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# Lifestyle modification programmes for patients with coronary heart disease: a systematic review and meta-analysis of randomized controlled trials

**Veronica Janssen[1], Véronique De Gucht[1], Elise Dusseldorp[2] and Stan Maes[1,2]**

## Abstract

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

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

**Results:** The study included 23 trials (involving 11,085 randomized patients). Lifestyle modification programmes were associated with reduced all-cause mortality (summary OR 1.34, 95% CI 1.10–1.64), cardiac mortality (summary OR 1.48, 95% CI 1.17–1.88), and cardiac readmissions and non-fatal reinfarctions (summary OR 1.35, 95% CI 1.17–1.55). Furthermore, lifestyle modification programmes positively affected risk factors and related lifestyle behaviours at post-treatment ($M = 10.2$ months), and some of these benefits were maintained at long-term follow up ($M = 33.7$ months). Improvements in dietary and exercise behaviour were greater for programmes 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 programmes – over and above benefits achieved by routine clinical care alone.

## Keywords

Cardiac rehabilitation, coronary heart disease, lifestyle modification, meta-analysis, secondary prevention, self-regulation

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## 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) programmes have long been recognized, and CR programmes have become widely available.[3] CR programmes aim to return patients to physical and psychosocial functioning and to reduce the risk of recurrent cardiovascular events.[4] Once, CR programmes were almost exclusively exercise based, but gradually they have become supplemented with health education, lifestyle counselling, and psychological treatment components, which better address the full range of modifiable risk factors. Such comprehensive lifestyle modification programmes 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

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modification programmes effectively improve risk factors and related health behaviours, quality of life, morbidity, and mortality (for example, see[7–11]).

Contemporary lifestyle modification programmes often comprise a variety of psychological methods to support behaviour change. Several researchers have called attention to the large differences in efficacy between such programmes, emphasizing the importance of clarifying factors that impact upon programme effectiveness.[11,12] Research has identified specific programme characteristics which moderate treatment effectiveness, such as setting, timing, and duration,[7,10,11] but these have provided little insight into the psychological mechanisms of change. Several meta-analyses and reviews have attempted to isolate effective behaviour-change techniques. Self-monitoring, for instance, has been found to be effective across populations and behaviours.[13–16] 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.[13,16] Self-regulation (SR) theories of behaviour change[17,18] assume that all behaviour is goal directed and that the motivation for behaviour 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 programmes that incorporate this set of techniques (i.e. goal setting, planning, self-monitoring, and feedback) may be more effective than programmes that do not employ such SR techniques.[13,19]

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.[10,20] 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.[20,21] A recent meta-analysis in the area of HIV by de Bruin and colleagues[22] showed that the quality of standard care offered to the control condition affected the incremental benefit of behaviour change intervention programmes. Within cardiac rehabilitation research, Linden and colleagues[11] commenced to investigate the differential effect of quality of care (high vs. 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 programmes in CHD patients tested over the last 10 years (1999–2009) improve risk factors and related health behaviours, 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 programmes incorporating all four SR techniques of behaviour change (i.e. goal setting, planning, self-monitoring, and feedback) compared to programmes that utilized none of these techniques will be examined. As current guidelines place large emphasis on addressing the full range of modifiable risk factors,[23] only programmes focusing on multiple risk factors and related lifestyle behaviours 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 programmes for CHD patients. We included studies with patients that were eligible for CR and/or belonged to one of the following diagnostic groups:[24] 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 programme 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 (BMI), waist/hip ratio, or smoking) as well as one or more health behaviours (i.e. dietary habits or exercise).[25] In case data reported did not allow calculation of effect sizes, or data were presented for mixed populations only (i.e. stroke/ischaemic 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), lifestyle, health behavio(u)r(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[26] and sample size. Following previous meta-analyses[10,27] 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.[28,29] 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 (available online). 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 programme in months × number of sessions), participation of partners, and type of behaviour 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, BMI, 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 ≥1 year ≤2 years, long term ≥2 years). Finally, each intervention was assessed for the presence of SR techniques of behaviour change (goal setting, self-monitoring, planning, and feedback). Behaviour 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, pp. 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[30] 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 programme), posttreatment (immediately following termination of the programme) 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 (≥1 year ≤2 years), and long term (≥2 years). If a study

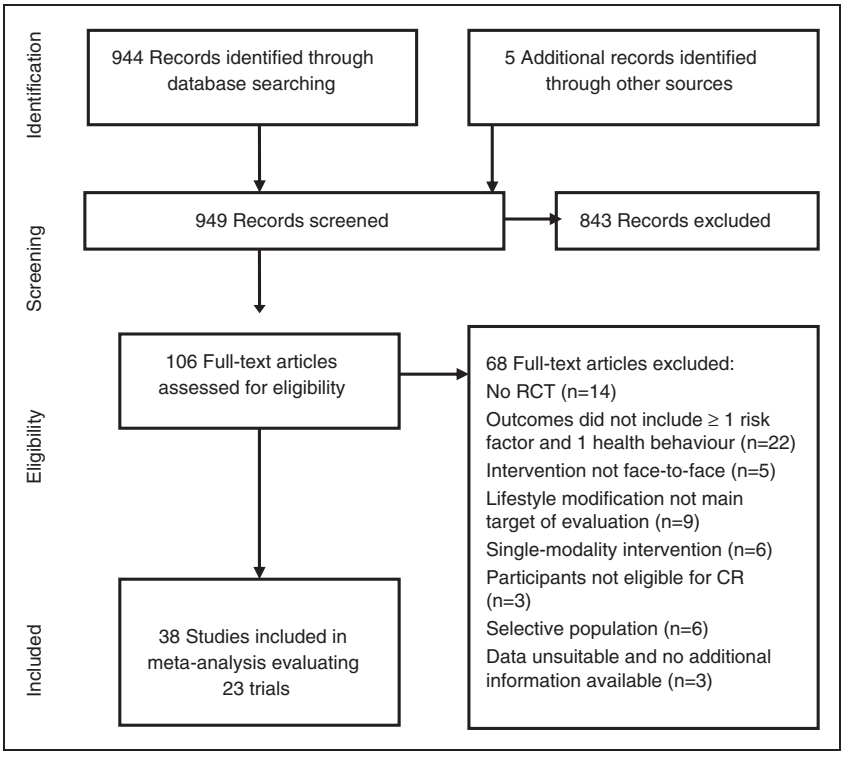


**Figure 1.** Flowchart of selection of trials.

reported several posttests within a measurement period, the last posttest within that period was chosen. For risk factor and health behaviour 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[31] that reported mortality data at 6 months and one study[32] 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 vs. 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) vs. 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 $\times$ 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) vs. low risk of bias (Jadad score $>$2 and sample size $\geq$35 per condition)].[28,29] 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 (Figure 1). The number of articles exceeded the number of trials as eight trials reported short-term and long-term data separately or reported different outcomes in different articles.[33–40] In total, 5537 participants were included in the intervention groups and

**Table 1.** Characteristics of included studies

| Publication | Sample size | Mean age (years) | Population | Measurement period (months) | Intervention content (intensity: no. of sessions/duration in months) | Control condition content |
|---|---|---|---|---|---|---|
| Aldana et al. (2007)[65] | 93 | 62 | CHD | Post treatment 6; follow up 12 | Intense cardiovascular disease risk factor programme based on the Ornish Programme for Reversing Heart Disease. The programme 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 programme 3x a week, dietary and smoking cessation counselling) |
| Allison et al. (2000)[66] | 326 | 58 | AP | Post treatment 6 | Nurse-run risk factor management programme. Intervention strategies included: instituting pharmacological lipid management, making appropriate referrals (f.i. to the diabetic clinic, social work, or psychology); counselling 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 |
| Brugemann et al. (2007)[67] | 137 | 57 | CABG, PCI | Post treatment 3; follow up 9 | Comprehensive cardiac rehabilitation programme, 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) |
| Campbell et al. (1998)[68]; Campbell et al. (1998)[69]; Murchie et al. (2003)[33]; Murchie et al. (2004)[70]; Delaney et al. (2008)[32] | 1173 | 66 | CHD | Post treatment 12; follow up 24, 48, 56 | Nurse-run clinics in general practice promoting medical and lifestyle aspects of secondary prevention. Regular follow ups offered over 1 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 |
| Cupples et al. (1994)[46]; Cupples et al. (1999)[34] | 688 | 63 | AP | Post treatment 24; follow up 60 | Practical advice regarding cardiovascular risk factors given by a health | Usual NHS care |

(continued)

**Table 1.** Continued

| Publication | Sample size | Mean age (years) | Population | Measurement period (months) | Intervention content (intensity: no. of sessions/duration in months) | Control condition content |
|---|---|---|---|---|---|---|
| | | | | | visitor. Patients were reviewed at 4-month intervals and given appropriate health education (7 sessions/24 months) | |
| Giannuzzi et al. (2008)[43] | 3241 | 58 | MI | Post treatment 6; follow up 24, 36 | Long-lasting multifactorial educational and behavioural programme 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 |
| Higgins et al. (2001)[71] | 99 | 48 | PCI | Post treatment 2; follow up 12 | Two in-hospital education sessions and an individualized, comprehensive, home-based cardiac rehabilitation programme combining risk factor modification with exercise and psychological counselling. The programme 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 |
| Jeong et al. (2002)[41] | 45 | 53 | MI | Post treatment 3 | Individualized teaching programme in hospital, supportive care via telephone contact or mail for 12 weeks post-discharge (3 sessions/3 months) | Routine care (verbal instruction) |
| Jiang et al. (2007)[72] | 167 | 62 | CHD | Post treatment 3; follow up 6 | Nurse-led home-based cardiac rehabilitation programme. In-hospital education aimed at self-managed cardiac rehabilitative care after discharge. After discharge, 12-week nurse-led home-based programme focused on lifestyle and treatment adherence. Follow-up visits and | Routine care |

(continued)

**Table 1.** Continued

| Publication | Sample size | Mean age (years) | Population | Measurement period (months) | Intervention content (intensity: no. of sessions/duration in months) | Control condition content |
|---|---|---|---|---|---|---|
| | | | | | telephone calls (19 sessions/3 months) | |
| Lear et al. (2002)[35]; Lear et al. (2003)[73]; Lear et al. (2005)[74]; Lear et al. (2006)[75] | 302 | 64 | CHD | Post treatment 12; follow up 24, 36, 48 | Extensive Lifestyle Management Intervention (ELMI) based on the principles of behavioural change and aimed at individualizing risk factor and lifestyle management. It consisted of cardiac rehabilitation sessions (exercise programme), risk factor and lifestyle counselling sessions, and telephone follow up (39 sessions/12 months) | Annual risk factor assessment visit + usual care by family physician |
| Lisspers et al. (1999)[76]; Hofman-Bang et al. (1999)[84]; Lisspers et al. (2005)[47] | 87 | 53 | PCI | Post treatment 12; follow up 24, 36, 60 | Comprehensive behaviourally oriented programme aimed at long-term changes in risk factor-related lifestyle behaviour. The programme 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 programme involving self-monitoring, feedback, and regular contacts with a nurse during 1 year (>100? sessions/12 months) | Standard care by own physician |
| McHugh et al. (2001)[77] | 98 | 62 | Patients on CABG waiting list | Post treatment 15 | A nurse-led shared care programme consisting of health education and motivational interviews, according to individual need, carried out monthly. Interventions addressed behavioural risk factors and were focused on tracking progress (15 sessions/15 months) | Usual care |
| Mildestvedt et al. (2007)[37]; Mildestvedt et al. (2008)[78] | 176 | 56 | CHD | Post treatment 6; follow up 24 | Standard cardiac rehabilitation programme including daily exercise groups, dietary and smoking cessation counselling. In addition, patients | Standard cardiac rehabilitation (daily physical training, dietary and smoking cessation counselling) |

(continued)

**Table 1.** Continued

| Publication | Sample size | Mean age (years) | Population | Measurement period (months) | Intervention content (intensity: no. of sessions/duration in months) | Control condition content |
|---|---|---|---|---|---|---|
| | | | | | received an individualized self-efficacy and autonomy supportive intervention consisting of two individual sessions and two follow-up telephone calls (4 sessions/24 months) | |
| Murphy et al. (2009)[49] | 903 | 68 | CHD | Post treatment 18 | Tailored care plans for practices (practice based training in prescribing and behaviour 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 4 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 |
| Nordmann et al. (2001)[33] | 201 | 62 | CHD | Post treatment 9; follow up 18 | Risk factor case management programme during hospitalization consisting of structured counselling 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 counselling |
| Ornish et al. (1990)[79]; Ornish et al. (1998)[48]; Pischke et al. (2008)[38] | 48 | 58 | CHD | Post treatment 12; follow up 60 | Intensive lifestyle changing programme: 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) |
| Salminen et al. (2006)[80] | 112 | 74 | CHD | Post treatment 16 | A health advocacy, counselling, and activation programme aimed at giving information on risk factors. The programme consisted of lectures, group discussions, light | Usual care |

(continued)

**Table 1.** Continued

| Publication | Sample size | Mean age (years) | Population | Measurement period (months) | Intervention content (intensity: no. of sessions/duration in months) | Control condition content |
|---|---|---|---|---|---|---|
| | | | | | exercises, and social activities (33 sessions/16 months) | |
| Smeulders et al. (2009)[81] | 317 | 67 | HF | Post treatment 1.5; follow up 6, 12 | Structured self-management programme focused on learning patients how to take responsibility for the day-to-day management of their disease. The programme 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 |
| The Vestfold Heartcare Study Group (2003)[45] | 197 | 55 | CHD | Post treatment 6; follow up 24 | 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 9 weeks of organized physical exercise sessions and group meetings every 3 months for 2 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 |
| Toobert et al. (1998)[82]; Toobert et al. (2000)[41] | 28 | 63 | CHD | Post treatment 4; follow up 12, 24 | Intensive lifestyle self-management programme consisting of a very-low fat vegetarian diet, exercise, smoking cessation, breathing and relaxation exercises, and group support based on the Ornish programme for Reversing Heart Disease (>100 sessions/15 months) | Usual care |
| Wallner et al. (1999)[42] | 60 | 59 | PCI | Post treatment 12 | Intensive lifestyle intervention including lifestyle advice, physical activity training programmes, food diaries, and 1-h sessions with a nutritionist in order to adopt a healthy diet. Follow | Conventional treatment by cardiologists and general practitioners |

(continued)

**Table 1.** Continued

| Publication | Sample size | Mean age (years) | Population | Measurement period (months) | Intervention content (intensity: no. of sessions/duration in months) | Control condition content |
|---|---|---|---|---|---|---|
| | | | | | up by regular telephone contact (17 sessions/12 months) | |
| Wood et al. (2008)[83] | 3088 | 63 | CHD | Post treatment 12 | Nurse-coordinated, multidisciplinary family-based cardiovascular disease prevention programme consisting of workshops, tailored advice, and a supervised-exercise class. Sessions also included partners and families (≥16 sessions/4 months) | UC hospitals |
| Zwisler et al. (2005)[42]; Zwisler et al. (2008)[44] | 770 | 66 | Cardiac rehabilitation patients | Post treatment 12 | Individually tailored multidisciplinary programme; patient education, exercise training, dietary counselling, smoking cessation, psychosocial support, and group workshops. Multidisciplinary advice, monitoring, and assessment of risk factors (>25 sessions?/12 months) | Usual care |

AP, angina pectoris; CABG, coronary artery bypass surgery; CHD, coronary heart disease; HF, heart failure; MI, myocardial infarction; PCI, percutaneous coronary intervention.

**Table 2.** Description of moderators

| Publication | Setting | Partners involved? | Exclusion on basis of diagnosis | Exclusion on basis of disease severity | Methodological quality | | | | No of sessions/ programme duration[b] | Psychological techniques used in intervention[c] | | | | | Control conditions[d] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Risk of bias | Sample size[a] | | Jadad Score | | GS | SM | PL | FB | High/low SR | |
| | | | | | | T (*n*) | C (*n*) | | | | | | | | |
| Aldana et al. (2007)[65] | Secondary care | No | No | No | High | 46 | 47 | 2 | High/long term | 0 | 0 | 0 | 1 | Low SR | LM + E |
| Allison et al. (2000)[66] | Secondary care | No | Yes (MI, CABG) | No | Low | 158 | 168 | 3 | Low/short term | 0 | 0 | 1 | 0 | Low SR | UC |
| Brugemann et al. (2007)[67] | Secondary care | No | Yes (HF NYHA III/IV) | Yes (NYHA III/IV | Low | 60 | 62 | 3 | High/long term | 0 | 0 | 0 | 0 | Low SR | LM + E |
| Campbell et al. (1998)[68]; Campbell et al. (1998)[69]; Murchie et al. (2003)[33]; Murchie et al. (2004)[70]; Delaney et al. (2008)[32] | Primary care | No | No | No | Low | 670 | 667 | 3 | Low/long term | 2 | 2 | 2 | 2 | High SR | UC |
| Cupples et al. (1994)[46]; Cupples et al. (1999)[34] | Primary care | No | No | No | Low | 317 | 300 | 3 | Low/long term | 0 | 0 | 0 | 0 | Low SR | UC |
| Giannuzzi et al. (2008)[43] | Secondary care | Yes | No | No | Low | 1620 | 1621 | 3 | Low/long term | 1 | 1 | 1 | 1 | Low SR | LM |
| Higgins et al. (2001)[71] | Secondary care | Yes | No | No | High | 50 | 49 | 2 | Low/short term | 2 | 2 | 2 | 2 | High SR | LM |
| Jeong et al. (2002)[41] | Secondary care | No | No | No | High | 22 | 23 | 3 | Low/short term | 0 | 0 | 0 | 0 | Low SR | UC |
| Jiang et al. (2007)[72] | Secondary care | Yes | No | No | Low | 83 | 84 | 3 | High/short term | 2 | 2 | 1 | 2 | High SR | UC |
| Lear et al. (2002)[35]; Lear et al. (2003)[73]; Lear et al. (2005)[74]; Lear et al. (2006)[75] | Secondary care | No | No | No | Low | 142 | 136 | 3 | High/long term | 2 | 2 | 1 | 2 | High SR | LM |
| Lisspers et al. (1999)[76]; Hofman-Bang et al. (1999)[84]; Lisspers et al. (2005)[47] | Secondary care | Yes | No | Yes (maximal exercise capacity <70 Watt) | High | 46 | 41 | 2 | High/long term | 2 | 2 | 2 | 2 | High SR | UC |
| McHugh et al. (2001)[77] | Primary care | No | No | No | High | 49 | 49 | 2 | Low/long term | 1 | 1 | 0 | 2 | Neither high nor low | UC |
| Mildestvedt et al. (2007)[37]; Mildestvedt et al. (2008)[78] | Secondary care | Yes | No | No | High | 84 | 75 | 2 | Low/long term | 2 | 0 | 1 | 0 | Neither high nor low | LM + E |
| Murphy et al. (2009)[49] | Primary care | No | No | No | Low | 360 | 405 | 3 | Low/long term | 2 | 2 | 2 | 1 | High SR | LM |
| Nordmann et al. (2001)[31] | Secondary Care | No | Yes (HF NYHA III/IV) | Yes (NYHA III/IV) | Low | 99 | 102 | 3 | Low/short term | 2 | 1 | 2 | 2 | High SR | LM |
| Ornish et al. (1990)[79]; Ornish et al. (1998)[48]; Pischke et al. (2008)[38] | Secondary Care | Yes | Yes (no MI in preceding 6 wks, not on lipid-lowering drugs, | Yes (ejection fraction >25%) | High | 20 | 15 | 2 | High/long term | 2 | 0 | 0 | 0 | Neither high nor low | UC |

(continued)

**Table 2.** Continued

| Publication | Setting | Partners involved? | Exclusion on basis of diagnosis | Exclusion on basis of disease severity | Methodological quality | | | | No of sessions/ programme duration[b] | Psychological techniques used in intervention[c] | | | | | Control conditions[d] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Risk of bias | Sample size[a] T (*n*) | Sample size[a] C (n) | Jadad Score | | GS | SM | PL | FB | High/low SR | |
| | | | not scheduled to have CABG) | | | | | | | | | | | | |
| Salminen et al. (2006)[80] | Primary care | No | No | No | High | 58 | 54 | 2 | High/long term | 0 | 0 | 0 | 0 | Low | UC |
| Smeulders et al. (2009)[81] | Secondary care | No | No | No | Low | 186 | 131 | 3 | Low/short term | 1 | 0 | 2 | 0 | Neither high nor low | UC |
| The Vestfold Heartcare Study Group (2003)[45] | Secondary care | Yes | No | No | Low | 98 | 99 | 3 | High/long term | 2 | 2 | 1 | 2 | High | LM |
| Toobert et al. (1998)[82]; Toobert et al. (2000)[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 | 95 | 96 | 2 | High/long term | 1 | 0 | 2 | 1 | Neither high nor low | UC |
| Wallner et al. (1999)[42] | Secondary care | No | No | Yes (ejection fraction <30%) | High | 32 | 28 | 2 | High/long term | 2 | 2 | 1 | 2 | High | UC |
| Wood et al. (2008)[83] | Secondary care | Yes | Yes (severe HF) | Yes (severe HF) | Low | 946 | 994 | 3 | High/short term | 1 | 2 | 1 | 1 | Neither high nor low | UC |
| Zwisler et al. (2005)[40]; Zwisler et al. (2008)[44] | Secondary care | Yes | No | No | Low | 380 | 390 | 3 | High/long term | 1 | 0 | 1 | 1 | Low | UC |

AP, angina pectoris; CABG, coronary artery bypass surgery; CHD, coronary heart disease; HF, heart failure; MI, myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; [a]Sample size groups: C, control; T, treatment; [b]No of sessions/programme duration: high, >15; low, ≤15; long term, >12 months; short term, ≤12 months; [c]Psychological techniques used in intervention: GS, goal setting; SM, self-monitoring; PL, planning; FB, feedback (low, 0/1; high, 2); High/low self-regulation: (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); [d]Control conditions: LM, lifestyle modification; LM + E, lifestyle modification + exercise; UC, usual care.

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 three trials, control groups received full cardiac rehabilitation, including structured exercise sessions, education, and lifestyle counselling. 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), nine trials included all four SR techniques in their intervention (high SR). Six trials used some of these techniques, but not all (neither high nor low SR), and eight trials incorporated none of these techniques (low SR). Furthermore, Table 2 and Appendix 2 (available online) show that trial quality was moderate with Jadad scores between 2 and 3. Nevertheless, nine trials failed to specify the method of randomization or did not adequately describe this (Appendix 2). All trials reported on losses to follow up, and 11 trials carried out intention-to-treat analyses. Table 2 also shows that three studies[38,41,42] included fewer than 35 patients per condition.

## *Mortality*

All-cause mortality data with outcome assessment times between 12 and 60 months (M = 34.4 months) were available for six trials[31,33,34,43–45] reporting data for 6270 patients. Cardiac mortality data with this follow-up period were available for 5 trials[33,43,46–48] reporting on 5237 patients with outcome periods ranging from 36–60 months (M = 54.5 months). Lifestyle

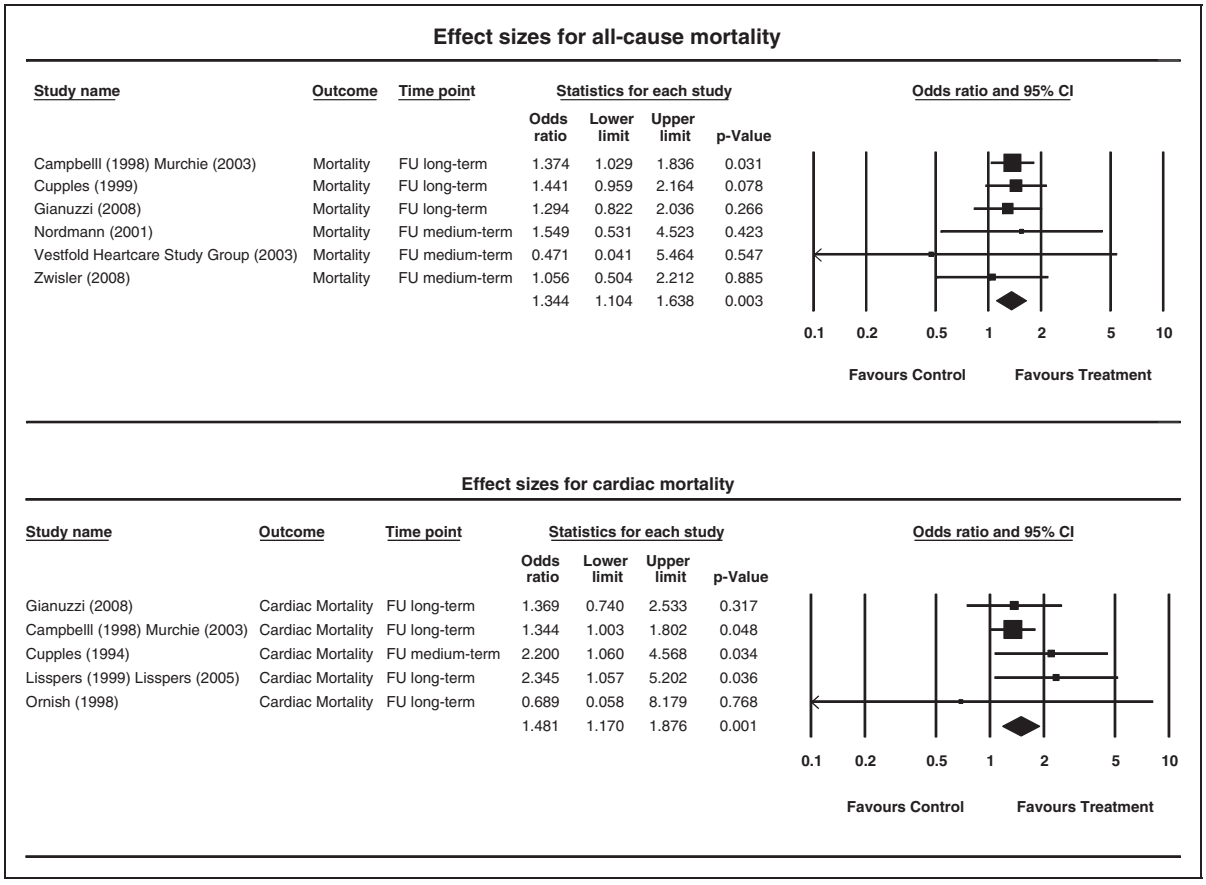


**Figure 2.** Forest plots for all-cause mortality and cardiac mortality.

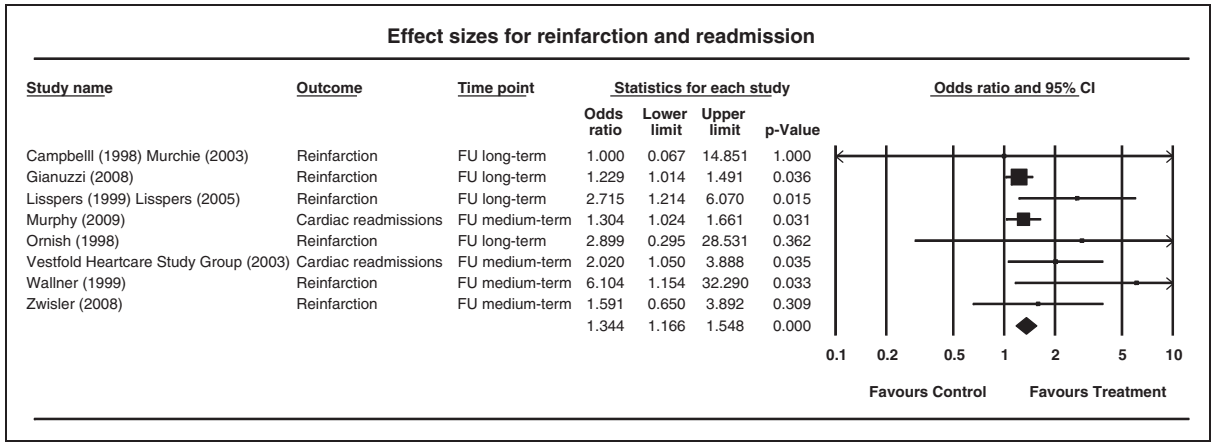


**Figure 3.** Forest plot for non-fatal reinfarction and cardiac readmissions to hospital.

modification programmes were associated with a significant reduction in all-cause mortality ($p < 0.00$, summary OR 1.34, 95% CI 1.10–1.64) and cardiac mortality ($p < 0.00$, summary OR 1.48, 95% CI 1.17–1.88). 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 the forest plots for both outcomes.

## Reinfarction and readmission

Reinfarction rates were available for six trials[33,42–44,47,48] at assessment time ≥12 months. Two trials[45,49] reported cardiac readmissions instead of reinfarction rates. We considered the combined outcomes of cardiac readmission and reinfarction such that outcome data were available for eight trials[33,42–45,47–49] reporting on 6479 patients with outcome assessments ranging between 12 and 60 months ($M = 31.8$ months). Lifestyle modification programmes were associated with a significant reduction in reinfarction and readmission ($p < 0.00$, summary OR 1.35, 95% CI 1.17–1.55) and there was no evidence of heterogeneity between the trials ($p = 0.24$, $I^2 = 23\%$). Figure 3 shows the forest plots for both outcomes.

## Risk factors and lifestyle behaviours

Table 3 presents summary effects and heterogeneity statistics for the separate risk factors and related lifestyle behaviours 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 behaviours (exercise, dietary habits). However, data showed evidence of significant heterogeneity. At follow-up assessment, significant summary effects were found for diastolic blood pressure, BMI, exercise, and dietary habits. Risk factor data appeared mostly homogenous, but the dietary outcomes showed evidence of heterogeneity. The forest plots for all outcomes are displayed in Appendix 3 (available online).

## Additional analyses

*Sensitivity 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 behaviour (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 ($\kappa = 3$) decreased the summary effect from OR 1.35 ($p < 0.00$, 95% CI 1.16–1.57, $k = 8$) to 1.30 (95% CI 1.12–1.50, $k = 5$]). For smoking, the summary effect decreased from OR 1.21 ($p = 0.05$, 95% CI 1.00–1.47, $k = 18$) to 1.18 ($p < 0.00$, 95% CI 1.06–1.31, $k = 12$). For total cholesterol, the summary effect decreased from Hedges' g 0.20 ($p < 0.00$, 95% CI 0.10–0.32, $k = 17$) to 0.08 ($p < 0.00$, 95% CI 0.04–0.13, $k = 10$). For dietary behaviour, the summary effect decreased from Hedges' g 0.41 ($p < 0.00$, 95% CI 0.01–0.60, $k = 16$) to 0.25 ($p < 0.00$, 95% CI 0.11–0.40, $k = 9$)

*Subgroup analyses.* Subgroup analyses were carried out in order to examine if treatment effects varied in relation to the following characteristics: (a) setting (primary vs. secondary care) involvement of partners (yes/no); (b) exclusion criteria (on the basis of cardiac

**Table 3.** Effects of lifestyle modification programmes on risk factors and lifestyle behaviours

| Outcome | Assessment period | Follow up (months; mean, range) | No. of randomized participants | Hedges' g (95% CI) | Homogeneity of variance ($I^2$)[a] | No. of trials (references)[b] |
|---|---|---|---|---|---|---|
| Systolic blood pressure | Posttreatment | 10.8 (3–24) | 10,322 | 0.09 (0.02–0.17)* | 46.39* | 16 (31,38,39,42,43–46,48,49,65,66,72,73,77,80,83) |
| | Follow up | 34.0 (12–60) | 4885 | 0.01 (−0.19–0.20) | 79.33** | 9 (31,34,38,39,10,43,45,46,48,65,73,75,76,84) |
| Diastolic blood pressure | Posttreatment | 10.8 (3–24) | 10,322 | 0.07 (0.01–0.14)* | 36.75 | 16 (31,38,39,42,43–46,48,49,65,66,72,73,77,80,82) |
| | Follow up | 34.0 (12–60) | 4885 | 0.08 (0.02–0.15)** | 0.00 | 9 (31,34,38,39,40,43,45,46,48,65,73,75,76,84) |
| Body mass index | Posttreatment | 10.3 (1.5–24) | 10,020 | 0.07 (−0.01–0.14) | 43.48* | 15 (31,34,39,41–44,46,49,65,71,72,77,78,81,83,84) |
| | Follow up | 27.3 (12–60) | 5056 | 0.07 (0.02–0.13)** | 0.00 | 9 (31,34,65,39,43,71,73,75,76,81,84) |
| Total cholesterol | Posttreatment | 10.7 (3–24) | 10,307 | 0.20 (0.08–0.32)** | 80.01** | 17 (31,38,39–44,46,48,49,65,66,67,72,73,77,80,83) |
| | Follow up | 35.3 (12–60) | 4688 | 0.03 (−0.03–0.09) | 42.62 | 8 (31,34,38,39,43,46,48,65,73,75,76,84) |
| Smoking | Posttreatment | 10.1 (1.5–24) | 11,874 | OR = 1.21 (1.00–1.47)** | 52.40** | 18 (31,33,41–46,49,66,68,71,72,73,76,77,80,81,83,84) |
| | Follow up | 30.8 (12–60) | 6509 | OR = 1.19 (0.84–1.68) | 58.51* | 11 (31,33,34,37,39,43,45,68,71,73,75,76,81,84) |
| Exercise | Posttreatment | 9.73 (1.5–24) | 11,925 | 0.32 (0.20–0.44)** | 83.67** | 20 (33,38,39,41–46,48,49,66,68,71–73,76–78,80,81,83,84) |
| | Follow up | 33.5 (12–60) | 6356 | 0.11 (0.06–0.17)** | 41.43 | 11 (33,34,38,39,43,45,46,48,68,71,73,75,76,78,81,84) |
| Dietary behaviour, fat intake | Posttreatment | 9.71 (3–24) | 10,915 | 0.38 (0.21–0.56)** | 90.23** | 17 (31,33,37–39,42,43,45,46,48,49,65,66,68,72,73,76,83,84) |
| | Follow up | 35.13 (12–60) | 6234 | 0.27 (0.05–0.50)* | 90.04** | 11 (31,33,34,37,38,39,43,45,46,48,65,68,73,75,76,84) |
| Dietary behaviour, energy intake | Posttreatment | 9.3 (3–24) | 4854 | 0.28 (0.12–0.44)** | 69.43** | 10 (31,38,339,42,43,45,46,48,67,72,76,84) |
| | Follow up | 35.14 (18–60) | 4490 | 0.12 (0.01–0.24) | 32.69 | 7 (31,34,38,39,43,45,46,48,76,84) |

*$p \leq 0.05$; **$p \leq 0.01$; [a]$I^2$: 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; [b]For Cupples and et al.,[34] the confidence intervals were used to calculate the standard deviation of change. For Nordmann et al.[31] 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

| | | | | | | | Dietary behaviour | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Smoking | | | Exercise | | | Fat intake | | | Energy intake | | |
| Outcome | k | OR | *p* | k | g | *p* | k | g | *p* | k | g | *p* |
| POSTTREATMENT | | | | | | | | | | | | |
| 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[a] | | | | | | | | | | | | |
| 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[b] | | | | | | | | | | | | |
| 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 | |
| FOLLOW UP | | | | | | | | | | | | |
| 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 | ≤0.01 | 2 | 0.03 | NS |
| Yes | 6 | 1.92 | | 7 | 0.12 | | 6 | 0.80 | | 5 | 0.15 | |
| Exclusion diagnosis | | | | | | | | | | | | |
| No | 10 | 1.29 | – | 10 | 0.13 | – | 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[a] | | | | | | | | | | | | |
| 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[b] | | | | | | | | | | | | |
| 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 | |

*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 ($p > 0.05$); –, too few studies in cell to allow meaningful comparison; [a]Control condition: LM, lifestyle modification; LM + E, lifestyle modification + exercise; UC, usual care; [b]Self-regulation techniques: low, score of 1 or less on individual constructs; high, score of 2 on at least three out of four constructs, score of 0 on none of the constructs.

diagnosis yes/no, on the basis of disease severity yes/no); (c) extent to which each of the SR behaviour change techniques (goal setting, self-monitoring, planning, feedback) was present in the intervention (low SR vs. 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 behaviours, 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 behaviour (fat intake). Third, the magnitude of effect sizes appeared to be greater in trials where the control condition was standard cardiac care vs. 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 programmes were smaller in terms of improved diet (fat intake), exercise behaviour 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, programmes that included this set of techniques (i.e. goal setting, planning, self-monitoring, and feedback) were more successful in changing exercise behaviour and dietary habits (fat intake) than programmes 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.* Meta-regression analysis revealed no significant association between the continuous study variable 'programme intensity' (no of sessions × 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[50] 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[51] 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 programmes for CHD patients reduce mortality, reincidence, and readmission rates. Overall, lifestyle modification programmes included in this meta-analysis reduced mortality by 34% and cardiac reincidence and readmissions by 35% over a follow-up period ranging 1–5 years. This is consistent with reductions in mortality and cardiac recurrence observed by previous meta-analyses and systematic reviews.[7,14,27,52,53]

Comprehensive lifestyle modification programmes were also shown to positively affect risk factors and related lifestyle behaviours both at posttreatment (M = 10.2 months) and at follow up (M = 33.7 months). At posttreatment, lifestyle modification programmes were associated with significant reductions in blood pressure (both systolic and diastolic), total cholesterol, and smoking, and significant improvements in exercise behaviour 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 behaviour.[10,11] Evidence from large population studies suggests that, jointly, such small individual reductions lead to clinically important improvements in risk factor profile.[54]

At follow up, treatment benefits were maintained for exercise behaviour 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 behaviour, 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 programme effectiveness, we found changes in lifestyle to vary dependent upon whether or not SR techniques of behaviour change were utilized in the lifestyle modification programme. More specifically, programmes that included all four SR techniques were more successful in changing exercise behaviour 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 programme has terminated. Research on long-term adherence typically shows that maintenance of lifestyle change is problematic as many cardiac patients relapse into old habits.[55,56] Future lifestyle modification programmes 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.[43]

As speculated, we found the incremental benefit of lifestyle modification programmes to be smaller in terms of non-smoking, improved diet, and exercise behaviour in settings where standard care was elaborate. This accords with the meta-analysis by de Bruin and colleagues,[22] which demonstrated that quality of standard care determined treatment outcomes in HIV behaviour-change interventions. These findings suggest that future meta-analyses on comprehensive CR programmes 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 programme effectiveness, such as intensity of the programme, provision of booster sessions and relapse prevention, modes of intervention delivery (e.g. face-to-face, internet, or telephone) used, and type of participants included. Increasingly, trials have been investigating the efficacy of CR programmes 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 programmes.

Secondly, several authors have expressed serious concerns over the inclusion of lesser quality studies in systematic reviews and meta-analyses.[57–59] In an attempt to address this, we controlled for study quality by independently analysing 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.[58]

Thirdly, several authors have voiced concern over the inadequate way in which the content of behavioural interventions tends to be reported in the literature.[13,60,61] Not only do intervention descriptions often fall short of describing exactly which behaviour 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[60] or Schulz and colleagues.[62]

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,[63] 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.[64] However, the extra time, effort, and complexity involved in obtaining and analysing raw patient data requires a new infrastructure and, most probably, a shift in scientific mentality.

## Conclusions

The evidence summarized in this meta-analysis suggests benefit from recent lifestyle modification programmes (1999–2009) for multiple outcomes, over and above improvements achieved by routine clinical care alone. Furthermore, our findings suggest that programmes using all four SR techniques of behaviour change (i.e. goal setting, self-monitoring, planning, and feedback) were more successful in changing lifestyle behaviours than programmes 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 programmes should therefore incorporate psychological techniques and

strategies that specifically target relapse prevention and maintenance of behaviour change.

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## Conflict of interest

The authors declare that there is no conflict of interest.

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