

# Psychological interventions for coronary heart disease (Review)

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[Intervention Review]

# Psychological interventions for coronary heart disease

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## ABSTRACT

### Background

Psychological interventions can form part of comprehensive cardiac rehabilitation programmes (CCR). These interventions may include stress management interventions, which aim to reduce stress, either as an end in itself or to reduce risk for further cardiac events in patients with heart disease.

### Objectives

To determine the effectiveness of psychological interventions, in particular stress management interventions, on mortality and morbidity, psychological measures, quality of life, and modifiable cardiac risk factors, in patients with coronary heart disease (CHD).

### Search strategy

We searched CCTR to December 2001 (Issue 4, 2001), MEDLINE 1999 to December 2001 and EMBASE 1998 to the end of 2001, PsychINFO and CINAHL to December 2001. In addition, searches of reference lists of papers were made and expert advice was sought.

### Selection criteria

RCTs of non-pharmacological psychological interventions, administered by trained staff, either single modality interventions or a part of CCR with minimum follow up of 6 months. Adults of all ages with CHD (prior myocardial infarction, coronary artery bypass graft or percutaneous transluminal coronary angioplasty, angina pectoris or coronary artery disease defined by angiography). Stress management (SM) trials were identified and reported in combination with other psychological interventions and separately.

### Data collection and analysis

Studies were selected, and data were abstracted, independently by two reviewers. Authors were contacted where possible to obtain missing information.

### Main results

Thirty six trials with 12,841 patients were included. Of these, 18 (5242 patients) were SM trials. Quality of many trials was poor with the majority not reporting adequate concealment of allocation, and only 6 blinded outcome assessors. Combining the results of all trials showed no strong evidence of effect on total or cardiac mortality, or revascularisation. There was a reduction in the number of non-fatal reinfarctions in the intervention group (OR 0.78 (0.67, 0.90), but the two largest trials (with 4809 patients randomized)

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were null for this outcome, and there was statistical evidence of publication bias. Similar results were seen for the SM subgroup of trials. Provision of any psychological intervention or SM intervention caused small reductions in anxiety and depression. Few trials reported modifiable cardiac risk factors or quality of life.

### Authors' conclusions

Overall psychological interventions showed no evidence of effect on total or cardiac mortality, but did show small reductions in anxiety and depression in patients with CHD. Similar results were seen for SM interventions when considered separately. However, the poor quality of trials, considerable heterogeneity observed between trials and evidence of significant publication bias make the pooled finding of a reduction in non-fatal myocardial infarction insecure.

## PLAIN LANGUAGE SUMMARY

**It is unclear whether stress management and other forms of psychological intervention for people with heart disease reduces heart attacks, anxiety or depression, but it is thought that their inclusion in rehabilitation programmes may help**

Stress management training aims to help people cope with stress. It is often included in rehabilitation for people following heart attack or cardiac surgery. The aim is to reduce stress, often apparent through high levels of anxiety and depression, and prevent further heart attacks. The review found there are not enough trials to show whether stress management training is effective on its own. When combined with other education and exercise strategies in rehabilitation, or given in the context of other psychological interventions, there was a reduction in anxiety and depression but no strong evidence of any effect on a reduction in heart attacks.

## BACKGROUND

Coronary heart disease is the single leading cause of death for both men and women in developed countries, for example in England accounting for one in four male deaths and one in six female deaths (BHF 2003). Many, but by no means all (Davidson 1995), of the two thirds of patients who survive their myocardial infarction (MI) or who have cardiac surgery, will be offered some form of cardiac rehabilitation. The nature of the intervention available differs between centres, with the majority involving a combination of a short-term exercise programme and health education (Maes 1992).

Less frequently available as part of cardiac rehabilitation and secondary prevention are psychological interventions aimed at reducing risk factors and increasing effective coping. These interventions are numerous and often ill-defined, and include interventions such as risk factor counseling and psychotherapy. In contrast, interventions which include some form of stress management are well defined, are skills-based, and aim to teach patients to cope more effectively with stress. They typically involve the use of relaxation either alone or, potentially more powerfully, in combination with a variety of cognitive or behavioural strategies (Meichenbaum 1985), including problem-solving skills, and cognitive self-instruction or restructuring techniques.

Research focusing on the effectiveness of stress management interventions for coronary heart disease has focused on two research questions. Firstly, does the use of stress management techniques reduce the stress or distress associated with a cardiac event? Secondly, do these procedures reduce the risk of further clinical events? The latter hypothesis is premised on the assumption that stress contributes to risk for further events either directly or as a function of potentially stress-related behaviours such as smoking (Parrott 1995; Todd 1996). Another series of studies have focused on the use of stress management procedures in reducing the degree to which patients express Type A behaviour or hostility (Burrell 1986; Friedman 1986), a form of behaviour thought to be associated with coronary heart disease (Bennett 1990).

A narrative review of the effectiveness of these procedures focusing on the use of stress management procedures in post-MI patients concluded that the majority of programmes targeted at reducing Type A behaviours, or which taught stress management techniques, may have been effective in reducing psychological distress and increasing effective coping, although frequently only in the short-term (Bennett 1994). However, there was at that time little evidence that such changes afforded benefits in terms of coronary heart disease mortality or morbidity. Several overviews of studies evaluating the effectiveness of psychological interventions on clinical outcome have been published more recently (Dusseldorp

1999; Linden 1996; West 1995). Each overview differs in its selection of studies depending on publication date and the different definitions of the psychological interventions under evaluation. The earliest overview found a beneficial effect of the intervention on mortality, but also reported significant heterogeneity between trials and cautioned against the significance of pooling small studies (West 1995). Similarly, Linden and colleagues (Linden 1996) found that patients who did not enter a psychosocial programme were significantly more likely to experience a death or a cardiac recurrence in the two years following their infarction than those who did. After this, any protective effect was weaker. A significant reduction in both cardiac mortality and recurrence of MI was also reported in the most recent meta-analysis (Dusseldorp 1999). However, none of these reviews were fully systematic in their coverage, and some included non-randomised studies. In addition, these reviews did not disaggregate differing psychosocial interventions such as counseling (Dracup 1984), case-management (DeBusk 1994), risk behaviour education (including advice on smoking and diet) (Horlick 1984; Karvetti 1981) and what they term stress management trials (Gillis 1993; Mitsibounas 1992) in their analyses. Accordingly, these data provide no definitive measure of the effectiveness of stress management procedures in patients with coronary heart disease, and therefore a further systematic review is indicated addressing the above issues.

## OBJECTIVES

To determine the effectiveness of psychological interventions, and in particular stress management training, in patients with CHD. Principal outcome measures included CHD-related morbidity and mortality, measures of psychological well-being, and modifiable cardiac risk factors.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Randomised controlled trials with parallel group design.

#### Types of participants

Adults of all ages with CHD. Patients included those who had experienced a myocardial infarction (MI), a revascularisation procedure (coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA)), those with angina, or angiographically defined CHD.

### Types of interventions

All non-pharmacological psychological interventions delivered by health care workers with specific training in these techniques were considered. Trials were only considered where the comparison group was usual care/no intervention. Usual care could include other components of cardiac rehabilitation (e.g. exercise, health education) only if the intervention was usual care plus the psychological intervention. Trials were only considered where the follow up was 6 months or more following the start of the intervention. Trials reporting the use of stress management procedures were identified. Stress management was defined as the use of specific cognitive behavioural strategies used to help the patient reduce, or manage, their stress. These included learning relaxation, the use of cognitive techniques such as self-instruction training (Meichenbaum 1985) and cognitive challenge (e.g. Beck 1997), and/or consideration of specific coping strategies to be used at times of stress. Less specific therapeutic approaches including counseling, psychodynamic, or educational interventions were excluded from this definition, as were self-management techniques used to change risk factors such as smoking and low levels of exercise that were not specifically targeted at stress reduction. The cognitive behavioural treatment of other aversive mood states including anger and depression are also excluded. Stress management trials were reported in combination with other psychological interventions and also reported separately.

### Types of outcome measures

#### Primary outcomes

All-cause and CHD-related mortality

MI, CABG, PTCA

Anxiety, Depression, measures of stress and Type A behaviour/hostility

#### Secondary outcomes

Modifiable cardiac risk factors (blood pressure and serum cholesterol levels, smoking)

Health related quality of life

### Search methods for identification of studies

The Cochrane Controlled Trials Register (CCTR) was searched to December 2001 (Issue 4 2001) using the search strategies outlined below. This was updated by searching MEDLINE 1999 to the end of 2001 on Ovid using a standard RCT filter (Dickersin 1994) and EMBASE 1998 to the end of 2001 using an EMBASE RCT filter (Lefebvre 1996). PsychINFO and CINAHL were also searched from the earliest date available to December 2001 using the search terms outlined below. In addition, searches of reference lists of papers were made and expert advice was sought. No language restrictions were applied.

#### CCTR search strategy

MYOCARDIAL-ISCHEMIA\*:ME

CORONARY-ARTERY-BYPASS\*:ME  
 (ISCHEMI\* near HEART)  
 (ISCHAEMI\* near HEART)  
 (CORONARY near DISEASE\*)  
 (CORONARY near BYPASS)  
 (CORONARY near THROMBO\*)  
 (CORONARY near ANGIOPLAST)  
 (CORONARY near ANGIOPLAST\*)  
 (MYOCARD\* near ISCHEMI\*)  
 (MYOCARD\* near ISCHAEMI\*)  
 (MYOCARD\* near INFARCT\*)  
 (HEART near INFARCT\*)  
 ANGINA  
 ((((((((((((((#1 or #2) or #3) or #4) or #5) or #6) or #7) or #8) or #9) or #10) or #11) or #12) or #13) or #14)  
 REHABILITATION\*:ME  
 REHABILITAT\*  
 PSYCHOTHERAPY\*:ME  
 COUNSELING\*:ME  
 RELAXATION-TECHNIQUES\*:ME  
 PSYCHOTHERAP\*  
 COUNSELING  
 COUNSELLING  
 RELAX\*  
 (BEHAVIOR\* near MODIF\*)  
 (BEHAVIOUR\* near MODIF\*)  
 (BEHAVIOR\* near THERAP\*)  
 (BEHAVIOUR\* near THERAP\*)  
 (COGNITIVE\* near THERAP\*)  
 (STRESS near MANAGE\*)  
 MEDITATION\*:ME  
 MEDITAT\*  
 ANXIETY:ME  
 (ANXIETY near MANAGE\*)  
 DISTRESS\*  
 PSYCHOPATHOLOGY\*:ME  
 PSYCHOPATHOL\*  
 AUTOGENIC-TRAINING\*:ME  
 AUTOGENIC\*  
 HEALTH-EDUCATION\*:ME  
 (HEALTH near EDUCAT\*)  
 (PATIENT near EDUCAT\*)  
 (SELF near MANAGE\*)  
 PSYCHOEDUCAT\*  
 ((((((((((((((((((((((((((#15 or #16) or #17) or #18) or #19) or #20) or #21) or #22) or #23) or #24) or #25) or #26) or #27) or #28) or #29) or #30) or #31) or #32) or #33) or #34) or #35) or #36) or #37) or #38) or #39) or #40) or #41) or #42) or #43) or #44)  
 (#45 and #46)

## Data collection and analysis

From the searching, titles and abstracts were examined by two reviewers (SE, PB or KR), potentially relevant references were then retrieved. Two reviewers (KR, PB) then independently selected trials to be included in the review, by the use of a 7-question inclusion/exclusion form. In all cases disagreements about any study inclusions have been resolved by consensus among the authors and a third reviewer was consulted if disagreement persisted. Once studies had been formally included in the review, data were abstracted independently by two reviewers (KR, PB), and chief investigators were contacted where necessary to provide additional information. Trials included in the review were then divided into those reporting a stress management intervention determined from the reported methods section, and other psychological interventions. Agreement between co-reviewers was sought on what constituted a stress management intervention.

In addition to study outcome data, the quality of trials was assessed independently in terms of concealment of allocation, losses to follow up and blind assessment of outcomes. Data concerning patient characteristics; age, sex, type of CHD, identified levels of psychopathology as selection criteria, and details of the intervention, and length of follow up, were also collected as stated a priori with the intention of performing stratified analysis of the data using meta-regression.

Dichotomous outcomes for each study have been expressed as odds ratios and 95% confidence intervals (CI). Continuous variables have been expressed as the mean change from baseline to follow up, and the standard deviation difference from baseline to follow up for each comparison group. Where standard deviation differences have not been reported in the source papers, allowance has been made for within patient correlation from baseline to follow up measurements by using the correlation coefficient between the two (Cochrane Heart Group; Follmann 1992). A weighted mean difference (WMD) or standardised mean difference (SMD) and 95% CI have been calculated for each study. Data from each study were pooled as appropriate using a fixed effect model, except where substantial heterogeneity existed according to the Z statistic, and a random effects model was used (where a random effects model was used this is indicated in parentheses). For outcomes where there was insufficient data or where it was inappropriate to combine studies statistically, a qualitative overview is presented. Sensitivity analyses were carried out, excluding studies of low methodological quality.

## RESULTS

### Description of studies

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

From the searching, 6535 studies were found, the title and abstracts of these were screened and 331 went forward for formal inclusion or exclusion. 36 trials met the inclusion criteria with 12841 patients randomised. Of these 36 trials, 15 report a psychological intervention in isolation, and 20 report a psychological intervention plus other rehabilitation interventions. For the majority of trials the comparison group was usual medical care as defined in the paper; 6 trials fell into the category of psychological intervention plus other rehabilitation intervention versus other rehabilitation intervention.

Eighteen of the 36 included trials evaluated stress management interventions as determined from the methods reported in the paper, with 5242 patients randomised. Of these 18 trials, 7 report a stress management intervention in isolation, and 11 report a stress management intervention plus other rehabilitation interventions. Details of the studies included in the review are shown in the table of characteristics of included studies. Reasons for exclusion for the majority of studies included study design, primary rather than secondary prevention programmes, and the follow up period being less than 6 months. Details and reasons for exclusion for the studies which most closely missed the strict inclusion criteria are presented in the table of excluded studies.

The majority of included trials studied CHD patients with no identified levels of psychopathology prior to randomisation. Four trials did however use this as an inclusion criteria ([Black](#); [Brown](#); [ENRICHD](#); [Stern](#)), where thresholds were derived from the Global Severity Index of the Symptom Checklist 90 revised (greater than 63 and 70 respectively for [Black](#) and [Brown](#)), the Beck depression scale (greater than 13 - [Brown](#)), the Taylor Manifest Anxiety Scale and Zung Depression Scale (greater than 19 and 40 respectively - [Stern](#)), and the Hamilton rating scale for depression ([HAM-D](#); [ENRICHD](#)). One study had more than one psychological intervention group ([Johnston](#)). In this case, the intervention group was taken as the inpatient programme and not the extended programme as the latter was added purely as a comparison to the former, and not to usual medical care.

## Risk of bias in included studies

The methodological quality of the included studies are presented in [Table 1](#). The methodological quality of trials in terms of the method of randomisation, allocation concealment, blinding of outcome assessors and losses to follow up, is as reported in the papers. For the majority of studies, both the method of randomisation, and method of allocation concealment were unclear. Several studies used block randomisation where the unit of randomisation was the ward for example, to prevent contamination between the intervention and control groups ([Burell](#); [Elderen](#); [Ibrahim](#); [Johnston](#); [Oldenburg 1985](#); [Oldenburg 1995](#); [Stern](#)). For 4 of these 6 studies, the method of allocation concealment was not

optimal, where allocation was alternate, based on days of the week, or date of admission ([Ibrahim](#); [Johnston](#); [Oldenburg 1985](#); [Oldenburg 1995](#)). Only 6/36 studies report that outcome assessors were blind to group allocation. Losses to follow up varied from none to 63%. Using an arbitrary cut-off of 20%, 8/36 studies reported a greater than 20% loss to follow up.

## Effects of interventions

### All psychological interventions

Whether a psychological intervention contained a stress management component was determined from the reported methods section of published papers and therefore could not be used as a robust inclusion criteria as we were limited by the description provided by the investigators. For this reason, all trials identified reporting a psychological intervention have been examined, and results are compared with the subgroup we identified as being stress management trials. Results are presented for all trials - any psychological intervention +/- other rehabilitation versus usual care/other rehabilitation.

### Clinical events

When considering all included trials reporting any psychological intervention, there was no strong evidence of any effect of the intervention on total mortality in the 22 trials (10634 patients) reporting this as an outcome (pooled effect estimate OR 0.93, 95% CI 0.81 to 1.06). Cardiac mortality was reported in 11 trials (7544 patients) where similarly there was no strong evidence of a reduction in the intervention group (OR 0.86, 95% CI 0.72 to 1.03).

There was a statistically significant 22% reduction in non-fatal myocardial infarction in the intervention group in the 18 trials (10200 patients) reporting this outcome (OR 0.78 95% CI 0.67 to 0.90).

Revascularisation was reported as the combined outcome of CABG and PTCA. The pooled effect estimate for this outcome for the 15 trials (8368 patients) reporting it was OR 0.87 95% CI (0.67 to 1.13 - random effects model).

Significant heterogeneity of effects were seen for some of these clinical outcomes, and there was evidence of publication bias for the non-fatal myocardial infarction findings (see below). The evidence was dominated by two large trials ([ENRICHD](#), [Jones](#)), both of which produced null findings for all clinical outcomes.

### Modifiable cardiac risk factors

Total cholesterol was measured in only 9 trials overall (1525 patients) where a statistically significant reduction was seen with the intervention (WMD -0.27 (-0.55 to 0.0) random effects model). No significant results were seen for LDL or HDL cholesterol, or triglycerides.

Blood pressure was reported in only 5 trials (805 patients) where significant heterogeneity was seen between trials, showing favourable effects in 3 trials, and harmful effects in 2 trials. Similarly, heterogeneity was seen between trials reporting smoking as



an outcome (8 trials, 3690 patients randomised), with the largest trial containing over 60% of the weight in the meta-analysis showing a null effect (Jones).

### **Psychological outcomes**

Anxiety was measured in only 9 trials (2756 patients) overall using a number of different measures. Pooled results are presented as standardised mean differences (SMD) to take account of the number of different scales used. A small but statistically significant reduction in anxiety with the intervention was seen, where the SMD was -0.08 (-0.16 to -0.01).

Depression was measured in 11 trials overall (4535 patients), again using a number of different measures. There was significant heterogeneity between trials. Across all trials there was a significant reduction in depression (SMD -0.3 (-0.48 to -0.13) random effects model).

Several studies reported composite measures for anxiety, depression and mental health, and these form a separate category. For the 5 trials overall (347 patients) there is a significant beneficial reduction (SMD -0.22 (-0.44 to -0.01).

### **Publication bias**

Evidence of publication bias using both total mortality and non-fatal MI as outcomes for any psychological intervention was examined both visually in the form of funnel plots, and statistically (Egger 1997). There was evidence of significant publication bias for non-fatal reinfarction (Egger test, bias coefficient = -0.98,  $p = 0.03$ ), but not for total mortality (Egger test, bias coefficient = 0.3,  $p = 0.37$ ).

### **Stress management interventions**

Results for the 18 trials which were identified as those including some form of stress management, were divided into stress management intervention versus usual care, stress management intervention plus other rehabilitation versus usual care and stress management intervention plus other rehabilitation versus other rehabilitation, as reported in the source papers. However, the number of trials in each category were small and hence pooled findings were underpowered and represent multiple comparisons increasing the risk of false positive findings. Results have therefore been presented as those 18 trials with any stress management intervention +/- other rehabilitation versus usual care/other rehabilitation.

### **Clinical Events**

When considering all stress management trials, there was no strong evidence of effect of the intervention on total mortality in the 10 trials (3425 patients) reporting this as an outcome (OR 0.88, 95% CI 0.67 to 1.15). Cardiac mortality was reported in 4 trials where weak evidence of a reduction in the number of deaths was seen in the intervention group (pooled effect estimate OR 0.62, 95% CI (0.38 to 0.99)), and of a 31% reduction in non-fatal myocardial infarction in the intervention group in the 8 trials (3990 patients) reporting this outcome (OR 0.69 95% CI 0.52 to 0.92). One of these 8 trials recruited patients with identified levels of psychopathology prior to randomisation (Stern). Only one of these 8 trials examined the effects of a stress management intervention

without the influence of other rehabilitation interventions (Jones). Revascularisation was reported as the combined outcome of CABG and PTCA. The pooled effect estimate for this outcome for the 7 trials (3025 patients) reporting it was OR 0.82, 95% CI (0.42 to 1.62 - random effects model).

### **Modifiable Risk Factors**

Total cholesterol was measured in only 4 trials overall (634 patients) where no effect of the intervention was seen (WMD 0.02 (-0.12 to 0.15)). Similar results were found for LDL and HDL cholesterol, and triglycerides.

Blood pressure was reported in only 2 trials (468 patients) which showed significant heterogeneity and no overall effect of the intervention was seen.

The number of smokers at follow-up were reported in 3 trials (2472 patients), and all had a similar baseline prevalence in the intervention and control groups. There was no evidence of any benefit of intervention (OR 1.03, 95% CI (0.85, 1.24))

### **Health Related Quality of Life (HRQoL)**

HRQoL was reported in 5 trials overall using several different instruments. Results are reported qualitatively in Table 2. Two trials showed benefit of the intervention, where Johnston found significant effects on QoL using the Functional Limitations Profile, and Oldenburg 1985 found improvements in 1 of 4 factors on the Heart Attack Inventory identified from Principal Components Analysis (psychosocial dysfunction factor).

### **Psychological outcomes**

Anxiety was measured in 7 trials overall using a number of different measures. These included the Taylor Manifest Anxiety Scale (Burgess; Stern; Taylor 1953), Spielberger State-Trait Anxiety Inventory (HofmanBang; Oldenburg 1995; STAI 1970), Hospital Anxiety and Depression Scale (HAD 1983; Johnston; Lewin), and the Personal Disturbance Scale (Jones) devised by Bedford, Foulds and Sheffield (Bedford 1976). Pooled results are presented as standardised mean differences (SMD) to take account of the number of different scales used. For the 7 trials overall (2651 patients) there was only weak evidence of a small decrease in anxiety with the intervention (SMD -0.07 (-0.15, 0.01)).

Depression was measured in 8 trials overall again using a number of different measures. These included the Zung depression scale (Burgess; Stern; Zung 1965), the depression score from the symptom checklist 90 revised (SCL-90-R) (Black; SCL-90-R), Hospital Anxiety and Depression Scale (Johnston, Lewin), Beck Depression Inventory (Beck 1961; HofmanBang), the Personal Disturbance Scale of Bedford et al (Jones), and the Centre for Epidemiological Studies Depression Scale (CES-D) (CES-D 1977; Toobert). Pooled results are presented as SMD. For the 8 trials overall (2642 patients) there was evidence of a reduction in depression scores in the intervention group (SMD -0.32 (-0.56 to -0.08) - random effects model). Results are dominated by one large trial (Jones) which showed a null effect, and hence significant heterogeneity between studies.

Several studies reported composite measures for anxiety, depres-

sion and mental health. Scales included the Global Severity Index of the SCL-90R (Black, Brown), the depression, anxiety and somatization scales of the SCL-90R (Oldenburg 1995), Impact of events scale (Burgess; Horowitz 1979) and the mental health component of the medical outcomes study short form SF36 (MOS-36) (MOS SF36; Toobert). Pooled results are presented as SMD. For the 5 trials overall (347 patients) there was evidence of a reduction (SMD -0.22 (-0.44 to -0.01)).

Other psychological outcomes measured included stress and Type A attitudes. Results are presented qualitatively in Table 3. Perceived stress was measured in 2 trials, where one showed no effect of the intervention (Toobert) and the other showed a significant reduction with the intervention (Gallacher). The total Derogatis Stress Profile scores (Derogatis 1987) were also significantly reduced in the intervention group in this latter trial (Gallacher). Type A attitudes were measured in two trials. Differences with the intervention were shown in only one of several measures in one trial (HofmanBang), but the Recurrent Coronary Prevention Project (RCCP), showed significant reductions in Type A behaviour when assessed by video taped clinical interview and participant questionnaire.

## DISCUSSION

The current systematic review differs from those previously conducted in this area (Dusseldorp 1999; Linden 1996; West 1995) in a number of respects. The search strategy used was more extensive with no language restrictions and includes more recent trials than previous reviews. We have also attempted to identify those trials evaluating some form of stress management from other psychological interventions. To avoid selection bias which may be introduced when using reported details of the interventions as part of the inclusion criteria, we have attempted to identify all trials reporting psychological interventions, and then identify from these a subgroup of stress management trials to compare the overall effects. Stress management was defined as training in the use of core stress management techniques: relaxation alone or in combination with cognitive strategies and/or problem solving skills. Interventions including discussion of issues or venting emotions were not included in this subgroup.

The trials identified for inclusion within this review were extremely heterogeneous. Within the stress management subgroup, some trials evaluated stress management as a single intervention, and others evaluated stress management as part of a comprehensive cardiac rehabilitation programme (CCR). For the majority of trials the control group was usual medical care. However, we also included some trials where the control group was another component of CCR if it also formed part of the non-stress management component of the intervention. Most trials recruited patients without identified levels of psychopathology prior to randomisation. Due

to the small number of trials reporting particular outcomes for each of these above categories, results have been presented as the combined result for all trials identified as having a stress management intervention. Whilst presenting the data in this way allows us to estimate an overall summary effect estimate, the effectiveness of the stress management intervention per se is difficult to separate from the effectiveness of other rehabilitation interventions, a problem in common with all evaluations of complex health-care interventions. While stress management may be considered more appropriate for post-MI patients due to the proposed aetiological links between stress and coronary heart disease (Stansfeld 2002), such observational association evidence is prone to bias and a range of interpretations (Macleod 2002). Similar observational evidence also supports an association between depressed mood and anxiety and coronary heart disease (Barefoot 1996; Ford 1998; Hemingway 1999). It may therefore be inferred that both stress management and more general psychological interventions aiming to reduce depression and anxiety would be helpful in reducing recurrent cardiovascular events.

Other sources of heterogeneity include patient type, with some patients receiving the intervention post MI, some post surgery, and include also patients with angina and chronic CHD. Similarly, trial quality, the type and intensity of intervention, and length of follow up differ between trials. It was our intention to assess these areas of heterogeneity by performing stratified analysis of the data with meta-regression, however, this was problematic due to limited information, particularly with regard to trial quality, and also because of the relatively small number of trials.

Overall, results from the stress management subgroup are consistent with those for all psychological interventions. The primary outcomes of interest were clinical events and psychological variables. We could find no evidence of a reduction in total mortality in trials of all psychological interventions, or those reporting the effects of stress management. There was some evidence of a reduction in non-fatal reinfarction in the intervention group when considering all psychological trials and stress management interventions. However, for all psychological interventions there was evidence of significant publication bias for this outcome due to the two largest trials representing nearly 50% of the weight in the meta-analysis showing no evidence of effect. The fact that differences in the effect size were seen between total mortality and non-fatal reinfarction also suggests that there may be ascertainment or measurement bias associated with non-fatal events which may have arisen due to failure to blind outcome assessors and the low quality of reporting of concealment of allocation.

Psychological outcomes were reported in relatively few trials. Results have been divided into anxiety, depression, composite psychological outcomes (reporting anxiety and depression together, and/or mental health), and others (stress and type A behaviour). Results have been expressed as standardised mean differences to take account of the number of different scales used. Small but

significant beneficial effects were seen on anxiety for both all psychological interventions, and the stress management subgroup. A similar pattern was seen for composite psychological outcomes. Depression was significantly reduced in both all psychological interventions and the stress management subgroup overall. Significant heterogeneity is seen for this outcome, due to the large trial reporting a single modality stress management intervention which showed a null effect (Jones). Cautious interpretation of the effect of stress management interventions on depression is therefore required.

Very few trials reported modifiable cardiac risk factors (lipid levels, blood pressure, smoking), and whilst there were no suggestions for an effect of stress management interventions, no conclusions can be drawn.

There was substantial heterogeneity between trials included in this review. Much of this is attributable to the findings of the two large, well-conducted trials (Jones, ENRICH) which produced null findings. Differences in findings in this review and those of previous reviews are mostly attributable to differences in trial inclusion, and in particular, inclusion of the recently completed ENRICH trial. The current review aims to identify trials of clearly defined stress management interventions in an attempt to separate out the evaluation of these from other psychological interventions.

## AUTHORS' CONCLUSIONS

### Implications for practice

Overall, the current evidence suggests that psychological interventions for patients with CHD have small beneficial effects on anxiety and depression, but no effect on total or cardiac mortality. The apparent effect on non-fatal myocardial infarction may be due to publication or ascertainment bias. The small number of trials evaluating the effectiveness of stress management as a single intervention preclude strong implications for practice. Combined psychological interventions appear more likely to result in appropriate

behavioural change which in itself is worth achieving. We were unable to examine whether stress management interventions may be more effective when focused on those patients with evidence of high distress in the current review due to the small number of trials including such patients.

### Implications for research

Trials with a stress management component intervention showed weak evidence of a reduction in anxiety and depression. However, the findings arose principally from small trials that include other rehabilitation interventions, and the possibility that these interventions, rather than stress management, are the effective intervention(s), cannot be excluded. No evidence of effect was seen for all cause or cardiac mortality, and inconclusive effects were seen for non-fatal reinfarction. Following the results of two large negative RCTs - one of stress management (Jones) and the other of psychological intervention (ENRICH), it is doubtful that further similar trials of these interventions for clinical outcomes are needed or will be conducted. Negative trials that have not been published should be presented in the public domain to aid future research synthesis. Any future trials in this area need to be more careful to avoid sources of bias by using better designs. Further work evaluating stress management as defined in this review and other psychological interventions should focus on those patients with psychological distress who may benefit and attempt to achieve sufficiently intensive intervention to alter psychological outcomes. If promising interventions are found, it may then be worth testing them in larger trials for effects on recurrent clinical events.

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\* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

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

#### Allison

Methods	RCT
Participants	Unstable angina. Patients randomised post discharge from hospital admission for acute chest pain. Only those patients deemed to be of intermediate or high risk were randomised. Intervention started 6-10 days post discharge. No identified levels of psychopathology prior to intervention. 441 patients randomised, 56% male, mean age 58 years
Interventions	Nurse led counselling on exercise, diet and smoking cessation, referrals and drug management. Individual risk reducing plan developed for each patient. One hour appointment 6-10 days post discharge, and at 25-35 days, final follow up 24-28 weeks post discharge. Control group received usual medical care
Outcomes	Clinical events (cardiac mortality, MI, CABG)
Notes	

#### Black

Methods	RCT
Participants	Acute CHD events (MI, revascularisation, angina), patients randomised within 3 months of hospital stay. Identified levels of psychopathology as selection criteria, threshold-Global Severity Index T score $\geq 63$ (of the symptom checklist 90 revised). 60 patients randomised, mean age 60.2 years, 88% men
Interventions	Includes stress management intervention. Complex psychological intervention plus other rehabilitation interventions. All patients received CCR, the intervention group received also 1 or more of the following: individualised relaxation training, SM, efforts to reduce behavioural risk factors, efforts to increase compliance, and cognitive-behavioural interventions for identified anxiety/depression/hostility. 1-7 weekly sessions with a clinical psychologist. Follow-up 21 months
Outcomes	Clinical events (total mortality, MI, CABG, PTCA combined), anxiety and depression
Notes	Contacted authors for breakdown of clinical events and depression scores and GSI at baseline and 12 months

#### Brown

Methods	RCT
Participants	MI or CABG within 4-24 months. Identified levels of psychopathology as selection criteria, threshold - 13+ on the Beck Depression Scale, or 70+ on the global severity index. 54 patients randomised, mean age 60.7, 54% men. Patients were older, and there were more women in the intervention group. Patients recruited from CR departments, newspapers and ads

**Brown** (Continued)

Interventions	Includes stress management intervention. Complex psychological intervention. Intervention included relaxation, cognitive restructuring, assertion anger management and time management, administered by clinical psychologist and psychiatrist. One group session of 1 hour per week, for 12 weeks. Partners were also trained to give positive feedback and reinforcement. Control group had time with therapists where they received non-specific treatment effects of encouragement and reassurance, excluding key behaviour therapies. Follow-up 15 months
Outcomes	Anxiety, depression.
Notes	

**Burrell**

Methods	Multicentre RCT. Block randomisation.
Participants	CABG patients, randomised 3-12 months post surgery. No identified levels of psychopathology prior to intervention. 261 patients randomised, mean age 57.5 years, 86% men
Interventions	Includes stress management intervention. Complex psychological intervention plus other rehabilitation interventions. Intervention comprised group sessions aimed at modifying coronary prone behaviour, and emotional distress, and improving stress management and coping skills. Intervention administered by a clinical psychologist, 17 sessions of 180 minutes, in year 1, and 5-6 booster sessions in years 2 and 3. Both intervention and control groups also had access to CR programmes offered by their hospital, and no attempt was made to interfere with routine medical care. Follow up 5-6.5 years post surgery
Outcomes	Total and cardiac mortality, non-fatal MI, CABG (re operation), PTCA, self reported type A behaviour
Notes	

**Burgess**

Methods	RCT
Participants	Acute MI, intervention started 1 week pre-discharge. No identified levels of psychopathology prior to intervention. 180 patients randomised, mean age 51 years, 85% men
Interventions	Includes stress management intervention. Complex psychological intervention. Intervention comprised 3 parts: cognitive behavioural intervention model to limit patient distress; minimising social network strain by offering guidance and moral support to spouse; facilitate job re-entry. Intervention administered by trained nurse clinicians, home visits, each patient receiving an average of 2.77 visits over a 3 month period. Both intervention and control patients also had access to CCR, but this was limited in scope as recently developed. Follow up 13 months
Outcomes	Total mortality, anxiety and depression.
Notes	

**Cowan**

Methods	RCT
Participants	Survivors of out of hospital VF or asystole. No identified levels of psychopathology prior to intervention. 133 patients randomised, 73% men, no age given
Interventions	Includes stress management intervention. Psychosocial intervention with 3 components - physiologic relaxation with computerised biofeedback training to reduce HR and RR; cognitive behavioural therapy aimed at self management and coping strategies for anxiety, depression and anger; HE focused on CMV risk factors. Control group received usual medical care. Each patient received 11 sessions of 90 minutes, twice a week. Follow up period - 2 years
Outcomes	Total mortality, cardiac mortality, non-fatal MI
Notes	

**Debusk**

Methods	RCT
Participants	Acute MI, patients randomised on day 3 post event. No identified levels of psychopathology prior to intervention. 585 patients randomised, 79% men, mean age 57 years
Interventions	Comprehensive cardiac rehabilitation. Special intervention included behavioural interventions derived from social learning theory, where patients learn how to monitor health habits they seek to change and set attainable goals. Focus on coronary risk factor modification. Physician led, nurse managed, home based case management system. Nursing effort approximately 9 hours contact per patient over a 12 month period. Maximum of 14 phone contacts, 8 patient visits to outpatients and 4 patient visits to the nurse manager. Control group received some rehabilitation but not the special intervention. Duration of follow up - 12 months
Outcomes	Total and cardiac mortality, non-fatal MI, CABG/PTCA, smoking and serum cholesterol
Notes	

**Elderen**

Methods	RCT. Block randomisation.
Participants	Acute MI, patients randomised before hospital discharge. No identified levels of psychopathology prior to intervention. 60 patients randomised, 82% men, mean age 57 years
Interventions	Individual counselling whilst in hospital. Group counselling/health education including risk factors, anxiety and depression, medication (two 90 minute sessions). Phone contact by nurse once a week for reassurance and reinforcement for 6 weeks post discharge. Control group received usual medical care. Follow up at 12 months
Outcomes	Smoking, anxiety and depression.
Notes	

**ENRICHD**

Methods	Multicentre RCT
Participants	Recruited when recovering from an acute MI. Identified levels of depression prior to the intervention formed part of the inclusion criteria. 2481 patients were randomised, 66% men, mean age 61 years
Interventions	Programme aims to reduce depression and increase social support by using cognitive behavioural therapy and pharmacotherapy if indicated. Referral to cardiac rehabilitation/support groups by patients own physician was considered to be usual care, and was available for both intervention and control patients. Intervention consisted of individual and group therapy, number of sessions per patient was variable, but intervention did not last longer than 6 months. Mean follow up was 41 months
Outcomes	Total mortality, non-fatal MI Measures of depression and social support. (Full data not yet available)
Notes	

**Erdman**

Methods	RCT
Participants	MI within previous 6 months. No identified levels of psychopathology prior to intervention. 80 patients randomised, mean age 51 years, all men
Interventions	Includes stress management intervention. Complex psychological intervention plus other rehabilitation interventions. Intervention included relaxation exercises and counselling on risk factors, how to cope with emotional distress, and modification of type A behaviour. Intervention administered by a psychologist. Patients also followed an exercise rehabilitation programme. Both interventions involved group sessions, 2/week of 120 Min, for 6 months. Control group received advice on risk factors and physical fitness training. Follow-up 5 years
Outcomes	Psychologic scale including well being, despondency, and social inhibition
Notes	

**Frasure Smith**

Methods	RCT
Participants	MI patients. Patients randomised irrespective of identified levels of psychopathology, but intervention recieved only by those who had 5 plus symptoms on the GHQ when screened each month. 769 patients randomised, , 230 excluded post randomisation, 78 refused, leaving 461 who started the programme. All male patients, mean age 58 years
Interventions	Patients phoned once a month for 6 months and asked to respond to questions from the GHQ as an index of cognitive behaviour and stress. Those with 5 or more symptoms on the GHQ were visited at home by a nurse and recieved an individually tailored combination of teaching and support, referral and consultation strategies. The visits continued until the problem resolved. Average duration of sessions was 1 hour, average number of sessions was 5 over the 6 month period (for approximately half of the patients in the intervention group who had 5 plus symptoms). Control group received usual medical care. Final follow up cut-off was 5 years (maximum of 8.3 years)

**Frasure Smith** (Continued)

Outcomes	Total mortality, cardiac mortality and non-fatal MI
Notes	Known as the IHD Life Stress Monitoring Programme.

**Frasure Smith 1997**

Methods	RCT
Participants	Acute MI, randomised at hospital discharge. Patients randomised irrespective of identified levels of psychopathology, but intervention received only by those who had 5 plus symptoms on the GHQ when screened each month. 1376 patients randomised, 66% men, mean age 59 years
Interventions	Same protocol as above. Intervention lasted for 12 months, follow up at 12 months
Outcomes	Total mortality, cardiac mortality, non-fatal MI, CABG, anxiety and depression
Notes	Known as the M-HART Study

**Fridlund**

Methods	RCT
Participants	MI patients, no identified levels of psychopathology prior to intervention. 178 patients randomised, mean age 56 years, 87% men
Interventions	Psychological intervention plus other rehabilitation interventions. Intervention included exercise and relaxation training, and the psychosocial component was divided into 2 intervention strategies: lifestyle and stress orientated and social support orientated. Intervention administered by psychologist, rehab nurse and physician. One group rehab session per week, 2 hours duration, for 6 months. Control group received usual medical care which included information on risk factors and discussions about return to work. Follow-up 12 months
Outcomes	Total mortality, non-fatal MI, CABG/PTCA, WHO questionnaire including anxiety, depression and anger
Notes	

**Gallacher**

Methods	RCT
Participants	Angina patients identified from 30 GP registers, prescribed nitrates or Ca <sup>2+</sup> antagonists. No identified levels of psychopathology prior to intervention. 452 patients randomised, all men
Interventions	Includes stress management intervention. Complex psychological intervention. Intervention comprised 3 group sessions of 1 hour duration, with 4 and 6 weekly intervals, and included relaxation, cognitive coping strategies and general strategies for managing lifestyle and problem solving, administered by a clinical psychologist. Each patient received a manual of reference material and were given "homework" to do between sessions. Control group received usual medical care. Follow-up 6 months

**Gallacher** (Continued)

Outcomes	Blood pressure, smoking, lipid levels, stress.
Notes	

**Gutschker**

Methods	RCT
Participants	Acute MI, patients randomised 28 days post MI. No identified levels of psychopathology prior to intervention. 382 patients randomised, all men, mean age 56 years
Interventions	Risk factor counselling, plus exercise training. Group therapy once a week for 13 weeks, then monthly for 2 years. Control group received usual medical care
Outcomes	Total and cardiac mortality, smoking.
Notes	German translation

**HofmanBang**

Methods	RCT
Participants	PTCA patients, patients received the intervention 1-2 weeks post surgery. No identified levels of psychopathology prior to intervention. 93 patients randomised, mean age 53 years, 84% men
Interventions	Includes stress management intervention. Complex psychological intervention plus other rehabilitation interventions. Intervention included training in applied relaxation, type A drills, behaviour changing activities such as SM, diet, exercise and smoking. Each patient was assigned a personal coach who was a specially trained nurse. Intervention administered during a 4 week residential stay, and continued with regular follow up checks. Control group received usual medical care. Follow-up 2 years
Outcomes	Total mortality, non-fatal MI, CABG, PTCA, smoking, lipid levels, anxiety, depression, anger
Notes	

**Ibrahim**

Methods	RCT
Participants	Post MI patients. No identified levels of psychopathology prior to intervention. 118 patients randomised in blocks of 12 to intervention or control. Allocation was alternate. Patients 35-65 years, mean age not stated, 90% men
Interventions	Group therapy sessions given by clinical psychologist once a week for a year, 1.5 hour sessions. The aim was to provide an atmosphere in which problems and solutions common to cardiac patients could be shared. Duration of follow-up was 18 months

**Ibrahim** (Continued)

Outcomes	Total mortality.
Notes	

**Johnston**

Methods	RCT Block randomisation
Participants	Acute MI, patients randomised within 72 hours of admission. No identified levels of psychopathology prior to intervention. 117 patients randomised, mean age 56 years, 65% men
Interventions	Includes stress management intervention. Complex psychological intervention plus other rehabilitation interventions. 2 intervention groups - an inpatient programme which comprised health education and individualised counselling and emotional support, including discussions on the effects of stress and how to manage it. Intervention administered by a nurse counselor. Inpatient programme comprised 5 sessions, average 3.7 hours with a counselor. The second intervention included the inpatient programme plus an extended programme over 6 weeks post discharge where most patients chose to discuss the resumption of normal activities. Control group received usual medical care. Follow-up 12 months
Outcomes	Total mortality, anxiety and depression, HRQoL
Notes	

**Jolly**

Methods	Cluster RCT of GP practices
Participants	Mix of MI and angina patients, recruited as in patients or those who had accessed a rapid access chest clinic within 3 months. No identified levels of psychopathology prior to intervention. 597 patients randomised, 71% men, mean age 63.5 years
Interventions	Practice nurses trained in theory behaviour change to provide follow up care between hospital discharge and attendance at cardiac rehabilitation. Each patient had a record with structured follow up, and prompts to discuss fears and anxieties, risk factors, medication and health behaviour. Visits to GP every 2 weeks for 2 months and then 3 monthly to follow up period of 12 months
Outcomes	Total mortality, blood pressure, smoking, serum cholesterol.
Notes	



**Jones**

Methods	Multicentre RCT
Participants	Acute MI, Patients randomised at hospital discharge. No identified levels of psychopathology prior to intervention. 2328 patients randomised, no age restriction, 73% men
Interventions	Includes stress management intervention. Complex psychological intervention. Intervention included taught relaxation and coping skills, psychological therapy and opportunities for individual and group counselling. Intervention administered by clinical psychologists and health visitors, 7 sessions of 2 hours duration. Control group received usual medical care. Follow-up 12 months
Outcomes	Total mortality, non-fatal MI, non-fatal stroke, CABG/PTCA, anxiety and depression
Notes	

**Lewin**

Methods	RCT
Participants	Acute MI, patients randomised 3 days post event. No identified levels of psychopathology prior to intervention. 190 patients randomised, mean age 55.8 years, 72% men
Interventions	Includes stress management intervention. Complex psychological intervention plus other rehabilitation interventions. Heart manual - home based programme, administered by trained facilitator. Tape based relaxation and stress management programme. Other interventions included exercise. Programme consisted of 6 weekly sections, and facilitator contacted patients at 1, 3 and 6 weeks for adherence checks and further information/support. Spouses given information and advice and asked to encourage patients to comply. Control group received leaflets and the same contact from the facilitator, but only enquired about recovery and offered general support and advice. Follow up - 12 months
Outcomes	Anxiety and depression.
Notes	

**Lidell**

Methods	RCT
Participants	Acute MI. No identified levels of psychopathology prior to intervention. 116 patients randomised, 87% men, mean age 56 years
Interventions	Comprehensive cardiac rehabilitation involving input from a psychologist - group discussions about lifestyle and health risks after MI, and psychosocial consequences of MI. One hour exercise and one hour discussion once a week for 6 months, plus home training programme. Control group received usual medical care. 5 years follow up
Outcomes	Total mortality, non-fatal MI, CABG/PTCA
Notes	

**McHugh**

Methods	RCT
Participants	Elective CABG patients, intervention administered whilst patients were on the waiting list for surgery. No identified levels of psychopathology prior to intervention. 121 patients randomised, 75.5% male, mean age 62 years
Interventions	Risk factor behavioural counselling based on the patients readiness to change. Intervention administered by cardiac liaison nurse and GP practice nurse prior to cardiac surgery. Intervention tailored to individual patient needs, consisting of monthly sessions. Follow up at admission for CABG, mean waiting time 8 months. Control group received usual medical care
Outcomes	Blood pressure, smoking, serum cholesterol, HRQoL.
Notes	

**Mitsibounas 1992**

Methods	RCT
Participants	Acute MI patients randomised 6-8 days post MI. No identified levels of psychopathology prior to intervention. 43 patients randomised, 88% men, mean age 53 years
Interventions	Psychosocial intervention aimed at resolving psychological conflicts to reduce the severity of risk factors post MI. Includes taught relaxation techniques. Group sessions for one hour every 2 weeks for a year. Control group received usual medical care. Follow up at one year
Outcomes	Blood pressure, smoking, serum cholesterol.
Notes	

**Nordmann**

Methods	RCT Cluster randomisation
Participants	MI or angina patients from ITU. Intervention started during hospitalisation. No identified levels of psychopathology prior to intervention. 201 patients randomised, 78% male, mean age 61.5 years
Interventions	Risk factor counselling in hospital. Personal targets set to increase motivation, and reminders sent to the patient and GP at regular intervals. Control group received usual medical care. Duration of follow up - 18 months
Outcomes	Blood pressure, smoking, serum cholesterol.
Notes	

### Oldenburg 1985

Methods	RCT Block randomisation.
Participants	Patients following first acute MI over a 12 month period. No identified levels of psychopathology prior to intervention. 46 patients randomised, mean age 56 years 89% men
Interventions	Includes stress management intervention. Complex psychological intervention. Patients randomised to 3 groups: group 1 - individual counselling, relaxation training and education; group 2 - relaxation training and education; control - routine medical care. Counselling group received 6-10 sessions of 45 Min duration whilst in hospital, within 48 hours of admission. Audiotapes were given for relaxation training (progressive muscular relaxation, breathing, cognitive tension awareness) and education (including how to modify type A behaviour). Follow up - 12 months
Outcomes	Total mortality, cardiac surgery and Heart attack Inventory (including GHQ, Spielberger State Anxiety)
Notes	Requested baseline and follow-up mean data and SDs for Heart Attack Inventory

### Oldenburg 1995

Methods	RCT Block randomisation.
Participants	CABG patients, intervention started 4-8 weeks post discharge. No identified levels of psychopathology prior to intervention. 91 patients randomised, mean age 59.5 years, 91% men
Interventions	Includes stress management intervention. Complex psychological intervention plus other rehabilitation interventions. Intervention followed social learning theory, tailored to individual patients - goal setting, skills training, feedback, reinforcement and social support. Relaxation training. Intervention group received also CCR, specifically exercise. One 3 hour session/week for 6 weeks and booster sessions at 8 months and 1 year. Control group received usual medical care. Follow-up 12 months
Outcomes	Smoking, lipids, HRQoL, anxiety and depression.
Notes	

### Ornish

Methods	RCT
Participants	CHD, defined by angiography. No identified levels of psychopathology prior to intervention. 93 patients randomised, 48 declined post randomisation. Mean age 59.6 years, 91% men
Interventions	Includes stress management intervention. Complex psychological intervention plus other rehabilitation interventions. SM training included stretching, breathing, meditation, progressive relaxation and imagery. Intervention administered by clinical psychologist. Intensive 7 day retreat, and recommended 1 hour/day assisted by relaxation tapes for the duration of follow-up of 5 years. Other interventions included a 10% vegetarian diet, moderate exercise, and smoking cessation (lifestyle heart trial). Control group - usual care - patients told to follow lifestyle advice from their personal physicians

**Ornish** (Continued)

Outcomes	Total and cardiac mortality, non-fatal MI, CABG, and risk factors blood pressure, lipid levels
Notes	Main outcome - angiographic changes over 5 years.

**PRECOR**

Methods	RCT
Participants	Acute MI, patients randomised 30-60 days post MI. No identified levels of psychopathology prior to intervention. 182 patients randomised, all men, mean age 50 years
Interventions	Comprehensive cardiac rehabilitation and counselling programme. Group sessions of risk factor counselling. Control group received usual medical care. Duration of follow up - 2 years
Outcomes	Total mortality, non-fatal MI, CABG
Notes	

**Rahe**

Methods	RCT
Participants	First MI. Patients randomised after hospital discharge (approximately 1 month). No identified levels of psychopathology prior to intervention. 44 patients randomised, 89% men, mean age 53 years
Interventions	Group therapy, topics covered included life stress and the onset of MI, , contribution of physical and psychological risk factors, coronary prone behaviour, home problems and return to work. 90 minute sessions every fortnight for 12 weeks. Control group received usual medical care. Duration of follow up 3-4 years
Outcomes	Total mortality, non-fatal MI, CABG
Notes	

**RCCP**

Methods	RCT. Patients randomised 2:1 to the intervention and comparison groups
Participants	MI within 6 months. No identified levels of psychopathology prior to intervention. 862 patients randomised, 92% men, mean age 53 years
Interventions	Includes stress management intervention. All patients (intervention and control) received risk factor counselling from cardiologists. Group sessions every 2 weeks for 3 months, monthly for 3 months and 3 monthly thereafter. In addition to risk factor counselling, the intervention group received type A behavioural counselling administered by a psychiatrist or clinical psychologist. The intervention included relaxation learning - progressive muscle relaxation, mental relaxation, behavioural learning - recognition and modification of exaggerated arousal reactions, instruction of self observation and self assessment, restructuring of environment, and cognitive affective learning. Average number

**RCCP** (Continued)

	of sessions for comparison group was 33 of 90 minutes duration over a 4.5 year intervention period. Average number of sessions for the intervention group was 62 sessions over 4.5 years. Duration of follow up - 4.5 years
Outcomes	Cardiac mortality, non-fatal MI, Type A behaviour.
Notes	

**Stern**

Methods	RCT Block randomisation.
Participants	Documented MI between 6 weeks and 1 year. Identified levels of psychopathology as selection criteria, threshold - Taylor Manifest Anxiety Scale of 19+, Zung Depression Scale of 40+. 64 patients randomised. Patients aged 30-69 years, 80% men
Interventions	Includes stress management intervention. Complex psychological intervention. SM training included Jacobsen relaxation exercises, group counselling and discussions on stress and type A behaviour, and other risk factors. Patients randomised to an exercise group, group counselling group, or control. Group counselling intervention administered by psychiatrist, nurse and social worker - 1 session/week of 60-75 Min for 12 weeks. Patients encouraged to do relaxation exercises at least twice daily at home, follow up period 12 months. Control - usual medical care - patients were requested not to join and exercise programme or attend counselling
Outcomes	Total mortality, non-fatal MI, CABG. Data incomplete for anxiety and depression
Notes	

**Thompson**

Methods	RCT Block randomisation.
Participants	Uncomplicated first MI, recruited from CCU. No identified levels of psychopathology prior to intervention. 60 men randomised (and their wives), less than 65 years. Data reported for patients only
Interventions	In-hospital counselling intervention offering structured support and education on risk factors. Counselling focused on patients and spouses reactions to the MI. Four 30 minute sessions of counselling whilst in CCU. Control group received usual medical care. Follow up 6 months
Outcomes	Anxiety and depression
Notes	

**Toobert**

Methods	RCT
Participants	Documented chronic CHD (mean time since diagnosis 11 years), participants recruited via advertisements. 28 participants randomised, mean age 63 years, all women
Interventions	Includes stress management intervention. Single psychological intervention plus other rehabilitation interventions. Intervention included Hatha Yoga, progressive deep relaxation, meditation administered by a trained yoga instructor. Other rehabilitation interventions as for Ornish (lifestyle heart trial - strict vegetarian diet, exercise, SM). 7 day retreat where yoga performed twice daily, and 2 weekly meetings of 4 hours each. Group discussions, yoga and relaxation continued twice a week for 6 months and 1/month for 3 months. Participants requested to continue at home for 1 hour per day. Control group - usual medical care. Follow up 12 months
Outcomes	Anxiety, depression and perceived stress.
Notes	

**Van Dixhoorn**

Methods	RCT
Participants	Acute MI - patients randomised within 1 month of event. No identified levels of psychopathology prior to intervention. 156 patients randomised, mean age 55.5 years, 94% men
Interventions	Includes stress management intervention. Single psychological intervention plus other rehabilitation interventions. Intervention group received relaxation training (biofeedback frontalis muscle tension, breathing) and exercise training. Intervention administered by trained therapists. Control group received the exercise intervention only. Relaxation training included 1 session of 1 hour per week for 6 weeks, and patients were also instructed to practise at home. Follow up - 5 years
Outcomes	Cardiac mortality, non-fatal MI, cardiac surgery.
Notes	

**Vermeulen**

Methods	RCT
Participants	MI patients. Patients randomised 6 weeks after hospital discharge. No identified levels of psychopathology prior to intervention. 98 patients randomised, all men, mean age 49 years
Interventions	Comprehensive cardiac rehabilitation. Mentions psychological intervention, but no details given. Duration of follow-up 5 years
Outcomes	Cardiac mortality, non-fatal MI, smoking, serum cholesterol.
Notes	

RCT - randomised controlled trial

CHD - coronary heart disease  
 SM - stress management  
 MI - myocardial infarction  
 CABG - coronary artery bypass graft  
 PTCA - percutaneous transluminal angioplasty  
 GHQ - general health questionnaire  
 SD - standard deviation  
 HRQoL - health related quality of life  
 CCR - comprehensive cardiac rehabilitation  
 CHF - congestive heart failure  
 CCU - coronary care unit  
 VF - ventricular fibrillation  
 HR - heart rate  
 RR - respiratory rate  
 CV - cardiovascular  
 HE - health education

### Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Amerosa Tupler	Follow up period too short.
Ashton	Follow up period too short.
Beresnevaite	Usual care group recieved and intervention not recieved by the intervention group
Blankfield	Follow up period too short.
Blumenthal	Not a RCT.
Bundy	Follow up period too short.
Clark	Not all patients recieved the intervention, very few chose the stress management intervention
Egger	Not a RCT.
Elliot	Follow up period too short.
Fielding	Follow up period too short.
Fletcher	No relevant outcomes.
Garding	Follow up period too short.
Gidron	Follow up period too short.

(Continued)

Gortner	Data for intervention and control groups not reported, and subsequently groups combined for a “cohort ” analysis
Gruen	Follow up period too short.
Guzzetta	Follow up period too short.
Heller	Intervention not administered by trained staff.
Horlick	No follow up data reported.
Israelsson	No relevant outcomes.
Langosch	Not a RCT.
Naismith	No relevant outcomes.
Ohm	No relevant outcomes.
Oldridge	Specifically states that staff administering intervention were not trained
Rakov	No relevant outcomes. Russian translation.
Schindler	Follow up period too short.
Taylor	Not all patients recieved the intervention, unclear how many
Thomas	Follow up period too short.
Trzcieńska-Green	Follow up period too short - controls were offered treatment after 10 weeks
Turner	Unclear when the follow up assessment is - likely too short. Feasibility study not designed to show differences between intervention and control, but the power of the intervention. For this reason patients are randomised 2:1 to the intervention. Very small sample size, with very high drop-out rates, particularly in the control group
Zamarra	Not a RCT.

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

#### CORE

Trial name or title	Akershus Comprehensive Cardiac Rehabilitation Trial ( the CORE Study)
Methods	



**CORE** (Continued)

Participants	RCT set in Akershus County, Oslo. 500 patients randomised, aged 40-85 years after MI, CABG, PTCA or stabilized acute coronary syndrome. Pragmatic trial - intervention offered to a heterogeneous group of patients
Interventions	Comprehensive cardiac rehabilitation including structured counselling to modify risk factors and brief counselling will be offered individually at 6 months
Outcomes	Special emphasis on the assessment of quality of life
Starting date	April 2000. Follow up should be complete by April 2004
Contact information	Study design described at <a href="http://cvm.controlled-trials.com/content/1/3/177">http://cvm.controlled-trials.com/content/1/3/177</a>
Notes	

## DATA AND ANALYSES

### Comparison 1. Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Total Mortality	22	10634	Odds Ratio (M-H, Fixed, 95% CI)	0.93 [0.81, 1.06]
2 Cardiac Mortality	11	7544	Odds Ratio (M-H, Fixed, 95% CI)	0.86 [0.72, 1.03]
3 Non-fatal MI	18	10200	Odds Ratio (M-H, Fixed, 95% CI)	0.78 [0.67, 0.90]
4 Revascularisation (CABG and PTCA combined)	15	8368	Odds Ratio (M-H, Fixed, 95% CI)	0.90 [0.78, 1.02]
5 Total Cholesterol	9	1525	Mean Difference (IV, Fixed, 95% CI)	-0.28 [-0.37, -0.19]
6 LDL Cholesterol	4	748	Mean Difference (IV, Fixed, 95% CI)	-0.44 [-0.56, -0.32]
7 HDL Cholesterol	5	1187	Mean Difference (IV, Fixed, 95% CI)	0.05 [0.01, 0.08]
8 Triglycerides	4	645	Mean Difference (IV, Fixed, 95% CI)	-0.03 [-0.22, 0.17]
9 Systolic Blood Pressure	5	805	Mean Difference (IV, Fixed, 95% CI)	-3.17 [-5.31, -1.04]
10 Diastolic Blood Pressure	5	805	Mean Difference (IV, Fixed, 95% CI)	-1.83 [-3.35, -0.32]
11 Smoking	8	3690	Odds Ratio (M-H, Fixed, 95% CI)	0.98 [0.84, 1.15]
12 Anxiety	9	2756	Mean Difference (IV, Fixed, 95% CI)	-0.17 [-0.34, 0.01]
13 Depression	11	4535	Mean Difference (IV, Fixed, 95% CI)	-0.42 [-0.64, -0.19]
14 Psychosocial composite measures	5	347	Mean Difference (IV, Fixed, 95% CI)	-2.71 [-5.55, 0.12]

### Comparison 2. Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

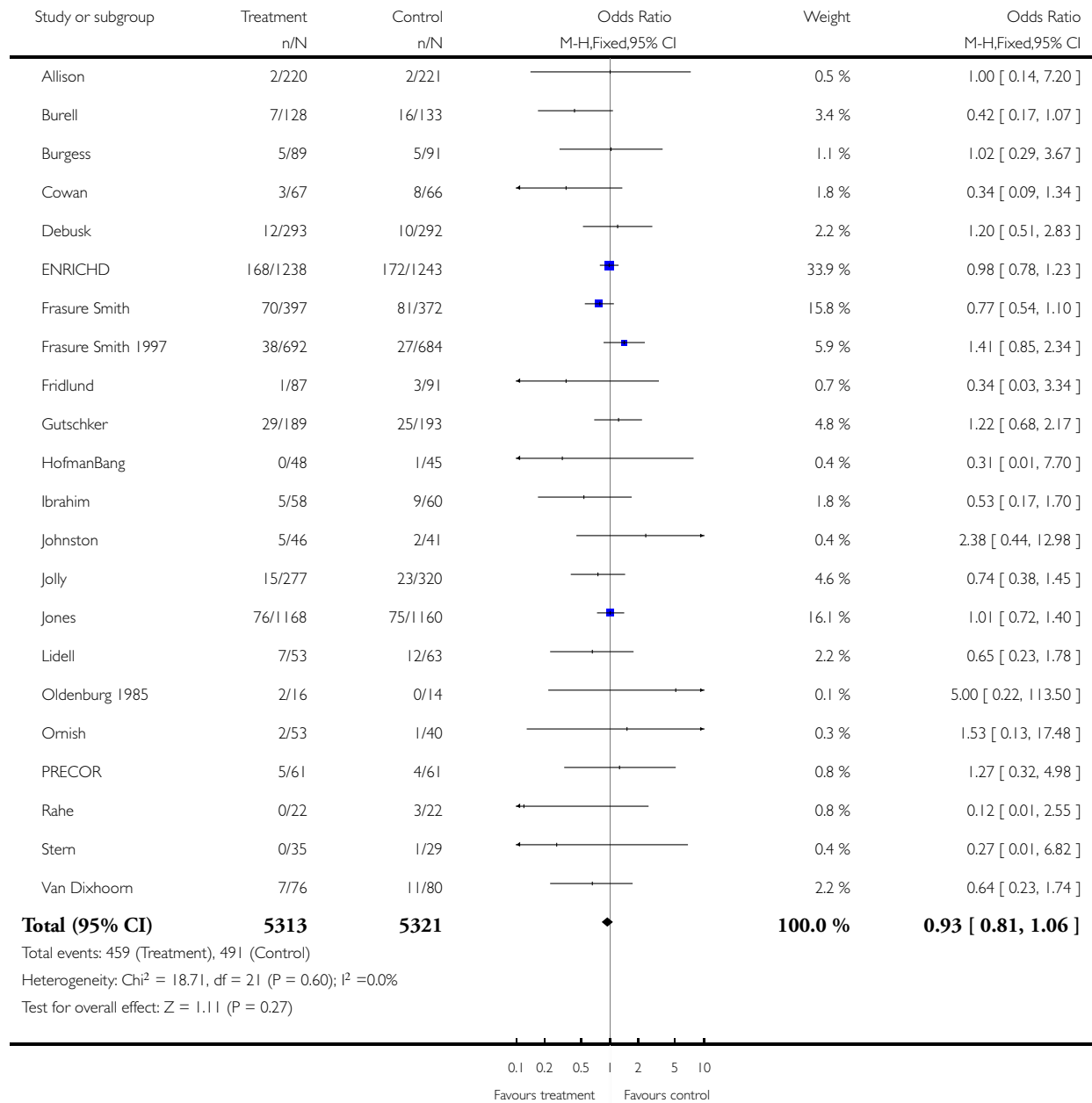
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Total Mortality	10	3425	Odds Ratio (M-H, Fixed, 95% CI)	0.88 [0.67, 1.15]
2 Cardiac Mortality	4	1412	Odds Ratio (M-H, Fixed, 95% CI)	0.62 [0.38, 0.99]
3 Non-fatal MI	8	3990	Odds Ratio (M-H, Fixed, 95% CI)	0.69 [0.52, 0.92]
4 Revascularisation (CABG and PTCA combined)	7	3025	Odds Ratio (M-H, Fixed, 95% CI)	0.80 [0.59, 1.08]
5 Total Cholesterol	4	634	Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.12, 0.15]
6 LDL Cholesterol	2	115	Mean Difference (IV, Fixed, 95% CI)	0.18 [-0.08, 0.43]
7 HDL Cholesterol	3	554	Mean Difference (IV, Fixed, 95% CI)	0.06 [0.02, 0.10]
8 Triglycerides	2	115	Mean Difference (IV, Fixed, 95% CI)	0.21 [-0.28, 0.70]
9 Systolic Blood Pressure	2	468	Mean Difference (IV, Fixed, 95% CI)	0.04 [-3.59, 3.67]
10 Diastolic Blood Pressure	2	468	Mean Difference (IV, Fixed, 95% CI)	-1.17 [-3.56, 1.23]
11 Smoking	3	2472	Odds Ratio (M-H, Fixed, 95% CI)	1.03 [0.85, 1.24]
12 Anxiety	7	2651	Mean Difference (IV, Fixed, 95% CI)	-0.15 [-0.33, 0.03]
13 Depression	8	2642	Mean Difference (IV, Fixed, 95% CI)	-0.18 [-0.42, 0.06]
14 Psychological composite measures	5	347	Mean Difference (IV, Fixed, 95% CI)	-2.71 [-5.55, 0.12]

### Analysis 1.1. Comparison 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 1 Total Mortality.

Review: Psychological interventions for coronary heart disease

Comparison: 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 1 Total Mortality

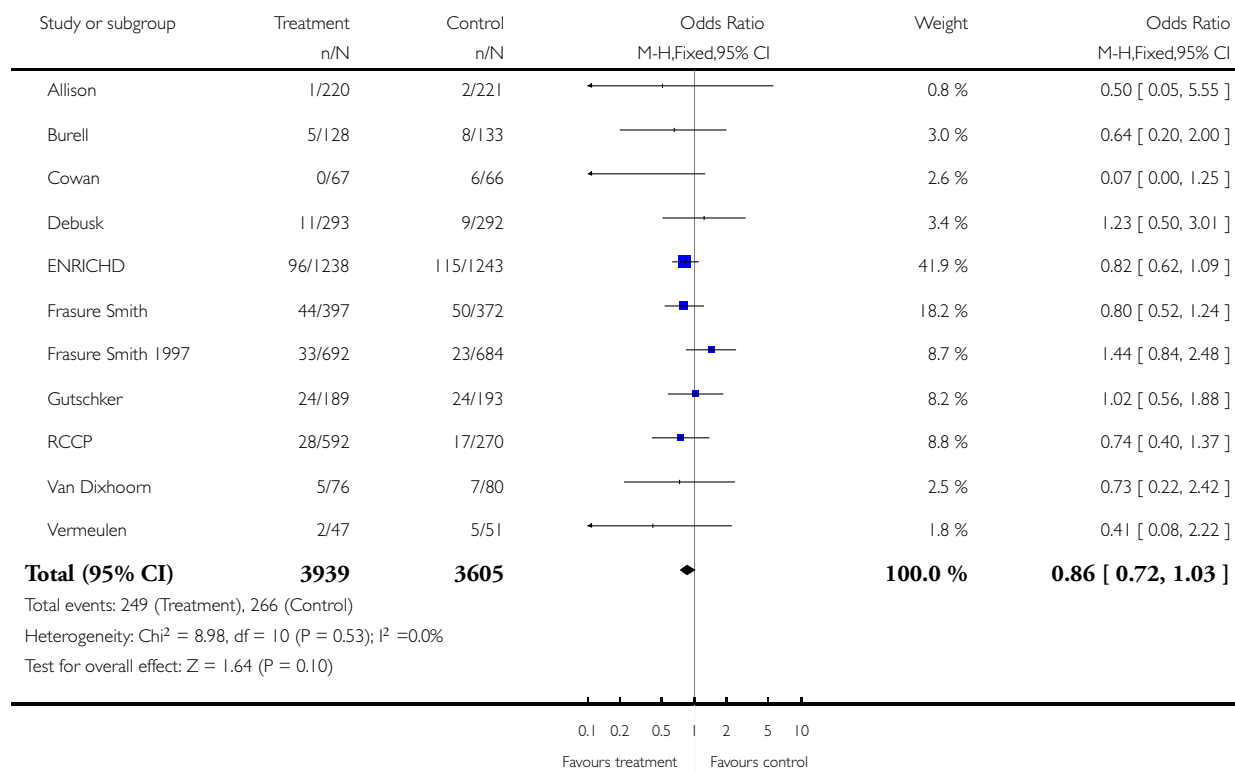


## Analysis 1.2. Comparison 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 2 Cardiac Mortality.

Review: Psychological interventions for coronary heart disease

Comparison: 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 2 Cardiac Mortality

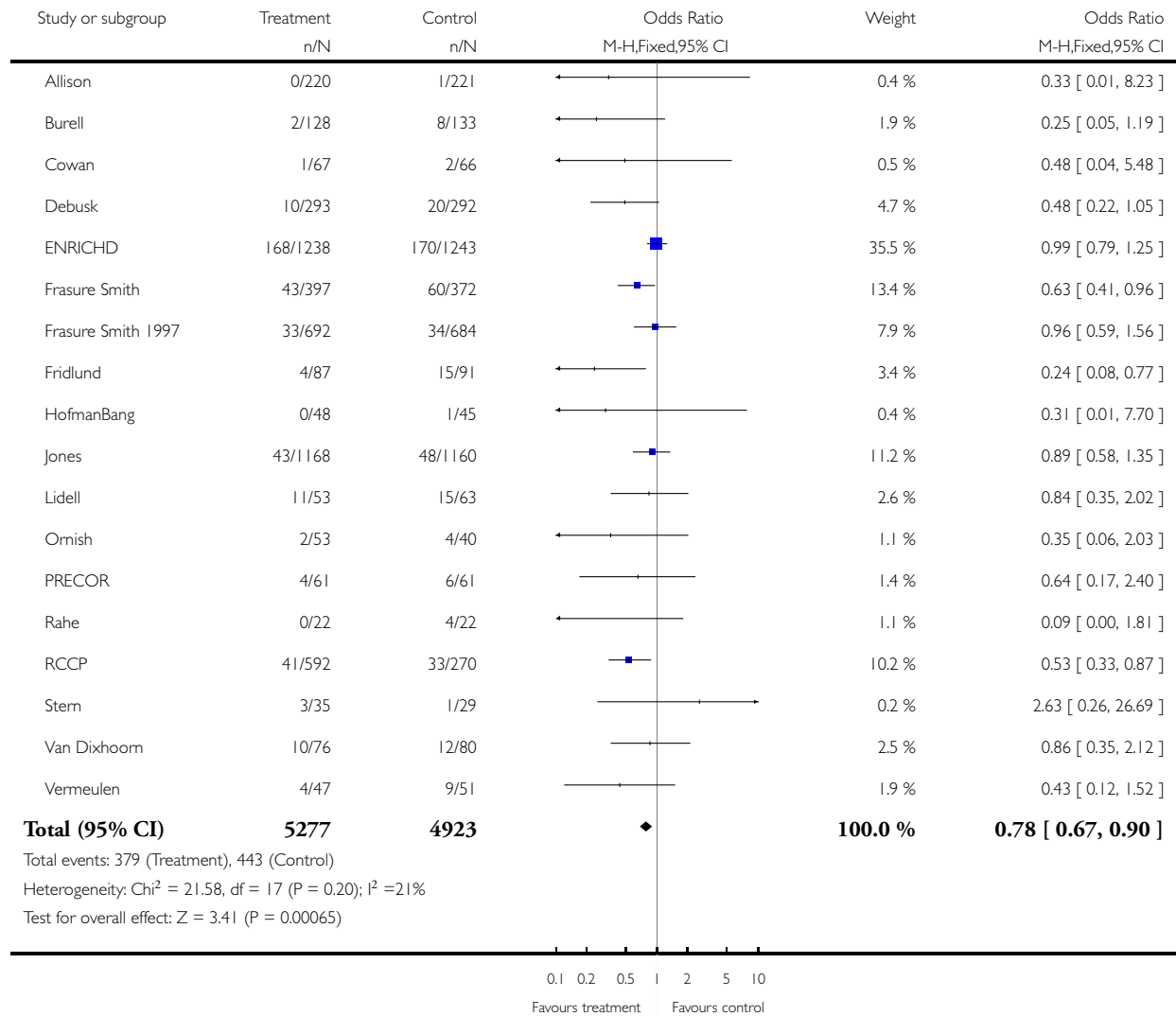


### Analysis 1.3. Comparison 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 3 Non-fatal MI.

Review: Psychological interventions for coronary heart disease

Comparison: 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 3 Non-fatal MI

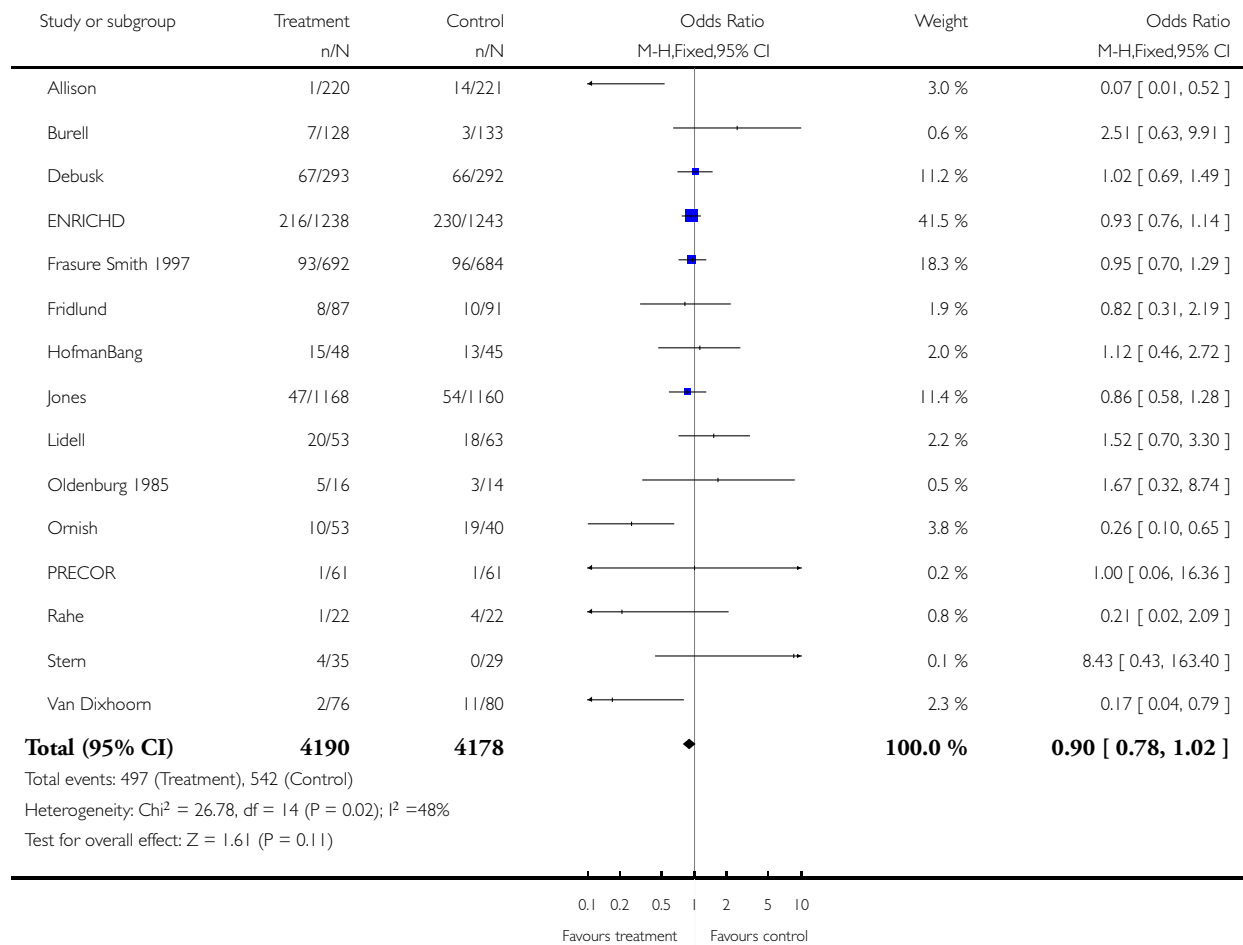


**Analysis 1.4. Comparison 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 4 Revascularisation (CABG and PTCA combined).**

Review: Psychological interventions for coronary heart disease

Comparison: 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 4 Revascularisation (CABG and PTCA combined)

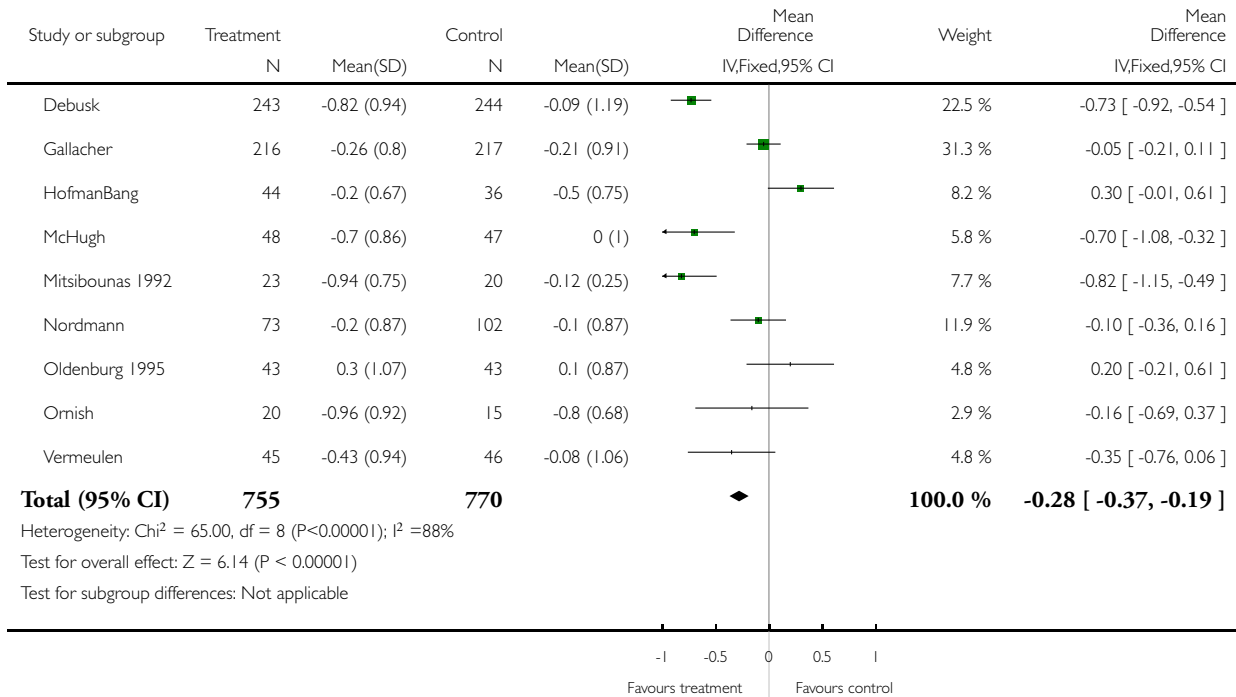


### Analysis 1.5. Comparison 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 5 Total Cholesterol.

Review: Psychological interventions for coronary heart disease

Comparison: 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 5 Total Cholesterol

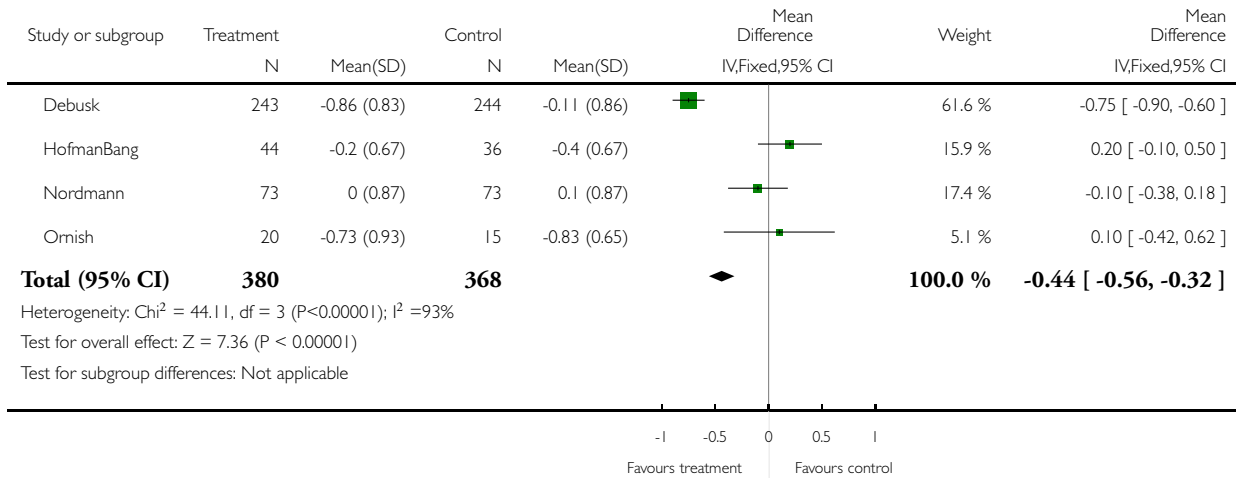


**Analysis 1.6. Comparison 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 6 LDL Cholesterol.**

Review: Psychological interventions for coronary heart disease

Comparison: 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 6 LDL Cholesterol



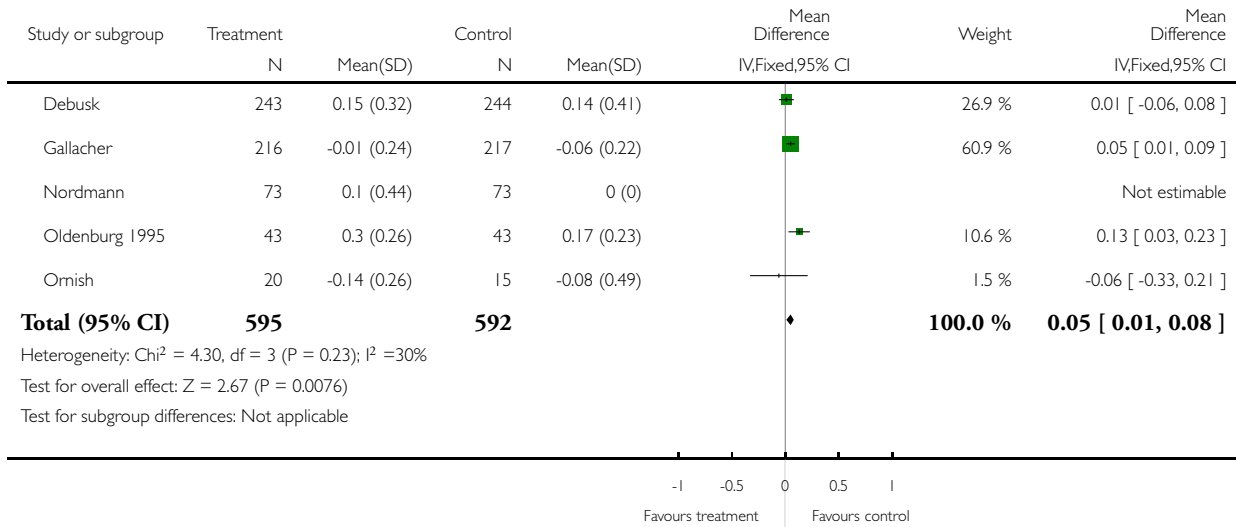


**Analysis 1.7. Comparison 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 7 HDL Cholesterol.**

Review: Psychological interventions for coronary heart disease

Comparison: 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 7 HDL Cholesterol

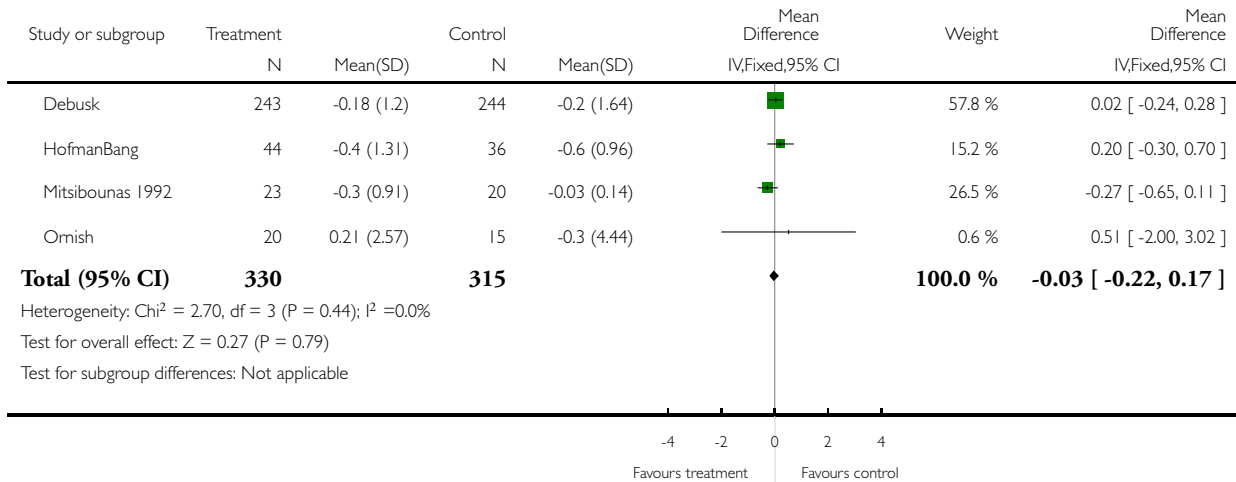


**Analysis 1.8. Comparison 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 8 Triglycerides.**

Review: Psychological interventions for coronary heart disease

Comparison: 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 8 Triglycerides

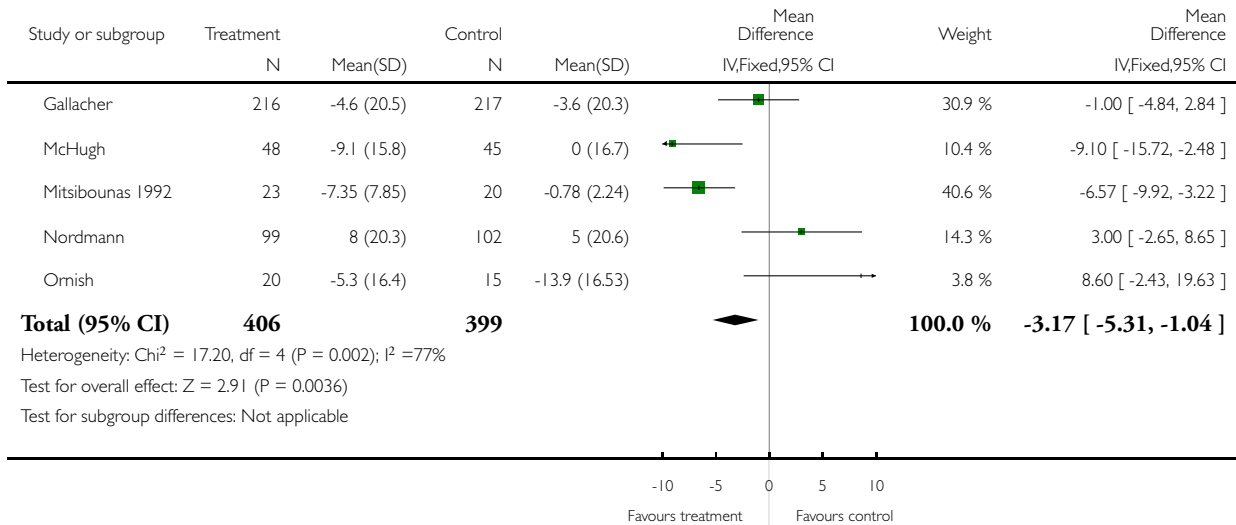


**Analysis 1.9. Comparison 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 9 Systolic Blood Pressure.**

Review: Psychological interventions for coronary heart disease

Comparison: 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 9 Systolic Blood Pressure

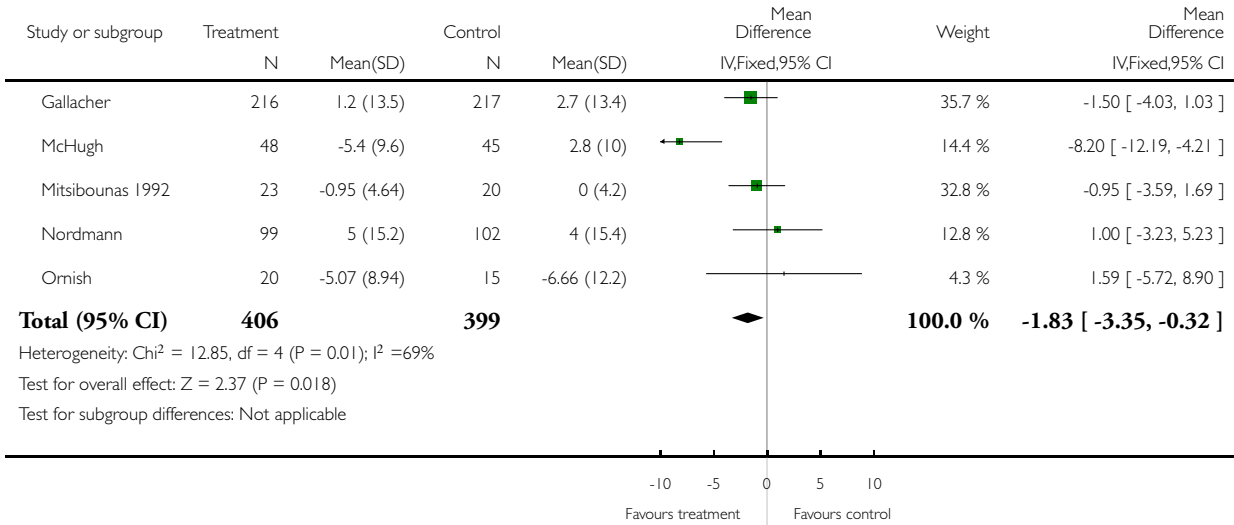


**Analysis 1.10. Comparison 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 10 Diastolic Blood Pressure.**

Review: Psychological interventions for coronary heart disease

Comparison: 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 10 Diastolic Blood Pressure

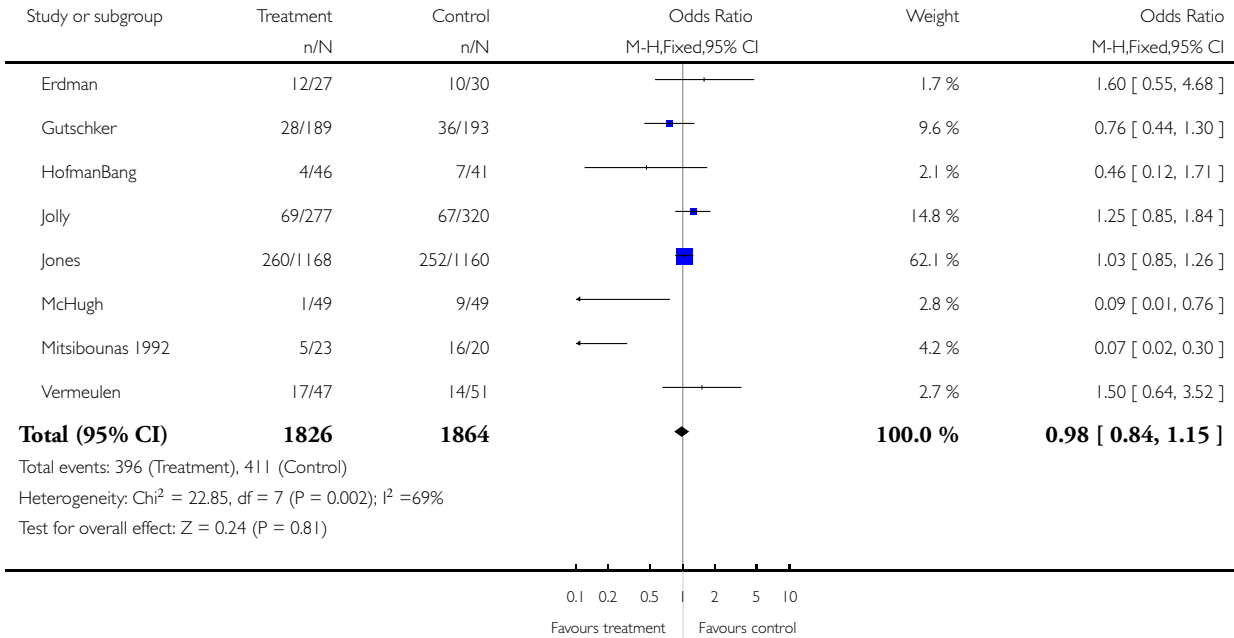


**Analysis 1.11. Comparison 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 11 Smoking.**

Review: Psychological interventions for coronary heart disease

Comparison: 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 11 Smoking

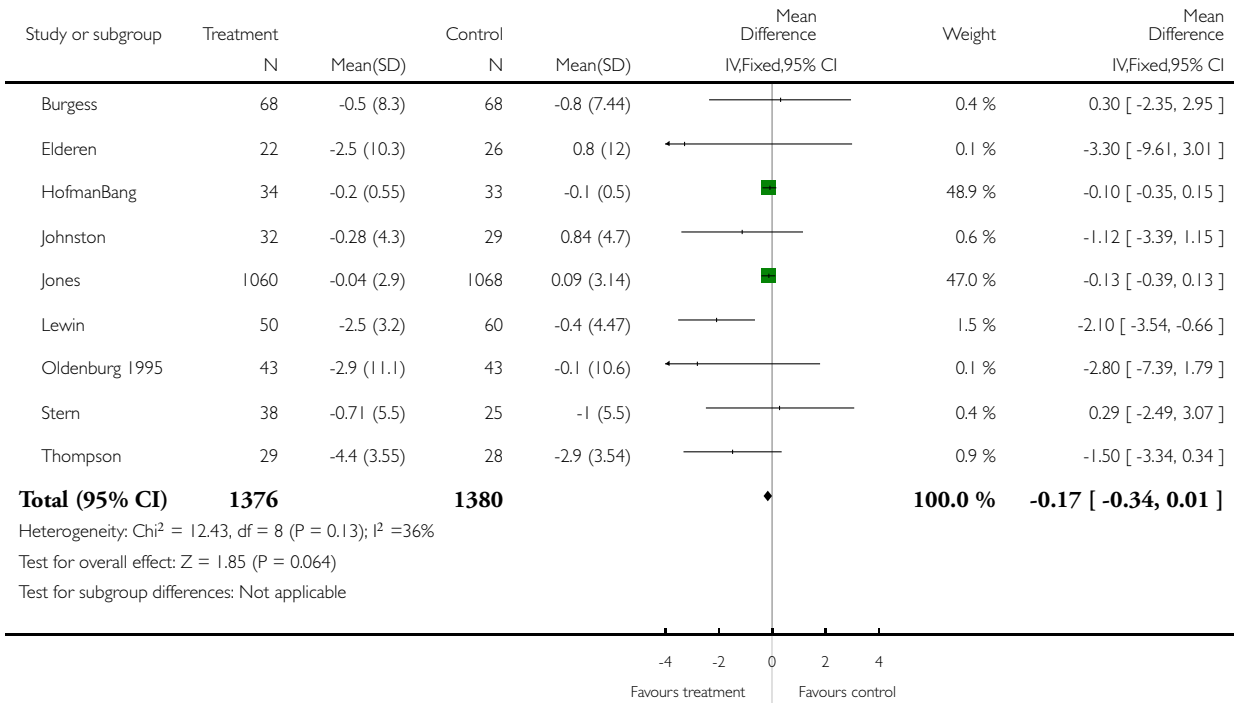


**Analysis 1.12. Comparison 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 12 Anxiety.**

Review: Psychological interventions for coronary heart disease

Comparison: 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 12 Anxiety

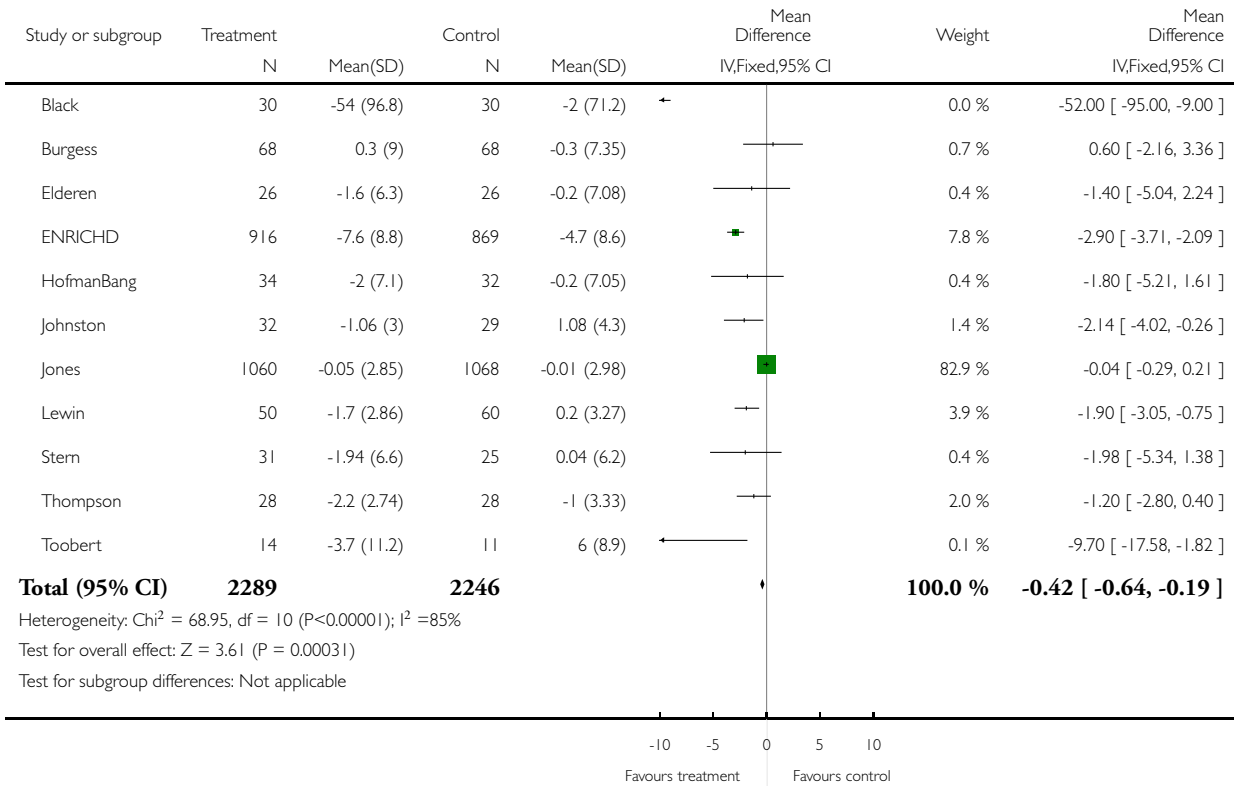


**Analysis 1.13. Comparison 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 13 Depression.**

Review: Psychological interventions for coronary heart disease

Comparison: 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 13 Depression

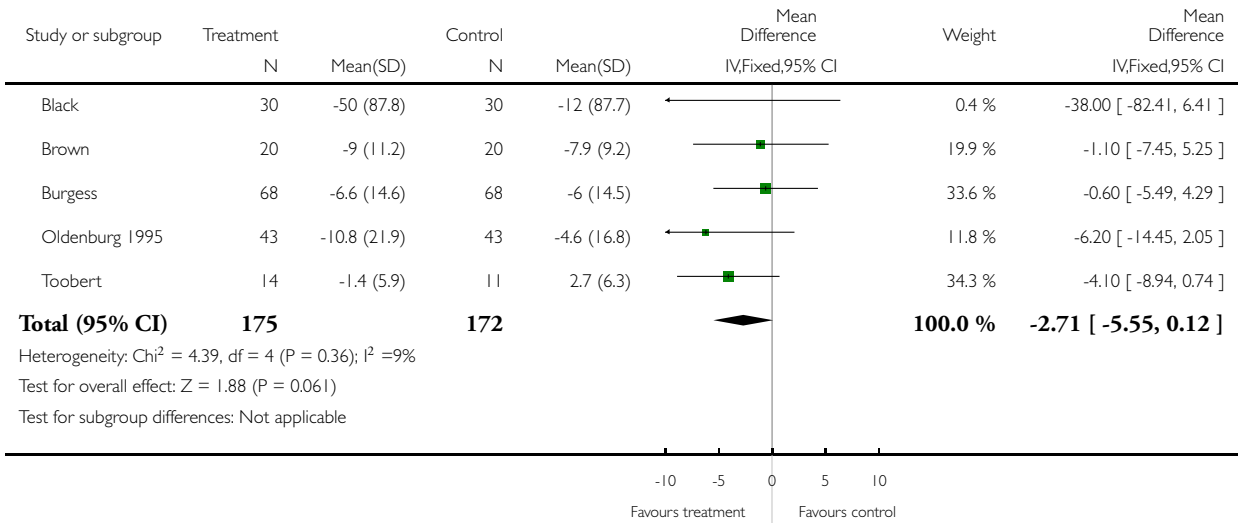


**Analysis 1.14. Comparison 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 14 Psychosocial composite measures.**

Review: Psychological interventions for coronary heart disease

Comparison: 1 Any psychological intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 14 Psychosocial composite measures



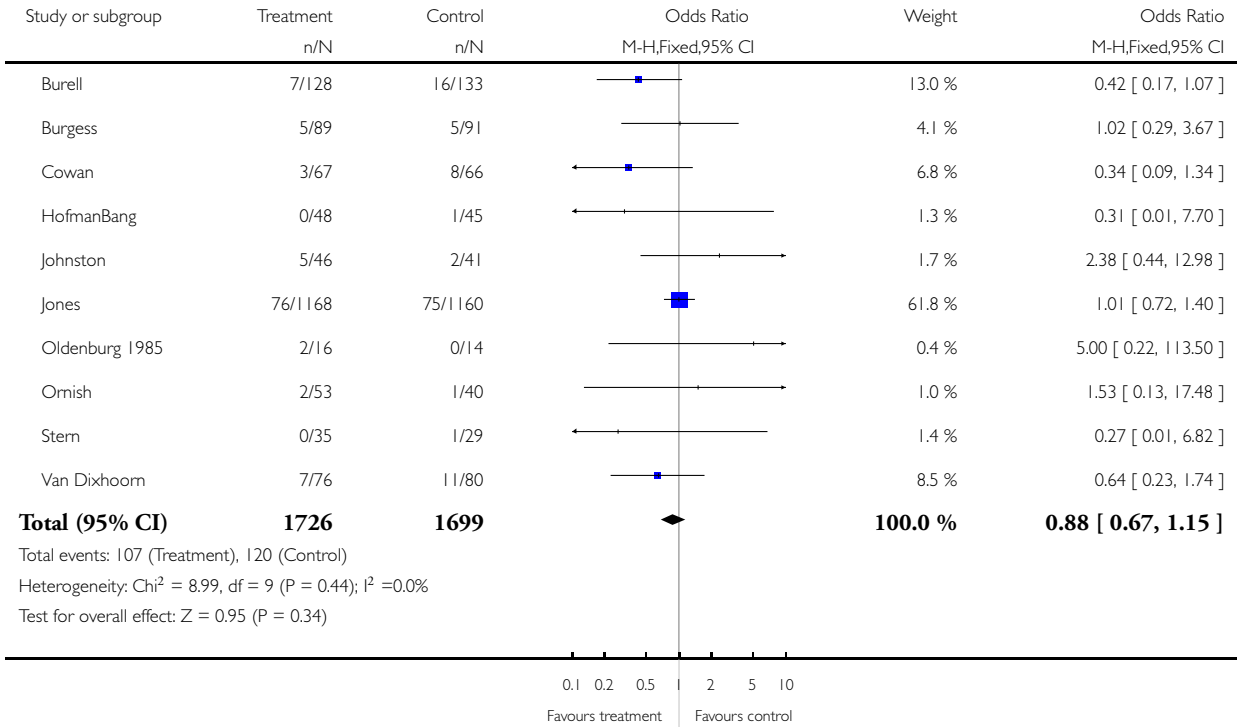


**Analysis 2.1. Comparison 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 1 Total Mortality.**

Review: Psychological interventions for coronary heart disease

Comparison: 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 1 Total Mortality

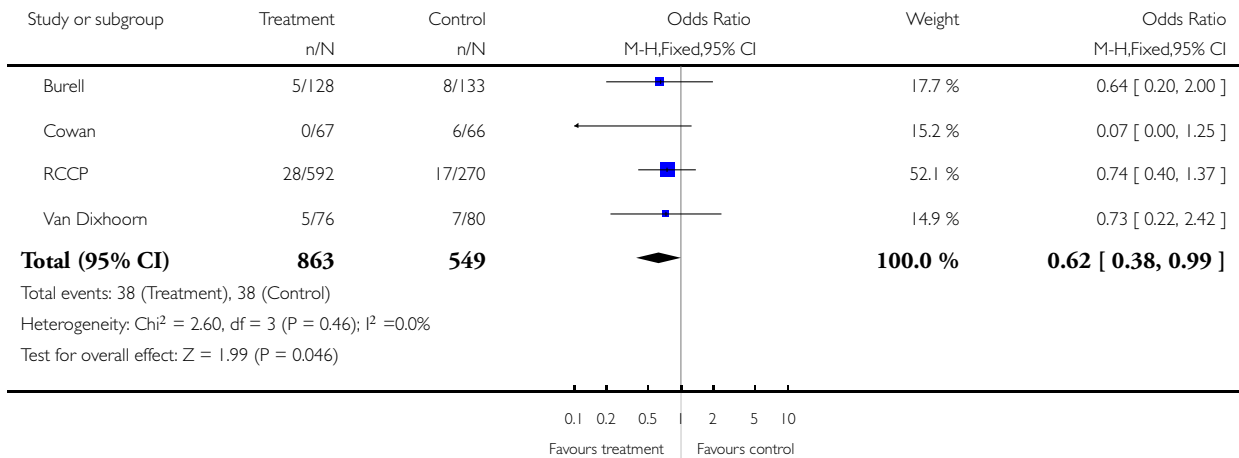


**Analysis 2.2. Comparison 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 2 Cardiac Mortality.**

Review: Psychological interventions for coronary heart disease

Comparison: 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 2 Cardiac Mortality

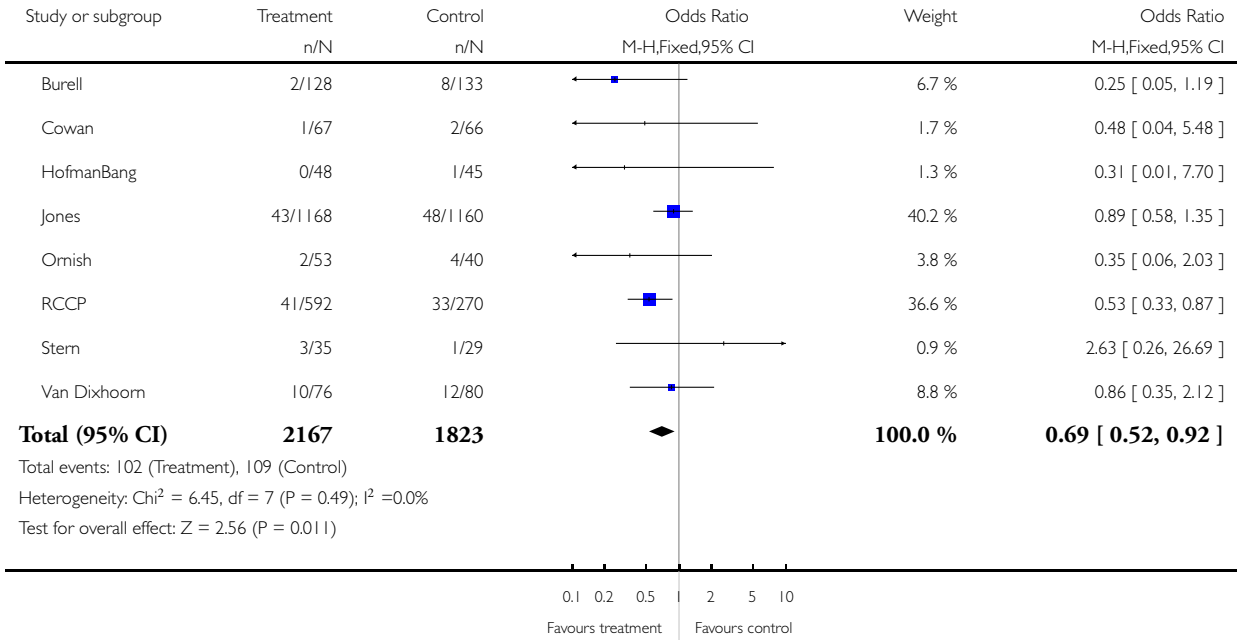


**Analysis 2.3. Comparison 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 3 Non-fatal MI.**

Review: Psychological interventions for coronary heart disease

Comparison: 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 3 Non-fatal MI

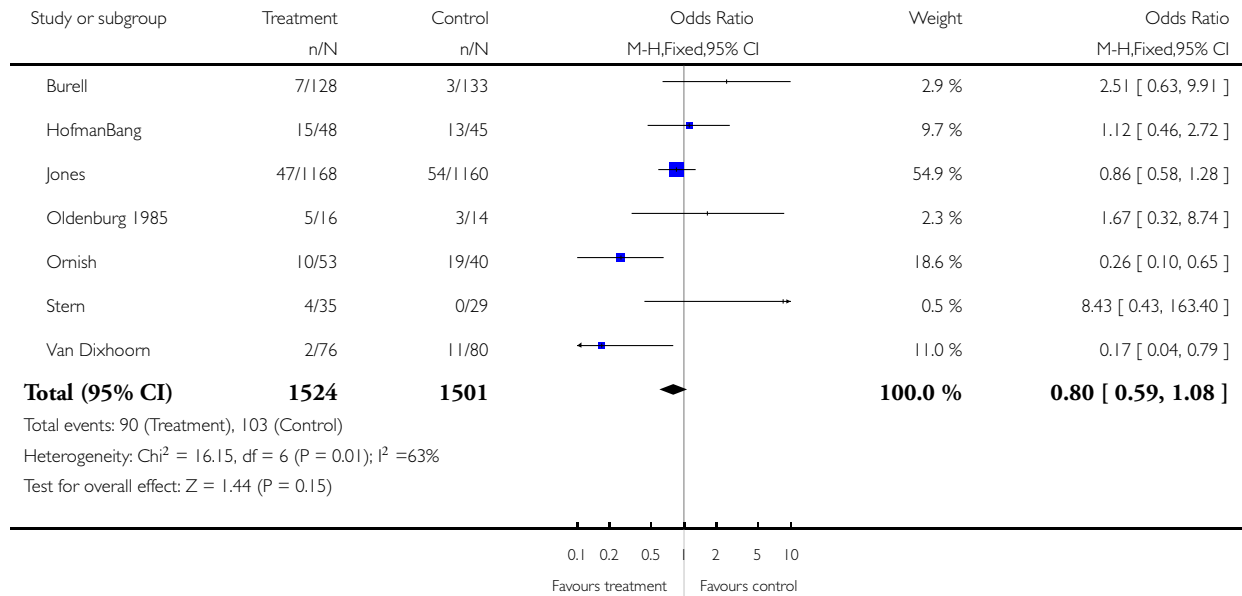


**Analysis 2.4. Comparison 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 4 Revascularisation (CABG and PTCA combined).**

Review: Psychological interventions for coronary heart disease

Comparison: 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 4 Revascularisation (CABG and PTCA combined)

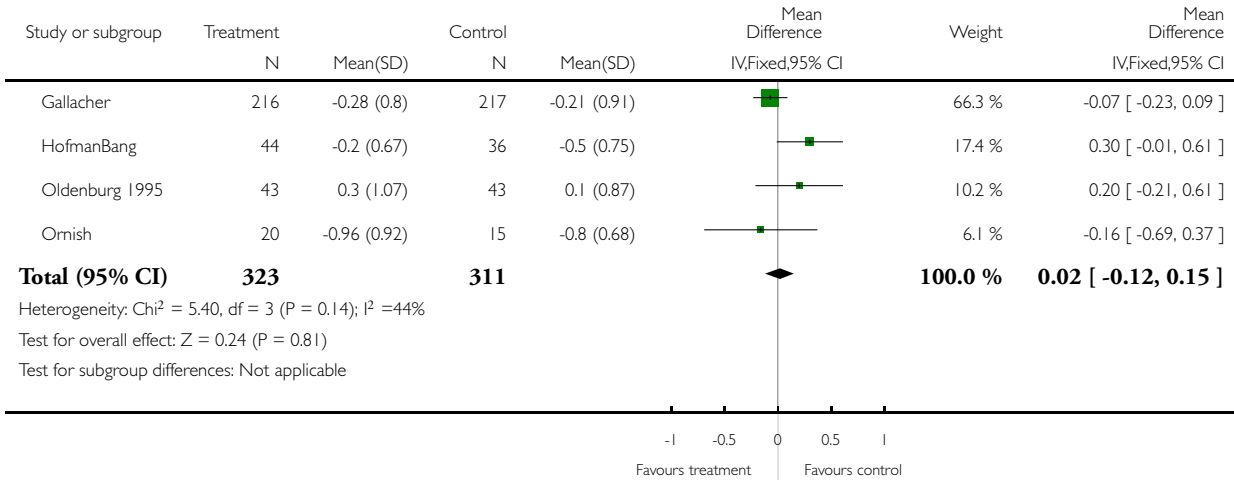


**Analysis 2.5. Comparison 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 5 Total Cholesterol.**

Review: Psychological interventions for coronary heart disease

Comparison: 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 5 Total Cholesterol

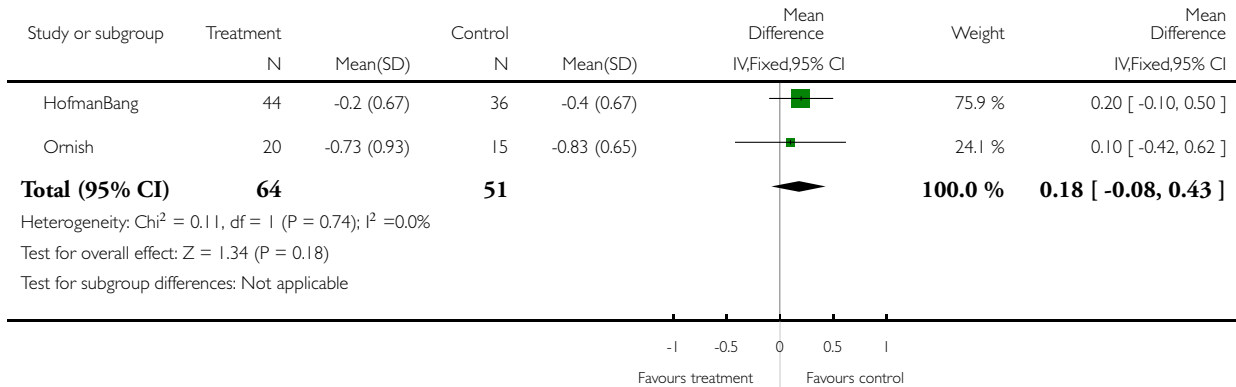


**Analysis 2.6. Comparison 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 6 LDL Cholesterol.**

Review: Psychological interventions for coronary heart disease

Comparison: 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 6 LDL Cholesterol

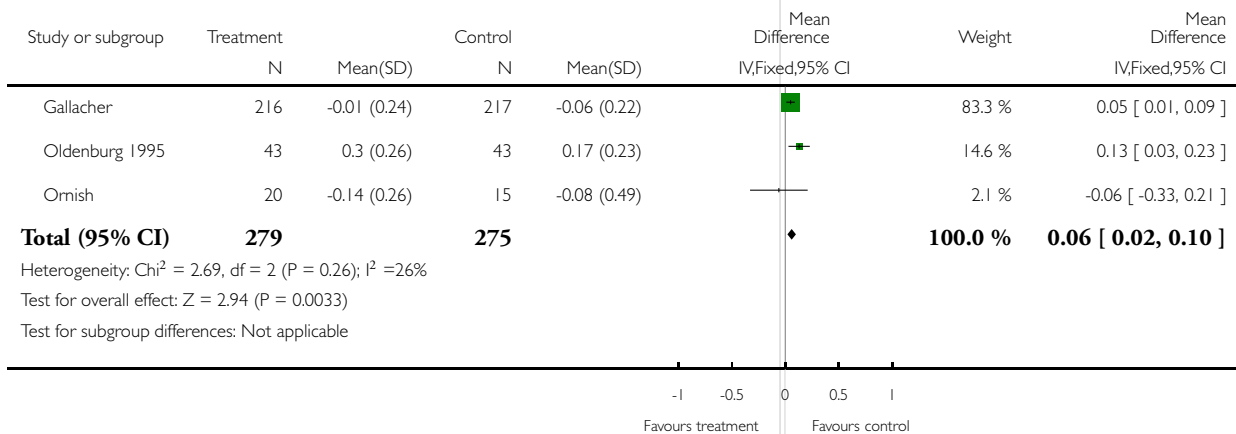


**Analysis 2.7. Comparison 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 7 HDL Cholesterol.**

Review: Psychological interventions for coronary heart disease

Comparison: 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 7 HDL Cholesterol

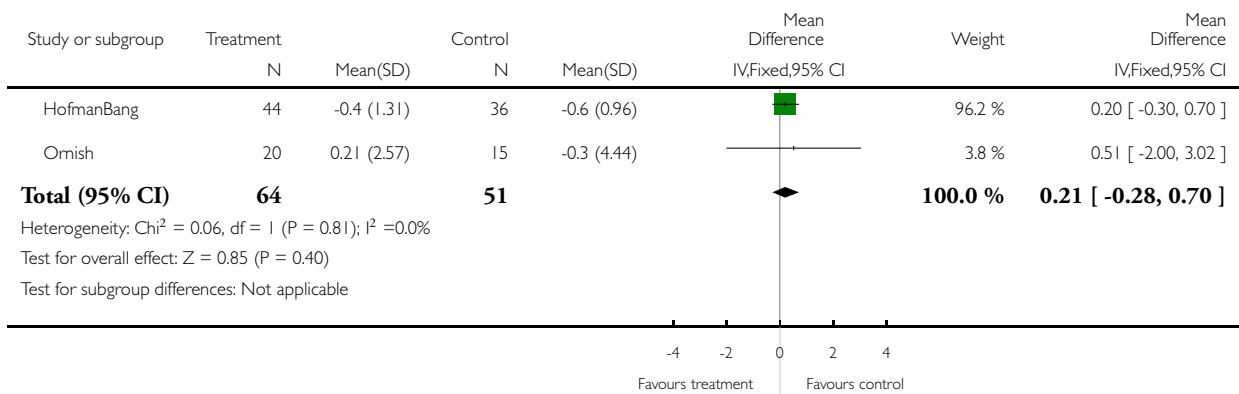


**Analysis 2.8. Comparison 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 8 Triglycerides.**

Review: Psychological interventions for coronary heart disease

Comparison: 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 8 Triglycerides

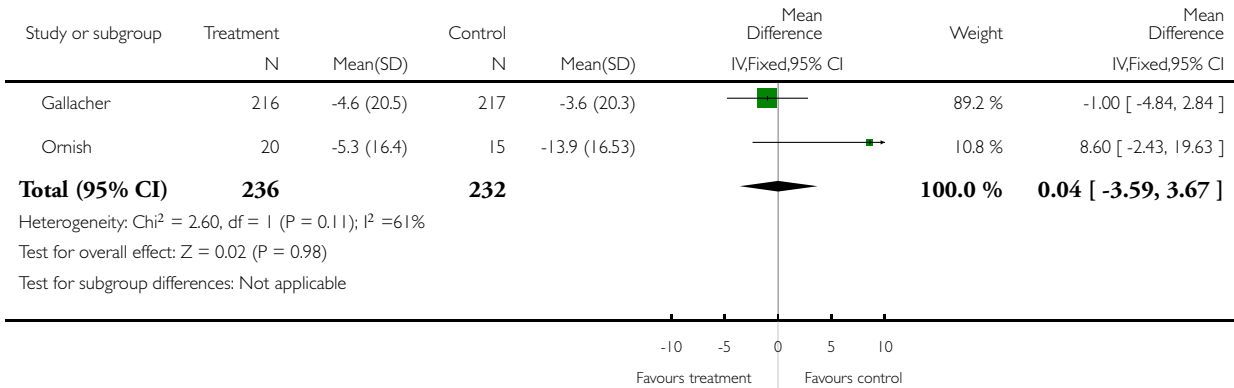


**Analysis 2.9. Comparison 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 9 Systolic Blood Pressure.**

Review: Psychological interventions for coronary heart disease

Comparison: 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 9 Systolic Blood Pressure

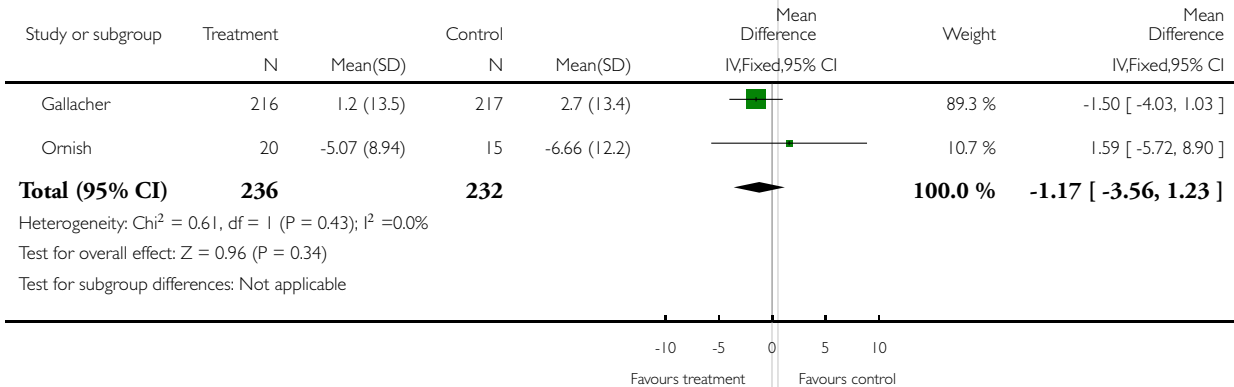


**Analysis 2.10. Comparison 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 10 Diastolic Blood Pressure.**

Review: Psychological interventions for coronary heart disease

Comparison: 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 10 Diastolic Blood Pressure



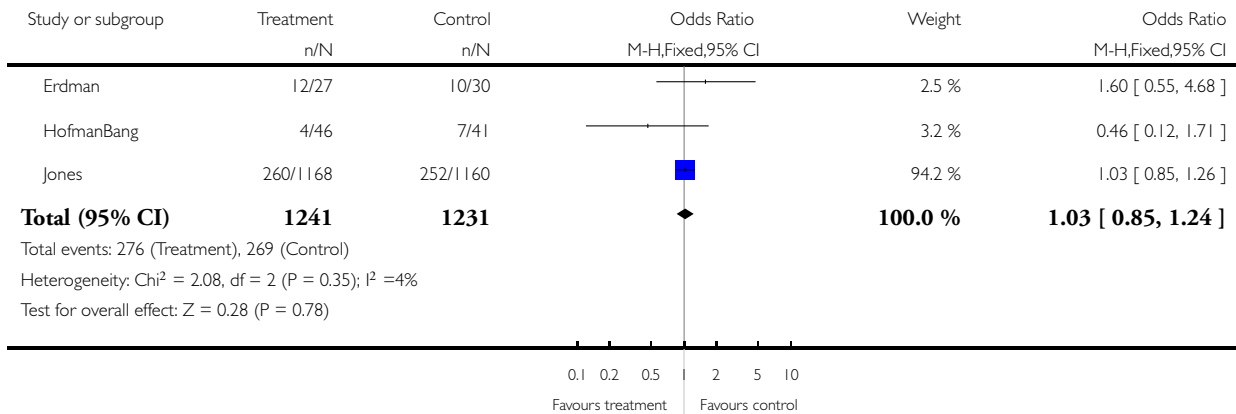


**Analysis 2.11. Comparison 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 11 Smoking.**

Review: Psychological interventions for coronary heart disease

Comparison: 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 11 Smoking

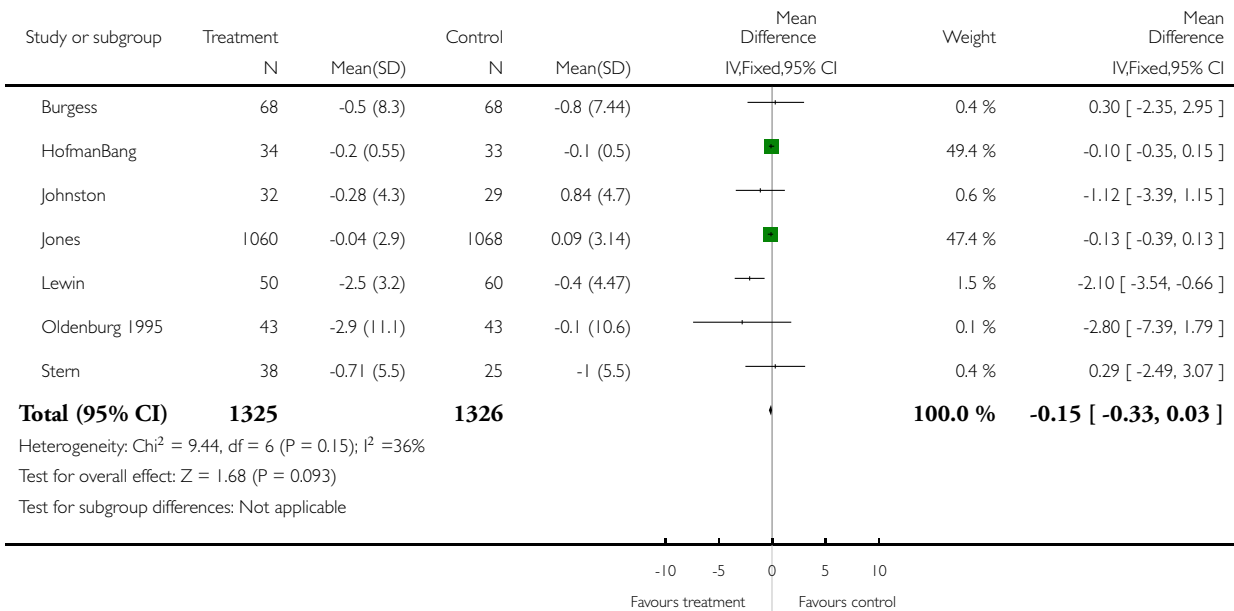


**Analysis 2.12. Comparison 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 12 Anxiety.**

Review: Psychological interventions for coronary heart disease

Comparison: 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 12 Anxiety

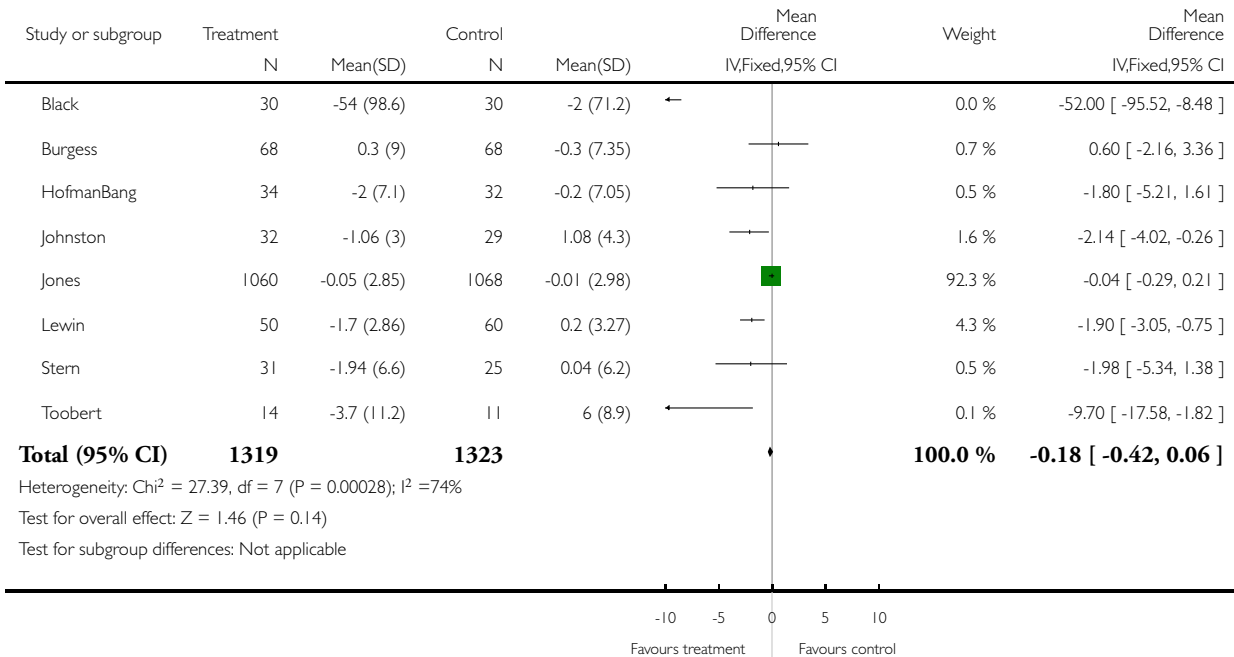


**Analysis 2.13. Comparison 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 13 Depression.**

Review: Psychological interventions for coronary heart disease

Comparison: 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 13 Depression

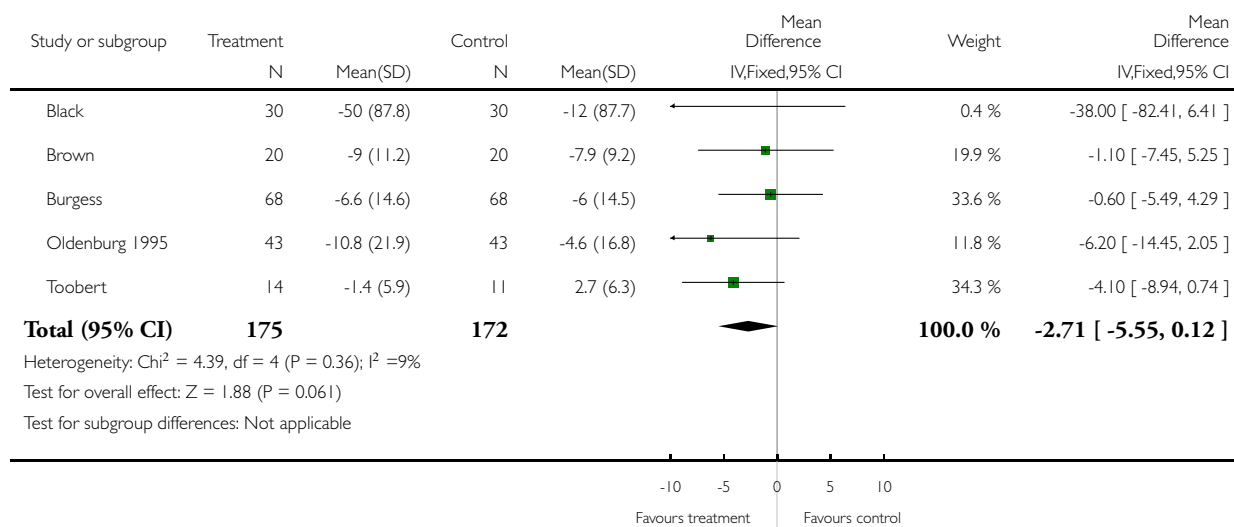


**Analysis 2.14. Comparison 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation), Outcome 14 Psychological composite measures.**

Review: Psychological interventions for coronary heart disease

Comparison: 2 Any stress management intervention +/- other rehabilitation vs control (usual care/other rehabilitation)

Outcome: 14 Psychological composite measures



**ADDITIONAL TABLES**

**Table 1. Methodological Quality of Included Studies, for all trials**

Study ID	Randomisation	Allocation	Assessors Blind?	Loss to follow up
Black	Unclear	Unclear	Unclear	17% failed to attend in the intervention group. No drop-outs but 20% crossovers from usual care to intervention group. Analysis follows intention to treat principals
Brown	Unclear	Unclear	Unclear	23% dropout in the intervention group, 29% in the control group

**Table 1. Methodological Quality of Included Studies, for all trials** (Continued)

Burell	(Block randomisation)	Unclear	Unclear	No details - unclear. Clinical event data, used intention to treat analyses
Burgess	Telephone from central office. Stratified by sex.	Sealed envelope	Unclear	No details - unclear.
Cowan	Unclear	Unclear	Unclear - ? state assessors partially blind to group assignment	Report 4% dropout in each group, excluding deaths. No further details
Erdman	Unclear	Unclear	Unclear	20% dropout in each group.
Gallacher	Unclear	Sealed envelopes	Unclear	35% dropout in the intervention group, 28% in the control group
Hofmanbang	Unclear	Unclear	Unclear	4% dropout in the intervention group, 9% in the control group
Johnston	(Block randomisation)	Inadequate - alternate allocation as per gender and days of the week to avoid contamination	Unclear	17% dropout for inpatient intervention, 20% in the control group
Jones	Unclear	Unclear	Yes	5.1% dropout in the intervention group, 5.4% in the control group
Lewin	Unclear	Unclear	Yes	7% dropout in both groups
Oldenburg 1985	(Block randomisation)	Inadequate - each study condition allocated to a particular month	Unclear	Only losses to follow up mentioned are deaths.
Oldenburg 1995	(Block randomisation)	Inadequate - allocated in 2 week blocks based on the date of admission	Unclear	5.5% loss to follow up overall
Ornish	Unclear	Unclear	Yes	62% dropout in the intervention group, 63% in the control group

**Table 1. Methodological Quality of Included Studies, for all trials** (Continued)

RCCP	Unclear (randomisation 2:1 to intervention and comparison group)	Unclear	Unclear	43% dropout in the intervention group, 40% in the comparison group over 4.5 years
Stern	(Block randomisation)	Unclear	Unclear	No dropouts reported
Toobert	Unclear	Unclear	Unclear	No dropouts reported
Van Dixhoorn	Unclear	Unclear	Unclear - but report only clinical outcomes	Only losses to follow up mentioned are deaths.
OTHER PSYCHOLOGICAL INTERVENTIONS				
Allison	Ranuni function in SAS package to generate random numbers	Unclear - patients phoned post randomisation and asked to participate, allocation concealed until first visit	Unclear - but report complete data only for clinical events	42% dropout in the intervention group, 37% in the control group. Dropout higher as refusals post randomisation and prior to intervention
Debusk	Assignment by computer programme done centrally	Unclear	Unclear	15% dropout in the intervention group, 12% dropout in the control group
Elderem	(Block randomisation)	Unclear	Unclear	27% dropout from the intervention group, 13% dropout from the control group
ENRICHHD	Telephone call to a central coordinating office - automated randomisation system. Assignment stratified by clinical centre	Allocation as per randomisation system	Interventionalists are not blinded, but outcome assessors are	No data yet available
Frasure Smith	Unclear	Unclear	Unclear	Up to 46% dropout for the study as a whole. Many patient exclusions and refusals post randomisation before the programmes started. Of those who started,

**Table 1. Methodological Quality of Included Studies, for all trials** (Continued)

				24% in the intervention group died or were lost to follow up at 4 years, and 28% in the control group
Frasure Smith 97	Telephone from central coordinating office	Sealed opaque envelopes	Yes	13% dropout in the intervention group, 15% in the control group
Fridlund	Unclear	Unclear	Unclear	40% dropout in the intervention group, 36% in the control group
Gutschker	Unclear	Unclear	Unclear	2% dropout in the intervention group, none in the control group
Ibrahim	Block randomisation	Alternate allocation of groups	Unclear	No details reported. Mortality data is the only usable outcome
Jolly	(Cluster randomisation)	Unclear	Unclear	10% dropout in the intervention group, 9% in the control group
Lidell	Unclear	Unclear	Unclear	4% dropout in the intervention group, 17.5% in the control group
McHugh	Unclear	Unclear	Unclear	21% dropout in the intervention group, 17% in the control group
Mitsibounas	Unclear	Unclear	Unclear	No dropouts
Nordman	(Cluster randomisation)	Sealed envelopes	Unclear	26% dropout in the intervention group, 29% in the control group
PRECOR	Unclear	Unclear	Unclear	No dropouts
Rahe	Unclear	Unclear	Unclear	9% dropout in the intervention group, 9% in the control group
Thompson	Unclear	Unclear	Yes	3% dropout in the intervention group, 7% in the

**Table 1. Methodological Quality of Included Studies, for all trials** (Continued)

				control group
Vermeulen	Unclear	Unclear	Unclear	4% dropout in the intervention group, 10% in the control group

**Table 2. Stress management interventions - Health Related Quality of Life**

Study ID	Patients	Intervention(s)	Outcome measures	Results
Hofmanbang	PTCA patients. Identified psychopathology prior to randomisation not an inclusion criteria	Complex psychological intervention plus other rehabilitation interventions	Angina QoL questionnaire (reference - Wiklund)	Results are presented for the total score, and separately for somatic symptoms, physical activity, emotional distress and life satisfaction. The authors found no significant differences between the intervention and control groups over different time periods for each of these domains
Johnston	Acute MI patients. Identified psychopathology prior to randomisation not an inclusion criteria	Complex psychological intervention plus other rehabilitation interventions	Functional Limitations Profile (FLP) (reference - FPL)	Significant effects of both the inpatient and extended intervention were found on reducing disability measured by the FLP at 2, 6 and 12 months. Separate components of this scale (physical, psychosocial) also showed significant benefits of the interventions
Oldenburg 1985	MI patients. Identified psychopathology prior to randomisation not an inclusion criteria	Complex psychological intervention.	Heart Attack Inventory - comprised 14 previously well established, valid and reliable scales - including scales derived from the Framingham Study, the GHQ, and Speil-	From Principal Components Analysis, 4 factors were identified as a psychological dysfunction factor, and unhealthy lifestyle factor, a dependence on health-



**Table 2. Stress management interventions - Health Related Quality of Life** (Continued)

			berger State Anxiety. Authors used principal components analysis to reduce the number of variables, and therefore results from different scales are not reported separately	care factor and the final factor included alcohol consumption, physical activity and attitudes towards health. On factor 1 there were significant differences between the intervention and control, in favour of the intervention group. There were no significant differences between groups in any of the other factors
Oldenburg 1995	CABG patients. Identified psychopathology prior to randomisation not an inclusion criteria	Complex psychological intervention plus other rehabilitation interventions	General Health Questionnaire (reference - GHQ)	The proportion of patients with a high GHQ score (defined as a score of 4 or more) declined over time, to a similar extent in both the intervention and control groups
Erdman	MI patients. Identified psychopathology prior to randomisation not an inclusion criteria	Complex psychological intervention plus other rehabilitation interventions	Psychologic questionnaire developed by the author.	Psychologic scale consisted of 4 domains - well-being, feelings of disability, despondency and social inhibition. No differences were seen between the intervention and control groups at 6 months or 5 years

**Table 3. Stress management interventions - other psychological outcomes**

Study	Patients	Intervention	Outcome measures	Results
Gallacher	Male angina patients. No identified levels of psychopathology prior to the intervention	Complex psychological intervention.	Derogatic stress profile and subjective stress score.	At 6 months follow up, both the total derogatis score and subjective stress score were significantly lower in the intervention group
Toobert	Chronic CHD, all women. No identified levels of psychopathology prior to the intervention	Single psychological intervention plus other rehabilitation interventions	Cohens percieved stress scale (reference - Cohen)	At 12 months follow up the mean percieved stress score was similar in the intervention and control groups

**Table 3. Stress management interventions - other psychological outcomes** (Continued)

Hofmanbang	PTCA patients. No identified levels of psychopathology prior to the intervention	Complex psychological intervention plus other rehabilitation interventions	Type A attitudes from the stress profile instrument, Bortner Type A index, and the HALTAM questionnaire which covers different areas of the Type A construct	At 12 months and 2 years Type A attitudes measured with the stress profile instrument were significantly reduced in the intervention group. No differences were seen in any of the other scales measuring Type A behaviour
RCCP	MI patients. No identified levels of psychopathology prior to the intervention	Type A behaviour counselling and risk factor counselling vs risk factor counselling	Type A attitudes assessed by video taped clinical interviews (VCI) and questionnaires for patients and spouses	Over 4.5 years there was a reduction in Type A behaviour when assessed by VCI decreased in both groups from baseline, but significantly more in the treatment group. From the participants questionnaire, the decline in Type A behaviour was greatest at the end of the first year, but continued to fall thereafter. The fall was less dramatic in the comparison group

## WHAT'S NEW

Last assessed as up-to-date: 31 January 2004.

Date	Event	Description
29 October 2008	Amended	Converted to new review format.

## HISTORY

Protocol first published: Issue 1, 2001

Review first published: Issue 2, 2004

Date	Event	Description
1 February 2004	New citation required and conclusions have changed	Substantive amendment

## CONTRIBUTIONS OF AUTHORS

All co-reviewers were involved in the design of the review and in providing critical comments about the manuscript. Karen Rees and Paul Bennett independently selected studies for inclusion and abstracted data from the source papers. Analyses were performed by Karen Rees. Karen Rees and Paul Bennett wrote the first draft of the review. Robert West, George Davey Smith, and Shah Ebrahim were the principal advisors.

## DECLARATIONS OF INTEREST

None

## SOURCES OF SUPPORT

### Internal sources

- Department of Social Medicine, University of Bristol, UK.
- Health Services Research Focus, University of Wales College of Medicine, UK.

### External sources

- British Heart Foundation, UK.

## NOTES

The Peninsula Technology Assessment Group (PenTAG) at Peninsula Medical School, Exeter, UK and the Cochrane Heart Group have been awarded a 3-year grant from the National Institute for Health Research to update existing Cochrane systematic reviews relevant to public health, primary care and rehabilitation.

This review is scheduled to be updated in the first year of the program. Publication of the updated review is anticipated by issue 2, 2009 at the latest.

## **INDEX TERMS**

### **Medical Subject Headings (MeSH)**

\*Psychotherapy; Coronary Disease [mortality; \*psychology; rehabilitation]; Stress, Psychological [\*therapy]

### **MeSH check words**

Humans