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## Effects of a self-regulation lifestyle program for post-cardiac rehabilitation patients

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**Title:** Effects of a self-regulation lifestyle program for post-cardiac rehabilitation patients

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**Lifestyle Modification Programs  
for Patients with Coronary Heart  
Disease: A Systematic Review and  
Meta-Analysis of Randomized  
Controlled Trials**

Janssen, V. / De Gucht, V. / Dusseldorp, E. / Maes, S. (in revision)  
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## Abstract

**Background** Lifestyle modification programs for coronary heart disease patients have been shown to effectively improve risk factors and related health behaviors, quality of life, re-incidence and mortality. However, improvements in routine cardiac care over the recent years may offset the incremental benefit associated with older programs.

**Purpose** To determine the efficacy of lifestyle modification programs for coronary heart disease patients developed over the last decade (1999-2009) by means of a systematic review and meta-analysis.

**Results** 23 trials (involving 11085 randomized patients) were included. Lifestyle modification programs were associated with reduced all-cause mortality (summary OR = 1.34; 95% CI: 1.10 to 1.64), cardiac mortality (summary OR = 1.48; 95% CI: 1.17 to 1.88), cardiac readmissions and non-fatal reinfarctions (summary OR = 1.35; 95% CI: 1.17 to 1.55). Furthermore, lifestyle modification programs positively affected risk factors and related lifestyle behaviors at posttreatment (M =10.2 months), and some of these benefits were maintained at long-term follow-up (M =33.7 months). Improvements in dietary and exercise behavior were greater for programs incorporating all four self-regulation techniques (i.e., goal-setting, self-monitoring, planning and feedback techniques) compared to interventions that included none of these techniques.

**Conclusion** The evidence summarized in this meta-analysis confirms the benefits of lifestyle modification programs - over and above benefits achieved by routine clinical care alone.

**Keywords:** cardiac rehabilitation, secondary prevention, lifestyle modification, self-regulation, coronary heart disease, meta-analysis.

## Introduction

Mortality rates for coronary heart disease (CHD) have been declining due to improvements in diagnosis, treatment and prevention, leaving a greater number of patients in need of optimal secondary prevention (1,2). The benefits of cardiac rehabilitation (CR) programs have long been recognized, and CR programs have become widely available (3). CR programs aim to return patients to physical and psychosocial functioning and to reduce the risk of recurrent cardiovascular events (4). Once, CR programs were almost exclusively exercise-based, but gradually they have become supplemented with health education, lifestyle counseling and psychological treatment components, which better address the full range of modifiable risk factors. Such comprehensive lifestyle modification programs have received increasing attention as evidence is emerging that the mortality-reduction potential of lifestyle changes in CHD patients is at least comparable to that demonstrated for cardiopreventive drug usage (5,6). There is a large body of evidence showing that lifestyle modification programs effectively improve risk factors and related health behaviors, quality of life, morbidity and mortality (e.g., 7-11).

Contemporary lifestyle modification programs often comprise a variety of psychological methods to support behavior change. Several researchers have called attention to the large differences in efficacy between such programs, emphasizing the importance of clarifying factors that impact upon program effectiveness (11-13). Research has identified specific program characteristics which moderate treatment effectiveness, such as setting, timing, and duration (7,11,12), but these have provided little insight into the psychological mechanisms of change. Several meta-analyses and reviews have attempted to isolate effective behavior-change techniques. Self-monitoring, for instance, has been found to be effective across populations and behaviors

(14-17). However, breaking up interventions into separate techniques and assessing the effectiveness of such techniques individually does not take into account the synergistic effects of combining sets of techniques (14,17). Self-regulation (SR) theories of behavior change (18,19) assume that all behavior is goal-directed and that the motivation for behavior change stems from the wish to reduce a discrepancy between one's current state and a desired state (i.e., goal-setting). Intent is then translated into action using implementation and planning techniques. Action is governed by self-monitoring and feedback strategies regarding goal-related progress. Thus, lifestyle modification programs that incorporate this set of techniques (i.e., goal-setting, planning, self-monitoring and feedback) may be more effective than programs that do not employ such SR techniques (14,20).

A further impetus for an update of existing meta-analyses is the observation that in more recent lifestyle modification trials, control patients tend to show improved risk factor management as well (12,21). In most non-pharmacological studies, routine clinical care serves as control condition, and several researchers have pointed out that older trials may pre-date improvements in routine cardiac care, such as added exercise and/or lifestyle modification components (21,22). A recent meta-analysis in the area of HIV by De Bruin and colleagues (23) showed that the quality of standard care offered to the control condition affected the incremental benefit of behavior change intervention programs. Within cardiac rehabilitation research, Linden and colleagues (11) commenced to investigate the differential effect of quality of care (high versus low) offered to the control condition, but they had to abandon their attempt because of a lack of studies in the separate types of control conditions.

The aim of this meta-analysis is to examine whether lifestyle modification programs in CHD patients tested over the last ten years (1999-2009) improve risk factors and related health

behaviors, reduce mortality and cardiac recurrences, and whether the effects on these clinical outcomes are moderated by the type of care offered to the control condition. In addition, the efficacy of programs incorporating all four SR techniques of behavior change (i.e., goal-setting, planning, self-monitoring and feedback) compared to programs that utilized none of these techniques will be examined. As current guidelines place large emphasis on addressing the full range of modifiable risk factors (24), only programs focusing on multiple risk factors and related lifestyle behaviors will be included.

## **Method**

### ***Search strategy and eligibility criteria.***

This meta-analysis included only randomized controlled trials (RCTs) published in English in peer-reviewed journals between 1999 and 2009, which tested face-to-face lifestyle modification programs for CHD patients. We included studies with patients that were eligible for CR and/or belonged to one of the following diagnostic groups (25): myocardial infarction with and without percutaneous intervention, angina pectoris with and without percutaneous intervention, heart surgery (including patients with prosthetic valve or valve repair surgery and coronary bypass artery grafting), implantable cardioverter defibrillator patients, and heart failure patients. Furthermore, studies were included only if: (a) the modification of lifestyle formed the main focus of the intervention; (b) the efficacy of the lifestyle modification program formed the main target of evaluation; (c) at least one face-to-face session between the health care provider and the patient took place; (d) the outcomes reported included one or more modifiable risk factors (i.e., cholesterol levels, blood pressure, body mass index, waist/hip ratio, or smoking) as well as one or more health behaviors (i.e., dietary habits or exercise) (26). In case data reported did not allow calculation of effect sizes, or data were presented for mixed

populations only (i.e., stroke/ ischemic attack patients and CHD patients), we contacted the principle author in an attempt to obtain the missing data, or request CHD specific information. We excluded studies that evaluated single-modality interventions (i.e., focused on the modification of a single risk factor only), or used selective populations (i.e., CR non-attenders).

We searched Web of Science, PubMed, Medline, PsychINFO, and the Cochrane Library for relevant articles published between 1999-2009 using an updated version of Dusseldorp and colleagues' (7) search algorithm "cardiovascular disease, coronary heart disease, coronary artery disease, percutaneous angioplasty, PTCA, PCI, myocardial infarction, coronary bypass surgery, coronary artery bypass graft, CABG, health education, psychological intervention(s), psychoeducational intervention(s), behavio(u)r modification, cognitive behavio(u)ral intervention(s), cardiac rehabilitation, secondary prevention, self-management, risk factor(s), smoking, cholesterol, triglycerides, blood pressure, body mass index, overweight, weight, obesity, diet, dietary behavio(u)r, exercise, physical activity". The detailed search strategy is available from the authors. In addition, reference lists from existing reviews and meta-analyses were hand-searched to locate additional studies.

### ***Study selection and quality assessment***

Two investigators (VJ and IB) independently reviewed potentially eligible titles and abstracts using a pilot-tested standardized form with written instructions. All articles published within the relevant time period (1999-2009) were considered for inclusion. Disagreements were resolved by consensus. The methodological quality of each eligible study was assessed using the Jadad quality criteria (27) and sample size. Following previous meta-analyses (12,28) we did not include allocation concealment in the Jadad scoring procedure, as blinding of assessors and participants is difficult to accomplish in the study of lifestyle interventions. Thus, the



Jadad score consisted of two items assessing randomization and one item assessing losses to follow-up, leading to a maximum score of 3 points. It is known that meta-analyses incorporating a relatively high number of small positive trials tend to overestimate the magnitude of effect sizes. Several authors have suggested that studies with less than 35 patients per condition should be considered too small (29,30). Therefore, study size was coded as a means of quality control.

### ***Coding and data extraction***

Two coders (VJ and IB) independently extracted all relevant information from each eligible article by using a standardized data extraction form based on Dusseldorp and colleagues' (7) coding scheme. For the complete coding form, see Appendix 1. Articles were coded for the following study features: (a) bibliographic information; (b) location (country, setting [primary vs. secondary care]); (c) characteristics of trial patients (mean age, gender, diagnosis) and the trial's inclusion and exclusion criteria; (d) quality criteria; (e) content information for the intervention (intensity [duration of the program in months x number of sessions], participation of partners, and type of behavior change technique used [goal-setting, self-monitoring, planning, feedback]); (f) type of care offered to the control condition (content of standard care and additional services, such as structured exercise, lifestyle modification or stress- management); (g) type of outcome (systolic blood pressure, diastolic blood pressure, body mass index, total cholesterol, smoking, exercise [min/wk], dietary habits [saturated fat intake, energy in kJ/kcal], cardiac readmission and reinfarction, cardiac mortality, all-cause mortality); (h) effect size data for pre-, posttest and follow-up measurements (short-term < 12 months, medium term  $\geq$  1 year < 2 years, long-term  $\geq$  2 years). Finally, each intervention was assessed for the presence of SR techniques of behavior change (goal-setting, self-monitoring, planning, feedback). Behavior

change techniques were assigned a score of 0 ('not present'), 1 ('somewhat present) or 2 ('present') based on the extent to which the technique was used in the intervention (see Appendix 1, p 3 and 4 for coding form). Subsequently, interventions that included all four SR techniques were classified as 'high SR-interventions' (score of 2 on at least three constructs, score of 0 on none of the constructs). Interventions that did not employ these techniques were classified as 'low SR-interventions' (score of 0 or 1 on all four constructs). Interventions scoring high on some of the SR techniques and low on others were categorized as 'neither high nor low'. We carried out calibration exercises to enhance consistency among the review team before using the data extraction form. Discrepancies were resolved by consensus or third party arbitration (SM, VDG). The average agreement between the two coders (VJ and IB) was satisfactory (Cohen's  $\kappa = 0.74$ ).

### ***Data analysis***

Comprehensive Meta-Analysis Software version 2.2 (31) was used to calculate standardized difference effect size estimates (Hedges'g) for continuous data and odds ratios for categorical data. Summary effect sizes were computed as the weighted mean of the study effect sizes. We tested for statistical heterogeneity using the  $I^2$  statistic. For a heterogeneous set of effect sizes, the random summary effect estimates with 95% confidence intervals were reported, while for a homogeneous set the fixed estimates with 95% confidence intervals were reported. We differentiated between outcomes assessed at baseline (immediately preceding start of the program), posttreatment (immediately following termination of the program) and at follow-up. Following Dusseldorp and colleagues (7), we categorized follow-up outcome assessment time into three measurement periods: short-term (< 12 months), medium-term ( $\geq 1$  year < 2 years), and long-term ( $\geq 2$  years). If a study reported several posttests within a measurement period, the last posttest within that period was

chosen. For risk factor and health behavior outcomes, separate meta-analyses were conducted at both posttreatment and follow-up. For mortality, readmission and reinfarction rates, meta-analyses were conducted at outcome assessment time  $\geq 12$  months and  $\leq 5$  years (there was only one study (32) that reported mortality data at 6 months and one study (33) that reported 10-year follow-up data in addition to the 5-year follow-up). In all other cases, if a study reported mortality data at both medium- and long-term follow-up, the longest follow-up duration was chosen.

### ***Additional analyses***

In case of heterogeneity, comparative subgroup analyses were carried out to examine if the treatment effects varied in relation to the following moderators: (a) setting (primary versus secondary care) (b) exclusion criteria (on the basis of cardiac diagnosis yes/no, on the basis of disease severity yes/no) (c) presence of SR strategies (goal-setting, self-monitoring, planning, feedback) in the intervention ('high SR' [score of 2 on at least three out of four constructs, score of 0 on none of the constructs] versus 'low SR' [score of 0 or 1 on all four constructs]). Interventions scoring high on some of the constructs and low on others were categorized as 'neither high nor low' and not used in the comparative subgroup analyses.) (d) type of care offered to control group (usual care without [=0] or with [=1] exercise and/or lifestyle modification). Subsequently, meta-regression was used to examine the effects of the continuous study variable intensity (no of sessions x duration in months) on treatment effects.

Sensitivity analyses were pre-specified and carried out to explore whether treatment effects were affected by methodological quality ('high risk of bias' [Jadad score  $\leq 2$  and/or sample size  $< 35$  per condition] versus 'low risk of bias' [Jadad score  $> 2$  and sample size  $\geq 35$  per condition]) (29,30). In order to ascertain the validity of the results obtained, analyses were

repeated excluding these high risk of bias (i.e., low quality or small sample size) studies.

## Results

### *Study Characteristics and Quality*

Of 106 eligible randomized controlled articles, 68 were excluded; leaving a total of 38 articles evaluating 23 trials (see Figure 1). The number of articles exceeded the number of trials as 8 trials reported short-term and long-term data separately or reported different outcomes in different articles (34-41). In total, 5537 participants were included in the intervention groups and 5548 in the control groups. Table 1 shows characteristics of the included studies and a brief description of the content of both the intervention and the control condition.

The content of the control conditions differed across trials. In 14 trials, control groups received 'usual care'. This mostly consisted of standard care by the family physician or cardiologist. In six trials, control groups received some form of lifestyle modification. In most cases, this involved information on risk factors and lifestyle change, sometimes coupled with follow-up contact. This was coded as 'lifestyle modification'. In 3 trials, control groups received full cardiac rehabilitation, including structured exercise sessions, education and lifestyle counseling. This was coded as 'lifestyle modification plus exercise'. None of the patients in control conditions received stress-management training.

As regards intervention content (Table 2), 9 trials included all four SR techniques in their intervention ('high SR'). Six 6 trials used some of these techniques, but not all ('neither high, nor low SR') and 8 trials incorporated none of these techniques ('low SR'). Furthermore, Table 2 and appendix 2 show that trial quality was moderate with Jadad scores between 2 and 3. Nevertheless, 9 trials failed to specify the method of randomization or did not adequately describe this (see

appendix 2). All trials reported on losses to follow-up, and 11 trials carried out intention-to-treat analyses. Table 2 also shows that 3 studies (39,42,43) included fewer than 35 patients per condition.

## ***Synthesis of Results***

### **Mortality**

All-cause mortality data with outcome assessment times between 12 and 60 months ( $M = 34.4$  months) were available for 6 trials (32,34,35,44-46) reporting data for 6270 patients. Cardiac mortality data with this follow up period were available for 5 trials (34,44,47-49) reporting on 5237 patients with outcome periods ranging from 36 to 60 months ( $M = 54.5$  months). Lifestyle modification programs were associated with a significant reduction in all-cause mortality (summary OR = 1.34 [ $p < 0.00$ ; 95% CI: 1.10 to 1.64]) and cardiac mortality (summary OR = 1.48 [ $p < 0.00$ ; 95% CI: 1.17 to 1.88]). There was no evidence of heterogeneity between the trials for both analyses ( $p = 0.8$ ,  $I^2 = 0\%$ ) and ( $p = 0.5$ ,  $I^2 = 0\%$ ). Figure 2 shows forest plots for both outcomes.

### **Reinfarction and readmission**

Reinfarction rates were available for 6 trials (34,43-45,48,49) at assessment time  $\geq 12$  months. Two trials (46,50) reported cardiac readmissions instead of reinfarction rates. We considered the combined outcomes of cardiac readmission and reinfarction such that outcome data were available for 8 trials (34,43-46,48-50) reporting on 6479 patients with outcome assessments ranging between 12 and 60 months ( $M = 31.8$  months). Lifestyle modification programs were associated with a significant reduction in reinfarction and readmission (summary OR = 1.35 [ $p < 0.00$ ; 95% CI: 1.17 to 1.55]) and there was no evidence of heterogeneity between the trials ( $p = 0.24$ ,  $I^2 = 23\%$ ). Figure 3 shows forest plots.

## **Risk factors and lifestyle behaviors**

Table 3 presents summary effects and heterogeneity statistics for the separate risk factors and related lifestyle behaviors for posttreatment and follow-up data. At posttreatment, small but significant summary effects were found for nearly all risk factors (systolic and diastolic blood pressure, total cholesterol, and smoking) and lifestyle behaviors (exercise, dietary habits). However, data showed evidence of significant heterogeneity. At follow-up assessment, significant summary effects were found for diastolic blood pressure, body mass index, exercise and dietary habits. Risk factor data appeared mostly homogenous, but the dietary outcomes showed evidence of heterogeneity. Forest plots for all outcomes are displayed in Appendix 3.

## ***Additional analyses***

Sensitivity analyses were carried out in order to examine if treatment effects differed according to methodological quality. High risk of bias trials (low quality and/or small sample size) showed greater effect sizes for reinfarction and readmission rates, and smoking, total cholesterol, and dietary behavior (fat intake) outcomes than low risk of bias trials (high quality and adequate sample size). Repeating the analyses excluding high risk of bias studies reduced the magnitude of effect sizes, but the treatment effects remained significant. For reinfarction and readmission rates, excluding high risk of bias studies ( $k = 3$ ) decreased the summary effect from OR equals 1.35 [ $p < 0.00$ ; 95% CI: 1.16 to 1.57,  $k = 8$ ] to 1.30 [ $p < 0.00$ ; 95% CI: 1.12 to 1.50,  $k = 5$ ]). For smoking, the summary effect decreased from OR equals 1.21 ( $p = 0.05$ ; 95% CI: 1.00 to 1.47,  $k = 18$ ) to 1.18 ( $p < 0.00$ ; 95% CI: 1.06 to 1.31,  $k = 12$ ). For total cholesterol, the summary effect decreased from  $g$  equals 0.20 ( $p < 0.00$ ; 95% CI: 0.10 to 0.32,  $k = 17$ ) to 0.08 ( $p < 0.00$ ; 95% CI: 0.04 to 0.13,  $k = 10$ ). For dietary behavior, the summary effect decreased from  $g$  equals 0.41 ( $p < 0.00$ ; 95% CI: 0.01 to 0.60,  $k = 16$ ) to 0.25 ( $p < 0.00$ ; 95% CI: 0.11 to 0.40,  $k = 9$ )

Subgroup analyses were carried out in order to examine if treatment effects varied in relation to the following characteristics: (a) setting (primary versus secondary care) involvement of partners (yes/no) (b) exclusion criteria (on the basis of cardiac diagnosis yes/no, on the basis of disease severity yes/no) (c) extent to which each of the SR behavior change techniques (goal-setting, self-monitoring, planning, feedback) was present in the intervention ('low SR' versus 'high SR') and (d) type of care offered to control group, where standard care was coded as 'UC' (k=14). Standard care plus lifestyle modification (k=6) and standard care plus lifestyle modification and exercise (k=3) were coded as 'UC plus'. For the risk factors (i.e., systolic blood pressure, diastolic blood pressure, BMI and total cholesterol) effect sizes did not vary in relation to any of these characteristics. For the lifestyle behaviors, however, the variation in effect sizes could be accounted for by several moderators. The results are presented in Table 4. First, studies set in secondary care were associated with greater improvements in non-smoking, physical exercise, and dietary habits. Second, interventions involving partners of patients were associated with greater benefits in smoking cessation rates and dietary behavior (fat intake). Third, the magnitude of effect sizes appeared to be greater in trials where the control condition was standard cardiac care versus trials where the control condition consisted of 'usual care plus', i.e., offering lifestyle modification with/without exercise components, on top of standard cardiac care. Thus, the additional benefits of lifestyle modification programs were smaller in terms of improved diet (fat intake), exercise behavior and smoking in trials that offered 'usual care plus'. Finally, interventions incorporating all four SR psychological techniques were associated with greater lifestyle benefits. More specifically, programs that included this set of techniques (i.e., goal-setting, planning, self-monitoring and feedback) were more successful in changing exercise behavior and dietary habits (fat intake) than

programs that used none of these techniques. These differences did not seem to persist in the long-term. Because of the limited number of studies providing follow-up outcome data, however, the long-term results should be interpreted with caution. Meta-regression analysis revealed no significant association between the continuous study variable 'program intensity' (no of sessions x duration in months) and treatment effects (data not shown).

### ***Publication Bias***

Visual inspection of funnel plots revealed some asymmetry for smoking, exercise, and dietary habits outcomes. Fail-safe numbers for these outcomes were  $n = 56$  for smoking,  $n = 506$  for exercise,  $n = 502$  for fat intake and  $n = 83$  for energy intake. As a rule of thumb, Rosenthal (51) suggests that the fail-safe number should not be smaller than  $5n + 10$ , where  $n$  is the number of studies excluded in the meta-analysis. Correcting for publication bias using the 'trim and fill' method (52) led to slightly revised summary effects for smoking, exercise, and energy intake, but the treatment effects remained significant. There was no evidence of publication bias for all-cause mortality, cardiac mortality, reinfarction and readmission, blood pressure, BMI and total cholesterol outcomes as evidenced by symmetrical funnel plots and the 'trim and fill' method.

## **Discussion**

The evidence summarized in this meta-analysis suggests that comprehensive lifestyle modification programs for CHD patients reduce mortality, re-incidence and readmission rates. Overall, lifestyle modification programs included in this meta-analysis reduced mortality by 34% and cardiac re-incidence and readmissions by 35% over a follow-up period ranging from one to five years. This is consistent with reductions in mortality



and cardiac recurrence observed by previous meta-analyses and systematic reviews (7,15,28,53,54).

Comprehensive lifestyle modification programs were also shown to positively affect risk factors and related lifestyle behaviors both at posttreatment (M =10.2 months) and at follow-up (M =33.7 months). At posttreatment, lifestyle modification programs were associated with significant reductions in blood pressure (both systolic and diastolic), total cholesterol and smoking, and significant improvements in exercise behavior and dietary habits - even though the summative effect sizes were only small to moderate. Nevertheless, these findings are largely consistent with previous meta-analyses which have also reported very small effect sizes for blood pressure and small-to-moderate effect sizes for changes in cholesterol levels, smoking, and exercise behavior (11,12). Evidence from large population studies suggests that, jointly, such small individual reductions lead to clinically important improvements in risk factor profile (55).

At follow-up, treatment benefits were maintained for exercise behavior and dietary habits, but not for smoking. Furthermore, improvements had become evident for BMI, which may be a reflection of the time-lag between improved dietary habits and exercise behavior, and a subsequent healthier BMI. Surprisingly, effects did not persist in the long term for systolic blood pressure and cholesterol levels – although it should be noted that only a limited number of studies provided follow-up data for these end-points. As a result, these findings should be interpreted with caution.

As regards the factors that impact upon program effectiveness, we found changes in lifestyle to vary dependent upon whether or not SR techniques of behavior change were utilized in the lifestyle modification program. More specifically, programs that included all four SR techniques were more successful in changing exercise behavior and dietary habits (fat intake) compared to interventions that included none of these

techniques. However, at long-term follow-up we found these differences to dissipate, implying that the beneficial effects of such psychological strategies seem to wear off once the program has terminated. Research on long-term adherence typically shows that maintenance of lifestyle change is problematic as many cardiac patients relapse into old habits (56, 57). Future lifestyle modification programs might maintain these benefits by offering some form of continuation, for example by offering booster sessions that reinforce the continuous use of goal-setting, self-monitoring, and feedback strategies. Evidence from a recent large-scale trial suggests that such strategies may indeed be effective (44).

As speculated, we found the incremental benefit of lifestyle modification programs to be smaller in terms of non-smoking, improved diet and exercise behavior in settings where standard care was elaborate. This accords with the meta-analysis by De Bruin and colleagues (23), which demonstrated that quality of standard care determined treatment outcomes in HIV behavior-change interventions. These findings suggest that future meta-analyses on comprehensive CR programs should take into consideration the type of care offered to the control condition, thus accrediting ongoing developments in the routine management of CHD.

### ***Limitations and future research***

The interpretation of our results may be challenged by the heterogeneity observed, in particular with regards to the lifestyle outcomes. Sensitivity and subgroup analyses revealed some sources of heterogeneity, but were unable to account for all of the systematic variation in effect sizes. Future research should continue exploring factors that may moderate program effectiveness, such as intensity of the program, provision of booster sessions and relapse prevention, modes of intervention delivery (e.g., face-to-face, internet- or telephone-based) used, and type of participants included. Increasingly, trials have

been investigating the efficacy of CR programs in selective populations, such as women, the elderly, ethnic minorities, and high-risk patients. Future meta-analyses might identify subgroups that benefit most/least from CR programs.

Secondly, several authors have expressed serious concerns over the inclusion of lesser quality studies in systematic reviews and meta-analyses (58-60). In an attempt to address this, we controlled for study quality by independently analyzing low risk of bias trials. Re-analysis of our data thus decreased the magnitude of the summative effect sizes but did not alter results, rendering it less likely that our results are inconclusive or confounded. Nevertheless, it has been suggested that future meta-analyses should apply even stricter quality controls, for example by including only RCTs that adhere to the CONSORT guidelines (59).

Thirdly, several authors have voiced concern over the inadequate way in which the content of behavioral interventions tends to be reported in the literature (14,61,62). Not only do intervention descriptions often fall short of describing exactly which behavior change techniques were used, certain labels (e.g., 'lifestyle modification' or 'stress-management') may mean different things to different practitioners. Thus, future research should report the content of both intervention and control condition according to a taxonomy, for example as developed by Michie and colleagues (61) or Schulz and colleagues (63).

Finally, this meta-analysis used summary data from published studies – as is common in this field. Recently, however, it has been suggested that meta-analytic research should move from aggregating study-level data to the synthesis of individual patient data (64), which involves combining raw patient data from each study, in order to allow analysis as if it were one large dataset. Using individual patient data would reduce confirmatory publication bias and selective outcome reporting and aid meta-analyses and systematic reviews in reaching conclusions based on objective and compelling

evidence (65). However, the extra time, effort and complexity involved in obtaining and analyzing raw patient data requires a new infrastructure and, most probably, a shift in scientific mentality.

In conclusion, the evidence summarized in this meta-analysis suggests benefit from recent lifestyle modification programs (1999 – 2009) for multiple outcomes, over and above improvements achieved by routine clinical care alone. Furthermore, our findings suggest that programs using all four SR techniques of behavior change (i.e., goal-setting, self-monitoring, planning and feedback) were more successful in changing lifestyle behaviors than programs that did not use such techniques. Nevertheless, results also show that long-term lifestyle change and risk factor reduction pose a challenge. Future lifestyle modification programs should therefore incorporate psychological techniques and strategies that specifically target relapse prevention and maintenance of behavior change.

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*Table 1.*

Characteristics of included studies

<b>Author, year (ref.)</b>	<b>Sample size, N</b>	<b>Mean age</b>	<b>Population a</b>	<b>Measurement period b</b>
Aldana et al., 2007 (66)	93	62	CHD	PT= 6 mths FU= 12 mths
Allison et al., 2000 (67)	326	58	AP	PT= 6 mths
Brugemann et al., 2007 (68)	137	57	CABG PCI	PT= 3 mths FU= 9 mths
Campbell et al., 1998 (69) Campbell et al., 1998 (70) Murchie et al., 2003 (34) Murchie et al., 2004 (71) Delaney et al., 2008 (33)	1173	66	CHD	PT= 12 mths FU= 24 mths FU= 48 mths FU= 56 mths
Cupples et al., 1994 (47) Cupples et al., 1999 (35)	688	63	AP	PT= 24 mths FU= 60 mths
Giannuzzi et al., 2008 (44)	3241	58	MI	PT= 6 mths FU= 24 mths FU= 36 mths
Higgins et al., 2001(72)	99	48	PCI	PT= 2 mths FU= 12 mths
Jeong et al., 2002 (42)	45	53	MI	PT= 3 mths
Jiang et al., 2007 (73)	167	62	CHD	PT= 3 mths FU= 6 mths

<b>Intervention Content (Intensity: no of session/ duration in months)</b>	<b>Control Condition Content</b>
Intense cardiovascular disease risk factor program based on the Ornish Program for Reversing Heart Disease. The program involved a 10% fat vegetarian diet, supervised exercise, stress management training, smoking cessation, and group psychological support. (72 sessions/12 months)	Standard cardiac rehabilitation (structured exercise program 3x a week, dietary and smoking cessation counselling).
Nurse-run risk factor management program. Intervention strategies included: instituting pharmacologic lipid management, making appropriate referrals (f.i. to the diabetic clinic, social work, or psychology); counseling on exercise, diet, and smoking cessation; and reporting abnormal results to the patient's primary care physician. (3 sessions/6 months)	Usual care by physician + follow-up appointment with a cardiologist
Comprehensive cardiac rehabilitation program, which included one risk factor management teaching session and physical training thrice a week for 8 weeks. In addition, relaxation therapy and weekly psycho-education sessions. (27 sessions/2 months)	Standard cardiac rehabilitation (one risk factor management teaching session and physical training thrice a week for 6 weeks).
Nurse-run clinics in general practice promoting medical and life-style aspects of secondary prevention. Regular follow-ups offered over one year. Risk factors and symptoms were assessed and clinic visits included feedback, goal planning, and an agreed action plan. (6 sessions/12 months)	Usual care by own GP
Practical advice regarding cardiovascular risk factors given by a health visitor. Patients were reviewed at four monthly intervals and given appropriate health education (7 sessions/24 months)	Usual NHS care.
Long-lasting multifactorial educational and behavioural program following completion of initial cardiac rehabilitation. Sessions consisted of aerobic exercise, comprehensive lifestyle and risk factor counselling, clinical assessment, and reinforcement of preventive interventions. (11 sessions/36 months)	Usual care by family physician. Letter to own family physician recommending secondary prevention goals. Annual scheduled assessments with feedback to family physician.
Two in-hospital education sessions and an individualized, comprehensive, home-based cardiac rehabilitation program combining risk factor modification with exercise and psychological counseling. The program was based on Social Cognitive Theory and included goal-setting, detailed action plans, self-monitoring and feedback, skills training. (5 sessions/2 months)	Two in-hospital education sessions + 3-monthly post-discharge telephone calls focused on providing CHD information.
Individualized teaching program in hospital, supportive care via telephone contact or mail for 12 weeks post-discharge (3 sessions/ 3 months)	Routine care (verbal instruction)
Nurse-led home-based cardiac rehabilitation program. In-hospital education aimed at self-managed cardiac rehabilitative care after discharge. After discharge, 12-week nurse-led home-based program focused on lifestyle and treatment adherence. Follow-up visits and telephone calls. 19 sessions/ 3 months)	Routine care

<b>Author, year (ref.)</b>	<b>Sample size, N</b>	<b>Mean age</b>	<b>Population a</b>	<b>Measurement period b</b>
Lear et al., 2002 (36) Lear et al., 2003 (74) Lear et al., 2005 (75) Lear et al., 2006 (76)	302	64	CHD	PT= 12 mths FU= 24 mths FU= 36 mths FU= 48 mths
Lisspers et al., 1999 (77) Hofman-Bang et al., 1999 (85) Lisspers et al., 2005 (48)	87	53	PCI	PT= 12 mths FU= 24 mths FU= 36 mths FU= 60 mths
McHugh et al., 2001 (78)	98	62	Pts on CABG waiting list	PT= 15 mths
Mildestvedt et al., 2007 (38) Mildestvedt et al., 2008 (79)	176	56	CHD	PT= 6 mths FU= 24 mths
Murphy et al., 2009 (50)	903	68	CHD	PT= 18 mths
Nordmann et al., 2001 (32)	201	62	CHD	PT= 9 mths FU= 18 mths
Ornish et al., 1990 (80) Ornish et al., 1998 (49) Pischke et al., 2008 (39)	48	58	CHD	PT= 12 mths FU= 60 mths
Salminen et al., 2006 (81)	112	74	CHD	PT= 16 mths

Intervention Content (Intensity: no of session/ duration in months)	Control Condition Content
Extensive Lifestyle Management Intervention (ELMI) based on the principles of behavioral change and aimed at individualizing risk factor and lifestyle management. It consisted of cardiac rehabilitation sessions (exercise program), and risk factor and lifestyle counseling sessions and telephone follow-up. (39 sessions/ 12 months)	Annual risk factor assessment visit + usual care by family physician
Comprehensive behaviorally oriented program aimed at longterm changes in risk factor-related lifestyle behavior. The program started with a 4-week residential stay focused on health education, practical skills training and habit rehearsal. Follow-up consisted of an 11-month structured maintenance program involving self-monitoring, feedback, and regular contacts with a nurse during one year. (>100? sessions/ 12 months)	Standard care by own physician.
A nurse-led shared care program consisting of health education and motivational interviews, according to individual need, carried out monthly. Interventions addressed behavioral risk factors and were focused on tracking progress. (15 sessions/ 15 months)	Usual care.
Standard cardiac rehabilitation program including daily exercise groups, dietary and smoking cessation counseling. In addition, patients received an individualized self-efficacy and autonomy supportive intervention consisting of two individual sessions and two follow-up telephone calls. (4 sessions/ 24 months)	Standard cardiac rehabilitation (daily physical training, dietary and smoking cessation counseling).
Tailored care plans for practices (practice based training in prescribing and behavior change, administrative support, quarterly newsletter) and tailored care plans for patients based on Social Cognitive Theory (motivational interviewing, goal identification, and target setting for lifestyle change) with reviews every four months at the practices. (9 sessions/ 18 months)	Usual care in control general practices. Not organized in a formal manner, in some practices this included monitoring of risk factors and providing advice on lifestyle.
Risk factor case management program during hospitalization consisting of structured counseling about treatable cardiovascular risk factors. After hospital discharge, patients received two follow-up sessions where goals and progress were reviewed. (3 sessions/ 6 months)	Assessment + information about cardiovascular risk factors by treating physicians. No structured counseling.
Intensive lifestyle changing program: 10% fat vegetarian diet, aerobic exercise, stress management training, smoking cessation, group psychological support. (> 100 sessions?/ 12 months)	Usual care (following advice of personal physician).
A health advocacy, counseling and activation program aimed at giving information on risk factors. The program consisted of lectures, group discussions, light exercises and social activities. (33 sessions/ 16 months)	Usual care.



<b>Author, year (ref.)</b>	<b>Sample size, N</b>	<b>Mean age</b>	<b>Population a</b>	<b>Measurement period b</b>
Smeulders et al., 2009 (82)	317	67	HF	PT= 1.5 mths FU= 6 mths FU= 12 mths
The Vestfold Heartcare Study Group (2003) (46)	197	55	CHD	PT= 6 mths FU= 24 mths
Toobert et al., 1998 (83) Toobert et al., 2000 (40)	28	63	CHD	PT= 4 mths FU= 12 mths FU= 24 mths
Wallner et al., 1999 (43)	60	59	PCI	PT= 12 mths
Wood et al., 2008 (84)	3088	63	CHD	PT= 12 mths
Zwisler et al., 2005 (41) Zwisler et al., 2008 (45)	770	66	Cardiac Rehabilitation patients	PT= 12 mths

<b>Intervention Content (Intensity: no of session/ duration in months)</b>	<b>Control Condition Content</b>
Structured self-management program focused on learning patients how to take responsibility for the day-to-day management of their disease. The program enhances self-efficacy and incorporates skills mastery, reinterpretation of symptoms, modelling, and social persuasion. (6 sessions/ 6 weeks)	Usual care, consisting of regular check-ups at an outpatient clinic.
Nurse-delivered lifestyle intervention: six-week period of 'heart school' consisting of supervised exercise sessions and semiweekly group sessions focused on low fat diet, regular exercise, smoking cessation, stress reduction, psychosocial support and education. Follow-up consisted of another nine weeks of organized physical exercise sessions and group meetings every three months for two years. (> 50 sessions, 24 months)	Standardized nurse-based information on CHD & lifestyle measures. Follow-up in routine outpatient cardiology clinics and subsequently by patients' own GPs.
Intensive lifestyle self-management program consisting of a very-low fat vegetarian diet, exercise, smoking cessation, breathing and relaxation exercises, and group support based on the Ornish program for Reversing Heart Disease. (>100 sessions/ 15 months)	Usual care.
Intensive lifestyle intervention including lifestyle advice, physical activity training programs, food diaries and 1-h sessions with a nutritionist in order to adopt a healthy diet. Follow-up by regular telephone contact. (17 sessions/ 12 months)	Conventional treatment by cardiologists and general practitioners.
Nurse-coordinated, multi-disciplinary family-based cardiovascular disease prevention program consisting of workshops, tailored advice, and a supervised-exercise class. Sessions also included partners and families ( 16 sessions/ 4 months)	UC hospitals
Individually tailored multidisciplinary program; patient education, exercise training, dietary counseling, smoking cessation, psychosocial support and group workshops. Multidisciplinary advice, monitoring and assessment of risk factors. (>25 sessions?/ 12 months)	Usual care

<sup>a</sup> Population: AP= Angina Pectoris; CABG= Coronary Artery Bypass Surgery; CHD=Coronary Heart Disease; HF= Heart Failure; MI= Myocardial Infarction; PCI= Percutaneous Coronary Intervention

<sup>b</sup> PT= Posttreatment; FU= Follow-up

Table 2.

Description of moderators

Author, year (ref.)	Setting: primary vs secondary care	Partners involved?	Exclusion on basis of diagnosis iii	Exclusion on basis of disease severity iv	Methodological Quality			Jadad Score
					Risk of Bias	Sample Size viii		
						Tr n	Ctr n	
Aldana et al., 2007 (66)	Secondary care	No	No	No	High	46	47	2
Allison et al., 2000 (67)	Secondary care	No	Yes (MI, CABG)	No	Low	158	168	3
Brugemann et al., 2007 (68)	Secondary care	No	Yes (HF NYHA III/ IV)	Yes (NYHA III/ IV)	Low	60	62	3
Campbell et al., 1998 (69) Campbell et al., 1998 (70) Murchie et al., 2003 (34) Murchie et al., 2004 (71) Delaney et al., 2008 (33)	Primary care	No	No	No	Low	670	667	3
Cupples et al., 1994 (47) Cupples et al., 1999 (35)	Primary care	No	No	No	Low	317	300	3
Giannuzzi et al., 2008 (44)	Secondary care	Yes	No	No	Low	1620	1621	3
Higgins et al., 2001(72)	Secondary care	Yes	No	No	High	50	49	2
Jeong et al., 2002 (42)	Secondary care	No	No	No	High	22	23	3
Jiang et al., 2007 (73)	Secondary care	Yes	No	No	Low	83	84	3
Lear et al., 2002 (36) Lear et al., 2003 (74) Lear et al., 2005 (75) Lear et al., 2006 (76)	Secondary care	No	No	No	Low	142	136	3
Lisspers et al., 1999 (77) Hofman-Bang et al., 1999 (85) Lisspers et al., 2005 (48)	Secondary care	Yes	No	Yes (maximal exercise capacity < 70 Watt)	High	46	41	2
McHugh et al., 2001 (78)	Primary care	No	No	No	High	49	49	2
Mildestvedt et al., 2007 (38) Mildestvedt et al., 2008 (79)	Secondary care	Yes	No	No	High	84	75	2
Murphy et al., 2009 (50)	Primary Care	No	No	No	Low	360	405	3

Author, year (ref.)	No of sessions/ Program Duration	Psychological Techniques Intervention used in vi					Control Condition vii
		GS	SM	PL	FB	High/ Low SR	
Aldana et al., 2007 (66)	High/ Long-term	0	0	0	1	low SR	LM + E
Allison et al., 2000 (67)	Low/ Short-term	0	0	1	0	low SR	UC
Brugemann et al., 2007 (68)	High/ Long-term	0	0	0	0	low SR	LM + E
Campbell et al., 1998 (69) Campbell et al., 1998 (70) Murchie et al., 2003 (34) Murchie et al., 2004 (71) Delaney et al., 2008 (33)	Low/ Long-term	2	2	2	2	high SR	UC
Cupples et al., 1994 (47) Cupples et al., 1999 (35)	Low/ Long-term	0	0	0	0	low SR	UC
Giannuzzi et al., 2008 (44)	Low/ Long-term	1	1	1	1	low SR	LM
Higgins et al., 2001(72)	Low/ Short-term	2	2	2	2	high SR	LM
Jeong et al., 2002 (42)	Low/ Short-term	0	0	0	0	low SR	UC
Jiang et al., 2007 (73)	High/ Short-term	2	2	1	2	high SR	UC
Lear et al., 2002 (36) Lear et al., 2003 (74) Lear et al., 2005 (75) Lear et al., 2006 (76)	High/ Long-term	2	2	1	2	high SR	LM
Lisspers et al., 1999 (77) Hofman-Bang et al., 1999 (85) Lisspers et al., 2005 (48)	High/ Long-term	2	2	2	2	high SR	UC
McHugh et al., 2001 (78)	Low/ Long-term	1	1	0	2	neither high nor low	UC
Mildestvedt et al., 2007 (38) Mildestvedt et al., 2008 (79)	Low/ Long-term	2	0	1	0	neither high nor low	LM + E
Murphy et al., 2009 (50)	Low/ Long-term	2	2	2	1	high SR	LM

Author, year (ref.)	Setting: primary vs secondary care	Partners involved?	Exclusion on basis of diagnosis iii	Exclusion on basis of disease severity iv	Methodological Quality			Jadad Score
					Risk of Bias	Sample Tr n	Size viii Ctr n	
Nordmann et al., 2001 (32)	Secondary Care	No	Yes (HF NYHA III/IV)	Yes (NYHA III/ IV)	Low	99	102	3
Ornish et al., 1990 (80) Ornish et al., 1998 (49) Pischke et al., 2008 (39)	Secondary Care	Yes	Yes (no MI in preceding 6 wks, not on lipid-lowering drugs, not scheduled to have CABG)	Yes (ejection fraction > 25%)	High	20	15	2
Salminen et al., 2006 (81)	Primary care	No	No	No	High	58	54	2
Smeulders et al., 2009 (82)	Secondary care	No	No	No	Low	186	131	3
The Vestfold Heartcare Study Group (2003) (46)	Secondary care	Yes	No	No	Low	98	99	3
Toobert et al., 1998 (83) Toobert et al., 2000 (40)	Secondary care	Yes	Yes (no MI in preceding 6 wks, not on lipid-lowering drugs, not scheduled to have CABG)	Yes (ejection fraction <25%)	High	95	96	2
Wallner et al., 1999 (43)	Secondary care	No	No	Yes (ejection fraction <30%)	High	32	28	2
Wood et al., 2008 (84)	Secondary care	Yes	Yes (severe HF)	Yes (severe HF)	Low	946	994	3
Zwisler et al., 2005 (41) Zwisler et al., 2008 (45)	Secondary care	Yes	No	No	Low	380	390	3

iii AP = Angina Pectoris; CABG = Coronary Artery Bypass Surgery; CHD = Coronary Heart Disease;

HF = Heart Failure; MI = Myocardial Infarction; PCI = Percutaneous Coronary Intervention

iv NYHA = New York Heart Association functional classification system

v No of sessions: High= > 15 Low= ≤15; Program duration: Long-term= >12 months, Short-term = ≤12 months

vi Psychological Techniques: GS= goal-setting; SM= self-monitoring; PL= planning; FB= feedback.

'low' = 0/1 'high' = 2

High/Low SR: 'low' = score of 1 or 0 on all individual constructs, 'high' = score of 2 on at least three constructs, score of 0 on none of the constructs

vii Control Condition: UC= usual care; LM= lifestyle modification; LM + E= lifestyle modification + exercise

viii Sample Size: Tr N = treatment sample size used in analyses posttreatment; Ctr N = control sample size used in analyses posttreatment

Author, year (ref.)	No of sessions/ Program Duration	Psychological Techniques Intervention used in vi					Control Condition vii
		GS	SM	PL	FB	High/ Low SR	
Nordmann et al., 2001 (32)	Low/ Short-term	2	1	2	2	high SR	LM
Ornish et al., 1990 (80) Ornish et al., 1998 (49) Pischke et al., 2008 (39)	High/ Long-term	2	0	0	0	neither high nor low	UC
Salminen et al., 2006 (81)	High/ Long-term	0	0	0	0	low	UC
Smeulders et al., 2009 (82)	Low/ Short-term	1	0	2	0	neither high nor low	UC
The Vestfold Heartcare Study Group (2003) (46)	High/ Long-term	2	2	1	2	high	LM
Toobert et al., 1998 (83) Toobert et al., 2000 (40)	High/ Long-term	1	0	2	1	neither high nor low	UC
Wallner et al., 1999 (43)	High/ Long-term	2	2	1	2	high	UC
Wood et al., 2008 (84)	High/ Short-term	1	2	1	1	neither high nor low	UC
Zwisler et al., 2005 (41) Zwisler et al., 2008 (45)	High/ Long-term	1	0	1	1	low	UC

*Table 3.*

Effects of lifestyle modification programs on risk factors and lifestyle behaviours.  
 Values are Hedges'g unless stated otherwise.

Outcome	Trials (ref.)	Assessment period	Mean (range) follow-up (months)	No of randomised participants	Hedges'g	(95% CI)	Homogeneity of variance $I^2$
Systolic blood pressure	16 (32,39,40,43,44-47,49,50, 66,67,73,74,78,81,84)	posttreatment	10.8 (3-24)	10322	0.09*	(0.02 - 0.17)	46.39*
	9 (32,35,39,40,41,44,46,47,49, 66,74,76,77,85)	follow-up	34.0 (12-60)	4885	0.01	(-0.19 - 0.20)	79.33**
Diastolic blood pressure	16 (32,39,40,43,44-47,49,50, 66,67,73,74,78,81,84)	posttreatment	10.8 (3-24)	10322	0.07*	(0.01 - 0.14)	36.75
	9 (32,35,39,40,41,44,46,47,49, 66,74,76,77,85)	follow-up	34.0 (12-60)	4885	0.08**	(0.02 - 0.15)	0.00
Body mass index	15 (32,35,40,42-45,47,50,66, 72,74,77,78,82,84,85)	posttreatment	10.3 (1.5-24)	10020	0.07	(-0.01 - 0.14)	43.48*
	9 (32,35,66,40,44,72,74,76,77, 82,85)	follow-up	27.3 (12-60)	5056	0.07**	(0.02 - 0.13)	0.00
Total cholesterol	17 (32,39,40-45,47,49,50,66, 67,68,73,74,78,81,84)	posttreatment	10.7 (3-24)	10307	0.20**	(0.08 - 0.32)	80.01**
	8 (32,35,39,40,44,47,49,66,74, 76,77,85)	follow-up	35.3 (12-60)	4688	0.03	(-0.03 - 0.09)	42.62
Smoking	18 (32,34,42-47,50,67,69,72, 73,74,77,78,81,82,84,85)	posttreatment	10.1 (1.5-24)	11874	OR=1.21*	(1.00 - 1.47)	52.40**
	11 (32,34,35,38,40,44,46,69, 72,74,76,77,82,85)	follow-up	30.8 (12-60)	6509	OR=1.19	(0.84 - 1.68)	58.51*
Exercise	20 (34,39,40,42-47,49,50,67, 69,72-74,77-79,81,82,84,85)	posttreatment	9.73 (1.5 -24)	11925	0.32**	(0.20 - 0.44)	83.67**
	11 (34,35,39,40,44,46,47,49, 69,72,74,76,77,79,82,85)	follow-up	33.5 (12-60)	6356	0.11**	(0.06 - 0.17)	41.43
Dietary behavior Fat intake	17 (32,34,38-40,43,44,46,47,49, 50,66,67,69,73,74,77,84,85)	posttreatment	9.71 (3-24)	10915	0.38**	(0.21 - 0.56)	90.23**
	11 (32,34,35,38,39,40,44,46, 47,49,66,69,74,76,77,85)	follow-up	35.13 (12-60)	6234	0.27*	(0.05 - 0.50)	90.04**
Dietary behavior Energy intake	10 (32,39,40,43,44,46,47,49, 68,73,77,85)	posttreatment	9.3 (3-24)	4854	0.28**	(0.12 - 0.44)	69.43**
	7 (32,35,39,40,44,46,47,49,77, 85)	follow-up	35.14 (18-60)	4490	12*	(0.01 - 0.24)	32.69

Note:\*\* $p < 0.01$ ; \*  $p < 0.05$

*I*: For a heterogeneous set of effect sizes, the random summary effect estimates with 95% confidence intervals were reported, while for a homogeneous set the fixed estimates with 95% confidence intervals were reported. For Cupples and colleagues(35), the confidence intervals were used to calculate the standard deviation of change. For Nordmann and colleagues (32) the between-group p values were converted to F values assuming a pretest/ posttest correlation of 0.50.

*Table 4.*

Comparative subgroup analyses assessing the effect of study and treatment characteristics upon effect size, separated by outcome posttreatment

POSTTREATMENT		Smoking			Exercise			Dietary Behaviour: Fat intake			Dietary behaviour: Energy intake		
		k	OR	p	k	g	p	k	g	p	k	g	p
Care Setting:	Primary	7	0.96	≤ 0.05	6	0.14	≤ 0.01	4	0.08	≤ 0.01	2	0.06	≤ 0.05
	Secondary	11	1.40		14	0.45		13	0.58		8	0.39	
Partners involved:	no	11	1.01	≤ 0.05	10	0.23	ns	9	0.17	ns	4	0.05	≤ 0.01
	yes	7	1.45		10	0.42		8	0.71		6	0.51	
Exclusion diagnosis:	no	15	1.29	ns	17	0.34	ns	12	0.40	ns	7	0.34	ns
	yes	3	1.14		3	0.27		5	0.55		3	0.15	
Exclusion severity:	no	13	1.19	ns	15	0.30	ns	10	0.34	ns	4	0.43	ns
	yes	5	1.33		5	0.39		7	0.55		6	0.18	
Control condition #:	UC	12	1.19	ns	14	0.42	≤ 0.05	9	0.71	≤ 0.01	6	0.47	ns
	UC plus	6	1.28		6	0.14		8	0.19		4	0.13	
SR techniques high vs. low ^	low	6	1.17	ns	6	0.17	≤ 0.05	5	0.14	≤ 0.05	3	0.11	ns
	high	9	1.33		8	0.60		8	0.46		5	0.38	

*Note: p-values concern subgroup effects k = number of studies included per subgroup per outcome; OR= Odds Ratio; g = Hedges' g effect size; ns = not significant (p> 0.05); n/a = too few studies in cell to allow meaningful comparison; # Control Condition: UC= usual care; LM= lifestyle modification; LM + E= lifestyle modification + exercise^SRtechniques high versus low; 'low' = score of 1 or 0 on all individual constructs, 'high' = score of 2 on at least three out of four constructs, score of 0 on none of the constructs*



Table 4 cont.

Comparative subgroup analyses assessing the effect of study and treatment characteristics upon effect size, separated by outcome at follow-up

FOLLOW-UP		Smoking			Exercise			Dietary Behaviour: Fat intake			Dietary behaviour: Energy intake		
		k	OR	p	k	g	p	k	g	p	k	g	p
Care Setting:	Primary	3	0.67	≤ 0.01	2	0.12	ns	3	-0.01	≤ 0.01	2	0.03	ns
	Secondary	8	1.58		9	0.11		8	0.55		5	0.19	
Partners involved:	no	5	0.76	≤ 0.01	4	0.10	ns	5	0.04	≤ 0.05	2	0.03	ns
	yes	6	1.92		7	0.12		6	0.80		5	0.15	
Exclusion diagnosis:	no	10	1.29	n/a	10	0.13	n/a	9	0.16	ns	5	0.14	ns
	yes	1	0.64		1	0.53		2	3.40		2	-0.04	
Exclusion severity:	no	8	1.37	ns	8	0.12	ns	7	0.21	ns	3	0.15	ns
	yes	3	1.10		3	0.11		4	0.80		4	0.12	
Control condition #:	UC	5	0.82	≤ 0.05	6	0.18	ns	5	0.83	≤ 0.05	4	0.09	ns
	UC plus	6	1.62		5	0.10		6	0.16		3	0.15	
SR techniques high vs. low ^	low	2	1.04	ns	2	0.09	ns	3	0.16	ns	2	0.13	ns
	high	6	1.50		5	0.19		5	0.21		3	0.14	

Note: p-values concern subgroup effects k = number of studies included per subgroup per outcome; OR= Odds Ratio; g = Hedges' g effect size; ns = not significant (p> 0.05); n/a = too few studies in cell to allow meaningful comparison; # Control Condition: UC= usual care; LM= lifestyle modification; LM + E= lifestyle modification + exercise^SRtechniques high versus low; 'low' = score of 1 or 0 on all individual constructs, 'high' = score of 2 on at least three out of four constructs, score of 0 on none of the constructs

Figure 1.  
Flowchart of selection of trials.

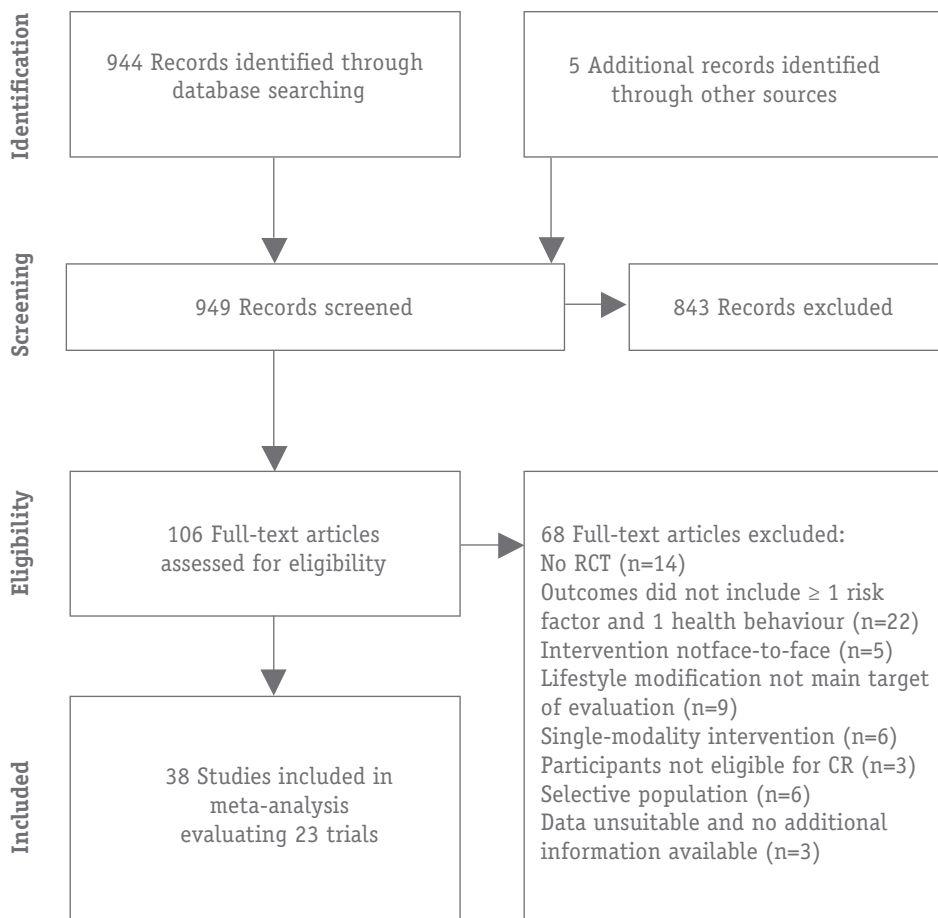
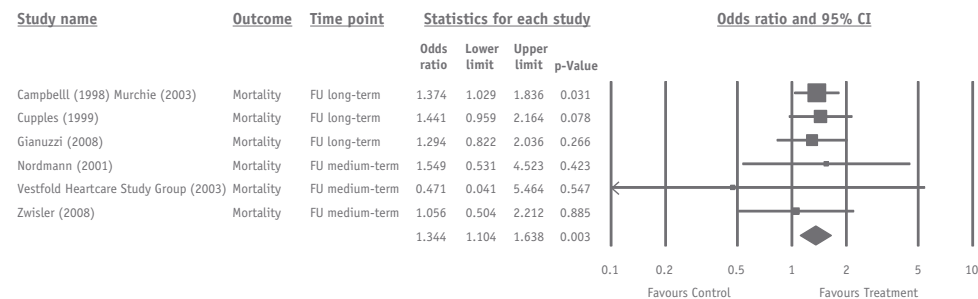


Figure 2.

Forest plots for all-cause mortality and cardiac mortality.

## Effect sizes for all-cause mortality



## Effect sizes for cardiac mortality

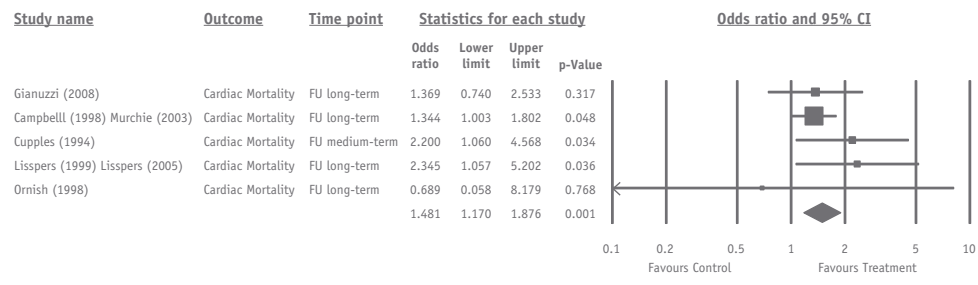
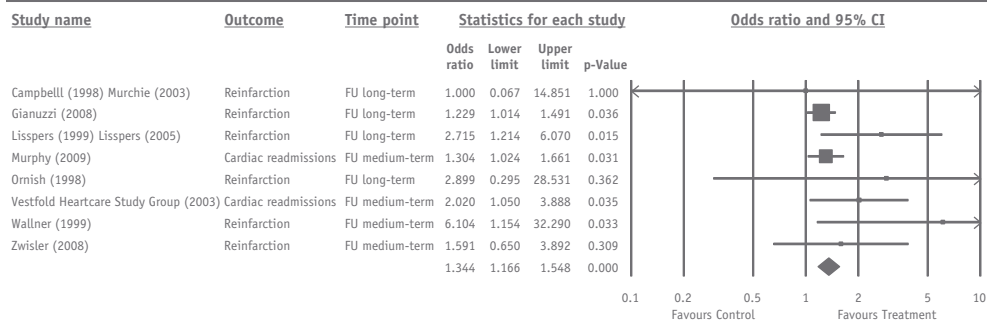


Figure 3.

Forest plot for non-fatal reinfarction and cardiac readmissions to hospital.

## Effect sizes for reinfarction and readmission





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Appendix 1.

**LIFESTYLE MODIFICATION PROGRAMS FOR CHD PATIENTS CODING FORM**

Coder name:

Study identification number:

First Author et al. (Year):

Which type of evaluation(s) is/ are made in the study? (between treatment and control/ comparison groups?)

Code		Treatment Group	Control Group
1	<input type="checkbox"/>	Behaviour Modification	Standard Care
2	<input type="checkbox"/>	Behaviour Modification + Physical Training	Standard Care
3	<input type="checkbox"/>	Behaviour Modification + Physical Training	Standard Care + Physical Training
4	<input type="checkbox"/>	Behaviour Modification + Physical Training + Stress Management	Standard Care
5	<input type="checkbox"/>	Behaviour Modification + Physical Training + Stress Management	Standard Care + Physical Training
6	<input type="checkbox"/>	Behaviour Modification + Stress Management	Standard Care
7	<input type="checkbox"/>	Behaviour Modification + Stress Management	Standard Care + Physical Training

What is (are) the name(s) of the psychosocial program(s)?

What is reported as being the goal of the treatment? (in words)

Evaluation / general remarks:

## DATA ON SAMPLE CHARACTERISTICS

- NO            \_\_\_    Number of total participants in study
- TYP           \_\_\_    Type of patients included in the study:
- (1) Coronair bypass/CABG
  - (2) Myocardical Infarct/MI
  - (3) PTCA / PCI / Dotter
  - (4) Cardiac Valve Surgery
  - (5) ICD
  - (6) Heartfailure
  - (7) Angina Pectoris
  - (8) Coronary Heart Disease
  - (9) Other (specify).....
- CO            \_\_\_    Demographic feature of patients: nationality
- (1) American
  - (2) European
  - (3) Australian
  - (4) Canadian
  - (5) Asian
  - (9) Other (specified) ....
- GEN           \_\_\_    at pretest (1) only male (2) only female (3) both male and female
- FEM           \_\_\_%    percentage female
- AGE           \_\_\_    Mean age (rounded) of total group of patients included in study
- AGE\_TR       \_\_\_    Mean age (rounded) of treatment group patients included in study
- AGE.CG       \_\_\_    Mean age (rounded) of control group patients included in study
- EXC           \_\_\_    Patient exclusion criteria used? (1) yes (2) no (9) Unknown
- KINDEXC      \_\_\_    Specific Kinds of Patients **Excluded:**
- (1) prior or future hospitalisation for cardiac reasons
  - (2) other cardiac complications
  - (3) specific cardiac diagnoses;.....
  - (4) age-criterium:.....
  - (5) gender-criterium:.....
  - (6) somatic comorbidity
  - (7) psychological problems/ mental illness
  - (8) practical reasons (specified).....
  - (9) other (specified):.....

## CODING FOR TREATMENT GROUP

- TRPAR     \_\_\_     Were partners involved in the treatment? (1) yes (2) no (9) unknown
- P\_EXT     \_\_\_     To what extent were partners involved in the treatment?  
(1) participation in one session ,(2) participation in two sessions,  
(3) participation in multiple sessions
- TRPROF   \_\_\_     The treatment was carried out by a  
(1) psychologist/psychotherapist/psychiatrist  
(2) physician  
(3) other specialist (e.g. physiotherapist, social worker, nurse ...)  
(4) multi disciplinary team, including a psychologist /  
    psychotherapist / psychiatrist specified  
(5) multi disciplinary without a psychologist / psychotherapist /  
    psychiatrist specified or unspecified  
(6) other, specified.....
- TRTARG   \_\_\_     Target group of intervention was  
(1) individual patient or couples separately  
(2) group of patients or group of couples  
(3) both 1 and 2

## GUIDELINES FOR CLASSIFICATION OF TREATMENT

Behaviour Modification is defined as: instructional activities focused on health education and/or health behavior change. This involves personal contacts between a health professional and coronary heart patients (and partners) in order to facilitate positive changes in risk factors for coronary heart disease and/ or unhealthy behaviours and must include at least one face-to-face session.

Physical Training means not information about physical activities or physiotherapy, but actual exercise training (this training can also be directed by a manual).

- TRTYPE   \_\_\_     The program included: (more than one box may be ticked)
- (1) Behaviour modification directed at modification of at least one risk factor and one health behaviour
  - (2) Stress Management
  - (3) Physical Training
  - (4) Information supply (by leaflets or education)
  - (5) Standard care

TRSET	___	Setting of the treatment (1) primary care (2) secondary care
TRSES#	___	Total number of sessions
TRFOL#	___	Number of follow up sessions
TRDUR	___	Duration of total program.....months.....weeks
TRDUR_0	___	Other information on treatment duration

## CODING FOR SELF-REGULATION CONSTRUCTS

SRGOAL	___	Goal-setting <ul style="list-style-type: none"> <li><input type="checkbox"/> (0) – No mention of goal-setting</li> <li><input type="checkbox"/> (1) – Goal-setting mentioned explicitly, but no description of actual goals</li> <li><input type="checkbox"/> (2) – Goal-setting mentioned explicitly, and content of goals is specified For Example: “realistic goals,” or specification with regard to time</li> </ul>
SRPLAN	___	Planning <ul style="list-style-type: none"> <li><input type="checkbox"/> (0) – No mention of planning</li> <li><input type="checkbox"/> (1) – Mentioned simply as planning, OR by use of one of the terms ‘sub-goals’ ‘steps’ ‘laddering’ or breaking large goals down into smaller goals.</li> <li><input type="checkbox"/> (2) – Planning mentioned specifically in regard to either where, when, how, or with whom a specific action is to take place. May also be termed “action planning” or “implementation intention”</li> </ul>
SRMON	___	Self-monitoring <ul style="list-style-type: none"> <li><input type="checkbox"/> (0) – No mention of self-monitoring OR mentioned in the form of an emotional diary”</li> <li><input type="checkbox"/> (1) – Self-monitoring mentioned explicitly mentioned, but unspecified.</li> <li><input type="checkbox"/> (2) – Self-monitoring mentioned in regard to a specific behavior.</li> </ul>
SRPROG	___	Progress Evaluation/Feedback <ul style="list-style-type: none"> <li><input type="checkbox"/> (0) – Not mentioned; Self-monitoring diaries not reviewed</li> <li><input type="checkbox"/> (1) – Feedback is provided to patients regularly</li> <li><input type="checkbox"/> (2) – Feedback is provided regularly regarding goal-related progress</li> </ul>

## CODING FOR CONTROL / COMPARISON GROUP

- CONPROF    —    The treatment was done by a  
                  (1) psychologist/psychotherapist/psychiatrist  
                  (2) other specialist (e.g. physiotherapist, social worker, nurse ...)  
                  (3) multi disciplinary team, including a psychologist  
                      / psychotherapist/ psychiatrist specified  
                  (4) multi disciplinary without a psychologist / psychotherapist/  
                      psychiatrist specified or unspecified  
                  (5) not applicable
- CONTARG    —    Target group of intervention was:  
                  (1) individual patient or couples separately  
                  (2) group of patients or group of couples  
                  (3) both 1 and 2

## GUIDELINES FOR CLASSIFICATION OF CONTROL-TREATMENT

Behaviour Modification is defined as: instructional activities focused on health education and/or health behavior change. This involves personal contacts between a health professional and coronary heart patients (and partners) in order to facilitate positive changes in risk factors for coronary heart disease and / or unhealthy behaviours and must include at least one face-to face session.

Physical Training means not information about physical activities or physiotherapy, but actual exercise training (this training can also be directed by a manual).

NB. Information via leaflets belonging to standard care of coronary heart patients should not be labelled as behaviour modification but as minimal information supply (4).

- CONTYPE    —    The program included: (more than one box may be ticked)  
                   (1) Behaviour modification directed at modification of at least  
                      on risk factor  
                   (2) Stress Management  
                   (3) Physical Training  
                   (4) Information supply (by leaflets or education)  
                   (5) Standard care
- ST\_CARE    —    What did standard care consist of?

## CODING FOR METHODOLOGICAL QUALITY

- RAN        —    Assignment to conditions (1) random (2) non-random  
                  (9) unknown
- MATCH     —    Matching (1) by pairs (2) by stratifying (3) no matching  
                  (9) unknown
- ALLOC     —    How was the randomization procedure carried out?.....
- ASSESS    —    Where the assessors blind? (1) yes (2) no (3) unclear
- LOSS\_FU   —    Loss to follow up? (1) not reported (2) reported but withdrawals  
                  not included in analysis (3) withdrawals included in analysis  
                  (i.e. intention to treat analysis)
- N         —    No of participants per condition

## DATA ENTRY

BOX B: RESULTS FOR CONTINUOUS DATA

DEPENDENT VARIABLE:

Which **CONTINUOUS** dependent variables (DVS) have been measured?

Main outcome? Y/N	What was measured? Unit of measurement?	How has it been measured? (i.e. name of questionnaire, type of instrument used)	Type of observation (e.g. self-report, biometrical etc.)

BASE\_BASELINE (pretest measurement).....  
 POSTI\_POSTINTERVENTION (measurement directly post intervention).....  
 FU1\_ FOLLOW UP 1 (measurement less than 1 year).....  
 FU2\_ FOLLOW UP 2 (measurement between 1 year and 2 years ).....  
 FU3\_ FOLLOW UP 2 (measurement after 2 years).....

Please fill out for each measurement period:

Dependent Variable	N treatment	MEAN treatment (or mean change)	SD treatment (or SD change)	N control	MEAN control (or mean change)	SD control (or control change)	p-value t-test F-test	Change score + F for difference	Effect size + confidence interval	Direction of Effect	One-tailed/ Two-tailed



BOX B: RESULTS FOR CATEGORICAL DATA

DEPENDENT VARIABLE:

Which **CATEGORICAL** dependent variables (DVS) have been measured?

Main outcome? Y/N	Code of dependent variable	How were they measured (e.g. type of instrument/questionnaire, unit of measurement) Name subscales!!	Name of questionnaire	Type of observation (e.g. self-report, biometrical etc.)

BASE\_ BASELINE (pretest measurement).....  
 POSTI\_POSTINTERVENTION (measurement directly post intervention).....  
 FU1\_ FOLLOW UP 1 (measurement less than 1 year).....  
 FU2\_ FOLLOW UP 2 (measurement between 1 year and 2 years ).....  
 FU3\_ FOLLOW UP 2(measurement after 2 years).....

Please fill out for each measurement period:

Dependent Variable	N total	treatment yes / +	treatment no / -	control yes / +l	control no / -	p-value x2-value	Direction of Effect	Odds ratio	Estimated Effect Size R (ESR)

## Appendix 2.

### Methodological quality of included studies

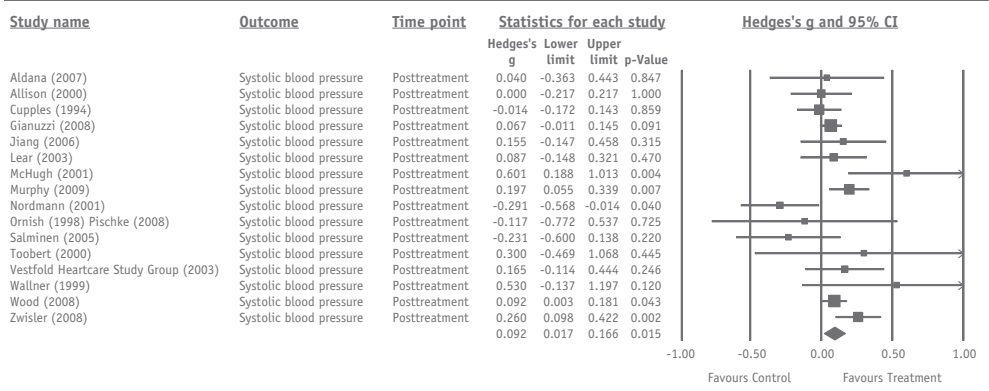
Author, year (ref.)	Described as Randomised	Method of Randomization Described and Appropriate	Description of Withdrawals or Losses to Follow-up	Jadad Score
Aldana et al., 2007 (66)	Yes	Unclear	Yes	2
Allison et al., 2000 (67)	Yes	Yes	Yes	3
Brugemann et al., 2007 (68)	Yes	Yes	Yes	3
Campbell et al., 1998 (69) Campbell et al., 1998 (70) Murchie et al., 2003 (34) Murchie et al., 2004 (71) Delaney et al., 2008 (33)	Yes	Yes	Yes	3
Cupples et al., 1994 (47) Cupples et al., 1999 (35)	Yes	Yes	Yes	3
Giannuzzi et al., 2008 (44)	Yes	Yes	Yes	3
Higgins et al., 2001 (72)	Yes	Unclear	Yes	2
Jeong et al., 2002 (42)	Yes	Yes	Yes	3
Jiang et al., 2007 (73)	Yes	Yes	Yes	3
Lear et al., 2002 (36) Lear et al., 2003 (74) Lear et al., 2005 (75) Lear et al., 2006 (76)	Yes	Yes	Yes	3
Lisspers et al., 1999 (77) Hofman-Bang et al., 1999 (85) Lisspers et al., 2005 (48)	Yes	Unclear	Yes	2
McHugh et al., 2001 (78)	Yes	Unclear	Yes	2
Mildestvedt et al., 2007 (38) Mildestvedt et al., 2008 (79)	Yes	Unclear	Yes	2

<b>Author, year (ref.)</b>	<b>Described as Randomised</b>	<b>Method of Randomization Described and Appropriate</b>	<b>Description of Withdrawals or Losses to Follow-up</b>	<b>Jadad Score</b>
Murphy et al., 2009 (50)	Yes	Yes	Yes	3
Nordmann et al., 2001 (32)	Yes	Yes	Yes	3
Ornish et al., 1990 (80) Ornish et al., 1998 (49) Pischke et al., 2008 (39)	Yes	Unclear	Yes	2
Salminen et al., 2006 (81)	Yes	Unclear	Yes	2
Smeulders et al., 2009 (82)	Yes	Yes	Yes	3
The Vestfold Heartcare Study Group (2003) (46)	Yes	Yes	Yes	3
Toobert et al., 1998 (83) Toobert et al., 2000 (40)	Yes	Unclear	Yes	2
Wallner et al., 1999 (43)	Yes	Unclear	Yes	2
Wood et al., 2008 (84)	Yes	Yes	Yes	3
Zwisler et al., 2005 (41) Zwisler et al., 2008 (45)	Yes	Yes	Yes	3

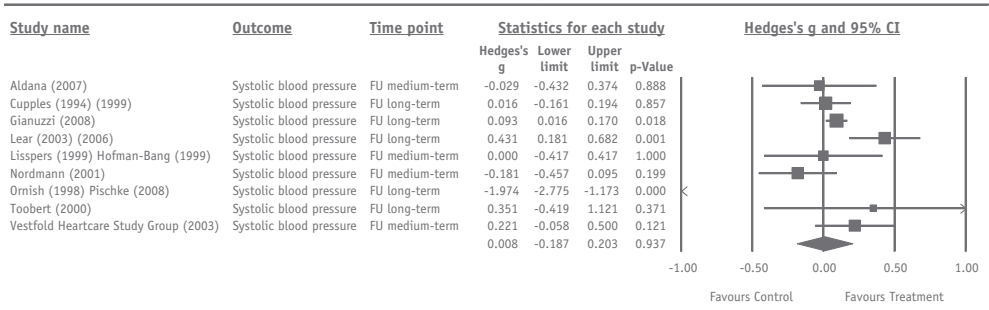
### Appendix 3.

Forest plots for all outcomes at posttreatment and follow-up.

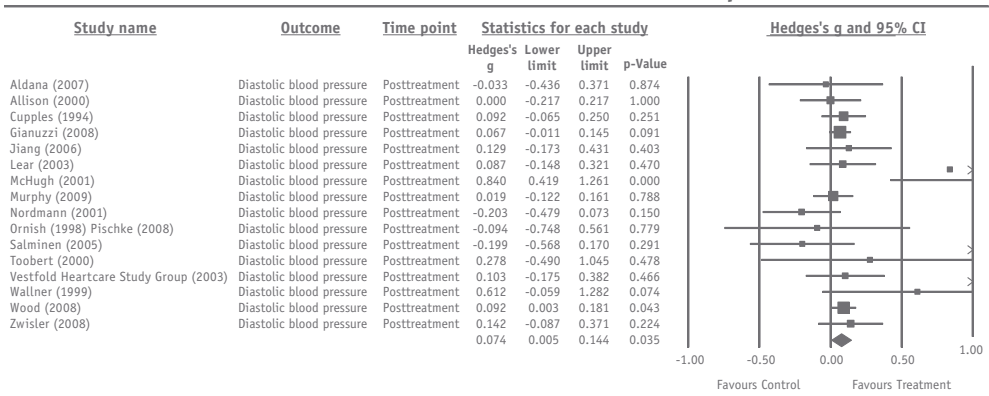
#### Posttreatment effect sizes for systolic blood pressure



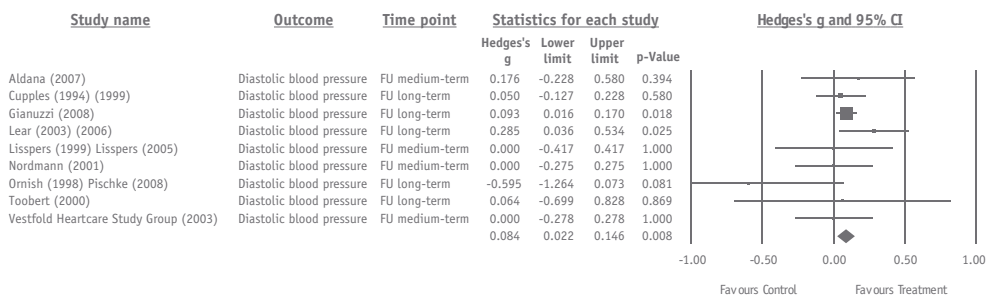
#### Follow-up effect sizes for systolic blood pressure



#### Posttreatment effect sizes for diastolic blood pressure

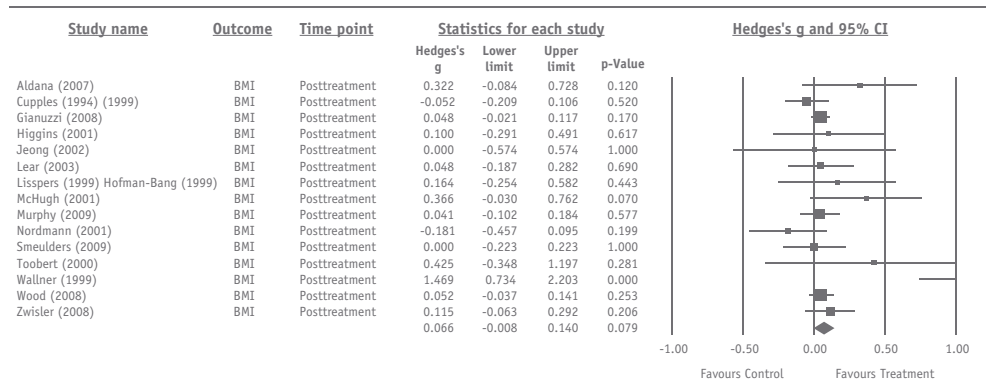


## Follow-up effect sizes for diastolic blood pressure

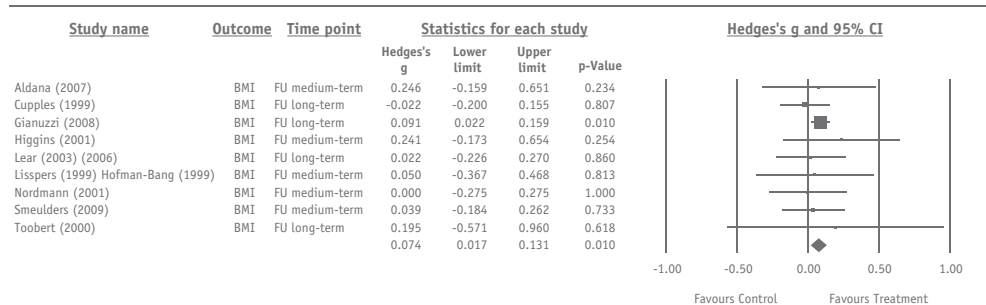


Note: Systolic and diastolic blood pressure were reported in mm/Hg. Three studies reported systolic and/or diastolic blood pressure management, as indicated by the % of patients achieving target levels of 140/90 mm/Hg (Wood, 2008; Zwisler, 2008) and 140/85 mm/Hg (Giannuzzi, 2008). Data from one trial (Campbell, 1998; Murchie, 2003) were excluded, as they defined blood pressure as managed when patients had reached target levels or were currently 'receiving attention' (without further definition).

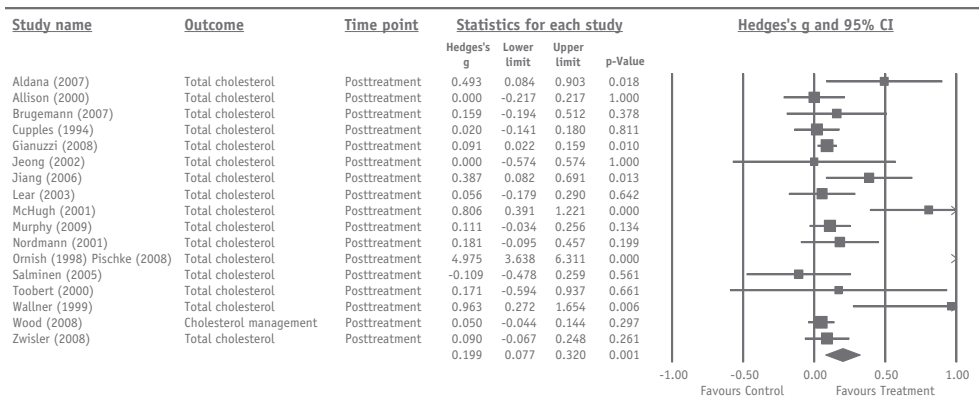
## Posttreatment effect sizes for BMI



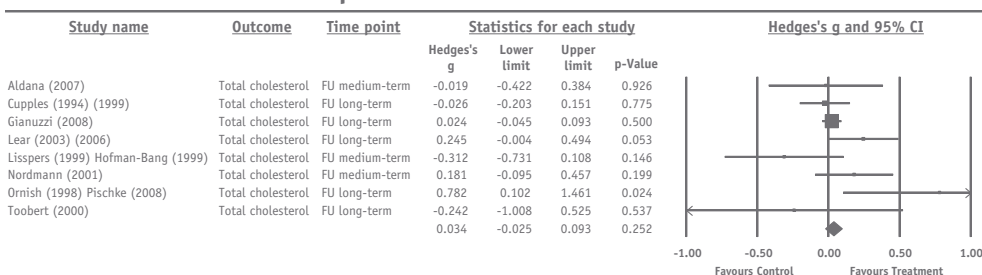
## Follow-up effect sizes for BMI



## Posttreatment effect sizes for total cholesterol

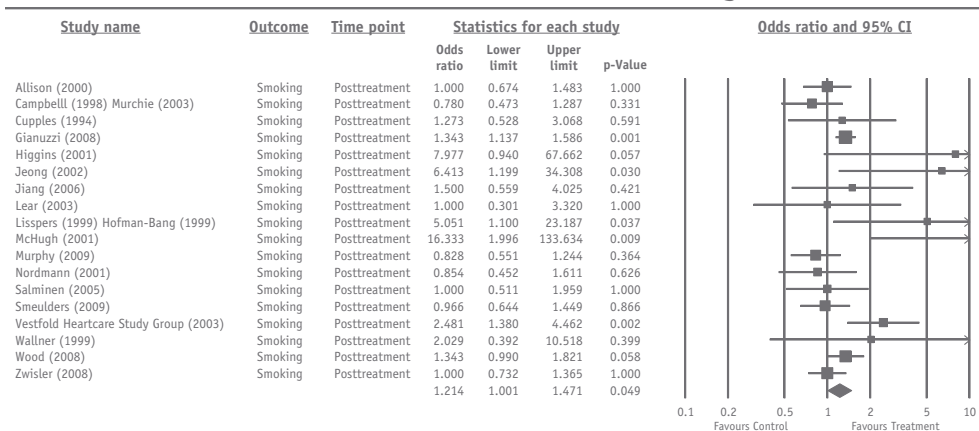


## Follow-up effect sizes for total cholesterol

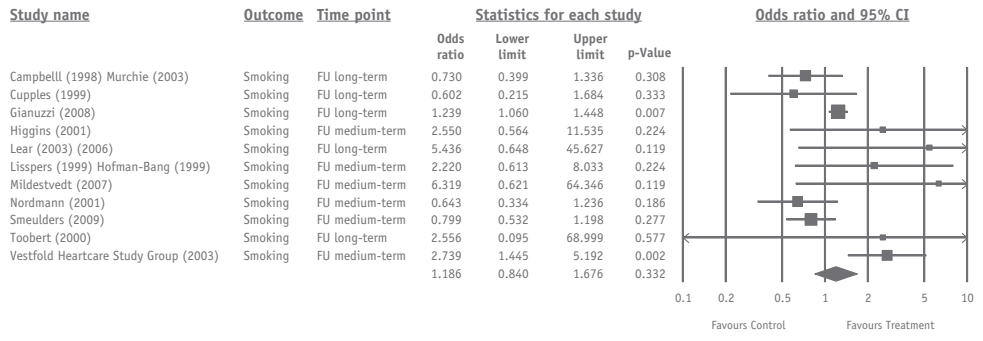


Note: Three studies reported total cholesterol management, as indicated by the % of patients reaching target levels of 5.2 mmol/l (Wood, 2008; Jeong, 2002) and 4.5 mmol/l (Zwisler, 2008). Data from one trial (Campbell, 1998; Murchie, 2003) were excluded, as they defined cholesterol as managed when patients had reached target levels or were currently 'receiving attention' (without further definition).

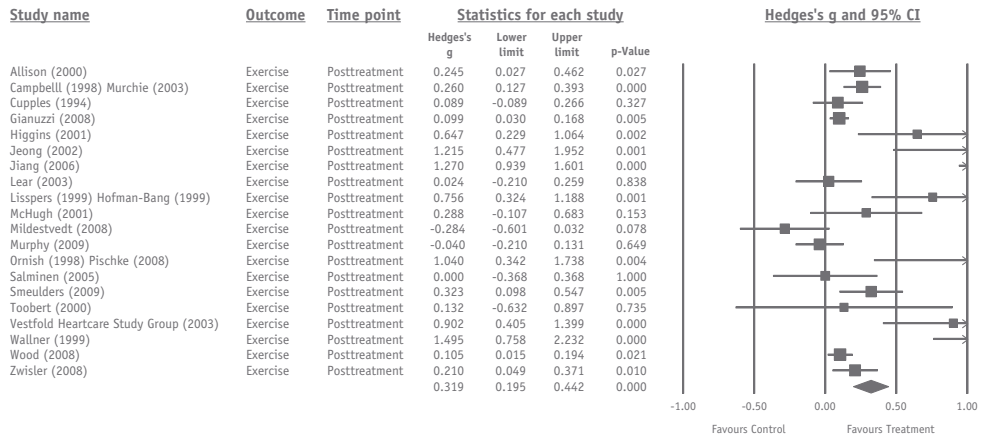
## Posttreatment effect sizes for smoking



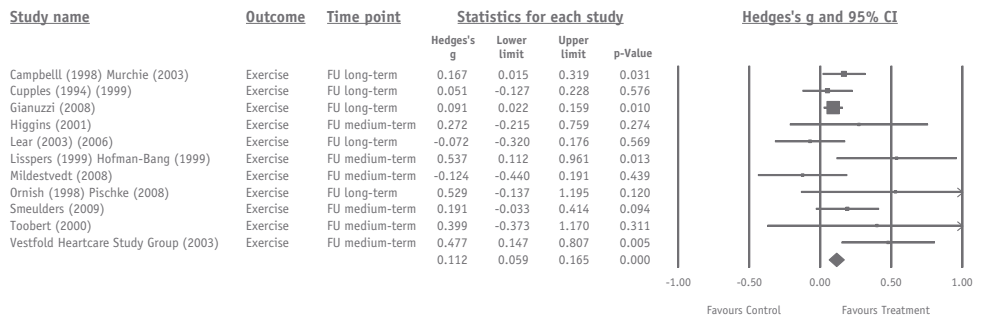
## Follow-up effect sizes for smoking



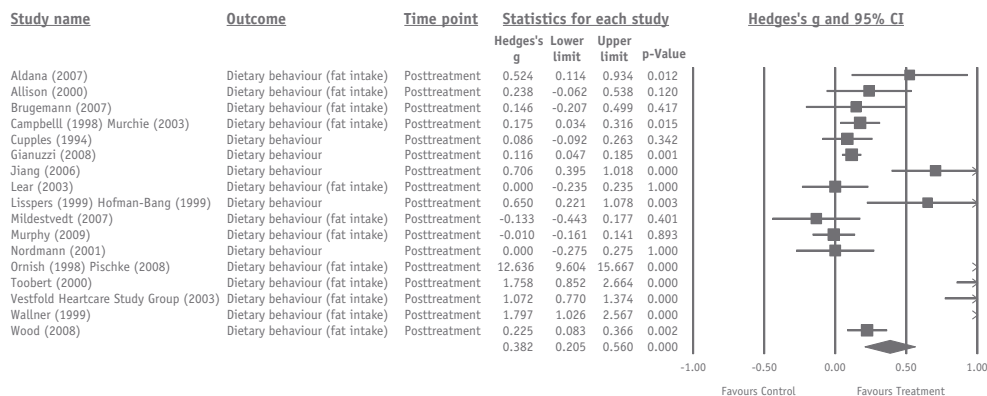
## Posttreatment effect sizes for exercise



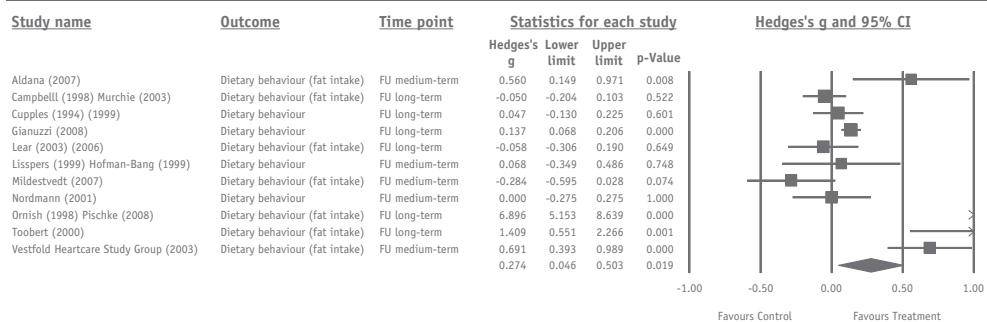
## Follow-up effect sizes for exercise



## Posttreatment effect sizes for dietary behaviour (fat intake)



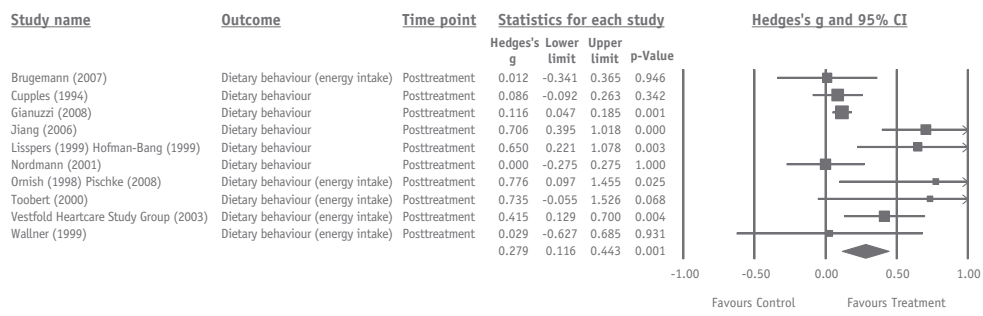
## Follow-up effect sizes for dietary behaviour (fat intake)



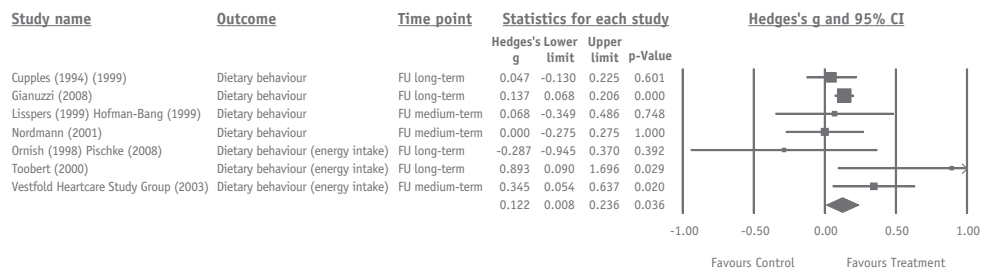
*Note : Dietary behaviour was recorded as fat intake, reported in grams per day (Vestfold Heart Care Study Group, 2003; Ornish, 1998/ Pischke 2008; Brugemann, 2007), % of calories (Aldana, 2007; Lear, 2003; Toobert, 2000; Wallner, 1999; Wood, 2008), 'fat score' (Murphy 2009), or as % of patients reaching a low fat diet (Mildestvedt, 2007; Campbell, 1998; Allison, 2000). Five studies reported adherence to a healthy diet, defined as 'an improved frequency of eating poultry, green vegetables, and high fibre food and decreased frequency of eating red meat, fried foods, biscuits, sweets, and saturated fat' (Cupples, 1999), 'Mediterranean-like diet score' (Giannuzzi, 2008), 'meeting the step II diet criteria of saturated fat <8% of total calories and cholesterol <250 mg (Jiang 2007), atherogenic diet index (Nordmann, 2001), 'heart-healthy diet of fat <30%, saturated fat < 10%, protein 15%, carbohydrates 60% (Lisspers, 1999/Hofman-Bang, 1999).*



## Posttreatment effect sizes for dietary behaviour (energy intake)



## Follow-up effect sizes for dietary behaviour (energy intake)



*Note:* Dietary behaviour was recorded as energy intake, reported in kJ or kC per day, Five studies reported adherence to a healthy diet, defined as ‘an improved frequency of eating poultry, green vegetables, and high fibre food and decreased frequency of eating red meat, fried foods, biscuits, sweets, and saturated fat’ (Cupples, 1999), ‘Mediterranean-like diet score’ (Giannuzzi, 2008), ‘meeting the step II diet criteria of saturated fat <8% of total calories and cholesterol <250 mg (Jiang 2007), atherogenic diet index (Nordmann, 2001), ‘heart-healthy diet of fat <30%, saturated fat < 10%, protein 15%, carbohydrates 60% (Lisspers, 1999/Hofman-Bang, 1999).

