The effectiveness of non-pharmacological interventions in improving psychological outcomes for heart transplant recipients: a systematic review protocol

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Center conducting the review
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Review objective
The objective of this review is to identify the effectiveness of non-pharmacological interventions on psychological outcomes for heart transplant recipients.

Background
The most recent epidemiological data suggests that 5.7 million Americans¹ 15 million Europeans,² and about 300 000 Australians live with heart failure.³ Heart transplant is the preferred treatment option for the subset of these patients who ultimately develop end-stage heart failure. This therapy results in greater five-year survival than maximal medical therapy or transplant alternatives, such as ventricular assist devices or artificial hearts.⁴ In 2010, there were 2,333 heart transplant operations performed in the United States.¹ In the UK, on average, 105 heart transplant operations are performed each year⁵ and in Australia, there were 76 heart transplant operations performed in 2011.⁶ While low rates of organ donation remain a barrier, it is expected that an increasing number of patients will receive this therapy in the future due to the rising prevalence of heart failure combined with the fact that heart transplant is still the most effective treatment for patients who remain symptomatic despite optimal medical therapy.¹,⁷

As such, it is important to consider the substantial literature documenting the prevalence, risk factors and consequences of poor psychological outcomes after heart transplant. Findings from primary research indicate that, while anxiety, distress and depressive symptoms generally improve after heart transplant, they remain higher than those of non-psychiatric community-based comparisons.⁸ Furthermore, clinically significant psychological symptoms are common among heart transplant...
recipients. In addition, research has shown that a considerable proportion of patients are likely to develop a psychological disorder after heart transplant. For example, 63% of a sample of 64 heart transplant recipients developed an affective disorder and 26% of a sample of 191 heart transplant recipients were diagnosed with an adjustment disorder.

A number of risk factors for these poor psychological outcomes after heart transplant have been identified in previous research. They include insufficient social support, avoidance or passive coping strategies, low sense of control, reduced functional status, sleep disorders and a high burden of comorbidities.

There has also been a considerable amount of research, which has examined the impact of poor psychological outcomes on quality of life and clinical outcomes for heart transplant recipients. This research has consistently demonstrated that poor psychological outcomes are associated with reduced quality of life, sub-optimal self-management, increased morbidity and increased mortality in the long-term. Although the reasons for these associations are complex and not completely understood, it is thought that psychological symptoms may either: directly exacerbate or hinder physiological health and recovery; or indirectly impact on physiological health by increasing unhealthy behaviours, such as medication non-adherence. Interventions targeted towards improving psychological outcomes for heart transplant recipients are therefore important because they have the potential to improve clinical outcomes as well as patients’ overall health and well-being.

However, a review published in 2006 identified that, unlike the large body of literature examining the prevalence, risk factors and consequences of poor psychological outcomes after heart transplant, intervention research focused on improving psychological outcomes was sparse. The lack of research also led a workgroup of the Nursing and Social Sciences Council of the International Society for Heart and Lung Transplantation (ISHLT) to recommend that intervention studies to maximise psychological outcomes should be conducted.

The workgroup suggested that intervention studies adopt non-pharmacological interventions that have previously demonstrated effectiveness in improving psychological outcomes for patients with other chronic diseases relevant to the heart transplant population. Examples of effective non-pharmacological interventions include cognitive behaviour therapy, stress management and relaxation. The workgroup further proposed that new interventions be designed specifically for heart transplant recipients. In this regard, the vast amount of information that is available on risk factors for poor psychological outcomes in heart transplant recipients indicates that non-pharmacological interventions addressing these risk factors might be effective. For example, research has shown that poor psychological outcomes are associated with low sense of control. Therefore, non-pharmacological interventions aimed at increasing perceived control, such as tailored education and counselling, would likely improve psychological outcomes. Similarly, non-pharmacological interventions targeted at addressing other risk factors, such as poor social support, avoidance coping strategies, sleep disorders and reduced functional status, might also be effective in improving psychological outcomes for heart transplant recipients.

Potentially then, since the ISHLT report and the previous review in 2006, studies reporting on the effectiveness of non-pharmacological interventions in improving psychological outcomes for heart transplant recipients may have been published. Thus, further information may currently be available to inform policy and practice decision-making regarding the implementation of such interventions. Accordingly, an evaluation of the existing evidence is required. This review seeks to appraise and
synthesize the evidence that is currently available to support the use of non-pharmacological interventions to improve psychological outcomes for heart transplant recipients.

**Keywords**

Heart transplant; anxiety; depression; stress; psychological outcomes; intervention

**Inclusion criteria**

**Types of participants**

This review will consider studies that include community living adults of all races and ethnicities who have received a heart transplant (inclusive of multi-organ recipients such as heart and lung transplants).

**Types of interventions**

This review will consider studies that evaluate the effectiveness of any intervention that does not involve the administration of a medication. These may be psychological interventions including, but not limited to, cognitive behaviour therapy, stress management and psychotherapy as well as other non-psychological interventions including, but not limited to, exercise and relaxation techniques.

Comparator: This review will consider studies that evaluate the effectiveness of non-pharmacological interventions compared with no intervention, another variation of a non-pharmacological intervention, combination of non-pharmacological intervention and pharmacological intervention, or pharmacological intervention.

**Types of outcomes**

This review will consider studies that include the following outcome measures:

- Clinical diagnosis of anxiety
- Clinical diagnosis of depression
- Anxiety symptoms as measured by a validated scale
- Depressive symptoms as measured by a validated scale
- Symptoms of stress as measured by a validated scale
- Mental health as measured by a validated quality of life scale.

**Types of studies**

This review will consider any experimental study design including randomised controlled trials, non-randomised controlled trials, quasi-experimental and before and after studies for inclusion.

**Search strategy**

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilised in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by an analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies. Studies published in English will be
considered for inclusion in this review. Studies published from the onset of the database to the current date of the review will be considered for inclusion in this review.

The databases to be searched include:

Medline, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Excerpta Medica Database (EMBASE), Cochrane Database of Controlled Clinical Trials and PsycINFO

The search for unpublished studies will include:

ProQuest Dissertation & Theses and Virginia Henderson International Nursing Library

The search for conference proceedings will include:

Web of Science-ISI proceedings

Initial keywords to be used will be:

Heart transplant, anxiety, depression, quality of life, distress

The reference lists of retrieved papers, conference proceedings and unpublished literature (eg theses) will be scrutinised for further primary research using the Google Scholar search engine, including its forward citation search capacity.

Assessment of methodological quality

Quantitative papers selected for retrieval will be assessed by two independent reviewers for methodologic al validity prior to inclusion in the review using standardised critical appraisal instruments from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix 1). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Data collection

Data will be extracted from papers included in the review using the standardized data extraction tool from JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

Data synthesis

Quantitative data will, where possible be pooled in statistical meta-analysis using JBI-MAStARI. All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the standard Chi-square and also explored using subgroup analyses based on the different study designs included in this review. Where statistical pooling is not possible the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate.

Conflicts of interest

None.

Acknowledgements

None.
References


Appendix I: Appraisal instruments

MAStARI Appraisal instrument

**JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
<th>Not Applicable</th>
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<tbody>
<tr>
<td>1. Was the assignment to treatment groups truly random?</td>
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<td>2. Were participants blinded to treatment allocation?</td>
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<td>3. Was allocation to treatment groups concealed from the allocator?</td>
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<td>4. Were the outcomes of people who withdrew described and included in the analysis?</td>
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<td>5. Were those assessing outcomes blind to the treatment allocation?</td>
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<td>6. Were the control and treatment groups comparable at entry?</td>
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<td>7. Were groups treated identically other than for the named interventions</td>
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<td>8. Were outcomes measured in the same way for all groups?</td>
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<td>9. Were outcomes measured in a reliable way?</td>
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<td>10. Was appropriate statistical analysis used?</td>
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Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

________________________________________________________________________________________

________________________________________________________________________________________
Appendix II: Data extraction instruments

MAStARI data extraction instrument

JBI Data Extraction Form for Experimental / Observational Studies

Reviewer ______________________ Date ______________________

Author ______________________ Year ______________________

Journal, ______________________ Record Number ______________________

Study Method

RCT ☐ Quasi-RCT ☐ Longitudinal ☐
Retrospective ☐ Observational ☐ Other ☐

Participants

Setting

Population

Sample size

Group A ______________________ Group B ______________________

Interventions

Intervention A

Intervention B

Authors Conclusions:

Reviewers Conclusions: