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Psychological interventions for depression and anxiety in patients with coronary heart disease, heart failure or atrial fibrillation (Review)

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[Intervention Review]

Psychological interventions for depression and anxiety in patients with coronary heart disease, heart failure or atrial fibrillation

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ABSTRACT

Background

Depression and anxiety occur frequently (with reported prevalence rates of around 40%) in individuals with coronary heart disease (CHD), heart failure (HF) or atrial fibrillation (AF) and are associated with a poor prognosis, such as decreased health-related quality of life (HRQoL), and increased morbidity and mortality. Psychological interventions are developed and delivered by psychologists or specifically trained healthcare workers and commonly include cognitive behavioural therapies and mindfulness-based stress reduction. They have been shown to reduce depression and anxiety in the general population, though the exact mechanism of action is not well understood. Further, their effects on psychological and clinical outcomes in patients with CHD, HF or AF are unclear.

Objectives

To assess the effects of psychological interventions (alone, or with cardiac rehabilitation or pharmacotherapy, or both) in adults who have a diagnosis of CHD, HF or AF, compared to no psychological intervention, on psychological and clinical outcomes.

Search methods

We searched the CENTRAL, MEDLINE, Embase, PsycINFO and CINAHL databases from 2009 to July 2022. We also searched three clinical trials registers in September 2020, and checked the reference lists of included studies. No language restrictions were applied.

Selection criteria

We included randomised controlled trials (RCTs) comparing psychological interventions with no psychological intervention for a minimum of six months follow-up in adults aged over 18 years with a clinical diagnosis of CHD, HF or AF, with or without depression or anxiety. Studies had to report on either depression or anxiety or both.

Data collection and analysis

We used standard Cochrane methods. Our primary outcomes were depression and anxiety, and our secondary outcomes of interest were HRQoL mental and physical components, all-cause mortality and major adverse cardiovascular events (MACE). We used GRADE to assess the certainty of evidence for each outcome.

Main results

Twenty-one studies (2591 participants) met our inclusion criteria. Sixteen studies included people with CHD, five with HF and none with AF. Study sample sizes ranged from 29 to 430. Twenty and 17 studies reported the primary outcomes of depression and anxiety, respectively.

Despite the high heterogeneity and variation, we decided to pool the studies using a random-effects model, recognising that the model does not eliminate heterogeneity and findings should be interpreted cautiously.

We found that psychological interventions probably have a moderate effect on reducing depression (standardised mean difference (SMD) -0.36, 95% confidence interval (CI) -0.65 to -0.06; 20 studies, 2531 participants; moderate-certainty evidence) and anxiety (SMD -0.57, 95% CI -0.96 to -0.18; 17 studies, 2235 participants; moderate-certainty evidence), compared to no psychological intervention.

Psychological interventions may have little to no effect on HRQoL physical component summary scores (PCS) (SMD 0.48, 95% CI -0.02 to 0.98; 12 studies, 1454 participants; low-certainty evidence), but may have a moderate effect on improving HRQoL mental component summary scores (MCS) (SMD 0.63, 95% CI 0.01 to 1.26; 12 studies, 1454 participants; low-certainty evidence), compared to no psychological intervention.

Psychological interventions probably have little to no effect on all-cause mortality (risk ratio (RR) 0.81, 95% CI 0.39 to 1.69; 3 studies, 615 participants; moderate-certainty evidence) and may have little to no effect on MACE (RR 1.22, 95% CI 0.77 to 1.92; 4 studies, 450 participants; low-certainty evidence), compared to no psychological intervention.

Authors' conclusions

Current evidence suggests that psychological interventions for depression and anxiety probably result in a moderate reduction in depression and anxiety and may result in a moderate improvement in HRQoL MCS, compared to no intervention. However, they may have little to no effect on HRQoL PCS and MACE, and probably do not reduce mortality (all-cause) in adults who have a diagnosis of CHD or HF, compared with no psychological intervention. There was moderate to substantial heterogeneity identified across studies. Thus, evidence of treatment effects on these outcomes warrants careful interpretation. As there were no studies of psychological interventions for patients with AF included in our review, this is a gap that needs to be addressed in future studies, particularly in view of the rapid growth of research on management of AF. Studies investigating cost-effectiveness, return to work and cardiovascular morbidity (revascularisation) are also needed to better understand the benefits of psychological interventions in populations with heart disease.

PLAIN LANGUAGE SUMMARY

Psychological interventions for depression and anxiety in patients with heart disease

Do psychological interventions reduce depression and anxiety in patients with coronary heart disease, heart failure or atrial fibrillation compared to no psychological intervention?

Key messages

- Psychological interventions for depression and anxiety probably result in a moderate reduction in depression and anxiety in patients with coronary heart disease or heart failure.

- Psychological interventions for depression and anxiety may result in a moderate improvement in mental health-related quality of life, but not physical health-related quality of life, in patients with coronary heart disease or heart failure.

- As there were no studies involving patients with atrial fibrillation, the effects of psychological interventions on depression and anxiety in this population are unknown.

What is heart disease?

The term 'heart disease' refers to a range of disorders affecting the heart, including: coronary heart disease (reduced blood flow to the heart), heart failure (weakness in pumping of the heart) and atrial fibrillation (uneven beating of the heart).

Why might psychological interventions help patients with heart disease?

There is growing evidence to suggest that many (around 40%) of people with heart disease have depression or anxiety, often long-lasting. Psychological interventions are therapies used to produce more positive thoughts, feelings and behaviours, e.g. cognitive behavioural therapy for developing more accurate and balanced beliefs, and mindfulness, a meditation-based therapy. There is strong evidence that

these interventions are an effective treatment in a range of psychological disorders, conditions that negatively affect mood, thinking and behaviour. However, the evidence is unclear as to whether psychological interventions are effective in reducing depression and anxiety in adults with coronary heart disease, heart failure or atrial fibrillation.

What did we want to find out?

We wanted to find out if psychological interventions for depression and anxiety reduce depression and anxiety in people with coronary heart disease, heart failure or atrial fibrillation compared with people receiving no psychological intervention.

We also wanted to find out if psychological interventions for depression and anxiety improve any other related factors, such as mental (mood; thinking) and physical (body; fitness) health-related quality of life, deaths and major adverse heart events (e.g. heart-related hospital admissions; heart-related deaths).

What did we do?

We searched databases for studies of psychological interventions for people aged over 18 years with heart disease.

We compared and summarised the results of these studies and rated our confidence in the evidence, based on factors such as study methods and sizes.

What did we find?

We found 21 eligible studies involving 2591 people. Of these 21 studies, 16 included people with coronary heart disease, five with heart failure and none with atrial fibrillation. We found wide variation in the kinds of interventions included in the review, in terms of what the interventions included, how and by whom they were delivered, and the clarity with which they were reported.

Compared to no psychological intervention, we found that psychological interventions for depression and anxiety probably reduce depression and anxiety, and may improve mental health-related quality of life in adults who have a diagnosis of coronary heart disease or heart failure, but not physical health. Further, they probably do not reduce mortality and do not reduce the risk of major cardiac events.

What are the limitations of the evidence?

There was much variation in the types of psychological interventions (e.g. cognitive behavioural therapy, mindfulness, a mix of therapies), patients (different types of coronary heart disease and heart failure) and tools used to measure outcomes (a range of tools to measure the same outcome, e.g. anxiety). This made it difficult to compare the effects of psychological interventions across studies.

Also, there was some indication of inconsistent findings, not all findings were reported (only a selection) and a lack of blinding (participants knowing which group they were in) in the included studies. Further, some studies had very small sample sizes, or there were not enough studies to draw conclusions about the impact of psychological interventions (i.e. costs, deaths and major adverse heart events). Taken together, our confidence in the overall effects of psychological interventions was reduced across the main outcomes.

How up-to-date is this evidence?

The evidence is up-to-date as of July 2022.

SUMMARY OF FINDINGS

Summary of findings 1. Psychological interventions for depression and anxiety compared to no psychological interventions for patients with coronary heart disease or heart failure

Psychological interventions for depression and anxiety compared to no psychological interventions for patients with coronary heart disease or heart failure

Patient or population: patients with coronary heart disease or heart failure

Setting: hospital or community

Intervention: psychological interventions for depression and anxiety

Comparison: no psychological intervention

Outcome	Anticipated absolute effects (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty	Comment
	Risk with no psychological interventions	Risk with psychological intervention				
Depression Measured with:BDI, BDI II, BDI-FS, CDS, CID, HADS, HAM-D, PHQ-9 and ZDS (lower = better) Follow-up: 6 to 12 months	See comment	**SMD 0.36 SD lower** (0.65 lower to 0.06 lower)	-	2531 (20 RCTs)	⨁⨁⨁◯ Moderate[a]	Psychological interventions for depression and anxiety probably result in a moderate reduction in depression (all measures), compared to no psychological intervention. The mean score in the intervention groups was 0.36 standard deviations lower than in the no psychological intervention comparison groups. A standard deviation of 0.36 represents a moderate effect according to Cohen's effects sizes (Cohen 1988).
Anxiety Measured with: BAI, GAD, HADS, SAS, SCL-90-R and STAI (lower = better) Follow-up: 6 to 12 months	See comment	**SMD0.57 SD lower** (0.96 lower to 0.18 lower)	-	2235 (17 RCTs)	⨁⨁⨁◯ Moderate[a]	Psychological interventions for depression and anxiety probably result in a moderate reduction in anxiety (all measures), compared to no psychological intervention. The standard mean score in the intervention groups was 0.57 standard deviations lower compared to the no psychological intervention comparison groups. A standard deviation of 0.57 represents a moderate effect according to Cohen's effects sizes (Cohen 1988).
Health-related quality of life, phys-	See comment	**SMD 0.48 SD higher** (0.02	-	1454 (12 RCTs)	⨁⨁◯◯ Low[b,c]	Psychological interventions for depression and anxiety probably have little to no effect on HRQoL (PCS), compared to no psychological intervention.

ical component summary Measured with: EQ-5D, KCCQ, MLHFQ, SF-12/36 Follow-up: 6 to 12 months		lower to 0.98 higher)				
Health-related quality of life, mental component summary Measured with: EQ-5D, KCCQ, MLHFQ, SF-12/36 Follow-up: 6 to 12 months	See comment	**SMD 0.63 SD higher** (0.01 higher to 1.26 higher)	-	1454 (12 RCTs)	⊕⊕◯◯ Low[b,d]	Psychological interventions for depression and anxiety may result in a moderate increase in HRQoL (MCS), compared to no psychological intervention. The mean score in the intervention groups was 0.63 standard deviations higher compared to the no psychological intervention control groups. A standard deviation of 0.63 represents a moderate to large effect according to Cohen's effects sizes (Cohen 1988).
Mortality (all-cause) Follow-up: 12 to 36 months	47 per 1000	**41 per 1000** (35 to 47)	**RR 0.81** (0.39 to 1.69)	615 (3 RCTs)	⊕⊕⊕◯ Moderate[e]	Psychological interventions for depression and anxiety probably result in little to no difference in mortality (all-cause), compared to no psychological intervention.
Major adverse cardiovascular events (MACE) Follow-up: 6 to 36 months	131 per 1000	**161 per 1000** (131 to 191)	**RR 1.22** (0.77 to 1.92)	450 (4 RCTs)	⊕⊕◯◯ Low[b,d]	Psychological interventions for depression and anxiety probably result in little to no difference in MACE, compared to no psychological intervention.

*__The risk in the intervention group__ (and its 95% CI) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

BAI:Beck Anxiety Inventory; **BDI**: Beck Depression Inventory; **BDI II**: Beck Depression Inventory II; **BDI-FS**: Beck Depression Inventory fast screen;**CDS**: Cardiac Depression Scale; **CI**: confidence interval; **CID**: Clinical Interview for Depression; **EQ-5D**; EuroQol-5D; **GAD**: Generalised Anxiety Disorder Assessment;**HADS**: Hospital Anxiety and Depression Scale; **HAM-D**: Hamilton Depression Rating Scale; **HRQoL (MCS)**: health-related quality of life mental component summary; **HRQoL (PCS)**: health-related quality of life physical component summary;**KCCQ**: Kansas City Cardiomyopathy Questionnaire; **MLHFQ**: Minnesota Living with Heart Failure Questionnaire; **PHQ-9**: Patient Health Questionnaire-9; **RCTs**: randomised controlled trials; **SAS**: Zung Self-rating Anxiety Scale; **SCL-90-R**: Symptom Checklist 90-Revised; **SD**:standard deviation; **SF12/36**: Short Form Health Survey 12 & 36; **SMD**: standardised mean difference; **STAI**: State-Trait Anxiety Inventory; **ZDS**: Zung Self-Rating Depression Scale

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

[a]Downgraded by 1 level for inconsistency; inconsistent directions of effect and considerable heterogeneity (depression: $I^2 = 90\%$; anxiety: $I^2 = 93\%$; HADS-A: $I^2 = 53\%$; BAI: $I^2 = 99\%$).

[b]Downgraded by 1 level for inconsistency; statistical heterogeneity was present (HADS-D: $I^2 = 49\%$; BDI-II: $I^2 = 75\%$; HRQoL (PCS): $I^2 = 93\%$; HRQoL (MCS): $I^2 = 95\%$; PHQ-9: $I^2 = 36\%$).

[c]Downgraded by 1 level for imprecision; sufficient number of participants (depression PHQ-9: n = 610; HADS-A: n = 1334; GAD-A: n = 504; HRQoL (PCS): n =1454), but the confidence interval includes both appreciable harm and appreciable benefit (i.e. 95% CI spans 0).

[d]Downgraded by 1 level for strongly suspected publication bias; Eggers test P = 0.012.

[e]Downgraded by 1 level for imprecision; sufficient number of events (mortality: n = 615), but the CI around the RR includes an RR of 1 and the upper and lower boundary of the CI is less than 25%.

BACKGROUND

Description of the condition

For the purpose of this Cochrane systematic review, heart disease encompassed three of the most common cardiovascular conditions: coronary heart disease (CHD), heart failure (HF) and atrial fibrillation (AF). CHD is when the coronary arteries become narrowed, reducing the supply of blood to the heart and is the number one cause of death, accounting for 9.43 million deaths worldwide in 2016, approximately 4.95 million men and 4.48 million women (BHF 2022; WHO 2018). Heart failure is when the heart is not adequately pumping blood (BHF 2022b), and AF is when the heart beats irregularly (BHF 2021). The global prevalence estimates for CHD, HF and AF are 200 million, 64 million and 60 million, respectively (BHF 2022), with HF and AF seen as cardiovascular disease epidemics with similar underlying risk factors and pathophysiology (Benjamin 2017; Staerk 2017). People with heart disease experience substantial burden that includes fatigue, shortness of breath, poor health-related quality of life (HRQoL), increased risk of mortality and hospital admissions, and high healthcare costs (Baumeister 2015; Garster 2009; Gheorghe 2018; Giedrimiene 2017; Long 2019; Schmidt 2016).

Over the past two decades, significant reductions in mortality have been achieved in people with heart disease through pharmacological and device therapy (Anderson 2014; Mensah 2017). Subsequently, the focus has shifted towards psychological outcomes (Ladwig 2022; Richards 2017; Wan 2014). Depression and anxiety are highly prevalent (with reported rates of around 40%) in people diagnosed with CHD, HF or AF, and result in worse outcomes, such as poorer HRQoL, and increased morbidity and mortality (Dhar 2016; Freedland 2015; Gale 2014). To improve patient outcomes, psychological approaches tackling stress are included in cardiovascular prevention guidelines internationally (e.g. BACPR 2023; NICE 2018; Piepoli 2016), although there is a move towards targeting psychological interventions (Thompson 2023); for example, mood states (Reavell 2018), and adherence to lifestyle change (Khanji 2018) and medicines (Bosworth 2018).

The updated Cochrane review of psychological interventions for CHD found there was no evidence that psychological treatments affected total mortality, the risk of revascularisation procedures or the rate of non-fatal MI, although the rate of cardiac mortality was reduced and psychological symptoms (depression, anxiety or stress) were alleviated; however, the GRADE assessments suggested considerable uncertainty surrounding these effects (Richards 2017). Considerable uncertainty also remains regarding the people who would benefit most from treatment (i.e. people with or without psychological disorders at baseline) and the specific components of successful interventions. For example, in the review, participants had varying levels of psychopathology, and of the 35 included studies, 10 did not report the psychological status of participants at baseline despite testing the effectiveness of a psychological intervention. Due to the high proportion of studies having a mixed population (i.e. participants with and without a reported psychological disorder at baseline, and studies not reporting psychological status), the evidence remains equivocal as to whether psychological interventions should solely target people with CHD and with established psychological disorders, as opposed to mixed populations (Richards 2017; Richards 2018a). Additionally, a systematic review (with 2851 participants) examining anxiety, treatment and morbidity risk in patients diagnosed with CHD concluded that there was a paucity of RCTs investigating anxiety in CHD and called for future research to focus on both depression and anxiety (Tully 2014). To assist in determining whether those in greatest need benefit most from psychological interventions, the current review focused on adults with a diagnosis of heart disease, with and without 'reported' depression and anxiety (i.e. studies not reporting baseline assessments of depression and anxiety were excluded).

As CHD, HF and AF are the three most prevalent cardiovascular conditions and growing global health and economic challenges (Cozzolino 2018; Lesyuk 2018; Shafie 2018), this Cochrane review extended previous reviews that have focused on specific cardiovascular diagnoses (Carney 2017; Lichtman 2014; Richards 2017; Whalley 2011). Further, a comparison of studies of psychological interventions for people with heart disease, with and without reported depression or anxiety, assisted in determining the possible efficacy in these subpopulations.

Description of the intervention

This review included psychological interventions delivered by healthcare workers trained in their delivery. In the case of interventions that are delivered online, we considered all psychological interventions targeting depression or anxiety, developed by psychologists or healthcare workers with training in psychological techniques. By nature, psychological interventions are varied (i.e. in terms of content, composition), ranging from traditional psychological therapies (e.g. cognitive behavioural therapy) used to identify and correct dysfunctional emotions, behaviours and cognitions through a goal-orientated, systematic procedure in people with cardiac conditions (Kaplan 2009), to third-wave cognitive behavioural therapies (e.g. mindfulness-based stress reduction).

In 2009, the UK National Institute for Health and Care Excellence (NICE) first published guidelines for the effective delivery of psychological interventions for depression among those people with chronic health conditions. The guidelines stipulated that interventions of this type be delivered by competent delivery agents or practitioners and advocated a more structured approach to guide interventions (NICE 2009). Accordingly, this review focused on psychological interventions addressing depression and anxiety in people with heart disease, delivered by healthcare workers trained in the delivery of the intervention and for those delivered online, that were developed by psychologists or healthcare workers with training in psychological techniques.

Best practice guidelines advocate that people diagnosed with heart disease are offered cardiac rehabilitation (CR) (BACPR 2023; Lichtman 2014; NICE 2018; Piepoli 2016; Ponikowski 2016; Woodruffe 2015). The following definition encompasses the key concepts of CR: “The coordinated sum of activities required to influence favourably the underlying cause of cardiovascular disease, as well as to provide the best possible physical, mental and social conditions, so that the patients may, by their own efforts, preserve or resume optimal functioning in their community and through improved health behaviour, slow or reverse progression of disease” (BACPR 2023, p 1). Typical components of CR consist of assessment and management plans, health behaviour change and education, lifestyle risk factor management (diet, smoking, exercise), medication management and psychosocial health (Dalal 2015; Thomas 2019). Psychosocial components in CR programmes

were introduced to enhance HRQoL, increase treatment adherence and improve cardiovascular prognosis (Pogosova 2015). However, often dependent on resource availability and geographic location, CR programmes vary in their core components, intensity, duration, setting and delivery team. For example, less than one-quarter of CR programmes across the UK provide specific psychological treatments (NACR 2021). Furthermore, a recent cross-sectional study of CR in 111 countries identified significant regional variation and relatively low numbers of programmes that included a psychosocial component (Supervia 2019). Notwithstanding, the benefits of CR are well established, including increased HRQoL, and reductions in rehospitalisation, morbidity and mortality rates (Anderson 2016; Long 2019). This review included psychological interventions delivered alone or with CR, as long as CR was part of usual medical care and offered routinely to both study arms: thus, the comparator is no psychological intervention.

Evidence-based guidelines recommend medication (e.g. selective serotonin reuptake inhibitors or selective serotonin norepinephrine reuptake inhibitors) as a first-step therapy in the treatment of major depressive disorder (Jobst 2016; Qaseem 2016). Current evidence reports that adjunct use of pharmacotherapy for an underlying psychological condition may increase intervention effectiveness compared with interventions without pharmacotherapy (Richards 2017; Richards 2018a). However, pharmacotherapy treatment for mental health disorders can present cardiovascular risk due to side effects of the drugs or interactions with other medications (Pina 2018). People most likely to receive medication are those with the most severe forms of depressive illness (Gartlehner 2017). Including people across the spectrum of disease severity is essential to determining who benefits the most from psychological intervention. This review included psychological interventions, with and without adjunct pharmacotherapy.

Current evidence-based guidelines recommend group-based psychological therapies for less severe depression and anxiety (NICE 2022), along with family involvement, where appropriate. Systematic reviews have found group-based CBT to be more effective than controls for depression and anxiety (Barkowski 2020; Okumura 2014). Family members, such as partners, often also play a key role in supporting people with heart disease (Rohrbaugh 2006). Including different modes of delivery of CBT and whether or not families are involved is key to understanding which treatment modes are most effective in people with heart disease.

How the intervention might work

There is considerable evidence that depression and anxiety are risk factors for the development of heart disease (Dhar 2016), with depression an established independent risk factor for CHD (Van Der Kooy 2007). Both are strongly associated with poor cardiac outcomes (Carney 2017; May 2017; Seldenrijk 2015). Those with established heart disease are likely to experience depression and anxiety, with prevalence rates frequently reported at around 40% (Colquhoun 2013; Seldenrijk 2015), and some large-scale studies report levels of depression over 60% (Carney 2004; Kotseva 2009). Hence, the evidence for a bidirectional relationship between negative emotional states and heart disease is substantial. While the pathways are not completely understood, factors impacting the poorer prognosis of people with heart disease and with depression or anxiety, or both, are multifactorial, including lifestyle, behavioural and, more recently, biological (Dickens 2015). Lifestyle and behavioural factors include increased rates of smoking, alcohol intake, physical inactivity and obesity (Dhar 2016). Major depressive disorder is also a predictor of poor disease treatment, management and medication adherence (Bauer 2012; Goldstein 2017). For example, patients who are depressed are far less likely to be motivated to complete or even attend CR programmes (Chauvet-Gelinier 2017). Major depressive disorder can cause autonomic nervous system dysfunction, elevated cortisol levels and elevated markers of inflammation with subsequent deleterious downstream effects, including hypertension, left ventricular hypertrophy and coronary vasoconstriction (Dhar 2016). The evidence is building to suggest that both depression and anxiety contribute to the pathogenesis of heart disease (O'Neill 2016; Seldenrijk 2015). Of significance is the growing recognition of the role of psychological determinants in cardiac illness and recovery (Chauvet-Gelinier 2017), which has implications for psychological interventions and subsequent adoption and maintenance of healthy lifestyle behaviours, medication adherence and potential for improved clinical outcomes in those with heart disease.

Why it is important to do this review

In their 2017 Cochrane review update, Richards 2017 concluded, according to GRADE methodology, that uncertainty remains regarding the benefits of psychological interventions among people with CHD (i.e. reducing cardiac mortality and reducing psychological symptoms), and large-scale studies are still warranted. In this new Cochrane review, we included HF and AF in addition to CHD, thus increasing the likelihood of the inclusion of additional large-scale studies in the existing evidence base. Adding to the uncertainty was the number of studies with no reported psychopathologies at baseline (Richards 2017). This review included people with heart disease with reported levels (including scores indicating absence) of depression or anxiety at baseline, adding to the knowledge base on the effectiveness of optimally targeted psychological interventions. Further, many national and international cardiovascular disease secondary prevention and rehabilitation guidelines acknowledge the importance of the provision of psychological interventions in addition to standard rehabilitation (Lichtman 2014; NICE 2009; Piepoli 2016; Woodruffe 2015), especially in people with depression or anxiety with comorbid cardiovascular disease, and will therefore benefit from the evidence of this review.

OBJECTIVES

To assess the effects of psychological interventions (alone, or with cardiac rehabilitation or pharmacotherapy, or both) in adults who have a diagnosis of CHD, HF or AF, compared to no psychological intervention, on psychological and clinical outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) with parallel-group, individual participant, cluster-allocation or cross-over design, comparing the independent effects of a psychological intervention versus a no psychological intervention comparator. We considered studies where follow-up was six months or more following the start of the intervention or randomisation. We included studies reported as full text, those published as abstract only and unpublished data. We

excluded quasi-RCTs, as these use a method of allocation that is not truly random.

Types of participants

Adults, 18 years of age and older, with heart disease, with and without depression or anxiety, managed in either hospital or community settings. Participants with heart disease included people who had a clinical diagnosis of CHD, HF or AF. Participants with CHD included those who have experienced a myocardial infarction (MI), a revascularisation procedure such as coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI), and people with angina or angiographically defined CHD. Participants with HF included reduced (< 40%) ejection fraction (HFrEF), mid-range (40% to 49%) ejection fraction (HFmrEF) and those with preserved (≥ 50%) ejection fraction HF (HFpEF; Ponikowski 2016; Watson 2018). We included participants with all types of AF.

Participants may have had comorbid conditions (i.e. conditions other than CHD, HF or AF). However, we excluded studies if the population was mixed; for example, participants with CHD or diabetes when, (1) the data were not stratified by condition and (2) if more than 50% of participants did not have a diagnosis of CHD, HF or AF. Thus, studies that did not focus (majority of the population) on participants with CHD, HF or AF were excluded (Richards 2017). We also excluded studies including participants without a baseline assessment of depression or anxiety, patient-reported or otherwise. Prior to excluding any such studies, we contacted the study authors to request the data for the subgroup of interest.

Types of interventions

We considered all psychological interventions for depression or anxiety delivered by psychologists or healthcare workers with specific training in psychological techniques, including those delivered online. Included interventions could vary in content and composition, ranging from cognitive behavioural therapies (e.g. rational emotive therapy, restructuring), to third-wave cognitive behavioural therapies (e.g. mindfulness-based stress reduction). We classified psychological interventions as per the Cochrane Common Mental Disorders (CCMD) classification of psychological interventions (Cochrane Common Mental Disorders 2019). We excluded less specific approaches, such as therapeutic counselling or educational interventions from this delineation, along with self-management techniques used to change cardiac risk factors such as smoking and low levels of exercise. We excluded studies that did not specify that healthcare workers delivering the intervention were specifically trained, or following a treatment protocol. When uncertainty existed, prior to excluding any such studies, we contacted the study authors to determine whether specific training took place. We excluded studies where the evaluation of the intervention was solely directed at improving adherence to other cardiovascular efficacious treatments (e.g. medications, exercise) or modifying lifestyle factors (e.g. smoking, diet). We only considered studies where the effect of the psychological intervention could be evaluated independently.

We included studies that compared psychological treatment with no psychological intervention, which was commonly the receipt of usual care (sometimes described as treatment as usual). Thus, the comparator of no psychological intervention could include routine medical care provided to people with heart disease, and co-interventions including referral to or participation in (or both) a comprehensive CR programme. Although psychological interventions often include co-interventions (e.g. cardiac risk factor education), we excluded studies where the co-interventions were not offered to both intervention and comparator groups. We included studies of psychological interventions offered in conjunction with pharmacotherapy for a mood disorder (Richards 2017). These interventions were eligible for inclusion as long as the effect of the psychological intervention could be evaluated independently from co-interventions.

Types of outcome measures

Primary outcomes

1. Depression
2. Anxiety

We measured depression and anxiety as change in symptoms (mean score). We accepted psychometrically validated measures of depression or anxiety, self-reported or other, along with clinical diagnosis. We grouped primary outcomes as per the following time points: short term (up to six months), medium term (6 to 12 months) and long term (more than 12 months), and reported the longest follow-up available in the summary of findings table. As this review reported on patients 'with and without depression or anxiety', reporting on one or more of the primary outcomes of depression or anxiety was an inclusion criterion.

Validated tools for depression included: Beck Depression Inventory (BDI; Beck 1961); Beck Depression Inventory II (BDI II; Beck 1996); Beck Depression Inventory fast screen (BDI-FS; Poole 2009); Behavioral Activation for Depression Scale (BADS; Kanter 2007); Cardiac Depression Scale (CDS; Hare 1996); Center for Epidemiological Studies Depression Scale (CES-D; Radloff 1977); Comprehensive Psychopathological Rating Scale (CPRS; Asberg 1978); Comprehensive Psychopathological Rating Scale Self-Affective (CPRS S-A; Svanborg 1994); Depression, Anxiety and Stress Scale (DASS21; Lovibond 1995); Delusions-Symptoms-States Inventory/states of Anxiety and Depression (DSSI/sAD; Bedford 1976); Hospital Anxiety and Depression Scale (HADS-D; Zigmond 1983); Hamilton Depression Rating Scale (HAM-D; Hamilton 1960); Maastricht Questionnaire for Vital Exhaustion and Depression (Williams 2010); Montgomery-Åsberg Depression Rating Scale (MADRS; Montgomery 1979); Patient Health Questionnaire-9 (PHQ-9; Kroenke 2001); Symptom Checklist 90-R (SCL-90-R; Derogatis 1992); and Zung Self-Rating Depression Scale (ZDS; Zung 1965).

Validated tools for anxiety included: Beck Anxiety Inventory (BAI; Beck 1988); Cardiac Anxiety Questionnaire (CAQ; Eifert 2000); Delusions Symptoms States Inventory/states of Anxiety and Depression (DSSI/sAD; Bedford 1976); Generalised Anxiety Disorder Assessment (GAD-7; Spitzer 2006); Hospital Anxiety and Depression Scale (HADS-A; Zigmond 1983); Overall Anxiety Severity and Impairment Scale (OASIS) (Campbell-Sills 2009); State-Trait Anxiety Inventory (STAI; Spielberger 1983); Symptom Checklist 90-R (SCL-90-R; Derogatis 1992); Taylor Manifest Anxiety Scale (Taylor 1953); and Zung Self-rating Anxiety Scale (SAS; Zung 1971).

Whilst validated tools measuring symptoms of depression or anxiety were eligible for inclusion, it is important to note that there is variation in the symptoms profiles captured by different tools. For example, for depression, both BDI-II and PHQ-9 tools assess

psychological and somatic symptoms, whilst the HADS focuses on psychological symptoms; similarly for anxiety, the BAI also includes somatic and psychological symptoms, whilst the GAD-7 focuses on psychological symptoms.

Secondary outcomes

1. Health-related quality of life (HRQoL) standardised tools only, with physical component summary (PCS) and mental component summary (MCS) scores, where reported
2. Self-efficacy standardised and non-standardised tools
3. All-cause mortality
4. Cardiovascular mortality
5. All-cause hospitalisations (participants with at least one event)
6. Cardiovascular hospitalisations (participants with at least one event)
7. Cardiovascular morbidity: non-fatal MI (participants with at least one event)
8. Cardiovascular morbidity: revascularisation (CABG, PCI; participants with at least one event), disability-adjusted life years (DALYs)
9. Major adverse cardiovascular events (MACE)
10. Intervention acceptability
11. Return to work
12. Costs and cost-effectiveness: costs per quality-adjusted life years (QALYs)
13. Adverse events

Validated tools for HRQoL (generic and condition-specific) included: Cantril Self-Anchoring Striving Scale (Ladder of Life; Cantril 1965); Chronic Heart Failure Assessment Tool (CHAT; Dunderdale 2008); Chronic Heart Failure Questionnaire (CHFQ; Guyatt 1989); Dartmouth COOP scales (Nelson 1987); EuroQol-5D (EQ-5D; Rabin 2001); HeartQoL (Oldridge 2014); Kansas City Cardiomyopathy Questionnaire (KCCQ; Green 2000); Karnofsky Performance Status Scale (Schag 1984); Left Ventricular Disease Questionnaire (LVDQ; O'Leary 2000); MacNew Questionnaire (Valenti 1996); Minnesota Living with Heart Failure Questionnaire (LHFQ; Rector 1987); Myocardial Infarction Dimensional Assessment Scale (MIDAS; Thompson 1998); Psychological General Well-Being Index (Dupuy 1984); Quality of Life Questionnaire in Severe Heart Failure (QLQ-SHF; Wiklund 1987); Seattle Angina Questionnaire (Spertus 1995); Short Form 36-item Health Survey (SF-36; Ware 1994); Short Form 12-item Health Survey (SF-12; Ware 1995).

Validated tools for self-efficacy included: Generalized Self-Efficacy Scale (GES; Schwarzer 1995); General Self-Efficacy Scale (GES-6; Romppel 2013); New General Self-Efficacy Scale (NGSE; Chen 2001); Self-Efficacy Survey (Panc 2013).

Intervention acceptability was assessed using 1) retention rates and 2) reporting a narrative summary of qualitative data on utility, adherence, barriers and satisfaction (Saracutu 2018; Sekhon 2017).

We reported adverse events in a narrative summary, including a notable absence of evidence addressing whether there are adverse outcomes arising from participation in a psychological intervention.

Reporting one or more of the above-listed secondary outcomes in the study was not an inclusion criterion for the review. Where a published report did not appear to report one of these outcomes, we accessed the study protocol and contacted the study authors to ascertain whether the outcomes were measured but not reported.

We grouped secondary outcomes as per the following time points: short term (up to six months), medium term (6 to 12 months) and long term (more than 12 months) and reported the longest follow-up available in the summary of findings table. As part of the narrative, we included in the review relevant studies that measured these outcomes but did not report the data at all, or not in a usable format.

Search methods for identification of studies

Electronic searches

We identified studies through systematic searches of bibliographic databases and trial registries. We searched the following databases on 5 July 2022 and trial registers on 7 July 2022.

- Cochrane Central Register of Controlled Trials (CENTRAL 2022, Issue 7) in the Cochrane Library (searched 5 July 2022).
- MEDLINE Ovid (2009 to 5 July 2022).
- Embase Ovid (2009 to 5 July 2022).
- PsycINFO Ovid (2009 to 5 July 2022).
- CINAHL EBSCO (2009 to 5 July 2022).
- World Health Organization (WHO) International Clinical Trials Registry platform (ICTRP) (apps.who.int/trialsearch; searched 7 July 2022).
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov; searched 7 July 2022).

The Cochrane sensitivity-precision maximising RCT filter was used for MEDLINE, and for Embase, terms as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* were applied (Lefebvre 2022). Adaptations of these RCT filters were applied to the other databases, except CENTRAL. Searches were updated four times: 28 January 2020, 19 March 2020, 22 April 2021 and 5 July 2022, with date limits applied to retrieve records added to the databases from 2009 only. See Appendix 1 for details of the search strategy used. The results from all databases were de-duplicated from each other.

We searched all databases from 2009 (in accordance with NICE 2009 guidelines) to the present, and imposed no restriction on the language of publication or publication status. In 2009, there were many scientific advances in understanding the relationship between depression and heart disease, with lasting implications for the treatment of depression in people with the disease (Davidson 2010). These advances included the publication of results from three RCTs reporting the efficacy of depression interventions in people with CHD (Carney 2009; Freedland 2009; Rollman 2009). In late 2008, the American Heart Association released a science advisory, *Depression and coronary heart disease: recommendations for screening, screening referral and treatment* (Lichtman 2014). In 2009, NICE first published guidelines for the effective delivery of psychological interventions for depression among those with chronic health conditions, with particular attention paid to heart disease (NICE 2009). The guidelines advocated a more structured approach to guide interventions and stipulated that interventions

of this type be delivered by competent delivery agents or practitioners (NICE 2009).

We did not perform a separate search for adverse effects resulting from psychological interventions used for the treatment of depression or anxiety. We considered adverse effects as described in the included studies only.

Searching other resources

We handsearched the reference lists of all included studies and previous systematic reviews for additional references to studies. We contacted the main authors of included studies and experts within the area to ask for any missed, unreported or ongoing studies. We also searched for any retraction statements and errata for included studies.

Data collection and analysis

Selection of studies

Two review authors independently screened titles and abstracts for inclusion (CFS and KMcG in 2020, 2021; KMcG and SHR in 2022) using the systematic review software, Covidence (Covidence 2022). Potential studies identified as a result of the search were coded as 'eligible' or 'potentially eligible/unclear'. If there were any disagreements, a third author was asked to arbitrate (JDL in 2020, 2021; CFS in 2022). We retrieved the full-text study reports/publications and two review authors (CFS and KMcG) independently screened the full texts, identified studies for inclusion, and identified and recorded reasons for exclusion of the ineligible studies. We resolved any disagreements through discussion or, if required, we consulted a third person (JDL). We identified and excluded duplicates and collated multiple reports of the same study so that each study, rather than each report, was the unit of interest in the review. We recorded the selection process in sufficient detail to complete a PRISMA flow diagram and 'Characteristics of excluded studies' table (Page 2021).

Data extraction and management

We extracted data using the systematic review software, Covidence 2022. The data extraction form was built and customised in Covidence (Covidence 2022), to allow for consistency in data extraction processes, efficient data sharing, data management and identification of discrepancies. In line with guidance in the *Cochrane Handbook for Systematic Reviews of Interventions* (Li 2022), we piloted the data extraction form using two studies included in this review, to ensure usability and appropriateness for this review.

Two review authors (CFS and KMcG) independently extracted the following information from the included studies.

1. Methods: study design, total duration of the study, number of study centres and location, study setting and date of study.
2. Participants: number randomised, the number lost to follow-up/withdrawn, number analysed, mean age, age range, gender, severity of the condition, diagnostic criteria, inclusion criteria and exclusion criteria.
3. Interventions: intervention (including the goals of treatment and components used to achieve those goals), comparison and co-interventions. We described psychological interventions as per CCMD classifications.
4. Outcomes: primary and secondary outcomes specified and collected, and time points reported.
5. Notes: funding for study, and notable conflicts of interest of study authors.

We resolved disagreements by consensus or by involving a third person (JDL). However, we extracted only ‘new’ variables for studies that were included in Richards 2017. One review author (CFS) transferred data into Review Manager Web (RevMan Web 2022). We double-checked that data were entered correctly by comparing the data presented in the systematic review with the data extraction form. A second review author (KMcG) spot-checked study characteristics for accuracy against the study report.

Assessment of risk of bias in included studies

Three review authors (CFS, KMcG, LL) independently assessed risk of bias for the outcomes included in our summary of findings table, using Version 2 of the Cochrane risk of bias assessment tool, suitable for individually randomised, parallel-group trials (RoB 2) (Higgins 2023c). We resolved any disagreements by discussion or by involving another review author (JDL).

We assessed the risk of bias of specific results of a study according to the effect of assignment to the interventions at baseline, regardless of whether the interventions were received as intended (the ‘intention-to-treat effect’), across the domains listed below. We used the Excel tool (RoB 2 2019) to manage the assessment of bias.

1. Bias arising from the randomisation process.
2. Bias due to deviations from intended interventions.
3. Bias due to missing outcome data.
4. Bias in measurement of the outcome.
5. Bias in selection of the reported result.
6. Bias arising from identification or recruitment of individual participants within clusters.

We included domain 6, as per the revised Cochrane risk of bias tool for randomised trials (RoB 2) (Sterne 2019), and used the RoB 2 tool for cluster-randomised trials (RoB 2 CRT) (Eldridge 2021), to consider whether the reported data analysis had appropriately taken account of the aggregate nature of the data. We paid particular attention to randomisation processes (e.g. allocation sequence, timing, baseline imbalances) and blinding (e.g. recruitment bias, identification bias) (Eldridge 2021). No cross-over trials were assessed as eligible for this review.

We used the signalling questions in RoB 2 and rated each domain as 'low risk of bias', 'some concerns' or 'high risk of bias'. We summarised the risk of bias judgements across different studies for each of the domains listed for each outcome. We decided the risk of bias for an outcome (e.g. depression as measured by BDI-II) by its performance in each domain: "A judgement of ‘High’ risk of bias for any individual domain led to the result being at ‘High’ risk of bias overall. A judgement of ‘Some concerns’ for any individual domain led to the result being at ‘Some concerns’; however, a judgement of 'Some concerns' in multiple domains may have led to the result being at ‘High’ risk, overall", noting that both the proposed domain level and overall risk of bias judgements could be overridden by the review authors, with justification. A judgement of 'Low' risk of bias overall was reached when the outcome was assessed as low risk across all domains (Higgins 2023c).

When considering treatment effects, we took into account the risk of bias for the studies that contributed to that outcome.

Assessment of bias in conducting the systematic review

We conducted the review according to the published protocol (Ski 2020) and reported any deviations from it in the Differences between protocol and review section of the systematic review.

Measures of treatment effect

We expressed dichotomous outcomes for each comparison as risk ratios with 95% confidence intervals (CI). We expressed continuous data as the mean difference with 95% CI, or where an outcome was measured and reported in more than one way, as a standardised mean difference with 95% CI. We expressed continuous data as the mean change (and standard deviation (SD)) in outcomes between baseline and follow-up for both psychological intervention and control groups; when not available, we used the absolute mean (and SD) outcome at follow-up for both groups. We reported sample sizes based on the number randomised to treatment conditions.

We considered treatment effects for depression, anxiety and HRQoL in terms of clinically meaningful differences; for example, we considered a 1.5 difference on the HADS as clinically meaningful (Puhan 2008).

We narratively described skewed data reported as medians and interquartile ranges.

Unit of analysis issues

For studies with more than one relevant intervention arm included in the same analysis, we divided the number randomised in the control group by the number of intervention arms, to obtain the denominator for data analysis.

In accordance with Section 9.3.4 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2023a), where we included data with repeated observations on participants, we defined several outcomes based on different periods of follow-up and conducted separate analyses. The analysis included all studies with the measurement at the end of the follow-up period.

Where we included cluster-RCTs, we considered whether the reported data analysis had appropriately taken account of the aggregate nature of the data. For the one cluster-RCT included (Richards 2018a), in accordance with MECIR and with Section 23.1.4 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2023b), we used the continuous effect estimates from analyses undertaken by the study authors that took account of clustering.

Dealing with missing data

We contacted investigators or study sponsors in order to verify key study characteristics and obtain missing numerical outcome data where possible (e.g. when a study was identified as abstract only). No imputation of missing data was undertaken.

Assessment of heterogeneity

Given the nature of this review question, we expected a high level of clinical heterogeneity due to variation in populations, psychological interventions, outcomes and comparators across included trials. We assessed studies for clinical heterogeneity by inspecting participant characteristics, interventions and outcomes reported. We also inspected methodological heterogeneity, by looking at variability in study design and risk of bias.

We used the I^2 statistic to assess statistical heterogeneity across the studies (Higgins 2003), but acknowledge that there was substantial uncertainty in the value of the I^2 statistic when there was only a small number of studies reporting a particular outcome of interest. We also considered the P value from the Chi^2 test with a significance level at $P < 0.05$ (Deeks 2022).

We used meta-regression to explore potential causes of statistical heterogeneity (Deeks 2022), i.e. to determine whether particular covariates explain any of the heterogeneity of treatment effects between studies.

Assessment of reporting biases

When we were able to pool 10 or more studies, we created and examined a funnel plot and used the Egger test (Egger 1997), to explore possible small study biases for the primary outcomes.

Data synthesis

Given the likely clinical heterogeneity in studies of psychological interventions (population, interventions, comparators and outcomes) (Richards 2017), we elected a priori to pool the data from each study using a random-effects model (Mantel-Haenszel model for dichotomous outcomes). This provided a more conservative statistical comparison of the difference between intervention and control because a confidence interval around the effect estimate is wider than a confidence interval around a fixed-effect estimate. The similarities across studies in: population, adults with heart disease; design, randomised controlled trials; and outcomes, standardised mean difference allowing for units of outcome measures to be uniform across studies, provided further justification for pooling of data, and in consideration of potential heterogeneity being explored through meta-regression subanalyses. Additionally, due to concerns that measures may not be equally sensitive in capturing the underlying construct (Kendrick 2009; Richards 2017), we stratified pooled data of outcome measures individually (e.g. depression: HADS-A, GAD-7, BAI). We completed data synthesis and analyses using Review Manager Web software (RevMan Web 2022). For primary and secondary outcomes, where there were insufficient data, or where it was inappropriate to combine studies statistically, we presented a narrative review using the vote-counting method (Hedges 1980). The analysis included all eligible studies, irrespective of risk of bias.

Subgroup analysis and investigation of heterogeneity

We explored potential heterogeneity in psychological interventions via the following three approaches.

1. Detailed tabulation of population, intervention, comparator and outcomes (PICO) for each study.
2. Within-study subgroup analyses (supported by subgroup x intervention/control interaction terms).
3. Between-study analyses via meta-regression.

We conducted meta-regression, where data permitted (≥ 10 studies; Higgins 2023a), for the following pre-specified subgroups for the two primary outcomes of depression and anxiety.

1. Studies of psychological interventions with and without co-intervention of CR.
2. Studies of psychological interventions with and without co-intervention of pharmacotherapy.
3. Studies of psychological interventions targeting heart disease populations (CHD or AF or HF).
4. Studies of psychological interventions targeting populations with depression or anxiety, or those not specified (i.e. no specific target population identified).
5. Studies with analysis of mode of psychological intervention (individual or group or combined individual and group).
6. Studies of psychological interventions with and without family involved in the intervention.
7. Studies of psychological interventions specifically targeting depression or anxiety or not (i.e. other than depression and anxiety or not specified).

We performed univariable meta-regression analyses using the 'metareg' command in STATA (StataCorp 2019).

Sensitivity analysis

We did not carry out a sensitivity analysis, to test whether key methodological factors or decisions affected the main results, as planned.

Reaching conclusions

We based our conclusions only on findings from the quantitative or narrative synthesis of included studies for this review. We avoided making recommendations for practice and our implications for research suggests priorities for future research and outlines the remaining uncertainties in the area.

Summary of findings and assessment of the certainty of the evidence

Using GRADEpro GDT, we created a summary of findings table for the comparison, psychological interventions versus no psychological interventions. We included the following outcomes in the table, at the longest follow-up available: depression (all measures), anxiety (all measures), HRQoL (PCS), HRQoL (MCS), all-cause mortality and MACE.

We used the five GRADE considerations (risk of bias, inconsistency, imprecision, indirectness and publication bias) to assess the certainty of the body of evidence as it relates to the studies that contributed data to the meta-analyses for the prespecified outcomes. We used methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2023), using GRADEpro software (GRADEpro GDT 2022). We justified all decisions to downgrade the certainty of the evidence using footnotes and we made comments to aid the reader's understanding of the review where necessary.

Two review authors (CFS and LL), working independently, made judgements about evidence certainty, with disagreements resolved by discussion or by involving a third review author (RST). We justified all judgements, documented them and incorporated them into reporting of results for each outcome.

We extracted study data, formatted our comparisons in data tables and prepared a summary of findings table before writing the results and conclusions of our review.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies; Characteristics of studies awaiting classification.

Results of the search

The search resulted in 16,756 records, with an additional 25 records obtained via searching of other resources, including trial registries and handsearching. A total of 10,979 unique records were retained for screening once duplicates (n = 5802) were removed. At title and abstract screening, 10,560 records were excluded as irrelevant. The remaining 419 reports underwent full-text review. Of these, we excluded 363 studies that appeared to be irrelevant to the review after careful examination of eligibility criteria (see Excluded studies). Twenty-one randomised controlled trials (44 reports) fulfilled the inclusion criteria and were included in the review (Agren 2012; Bekelman 2018; Chair 2013; Chang 2020; Crossmann 2010; Davidson 2010; Freedland 2009; Gary 2010; Habibovic 2017; Humphries 2021; Moradi 2016; Nahlén Bose 2016; Nijjar 2019; O'Neil 2014a; O'Neil 2014b; Rafanelli 2020; Richards 2018; Tagney 2013; Turner 2014; Wells 2021; Zetta 2011). Five ongoing studies were identified (Chung 2014; Holdgaard 2021; ISRCTN33129243; Moser 2012a; NCT04986969). Five studies are awaiting classification (Eckert 2010; Gu 2017a; Oranta 2010; Sobczak 2016; Spruill 2021). See Figure 1.

Figure 1. PRISMA flow diagram of study selection process

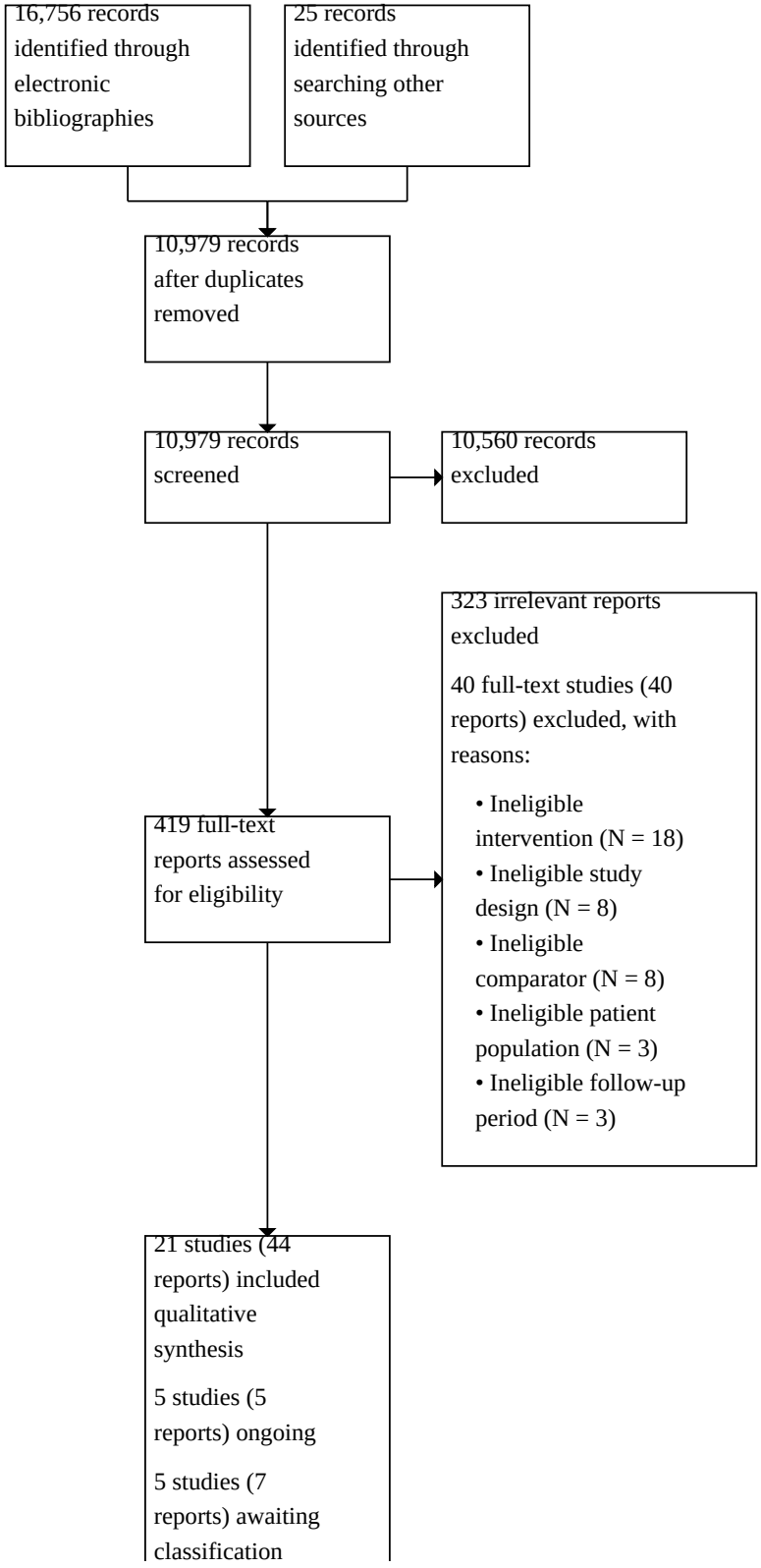
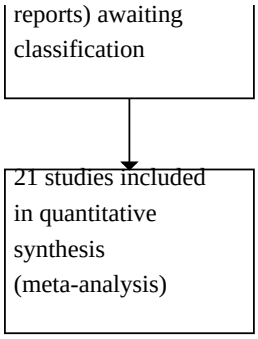


Figure 1. (Continued)



Included studies

We contacted four study authors and all replied with requested information: Bekelman 2018 provided data on primary outcomes for meta-analysis; Nahlén Bose 2016 provided baseline data for primary outcomes; Rafanelli 2020 provided data on cardiovascular hospitalisations; and Richards 2018 clarified costs for the usual care group.

Study design

Of the 21 included studies, one study was a cluster-randomised controlled trial (Richards 2018); all others were parallel-group randomised controlled trials.

Setting

Five studies were conducted in the USA (Bekelman 2018; Davidson 2010; Freedland 2009; Gary 2010; Nijjar 2019), four in the UK (Richards 2018; Tagney 2013; Wells 2021; Zetta 2011), three in Australia (O'Neil 2014a; O'Neil 2014b; Turner 2014), three in Sweden (Agren 2012; Humphries 2021; Nahlén Bose 2016) and single studies in China (Chang 2020), Germany (Crossmann 2010), Hong Kong (Chair 2013), Italy (Rafanelli 2020), Iran (Moradi 2016), and the Netherlands (Habibovic 2017).

Participants

The total sample size for the review was 2591, ranging from 29 participants (Richards 2018) to 430 participants (O'Neil 2014b). Of the 21 studies, the study population in 16 of them was individuals with CHD, including myocardial infarction (MI), acute coronary syndrome (ACS) and coronary artery bypass grafting (CABG) (Chair 2013; Chang 2020; Crossmann 2010; Davidson 2010; Freedland 2009; Humphries 2021; Moradi 2016; Nijjar 2019; O'Neil 2014a; O'Neil 2014b; Rafanelli 2020; Richards 2018; Tagney 2013; Turner 2014; Zetta 2011; Wells 2021), and in five studies individuals with HF (Agren 2012; Bekelman 2018; Gary 2010; Habibovic 2017; Nahlén Bose 2016). No studies of individuals with AF were identified. Table 1 presents a PICOS (participants, intervention, comparator, study design) summary across the included studies.

Six studies included participants with existing depression, i.e. depression was listed within the eligibility criteria (Davidson 2010; Freedland 2009; Gary 2010; O'Neil 2014a; Rafanelli 2020; Richards 2018), one study targeted participants with existing anxiety (Moradi 2016), and two studies included participants with existing anxiety or depression (Humphries 2021; Wells 2021). The remaining 12 studies did not specify existing depression or anxiety as inclusion criteria (Agren 2012; Bekelman 2018; Chair 2013; Chang 2020; Crossmann 2010; Habibovic 2017; Nahlén Bose 2016; Nijjar 2019; O'Neil 2014b; Tagney 2013; Turner 2014; Zetta 2011). Further, the majority of studies excluded patients with psychiatric or related diseases apart from four studies (Crossmann 2010; Moradi 2016; Nijjar 2019; Tagney 2013), which did not specify this as an exclusion criterion.

The mean age of participants ranged from 56 years in Turner 2014 to 71 years in Agren 2012. The percentage of female participants ranged from 14.3% in Crossmann 2010 to 58.1% in Gary 2010. The percentage of white participants was reported in eight of the 21 studies, ranging from 68.3% in Zetta 2011 to 100% in Richards 2018.

Interventions

We identified notable diversity in the psychological interventions across the 21 studies, as shown in Table 1. Of the included studies, 14 used CBT (Agren 2012; Chang 2020; Crossmann 2010; Davidson 2010; Freedland 2009; Gary 2010; Habibovic 2017; Humphries 2021; Nahlén Bose 2016; O'Neil 2014a; Rafanelli 2020; Tagney 2013; Turner 2014; Zetta 2011), two motivational interviewing (Bekelman 2018; Chair 2013), one mindfulness (Nijjar 2019), one behavioural social cognitive therapy (O'Neil 2014b), one metacognitive therapy (Wells 2021), one eye movement desensitisation and reprocessing (EMDR; Moradi 2016), and one behavioural activation and mental healthcare co-ordination (Richards 2018).

Two CBT studies (Nahlén Bose 2016; Zetta 2011), one mindfulness study (Nijjar 2019) and a metacognitive therapy study (Wells 2021) were delivered face-to-face in group settings. Two CBT studies delivered the intervention entirely online (Habibovic 2017; Humphries 2021); all other studies delivered the intervention to individuals face-to-face.

One study, Rafanelli 2020, included an active control, which entailed the same amount of time and attention as per the intervention group (i.e. diary work and empathic listening). All other studies compared the intervention to no psychological intervention, also referred to as usual care, which consisted of traditional care in hospital and outpatient education and support received at the discretion of their clinicians.

Six studies included co-interventions in both intervention and control arms: five cardiac rehabilitation (Bekelman 2018;

Chair 2013; Nijjar 2019; Richards 2018; Wells 2021) and one pharmacotherapy for mood disorder (Davidson 2010).

Outcomes

Primary outcomes

Twenty studies (2531 participants) reported depression as an outcome (Agren 2012; Bekelman 2018; Chair 2013; Chang 2020; Crossmann 2010; Davidson 2010; Freedland 2009; Gary 2010; Habibovic 2017; Humphries 2021; Nahlén Bose 2016; Nijjar 2019; O'Neil 2014a; O'Neil 2014b; Rafanelli 2020; Richards 2018; Tagney 2013; Turner 2014; Wells 2021; Zetta 2011), of which five included cardiac rehabilitation as a co-intervention (Bekelman 2018; Chair 2013; Nijjar 2019; Richards 2018; Wells 2021) and one included pharmacotherapy (Davidson 2010) (Table 1). Of those included, one study had two comparisons due to multiple intervention arms (Crossmann 2010), resulting in 21 comparisons overall. Depression was measured using the seven-item Hospital Anxiety and Depression Scale (HADS) depression sub-scale (HADS-D: Zigmond 1983) in seven studies (Chair 2013; Crossmann 2010; Humphries 2021; Nahlén Bose 2016; O'Neil 2014b; Wells 2021; Zetta 2011), the Patient Health Questionnaire-9 (PHQ-9: Kroenke 2001) in four studies (Bekelman 2018; Habibovic 2017; Nijjar 2019; O'Neil 2014a), the 21-item Beck Depression Inventory II (BDI II: Beck 1996) in three studies (Agren 2012; Richards 2018; Turner 2014), and the Hamilton Depression Rating Scale (HAM-D: Hamilton 1960) in two studies (Freedland 2009; Gary 2010). Other measures used included the Beck Depression Inventory (BDI: Beck 1961) in Davidson 2010, the Beck Depression Inventory fast screen (BDI-FS: Poole 2009) in Tagney 2013, the Cardiac Depression Scale (CDS: Hare 1996) in O'Neil 2014a, and the Zung Self-Rating Depression Scale (ZDS: Zung 1965) in Chang 2020.

Seventeen studies (2235 participants) reported anxiety as an outcome (Bekelman 2018; Chair 2013; Chang 2020; Crossmann 2010; Freedland 2009; Habibovic 2017; Humphries 2021; Moradi 2016; Nahlén Bose 2016; Nijjar 2019; O'Neil 2014b; Rafanelli 2020; Richards 2018; Tagney 2013; Turner 2014; Wells 2021; Zetta 2011), of which five included cardiac rehabilitation as a co-intervention (Bekelman 2018; Chair 2013; Nijjar 2019; Richards 2018; Wells 2021). Of those included, two studies had two comparisons due to multiple intervention arms (Crossmann 2010; Tagney 2013), resulting in 19 comparisons overall. Anxiety was measured using the HADS anxiety sub-scale (HADS-A: Zigmond 1983) in eight studies (Chair 2013; Crossmann 2010; Humphries 2021; Nahlén Bose 2016; O'Neil 2014b; Turner 2014; Wells 2021; Zetta 2011), the Beck Anxiety Inventory (BAI: Beck 1988) in three studies (Freedland 2009; Moradi 2016; Richards 2018), and the Generalised Anxiety Disorder Assessment (GAD-7; Spitzer 2006) in three studies (Bekelman 2018; Habibovic 2017; Nijjar 2019). Other measures included the State-Trait Anxiety Inventory (STAI; Spielberger 1983) in Tagney 2013, the Symptom Checklist 90-R (SCL-90-R; Derogatis 1992) in Rafanelli 2020, and the Zung Self-rating Anxiety Scale (SAS; Zung 1971) in Chang 2020.

Secondary outcomes

Twelve studies (1454 participants) reported HRQoL as an outcome (Agren 2012; Bekelman 2018; Chair 2013; Chang 2020; Crossmann 2010; Freedland 2009; Gary 2010; Habibovic 2017; Nahlén Bose 2016; O'Neil 2014a; Richards 2018; Wells 2021), of which four included cardiac rehabilitation as a co-intervention (Bekelman 2018; Chair 2013; Richards 2018; Wells 2021). Of those included, one study had two comparisons due to multiple intervention arms (Crossmann 2010), resulting in 13 comparisons overall. HRQoL was measured using a range of measures, including the Short-Form 36-item Health Survey (SF-36: Ware 1994) in four studies (Chair 2013; Crossmann 2010; Freedland 2009; Nahlén Bose 2016), followed by the Short-Form 12-item Health Survey (SF-12; Ware 1995) in four studies (Agren 2012; Chang 2020; Habibovic 2017; O'Neil 2014a), the EuroQol-5 Dimension (EQ-5D; Rabin 2001) in two studies (Richards 2018; Wells 2021), the Kansas City Cardiomyopathy Questionnaire (KCCQ-12; Green 2000) in one study (Bekelman 2018), the Minnesota Living with Heart Failure Questionnaire (MLHFQ; Rector 1987; Rector 1992) in one study (Gary 2010), the Seattle Angina Questionnaire (SAQ; Spertus 1995) in one study (Chang 2020) and the HeartQoL questionnaire (HeartQoL; Oldridge 2014) in one study (Richards 2018). Where possible, HRQoL was broken down into physical component summary (PCS) and mental component summary (MCS) scores.

Two studies (174 participants) reported self-efficacy as an outcome (Chair 2013; Turner 2014), of which one included cardiac rehabilitation as a co-intervention (Chair 2013). One study, Chair 2013, used the General Self-Efficacy Scale (Zhang 1995) and the other, Turner 2014, used a self-efficacy scale developed specifically for the study. Three studies (615 participants) reported all-cause mortality as an outcome (Bekelman 2018; Humphries 2021; Rafanelli 2020), of which two studies included cardiac rehabilitation as a co-intervention (Bekelman 2018; Wells 2021). Four studies (450 participants) reported on major adverse cardiovascular events (MACE) (Davidson 2010; Humphries 2021; Rafanelli 2020; Richards 2018), of which one had cardiac rehabilitation as a co-intervention (Richards 2018).

Due to lack of data to permit meaningful statistical analysis, the following outcomes underwent narrative analysis. Six studies measured intervention acceptability (Gary 2010; Nijjar 2019; O'Neil 2014a; O'Neil 2014b; Richards 2018; Wells 2021), of which two included cardiac rehabilitation as a co-intervention (Richards 2018; Wells 2021). Intervention acceptability was mainly captured through intervention adherence, with one study measuring retention (Nijjar 2019). Three studies reported adverse events as an outcome (Davidson 2010; Richards 2018; Wells 2021); one study captured adverse events using a standardised checklist covering major and minor cardiovascular symptoms and physical and psychiatric symptoms (Davidson 2010), another reported on mental health events (e.g. self-harm, suicidality) and physical events such as infective conditions, asthma or cardiac complications (e.g. chest pain, additional stent requirement, postural hypotension) (Richards 2018), and one reported on increased suicidality, death and self-injury (Wells 2021). All-cause hospitalisation was reported by two studies (Bekelman 2018; Nahlén Bose 2016). Cardiovascular hospitalisations was measured by one study (Nahlén Bose 2016). Cardiovascular mortality was reported by two studies (Humphries 2021; Rafanelli 2020). Cardiovascular morbidity (non-fatal) was reported by two studies (Humphries 2021; Rafanelli 2020). No study measured cardiovascular morbidity (re-vascularisation) or return to work. One study, Richards 2018, reported on costs (not cost-effectiveness as per QALYs) including estimated elements of costs and the cost per participant receiving the psychological intervention.

Funding

Nineteen studies reported funding along with acknowledgement of the funding source; all studies were supported by public funding (Agren 2012; Bekelman 2018; Chair 2013; Crossmann 2010; Davidson 2010; Freedland 2009; Gary 2010; Habibovic 2017; Humphries 2021; Moradi 2016; Nahlén Bose 2016; Nijjar 2019; O'Neil 2014a; O'Neil 2014b; Rafanelli 2020; Richards 2018; Turner 2014; Wells 2021; Zetta 2011). Further detail on funding of these studies is provided in Characteristics of included studies under the sub-heading 'Sponsorship source'.

Excluded studies

A total of 363 studies that appeared to be relevant to the review were excluded after careful examination of eligibility criteria during the full-text review (see Excluded studies). Of these, we classed 323 as 'irrelevant records', and excluded 40 full-text studies with reasons: 'ineligible intervention' (n = 18); 'ineligible study design' (n = 8); 'ineligible comparator' (n = 8); 'ineligible patient population' (n = 3); and 'ineligible follow-up period' (n = 3). In two instances, we had to seek further information from study authors before reaching an 'exclude' decision (Agren 2015; Moulaert 2013). For more information regarding exclusions, see Figure 1 and Characteristics of excluded studies.

Ongoing studies

We identified five ongoing studies (Chung 2014; Holdgaard 2021; ISRCTN33129243; Moser 2012a; NCT04986969). Authors were contacted to provide additional information on published outcomes. Information provided by Chung 2014 and Moser 2012a confirmed no complete data were available to share, but upcoming publications were in process (Characteristics of ongoing studies).

Studies awaiting classification

We identified five studies as awaiting classification (Eckert 2010; Gu 2017a; Oranta 2010; Sobczak 2016; Spruill 2021). Study authors were contacted, with details provided in Studies awaiting classification.

Risk of bias in included studies

We performed a risk of bias assessment for all outcomes (primary and secondary, when data were provided) using RoB 2 (Higgins 2023c). The results of the assessment can be found in the RoB 2 tables (Risk of bias (tables)), with results of the assessment also displayed in the analyses in the forest plots. Detailed assessments, including signalling questions, are available from the corresponding author (CFS), on reasonable request. Below, we provide a summary of the assessment.

Overall risk by study

The overall risk of bias of outcomes across studies was similar for all studies assessed as 'some concerns', with one exception that we judged as of 'high concern' overall (Tagney 2013). For the majority assessed as 'some concerns', these related mostly to bias in the measurement of outcomes and deviations from intended interventions. The one study assessed as 'high concern' was primarily due to a high level of missing data for both primary outcomes (Tagney 2013). Further to this, those in the intervention group were significantly more likely to have lower STAI-S and self-criticism scores at baseline. There were no studies with a low risk of bias across all domains.

Overall risk by outcome

We assessed the overall risk of bias for all outcomes as 'some concerns', apart from mortality, which we assessed as 'low risk of bias' overall. There were no outcomes judged as a high risk of bias overall. The following summarises the risk of bias per outcome for all outcomes that are included in the summary of findings table (Summary of findings 1).

Depression

Twenty studies reported depression outcomes (Agren 2012; Bekelman 2018; Chair 2013; Chang 2020; Crossmann 2010; Davidson 2010; Freedland 2009; Gary 2010; Habibovic 2017; Humphries 2021; Nahlén Bose 2016; Nijjar 2019; O'Neil 2014a; O'Neil 2014b; Rafanelli 2020; Richards 2018; Tagney 2013; Turner 2014; Wells 2021; Zetta 2011). We assessed all outcomes (HADS-D, PHQ-9, BDI-II) as having 'some concerns' of risk of bias largely due to bias in risk of measurement and deviations from intended interventions (Analysis 1.2; Analysis 1.3; Analysis 1.4). We assessed all studies as 'some concerns' overall, apart from Tagney 2013, which we assessed as high risk, due to missing data (Analysis 1.1).

Anxiety

Seventeen studies reported anxiety outcomes (Bekelman 2018; Chair 2013; Chang 2020; Crossmann 2010; Freedland 2009; Habibovic 2017; Humphries 2021; Moradi 2016; Nahlén Bose 2016; Nijjar 2019; O'Neil 2014b; Rafanelli 2020; Richards 2018; Tagney 2013; Turner 2014; Wells 2021; Zetta 2011). We assessed all outcomes (BAI, HADS-A, GAD-7) as having 'some concerns' of risk of bias, primarily due to bias in measurement and deviations from intended interventions (Analysis 1.6; Analysis 1.7; Analysis 1.8). We assessed all studies as 'some concerns' overall, apart from Tagney 2013, which we assessed as high risk, due to missing data and because those in the intervention group were significantly more likely to have lower STAI-S scores at baseline (Analysis 1.5).

Health-related quality of life (HRQoL)

Twelve studies reported HRQoL (PCS and MCS) outcomes (Agren 2012; Bekelman 2018; Chair 2013; Chang 2020; Crossmann 2010; Freedland 2009; Gary 2010; Habibovic 2017; Nahlén Bose 2016; O'Neil 2014a; Richards 2018; Wells 2021). Results for HRQoL (MCS) and HRQoL (MCS) were akin. Of these, the most commonly used instruments were either the SF-12 or SF-36 health surveys (Agren 2012; Chair 2013; Chang 2020; Crossmann 2010; Freedland 2009; Habibovic 2017; O'Neil 2014a). We assessed all outcomes as having 'some concerns' of risk of bias overall, largely due to bias in measurement (Analysis 1.9; Analysis 1.11).

Self-efficacy

Two studies reported self-efficacy outcomes (Chair 2013; Turner 2014): one, Chair 2013, using the General Self-Efficacy Scale and the other, Turner 2014, using a scale developed specifically for the study. We assessed outcomes as having 'some concerns' of risk of bias overall, due to bias in the measurement of outcomes and deviations from intended interventions (Analysis 1.13).

All-cause mortality

Three studies reported all-cause mortality (Bekelman 2018; Rafanelli 2020; Wells 2021), which we assessed as having 'low' risk of bias across all domains (Analysis 1.14).

Major adverse cardiovascular events (MACE)

Four studies reported on MACE (Davidson 2010; Humphries 2021; Rafanelli 2020; Richards 2018), which we assessed as having 'some concerns' of risk of bias overall, largely due to bias in measurement of outcomes (Analysis 1.15).

Effects of interventions

See: **Summary of findings 1** Psychological interventions for depression and anxiety compared to no psychological interventions for patients with coronary heart disease or heart failure

We performed a series of meta-regressions for eligible studies, where data permitted (≥ 10 studies; Higgins 2023a), to investigate how much heterogeneity of treatment effect was explained by our prespecified study characteristics for the two primary outcomes of depression and anxiety (Subgroup analysis and investigation of heterogeneity). We calculated effect estimates using standardised mean difference (SMD) with 95% CI. Analyses are not shown in the review, but results are presented below under the respective outcomes.

Primary outcomes

Depression

A total of 20 studies measuring depression were eligible for inclusion in the random-effects meta-analysis. There was a standardised mean difference (SMD) of -0.36 (95% CI -0.65 to -0.06; P = 0.02; 20 studies (21 comparisons), 2531 participants; Analysis 1.1), suggesting that psychological interventions probably result in a moderate reduction in depression compared to no psychological intervention. Due to inconsistent directions of effect and substantial heterogeneity (I^2 = 90%), the GRADE rating was reduced to moderate certainty. The large effect size of Chang 2020 was a noticeable outlier; when this study was removed, the effect disappeared (P = 0.08).

Three different outcome measures for depression (HADS-D; PHQ-9; BDI-II) were eligible for inclusion in the random-effects meta-analyses. For the HADS-D, psychological interventions probably result in little to no difference in depression compared to no psychological intervention (SMD -0.39, 95% CI -0.86 to 0.07; P = 0.10; 7 studies (8 comparisons), 1305 participants; Analysis 1.2). Due to moderate heterogeneity (I^2 = 49%), the GRADE rating was reduced to moderate certainty. For the BDI-II, the evidence suggests that psychological interventions may result in little to no difference in depression compared to no psychological intervention (SMD 1.56, 95% CI -3.60 to 6.72; P = 0.55; 3 studies, 166 participants; Analysis 1.3). Due to substantial heterogeneity (I^2 = 75%) and the small number of participants (fewer than 400), the GRADE rating was reduced to low certainty. For the PHQ-9, the evidence suggests that psychological interventions may result in little to no difference in depression compared to no psychological intervention (SMD -1.03, 95% CI -2.95 to 0.89; P = 0.29; 4 studies, 610 participants; Analysis 1.4). Due to moderate heterogeneity (I^2 = 36%) and the confidence intervals crossing zero, in both directions, the GRADE rating was reduced to low certainty.

Univariate meta-regression analyses showed no evidence of association for the outcome of depression (0.12, 95% CI -0.95 to 1.20; P = 0.81), when comparing psychological interventions specifically targeting depression or not.

Univariate meta-regression suggested no evidence of associations with other prespecified study characteristics of psychological interventions: with and without co-intervention of cardiac rehabilitation (0.77, 95% CI -0.71 to 2.26, P = 0.29); with and without co-intervention of pharmacotherapy (-1.16, 95% CI -3.45 to 1.13, P = 0.30); targeting heart disease population (CHD or AF or HF; -0.02, 95% CI -0.81 to 0.85, P = 0.96); mode (individual or group or combined individual and group; -0.35, 95% CI -1.55 to 0.06, P = 0.55); with and without family involvement (0.91, 95% CI -1.41 to 3.23, P = 0.42); targeting a population with depression or not (i.e. other than depression or not specified; -0.07, 95% CI -0.72 to 0.59, P = 0.83).

Anxiety

A total of 17 studies measuring anxiety were eligible for inclusion in the random-effects meta-analysis. There was an SMD of -0.57 (95% CI -0.96 to -0.18; P = 0.004; 17 studies (19 comparisons), 2235 participants; Analysis 1.5), suggesting that psychological interventions probably result in a moderate reduction in anxiety, compared to no psychological intervention. Due to inconsistent directions of effect and substantial heterogeneity (I^2 = 93%), the GRADE rating was reduced to moderate certainty. The large effect sizes of Chang 2020 and Moradi 2016 were noticeable outliers; with removal of either of these studies, the effect remained (P = 0.05).

Three outcome measures for anxiety (GAD-7; HADS-A; BAI) were eligible for inclusion in the random-effects meta-analyses. For the HADS-A, the evidence suggests that psychological interventions may result in little to no difference in anxiety compared to no psychological intervention (SMD -0.46, 95% CI -0.98 to 0.07; P = 0.09; 8 studies (9 comparisons), 1334 participants; Analysis 1.6). Due to substantial heterogeneity (I^2 = 53%) and the confidence intervals crossing zero, the GRADE rating was reduced to low certainty. For the GAD-7, psychological interventions probably result in little to no difference in anxiety compared to no psychological intervention (SMD 1.27, 95% CI -0.63 to 3.17; P = 0.19; 3 studies, 504 participants; Analysis 1.7). Due to the confidence intervals crossing zero, the GRADE rating was reduced to moderate certainty. For the BAI, the evidence is uncertain about the effect of psychological interventions on anxiety (SMD -11.56, 95% CI -38.12 to 15.00; P = 0.39; 3 studies, 153 participants; Analysis 1.8), compared to no psychological intervention. Due to substantial heterogeneity (I^2 = 99%), and substantial imprecision due to the small number of participants and the confidence intervals crossing the effect size of 0.5 in either direction, the GRADE rating was reduced to very low certainty.

Univariate meta-regression analyses showed evidence of association for the outcome of anxiety (7.41, 95% CI 4.47 to 10.35, P < 0.001), when comparing psychological interventions specifically targeting depression or anxiety or not. The effect for anxiety was driven by one study (Moradi 2016), where the psychological intervention targeted anxiety and showed a larger effect than the remaining 16 studies.

Univariate meta-regression suggested no evidence of associations with other prespecified study characteristics of psychological interventions: with and without co-intervention of cardiac rehabilitation (1.37, 95% CI 1.37 to -1.50, P = 0.32); targeting heart disease population (CHD or AF or HF; -0.37, 95% CI -2.12 to 1.38, P =

0.66); mode (individual or group or combined individual and group; -0.72, 95% CI -3.25 to 1.81, P = 0.55); targeting a population with anxiety or not (i.e. other than anxiety or not specified; 0.97, 95% CI -1.24 to 3.18, P = 0.36).

Estimates were not calculable for reported outcome of anxiety for the following pre-specified study characteristics due to a lack of trials: (1) with and without co-interventions of pharmacotherapy and (2) with and without family involvement.

Secondary outcomes

Health-related quality of life

Physical component summary HRQoL (PCS)

Twelve studies measuring HRQoL (PCS) were eligible for inclusion in the random-effects meta-analysis. The evidence suggests that psychological interventions may result in little to no difference in HRQoL (PCS) compared to no psychological intervention (SMD 0.48, 95% CI -0.02 to 0.98; P = 0.06; 12 studies (13 comparisons), 1454 participants; Analysis 1.9). The confidence interval crossed zero and there was substantial heterogeneity (I^2 = 93%), which reduced the GRADE rating to low certainty.

Eight studies used the SF-12/SF-36 (838 participants) to measure HRQoL (PCS), of which seven were included in the meta-analysis. The evidence suggests that psychological interventions may result in little to no difference in physical HRQoL compared to no psychological intervention (mean difference (MD) 4.57, 95% CI -3.68 to 12.81; P = 0.28; 7 studies (8 comparisons), 838 participants; Analysis 1.10). The confidence interval crossed zero and there was substantial heterogeneity (I^2 = 99%), which reduced the GRADE rating to low certainty.

Mental component summary HRQoL (MCS)

Twelve studies measuring HRQoL (MCS) were eligible for inclusion in the random-effects meta-analysis. The evidence suggests that psychological interventions may result in a moderate increase in HRQoL (MCS) compared to no psychological intervention (SMD 0.63, 95% CI 0.01 to 1.26 ; P = 0.05; 12 studies (13 comparisons), 1454 participants; Analysis 1.11). There was a strong indication of publication bias (Eggers test: P = 0.012) and substantial heterogeneity (I^2 = 95%), which reduced the GRADE rating to low certainty.

Eight studies used the SF-12/SF-36 (838 participants) to measure HRQoL (MCS), of which seven were included in the meta-analysis. The evidence suggests that psychological interventions may result in little to no difference in HRQoL (MCS) compared to no psychological intervention (MD 4.21, 95% CI -3.35 to 11.77; P = 0.27; 7 studies (8 comparisons), 838 participants; Analysis 1.12). The confidence interval crossed zero in both directions and there was substantial heterogeneity (I^2 = 98%), which reduced the GRADE rating to low certainty.

Self-efficacy

For the two studies that reported self-efficacy, the evidence suggests that psychological interventions may result in little to no difference in self-efficacy compared to no psychological intervention (SMD 0.14, 95% CI -0.31 to 0.59; P = 0.55; 2 studies (3 comparisons), 174 participants; Analysis 1.13). As the confidence interval crossed zero and there was moderate heterogeneity (I^2 = 42%), the GRADE rating was reduced to low certainty.

All-cause mortality

For the three studies that reported all-cause mortality, the evidence suggests that psychological interventions probably result in little to no difference in all-cause mortality compared to no psychological intervention (risk ratio (RR) 0.81, 95% CI 0.39 to 1.69; P = 0.58; 3 studies, 615 participants; Analysis 1.14). The 95% confidence interval around the RR included 1, meaning the GRADE rating was reduced to moderate certainty as a result of imprecision.

Cardiovascular mortality

There was no evidence of a difference between intervention and comparator groups with regards to the occurrence of cardiovascular mortality (Humphries 2021; Rafanelli 2020); both studies reported one death in both intervention and comparator groups.

All-cause hospitalisations

There was no evidence of a difference between intervention and comparator groups with regards to the occurrence of all-cause hospitalisations (Bekelman 2018; Nahlén Bose 2016). One study, Bekelman 2018, reported no differences between the intervention group (18 participants with 1 hospitalisation and 9 participants with ≥ 2 hospitalisations) and the comparator group (30 participants with 1 hospitalisation and 6 participants with ≥ 2 hospitalisations). The other study, Nahlén Bose 2016, only reported that there were no significant differences between the intervention and comparator groups for hospitalisations.

Cardiovascular hospitalisations

One study, Rafanelli 2020, reported on cardiovascular hospitalisations, and found no evidence of a difference between the intervention (n = 1) and comparator (n = 1) groups.

Cardiovascular morbidity (non-fatal)

There was no evidence of a difference between intervention and comparator groups with regards to the occurrence of cardiovascular morbidity (non-fatal) (Humphries 2021; Rafanelli 2020). One study, Humphries 2021, reported 35 events in the intervention group and 24 in the comparator group, and the other study, Rafanelli 2020, reported 8 events in the intervention group and 5 in the comparator group.

Cardiovascular morbidity (revascularisation)

No study measured cardiovascular morbidity (revascularisation).

Major adverse cardiovascular events (MACE)

For the four studies that reported MACE, the evidence suggests that psychological interventions may result in little to no difference in MACE compared to no psychological intervention (RR 1.22, 95% CI 0.77 to 1.92; P = 0.39; 4 studies; 450 participants; Analysis 1.15). The 95% CI around the RR included 1 and there was moderate heterogeneity (I^2 = 35%), which reduced the GRADE rating to low certainty as a result of imprecision.

Intervention acceptability

Of the six studies that measured psychological intervention acceptability, most reported good rates of adherence. One study reported 72% adherence, based on the percentage of the number of sessions attended by those prescribed (Gary 2010). Another study reported an adherence rate of 96.3%, based on a percentage of people missing two or fewer of the nine prescribed sessions (Nijjar 2019). O'Neil 2014a reported that 83% of participants completed five or more out of 10 telephone sessions, and in another study 61% of participants completed five or more sessions of 10 (O'Neil 2014b). One study reported that around 53% received the maximum number of eight sessions (Richards 2018), and another reported that 61% of participants attended four or more of the six sessions (Wells 2021). Finally, one study reported that 45 of the 46 surviving patients were retained in the study (Nijjar 2019).

Return to work

No study measured return to work.

Costs and cost-effectiveness: costs per quality-adjusted life years (QALYs)

One study, Richards 2018, reported on costs, estimating GBP 959 for the psychological intervention per patient (no costs were reported for the comparison group), noting that no adjustments were made for the small sample (29 participants).

Adverse events

Three studies monitored adverse events throughout the trial and each reported no evidence of a difference between intervention and comparator groups (Davidson 2010; Richards 2018; Wells 2021). Davidson 2010 presented data on non-depression-related psychiatric problems (intervention group: n = 68; comparator group: n = 59), reporting "similar adverse events between groups". Richards 2018 recorded 11 adverse events relating to six participants and reported that "none were judged to be related to the trial intervention or research procedures by an independent monitoring committee", and Wells 2021 documented that "no adverse events were reported".

DISCUSSION

This Cochrane review investigated the effects of psychological interventions compared with no psychological intervention on the outcomes of depression, anxiety, HRQoL physical component summary (PCS) and mental component summary (MCS), self-efficacy, all-cause and cardiovascular mortality and hospitalisations, cardiovascular morbidity (non-fatal MI and revascularisation), major adverse cardiovascular events (MACE), intervention acceptability, adverse events, costs and return to work in adults with coronary heart disease (CHD), heart failure (HF) or atrial fibrillation (AF).

Summary of main results

This Cochrane review includes 21 randomised controlled trials (RCTs) (2591 patients). Sixteen studies included people with CHD, five with HF and none with AF. Study sample sizes ranged from 29 to 430. Twenty studies reported on the outcome of depression, 17 on anxiety, 12 on health-related quality of life (HRQoL) (physical component summary score (PCS) and mental component summary score (MCS)), three on mortality (all-cause) and four on MACE. We judged the results for all these outcomes to have some concerns overall, with the exception of mortality, which we rated at low risk.

Based on moderate certainty of evidence, this review indicates that all types of psychological interventions, when pooled together and when compared to no psychological intervention, probably result in a moderate reduction in depression and anxiety in adults with CHD or HF (Summary of findings 1). However, these effects should be interpreted with caution, given the high levels of heterogeneity observed, as well as the potential effect of any modifiers.

Meta-regression analyses showed that psychological interventions specifically targeting anxiety are probably more effective than non-targeted interventions, though further research studies are needed to substantiate this finding. Other meta-regression subgroup analyses showed no association with and without co-interventions targeting anxiety and depression (i.e. cardiac rehabilitation (CR), CR and pharmacotherapy; targeting heart disease populations (CHD or AF or HF); mode (individual or group or combined individual and group)) or depression only (i.e. pharmacotherapy; with and without family involvement).

In terms of secondary outcomes, we found that psychological interventions, compared to no psychological intervention, may have little to no effect on HRQoL PCS, but may result in a moderate improvement in HRQoL MCS, as reported by 12 studies, although substantial heterogeneity reduced the GRADE rating to low. Additionally, psychological interventions probably result in little or no difference in all-cause mortality (three studies), and may have little to no effect on self-efficacy (two studies) and MACE (four studies), compared to no psychological intervention.

Intervention acceptability was generally good, as reported by intervention adherence in six studies. There was no indication of adverse events, all-cause hospitalisation, cardiovascular morbidity (non-fatal MI) or cardiovascular mortality being related to the psychological intervention. One study, with 29 participants, assessed costs in the treatment arm only for the psychological intervention, and one study assessed cardiovascular hospitalisations and found equal numbers in the treatment and comparator groups. No studies reported on return to work or cardiovascular morbidity (revascularisation).

Overall, there is evidence for a probable beneficial effect of psychological interventions on depression and anxiety outcomes for adults with CHD or HF. However, the evidence base is small and we cannot draw firm conclusions about the effects of these interventions on these outcomes given the high heterogeneity and effects of possible outliers, or on most other outcomes. Additionally, the evidence does not permit firm conclusions about the effects of specific types of psychological interventions either (e.g. CBT, motivational interviewing).

Overall completeness and applicability of evidence

This Cochrane review summarises the evidence regarding psychological interventions for adults with CHD or HF in a variety of settings. The included studies comprised different CHD (e.g. myocardial infarction (MI), acute coronary syndrome (ACS), percutaneous coronary intervention (PCI)) and HF (e.g. reduced ejection fraction (HFReF), preserved ejection fraction (HFPeF)) samples; investigated various types of psychological interventions

(e.g. CBT, mindfulness); and were located in different countries with different healthcare systems, thus impacting the generalisability of the results.

The overall completeness and applicability of the evidence is limited, due to insufficient investigation or reporting of primary and secondary outcomes. For example, costs and cardiovascular hospitalisations were only reported in a single study. As such, evidence of treatment effects on these outcomes warrants careful interpretation. Further, no studies investigated return to work or cardiovascular morbidity (revascularisation), thus more research is needed on these outcomes. Also, most studies were underpowered to detect effects of psychological interventions on all-cause mortality and major adverse cardiac events. In addition, the samples of the included studies most likely differed regarding subtypes and severity of depression and anxiety, as the studies comprised participants with a wide range of depressive and anxious symptoms. Of note, although the majority of studies excluded patients with psychiatric or related diseases, four did not. Finally, the type, length and mode of delivery of psychological interventions examined in the included studies also varied greatly. We were unable to determine whether the number and intensity of sessions needed to show substantial benefits from such interventions were sufficient and/or specifically tailored to the needs, problems and treatment response of individual patients.

We believe this Cochrane review is the first to include only randomised controlled trial data that specifically examines the effect of psychological interventions on depression and anxiety in people with CHD, HF or AF. All included studies were published during the last 15 years, although no studies for people with AF were identified.

We used an extensive search strategy, including several bibliographic databases and other sources relevant to the focus of the review. We also included a wide range of types of psychological interventions. However, this variety also makes it difficult to identify which types of psychological interventions might be most effective in reducing depression and anxiety. Similarly, a wide range of outcome measures were used to assess symptoms of depression and anxiety. This poses challenges when synthesising changes in symptom burden, as some tools include only psychological symptoms, while others assess both psychological and somatic symptoms. Tools that include somatic symptoms might introduce bias, as the somatic symptoms (e.g. tiredness and fatigue) may be driven by the underlying cardiac condition. For this reason, although we pooled all tools to examine the overall effects of psychological interventions on depression and anxiety, where possible, we present pooled data for individual tools.

The applicability of the evidence was also limited by study characteristics. Eight of the included studies had sample sizes of fewer than 100 participants, which might mean we are underpowered to detect evidence of effects favouring psychological interventions over control, or vice versa, indicating that further large-scale and rigorously designed research is needed in this field. Moreover, most studies assessed effects at between six and 12 months follow-up; hence, most evidence can not be applied to long-term effects.

Quality of the evidence

Using the GRADE approach (Schünemann 2023), we assessed the certainty of the evidence to range from moderate to low across all primary and secondary outcomes.

While we believe this to be the most comprehensive systematic review to date of RCTs in adults with CHD, HF or AF, it has some limitations. There was inconsistent evidence for the benefit of psychological interventions, compared to no psychological intervention, with substantial heterogeneity across the two primary outcomes of depression (I^2 = 90%) and anxiety (I^2 = 93%), and also secondary outcomes of HRQoL (PCS: I^2 = 90%; MCS: I^2 = 90%). We downgraded the certainty of evidence for depression and anxiety to moderate certainty due to heterogeneity and inconsistent direction of effect. Certainty of evidence for HRQoL (PCS) was downgraded to low, due to heterogeneity, inconsistent direction of effect and imprecision. Certainty of evidence for HRQoL (MCS) was downgraded to low due to heterogeneity, inconsistent direction of effect and publication bias. Certainty of evidence was downgraded for all-cause mortality to moderate certainty, due to imprecision, and major adverse cardiovascular events to low, due to moderate heterogeneity and imprecision.

Meta-analyses for depression and anxiety outcomes were hampered because of the lack of consistent outcome questionnaires across studies. Furthermore, studies varied in their approach to outcome reporting - some reported mean scores at follow-up and others reported mean change scores from baseline to follow-up or did not report sufficient information (no variances reported) to allow their inclusion in meta-analysis.

Risk of bias across studies contributing to the results was similar for all outcomes, predominantly of 'some concerns', relating mostly to bias in the measurement of outcomes and deviations from intended interventions (see Risk of bias in included studies). Studies did not adequately describe their randomisation procedure, allocation concealment, blinding and statistical analysis, i.e. some studies did not report intention-to-treat (ITT) analyses or how they handled missing data. Of note, it is impossible to blind a psychological intervention. There were, however, very few reported attempts to blind study staff to the allocation of participants during randomisation. One study, Tagney 2013 (n = 49), was an exception. It was judged to be of high overall risk for depression and anxiety, primarily due to high levels of missing data; yet due to the small sample size, we considered it unlikely to affect the overall risk of bias for these two outcomes. Mortality was the only outcome assessed as low risk of bias across all domains. On the whole, we felt that these potential study limitations were unlikely to lower confidence in the estimates of effect for all outcomes; as such, we did not downgrade any outcome for risk of bias.

Potential biases in the review process

We need to recognise two important limitations of this review. First, study outcomes were pooled using meta-analysis in spite of a high level of clinical and statistical heterogeneity, albeit using a random-effects model. Of note, it was only possible to explore heterogeneity in two outcomes (all depression and all anxiety measures), due to a lack of studies consistently reporting outcomes. Second, the high number of subgroup analyses may have led to a type 1 error.

Although heterogeneity is to be expected in psychological interventions due to the range of approaches and therapies used, we did exclude less specific approaches, i.e. therapeutic counselling or educational interventions or those aimed at improving adherence to cardiac risk factor modification (e.g. medicines, lifestyle change). Regardless, we found high levels of clinical and statistical heterogeneity across the studies, which aligns with Richards 2017 reporting an increasing number of multifactorial psychological interventions being used with heart disease populations. As such, we decided to pool our data to yield new estimates of treatment effects to contribute to the existing and increasing interest in psychological interventions in heart disease populations, while accounting for and exploring the heterogeneity of the primary outcomes through subgroup analysis.

Much uncertainty remains regarding the people who would benefit most from treatment, i.e. those with or without pre-existing depression and/or anxiety (Richards 2017). Thus, including people across the spectrum of disease severity was seen as an important consideration to determine who would benefit most from psychological interventions. As such, we combined studies with those without pre-existing illness and those with pre-existing illness, which may also be seen as a limitation with regard to population heterogeneity. To account for pre-existing illness on treatment effect, we performed the sub-analysis, targeting a population with depression or anxiety or not, which found no evidence of association. Additionally, four studies did not exclude patients with psychiatric conditions, which may also have added to the heterogeneity of the population.

Selection bias was minimised by conducting a rigorous and extensive search using a wide range of search terms and databases to ensure a robust search strategy and identification of as many potentially eligible studies as possible. We chose to include only randomised controlled trials as they provide the strongest level of evidence available.

In this type of review, there is some risk of publication bias, as was the case for HRQoL (MCS), meaning that negative studies may not have been published and potentially skewing the data toward a more positive result. The comprehensive search strategy incorporated inclusion of non-English language papers to mitigate the likelihood of publication bias. Although the search was thorough, it is possible that we may not have identified some unpublished studies. We checked the reference lists of all included studies and relevant systematic reviews to identify additional studies missed from the original electronic searches (for example, unpublished or in-press citations).

We contacted the authors of included studies in order to resolve any queries related to their study or to obtain missing information relevant to this review, or both. Despite requests for data, not all authors responded, which meant that potentially relevant studies may not have been included in the analyses. In order to reduce the potential bias associated with retrieving, collecting, selecting and extracting data, two review authors independently worked on these steps in accordance with the guidance in the *Cochrane Handbook for Systematic Reviews of Interventions* (Lefebvre 2022).

The evidence in this review is up-to-date as of 5 July 2022, which may be seen as a limitation; however, we believe we have included all relevant studies and do not consider this to have impacted on the conclusions of the review.

Agreements and disagreements with other studies or reviews

The generalisability of previous systematic reviews of psychological interventions for people with heart disease has been limited to specific patient populations with conditions such as CHD (Richards 2018a). An updated Cochrane review examined the effectiveness of psychological interventions in people with CHD (Richards 2017), but did not look at other major cardiovascular conditions. A recent Cochrane review examined psychological and pharmacological interventions for depression in patients with CHD (Tully 2021), but did not assess the impact on other major psychological or cardiovascular conditions.

A Cochrane review of psychological interventions for people with CHD found that psychological interventions targeting stress or emotional disorders, compared with usual care, had a beneficial effect on depression (Richards 2017), which is broadly comparable to the current review. Also, Richards 2017 found a 22% reduction in the risk of myocardial infarction in favour of psychological interventions. Overall, psychological interventions had no effect on all-cause mortality or major adverse cardiovascular events, although, like our review, these outcomes were only assessed in a small number of studies.

A recent network meta-analysis of RCTs of antidepressant drug therapy, psychotherapy alone and combined, exercise and collaborative care for depression in people with CHD found that, in terms of the primary outcomes (acceptability and change in depressive symptoms eight weeks after treatment commencement), all treatments were equally acceptable, but the strongest effects were evident for combination therapy, exercise and drug therapy (Doyle 2021). However, the Cochrane review of psychological and pharmacological interventions for depression in patients with CHD found low-certainty evidence that psychological intervention may result in a reduction in depression symptoms at the end of treatment (Tully 2021). A systematic review of studies of collaborative care interventions for patients with CHD and depression found a reduction in major cardiac events in the short term and a small-to-moderate effect on depression severity and an increased depression remission rate (Tully 2015); similar results were also found in an earlier systematic review for anxiety (Tully 2014). In a systematic review by Dickens 2013 of psychological interventions in CHD populations, CBT and problem-solving were found to have significant yet small-in-magnitude improvements in depression. Similar again was an updated Cochrane review of psychological interventions in CHD that found reduced standardised mean depression and anxiety scores (Welton 2009). Although these previous reviews report somewhat similar outcomes to the current findings, it is difficult to make direct comparisons with our Cochrane review, due to important differences in terms of populations (cardiac condition/s, e.g. HF, coronary artery disease (CAD), CHD), psychological interventions (e.g. targeting anxiety, depression or other) and primary outcomes (e.g. clinical versus behavioural).

In line with our findings, other review authors in this field, such as Doyle 2021, have highlighted the need for further rigorous research, particularly given the low methodological quality of the primary studies.

AUTHORS' CONCLUSIONS

Implications for practice

Psychological interventions for depression and anxiety probably result in a moderate reduction in depression and in anxiety, may result in a moderate increase in health-related quality of life (HRQoL) (mental component summary (MCS)), but probably have little to no effect on mortality and may not improve HRQoL physical component summary (PCS) and major adverse cardiovascular events (MACE) in adults with coronary heart disease (CHD) or heart failure (HF). We found no studies of psychological interventions in people with atrial fibrillation (AF) in this review.

These findings are relevant to the populations studied in these reviews, mostly older, white, male patients and not necessarily representative of the majority of the population treated for CHD or HF. Further, as most studies have evaluated multifactorial psychological interventions, this hinders explanation of the effects of psychological interventions on anxiety and depression. What it does indicate is that these interventions are increasingly being tailored around an individual's needs and preferences, which may include offering people combinations of psychological therapies, pharmacological management and cardiac rehabilitation. Whilst it is important to take into account patient values and preferences, also for consideration are healthcare settings, resources and costs, and any new evidence.

Our review highlights a broad range of psychological interventions that, in varying ways and degrees of explicitness, intend to reduce depression and anxiety among people with heart disease in order to improve health outcomes. As is the case in the development and evaluation of any complex health interventions, understanding how and why a psychological intervention has an impact on health outcomes is essential to establishing effect. This requires clinicians, researchers and patients aiming to describe and understand the nature and effects of these interventions and heterogeneity, and how outcomes are influenced by both context and intervention mechanisms. For example, to ensure that patients are receiving the same type of psychological intervention, its delivery might be improved by using a core standardised treatment manual, but with flexibility according to individual patient need and preference.

Implications for research

Depression and anxiety in people with heart disease are associated with increased morbidity and mortality (Baumeister 2015; Lichtman 2014). Though psychological interventions may have potential to reduce depression and anxiety in people with heart disease, the rather sparse evidence regarding the specific targeting and durability of these interventions on depression, anxiety and other outcomes in CHD or HF populations leads to uncertainty in the evidence base.

There is a need for better designed, conducted and reported studies of reproducible psychological interventions targeting such outcomes in these populations as well as those with AF or other heart conditions. The type of psychological intervention needs to be clearly described in terms of content, dose, duration and delivery mode, and, if it is combined with other forms, the differential effects of psychological interventions could be examined in 'head-to-head' comparative studies.

The target population needs to be defined clearly, for example, in terms of cardiac and psychological diagnosis (e.g. type and severity of anxiety disorder, and comorbidities). There is a need to determine the minimum dose required for a clinical meaningful treatment response, and to clearly articulate the treatment targets within the chosen population, inclusive of considerations for those with comorbid 'depression and anxiety'. Although the majority of studies reported on both depression and anxiety, very few factored this co-morbidity into their analyses. In consideration of the high prevalence of both conditions in populations with heart disease, accounting for comorbid depression and anxiety may be beneficial to determine which populations benefit most from psychological interventions.

With an increase in personalised and multifactorial psychological interventions, further examination of those at particularly high risk of poor outcomes (e.g. people with established psychopathology) and the effectiveness of specific therapies (e.g. cognitive behavioural therapy (CBT) and mindfulness) may also be beneficial to identify what works best and for whom.

In our review, timing of psychological intervention varied widely, including pre-discharge, within one week of hospitalisation, and up to three and six months' post-discharge when somatic symptoms are more likely to be resolved. Determining optimal timing for psychological interventions may contribute to a personalised approach in the delivery of these interventions. Additionally, the standard of evidence may be improved by studies reporting long-term outcomes based on intention-to-treat analysis.

There is also a need to gain consensus on the core outcome measures to assess depression and anxiety within these studies, including, for example, using a combination of generic and cardiac-specific outcome measures that have utility in current clinical practice, and where the impact of the underlying heart condition (e.g. the loading of somatic symptoms) is factored into the selection. Further, the choice of intervention and key outcomes should involve patients, take account of their preferences, and include outcomes such as acceptability, return to work and cost-benefit.

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The following people conducted the editorial process for this article:

- Sign-off Editor (final editorial decision): Norio Watanabe, Soseikai General Hospital, Kyoto.
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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Agren 2012

Study characteristics	
Methods	**Aim of study:** to evaluate the effects of an integrated dyad care programme with education and psychosocial support to patients with CHF and their partners during a post-discharge period after acute deterioration of CHF **Study design:** parallel-group, randomised controlled trial **Number of centres:** multisite (2): 1 university hospital and 1 county hospital in southeastern Sweden **Country:** Sweden
Participants	**N randomised:** 155 (intervention 71; control 84) **Diagnosis:** (% of participants) HF 155 (100%); intervention 71 (100%); control 84 (100%) **Severity:** class III/IV 105 (67.7%); intervention 46 (64.7%); control 59 (70.2%) **Psychopathology:** Major depression:6 (4%); intervention 3 (4%); control 3 (4%) Moderate depression:17 (11%); intervention 10 (14%); control 7 (8%) Minor depression:23 (15%); intervention 11 (15%); control 12 (14%)

Agren 2012 *(Continued)*

	Age (mean ± SD), years: total NR; intervention 69 ± 13; control 73 ± 10 **Percentage male** total 75.4%; intervention 69.1%; control 80.9% **Percentage white** NR **Inclusion criteria:** dyad consisting of a patient diagnosed with CHF based on the European Society of Cardiology guidelines, New York Heart Association (NYHA) functional class II–IV, with a partner living in the same household as the patient, recently discharged from hospital (i.e. 2 to 3 weeks) after a CHF acute exacerbation **Exclusion criteria:** for dyads: dementia or other severe psychiatric illnesses; drug abuse; difficulties in understanding or reading the Swedish language; undergoing cardiac surgery including cardiac transplant; or participating in other studies
Interventions	• Total duration: 12 weeks • Cognitive behavioural strategies; education; psychosocial support; and TAU • Type of psychological intervention (CCDAN): CBT • Frequency: first session conducted 2 weeks after discharge and the 2 remaining sessions occurred 6 and 12 weeks after discharge • Number of sessions: 3 • Length of sessions: ≥ 60 minutes • Delivered by: nurses, who received training on how to perform the intervention; 3 days of theoretical training followed by individual and practical training • Delivery format: nurse-led face-to-face counselling, a computer-based CD-ROM program, and other written teaching materials • Delivery to: CHF patient-partner dyads (71) • Targeting: depression; HRQoL; perceived control; self-care; caregiver burden • Co-intervention: none • Delivery setting: in hospital OR in home • Components: each of the 3 modules contained cognitive, supportive and behavioural components **Control/comparison:** usual care (including traditional care in hospital and outpatient education and support) delivered to CHF patient-partner dyads
Outcomes	Depression (BDI-II); HRQoL (SF-12 PCS); HRQoL (SF-12 MCS) **Timings:** baseline, 3 and 12 months
Identification	**Country and settings:** Sweden; multicentre **Author's name:** Agren S **Institution:** Linköping University, Linköping, Sweden **Email:** susanna.agren@liu.se **Address:** Department of Medicine and Health, Division of Nursing, Linköping University, S-58185Linköping, Sweden **Year:** 2012 **Maximum follow-up:** 12 months **Dates participants were recruited:** January 2005 to December 2008
Notes	**Funding/sponsorship source:** Linköping University, Swedish Research Council, Swedish Institute for Health Sciences, Heart and Lung Foundation, Heart and Lung Disease National Association, and Lions Research Foundation

Agren 2012 *(Continued)*

	Conflicts of interest: none declared

Bekelman 2018

Study characteristics	
Methods	**Aim of study:** to determine whether a symptom and psychosocial collaborative care intervention improves heart failure-specific health status, depression, and symptom burden in patients with heart failure **Study design:** parallel-group, randomised controlled trial **Number of centres:** multisite (3 health systems): urban safety net; veterans affairs; academically affiliated health systems **Country:** USA
Participants	**N randomised:** 317 (intervention 158; control 159) **Diagnosis:** (% of participants):HF: 317 (100%); intervention 158 (100%); control 159 (100%) **Severity:** class III/IV 194 (61.2%); intervention 95 (60.5%); control 99 (63.1%) **Psychopathology:** Depression positive screen: 149 (47.4%); intervention 75 (47.8%); control 74 (47.1%) Anxiety positive screen: 71 (22.6%); intervention 32 (20.4%); control 39 (24.8%) **Age (mean ± SD)**: total NR; intervention 64.5 ± 10.9; control 66.5 ± 11.8 **Percentage male:** total 78.6%; intervention 81.5%; control 75.8% **Percentage white:** total 71.9%; intervention 70.7%; control 73.2% **Inclusion criteria:** The eligibility criteria aimed to enrol patients with chronic heart failure and reduced health status who were likely to need the additional resources provided by the intervention. Patients with heart failure were identified through the study sites' electronic health records. The diagnosis was defined using previously validated administrative data supplemented with data on required diuretic dosing (furosemide ≥ 80 mg/d or equivalent), left ventricular ejection fraction of 40% or less, brain-type natriuretic peptide (BNP) levels of 250 pg/mL or more (to convert to nanograms per litre, multiply by 1.0), or N-terminal prohormone level of BNP of 1000 pg/mL or more. During the study screening process, patients who reported reduced heart failure-specific health status (a Kansas City Cardiomyopathy Questionnaire Short Version [KCCQ] score of ≤ 70) or reported at least 1 of the study's target symptoms (fatigue, shortness of breath, pain and/or depression) were targeted for enrolment. Early in the study, the cut-offs for diuretic dosing and BNP were relaxed (furosemide level of ≥ 20 mg/d, BNP level of ≥ 100 pg/mL, or N-terminal prohormone level of BNP of ≥ 500 pg/mL), and both reduced heart failure-specific health status and 1 of the target symptoms were required to increase the eligible study population while still enrolling symptomatic patients. **Exclusion criteria:** patients with active substance abuse or serious mental illness
Interventions	• Total duration: < 6 months • Applied motivational interviewing; targeted behavioural change; structured psychosocial intervention; and CR • Type of psychological intervention (CCDAN): third wave cognitive behavioural therapies (behavioural activation; motivational interviewing) • Frequency: nurse phone call every 2 to 3 weeks; social worker weekly; team weekly • Number of sessions: nurse 6 to 8; social worker 6 to 8

Bekelman 2018 *(Continued)*

- Length of sessions: NR
- Delivered by: registered nurse and social worker, both trained in intervention delivery; plus team comprising a primary care clinician, palliative care specialist and cardiologist
- Delivery format: face-to-face; telephone
- Delivery to: individuals (patients with HF)
- Targeting: depression; anxiety; HRQoL
- Co-intervention: cardiac rehabilitation (CR)
- Delivery setting: hospital or telephone
- Components: intervention comprised 3 components. A registered nurse addressed symptoms, a social worker provided structured psychosocial care, and a team reviewed patients' care and provided orders for tests and medications to patients' clinicians for review and signature. The nurse applied motivational interviewing to promote changes in health behaviours (e.g. medication adherence, diet and physical activities) that could improve patient symptoms. The social worker provided a structured telephone-based psychosocial intervention to help patients with heart failure adjust to living with illness and address depression symptoms, if present.

Control/comparison: TAU + CR. Patients received care at the discretion of their clinicians, which could include care from cardiology, palliative care and mental health. Patients were given an information sheet developed for the study that outlined self-care for heart failure. Patients who had significant depressive symptoms were notified of this, and their clinicians were also contacted. Referring clinicians then assumed responsibility for depression care at their discretion, with no constraints on treatment or referrals

Delivered by: primary care physician or nurse practitioner, with referral to appropriate professionals, as required

Co-intervention: cardiac rehabilitation (CR)

Outcomes	Depression (PHQ-9); anxiety (GAD-7); HRQoL (KCCQ); hospitalisations; all-cause mortality **Timings**: baseline, 3 and 6 months
Identification	**Country and settings:** USA; multisite (3): 3 health systems (urban safety net; veterans affairs; academically affiliated health systems) **Author's name:** Bekelman DB **Institution:** Department of Veterans Affairs, Eastern Colorado Health Care System **Email:** david.bekelman@va.gov **Address:** Department of Veterans Affairs, Eastern Colorado Health Care System, 1055 Clermont St, Research (151), Denver, CO 80220 **Year:** 2018 **Maximum follow-up:** 12 months **Dates participants were recruited:** August 2012 to April 2015
Notes	**Contact with authors:** study author (DB) was contacted; responded and provided information to assist with meta-analysis, with mean and SD for intervention and control group for depression and anxiety measures **Funding/sponsorship source:** National Institute of Nursing Research, National Institutes of Health; National Center for Advancing Translational Sciences Colorado Clinical and Translational Science Award; Veterans Affairs Health Services Research and Development Service **Comments:** participants received remuneration (USD 10 to 15 per time point) **Conflicts of interest**: none reported

Chair 2013

Study characteristics	
Methods	**Aim of study:** to investigate the long-term effects of motivational interviewing on clinical outcomes, psychological outcomes, health-related quality of life among cardiac rehabilitation patients with poor motivation **Study design:** parallel-group, randomised controlled trial **Number of centres:** single site (1): hospital cardiac rehabilitation centre **Country:** China (Hong Kong)
Participants	**N randomised:** 146 (intervention 73; control 73) **Diagnosis:** (% of participants):CHD146 (100%); intervention 73 (100%); control 73 (100%) **Severity:** NR **Psychopathology:** no depression or anxiety reported **Age (mean ± SD)**, years: total 66.4 ± 10.7; intervention 66.8 ± 10.3; control 66.0 ± 11.2 **Percentage male:** total 68.4%; intervention 64.4%; control 72.6% **Percentage white:** NR **Inclusion criteria:** diagnosis of coronary heart disease; aged 18 years or above; poor motivation to change to a healthy lifestyle; able to perform daily activity independently when joining the programme **Exclusion criteria:** diagnosis of mental illness; a history of substance abuse; major hearing difficulties
Interventions	• Usual care + total duration: 12 months • Motivational interviewing; + CR • Type of psychological intervention (CCDAN): third wave cognitive behavioural therapies (motivational interviewing) • Frequency: MI sessions in weeks 1, 3, 5 and 7 for first 8 weeks; monthly to 6 months; once at 9 and 12 months • Number of sessions: 10 + CR • Length of sessions: 30 to 45 minutes • Delivered by: 2 research nurses with a mental health background were specifically trained with motivational interviewing skills to perform the intervention • Delivery format: face-to-face • Delivery to: individual • Targeting: depression; anxiety; HRQoL • Co-intervention: CR • Delivery setting: hospital (CR) • Components: MI + CR. MI sessions tailored to the patient's stage of change. Participants were also invited to think over the importance of their roles in managing the disease and planning rehabilitation. If participants showed a desire to receive more health information, this was offered. **Control/comparison**: CR programme comprising exercise sessions, group education sessions and one individualised education session with a dietitian. In addition, participants received one supervised exercise session.
Outcomes	Depression (HADS-D); anxiety (HADS-A); self-efficacy (General Self-Efficacy Scale); HRQoL (SF-36 PCS); HRQoL (SF-36 MCS)

Chair 2013 *(Continued)*

	Timings: baseline, 6, 9 and 12 months
Identification	**Country and settings:** China (Hong Kong); single centre **Author's name:** Chair SY **Institution:** Chinese University of Hong Kong **Email:** sychair@cuhk.edu.hk **Address:** The Chinese University of Hong Kong, Room 825, 8/F Esther Lee Building, The Nethersole School of Nursing, The Chinese University of Hong Kong, Shatin, Hong Kong 852, China **Year:** 2013 **Maximum follow-up:** 12 months **Dates participants were recruited:** NR
Notes	**Pretreatment:** Those in the intervention group were significantly more likely to have lower family income (below HKD10,000). **Sample size calculation:** "... a previous motivational interviewing study evaluated behavioural changes on cardiac clients was based for sample size calculation using the software of nQuery Advisor 4.0. Keeping α= 0.05, using multivariate repeated measure analysis of covariance tests to test the mean outcome differences between the two groups and across time, 56 participants/group are required to achieve 80% power with the variance of means = 30, standard deviation within group = 25 and the correlation between group = 0.3514. However, 146 participants were judged necessary considering a potential 30% drop-out rate" **Funding/sponsorship source:** Health and Health Services Research Fund, Hong Kong **Conflicts of interest**: none declared

Chang 2020

Study characteristics	
Methods	**Aim of study:** to study the effect of nurse-led counselling on anxiety symptoms and quality of life following percutaneous coronary intervention for stable coronary artery disease **Study design:** parallel-group, randomised controlled trial **Number of centres:** single site (1): medical centre located in rural and remote China Hospital **Country:** China
Participants	**N randomised:** 80 (intervention 40; control 40) **Diagnosis:** (% of participants): CAD80 (100%); intervention 40 (100%); control 40 (100%) **Severity:** Single CAD: 41 (51.3%); intervention 20 (50.0%); control 21 (52.5%) Double CAD:27 (33.7%); intervention 15 (37.5%); control 12 (30.0%) Triple CAD:12 (15.0%); intervention 5 (12.5%); control 7 (17.5%) **Psychopathology:** Moderate-severe depression:6 (7.5%); intervention 3 (7.5%); control 3 (7.5%)

Chang 2020 *(Continued)*

	Anxiety: 5 (6.3%); intervention 2 (5.0%); control 3 (7.5%) **Age (mean ± SD)**, years: total 59.34 ± 8.2; intervention 59.7 ± 8.7; control 59.0 ± 7.7 **Percentage male:** total 75%; intervention 75%; control 75% **Percentage white:** NR **Inclusion criteria:** aged 18 years or older; scheduled for elective PCI for stable coronary artery disease (CAD was defined as a stenosis of more than 70% in at least one major coronary artery with clinical or laboratory evidence of myocardial ischaemia (e.g. ST segment depression on ECG during angina or stress testing)) **Exclusion criteria:** (a) unable to give written informed consent; (b) unable to participate in regular follow-ups at hospital clinics; (c) a history of psychological disorders or mental health illnesses; and (d) a history of other chronic illnesses or heart failure (left ventricular ejection fraction < 45%)
Interventions	• Total duration: 2 days • Structured counselling (comprising CBT; relaxation techniques) and TAU • Type of psychological intervention (CCDAN): CBT and behaviour therapy (relaxation) • Frequency: pre- and post-PCI • Number of sessions: 2 • Length of sessions: 30 minutes • Delivered by: nurse consultants with psychological therapies and counselling qualifications • Delivery format: face-to-face • Delivery to: individual • Targeting: anxiety; depression; HRQoL; cardiac outcomes • Co-intervention: none • Delivery setting: hospital • Components: The intervention comprised individualised cognitive behavioural therapies and teaching of relaxation techniques. These measures included identifying the causes of anxiety, challenging and changing unhelpful thoughts or attitudes that may trigger or aggravate anxiety, and the development of personal coping strategies for anxiety prevention and treatment. The post-PCI counselling focused on improving the patients' comfort level and confidence in participating in post-PCI care recommendations. **Control/comparison**: usual care (to include standard pre-PCI care and general counselling about the procedure)
Outcomes	Depression (Zung self-rating depression scale); anxiety (Zung self-rating anxiety scale); HRQoL (SF-12 PCS); HRQoL (SF-12 MCS); HRQoL (SAQ: QoL domain) **Timings**: baseline, 6 and 12 months
Identification	**Country and settings:** China; single-site **Author's name:** Chang, Zongxia **Institution:** Liaocheng People's Hospital **Email:** lwang@csu.edu.au **Address:** correspondence to: Professor Le-xin Wang, Department of Cardiology, Liaocheng People's Hospital, Liaocheng City, Shandong 252000, China **Year:** 2020 **Maximum follow-up:** 12 months after PCI **Dates participants recruited:** January to December 2014

Chang 2020 *(Continued)*

Notes	**Sample size calculation:** "To detect a 10-point difference in the physical or mental health scores on the SF-12 scale, and in the three domains of the SAQ, a minimum of 34 patients were required for this study, to achieve a significance of 0.05 with a power of 80%" **Funding/sponsorship source:** NR **Conflicts of interest**: none reported

Crossmann 2010

Study characteristics	
Methods	**Aim of study:** to evaluate a minimal, easy, accessible intervention targeting anxiety and reduced quality of life in patients with an implantable cardioverter defibrillator (ICD) **Study design:** parallel-group, randomised controlled trial **Number of centres:** multisite (3): 2 university hospitals; 1 private hospital **Country:** Germany
Participants	**N randomised:** 134 (intervention 65; control 69) **Diagnosis:** (% of participants): ICD patients (analysed): 119 (100%); intervention 63 (100%); control 56 (100%) **Severity:** ICD for primary prevention: 79 (66%); intervention 39 (63%); control 40 (67%) **Psychopathology:** lifetime history of psychotherapy:11 (9%); intervention 7 (12%); control 4 (7%) **Age (mean ± SD)**, years: total NR; intervention 60.6 ± 12.6; control 61.1 ± 12.0 **Percentage male:** total 85.7%; intervention 83.9%; control 87.3% **Percentage white:** NR **Inclusion criteria:** patients who received an ICD for the first time; aged 18 to 75 years **Exclusion criteria:** NR
Interventions	• Total duration: 6 months • Psychological treatment; education; support; and TAU • Type of psychological intervention (CCDAN): psychological therapy: aspects of CBT (self-control; goal setting; coping) and behavioural therapy (adjustment) • Frequency: monthly • Number of sessions: 6 • Length of sessions: mean phone call duration of 6.84 minutes • Delivered by: therapist/psychologist; self-directed aspect via manual • Delivery format: telephone + manual/booklet • Delivery to: individual • Targeting: depression; anxiety; HRQoL (PCS); HRQoL (MCS); cardiac anxiety; psychological distress • Co-intervention: none • Delivery setting: community (home) • Components: intervention comprised 20-page booklet; up to 6-monthly phone calls by study therapist. Booklet described medical and technical details of ICDs in lay terms, the psychological process of post-implant adjustment, ICD-related anxiety, ICD discharges and negative psychosocial consequences. The booklet explored symptoms and consequences of anxiety and coping

Crossmann 2010 *(Continued)*

	strategies. Semi-structured phone calls looked at reducing avoidance behaviour, reducing cognitive bias and reducing anxiety. **Control/comparison**: usual care (TAU: comprised medical routine check-ups at the implanting hospital 1 month, 3 months, and 6 months after ICD implantation and a booklet provided by the ICD manufacturer on technical aspects of wearing an ICD)
Outcomes	Depression (HADS-D); anxiety (HADS-A); HRQoL (SF-36 PCS); HRQoL (SF-36 MCS); psychological distress (SCK-K-9); cardiac anxiety (CAQ-Fear); cardiac anxiety (CAQ-Avoidance); cardiac anxiety (CAQ-Attention) **Timings**: baseline and 6 months
Identification	**Country and settings:** Germany; multicentre **Author's name:** Crössman A **Institution:** University of Würzburg, Germany **Email:** pauli@psychologie.uni-wuerzburg.de **Address:** correspondence to: Paul Pauli, PhD, Department of Psychology, University of Würzburg, Marcusstrasse 9-11, 97070, Würzburg, Germany **Year:** 2010 **Maximum follow-up:** 6 months **Dates participants were recruited:** July 2003 to June 2004
Notes	**Sample size calculation:** "Power analysis, assuming a medium effect size for the main treatment effect and a dropout rate of 20%, indicated a statistical power of 80% for a sample size of n = 138" **Funding/sponsorship source:** Stiftung Begabtenförderung Cusanuswerk; DFG funded RTG 1253/1; FOR 605 **Conflicts of interest**: none reported

Davidson 2010

Study characteristics	
Methods	**Aim of study:** to determine the acceptability and efficacy of enhanced depression treatment in patients with ACS **Study design:** parallel-group, randomised controlled trial **Number of centres:** multisite (5): Mount Sinai Hospital; New York Presbyterian Hospital: New York; New Haven Hospital; Hospital of St Raphael; Veterans Affairs Connecticut Healthcare System: Connecticut **Country:** USA
Participants	**N randomised:** 157 (intervention 80; control 77) **Diagnosis:** (% of participants): ACS157 (100%); intervention 80 (100%); control 77 (100%) **Severity/type:** unstable angina 118 (75.2%); intervention 58 (73%); control 60 (78%) **Non-STEMI:** 22 (14%); intervention 13 (16%); control 9 (12%)

Davidson 2010 *(Continued)*

	STEMI: 16 (10.2%); intervention 8 (10%); control 8 (10%) **Psychopathology:** BDI ≥ 10:157 (100%); intervention 80 (100%); control 77 (100%) **Age (mean ± SD)**, years: total NR; intervention 59.3 ± 10.6; control 61.1 ± 10.6 **Percentage male:** total 46.5%; intervention 46.3%; control 46.7% **Percentage white:** NR **Inclusion criteria:** men and women recruited during a hospitalisation for ACS (i.e. with a verified diagnosis of AMI or UA); had persistent depressive symptoms (score of 10 or higher on the Beck Depression Inventory (BDI) within 1 week of hospitalisation and 3 months later. Patients with BDI scores below 5 at both assessments who met all other eligibility criteria were included in the non-depressed observational cohort. **Exclusion criteria:** alcohol or other drug dependency; dementia; current or past psychosis or bipolar disorder; terminal illness; unavailability for follow-up; BDI score of 45 or higher; or suicidality (self-reported or determined during a clinical interview)
Interventions	• Total duration: 6 months • Enhanced care approach; psychotherapy and/or pharmacotherapy; problem-solving therapy; and TAU • Type of psychological intervention (CCDAN): PST • Frequency: PST - weekly; pharmacotherapy - initially 1- to 2-week intervals for dose titration, every 3 to 5 weeks thereafter as needed for the remainder of the study • Number of sessions: mean (SD) number of treatment sessions was 8.2 (5.2) for patients who initially chose PST, 6.0 (3.7) for patients who initially chose antidepressant medication, and 19.5 (6.4) for patients who initially chose both • Length of sessions: 30 to 45 minutes (PST sessions) • Delivered by: clinical nurse specialist, psychologist, social worker and/or psychiatrist • Delivery format: face-to-face or by telephone • Delivery to: individual • Targeting: depression • Co-intervention: pharmacotherapy • Delivery setting: unclear • Components: 5 components: 1) an enhanced care approach; 2) patient choice of psychotherapy and/or pharmacotherapy; 3) a form of psychotherapy called problem-solving therapy (PST); 4) a stepped-care approach in which symptom severity was reviewed and treatment was augmented accordingly; 5) a standardised instrument used to track depressive symptoms **Control/comparison**: TAU: usual care defined by the patient's treating physicians + pharmacotherapy
Outcomes	Depression (BDI); MACE; antidepressant use; psychotherapy use **Timings**: baseline, 3 and 6 months
Identification	**Country and settings:** USA; multicentre **Author's name:** Davidson KW **Institution:** Columbia University College of Physicians and Surgeons **Email:** kd2124@columbia.edu **Address:** Karina W. Davidson, PhD, Department of Medicine, Columbia University College of Physicians and Surgeons, PH9 Center, 622W168th St, Room 948, New York, NY 10032

Davidson 2010 *(Continued)*

	Year: 2010 **Maximum follow-up:** 9 months **Dates participants recruited:** 1 January 2005 to 29 February 2008
Notes	**Sample size calculation:** "The 2-sided was set at.05, and power was set at 0.90. The sample size was chosen to ensure this level of power to detect a 30% group difference (intervention vs usual care groups) in the proportion of patients who were satisfied with their depression care at the conclusion of the 6-month study. This required enrolling 80 patients per group, allowing for 20% loss (eg, 64 per group with 9-month outcome data would provide a power of 0.93 to detect any 30% group difference in satisfaction, eg, 90% vs 60%, 65% vs 35%, or 35% vs 5%)" **Funding /sponsorship source:** National Heart, Lung, and Blood Institute; National Center for Research Resources **Conflicts of interest**: none reported

Freedland 2009

Study characteristics	
Methods	**Aim of study:** to test the efficacy of 2 non-pharmacological interventions for depression after coronary artery bypass surgery compared with usual care **Study design:** parallel-group, randomised controlled trial **Number of centres:** multisite (3): Washington University–affiliated hospitals (Barnes-Jewish, Christian or Missouri Baptist Hospitals) in St Louis, Missouri **Country:** USA
Participants	**N randomised:** 123 (intervention A 41; intervention B 42; control 40) **Diagnosis:** (% of participants): CABG123 (100%); intervention A 41 (100%); intervention B 42 (100%); control 40 (100%) **Psychopathology:** Major depression:81 (66%); intervention A 26 (63%); intervention B 30 (71%); control 25 (62%) Minor depression:42 (34%); intervention A 15 (37%); intervention B 12 (29%); control 15 (38%) **Age (mean ± SD)**, years: total NR; intervention A 62 ± NR; intervention B 59 ± NR; control 61 ± NR **Percentage male:** total 50.4%; intervention A 44%; intervention B 50%; control 57% **Percentage white:** total 81.3%; intervention A 88%; intervention B 67%; control 90% **Inclusion criteria:** those aged 21 years or older; having undergone CABG surgery within the past year at a Washington University-affiliated hospital; scored 10 or higher on the Beck Depression Inventory (BDI) and who met DSM-IV criteria for a current major or minor depressive episode, as determined by the Depression Interview and Structured Hamilton (DISH) were enrolled in the trial. **Exclusion criteria:** severe psychiatric comorbidities, such as schizophrenia or bipolar disorder; active alcoholism or substance abuse; severe cognitive impairment; non-cardiac illnesses with a poor 1-year prognosis; being too medically ill; living too far away to participate; being unable to communicate in English; receiving ongoing psychotherapeutic services. Current use of an antidepressant medication was not an exclusion criterion, as long as the patient had been taking a therapeutic dose for at least 6 weeks.

Freedland 2009 *(Continued)*

Interventions	**Intervention A** • Total duration: 12 weeks • CBT; telephone follow-up; case review; and TAU • Type of psychological intervention (CCDAN): CBT • Frequency: weekly (in most cases) • Number of sessions: 12 • Length of sessions: 50 to 60 minutes • Delivered by: 1 of 3 therapists (2 clinical psychologists and a clinical social worker) with training and experience in CBT • Delivery format: face-to-face; telephone; treatment manual • Delivery to: individual • Targeting: depression; anxiety; HRQoL • Co-intervention: none • Delivery setting: community - outpatient clinic • Components: therapist-delivered CBT sessions - some standard CBT techniques were modified for cardiac patients. Initial sessions focused on target problem identification, problem-solving and behavioural activation. Subsequent sessions emphasised cognitive techniques. Final 2 sessions also looked at consolidation of the self-therapy and relapse-prevention skills that were promoted by intervention. Brief telephone contacts between treatment sessions allowed, as needed. **Intervention B** • Total duration: 12 weeks • SSM; telephone follow-up; case review; relaxation; and TAU • Type of psychological intervention (CCDAN): CBT: stress management • Frequency: weekly (in most cases) • Number of sessions: 12 • Length of sessions: 50 to 60 minutes • Delivered by: 1 of 3 therapists (2 clinical psychologists and a clinical social worker) with training and experience in counselling and stress-management interventions • Delivery format: face-to-face; telephone • Delivery to: individual • Targeting: depression; anxiety; HRQoL • Co-intervention: none • Delivery setting: community - outpatient clinic • Components: therapist-delivered SSM sessions in the setting of a supportive therapeutic relationship with the objective of improving the patient's ability to cope with stressful life events and daily stressors. Initial session focused on the link between depression and heart disease, that the ability to cope with stress depends on skills that can be improved through training and practice. Subsequent sessions provided patients with systematic instruction and guided practice in progressive relaxation training and other techniques. As patients gained proficiency in relaxation skills, they were asked to apply them to stressful situations. Brief telephone contacts between treatment sessions. **Control/comparison**: TAU: usual care
Outcomes	Depression (HAM-D); depression (BDI); anxiety (BAI); HRQoL (SF-36 PCS); HRQoL (SF-36 MCS) **Timings**: baseline, 3, 6 and 9 months
Identification	**Country and settings:** USA; multisite (outpatient research clinic) **Author's name:** Freedland KE **Institution:** Washington University School of Medicine

Freedland 2009 *(Continued)*

	Email: freedlak@bmc.wustl.edu **Address:** Kenneth E. Freedland, PhD, Department of Psychiatry, Washington University School of Medicine, 4320 Forest Park Ave, Ste 301, St Louis, MO 63108 **Year:** 2009 **Maximum follow-up:** 9 months **Dates participants recruited:** Enrolment: December 2001 to August 2005
Notes	**Pretreatment:** CBT and TAU group had significantly lower numbers of African American participants than SSM group **Sample size calculation:** "A target sample size estimate of 43 patients per group was based on 80% power to detect a treatment-control difference of 4 points on the Hamilton Rating Scale for Depression (HAM-D) at 3 months" **Funding/sponsorship source:** National Institute of Mental Health **Conflicts of interest**: none reported

Gary 2010

Study characteristics	
Methods	**Aim of study:** to compare the effectiveness of a combined 12-week home-based exercise (EX)/cognitive behavioural therapy (CBT) programme with CBT; EX; and usual care in stable New York Heart Association Class II to III heart failure (HF) patients diagnosed with depression **Study design:** parallel-group, randomised controlled trial **Number of centres:** multisite (4): hospital sites: HF clinic in Northeast Georgia **Country:** USA
Participants	**N randomised:** 74 (intervention A 19; intervention B 18; control 17) *EX only comprised 20 participants but had no cognitive component, so was excluded from analyses* **Diagnosis:** (% of participants): HF74 (100%); intervention A 19 (100%); intervention B 18 (100%); control 17 (100%) **Severity:** class III 42 (56.7%); intervention A NR; intervention B NR; control NR **Psychopathology:** Major depression history:52 (77.0%); intervention A NR; intervention B NR; control NR Antidepressants:22 (29.7%); intervention A NR; intervention B NR; control NR Anti-anxiety: 9 (12.2%); intervention A NR; intervention B NR; control NR **Age (mean ± SD)**, years: total 65.8 ± 13.5; intervention A NR; intervention B NR; control NR **Percentage male:** total 41.9%; intervention A NR; intervention B NR; control NR **Percentage white:** total 71.6%; intervention A NR; intervention B NR; control NR **Inclusion criteria:** (a) documented medical diagnosis of HF; (b) LVEF of ≥ 15% documented within the last year by echocardiogram, cardiac catheterisation ventriculography, or radionuclide ventriculography; (c) receiving therapy for HF according to guidelines published by the American College of Cardiology American Heart recommendations (angiotensin-converting enzyme inhibitors,

Gary 2010 *(Continued)*

	diuretics, beta blockers, angiotensin receptor blockers, hydralazine and nitrate combination, etc.); (d) Hamilton Rating Scale for Depression (HAM-D) score ≥ 11; (e) positive results on the Mini International Neuropsychiatric Interview (MINI) for minor or major depression; and (e) DSM-IV diagnosis for depression for 14 days; or 7 days if history of major depressive disorder (MDD) in the last 6 months. Participants also had to be (a) English speaking, (b) living independently (noninstitutionalised) within 100 miles of Atlanta, GA, (c) able to respond to questions appropriately, (d) able to hear adequately to respond to verbal questions, (e) not involved in any structured EX programme or walking 3 times per week for a minimum of 20 min, (f) not participating in any psychotherapy, and (g) not hospitalised within the last 60 days **Exclusion criteria:** (a) suicide ideation according to psychiatric assessment or MINI evaluation; (b) major psychiatric comorbidity such as schizophrenia, personality disorder or dementia; (c) planned surgery; (d) not diagnosed with HF in the past 3 months; (e) renal insufficiency (serum creatinine > 2.5 mg/dL); (f) uncontrolled hypertension; (g) acute bereavement or loss of significant other within the last month or currently involved in family crisis such as divorce; (h) any disorder interfering with independent ambulation; and (i) terminal illness such as cancer
Interventions	**Intervention A** • Total duration: 12 weeks • CBT; monitoring depressive symptoms; cognitive and behavioural skills; and TAU • Type of psychological intervention (CCDAN): CBT • Frequency: weekly • Number of sessions: 12 • Length of sessions: 1 hour • Delivered by: a psychologist trained in CBT, with CBT supervision • Delivery format: face-to-face and phone follow-up • Delivery to: individual • Targeting: depression; HRQoL • Co-intervention: none • Delivery setting: home • Components: CBT for depression was structured, collaborative, short-term and problem-focused; teaching patients a variety of cognitive and behavioural skills employed to combat depression. The first 2 to 3 sessions were used to (1) build and establish rapport with the patient, (2) review principles of the cognitive model (agenda, thoughts, influence, behaviour), (3) educate the patient about depression (negative schema), (4) teach the patient about CBT methods that may be used(i.e. identifying automatic thoughts, activity scheduling, role-playing, homework), (5) establish mutual collaborative goals for therapy, and (6) clarify concerns and answer any questions about CBT **Intervention B** • Total duration: 12 weeks • CBT; monitoring depressive symptoms; cognitive and behavioural skills; exercise; and TAU • Type of psychological intervention (CCDAN): CBT • Frequency: weekly • Number of sessions: 12 • Length of sessions: CBT - 1 hour; EX - 30 to 45 minutes • Delivered by: trained nurse; and a psychologist trained in CBT • Delivery format: face-to-face and phone follow-up • Delivery to: individual • Targeting: depression; HRQoL • Co-intervention: none • Delivery setting: home • Components: combined CBT (as above) and EX interventions. Received a combination of the weekly walking (EX) and CBT sessions. One interventionist delivered both the EX and CBT programme, either concurrently or separately, depending on patient tolerance.

Gary 2010 *(Continued)*

	Control/comparison: TAU: usual care (CG group received no information or counselling from their health care provider other than that normally provided)
Outcomes	Depression (HAM-D); HRQoL (MLHFQ); intervention acceptability **Timings**: baseline, 3 and 6 months
Identification	**Country and settings:** USA; hospital **Author's name:** Gary RA **Institution:** Emory University, Atlanta **Email:** ragary@emory.edu **Address:** Rebecca A Gary, Nell Hodgson Woodruff School of Nursing, Emory University, Atlanta, GA 30322, USA **Year:** 2010 **Maximum follow-up:** 3 months **Dates participants recruited:** NR. 14-month recruitment
Notes	**Sample size calculation:** NR **Funding/sponsorship source:** Southeast Affiliate of the American Heart Association Beginning Grant-in-Aid, Atlanta Clinical and Translational Science Institute at Emory University School of Medicine **Comments:** payment incentives suggested **Conflicts of interest**: none reported

Habibovic 2017

Study characteristics	
Methods	**Aim of study:** to evaluate a WEB-based distress management program for ICD patients (WEBCARE) developed to mitigate anxiety and depression and enhance health-related quality of life in ICD patients **Study design:** parallel-group, randomised controlled trial **Number of centres:** multisite (6): 6 Dutch referral hospitals (Amphia, Breda; Canisius-Wilhelmina, Nijmegen; Catharina, Eindhoven; Erasmus Medical Center, Rotterdam; Onze Lieve Vrouwe Gasthuis, Amsterdam; Vlietland, Schiedam) **Country:** Netherlands
Participants	**N randomised:** 289 (intervention 146; control 143) **Diagnosis:** (% of participants):**HF** 157 (54.3%); intervention 78 (53.4%); control 79 (55.2%) **Severity:** Class III/IV 45 (19.4%); intervention 20 (17.4%); control 25 (21.4%) LVEF ≤ 35:184 (63.7%); intervention 87 (59.6%); control 97 (67.8%) **Psychopathology:** no depressive symptoms reported

Habibovic 2017 *(Continued)*

	Age (mean ± SD), years: total 58.5 ± 9.9; intervention 58.2 ± 9.9; control 58.6 ± 10.2 **Percentage male:** total 81.3%; intervention 82.2%; control 80.4% **Percentage white:** NR **Inclusion criteria:** first-time ICD implant; aged 18 to 75 years; speak and understand Dutch; have access to the internet and ability to use the internet; provide written informed consent **Exclusion criteria:** significant cognitive impairments (e.g. dementia); history of psychiatric illness other than affective/anxiety disorders; life-threatening comorbidities (e.g. cancer); life expectancy
Interventions	• Total duration: 12 weeks • Psycho-education; problem-solving; relaxation; and TAU • Type of psychological intervention (CCDAN): behaviour therapy/behaviour modification (psychoeducation); CBT (problem-solving) • Frequency: fortnightly - patients could only proceed to the next lesson if they had finished the former and sent the homework assignment to their coach • Number of sessions: 6 • Length of sessions: patients were allowed to complete the 6 lessons in their own time and pace • Delivered by: masters-level psychologists trained according to a standardised protocol to provide online feedback to patients • Delivery format: online • Delivery to: individual • Targeting: depression; anxiety; HRQoL • Co-intervention: none • Delivery setting: community (home) • Components: 6 lessons. 1: educational (psychological problems experienced by ICD patients). From lesson 2: a more active problem-solving approach was introduced. Lesson 3: patients were asked to choose one problem that they labelled as an "important problem that can be solved" and actively work on this problem using problem-solving techniques. Lesson 4: patients were asked to choose a problem from the "unimportant problems that can be solved" and actively work on these using techniques like engaging in positive thinking, stop ruminating, and so on. Lesson 5: patients worked with problems that cannot be solved. Lesson 6: patients were asked to make a future plan of goals they wanted to achieve and how they would go about this. All patients also received a CD with relaxation training exercises. **Control/comparison**: TAU: usual care
Outcomes	Depression (PHQ-9); anxiety (GAD-7); HRQoL (SF-12 PCS); HRQoL (SF-12 MCS) **Timings**: baseline, 3, 6 and 12 months
Identification	**Country and settings:** Netherlands; Hospital **Author's name:** Habibović, Mirela **Institution:** Tilburg University **Email:** M.Habibovic@uvt.nl **Address:** Mirela Habibović, CoRPS-Department of Medical and Clinical Psychology, Tilburg University, Warandelaan 2, P.O. Box 90153, 5000 LE Tilburg **Year:** 2017 **Maximum follow-up:** 12 months **Dates participants recruited:** April 2010 to February 2013

Habibovic 2017 *(Continued)*

Notes	**Pretreatment:** those in the intervention group (WEBCARE) were significantly less likely to have undergone a PCI or to use ACE-inhibitors compared with those in the control group **Sample size calculation:** "Based on a sample size calculation with a power of .80 (two-tailed test), an alpha of .05, and an effect size of.30, 350 participants were required (175 in each condition) to demonstrate an effect on the primary endpoint (symptoms of anxiety)" **Funding/sponsorship source:** Netherlands Organization for Health Research and Development and by Dutch Heart Foundation **Conflicts of interest**: none reported

Humphries 2021

Study characteristics	
Methods	**Aim of study:** to evaluate the long-term effectiveness of internet-based cognitive behavioural therapy on self-reported symptoms of anxiety and depression in patients 12 months after a myocardial infarction and to explore subsequent occurrences of cardiovascular disease events **Study design:** parallel-group, randomised controlled trial **Number of centres:** multisite (25): cardiac units across Sweden **Country:** Sweden
Participants	**N randomised:** 239 (intervention 117; control 122) **Diagnosis:** (% of participants): acute MI 239 (100%); intervention 117 (100%); control 122 (100%) **Psychopathology:** NR **Age (mean ± SD)**, years: 59.6 ± 8.49; intervention 58.4 ± 9.0; control 60.8 ± 7.8 **Percentage male:** total 66.5%; intervention 62.4%; control 70.5% **Percentage white:** NR **Inclusion criteria:** < 75 years of age, reporting symptoms of anxiety or depression (scoring > 7 on any of the 2 HADS anxiety and depression subscales) within 3 months following their myocardial infarction. Myocardial infarction was defined according to International Statistical Classification of Disease Tenth Revision (ICD-10) code I21 and diagnosed by a cardiologist. **Exclusion criteria:** patients scheduled for coronary artery bypass surgery, with low adherence (such as missing appointments with the cardiac nurse or substance use), or expected to live < 1 year, as judged on-site by the recruiting nurse, were not eligible.
Interventions	• Total duration: 14 weeks • CBT (online - iCBT); and TAU • Type of psychological intervention (CCDAN): CBT • Frequency: weekly • Number of sessions: tailored iCBT; with only the 1st of the 10 modules compulsory; and patient able to choose which modules to complete • Length of sessions: NR • Delivered by: delivered via the a secure web-portal; therapist guided and partly customisable • Delivery format: online; includes texts, presentations, assignments and self-monitoring, and offers a weekly feedback from a psychologist over the internet • Delivery to: MI patients

Humphries 2021 *(Continued)*

	• Targeting: depression; anxiety; mortality; adverse events • Co-intervention: none • Delivery setting: online • Components: comprising 11 modules, of which the first is mandatory. Patients encouraged to choose 2/3 modules from the 10; tailoring the programme to them. Each module consists of 2 to 4 steps and 1 to 2 homework activities. Homework assignments were included in each module, and the portal also included a library that was accessible at all times with content and material including media such as videos and informational text. **Control/comparison:** TAU: usual care - standard protocol secondary prevention and cardiac rehabilitation offered by the regional health care system. This usually includes, but is not limited to, preventive medications, education about cardiovascular risk factors, smoking cessation, organised and tailored physical exercise, and in some areas, access to counselling or psychosocial support.
Outcomes	Depression (HADS; MADRS-S); anxiety (HADS; CAQ); mortality; adverse events **Timings**: baseline, 14 weeks and 12 months
Identification	**Country and settings:** Sweden; multicentre (25 cardiac clinics) **Author's name:** Humphries SM **Institution:** Uppsala University, Uppsala, Sweden **Email:** sophia.humphries@kbh.uu.se **Address:** Clinical Psychology in Healthcare, Department of Women's and Children's Health, Uppsala University, Akademiska Hospital, Uppsala, 75185, Sweden **Year:** 2021 **Maximum follow-up:** 12 months **Dates participants were recruited:** September 2013 to December 2016
Notes	**Funding/sponsorship source:** Swedish Research Council (2009-1093); The Swedish Heart and Lung Association (E 148/11); the Uppsala-Örebro Regional Research Council (22 86 61); Swedish Research Council for Health, Working Life, and Welfare (2014-4947); and the Vårdal Foundation (2014-0114) **Conflicts of interest**: none declared

Moradi 2016

Study characteristics	
Methods	**Aim of study:** to evaluate a 12-month follow-up of the effect of eye movement desensitisation and reprocessing (EMDR) on anxiety levels in myocardial patients **Study design:** parallel-group, randomised controlled trial **Number of centres:** single site (1): ICU of Bu-Ali Sina Hospital of Qazvin **Country:** Iran
Participants	**N randomised:** 60 (intervention 30; control 30) **Diagnosis:** (% of participants): MI 60 (100%); intervention 30 (100%); control 30 (100%) **Severity:**

Moradi 2016 *(Continued)*

	Anterior MI: 28 (46.7%); intervention 14 (46.7%); control 14 (46.7%) Inferior MI:15 (25.0%); intervention 7 (23.3%); control 8 (26.7%) Posterior MI: 10 (16.7%); intervention 6 (20.0%); control 4 (13.3%) **Psychopathology:** NR **Age (mean ± SD)**, years: total 50.97 ± 8.25; intervention NR; control NR **Percentage male:** total 83.3%; intervention 83.3%; control 83.3% **Percentage white:** NR **Inclusion criteria:** myocardial infarction diagnosis by a specialist physician, passing the intense period of the disease, stability of the haemodynamic condition of the patient, literacy, aged 30 to 70 years, intensive infarction, history of spasms, psychological diseases, addiction, strabismus and visionary problems **Exclusion criteria:** inability to tolerate the EMDR procedure and not cooperating with the therapist
Interventions	• Total duration: 2 days • EMDR • Type of psychological intervention (CCDAN): behaviour therapy/behaviour modification: systematic desensitisation therapy - eye movement desensitisation reprocessing • Frequency: every other day (a day between both sessions) • Number of sessions: 2 • Length of sessions: 45 to 90 minutes • Delivered by: study researchers following standardised protocol for EMDR • Delivery format: face-to-face • Delivery to: individual • Targeting: anxiety • Co-intervention: none • Delivery setting: hospital • Components: brief session (time frame) for delivery of all 8 phases of EMDR therapy provided. In reprocessing phases, patients were instructed to identify an image representing the worst part of their cardiac event, a negative irrational self-belief associated with the image, a positive adaptive cognition, emotions and attendant body sensations. While focusing on the image, negative belief and sensations, patients were guided to simultaneously move their eyes back and forth following the therapist's fingers as they moved across his or her field of vision for a "set" of approximately 24 to 36 seconds. After this, patients reported any new emerging associations. Such associations generally became the focus of the next set of dual attention or were guided by the clinician. This process continued until the target memory was desensitised. The treatment process was used to address memories of the cardiac event and associated triggers, as well as anticipatory anxiety. **Control/comparison**: no treatment
Outcomes	Anxiety (BAI) **Timings**: baseline, 6 and 12 months
Identification	**Country and settings:** Iran; hospital **Author's name:** Moradi M **Institution:** Qazvin University of Medical Science, Iran **Email:** c/o: mbehnammoghadam@yahoo.com **Address:** corresponding author: Mohammad Behnam Moghadam, Critical Department, School of Nursing and Midwifery, Yasuj University of Medical Sciences, Yasuj, IR Iran

Moradi 2016 *(Continued)*

	Dates participants recruited: NR **Maximum follow-up:** 12 months **Year:** 2016
Notes	**Pretreatment:** those in the intervention group were significantly more likely to identify as 'smoker' compared with those in the control group. **Sample size calculation:** NR **Funding/sponsorship source:** Qazvin University of Medical Science, Deputy for Research **Conflicts of interest**: none reported

Nahlén Bose 2016

Study characteristics	
Methods	**Aim of study:** to evaluate a nurse-led coping effectiveness training (CET) group intervention for patients with CHF **Study design:** parallel-group, randomised controlled trial **Number of centres:** single (1): heart failure outpatient clinic in a hospital in Stockholm County Council in Sweden **Country:** Sweden
Participants	**N randomised:** 103 (intervention 52; control 51) **Diagnosis:** (% of participants) **CHF** 103 (100%); intervention 52 (100%); control 51 (100%) **Severity:** Class III: 14 (14.9%); intervention 5 (11.4%); control 9 (18.0%) LVEF > 50: 13 (13.8%); intervention 5 (11.4%); control 8 (16.0%) LVEF 40 to 49: 31 (32.8%); intervention 13 (29.5%); control 18 (36.0%) LVEF 30 to 39: 36 (38.3%); intervention 18 (40.9%); control 18 (36.0%) LVEF < 30: 14 (14.9%); intervention 8 (18.2%); control 6 (12.0%) **Psychopathology:** comorbid depression7 (7.4%); intervention 3 (6.8%); control 4 (8.0%) **Age (mean ± SD)**, years: total NR; intervention 72.2 ± 9.7; control 69.0 ± 8.6 **Percentage male:** total 69.1%; intervention 65.9%; control 72.0% **Percentage white:** NR **Inclusion criteria:** classified as NYHA class II–III; aged over 18 years **Exclusion criteria:** cognitive dysfunction; a life-threatening disease such as cancer or primary organ failure; and/or severe psychiatric diagnosis such as psychosis or severe depression; and not being able to understand the Swedish language
Interventions	• Total duration: 7 weeks

Nahlén Bose 2016 *(Continued)*

- Coping effectiveness training; stress and coping; education; participation; and TAU
- Type of psychological intervention (CCDAN): CBT: stress management/problem-solving/coping
- Frequency: weekly
- Number of sessions: 7
- Length of sessions: 90 minutes
- Delivered by: cardiac nurse specialist in CHF received supervision from a psychologist, and received supervision after each CET session
- Delivery format: face-to-face; workbook
- Delivery to: group (7 to 12 people in each group)
- Targeting: depression; anxiety; HRQoL
- Co-intervention: none
- Delivery setting: NR: hospital (cardiac nurse: CET); community (home assignments)
- Components: participants received CET sessions and a workbook with a brief summary of every session as well as home assignments. 7 sessions: 1) Introduce the concept of stress and coping; 2) Appraisal and coping strategies; 3) Problem-focused coping, e.g. problem solving method; 4) Emotion focused coping, e.g. relaxation training; 5) Challenging negative thoughts; 6) Adaptive and maladaptive coping; 7) Present different kind of social support. Home assignment: 1) Identify own signs of stress; 2) Identify which stressors can be changed or not; 3) Practice a problem-solving method; 4) Practice relaxation and engage in pleasant activities; 5) Replace negative thinking with more realistic thoughts; 6) Continue an adaptive and stop 1 maladaptive strategy; 7) Encouragement to practice skills learned during CET

Control/comparison: usual care for patients with CHF such as nurse-led heart failure outpatient clinic, cardiology specialist outpatient or primary health care

Outcomes	Depression (HADS-D); anxiety (HADS-A); HRQoL (RAND-36 PCS); HRQoL (RAND-36 MCS) **Timings**: baseline, immediately post-intervention, 6 weeks, 6 and 12 months
Identification	**Country and settings:** Sweden; hospital **Author's name:** Nahlén Bose, Catarina **Institution:** Karolinska Institutet **Email:** catarina.nahlen.bose@rkh.se **Address:** Catarina Nahlén Bose, Department of Clinical Sciences Danderyd Hospital AB, Karolinska Institutet, SE-182 88 Stockholm, Sweden **Dates participants recruited:** 2011 to 2013 **Maximum follow-up:** 12 months **Year:** 2016
Notes	**Contact with authors:** study author (CB) was contacted; responded and provided requested baseline data for anxiety and depression measures used in the study. **Sample size calculation:** "A prospective power analysis was calculated based on PANAS with a moderate effect size of Cohen's d = 0.50 and alpha = 0.05, indicating that to obtain a power of 0.80, a sample size of 72 patients was required. 26 Cohen's d of 0.50 is equivalent to about 0.5 standard deviations and a four-point difference in the subscales in PANAS could be considered a minimal important difference. To account for attrition another 15 participants were added to each arm to ensure an adequate sample size" **Funding/sponsorship source:** Swedish Heart and Lung Association, Solstickan Foundation, Department of Cardiology Danderyd Hospital, Stockholm, Sweden, Karolinska Institutet Department of Clinical Sciences Danderyd Hospital, Stockholm County Council (ALF), Sophiahemmet Research Foundation, and Mats Kleberg Foundation

Nahlén Bose 2016 *(Continued)*

	Conflicts of interest: none declared

Nijjar 2019

Study characteristics	
Methods	**Aim of study:** to estimate treatment effects and variability of mindfulness-based stress reduction (MBSR) (intervention) on levels of depression, anxiety, stress, health-related quality of life, and CV risk factors and biomarkers in CR eligible patients **Study design:** parallel-group, randomised controlled trial **Number of centres:** multisite (> 3): trial registration states recruitment from 3 sites within the Fairview Hospital system offering CR (Ridges in Burnsville, Southdale in Edina and University of Minnesota Riverside Campus in Minneapolis); also through electronic health records, clinic visits with health care providers, advertisement/flyers located at clinics and the CR locations, and inclusion of the study on www.studyfinder.umn.edu **Country:** USA
Participants	**N randomised:** 47 (intervention 31; control 16) **Diagnosis:** (% of participants) CAD (stable angina, MI, PCI, CABG):37 (78.7%); intervention 24 (77.4%); control 13 (81.2%) HF:1 (6.2%); intervention 2 (6.5%); control 1 (6.2%) Cardiac surgery (valve replacement): 5 (10.6%); intervention 4 (12.9%); control 1 (6.2%) Other:2 (4.3%); intervention 1 (3.2%); control 1 (6.2%) **Severity:** NR **Psychopathology:** Moderate depression PHQ-9 ≥ 10:10 (21.3%); intervention nr; control NR Moderate anxiety GAD-7 ≥ 10: 7 (14.8%); intervention NR; control NR **Age (mean ± SD)**, years: total 58.6 ± 10.8; intervention 57.5 ± 11.5; control 60.7 ± 9.3 **Percentage male:** total 61.7%; intervention 54.8%; control 75.0% **Percentage white:** total 78.7%; intervention 77.4%; control 81.2% **Included criteria:** aged 21 and older; medically eligible; been referred for traditional exercise-based CR (heart attack within the past 12 months, open heart surgery such as coronary bypass/valve/heart transplant, coronary angioplasty or stent placement, current stable angina or heart failure); willing to participate in all assessments and be randomised to either study condition; able to give informed consent **Excluded criteria:** have a cardiac pacemaker and is pacemaker-dependent or has an untreated atrial arrhythmia; previously completed an MBSR course; unable to read and write in English
Interventions	• Total duration: 8 weeks • MBSR; mindfulness; relaxation; discussion; education; and TAU • Type of psychological intervention (CCDAN): third-wave CBT: mindfulness • Frequency: weekly group sessions; single retreat • Number of sessions: 8 group sessions; 1 retreat

Nijjar 2019 *(Continued)*

	• Length of sessions: 2.5-hour group sessions, and 1 day (6.5 hours) retreat • Delivered by: taught per a standard protocol by trained facilitators from the University of Minnesota Center for Spirituality and Healing • Delivery format: face-to-face; educational materials • Delivery to: group • Targeting: depression; anxiety • Co-intervention: NR - 22 (46.8%) of total cohort (IG and CG) currently enrolled in phase 2 exercise-based CR • Delivery setting: NR • Components: MBSR comprises group sessions, and a retreat, taught per standard protocol in a group setting. The course includes instruction and practice of meditation, breathing techniques, gentle yoga and Tai Chi poses, with shared discussion, brief readings and home practice between sessions. **Control/comparison**: usual care and standard educational materials on healthy lifestyles and stress management
Outcomes	Depression (PHQ-9); anxiety (GAD-7); intervention acceptability (2 questions: How important has MBSR been to you?; How would you rate your ability to handle stressful situations as a result of taking MBSR? (scored 1 to 5)) **Timings**: baseline, 3 and 9 months
Identification	**Country and settings:** USA; hospital **Author's name:** Nijjar PS **Institution:** University of Minnesota Medical School **Email:** nijja003@umn.edu **Address:** Prabhjot S. Nijjar, Cardiovascular Division, Department of Medicine, University of Minnesota Medical School, 420 Delaware Street SE, Minneapolis, MN 55455, USA **Year:** 2019 **Maximum follow-up:** 7 months (9 months post-randomisation) **Dates participants recruited:** 2016 to 2017
Notes	**Comments:** at the end of the study, control participants received a compact disc and workbook on MBSR. Participants were given monetary incentives for completion of each assessment. **Sample size calculation:** "Sample size calculations were not done due to the pilot nature of the study" **Funding/sponsorship source:** Grant-in-Aid of Research, Artistry, and Scholarship to Dr. Everson-Rose from the Office of the Vice President for Research, University of Minnesota; the University of Minnesota's Clinical & Translational Science Institute (CTSI) through the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH) Award Number UL1TR000114; the Program in Health Disparities Research, the Division of Cardiology, and the Masonic Cancer Center at the University of Minnesota **Conflicts of interest**: none declared

O'Neil 2014a

Study characteristics

O'Neil 2014a *(Continued)*

Methods	**Aim of study:** to evaluate the efficacy and feasibility of a tele-health program (MoodCare) that integrates depression management into a cardiovascular disease risk reduction programme for acute coronary syndrome patients with low mood **Study design:** parallel-group, randomised controlled trial **Number of centres:** multisite (6): 6 metropolitan hospitals in the states of Victoria (The Austin, St Vincent's, Geelong and Royal Melbourne Hospitals) and Queensland (Royal Brisbane and Women's and The Prince Charles Hospitals) **Country:** Australia
Participants	**N randomised:** 121 (intervention 61; control 60) **Diagnosis:** (% of participants): ACS121 (100%); intervention 61 (100%); control 60 (100%) **Severity:** NR **Psychopathology:** Moderately severe/severe depression: 22 (18.2%); intervention 8 (13.1%); control 13 (21.7%) Moderate depression: 35 (28.9%); intervention 18 (29.5%); control 17 (28.3%) Mild depression: 38 (31.4%); intervention 21 (34.4%); control 17 (28.3%) Moderately severe/severe anxiety: 14 (11.6%); intervention 9 (14.7%); control 6 (10.0%) Moderate anxiety: 21 (17.4%); intervention 8 (13.1%); control moderate anxiety 13 (21.7%) Mild anxiety: 39 (32.2%); intervention 23 (37.7%); control 16 (26.7%) **Age (mean ± SD)**, years: total 60 ± NR; intervention 61 ± 10.2; control 59 ± 10.7 **Percentage male:** total 75.2%; intervention 73.8%; control 76.7% **Percentage white:** NR **Inclusion criteria:** clinical diagnosis of ACS (MI – ST elevation MI (STEMI or non-STEMI) or unstable angina (with confirmed coronary artery disease on angiogram), 21 to 85 years of age, available for the duration of the study via the telephone, fluent in English and recorded a PHQ-9 score between 5 and 19 **Exclusion criteria:** cognitive impairment or a diagnosis of a psychiatric condition interfering with study involvement (e.g. bipolar illness, psychotic illness of any type, dementia, acute suicidality, severe personality disorder), participation in regular psychotherapy with a mental health professional at the time of hospital admission, terminal illness or any inability to participate in an unsupervised tele-based mood and lifestyle intervention as confirmed by a treating clinician
Interventions	• Total duration: 6 months • CBT; motivational interviewing; goal setting; behavioural activation; health tracking; and TAU • Type of psychological intervention (CCDAN): CBT • Frequency: NR • Number of sessions: up to 10: median = 8 sessions • Length of sessions: mean length of session: 48.4 minutes • Delivered by: qualified psychologists (master's level) with a minimum of 2 years clinical CBT experience (interventionists) • Delivery format: telephone • Delivery to: individual • Targeting: depression; HRQoL; intervention acceptability • Co-intervention: none • Delivery setting: community (home)

O'Neil 2014a *(Continued)*

	• Components: interventionists provided information to participants via telephone-based structured intervention sessions, with the aim of improving their mental health and CVD risk factor profiles using motivational interviewing, goal setting, behavioural activation and cognitive restructuring. Sessions were delivered most intensively over the first 3 months when ACS patients are most likely to be affected by depression. Participants were given a handbook containing general health resources, session activities, CVD risk factor goals, monitoring forms and recording sheets for tracking mood and thoughts. **Control/comparison**: TAU: usual care via their healthcare providers
Outcomes	Depression (CDS); depression (PHQ-9); HRQoL (SF-12 PCS); HRQoL (SF-12 MCS); intervention acceptability **Timings**: baseline and 6 months
Identification	**Country and settings:** Australia; hospital **Author's name:** O'Neil A **Institution:** Deakin University **Email:** aoneil@barwonhealth.org.au **Address:** Adrienne O'Neil, School of Medicine, Deakin University, PO Box 281, Geelong, VIC 3220, Australia **Year:** 2014 **Maximum follow-up:** 6 months **Dates participants recruited:** recruitment commenced in December 2009 (with screening ongoing for approximately 15 months)
Notes	**Comments:** one author declared CoI **Pretreatment:** a significantly higher proportion of intervention participants: had visited a general practitioner (GP) in the past 6 months; and were born in Australia, compared to CG **Sample size calculation:** "Sample size analysis indicated that 50 subjects per group (intervention and control) or a total of 100 were required to complete the study in order to detect an absolute intervention effect with 80% power and type I error of 5% (two-tailed). Sample size was calculated based on an overall difference between participants in the intervention and control groups in the primary outcome measure of depression scores at 6 months" **Funding/sponsorship source:** Australian Government Department of Health and Ageing Grant under the Sharing Health Care Initiative; beyondblue: the national depression and anxiety initiative; Heart Foundation; National Health and Medical Research Council; Australian Research Council (ARC) **Conflicts of interest**: Authors O'Neil, Taylor, Sanderson, Cyril, Chan, Hawkes, Jelinek, Venugopal, Atherton, Amerena, Grigg, Walters, and Oldenburg declare that they have no conflict of interest. DL Hare developed the CDS and has received research, fellowship, and consultancy funds from the National Health and Medical Research Council (NHMRC), theNationalHeart Foundation ofAustralia, the AustinMedical Research Foundation, beyondblue, and Diabetes Australia for the development and researching of this scale. He has also received payment for research projects, consultancies, travel, advisory board memberships, and lectures from industry including Abbott, Amgen, AstraZeneca, Biotronic, Bristol-Myers Squibb, Boehringer Ingelheim, CSL Biotherapies, Hoffmann-La Roche, Hospira, Lundbeck (Denmark), Medtronic, Menarini, Merck KA (Germany), Merck (US), MSD, Pfizer, Roche, Sanofi-Aventis, Servier, and Wyeth. All procedures, including the informed consent process, were conducted in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000.

O'Neil 2014b

Study characteristics	
Methods	**Aim of study:** to investigate the effects of a telephone-delivered health coaching programme on depression and anxiety outcomes of MI patients **Study design:** parallel-group, randomised controlled trial **Number of centres:** multisite (2): 2 large metropolitan hospitals in Brisbane, Australia (Royal Brisbane and Women's and The Prince Charles Hospitals) **Country:** Australia
Participants	**N randomised:** 430 (intervention 215; control 215) **Diagnosis:** (% of participants):MI297 (100%); intervention 141 (100%); control 156 (100%) - data available for completers **Severity:** NR **Psychopathology:** NR **Age (mean ± SD)**, years: total NR; intervention 62.0 ± 11.0; control 59.7 ± 10.4 **Percentage male:** total 79.1%; intervention 78.7%; control 79.5% **Percentage white:** NR **Inclusion criteria:** diagnosis of MI (typical rise in serum level of troponin with at least one of the following: ischaemic symptoms; development of pathological Q waves on the electrocardiogram (ECG); ECG changes indicative of ischaemia (ST-segment elevation or depression); or coronary artery intervention); adults aged 18 to 80 years; ability to understand English; availability via telephone for the duration of the trial; and no other medical condition that would interfere with optimal participation or produce a significant risk to the patient, as defined by the referring specialist **Exclusion criteria:** NR
Interventions	• Total duration: 6 months • Social cognitive theory; health coaching (HC); phone calls; behaviour change; education; and TAU • Type of psychological intervention (CCDAN): behavioural therapy: social cognitive theory • Frequency: weekly at first when participant needs were most intensive (3 sessions), fortnightly for 3 sessions when participants are developing the tools for self-management, and monthly thereafter (4 sessions) to consolidate knowledge and skills learned over the first half of the programme • Number of sessions: 10 • Length of sessions: 30 minutes • Delivered by: a specially trained 'health coach' – a qualified health professional (e.g. registered nurse, medical doctor) • Delivery format: telephone • Delivery to: individual • Targeting: depression; anxiety • Co-intervention: none • Delivery setting: home • Components: first session used to introduce and describe the programme; outline the expectations of the participant. Sessions 2 to 10 were structured: (i) introduction and identification of any cardiac symptom changes; (ii) assessment and HC on relevant CHD risk factors; (iii) follow-up on progress towards previous actions and goals; and (iv) session review, including a summary of actions required and scheduling of the next session. The HC sessions were based on the guidelines for CHD, which included recommendations for enhancing emotional wellbeing: (i) maintaining

O'Neil 2014b *(Continued)*

	psychological and social health (emotional wellbeing), (ii) monitoring feeling down or depressed and seeking help when needed, (iii) monitoring support from others and seeking help if needed. **Control/comparison**: TAU: usual care (including: an existing written educational resource produced by the National Heart Foundation of Australia, 'My Heart My Life', containing information about CHD and the associated risk factors; they were also sent a quarterly informative newsletter based on existing written educational materials)
Outcomes	Depression (HADS-D); anxiety (HADS-A); intervention acceptability **Timings:** baseline and 6 months
Identification	**Country and settings:** Australia; hospital **Author's name:** O'Neil A **Institution:** Deakin University **Email:** aoneil@barwonhealth.org.au **Address:** Adrienne O'Neil, Barwon Psychiatric Research Unit, Deakin University, PO Box 281, Geelong, VIC 3220, Australia **Year:** 2014 **Maximum follow-up:** 6 months **Dates participants recruited:** December 2007 to January 2009
Notes	**Pretreatment:** those in the intervention group were significantly less likely to be employed compared with those in the control group. **Sample size calculation:** "The original sample size analysis indicated that 129 subjects per group (intervention and control) or a total of 258 were required to detect, with 90% power and type I error of 5% (two-tailed), an absolute intervention effect of 20% or greater (based on a primary outcome variable of undertaking the recommended level of physical activity, of 44% of control and 69% of the intervention over the study period). Sample size was significantly increased above 258 to allow for participant dropout and subgroup analyses at follow-up". **Funding/sponsorship source:** National Health and Medical Research Council; the National Heart Foundation of Australia; and the Australian Research Council **Conflicts of interest**: none declared

Rafanelli 2020

Study characteristics	
Methods	**Aim of study:** to evaluate the efficacy of the sequential combination of CBT and WBT, compared to clinical management (CM), in terms of depressive symptoms (primary outcome), psychological distress and wellbeing, as well as cardiovascular events, biomarkers and mortality (secondary outcomes), both after treatment and up to a 30-month follow-up **Study design:** parallel-group, randomised controlled trial **Number of centres:** multisite (2): Cardiology Divisions of Maggiore Hospital (Bologna, Italy) and Molinette Hospital (Torino, Italy) **Country:** Italy
Participants	**N randomised:** 100 (intervention 50; control 50)

Rafanelli 2020 *(Continued)*

	Diagnosis: (% of participants) ACS: 100 (100.0%); intervention 50 (100.0%); control 50 (100.0%) STEMI: 66 (66.0%); intervention 33 (66.0%); control 33 (66.0%) NSTEMI: 27 (27.0%); intervention 14 (28.0%); control 13 (26.0%) Unstable angina: 7 (7.0%); intervention 3 (6.0%); control 4 (8.0%) **Severity:** NR **Psychopathology:** Major depression: 5 (5.0%); intervention 2 (4.0%); control 3 (6.0%) Minor depression: 56 (56.0%); intervention 32 (64.0%); control 24 (48.0%) Dysthymia: 1 (1.0%); intervention 1 (2.0%); control (0.0%) **Age (mean ± SD)**, years: total 58.8 ± 10.5 intervention 57.6 ± 9.99 control 60.02 ± 10.94 **Percentage male:** total 69%; intervention 62%; control 76% **Percentage white:** NR **Inclusion criteria:** current diagnosis of major/minor depression or dysthymia according to DSM-IV-TR and/or demoralisation according to Diagnostic Criteria for Psychosomatic Research (DCPR) criteria **Exclusion criteria:** a positive history of bipolar disorder (DSM-IV-TR), major depression with psychotic features, a positive history of substance abuse/dependence during the previous 12 months, suicide risk and current use of antidepressants and/or psychotherapy
Interventions	• Total duration: 12 weeks • CBT; wellbeing therapy (WBT) • Type of psychological intervention (CCDAN): CBT • Frequency: weekly • Number of sessions: 12 • Length of sessions: 45 minutes • Delivered by: psychotherapists who had received specific training • Delivery format: face-to-face • Delivery to: individuals (ACS patients) • Targeting: depression; anxiety; adverse events • Co-intervention: none • Delivery setting: unclear • Components: sequential CBT/WBT. CBT to address distress associated with hospitalisation and medical events. WBT used to improve or balance one or more of the 6 dimensions of psychological wellbeing (environmental mastery, purpose in life, personal growth, autonomy, self-acceptance and positive relations with others), supplemented with suggestions for lifestyle modifications geared toward cardiovascular health, including treatment adherence. **Control/comparison**: clinical management (active control), which entails the same amount of time and attention from a professional figure than the intervention group, but specific interventions (such as exposure strategies, diary work and cognitive restructuring) were proscribed. It consists of empathic listening, review of the patient's clinical status and providing opportunities for disclosure of distress and worries, and encouragement of treatment adherence.
Outcomes	Depression (CID); depression (SQ-Depression subscale); anxiety (SQ-Anxiety); adverse events **Timings**: baseline, immediately following intervention, 3, 6, 12 and 30 months

Rafanelli 2020 *(Continued)*

Identification	**Country and settings:** Italy; Hospital **Author's name:** Rafanelli C **Institution:** University of Bologna **Email:** chiara.rafanelli@unibo.it **Address:** Department of Psychology, University of Bologna, Viale Berti Pichat 5IT, 40127 Bologna (Italy) **Year:** 2020 **Maximum follow-up:** 30 months **Dates participants recruited:** NR
Notes	**Contact with authors:** study author (CR) was contacted; responded and provided raw data for re-hospitalisations due to cardiac complications **Sample size calculation:** "The sample size was estimated using Piface software, which identified a minimum of 16 participants per arm to detect the expected superiority of CBT/WBT on Clinical Management (CM), with a power of 80% and a significance level of 5%. Thus, with 50 patients per group we expected a “large” effect size (Cohen’s d = 0.8)" **Funding/sponsorship source:** Compagnia di San Paolo di Torino, Italy **Conflicts of interest**: none declared

Richards 2018

Study characteristics	
Methods	**Aim of study:** to pilot an enhanced psychological care (EPC) intervention embedded within cardiac rehabilitation **Study design:** parallel-group, cluster-randomised controlled trial **Number of centres:** multisite (8): CR teams in South West England **Country:** UK
Participants	**N randomised:** 29 (intervention 15: from 5 cardiac teams; control 14: from 3 cardiac teams) **Diagnosis:** (% of participants) ACS and/or revascularisation: 22 (75.9%); intervention 11 (73.0%); control 11 (79.0%) Other (AF/HF/IHD/chest pain): 4 (13.8%); intervention 1 (7.0%); control 3 (21.0%) Other cardiac procedure (pacemaker, valve surgery): 3 (10.3%); intervention 3 (20.0%); control 0 (00%) **Psychopathology:** Moderate depressive episode: 3 (10.3%); intervention 3 (21.0%); control 0(0.0%) Mild depressive episode: 7 (24.1%); intervention 4 (29.0%); control 3 (23.0%) Mixed anxiety and depressive disorder (mild): 2 (6.9%); intervention 1 (7.0%); control 1 (8.0%) **Age (mean ± SD)**, years: total 63.8 ± 9.5; intervention 62.7 ± 8.9; control 68.1 ± 8.6

Richards 2018 *(Continued)*

	Percentage male: total 51.7%; intervention 53.0%; control 50.0% **Percentage white:** total 100%; intervention 100%; control 100% **Inclusion criteria:** aged 18 years or over; referred for CR based on local clinical referral protocols; PHQ-9 score of 10 or more **Exclusion criteria:** individuals reporting having been actively treated for depression (psychological or drug therapy) within the previous 6 months; where there is evidence of alcohol or drug dependency; being acutely suicidal; having poorly controlled bipolar disorder or psychosis/psychotic symptoms based on a clinical review (seeking external confirmation from the GP or other clinicians as required)
Interventions	• Total duration: 8 weeks • Enhanced psychological care; behavioural activation (BA); support; self-help; and CR • Type of psychological intervention (CCDAN): third-wave cognitive therapies: behavioural activation • Frequency: once/twice per week (with CR) • Number of sessions: 8 to 16 sessions • Length of sessions: 30 minutes integrated in CR • Delivered by: CR nurses trained to deliver EPC. Nurses were also supplied with a manual to support intervention delivery • Delivery format: face-to-face; handbook • Delivery to: individual • Targeting: depression; anxiety; HRQoL; cardiac events; costs; intervention acceptability • Co-intervention: CR • Delivery setting: hospital and community • Components: EPC is embedded within existing CR care pathway. EPC comprises mental health care co-ordination, including an embedded participant-led BA programme designed to tackle depressive symptoms. First CR session: CR nurses will look to: Explain to participant the options available, i.e. supported self-help BA manual, with or without onward referral to relevant mental healthcare services, depending on individual preferences. Agree mental health treatment plan and take relevant action. Remaining sessions: content tailored depending on whether the participant has decided to follow self-help BA manual. These sessions can be brief depending on patient progress. Using the self-help BA manual: CR nurse will, at each session, assess symptoms and risk, review treatment choices, support BA, and future planning. BA support is aimed at helping participants to engage with the self-help manual, explaining ideas and methods as required. At the midpoint (around 4 weeks), dedicated clinic time should be allocated to reviewing progress and carefully review treatment options. At the final session (around week 6 to 8) dedicated time should be allocated to reviewing progress, and structured details of the care received will be sent to their GP. **Control/comparison**: cardiac rehabilitation (CR) comprising structured exercise and education (e.g. managing cardiac risk factors) and psychological input (e.g. stress management and/or relaxation training)
Outcomes	Depression (BDI-II); anxiety (BAI); HRQoL (EQ-5D 5L); HRQoL (EQ-5D VAS); HRQoL (Heart QoL); cardiac events; intervention acceptability **Timings**: baseline, 5 and 8 months
Identification	**Country and settings:** UK; hospital **Author's name:** Richards SH **Institution:** University of Leeds **Email:** s.h.richards@leeds.ac.uk **Address:** Suzanne H. Richards, 1039A, Level 10, Worsley Building, University of Leeds Institute of Health Sciences, University of Leeds, Leeds LS2 9JN, UK

Richards 2018 *(Continued)*

	Year: 2018
	Maximum follow-up: 8 months
	Dates participants recruited: December 2014 to February 2015
Notes	**Contact with authors:** study author (SR) was contacted; responded and clarified costs for usual care group
	Comments: one author has listed CoI
	Pretreatment: those in the intervention group were more likely to: be in 1 of the 3 most deprived deciles; and report higher levels of depression at baseline compared with those in the CG.
	Sample size calculation: "Assuming an ICC of 0.05, we estimated the sample size in each of scenarios for a future, definitive cluster RCT based on the BDI-II MCID observed at the 8-month follow-up. An adequately powered definitive cluster RCT would require 50 cardiac teams and 650participants (13 participants recruited per team), randomising 25 cardiac teams and 325 participants to each trial arm. This sample size is large enough to detect an effect size of 0.35 SD units on the BDI-II with 90% power at the two-sided 5% level of significance. Consistent with our pilot data, this calculation assumed 80% follow-up at participant level at 8 months. Using pilot data, on average it took a cardiac team 1.38 months to recruit a participant. Thus, the length of recruitment for the definitive trial is estimated to be 18 months"
	Funding/sponsorship source: UK NIHR Health Technology Assessment Programme
	Conflicts of interest: RST is a co-chief investigator on the REACH-HF programme of research, which is developing and evaluating a home-based cardiac rehabilitation intervention for people with heart failure and their carers (NIHR PGfAR RP-PG-0611-12,004) and leads a portfolio of Cochrane reviews of cardiac rehabilitation that includes psychological interventions. None of the other authors have any competing interests to declare.

Tagney 2013

Study characteristics	
Methods	**Aim of study:** to test a psycho-educational support intervention, for patients with ICD, with usual care using arrhythmia clinical nurse specialists
	Study design: parallel-group, randomised controlled trial
	Number of centres: single site: (1): English cardiac centre
	Country: UK
Participants	**N randomised:** 49 (intervention 24; control 25)
	Diagnosis: (% of participants)
	IHD (including prior CABG/PCI): 29 (59.2%); intervention 16 (66.7%); control 13 (52.0%)
	Non-ischaemic cardiomyopathy: 14 (28.6%); intervention 6 (25.0%); control 8 (32.0%)
	Familial SCD syndrome:6 (12.2%); intervention 2 (8.3%); control 4 (16.0%)
	Severity: NR
	Psychopathology: NR
	Age (median ± IQR), years: total 65 ± 23; intervention 67.5 ± 17; control 63 ± 22
	Percentage male: total 81.6%; intervention 91.6%; control 72.0%

Tagney 2013 *(Continued)*

	Percentage white: total 98.0%; intervention 95.8%; control 100.0% **Inclusion criteria:** over 18 years; device for both primary and secondary prevention reasons **Exclusion criteria:** those due to have their device implanted as part of a series of interventions within the same admission (for example, those requiring revascularisation procedures - coronary artery by-pass (CABG) operation or percutaneous coronary intervention (PCI)); who could not read and write in English; those with learning difficulties; those referred via a 'treat-and-return' pathway
Interventions	• Total duration: 6 weeks • Psycho-educational; behavioural therapy; supportive; and TAU • Type of psychological intervention (CCDAN): CBT; third-wave: mindfulness • Frequency: NR - sessions post ICD within 7 to 10 days and at 6-week device follow-up • Number of sessions: 2 • Length of sessions: each telephone call lasted between 15 and 30 minutes, depending on individual need and willingness to engage • Delivered by: nurse specialists trained in intervention approach and delivery • Delivery format: face-to-face/telephone • Delivery to: individual • Targeting: depression; anxiety • Co-intervention: none • Delivery setting: hospital/home • Components: 3 components: 1) Physiological components included: disease-specific information; device specific information; managing expectations; activity levels; medication issues and comorbidities; and EoL considerations. 2) Psychological: normalising fears and anxieties; rationalising behaviours; coping; common emotions and experiences; managing stress and anxiety, relaxation techniques; family communication. 3) Social: living alone or with family; social support structure; transport; travel; GP knowledge **Control/comparison**: TAU: usual care (most often provided by arrhythmia clinical nurse specialists)
Outcomes	Depression (BDI-FS); anxiety (STAI-S); anxiety (STAI-T) **Timings**: 6 weeks and 6 months
Identification	**Country:** UK **Setting:** hospital **Author's name:** Tagney J **Institution:** University of the West of England **Email:** jenny2.tagney@uwe.ac.uk **Address:** Level 7, The New Bristol Heart Institute, Bristol Royal Infirmary (BRI), Bristol, BS2 8HW **Year:** 2013 **Maximum follow-up:** 6 months **Dates participants recruited:** April 2009 to July 2011 **Conflicts of interest**: None reported
Notes	**Pretreatment:** Those in the intervention group were significantly more likely to: have lower STAI-S scores at baseline; and have lower levels of self-criticism. Differences were noted on a range of measures, dependent on device implantation for primary or secondary prevention; and by elective admission route.

Tagney 2013 *(Continued)*

Sample size calculation: "The STAI had not previously been used to inform sample size calculations in populations of people with an ICD. Therefore, in order to guide the development of a power calculation to inform sample size for the current study, a statistician was consulted and consideration given to the anticipated change in STAI-S scores following the intervention (as STAI-T scores are anticipated to remain constant). Normative data for the general population and for a general medical and surgical population indicated that if the intervention is of moderate benefit then a mean STAI-S score change of 9 (standard deviation [SD] 12) could be anticipated. These parameters indicated that, in order to achieve 95% power and 0.05 alpha level with a onesided Bonferroni corrected paired samples t-test, a minimum of n = 26 patients were needed in the intervention group to detect the change and to determine whether benefits were maintained. The corresponding between groups comparison using the independent samples t-test indicated that a minimum of at least n = 28 would be needed in both groups to achieve 95% power in a onesided test and thus achieve measures of statistical significance in a normally distributed sample. The attrition rate was expected to be small based on previous retrospective and cross-sectional local research with similar populations therefore a recruitment target of n = 70 participants was proposed to allow 20% attrition to achieve final sample of n = 56"

Funding/sponsorship source: NR

Turner 2014

Study characteristics	
Methods	**Aim of study:** to determine whether a programme designed to support cardiac patients in behaviour change and mood management was effective in improving mood and related health behaviours in these patients **Study design:** parallel-group, randomised controlled trial **Number of centres:** multisite (2): 2 major university teaching hospitals **Country:** Australia
Participants	**N randomised:** 42 (intervention 21; control 21) **Diagnosis:** (% of participants): AMI/PCI (vs CABG) 26 (61.9%); intervention 10 (47.6%); control 16 (76.2%) **Severity:** NR **Psychopathology:** BDI-II > 13:42 (100%); intervention 21 (100%); control 21 (100%) Antidepressant medication:3 (7.1%); intervention 1 (4.8%); control 2 (11.8%) **Age (mean ± SD)**, years: total NR; intervention 55.6 ± 8.8; control 57 ± 11.2 **Percentage male:** total 78.6%; intervention 85.7%; control 71.4% **Percentage white:** NR **Inclusion criteria:** admitted to hospital for AMI, or for coronary artery bypass graft surgery (CABG) or percutaneous coronary intervention (PCI); aged 75 years or less; residing in metropolitan Melbourne; and having an adequate command of English **Exclusion criteria:** serious physical or psychiatric illness/disability; anticipated transport difficulties; non-availability for follow-up; and refusal
Interventions	• Total duration: 8 weeks • CBT; motivational interviewing; cognitive and behavioural skills; handouts; workbook; and TAU

Turner 2014 *(Continued)*

	• Type of psychological intervention (CCDAN): CBT • Frequency: weekly • Number of sessions: 8 • Length of sessions: 1.5 hours • Delivered by: experienced psychologists who followed manualised guidelines • Delivery format: face-to-face; handouts; group workbook • Delivery to: group • Targeting: depression; anxiety; self-efficacy • Co-intervention: none • Delivery setting: hospital • Components: ICBT comprises integrated motivational interviewing and CBT; in this instance for use with CHD patients with clinically significant symptoms of depression. Eight modules cover key areas of physical activity, diet, medication adherence, smoking cessation, depression, anxiety, anger and social support. **Control/comparison**: TAU: usual care
Outcomes	Depression (BDI-II); anxiety (HADS-A); self-efficacy (SE scale: controlling depression); self-efficacy (SE scale: controlling anxiety) **Timings**: baseline, 4 and 12 months
Identification	**Country and settings:** Australia; Hospital **Author's name:** Turner A **Institution:** Heart Research Centre, Victoria, Australia **Email:** alyna.turner@heartresearchcentre.org **Address:** Alyna Turner, Heart Research Centre, PO Box 2137, The Royal Melbourne Hospital, Victoria 3050, Australia **Year:** 2014 **Maximum follow-up:** 12 months **Dates participants recruited:** March 2007 to November 2008
Notes	**Pretreatment:** those in the intervention group were significantly more likely to be partnered compared with those in the control group. **Sample size calculation:** NR in paper - in associated article - "Before commencement of the trial, we estimated that 137 patients would be required in each group to achieve a small to medium interaction effect (d 0.40), using a conservative P value of.015 (to account for multiple comparisons) and power set at 0.80. Differences of 0.40 standard deviations from the mean were nominated because smaller differences may not be clinically significant" **Funding/sponsorship source:** Australian Rotary Health; the Norman H Johns Trust **Conflicts of interest**: none declared

Wells 2021

Study characteristics	
Methods	**Aim of study:** to evaluate the effects of metacognitive therapy (MCT) on anxiety and depressive symptoms when delivered alongside cardiac rehabilitation (CR)

Wells 2021 *(Continued)*

	Study design: parallel-group, randomised controlled trial **Number of centres:** multisite (5): 5 National Health Service Trusts across NW of England **Country:** UK
Participants	**N randomised:** 332 (intervention 163; control 169) **Diagnosis:** (% of participants) ACS: 219 (66%); intervention 118 (72.4%); control 101 (59.8%) HF: 37 (11.1%); intervention 21 (12.9%); control 16 (9.5%) **Psychopathology:** NR **Age (mean ± SD)**, years: total NR; intervention 60.4 ± 11.7; control 60.3 ± 10.5 **Percentage male:** total 65.7%; intervention 108 (66.3%); control 110 (65.1%) **Percentage white:** total 88.0%; intervention 146 (90.1%); control 146 (86.9%) **Inclusion criteria:** 1) Meets Department of Health and/or British Association for Cardiac Prevention and Rehabilitation CR eligibility criteria; 2) A score of ≥ 8 on either the depression or anxiety subscale of the Hospital Anxiety and Depression Scale (HADS); 3) Aged 18 years or older; 4) A competent level of English language skills (able to read, understand and complete questionnaires in English) **Exclusion criteria:** 1) Cognitive impairment which precludes informed consent or ability to participate; 2) Life expectancy of less than 12 months; 3) Acute suicidality; 4) Active psychotic disorders; 5) Current drug or alcohol abuse; 6) Antidepressant or anxiolytic medications initiated in the previous 8 weeks; 7) Concurrent psychological intervention for emotional distress
Interventions	• Total duration: 6 weeks • Meta-cognitive therapy (MCT); identification of triggering thoughts for worry, rumination and unhelpful coping; flexibility and control over negative thinking; strengthening adaptive metacognitions; and CR • Type of psychological intervention (CCDAN): MCT - third wave cognitive behavioural therapy • Frequency: weekly • Number of sessions: 6 • Length of sessions: 60 to 90 minutes • Delivered by: 2 CR professionals at each site (i.e. physiotherapist, CR nurse, occupational therapists) or research nurses. Therapists received 2 days of training in group-MCT followed by supervised practice in delivering the intervention to a pilot group, and an additional 1-day workshop to address difficulties experienced in delivering the intervention. Therapists guided by a treatment manual. • Delivery format: face-to-face • Delivery to: group • Targeting: depression; anxiety; HRQoL • Co-intervention: CR • Delivery setting: hospital or community settings • Components: there are 8 major treatment techniques used across the 6 sessions, namely 1) formulation, 2) socialisation, 3) the spatial attentional control exercise, 4) detached mindfulness, 5) worry and rumination postponement, 6) modifying metacognitive beliefs about the uncontrollability and danger of worry and rumination, 7) a 'helpful behaviours prescription', and 8) individual treatment summaries. Sessions include group discussions, experiential learning and homework tasks that participants will be expected to complete between sessions. Participants will complete a set of 'belief thermometers' at the start of each session, which measure 3 core metacognitive beliefs. The thermometers will be used to monitor change over the course of the intervention.

Wells 2021 *(Continued)*

	Control/comparison: CR only: weekly over a period of 8 to 10 weeks. Educational seminars covered topics including lifestyle and medical risk factor management. In addition, sites provided elements of psychosocial interventions, including talks on stress management and relaxation.
Outcomes	Depression (HADS-D); anxiety (HADS-A); HRQoL (EQ-5D-5L) **Timings**: baseline, 4 and 12 months
Identification	**Country and settings:** England; health trusts **Author's name:** Wells A **Institution:** University of Machester, UK **Email:** adrian.wells@manchester.ac.uk **Address:** Adrian Wells, PhD, University of Manchester, 2nd Floor, Rawnsley Building, Oxford Road, Manchester Royal Infirmary, Manchester, United Kingdom, M13 9WL **Year:** 2021 **Maximum follow-up:** 12 months **Dates participants recruited:** NR
Notes	**Sample size calculation:** "The trial was designed to detect a SMD between trial arms of 0.4 in HADS total score at 4-month follow-up with 90% power, where 0.4 is in the middle of the range of effect sizes reported for other forms of psychological interventions for depression. The first 52 patients constituted an internal pilot study for the purpose of ascertaining feasibility of recruitment, ascertaining retention, and computing a definitive sample size for the main trial.14,28 The pilot sample SD in HADS scores at baseline was 5.7, and based on this, the retention rate, and other statistical parameters from the pilot, a total recruited sample of 332 patients was required to detect an effect of 0.4, equivalent to a 2.2-point difference in HADS total score" **Funding/sponsorship source:** National Institute for Health Research under its Program Grants for Applied Research Program (grant No. RP-PG-1211-20011) **Conflicts of interest**: Dr Wells is the director of the MCT-Institute and developer of MCT. AW has written books on cognitive behaviour therapy and MCT. The other authors report no conflicts.

Zetta 2011

Study characteristics	
Methods	**Aim of study:** to evaluate the angina plan (AP), a cognitive behavioural nurse-facilitated self-help intervention against standard care (SC) **Study design:** parallel-group, randomised controlled trial **Number of centres:** multisite (2): medical admissions or coronary care unit in daily practice in 2 hospitals incorporating a teaching hospital and a smaller district general hospital **Country:** UK
Participants	**N randomised:** 233 (intervention 117; control 116) **Diagnosis:** (% of participants): presence of CHD and/or angina: 181 (83.0%); intervention 94 (86.0%); control 87 (80.0%) **Severity:** NR

Zetta 2011 *(Continued)*

	Psychopathology: NR **Age (mean ± SD)**, years: total NR; intervention 64.8 ± 10.0; control 65.94 ± 9.9 **Percentage male:** total 68.3%; intervention 72.0%; control 65.0% **Percentage white:** NR **Inclusion criteria:** patients living in the hospital catchment area; able to speak, read and understand English; either sex; aged 18 years and over; definite angina based on clinical history, a positive exercise tolerance test, negative cardio-specific enzymes measurement or past coronary angiography **Exclusion criteria:** patients with current symptoms of psychosis or dementia; life-threatening comorbidities, or a concurrent illness(es) preventing participation based on clinical opinion; patients who are unable to comply with the study procedure; patients currently attending cardiac rehab for a previous cardiac event. Withdrawal criteria: those identified with MI; need to transfer for emergency cardiac surgery/intervention; patients who request to withdraw.
Interventions	• Total duration: 12 weeks • CBT; risk factors; education; angina management; goal setting; relaxation; and TAU • Type of psychological intervention (CCDAN): CBT • Frequency: hospital consultation; audio: daily; phone support at the end of weeks 1, 4, 8 and 12 • Number of sessions: 1 x hospital consultation; 84 x audio; 4 x phone support • Length of sessions: 45-minute in-hospital consultation; AP use - patients were asked to practice relaxation, using the audio for 20 minutes each time. Brief (5-10 minutes) phone calls. • Delivered by: nurses who have undertaken specific and structured training to deliver the intervention • Delivery format: face-to-face/manual/audio/telephone • Delivery to: individual • Targeting: depression; anxiety • Co-intervention: none • Delivery setting: community • Components: cognitive behavioural nurse-facilitated self-help intervention (AP). During an in-hospital consultation, the AP nurse completes assessment and initiates the AP intervention. Patient cardiac misconceptions are identified using a brief questionnaire within the AP pack at the start of the consultation to allow the nurse to proactively target and correct these misconceptions. Individual cardiovascular risk is assessed and advice on risk factor modification given. Participants receive the AP, which includes a patient-held “work-book” and an audiotaped relaxation and information programme. The workbook provides information on angina and its management, cardiovascular risk, relaxation, exercise and goal setting and pacing techniques. Throughout, method of “goal setting and pacing”, based on the principles of CBT, is used by the AP facilitator to introduce lifestyle change and support recovery. **Control/comparison**: TAU/SC: usual care: minimal intervention by nurses during their admission which identified patient’s risk factors, provided advice on their condition and risk factor reduction where possible depending on staff workload and skill mix
Outcomes	Depression (HADS-D); anxiety (HADS-A) **Timings**: baseline and 6 months
Identification	**Country and settings:** UK (Scotland); hospital **Author's name:** Zetta S **Institution:** University of Dundee **Email:** skzetta@aim.com

Zetta 2011 *(Continued)*	**Address:** Dr. Stella Zetta, Thettalon 19, Karditsa, 43100, Greece **Year:** 2011 **Maximum follow-up:** 6 months **Dates participants recruited:** August 2003 to October 2004
Notes	**Comments:** none. SF-36 is not reported in the traditional manner with PCS and MCS scores - accordingly, these data could not be incorporated into the analysis. HADS reported as "Transformed by square root" **Sample size calculation:** "This trial was powered (98%) to be able to detect a difference of 1.5 units (SD = 3) on the HADS anxiety scale with a sample size of 260 participants at the 6-month evaluation" **Funding/sponsorship source:** grant provided by the Chief Scientist Office; studentship provided by the School of Nursing and Midwifery, University of Dundee **Conflicts of interest**: none declared

ACE: angiotensin-converting enzyme; **ACS:** acute coronary syndrome; **AMI:** acute myocardial infarction; **AP:** angina plan; **BA:** behavioural activation; **BAI:** Beck Anxiety Inventory; **BDI/II:** Beck Depression Inventory/Second version; **BDI-FS:** Beck Depression Inventory-Fast Screen; **CABG:** coronary artery bypass graft; **CAD:** coronary artery disease; **CAQ:** Cardiac Anxiety Questionnaire; **CBT:** cognitive behavioural therapy; **CCDAN:** Cochrane Collaboration Depression, Anxiety and Neurosis group; **CD/ROM:** compact disc/read-only memory; **CDS:** Cardiac Depression Scale; **CET:** coping effectiveness training; **CG:** control group; **CHD:** coronary heart disease; **CHF:** chronic heart failure; **CID:** Clinical Interview for Depression; **CM:** clinical management; **CoI:** conflict of interest; **CR:** cardiac rehabilitation; **CV:** cardiovascular**;** **CVD:** cardiovascular disease; **DSM-IV/TR:** Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition/Text Revision; **ECG:** electrocardiogram; **EoL:** end of life; **EQ-5D-5L:** EuroQol-5 dimension-5 level; **EQ-5D VAS:** EuroQol-5 dimension visual analogue scale; **EMDR:** eye movement desensitisation and reprocessing; **EPC:** enhanced psychological care; **EX:** home-based exercise therapy; **GAD-7:** Generalised Anxiety Disorder, 7-item; **GP:** general practitioner; **HADS-A:** Hospital Anxiety and Depression Scale - Anxiety; **HADS-D:** Hospital Anxiety and Depression Scale - Depression; **HAM-D:** Hamilton Depression Rating Scale; **HC:** health coaching/coach; **HF:** heart failure; **HRQoL:** health-related quality of life; **ICC:** interclass correlation coefficient; **ICBT**: integrated motivational interviewing and CBT; **ICD:** implantable cardioverter defibrillator; **ICU:** intensive care unit; **IG:** intervention group; **IHD:** ischaemic heart disease; **IQR:** interquartile range; **KCCQ:** Kansas City Cardiomyopathy Questionnaire; **LVEF:** left ventricular ejection fraction; **MACE:** major adverse cardiovascular events; **MADRS-S:** Montgomery – Åsberg Depression Rating Scale – Self report; **MBSR:** mindfulness-based stress reduction; **MCID:** minimal clinically important difference; **MCS:** mental component summary; **MCT:** metacognitive therapy; **MI:** myocardial infarction; **MINI:** Mini International Neuropsychiatric Interview; **MLHFQ:** Minnesota Living with Heart Failure Questionnaire; **N:** number; **Non-STEMI:** non-ST-elevation myocardial infarction; **NR:** not reported; **NW:** North West; **NYHA:** New York Heart Association; **PANAS:** Positive and Negative Affect Schedule; **PCI:** percutaneous coronary intervention; **PCS:** physical component summary; **PHQ-9:** Patient Health Questionnaire, 9-item; **PST:** problem-solving therapy; **QoL:** quality of life; **RAND-36:** RAND Corporation Short Form Health Survey-36-item; **RCT:** randomised controlled trial; **REACH-HF:** Rehabilitation Enablement in Chronic Heart Failure; **SAQ:** Social Anxiety Questionnaire; **SC:** standard care; **SCD:** sudden cardiac death; **SD:** standard deviation; **SE:** self-efficacy; **SF-12/36:** Short Form Survey-12-item/-36-item; **SCK-K-9:** short version of the Symptom Check List-9-item; **SQ:** Symptom Questionnaire; **SSM:** supportive stress management; **STAI-S:** State-Trait Anxiety Inventory - State; **STAI-T:** State-Trait Anxiety Inventory - Trait; **STEMI:** ST-elevation myocardial infarction; **TAU:** treatment as usual; **UA:** unstable angina; **vs:** versus; **WBT:** wellbeing therapy

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

Study	Reason for exclusion
Agren 2015	Ineligible intervention: focus appeared mainly educational; authors contacted and confirmed not psychological
Angermann 2012	Ineligible intervention: disease management/education; not psychological intervention
Blasco 2012	Ineligible intervention: telemedicine evaluation; no psychological intervention

Study	Reason for exclusion
Camacho 2018	Ineligible patient population: diabetes and/or CHD, CHD < 50%
Cao 2017	Ineligible intervention: tailored educational programme - not psychological intervention
Elkoustaf 2019	Ineligible study design: comparator group also received intervention; no usual care group
Eraballi 2018	Ineligible intervention: yoga; no psychological component to intervention
Grady 2014	Ineligible comparator: comparator group also received part intervention in the educational materials
He 2019	Ineligible intervention: nursing and health education
Herrmann-Lingen 2016	Ineligible comparator: control group were provided with additional session on psychosocial aspects of CAD
Huffman 2019	Ineligible comparator: feasibility testing of telephone-delivered combined positive psychology/motivational interviewing intervention. No comparator group: both received intervention.
Jo 2014	Ineligible intervention: education programme for self-care
Kadda 2015	Ineligible intervention: lifestyle intervention focused on lifestyle change
Karbasdehi 2018	Ineligible follow-up period: pre-/post-tesing of intervention only
Katon 2010	Ineligible comparator: collaborative care for diabetes; both groups received intervention for depression
Keeping 2010	Ineligible intervention: telehealth programme with education focus, not psychological
Meindersma 2017	Ineligible intervention: cardiac rehabilitation and telemonitoring, not a psychological intervention
Morgan 2013	Ineligible study design: usual care group only followed up > 3 months
Moulaert 2013	Ineligible intervention: multifactorial, interaction in society, psychosocial - contacted authors, confirmed not a psychological intervention
Navidian 2017	Ineligible comparator: both groups received intervention through education
Nyklicek 2012	Ineligible study design: comparator group also received intervention
O'Doherty 2015	Ineligible study design: participants were not randomised
Park 2015	Ineligible intervention: self-efficacy-based, however not a psychological intervention
Raghuram 2014	Ineligible intervention: yoga or physiotherapy, not a psychological intervention
Russell 2015	Ineligible study design: 2 intervention groups, no control group
Salmoirago Blotcher 2011	Ineligible study design: not an RCT, baseline data, no follow-up
Salzwedel 2019	Ineligible intervention: not delivered by trained health workers
Schneider 2019	Ineligible patient population: hypertension only

Study	Reason for exclusion
Serber 2016	Ineligible comparator: 2 intervention groups; control group also receiving part intervention through education
Sherwood 2011	Ineligible study design: no control group, both groups received intervention
Smagula 2019	Ineligible comparator: comparator group received part intervention
Spindler 2019	Ineligible intervention: psychological outcomes, however intervention not a psychological intervention
Sullivan 2009	Ineligible study design: patients not randomised, group allocation based on geographical location
Taghadosi 2014	Ineligible follow-up period: pre-post intervention only
Tyrer 2014	Ineligible patient population: < 50% CHD
Uysal 2012	Ineligible intervention: lifestyle focused, not a psychological intervention
Yardımcı 2017	Ineligible intervention: intervention based on social learning environment - not a psychological intervention
Yudi 2017	Ineligible intervention: interactive and personalised feedback and support, not a psychological intervention
Zeighami 2018	Ineligible follow-up period: pre-post assessments only
Zuidersma 2013	Ineligible comparator: intervention group offered choice of 3 treatments, 2 of which were drugs

CAD: coronary artery disease; **CHD:** coronary heart disease **RCT:** randomised controlled trial.

Characteristics of studies awaiting classification *[ordered by study ID]*

Eckert 2010

Methods	**Aim of study:** to evaluate whether screening for depression, academic detailing and tailored psychiatric advice can reduce depression in patients with CHD, relative to usual care **Study design:** cluster-randomised controlled trial **Number of centres:** multisite (18 general practices) **Country:** Australia
Participants	**N randomised:** 282 (intervention: 9 general practices; control, 9 general practices) **Diagnosis:** CHD **Age (mean ± SD):** 70 ± 10 years **Percentage male:** 65% **Inclusion criteria:** CHD
Interventions	• Tailored psychiatric advice • Delivery to: CHD patients • Targeting: depression • Co-intervention: none

Eckert 2010 *(Continued)*

	• Delivery setting: general practices • Components: academic detailing and tailored psychiatric advice **Control/comparison:** TAU
Outcomes	Depression (CES-D) **Timings:** baseline, 2 and 6 months
Notes	Limited statistics on depression; lack of detail on intervention delivery **Contact with authors:** study author (YG) was contacted re. data on depression and intervention delivery; no response

Gu 2017a

Methods	**Aim of study:** to determine the effect of a mindfulness-based stress reduction programme, with routine medical care on psychosocial functioning and markers of cardiovascular risk **Study design:** parallel-group, randomised controlled trial **Number of centres:** NR **Country:** China
Participants	146 patients with IHD and exercise-induced myocardial ischaemia **N randomised:** 155 (intervention 71; control 84) **Diagnosis:** HD and exercise-induced myocardial ischaemia **Age (mean ± SD)**, years: total NR; intervention 69 ± 13; control 73 ± 10 **Percentage male:** 59% **Inclusion criteria:** IHD patients
Interventions	• Total duration: 12 weeks • Type of psychological intervention (CCDAN): third wave, mindfulness meditation • Frequency: twice-weekly • Number of sessions: 24 • Length of sessions: 2.5 hours • Delivery to: IHD patients • Targeting: depression • Co-intervention: none • Delivery setting: in hospital OR in home • Components: mindfulness-based stress reduction programme **Control/comparison:** TAU
Outcomes	Depression (BDI-II) **Timings:** NR
Notes	Insufficient reporting of data; lack of clarity re: delivery agent/intervention content; time frame not specified

Gu 2017a *(Continued)*

	Contact with authors: study author (YG) was contacted re. data collection timepoints; no response

Oranta 2010

Methods	**Aim of study:** to evaluate interpersonal counselling implemented by a registered nurse on the outcomes for depressive symptoms and distress in MI patients **Study design:** parallel-group, randomised controlled trial **Number of centres:** 1 hospital site **Country:** Finland
Participants	**N randomised:** 103 (intervention 51; control 52) **Diagnosis:** MI **Age (mean ± SD):** total mean = 59.6 years, intervention group 58.1 ± 10.4 years (range 27 to 74); control group (n = 52) 61.2 ± 9.7 years (range 33 to 74) **Percentage male:** total 70.9% **Inclusion criteria:** troponin T level > 0.03 µg/l, and at least 1 of 3 criteria for an acute MI: typical clinical presentation, presence of new ischaemic ECG changes or new diagnostic findings in imaging, e.g. echocardiogram **Exclusion criteria:** NR
Interventions	• Total duration: NR • Cognitive behavioural strategies; education; psychosocial support; and TAU • Type of psychological intervention (CCDAN): CBT • Frequency: NR • Number of sessions: between 1 and 6 • Length of sessions: NR • Delivered by: a psychiatric nurse trained for 1 day in the use of IPC • Delivery format: face-to-face counselling and by telephone • Delivery to: MI patients • Targeting: depression • Co-intervention: none • Delivery setting: first session in hospital, other session in hospital or home, last session by telephone at home • Components: focusing on the patient's current psychosocial functioning. Starting phase (linking the depressive symptoms to the patient's interpersonal situation), encouragement phase (working on the problem area; coping strategies), ending phase (encouraging and consolidating the gains; developing ways of identifying and countering depressive symptoms in the future) **Control/comparison:** TAU
Outcomes	Depression (BDI; SCL-25) **Timings:** 6 and 18 months
Notes	Missing baseline data; contacted author but no reply

Sobczak 2016

Methods	**Aim of study:** to identify the influence of implementation of cognitive behavioural intervention in patients after cardiovascular implantable electronic device implantation **Study design:** parallel-group, randomised controlled trial **Number of centres:** 1 clinical cardiology centre **Country:** Poland
Participants	**N randomised:** 128 (intervention 71; control 84) **Diagnosis:** ICD (% of participants) ICD128 (100%); intervention 67 (100%); control 61 (100%) **Age (mean ± SD)years**: intervention 64.5 ± 8.9; control 67.8 ± 11.4 **Percentage male:** total 63.3%; intervention 69.1%; control 80.9% **Inclusion criteria:** qualified for implantation of CIED during hospitalisation, age > 18, written consent to take part in the trial **Exclusion criteria:** acute coronary syndrome, class IV heart failure according to NYHA classification guidelines, cardiogenic shock, cancer, addiction to alcohol, taking antidepressants or anxiolytics, no written consent from the patient to take part in the trial
Interventions	• Total duration: 12 weeks • Cognitive behavioural strategies; education • Type of psychological intervention (CCDAN): CBT • Frequency: before and after implantation; 3 to 7 days post-implantation, 1-month post implantation • Number of sessions: 4 • Length of sessions: 35 to 40 minutes • Delivered by: 2 psychologists who have earlier completed courses in CBT • Delivery format: face-to-face • Delivery to: ICD patient • Targeting: depression, anxiety; HRQoL • Co-intervention: none • Delivery setting: in hospital • Components: education, self-control, cognitive restructuring, and skills development and training **Control/comparison:** TAU
Outcomes	Depression; anxiety; HRQoL (EQ-5D) **Timings:** baseline and 6 months
Notes	Lacking baseline and follow-up depression and anxiety data; lack of detail on intervention components/content; contacted author but no reply

Spruill 2021

Methods	**Aim of study:** to assess the efficacy of a telephone-based stress management programme on perceived stress, depressive symptoms, anxiety and quality of life (QOL) among women with MI **Study design:** parallel-group, randomised controlled trial

Spruill 2021 *(Continued)*

	Number of centres: multisite, 12 hospitals **Country:** US and Canada
Participants	**N randomised:** 130 (intervention 71; control 84) **Diagnosis:** MI **Age (mean ± SD)**, years: 59.8 ± 12.8 years **Percentage male:** 0% **Inclusion criteria:** women with elevated stress levels (Perceived Stress Scale (PSS-4) ≥ 6) at least 2 months after MI **Exclusion criteria:** NR
Interventions	**Intervention:** • Total duration: 8 weeks • Stress management: mindfulness-based cognitive therapy adapted for telephone: MBCT-T • Type of psychological intervention (CCDAN): third wave • Frequency: weekly • Number of sessions: 8 • Length of sessions: NR • Delivered by: NR • Delivery format: group delivery • Delivery to: MI patients • Targeting: depression; anxiety; HRQoL; stress • Co-intervention: none • Delivery setting: telephone • Components: mindfulness-based cognitive therapy **Control/comparison:** enhanced usual care (EUC; heart disease education)
Outcomes	Depression (PHQ-9); anxiety (HADS); QOL (SAQ) **Timings:** baseline and 6 months
Notes	Abstract; limited information on intervention delivery; limited statistical information on outcomes at 6 months; contacted author who advised that the full paper had not yet been published

BDI/II: Beck Depression Inventory I/II; **CBT:** cognitive behavioural therapy;**CCDAN:** Cochrane Collaboration Depression, Anxiety and Neurosis group; **CES-D:** Center for Epidemiologic Studies Depression Scale; **CHD:** coronary heart disease; **CIED:** cardiac implantable electronic devices; **EQ-5D:** EuroQoL 5-dimension; **EUC:** enhanced usual care; **HRQoL:** health-related quality of life; **ICD:** implantable cardioverter defibrillator; **IHD:** ischaemic heart disease; **IPC:** ischaemic preconditioning; **MBCT-T:** Mindfulness-Based Cognitive Therapy adapted for Telephone; **MI:** myocardial infarction; **N:** number; **NR:** not reported; **NYHA:** New York Heart Association; **PHQ-9:** Patient Health Questionnaire 9-item; **QOL:** quality of life; **SAQ:** Seattle Angina Questionnaire; **SCL-25:** Symptom Check List-25 items; **SD:** standard deviation; **TAU:** treatment as usual

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

Chung 2014

Study name	Feasibility of the family cognitive educational intervention to improve depressive symptoms and quality of life in patients with heart failure and their family caregivers

Chung 2014 *(Continued)*

Methods	**Aim of study:** to examine the feasibility and efficacy of the Family Cognitive Education Therapy intervention that combines cognitive behavioural therapy (CBT) with an educational self-care intervention in patients with HF and their caregivers **Study design:** parallel-group, randomised controlled trial **Country:** US
Participants	**N randomised:** 21 (intervention 12; control 12) **Diagnosis:** (% of participants): HF 24 (dyads with carer) (100%); intervention 12; control 12 **Percentage male/white:** NR **Inclusion criteria:** dyad consisting of a patient diagnosed with CHF
Interventions	Family cognitive education therapy intervention: combines cognitive behavioural therapy (CBT) and educational self-care intervention for HF patients and their carers **Control/comparison:** usual care delivered to patient-partner dyads
Outcomes	Depression (PHQ-9); HRQoL (SF-36) **Timings:** 2 and 6 months
Starting date	Unknown
Contact information	Chung, M.L. Office 529, College of Nursing, College of Nursing Building, 751 Rose Street, University of Kentucky, Lexington, KY Email: misook.chung@uky.edu
Notes	Contact with author confirmed article in preparation but not available at present **Conflicts of interest:** none reported

Holdgaard 2021

Study name	OPTIMA: psychological distress and the effect of intensive group-based cognitive therapy in patients with ischemic heart disease
Methods	**Aim of study:** to develop an efficient and cost-effective model for the use of intensive group-based cognitive therapy to address psychological distress in patients with newly diagnosed CAD and/or surgically treated valvular heart disease (VHD) and concomitant psychological distress. **Study design:** parallel-group, randomised controlled trial **Number of centres:** multisite (3 hospital cardiology departments) **Country:** Denmark
Participants	**N randomised:** 148 (intervention 74; control 74) **Diagnosis:** CHD (CAD and VHD) **Inclusion criteria:** referred to CR and accepting CR; newly diagnosed CAD and/or surgically treated VHD; HADS score > 8 for HADS-A and/or HADS-D; age < 65 years; able to speak and understand Danish

Holdgaard 2021 *(Continued)*

	Exclusion criteria: ejection fraction < 35%; other serious comorbidity expected to have a serious impact on life expectancy; known abuse of alcohol or euphoric drugs; known more serious psychopathology such as schizophrenia, bipolar disorder, severe personality disorder and treatment with psychoactive drugs
Interventions	Intervention: group based cognitive therapy + CR • Total duration: NR • Cognitive behavioural strategies and education • Type of psychological intervention (CCDAN): CBT • Number of sessions: 5 • Length of sessions: 1.5 to 2 hours • Delivered by: led by an experienced nurse under the supervision of a psychologist who is a specialist in CBT • Delivery format: nurse-led face-to-face group 3 to 4 patients • Delivery to: CAD and VHD patients • Targeting: depression; anxiety; HRQoL • Co-intervention: CR • Components: introduction to CBT and mapping of own values; anxiety and anxiety reduction techniques; functional analysis (awareness of consequences of own behaviour; concerns and strategies for dealing with concerns; balance between requirements and forces as well as conclusion **Control/comparison:** usual care + CR
Outcomes	Depression and anxiety (HADS) **Timings:** 3, 6 and 12 months
Starting date	February 2020
Contact information	Annette Holdgaard, Department of Cardiology, Bispebjerg-Frederiksberg Hospital, Bispebjerg Bakke 23, Bygning 67, 2400 Copenhagen, NV Denmark Email: annette.holdgaard@regionh.dk
Notes	Delayed due to COVID-19

ISRCTN33129243

Study name	Cognitive behavioural therapy to reduce anxiety and depression in atrial fibrillation (CBT-AF)
Methods	**Aim of study:** to investigate whether or not the new cognitive behavioural therapy (CBT) intervention helps to reduce anxiety and/or depression among patients with atrial fibrillation compared to people who receive usual care **Study design:** parallel-group, randomised controlled trial **Number of centres:** 64 GP practices and 2 specialist AF clinics **Country:** UK
Participants	**N randomised:** 128 **Diagnosis:** AF 128 (100%) **Inclusion criteria:** aged 18 years and over; diagnosed with atrial fibrillation (AF) within the last 12 months; defined as 'case' (score of ≥ 8 on the GAD-7 and ≥ 10 on the PHQ-9)

ISRCTN33129243 *(Continued)*

	Exclusion criteria: diagnosed with AF for longer than 12 months; terminal illness; cognitive impairment which prevents them from being able to give informed consent; unable to speak and/or read English
Interventions	• Total duration: 16 weeks • Cognitive behavioural strategies; education • Type of psychological intervention (CCDAN): CBT • Frequency: weekly sessions • Number of sessions: 16 • Length of sessions: ≥ 60 minutes • Delivered by: 1 of 2 trained therapists • Delivery format: individual face-to-face • Delivery to: AF patient • Targeting: depression and anxiety • Co-intervention: pharmacotherapy • Delivery setting: GP practice • Components: discussion of patient's current reported difficulties, their concerns and misconceptions surrounding the disease and its treatment **Control/comparison:** usual care plus pharmacotherapy
Outcomes	Depression (PHQ-9); anxiety (GAD -7); HRQoL (EQ-5D; AFeQT) **Timings:** 6 and 12 months post-randomisation
Starting date	April 2016
Contact information	Dr Deirdre Lane, Sandwell and West Birmingham Hospitals NHS Trust (UK) Email: deirdrelane@nhs.net
Notes	Intention to publish date: 31 December 2023

Moser 2012a

Study name	Randomized controlled trial of a biobehavioral intervention for depression in-patients with heart failure
Methods	**Aim of study:** to examine the impact on HRQOL and event-free survival of a biobehavioural intervention for depression management and prevention **Study design:** parallel-group, randomised controlled trial **Country:** US
Participants	**N randomised:** 280 **Diagnosis:** HF (n = 280) **Severity:** class III/IV:48% **Age (mean ± SD)** 61 ± 12 years **Percentage male:** total 56% **Inclusion criteria:** HF

Moser 2012a *(Continued)*

Interventions	6-week intervention consisting of CBT along with relaxation therapy • Total duration: 6 weeks • Cognitive behavioural strategies; education • Type of psychological intervention (CCDAN): CBT • Frequency: weekly • Number of sessions: 6 • Length of sessions: ≥ 60 minutes • Delivered by: psychiatric nurse practitioner with cardiac expertise • Delivery format: nurse-led face-to-face • Delivery to: HF patient • Targeting: depression; HRQoL • Co-intervention: none • Delivery setting: in hospital OR in home • Components: CBT targeted at depressive symptoms or emotional distress along with relaxation therapy **Control/comparison:** TAU
Outcomes	Depression (PHQ-9); HRQoL (MLHFQ) **Timings:** baseline, 3 and 12 months
Starting date	July 2004
Contact information	Moser DK, University of Kentucky. Suite 403, 2201 Regency Road, Lexington KY 40503 Email: debra.moser@uky.edu
Notes	Contact with the author confirmed publication outlining results is in process but incomplete; will advise when available

NCT04986969

Study name	Online cognitive behavioral therapy for depressive symptoms in rural patients with cardiac disease (COMBAT-DS)
Methods	**Aim of study:** to compare vcCBT, iCBT and usual care in rural CHD patients on the primary outcome of depressive symptoms **Study design:** parallel-group, randomised controlled trial **Number of centres:** online **Country:** US
Participants	**N randomised:** 500 **Diagnosis:** CHD **Age (mean ± SD)**, years: total NR; intervention 69 ± 13; control 73 ± 10 **Setting:** rural outpatients **Inclusion criteria:** at least moderate depressive symptoms (PHQ-9 ≥ 10); rural dwelling; has had physician-documented acute coronary syndrome (ACS) event

NCT04986969 *(Continued)*	**Exclusion criteria:** cognitive impairment; major psychiatric comorbidities, which might require additional treatment; presence of non-CHD conditions likely to be fatal within next year
Interventions	• Total duration: 12 weeks • Cognitive behavioural strategies; education • Type of psychological intervention (CCDAN): CBT • Delivered by: trained therapist • Delivery format: video-conferenced face-to-face versus self-administered internet-based • Delivery to: rural CHD patients • Targeting: depression • Co-intervention: none • Delivery setting: in home, rural setting • Components: 2 intervention arms. Intervention 1: real-time, face-to-face, video-conferenced CBT (vcCBT) with a trained CBT therapist. Intervention 2: self-administered internet-based CBT (iCBT) via a well-tested online CBT programme, MoodGymEach of the 3 modules contained cognitive, supportive and behavioural components **Control/comparison:** TAU
Outcomes	Depression (PHQ-9) **Timings:** baseline, 3, 6, and 12 months
Starting date	15 April 2021
Contact information	Debra K Moser Email: dmoser@uky.edu
Notes	—

AF: atrial fibrillation; **AFeQT:** Atrial Fibrillation Effects on QualiTy–of-life; **CAD:** coronary artery disease; **CBT:** cognitive behavioural therapy; **CCDAN:** Cochrane Collaboration Depression, Anxiety and Neurosis group; **CHD:** coronary heart disease;**COVID:** coronavirus disease; **CR:** cardiac rehabilitation; **EQ-5D:** EuroQol-5 dimension; **GAD-7:** generalised anxiety disorder-7 item; **GP:** general practitioner; **HADS:** Hospital Anxiety and Depression Scale; **HF:** heart failure; **HRQoL:** health-related quality of life; **iCBT:** Internet-based cognitive behavioural therapy; **IHD:** ischaemic heart disease; **MACE:** major adverse cardiovascular events; **MI:** myocardial infarction; **MLHFQ:** Minnesota Living with HF Questionnaire;**N:** number; **NR:** not reported; **PHQ-9:** Patient Health Questionnaire; **RCT:** randomised controlled trial; **SF36:** Short Form Survey-36-item; **TAU:** treatment as usual; **vc:** video-conferenced; **VHD:** valvular heart disease.

RISK OF BIAS

Legend: ✓ Low risk of bias ✗ High risk of bias ~ Some concerns

Risk of bias for analysis 1.1 Depression

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Agren 2012	✓	✓	~	~	✓	~

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Bekelman 2018	✓	✓	✓	~	✓	~
Chair 2013	✓	~	✓	~	✓	~
Chang 2020	✓	✓	✓	~	✓	~
Crossmann 2010	✓	✓	✓	~	✓	~
Crossmann 2010	✓	✓	✓	~	✓	~
Davidson 2010	✓	✓	✓	~	✓	~
Freedland 2009	✓	✓	✓	~	✓	~
Gary 2010	~	✓	✓	~	✓	~
Habibovic 2017	✓	✓	✓	~	✓	~
Humphries 2021	✓	✓	✓	~	✓	~
Nahlén Bose 2016	✓	✓	✓	~	✓	~
Nijjar 2019	✓	✓	✓	~	✓	~
O'Neil 2014a	✓	✓	✓	~	✓	~
O'Neil 2014b	✓	~	✓	~	✓	~
Rafanelli 2020	✓	✓	✓	~	✓	~
Richards 2018	✓	~	✓	~	✓	~
Tagney 2013	✓	~	✗	~	✓	✗
Turner 2014	✓	✓	✓	~	✓	~
Wells 2021	✓	✓	✓	~	✓	~

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Zetta 2011	✓	✓	✓	~	✓	~

Risk of bias for analysis 1.2 HADS-D

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Chair 2013	✓	~	✓	~	✓	~
Crossmann 2010	✓	✓	✓	~	✓	~
Crossmann 2010	✓	✓	✓	~	✓	~
Humphries 2021	✓	✓	✓	~	✓	~
Nahlėn Bose 2016	✓	✓	✓	~	✓	~
O'Neil 2014b	✓	~	✓	~	✓	~
Wells 2021	✓	✓	✓	~	✓	~
Zetta 2011	✓	✓	✓	~	✓	~

Risk of bias for analysis 1.3 BDI-II

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Agren 2012	✓	✓	~	~	✓	~
Richards 2018	✓	~	✓	~	✓	~

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Turner 2014	✓	✓	✓	~	✓	~

Risk of bias for analysis 1.4 PHQ-9

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Bekelman 2018	✓	✓	✓	~	✓	~
Habibovic 2017	✓	✓	✓	~	✓	~
Nijjar 2019	✓	✓	✓	~	✓	~
O'Neil 2014a	✓	✓	✓	~	✓	~

Risk of bias for analysis 1.5 Anxiety

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Bekelman 2018	✓	✓	✓	~	✓	~
Chair 2013	✓	~	✓	~	✓	~
Chang 2020	✓	✓	✓	~	✓	~
Crossmann 2010	✓	✓	✓	~	✓	~
Crossmann 2010	✓	✓	✓	~	✓	~
Freedland 2009	✓	✓	✓	~	✓	~

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Habibovic 2017	✓	✓	✓	~	✓	~
Humphries 2021	✓	✓	✓	~	✓	~
Moradi 2016	~	✓	✓	~	✓	~
Nahlén Bose 2016	✓	✓	✓	~	✓	~
Nijjar 2019	✓	✓	✓	~	✓	~
O'Neil 2014b	✓	~	✓	~	✓	~
Rafanelli 2020	✓	✓	✓	~	✓	~
Richards 2018	✓	~	✓	~	✓	~
Tagney 2013	✓	~	✗	~	✓	✗
Tagney 2013	✓	~	✗	~	✓	✗
Turner 2014	✓	✓	✓	~	✓	~
Wells 2021	✓	✓	✓	~	✓	~
Zetta 2011	✓	✓	✓	~	✓	~

Risk of bias for analysis 1.6 HADS-A

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Chair 2013	✓	~	✓	~	✓	~
Crossmann 2010	✓	✓	✓	~	✓	~

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Crossmann 2010	✓	✓	✓	~	✓	~
Humphries 2021	✓	✓	✓	~	✓	~
Nahlén Bose 2016	✓	✓	✓	~	✓	~
O'Neil 2014b	✓	~	✓	~	✓	~
Turner 2014	✓	✓	✓	~	✓	~
Wells 2021	✓	✓	✓	~	✓	~
Zetta 2011	✓	✓	✓	~	✓	~

Risk of bias for analysis 1.7 GAD-7

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Bekelman 2018	✓	✓	✓	~	✓	~
Habibovic 2017	✓	✓	✓	~	✓	~
Nijjar 2019	✓	✓	✓	~	✓	~

Risk of bias for analysis 1.8 BAI

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Freedland 2009	✓	✓	✓	~	✓	~

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Moradi 2016	~	✓	✓	~	✓	~
Richards 2018	✓	~	✓	~	✓	~

Risk of bias for analysis 1.9 HRQoL (PCS)

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Agren 2012	✓	✓	~	~	✓	~
Bekelman 2018	✓	✓	✓	~	✓	~
Chair 2013	✓	~	✓	~	✓	~
Chang 2020	✓	✓	✓	~	✓	~
Crossmann 2010	✓	✓	✓	~	✓	~
Crossmann 2010	✓	✓	✓	~	✓	~
Freedland 2009	✓	✓	✓	~	✓	~
Gary 2010	~	✓	✓	~	✓	~
Habibovic 2017	✓	✓	✓	~	✓	~
Nahlén Bose 2016	✓	✓	✓	~	✓	~
O'Neil 2014a	✓	✓	✓	~	✓	~
Richards 2018	✓	~	~	✓	✓	~
Wells 2021	✓	✓	✓	~	✓	~

Risk of bias for analysis 1.10 SF12/36 (PCS)

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Agren 2012	✓	✓	~	~	✓	~
Chair 2013	✓	~	✓	~	✓	~
Chang 2020	✓	✓	✓	~	✓	~
Crossmann 2010	✓	✓	✓	~	✓	~
Crossmann 2010	✓	✓	✓	~	✓	~
Freedland 2009	✓	✓	✓	~	✓	~
Habibovic 2017	✓	✓	✓	~	✓	~
O'Neil 2014a	✓	✓	✓	~	✓	~

Risk of bias for analysis 1.11 HRQoL (MCS)

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Agren 2012	✓	✓	~	~	✓	~
Bekelman 2018	✓	✓	✓	~	✓	~
Chair 2013	✓	~	✓	~	✓	~
Chang 2020	✓	✓	✓	~	✓	~
Crossmann 2010	✓	✓	✓	~	✓	~
Crossmann 2010	✓	✓	✓	~	✓	~

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Freedland 2009	✓	✓	✓	~	✓	~
Gary 2010	~	✓	✓	~	✓	~
Habibovic 2017	✓	✓	✓	~	✓	~
Nahlén Bose 2016	✓	✓	✓	~	✓	~
O'Neil 2014a	✓	✓	✓	~	✓	~
Richards 2018	✓	~	✓	~	✓	~
Wells 2021	✓	✓	✓	~	✓	~

Risk of bias for analysis 1.12 SF12/36 (MCS)

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Agren 2012	✓	✓	~	~	✓	~
Chair 2013	✓	~	✓	~	✓	~
Chang 2020	✓	✓	✓	~	✓	~
Crossmann 2010	✓	✓	✓	~	✓	~
Crossmann 2010	✓	✓	✓	~	✓	~
Freedland 2009	✓	✓	✓	~	✓	~
Habibovic 2017	✓	✓	✓	~	✓	~
O'Neil 2014a	✓	✓	✓	~	✓	~

Risk of bias for analysis 1.13 Self-efficacy

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Chair 2013	✓	~	✓	~	✓	~
Turner 2014	✓	✓	✓	~	✓	~
Turner 2014	✓	✓	✓	~	✓	~

Risk of bias for analysis 1.14 Mortality (all-cause)

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Bekelman 2018	✓	✓	✓	✓	✓	✓
Rafanelli 2020	✓	✓	✓	✓	✓	✓
Wells 2021	✓	✓	✓	✓	✓	✓

Risk of bias for analysis 1.15 MACE

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Davidson 2010	✓	✓	✓	✓	✓	✓
Humphries 2021	✓	✓	✓	~	✓	✓
Rafanelli 2020	✓	✓	✓	✓	✓	✓
Richards 2018	✓	~	✓	~	✓	~

DATA AND ANALYSES

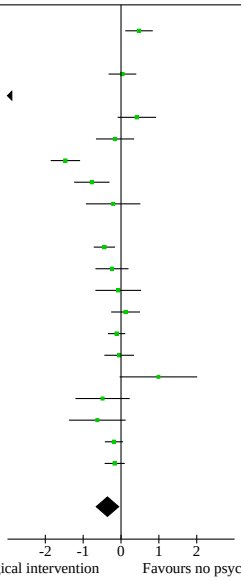
Comparison 1. Psychological intervention vs no psychological intervention

Outcome or sub-group title	No. of studies	No. of partici-pants	Statistical method	Effect size
1.1 Depression	20	2531	Std. Mean Difference (IV, Random, 95% CI)	-0.36 [-0.65, -0.06]
1.2 HADS-D	7	1305	Mean Difference (IV, Random, 95% CI)	-0.39 [-0.86, 0.07]
1.3 BDI-II	3	166	Mean Difference (IV, Random, 95% CI)	1.56 [-3.60, 6.72]
1.4 PHQ-9	4	610	Mean Difference (IV, Random, 95% CI)	-1.03 [-2.95, 0.89]
1.5 Anxiety	17	2235	Std. Mean Difference (IV, Random, 95% CI)	-0.57 [-0.96, -0.18]
1.6 HADS-A	8	1334	Mean Difference (IV, Random, 95% CI)	-0.46 [-0.98, 0.07]
1.7 GAD-7	3	504	Mean Difference (IV, Random, 95% CI)	1.27 [-0.63, 3.17]
1.8 BAI	3	153	Mean Difference (IV, Random, 95% CI)	-11.56 [-38.12, 15.00]
1.9 HRQoL (PCS)	12	1454	Std. Mean Difference (IV, Random, 95% CI)	0.48 [-0.02, 0.98]
1.10 SF12/36 (PCS)	7	838	Mean Difference (IV, Random, 95% CI)	4.57 [-3.68, 12.81]
1.11 HRQoL (MCS)	12	1454	Std. Mean Difference (IV, Random, 95% CI)	0.63 [0.01, 1.26]
1.12 SF12/36 (MCS)	7	838	Mean Difference (IV, Random, 95% CI)	4.21 [-3.35, 11.77]
1.13 Self-efficacy	2	174	Std. Mean Difference (IV, Random, 95% CI)	0.14 [-0.31, 0.59]
1.14 Mortality (all-cause)	3	615	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.39, 1.69]
1.15 MACE	4	450	Risk Ratio (M-H, Fixed, 95% CI)	1.22 [0.77, 1.92]

Analysis 1.1. Comparison 1: Psychological intervention vs no psychological intervention, Outcome 1: Depression

Study or Subgroup	Psychological intervention Mean	SD	Total	No psychological intervention Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Agren 2012	12.4	6.1	57	9.3	6.8	63	5.7%	0.48 [0.11 , 0.84]
Bekelman 2018	7.61	0	121	9.07	0	119		Not estimable
Chair 2013	2.5	2.7	52	2.4	2.6	64	5.7%	0.04 [-0.33 , 0.40]
Chang 2020	24.5	2.8	40	47	6.5	40	4.2%	-4.45 [-5.28 , -3.62]
Crossmann 2010	5.96	3.7	34	4.52	3.02	28	5.3%	0.42 [-0.09 , 0.92]
Crossmann 2010	5.71	3.43	33	6.42	5.4	28	5.3%	-0.16 [-0.66 , 0.35]
Davidson 2010	13.2	3.1	58	17.7	3	74	5.6%	-1.47 [-1.86 , -1.08]
Freedland 2009	5.5	6.3	40	10.3	6	36	5.4%	-0.77 [-1.24 , -0.30]
Gary 2010	7.1	4.9	16	8.2	5.4	14	4.6%	-0.21 [-0.93 , 0.51]
Habibovic 2017	4.7	0	105	4.35	0	112		Not estimable
Humphries 2021	6.2	3.8	89	7.8	3.5	112	5.9%	-0.44 [-0.72 , -0.16]
Nahlén Bose 2016	4.29	2.96	37	5.15	4	45	5.5%	-0.24 [-0.68 , 0.20]
Nijjar 2019	4.45	3.76	31	4.74	4.23	16	5.0%	-0.07 [-0.68 , 0.53]
O'Neil 2014a	89.1	28.6	53	85.8	25.8	53	5.7%	0.12 [-0.26 , 0.50]
O'Neil 2014b	3.5	3.4	141	3.9	3.5	156	6.0%	-0.12 [-0.34 , 0.11]
Rafanelli 2020	29.7	6.51	50	30.03	7.05	50	5.6%	-0.05 [-0.44 , 0.34]
Richards 2018	12.6	6.6	9	7	3.5	8	3.6%	0.99 [-0.04 , 2.01]
Tagney 2013	0	2	13	1	2	19	4.6%	-0.49 [-1.20 , 0.23]
Turner 2014	11.95	7.87	14	18	10.61	15	4.5%	-0.63 [-1.37 , 0.12]
Wells 2021	6.78	4.33	132	7.57	4.1	136	6.0%	-0.19 [-0.43 , 0.05]
Zetta 2011	2	0.93	109	2.15	0.86	109	5.9%	-0.17 [-0.43 , 0.10]
Total (95% CI)			**1234**			**1297**	**100.0%**	**-0.36 [-0.65 , -0.06]**

Heterogeneity: Tau² = 0.37; Chi² = 180.81, df = 18 (P < 0.00001); I² = 90%
Test for overall effect: Z = 2.38 (P = 0.02)
Test for subgroup differences: Not applicable

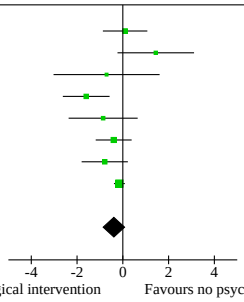


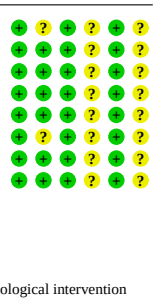
Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.2. Comparison 1: Psychological intervention vs no psychological intervention, Outcome 2: HADS-D

Study or Subgroup	Psychological intervention Mean	SD	Total	No psychological intervention Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Chair 2013	2.5	2.7	52	2.4	2.6	64	13.2%	0.10 [-0.87 , 1.07]
Crossmann 2010	5.96	3.7	34	4.52	3.02	28	6.2%	1.44 [-0.23 , 3.11]
Crossmann 2010	5.71	3.43	33	6.42	5.4	28	3.6%	-0.71 [-3.03 , 1.61]
Humphries 2021	6.2	3.8	89	7.8	3.5	112	12.4%	-1.60 [-2.62 , -0.58]
Nahlén Bose 2016	4.29	2.96	37	5.15	4	45	7.3%	-0.86 [-2.37 , 0.65]
O'Neil 2014b	3.5	3.4	141	3.9	3.5	156	16.4%	-0.40 [-1.19 , 0.39]
Wells 2021	6.78	4.33	132	7.57	4.1	136	12.6%	-0.79 [-1.80 , 0.22]
Zetta 2011	2	0.93	109	2.15	0.86	109	28.4%	-0.15 [-0.39 , 0.09]
Total (95% CI)			**627**			**678**	**100.0%**	**-0.39 [-0.86 , 0.07]**

Heterogeneity: Tau² = 0.18; Chi² = 13.81, df = 7 (P = 0.05); I² = 49%
Test for overall effect: Z = 1.65 (P = 0.10)
Test for subgroup differences: Not applicable



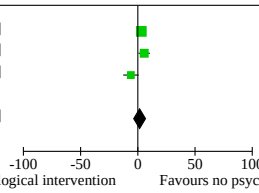


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.3. Comparison 1: Psychological intervention vs no psychological intervention, Outcome 3: BDI-II

Study or Subgroup	Psychological intervention Mean	SD	Total	No psychological intervention Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Agren 2012	12.4	6.1	57	9.3	6.8	63	42.1%	3.10 [0.79 , 5.41]
Richards 2018	12.6	6.6	9	7	3.5	8	32.3%	5.60 [0.65 , 10.55]
Turner 2014	11.95	7.87	14	18	10.61	15	25.6%	-6.05 [-12.82 , 0.72]
Total (95% CI)			**80**			**86**	**100.0%**	**1.56 [-3.60 , 6.72]**

Heterogeneity: Tau² = 15.07; Chi² = 7.85, df = 2 (P = 0.02); I² = 75%
Test for overall effect: Z = 0.59 (P = 0.55)
Test for subgroup differences: Not applicable

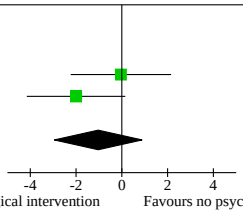


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.4. Comparison 1: Psychological intervention vs no psychological intervention, Outcome 4: PHQ-9

Study or Subgroup	Psychological intervention Mean	SD	Total	No psychological intervention Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Bekelman 2018	7.61	0	121	9.07	0	119		Not estimable
Habibovic 2017	4.45	0	31	4.35	0	112		Not estimable
Nijjar 2019	4.7	3.76	105	4.74	4.23	16	49.4%	-0.04 [-2.23 , 2.15]
O'Neil 2014a	6.1	5.5	53	8.1	5.8	53	50.6%	-2.00 [-4.15 , 0.15]
Total (95% CI)			**310**			**300**	**100.0%**	**-1.03 [-2.95 , 0.89]**

Heterogeneity: Tau² = 0.69; Chi² = 1.56, df = 1 (P = 0.21); I² = 36%
Test for overall effect: Z = 1.05 (P = 0.29)
Test for subgroup differences: Not applicable

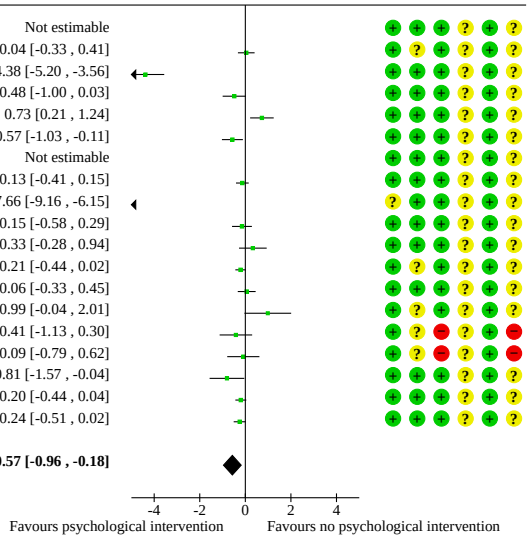


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.5. Comparison 1: Psychological intervention vs no psychological intervention, Outcome 5: Anxiety

Study or Subgroup	Psychological intervention Mean	SD	Total	No psychological intervention Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Bekelman 2018	4.22	0	121	5.11	0	119		Not estimable
Chair 2013	2.5	2.5	52	2.4	2.4	64	6.5%	0.04 [-0.33 , 0.41]
Chang 2020	18.9	5.8	40	47.1	6.9	40	5.2%	-4.38 [-5.20 , -3.56]
Crossmann 2010	4.71	3.41	33	6.74	4.86	28	6.1%	-0.48 [-1.00 , 0.03]
Crossmann 2010	6.19	3.73	34	3.33	4.06	28	6.1%	0.73 [0.21 , 1.24]
Freedland 2009	9.1	8.8	40	14.2	9	36	6.3%	-0.57 [-1.03 , -0.11]
Habibovic 2017	4.5	0	105	3	0	112		Not estimable
Humphries 2021	6.8	3.7	89	7.3	3.9	112	6.6%	-0.13 [-0.41 , 0.15]
Moradi 2016	6.73	2.09	30	42.36	6.15	30	3.4%	-7.66 [-9.16 , -6.15]
Nahlén Bose 2016	4.17	3.72	37	4.77	4.23	45	6.3%	-0.15 [-0.58 , 0.29]
Nijjar 2019	3.8	4.34	31	2.53	2.31	16	5.9%	0.33 [-0.28 , 0.94]
O'Neil 2014b	4.2	3.7	141	5	3.9	156	6.7%	-0.21 [-0.44 , 0.02]
Rafanelli 2020	6.62	4.51	50	6.33	5.09	50	6.4%	0.06 [-0.33 , 0.45]
Richards 2018	12.7	7.1	9	6.4	4.6	8	4.6%	0.99 [-0.04 , 2.01]
Tagney 2013	32	11.1	13	36	8.1	19	5.6%	-0.41 [-1.13 , 0.30]
Tagney 2013	30	11.8	13	31	10.4	19	5.6%	-0.09 [-0.79 , 0.62]
Turner 2014	6.93	3.38	14	10.04	4.06	15	5.4%	-0.81 [-1.57 , -0.04]
Wells 2021	8.3	4.63	132	9.17	4.14	136	6.7%	-0.20 [-0.44 , 0.04]
Zetta 2011	2.16	1.08	109	2.41	0.95	109	6.6%	-0.24 [-0.51 , 0.02]
Total (95% CI)			**1093**			**1142**	**100.0%**	**-0.57 [-0.96 , -0.18]**

Heterogeneity: Tau² = 0.57; Chi² = 223.77, df = 16 (P < 0.00001); I² = 93%
Test for overall effect: Z = 2.88 (P = 0.004)
Test for subgroup differences: Not applicable

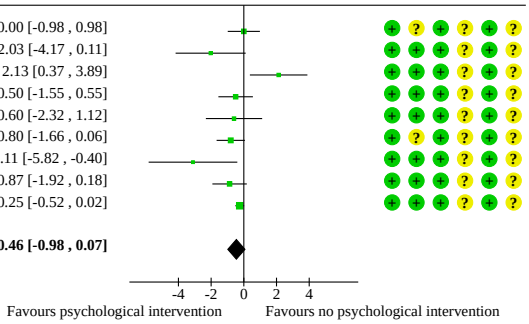


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.6. Comparison 1: Psychological intervention vs no psychological intervention, Outcome 6: HADS-A

Study or Subgroup	Psychological intervention Mean	SD	Total	No psychological intervention Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Chair 2013	2.4	2.9	52	2.4	2.4	64	13.6%	0.00 [-0.98 , 0.98]
Crossmann 2010	4.71	3.41	33	6.74	4.86	28	4.8%	-2.03 [-4.17 , 0.11]
Crossmann 2010	6.19	3.73	34	4.06	3.33	28	6.6%	2.13 [0.37 , 3.89]
Humphries 2021	6.8	3.7	89	7.3	3.9	112	12.6%	-0.50 [-1.55 , 0.55]
Nahlén Bose 2016	4.17	3.72	37	4.77	4.23	45	6.8%	-0.60 [-2.32 , 1.12]
O'Neil 2014b	4.2	3.7	141	5	3.9	156	15.2%	-0.80 [-1.66 , 0.06]
Turner 2014	6.93	3.38	14	10.04	4.06	15	3.2%	-3.11 [-5.82 , -0.40]
Wells 2021	8.3	4.63	132	9.17	4.14	136	12.7%	-0.87 [-1.92 , 0.18]
Zetta 2011	2.16	1.08	109	2.41	0.95	109	24.4%	-0.25 [-0.52 , 0.02]
Total (95% CI)			**641**			**693**	**100.0%**	**-0.46 [-0.98 , 0.07]**

Heterogeneity: Tau² = 0.27; Chi² = 17.07, df = 8 (P = 0.03); I² = 53%
Test for overall effect: Z = 1.71 (P = 0.09)
Test for subgroup differences: Not applicable

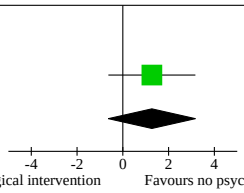


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.7. Comparison 1: Psychological intervention vs no psychological intervention, Outcome 7: GAD-7

Study or Subgroup	Psychological intervention Mean	SD	Total	No psychological intervention Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Bekelman 2018	4.22	0	121	5.11	0	119		Not estimable
Habibovic 2017	4.5	0	105	3	0	112		Not estimable
Nijjar 2019	3.8	4.34	31	2.53	2.31	16	100.0%	1.27 [-0.63 , 3.17]
Total (95% CI)			**257**			**247**	**100.0%**	**1.27 [-0.63 , 3.17]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.31 (P = 0.19)
Test for subgroup differences: Not applicable

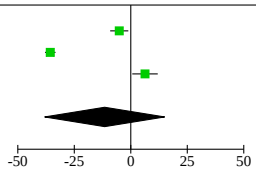


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.8. Comparison 1: Psychological intervention vs no psychological intervention, Outcome 8: BAI

Study or Subgroup	Psychological intervention Mean	SD	Total	No psychological intervention Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Freedland 2009	9.1	8.8	40	14.2	9	36	33.4%	-5.10 [-9.11 , -1.09]
Moradi 2016	6.73	2.09	30	42.36	6.15	30	33.5%	-35.63 [-37.95 , -33.31]
Richards 2018	12.7	7.1	9	6.4	4.6	8	33.1%	6.30 [0.67 , 11.93]
Total (95% CI)			**79**			**74**	**100.0%**	**-11.56 [-38.12 , 15.00]**

Heterogeneity: Tau² = 546.46; Chi² = 292.84, df = 2 (P < 0.00001); I² = 99%
Test for overall effect: Z = 0.85 (P = 0.39)
Test for subgroup differences: Not applicable

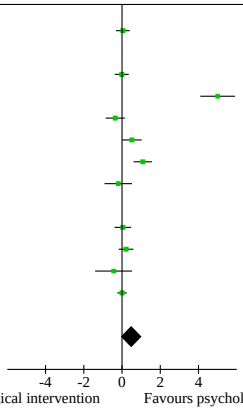


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.9. Comparison 1: Psychological intervention vs no psychological intervention, Outcome 9: HRQoL (PCS)

Study or Subgroup	Psychological intervention Mean	SD	Total	No psychological intervention Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F
Agren 2012	31.7	9.8	57	31.3	7.9	63	9.7%	0.04 [-0.31 , 0.40]	+ + ? ? + ?
Bekelman 2018	53.1	0	121	48.2	0	121		Not estimable	+ + + ? + ?
Chair 2013	47.5	9.5	52	47.6	9.5	64	9.7%	-0.01 [-0.38 , 0.36]	+ ? + ? + ?
Chang 2020	81.6	4.4	40	55.3	5.9	40	7.7%	5.00 [4.10 , 5.91]	+ + + ? + ?
Crossmann 2010	35.47	9.37	34	38.46	6.93	28	9.3%	-0.35 [-0.86 , 0.15]	+ + + ? + ?
Crossmann 2010	44.34	8.71	33	39.26	10.89	28	9.3%	0.51 [0.00 , 1.03]	+ + + ? + ?
Freedland 2009	37.6	1.5	40	35.9	1.6	36	9.3%	1.09 [0.60 , 1.57]	+ + + ? + ?
Gary 2010	-34.3	23.6	16	-28.9	29.9	14	8.5%	-0.20 [-0.92 , 0.52]	? + + ? + ?
Habibovic 2017	43.9	0	105	43.95	0	112		Not estimable	+ + + ? + ?
Nahlén Bose 2016	237.8	94.93	37	233.59	101.05	45	9.5%	0.04 [-0.39 , 0.48]	+ + + ? + ?
O'Neil 2014a	38	9.2	53	35.9	10.4	53	9.7%	0.21 [-0.17 , 0.59]	+ + + ? + ?
Richards 2018	0.827	0.116	9	0.876	0.092	8	7.4%	-0.44 [-1.41 , 0.53]	+ ? ? + + ?
Wells 2021	0.62	0.28	118	0.62	0.27	127	10.0%	0.00 [-0.25 , 0.25]	+ + + ? + ?
Total (95% CI)			**715**			**739**	**100.0%**	**0.48 [-0.02 , 0.98]**	

Heterogeneity: Tau² = 0.63; Chi² = 134.29, df = 10 (P < 0.00001); I² = 93%
Test for overall effect: Z = 1.88 (P = 0.06)
Test for subgroup differences: Not applicable

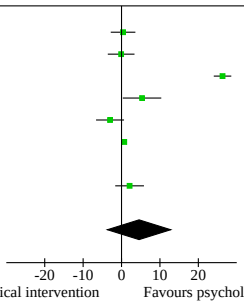


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.10. Comparison 1: Psychological intervention vs no psychological intervention, Outcome 10: SF12/36 (PCS)

Study or Subgroup	Psychological intervention Mean	SD	Total	No psychological intervention Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F
Agren 2012	31.7	9.8	57	31.3	7.9	63	14.3%	0.40 [-2.81 , 3.61]	+ + ? ? + ?
Chair 2013	47.5	9.5	52	47.6	9.5	64	14.3%	-0.10 [-3.58 , 3.38]	+ ? + ? + ?
Chang 2020	81.6	4.4	40	55.3	5.9	40	14.5%	26.30 [24.02 , 28.58]	+ + + ? + ?
Crossmann 2010	44.34	8.71	33	39	10.89	28	13.9%	5.34 [0.33 , 10.35]	+ + + ? + ?
Crossmann 2010	35.47	9.37	34	38.46	4.93	28	14.2%	-2.99 [-6.63 , 0.65]	+ + + ? + ?
Freedland 2009	37.6	1.5	40	36.9	1.6	36	14.6%	0.70 [0.00 , 1.40]	+ + + ? + ?
Habibovic 2017	43.9	0	105	45.95	0	112		Not estimable	+ + + ? + ?
O'Neil 2014a	38	9.2	53	35.9	10.4	53	14.2%	2.10 [-1.64 , 5.84]	+ + + ? + ?
Total (95% CI)			**414**			**424**	**100.0%**	**4.57 [-3.68 , 12.81]**	

Heterogeneity: Tau² = 120.80; Chi² = 457.49, df = 6 (P < 0.00001); I² = 99%
Test for overall effect: Z = 1.09 (P = 0.28)
Test for subgroup differences: Not applicable

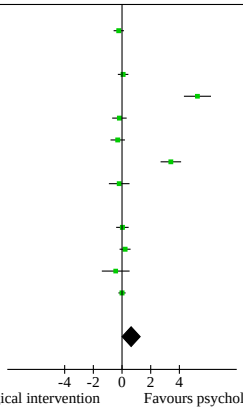


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.11. Comparison 1: Psychological intervention vs no psychological intervention, Outcome 11: HRQoL (MCS)

Study or Subgroup	Psychological intervention Mean	SD	Total	No psychological intervention Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Agren 2012	35.35	11.2	57	37.98	11.9	63	9.6%	-0.23 [-0.59 , 0.13]
Bekelman 2018	54.1	0	121	48.2	0	121		Not estimable
Chair 2013	52.1	6.9	52	51.6	6.3	64	9.6%	0.08 [-0.29 , 0.44]
Chang 2020	79.4	5.1	40	54.1	4.4	40	8.1%	5.26 [4.32 , 6.20]
Crossmann 2010	44.92	12.11	33	47.07	11.12	28	9.3%	-0.18 [-0.69 , 0.32]
Crossmann 2010	46.02	9.53	34	48.75	8.36	28	9.3%	-0.30 [-0.80 , 0.20]
Freedland 2009	49.1	1.9	40	42.4	2	36	8.8%	3.40 [2.69 , 4.12]
Gary 2010	-34.3	23.6	16	-28.9	29.9	14	8.7%	-0.20 [-0.92 , 0.52]
Habibovic 2017	46.5	0	105	48.3	0	112		Not estimable
Nahlén Bose 2016	265.35	92.72	37	262.76	102	45	9.4%	0.03 [-0.41 , 0.46]
O'Neil 2014a	38	9.2	53	35.9	10.4	53	9.5%	0.21 [-0.17 , 0.59]
Richards 2018	0.827	0.116	9	0.876	0.092	8	8.0%	-0.44 [-1.41 , 0.53]
Wells 2021	0.62	0.28	118	0.62	0.27	127	9.7%	0.00 [-0.25 , 0.25]
Total (95% CI)			**715**			**739**	**100.0%**	**0.63 [0.01 , 1.26]**

Heterogeneity: Tau² = 1.04; Chi² = 205.15, df = 10 (P < 0.00001); I² = 95%
Test for overall effect: Z = 1.98 (P = 0.05)
Test for subgroup differences: Not applicable

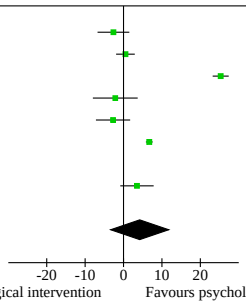


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.12. Comparison 1: Psychological intervention vs no psychological intervention, Outcome 12: SF12/36 (MCS)

Study or Subgroup	Psychological intervention Mean	SD	Total	No psychological intervention Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Agren 2012	35.35	11.2	57	37.98	11.9	63	14.2%	-2.63 [-6.76 , 1.50]
Chair 2013	52.1	6.9	52	51.6	6.3	64	14.6%	0.50 [-1.93 , 2.93]
Chang 2020	79.4	5.1	40	54.1	4.4	40	14.6%	25.30 [23.21 , 27.39]
Crossmann 2010	44.92	12.11	33	47.07	11.12	28	13.6%	-2.15 [-7.98 , 3.68]
Crossmann 2010	46.02	9.53	34	48.75	8.36	28	14.1%	-2.73 [-7.19 , 1.73]
Freedland 2009	49.1	1.9	40	42.4	2	36	14.8%	6.70 [5.82 , 7.58]
Habibovic 2017	44.5	0	105	48.3	0	112		Not estimable
O'Neil 2014a	44.8	11	53	41.3	11.8	53	14.1%	3.50 [-0.84 , 7.84]
Total (95% CI)			**414**			**424**	**100.0%**	**4.21 [-3.35 , 11.77]**

Heterogeneity: Tau² = 100.41; Chi² = 371.37, df = 6 (P < 0.00001); I² = 98%
Test for overall effect: Z = 1.09 (P = 0.27)
Test for subgroup differences: Not applicable

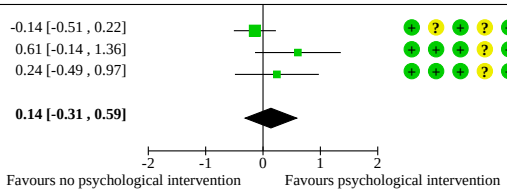


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.13. Comparison 1: Psychological intervention vs no psychological intervention, Outcome 13: Self-efficacy

Study or Subgroup	Psychological intervention Mean	SD	Total	No psychological intervention Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Chair 2013	2.8	0.7	52	2.9	0.7	64	50.4%	-0.14 [-0.51 , 0.22]
Turner 2014	7.14	1.75	14	5.93	2.09	15	24.4%	0.61 [-0.14 , 1.36]
Turner 2014	6.71	2.2	14	6.2	1.9	15	25.2%	0.24 [-0.49 , 0.97]
Total (95% CI)			**80**			**94**	**100.0%**	**0.14 [-0.31 , 0.59]**

Heterogeneity: Tau² = 0.07; Chi² = 3.46, df = 2 (P = 0.18); I² = 42%
Test for overall effect: Z = 0.60 (P = 0.55)
Test for subgroup differences: Not applicable

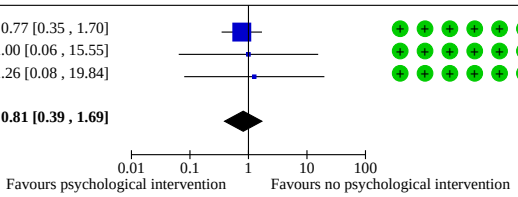


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.14. Comparison 1: Psychological intervention vs no psychological intervention, Outcome 14: Mortality (all-cause)

Study or Subgroup	Psychological intervention Events	Total	No psychological intervention Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bekelman 2018	10	157	13	157	87.3%	0.77 [0.35 , 1.70]
Rafanelli 2020	1	50	1	50	6.7%	1.00 [0.06 , 15.55]
Wells 2021	1	89	1	112	5.9%	1.26 [0.08 , 19.84]
Total (95% CI)		**296**		**319**	**100.0%**	**0.81 [0.39 , 1.69]**
Total events:	12		15			

Heterogeneity: Chi² = 0.14, df = 2 (P = 0.93); I² = 0%
Test for overall effect: Z = 0.55 (P = 0.58)
Test for subgroup differences: Not applicable

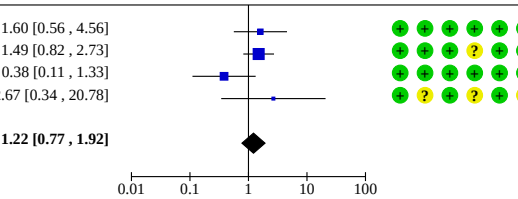


Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

Analysis 1.15. Comparison 1: Psychological intervention vs no psychological intervention, Outcome 15: MACE

Study or Subgroup	Psychological intervention Events	Total	No psychological intervention Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Davidson 2010	8	50	5	50	17.2%	1.60 [0.56 , 4.56]
Humphries 2021	19	89	16	112	48.8%	1.49 [0.82 , 2.73]
Rafanelli 2020	3	58	10	74	30.3%	0.38 [0.11 , 1.33]
Richards 2018	3	9	1	8	3.6%	2.67 [0.34 , 20.78]
Total (95% CI)		**206**		**244**	**100.0%**	**1.22 [0.77 , 1.92]**
Total events:	33		32			

Heterogeneity: Chi² = 4.59, df = 3 (P = 0.20); I² = 35%
Test for overall effect: Z = 0.85 (P = 0.39)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions
(C) Bias due to missing outcome data
(D) Bias in measurement of the outcome
(E) Bias in selection of the reported result
(F) Overall bias

ADDITIONAL TABLES

Table 1. PICOS summary table

Study	P (Participants)	I (Intervention)	C (Comparator)	O (Outcomes)	S (Study design)
Agren 2012	HF (n = 155)	CBT, psychosocial support, education	TAU	Depression (BDI-II); HRQoL (SF12)	Parallel-group RCT
Bekelman 2018	HF (n = 317)	Applied motivational interviewing, psychosocial support (+ CR)	TAU (+ CR)	Depression (PHQ-9); anxiety (GAD-7); HRQoL (KCCQ); mortality	Parallel-group RCT
Chair 2013	CHD (n = 146)	Motivational interviewing, including CBT (+ CR)	TAU (+ CR)	Depression (HADS-D); anxiety (HADS-A); HRQoL (SF-36)	Parallel-group RCT
Chang 2020	CHD (CAD, n = 80)	CBT, relaxation techniques, coping strategies	TAU	Depression (ZDS); anxiety (SAS); HRQoL (SF-12)	Parallel-group RCT
Crossmann 2010	CHD (ICD, n = 134)	CBT/psychological therapy, tele-support, education	TAU	Depression (HADS-D); anxiety (CAQ; HADS-A); HRQoL (SF-36)	Parallel-group RCT
Davidson 2010	CHD (ACS, n = 157)	Psychotherapy, problem-solving (+ Pharm)	TAU (+ Pharm)	Depression (BDI); MACE	Parallel-group RCT
Freedland 2009	CHD (CABG, n = 123)	CBT, tele-support	TAU	Depression (HAM-D); depression (BDI); anxiety (BAI); HRQoL (SF-36)	Parallel-group RCT
Gary 2010	Diagnosis: HF (n = 74)	CBT, education	TAU	Depression (HAM-D); HRQoL (MLHFQ)	Parallel-group RCT
Habibovic 2017	Diagnosis: HF (n = 289)	CBT/behaviour therapy, psychoeducation; problem-solving; relaxation techniques	TAU	Depression (PHQ-9); anxiety (GAD-7); HRQoL (SF-12)	Parallel-group RCT
Humphries 2021	Diagnosis: CHD (MI, n = 239)	Internet-based CBT, online educational support	TAU	Depression (HADS-D); anxiety (HADS-A; CAQ); MACE	Parallel-group RCT
Moradi 2016	Diagnosis: CHD (MI, n = 60)	Behaviour therapy, eye movement desensitisation and reprocessing	TAU	Anxiety (BAI)	Parallel-group RCT
Nahlén Bose 2016	Diagnosis: HF (CHF, n = 103)	Coping effectiveness training	TAU	Depression (HADS-D); anxiety (HADS-A); HRQoL (SF-36)	Parallel-group RCT
Nijjar 2019	Diagnosis CHD (CAD, n = 47)	Mindfulness-based stress reduction, education	TAU (+ CR)	Depression (PHQ-9); anxiety (GAD-7)	Parallel-group RCT
O'Neil 2014a	Diagnosis: CHD (ACS, n = 121)	CBT/behavioural activation, cognitive restructuring, motivational interviewing, goal setting	TAU	Depression (CDS; PHQ-9); HRQoL (SF-12)	Parallel-group RCT

Table 1. PICOS summary table *(Continued)*

O'Neil 2014b	Diagnosis: CHD (MI, n = 430)	Social cognitive behavioural therapy, education	TAU	Depression (HADS-D); anxiety (HADS-A);	Parallel-group RCT
Rafanelli 2020	Diagnosis: CHD (ACS, n = 100)	CBT, wellbeing therapy	TAU (active control)	Depression (CID; SCL-90-R); anxiety (SCL-90-R); mortality; MACE	Parallel-group RCT
Richards 2018	Diagnosis CHD (ACS, n = 29)	Enhanced psychological care, behavioural activation, education (+ CR)	TAU (+ CR)	Depression (BDI-II); anxiety (BAI); HRQoL (EQ5D; HeartQoL); MACE	Parallel-group, cluster-RCT
Tagney 2013	Diagnosis CHD (IHD, n = 49)	Behavioural therapy, psychoeducation	TAU	Depression (BDI-FS); anxiety (STAI)	Parallel-group RCT
Turner 2014	Diagnosis: CHD (AMI/PCI, n = 42)	Integrated motivational interviewing and CBT	TAU	Depression (BDI-II); anxiety (HADS-A)	Parallel-group RCT
Wells 2021	Diagnosis CHD (ACS, n = 332)	Meta-cognitive therapy, education (+ CR)	TAU (+ CR)	Depression (HADS-D); anxiety (HADS-A); HRQoL (EQ-5D); mortality	Parallel-group RCT
Zetta 2011	Diagnosis CHD (n = 233)	CBT, relaxation techniques, education	TAU	Depression (HADS-D); anxiety (HADS-A)	Parallel-group RCT

ACS: acute coronary syndrome; **BAI**:Beck Anxiety Inventory; **BDI**: Beck Depression Inventory; **BDI II**: Beck Depression Inventory II; **BDI-FS**: Beck Depression Inventory fast screen; **CABG**: coronary artery bypass graft;**CAD**: coronary artery disease; **CBT**: cognitive behavioural therapy; **CDS**: Cardiac Depression Scale;**CHD**: coronary heart disease; **CID**: Clinical Interview for Depression; **CR**: cardiac rehabilitation; **EQ-5D**; EuroQol-5D; **GAD**: Generalised Anxiety Disorder Assessment;**HADS**: Hospital Anxiety and Depression Scale; **HAM-D**: Hamilton Depression Rating Scale; **HF**: heart failure; **HRQoL**: health-related quality of life; **iCBT**: online CBT; **ICD**: implantable cardioverter defibrillator;**IHD**: ischaemic heart disease; **MACE**: major adverse cardiovascular events; **MI**: myocardial infarction; **MLHFQ**: Minnesota Living with Heart Failure Questionnaire; **n**: number; **PCI**: percutaneous coronary intervention; **Pharm**: pharmacotherapy; **KCCQ;** Kansas City Cardiomyopathy Questionnaire; **PHQ-9**: Patient Health Questionnaire-9; **RCT**: randomised controlled trial; **SAS:** Zung Self-rating Anxiety Scale; **SCL-90-R**: Symptom Checklist 90-Revised; **SF12/36**: Short Form Health Survey 12/36; **STAI**: State-Trait Anxiety Inventory; **TAU**: treatment as usual; **ZDS**: Zung Self-Rating Depression Scale.

APPENDICES

Appendix 1. Search strategies (2022)

CENTRAL

#1 MeSH descriptor: [Heart Diseases] explode all trees
#2 (heart NEAR/4 disease*):ab,ti
#3 MeSH descriptor: [Coronary Disease] explode all trees
#4 (coronary NEAR/2 disease*):ab,ti
#5 CHD:ab,ti
#6 MeSH descriptor: [Heart Failure] explode all trees
#7 (heart NEAR/6 fail*):ab,ti
#8 MeSH descriptor: [Atrial Fibrillation] explode all trees
#9 Atrial fibrillation:ab,ti
#10 MeSH descriptor: [Myocardial Ischemia] explode all trees
#11 (myocard* NEAR/4 (ischaemi* or ischemi*)):ab,ti
#12 ((ischaemi* or ischemi*) NEAR/4 heart):ab,ti
#13 MeSH descriptor: [Myocardial Infarction] explode all trees
#14 (myocard* NEAR/4 infarct*):ab,ti
#15 (heart NEAR/4 (infarct* or attack*)):ab,ti
#16 MeSH descriptor: [Angina Pectoris] explode all trees

#17 angina:ab,ti
#18 stenocardia*:ab,ti
#19 MeSH descriptor: [Percutaneous Coronary Intervention] explode all trees
#20 (percutaneous coronary NEAR/2 (interven* or revascular*)):ab,ti
#21 (pci or ptca):ab,ti
#22 MeSH descriptor: [Coronary Artery Bypass] explode all trees
#23 (coronary NEAR/4 bypass*):ab,ti
#24 CABG:ab,ti
#25 aortocoronary bypass*:ab,ti
#26 MeSH descriptor: [Heart Bypass, Left] this term only
#27 MeSH descriptor: [Heart Bypass, Right] this term only
#28 MeSH descriptor: [Myocardial Revascularization] explode all trees
#29 myocard*:ab,ti
#30 cardiac*:ab,ti
#31 MeSH descriptor: [Angioplasty] explode all trees
#32 angioplast*:ab,ti
#33 ((coronary or arterial) NEAR/4 dilat*):ab,ti
#34 endoluminal repair*:ab,ti
#35 MeSH descriptor: [Stents] explode all trees
#36 stent*:ab,ti
#37 MeSH descriptor: [Atherectomy] explode all trees
#38 atherectom*:ab,ti
#39 acute coronary syndrom*:ab,ti
#40 #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 or #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
#41 MeSH descriptor: [Psychotherapy] explode all trees
#42 psychotherap*:ab,ti
#43 ((psycholog* or psychosocial) NEAR/1 intervent*):ab,ti
#44 MeSH descriptor: [Relaxation Therapy] this term only
#45 relax*:ab,ti
#46 MeSH descriptor: [Counseling] explode all trees
#47 (counselling or counseling):ab,ti
#48 MeSH descriptor: [Stress, Psychological] this term only
#49 (stress NEAR/4 (management or reduc*)):ab,ti
#50 MeSH descriptor: [Autogenic Training] this term only
#51 autogenic*:ab,ti
#52 MeSH descriptor: [Meditation] this term only
#53 meditat*:ab,ti
#54 MeSH descriptor: [Mindfulness] this term only
#55 Mindfulness:ab,ti
#56 MeSH descriptor: [Cognitive Behavioral Therapy] this term only
#57 (cognitive NEAR/4 (therap* or technique*)):ab,ti
#58 CBT:ab,ti
#59 ((behavior* or behaviour*) NEAR/4 (modify or modificat* or therap* or change)):ab,ti
#60 (manage* NEAR/2 (anxiety or depres*)):ab,ti
#61 MeSH descriptor: [Psychopathology] this term only
#62 psychopathol*:ab,ti
#63 distress*:ab,ti
#64 hypnotherap*:ab,ti
#65 (goal* NEAR/3 setting):ab,ti
#66 (psycho-educat* or psychoeducat*):ab,ti
#67 (motivat* NEAR/3 interv*):ab,ti
#68 #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 or #54 or #55 or #56 or #57 or #58 or #59 or #60 or #61 or #62 or #63 or #64 or #65 or #66 or #67
#69 #40 and #68 with Publication Year from 2009 to 2021, in Trials

Search date: 05 July 2022

MEDLINE Ovid

1 exp Heart Diseases/
2 (heart adj4 disease*).tw.
3 exp Coronary Disease/

4 (coronary adj2 disease*).tw.
5 CHD.tw.
6 exp Heart Failure/
7 (heart adj6 fail*).tw.
8 exp Atrial Fibrillation/
9 Atrial fibrillation.tw.
10 exp Myocardial Ischemia/
11 (myocard* adj4 (ischaemi* or ischemi*)).tw.
12 ((ischaemi* or ischemi*) adj4 heart).tw.
13 exp Myocardial Infarction/
14 (myocard* adj4 infarct*).tw.
15 (heart adj4 (infarct* or attack*)).tw.
16 exp Angina Pectoris/
17 angina.tw.
18 stenocardia*.tw.
19 exp Percutaneous Coronary Intervention/
20 (percutaneous coronary adj2 (interven* or revascular*)).tw.
21 (pci or ptca).tw.
22 exp Coronary Artery Bypass/
23 (coronary adj4 bypass*).tw.
24 CABG.tw.
25 aortocoronary bypass*.tw.
26 Heart Bypass, Left/ or Heart Bypass, Right/
27 exp Myocardial Revascularization/
28 myocard*.tw.
29 cardiac*.tw.
30 exp Angioplasty/
31 angioplast*.tw.
32 ((coronary or arterial) adj4 dilat*).tw.
33 endoluminal repair*.tw.
34 exp Stents/
35 stent*.tw.
36 exp Atherectomy/
37 atherectom*.tw.
38 acute coronary syndrom*.tw.
39 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 or 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
40 exp Psychotherapy/
41 psychotherap*.tw.
42 ((psycholog* or psychosocial) adj intervent*).tw.
43 exp Relaxation Techniques/
44 Relaxation therapy/
45 relax*.tw.
46 exp Counseling/
47 (counselling or counseling).tw.
48 Stress, Psychological/
49 (stress adj4 (management or reduc*)).tw.
50 Autogenic Training/
51 autogenic*.tw.
52 Meditation/
53 meditat*.tw.
54 Mindfulness/
55 Mindfulness.tw.
56 Cognitive Behavioral Therapy/
57 (cognitive adj4 (therap* or technique*)).tw.
58 CBT.tw.
59 ((behavior* or behaviour*) adj4 (modify or modificat* or therap* or change)).tw.
60 (manage* adj2 (anxiety or depres*)).tw.
61 Psychopathology/
62 psychopathol*.tw.
63 distress*.tw.
64 hypnotherap*.tw.

65 (goal* adj3 setting).tw.
66 (psycho-educat* or psychoeducat*).tw.
67 (motivat* adj3 interv*).tw.
68 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67
69 39 and 68
70 randomized controlled trial.pt.
71 controlled clinical trial.pt.
72 randomized.ab.
73 placebo.ab.
74 clinical trials as topic.sh.
75 randomly.ab.
76 trial.ti.
77 70 or 71 or 72 or 73 or 74 or 75 or 76
78 exp animals/ not humans.sh.
79 77 not 78
80 69 and 79
81 limit 80 to yr="2009-2022"

Search date: 05 July 2022

Embase Ovid

1 exp heart disease/
2 (heart adj4 disease*).tw.
3 exp coronary artery disease/
4 (coronary adj2 disease*).tw.
5 CHD.tw.
6 exp heart failure/
7 (heart adj6 fail*).tw.
8 exp atrial fibrillation/
9 Atrial fibrillation.tw.
10 exp heart muscle ischemia/
11 (myocard* adj4 (ischaemi* or ischemi*)).tw.
12 ((ischaemi* or ischemi*) adj4 heart).tw.
13 exp heart infarction/
14 (myocard* adj4 infarct*).tw.
15 (heart adj4 (infarct* or attack*)).tw.
16 exp angina pectoris/
17 angina.tw.
18 stenocardia*.tw.
19 exp percutaneous coronary intervention/
20 (percutaneous coronary adj2 (interven* or revascular*)).tw.
21 (pci or ptca).tw.
22 exp coronary artery bypass graft/
23 (coronary adj4 bypass*).tw.
24 CABG.tw.
25 aortocoronary bypass*.tw.
26 heart left ventricle bypass/ or extracorporeal circulation/
27 exp heart muscle revascularization/
28 myocard*.tw.
29 cardiac*.tw.
30 exp angioplasty/
31 angioplast*.tw.
32 ((coronary or arterial) adj4 dilat*).tw.
33 endoluminal repair*.tw.
34 exp stent/
35 stent*.tw.
36 exp atherectomy/
37 atherectom*.tw.
38 acute coronary syndrom*.tw.
39 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 or 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

40 exp psychotherapy/
41 psychotherap*.tw.
42 ((psycholog* or psychosocial) adj intervent*).tw.
43 exp relaxation training/
44 relax*.tw.
45 exp counseling/
46 (counselling or counseling).tw.
47 mental stress/
48 (stress adj4 (management or reduc*)).tw.
49 autogenic training/
50 autogenic*.tw.
51 meditation/
52 meditat*.tw.
53 mindfulness/
54 Mindfulness.tw.
55 cognitive behavioral therapy/
56 (cognitive adj4 (therap* or technique*)).tw.
57 CBT.tw.
58 ((behavior* or behaviour*) adj4 (modify or modificat* or therap* or change)).tw.
59 (manage* adj2 (anxiety or depres*)).tw.
60 mental disease/
61 psychopathol*.tw.
62 distress*.tw.
63 hypnotherap*.tw.
64 (goal* adj3 setting).tw.
65 (psycho-educat* or psychoeducat*).tw.
66 (motivat* adj3 interv*).tw.
67 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66
68 39 and 67
69 random$.tw.
70 factorial$.tw.
71 crossover$.tw.
72 cross over$.tw.
73 cross-over$.tw.
74 placebo$.tw.
75 (doubl$ adj blind$).tw.
76 (singl$ adj blind$).tw.
77 assign$.tw.
78 allocat$.tw.
79 volunteer$.tw.
80 crossover procedure/
81 double blind procedure/
82 randomized controlled trial/
83 single blind procedure/
84 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83
85 (animal/ or nonhuman/) not human/
86 84 not 85
87 68 and 86
88 limit 87 to yr="2009-2022"
89 limit 88 to embase

Search date: 05 July 2022

PsycINFO Ovid

1 exp heart disorders/
2 (heart adj4 disease*).tw.
3 exp Cardiovascular Disorders/
4 (coronary adj2 disease*).tw.
5 CHD.tw.
6 (heart adj6 fail*).tw.
7 exp "Fibrillation (Heart)"/

8 Atrial fibrillation.tw.
9 ischemia/
10 (myocard* adj4 (ischaemi* or ischemi*)).tw.
11 ((ischaemi* or ischemi*) adj4 heart).tw.
12 exp Myocardial Infarctions/
13 (myocard* adj4 infarct*).tw.
14 (heart adj4 (infarct* or attack*)).tw.
15 exp Angina Pectoris/
16 angina.tw.
17 stenocardia*.tw.
18 (percutaneous coronary adj2 (interven* or revascular*)).tw.
19 (pci or ptca).tw.
20 (coronary adj4 bypass*).tw.
21 CABG.tw.
22 aortocoronary bypass*.tw.
23 myocard*.tw.
24 cardiac*.tw.
25 angioplast*.tw.
26 ((coronary or arterial) adj4 dilat*).tw.
27 endoluminal repair*.tw.
28 stent*.tw.
29 atherectom*.tw.
30 acute coronary syndrom*.tw.
31 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 or 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
32 exp Psychotherapy/
33 psychotherap*.tw.
34 ((psycholog* or psychosocial) adj intervent*).tw.
35 exp Relaxation Therapy/
36 relax*.tw.
37 exp Counseling/
38 (counselling or counseling).tw.
39 Psychological Stress/
40 (stress adj4 (management or reduc*)).tw.
41 Autogenic Training/
42 autogenic*.tw.
43 Meditation/
44 meditat*.tw.
45 Mindfulness/
46 Mindfulness.tw.
47 Cognitive Behavior Therapy/
48 (cognitive adj4 (therap* or technique*)).tw.
49 CBT.tw.
50 ((behavior* or behaviour*) adj4 (modify or modificat* or therap* or change)).tw.
51 (manage* adj2 (anxiety or depres*)).tw.
52 Psychopathology/
53 psychopathol*.tw.
54 distress*.tw.
55 hypnotherap*.tw.
56 (goal* adj3 setting).tw.
57 (psycho-educat* or psychoeducat*).tw.
58 (motivat* adj3 interv*).tw.
59 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 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58
60 31 and 59
61 random$.tw.
62 factorial$.tw.
63 crossover$.tw.
64 cross-over$.tw.
65 placebo$.tw.
66 (doubl$ adj blind$).tw.
67 (singl$ adj blind$).tw.

68 assign$.tw.
69 allocat$.tw.
70 volunteer$.tw.
71 control*.tw.
72 "2000".md.
73 or/61-72
74 60 and 73
75 limit 74 to yr="2009-2022"

Search date: 05 July 2022

CINAHL EBSCO

S90 S66 AND S89 Limiters - Published Date: 20090101-20210430
S89 S88 NOT S87
S88 S67 OR S68 OR S69 OR S70 OR S71 OR S72 OR S73 OR S74 OR S75 OR S76 OR S77 OR S78 OR S79 OR S80 OR S81
S87 S85 NOT S86
S86 MH (human)
S85 S82 OR S83 OR S84
S84 TI (animal model*)
S83 MH (animal studies)
S82 MH animals+
S81 AB (cluster W3 RCT)
S80 MH (crossover design) OR MH (comparative studies)
S79 AB (control W5 group)
S78 PT (randomized controlled trial)
S77 MH (placebos)
S76 MH (sample size) AND AB (assigned OR allocated OR control)
S75 TI (trial)
S74 AB (random*)
S73 TI (randomised OR randomized)
S72 MH cluster sample
S71 MH pretest-posttest design
S70 MH random assignment
S69 MH single-blind studies
S68 MH double-blind studies
S67 MH randomized controlled trials
S66 S38 AND S65
S65 S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64
S64 TX (motivat* N3 interv*)
S63 TX (psycho-educat* or psychoeducat*)
S62 TX (goal* N3 setting)
S61 TX hypnotherap*
S60 TX distress*
S59 TX psychopathol*
S58 (MH "Psychopathology")
S57 TX (manage* N2 (anxiety or depres*))
S56 TX ((behavior* or behaviour*) N4 (modify or modificat* or therap* or change))
S55 TX CBT
S54 TX (cognitive N4 (therap* or technique*))
S53 (MH "Cognitive Therapy")
S52 TX Mindfulness
S51 (MH "Mindfulness")
S50 TX meditat*
S49 (MH "Meditation")
S48 TX autogenic*
S47 TX (stress N4 (management or reduc*))
S46 (MH "Stress, Psychological")
S45 TX (counselling or counseling)
S44 (MH "Counseling+")
S43 TX relax*
S42 (MH "Relaxation Techniques+")

S41 TX ((psycholog* or psychosocial) N1 intervent*)
S40 TX psychotherap*
S39 (MH "Psychotherapy+")
S38 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37
S37 TX acute coronary syndrom*
S36 TX atherectom*
S35 (MH "Atherectomy+")
S34 TX stent*
S33 (MH "Stents+")
S32 TX endoluminal repair*
S31 TX ((coronary or arterial) N4 dilat*)
S30 TX angioplast*
S29 (MH "Angioplasty+")
S28 TX cardiac*
S27 TX myocard*
S26 (MH "Myocardial Revascularization+")
S25 TX aortocoronary bypass*
S24 TX CABG
S23 TX (coronary N4 bypass*)
S22 (MH "Coronary Artery Bypass+")
S21 TX (pci or ptca)
S20 TX (percutaneous coronary N2 (interven* or revascular*))
S19 (MH "Percutaneous Coronary Intervention")
S18 TX stenocardia*
S17 TX angina
S16 (MH "Angina Pectoris+")
S15 TX (heart N4 (infarct* or attack*))
S14 TX (myocard* N4 infarct*)
S13 (MH "Myocardial Infarction+")
S12 TX ((ischaemi* or ischemi*) N4 heart)
S11 TX (myocard* N4 (ischaemi* or ischemi*))
S10 (MH "Myocardial Ischemia+")
S9 TX Atrial fibrillation
S8 (MH "Atrial Fibrillation")
S7 TX (heart N6 fail*)
S6 (MH "Heart Failure+")
S5 TX CHD
S4 TX (coronary N2 disease*)
S3 (MH "Coronary Disease+")
S2 TX (heart N4 disease*)
S1 (MH "Heart Diseases+")

Search date: 05 July 2022

WHO ICTRP (Trial Registry)

Condition or Disease: "Heart disease" OR "Coronary Heart Disease" OR "CHD" OR "Heart Failure" OR "Chronic Heart Failure" OR "CHF" OR "HF" OR "Atrial Fibrillation" OR "AF"

Intervention: "Psychological" OR "Psychosocial"

Date of Registration: 01 January 2009 to 07 July 2022

Clinicaltrials.gov (Trial Registry)

Condition or Disease: "Heart disease" OR "Coronary Heart Disease" OR "CHD" OR "Heart Failure" OR "Chronic Heart Failure" OR "CHF" OR "HF" OR "Atrial Fibrillation" OR "AF"

Study Type: Interventional

Outcome Measure: "Depression" OR "Anxiety"

Date range: 01 January 2009 to 07 July 2022

HISTORY

Protocol first published: Issue 12, 2019

CONTRIBUTIONS OF AUTHORS

CFS contributed to the design and conceptual focus of the review, search strategy and searching of other sources, assessed the eligibility of studies, extracted and checked study data, assessed risk of bias and the certainty of the evidence, contributed to the interpretation of all data, led the drafting of the review and communications to authors, and co-ordinated the overall study.

RST contributed to the design and conceptual focus of the review, designed and supported the statistical analysis, led the interpretation of data, and resolved disagreements concerning GRADE assessments.

KMG contributed to the search, led the searching of other sources, assessed the eligibility of studies, extracted and checked data, contributed to the interpretation of data and assessed risk of bias.

LL contributed specialist expertise on GRADE assessment and development of the summary of findings table, assessed GRADE ratings of studies, led the interpretation of GRADE data and reviewed RoB 2 assessments.

JDL contributed to the design, conceptual focus of the review and writing of the review, checked and interpreted data, and resolved differences in opinions regarding study eligibility, data extraction and RoB 2 assessments.

SHR contributed to the design and conceptual focus of the review, and title and abstract screening for the final search update (2022).

DRT contributed to the design and conceptual focus of the review, the interpretation of the data and writing of the review.

All authors reviewed and approved the review content prior to submission. CFS is the guarantor for the review.

DECLARATIONS OF INTEREST

CFS has declared that she has no known conflicts of interest.
RST is a former editor of Cochrane Heart. He was not involved in the editorial process for the review.
KMG has declared that she has no known conflicts of interest.
JDL has declared that he has no known conflicts of interest.
DRT has declared that he has no known conflicts of interest.
SHR is first author and methodological lead for a clinical trial included within this review (Richards 2018); the University of Exeter was the lead centre commissioned to conduct the research. The CADENCE study was funded by the UK National Institute of Health Research Health Technology Assessment Programme (project 12/189/06): the funder was not involved in the design, delivery or analysis of the CADENCE study. SHR was not involved in assessing the eligibility of this study, nor in the data extraction, risk of bias assessment or grading of the certainty of the evidence.
LL has declared that she has no known conflicts of interest.

SOURCES OF SUPPORT

Internal sources

- Internal support, Other

  No sources of support provided

External sources

- National Institute for Health Research (NIHR), UK

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Below, we report differences between the review and our published protocol (Ski 2020).

- As our review began at the time of COVID-19, this highlighted the importance of online interventions and, as such, we adapted and updated our March 2020 search to include psychological interventions delivered online for all years (from 2009 to final update, July 2022).

- In the review, the systematic review software Covidence 2022 was used for title/abstract screening, full-text screening and data extraction, as it is recognised by Cochrane as the primary screening and data extraction tool for Cochrane authors conducting standard intervention reviews.
- For the final updated search (July 2022), SHR and KMcG screened abstracts (in the protocol, Ski 2020, this was CFS and KMcG), and CFS was consulted to resolve any disagreements. SHR was added to the final screening update to assist with a timely completion of the review.
- Co-author LL was invited to join this review to provide expertise on assessment of risk of bias using the revised tool, and, specifically, to assist CFS and KMG with the application of RoB 2 to assess results for bias and presentation of RoB 2 in the review.
- Health-related quality of life (HRQoL) was listed as a secondary outcome in the protocol. Given the nature of this review, with a focus on anxiety and depression, along with the increasing use of distinct physical and mental assessments of HRQoL in cardiovascular RCTs (Hernández-Segura 2022; Soloveva 2023), we have included physical HRQoL (PCS) and mental HRQoL (MCS) as secondary outcomes in this review and reported both in the summary of findings table.
- Major adverse cardiovascular events (MACE) was also added to secondary outcomes and included in the summary of findings table, due to its increasing relevance and use in cardiovascular RCTs (Bosco 2021).
- Given the nature of this review (as above) with a focus on psychological outcomes, we decided to report key psychological and clinical outcomes only in the summary of findings table; thus, cardiovascular mortality, cardiovascular hospitalisations and cost-effectiveness are reported narratively in Results (Effects of interventions) and not in the summary of findings table.
- No study measured depression or anxiety as dichotomous outcomes in this review. Should we find any for inclusion in future updates of this review, we will manage measures of treatment effect using risk ratios with 95% confidence intervals for each comparison.
- We did not include any cross-over trials in this review. Should we find any for inclusion in future updates of this review, we will include data from the first period of comparison of the treatment and control arms. We will not include data from the second period due to anticipated carryover effects, i.e. no wash-out period for the psychosocial intervention. As per Cochrane guidance, this would entail use of the RoB 2 tool standardised for parallel-group randomised trials (Higgins 2023b).
- Due to the number of subgroup analyses, and the risk of type I error, these were limited to the two primary outcomes of depression and anxiety in the review.
- The following subgroup analyses were not performed: 'Trials of psychological interventions with and without co-interventions of CR and pharmacotherapy', due to no trials having both co-interventions, and 'Trials that employ different treatment components, i.e. relaxation, stress management techniques, cognitive techniques, emotional support or client-led discussion, or combinations', due to all studies implementing multi-component psychological interventions.
- We did not undertake sensitivity analyses for (1) studies with a low risk of bias, as none were judged as overall low risk of bias according to the RoB 2 tool, (2) missing data thought to introduce bias, as we did not compute missing SD or other data, and (3) assumption of heterogeneity using a fixed-effect pooled estimate and 95% CI, as the conclusions from our meta-analysis did not appear to be sensitive to running them as a random-effects models (e.g. for depression and anxiety, a fixed-effect model favoured psychological interventions compared to no psychological intervention (depression: SMD -0.24, 95% CI -0.33 to -0.15; anxiety: SMD -0.23, 95% CI -0.33 to -0.14).