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# Psychological interventions for depression in adolescent and adult congenital heart disease (Review)

Leo DG, Islam U, Lotto RR, Lotto A, Lane DA

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[Intervention Review]

# Psychological interventions for depression in adolescent and adult congenital heart disease

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## ABSTRACT

### Background

Despite improvements in medical care, the quality of life of adults and adolescents with congenital heart disease remains strongly affected by their condition, often leading to depression. Psychotherapy, cognitive behavioural therapy, and other talking therapies may be effective in treating depression in both adults and young adults with congenital heart disease. The aim of this review was to assess the effects of treatments, such as psychotherapy, cognitive behavioural therapies, and talking therapies for treating depression in this population.

### Objectives

To evaluate the effects (both harms and benefits) of psychological interventions for reducing symptoms of depression in adolescents (aged 10 to 17 years) and adults with congenital heart disease. Psychological interventions include cognitive behavioural therapy, psychotherapy, or 'talking/counselling' therapy for depression.

### Search methods

We updated searches from the 2013 Cochrane Review by searching CENTRAL, four other databases, and Conference Proceedings Citation Index to 7 March 2023, and two clinical trial registers to February 2021. We applied no language restrictions.

### Selection criteria

Randomised controlled trials (RCTs) comparing psychological interventions to no intervention in the congenital heart disease population, aged 10 years and older, with depression.

### Data collection and analysis

Two review authors independently screened titles and abstracts, and independently assessed full-text reports for inclusion. Further information was sought from the authors if needed. Data were extracted in duplicate. We used standard Cochrane methods. Our primary outcome was a change in depression. Our secondary outcomes were: acceptability of treatment, quality of life, hospital re-admission, non-fatal cardiovascular events, cardiovascular behavioural risk factor, health economics, cardiovascular mortality, all-cause mortality. We used GRADE to assess the certainty of evidence for our primary outcome only.


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**Main results**

We identified three new RCTs (480 participants). Participants were adults with congenital heart disease. Included studies varied in intervention length (90 minutes to 3 months) and follow-up (3 to 12 months), with depression assessed post-intervention and at follow-up. Risk of bias assessment identified an overall low risk of bias for the main outcome of depression.

Psychological interventions (talking/counselling therapy) may reduce depression more than usual care at both three-month (mean difference (MD) -1.07, 95% confidence interval (CI) -1.84 to -0.30; P = 0.006; $I^2$ = 0%; 2 RCTs, 156 participants; low-certainty evidence), and 12-month follow-up (MD -1.02, 95% CI -1.92 to -0.13; P = 0.02; $I^2$ = 0%; 2 RCTs, 287 participants; low-certainty evidence).

There was insufficient evidence to draw conclusions about the impact of psychological interventions on quality of life.

None of the included studies reported on our other outcomes of interest.

Due to the low number of studies included, we did not undertake any subgroup analyses. One study awaits classification.

**Authors' conclusions**

Psychological interventions may reduce depression in adults with congenital heart disease compared to usual care. However, the certainty of the evidence is low.

Further research is needed to establish the role of psychological interventions in this population, defining the optimal duration, method of administration, and number of sessions required to obtain the greatest benefit.

## PLAIN LANGUAGE SUMMARY

**Psychological treatments for depression in young adults and adults born with heart problems**

**Key message**

• Psychological interventions (talking/counselling therapy) may reduce symptoms of depression in adults with congenital heart disease.

• Further studies are required to define the best psychological treatment for this population, such as the duration, frequency, and type of intervention.

**What is congenital heart disease?**

Congenital heart disease is an umbrella term used to define a range of birth defects that affect the way in which the heart works.

**Why is important to do this review?**

Sometimes, young adults and adults who are born with heart problems have depression. Besides anti-depressant medicine, treatments to help reduce the depression include different types of talking therapies (known as psychological therapy). The benefits of having treatment with talking therapy may include a reduction in depression and improved quality of life, but the treatment may not help relieve the depression.

**What did we want to find out?**

Our aim was to examine the effects (both harms and benefits) of psychological interventions for treating depression in young adults and adults with congenital heart disease.

**What did we do?**

We updated the searches of the medical literature to March 2023. We selected studies that met our criteria, assessed the risk of bias for depression, compared the results of these studies, and rated our confidence in the evidence based on these studies (e.g. assessment methods and size of the sample).

**What did we find?**

We found three studies, with a total of 480 participants with congenital heart disease, which looked at how psychological interventions (talking/counselling therapy) impacted depression. The psychological interventions lasted between 90 minutes and 3 months. These studies were conducted in Canada, Sweden, and the Netherlands. Studies were funded by grants from the National Research Council of the respective countries.

The results of our review suggest that a psychological intervention may help to reduce the symptoms of depression in adults with congenital heart disease. However, the type and length of the intervention varied between studies, so it may be possible that some interventions may make little or no difference to reducing depression.


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**What are the limitations of the evidence?**

There were only three studies that met the criteria for the review, and the certainty of the evidence was low. There was insufficient evidence to draw conclusions about the impact of psychological interventions (talking/counselling therapy) on quality of life.

**How up to date is this evidence?**

This evidence is up to date to March 2023.


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## Summary of findings 1. Psychological intervention versus usual care for depression in people with congenital heart disease

**Psychological intervention versus usual care for depression in people with congenital heart disease**

**Patient or population:** adolescents and adults with congenital heart disease

**Setting:** worldwide

**Intervention:** psychological intervention (talking/counselling therapy)

**Comparison:** usual care

| Outcomes | Illustrative Comparative Risks (95% CI) | | Relative Effect (95% CI) | Number of participants (studies) | Quality of the Evidence (GRADE) | Comments |
|---|---|---|---|---|---|---|
| | Assumed risk **for usual care** | **Corresponding risk for psychological interventions** | | | | |
| **Change in depression score**<br>*(measured with HADS; 3-month follow-up)* | Mean change in HADS score ranged across control groups from **0.1 to 0.2** | Mean difference in the intervention groups was 1.07 lower<br>(1.84 lower to 0.30 lower) | Not estimable | 156 (2 RCTs) | ΘΘOO<br>Low[a] | MD -1.07, 95% CI -1.84 to -0.30 |
| **Change in depression score**<br>*(measured with HADS; 12-month follow-up)* | Mean change in HADS score ranged across control groups from **0 to 0.2** | Mean difference in the intervention groups was 1.02 lower<br>(1.92 lower to 0.13 lower) | Not estimable | 287 (2 RCTs) | ΘΘOO<br>Low[b] | MD -1.02, 95% CI -1.92 to -0.13 |

**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.
[a]Downgraded 2 levels due to difference in interventions (applicability)
[b]Downgraded 2 levels due to difference in interventions (applicability)
**CI**: confidence interval; **HADS**: Hospital Anxiety and Depression Scale; **MD**: mean difference; **RCT**: randomised controlled trial

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# BACKGROUND

## Description of the condition

Congenital heart disease is defined as a structural anomaly of the heart or great vessels that is, or could be of functional significance (Morris 2001). The spectrum of congenital heart disease varies considerably in its complexity, from simple congenital heart disease, such as a small atrial septal defect or isolated congenital aortic valve disease, to conditions of great complexity, such as Eisenmenger syndrome and transposition of the great arteries (ACC/AHA 2018). The generally accepted best estimate of the birth prevalence of congenital heart disease is 8 per 1000 live births (Hoffman 2019); however, this does not take into account geographical differences. An updated systematic review and meta-analysis of the birth prevalence of congenital heart disease worldwide revealed the highest rate in Asia, at 9.34 per 1000 live births (95% confidence interval (CI) 8.07 to 10.70), and the lowest in Africa (2.31 per 1000 live births; 95% CI 0.42 to 5.69 (Liu 2019)). The birth prevalence of congenital heart disease is also much higher in Europe (8.2 per 1000 live births, 95% CI 8.1 to 8.3) compared to North America (6.9 per 1000 live birth, 95% CI 6.7 to 7.1 (Van der Linde 2011)). The prevalence of specific heart defects also varies, with ventricular septal defects being the most common overall, although the prevalence of the type of heart defect also varies by continent (Liu 2019).

With better medical care, more children born today with heart defects are surviving to adulthood. A recent systematic review estimated that there were approximately 11,998,283 people living with congenital heart disease worldwide in 2017 (Zimmerman 2020). The adult congenital heart disease population includes those who:

- never underwent cardiac surgery;
- underwent cardiac surgery and require no further operation;
- had palliative surgery, with or without anticipation of reparative surgery; and
- are inoperable, apart from organ transplantation.

Many of these adults require lifelong follow-up and treatment (ACC/AHA 2018).

## Description of the intervention

The latest clinical guidelines on congenital heart disease identified that the healthcare system often does not provide adequate transition from paediatric to adult care; one important barrier to healthcare among people with congenital heart disease is the provision of adequate management of those with cognitive or psychosocial impairment (ACC/AHA 2018; Sable 2011). The American College of Cardiology (ACC) and American Heart Association (AHA) recommend that individual and family psychosocial screening should be undertaken in all people with congenital heart disease, including screening for cognitive, mood, and psychiatric disorders. This is based on expert opinion, as there is very limited evidence to support the treatment effect (ACC/AHA 2018).

## How the intervention might work

Chronic medical illness is often associated with emotional problems; however, there is relatively little research on the psychological sequelae of congenital heart disease, and its impact remains ill-defined (Gleason 2019; Roseman 2019). It also seems that the cardiac lesion is not always the major problem for this population (Steiner 2021). Significant improvements in survival and reductions in morbidity have meant that issues pertaining to quality of life (QoL), such as employment, exercise participation, and pregnancy now predominate, and may lead to emotional distress (Andonian 2020; Apers 2016; Deng 2016; Lane 2002). A recent review, examining the prevalence of depression and anxiety in adults with congenital heart disease, demonstrated that approximately 31% of adults with congenital heart disease suffer from mood disorders, with approximately 28% experiencing anxiety disorders (Jackson 2018). It is now well recognised that psychotherapy has a positive impact on treating anxiety and depression in the congenital heart disease population, despite the lack of appropriate guidelines to advocate widespread implementation (Kovacs 2009).

## Why it is important to do this review

A previous review, aiming to understand neurocognitive and psychological outcomes of congenital heart disease in adults, demonstrated that mental health professionals and mental health care may have an important role in improving the well-being of this population (Kovacs 2021). It is now clear that adults with congenital heart disease have a higher risk of experiencing symptoms of depression and anxiety (Roseman 2019). There is also some evidence that provision of social support is effective in alleviating stress from physical illness, although depression per se has not been studied (Kovacs 2009). Hence, it is important to consider the corresponding young adult population with congenital heart disease who may have significant depression, and identify effective interventions.

# OBJECTIVES

To evaluate the effects (both harms and benefits) of psychological interventions for reducing symptoms of depression in adolescents (aged 10 to 17 years) and adults with congenital heart disease. Psychological interventions include cognitive behavioural therapy, psychotherapy, or 'talking/counselling' therapy for depression.

# METHODS

## Criteria for considering studies for this review

### Types of studies

Individually randomised controlled trials (RCTs) and cluster-randomised trials.

Cross-over trials were not eligible for our review, as the inclusion in the control group (standard care) of participants who had been previously exposed to the psychological intervention would potentially compromise the results of the trial (there is no wash-out period for a psychological intervention).

### Types of participants

Adolescents (aged 10 to 17 years) and adults (aged 18 years and older) with congenital abnormalities of the heart or great vessels, defined by clinical diagnosis alone, or in combination with echocardiography, angiography, and other diagnostic procedures, with or without depression, were eligible for this review.


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Depression was defined as either major depression, or depressive symptomology (above or below a predefined cutoff on the questionnaires used in each study (DSM-5)).

### Types of interventions

The main comparison was between psychological interventions and no intervention (e.g. usual care or placebo).

Eligible psychological interventions were:

- Cognitive behavioural therapy
- Psychotherapy
- Talking/counselling therapy

We included trials in which participants received antidepressant medication only if both groups (treatment and no intervention groups) had received them in equal amounts. The three eligible psychological interventions were defined as described below.

#### Cognitive behavioural therapy

Cognitive behavioural therapy, for the purposes of this review, was based on the definition used by Jones 2012. The intervention was classified as well-defined if it demonstrated clearly that a component of the intervention:

- involved the recipients establishing links between their thoughts, feelings, and actions with respect to the target symptom; and
- the correction of the person's misconceptions, irrational beliefs and reasoning biases related to the target symptom.

A further component of the intervention involved either or both of the following:

- the recipient monitoring his or her own thoughts, feelings, and behaviours with respect to the target symptom; and
- the promotion of alternative ways of coping with the target symptom.

All therapies that did not meet these inclusion criteria, but were described as cognitive behavioural therapy or cognitive therapy, were labelled as less well-defined cognitive behavioural therapy.

#### Psychotherapy

Any psychological intervention described as non-cognitive behavioural therapy

#### Talking or counselling therapy

Other psychological interventions, such as non-directive counselling, supportive therapy, and other talking therapies

These three interventions were combined as a single comparison of 'any psychological intervention versus no treatment'. We planned subgroup analyses for the different psychological interventions, if sufficient data were available.

### Types of outcome measures

#### *Primary outcomes*

Reduction in depression measured as:

- the number of participants whose depression score, following the intervention, was below that defined as indicating depression in each study. This was treated as a dichotomous outcome; and
- change in depression score (from validated scales) following the intervention, for each study. This was treated as a continuous outcome.

Depression scores are derived from questionnaires administered to people with depression, and mainly used for research purposes, to confirm a diagnosis of depression, and to assess its severity, e.g. the Goldberg and Beck questionnaires (Beck 1961; Goldberg 1988). Each questionnaire uses a numerical scale indicating the severity of depression.

Reporting one or more of the outcomes listed here in the trial was not an inclusion criterion for the review.

When an included study reported more than one measurement scale for the same outcome, we only included validated scales. When more than one validated scale was used, priority was given to the most commonly used scale in clinical settings, but we included data from all validated scales. For the outcome of depression, our hierarchy of tools was as follows: Hospital Anxiety and Depression Scale (HADS), Zung Depression Scale, Beck Depression Inventory (BDI), Patient Health Questionnaire (PHQ-9), Center for Epidemiologic Studies – Depression (CES-D) scale, then other validated scores for depression.

We collected data on the reduction in depression measured as scores over time, and also by categorical or binary outcomes (improved, no change, worsening) between baseline and end of intervention/follow-up.

#### *Secondary outcomes*

- Acceptability of treatment, assessed directly as a continuous outcome, by questioning participants in the trial and using satisfaction measurements, and indirectly, by the number of people who failed to complete the intervention;
- Quality of life (QoL), assessed as a continuous outcome, by using validated scales, such as the EQ-5D, the SF-36 questionnaires, and a visual analogue scale (VAS);
- Hospital re-admission related to congenital heart disease abnormality (including further reparative surgery), assessed as a continuous outcome, based on the number of people with at least one admission during the study follow-up period;
- Non-fatal cardiovascular events (stroke, new cardiac arrhythmia, pulmonary embolism, peripheral arterial embolism, gastrointestinal embolism), assessed by relative risk;
- Cardiovascular behavioural risk factor (e.g. smoking, exercise, alcohol consumption), modification and adoption of health-promoting behaviours (e.g. adherence to medication), assessed as a dichotomous outcome for all risk factors overall;
- Health economics, i.e. the financial gain to the health service by intervening, assessed by the analysis of the costs for the treatment;
- Cardiovascular mortality, assessed by relative risk;
- All-cause mortality, assessed by relative risk.

Where studies included composite outcomes (e.g. non-fatal cardiovascular events) or outcomes related to cardiac behavioural


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risk factors (e.g. smoking, physical activity), efforts were made to present them as individual outcomes, based on the availability of the data. If the study did not report sufficient data on the individual outcomes, we contacted the study author and asked them to provide these details, if available.

We originally planned to assess the results of the included studies at the longest follow-up available; however, due to the limited number of included studies, we decided to assess the outcomes at two separate follow-up periods (3-month and 12-month), based on the availability of the data for the studies included in the meta-analyses.

## Search methods for identification of studies

### Electronic searches

We updated the search from the previously published Cochrane Review by searching the following bibliographic databases (Lane 2013).

- Cochrane Central Register of Controlled Trials (CENTRAL; 2023, Issue 2) in the Cochrane Library (searched 7 March 2023)
- MEDLINE OVID (1946 to 6 March 2023)
- Embase OVID (1980 to 2023 week 09)
- PsycINFO OVID (1806 to February week 3, 2023)
- BIOSIS Clarivate Analytics (1926 to 7 March 2023)
- CINAHL EBSCOhost (1973 to 7 March 2023)
- Conference Proceedings Citation Index – Science (CPCI-S) on Web of Science (Clarivate Analytics; 1990 to 7 March 2023)

We also searched Clinical trials.gov (www.clinicaltrials.gov) and the World Health Organisation (WHO) International Clinical Trials Registry platform (ICTRP) (apps.who.int/trialsearch/) on 12 February 2021, for ongoing or unpublished trials.

Details of the search strategy can be found in Appendix 1.

For the previous review, we searched the Database of Reviews of Effectiveness in the Cochrane Library (2013, Issue 1). We did not update this search as DARE is no longer updated (Appendix 2).

We searched all electronic databases, using a strategy that combined selected MeSH terms and free text terms relating to people with congenital heart disease, and terms relating to psychological therapies.

We used the Cochrane sensitivity-maximising RCT filter for MEDLINE and for Embase, using terms recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2022). Adaptations of this filter were applied to CINAHL, BIOSIS, and PsycINFO. Papers were not excluded on the basis of language. We searched reference lists of all relevant papers resulting from the electronic database to identify other potentially relevant articles.

The reporting of search results was conducted in accordance with PRISMA (Page 2021). Information about the number of studies identified, included and excluded, and the reasons for exclusion are summarising using a flow diagram (Figure 1).


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**Figure 1. Flow diagram for study selection**

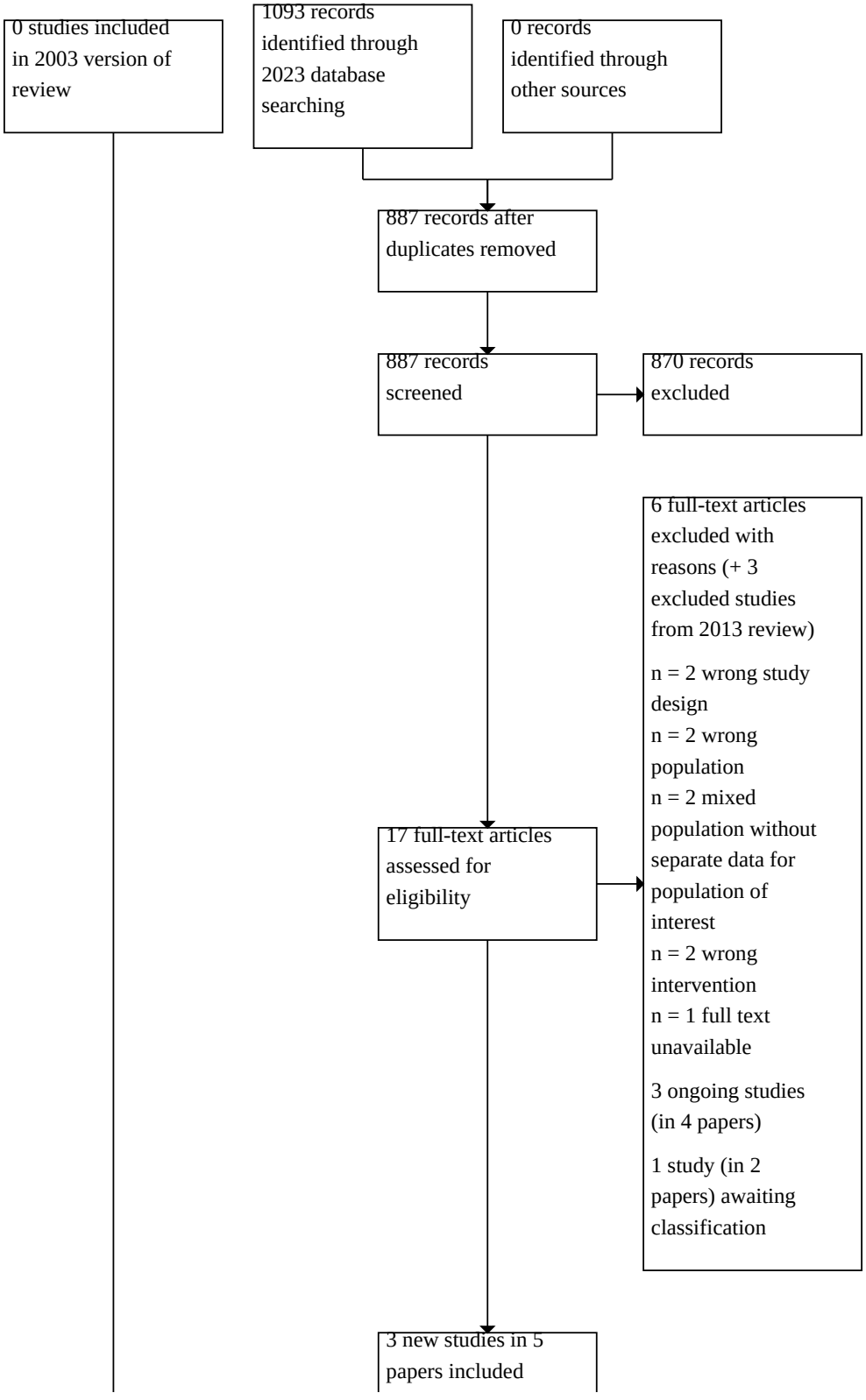



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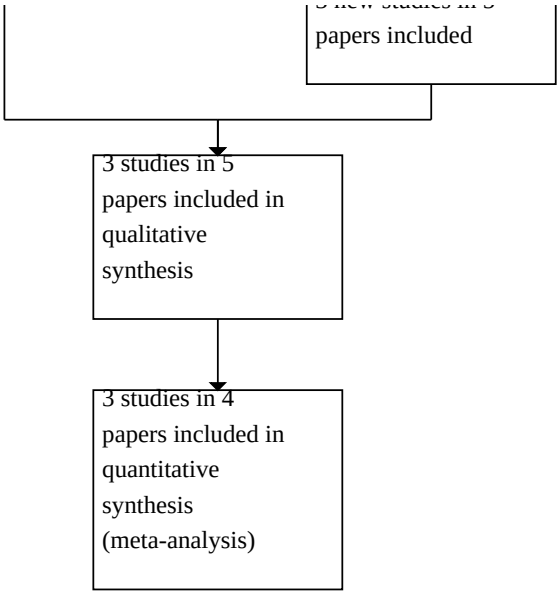
**Figure 1. (Continued)**




#### Searching other resources

For the original review, we handsearched dissertation abstracts (from the Radcliffe Science Library, University of Oxford), and abstracts from the European Society of Cardiology meetings, the American College of Cardiology meetings, and the Royal College of Psychiatrists Annual Meeting, all from 2002 and 2008. These are now covered by the electronic search of the Conference Proceedings Citation Index – Science (CPCI-S) on Web of Science.

### Data collection and analysis

#### Selection of studies

Two review authors (DGL, UI) independently selected suitable studies for inclusion/exclusion, with any disagreements resolved by discussion and recourse to a third reviewer (DAL), as necessary. We documented all rejected papers and the reasons for exclusion.

For the first round, we screened titles and abstracts of reports identified in the searches (databases, reference checking, personal communications, etc), discarding those that clearly did not meet our inclusion criteria. We retrieved the full-text papers for all remaining titles and abstracts that we deemed potentially relevant. All papers in languages other than English were translated/reviewed by someone who spoke the language. Two review authors then independently reviewed these articles to assess their relevance for inclusion.

#### Data extraction and management

For the 2023 review, two review authors (DGL, UI) independently undertook the data extraction, using a predefined form. Disagreements were resolved by consensus and by recourse to a third review author (DAL). If necessary, we contacted study authors for further information.

Data extracted included:

- Participant characteristics - number of participants, age, sex, ethnicity, and type of congenital heart disease;
- Type of depression - clinical diagnosis of major or minor depression, or depressive symptomatology assessed by questionnaire. Type of assessment tool used to assess depression e.g. Beck Depression Inventory, Zung Depression Scale, Hospital Anxiety and Depression Scale, structured interview, DSM-IV criteria. Cutoff used on depression scale, percentage of people defined as depressed/non-depressed on this basis, mean (standard deviation (SD))/median (interquartile range) depression value;
- Type of intervention - cognitive behavioural therapy, psychotherapy, talking/counselling therapy, no intervention versus psychological intervention; usual care versus psychological intervention; and 'attention placebo' versus psychological intervention. Details of the intervention; who delivered the intervention, individual or group sessions, number of sessions, etc.;
- Type of outcomes – all outcomes planned and reported by the trial, which may include: level of depression at baseline, and at subsequent follow-ups, acceptability of treatment, quality of life, number of hospital re-admissions, non-fatal cardiovascular events, reduction of cardiovascular behavioural risk factors, health economics, and death (cardiovascular and all-cause mortality);
- Timing of follow-up – all follow-up periods available after the end of the intervention.

Where included trials reported mixed participants (e.g. participants from different age groups, of which only a part matched the age criteria for inclusion), we contacted the study author to check for availability of a separate dataset and analyses for the group of interest. When it was not possible to obtain this information, the study was only included if the proportion of the population of interest constituted 80% or more of the entire study population.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We planned to conduct a sensitivity analysis to assess the impact of including studies with mixed populations, if enough data were available.

When continuous data were presented from different scales, rating the same effect, we presented both sets of data and inspected the general direction of the effect. We reported the mean and standard deviation or median and interquartile range (as appropriate). When these data were not reported in the paper, we contacted the lead author in an attempt to obtain this missing information. Where possible, we calculated these data using other measures of variation that were reported, such as the confidence intervals.

### Assessment of risk of bias in included studies

Risk of bias for the outcome of depression was assessed independently by two review authors, using the RoB 2 tool (Higgins 2022). Overall risk of bias was determined following the tool algorithm. Any disagreement was resolved by consensus or by recourse to a third review author. If necessary, we contacted the study authors for further information. We assessed the following risk of bias domains.

- Bias arising from the randomisation process
- Bias due to deviations from intended interventions
- Bias due to missing outcome data
- Bias in measurement of the outcome
- Bias in selection of the reported result

We planned to use a dedicated version of the RoB 2 tool to assess cluster-RCTs if any were identified, which includes the additional domain:

- Risk of bias arising from the timing of identification or recruitment of participants in a cluster-randomised trial.

We assessed the risk of bias in each domain as low risk, some concerns, or high risk, based on the effect of assignment to the intervention at baseline (intention-to-treat effect). Supporting information for decisions was added to the risk of bias table. We used the Excel tool (available on the RoB 2 website) to manage the assessment of bias for each study. Outcomes assessed for risk of bias are reported in the summary of findings table.

### Measures of treatment effect

We used mean difference (MD) for continuous outcomes. We planned to use standardised mean difference (SMD) when studies reported continuous outcomes assessed with different measurement tools. We planned to interpret SMD using Cohen's effect, which suggests a score < 0.40 represents a small effect, a score from 0.40 to 0.70 a moderate effect, and a score > 0.70 a large effect (Cohen 1988).

We converted continuous outcome measures to dichotomous data when possible and appropriate, re-expressing odds ratio (OR) as standardised mean difference as per the *Cochrane Handbook* guidelines. Categorical data were reported using counts and percentages.

For the outcome of depression, we used the authors' designated cutoff point for determining clinical effectiveness where appropriate, or identified validated cutoffs on rating scales from the literature, and divided participants on the basis of whether they had clinically improved or not clinically improved. For dichotomous outcomes, we estimated a Mantel-Haenszel odds ratio with its associated 95% confidence intervals (CI). As a summary measure of effectiveness, when possible, we calculated the number needed to treat for an additional beneficial outcome (NNTB).

If any of the included trials reported a mixture of change from baseline values and post-intervention values, we combined these data in a meta-analysis, as per *Cochrane Handbook* guidelines (section 10.5.2). Separate group analyses were performed, grouping trials that reported post-intervention values, and trials that reported changes from baseline values.

### Unit of analysis issues

No cluster-randomised trials were found.

For trials with more than two arms that included the treatment of interest, we planned to combine the treatment arms for the main analysis and compare them with the control arm to examine the overall effect; this was to avoid double counting the participants. For dichotomous outcomes, we combined the sample size and number of people with events. For continuous outcomes, we combined the mean and standard deviation, using the formula for combining summary statistics across two groups, as per the *Cochrane Handbook* section 6.6.

### Dealing with missing data

Where possible, we made no attempt to impute missing data. We contacted the author(s) of the included studies to obtain any missing data, when possible. If we had no success in obtaining missing data from the authors, we inputted missing data, using the *Cochrane Handbook* guidelines. Data reported as mean (standard error (SE)) were converted to mean (SD) using the RevMan Excel calculator available at training.cochrane.org/resource/revman-calculator. When data were only presented as mean, without SD, we calculated the missing SD using the correlation coefficient calculated, as per *Cochrane Handbook* (section 6.5.2.8) guidelines.

### Assessment of heterogeneity

We checked for differences between the results of each included trial, using a test for heterogeneity. Heterogeneity was assessed visually and using the $I^2$ statistic: 0% to 40% may be considered not important, 30% to 60% may represent moderate heterogeneity, 50% to 90% may represent substantial heterogeneity; 75% to 100% may represent considerable heterogeneity (as per section 10.10.2 of the *Cochrane Handbook*). If there was statistically significant heterogeneity ($I^2 > 50\%$), we planned to present the data separately, rather than pool them.

### Assessment of reporting biases

There were not enough studies in this review to test for reporting bias. However, should we include 10 or more in future versions, we will enter data from all included trials into a funnel plot (size of study versus effect size based on the primary outcome of change in depression pre-/post-intervention) to attempt to detect the possibility of publication bias (Egger 1997). Asymmetry of the funnel plot may indicate publication bias. We will also assess other possible causes of asymmetry of the funnel plot, such as clinical or methodological heterogeneity, or both.


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### Data synthesis

We undertook meta-analysis, using RevMan Web, only when this was meaningful, i.e. if the treatments, participants, and underlying clinical questions were similar enough for pooling to make sense (RevMan Web 2023). Where there was significant heterogeneity ($I^2$ > 50%), we used a random-effects model, attempting to explore the reasons for this heterogeneity in subgroup analyses.

### Subgroup analysis and investigation of heterogeneity

We investigated factors that may lead to differences between the results of individual studies, using subgroup analyses. We planned to investigate:

- differences between studies that defined depression operationally (clinician diagnosis or validated questionnaire) and not operationally;
- differences between well-defined and less well-defined psychological interventions;
- differences in intervention results between adolescents and adults.

Well-defined psychological interventions were intended as psychological interventions for which the theoretical basis was consolidated for their use in treating mental health disorders in clinical practice. Examples of interventions consolidated for treating mental health in clinical practice are cognitive behavioural therapy or psychotherapy; less well-defined psychological interventions were intended as psychological interventions for which the theoretical bases are not consolidated, and thus, are not evidence-based treatments (Lee 2015). An example of a less well-defined intervention is thought field therapy.

We will undertake a subgroup analysis for the three different psychological interventions when sufficient data are available (cognitive behavioural therapy versus control; psychotherapy versus control; and talking therapy versus control).

If sufficient data were available, we planned another subgroup analysis by age: adolescents only (10 to17 years); adults only (aged 18+ years). In studies that included a mixed population (e.g. both children and adolescents), we planned to undertake a subgroup analysis by age if sufficient data were available. When insufficient data were present, we contacted the study author(s) and asked for additional data on outcomes divided by age group.

Additional influences on the intervention, such as factors that may affect the outcome results (e.g. who delivered the intervention, length of the intervention) were also considered for possible subgroup analyses.

### Sensitivity analysis

We planned to perform sensitivity analyses based on risk of bias in the included studies (i.e. removing high risk of bias studies from the main analysis).

### Summary of findings and assessment of the certainty of the evidence

We created a summary of findings table with the main outcomes (reduction in depression, and depression score). We used the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) to assess the quality of the body of evidence as it related to the studies that contributed data to the meta-analyses for these outcomes. We used methods and recommendations described in Section 8.5 and Chapters 12, 14, and 15 of the *Cochrane Handbook* (Higgins 2022). We justified all decisions to downgrade the quality of studies using footnotes, and we made comments to aid the reader's understanding of the review where necessary. We used RoB 2 to support the certainty of evidence, as described in Section 14.2.2 of the *Cochrane Handbook* (Higgins 2022).

## RESULTS

### Description of studies

#### Results of the search

No studies were included in the previous review.

For the updated 2023 review, the database searches identified 1093 papers. After duplicates were removed, 887 records were left. After independent screening of the titles and abstracts by two reviewers (DGL and UI), 870 papers were determined ineligible. The full text of the 17 remaining papers was retrieved and screened against the inclusion/exclusion criteria, resulting in the inclusion of five (29%) papers describing three studies (Gotink 2017; Kovacs 2018; Rönning 2014; Figure 1). Three ongoing studies (in four papers) were identified (Moon 2021b; NCT04738474; Wells 2021). One study (in two papers) is awaiting classification (Moon 2021). We excluded six papers.

#### Included studies

The three included studies were published in 2014 (Rönning 2014), 2017 (Gotink 2017), and 2018 (Kovacs 2018), with sample sizes ranging from 42 (Kovacs 2018), to 324 participants (Gotink 2017), for a total sample size of 480 participants. All studies reported on adult populations only, with the mean age ranging from 32.8 (Kovacs 2018), to 43.3 years (Gotink 2017), and the proportion of males varying from 50% (Kovacs 2018), to 56% (Gotink 2017). Two studies only included participants with congenital heart disease (with defect complexity ranging from simple to moderate (Kovacs 2018; Rönning 2014)), while one study included a mixed population with several cardiac diseases (e.g. valvular heart disorder; pacemaker; etc (Gotink 2017)). We contacted the study author who provided the relevant data for the participants with congenital heart disease (Gotink 2017). Included studies were conducted in Canada (Kovacs 2018), the Netherlands (Gotink 2017), and Sweden (Rönning 2014).

Gotink 2017 used a mindfulness-based stress reduction (MBSR) technique, which included meditation, yoga, and present moment awareness exercises. Kovacs 2018 used cognitive behavioural therapy (CBT) techniques, while Rönning 2014 provided a single educational session using virtual learning. Length of the intervention ranged from 90 minutes (Rönning 2014), to 12 weeks (Gotink 2017). Follow-up periods ranged from 3 months (Kovacs 2018; Rönning 2014), to 12 months (Gotink 2017; Rönning 2014).

All included studies compared the intervention to usual care, which consisted of routine appointments with their general practitioner (GP), or outpatient clinics with their healthcare team.

All included studies reported symptoms of depression and anxiety using the Hospital Anxiety (HADS-A) and Depression (HADS-D) Scale. Two studies reported changes in quality of life using the


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SF-36 (Gotink 2017), SF-12 (Kovacs 2018), and visual analogue scales (Gotink 2017; Kovacs 2018).

#### Excluded studies

We excluded nine studies in total (Campbell 1995; Freedenberg 2017; Goldbeck 2011; Kendall 2011; Moon 2017; Pereira 1995; Tulloh 2018; Wang 1996; Weiss 1992), six of which were excluded for this updated review (Campbell 1995; Freedenberg 2017; Goldbeck 2011; Kendall 2011; Moon 2017; Tulloh 2018). The summary of the reasons for exclusion can be found in the Characteristics of excluded studies: two studies had an inappropriate study design; two studies were in an ineligible population; two studies had mixed populations (> 20%) and we were unable to obtain the dataset for the congenital heart disease participants alone from the study authors; two studies were of ineligible interventions; and the full-text of one study was not available.

### Risk of bias in included studies

A summary of the risk of bias assessment for the included papers can be found in the Risk of bias table for Analysis 1.1; and in the Risk of bias table for Analysis 1.2. We assessed all included studies at an overall low risk of bias for the main outcome (depression). We assessed one study at high risk of bias for the outcome of quality of life, due to the use of multiple eligible scale measurement tools (Gotink 2017).

### Effects of interventions

See: **Summary of findings 1** Psychological intervention versus usual care for depression in people with congenital heart disease

#### Psychological intervention versus usual care

##### *Primary outcomes*

###### Reduction in depression

All three included studies assessed depression (HADS-D scores) and were included in the meta-analysis.

Psychological interventions may reduce depression compared to usual care at 3-month follow-up (mean difference (MD) -1.07, 95% confidence interval (CI) -1.84 to -0.30; P = 0.006; $I^2$ = 0%; 2 studies, 156 participants; low-certainty evidence; Analysis 1.1), and at 12-month follow-up (MD -1.02, 95% CI -1.92 to -0.13; P = 0.02; $I^2$ = 0%; 2 studies, 287 participants; low-certainty evidence; Analysis 1.2).

##### *Secondary outcomes*

###### Acceptability of treatment

None of the included studies reported this outcome.

###### Quality of life

Two studies reported changes in the quality of life. However, they did not have comparable follow-up times, and we did not pool their results in a meta-analysis (Gotink 2017; Kovacs 2018). A narrative synthesis is reported below.

One study (324 participants) measured quality of life after a 12-week psychological intervention (MBSR) and a 12-month follow-up (Gotink 2017). The results for quality of life were inconclusive between groups at 12-month follow-up (MBSR MD 0.5 (SD 12.6); usual care MD 2.3 (SD 12.7); P = 0.288).

One study (42 participants) reported quality of life after a two-month psychological intervention (MBSR) and a three-month follow-up (Kovacs 2018). The results for quality of life were inconclusive between groups at three-month follow-up (MBSR MD 1.3 (SD 12), usual care MD 6.2 (SD 20); P = 0.43).

###### Hospital re-admission related to congenital heart disease abnormality

None of the included studies reported this outcome.

###### Non-fatal cardiovascular events

None of the included studies reported this outcome.

###### Cardiovascular behavioural risk factor

None of the included studies reported this outcome.

###### Health economics

None of the included studies reported this outcome.

###### Cardiovascular mortality

None of the included studies reported this outcome.

###### All-cause mortality

None of the included studies reported this outcome.

##### *Subgroup/sensitivity analyses*

We did not undertake subgroup or sensitivity analyses due to the low number of included studies.

## DISCUSSION

### Summary of main results

This updated review assessed the effects of psychological interventions on depression in adults and adolescents with congenital heart disease. The previous version of this review did not find any relevant studies (Lane 2013). We identified nine studies (in 10 reports), published over the last nine years, which investigated the impact of psychological interventions on depression in this population (Freedenberg 2017; Gotink 2017; Kovacs 2015; Kovacs 2018; Moon 2017; Moon 2021; Rönning 2014; Tulloh 2018; Wells 2021); three of which (in five reports) met our inclusion criteria (Gotink 2017; Kovacs 2018; Rönning 2014).

Psychological interventions may reduce depression in adults with congenital heart disease compared to usual care. However, the certainty of the evidence is low. Due to the paucity of studies, further research in larger cohorts is required to fully elucidate the impact of psychological interventions on depression and other outcomes.

### Overall completeness and applicability of evidence

We only identified three studies that met the inclusion criteria for this review. Only studies involving adults were identified. The interventions in the included studies varied, and the certainty of the evidence for our primary outcome was low. There was insufficient evidence to draw any conclusions about the impact of psychological interventions on quality of life, and none of the included studies reported on our other outcomes of interest.


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### Quality of the evidence

Several limitations are noteworthy. Included studies presented different durations of the intervention, length and frequency of the therapy sessions, and length of follow-up. It may be relevant to note that depression was the primary outcome in only one included study (Kovacs 2018), while the other two studies reported depression as a secondary outcome (Gotink 2017; Rönning 2014).

Certainty of the evidence for depression was low due to differences in interventions among studies, which may impact applicability.

### Potential biases in the review process

Potential biases in the review process arise from the paucity of the data, which impacts the applicability of the findings. Only a few studies addressed the topic, and we did not have enough data to conduct subgroup and sensitivity analyses. When we could not find the full text of studies that were potentially eligible, we contacted the authors; however, we had to exclude studies when we did not obtain a response. Some identified studies reported data from a mixed population, and despite our attempts to obtain the raw data from the authors on the participants with congenital heart disease, to enable us to include them, we did not obtain a response, and we had to exclude these studies from the analysis.

### Agreements and disagreements with other studies or reviews

Current American Heart Association/American College of Cardiology guidelines suggest that people with congenital heart disease should be assessed for symptoms of depression (ACC/AHA 2018). The meta-analyses showed improvements in depression (assessed with the Hospital Anxiety and Depression Scale (HADS-D)) at 3- and 12-month follow-up, suggesting a beneficial impact of psychological interventions to treat depression in the congenital heart disease population. All pooled studies used a talking/counselling therapy approach (e.g. cognitive behavioural therapy, mindfulness-based stress reduction (MBSR)), which has proven effectiveness in treating depression in people affected by other heart diseases (non-congenital, e.g. heart failure, atrial fibrillation) as reported in a previous scoping review (Zambrano 2020). Psychotherapy also appears to be considered positively by those with congenital heart disease, who are keen to access psychological treatments and peer-support (Kovacs 2009). An excluded randomised two-group study, comprising a mixed cohort of 46 participants with congenital heart disease (52% of the participants) and other heart diseases, did not find that MBSR reduced the level of depression after a six-week intervention, which contrasts with the results of this review; however, the study was underpowered (Freedenberg 2017).

Quality of life was not assessed consistently among the included studies, and the use of different scales to assess this outcome meant we were unable to directly compare the results. However, when taken individually, studies that investigated the impact of a psychological intervention on quality of life did not report any significant difference in quality of life post-intervention (Gotink 2017; Kovacs 2018). It is well established that people with congenital heart disease report a lower quality of life, which is often affected by depression symptoms (Gleason 2019).

## AUTHORS' CONCLUSIONS

### Implications for practice

Current, low-certainty evidence suggests a positive impact of psychological interventions on depression for adults with congenital heart disease. There was insufficient evidence to draw conclusions about the impact of psychological interventions (e.g. talking/counselling therapy) on quality of life. None of the included studies reported on our other outcomes of interest.

### Implications for research

The current review showed a clear lack of studies focusing on the role that psychological interventions have in reducing symptoms of depression in adolescents and adults with congenital heart disease, making it evident that further research is needed to establish the role that these interventions may have in this population. It is important to define the optimal length, method of administration, and number of sessions required to obtain the most benefit. More randomised controlled trials (RCTs) should investigate the effects that psychological interventions (e.g. mindfulness) have in reducing symptoms of depression in this population compared to usual care. In addition, RCTs should compare the effectiveness of one treatment over another (e.g. mindfulness versus talking therapy) to establish which treatment is more effective in treating symptoms of depression in adolescents and adults with congenital heart disease. To properly assess effectiveness of treatment, it should be delivered by qualified professionals (e.g. psychologist), and for an appropriate length of time (e.g. a minimum of six to eight sessions). Studies should also have appropriate follow-up (e.g. at least six months after the end of the intervention) to determine the longer-term effect of the treatment. Finally, studies should evaluate the effect of treatments on both adolescents and adults, in order to identify differences between the two groups and inform clinical guidelines.

We identified one ongoing study that aims to address the effectiveness of psychological interventions in reducing symptoms of depression in adults with congenital heart disease. It is clear that to have appropriate evidence to inform guidelines on this topic, further studies are required.

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* Indicates the major publication for the study

# CHARACTERISTICS OF STUDIES

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

### Gotink 2017

| ***Study characteristics*** | |
|---|---|
| Methods | Single blinded pragmatic RCT |
| Participants | 324 adults aged 18 to 65 years (mean age 43.2 years SD ± 14.1 years) with existing diagnosed heart disease (ischaemic, valvular, congenital, cardiomyopathy) randomised into 2 groups: intervention (N = 215) and comparator (N = 109) |


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**Gotink 2017** *(Continued)*

| | |
|---|---|
| Interventions | A 12-week online training in MBSR (meditation, yoga, present moment awareness of body sensations and thoughts, and cognitive reappraisal) in addition to standard care<br><br>Comparison: usual care (no specific details)<br><br>Follow-up: 12 months |
| Outcomes | Primary outcome(s): exercise capacity (6-minute walk test)<br><br>Secondary outcome(s): blood pressure, heart rate, respiratory rate, NT-proBNP, cortisol levels (scalp hair sample), mental and physiological functioning (SF-36), anxiety and depression (HADS), perceived stress (PSS), and social support (PSSS12). |
| Notes | Funding: Gotink, Younge, Roos-Hesselink and Hunink were supported by an internal grant from the Erasmus Medical Center<br><br>Competing Interests: none<br><br>Country: Netherlands |

**Kovacs 2018**

| ***Study characteristics*** | |
|---|---|
| Methods | 2-parallel arm non-blinded pilot RCT |
| Participants | 42 adults (mean age 32.8 years SD ± 11.8 years) with documented CHD, and a HADS score ≥ 8, randomly allocated to the intervention group (N = 21) and to the control group (N = 21) |
| Interventions | 90-minute weekly sessions of the ACHD-CARE program per 8 weeks. Participants in the intervention group were divided into groups of 4 to 6 participants each. In addition, they received weekly handouts and homework to reinforce the strategies learned<br><br>Comparison: usual care (no specific details)<br><br>Follow-up: 3 months |
| Outcomes | Main outcome(s): self-reported scores on anxiety and depression (HADS-A and HADS-D scores); QoL (Satisfaction with Life Scale, SF-12 v2, VAS scale)<br><br>Secondary outcome(s): to determine the feasibility of a large RCT assessing recruitment and retention; resources used and management; intervention acceptability; scientific outcomes (treatment fidelity and adverse events) |
| Notes | Funding: Canadian Institutes of Health Research (Operating Grant Number 123251)<br><br>Competing Interests: none<br><br>Country: Canada |

**Rönning 2014**

| ***Study characteristics*** | |
|---|---|
| Methods | Prospective randomized controlled design |


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**Rönning 2014** *(Continued)*

| | |
|---|---|
| Participants | 114 adults participants with CHD (mean age 34 years, SD 13.5 years), randomly assigned to intervention group (N = 56) and to control group (N = 58) |
| Interventions | Individualized care by face-to-face psycho-education by the multidisciplinary team consisted of a visit (90 minutes) to the physician/nurse and a 1-month follow-up by telephone.<br><br>Comparator: usual care (including a visit to a specialised cardiologist with clinical evaluations and/or echocardiography and/or exercise tests)<br><br>Follow-up: 3 and 12 months |
| Outcomes | Main outcome(s): the Knowledge Scale for Adults with Congenitally Malformed Hearts (KnoCoMH)<br><br>Secondary Outcome(s): the Control Attitudes Scale (CAS) to measure perceived control over the cardiac condition; Hospital Anxiety and Depression Scale (HADS) to measure symptoms of anxiety and depression |
| Notes | Funding: Grants from The Research Council in South-East Sweden (FORSS), Heart-Lung Foundation and Östergötland County Council<br><br>Conflict of interest: none<br><br>Country: Sweden |

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

| Study | Reason for exclusion |
|---|---|
| Campbell 1995 | Wrong population |
| Freedenberg 2017 | Results from mixed population (> 20%) |
| Goldbeck 2011 | Not a randomised controlled trial. The population are children aged 4 to 17 years with congenital heart disease, cancer, or cystic fibrosis (plus their families) who were consecutively enroled in a 4-week family-oriented inpatient rehabilitation programme. 75 children have congenital heart disease (CHD) but the mean (SD) age is 7.8 (3.4) years and therefore, the participants are too young. |
| Kendall 2011 | Intervention was exercise and lifestyle advice; no psychological intervention or assessment of depression. |
| Moon 2017 | Results are from mixed population (i.e. not only CHD population): author was contacted seeking raw data but no answer received. |
| Pereira 1995 | Wrong intervention |
| Tulloh 2018 | The study was not powered to identify clinically important differences between intervention and treatment as usual, but aimed to determine response rates and whether a future trial would be possible. |
| Wang 1996 | Full text not available |
| Weiss 1992 | Clinical trial but studied infants |

yrs: years; CHD: congenital heart disease


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

**Moon 2021**

| | |
|---|---|
| Methods | Randomised control trial |
| Participants | 42 adults with congenital heart disease (N = 21 intervention group; N = 21 control group) |
| Interventions | 8-weeks of Rational Emotive Behavior Therapy (REBT) |
| Outcomes | Hamilton Depression Rating Scale, Beck Depression Inventory, Shorten General Attitude and Belief Scale, and salivary cortisol levels |
| Notes | |

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

**Moon 2021b**

| | |
|---|---|
| Study name | Psychosocial and cardiac rehabilitation program and adults with congenital heart disease |
| Methods | RCT |
| Participants | Adults (18 to 23 years old) with Fontan procedure |
| Interventions | psychosocial and cardiac rehabilitation program |
| Outcomes | Primary: heart rate variability<br>Secondary: self-efficacy, symptom limited exercise test, physical activity<br>depression and anxiety, disease-related knowledge |
| Starting date | |
| Contact information | |
| Notes | |

**NCT04738474**

| | |
|---|---|
| Study name | Assessing and promoting resilience in patients with adult congenital heart disease (PRISM ACHD) |
| Methods | RCT |
| Participants | adults with congenital heart disease |
| Interventions | Promoting Resilience in Stress Management (PRISM) intervention |
| Outcomes | Primary: study feasibility<br>Secondary: resilience, quality of life, psychological distress, competence in managing healthcare |
| Starting date | |


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**NCT04738474** *(Continued)*

| | |
|---|---|
| Contact information | |
| Notes | |

**Wells 2021**

| | |
|---|---|
| Study name | Improving the effectiveness of psychological interventions for depression and anxiety in cardiac rehabilitation: PATHWAY - a single-blind, parallel, randomized, controlled trial of group metacognitive therapy |
| Methods | Multicentre, two-arm, single-blind, randomised controlled trial |
| Participants | Adults undergoing cardiac rehabilitation with elevate anxiety, depressive symptoms, or both |
| Interventions | Six weekly sessions of group-based metacognitive therapy delivered by either cardiac rehabilitation professionals or research nurses. |
| Outcomes | The primary outcome was severity of anxiety and depressive symptoms at 4-month follow-up, measured by the Hospital Anxiety and Depression Scale total score.<br><br>Secondary outcomes were individual Hospital Anxiety and Depression Scales, traumatic stress symptoms, and psychological mechanisms, including metacognitive beliefs and repetitive negative thinking. |
| Starting date | 2015 |
| Contact information | Adrian Wells<br><br>School of Psychological Sciences, Faculty of Biology, Medicine and Health, Rawnsley Building, Manchester Royal Infirmary, The University of Manchester, Oxford Road, Manchester M13 9WL, UK; and Greater Manchester Mental Health NHS Foundation Trust, Rawnsley Building, Manchester Royal Infirmary, Oxford Road, Manchester M13 9WL, UK<br><br>E-mail: adrian.wells@manchester.ac.uk |
| Notes | |

## RISK OF BIAS

**Legend:** Low risk of bias | High risk of bias | Some concerns

**Risk of bias for analysis 1.1 Mean difference in HADS-D scores at 3-month follow-up**

| | Bias | | | | | |
|---|---|---|---|---|---|---|
| **Study** | **Randomisation process** | **Deviations from intended interventions** | **Missing outcome data** | **Measurement of the outcome** | **Selection of the reported results** | **Overall** |
| Kovacs 2018 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |


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

**Risk of bias for analysis 1.2 Mean difference in HADS-D scores at 12-month follow-up**

| | Bias | | | | | |
|---|---|---|---|---|---|---|
| **Study** | **Randomisation process** | **Deviations from intended interventions** | **Missing outcome data** | **Measurement of the outcome** | **Selection of the reported results** | **Overall** |
| Gotink 2017 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Rönning 2014 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

## DATA AND ANALYSES

### Comparison 1. Depression scores

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1.1 Mean difference in HADS-D scores at 3-month follow-up | 2 | 156 | Mean Difference (IV, Random, 95% CI) | -1.07 [-1.84, -0.30] |
| 1.2 Mean difference in HADS-D scores at 12-month follow-up | 2 | 287 | Mean Difference (IV, Random, 95% CI) | -1.02 [-1.92, -0.13] |


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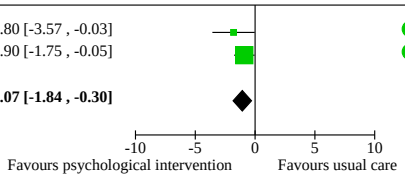
## Analysis 1.1. Comparison 1: Depression scores, Outcome 1: Mean difference in HADS-D scores at 3-month follow-up

| Study or Subgroup | Psychological intervention Mean | SD | Total | Usual care Mean | SD | Total | Weight | Mean Difference IV, Random, 95% CI |
|---|---|---|---|---|---|---|---|---|
| Kovacs 2018 | -1.7 | 2.5 | 21 | 0.1 | 3.3 | 21 | 18.9% | -1.80 [-3.57 , -0.03] |
| Rönning 2014 | -0.7 | 2.8 | 56 | 0.2 | 1.7 | 58 | 81.1% | -0.90 [-1.75 , -0.05] |
| **Total (95% CI)** | | | **77** | | | **79** | **100.0%** | **-1.07 [-1.84 , -0.30]** |

Heterogeneity: Tau² = 0.00; Chi² = 0.81, df = 1 (P = 0.37); I² = 0%
Test for overall effect: Z = 2.73 (P = 0.006)
Test for subgroup differences: Not applicable



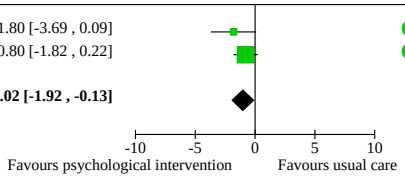

Risk of Bias: A B C D E F

**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: Depression scores, Outcome 2: Mean difference in HADS-D scores at 12-month follow-up

| Study or Subgroup | Psychological intervention Mean | SD | Total | Usual care Mean | SD | Total | Weight | Mean Difference IV, Random, 95% CI |
|---|---|---|---|---|---|---|---|---|
| Gotink 2017 | -1.8 | 7.42 | 64 | 0 | 2.81 | 109 | 22.4% | -1.80 [-3.69 , 0.09] |
| Rönning 2014 | -0.6 | 3 | 56 | 0.2 | 2.5 | 58 | 77.6% | -0.80 [-1.82 , 0.22] |
| **Total (95% CI)** | | | **120** | | | **167** | **100.0%** | **-1.02 [-1.92 , -0.13]** |

Heterogeneity: Tau² = 0.00; Chi² = 0.83, df = 1 (P = 0.36); I² = 0%
Test for overall effect: Z = 2.24 (P = 0.02)
Test for subgroup differences: Not applicable




Risk of Bias: A B C D E F

**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

# APPENDICES

## Appendix 1. Search strategy 2023

### CENTRAL

#1 MeSH descriptor: [Heart Defects, Congenital] explode all trees

#2 congenital* near/6 heart

#3 congenital* near/6 cardiac

#4 heart near/6 malform*

#5 cardiac near/6 malform*

#6 heart near/6 defect*

#7 cardiac near/6 defect*

#8 coarctation near/6 aort*

#9 septal near/6 defect*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#10 septum near/6 defect*

#11 patent next ductus next arteriosus

#12 transposition near/6 arteries

#13 transposition near/6 vessels

#14 guch

#15 fallot* near/6 tetralogy

#16 (#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)

#17 MeSH descriptor: [Psychotherapy] explode all trees

#18 MeSH descriptor: [Counseling] explode all trees

#19 cognitive* near/3 therap*

#20 behavi* near/3 therap*

#21 psychotherap*

#22 psycho-therap*

#23 talk*

#24 counsel*

#25 psycholog* near/3 treat*

#26 psycholog* near/3 intervent*

#27 psycholog* near/3 therap*

#28 psycholog* near/3 manag*

#29 MeSH descriptor: [Patient Education as Topic] this term only

#30 MeSH descriptor: [Depressive Disorder] explode all trees

#31 MeSH descriptor: [Depression] this term only

#32 depression

#33 depressive

#34 #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

#35 #16 and #34 Date added to CENTRAL trials database: 05/02/2013-14/12/2020

**MEDLINE OVID**

1. exp Heart Defects, Congenital/

2. exp Heart Diseases/cn [Congenital]

3. (congenital* adj3 heart).tw.

4. (congenital* adj3 cardiac).tw.

5. heart defect*.tw.

6. guch.tw.

7. (coarctation adj3 aorta*).tw.

8. (septal adj3 defect*).tw.


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9. patent ductus arteriosus.tw.

10. (transposition adj3 arteries).tw.

11. (transposition adj3 vessels).tw.

12. (fallot* adj3 tetralogy).tw.

13. or/1-12

14. exp Psychotherapy/

15. exp Counseling/

16. counsel*.tw.

17. psychotherap*.tw.

18. (cognitive adj3 therap*).tw.

19. (behavi* adj3 therap*).tw.

20. talk*.tw.

21. (psycholo* adj3 (intervent* or therap* or treat* or manage*)).tw.

22. Patient Education as Topic/

23. exp Depressive Disorder/

24. Depression/

25. or/14-24

26. 13 and 25

27. randomized controlled trial.pt.

28. controlled clinical trial.pt.

29. randomized.ab.

30. placebo.ab.

31. drug therapy.fs.

32. randomly.ab.

33. trial.ab.

34. groups.ab.

35. 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34

36. exp animals/ not humans.sh.

37. 35 not 36

38. 26 and 37

39. limit 38 to ed=20130205-20201214

**Embase OVID**

1. exp congenital heart disease/

2. exp heart disease/cn [Congenital Disorder]

3. (congenital* adj3 heart).tw.


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4. (congenital* adj3 cardiac).tw.

5. heart defect*.tw.

6. (coarctation adj3 aorta*).tw.

7. (septal adj3 defect*).tw.

8. patent ductus arteriosus.tw.

9. (transposition adj3 arteries).tw.

10. (transposition adj3 vessels).tw.

11. guch.tw.

12. (fallot* adj3 tetralogy).tw.

13. or/1-12

14. exp psychotherapy/

15. exp counseling/

16. counsel*.tw.

17. psychotherap*.tw.

18. (cognitive adj3 therap*).tw.

19. (behavi* adj3 therap*).tw.

20. talk*.tw.

21. (psycholo* adj3 (intervent* or therap* or treat* or manage*)).tw.

22. patient education/

23. exp depression/

24. or/14-23

25. 13 and 24

26. random$.tw.

27. factorial$.tw.

28. crossover$.tw.

29. cross over$.tw.

30. cross-over$.tw.

31. placebo$.tw.

32. (doubl$ adj blind$).tw.

33. (singl$ adj blind$).tw.

34. assign$.tw.

35. allocat$.tw.

36. volunteer$.tw.

37. crossover procedure/

38. double blind procedure/


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39. randomized controlled trial/

40. single blind procedure/

41. 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40

42. (animal/ or nonhuman/) not human/

43. 41 not 42

44. 25 and 43

45. limit 44 to dd=20130205-20201214

**PsycINFO**

1. congenital disorders/

2. heart disorders/

3. 1 and 2

4. (congenital* adj3 heart).tw.

5. (congenital* adj3 cardiac).tw.

6. heart defect*.tw.

7. guch.tw.

8. (coarctation adj3 aorta*).tw.

9. (septal adj3 defect*).tw.

10. patent ductus arteriosus.tw.

11. (transposition adj3 arteries).tw.

12. (transposition adj3 vessels).tw.

13. (fallot* adj3 tetralogy).tw.

14. or/3-13

15. exp Psychotherapy/

16. exp Counseling/

17. counsel*.tw.

18. psychotherap*.tw.

19. (cognitive adj3 therap*).tw.

20. (behavi* adj3 therap*).tw.

21. talk*.tw.

22. (psycholo* adj3 (intervent* or therap* or treat* or manage*)).tw.

23. client education/

24. exp Affective Disorders/

25. exp Neurosis/

26. or/15-25

27. 14 and 26


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28. limit 27 to up=20130205-20201214

**CINAHL**

S37 S18 AND S36

S36 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

S35 TX cross-over*

S34 TX crossover*

S33 TX volunteer*

S32 (MH "Crossover Design")

S31 TX allocat*

S30 TX control*

S29 TX assign*

S28 TX placebo*

S27 (MH "Placebos")

S26 TX random*

S25 TX (doubl* N1 mask*)

S24 TX (singl* N1 mask*)

S23 TX (doubl* N1 blind*)

S22 TX (singl* N1 blind*)

S21 TX (clinic* N1 trial?)

S20 PT clinical trial

S19 (MH "Clinical Trials+")

S18 S16 AND S17

S17 EM 2008-2013

S16 S7 AND S15

S15 S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14

S14 cognitive therapy

S13 depression

S12 psychotherapy

S11 counsel*

S10 (MH "Psychotherapy+")

S9 (MH "Counseling+")

S8 (MH "Affective Disorders+")

S7 S1 OR S2 OR S3 OR S4 OR S5 OR S6

S6 heart defect*

S5 septal n3 defect


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S4 fallot*

S3 congenital n3 cardiac

S2 congenital n3 heart

S1 (MH "Heart Defects, Congenital+")

**BIOSIS**

#10 #9 AND #8 Timespan: 2013-2020

# 9 TS=(random* or RCT or trial or groups)

# 8 #7 AND #6

# 7 TS=(depression or psychotherap* or counsel* or talk* or (cognitive same therap*))

# 6 #5 OR #4 OR #3 OR #2 OR #1

# 5 TS=(fallot* or "patent ductus" or (transposition NEAR/3 arteries) or (transposition NEAR/3 vessels) or guch)

# 4 TS=(septal NEAR/3 defect*)

# 3 TS=(congenital NEAR/3 cardiac)

# 2 TS=(heart NEAR/3 defect*)

# 1 TS=(congenital NEAR/3 heart)

**CPCI-S**

# 10 #9 AND #8 Timespan: 2013-2020

# 9 TS=(random* or blind* or allocat* or assign* or trial* or placebo* or crossover* or cross-over*)

# 8 #7 AND #6

# 7 TS=(depression or psychotherap* or counsel* or talk* or (cognitive same therap*))

# 6 #5 OR #4 OR #3 OR #2 OR #1

# 5 TS=(fallot* or "patent ductus" or (transposition NEAR/3 arteries) or (transposition NEAR/3 vessels) or guch)

# 4 TS=(septal NEAR/3 defect*)

# 3 TS=(congenital NEAR/3 cardiac)

# 2 TS=(heart NEAR/3 defect*)

# 1 TS=(congenital NEAR/3 heart)

## Appendix 2. Search strategies 2013

**CENTRAL**

#1 MeSH descriptor: [Heart Defects, Congenital] explode all trees
#2 congenital* near/6 heart
#3 congenital* near/6 cardiac
#4 heart near/6 malform*
#5 cardiac near/6 malform*
#6 heart near/6 defect*
#7 cardiac near/6 defect*
#8 coarctation near/6 aort*
#9 septal near/6 defect*
#10 septum near/6 defect*
#11 patent next ductus next arteriosus
#12 transposition near/6 arteries


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#13 transposition near/6 vessels
#14 guch
#15 fallot* near/6 tetralogy
#16 (#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)
#17 MeSH descriptor: [Psychotherapy] explode all trees
#18 MeSH descriptor: [Counseling] explode all trees
#19 cognitive* near/3 therap*
#20 behavi* near/3 therap*
#21 psychotherap*
#22 psycho-therap*
#23 talk*
#24 counsel*
#25 psycholog* near/3 treat*
#26 psycholog* near/3 intervent*
#27 psycholog* near/3 therap*
#28 psycholog* near/3 manag*
#29 MeSH descriptor: [Patient Education as Topic] this term only
#30 MeSH descriptor: [Depressive Disorder] explode all trees
#31 MeSH descriptor: [Depression] this term only
#32 depression
#33 depressive
#34 #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
#35 #16 and #34

**MEDLINE**

1. exp Heart Defects, Congenital/
2. exp Heart Diseases/cn [Congenital]
3. (congenital* adj3 heart).tw.
4. (congenital* adj3 cardiac).tw.
5. heart defect*.tw.
6. guch.tw.
7. (coarctation adj3 aorta*).tw.
8. (septal adj3 defect*).tw.
9. patent ductus arteriosus.tw.
10. (transposition adj3 arteries).tw.
11. (transposition adj3 vessels).tw.
12. (fallot* adj3 tetralogy).tw.
13. or/1-12
14. exp Psychotherapy/
15. exp Counseling/
16. counsel*.tw.
17. psychotherap*.tw.
18. (cognitive adj3 therap*).tw.
19. (behavi* adj3 therap*).tw.
20. talk*.tw.
21. (psycholo* adj3 (intervent* or therap* or treat* or manage*)).tw.
22. Patient Education as Topic/
23. exp Depressive Disorder/
24. Depression/
25. or/14-24
26. 13 and 25
27. randomized controlled trial.pt.
28. controlled clinical trial.pt.
29. randomized.ab.
30. placebo.ab.
31. drug therapy.fs.
32. randomly.ab.
33. trial.ab.
34. groups.ab.
35. 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34
36. exp animals/ not humans.sh.


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37. 35 not 36
38. 26 and 37
39. (200809* or 200810* or 200811* or 200812* or 2009* or 2010* or 2011* or 2012* or 2013*).ed.
40. 38 and 39

**Embase**

1. exp congenital heart disease/
2. exp heart disease/cn [Congenital Disorder]
3. (congenital* adj3 heart).tw.
4. (congenital* adj3 cardiac).tw.
5. heart defect*.tw.
6. (coarctation adj3 aorta*).tw.
7. (septal adj3 defect*).tw.
8. patent ductus arteriosus.tw.
9. (transposition adj3 arteries).tw.
10. (transposition adj3 vessels).tw.
11. guch.tw.
12. (fallot* adj3 tetralogy).tw.
13. or/1-12
14. exp psychotherapy/
15. exp counseling/
16. counsel*.tw.
17. psychotherap*.tw.
18. (cognitive adj3 therap*).tw.
19. (behavi* adj3 therap*).tw.
20. talk*.tw.
21. (psycholo* adj3 (intervent* or therap* or treat* or manage*)).tw.
22. patient education/
23. exp depression/
24. or/14-23
25. 13 and 24
26. random$.tw.
27. factorial$.tw.
28. crossover$.tw.
29. cross over$.tw.
30. cross-over$.tw.
31. placebo$.tw.
32. (doubl$ adj blind$).tw.
33. (singl$ adj blind$).tw.
34. assign$.tw.
35. allocat$.tw.
36. volunteer$.tw.
37. crossover procedure/
38. double blind procedure/
39. randomized controlled trial/
40. single blind procedure/
41. 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40
42. (animal/ or nonhuman/) not human/
43. 41 not 42
44. 25 and 43
45. ("200837" or "200838" or "200839" or 20084* or 20085* or 2009* or 2010* or 2011* or 2012* or 2013*).em.
46. 44 and 45

**PsycINFO**

1. congenital disorders/
2. heart disorders/
3. 1 and 2
4. (congenital* adj3 heart).tw.
5. (congenital* adj3 cardiac).tw.
6. heart defect*.tw.
7. guch.tw.


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8. (coarctation adj3 aorta*).tw.
9. (septal adj3 defect*).tw.
10. patent ductus arteriosus.tw.
11. (transposition adj3 arteries).tw.
12. (transposition adj3 vessels).tw.
13. (fallot* adj3 tetralogy).tw.
14. or/3-13
15. exp Psychotherapy/
16. exp Counseling/
17. counsel*.tw.
18. psychotherap*.tw.
19. (cognitive adj3 therap*).tw.
20. (behavi* adj3 therap*).tw.
21. talk*.tw.
22. (psycholo* adj3 (intervent* or therap* or treat* or manage*)).tw.
23. client education/
24. exp Affective Disorders/
25. exp Neurosis/
26. or/15-25
27. 14 and 26
28. (200809* or 200810* or 200811* or 200812* or 2009* or 2010* or 2011* or 2012* or 2013*).up.
29. 27 and 28

**BIOSIS**

#10 #9 AND #8
# 9 ts=(random* or RCT or trial or groups)
# 8 #7 AND #6
# 7 TS=(depression or psychotherap* or counsel* or talk* or (cognitive same therap*))
# 6 #5 OR #4 OR #3 OR #2 OR #1
# 5 TS=(fallot* or "patent ductus" or (transposition NEAR/3 arteries) or (transposition NEAR/3 vessels) or guch)
# 4 TS=(septal NEAR/3 defect*)
# 3 TS=(congenital NEAR/3 cardiac)
# 2 TS=(heart NEAR/3 defect*)
# 1 TS=(congenital NEAR/3 heart)

**CINAHL**

S37 S18 AND S36
S36 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
S35 TX cross-over*
S34 TX crossover*
S33 TX volunteer*
S32 (MH "Crossover Design")
S31 TX allocat*
S30 TX control*
S29 TX assign*
S28 TX placebo*
S27 (MH "Placebos")
S26 TX random*
S25 TX (doubl* N1 mask*)
S24 TX (singl* N1 mask*)
S23 TX (doubl* N1 blind*)
S22 TX (singl* N1 blind*)
S21 TX (clinic* N1 trial?)
S20 PT clinical trial
S19 (MH "Clinical Trials+")
S18 S16 AND S17
S17 EM 2008-2013
S16 S7 AND S15
S15 S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14
S14 cognitive therapy
S13 depression


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S12 psychotherapy
S11 counsel*
S10 (MH "Psychotherapy+")
S9 (MH "Counseling+")
S8 (MH "Affective Disorders+")
S7 S1 OR S2 OR S3 OR S4 OR S5 OR S6
S6 heart defect*
S5 septal n3 defect
S4 fallot*
S3 congenital n3 cardiac
S2 congenital n3 heart
S1 (MH "Heart Defects, Congenital+")

**Web of Science**

# 10 #9 AND #8
# 9 TS=(random* or blind* or allocat* or assign* or trial* or placebo* or crossover* or cross-over*)
# 8 #7 AND #6
# 7 TS=(depression or psychotherap* or counsel* or talk* or (cognitive same therap*))
# 6 #5 OR #4 OR #3 OR #2 OR #1
# 5 TS=(fallot* or "patent ductus" or (transposition NEAR/3 arteries) or (transposition NEAR/3 vessels) or guch)
# 4 TS=(septal NEAR/3 defect*)
# 3 TS=(congenital NEAR/3 cardiac)
# 2 TS=(heart NEAR/3 defect*)
# 1 TS=(congenital NEAR/3 heart)

## Appendix 3. Search strategies 2008

**The Cochrane Library**

#1 MeSH descriptor HEART DEFECTS, CONGENITAL explode all trees
#2 (congenital* in All Text near/6 heart in All Text)
#3 (congenital* in All Text near/6 cardiac in All Text)
#4 (heart in All Text near/6 malform* in All Text)
#5 (cardiac in All Text near/6 malform* in All Text)
#6 (heart in All Text near/6 defect* in All Text)
#7 (cardiac in All Text near/6 defect* in All Text)
#8 (coarctation in All Text near/6 aort* in All Text)
#9 (septal in All Text near/6 defect* in All Text)
#10 (septum in All Text near/6 defect* in All Text)
#11 patent next ductus next arteriosus in All Text
#12 (transposition in All Text near/6 arteries in All Text)
#13 (transposition in All Text near/6 vessels in All Text)
#14 guch in All Text
#15 (fallot* in All Text near/6 tetralogy in All Text)
#16 (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10)
#17 (#11 or #12 or #13 or #14 or #15)
#18 (#16 or #17)
#19 MeSH descriptor psychotherapy explode all trees
#20 MeSH descriptor counseling explode all trees
#21 (cognitive* in All Text near/3 therap* in All Text)
#22 (behavi* in All Text near/3 therap* in All Text)
#23 psychotherap* in All Text
#24 psycho-therap* in All Text
#25 talk* in All Text
#26 counsel* in All Text
#27 (psycholog* in All Text near/3 treat* in All Text)
#28 (psycholog* in All Text near/3 intervent* in All Text)
#29 (psycholog* in All Text near/3 therap* in All Text)
#30 (psycholog* in All Text near/3 manag* in All Text)
#31 MeSH descriptor Patient Education as Topic this term only
#32 MeSH descriptor depressive disorder explode all trees
#33 MeSH descriptor depression this term only


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#34 depression in All Text
#35 depressive in All Text
#36 (#19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28)
#37 (#29 or #30 or #31 or #32 or #33 or #34 or #35)
#38 (#36 or #37)
#39 (#18 and #38)

**MEDLINE Ovid**

1 exp Heart Defects, Congenital/ (92667)
2 exp Heart Diseases/cn [Congenital] (5022)
3 (congenital$ adj3 heart).tw. (19019)
4 (congenital$ adj3 cardiac).tw. (2626)
5 heart defect$.tw. (6343)
6 guch.tw. (34)
7 or/1-6 (102459)
8 (coarctation adj3 aorta$).tw. (3529)
9 (septal adj3 defect$).tw. (15329)
10 patent ductus arteriosus.tw. (4725)
11 (transposition adj3 arteries).tw. (374)
12 (transposition adj3 vessels).tw. (335)
13 (fallot$ adj3 tetralogy).tw. (5731)
14 or/8-13 (27071)
15 7 or 14 (106197)
16 exp Psychotherapy/ (120950)
17 exp Counseling/ (25850)
18 counsel$.tw. (44037)
19 psychotherap$.tw. (24661)
20 (cognitive adj3 therap$).tw. (5458)
21 (behavi$ adj3 therap$).tw. (8812)
22 talk$.tw. (17486)
23 (psycholo$ adj3 (intervent$ or therap$ or treat$ or manage$)).tw. (6458)
24 exp Patient Education/ (53480)
25 exp Depressive Disorder/ (61095)
26 exp Depression/ (51478)
27 or/16-26 (348123)
28 15 and 27 (867)
29 randomized controlled trial.pt. (265310)
30 controlled clinical trial.pt. (80098)
31 Randomized controlled trials/ (57145)
32 random allocation/ (62876)
33 double blind method/ (100416)
34 single-blind method/ (12523)
35 or/29-34 (447710)
36 exp animal/ not humans/ (3361453)
37 35 not 36 (419082)
38 clinical trial.pt. (458128)
39 exp Clinical Trials as Topic/ (211999)
40 (clin$ adj25 trial$).ti,ab. (152325)
41 ((singl$ or doubl$ or trebl$ or tripl$) adj (blind$ or mask$)).ti,ab. (97162)
42 placebos/ (28120)
43 placebo$.ti,ab. (113761)
44 random$.ti,ab. (426608)
45 research design/ (54456)
46 or/38-45 (946096)
47 46 not 36 (878623)
48 37 or 47 (903831)
49 48 and 28 (33)
50 limit 49 to yr="2005 - 2008

**Embase Ovid**

1 exp Congenital heart disease/ (44312)


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2 exp Heart Disease/cn [Congenital] (20220)
3 (congenital$ adj3 heart).tw. (12730)
4 (congenital$ adj3 cardiac).tw. (2010)
5 heart defect$.tw. (3521)
6 or/1-5 (50906)
7 (coarctation adj3 aorta$).tw. (2001)
8 (septal adj3 defect$).tw. (9715)
9 patent ductus arteriosus.tw. (3083)
10 (transposition adj3 arteries).tw. (220)
11 (transposition adj3 vessels).tw. (72)
12 guch.tw. (30)
13 (fallot$ adj3 tetralogy).tw. (3194)
14 or/7-13 (16235)
15 6 or 14 (54088)
16 exp Psychotherapy/ (76323)
17 exp Counseling/ (45534)
18 counsel$.tw. (35520)
19 psychotherap$.tw. (22114)
20 (cognitive adj3 therap$).tw. (7005)
21 (behavi$ adj3 therap$).tw. (9678)
22 talk$.tw. (12878)
23 (psycholo$ adj3 (intervent$ or therap$ or treat$ or manage$)).tw. (7011)
24 exp Patient Education/ (26171)
25 exp Depressive Disorder/ (149598)
26 exp Depression/ (149598)
27 or/16-26 (302364)
28 27 and 15 (1131)
29 controlled clinical trial/ (51061)
30 random$.tw. (379675)
31 randomized controlled trial/ (162335)
32 follow-up.tw. (340983)
33 double blind procedure/ (70455)
34 placebo$.tw. (107378)
35 placebo/ (117925)
36 factorial$.ti,ab. (7850)
37 (crossover$ or cross-over$).ti,ab. (38577)
38 (double$ adj blind$).ti,ab. (83195)
39 (singl$ adj blind$).ti,ab. (7288)
40 assign$.ti,ab. (105039)
41 allocat$.ti,ab. (33169)
42 volunteer$.ti,ab. (96566)
43 Crossover Procedure/ (20632)
44 Single Blind Procedure/ (7792)
45 or/29-44 (986754)
46 28 and 45 (141)
47 limit 46 to yr="2005 - 2008" (68)
48 from 47 keep 1-68 (68)

**PsycINFO Ovid**

1 Congenital disorders/ (1614)
2 Heart Disorders/ (4197)
3 1 and 2 (135)
4 (congenital$ adj3 heart).tw. (347)
5 (congenital$ adj3 cardiac).tw. (28)
6 heart defect$.tw. (112)
7 guch.tw. (0)
8 or/3-7 (404)
9 (coarctation adj3 aorta$).tw. (7)
10 (septal adj3 defect$).tw. (29)
11 patent ductus arteriosus.tw. (15)
12 (transposition adj3 arteries).tw. (6)


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13 (transposition adj3 vessels).tw. (0)
14 (fallot$ adj3 tetralogy).tw. (8)
15 or/9-14 (62)
16 8 or 15 (451)
17 exp Psychotherapy/ (145732)
18 exp Counseling/ (57963)
19 counsel$.tw. (74885)
20 psychotherap$.tw. (88391)
21 (cognitive adj3 therap$).tw. (14449)
22 (behavi$ adj3 therap$).tw. (22081)
23 talk$.tw. (20305)
24 (psycholo$ adj3 (intervent$ or therap$ or treat$ or manage$)).tw. (17564)
25 client education/ (2441)
26 exp affective disorders/ (84366)
27 exp neurosis/ (7660)
28 or/17-27 (370715)
29 16 and 28 (31)
30 limit 29 to yr="2005 - 2009" (11)

**BIOSIS on ISI Web of Knowledge**

ts=(((congenital same heart) or (heart same defect) or (heart same defects) or (congenital same cardiac) or (septal same defect*)) and (depression or psychotherap* or counsel* or talk* or (cognitive same therap*))) and ts=(random* or RCT or trial or groups)
Databases=PREVIEWS Timespan=2005-2008
or
ts=((fallot* or (patent ductus) or (transposition same arteries) or (transposition same vessels) or guch) and (depression or psychotherap* or counsel* or talk* or (cognitive same therap*))) and ts=(random* or RCT or trial or groups)
Databases=PREVIEWS Timespan=2005-2008

**CINAHL EBSCO**

(MH "Affective Disorders+") or (MH "Counseling+") or (MH "Psychotherapy+") or counsel* or psychotherapy or depression or cognitive therapy)
And
(MH "Heart Defects, Congenital+") or (congenital n3 heart) or (congenital n3 cardiac) or fallot* or (septal n3 defect) or (heart defect*)

## Appendix 4. Search strategies 2005

**MEDLINE**

1 exp Heart Defects, Congenital/
2 exp Heart Diseases/cn [Congenital]
3 (congenital$ adj3 heart).tw.
4 (congenital$ adj3 cardiac).tw.
5 heart defect$.tw.
6 or/1-5
7 (coarctation adj3 aorta$).tw.
8 (septal adj3 defect$).tw.
9 patent ductus arteriosus.tw.
10 (transposition adj3 arteries).tw.
11 (transposition adj3 vessels).tw.
12 or/7-11
13 6 or 12
14 exp Psychotherapy/
15 exp Counseling/
16 counsel$.tw.
17 psychotherap$.tw.
18 (cognitive adj3 therap$).tw.
19 (behavi$ adj3 therap$).tw.
20 talk$.tw.
21 (psycholo$ adj3 (intervent$ or therap$ or treat$ or manage$)).tw.
22 exp Patient Education/
23 exp Depressive Disorder/


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24 exp Depression/
25 or/14-24
26 6 and 25

## WHAT'S NEW

| Date | Event | Description |
|---|---|---|
| 3 October 2023 | New citation required and conclusions have changed | Three new studies were identified and included. Three ongoing studies were identified and two studies are awaiting classification. Psychological interventions may reduce depression compared to usual care. |
| 3 October 2023 | New search has been performed | Searches re-run |

## HISTORY

Protocol first published: Issue 4, 2001
Review first published: Issue 2, 2005

| Date | Event | Description |
|---|---|---|
| 1 August 2013 | New citation required but conclusions have not changed | One new ongoing study was identified. Three further studies were added to the excluded studies list. The text has been changed to reflect this.<br><br>The conclusions of the review remain unchanged. |
| 28 February 2013 | New search has been performed | The searches were re-run. |
| 30 September 2008 | New search has been performed | In this update, we re-ran the searches up to September 2008. Some changes were made to update the database search strategies. No new studies were identified. The text has been changed to reflect this.<br>The conclusions of the review remain unchanged.<br><br>Order of authors changed. |
| 9 September 2008 | Amended | Converted to new review format. |

## CONTRIBUTIONS OF AUTHORS

Dr DG Leo: contributed to the search and selection of studies for inclusion in the review, the assessment of the risk of bias of the included studies, the analysis and interpretation of the data, and the assessment of the certainty in the body of evidence; participated in writing and updating the review

U Islam: contributed to the search and selection of studies for inclusion in the review, the assessment of the risk of bias of the included studies, the analysis and interpretation of the data

Dr RR Lotto: participated in writing and updating the review

Prof A Lotto: participated in writing and updating the review

Prof DA Lane: conceived the review, designed the protocol, ran the initial search strategies, contributed to the search and selection of studies for inclusion in the review, the assessment of the risk of bias of the included studies, the analysis and interpretation of the data, the assessment of the certainty in the body of evidence; participated in writing and updating the review


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## DECLARATIONS OF INTEREST

DG Leo: has declared that they have no conflict of interest

U Islam: has declared that they have no conflict of interest

RR Lotto: has declared that they have no conflict of interest

A Lotto: has declared that they have no conflict of interest

D Lane: has received investigator-initiated educational grants from Bristol-Myers Squibb (BMS) and Pfizer; has been a speaker for Bayer, Boehringer Ingeheim, and BMS/Pfizer; and has consulted for BMS and Boehringer Ingelheim, all outside the submitted work.

## SOURCES OF SUPPORT

### Internal sources

- none, Other

  none for the 2023 update

### External sources

- none, Other

  none for the 2023 update

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

If the data were available, we had planned to conduct subgroup analysis on the primary outcomes measured in this review, to determine whether there was a difference based on the 'well-defined' or 'less well-defined' classification of cognitive behavioural therapy. Should data become available for future updates of this review, we will conduct such analyses. None of the planned subgroup analyses and sensitivity analyses were conducted, as appropriate data were not available.

For this updated review, we changed the age range for adolescents to 10 to 17 years, in line with the definition of adolescents made by the World Health Organization.

## INDEX TERMS

### Medical Subject Headings (MeSH)

Adolescent; *Cognitive Behavioral Therapy [methods]; Depression [therapy]; *Heart Defects, Congenital [complications]; Humans; Psychosocial Intervention; Psychotherapy [methods]; Quality of Life; Young Adult


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