroup analyses, Outcome 10 Total dietary fat (setting).

Review: Dietary advice for reducing cardiovascular risk

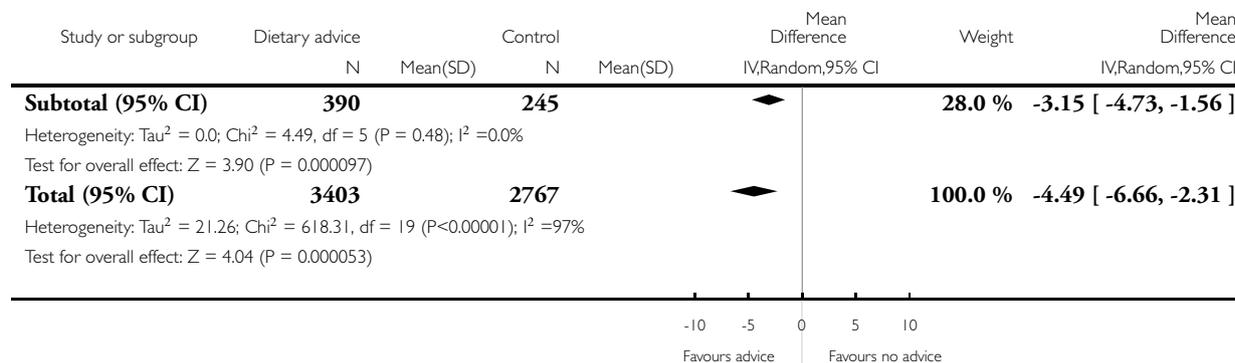
Comparison: 2 Subgroup analyses

Outcome: 10 Total dietary fat (setting)



(Continued ...)

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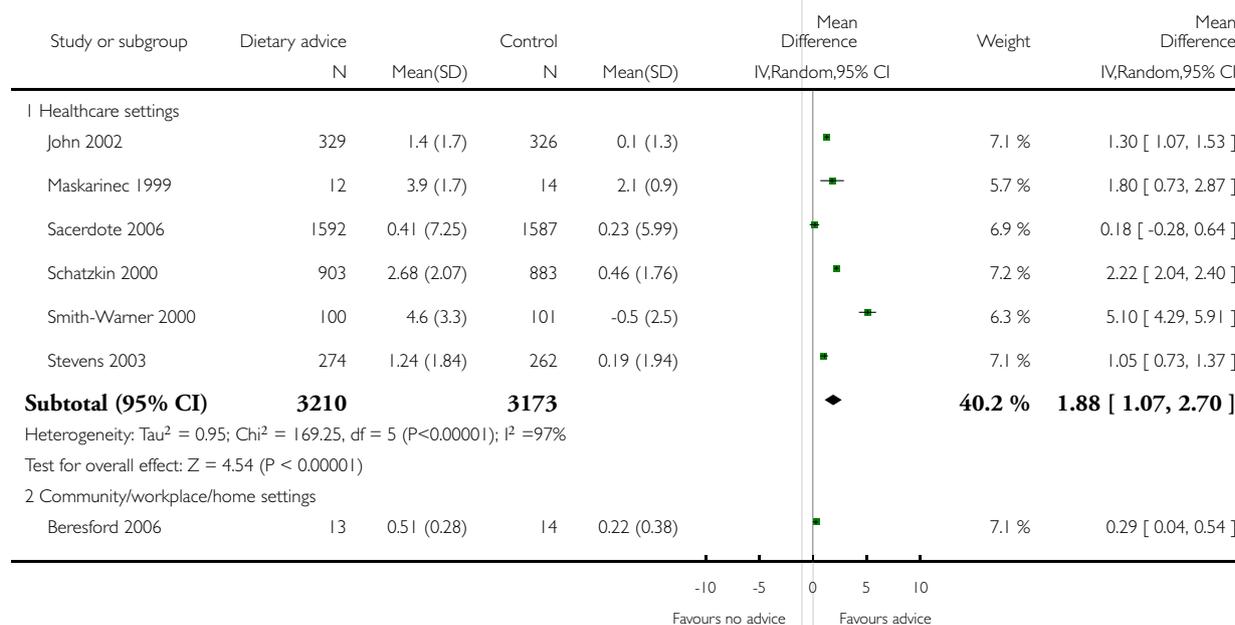


Analysis 2.11. Comparison 2 Subgroup analyses, Outcome 11 Fruit & vegetable servings/day (setting).

Review: Dietary advice for reducing cardiovascular risk

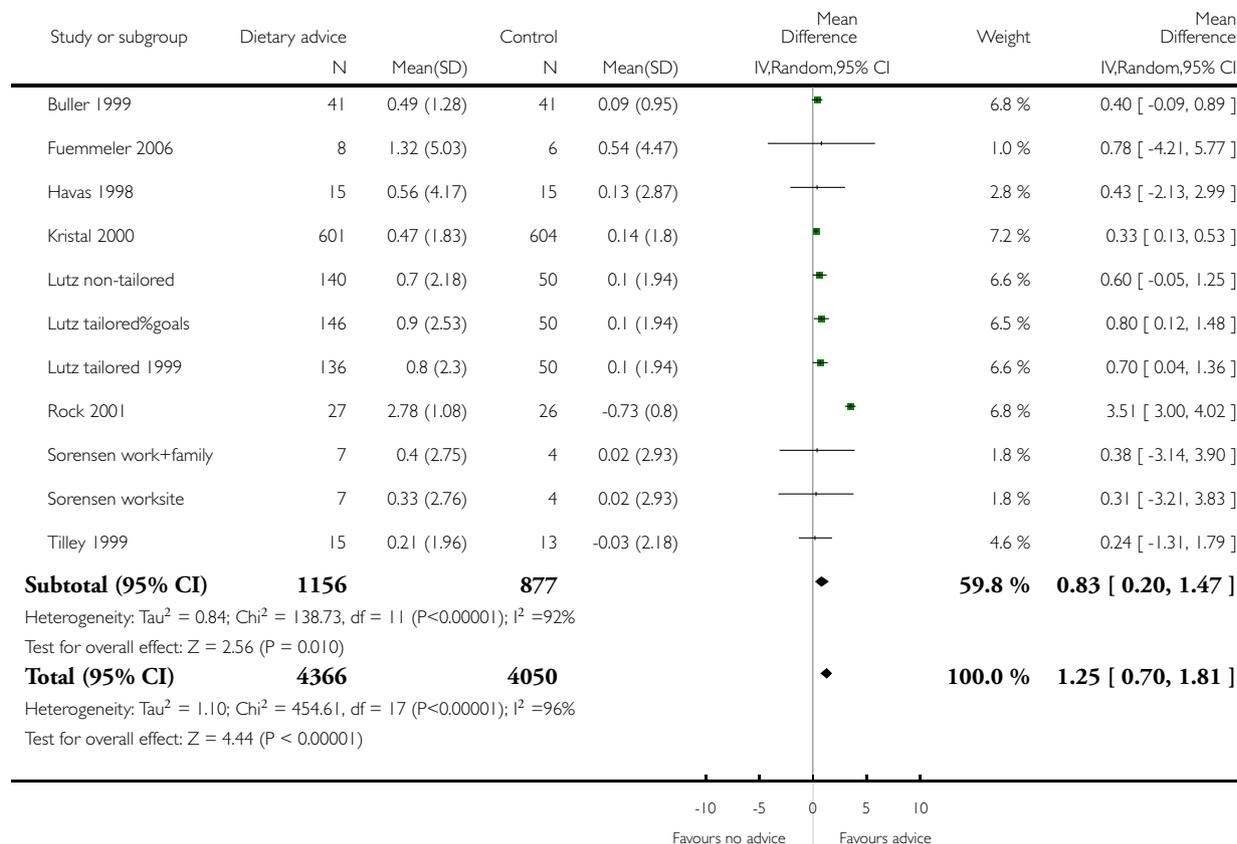
Comparison: 2 Subgroup analyses

Outcome: 11 Fruit % vegetable servings/day (setting)



(Continued ...)

(... Continued)

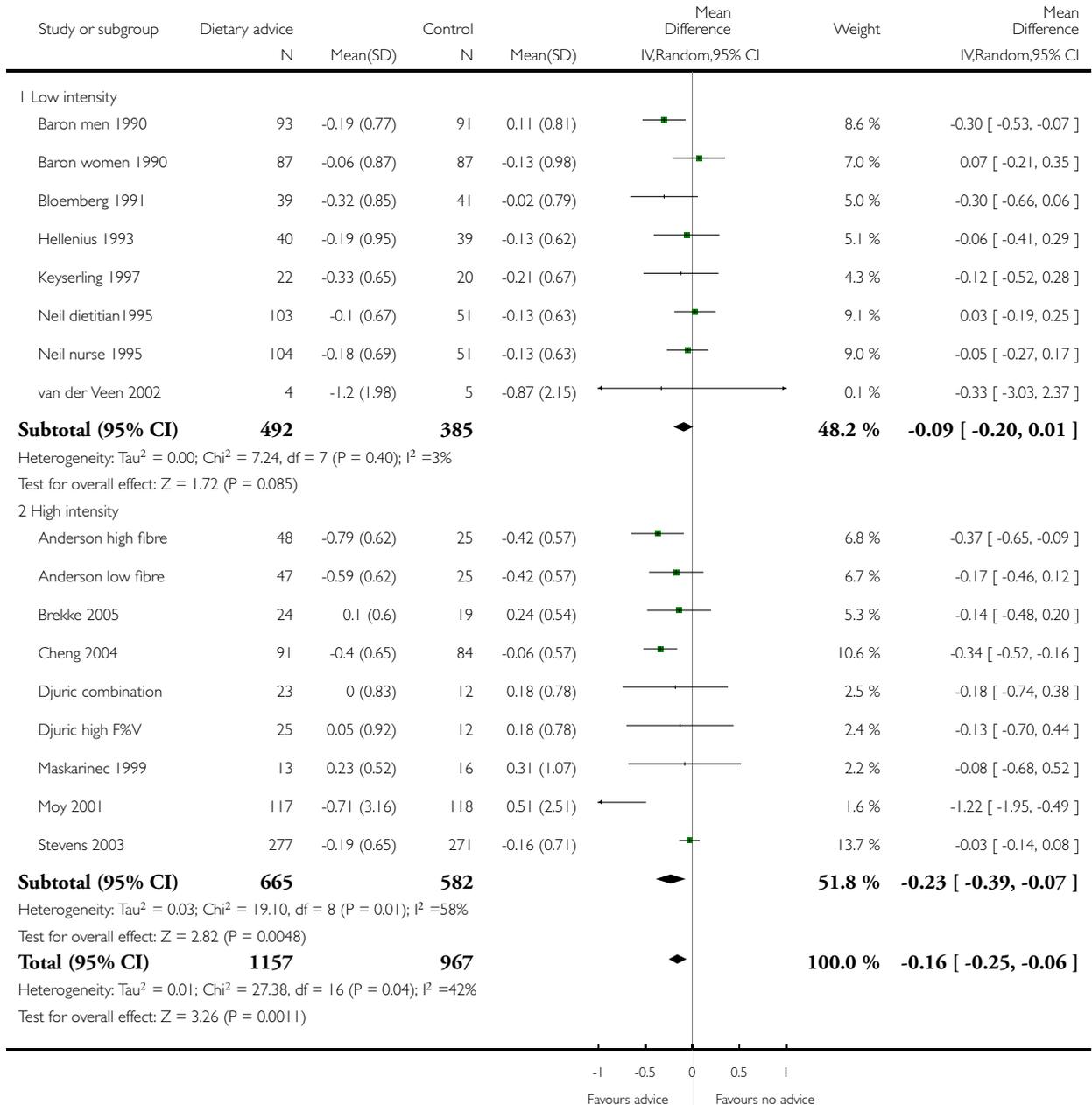


Analysis 2.12. Comparison 2 Subgroup analyses, Outcome 12 Total cholesterol (intensity).

Review: Dietary advice for reducing cardiovascular risk

Comparison: 2 Subgroup analyses

Outcome: 12 Total cholesterol (intensity)

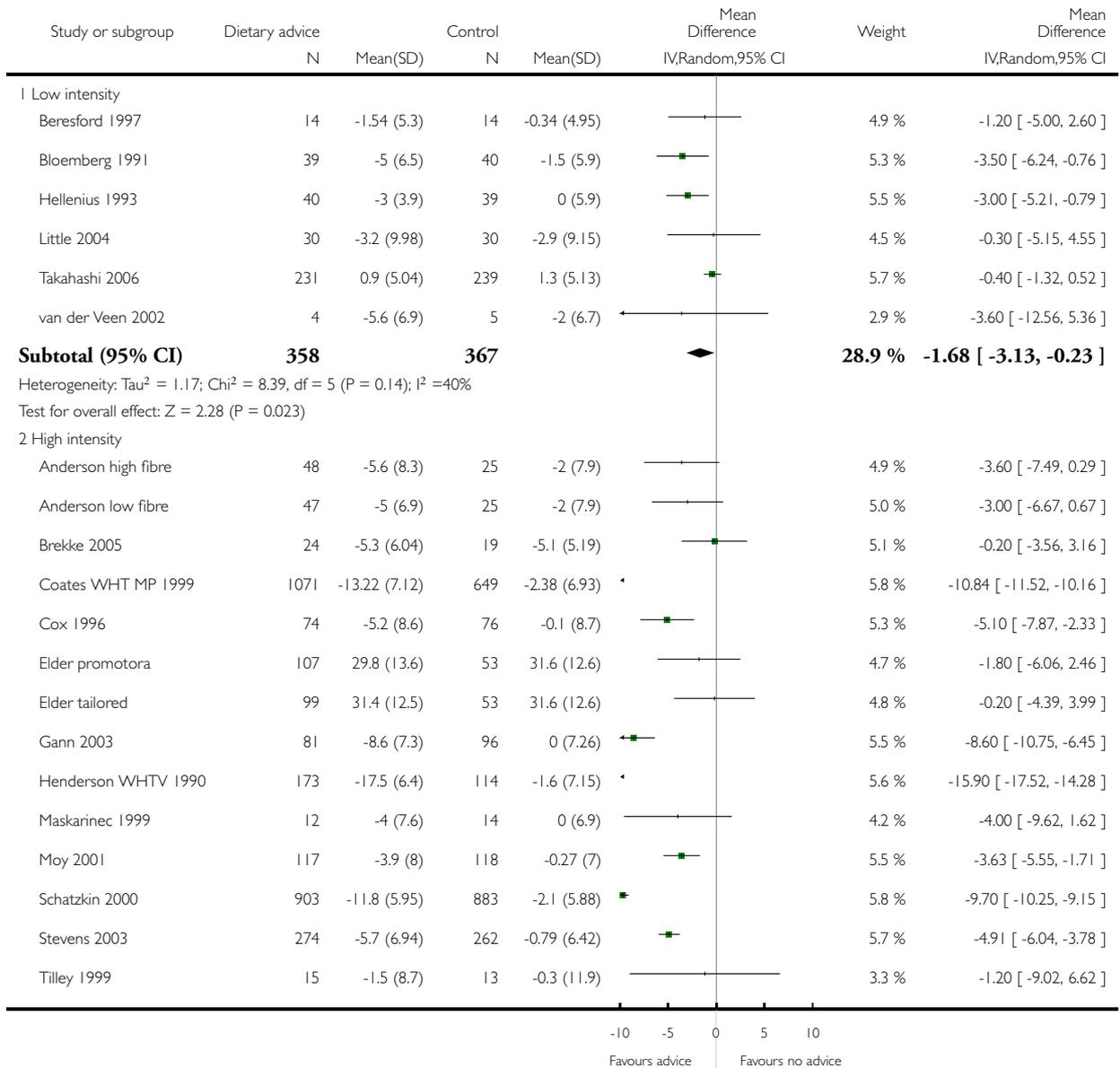


Analysis 2.13. Comparison 2 Subgroup analyses, Outcome 13 Total dietary fat (intensity).

Review: Dietary advice for reducing cardiovascular risk

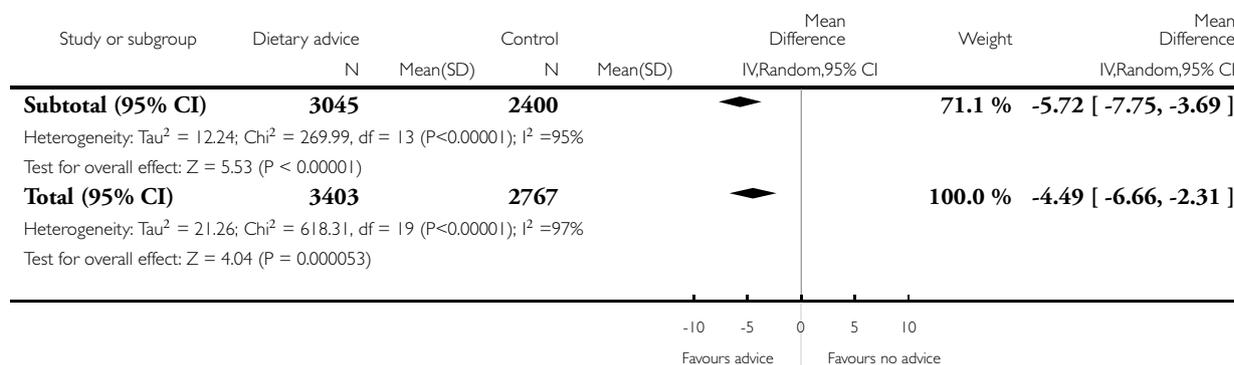
Comparison: 2 Subgroup analyses

Outcome: 13 Total dietary fat (intensity)



(Continued ...)

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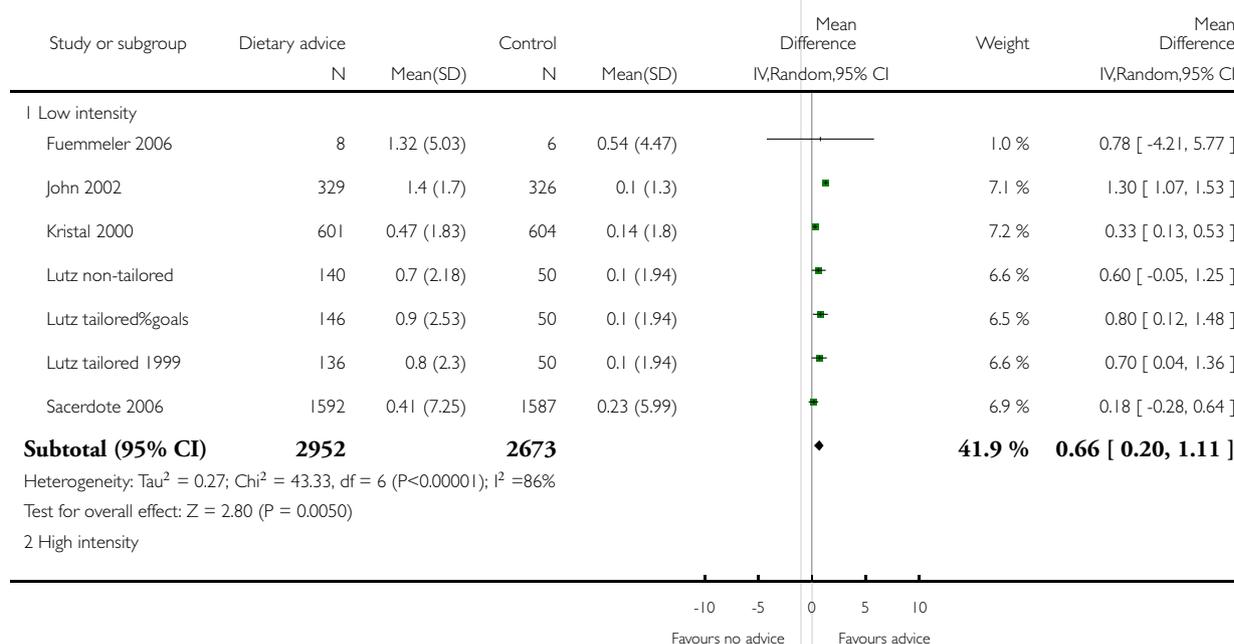


Analysis 2.14. Comparison 2 Subgroup analyses, Outcome 14 Fruit & vegetable servings/day (intensity).

Review: Dietary advice for reducing cardiovascular risk

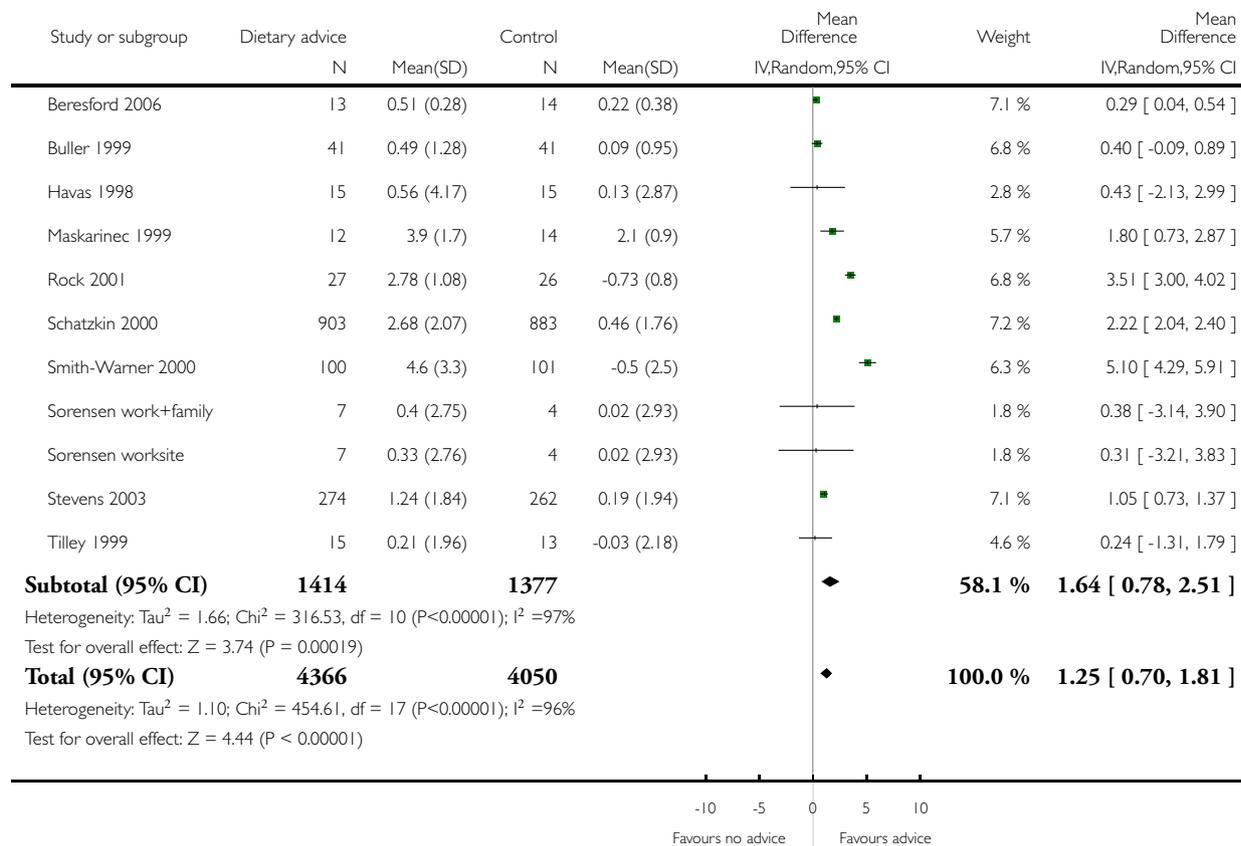
Comparison: 2 Subgroup analyses

Outcome: 14 Fruit % vegetable servings/day (intensity)



(Continued ...)

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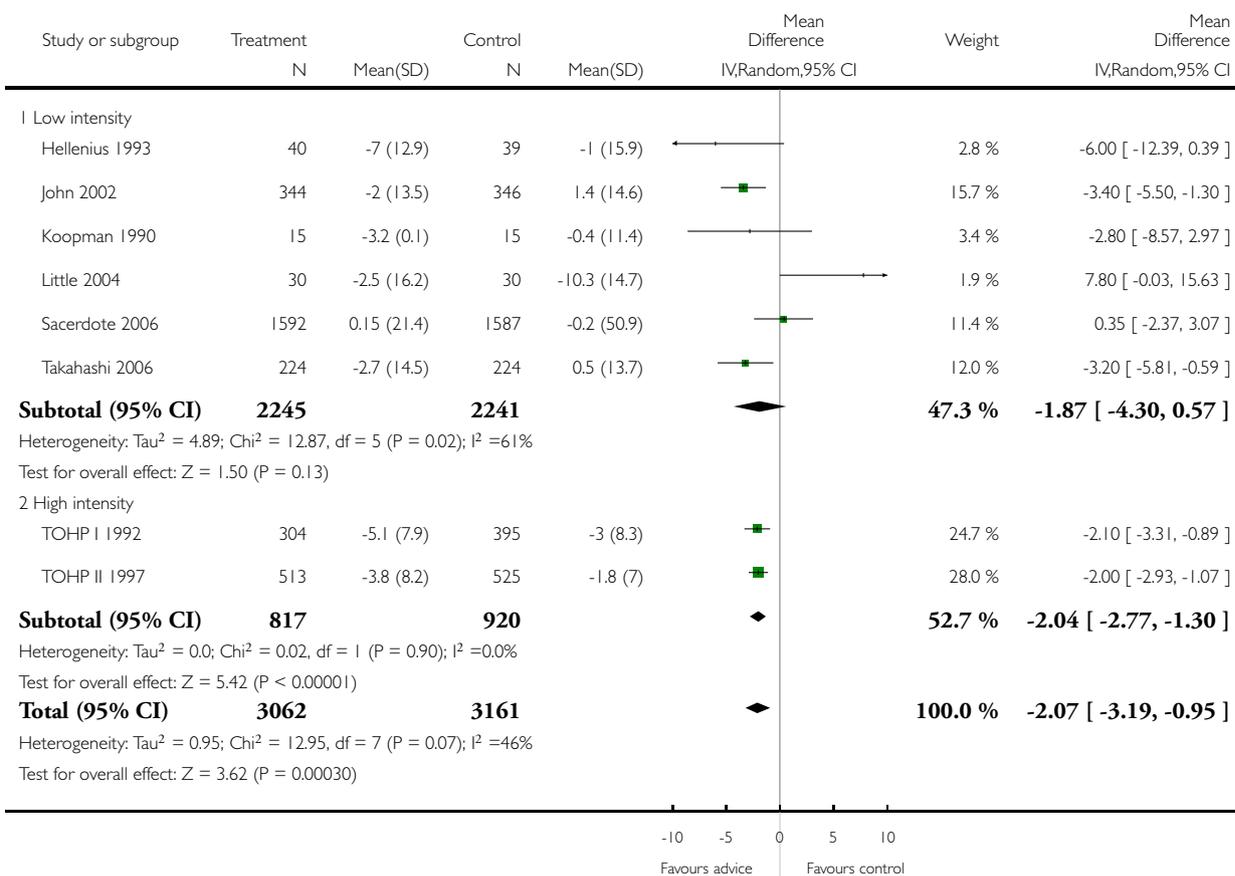


Analysis 2.15. Comparison 2 Subgroup analyses, Outcome 15 SBP mmHg (intensity).

Review: Dietary advice for reducing cardiovascular risk

Comparison: 2 Subgroup analyses

Outcome: 15 SBP mmHg (intensity)

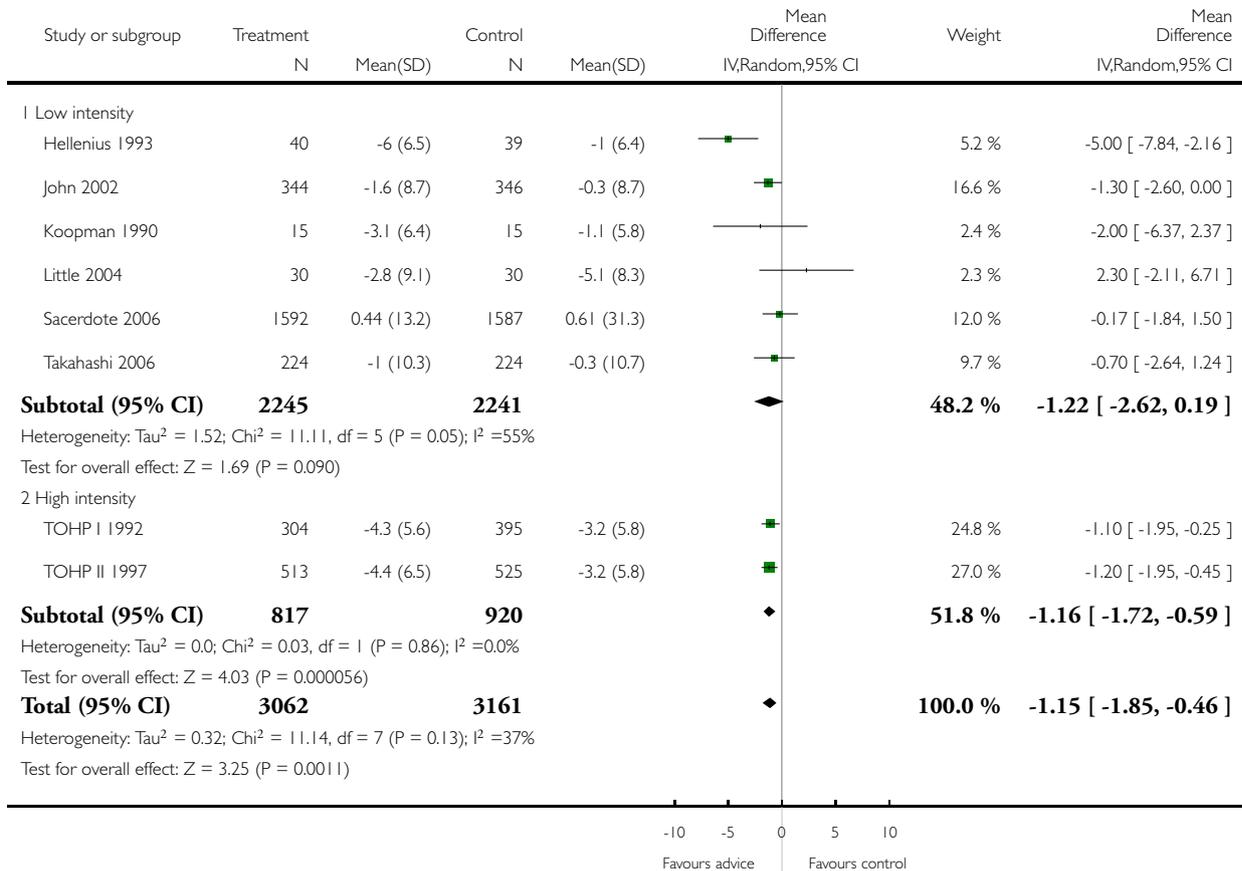


Analysis 2.16. Comparison 2 Subgroup analyses, Outcome 16 DBP mmHg (intensity).

Review: Dietary advice for reducing cardiovascular risk

Comparison: 2 Subgroup analyses

Outcome: 16 DBP mmHg (intensity)

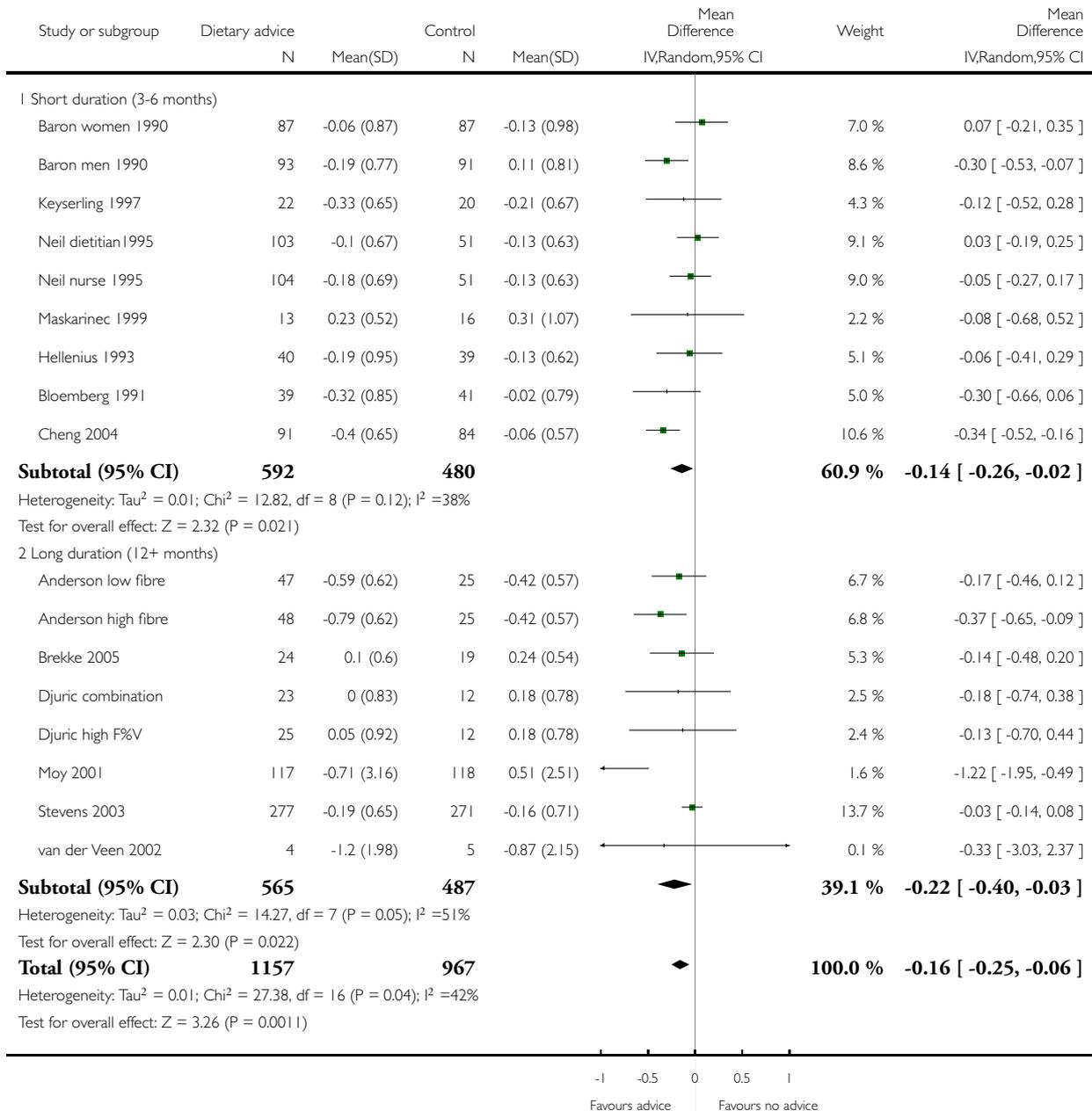


Analysis 2.17. Comparison 2 Subgroup analyses, Outcome 17 Total cholesterol (duration).

Review: Dietary advice for reducing cardiovascular risk

Comparison: 2 Subgroup analyses

Outcome: 17 Total cholesterol (duration)

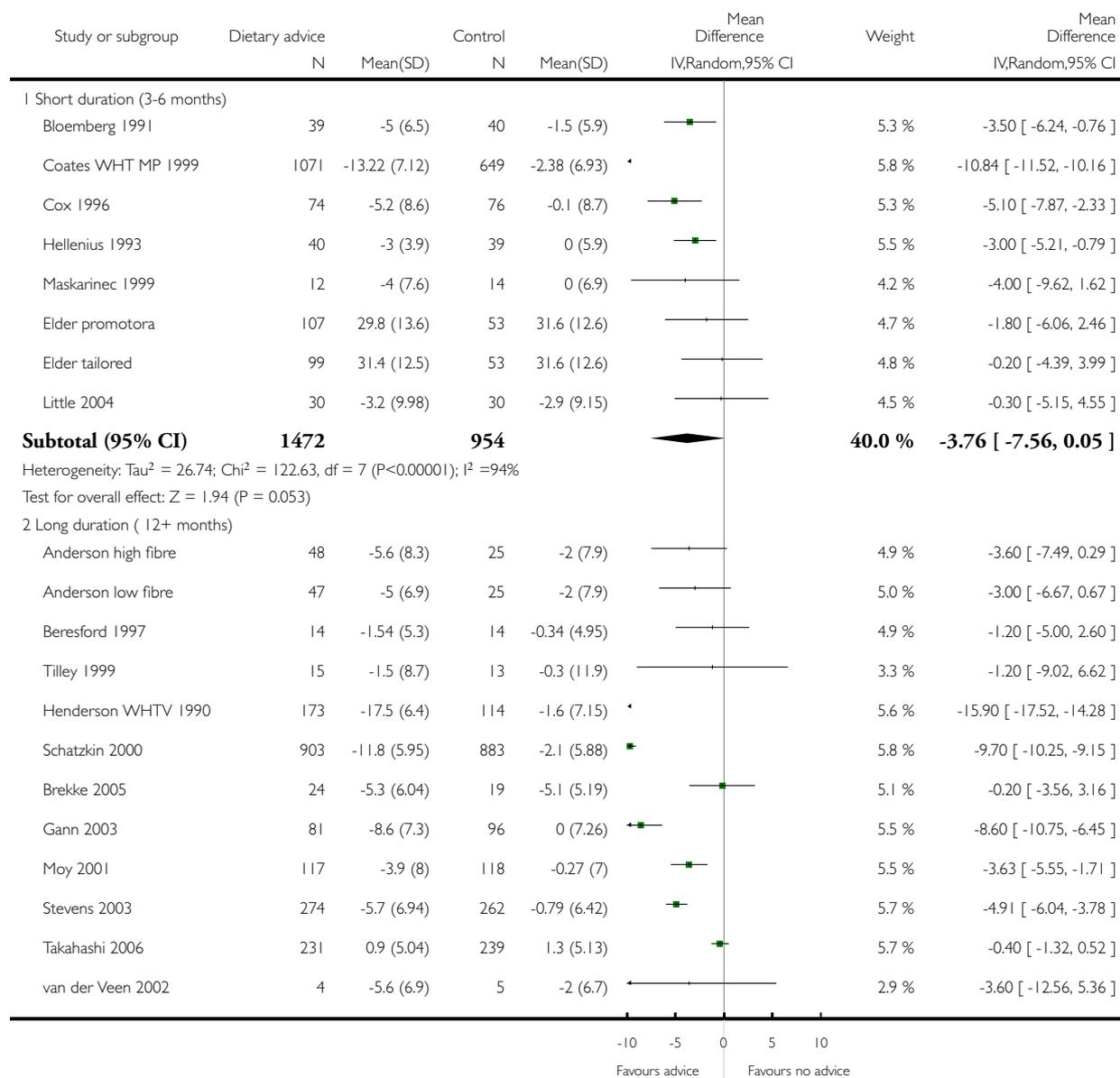


Analysis 2.18. Comparison 2 Subgroup analyses, Outcome 18 Total dietary fat (duration).

Review: Dietary advice for reducing cardiovascular risk

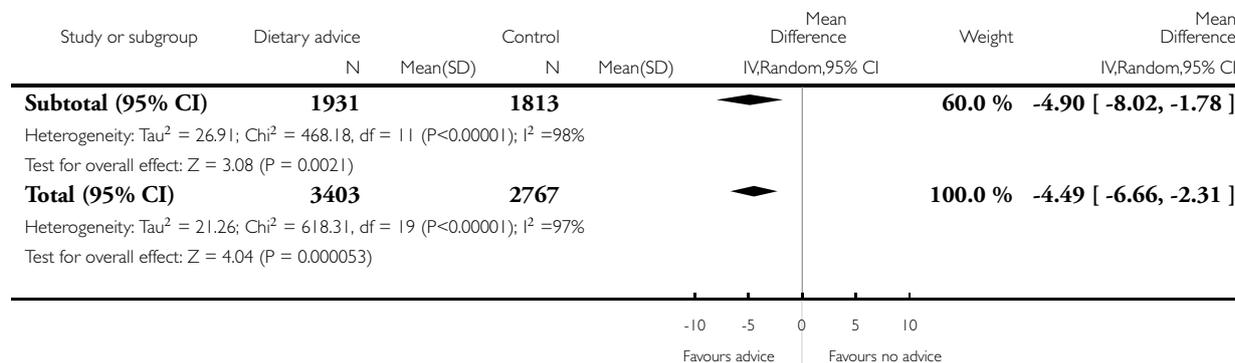
Comparison: 2 Subgroup analyses

Outcome: 18 Total dietary fat (duration)



(Continued ...)

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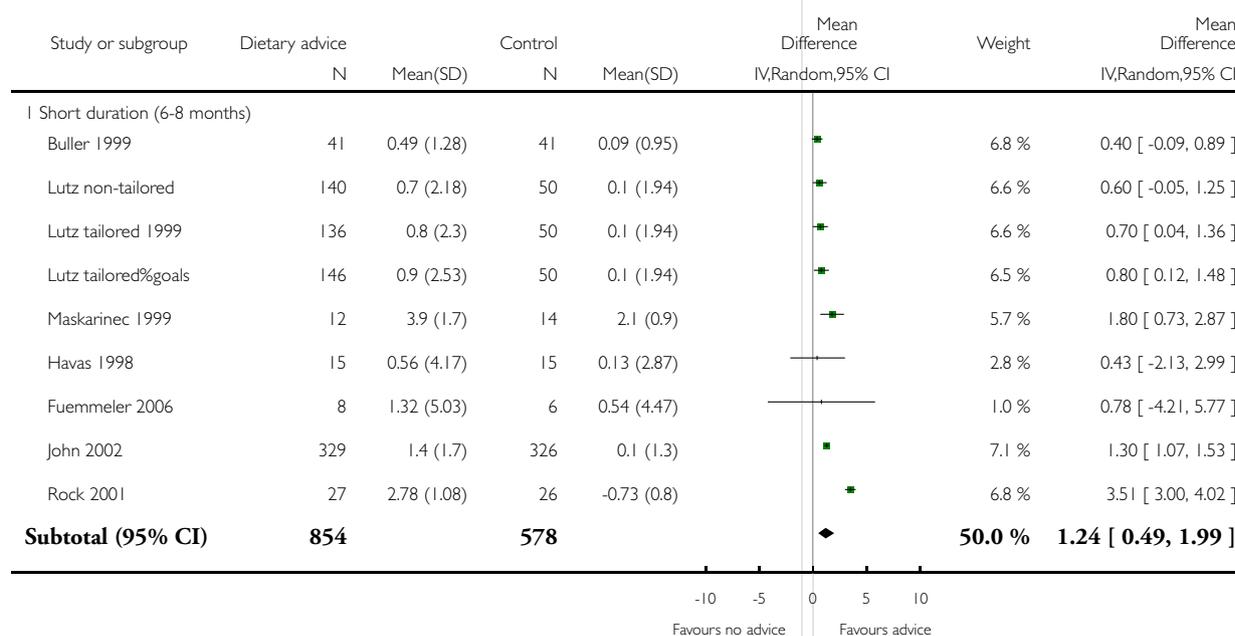


Analysis 2.19. Comparison 2 Subgroup analyses, Outcome 19 Fruit & vegetable servings/day (duration).

Review: Dietary advice for reducing cardiovascular risk

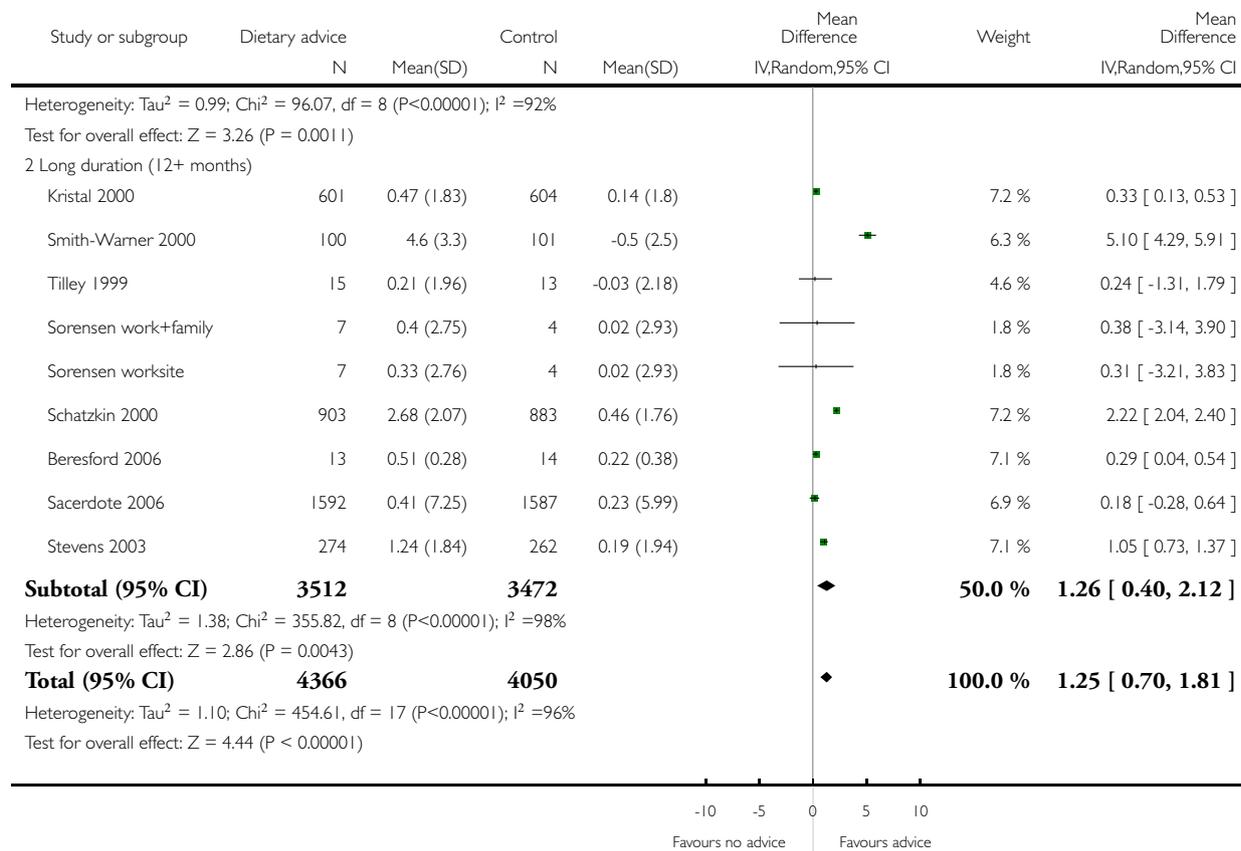
Comparison: 2 Subgroup analyses

Outcome: 19 Fruit % vegetable servings/day (duration)



(Continued ...)

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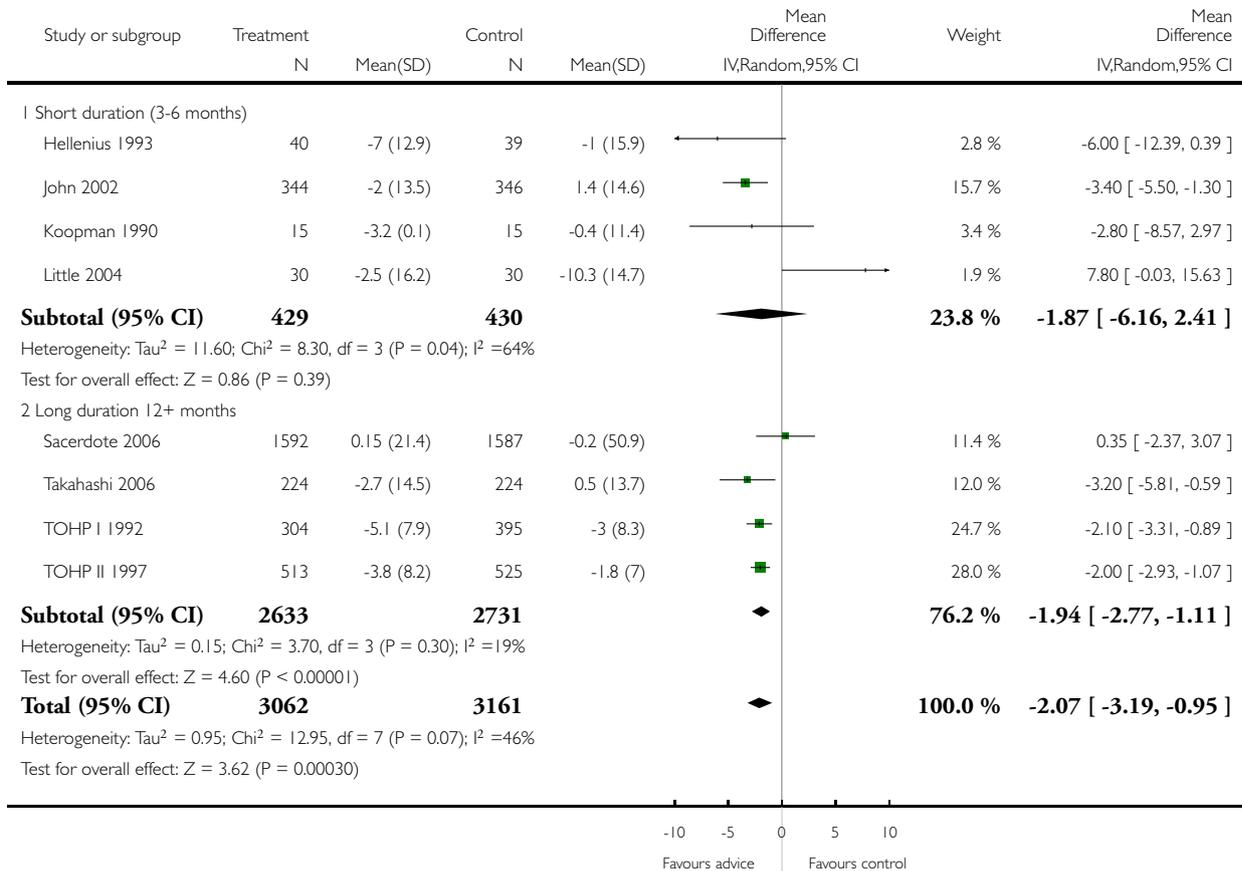


Analysis 2.20. Comparison 2 Subgroup analyses, Outcome 20 SBP mmHg (duration).

Review: Dietary advice for reducing cardiovascular risk

Comparison: 2 Subgroup analyses

Outcome: 20 SBP mmHg (duration)

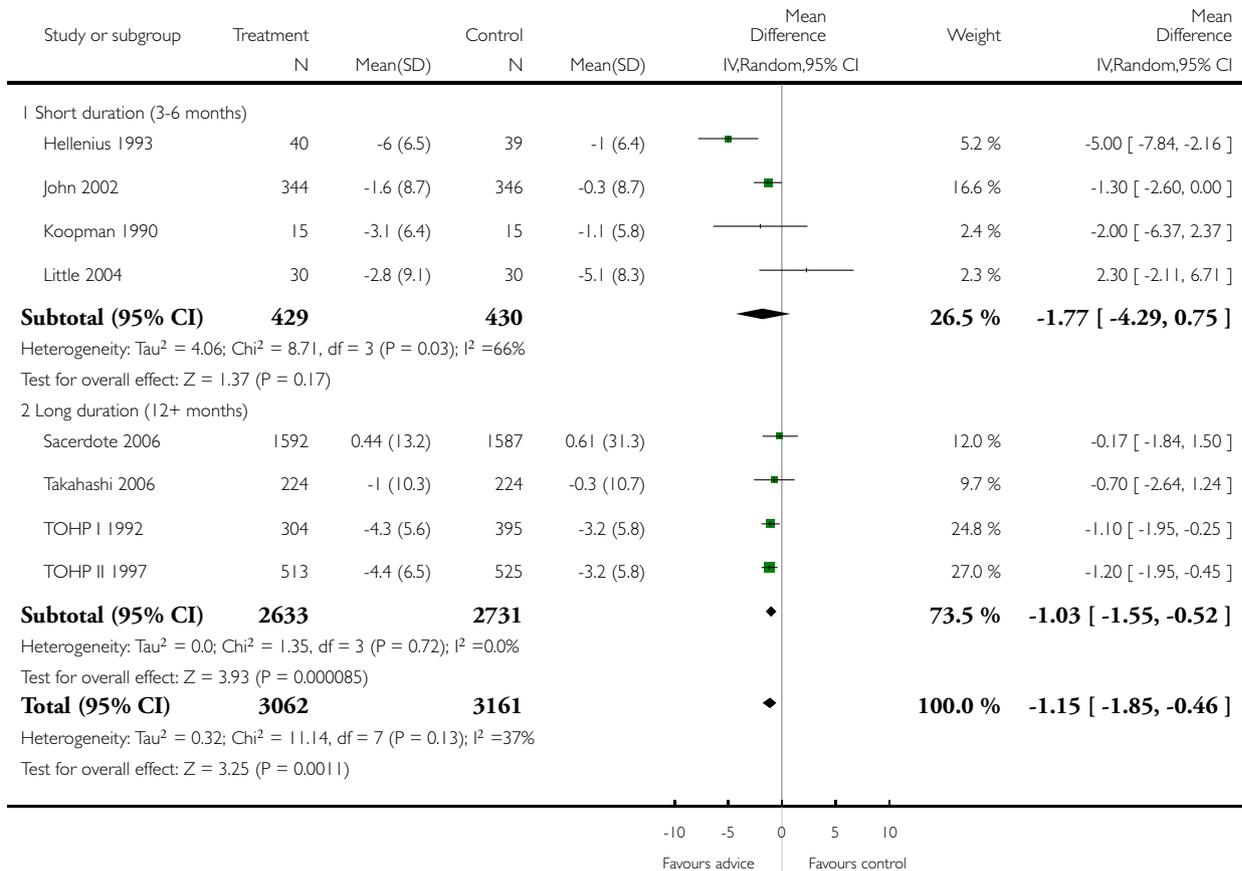


Analysis 2.21. Comparison 2 Subgroup analyses, Outcome 21 DBP mmHg (duration).

Review: Dietary advice for reducing cardiovascular risk

Comparison: 2 Subgroup analyses

Outcome: 21 DBP mmHg (duration)



ADDITIONAL TABLES

Table 1. MEDLINE (Ovid) search strategy

1 exp Communication/
2 exp Counseling/
3 exp Health Education/
4 Life Style/

Table 1. MEDLINE (Ovid) search strategy (Continued)

5 Practice Guidelines/
6 (diet\$ adj1 (therap\$ or educat\$ or counsel\$ or intervention\$ or treatment\$)).tw.
7 (nutriti\$ adj1 (therap\$ or educat\$ or counsel\$ or intervention\$)).tw.
8 (health adj1 (therap\$ or counsel\$ or educat\$)).tw.
9 (intake\$ adj3 (increas\$ or decreas\$ or reduc\$ or rais\$ or low\$ or chang\$ or restrict\$ or high\$)).tw.
10 (intake\$ adj3 (increas\$ or decreas\$ or reduc\$ or rais\$ or low\$ or chang\$ or restrict\$ or high\$)).tw.
11 (consumption adj3 (increas\$ or decreas\$ or reduc\$ or rais\$ or low\$ or chang\$ or restrict\$ or high\$)).tw.
12 ((salt or sodium) adj3 (decreas\$ or reduc\$ or low\$ or chang\$ or restrict\$)).tw.
13 ((fish or fruit\$ or vegetable\$) adj3 (increas\$ or rais\$ or chang\$ or high\$)).tw.
14 (diet\$ adj3 chang\$).tw.
15 (lifestyle\$ adj3 chang\$).tw.
16 guideline\$.tw.
17 (group adj counsel\$).tw.
18 (brief adj intervention\$).tw.
19 (health adj behav\$ adj intervention\$).tw.
20 advice.tw.
21 leaflet\$.tw.
22 video\$.tw.
23 ((fat or fats or cholesterol) adj3 (decreas\$ or reduc\$ or low\$ or chang\$ or restrict\$)).tw.
24 or/1-23
25 diet/
26 Diet, Atherogenic/
27 Diet, Mediterranean/
28 exp Energy Intake/
29 exp Dietary Fats/
30 Dietary Fiber/
31 Potassium, Dietary/
32 exp Sodium, Dietary/
33 exp Ascorbic Acid/
34 beta Carotene/
35 exp Folic Acid/
36 exp Vitamin E/
37 exp Fish Oils/
38 exp Plant Oils/
39 exp Dairy Products/
40 exp Fruit/
41 exp Meat/
42 exp Vegetables/
43 exp Fatty Acids, Unsaturated/
44 Food Habits/
45 diet\$.tw.
46 food\$.tw.
47 (lipid\$ adj3 (low\$ or reduc\$ or modifi\$)).tw.
48 polyunsaturat\$.tw.
49 (polyunsaturat\$ or poly-unsaturat\$).tw.
50 (monunsaturat\$ or mono-unsaturat\$).tw.
51 (omega\$ adj3 fat\$).tw.
52 (omega3 or omega-3).tw.
53 marg?rine\$.tw.

Table 1. MEDLINE (Ovid) search strategy (Continued)

54 butter\$.tw.
55 (meat or meats).tw.
56 fish.tw.
57 vegetable\$.tw.
58 fruit\$.tw.
59 legum\$.tw.
60 soy\$.tw.
61 bean\$.tw.
62 oat\$.tw.
63 grain\$.tw.
64 starch\$.tw.
65 exp Dietary Carbohydrates/
66 carbohydrate\$.tw.
67 roughage.tw.
68 ((non-starch or nonstarch) adj (poly-saccharide\$ or polysaccharide\$)).tw.
69 (nut or nuts).tw.
70 lard\$.tw.
71 salt.tw.
72 (antioxidant\$ or anti-oxidant\$).tw.
73 folic.tw.
74 folate\$.tw.
75 ascorb\$.tw.
76 tocopherol\$.tw.
77 alphanatocopherol\$.tw.
78 vitamin c.tw.
79 vitamin e.tw.
80 (betacarotene or beta-carotene or carotenoid\$).tw.
81 (betacarotene or beta-carotene or carotenoid\$).tw.
82 (sodium adj2 intake\$).tw.
83 (potassium adj2 intake\$).tw.
84 (fat\$ adj3 (low\$ or modifi\$ or animal\$ or vegetable\$ or acid\$ or saturat\$ or unsaturat\$)).tw.
85 (oil\$ adj3 (vegetable\$ or olive\$ or rape\$ or sunflow\$ or linseed\$ or saturat\$ or unsaturat\$)).tw.
86 or/25-85
87 exp diet therapy/
88 24 and 86
89 87 or 88
90 exp animals/ not human/
91 89 not 90
92 exp child/ not exp adult/
93 91 not 92

Table 2. EMBASE (Ovid) search strategy

1 exp Interpersonal Communication/
2 exp Counseling/
3 exp Health Education/
4 Life Style/

Table 2. EMBASE (Ovid) search strategy (Continued)

5 Practice Guideline/
6 (diet\$ adj1 (therap\$ or educat\$ or counsel\$ or intervention\$ or treatment\$)).tw.
7 (nutriti\$ adj1 (therap\$ or educat\$ or counsel\$ or intervention\$)).tw.
8 (health adj1 (therap\$ or counsel\$ or educat\$)).tw.
9 (intake\$ adj3 (increas\$ or decreas\$ or reduc\$ or rais\$ or low\$ or chang\$ or restrict\$ or high\$)).tw.
10 (intake\$ adj3 (increas\$ or decreas\$ or reduc\$ or rais\$ or low\$ or chang\$ or restrict\$ or high\$)).tw.
11 (consumption adj3 (increas\$ or decreas\$ or reduc\$ or rais\$ or low\$ or chang\$ or restrict\$ or high\$)).tw.
12 ((salt or sodium) adj3 (decreas\$ or reduc\$ or low\$ or chang\$ or restrict\$)).tw.
13 ((fish or fruit\$ or vegetable\$) adj3 (increas\$ or rais\$ or chang\$ or high\$)).tw.
14 (diet\$ adj3 chang\$).tw.
15 (lifestyle\$ adj3 chang\$).tw.
16 guideline\$.tw.
17 (group adj counsel\$).tw.
18 (brief adj intervention\$).tw.
19 (health adj behav\$ adj intervention\$).tw.
20 advice.tw.
21 leaflet\$.tw.
22 video\$.tw.
23 ((fat or fats or cholesterol) adj3 (decreas\$ or reduc\$ or low\$ or chang\$ or restrict\$)).tw.
24 or/1-23
25 diet/
26 Diet, Atherogenic/
27 Mediterranean Diet/
28 low calory diet/
29 exp lipid diet/
30 exp Dietary Intake/
31 exp Dietary Fats/
32 Dietary Fiber/
33 Potassium, Dietary/
34 exp Sodium, Dietary/
35 exp Ascorbic Acid/
36 beta Carotene/
37 exp Folic Acid/
38 exp Vitamin E/
39 exp Fish Oils/
40 exp Plant Oils/
41 exp Dairy Products/
42 exp Fruit/
43 exp Meat/
44 exp Vegetables/
45 exp Unsaturated Fatty Acid/
46 exp alpha tocopherol/
47 exp edible oil/
48 exp vegetable oil/
49 exp essential fatty acid/
50 exp saturated fatty acid/
51 Feeding behavior/
52 diet\$.tw.
53 food\$.tw.

Table 2. EMBASE (Ovid) search strategy (Continued)

54 (lipid\$ adj3 (low\$ or reduc\$ or modifi\$)).tw.
55 polyunsaturat\$.tw.
56 (polyunsaturat\$ or poly-unsaturat\$).tw.
57 (monunsaturat\$ or mono-unsaturat\$).tw.
58 (omega\$ adj3 fat\$).tw.
59 (omega3 or omega-3).tw.
60 marg?rine\$.tw.
61 butter\$.tw.
62 (meat or meats).tw.
63 fish.tw.
64 vegetable\$.tw.
65 fruit\$.tw.
66 legum\$.tw.
67 soy\$.tw.
68 bean\$.tw.
69 oat\$.tw.
70 grain\$.tw.
71 starch\$.tw.
72 exp Dietary Carbohydrates/
73 carbohydrate\$.tw.
74 roughage.tw.
75 ((non-starch or nonstarch) adj (poly-saccharhide\$ or polysaccharide\$)).tw.
76 (nut or nuts).tw.
77 lard\$.tw.
78 salt.tw.
79 (antioxidant\$ or anti-oxidant\$).tw.
80 folic.tw.
81 folate\$.tw.
82 ascorb\$.tw.
83 tocopherol\$.tw.
84 alphotocopherol\$.tw.
85 vitamin c.tw.
86 vitamin e.tw.
87 (betacarotene or beta-carotene or crotenoid\$).tw.
88 (betacarotene or beta-carotene or carotenoid\$).tw.
89 (sodium adj2 intake\$).tw.
90 (potassium adj2 intake\$).tw.
91 (fat\$ adj3 (low\$ or modifi\$ or animal\$ or vegetable\$ or acid\$ or saturat\$ or unsaturat\$)).tw.
92 (oil\$ adj3 (vegetable\$ or olive\$ or rape\$ or sunflow\$ or linseed\$ or saturat\$ or unsaturat\$)).tw.
93 or/25-92
94 exp diet therapy/
95 24 and 93
96 94 or 95
97 exp child/ not Adult/
98 96 not 97

Table 3. Methodological quality of included studies

Study ID	Randomisation	Alloc. concealment	Blinding?	Loss to follow-up
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
Brekke	Minimisation method for small clinical trials (Altman) to balance a large number of strata	Unclear	Unclear	8.5% of individuals lost to follow-up over 12 months
Buller	Unclear	Adequate. Project statistician	Unclear	Clusters analysed, but response rate to follow-up surveys for individuals only 64% at 6 months
Cheng	Random number table	Unclear	Unclear	16% of individuals lost to follow-up at 4 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
Djuric	Unclear	Unclear	Unclear	16.3% of individuals lost to follow-up over 12 months, 37% at 2 years. Data were analysed at 12 months
Elder	Unclear	Unclear	Unclear	12.3% loss to follow-up at 12 weeks, 21.5% at 12 months. Data have been analysed at 12 weeks

Table 3. Methodological quality of included studies (Continued)

Fuemmeler	Unclear	Unclear	Unclear	Clusters analysed, no loss of clusters, 16% of individuals lost to follow-up over 12 months
Gann	Random number table	Unclear	Unclear	16.9% of individuals lost to follow-up over 12 months
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
John	Computer generated randomisation list	Unclear	Unclear	7.7% of individuals lost to follow-up over 6 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
Little	Random number table	Adequate - opaque sealed envelopes	Unclear	14% lost to follow-up for prompt plus salt and control group at 6 months. 27% loss to follow-up in the prompt group - these data were excluded
Lutz	Unclear	Unclear	Unclear	19% loss to follow-up at 6 months
Maskarinec	Unclear	Unclear	Unclear	12% loss to follow-up over 6 months
Moy	Unclear	Unclear	Unclear	23% lost to follow-up over 12 months but authors used ITT analysis

Table 3. Methodological quality of included studies (Continued)

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
Rock	Unclear	Unclear	Unclear	5.4% of individuals lost to follow-up over 6 months
Sacerdote	Random numbers generated by computer	Unclear	Outcome assessors	6.4% lost to follow-up over 12 months
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
Stevens	Unclear	Unclear	Unclear	13% lost to follow-up over 12 months
Takahashi	Unclear	Unclear	Unclear	2.9% loss to follow-up for questionnaire based outcomes, 17.2% for blood pressure outcomes over 12 months
Tilley	Random number table	Unclear	Unclear	1.6% individuals lost to follow-up at 12 months, 3.5% at 24 months
TOHP I	Unclear	Unclear	Outcome assessors	20% loss to follow-up over 12 months
TOHP II	Unclear	Adequate. Telephone coordinating centre or opaque envelopes	Outcome assessors	7.5% loss to follow-up at 18 months
van der Veen	Unclear	Unclear	Unclear	Clusters analysed, no loss of clusters but 9% of individuals lost to follow-up over 12 months

Table 4. 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
Brekke 2005	4.95	not available
Coates 1999 HT MP	5.7	not available
Cheng 2004	6.0	not available
Djuric 2006	4.43	not available
Hellenius 1993	6.0	130/82
John 2002	5.12	129/80
Keyserling 1997	6.5	not available
Koopman 1990	not available	144/95
Little 2004	not available	154/93
Moy 2001	not available	not available
Neil 1995	7.4	not available
Sacerdote 2006	not available	129/79
Stevens 2003	6.01	not available
Takahashi 2006	not available	128/76
TOHP I	not available	125/84
TOHP II 1997	not available	127/86
van der Veen 2002	6.6	not available

WHAT'S NEW

Last assessed as up-to-date: 29 July 2007.

Date	Event	Description
8 September 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 2, 2000

Review first published: Issue 4, 2005

Date	Event	Description
30 July 2007	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Eric Brunner, Margaret Thorogood and Karen Rees wrote the original review.

For the update:

Karen Rees selected studies, abstracted data, analysed the data and co-wrote the review

Kirsten Ward selected studies and abstracted data

Margaret Burke ran the searches

Eric Brunner selected studies, gave advice and co-wrote the review

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Department of Epidemiology and Public Health, University College London, UK.
- University of Warwick Medical School, UK.
- Department of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, UK.

External sources

- Coronary Prevention Group, UK.
- Department of Health Cochrane Review Incentive Scheme 2006, UK.

INDEX TERMS

Medical Subject Headings (MeSH)

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

MeSH check words

Humans