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The Effects of Psychosocial Interventions in Cancer and Heart Disease

A Review of Systematic Reviews



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REPORT 30



THE EFFECTS OF PSYCHOSOCIAL INTERVENTIONS IN CANCER AND HEART DISEASE: A REVIEW OF SYSTEMATIC REVIEWS

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TABLE OF CONTENTS

ACKNOWLEDGMENTS	iv
EXECUTIVE SUMMARY	vii
1 BACKGROUND	1
1.1 Methods	2
1.1.1 Search strategy	2
1.1.2 Inclusion/exclusion criteria	2
1.1.2.1 Study design	2
1.1.2.2 Participants	2
1.1.2.3 Interventions	2
1.1.2.4 Outcomes	3
1.1.3 Procedure	3
1.1.3.1 Initial assessment	3
1.1.3.2 Data extraction	3
1.1.3.3 Quality assessment	3
1.1.3.4 Synthesis	3
1.2 Results	
Results of searches	4
2 PSYCHOSOCIAL INTERVENTIONS FOR CANCER PATIENTS	5
2.1 Psychoeducational interventions	5
2.1.1 Characteristics of reviews	5
2.1.2 Quality of reviews	5
2.1.3 Results of reviews	6
2.1.3.1 Psychological outcomes	6
2.1.3.2 Physical outcomes	7
2.1.3.3 Other outcomes	7
2.1.3.4 Moderating variables	7
2.1.4 Research implications	7
2.2 Relaxation interventions	8
2.2.1 Characteristics of reviews	8
2.2.2 Quality of reviews	8
2.2.3 Results of reviews	9
2.2.3.1 Psychological outcomes	9
2.2.3.2 Physical outcomes	9
2.2.3.3 Other outcomes	9
2.2.3.4 Moderating variables	9
2.2.4 Research implications	9
2.3 Group interventions	10
2.3.1 Characteristics of reviews	10
2.3.2 Quality of reviews	10
2.3.3 Results of reviews	11
2.3.3.1 Psychological outcomes	11
2.3.3.2 Physical outcomes	11
2.3.3.3 Moderating variables	11
2.3.4 Research implications	11
2.4 Broader scope reviews	12
2.4.1 Characteristics of reviews	12

2.4.2	Quality of reviews	13
2.4.3	Results of reviews	13
2.4.3.1	Psychological outcomes	13
	General results	13
	Specific interventional approaches	14
2.4.3.2	Physical outcomes	15
2.4.3.3	Quality of life	16
2.4.3.4	Moderating variables	17
2.4.4	Research implications	17
3	PSYCHOSOCIAL INTERVENTIONS FOR HEART DISEASE PATIENTS	19
3.1	Educational interventions	19
3.1.1	Characteristics of reviews	19
3.1.2	Quality of reviews	19
3.1.3	Results of reviews	20
3.1.3.1	Psychological outcomes	20
3.1.3.2	Physical outcomes	20
3.1.3.3	Moderating variables	20
3.1.4	Research implications	20
3.2	Broad scope reviews	20
3.2.1	Characteristics of reviews	20
3.2.2	Quality of reviews	21
3.2.3	Results of reviews	22
3.2.3.1	Psychological outcomes	22
3.2.3.2	Physical outcomes	23
	Mortality and morbidity	23
	Modification of risk factors in heart disease	24
	Quality of life	24
3.2.3.3	Moderating variables	25
3.2.4	Research implications	25
4	DISCUSSION	27
5	SUMMARY AND CONCLUSIONS	31
5.1	Recommendations for future research	31
6	REFERENCES	33
APPENDIX 1:	Number of possible systematic reviews of psychosocial interventions in chronic illness (identified for titles and abstracts)	37
APPENDIX 2:	Journals handsearched in the DARE process	38
APPENDIX 3:	Search strategies	40
APPENDIX 4:	Review inclusion/exclusion details - Cancer	47
APPENDIX 5:	Review inclusion/exclusion details - Heart disease	51
APPENDIX 6:	Review inclusion/exclusion details - Reviews including both heart disease and cancer	53
APPENDIX 7:	Included primary studies - Cancer reviews	54
APPENDIX 8:	Included primary studies - Heart disease reviews	78
APPENDIX 9:	Included primary studies - Reviews including both heart disease and cancer	86
APPENDIX 10:	Data extraction - Cancer reviews	89
APPENDIX 11:	Data extraction - Heart disease reviews	140
APPENDIX 12:	Data extraction - Reviews including both heart disease and cancer	163

EXECUTIVE SUMMARY

Objective

To conduct a review of existing systematic reviews, in order to (i) examine the types of psychosocial interventions that have been used with people suffering from heart disease or cancer, (ii) evaluate the effects of such interventions on physical outcomes, psychological outcomes or health care usage, and (iii) evaluate the methodological quality of the included systematic reviews.

Methods

A wide range of databases was searched for relevant systematic reviews of the literature. This process was supplemented by handsearching of 67 journals and contacting authors in the area. To be considered a "systematic review," identified texts had to meet two criteria defined by CRD's Database of Abstracts of Reviews of Effects (DARE), relating to the review question and literature search. Those that evaluated the effects of any kind of psychosocial intervention(s) in individuals with cancer or heart disease were included. Psychotropic medications, exercise training alone and 'black-box' interventions such as cardiac rehabilitation or interventions that included medical care such as secondary prevention through medication change were excluded. The quality of included reviews was assessed using a checklist adapted from that used for DARE. Two reviewers were involved in the review selection, extraction and quality assessment processes, with any disagreements resolved by a third reviewer.

The included reviews were combined in a narrative synthesis. Results were grouped by condition (heart disease and cancer) and, where possible, by type of intervention within each condition. Where results could not easily be classified by type of intervention, they were grouped according to outcome (psychological, physical, or other). Where possible, important differences between reviews and their potential effects on findings were highlighted. Within each section of the results, an overall summary of the methodological quality of the reviews is given and, where possible, emphasis is placed upon the reviews of higher quality. Implications for future primary research, as indicated in the included systematic reviews, have been summarised. The findings from the collection of reviews formed the basis of recommendations for the need, design and conduct of future systematic reviews in the area.

Results

A total of 5,735 references were identified from the literature searches, with a total of 35 systematic reviews finally considered appropriate for inclusion.

Of the 35 included systematic reviews of the effects of psychosocial interventions, 22 related to cancer, 10 to heart disease, and three included primary studies that contained both groups of patients. Of the 10 heart disease reviews, two existed only as protocols at the time of report production.

The 35 reviews covered a very broad range of psychosocial interventions, including approaches such as group therapy, individual therapy, family therapy, counselling, psychoanalysis, education, stress management, cognitive behavioural therapy, relaxation, imagery, meditation training, emotional expression, biofeedback, coping skills training, problem solving training, social skills training, cognitive/attentional distraction, hypnosis, desensitisation, rehearsal modelling, and contingency management. The methodological quality of these reviews was generally quite low; with only ten reviews (29%) meeting more than four of the seven quality criteria.

Overall, the results of the included reviews indicated some beneficial effect of psychosocial intervention on broad psychological outcomes for patients with heart disease and cancer. In terms of physical outcomes the evidence remains unclear in cancer, but appears to be more promising in heart disease.

Conclusions

Cancer

In general, the reviews of psychosocial interventions in cancer patients indicated that psychosocial interventions are likely to produce some beneficial effect on psychological distress or emotional adjustment of patients. The effects on specific outcomes such as depression are unclear. Findings relating to the relative effects of different treatment settings and paradigms (e.g. CBT vs. counselling) were inconsistent. The findings of reviews investigating physical outcomes (such as immune outcomes, survival) mostly failed to detect any beneficial effect of psychosocial intervention on these outcomes, though there is insufficient high quality evidence to determine whether small effects might exist. Due to the considerable limitations of the reviews concerned with psychosocial interventions in cancer, recommendations are made for the conduct of any future reviews in this area.

Heart disease

Six of the eight heart disease reviews favoured the adoption of psychosocial interventions into cardiac care. Those reviews that investigated psychological outcomes generally reported some benefit of psychosocial interventions for the reduction of psychological distress and modification of type A behaviour (a behaviour pattern characterised by aggressiveness, ambitiousness, restlessness and a strong sense of time urgency). There is some limited evidence about the positive effects of psychosocial interventions on morbidity and mortality. There is equivocal evidence about the effects of psychosocial interventions on heart disease risk factors. Educational interventions may influence some behavioural (e.g. exercise and diet) and clinical (blood pressure and mortality) outcomes in heart disease.

1. BACKGROUND

Substantial psychological co-morbidity has frequently been observed in people with chronic illness.¹ For example, major depression in people who have suffered a myocardial infarction (MI) has been reported to be around 15 to 20%, with an additional 27% reporting symptoms of minor depression.² Similarly, in people with cancer, depression as a co-morbid syndrome has been estimated to affect 15 to 25% of patients,³ although rates of over 40% have been reported for certain malignancies.⁴

A recent systematic review assessing the prevalence of depression in patients with advanced cancer reported a median prevalence of 29% (interquartile range 19.50 to 34.25%) from studies using questionnaires and a prevalence ranging from 5 to 26% (median 15%) based on psychiatric interviews.⁵ It is important to understand the diagnostic criteria used to establish depression as this will affect the prevalence estimate.

Other psychological problems reported in the literature include anxiety and psychological distress. The percentage of cancer patients with an anxiety disorder has been estimated to range from less than 1% to around 50% and similar figures have also been reported for psychological distress.⁶

Psychological morbidity in chronic illness has been shown to be independently associated with increased symptom report, disability and the utilisation of health care resources.^{1, 7-9} Considering the prevalence of chronic illnesses such as coronary heart disease (causing 110,000 deaths in England in 1998¹⁰) and cancer (death rate of around 248 per 100,000 population in England in 2000¹¹), the potential impact of psychological morbidity in these conditions is likely to be considerable.

Several approaches to patient care have been developed which take into account the social, psychological and behavioural dimensions of illness, based upon the biopsychosocial model of health.¹² The biopsychosocial model was advocated by Engel in 1977, as a way of better understanding the determinants of disease and arriving at rational treatments and patterns of healthcare. He argued that the patient, the social context in which they live and the complementary system devised by society to deal with the disruptive effects of illness must all be taken into account.¹²

Since the biopsychosocial model was advocated a number of psychosocial interventions have been developed and evaluated in a range of conditions including asthma, arthritis, diabetes mellitus, coronary heart disease and cancer.¹³⁻¹⁷ It has been suggested that adopting a biopsychosocial approach to patient care can improve patient outcomes, including psychological distress,¹⁶ disease-related symptoms¹⁸ and survival.¹ Psychosocial interventions may also impact on the costs associated with disorders involving anxiety and/or depression.¹⁹

An initial scoping exercise was undertaken to identify from the literature which chronic illnesses, psychosocial interventions, and outcomes had been studied most frequently. We decided to focus on systematic reviews, rather than primary studies, due to the number of reviews available, which in theory should have covered most of the primary studies evaluating psychosocial interventions. The results of this exercise indicated that a number of chronic conditions had been the focus of systematic reviews, with heart disease and cancer predominating (see appendix 1). The types of interventions evaluated include cognitive behavioural therapy, psychotherapy, counselling, stress management, psycho-educational care, family therapy and relaxation therapy. The outcomes measured included physical outcomes such as blood pressure, cardiac mortality, heart rate, nausea, vomiting; psychological outcomes such as distress and coping, anxiety, depression and mood, as well as quality of life and cost related outcomes such as hospital re-admission. As a result of this scoping exercise we decided to focus on patients with heart disease or cancer.

1.1 Methods

A review of existing systematic reviews was conducted, in which we attempted to:

- i. examine the types of psychosocial interventions that have been used with people suffering from heart disease or cancer
- ii. evaluate the effects of such interventions on physical outcomes, psychological outcomes or health care usage
- iii. evaluate the methodological quality of the included systematic reviews.

1.1.1 Search strategy

The best single source of information on systematic reviews is the Cochrane Library. Within it, the Cochrane Database of Systematic Reviews (CDSR) contains complete reviews and protocols of reviews in progress, prepared to the standard required by the Cochrane Collaboration. The Cochrane Library also contains the Database of Abstracts of Reviews of Effects (DARE), a database containing structured abstracts of systematic reviews that have met defined quality criteria as evaluated by the staff at CRD (<http://www.york.ac.uk/inst/crd>). Systematic reviews are identified for potential inclusion on DARE through regular searching of the following electronic databases: Current Contents Clinical Medicine, MEDLINE, CINAHL, ERIC, Biosis, AMED and PsychINFO. This process is supplemented by hand searching of 67 individual journals (see Appendix 2.1 for a list of these journals).

Other electronic databases also searched included the National Research Register (including CRD Ongoing Reviews Database), EMBASE, Health Technology Assessment Database, SIGN Guidelines, National Guideline Clearinghouse, National Coordinating Centre for Health Technology Assessment, NICE web page (published appraisals), and Health Services/Technology Assessment Texts (HSTAT).

Indexes to and summaries of clinical effectiveness sources (including reviews, appraisals of reviews, and evidence based guidelines) were searched using the following databases: TRIP, SchARR Lock's Guide to the Evidence, Clinical Evidence and Health Evidence Bulletins Wales (see Appendix 2.2 for details of the search strategies).

1.1.2 Inclusion/exclusion criteria

1.1.2.1 Study design

To be included, a review had to use systematic methods as defined by CRD's Database of Abstracts of Reviews of Effects (DARE). To allow a broad overview of the existing literature, reviews only had to meet the two mandatory DARE criteria: that there is a defined review question, and that an effort is made to identify all the relevant literature. The quality of the included systematic reviews was assessed and differences have been addressed in the results and discussion sections of this report.

1.1.2.2 Participants

Patients with heart disease (including conditions such as coronary heart or artery disease, cardiovascular disease, myocardial infarction (MI), and angina) or cancer (of any type) were eligible for inclusion. Reviews that examined multiple conditions were excluded unless they presented their findings separately for patients with heart disease and/or cancer.

1.1.2.3 Interventions

One or more psychosocial interventions must have been evaluated, which could include cognitive behaviour therapy (CBT) or another type of intervention such as psychotherapy, anxiety/depression management, stress management, counselling, family therapy, education or psycho-education, health education, relaxation techniques, social support (outside of family), or any behavioural interventions designed to modify risk factors such as diet, exercise or smoking (in people with either cancer or heart disease).

Reviews which included only studies of psychotropic medications, exercise training alone and 'black-box' interventions such as cardiac rehabilitation or interventions that include medical care such as secondary prevention through medication change were excluded.

1.1.2.4 Outcomes

Reviews were included if they examined psychological outcomes such as depression or anxiety, physical outcomes such as morbidity or mortality, or health care usage such as admission to care, consultant episodes and acute events such as surgery. In heart disease, physical and usage outcomes could include myocardial infarctions, cardiovascular mortality and overall mortality, bypass surgery, angioplasty, reduction in risk factors/behaviours, admission to hospital, GP visits and quality of life. For cancer, physical outcomes could include survival, physical well-being (e.g. nausea, vomiting and/or pain) or quality of life.

1.1.3 Procedure

1.1.3.1 Initial assessment

Two reviewers independently assessed all titles and abstracts identified from the literature searches for relevance. Full paper copies of potentially relevant systematic reviews were then obtained. The retrieved papers were assessed for inclusion by one reviewer and independently assessed by a second reviewer using the inclusion/exclusion criteria outlined above. Any disagreements were discussed with a third reviewer. References were managed in Endnote and Microsoft Access.

1.1.3.2 Data extraction

Data were extracted from relevant systematic reviews by one reviewer and checked by another. Any disagreements were discussed with a third reviewer. Data extraction forms were developed using Microsoft Access.

The following information was extracted and recorded: review details (authors, year, country), search strategy (including sources used), inclusion/exclusion criteria (study design, participants, interventions and outcomes), number of studies and the number of participants included in the review, bibliographic details of each study included in the review, interventions and outcomes examined, methods used to assess validity, methods used to synthesise the findings and assess heterogeneity, methods used to assess publication bias, number of reviewers involved in each stage of the review process, results obtained and authors' conclusions and recommendations (see appendices 5.1 to 5.3)

1.1.3.3 Quality assessment

The quality of each systematic review was assessed by one reviewer and checked by another. Quality was assessed using a checklist adapted from CRD's criteria for the Database of Abstracts of Reviews of Effects (DARE). This involved an evaluation of the following:

- Is there a defined search strategy?
- Is there a well-defined question?
- Are inclusion/exclusion criteria stated?
- Are study designs and number of studies clearly stated?
- Have the primary studies been quality assessed?
- Have the studies been appropriately synthesised?
- Has more than one author been involved in each stage of the process?

This checklist was intended to give a broad indication of the quality of included systematic reviews. It is not a scale and all of the criteria have been given equal weight.

1.1.3.4 Synthesis

The included reviews were combined in a narrative synthesis. Results were grouped by condition (heart disease and cancer) and, where possible, by type of intervention within each condition. Where results could not easily be classified by type of intervention, they were grouped according to outcome (psychological, physical, or other). Where possible, important differences between reviews (e.g. databases searched, years of search, inclusion criteria, methods of synthesis) and their possible effects on the results of the review were highlighted.

Within each section of the results, an overall summary of the methodological quality of each review is given and, where possible, emphasis is placed upon the reviews of higher quality. Where reviews investigated “moderating variables” (characteristics of participants and/or studies which might influence estimates of effect), this information has been reported. Implications for future primary research were summarised. The findings from the collection of reviews formed the basis of recommendations for the need, design and conduct of any future systematic reviews.

1.2 Results

Results of searches

A total of 5,735 references were identified from the literature searches. On the basis of titles and abstracts alone, 135 of these were considered to be potentially relevant and were ordered as full papers. Two reviewers screened all 135 full publications according to the previously described inclusion criteria, and selected a total of 35 systematic reviews for inclusion (see appendices 3.1 to 3.3).^{16, 18, 20-52}

Of the 35 included systematic reviews evaluating the effects of psychosocial interventions, 22 related to cancer, 10 to heart disease, and three included primary studies that contained both groups of patients. Data were fully extracted from these reviews and are presented in appendices 5.1 to 5.3. Of the 10 heart disease reviews, two existed only as Cochrane protocols at the time of selection. However, data were extracted from these protocols should the full reviews be published within the timeframe of this project. At the time of writing this report, neither of these reviews were sufficiently complete to contribute any results.^{47, 48}

A total of 506 individual publications (primary studies) were included in the reviews (336 in cancer reviews, 170 in heart disease reviews). A total of 78 primary studies were included in those reviews that included patients with cancer and heart disease. Appendices 4.1 to 4.3 give details of the inclusion criteria for each review and the primary studies included.

The results of the completed reviews are presented according to their disease focus (cancer or heart disease). Two of the reviews that covered both disease groups provided insufficient data to be usefully incorporated into the synthesis.^{25, 31} The results of the third¹⁶ were incorporated into each section where appropriate. Details of all three reviews are presented in the appendices.

2. PSYCHOSOCIAL INTERVENTIONS FOR CANCER PATIENTS

Two of the included reviews evaluated the effects of psychoeducational interventions.^{38, 40} Two reviews evaluated relaxation-based interventions,^{23, 44} and three reviews focused entirely on interventions delivered in a group setting.^{26, 34, 35} The remaining 16 reviews evaluated a broad range of psychological or psychosocial interventions.^{16, 18, 20-22, 24, 28, 32, 39, 41, 43, 45, 46, 50-52} The reviews which stated that they focused on particular types of approach are presented first, followed by those reviews that assessed psychosocial interventions more generally.

2.1 Psychoeducational interventions

2.1.1 Characteristics of reviews

In two of the identified reviews,^{38, 40} the authors' aimed to evaluate only the effects of what they considered to be 'psychoeducational' interventions in patients with cancer. One of these reviews, published in 2002, defined psychoeducational interventions as "therapeutic approaches that involve information giving and receiving, discussion of concerns, problem solving, coping skills training, expression of emotion, and social support".³⁸ The second review, published in 1995, was concerned with 'psychoeducational care' which the authors considered to consist of "educational and psychosocial interventions."⁴⁰ Across the two reviews, searches covered the period from 1966 to 2000. However, one of the reviews only attempted to identify studies published since 1980.³⁸

Psychoeducational interventions were broadly classified into the following approaches: non-behavioural counselling/psychotherapy (where no specific behavioural or coping skills are taught), behavioural/cognitive therapy (including coping skills training, progressive muscle relaxation training, systematic desensitisation etc), education/information alone, social support (provided by persons other than professionals), and other forms of psychosocial approach that could not be easily classified (e.g. music therapy).^{38, 40}

Both reviews included only studies that had evaluated psychoeducational interventions in adult cancer patients. The majority of primary studies in both reviews included participants with a variety of cancer diagnoses, though women with breast cancer made up the largest group of participants. In the review by Barsevick et al a small proportion of studies were limited to male participants with testicular and prostate cancer, as well as those with mixed diagnoses.³⁸

Barsevick et al limited their review to the investigation of the effects of psychoeducational interventions on depressive symptoms.³⁸ Seventeen different measures of depression were used across the included studies, with the most common being The Profile of Mood States⁵³ and the Hospital Anxiety and Depression Scale.⁵⁴ In the review by Devine and Westlake, both psychological (anxiety, depression, mood) and physical (nausea, vomiting, pain) outcomes were examined, along with patients' knowledge about their condition.⁴⁰

Both reviews included a wide variety of study designs, limiting inclusion to either "experimental, quasi-experimental, and pre-post single group study designs"⁴⁰ or "scientific studies, qualitative or quantitative systematic reviews, or practice guidelines based on research."³⁸ One review stated that controlled studies would only be included if they used a usual care or attentional control group.³⁸ Devine and Westlake included 116 studies, 98 of which (including 5,326 patients) provided sample size and at least one effect size value.⁴⁰ Of the primary studies included in the review by Barsevick et al, 26 were RCTs (including at least 1465 patients), seven were quasi-experimental studies (869 patients), and five were descriptive studies (730 patients).

2.1.2 Quality of reviews

The review by Devine and Westlake⁴⁰ met four of the seven methodological criteria and the review by Barsevick et al³⁸ met three. Both reviews indicated that their objective was to determine the effects of psychoeducational care in cancer patients. In each review multiple

databases were searched and further attempts to identify relevant literature from reference lists of retrieved papers were made. Devine and Westlake also attempted to identify unpublished literature.⁴⁰ Both reviews selected papers using broad, but seemingly appropriate, inclusion criteria. However, despite ostensibly being reviews of the same literature, as their objectives would suggest, there was very little overlap between the two reviews in terms of the primary studies that were included. Whether this is due to differences in their search strategies and inclusion criteria is not clear. The lack of overlap of included studies may be partly explained by one review focusing solely on depression as an outcome,³⁸ though the lack of any consistent definition of what constitutes a “psychoeducational” intervention is also likely to be of importance. However, as little detail was presented regarding the individual primary studies included, it is difficult to further investigate this issue using the published reviews alone. The primary studies would have to be retrieved in order to fully investigate.

Both reviews carried out some form of validity assessment. One review graded primary studies according to the level of evidence they provided, using criteria previously developed by the authors.³⁸ However, included studies which did not report statistically significant results in favour of psychoeducational interventions were not given an evidence grade, but were simply classed as “non-significant.” Therefore, there was no indication of the validity of these ‘non-significant’ studies in relation to those studies which supported the authors’ hypothesis. The other review used regression to estimate the relationship between threats to validity (publication status, lack of randomisation, lack of placebo control group) and size of effect.⁴⁰ Though they did not formally assess the validity of individual studies, this approach is preferable to that of the other review in which 18 studies reporting non-significant effects were essentially ignored.³⁸

One of the reviews calculated effect sizes for each outcome, weighted these by the inverse of their variance and combined them using meta-analytic methods.⁴⁰ This approach is more likely to provide unbiased estimates of effect than the approach of disregarding any studies without statistically significant findings.³⁸ The review which used meta-analysis indicated that two or more reviewers were involved in the coding of included studies,⁴⁰ otherwise neither review states whether more than one researcher was involved in the processes of study selection, data extraction or validity assessment.

2.1.3 Results of reviews of ‘psychoeducational’ care for cancer patients

2.1.3.1 Psychological outcomes

Barsevick et al reviewed the findings of 48 primary studies (36 RCTs, seven quasi-experimental studies and five descriptive studies) that evaluated depression as an outcome.³⁸ Of these, 30 provided evidence to support the use of psychoeducational interventions for depression in patients with cancer. Eleven of 17 behavioural intervention studies (65%) and seven of ten counselling intervention studies (70%) had positive results.

Four of seven education interventions (57%) were beneficial in relieving depression, and seven of 12 combined interventions that included education (58%) had beneficial results. Six overviews of the literature were also discussed in Barsevick’s review,^{40 18, 28, 34, 51, 55} five of which are included elsewhere in this report.^{18, 28, 34, 40, 51} Three of these overviews reported qualitative or narrative syntheses of the primary studies and concluded that psychoeducational interventions had a beneficial effect on depression.^{34, 51, 55} The other three overviews reported quantitative syntheses and two of the three meta-analyses^{18, 40} reached similarly positive conclusions, with the third reporting no clinically significant effect.²⁸ All three meta-analyses have been included and are reviewed in this report. The authors also noted that an evidence-based treatment guideline recommended counselling psychotherapy in combination with pharmacologic treatment for cancer patients with major depression.⁵⁶

The review by Devine and Westlake⁴⁰ also indicated a beneficial effect of ‘psychoeducational’ interventions on depression in cancer patients (the findings of this review were discussed by Barsevick et al). Devine and Westlake carried out a quantitative analysis by deriving standardised mean differences from included studies.⁴⁰ For

depression, 40 effect sizes were calculated, of which 92% favoured the intervention. An overall homogeneous summary effect size of 0.54 (95% CI: 0.43, 0.65) was calculated for depression. Specific interventions included in the meta-analysis were education alone (4 studies; $d=0.50$), nonbehavioural/noncognitive counseling alone (5 studies; $d=0.66$), muscle relaxation or muscle relaxation with guided imagery only (12 studies; $d=0.40$), and combination-type treatments with educational, behavioural or non-behavioural counseling (12 studies; $d=0.52$). All of these effect size values were statistically significant and homogeneous. (For an explanation of effect sizes, see discussion section.)

The review by Devine and Westlake also included anxiety as an outcome and calculated 55 effect sizes, of which 95% favoured the intervention. The summary effect size was 0.56 (95% CI: 0.42, 0.70), though the included effect sizes were heterogeneous. Statistically significant effects on anxiety were found for certain therapeutic approaches, but these were reported in too few studies for inclusion in the meta-analysis. The overall summary effect size calculated for 'mood' was 0.45 (95% CI: 0.32, 0.58), favouring intervention, though again this was heterogeneous.

2.1.3.2 Physical outcomes

The meta-analysis by Devine and Westlake also included studies which reported 'physical well-being' outcomes. Beneficial effects of 'psychoeducational care' were reported for nausea (0.69 (95% CI: 0.45, 0.92)), vomiting (0.34 (95% CI: 0.09, 0.69)) and pain (0.43 (95% CI: 0.16, 0.69)), though only the effect for vomiting was homogeneous.

2.1.3.3 Other outcomes

The effect of psychoeducational care on patients' knowledge was calculated by Devine and Westlake from 18 individual effect sizes (95% were positive), yielding a summary effect size of 0.90 (95% CI: 0.61, 1.20) which was heterogeneous.

2.1.3.4 Moderating variables

The two reviews included some information on the effects of potential moderating variables. Devine and Westlake⁴⁰ reported larger intervention effects in reducing nausea amongst studies that selected patients with documented nausea, vomiting, or high anxiety prior to treatment. The same review indicated that treatment effects on nausea were larger before chemotherapy than during chemotherapy (nine studies) and after chemotherapy than during chemotherapy (six studies). The combined results of nine studies indicated that the treatment effect for nausea was considerably greater at the last chemotherapy cycle than the first.⁴⁰

2.1.4 Research implications

Both reviews of psychoeducational interventions made recommendations for future primary research in this area. Devine and Westlake⁴⁰ emphasised that better reporting of study design characteristics, participants and interventions is required. They further recommended that multiple experimental treatments be compared in the same study so that the relative effects of different types of psychoeducational care can be assessed. Barsevick et al³⁸ made a similar recommendation, but specified that there was a need for RCTs directly comparing behavioural therapy with counselling psychotherapy. They also recommended that RCTs in this area should: (a) include only patients who have depression at baseline to investigate the management rather than prevention of depression; (b) compare therapeutic interventions with inert alternative interventions that control for time and attention from health care providers; and (c) assess the effects of intervention intensity/longevity.

2.2. Relaxation interventions

2.2.1 Characteristics of reviews

Two of the identified reviews evaluated the effects of relaxation-based interventions in patients with cancer.^{23, 44} These reported searches of the literature from 1980 to 1995. Definitions differed in the two reviews of what constituted a relaxation intervention. Luebbert et al⁴⁴ limited inclusion to 'relaxation training' which was simply defined as "induction techniques which aimed to produce a relaxed physical and mental state in the patient". Wallace et al included relaxation and imagery interventions, with relaxation defined as "a technique that involved physical movement (rhythmic breathing and/or muscle tensing and relaxing in sequence) intended to cause reduction in perception of environmental stimuli, muscle tension, anxiety, stress and pain" and imagery defined as "purposeful mental thoughts imagined to achieve a desired therapeutic goal".²³ Hypnosis was included in the review by Luebbert et al, though this intervention was specifically excluded by Wallace et al.

Both reviews included primary studies that evaluated progressive muscle relaxation (PMR), guided imagery, and autogenic training interventions. Other interventions included audiotape relaxation, live instruction, distraction, and breathing exercises.

Both reviews focused on adult cancer patients. In one,²³ inclusion was limited to studies of patients with cancer pain and in the other only studies of patients undergoing medical (non-surgical) cancer treatment were eligible.⁴⁴

Luebbert et al included a wide variety of outcomes that were categorised as 'treatment-related symptoms' (blood pressure, pulse rate, nausea, pain, vomiting) or 'emotional adjustment' (depression, tension, anxiety, mood, hostility, fatigue, confusion, vigour).⁴⁴ The review by Wallace et al focused on cancer pain, but included studies measuring a range of outcomes including pain intensity, pain relief, distress, knowledge of pain, ability to decrease pain, degree of pain control, physical function, change in affective state, analgesic intake, anxiety, mood, sleep, posture, movement, visual concentration, and quality of family relationship.²³

The reviews also differed in the types of study designs eligible for inclusion. Luebbert et al⁴⁴ limited inclusion to RCTs reporting sufficient information to calculate effect sizes, and included 15 studies (n=742) which reported 56 independent effect sizes. Wallace et al did not state any specific inclusion criteria for study design,²³ but included ten studies (n>260), of which seven were controlled studies.

2.2.2 Quality of reviews

Although the two reviews focussing on relaxation interventions had different approaches to reviewing the evidence (Wallace et al using narrative synthesis, Luebbert et al through meta-analysis), both reviews met only three of the seven validity assessment criteria.

Both carried out a search of multiple electronic databases, supplemented by examination of bibliographies of retrieved texts. In both reviews, the review question was broadly defined in terms of participants and interventions. One review also restricted its inclusion criteria to RCTs.⁴⁴ However, it is clear from the stated criteria that there was a lack of consensus between the two reviews on what constituted a 'relaxation intervention.' Whereas both reviews included interventions such as progressive muscle relaxation and guided imagery, there were clear discrepancies relating to other interventional approaches (e.g. hypnosis).

Neither review stated how many reviewers were involved in selecting or extracting data from the identified studies nor were they presented in sufficient detail for the reader to examine the appropriateness or accuracy of these processes. No formal assessment of the validity of included primary studies was undertaken, nor was any thorough investigation of heterogeneity undertaken during the synthesis in either review.

2.2.3 Results of reviews

2.2.3.1 Psychological outcomes

Luebbert et al combined outcomes into eight different categories of 'emotional adjustment'.⁴⁴ Statistically significant summary effect sizes (ES) were found for depression (ES=0.5422), tension (ES=0.5156), anxiety (ES=0.4511), mood (ES=0.4421), and hostility (ES=0.3438). The authors interpreted the magnitudes of effect sizes in terms of the Cohen index (0.20=small effect, 0.50=medium effect, 0.80=large effect),⁵⁷ and concluded that relaxation training had a statistically significant medium effect on depression and a statistically significant small effect in the reduction of anxiety and hostility. Tension and mood were only measured in two studies. Summary effect sizes for fatigue, confusion and vigour outcomes were not statistically significant.

Wallace et al reported mixed findings on "affective variables" (anxiety, distress and mood), with three studies demonstrating positive changes associated with intervention and two demonstrating no difference between experimental and control groups.²³

2.2.3.2 Physical outcomes

Luebbert et al reported statistically significant and homogeneous summary effect sizes for relaxation training on measures of blood pressure (ES=0.5518), pulse rate (ES=0.5382), nausea (ES=0.4545), and pain (ES=0.4383).⁴⁴ The authors concluded that relaxation interventions had a small but statistically significant effect on the treatment-related symptoms of the medical treatment of cancer (nausea and pain). They also concluded that relaxation training had a statistically significant medium-sized effect on pulse rate and blood pressure in patients with cancer. The summary effect for vomiting was statistically significant (ES=0.5451 (95% CI: 0.12, 0.97)), but was heterogeneous and was not further interpreted or analysed by the authors.

Wallace et al reported that two of three controlled studies that investigated functional status found no statistically significant difference between experimental and control groups on this outcome.²³

2.2.3.3 Other outcomes

Wallace et al reported mixed results from studies that included measures of patients' control over pain.²³ One experimental study found that experimental groups had statistically significantly higher scores on ability to control pain over comparison groups, but this and a second experimental study found no difference in the degree of control over pain. A third study indicated that patients receiving intervention improved their feelings of control over pain.

2.2.3.4 Moderating variables

Luebbert et al investigated the effects of potential moderator variables in their meta-analysis.⁴⁴ They reported a statistically significant difference between relaxation training offered independently and that offered in conjunction with medical treatment for anxiety, in favour of independent treatment ($p=0.0079$). The authors of this review also reported there was a tendency towards statistically significant differences favouring low intensity (less than 2 hours duration) over high intensity interventions for anxiety ($p=0.05$).

2.2.4 Research implications

Wallace et al made several recommendations for the conduct of primary research investigating the effects of relaxation/imagery interventions on cancer pain.²³ They stated that further research needed to consist of controlled studies with 'usual care' control groups, which clearly report details of the intervention, disease state, pain problem, outcome measures and concomitant treatments. They indicated that functional status and affective variables need to be measured as outcomes, analgesic intake be measured as a covariate (variables that are not of primary interest, but are measured because they are likely to affect the variable of primary interest) rather than an outcome measure, and that adherence needs to be investigated. The review authors also stated that long-term effects need to be investigated and longitudinal studies need to be conducted when appropriate.

Luebbert et al indicated that the influence of individual factors on the variance of effect would be a worthwhile target for future research.⁴⁴

2.3 Group interventions

2.3.1 Characteristics of reviews

Three reviews were identified which aimed to evaluate the effects of psychosocial interventions delivered to cancer patients in a group format.^{26, 34, 35} A review by Bottomley³⁵ limited inclusion to studies that examined the effects of professionally conducted intervention groups (rather than those of a self-help nature or facilitated by non-professional leaders). The other two reviews (including another by Bottomley) simply stated that studies were selected if they evaluated “group interventions”³⁴ or a “psychological intervention in a group format.”²⁶ The reported searches covered the literature from 1970 to 2000.

One review focused on the effects of group interventions delivered to children or adolescents (aged up to 18 years) with an identified chronic condition, including those with cancer.²⁶ One review specifically limited inclusion to adult cancer patients³⁵ and the third included any cancer patients, though examination of the included studies indicates that all patients in this review were adults.³⁴

The review of group interventions in paediatric populations did not state any inclusion criteria relating to study outcomes, simply that interventions had to have “the goal of improving psychological adjustment to the illness or reducing physical symptoms.”²⁶ Of the two reviews by Bottomley, one included only studies which measured survival³⁴ and the other did not state any criteria specific to outcomes, but included studies which measured depression, anxiety, coping, self esteem, information, locus of control, general health status, quality of life, “qualitative” (no further details given) and various ad hoc outcomes.³⁵

The review by Bottomley that investigated the effects of group interventions on survival, included RCTs.³⁴ A total of three trials (n=278) were included. The other reviews did not state any inclusion criteria in relation to study design. The 1997 review by Bottomley included 27 studies (n=2064), 15 of which were controlled and 11 of these were randomised.³⁵ Plante et al included 17 studies relating specifically to cancer (number of participants not given).²⁶

2.3.2 Quality of reviews

The review by Plante et al²⁶ met two of the seven systematic review validity criteria: two databases were searched with following up of references and inclusion criteria were partially stated for participants and interventions. However, the review question was very broadly defined to include a wide range of chronic diseases, the characteristics of included studies were not available and many of the identified studies in paediatric cancer populations were simply not included in the narrative synthesis. No explanation was given as to why these studies had been excluded from the synthesis.

The two reviews by Bottomley^{34, 35} also combined retrieved studies using narrative synthesis, though they used this approach more systematically. Meeting four of the quality criteria, both reviews had a reasonably well-defined question, undertook a search of multiple databases (including sources of unpublished data), and provided details of the included studies. Validity assessment was not formally undertaken in either review, though the review evaluating survival outcomes did develop a list of variables important in the design and interpretation of the included RCTs.³⁴

No review in this section indicated that any more than a single reviewer was involved at any stage of the process.

2.3.3 Results of reviews

2.3.3.1 Psychological outcomes

One review included 27 primary studies.³⁵ Fourteen of these evaluated what were broadly classified as 'supportive' interventions and eleven evaluated interventions considered to be 'structured' in approach. Most studies reported some benefit of intervention, with the exception of one study that found a negative effect for newly diagnosed breast cancer patients after receiving supportive therapy.⁵⁸ In this study, the intervention group were statistically significantly more depressed and had less vigour than a control group, at first post-intervention assessment. Only two studies compared both 'supportive' and 'structured' interventions against control.⁵⁹ One RCT found statistically significant improvements in anxiety amongst mixed sex and diagnosis cancer patients randomised to either supportive discussion groups or structured coping skills training, compared to control.⁵⁹ Improvements were significantly greater in the coping skills group than the supportive discussion group. The second study included newly diagnosed, clinically distressed cancer patients and indicated that statistically significantly greater improvements in affective functioning and coping occurred post-intervention for patients receiving cognitive behavioural therapy (CBT) than those who received supportive group therapy or no intervention.⁶⁰ At three months post-intervention, both intervention groups had statistically significantly better psychological functioning (anxiety and depression) and coping styles than the refusal non-intervention group.

The review of interventions in children by Plante et al, classified interventions into three main groups: 'emotional support groups,' 'adaptation/skill development groups' and 'summer camps.'²⁶ Nine studies of 'emotional support groups' in children with cancer were included in the review, but the authors only reported the findings from a single study which found that participants receiving active treatment reported increased psychological symptoms. The results of a single 'adaptation/skill development' study were reported. The study found (at 6 months follow-up) that a combination of a multifamily format with a cognitive-behavioural approach decreased anxiety and posttraumatic stress disorder (PTSD) symptoms in all family members and improved family functioning in several domains. Seventeen studies of summer camp interventions included children with cancer. Uncontrolled studies found summer camps increased knowledge of cancer, and improved social and physical activity after camp had finished. However, summer camps were reported to result in equivocal findings regarding self-concept.

2.3.3.2 Physical outcomes

Bottomley³⁴ reviewed three RCTs that specifically measured the effect of psychosocial intervention on survival in cancer patients.⁶¹⁻⁶³ Two of these RCTs reported positive effects on survival. One found at 10 year follow-up (after randomisation) that survival time was 36.6 months in the intervention group compared to 18.9 months in the control group. Another found at 5-6 year follow up that statistically significantly fewer patients had died in the intervention than in the control group (3/34 compared to 10/34, $p=0.03$). The third RCT, however, found no statistically significant difference in survival between intervention and control groups at ten years follow-up. These three RCTs differed from one another in terms of participant diagnosis, interventional approach, duration of intervention and professional background of those delivering the interventions. The review author notes there are numerous variables clinically relevant to the course of the disease that were not taken into full consideration when the results of these studies were published.

2.3.3.3 Moderating variables

All three reviews took a narrative approach to combining the included studies. No formal approach for identifying moderator variables was therefore undertaken.

2.3.4 Research implications

The majority of research recommendations made by the reviews of 'group' psychosocial interventions were concerned with the design of good quality RCTs e.g. appropriate use of randomisation and controls, undertaking multi-centre trials with large samples and long-term follow up. Other general recommendations included improvement in the description of psychosocial interventions and procedures used, the use of appropriate standardised

outcome measures, use of robust qualitative as well as quantitative methods, and greater consideration of potential confounding factors.^{26, 35}

Recommendations for studies measuring the effect of psychosocial intervention on survival included careful grouping of disease sites plus examination of all prognostic variables in any analysis, and complete recording and longitudinal monitoring of changes in patients' medical status over the entire period until death.³⁴

2.4 Broader scope reviews

2.4.1 Characteristics of reviews

Sixteen of the included systematic reviews evaluated a broader range of psychological or psychosocial interventions than those discussed in earlier sections of the report. These were published between 1992 and 2004, and reported searches of the literature spanning from 1966 to 2002.^{16, 18, 20-22, 24, 28, 32, 39, 41, 43, 45, 46, 50-52}

Intervention approaches evaluated in the reviews included group therapy, individual therapy, family therapy, counselling, psychoanalysis, education, stress management, cognitive behavioural therapy, relaxation, imagery, meditation training, emotional expression, biofeedback, coping skills training, problem solving training, social skills training, cognitive/attentional distraction, hypnosis, desensitisation, rehearsal modelling, contingency management, home visits and telephone calls from health care professionals, and various combined approaches.

Very few of the included reviews provided any clear definition of what constituted a psychosocial or psychological intervention, though examination of the inclusion and exclusion criteria indicates that there is a lack of agreement between the reviews. Though many of the sixteen reviews appeared to include educational or psychoeducational interventions amongst other approaches, two specifically excluded interventions limited to exchange of information,^{43, 51} one of which also excluded educational programmes and self-help groups.⁵¹ One review of psychosocial interventions specifically excluded hypnosis,¹⁶ whereas this approach was considered appropriate elsewhere.³² Two other reviews selected primary studies according to the focus of the intervention, with one including only interventions aimed at reducing cancer treatment side effects⁴⁵ and the other excluding those studies which focused solely on the treatment of side effects.³²

All sixteen reviews selected intervention studies that were limited to the treatment of cancer patients. Seven of these limited inclusion to adult cancer patients^{16, 18, 21, 24, 32, 50, 52, 64} and two to children with cancer.^{22, 39} All reviews included participants with various types of cancer, with the exception of one which included only those with melanoma.²⁰ Participants in most reviews also tended to vary in terms of their stage of disease progression and the treatment they received, with the exception of a single review which focused on behavioural interventions in cancer patients undergoing or having already undergone traditional cancer treatment.⁴⁵

A wide range of both psychological and physical outcomes was measured in these reviews. Psychological outcomes included anxiety, depression, mood, stress, distress, anger, hostility, confusion, self-esteem, self-concept, locus of control, coping/control skills, emotional adjustment, vocational or domestic adjustment, health beliefs and general affect. Physical outcomes included nausea, vomiting, physiologic arousal, pain, fatigue, weight loss, functional ability, activity level, sexual relations, leisure activities, immune outcomes, recurrence rates, and survival. A small number of reviews also included quality of life outcomes and/or measures of interpersonal/social relationships.^{21, 32, 41}

Five of the reviews included only randomised controlled trials (RCTs)^{18, 32, 41, 43, 52} and six stated that only 'controlled' studies were included.^{16, 21, 28, 39, 50, 51} The remaining reviews either explicitly included a broader range of study designs,^{24, 45, 46} or did not state any inclusion criteria relating to design.^{20, 22} Among the 14 who provided sufficient information, the reviews in this section included between 166 and 5991 participants. Three reviews

included less than 1000 participants,^{22, 46, 50} five included 1000 to 2000,^{16, 20, 43, 45, 51} three included 2000-3000,^{28, 39, 41} and three reviews included over 3500 participants.^{18, 32, 65}

2.4.2 Quality of reviews

The sixteen reviews included in this section covered a broad range of psychosocial interventions and outcomes in people with cancer and between them incorporated over 300 primary studies.

These sixteen reviews met between two and six of the methodological criteria. Seven reviews fully specified their inclusion criteria in terms of study design, participants, interventions and outcomes^{16, 18, 24, 32, 39, 43, 66} whilst nine partially specified their criteria.^{20-22, 41, 45, 46, 50-52} Two reviews reported searching five electronic databases,^{46, 52} two reviews searched four databases^{41, 43} and five searched three databases.^{20, 21, 24, 28, 50, 64} However, the majority of reviews were limited to searching only two electronic databases, often consisting of a general medical database (e.g. Medline) and a psychology database (e.g. PsycLit).^{16, 18, 22, 32, 39, 45, 51} All but five of the sixteen broad scope reviews indicated some form of supplementary searching in the form of scanning reference lists of retrieved papers or hand searching of relevant journals. Only one review explicitly stated that efforts were made to identify and include (where relevant) unpublished research⁴¹ and one other clearly assessed publication bias.²⁸

Two-thirds of the broad scope psychosocial intervention reviews limited inclusion to 'stronger' study designs, either controlled studies,^{16, 21, 28, 39, 51} or more specifically, randomised controlled studies (RCTs).^{18, 32, 41, 43, 50, 52} Seven of the sixteen reviews formally assessed study validity. Two of these were limited to applying a broad 'strength of evidence' hierarchy,^{22, 24, 64} four used previously published scales,^{28, 41, 43, 52} and two used scales designed by the review authors themselves.^{39, 51}

Of the sixteen reviews, twelve combined the data in a narrative synthesis. Three of these utilised some form of 'vote-count' approach, in which conclusions were based on the number of identified studies reporting a statistically significant result in favour of the intervention.^{24, 51, 64, 67} Four reviews combined the primary data in a meta-analysis,^{18, 24, 28, 52} though only three of these formally assessed heterogeneity.^{18, 28, 52}

Four of the reviews indicated that more than one reviewer was involved at some stage of the review process (e.g. study selection, data extraction, validity assessment).^{39, 41, 45, 52} The remaining reviews did not provide any information about the process.

2.4.3 Results of reviews

2.4.3.1 Psychological outcomes

Thirteen of the 16 reviews investigated the effects of psychosocial interventions on psychological outcomes in patients with cancer. Where possible, emphasis will be placed on the findings from reviews of higher methodological quality.

General results

Many of the included reviews investigated the overall effects of 'psychosocial interventions' whereas some reported overall effects before investigating the effects of specific psychosocial approaches. The findings for the overall effects of psychosocial interventional approaches are presented first.

One review of psychosocial interventions for children with chronic health conditions met six of the seven quality criteria.³⁹ In children with cancer, this review found possible beneficial effects of psychosocial interventions on the Child Behaviour Checklist, the Social Support Scale for Children, adjustment to school, interaction, anger, and social competence. No beneficial effects on the Child Depression Inventory, the State-Trait Anxiety Scale for Children, family functioning, depressed mood, or upset/tension were reported. Findings on the Self Competence Scale were mixed. However, the results from only three studies in

cancer patients were included in this review and the majority of outcomes were from one study.

Other reviews that appeared to be of reasonable methodological quality included one by Sheard et al,²⁸ who conducted meta-analyses of controlled studies of psychosocial interventions for the prevention of anxiety and depression in cancer patients. The included primary studies were very heterogeneous. After conducting sensitivity analyses, the authors concluded that implementation of psychosocial interventions may result in a moderate beneficial effect on anxiety, but not depression. They indicated that interventions aimed at patients at high risk of psychological distress may have stronger effects, but did not make any clear distinction between the effects of different types of intervention. Another review of similar methodological quality by Sollner et al²⁰ concluded (on the basis of five primary studies) that psychosocial interventions were effective in patients with melanoma with respect to affective disorders, coping, distress and knowledge.

Six of the fifteen reviews (40%) which measured psychological outcomes met four of the review quality assessment criteria.^{16, 18, 32, 41, 43, 45} Four of these evaluated a broad range of psychosocial interventions.^{16, 18, 32, 43} Three used a narrative approach to synthesise data across psychosocial interventions and reached quite different conclusions. Hill et al¹⁶ examined the effects of interventions in both cancer and coronary heart disease and concluded that, for patients with cancer, psychosocial interventions broadly reduced psychological distress and that these effects have been found to persist at several months follow-up. Ross et al³² concluded that the evidence failed to demonstrate conclusive effects of psychosocial interventions on anxiety, depression, mood, or emotional adjustment of patients with cancer; whereas Sellick et al⁴³ stated that (based on the findings of 10 RCTs) there was sufficient evidence to indicate a positive effect of psychosocial intervention on depression in cancer patients. A large meta-analysis of RCTs by Meyer and Mark¹⁸ found statistically significant effects of psychosocial interventions on emotional and functional adjustment, treatment and disease related symptoms and compound/global measures. However, the summary effect sizes for these outcomes ranged from 0.19 to 0.28 which, according to Cohen's criteria,⁵⁷ would indicate fairly small effects of the included interventions.

Of the reviews that met three or fewer of the quality assessment criteria, two simply indicated that a wide range of psychological outcomes had been evaluated and that the majority of primary studies report some form of psychological benefit of psychosocial intervention.^{21, 50} A third undertook both 'vote count' and meta-analytic methods of synthesis and reported a statistically significant positive effect for psychosocial interventions on 'psychological outcomes' in cancer patients.^{24, 64}

Specific interventional approaches

Some of the included reviews either indicated that their focus was largely upon particular approaches used in psychosocial care, or carried out specific subgroup analyses to determine the effects of different interventional approaches. Often, a distinction was simply made between behavioural and non-behavioural/counselling methods, though in some cases further discrete categories were defined. These more specific results are presented below.

Trijsburg et al, classified psychosocial interventions as 'tailored counselling interventions,' 'structured counselling interventions' or 'behavioural interventions and hypnosis.'⁵¹ Effects of both types of counselling intervention were mixed, with around 50% of outcome variables measured favouring intervention. Around 70% of outcome variables measured favoured behavioural/hypnosis interventions over control. The authors concluded that tailored counselling appeared to be most effective with respect to distress, self-concept, (health) locus of control, and sexual problems. Structured counselling interventions were considered most effective with respect to depression and distress, and behavioural/hypnosis interventions most effective with respect to anxiety, anger, hostility and confusion.

Several reviews of moderate methodological quality (meeting four of seven quality criteria) attempted to investigate the effect of different psychosocial approaches.^{18, 41, 43, 45} Meyer

and Mark¹⁸ undertook subgroup meta-analyses according to type of intervention. Interventions were grouped as 'behavioural', 'information/education', 'non-behavioural counselling/therapy' and 'social support'. Statistically significant positive effects on emotional adjustment were reported for behavioural, information/education and non-behavioural counselling/therapy, but not social support. Statistically significant beneficial effects on treatment and disease-related symptoms were reported for behavioural and information/education interventions, and the latter were reported to positively influence functional adjustment. However, as with the overall results, these statistically significant effect sizes were of fairly small magnitude. It is also unclear what specific interventions were included in each of the categories developed by the review authors. The review by Redd et al⁴⁵ focused on 'behavioural interventions' (including relaxation, cognitive/attentional distraction, hypnosis, desensitisation, rehearsal modelling, contingency management, emotive imagery and cognitive restructuring), reporting that these types of intervention reduced cancer patients' acute anxiety and distress associated with diagnostic and treatment procedures. Newell et al⁴¹ concluded that "group therapy education, structured and unstructured counselling, and cognitive behavioural therapy" offered the most promise for their medium- and long-term benefits for many of the outcomes explored. However, though Newell's review evaluated a large number of RCTs several of the positive findings were based on the findings of very few (or just a single) primary studies. Sellick et al⁴³ indicated that effects of psychosocial interventions were similar whether delivered in a group or individual format.

Only one review that met fewer than three quality criteria investigated the effects of different approaches and/or settings. Cwikel et al^{24, 64} reported that the results from studies of interventions delivered in group and individual intervention studies were similar and that the positive psychological effects associated with 'cognitive treatments' were greater than those for 'non-cognitive treatments.'

2.4.3.2 Physical outcomes

Twelve of the 16 'broad scope' reviews evaluated the effects of psychosocial interventions on physical outcomes. Again, emphasis will be placed on the findings of those reviews that were methodologically more robust.

Only one review met all seven of the quality assessment criteria. This meta-analysis by Chow et al⁵² included eight randomised controlled trials that reported the effects of psychosocial intervention on survival in patients with cancer. Three studies reported some statistically significant positive effect of psychosocial intervention on survival and five reported non-significant differences between intervention and control groups. Data were pooled on survival at one year and at four years. When all eight trials were pooled, there was no statistically significant difference in overall survival at one year (relative risk (RR) 0.94 (95% CI: 0.72, 1.22)) or at four years (RR 0.93 (95% CI: 0.77, 1.13)). A subgroup analysis of the four trials that included only women with metastatic breast cancer similarly found no statistically significant survival difference at one year (RR 0.87 (95% CI: 0.67, 1.14)) or four years (RR 0.91 (95% CI: 0.76, 1.10)). The authors cautiously conclude that psychosocial intervention does not prolong survival in cancer, but state that they cannot rule out the possibility of a possibly small effect, due to the fact that the identified trials were small, short in duration and few in number. The authors also acknowledge that this small number of trials evaluated a heterogeneous group of interventions, meaning that useful comparisons of different interventional approaches could not be made. There was also insufficient high quality evidence to conclude whether intervention might work better in the short- or long-term, or in early stage versus late stage of illness in terms of survival.

Neither of the reviews that met five of the seven quality assessment criteria attempted to reach any conclusions about the physical effects of psychosocial interventions in general.^{20, 51} Trijsburg found that behavioural/hypnosis techniques had positive effects for pain, nausea and vomiting in the three studies where these techniques and outcomes were investigated.⁵¹ Sollner found positive effects for psychosocial interventions in melanoma patients in terms of the number of natural killer cells and Helper T-cell lymphocytes as well as in terms of survival and recurrence rates.²⁰ However, these results were from a single study.

Five reviews that met four quality criteria reported physical outcomes.^{18, 22, 32, 41, 45} Three of these reviews attempted to give an overall indication of the effects of psychosocial interventions. The meta-analysis by Meyer and Mark¹⁸ found a statistically significant effect in favour of intervention for 'treatment and disease related symptoms' (28 studies; $d=0.26$ (95% CI: 0.16, 0.37)) but not for 'medical' outcomes (5 studies; $d=0.17$, (95% CI: -0.10, 0.44)). A narrative synthesis by Ross et al³² included seven of the eight RCTs included in Chow et al's⁵² meta-analysis and found mixed results concerning survival, with four out of the eight RCTs finding psychosocial intervention to be positively associated with this outcome and four finding no such association. Newell et al used a 'vote-count' approach and found no strong evidence for the beneficial effects of psychosocial intervention for physical, immune, or survival outcomes.⁶⁷

All five of these reviews that met four quality criteria reported the effects on physical outcomes from particular interventions/approaches. Meyer and Mark found statistically significant positive effects on 'treatment and disease related symptoms' for approaches classified as 'behavioural' ($d=0.32$ (95% CI: 0.16, 0.48)) and 'informational/educational' ($d=0.21$ (95% CI: 0.01, 0.40)), but not those classified as 'nonbehavioural/counselling'. None of the interventional approaches were statistically significant in terms of the 'medical' outcomes.¹⁸ Newell et al found both self-practice and hypnosis to be effective in reducing conditioned nausea and vomiting associated with cancer treatment, but this finding was based on the results from a single RCT.⁴¹ Redd et al found that 12 of 13 RCTs which compared behavioural intervention approaches with no treatment or attentional controls favoured the intervention for reducing anticipatory nausea and vomiting, but not post-treatment side-effects in patients undergoing chemotherapy.⁴⁵ The same review reported that four of five RCTs and seven non-randomised studies found a positive effect for behavioural interventions on pain outcomes. The authors concluded that hypnotic-like methods held the most promise for reducing pain.⁴⁵ The four RCTs which reported a positive effect on survival in the review by Ross et al³² evaluated the following interventions: one year of group therapy with self-hypnosis,⁶¹ six weeks of psychoeducational group therapy,⁶² individual psychotherapy at least every second day during hospital stay⁶⁸ and four weeks post-surgical follow-up by specialised nurses⁶⁹ (the latter was excluded from Chow et al's⁵² meta-analysis because the intervention not only included psychosocial intervention but also clinical assessment in a specialised home care programme). Interventions found to be ineffective in terms of survival in the Ross review were: one year of individual counselling,⁷⁰ six months of group therapy,⁷¹ 35 weeks of supportive and cognitive behavioural therapy plus a weekend coping skills course,⁷² and eight weeks of cognitive behavioural therapy.⁷³ McQuaid et al²² evaluated the strength of evidence in support of interventions for reducing nausea and vomiting in children undergoing cancer treatment according to the "Chambless" criteria for empirically supported psychological therapies.⁷⁴ According to these criteria, interventions using imagery with suggestion were considered "well established," those based on distraction with relaxation were considered "probably efficacious" and the use of video games in this population was categorised as "promising."

Four reviews met three or fewer quality criteria.^{21, 24, 46, 50} For survival outcomes, one of these reviews reported an overall positive effect for psychosocial interventions²¹ and two failed to find such an effect.^{24, 46} In relation to non-survival physical outcomes, one review found psychosocial interventions to be generally useful for decreasing pain⁵⁰ and another found statistically significant positive effects for functional status and physical symptoms.²⁴

2.4.3.3 Quality of life

Four reviews reported quality of life (QoL) outcomes. These reviews met either three^{32, 41} or four^{21, 50} of the quality assessment criteria. However, insufficient evidence is available to determine the effect of psychosocial interventions on QoL. Two of the reviews did not present QoL outcomes separately^{21, 50} and one found that QoL was improved in four primary studies, though it is unclear exactly how many studies in total reported these outcomes.³² Of the various interventions evaluated by Newell et al, an overall effect on QoL was only found for structured counselling and this was based on the positive findings of a single study.⁴¹

2.4.3.4 Moderating variables

Seven reviews investigated, to a greater or lesser extent, the potential variables that might influence the effects of psychosocial interventions in patients with cancer.^{18, 24, 28, 32, 43, 45, 50}

Three reviews investigated the influence of screening for psychological distress at baseline on study outcomes.^{18, 24, 32} Ross et al emphasised that all five studies in their review which included only patients with psychological distress, reported 'significant' effects of psychosocial intervention on anxiety and/or depression.³² This is in contrast to the two meta-analyses that investigated this variable and found screening for distress did not significantly influence the effect.^{18, 24} Meyer and Mark also reported that patients' risk of psychological distress (categorised as 'low,' 'medium' or 'high') did not significantly impact on the effect of intervention.¹⁸

Three reviews attempted to assess the impact of delivering psychosocial interventions in group versus individual settings.^{28, 32, 50} All three indicated that the effects for both group and individually delivered interventions were similar, with Sheard et al indicating that effects for group interventions might be slightly larger (though this finding was not statistically significant).²⁸

Other potential moderating variables were examined in individual reviews. Sheard et al indicated that use of more experienced therapists was associated with greater reductions in anxiety and depression, that there appeared to be a dose-response relationship between intervention and outcome, and that effects were significantly greater for patients with more advanced disease.²⁸ However, these variables were not investigated elsewhere. Redd et al reported that the success of certain paediatric interventions (e.g. imaginative/hypnotic procedures) could be predicted by children's age, but this was based on observations from a single study.⁴⁵

2.4.4 Research implications

Several of the reviews of psychosocial interventions in people with cancer made general recommendations about improving the validity of primary studies in relation to aspects of randomisation, blinding, monitoring adherence, and handling of loss to follow-up.^{28, 32, 39, 41, 50} There did not appear to be any substantial change in these general recommendations over time.

A common recommendation for future research was the conduct of adequately powered, large scale primary studies to allow evaluation of the possibly small effects associated with psychosocial interventions.^{32, 39, 66} Trijsburg et al suggested that studies in this area need to adequately control for levels of attention and social support between groups, as well as controlling for psychological variables such as trait anxiety, neuroticism and level of premorbid functioning).⁵¹ Both Trijsburg et al⁵¹ and Meyer¹⁸ indicated that there is a need for more studies directly comparing different interventional approaches (e.g. educational programmes/information versus psychological interventions).

Although none of the included reviews explicitly stated an intention to identify data on cost-effectiveness, the relative lack of this type of research is apparent from the research recommendations made in the reviews. Four of the included reviews explicitly indicated the need for further research on the cost-effectiveness of psychosocial interventions in cancer.^{18, 39, 45, 50}

Several of the reviews noted the need to investigate the effects of psychosocial intervention on the specific population of patients at risk of, or suffering from, significant distress prior to the intervention.^{16, 18, 24, 28, 32, 50, 64} Ross et al suggested that screening for psychological distress or available social support could enhance any effect on well-being.³²

Several review authors noted that the primary research was generally limited to evaluating the magnitude of effects associated with psychosocial interventions. The reviews by McQuaid, Meyer, Redd, Ross and Chow all recommended that in addition to evaluating the

size of effect, further research needs to provide a clearer assessment of the specific mechanism of action for each intervention.^{18, 22, 45, 52, 75}

Some authors made recommendations intended to enhance the external validity of future research.^{18, 28, 32} Meyer¹⁸ noted that certain populations (i.e. men and ethnic minorities) were underrepresented in the existing body of literature, whilst the review by Sheard⁶⁶ (published in 2002) recommended that further research needs be conducted in a European oncology setting.

The findings of three meta-analyses generally suggested there is little or no effect of psychosocial interventions on survival and 'medical outcomes', yet because of the paucity of large, well designed trials, all explicitly recommended further primary research in this area.^{18, 24, 52}

3. PSYCHOSOCIAL INTERVENTIONS FOR HEART DISEASE PATIENTS

One review evaluated the effects of a specific intervention (education) in patients with heart disease.³⁷ Seven reviews assessed the effects of a range of psychosocial interventions.^{16, 27, 29, 30, 33, 36, 42} One, a Cochrane review, covered a variety of psychosocial interventions but specifically highlighted stress management.⁴⁹ The review focusing on education will be discussed first followed by the more general ones. Where the effects of specific interventions have been reported separately within the general reviews such effects will be highlighted. At the time of writing two relevant Cochrane reviews were in progress.^{47, 48} Protocols are currently available, and details from these protocols are given in the data extraction tables in Appendix 5.2.

3.1 Educational interventions

3.1.1 Characteristics of review

One systematic review evaluated the effects of educational interventions in patients with heart disease.³⁷ Specifically, the review investigated the effects of educational interventions on adult patients diagnosed with coronary artery disease, including MI, angina and also those undergoing CABG surgery. This review was published in 1992 and reported searches of the literature from 1971 to 1990.

No precise definition was given as to what might constitute an educational intervention. Intervention approaches evaluated in the review included one to one counselling, group education, interpersonal communication, audiovisual and memory aids, self-monitoring and social support.

A range of study designs was eligible for inclusion in the review. Overall sample sizes of included studies needed to be at least 10 in each experimental group at the end of the follow up period. Thirty-eight studies were included in the review with a total of 4967 participants. Twenty-eight studies had a control group (of which 15 were randomised, 7 matched comparison and 6 non-matched comparison) and ten were single group pre-test post-test.

No inclusion criteria for outcomes were pre-specified, however the review included a range of psychological and physical outcomes.

Studies were combined using meta-analysis and weighted by sample size and variance. Statistically homogeneous studies were combined to produce effect sizes for a range of outcomes (see discussion for guidance on the interpretation of effect sizes). Outlier studies were removed as necessary.

3.1.2 Quality of review

The review met six of the seven items used to assess methodological quality. It had clearly defined questions and specified inclusion criteria for study design, participants and interventions. Outcome criteria were not stated. The search was thorough using a range of electronic databases and the authors attempted to identify unpublished material. However, foreign language papers were not eligible for inclusion, which may have led to some publication bias. A formal assessment of the quality of the included studies was not performed. Data extraction was carried out by more than one reviewer, but it is unclear if other stages of the review process involved one or more reviewers. Also unclear is if studies combined in the meta-analyses were sufficiently homogeneous in terms of clinical populations and study designs. Reasons were given for the exclusion of outliers and one-group studies from the meta-analyses.

The authors stated some limitations of the review including the overall number of primary studies being relatively small when one-group studies were removed and the variety of outcomes in included studies leading to a small number of studies reporting each outcome.

In terms of limitations of the included studies, the authors commented that many interventions were designed without explicit reference to a theoretical or educational model.

3.1.3 Results

3.1.3.1 Psychological outcomes

The studies that measured stress were not homogeneous and therefore no effect size was calculated.

3.1.3.2 Physical outcomes

The review reported statistically significant effects for blood pressure (5 studies): 0.51 (95% CI: 0.24, 0.77) and mortality (7 studies): 0.24 (95% CI: 0.14, 0.33). No statistically significant effects were found for return to work or morbidity.

The review reported statistically significant effects for a range of behavioural outcomes, including exercise (12 studies): 0.18 (95% CI: 0.07, 0.29) and diet (9 studies): 0.19 (95% CI: 0.05, 0.34). No statistically significant effects were found for drug adherence or smoking.

The authors concluded that cardiac patient education programmes showed a measurable impact on clinical and behavioural outcomes.

3.1.3.3 Moderating variables

A number of moderating variables were examined including contact frequency, total length of contact and channel of intervention. Adherence to the five key educational principles of relevance to the participant, individualisation of the programme to the participant's needs, provision of feedback, reinforcement and facilitation of behaviour change was also addressed. No differences were found for contact frequency, total contact hours, channel of intervention and length of follow-up. Adherence to educational principles did, however, influence outcome.

3.1.4 Research implications

No research implications were stated in the review.

3.2 Broad scope reviews

3.2.1 Characteristics of reviews

Eight of the included systematic reviews aimed to evaluate the effects of a broad range of psychological or psychosocial interventions in patients with heart disease.^{16, 27, 29, 30, 33, 36, 42, 49} One of these assessed the effects of psychosocial interventions with particular reference to stress management.⁴⁹ The reviews were published between 1987 and 2004 and reported searches of the literature spanning from 1970 to 2001. Three reviews did not supply search dates.^{29, 30, 36}

Interventions evaluated in the reviews included health education, stress management, exercise training, information provision, counselling / advice, group or individual therapy, cognitive behaviour therapy, relaxation training, imaging, behaviour modification, emotional support, psychodynamic interpretation and combined approaches.

Inclusion criteria tended to be broad and all encompassing. In several reviews the emphasis was on interventions that reduced risk factors for the secondary prevention of cardiac events and mortality.^{27, 29, 30, 33, 42} One review specifically excluded interventions to address Type A behaviour (a behaviour pattern characterised by aggressiveness, ambitiousness, restlessness and a strong sense of time urgency).¹⁶ Some reviews specified that interventions were offered in addition to standard care,^{16, 27, 29, 30, 42} whilst others provided no details about any co-interventions.^{33, 36}

One review had stringent inclusion criteria and stated that psychosocial interventions had to be delivered by health care workers with specific training in such techniques but could be delivered as a single modality or as part of cardiac rehabilitation. Comparison groups needed to be usual care or no intervention and follow up needed to be of at least 6 months duration.⁴⁹

Three reviews merely stated that participants were patients with heart disease.^{16, 29, 42} The other five provided more detail about their inclusion criteria; which were patients who had experienced a cardiac event within the previous 6 months;²⁷ patients with established CHD, angina⁴⁹ or who had had AMI, PTCA or CABG;^{30, 49} adults recovering from CABG surgery³³ and people with Type A behaviour pattern and / or at risk of CHD morbidity / mortality.³⁶ In four of the reviews the number of participants ranged between 1000 and 2000,^{16, 30, 33, 36} in two reviews numbers were between 3000 and 4000^{29, 42} and one included approximately 9000 participants.²⁷ One review had 12,841 patients (including patients who had taken part in the large, recently conducted ENRICH trial). A subset of patients in this review had participated in stress management trials as defined by the review authors (5242 patients).

A wide range of both psychological and physical outcomes was evaluated across the eight reviews. Psychological outcomes included stress / distress levels, change in behavioural risk factors, anxiety, depression, mood states and type A personality behaviour. Physical outcomes included blood pressure, morbidity, mortality, cardiac mortality, recurrence of MI, CABG, incidence of angina pectoris, cholesterol levels, weight, smoking, exercise, physical functioning and post surgical physical measures. One review also evaluated resource use and quality of life, which included return to work, hospital stay and general quality of life.³³

Three of the reviews included only randomised controlled trials (RCTs),^{29, 30, 49} with one specifying that only trials with a parallel group design were acceptable.⁴⁹ Three stated that only 'controlled' studies were included.^{16, 27, 36} One review included reviews and meta-analyses in addition to controlled studies³³ whilst one did not state any inclusion criteria relating to study design.⁴²

3.2.2 Quality of reviews

Although each of the systematic reviews had a broad scope, all addressed a well-defined, if broad, question. Four reviews fully specified their inclusion criteria in terms of study design, participants, interventions and outcomes^{16, 27, 30, 49} whilst four partially defined their inclusion criteria.^{29, 33, 36, 42}

Across the eight reviews there was very little overlap in terms of the included primary studies. One possible explanation for this is the differences in inclusion criteria. An alternative explanation is differences in the sources searched and the search strategies used. In general the searching in each of the reviews was fairly limited. Only two reviews included a search of more than two electronic databases,^{33, 49} four searched two databases,^{16, 27, 30, 42} and two searched just one database.^{29, 36} Most reviews included some form of reference checking. Three reviews did not include details of the search dates.^{29, 30, 36} It was unclear in most reviews whether unpublished material was eligible for inclusion and in only two reviews was publication bias assessed.^{36, 49} One review had a very well developed search strategy and used a range of search terms.⁴⁹

Despite the likely differences in quality between the primary studies included in the reviews, only two reviews performed any quality assessment of included studies.^{42, 49}

Four reviews presented their results in the form of a narrative synthesis^{16, 30, 33, 42} and four performed meta-analysis^{27, 29, 36, 49} In general, none of the reviews provided a clear rationale as to why a given method of synthesis was used. Individual studies were often combined despite observed heterogeneity in study design, participants, interventions and outcomes. Of the four meta-analyses three tested for statistical heterogeneity.^{27, 29, 49} Dusseldorp et al combined studies where heterogeneity was detected, but attempted to identify moderating variables which might explain variation in the effect sizes.²⁷ Linden et al did not report any statistically significant heterogeneity. A Cochrane review used a random effects model of meta-analysis where substantial heterogeneity was detected. For outcomes where it was considered inappropriate to combine studies statistically, a narrative synthesis was provided.⁴⁹ Of those reviews that synthesised the results narratively, only one actively considered differential effects of studies of varying quality.⁴²

In terms of the review process it was unclear in five reports whether more than one reviewer had been involved in selecting papers and extracting data.^{16, 29, 30, 36, 42} One review appeared to have been carried out by just one reviewer³³ and one review appeared to involve two reviewers.²⁷ The Cochrane review indicated that more than one reviewer had been involved in the review process.⁴⁹

The Cochrane review⁴⁹ was the only review to meet all of the specified quality criteria. Its methodological quality is reflected in fully specified inclusion criteria, thorough, reproducible search, quality assessment of studies and more rigorous review process.

3.2.3 Results of reviews

Overall, six of the eight reviews favoured adoption of psychosocial interventions into cardiac care. One review was more equivocal and recommended further research.⁴² The Cochrane review recognised the potential of psychosocial interventions to have some effects on behaviour and psychological outcomes, and recommended that future research should focus on people with elevated levels of distress. Most of the reviews gave implications for further research and these are detailed in section 2.4.

Where possible emphasis has been placed on the reviews of higher methodological quality.

3.2.3.1 Psychological outcomes

Six reviews investigated the effects of psychosocial interventions on psychological outcomes of patients with heart disease.^{16, 29, 30, 33, 36, 49} These met between two and seven of the seven methodological quality criteria.

The Cochrane review, which met all of the methodological quality criteria, reviewed the findings of 36 RCTs, of which 18 focused on stress management as defined by the review authors.⁴⁹ Both the complete set of trials and the stress management subgroup showed small reductions for anxiety and depression. For all nine trials measuring anxiety, the standardised mean difference (SMD) was -0.08 (95% CI: $-0.16, -0.01$). For the seven stress management trials there was weak evidence of a small decrease in anxiety in those who received the intervention, $SMD = -0.07$ (95% CI: $-0.15, 0.01$). Depression was measured in a total of eleven trials with an SMD of -0.3 (95% CI: $-0.48, -0.13$), though there was significant heterogeneity between the trials. For the eight stress management trials there was evidence of a reduction in depression scores in the intervention group, $SMD = -0.32$ (95% CI: $-0.56, -0.08$). However the results were dominated by one large trial that showed a null effect. Five trials reporting composite measures for anxiety, depression and mental health, indicated that there was a statistically significant beneficial effect of the intervention, $SMD = -0.22$ (95% CI: $-0.44, -0.01$). Perceived stress was measured in two trials, one of which showed no effect whilst the other showed a statistically significant reduction in stress. One of several measures in a trial of Type A attitudes showed an effect of a stress management intervention whilst the other showed significant reductions in type A behaviour.

The review by Hill et al, which met four of the quality criteria, reviewed the findings of 12 studies and found that 10 reported some benefits of psychosocial interventions, including patient education, counselling and behavioural techniques.¹⁶ All three types of intervention might help alleviate psychological distress as defined mainly by self-report measures of anxiety and depression in adults. Benefits were shown both for post myocardial infarction patients or their spouses and for CABG patients. The review by Linden et al, which also met four of the quality criteria, included 23 RCTs of patients with coronary heart disease. This review included a meta-analysis of the effects of interventions on psychological distress. Benefits of psychosocial interventions were found in 14 of 15 studies with an effect size of -0.30 (SD 0.37). This review did not highlight which interventions were the most effective. The review by Sebrechts et al, which also met four of the quality criteria, found that the three included trials aiming to reduce Type A behaviour had statistically significant, positive results.³⁰ All three trials used a variety of cognitive-behavioural techniques to bring about behaviour change and were lengthy (lasting one to three years). All three trials demonstrated a decrease in cardiovascular recurrences after type A behaviour modification.

The review by Moore, which met three of the quality criteria, reported mixed results for the effects of psychosocial interventions on mood states in patients recovering from coronary artery bypass procedures.³³ The review by Nunes et al, which met just two of the quality criteria, found a positive effect for psychosocial interventions in the reduction of Type A behaviour (0.61 (95% CI: 0.41, 0.81, $p < 0.001$)) based on 10 studies.³⁶ No single type of psychosocial intervention correlated significantly with the Type A behaviour effect size but treatments with more components did.

3.2.3.2 Physical outcomes

Seven reviews investigated the effects of psychosocial interventions on physical outcomes of patients with heart disease.^{27, 29, 30, 33, 36, 42, 49} These met between two and seven of the methodological quality criteria.

Mortality and morbidity

In the Cochrane review there was no evidence of an effect on total mortality based on 22 trials (OR = 0.93 (95% CI: 0.81, 1.06)).⁴⁹ Similarly, based on 10 trials of stress management there was no evidence of an effect (OR = 0.88 (95% CI: 0.67, 1.15)). However, the review by Dusseldorp et al, which met six of the quality criteria, reported a statistically significant effect size of 1.52 (no CI given) for long-term survival in favour of the intervention, based on 37 RCTs or quasi-experimental controlled studies. Effect sizes for the total measurement period were not homogenous.²⁷ In the review by Linden et al, a meta-analysis of 10 RCTs found a beneficial effect on survival (at < 2 years the log OR was 1.70 (95% CI: 1.09, 2.64, $p = 0.02$)).²⁹ Survival after two years was not statistically significant but this was based on three studies only. Nunes et al reported a mean effect size of 0.44 (95% CI: 0.26, 0.62) for deaths at one year based on nine studies.³⁶ The remaining reviews did not report mortality as an outcome.

The Cochrane review also assessed cardiac mortality and found that across 11 trials there was no evidence of a reduction in the intervention group compared to the controls (OR = 0.86 (95% CI: 0.72, 1.03)).⁴⁹ In the four stress management trials reporting this outcome there was some evidence of a reduction in the number of deaths in the intervention group (OR = 0.62 (95% CI: 0.38, 0.99)).

The Cochrane review found a reduction in the number of non-fatal re-infarctions in the intervention group based on 18 trials (OR = 0.78 (95% CI: 0.67, 0.90) but the two largest trials which included 4809 patients between them did not report reductions in re-infarctions in the intervention groups. In the stress management trials reporting this outcome a reduction was also found (OR = 0.69 (95% CI: 0.52, 0.92)).⁴⁹ Dusseldorp et al reported that for the total term (a study's final post-test measurement), medium term (1-2 years after the start of the programme) and long-term periods (longer than two years after the start of the programme) there was a 20%, 26% and 29% reduction in recurrence of MI respectively.²⁷ However effect sizes were not homogeneous.

Dusseldorp et al reported a statistically significant effect size that was homogenous showing benefits of psychological interventions in patients with angina pectoris. (OR = 1.22, no CI given). Linden et al found that the addition of psychosocial interventions to standard cardiac rehabilitation programmes reduced morbidity.²⁹ Based on 8 RCTs the log OR at < 2 years was 1.84 (95% CI: 1.12, 2.99, $p = 0.02$) in favour of the interventions. Based on just 3 studies > 2 years morbidity was 1.64 (95% CI: 1.06, 2.54, $p = 0.02$). Nunes et al reported a mean effect size of 0.32 (95% CI: -0.03, 0.67) for MIs at 1 year and a mean effect size of 0.43 (95% CI: -0.95, 0.91) for the effect of psychosocial interventions on angina based on six studies.³⁶

For revascularisation, the Cochrane review reported a pooled estimate from 15 trials for the combined outcome of CABG and PTCA of 0.87 (95% CI: 0.67, 1.13). For the stress management trials the OR was 0.82 (95% CI: 0.42, 1.62).⁴⁹

For post-surgical physical measures another review found that interventions gave mixed results, with some positive results for pre-operative education / counselling.³³

The Cochrane review stated that the evidence was dominated by two large trials that produced null findings for all clinical outcomes. Other reviews did not comment on the relative weight of particular studies.

Modification of risk factors in heart disease

One review investigated the impact of psychosocial interventions on heart rate.²⁹ Based on five studies a beneficial effect size of -0.30 (0.17) was reported in the intervention group and -0.08 in the control group ($p < 0.01$).

Dusseldorp et al reported a statistically significant weighted average effect size of 0.121 (95% CI: 0.061, 0.180, $p < 0.025$, one tailed) for systolic blood pressure.²⁷ Linden et al also reported statistically significant effects of interventions for effects on systolic but not diastolic blood pressure based on 4 studies.²⁹

Dusseldorp et al reported beneficial effects at all terms for cholesterol (0.249 (95% CI: 0.100, 0.211, $p < 0.025$, one tailed)) but sets of effect sizes were not homogenous.²⁷ Linden et al investigated the impact of interventions on cholesterol level based on four studies but there was a huge difference between the numbers in the intervention and control groups making this effect size somewhat unreliable.²⁹

For weight reduction, Dusseldorp et al reported a statistically significant and beneficial weighted average effect size of 0.088 (95% CI: 0.027, 0.149, $p < 0.025$, one tailed).²⁷ Effect sizes were statistically significant at all terms and study effect sizes were homogenous. In a review by Godin, which met five of seven quality criteria, positive effects on diet from educational approaches supplemented by counselling were reported, but this was based on two studies.⁴² Both studies were successful in the modification of diet although both were based on dietary history interview rather than on objective outcomes.

For smoking behaviour, Dusseldorp et al found that the weighted average effect size (0.064 (95% CI: 0.033, 0.095, $p < 0.025$, one tailed)) was statistically significant for the total measurement period and for the medium term (1-2 years after the start of the programme).²⁷ However at each measurement term population effect size estimates suggested heterogeneity. In the review by Godin four of seven studies reported intervention success for smoking cessation but that study designs were superior in the studies that were not successful.⁴² All successful interventions focused exclusively on smoking. Three were multi-component including: advice, information and family support; daily inpatient education sessions, group and individual counselling and information; verbal and printed information and regular meetings. One focused on posters that detailed the harmful effects of smoking. Sebregts et al reported that two out of three psychological interventions for smoking cessation (one advice, the other a multi-component behavioural intervention) showed statistically significant results.³⁰ For one of the included studies the results were only statistically significant when severity of disease was taken into account. A third study evaluating a cognitive behavioural intervention showed no statistically significant differences between groups at 1 and 5.5 years.

Godin reported that three of six interventions resulted in positive outcomes whilst three did not achieve changes in exercise habits.⁴² All successful interventions were based on treadmill exercise testing supplemented with counselling. However interventions with no evidence of effect were fairly similar to successful ones so it is not clear which aspects of the interventions were associated with success. Moore reported that some interventions were successful in terms of promotion of physical activity. Audio taped discharge information and a psychoeducational programme including telephone counselling both had some positive effects. Slide / tape teaching and counselling with telephone follow up was partially successful.

Quality of life

The Cochrane review reported that of five stress management trials reporting QoL, two found beneficial effects of the intervention.⁴⁹

3.2.3.3 Moderating variables

Most of the reviews concentrated on the effects of psychosocial interventions on a range of outcomes. However, a number of reviews attempted to investigate variables that might affect the success or otherwise of an intervention.

Dusseldorp et al reported that studies with success on proximal targets (known risk factors and related behaviours) led to a 31% reduction in cardiac mortality compared to 14% reduction for studies with no evidence of effect on proximal targets.²⁷ At 1-10 years follow up a reduction of 36% in MI recurrence was found in studies which had been successful on proximal targets, whereas studies with no evidence of effect or with only partial effects on proximal targets showed just a 2% reduction in MI recurrence. The review authors note that the measurement of risk factors and related behaviours may not be entirely reliable and in the case of smoking was based on self-report which can introduce bias.

Godin concluded that when a general form of intervention was used to modify specific behaviours (e.g. group therapy) there was less success than when the intervention was content specific with regard to the targeted behavioural risk factors.⁴² Sebregts et al, however, stated that although behavioural modification of each separate risk factor may add considerably to usual care in coronary patients, programmes that focus on the modification of all of the important risk factors may be more effective.³⁰ Nunes et al found that interventions with more modalities correlated significantly with the effect size for reduction of type A behaviour pattern (TABP) ($r = 0.48$, $t = 2.14$, $p < 0.05$).³⁶ This review recommended a comprehensive approach addressing a number of different facets of TABP but the largest effect sizes were found for educating participants about the TABP or for cognitive therapy.

Linden et al reported that effect sizes were smaller and sometimes not statistically significant for follow up at > 2 years.²⁹

3.2.4 Research implications

Most of the reviews made suggestions for future research, which were often in agreement. The need for better study designs and reliable outcome measures was highlighted in several reviews.^{16, 29, 33, 36, 42, 49} Hill et al suggested more use of randomisation to study groups.¹⁶ Linden et al commented on the need to identify the most effective types of psychosocial interventions via controlled research.²⁹ Godin stated that reliable and valid outcome measures should be developed which are suited to CHD patients.⁴² He stated that multiple measures should be used where feasible for the study of multidimensional behaviours. Hill et al claimed that standardised measurements are needed to test the efficacy of an intervention and that outcomes should ideally not rely on self report measures.¹⁶

Several reviews identified the need to clearly establish the benefits of risk factor modification in secondary prevention of cardiac events.^{27, 30, 33, 42} Dusseldorp et al suggested that psychosocial interventions should be theory-driven focusing on the relationship between specific components of the intervention and changes in proximal and distal targets related directly to the needs of the individual patient.²⁷

One review stated that there is a need to investigate the impact of combination treatments of medication and psychosocial interventions.¹⁶ Three reviews identified the issue of timing and duration of interventions.^{16, 36, 49} Hill et al stated that interventions need to be introduced at an appropriate time point during the illness or recovery period.¹⁶ Nunes et al commented that studies should be of sufficient duration (follow up of at least 3 years) to determine whether improvements are sustained over time.³⁶ The authors of the Cochrane review commented that studies should be sufficiently intensive.⁴⁹

Several reviews commented on gender and other biases within the primary studies. Hill et al stated that future research should address issues of sampling and broaden study populations to include more women, ethnic minorities and children and family members such as spouses and provide more details of the study participants.¹⁶ This was supported by Nunes et al and Moore who also stated that studies should test the effectiveness of

interventions for shorter length of stay patients, those with multiple intervention procedures and those having minimal surgical techniques.^{33, 36}

Two reviews suggested that more research is needed to evaluate whether interventions should target those with elevated psychological distress rather than all patients.^{16, 49} This issue was also supported by Linden et al.²⁹

Study reporting was identified as a problem and something that needed further consideration in the future. Hill et al stated that researchers should provide more details of the interventions used, to allow for investigation of successful components especially in cases of multiple interventions.¹⁶

The Cochrane review commented that unpublished trials that demonstrate negative results for psychosocial interventions should be published in order to facilitate future research synthesis.

4. DISCUSSION

This review of reviews has demonstrated that there is no lack of research evaluating the effects of psychosocial interventions in patients with heart disease or cancer. A search of the literature identified 33 completed systematic reviews meeting the specified inclusion criteria (22 reviews in cancer, eight complete reviews in heart disease, and three reviews including both patient groups). These reviews were published between 1987 and 2004 and between them incorporated over 500 primary studies (336 in cancer, 170 in heart disease, see appendices 4.1 to 4.3). What does and does not constitute a “psychosocial intervention” has proven difficult to define consistently, as the types of intervention used in the management of psychological and physical problems in chronic illness vary widely.

What do the included reviews tell us about the effects of psychosocial interventions in patients with heart disease or cancer? In the overview presented here, we attempted to combine reviews according to the results they presented on psychological and/or physical outcomes. In terms of psychological outcomes, the findings tend towards the positive in both heart disease and cancer, whereas for physical outcomes, the evidence is more equivocal.

Much of the explanation as to why only vague conclusions can be drawn from the available body of evidence, lies in the detail of the systematic reviews. Although many of the included reviews appear to be answering the same (or very similar) questions (i.e. “what are the effects of psychosocial interventions in people with heart disease or cancer”), on closer inspection, they differ considerably. This is apparent from the lack of overlap in the primary studies included across the reviews (see appendices 4.1 to 4.3). For example, assessment of the reviews focusing solely on cancer patients shows that 130 of the primary studies were included just once, and all in the same review.⁴⁰ Two primary studies were included in 10 or more different reviews (Cain et al was included in ten reviews,⁷⁶ Linn et al in twelve⁷⁰). This lack of overlap is likely to be attributable to several different review characteristics. One obvious factor is the date of review publication, where later reviews might be expected to identify a greater number of primary studies. However, although the included reviews were published over a 17-year period, there did not appear to be a clear association between date of publication and number of included primary studies, nor did later reviews always include studies which had been included in earlier reviews. This finding might be expected if the methodological inclusion criteria applied in reviews became stricter over time, but this does not appear to be the case amongst this group of reviews.

The search strategies used, together with the dates and sources searched, are likely to determine the number of studies identified. In general, the reporting of the strategies adopted was poor, with little detail or explanation of the processes used to identify studies. However, in terms of the sources searched, all reviews reported which printed bibliographies or electronic databases were searched. All searched MEDLINE, although three reviews^{25, 29, 36} did not attempt to search further than this one database. Eleven^{16, 18, 22, 26, 27, 30, 32, 39, 42, 45, 51} reported searching two databases, MEDLINE with either PsycLIT or PsycINFO or PSYINDEX or Psychological Abstracts, and twenty-one reported searching three or more databases.^{20, 21, 23, 28, 31, 33-35, 37, 38, 40, 41, 43, 44, 46-50, 52, 65}

The range of dates specified in each search was variable and with many it was unclear whether the search had been from the earliest date available, or whether a specific range of dates had been selected, and if so why. Three reviews⁴⁷⁻⁴⁹ included non-English language studies, whilst eight^{26, 28, 33, 37, 39, 41, 45, 65} specified that the review would include only English language papers. The other reviews did not report any information about foreign language papers. Seven reviews^{28, 34, 35, 37, 40, 47, 48} reported their attempts to locate unpublished studies, with the majority searching a dissertations database. Two reviews contacted leading authors for unpublished work.^{41, 48}

The majority of reviews reported that the reference lists of the papers selected had been checked for additional papers not captured by the searches, and two reviews^{16, 31} reported hand searching selected journal titles.

Details reported about the search terms used varied between reviews. Eight reviews^{18, 21, 29, 33, 36, 39, 51, 65} did not report any of the keywords used, and whilst the majority gave some information about the terms used, it was unclear whether the authors were providing their complete strategy or a sample of the terms used. From the detail supplied it would be impossible to replicate the searches in most instances. However, several of the reviews demonstrated that a number of techniques had been used to improve the sensitivity of the searches and so maximise the number of studies retrieved. Ten reviews^{26, 28, 35, 37, 40, 41, 44, 47-49} indicated that they had included the use of synonyms in the strategies; three reviews^{37, 49, 50} indicated that relevant thesaurus terms used in the databases had been checked and searched, as well as text words, and three reviews^{41, 45, 49} used truncated terms to retrieve all the possible different endings of a word. It may be that other reviews also used these techniques, but did not report that they had done so.

The range of databases and dates searched, the exclusion of non-English language material and few attempts to locate grey literature (unpublished papers or ongoing studies) have implications for the number of studies identified for inclusion.⁷⁷ This may partly explain the lack of overlap in primary studies between the reviews, though the level of detail provided about the search process is inadequate in most instances to enable a thorough assessment to be carried out.⁷⁸

One characteristic that clearly contributed to the variation in primary studies between reviews was the wide range of criteria used to select studies for inclusion. Occasionally, these differences in inclusion criteria were due to specific aspects of the review question. For example, some reviews were concerned only with the effects of psychosocial interventions on specific outcomes, such as depression or survival, and included only studies that reported these outcomes.

Elsewhere, the reasons for differing inclusion criteria were less apparent. With the exception of three reviews that focused on paediatric populations,^{22, 26, 39} the majority of reviews included only studies of adult patients with the disease of interest. However, more specific aspects of the patient populations such as stage and (in the case of cancer) site of the disease were not generally addressed. In cancer, only one review explicitly considered the important variable of patients' baseline level of distress when selecting studies for inclusion.²⁸

The identified reviews also differed in the types of studies they included. Some reviews were limited to RCTs, some included any controlled study, and others either explicitly selected a broad range of designs, or did not state any study design criteria at all. Where inclusion was limited to controlled studies, the comparator most frequently specified was 'usual care,' though an appropriate comparator was frequently not stated and any definition of what constitutes 'usual care' in this context was rarely defined. It is possible that several reviews combined studies that included different 'usual care' control groups. None of the included heart disease or cancer reviews focused solely on studies that had carried out direct comparisons of different approaches to psychosocial care. None attempted to identify literature that compared psychosocial with pharmacological approaches.

The inclusion criteria that varied most notably between reviews were those relating to the interventions themselves. Definitions of what constituted a psychosocial intervention were rarely given, but examination of the intervention inclusion criteria indicates that there is very little consensus between authors on this issue. In this report, reviews that stated that their focus was on a particular psychosocial approach were considered together where possible. However, even where reviews were ostensibly concerned with the same group of interventions (e.g. 'relaxation' interventions), their inclusion criteria indicated differences in how these interventions were defined. In the case of 'relaxation' interventions, for example, one review considered hypnosis to be a relaxation technique,⁴⁴ whereas another review of the same literature did not.²³ This inconsistency was apparent throughout, with cognitive behavioural therapy (CBT) classified as being a valid educational approach in one review⁴⁰ and considered as a 'behavioural' approach, clearly distinct from education, elsewhere.⁴⁵ The lack of any consistent definition of what constitutes a psychosocial intervention (and

confusion between how to categorise sub-groups of interventions) has important implications for the conduct of systematic reviews.

Firstly, reviews which select primary studies on the basis of very poorly defined inclusion criteria are likely to include a highly heterogeneous collection of intervention and control groups, which unless appropriately categorised during the review process, will lead to findings of limited utility. Secondly, a reader hoping to discover the effects of a particular psychosocial approach based on a systematic review of the literature is likely to encounter different results depending upon which review they read. This has important implications, as one of the potential advantages of systematic reviews is their ability to resolve conflicting results that often arise between individual primary studies. Conflicting results amongst reviews produce difficulties for anyone involved in decision-making, including patients, health professionals and policy makers.

Further variation can be seen between the included systematic reviews in terms of the methods of synthesis undertaken. Most of the reviews included highly heterogeneous groups of studies, and the majority of these undertook some form of narrative synthesis. Several different approaches to narrative synthesis were used: one review presented summaries of every included study in chronological order of publication,³⁵ some grouped and discussed studies according to type of intervention or outcome, (e.g. Trijsburg et al,⁵¹ Wallace²³) and others attempted to partially quantify their findings by employing a 'vote-count' approach to synthesis (e.g. Newell et al,⁴¹ Cwikel⁶⁴). Because of the potential biases involved with narrative synthesis, reviews using this approach need to present characteristics of the primary studies in sufficient detail for the reader to make their own judgements about methodological quality and any important differences between studies and results. The reporting of study characteristics in the included narrative reviews was often quite limited, and any formal assessment of study quality was the exception rather than the rule. Subsequently, it was difficult to determine whether the conclusions of these reviews were valid.

The reviews which included a 'vote-count' of studies reporting statistically significant versus those reporting non-statistically significant findings rarely considered methodological differences between studies (e.g. Newell et al,⁴¹ Cwikel⁶⁴). Furthermore, in some cases 'vote-count' reviews reached conclusions about the effects of particular psychosocial approaches based on the statistical significance of only one or two primary studies (e.g. Newell et al⁴¹). In situations such as this, conclusions may be influenced by the statistical power of a single study (e.g. statistically non-significant effects may result from a study being too small to detect an effect).

Eleven reviews combined the identified studies using meta-analytic techniques.^{18, 24, 27-29, 36, 37, 40, 44, 49, 52} In most of these meta-analyses, it was clear that the included studies were highly heterogeneous in terms of study design, interventions, participants and outcomes. However, this heterogeneity rarely precluded reviewers from pooling the study data. These reviews used the unit free effect-size meta-analysis approach advocated by authors such as Glass⁷⁹ and Hedges and Olkin.⁸⁰ This method allows the pooling of different outcome measures by deriving a scale-free effect size from each study. This is achieved by calculating the standardised mean difference between intervention and control groups in standard deviation units. The review authors classify the included studies into categories of intervention and/or outcome, and then pool the individual study effect sizes within these categories. Some of the included meta-analyses that employed this method also coded various study characteristics as 'moderator variables' (e.g. whether patients were screened for distress) and examined the influence of these characteristics on the mean summary effect size estimates.^{18, 27, 36} Some reviews also tested for statistical heterogeneity between pooled estimates.^{28, 29, 37, 40, 44, 49, 52} However, not all of the meta-analyses investigated moderator variables or heterogeneity.^{24, 64}

Even where reviews have undertaken this type of meta-analysis with assessment of statistical heterogeneity and investigation of some moderator variables, there still may be limitations. Firstly, the approach usually involves the synthesis of studies that are highly heterogeneous in terms of study design, participants, intervention characteristics or

outcomes. Statistical testing for heterogeneity does not highlight clinically important differences between studies, and the influence of these differences will not be addressed unless specifically used as a variable to categorise studies or investigated as a moderator variable. Also, as meta-analyses of this type often include large numbers of studies, the characteristics of individual studies are rarely presented in sufficient detail as to allow the reader to examine the extent of clinical heterogeneity. Secondly, the approach used by authors to categorise studies by intervention or outcome may introduce bias. For example, a review might develop 'behavioural,' 'non-behavioural' and 'relaxation' intervention categories, but not specifically define any inclusion criteria for these categories. Due to the lack of consensus in how to define psychosocial interventions noted previously, interventions which use multiple approaches or ambiguous interventions (such as hypnosis-type methods) could be considered appropriate for inclusion in two or more categories. The subsequent effect sizes for each intervention type may be partly an artefact of the authors' classification of individual approaches within the specific framework that they have developed. Thirdly, even if studies were combined according to well-defined and commonly agreed criteria, there are limitations in presenting the reader with a single summary effect size per intervention. This kind of statistic is difficult to interpret in terms of clinical effect as it is not based on any single scale of measurement and is in fact usually derived from a composite outcome that incorporates several different outcomes of interest (e.g. anxiety, depression, hostility, anger). Apart from their lack of clinical meaning, summary effect sizes usually do not give a clear indication of the magnitude of effect. A widely used rule of thumb is that suggested by Cohen,⁵⁷ where effect sizes of 0.2, 0.5, and 0.8 are considered "small," "medium" and "large" respectively. However, interpretation of effect sizes is at least partly subjective and authors can use various justifications to support their own interpretation.¹⁸

During the writing of this report, another document was published that provides an overview of the evidence on supportive and palliative care for patients with cancer, including a section on psychological support services.⁸¹ This overview was based on a search of seven electronic databases and research registers up to March 2003, and included a range of research evidence (RCTs, non-randomised controlled studies, before-after studies, interrupted time series analyses, systematic reviews and meta-analyses). As with the systematic reviews discussed in previous section of the report, the authors did not clearly define what would constitute a "psychological support service." For completeness, the findings of this overview are briefly summarised below.

The authors identified and summarised the results of three meta-analyses^{18, 28, 40} and one systematic review.⁴¹ All four of these were identified and have been synthesised in earlier sections of this report. The overview also summarised data from 25 primary studies, 11 of which were included amongst the 336 primary studies listed in appendix 4.1. Of the 14 studies not covered by the 22 cancer reviews, three were outside the scope, as they were concerned with the psychosocial care of relatives of cancer patients, rather than patients themselves. Of the remaining 11 primary studies, most were published later than the existing systematic reviews. The authors of the overview concluded that there is evidence to suggest that psychosocial interventions are important for enhancing coping and quality of life for patients with cancer. They recommend that future research should focus on which psychotherapeutic interventions are most suitable for which patient groups.

5. SUMMARY AND CONCLUSIONS

In summary, a large volume of primary research has been undertaken on the effects of psychosocial interventions in patients with cancer or heart disease. The findings of the reviews in cancer were not entirely consistent but, on the whole, indicated that psychosocial interventions are likely to produce some beneficial effect on the general psychological distress or emotional adjustment of patients with cancer. How much of this benefit is attributable to providing patients with greater attention from healthcare workers and how much is specifically due to implementing psychosocial interventions is unclear. The effects of psychosocial interventions on more specific outcomes such as anxiety and depression are not clear. Attempts have been made to separate out different interventional approaches (e.g. behavioural vs. non-behavioural methods) but this has not been done in a consistent manner across reviews and may be responsible for the observed variation in findings. Where reviewers have attempted to investigate the effects of intervention setting (e.g. group vs. individual), the results have again been inconsistent. Evidence on the impact of psychosocial interventions on physical outcomes (e.g. immune outcomes, survival) in cancer patients is relatively sparse and the results are mixed. Consequently, findings from the reviews that examined these outcomes were largely inconclusive: the most recent meta-analysis of survival data concluded that psychosocial intervention does not appear to prolong survival in cancer patients, but due to the limitations of the existing literature, could not confidently rule out the existence of a small effect.

In heart disease, the findings of broad-based reviews and the one review of educational interventions generally favoured the adoption of psychosocial interventions into cardiac care. Two reviews were more equivocal and recommended further research.^{42, 49} Those reviews that investigated psychological outcomes generally reported reductions in psychological distress and modification of type A behaviour (a behaviour pattern characterised by aggressiveness, ambitiousness, restlessness and a strong sense of time urgency). There is some limited evidence about the positive effects of psychosocial interventions on morbidity (recurrence of MI, angina pectoris) and mortality but it is unclear which particular interventions would consistently affect which outcomes. There is equivocal evidence about the effects of psychosocial interventions on heart disease risk factors such as smoking, control of blood pressure and cholesterol, diet, weight modification and exercise. Although psychosocial interventions have the potential to reduce such risk factors, which in turn might impact on other outcomes, the design of suitable programmes is not yet clear. Accepting Mullen's broad interpretation of patient education, educational interventions appear to influence some behavioural (e.g. exercise and diet) and clinical (blood pressure and mortality) outcomes in heart disease.³⁷

5.1 Recommendations for future research

It can be seen from the data discussed here that, although numerous attempts have been made to review the research literature on the effects of psychosocial interventions, the resulting reviews have generally been of limited quality. There are currently two further Cochrane systematic reviews concerned with psychosocial interventions in heart disease being undertaken.^{47, 48} It is likely that these will be of a higher methodological quality than the majority of existing published reviews (based on the review protocols which are currently available: <http://www.update-software.com/clibng/cliblogon.htm>). However, high quality systematic reviews of psychosocial interventions in cancer are also lacking, and no ongoing reviews have been identified. Therefore, recommendations for conducting a high quality review about the effects of psychosocial interventions in cancer are made below.

Any future systematic review should be based on a comprehensive search of the literature. Such a search should cover appropriate medical and psychological databases as well as databases of unpublished studies (e.g. SIGLE), using search terms that cover the range of terms that have been used to describe psychosocial interventions. These database searches should be supplemented by examination of reference lists and attempts to identify both unpublished and non-English language literature.

The question posed in any future systematic review must be clearly defined, with clear and specific inclusion/exclusion criteria relating to study design, participants, interventions, and outcomes. There appears to be sufficient primary research to justify limiting inclusion to higher quality study designs, such as RCTs, for the purpose of assessing the effectiveness of psychosocial interventions. If limited to RCTs, reviews need to consider what would constitute an appropriate control group; if studies using a usual care control group are to be selected, how will 'usual care' be defined? Although simply limiting inclusion to studies of adult cancer patients is adequate, reviewers should consider important differences between groups of patients such as stage of disease, time since diagnosis/stage of treatment, and site of tumour. Patients' level of psychological 'distress' (e.g. anxiety, depression) at baseline also needs to be considered when evaluating/reviewing the effects of psychosocial interventions. If these characteristics are not used to select studies for inclusion in the review, they need to be extracted and taken into consideration during synthesis.

It is important when reviewing this literature to make clear *a priori* decisions about the characteristics that constitute the psychosocial intervention(s) of interest, and strictly select studies that meet these criteria. Recommendations made in some existing reviews and correspondence with experienced researchers in this field indicates that psychosocial interventions are poorly described and inconsistently defined in primary studies. Selection of studies based on the authors' own definition of intervention type is likely to introduce bias into the selection process.

Most of the existing published reviews give little or no detail regarding who was involved in the review process. To help minimise bias in a systematic review, two or more researchers should be involved throughout the processes of study selection, extraction and validity assessment.

Studies should be synthesised using the methods appropriate to the included data. Where meta-analysis is undertaken, both statistical and clinical heterogeneity should be investigated, and where narrative synthesis is carried out, the characteristics of primary studies should be clearly presented and discussed together with the results. In both approaches to synthesis, some form of validity assessment of the included primary studies should be undertaken, preferably using a previously validated scale or checklist appropriate to the study design(s) being assessed.

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**APPENDIX 1: NUMBER OF POSSIBLE SYSTEMATIC
REVIEWS OF PSYCHOLOGICAL INTERVENTIONS IN
CHRONIC ILLNESS (IDENTIFIED FROM TITLES AND
ABSTRACTS)***

	DARE, Cochrane Library, National Research Register	EMBASE	Total number of papers (% of overall total)
Heart disease	13	15	28 (25%)
Cancer	14	14	28 (25%)
Arthritis	2	14	16 (14%)
Asthma	9	9	18 (16%)
Diabetes	6	6	12 (11%)
Multiple conditions	5	7	12 (11%)
Total	49	65	114

(Percentages do not total 100 due to rounding)

**(A small number of reviews may have been double-counted, due to a lack of information available from the titles and abstracts)*

APPENDIX 2: JOURNALS HANDSEARCHED IN THE DARE PROCESS

- ACP Journal Club
- Addiction
- Alcologia
- American Journal of Public Health
- Annals of Internal Medicine
- Archives of Internal Medicine
- BMJ
- British Journal of General Practice
- Bulletin of the World Health Organization
- Canadian Medical Association Journal
- Clinical Therapeutics
- Controlled Clinical Trials
- Drug and Alcohol Review
- European Heart Journal
- European Journal of Public Health
- Evaluation
- Evaluation and the Health Professional
- Evidence-Based Medicine
- Evidence-Based Health Policy and Management
- Health Affairs
- Health Care Financing Review
- Health Direct
- Health Economics
- Health Education Research
- Health Manpower Management
- Health Policy
- Health Policy and Planning
- Health Promotion International
- Health Service Journal
- Health Service Research
- Health and Social Care in the Community
- Health Trends
- International Journal of Epidemiology
- International Journal of Health Planning and Management
- International Journal of Technology Assessment in Health Care

- JAMA
- Joint Commission Journal on Quality Improvement
- Journal of Advanced Nursing
- Journal of Applied Research in Intellectual Disabilities
- Journal of Clinical Effectiveness
- Journal of Drug Issues
- Journal of Epidemiology and Community Health
- Journal of Health Economics
- Journal of Health Politics, Policy and Law
- Journal of Health Services Research and Policy
- Journal of Managed Care
- Journal of Medical Ethics
- Journal of Public Health Medicine
- Journal of Studies on Alcohol
- Journal of the Royal Society of Medicine
- Lancet
- Medeconomics
- Medical Care
- Medical Care Research and Review
- Medical Decision Making
- Mental Health Review
- Milbank Quarterly
- New England Journal of Medicine
- NT Research
- Nursing Times
- Pharmacoeconomics
- Preventive Medicine
- Psychology and Health
- Quality in Health Care
- Quality of Life Research
- Statistical Methods in Medical Research
- Statistics in Medicine

APPENDIX 3: SEARCH STRATEGIES

Rapid appraisal

Databases searched

Cochrane Database of Systematic Reviews (CDRom) Issue 2 & 3

DARE (CAIRS B & T System)

Health Technology Assessment database (CAIRS B system)

NHS EED (CAIRS B system)

National Research Register (CDRom) Issue 2 2002

SIGN Guidelines www.sign.ac.uk

National Guideline Clearinghouse www.guideline.gov/index.asp

HSTAT <http://text.nlm.nih.gov>

Indexes and summaries of clinical effectiveness sources

TRIP (Turning Research Into Practice) www.tripdatabase.com

SchHARR Lock's Guide to the Evidence www.shef.ac.uk/uni/academic/R-Z/scharr/ir/sceb.html

Health Evidence Bulletins Wales www.hebw.uwcm.ac.uk

Clinical Evidence Issue 7 June 2002

DARE (CAIRS B system) searched 8.8.02

1. S psychotherap\$ or psycho-therap\$ or psycho(w)therap\$
2. S biopsychosocial or bio-psychosocial or bio-psycho-social
3. S psychosocial or psycho-social or psycho(w)social or psychological
4. S psychoeducation\$ or psycho-education\$ or psycho(w)education\$
5. S (behavio\$ (2w) (therap\$ or treatment\$ or intervention\$))
6. S (cognitive (2w) (therap\$ or treatment\$ or intervention\$))
7. S cbt
8. S counsel\$ or rehabilit\$
9. S (anxiety or depressi\$ or stress) (2w) manag\$
10. S family(w)therap\$
11. S social(w)support
12. S s1 or s2 or s3 or s4 or s5 or s6 or s7 or s8 or s9 or s10 or s11
13. S coronary or cardiac or myocardial or angina or heart
14. S cancer\$ or neoplasm\$ or carcinoma\$ or sarcoma\$ or malignan\$ or tumo\$r?
15. S arthritis
16. S asthma\$
17. S diabet\$
18. S s13 or s14 or s15 or s16 or s17
19. S s12 and s18

Cochrane Library CDSR Issue 2 2002 . Searched 2.8.02, Issue 3 searched 23.8.02?

1. Psychotherapy:ME
2. Behavior-Therapy*:ME
3. Psychotherapeutic-Processes*:ME
4. Social-support*:ME
5. Cognitive-Therapy*:ME
6. Psychotherpy-Brief*:ME
7. Psychotherapy-Multiple*:ME
8. Psychotherapy-Rational-Emotive*:ME
9. Counseling:ME
10. Psychotherapy-Group*:ME
11. ((Psycotherap* or Psycho-therap*) or (Psycho next therap*))
12. ((Biopsychosocial or Bio-Psychosocial) or Bio-Psycho-Social)
13. (((psychosocial or psycho-Social) or (psycho next social)) or psychological)
14. ((psychoeducation* or psycho-education*) or (Psycho next education*))
15. ((behavio* near therap*) or (behavio* near treatment*) or (behavio* near intervention*))
16. ((cognitive near therap*) or (behavio* near treatment*) or (behavio* near inervention*))

17. cbt
18. ((counselling or counseling) or rehabilit*)
19. (((anxiety next manag*) or (depressi* next manag*) or (stress next manag*))
20. (family next therap*)
21. (social next support)
22. Coronary-Disease*:ME
- 23 Heart-Diseases*:ME
24. (((((coronary or cardiac) or myocardial) or angina) or heart)
25. Neoplasms*:ME
26. Sarcoma*:ME
27. Carcinoaoma*:ME
28. ((((((cancer* or neoplasm*) or carcinoma*) or sarcoma*) or malignan*) or tumor*) or tumour*)
29. Arthritis*:ME
30. arthritis
31. Asthma*:ME
32. asthma*
33. Diabetes-Mellitus*:ME
34. diabet*
35. (((((((((#1 or #2) or #3) or #4) or #5) or #6) or #7) or #8) or #9) or #10)
36. (((((((((#11 or #12) or #13) or #14) or #15) or #16) or #17) or #18) or #19) or #20)
37. (35 or 36)
38. ((#22 or #23) or #24)
39. (((#25 or #26) or #27) or #28)
40. (#29 or #30)
41. (#31 or #32)
42. (#33 or #34)
43. (((#38 or #39) or #40) or #41) or #42)
44. (#37 and #43)

Health Technology Assessment Database (Cairs B) searched 14.8.02

1. S psychotherap\$ or psycho-therap\$ or psycho(w)therap\$
2. S biopsychosocial or bio-psycho-social or bio-psycho-social
3. S psychosocial or psycho-social or psycho(w)social or psychological
4. S psychoeducation\$ or psycho-education\$ or psycho(w)education\$
5. S (behavio\$ (2w) (therap\$ or treatment\$ or intervention\$))
6. S (cognitive (2w) (therap\$ or treatment\$ or intervention\$))
7. S cbt
8. S counsel\$ or rehabilit\$
9. S (anxiety or depressi\$ or stress) (2w) manag\$
10. S family(w)therap\$
11. S social(w)support
12. S s1 or s2 or s3 or s4 or s5 or s6 or s7 or s8 or s9 or s10 or s11
13. S coronary or cardiac or myocardial or angina or heart
14. S cancer\$ or neoplasm\$ or carcinoma\$ or sarcoma\$ or malignan\$ or tumo\$r?
15. S arthritis
16. S asthma
17. S diabet\$
18. S 13 or s14 or s15 or s16 or s17
19. S s12 and s18

National Research Register Issue 2 2002 searched 14.8.02

1. Psychotherapy:ME
2. Behavior-Therapy*:ME
3. Psychotherapeutic-Processes*:ME
4. Social-support*:ME
5. Cognitive-Therapy*:ME
6. Psychotherpy-Brief*:ME

7. Psychotherapy-Multiple*:ME
8. Psychotherapy-Rational-Emotive*:ME
9. Counseling:ME
10. Psychotherapy-Group*:ME
11. ((Psychotherap* or Psycho-therap*) or (Psycho next therap*))
12. ((Biopsychosocial or Bio-Psychosocial) or Bio-Psycho-Social)
13. (((psychosocial or psycho-Social) or (psycho next social)) or psychological)
14. ((psychoeducation* or psycho-education*) or (Psycho next education*))
15. ((behavio* near therap*) or (behavio* near treatment*) or (behavio* near intervention*))
16. ((cognitive near therap*) or (behavio* near treatment*) or (behavio* near intervention*))
17. cbt
18. ((counselling or counseling) or rehabilit*)
19. (((anxiety next manag*) or (depressi* next manag*) or (stress next manag*))
20. (family next therap*)
21. (social next support)
22. Coronary-Disease*:ME
- 23 Heart-Diseases*:ME
24. (((((coronary or cardiac) or myocardial) or angina) or heart)
25. Neoplasms*:ME
26. Sarcoma*:ME
27. Carcinoaoma*:ME
28. ((((((cancer* or neoplasm*) or carcinoma*) or sarcoma*) or malignan*) or tumor*) or tumour*)
29. Arthritis*:ME
30. arthritis
31. Asthma*:ME
32. asthma*
33. Diabetes-Mellitus*:ME
34. diabet*
35. (((((((((#1 or #2) or #3) or #4) or #5) or #6) or #7) or #8) or #9) or #10)
36. (((((((((#11 or #12) or #13) or #14) or #15) or #16) or #17) or #18) or #19) or #20)
37. (35 or 36)
38. ((#22 or #23) or #24)
39. (((#25 or #26) or #27) or #28)
40. (#29 or #30)
41. (#31 or #32)
42. (#33 or #34)
43. (((#38 or #39) or #40) or #41) or #42)
44. (#37 and #43)

SIGN Guidelines searched 6.8.02

Psychotherapy, behavior therapy, behavior treatment, behavior intervention, behaviour therapy
 behaviour treatment, behaviour intervention, psychosocial, biopsychosocial, psychological, psychoeducational, cognitive, cbt, counselling, rehabilitation, anxiety, depression, stress, family therapy, social support

National Guidelines Clearinghouse searched 7.8.02

Psychotherap* or psycho-therap* or 'psycho therap*'
 biopsychosocial or bio-psychosocial or bio-psycho-social
 psychosocial or psycho-social or 'psycho social'
 psychological
 psychoeducation* or psycho-education* or 'psycho education*'
 'behavio* therap*' or 'behavio* treatment*' or 'behavio* intervention*'
 'cognitive behavio*' or 'cognitive treatment*' or 'cognitive therap*' or 'cognitive intervention*'
 or cbt
 counseling or counselling
 rehabilit*

depressi* and manag*
anxiety and manag*
stress and manag*
'family therap*'
'social support'

TRIP searched 20.8.02

Psychotherap, psychosocial, psychoeducation, biopsychosocial , psychological, cognitive, cbt, behavio, counsel, rehabilit, anxiety, stress, depressi, 'family therap', 'social support'

The above psychological terms were searched using the AND operator with coronary, heart, cardiac, myocardial, angina, cancer, neoplasm, carcinoma, sarcoma, malignan, tumor ,tumour, arthritis, asthma, diabet

HSTAT searched 21.8.02

Psychotherap*, Psychosocial, Psychoeducation*, biopsychosocial Psychological*, Behavio*, Counsel*, cognitive, cbt, rehabilit*, anxiety and management, stress and management, depressi* and management, "Family therap*" "Social support"

SCHARR Lock's Guide to the Evidence searched 22.8.02

Psychotherapy, psychosocial, psychoeducation*, biopsychosocial psychological, behaviour, Counselling, Cognitive, cbt, rehabilitation, anxiety, stress, depression, family therapy, social support

Health Evidence Bulletins Wales searched 21.8.02

Psychotherapy, psychosocial, psychoeducation, biopsychosocial, psychological, behaviour, cognitive, cbt, counselling, rehabilitation, anxiety, stress, depression, family therapy, social support

Clinical Evidence Issue 7 2002. Searched 14.8.02

Psychotherapy, psychosocial, psychoeducational, biopsychosocial, psychological, behaviour, cognitive, cbt, rehabilitation, anxiety, stress, depression, family therapy, social support

NHSEED (Cairs B) searched 21.8.02

1. S psychotherap\$ or psycho-therap\$ or psycho(w)therap\$
2. S biopsychosocial or bio-psychosocial or bio-psycho-social
3. S psychosocial or psycho-social or psycho(w)social or psychological
4. S psychoeducation\$ or psycho-education\$ or psycho(w)education\$
5. S (behavio\$ (2w) (therap\$ or treatment\$ or intervention\$))
6. S (cognitive (2w) (therap\$ or treatment\$ or intervention))
7. S cbt
8. S counsel\$ or rehabilit\$
9. S (anxiety or depressi\$ or stress) (2w) manag\$
10. S family(w)therap\$
11. S social(w)support
12. S s1 or s2 or s3 or s4 or s5 or s6 or s7 or s8 or s9 or s10 or s11
13. S coronary or cardiac or myocardial or angina or heart
14. S cancer\$ or neoplasm\$ or carcinoma\$ or sarcoma\$ or malignan\$ or tumo\$r?
15. S arthritis
16. S asthma\$
17. S diabet\$
18. S s13 or s14 or s15 or s16 or s17
19. S s12 and s 18

20. S 13/xno
S s19 and s20

Embase not being included in the DARE database was searched with a systematic review filter and an economic evaluations filter.

Embase 1980-2002 week 37 (Ovid) systematic reviews search

Searched 17.9.02

1. exp psychotherapy/
2. psychosocial care/
3. counselling/
4. social support/
5. exp rehabilitation/
6. (biopsychosocial or bio psychosocial or bio psycho social).ti,ab
7. (psychosocial or psycho social or psychological).ti,ab
8. (psychoeducation\$ or psycho education\$).ti,ab
9. (behavio\$ adj2 (therap\$ or treatment\$ or intervention\$)).ti,ab
10. cognitive adj2 (therap\$ or treatment\$ or intervention\$)).ti,ab
11. cbt.ti,ab
12. ((anxiety or stress or depressi\$) adj2 manag\$.ti,ab
13. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
14. exp heart disease/
15. exp coronary artery disease/
16. exp neoplasm/
17. exp sarcoma/
18. exp carcinoma/
19. cancer/
20. tumor/
21. exp arthritis/
22. exp asthma/
23. exp diabetes mellitus/
24. 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23
25. 13 and 24
26. meta analysis/
27. metaanalys\$.ti,ab
28. meta-analys\$.ti,ab
29. meta analys\$.ti,ab
30. cochrane.ti,ab
31. (review\$ or overview\$).ti,ab
32. review.pt
33. (synthes\$ adj3 (literature\$ or research\$ or studies or data)).ti,ab
34. pooled analys\$.ti,ab
35. ((data adj2 pool\$) and studies).ti,ab
36. (medline or medlars or embase or cinahl or scisearch or psychinfo or psycinfo or psychlit or psyclit).ti,ab
37. ((hand or manual or database\$ or computer\$) adj2 search\$)).ti,ab
38. ((electronic or bibliographic\$) adj2 (database\$ or data base\$)).ti,ab
39. ((review\$ or overview\$) adj10 (systematic\$ or methodologic\$ or quantitative\$ or research\$ or literature\$ or studies or trial\$ or effective\$)).ti,ab
40. 26 or 27 or 278 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39
41. (retrospective\$ adj2 review\$).ti,ab,sh
42. (case\$ adj2 review\$).ti,ab,sh
43. (record\$ adj2 review\$).ti,ab,sh
44. (patient\$ adj2 review\$).ti,ab,sh
45. (patient\$ adj2 chart\$).ti,ab,sh
46. (peer adj2 review\$).ti,ab,sh
47. (chart\$ adj2 review\$).ti,ab,sh
48. (case\$ adj2 report\$).ti,ab,sh

49. (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ti,ab,sh
50. 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49
51. 50 not (50 and 40)
52. 40 not 51
53. editorial.pt
54. letter.pt
55. 53 or 54
56. 52 not 55
57. exp animal/
58. exp human/
59. 57 not (57 and 58)
60. exp nonhuman/
61. exp human/
62. 60 not (60 and 61)
63. 59 or 62
64. 56 not 63

**Embase 1980- 2002 week 37 (Ovid) economic evaluation search
Searched 18.9.02**

1. exp psychotherapy/
2. psychosocial care/
3. counselling/
4. social support/
5. exp rehabilitation/
6. (biopsychosocial or bio psychosocial or bio psycho social).ti,ab
7. (psychosocial or psycho social or psychological).ti,ab
8. (psychoeducation\$ or psycho education\$).ti,ab
9. (behavio\$ adj2 (therap\$ or treatment\$ or intervention\$)).ti,ab
10. cognitive adj2 (therap\$ or treatment\$ or intervention\$)).ti,ab
11. cbt.ti,ab
12. ((anxiety or stress or depressi\$) adj2 manag\$.ti,ab
13. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
14. exp heart disease/
15. exp coronary artery disease/
16. exp neoplasm/
17. exp sarcoma/
18. exp carcinoma/
19. cancer/
20. tumor/
21. exp arthritis/
22. exp asthma/
23. exp diabetes mellitus/
24. 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23
25. 13 and 24
26. health economics/
27. exp economic evaluation/
28. exp health care cost/
29. exp pharmacoeconomics/
30. 26 or 27 or 28 or 29
31. (econom\$ or cost or costs or costly or costing\$ or price or prices or pricing or pharmaco-economic\$).ti,ab
32. (expenditure\$ not energy).ti,ab
33. (value adj2 money).ti,ab
34. budget.ti,ab
35. 31 or 32 or 33 or 34
36. 30 or 35
37. letter.pt
38. editorial.pt

39. note.pt
40. 37 or 28 or 39
41. 36 not 40
42. (metabolic adj10 cost).ti,ab
43. ((energy or oxygen) adj10 cost).ti,ab
44. ((energy or oxygen) adj10 expenditure).ti,ab
45. 42 or 43 or 44
46. 41 not 45
47. exp animal/
48. exp animal experiment/
49. nonhuman/
50. (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ti,ab,sh
51. 47 or 48 or 49 or 50
52. exp human/
53. exp human experiment/
54. 52 or 53
55. 51 not (51 and 54)
56. 46 not 55
57. 25 and 56
- 58.

DARE Administration Database (CAIRS T) system searched 11.11.02

1. S psychotherap\$ or psycho-therap\$ or psycho(w)therap\$
2. S biopsychosocial or bio-psycho-social or bio-psycho-social
3. S psychosocial or psycho-social or psycho(w)social or psychological
4. S psychoeducation\$ or psycho-education\$ or psycho(w)education\$
5. S (behavio\$ (2w) (therap\$ or treatment\$ or intervention\$))
6. S (cognitive (2w) (therap\$ or treatment\$ or intervention))
7. S cbt
8. S counsel\$ or rehabilit\$
9. S (anxiety or depressi\$ or stress) (2w) manag\$
10. S family(w)therap\$
11. S social(w)support
12. S s1 or s2 or s3 or s4 or s5 or s6 or s7 or s8 or s9 or s10 s11
13. S coronary or cardiac or myocardial or angina or heart
14. S cancer\$ or neoplasm\$ or carcinoma\$ or sarcoma\$ or malignan\$ or tumo\$r?
15. S s13 or s14
16. s12 and s15

APPENDIX 4: REVIEW INCLUSION/EXCLUSION DETAILS - CANCER

Author, Year	Range of search dates	Study designs included	Participants included	Interventions included	Types of outcomes evaluated	Quality score
Psychoeducational interventions						
Devine, 1995 ⁴⁰	1966-1993.	Experimental quasi-experimental pre-post.	Adults with cancer.	Psychoeducational care: education, nonbehavioural/noncognitive counseling, and behavioural/cognitive counseling.	Physical (nausea, vomiting, pain) Psychological (anxiety, depression, mood) Other Knowledge	4
Barsevick, 2002 ³⁸	1980-2000	Scientific studies, systematic reviews, evidence based guidelines.	Adults with cancer.	'Psychoeducational interventions', defined as "therapeutic approaches that involve information giving and receiving, discussion of concerns, problem solving, coping skills training, expression of emotion, and social support". Controlled studies were only included if a usual care or attentional control group was used.	Psychological (depression)	3
Relaxation interventions						
Wallace, 1997 ²³	1982-1995.	Not stated.	Adults with cancer pain.	Relaxation and imagery (alone, together, or in combination with other intervention approaches)	Physical (pain, physical function, posture, movement, sleep) Psychological (distress, knowledge of pain, change in affective state, anxiety, mood, visual concentration) Quality of life (quality of family relationship)	3
Luebbert, 2001 ⁴⁴	1980-1995	RCTs.	Adult cancer patients (aged >16 years) undergoing medical cancer treatment.	Relaxation training. Defined as techniques which 'aim to reduce a relaxed physical and mental state' in the patient: PMR with or without guided imagery, hypnosis and autogenic training. Excluded from the review were: intervention packages/programmes, psychological intervention combined with different pharmacological treatments, general psychotherapy, relaxation as part of systematic desensitisation and biofeedback without relaxation training.	Physical (treatment-related symptoms: blood pressure, pulse rate, nausea, pain, vomiting) Psychological (depression, tension, anxiety, mood, hostility, fatigue, confusion, vigour).	3
Group interventions						
Bottomley, 1997 ³⁵	1976-1996	Not stated.	Adult cancer patients.	Group interventions that examined the effects of professionally conducted intervention groups (rather than those of a self-help nature or facilitated by non-professional leaders). Studies were broadly categorised into supportive or psychoeducational interventions).	Physical (general health status) Psychological (anxiety, depression, coping, self-esteem, information, locus of control) Quality of life	4
Bottomley, 1998 ³⁴	1976-1996	RCTs	Cancer patients.	'Group interventions'	Physical (survival)	4

Plante, 2001 ²⁶	1970-2000	Not stated.	Children or adolescents (birth to age 18 years) with cancer.	Group psychological interventions for paediatric groups.	Physical (physical activity) Psychological (psychological symptoms, anxiety and PTSD symptoms, knowledge of cancer, self concept).	2
Broad scope reviews						
Chow, 2004 ⁵²	Various – 2002	Randomised controlled trials (RCTs)	Adults (18+) with cancer.	'Psychosocial intervention'	Physical (survival)	7
Bauman, 1997 ³⁹	1979-1993	Controlled studies with >15 patients in the experimental group.	Children with cancer.	'Planned psychosocial interventions' in paediatric populations.	Psychological (various)	6
Trijsburg, 1992 ⁵¹	1976-1990	Controlled studies.	Cancer patients.	"Psychological interventions" (included group therapy, individual therapy and counselling, self-help counselling, problem solving, stress and activity management). Studies on the effects of educational programmes or information per se, or self-help groups were excluded.	Physical (fatigue, nausea/vomiting, weight loss, activity level, sexual relations, leisure activities, survival) Psychological (distress, self-concept, locus of control, anxiety, depression, anger, hostility, confusion).	5
Sollner, 1998 ²⁰	1977-1998	Not stated.	Persons with melanoma.	'Psychosocial interventions'	Physical (Survival, recurrence rates, immunological) Psychological (affective disorders, coping, distress, coping)	5
Sheard, 1999 ²⁸	Not stated.	Controlled studies.	Cancer patients.	Psychosocial or psychiatric interventions aimed specifically at alleviating psychological distress. Studies focusing on physical symptoms/survival were excluded.	Psychological (anxiety and depression)	5
Hill, 1992 ¹⁶	"The last 5 years"	Controlled studies.	Adult cancer patients.	Studies had to use a replicable global psychosocial intervention. Psychosocial interventions were defined as any of the following techniques: education, counselling, therapy (either group or individual), stress management and cognitive behaviour therapy methods. Interventions incorporating hypnosis techniques were excluded as were studies on pharmacological interventions.	Psychological (distress)	4
Meyer, 1995 ¹⁸	Not stated.	RCTs with 'no intervention' or sham procedure controls.	Adult cancer patients.	Psychosocial, behavioural or psychoeducational interventions.	Physical (functional adjustment, treatment- and disease-related symptoms, medical outcomes). Psychological (emotional adjustment)	4
McQuaid, 1999 ²²	1970-?	Not stated.	Children with cancer.	Psychological intervention (e.g. relaxation, biofeedback, psychoanalysis, social skills training, stress management, imagery, active cognitive distraction with relaxation, video games).	Physical (chemotherapy-related nausea, vomiting)	4

Sellick, 1999 ⁴³	1976-1996	RCTs	Cancer patients.	Psychological counselling interventions for depression in cancer. Included interventions that were individually tailored to the individual patient situation of existential concerns; cognitive behavioural structured sessions focusing on skill development in coping or problem solving; or behavioural interventions including relaxation or guided imagery. Studies were excluded if the intervention was limited to information exchange.	Psychological (depression)	4
Redd, 2001 ⁴⁵	1979-2000	RCTs, within-subject studies, case reports.	Cancer patients undergoing/having undergone traditional cancer treatment.	Behavioural interventions for cancer treatment side effects. Behavioural components in the selected studies included: relaxation, cognitive/attentional distraction, hypnosis, desensitisation, rehearsal modelling, contingency management, emotive imagery, cognitive restructuring.	Physical (nausea, vomiting, physiologic arousal, pain) Psychological (anxiety and distress).	4
Newell, 2002 ⁴¹	?-1998	RCTs of at least 'fair' methodological quality.	Cancer patients.	'Psychological interventions'	Physical (functional ability, nausea, vomiting, pain, fatigue, overall physical symptoms, conditioned nausea, conditioned vomiting, survival, immune outcomes) Psychological (anxiety, depression, general/overall affect, hostility, stress or distress, vocational or domestic adjustment, coping or control skills) Quality of life Social (interpersonal/social relationships, sexual/marital relationships)	4
Ross, 2002 ³²	1966-2001.	RCTs with an untreated control group.	Adult cancer patients (aged > 18 years).	Psychosocial interventions. Studies on interventions aimed exclusively at reducing the side-effects of treatment were excluded. Interventions evaluated in primary studies included: individual, group and family counselling, supportive group therapy alone and with self-hypnosis, psycho-educational group therapy, education on coping pain management and communication, supportive group sessions with and without leadership, group and individual cognitive behavioural therapy, individual psychotherapy, home visits and telephone calls from specialised nurses after surgery or during radiation therapy, preoperative information, relaxation training, meditation training, physical training, biofeedback, support from volunteers, emotional expression. Some interventions combined two or more of these approaches.	Physical (pain, survival) Psychological (anxiety, depression, emotional adjustment, mood) Quality of life	4
Frischenschlager, 1992 ²¹	1975-1990	Prospective or retrospective empirical controlled studies.	Adults with cancer.	Social support, psychotherapy, social advice, oncological (care/social work)	Physical (survival time, activities of daily living) Psychological (coping, mood states, depression, anxiety, sexuality) Quality of life	3

Edelman, 2000 ⁴⁶	Not stated.	Studies of "scientifically acceptable methodology"	Cancer patients.	'Psychological intervention' (ranging from brief education to CBT)	Physical (survival time)	3
Fredheim, 2001 ⁵⁰	1992-2000	Controlled studies.	Adult cancer patients.	'Psychological interventions' (Four main groups of intervention were identified: cognitive therapy, psychoeducational interventions, supportive psychotherapy, relaxation exercises and there were also combinations of treatments).	Physical (pain, general symptoms) Psychological (anxiety, depression, self-esteem, locus of control, psychological stress, social support, health beliefs, psychosocial adjustment and difficulties) Quality of life	3
Cwikel, 1997 ⁶⁵	1966-1996	Experimental, quasi-experimental or longitudinal studies.	Adult cancer patients.	Treatment methods that could be used by social workers	Physical (functional measures, symptoms, medical measures/survival) Psychological (general psychological outcomes).	2

APPENDIX 5: REVIEW INCLUSION/EXCLUSION DETAILS – HEART DISEASE

Author, Year	Range of dates of searches	Designs included	Participants included	Interventions included	Types of outcomes evaluated	Quality score
Educational interventions						
Mullen, 1992 ³⁷	1971-1990	RCTs, quasi-experimental comparison group studies, single group pre-post test designs.	Adults with CAD, including MI, CABG surgery and angina.	'Psychosocial or educational interventions', focusing on patient education.	Physical (blood pressure, morbidity, mortality) Psychological (stress) Other (return to work, exercise, diet, smoking).	6
Broad scope reviews						
Dusseldorp, 1999 ²⁷	1974-1998	RCTs or quasi-experimental controlled studies	Patients who had experienced a cardiac event within the previous 6 months.	Psychoeducational programmes including: health education, stress management and exercise training; health education and stress management; health education and exercise training, health education alone and stress management alone. Information provision not organised systematically was considered standard care.	Physical (cardiac mortality, recurrence of MI, CABG, incidence of angina pectoris, blood pressure, cholesterol, weight) Other (smoking)	6
Godin, 1989 ⁴²	1970-“date”	Not stated.	Individuals with CHD.	Interventions to modify behavioural risk factors for CHD.	Physical/psychological (change in behavioural risk factors: smoking diet, exercise).	5
Hill, 1992 ¹⁶	“The past 5 years”	Controlled studies.	Adults with heart disease.	Studies had to use a replicable global psychosocial intervention. Psychosocial interventions defined as: education, counselling, therapy (either group or individual), stress management and cognitive behaviour therapy methods. Interventions to address Type A behaviour in cardiac patients were excluded. Interventions incorporating hypnosis techniques were excluded as were studies on pharmacological interventions.	Psychological (distress)	4
Linden, 1996 ²⁹	Not stated.	RCTs.	Patients with coronary heart disease.	Psychosocial treatment offered in addition to usual care.	Physical (mortality, recurrence of cardiac events) Psychological (anxiety, depression)	4

Sebregts, 2000 ³⁰	Not stated.	RCTs.	Patients with established CHD, or who have had PTCA, AMI, or CABG.	Nonpharmacological interventions aimed at CHD risk factor modification. Interventions included counselling/advice, cognitive-behavioural approaches and those aimed at direct risk factor reduction such as exercise training or lipid lowering diets.	Physical (reduction in mortality and morbidity) Modification of one of the risk factors (smoking, serum cholesterol, physical exercise, type A behaviour, hypertension or body weight)	4
Moore, 1997 ³³	1980-1996	Controlled experimental studies, plus reviews and meta-analyses.	Adults recovering from CABG surgery.	General excluding cardiac rehabilitation programmes.	Physical (physical functioning, post surgical physical measures) Psychological (mood states, anxiety, family functioning) Resource use (length of hospital stay, return to work) Quality of life	3
Nunes, 1987 ³⁶	Not stated.	Controlled studies.	People with type A behaviour pattern and/or at risk of CHD morbidity/mortality.	No specific inclusion criteria are listed but the review included: education about CHD, Education about TABP, Relaxation Training, Cognitive therapy, Imaging, Behaviour Modification, Emotional support and Psychodynamic interpretation.	Physical (morbidity and mortality) Psychological (type A personality behaviour)	2
Rees, 2003 ⁴⁹	?-2001	RCTs with parallel group design	Adults of all ages with CHD including those who had suffered MI, a revascularisation procedure (CABG or PTCA), those with angina or angiographically defined CHD.	All non-pharmacological psychological interventions delivered by health care workers with specific training in such techniques were eligible. Particular emphasis placed on Stress Management.interventions Comparison group had to be usual care / no intervention.	Physical (all-cause and CHD-related mortality, MI, CABG, PTCA, modifiable cardiac risk factors – BP, cholesterol, smoking) Psychological (anxiety, depression, measures of stress and type A behaviour / hostility) Quality of life	No results available
Lip, 2003 ⁴⁷	Not stated.	RCTs	Adolescents (aged 15-17 years) and adults (aged 18 years and older) with congenital abnormalities of the heart or great vessels	Psychological interventions (CBT, non-cognitive psychotherapy, talking/counselling therapy).	Physical (morbidity, mortality) Psychological (depression, acceptability of treatment) Resource use (hospital readmission, health economic data) Quality of life Other (risk factor reduction)	Protocol only.
Lip, 2003 ⁴⁸	Not stated.	RCTs	Adults (aged 18+) with heart failure.	Psychological interventions (CBT, non-cognitive psychotherapy, talking/counselling therapy).	Physical (morbidity, mortality) Psychological (depression, acceptability of treatment) Resource use (hospital readmission, health economic data) Quality of life Other (risk factor reduction)	Protocol only.

APPENDIX 6: REVIEW INCLUSION/EXCLUSION DETAILS – REVIEWS INCLUDING BOTH CANCER AND HEART DISEASE

Author, Year	Range of years searched	Study designs included	Participants included	Interventions included	Outcomes evaluated	Quality score
Stetter, 2000 ²⁵	Not stated.	Controlled studies.	Clinically defined groups of patients suffering from a specific disorder or syndrome.	Autogenic training (AT) had to be applied for therapeutic purposes in at least one group. AT had to be the only or the main treatment method in one group or had to be added as a therapeutic component to one group only. Studies were excluded if AT played an inferior or not clearly discernible role within the treatment plan. AT needed to be administered giving participants chance to practise without therapeutic guidance. Studies were included even if not all six standard exercises of AT were included. However at least the heaviness and warmth concentration and the rest presentation had to be administered.	Physical/psychological (At least one outcome criterion relating to the disorder or syndrome had to be evaluated (physiological and behavioural or psychological)). Quality of life	5
Hill, 1992 ¹⁶	"The past 5 years".	Controlled studies.	Adult patients with heart disease or cancer.	Studies had to use a replicable global psychosocial intervention. Psychosocial interventions were defined as any of the following techniques: education, counselling, therapy (either group or individual), stress management and cognitive behaviour therapy methods. Interventions to address Type A behaviour in cardiac patients were excluded. Interventions incorporating hypnosis techniques were excluded as were studies on pharmacological interventions.	Psychological (distress)	4
Kibby, 1998 ³¹	1990-1995	Between-group and within-group study designs.	Children or adolescents (aged <18years) with a specific chronic illness.	'Psychological interventions' classified as behavioural, non-behavioural or didactic.	Physical/psychological (psychophysiological outcomes, psychosocial problems, procedure related distress, disease related knowledge) Resource use (medical services)	3

APPENDIX 7: INCLUDED PRIMARY STUDIES – CANCER REVIEWS

Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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Ali NS. Cancer Nursing 1989; 12: 236-42.			•																		•		2
Allison H. Social Work in Health Care 1983; 8(4): 29-44.				•			•																2
Arakawa S. Cancer Nurs 1997; 20: 342-9.																			•				1
Arathuzik D. Cancer Nurs 1994; 17: 207-14.					•													•		•			3
Baider L. General Hospital Psychiatry 1994; 16: 340-7.							•																1
Baider L. Journal of Adolescent Health Care; 1989; 10: 35-38.							•									•							2
Baider L. Journal of Psychosomatic Research 1984; 28(4); 323-30.																		•					1
Baider L. Psychother Psychosom 1997; 66: 44-9.																	•						1
Bailey LM. Music Therapy 1983; 3(1): 17-28.				•																			1
Baker BW. Masters Abstracts International 1984; 23: 142.				•																			1
Baum M. Nursing Mirror 1979; 146:38-40.				•																			1
Beck SCL. Dissertation Abstracts International 1988; 49: 5226B.				•																			1
Belzer H. Dissertation Abstracts International 1982; 43: 2700B.				•																			1

Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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Berglund G. Psycho-oncology 1994; 3:109-20.																			•		•		3
Bindemann S. European Journal of Cancer 1991; 27: 170-4.			•	•							•								•		•		5
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Bluebond-Langer, M. Journal of Psychosocial Oncology 1991; 9: 67-80.															•								1
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Braden C. Cancer Pract 1998; 6: 87-98.																					•		1

Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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Burish TG. J Behav Ther Exp Psychiatry 1979; 10: 357-61.																		•					1
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Cain EN. Cancer 1986; 57: 183-9.	•	•	•	•			•	•			•								•	•	•		10

Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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Carey MP. Dissertation Abstracts International 1987; 47: 1714B.				•																			1
Carpenter JG. Dissertation Abstracts International 1984; 45: 3931B.				•							•												2
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Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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Fukui S. Cancer 2000; 89: 1026-26.																			•		•		2
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Goodwin JO. International Journal of Nursing Studies 1979; 16: 29-40.			•																				1
Goodwin P. New England Journal of Medicine 2001; 345: 1719-26.																						•	1
Gordan WA. Journal of Consulting and Clinical Psychology 1980; 48: 743-59.	•	•		•			•			•									•				6
Graffam S. J Pain Symptom Manage 1987; 2: 229-31.		•			•																		2
Grant MM. Dissertation Abstracts International 1987; 48; 3248B.				•																			1
Greene PG. J Behav Ther Exp Psychiatry 1991; 22: 285-90.																		•					1

Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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Gruber BL. Scandinavian Journal of Behaviour Therapy 1988; 17: 25-35.				•																			1
Guerrant DJ. Dissertation Abstracts International 1984; 45: 3619B.				•							•												2
Gunn B. Dissertation Abstracts International 1989; 51: 985B.				•																			1
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Hagopian GA. Oncology Nursing Forum 1991; 18: 1199-1203.				•																			1
Hawkins PJ. Psychooncology 1995;4:101-6.																				•			1
Hayes FC. Dissertation Abstracts International 1981; 43: 3363B.				•							•												2
Heiney SP. Cancer Nursing 1990; 13: 13-20.																•							1
Heiney SP. Journal of Paediatric Oncology Nurses 1988; 5: 20-4.															•								1
Heinrich RL. Journal of Consulting and Clinical Psychology 1985; 53(4): 439-46.	•	•		•			•												•				5

Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
Helgeson V. Arch Gen Psychiatry 1999; 56: 340-347.																					•		1
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Herth K. J Adv Nurs 2000; 32: 1431-1441.																					•		1
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Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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McHugh P. British Journal of Cancer 1995; 71: 388-92.																			•				1
McQuellon R. Psycho-Oncology 1997; 7: 207-217.																			•		•		2
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Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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Telch CF. Dissertation Abstracts International 1985; 46: 1349B.				•																			1
Telch CF. J Consult Clin Psychol 1986; 54: 802-8.		•	•	•			•	•			•								•		•		8
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Vachon MLS. International Journal of Psychiatry in Medicine (1981-1982); 11(4): 365-72.		•		•			•	•											•				5
Van den Borne HW. Patient Educ Couns 1987; 9:33-51		•																					1
Varni JW, J Pediatr Psychol 1993; 18: 751-767.						•																	1
Vasterling J. J Behav Med 1993; 16(1): 65-80.			•														•	•	•				4
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Wall VJ. Am J Clin Hypn 1989; 31: 181-91.																		•					1

Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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Included papers (first author only)	Trijsburg, 1992	Frischensclager, 1992	Meyer, 1995	Devine, 1995	Wallace, 1997	Bauman, 1997	Cwikel, 1997	Bottomley, 1997	Bottomley, 1998	Sollner, 1998	Sheard, 1999	Sellick, 1999	McQuaid, 1999	Edelman, 2000	Fredheim, 2001	Plante, 2001	Luebbert, 2001	Redd, 2001	Barsevick, 2002	Newell, 2002	Ross, 2002	Chow, 2004	
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APPENDIX 8: INCLUDED PRIMARY STUDIES – HEART DISEASE REVIEWS

Included papers (first author only)	Nunes, 1987, USA	Godin, 1989, Canada	Mullen, 1992, USA	Linden, 1996, Canada	Moore, 1997, USA	Dusseldorp, 1999, Netherlands	Sebregts, 2000, Netherlands	Rees, UK, 2003	No. of reviews including study
Adsett CA, Can Med Assoc J. 1968; 99:577-584.	•			•					2
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Allison TG, Am J Cardiol. 2000; 86:133-138.								•	1
Anderson EA, J Consult Clin Psychol. 1987; 55: 513-520.					•				1
Anonymous. American Heart Journal. 2000; 139(1 Pt 1): 1-9.								•	1
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Barnard RJ, J Cardiac Rehab 1983; 3: 183-190.			•						1
Barnason S, Heart Lung 1995; 24: 124-132.					•				1
Barnason S, Prog Cardiovasc Nurs. 1995; 10: 11-20.					•				1
Beckie T, Heart Lung. 1989; 18: 46-55.					•				1
Bengtsson K, Scand J Rehab Med 1983; 15: 1-9.			•			•			2
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Bohachick P. Nurs Res. 1984; 33:283-287.				•					1
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Burgess AW, Soc Sci Med. 1987; 24:359-370.				•				•	2
Burrell G, J Rehabil Sci. 1995; 8:39-40.								•	1
Burrell G. in Allen R, Scheidt S, eds. Heart & Mind. The practice of cardiac psychology. Washington DC: American Psychological Association 1996: 291-310.							•	•	2
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Burt A, Lancet 1974; I: 304-306.		•	•						2
Carson(1982).							•		1
Chatham MA, Heart Lung. 1978; 6:995-999.					•				1
Chubb JM, Drug Intell Clin Pharm 1974; 8: 430-436.			•						1

Included papers (first author only)	Nunes, 1987, USA	Godin, 1989, Canada	Mullen, 1992, USA	Linden, 1996, Canada	Moore, 1997, USA	Dusseldorp, 1999, Netherlands	Sebregts, 2000, Netherlands	Rees, UK, 2003	No. of reviews including study
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Cowan MJ, Nursing Research. 2001; 50(2): 68-76.								•	1
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Erdman RAM, J Cardiac Rehabil 1986; 6: 206-213.		•						•	2
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Fielding R, Br J Soc Clin Psychol 1980; 19: 157-161.	•		•	•					3
Fraser GE, J Cardiopulmonary Rehabil 1988; 8:50-57.		•							1
Frasure-Smith N et al 1997 The Lancet 350; 473-479.						•		•	2
Frasure-Smith N, Psychosom Med 1985; 47: 431-445.			•			•			2
Frasure-Smith N, Psychosom Med. 1989;				•				•	2

Included papers (first author only)	Nunes, 1987, USA	Godin, 1989, Canada	Mullen, 1992, USA	Linden, 1996, Canada	Moore, 1997, USA	Dusseldorp, 1999, Netherlands	Sebregts, 2000, Netherlands	Rees, UK, 2003	No. of reviews including study
51: 485-513.									
Frasure-Smith N, Psychosomatic Medicine. 1985; 46(4): 293-313.								•	1
Frasure-Smith N, Psychology and Health. 1987; 1(3): 273-85.								•	1
Fridlund B et al 1991 Scandinavian Journal of Caring Sciences 5; 23-32.						•		•	2
Fridlund B, Journal of Clinical Nursing. 1992;1: 141-6.								•	1
Friedman M, Am Heart J 1986; 112: 653-665.						•	•	•	3
Friedman M, Am Heart J. 1984; 108: 237-248.				•			•		2
Friedman M. Circulation 1982;66: 83-92.							•	•	2
Gallacher JEJ, Psychology and Health. 1997;12(4): 523-32.								•	1
Giese H, J Cardiopulmonary Rehabil 1986; 6: 30-37.		•							1
Gill JJ, Am Heart J 1985; 110: 503-514.	•								1
Gillis CL, Heart Lung. 1993; 22: 125-133.					•	•			2
Gortner SR, J Adv Nurs. 1988; 13: 649-661.					•				1
Greenstein P, Ann Arbor, MI: University Microfilms International 1982.			•						1
Gruen W, J Consult Clin Psychol 1975; 43:223-232.	•			•					2
Gutschker A, Das deutsche Gesundheitswesen. 1982; 37(20): 918-31.								•	1
Guzetta CE, Heart Lung. 1989; 18: 609-616.				•					1
Hambrecht R. J Am Coll Cardiol 1993; 22:468-77.							•		1
Hart KE, J Behav Ther Exp Psychiatry 1984; 15: 133-139.	•								1
Healy CA, Ann Arbor, MI: University Microfilms International 1983.			•						1
Heath GW, J Cardiopulmonary Rehabil 1987; 7: 190-195.		•							1
Hedback B et al 1987 European Heart Journal 8; 234-242.						•			1
Hertanu JS, Arch Phys Med Rehabil 1986; 67: 431-435.			•						1

Included papers (first author only)	Nunes, 1987, USA	Godin, 1989, Canada	Mullen, 1992, USA	Linden, 1996, Canada	Moore, 1997, USA	Dusseldorp, 1999, Netherlands	Sebregts, 2000, Netherlands	Rees, UK, 2003	No. of reviews including study
Hickey N, Ir J Med Sci 1981; 150: 262-264.		•							1
Higgins C, J Cardiac Rehabil 1983; 3: 55-59.		•							1
HofmanBang C, European Heart Journal. 1999;20:1465-74.								•	1
Horlick L, J Psychosom Res. 1984; 28:485-492.				•		•			2
Ibrahim MA, Int J Psychiatry Med 1974; 5: 253-268.	•	•	•			•		•	5
Jenni MA, Cognit Ther Res 1979; 3: 61-73.	•								1
Johnston M, Psychosomatic Medicine. 1999; 61(2): 225-33.								•	1
Jolly K, Family Practice. 1998;15: 548-55.								•	
Jolly K, BMJ. 1999; 318: 706-711.								•	
Jones DA 1996 British Medical Journal 313; 1517-1521.						•		•	2
Kallio V, Lancet 1979; 2: 1091-1094.		•				•	•		3
Karvetti RL, J Am Diet Assoc 1981; 79:660-667.		•				•			2
Kavanagh T, Med Sci Sports 1973; 5: 34-39.			•						1
Kentala(1972).							•		1
Kubo H. Jpn Circ J 1992; 56:413-21.							•		1
Langosch W, J Psychosom Res 1982; 26: 475-484.	•		•						2
Levenkron JC, J Consult Clin Psychol 1983; 51: 192-204.	•								1
Lewin B, Lancet. 1992; 339 (8800): 1039-40.								•	1
Lidell E, Scandinavian Journal of Caring Sciences. 1996;10(2): 67-74.								•	1
Linde BJ, Nurs Res 1979; 28: 282-286.			•						1
Linden B 1995 Intensive and Critical Care Nursing 11; 10-19.						•			1
Lisspers J, Journal of Psychosomatic Research. 1999; 46(2): 143-54.								•	1
Louis AA, the European Journal of Heart Failure. 2002; 4(111-116).								•	1
Maelund JG, Scand J Rehab Med 1987; 19(5): 57-65.			•						1

Included papers (first author only)	Nunes, 1987, USA	Godin, 1989, Canada	Mullen, 1992, USA	Linden, 1996, Canada	Moore, 1997, USA	Dusseldorp, 1999, Netherlands	Sebregts, 2000, Netherlands	Rees, UK, 2003	No. of reviews including study
Mallaghan M, Br J Prev Soc Med 1977;31: 86-90.		•							1
Marra(1985).							•		1
Marshall J, Heart Lung. 1986; 15: 76-82.			•		•	•			3
Mayou R, Lancet 1981; 2:1399-1401.		•	•						2
Mayou RA, J Cardiac Rehabil 1983; 3: 397-402.		•				•			2
McHugh F, Heart. 2001;86: 317-323.								•	1
Mendes-de-Leon C, Psychosomatic Medicine. 1991;53(4): 407-19.								•	1
Miller P, Nurs Res,1988; 37: 297-302.			•						1
Mitsibounas DN et al 1992 Psychotherapy and Psychosomatics 58; 97-102.						•		•	2
Moore SM, Int J Nurs Stud. 1996; 33: 181-189.					•				1
Munro BH, Nurs Res. 1988; 37:231-235.				•					1
Nordmann A, Am J Med. 2001;110:543-550.								•	1
O'Callaghan WG, Eur Heart J 1984; 5: 649-651.			•						1
Ockene J. Health Psychol 1992;11:119-26.							•		1
Oldenburg B et al 1985 Journal of Consulting and Clinical Psychology 53; 852-859.						•		•	2
Oldenburg B et al 1989 Clinical and abnormal Psychology: Proceedings of the XXIV International Congress of Psychology of the International Union of Psychological Science (pp 429-438).						•			1
Oldenburg B, Journal of Cardiopulmonary Rehabilitation 1995;15(1): 39-46.								•	1
Oldridge NB, Acta Med Scand 1986 (suppl) 711: 123-129.		•							1
Oldridge NB, Can Med Assoc J 1978; 118: 361-364.			•						1
Oldridge NB, J Cardiac Rehabil 1983;3:257-262.			•						1
Oldridge NB. JAMA 1988; 260: 945-50.							•		1
Ornish D. JAMA 1983; 249: 54-9.	•						•		2
Ornish D. Lancet 1990; 336: 129-33.							•	•	2
Ornish D, JAMA 1998;280(23):2001-7.								•	1
Owens JF, Nurs Res. 1982; 31: 60-62.					•				1

Included papers (first author only)	Nunes, 1987, USA	Godin, 1989, Canada	Mullen, 1992, USA	Linden, 1996, Canada	Moore, 1997, USA	Dusseldorp, 1999, Netherlands	Sebregts, 2000, Netherlands	Rees, UK, 2003	No. of reviews including study
Penckofer S, J Cardiovasc Nurs. 1989; 3: 10-24.					•				1
Perk J et al 1990 Scandinavian Journal of Social Medicine 18; 45-51.					•				1
Perkins KA, Int J Addict 1986; 21: 1173-1182.		•							1
Powell LH, American Journal of Cardiology. 1988;72(17):1159-63.								•	1
Powell LH, Psychosom Med 1984; 46: 293-313.	•							•	2
Pozen MW, Med Care. 1977; 15:830-837.				•		•			2
Rahe RH, Med Care. Int J Psychiatry Med. 1975; 6:349-358.				•		•			2
Rahe RH, Psychosomatic Med 1979; 41: 229-242.	•	•	•	•				•	5
Rechnitzer (1983).							•		1
Reid V, Hum Nutr App Nutr 1984; 38A: 279-287.		•							1
Rice VH, Res Nurs Health. 1992; 15: 253-259.					•				1
Rigotti NA. Ann Intern Med. 1994; 120: 287-293							•		1
Roman (1983).							•		1
Rosenberg SG, Health Serv Ment Health Admin Health Rep 1971; 86: 793-802.			•						1
Roskies E, J Behav Med 1979; 2: 195-207.	•								1
Roviaro S, J Behav Med 1984; 7: 61-81.			•						1
Saint PA, Eur Heart J 1991; 12(5):612-6.								•	1
Salonen JT, Scand J Rehabil Med 1980; 12: 33-42.	•								1
Salonen JT, Scand J Soc Med 1985; 13: 103-108.			•			•			2
Scalzi CC, Heart Lung 1980; 9: 846-853.		•							1
Schindler BA, Gen Hosp Psychiatry. 1989; 11: 358-364.					•				1
Schulte MB, Patient Educ Couns. 1986; 8:233-244.				•					1
Shaw DK, Heart Lung. 1989; 18: 364-369.					•				1
Shaw LW, Am J Cardiol 1981; 48: 40-46.			•				•		2
Singh RB. BMJ 1992; 304: 1015-9.							•		1
Sivarajan ES, Heart Lung 1983; 12: 65-73.			•			•			2

Included papers (first author only)	Nunes, 1987, USA	Godin, 1989, Canada	Mullen, 1992, USA	Linden, 1996, Canada	Moore, 1997, USA	Dusseldorp, 1999, Netherlands	Sebregts, 2000, Netherlands	Rees, UK, 2003	No. of reviews including study
Steele JM, Heart Lung. 1987; 16: 306-310.					•				1
Stern MJ, Arch Intern Med. 1983; 143:1719-1725.	•			•		•		•	4
Stransky M et al 1986 International Journal of Rehabilitation Research 9; 381-384.						•			1
Suinn RM, J Behav Med 1978; 1: 25-35.	•								1
Taylor CB. Addict Behav. 1988; 13:331-5.							•		1
Taylor CB. Ann Intern Med. 1990; 113: 118-23.						•	•		2
Theorell T 1982 International Rehabilitation Medicine 5; 185-188.						•			1
Thompson DR, J Adv Nurs. 1989; 14:291-297.				•				•	2
Thompson DR, J Psychosom Res. 1990; 34:237-248.				•				•	2
Thompson DR, Patient Education and counselling. 1991; 18: 171-177.								•	1
Thompson DR, Journal of Advanced Nursing. 1990; 15(9): 1064-69.								•	1
Toobert DJ, Patient Education and Counseling. 1998;35(3): 177-88.								•	1
Tulpule TH, Ind Heart J 1980; 32:1-7.	•								1
Turner L, Heart Lung. 1995; 24:145-153.				•					1
Van Dixhoorn J, Am Heart J. 1989; 118:545-552.				•		•		•	3
Van Dixhoorn J, Eur Heart J. 1987; 8:1210-1214.				•				•	2
Van Dixhoorn J, J Psychom Res. 1990; 34:327-337.				•				•	2
Van Dixhoorn J, Journal of Cardiopulmonary Rehabilitation. 1999; 19(3): 178-85.								•	1
Van Elderen T et al 1994 Psychology and Health 9; 317-330.						•			1
Van Elderen T et al British Journal of Clinical Psychology 33; 367-378.						•		•	2
Vermeulen A, American Heart Journal. 1983. 105(5): 798-801.							•	•	2
Waites TF, Am J Cardiol 1983; 51: 1087-1090.			•						1
Wallace N, Med J Aust 1977; 245-247.	•								1
Watts GF. Lancet 1992; 339:563-9.							•		1

Included papers (first author only)	Nunes, 1987, USA	Godin, 1989, Canada	Mullen, 1992, USA	Linden, 1996, Canada	Moore, 1997, USA	Dusseldorp, 1999, Netherlands	Sebregts, 2000, Netherlands	Rees, UK, 2003	No. of reviews including study
Wilhelmsen L, Prev Med 1975; 4: 491-508.		•	•				•		3
Woodward GM, Can Med Ass J 1972; 106: 665-667.		•							1
World Health Organisation(1984).							•		1
Writing Committee for the ENRICHD Investigators, JAMA. 2003;289: 3106-3116.								•	1
Young DT, J Cardiac Rehab 1982; 2: 32-40.			•			•			2

APPENDIX 9: INCLUDED PRIMARY STUDIES – REVIEWS INCLUDING BOTH CANCER AND HEART DISEASE

Included primary studies (first author only)	Stetter, 2000	Hill, 1992	Kibby, 1998	No. of studies including paper
Aiken LH. Nurs Res 1971; 20: 212-217.		•		1
Ali NS. Cancer Nursing 1989; 12: 236-242.		•		1
Allen KD. Headache 1991; 31: 467-472.			•	1
Anderson EA. J Consult Clin Psychol 1987; 55: 513-520.		•		1
Baer PE. J Cardiac Rehab 1985; 5: 191-196.		•		1
Beckie T. Heart Lung 1989, 18: 46-55.		•		1
Beecroft PC. Clinical Nursing Research 1993; 2: 188-211.			•	1
Belsky J. American Journal of Clinical hypnosis 1994; 36: 282-292.			•	1
Boardway RH. Journal of Pediatric Psychology 1993; 18: 29-45.			•	1
Boggs SR. Journal of Pediatric Psychology 1992; 17: 111-118.			•	1
Broome M. Oncology Nursing Forum 1992; 19: 499-502.			•	1
Cain EN. Cancer 1986; 57: 183-189.		•		1
Campbell LA. Journal of Pediatric Psychology 1995; 20: 313-328.			•	1
Colland VT. Patient Education and Counselling 1993; 22: 141-152.			•	1
Cunningham AJ. Patient Educ Counsel 1989; 14: 101-114.		•		1
Dahl J. Journal of Asthma 1990; 27: 41-46.			•	1
Engel JM. Advances in Pain Research Therapy 1990; 15: 273-290.			•	1
Engel JM. Headache 1992; 32: 152-156.			•	1
Engel JM. the American Journal of Occupational Therapy 1992; 46: 591-596.			•	1
Engel JM. The Occupational Therapy Journal of Research 1990; 10: 283-299.			•	1
Engel JM. The Occupational Therapy Journal of Research 1994; 14: 183-190.			•	1
Fawzy FI. Arch Gen Psychiatry 1990; 47: 720-725.		•		1
Forester B. Am J Psychiatry 1985; 142: 22-27.		•		1
Frasure-Smith N. Psychosom Med 1989; 51: 485-513.		•		1
Golberg RJ. Psychother Psychosom 1985; 43: 141-150.		•		1
Gordon WA. J Consult Clin Psychol 1980; 48: 743-759.		•		1
Guarnieri P. Biofeedback and Self Regulation 1990; 15: 179-184.			•	1
Hansson K. Family Systems Medicine 1994; 12: 405-413.			•	1
Heinrich RL. J Consult Clin Pyschol 1985; 53: 439-446.		•		1

Included primary studies (first author only)	Stetter, 2000	Hill, 1992	Kibby, 1998	No. of studies including paper
Helm-Hylkema HVD. Psychoneuroendocrinology 1990; 15: 39-45.			•	1
Horlick L. J Psychosom Res 1984; 28: 485-492.		•		1
Jacknow DS. Developmental and Behavioural Pediatrics 1994; 15: 258-264.			•	1
Jacobs C. Am J clin Oncol 1983; 6: 347-350.		•		1
Jay S. Health Psychology 199; 10: 317-322.			•	1
Jay S. Pain 1991; 62: 3-9.			•	1
Johnson J. Cancer Nurs 1982; April: 117-123.		•		1
Kotses H. Biofeedback and Self Regulation 1991; 16: 1-21.			•	1
Laberke JA. Munchner Medizinische Wochenschrift 1952; 35: 1718-1724.	•			1
Laberke JA. Munchner Medizinische Wochenschrift 1952; 36: 1809-1816.	•			1
Lavigne JV. Arthritis Care and Research 1992; 5: 101-110.			•	1
Linn MW. Cancer 1982; 49: 1048-1055.		•		1
Maguire P. Br Med J 1980; 281: 1454-1456.		•		1
Manne SL. Journal of consulting and Clinical Psychology 1990; 58: 565-572.			•	1
Mansson ME. Oncology Nursing Forum 1993; 20: 39-45.			•	1
Mantovani G. Support Care Cancer 1996; 4: 129-140.	•			1
McCorkle R. Cancer 1989; 64: 1375-1382.		•		1
McGrath PJ. Pain 1992; 49: 321-324.			•	1
Moe EL. Journal of Pediatric Health Care 1992; 6: 251-255.			•	1
Moran G. Journal of the American Academy of Child and Adolescent Psychiatry 1991; 30: 926-935.			•	1
Oldenburg B. J Consul Clin Psychol 1985, 53: 852-859.		•		1
Osterhaus SOL. Journal of Pediatric Psychology 1993; 18: 697-715.			•	1
Perrin JM. Developmental and Behavioural Pediatrics 1992; 13: 241-247.			•	1
Pimm JB. New York Plenum Press 1984.		•		1
Polackova J. Activitas Nervosa Superior (Praha) 1982; 24(3): 178-180.	•			1
Pwers SW. Journal of Pediatric Psychology 1993; 18: 681-695.			•	1
Rakov AL. Voenno-Medicinskij Zurnal Taermedizin 1997; 318: 37-41.	•			1
Ryden O. acta Paediatrica 1994; 83: 285-291.			•	1
Schindler BA. Gen Hosp Psychiatry 1989; 11: 358-364.		•		1
Simma L. Munchner Medizinische Wochenschrift 1985; 21: 527-531.	•			1

Included primary studies (first author only)	Stetter, 2000	Hill, 1992	Kibby, 1998	No. of studies including paper
Slifer KJ. Developmental and Behavioural Pediatrics 1995; 16: 133-141.			•	1
Slifer KJ. Journal of Pediatric Oncology Nursing 1994; 11: 55-63.			•	1
Spiegel D. Arch Gen Psychiatry 1981; 38: 527-533.		•		1
Stark LJ. Journal of Applied Behaviour analysis 1993; 26: 435-450.			•	1
Stark LJ. Journal of Pediatric Psychology 1990; 15: 309-326.			•	1
Stern MJ. Arch Int Med 1983; 143: 1719-1725.		•		1
Stetter F. Praxis der Klinischen Verhaltenmedizin und Rehabilitation 1994; 25: 46-52.	•			1
Telch CF. J Consult Clin Psychol 1986; 54: 802-808.		•		1
Thomas-Dobersen DA. Journal of the American Dietetic Association 1993; 93: 535-540.			•	1
Thompson DR. J Psychosom Res 1990, 34: 237-248.		•		1
Thompson DR. J Psychosom Res 1990, 34: 249-258.		•		1
Vachon MLS. Int J Psychiatry in Med 1982; 11: 365-372.		•		1
Varni JW. Journal of Pediatric Psychology 1993; 18: 751-767.			•	1
Vasquez I. Psychotherapy and Psychosomatics 1993; 60: 106-112.			•	1
Walco GA. Pediatrics 1992; 89: 1075-1079.			•	1
Winterfeld H-J. Innere Medizin 1993; 48: 201-204.	•			1
Worden JW. Gen Hosp Psychiatry 1984; 6: 243-249.		•		1
Wysocki T. Anna Journal 1990; 17: 250-254.			•	1
Zeltzer IK. Pediatrics 1991; 88: 34-42.			•	1

APPENDIX 10: DATA EXTRACTION – CANCER REVIEWS

Reference Sollner ²⁰ 1998 Germany	Title Psychosocial stress, coping with illness and social support in patients with melanoma - A systematic review. Objective/review question To review the evidence of psychosocial correlation in melanoma patients in the context of previous reports.
Literature search Electronic searching of the following databases: PSYINDEX (from 1977 to 1998) and MEDLINE (from 1984 to 1998). Supplementary manual searching was conducted. The Science Citation Index was searched.	
Inclusion/exclusion criteria <u>Design</u> No a priori criteria relating to design were established. <u>Participants</u> Studies of persons with melanoma were eligible for inclusion in the review. <u>Interventions</u> For the purpose of this review only data relating to the effectiveness of interventions are discussed. Studies were eligible for inclusion if they assessed psychosocial interventions. <u>Outcomes</u> No a priori criteria relating to outcomes were established and a range of correlates were studied. Factors which were addressed in the located studies included psychological distress, coping with cancers, levels of support, needs for interventions and success of interventions offered. <u>Other</u> Studies which investigated stress levels, immune function and melanoma growth in animals were excluded from the study. <u>Study selection procedure</u> No information on how the studies were selected or on the number of reviewers selecting studies was given.	
Methods <u>Validity assessment tool</u> Not reported. <u>Validity assessment procedure</u> Not reported. <u>Data extracted from primary studies</u> Authors, year of publication, country, study design, patient population, measurement tools and results. <u>Data extraction procedure</u> No details about how the reviewers extracted the data were provided. <u>How were studies combined in the review?</u> Information from studies was discussed in a commentary of the studies and presented in a table of included studies. No statistical pooling was attempted. <u>How were studies weighted in the synthesis?</u> No method of weighting appears to have been used. <u>How was publication bias assessed?</u> The authors do not appear to have discussed the possibility of bias introduced by selective publication. <u>How was heterogeneity assessed?</u> The authors do not formally assess heterogeneity but discuss factors related to heterogeneity in the text of their review.	
Results <u>Number of studies included in the review</u> Five studies were included in the review of the effects of psychosocial interventions. <u>Number of participants</u> A total of 1,048 patients were included in the studies. Of these 965 had malignant melanoma and 83 had lung cancer. <u>Results of validity assessment</u> No validity assessment was conducted by the authors. <u>Main outcome</u> Cancer specific outcomes -survival were increased and recurrence rates were improved in those in the intervention arm of the one study which measured these outcomes. <u>Secondary outcome</u> Immunological outcomes - An improvement was seen in the number of Natural Killer Cells and Helper T-Cell lymphocytes in patients in the intervention arm of the one study which measured immunological outcomes. <u>Other outcomes</u> Psychological outcomes - A reduction in affective disorders, an improvement in the ability of individuals to cope with their disease, fewer distressed patients and higher knowledge levels were each seen in patients treated with psychosocial interventions in the five studies which assessed psychological outcomes. <u>Publication bias</u> Not reported <u>Heterogeneity</u> Not reported.	
Conclusions/interpretation <u>Authors interpretation</u>	

See conclusions

Conclusion

Short structure interventions can not only improve the quality of life but they can also allow for a reduced mortality and recurrence rates and improved survival.

Implications for research

The results of these trials need to be reproduced in long-term, prospective trials which include assessments of prognostic, immunological and psychological outcomes

Implications for practice

Specific implications for current practice are not outlined.

Quality assessment

Is there a defined search strategy? Yes. Search dates and terms were listed. It was not clear however why different databases were searched for different time periods.

Is there a well defined question? Yes. The question was clear in terms of population of interest and type of intervention. No a priori criteria were defined for outcomes or study design.

Are inclusion/exclusion criteria stated? Yes. The inclusion criteria applied can be inferred from the keywords searched and the data extracted from the study.

Are study designs and number of studies clearly stated? Yes. The authors list the type of studies and their types included in the various sections of the review.

Have the primary studies been quality assessed? No. No quality assessment was reported.

Have the studies been appropriately synthesised? Yes. No statistical pooling was attempted and this appears that this was appropriate in the presence of differences in the studies. Details are supplied and a descriptive overview was provided.

Has more than one author been involved at each stage of the review process? Unclear. No details on the process of conducting the review were provided.

Reviewer's comment

The methods used were not clearly reported. Appropriate details of the included studies were provided but the synthesis of the included studies was minimal. In their conclusions, the authors were guarded and this appears to be in keeping with the paucity of interventional studies found. The authors suggested appropriate avenues for further research.

Reference Frischenschlager ²¹ 1992 Austria	Title The effectiveness of psychosocial care of cancer patients - A critical review of empirical studies (1975-1990). Objective/review question To review the effectiveness of psychological care of patients with cancer.
Literature search Electronic searching of the following databases (from 1975): PsychINFO, Dimdi and CANCERLIT. No supplementary searching was reported.	
Inclusion/exclusion criteria <u>Design</u> Only empirical controlled studies of either retrospective or prospective design were included. Case studies were excluded. <u>Participants</u> Studies of adults with cancer were eligible for inclusion in the review. <u>Interventions</u> Studies were eligible for inclusion if they assessed social support, psychotherapy, social advice and Oncological (care/social work). <u>Outcomes</u> No a priori criteria relating to outcomes were established. <u>Other</u> Studies published as theses were excluded. <u>Study selection procedure</u> No details about how the reviewers applied the inclusion criteria were provided.	
Methods <u>Validity assessment tool</u> Not stated. <u>Validity assessment procedure</u> Not stated. <u>Data extracted from primary studies</u> Authors, year of publication, type of intervention, dependent variable, outcome measures, results and methodological criticisms. <u>Data extraction procedure</u> No details about how the reviewers extracted the data were provided. <u>How were studies combined in the review?</u> Studies were grouped according to the dependent variables and combined in a discussion. No meta-analysis was attempted. <u>How were studies weighted in the synthesis?</u> No method of weighting appears to have been used. <u>How was publication bias assessed?</u> The authors did not report any assessment of publication bias. The authors did not report any language restrictions but only the review only included studies published in English or German. <u>How was heterogeneity assessed?</u> Not assessed.	
Results <u>Number of studies included in the review</u> 41 studies were included. <u>Number of participants</u> Information on the number of participants in each study was not reported. <u>Results of validity assessment</u> None stated. <u>Main outcome</u> Survival - In five of the studies the survival time was increased in those patients in the intervention group. The results of the sixth trial were not reported for this outcome in the review. <u>Secondary outcome</u> Psychological effects of therapy including effects on coping, mood states, quality of life, activities of daily living, depression, anxiety and sexuality. Owing to the large variety in symptoms assessed and the variations in measurement tools, it is not possible to pool the findings. However, to summarise the findings, in most studies, psychological variables were found to be better in those patients treated with psychological therapies compared with those not given this treatment. <u>Other outcomes</u> Immune effects of therapy - While the text of the review mentions that three studies examined the immunological effects of psychological interventions, data on immunological outcomes are given for only two studies. Both studies reported improvements in the treated patients but in one study the improvements were neither immediate nor long-lasting. Pain - in two studies, pain levels were reduced by psychological interventions. <u>Publication bias</u> Not assessed <u>Heterogeneity</u> Not assessed	
Conclusions/interpretation <u>Authors interpretation</u> The current review of a considerable number of controlled studies documents that psychotherapy in cancer patients can be a sensible and useful addition in multiple ways.	

Conclusion

The authors concluded that, even in the absence of flawless research, there is an undoubted improvement in the quality of life of cancer patients treated with psychotherapy.

Implications for research

Further research is needed to allow the correct therapy for individual patients to be identified.

Implications for practice

Owing to the variation in the methods used, the authors report that they are not in a position to make a definitive statement as to which particular psychological treatment is best suited to which particular patient.

Quality assessment

Is there a defined search strategy? Yes. Database names and dates were given. No terms were provided.

Is there a well defined question? Yes. The question was defined in terms of the interventions, designs, participants and comparators.

Are inclusion/exclusion criteria stated? Yes. Full inclusion criteria were stated.

Are study designs and number of studies clearly stated? The designs of the studies were not stated. The number of included studies was provided.

Have the primary studies been quality assessed? No. Some methodological criticism of the studies was provided however.

Have the studies been appropriately synthesised? No synthesis of the studies appears to have been conducted.

Has more than one author been involved at each stage of the review process? The number of reviewers involved in each stage was not reported.

Reviewer's comment

The methods used were not clearly reported. Minimal details of the included studies was provided; for example the direction of the difference in outcomes between the intervention and control groups was indicated but the size of the difference was not reported. In addition results were not reported for every outcome listed in the table of studies. The synthesis of the included studies was minimal. The review would best be described as an annotated bibliography.

Reference McQuaid ²² 1999 USA	Title Empirically supported treatments of disease-related symptoms in pediatric psychology: Asthma, diabetes, and cancer Objective/review question To review empirical studies of psychological treatments for (1) reducing physical symptoms in children and adolescents with asthma, (2) improving glycaemic control in children and adolescents with diabetes and (3) reducing chemotherapy side effects in children and adolescents with cancer.
Literature search MEDLINE and PsychLit databases were searched for studies published after 1970. Reference lists of obtained articles were then searched for other relevant publications.	
Inclusion/exclusion criteria <u>Design</u> Not stated. <u>Participants</u> Children or adolescents with the relevant target condition (asthma, diabetes, or cancer). <u>Interventions</u> Studies had to include administration of a psychological intervention (e.g. relaxation, biofeedback, psychoanalysis, social skills training, stress management, imagery, active cognitive distraction with relaxation, video games). <u>Outcomes</u> Not stated. <u>Other</u> <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> None stated. <u>Validity assessment procedure</u> Not stated. <u>Data extracted from primary studies</u> Sample size and characteristics, diagnostic criteria, experimental design, patients' treatment stage at baseline, assessment measures used, treatment protocol, results and follow-up. <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Narrative summary by type of intervention. Types of intervention were classed according to the Chambless criteria for empirically validated therapies. <u>How were studies weighted in the synthesis?</u> None. <u>How was publication bias assessed?</u> Not assessed. <u>How was heterogeneity assessed?</u> Not assessed.	
Results <u>Number of studies included in the review</u> 10 cancer studies (reported in 9 articles). <u>Number of participants</u> n=166 <u>Results of validity assessment</u> None stated. <u>Main outcome</u> Imagery and active cognitive distraction with relaxation: Seven studies of imagery-based or active cognitive distraction with relaxation interventions reported that the intervention had a positive impact on nausea and vomiting associated with chemotherapy cancer pain. Uncontrolled studies: One uncontrolled study of active cognitive distraction and relaxation with a multiple baseline design (LeBaron 1984) found childrens postchemotherapy ratings of nausea and vomiting were reduced during 2-3 treatment-phase courses of chemotherapy. It was unclear whether reduction in symptoms meant reduced frequency, duration, or severity. Two single case studies of imagery-based intervention with A-B designs (Ellenberg et al 1980; Kaufman et al 1989) reported reduced frequency of anticipatory, concurrent, and postchemotherapy nausea and vomiting during the treatment phase. Kaufman et al (1980) found these benefits during follow up assment, but it is unclear whether the effects were due to the imagery and suggestion intervention or other intervention components (relaxation training, child practice of techniques at home, parental involvement). Zeltzer et al (1983) investigated an imagery-based intervention, finding frequency and perceived intensity of vomiting were reduced during a postintervention chemotherapy course compared to during a chemotherapy course. Controlled studies: Cotanch et al (1985) reported that patients receiving a single-session imagery-based intervention reported decreases in intensity and duration of nausea and in frequency, amount, severity and duration of vomiting compared to patients receiving cognitive distraction and relaxation. In a similar comparison of interventions, Zeltzer et al (1984) found a reduction in nausea and vomiting from baseline to treatment. Zelzer et al (1991) also compared and imagery-based intervention with active cognitive distraction with relaxation, found both groups had a shorter duration of nausea compared to an attention-control group, but only patients receiving the imagery intervention had shorter duration of	

vomiting.

Secondary outcome

Video games:

Three studies evaluated the effectiveness of access to video games in reducing treatment-related symptoms amongst paediatric cancer patients. Kolko et al (1985) conducted a multiple baseline ABAB design study with three adolescents. Clinic resources (e.g. TV) were available during baseline chemotherapy sessions and video games were available during treatment chemotherapy sessions. Both anticipatory and postchemotherapy symptoms were reduced to varying degrees, though vomiting and nausea were not measured separately from other symptoms.

Redd et al (1987) reported two studies. In the first found that ratings of nausea severity decreased from baseline to treatment in patients who received 10 minutes of video game access, but not in patients who only had access to clinic resources. The second used an ABAB design in which patients alternatively received did and did not have access to video games for 10 minutes. Nausea severity was rated at the end of each 10 minute period. Ratings of nausea severity decreased from each baseline to video game period and increased from video game to the second baseline period.

Other outcomes

Publication bias

None stated.

Heterogeneity

None stated.

Conclusions/interpretation

Authors interpretation

'Imagery with suggestion' was categorised as a "Well-established" intervention, supported by well-controlled research.

'Distraction with relaxation' interventions were classed as "probably efficacious".

'Video games' were classed as "promising".

Conclusion

See authors' interpretation.

Implications for research

Future research needs to provide a clearer assessment of the specific mechanism of effect of each intervention. This could be achieved by including additional measures of physiological and psychological treatment variables that change in conjunction with treatment effects. Clinical utility of these interventions would be enhanced by studying them in conjunction with medical management.

Implications for practice

Matching treatment approach to child temperament in psychological interventions for chemotherapy side effects (e.g. using video games with children who are uncomfortable with imagery-based intervention) could result in more effective treatments.

Quality assessment

Is there a defined search strategy? Yes.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Yes.

Are study designs and number of studies clearly stated? Yes.

Have the primary studies been quality assessed? No.

Have the studies been appropriately synthesised? Unclear.

Has more than one author been involved at each stage of the review process? Not stated.

Reviewer's comment

Two electronic databases were searched and articles identified from reference lists were followed up. Broad inclusion criteria were stated, though it was unclear how many reviewers selected papers for inclusion. Only ten studies, evaluating three different types of intervention, were found for treatment-related side-effects in paediatric cancer. It is unclear whether this constitutes all of the available literature in the area. Some distinction between controlled and uncontrolled studies was made in the summary, but no formal assessment of validity was undertaken. Only four of the ten included studies utilised a control group, and two studies reported only a single case each. Brief summaries of the included studies were presented in the review appendices, providing some detail regarding study designs, interventions and populations. Studies were combined in a narrative summary, categorised by type of intervention. An overall indication of the strength of evidence for the efficacy of each intervention was given by classifying interventions according to the Chambless criteria.

Reference Wallace ²³ 1997 USA	Title Analysis of recent literature concerning relaxation and imagery interventions for cancer pain Objective/review question To review the nursing/medical/psychological literature concerning relaxation and imagery interventions in adults with cancer pain over a 14 year period (1982-95).
Literature search Electronic searching of the following databases (1982-95): Index Medicus, Cumulative Index of Nursing and Allied Health Literature, PsychLit. Bibliographies of studies were also reviewed.	
Inclusion/exclusion criteria <u>Design</u> None stated. <u>Participants</u> Adult patients with cancer pain. <u>Interventions</u> Studies of (a) relaxation, (b) imagery, (c) combinations of relaxation as separate interventions, (d) relaxation and imagery used together, and (e) relaxation and imagery included as a part of a more comprehensive package for pain. Relaxation was defined as a technique that involved physical movement (rhythmic breathing and/or muscle tensing and relaxing in sequence) intended to cause reduction in perception of environmental stimuli, muscle tension, anxiety, stress and pain. Imagery was defined as purposeful mental thoughts imagined to achieve a desired therapeutic goal, in this case, pain relief. Literature on hypnosis was excluded from the review. Interventions were given alone and in combination. Approaches included progressive muscle relaxation (PMR), guided imagery, audiotape relaxation, live instruction, distraction, autogenic training and breathing exercises. <u>Outcomes</u> None stated. Outcomes measured in the include primary studies included: pain intensity, pain relief, distress, knowledge of pain, ability to decrease pain, degree of pain control, physical function, change in affective state, analgesic intake, anxiety, mood, sleep, posture, movement, visual concentration, and quality of family relationship. <u>Other</u> Studies that involved procedural pain or pain due to cancer treatment were excluded from the review. Only studies published between 1982 and 1995 were included in the review. <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> Not stated. <u>Validity assessment procedure</u> Not stated. <u>Data extracted from primary studies</u> Author(s), year, design, number of participants, type of intervention, outcome <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Narrative summary <u>How were studies weighted in the synthesis?</u> Not stated. <u>How was publication bias assessed?</u> Not stated. <u>How was heterogeneity assessed?</u> Not stated. Differences between the included studies in terms of study design, participant characteristics, interventions and outcomes were presented in the narrative summary.	
Results <u>Number of studies included in the review</u> Nine (stated by author), though ten are presented in the summary. Seven were controlled studies. <u>Number of participants</u> >260 (n in one control group not given) <u>Results of validity assessment</u> None stated. <u>Main outcome</u> Sensory variables: All studies measured pain intensity. Three found a significant decrease in intensity on a visual analogue scale (VAS) for the experimental over control group (Graffam, Sloman, Ferrell 1994), two found no change between groups (Arathuzik, Dalton 1987), and one found that the experimental group increased in pain intensity, though statistical comparisons were not made (Dalton 1988). One uncontrolled study found 33% patients had their pain improved after intervention (Fleming). Considering other measures of pain intensity, one study (Dalton 1987) found no difference between groups on any intensity measure (VAS, Pain Rating Index (PRI), Number of Words Chosen on McGill Pain Questionnaire (NWC)). One (Dalton 1988) found decreases on the PRI, but slight increases in the VAS for two experimental groups (significance not tested). One study (Sloman) found significant decreases in intensity as measured by the short-form McGill Pain Questionnaire (SF-MPQ), as well as other measures given above. <u>Secondary outcome</u> Affective variables (four studies): Considering anxiety, distress, and mood together, three studies demonstrated positive changes in these affective states (Graffam, Dalton 1995, Ferrell 1993) and two demonstrated no difference between	

experimental and control groups (Arathuzik, Sloman). None of the treatment group participants became worse, however.

Other outcomes

Control: One study (Arathuzik) found that experimental groups had significantly higher scores on ability to control pain over control groups, but this and another study (Dalton 1987) found no significant differences in degree of control over pain. One study (Dalton 1995) reported that patients did improve their feelings of control over pain after intervention.

Functional status: One case study (Dalton 1995) appeared to describe an improvement in patients' functional status, though two controlled studies (Dalton 1987, 1988) found no differences between groups on selected measures of function. A third controlled trial (Ferrell 1994) reported that the overall scores on an instrument that included functional status showed no significant differences in functional status.

Publication bias

Not stated.

Heterogeneity

Structure of the studies: Theoretical frameworks used in the included research were either not explained, unclear, or did not give specific direction to the selection and explanation of outcomes. Sample sizes varied from 16 to 40. All controlled studies used "usual care" as a control, with the exception of one study (Ferrell 1994) which compared nonpharmacologic interventions (including relaxation and imagery) against a "written information" control. The length of interventions was highly variable.

Conclusions/interpretation

Authors interpretation

Sensory variables: Overall, relaxation-imagery exercises do seem to decrease pain intensity in the cancer patient population.

Affective variables: The efficacy of the interventions to produce desirable change in affective states is not well studied and demonstrates equivocal results.

Control: No conclusive statement about the effect of these interventions on feelings of control can be made on the basis of these studies.

Functional status: At this juncture, the evidence suggests that these interventions do not appear to affect functional status.

Conclusion

The authors indicate that there is meagre evidence to support the use of relaxation and imagery in cancer pain. They state that: "There is some evidence that in cancer pain relaxation/imagery interventions seem to produce positive change in the sensory experience of pain. There is less evidence that relaxation/imagery interventions are able to change affective states, various measures of control, functional status, and a variety of other measures. Whether this lack of change has to do with the intervention itself, the measurement of the variable, or the type of variable is unclear".

Implications for research

(a) There is a tremendous need to demonstrate the effect of relaxation/imagery interventions in cancer pain management. (b) Descriptions of the disease state and pain problem being treated should be made in explicit terms. (c) Specific information about means and SDs of outcome variables is needed to allow other researchers to estimate effect sizes and sample sizes more readily. (d) Information about concomitant treatments that could affect pain outcomes should be reported, and comparisons between control and experimental groups should be made. (e) At this juncture, it seems advisable to study single interventions or employ designs that allow appraisal of single effects of multiple treatment strategies. (f) Documentation of the type of intervention or explanation of interventions would help clinicians and other researchers compare interventions across studies. (g) The effect of interventions on affective and functional status variables needs more study and careful selection. (h) Use of analgesic intake in this population may need to be used as a covariate instead of an outcome variable. (i) Measures of compliance as well as success in learning the relaxation/imagery technique need to be employed in these investigations. (j) Longitudinal studies need to be instituted at appropriate time in research programs. (k) until efficacy of relaxation and imagery is understood, control groups should continue to be 'usual care' in these studies. (l) long-term effects need to be investigated.

Implications for practice

Until more studies are conducted and published, large-scale use of these interventions in clinical practice is perhaps premature.

Quality assessment

Is there a defined search strategy? Yes. Database names and search terms given, though the search was limited to more recent literature (due to a previous review covering the earlier literature).

Is there a well defined question? Yes. Defined in terms of intervention and participants.

Are inclusion/exclusion criteria stated? Yes. For interventions and participants only.

Are study designs and number of studies clearly stated? No. The number of studies presented in the text and tables appear to differ, and very little information is given regarding the characteristics of individual studies.

Have the primary studies been quality assessed? No.

Have the studies been appropriately synthesised? Unclear. Insufficient data from primary studies is presented to determine the appropriateness of the approach taken.

Has more than one author been involved at each stage of the review process? Unclear/no. No relevant information given. Only one review author.

Reviewer's comment

The authors' recommendations for future research appear appropriate. However, conclusions about the efficacy of interventions should be treated with caution, due to the lack of information presented regarding the validity and outcomes of the few, often conflicting, primary studies included in the review.

Reference Meyer ¹⁸ 1995 USA	Title Effects of psychosocial interventions with adult cancer patients: A meta-analysis of randomised experiments Objective/review question To synthesise the results of published randomised, controlled outcome studies of psychosocial interventions with adult cancer patients.
Literature search Psychological Abstracts and Medline databases (dates not given), reference sections of located studies and review articles, by writing to researchers in the field and informal inquiries.	
Inclusion/exclusion criteria <u>Design</u> Published randomised controlled trials (RCTs). Control groups had to receive either no psychological intervention or an extremely minimal sham procedure. <u>Participants</u> Adult cancer patients. <u>Interventions</u> Psychosocial, behavioural, or psychoeducational interventions. <u>Outcomes</u> Patients' behavioural, emotional, physiological, or medical state. <u>Other</u> Hospice and terminal home care studies were excluded from the meta-analysis. <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> Not stated. <u>Validity assessment procedure</u> Not stated. <u>Data extracted from primary studies</u> Data on mean age, sex and type or location of cancer were extracted and presented in tables. Data on intervention type, outcome measures, and moderator variables were extracted from individual studies and organised into the following higher order categories: Dependent measures - (1) Emotional adjustment (including measures of mood state, fear and anxiety, depression, denial or repression, self-esteem, locus of control, satisfaction with medical care, other attitudes, personality traits and any other type of emotional adjustment or distress). (2) Functional adjustment (e.g. socialising, going back to work, Karnofsky Performance Status, self-report measures of social behaviours). (3) Treatment- or disease-related symptoms (e.g. chemotherapy-related nausea and vomiting, pain, coughing, nutritional measures). (4) Medical measures (e.g. leukocyte activity, tumour response to chemotherapy, physician rating of disease progression). (5) Compound and global measures (including measures which address more than one of the preceding categories). Treatment style categories - (1) Cognitive-behavioural interventions (cognitive, cognitive-behavioural and behavioural methods focused on changing specific thoughts or behaviours or on learning specific coping skills). (2) Informational and educational treatments (interventions primarily providing sensory, procedural, or medical information). (3) Nonbehavioural counselling/therapy (noncognitive and nonbehavioural verbal psychotherapy and counselling, including psychodynamic, existential, supportive or general counselling, and crisis intervention). (4) Social support (cases in which fellow patients or family members provide the intervention by being supportive). (5) Other (unusual treatments such as music therapy, or where dissimilar approaches are combined). If a treatment had a substantial behavioural component, it was placed in the 'cognitive-behavioural' category (even if it also had some emphasis on information/education etc). Moderator variables - (1) Risk for psychological distress (low, medium, or high). (2) Focus of intervention (chemotherapy-related symptoms, radiation-related symptoms, pain, or not specifically focused). (3) Patient screening (either included only patients with clear signs of distress, or included patients regardless of distress level). <u>Data extraction procedure</u> N/A <u>How were studies combined in the review?</u> Meta-analysis. An attempt was made to calculate the effect size for every measure in an article. Hedges and Olkin's methods were used to conduct separate meta-analyses of effect sizes for each of the five types of dependent measures. A unit-free effect size g was obtained from outcome measure scores by obtaining the difference between the control group mean and the treatment group mean and dividing the results by the pooled standard deviation. For certain complex designs, Shadish and Montgomery's methods were used to determine g. <u>How were studies weighted in the synthesis?</u> The effect size g was multiplied by a small sample size correction factor to obtain an unbiased value of d, the effect size used in the rest of the analysis. <u>How was publication bias assessed?</u> Only published articles were included in the meta-analysis. Publication bias was not addressed. <u>How was heterogeneity assessed?</u> Tests were conducted to determine whether a set of effect sizes could be considered as a sample from a single underlying effect size. The different treatment categories were compared in terms of the magnitude of effect size associated with each. Similar analyses were conducted for the moderator variables.	
Results <u>Number of studies included in the review</u>	

Forty-five randomised studies, reporting 62 treatment-control comparisons.

Number of participants

5991

Results of validity assessment

Not stated.

Main outcome

Combined weighted effect sizes for dependent measures:

Emotional adjustment: 41 studies, $d = 0.24$ (95% CI: 0.17, 0.32)
Functional adjustment: 16 studies, $d = 0.19$ (95% CI: 0.06, 0.32)
Treatment- and disease-related symptoms: 28 studies, $d = 0.26$ (95% CI: 0.16, 0.37)
Medical: 5 studies, $d = 0.17$ (95% CI: -0.10, 0.44)
Compound and global: 5 studies, $d = 0.28$ (95% CI: 0.08, 0.49)

Secondary outcome

Weighted effect sizes for dependent measures by treatment style:

(1) Behavioural -

Emotional adjustment: $d = 0.19$ (95% CI: 0.08, 0.30)
Functional adjustment: $d = 0.10$ (95% CI: -0.20, 0.40)
Symptoms: $d = 0.32$ (95% CI: 0.16, 0.48)
Medical: $d = 0.13$ (95% CI: -0.17, 0.43)
Compound and global: $d = 0.20$ (95% CI: -0.07, 0.49)

(2) Informational and educational -

Emotional adjustment: $d = 0.25$ (95% CI: 0.12, 0.37)
Functional adjustment: $d = 0.27$ (95% CI: 0.08, 0.46)
Symptoms: $d = 0.21$ (95% CI: 0.01, 0.40)
Medical: $d = 0.80$ (95% CI: 0.00, 1.60)
Compound and global: $d = 0.35$ (95% CI: -0.02, 0.72)

(3) Nonbehaviour counselling/therapy -

Emotional adjustment: $d = 0.39$ (95% CI: 0.19, 0.58)
Functional adjustment: $d = 0.12$ (95% CI: -0.12, 0.37)
Symptoms: $d = 0.17$ (95% CI: -0.05, 0.39)
Medical: $d = -0.20$ (95% CI: -1.04, 0.64)
Compound and global: $d = 0.45$ (95% CI: -0.12, 1.02)

(4) Social support -

Emotional adjustment: $d = -0.23$ (95% CI: -1.14, 0.67)
Functional adjustment: $d = -0.08$ (95% CI: -1.02, 0.85)

(5) Other -

Emotional adjustment: $d = 0.33$ (95% CI: -0.10, 0.76)
Symptoms: $d = 0.45$ (95% CI: 0.09, 0.82)

Other outcomes

Potential moderator variables:

There was no significant effect of risk category on any of the dependent measures. Neither was there any significant effect of study focus or screening for distress on effect sizes for any of the dependent measures.

Publication bias

Not assessed.

Heterogeneity

For four of the five dependent measure categories, the set of effect sizes was homogenous. The exception was for measures of emotional adjustment; however, when one outlier was removed (Ali & Khalil, 1989), the remaining studies had homogenous effect sizes. The discrepant study was the only one from a country (Egypt) where patients were not notified of their cancer diagnosis. This study was deleted from all the results.

Conclusions/interpretation

Authors interpretation

Depending on one's perspective, it is possible to interpret the effect sizes found as very important or as relatively small. These effect sizes appear somewhat less clinically significant than those for psychotherapy in general (Matt, 1989), yet fall into the range suggested for psychological interventions that work by Hunter and Schmidt (1990). According to Cohen's (1977) criteria, the observed effect sizes tended to be fairly small, but it has been pointed out that small effects may be of crucial importance (Rosenthal, 1984). The failure to reject the null hypothesis of no differences between categories in all subset analyses raises two possibilities: There may really be no difference between the effect sizes of different categories, or there may have been insufficient statistical power to find true differences.

Conclusion

The results clearly indicate that psychological interventions have positive effects on emotional adjustment, functional adjustment, and treatment- and disease related symptoms in adult cancer patients.

Implications for research

-More direct comparisons of different treatments should be made. Another productive direction involves focusing on medical outcomes and survival. One desirable strategy would be to integrate research on psychosocial interventions into

new or existing studies of medical interventions.

-Increased attention to studying the mechanisms of beneficial outcomes would be useful.

-There is a need to investigate ways of increasing the impact of interventions and decreasing their cost.

-Improving the acceptability of psychosocial interventions for both medical personnel and patients, as well as ensuring easy accessibility, would be worthwhile. Additional research, designed with attention to statistical power, might also fruitfully address whether psychosocial interventions are less effective for low-distress and low-risk patients.

- Future attention to potential moderator variables seems desirable.

- Future research needs to focus on other populations such as men and ethnic minorities.

Implications for practice

None stated.

Quality assessment

Is there a defined search strategy? Yes. Two electronic databases searched, plus following up references and contacting authors. However, no further details (search dates or terms) were given.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Yes. Relevant criteria are stated, though no specifics (i.e. definition of 'psychosocial intervention') given.

Are study designs and number of studies clearly stated? Yes. All RCTs, small amount of info available on numbers.

Have the primary studies been quality assessed? No.

Have the studies been appropriately synthesised? Unclear. See reviewer's comment.

Has more than one author been involved at each stage of the review process? Unclear. Not stated by authors.

Reviewer's comment

Though the sources searched for studies were mentioned, very little detail of the searches was provided. The inclusion criteria seemed appropriate, but these were broad and authors did not explicitly define criteria such as 'psychosocial interventions'. Only published studies were included in the meta-analysis, providing an opportunity for publication bias to influence the results. Only RCTs were included, but no systematic assessment of these trials were undertaken, and very little detail of individual studies was available.

The approach used for this meta-analysis involved coding a wide range of interventions and outcomes into a small number of broad categories. Whilst the authors report the observed effect sizes to be generally statistically homogeneous, no investigation of clinical heterogeneity between studies is undertaken. Though the effects of moderator variables were investigated to an extent, the potential influence on outcomes of different patient characteristics, interventions and settings cannot be clearly determined from this analysis. The authors point out that the clinical significance of the observed effect sizes is at least partly subjective. They conclude that the positive effects are important, but considering that these effects could be also considered small and that there are several opportunities for bias and confounding in this analysis, such conclusions should be treated with caution.

On the other hand, inclusion was limited to RCTs rather than all types of controlled study and the authors recommendations for future research appear sensible. They note that the populations studied in their meta-analysis were mainly composed of white women living in the US and raise appropriate concerns about the generalisability of these results.

<p>Reference Cwikel⁶⁵ 1997 Israel</p>	<p>Title Three articles based on one review:</p> <ol style="list-style-type: none"> 1. Social work with adult cancer patients: A vote-count review of intervention research (#1291). 2. A comparison of a vote count and a meta-analysis review of intervention research with adult cancer patients (#4521). 3. Psychosocial factors that affect the survival of adult cancer patients: A review of research (#1821). <p>Objective/review question</p> <ol style="list-style-type: none"> 1. To answer the questions: (a) which treatment modalities are applicable to which patients at which stage? (b) are there indicators which may help to provide a better match between patient characteristics and treatment modality in order to maximise beneficial results? (c) what is the role of the oncology social worker, given what is known about treatment efficacy? 2. To compare two methods of aggregating the results of intervention research: vote count review and meta-analysis. The secondary goal is to examine whether results from either of these types of reviews can address some of the unresolved intervention issues in psychosocial oncology. 3. To determine whether empirical research indicates that psychosocial interventions have a beneficial effect on the survival of participants with cancer.
<p>Literature search MEDLINE and PsycLIT and Social Work Abstracts databases were searched for studies published between 1966 and 1996. Additional studies were identified through references in located studies and review articles.</p>	
<p>Inclusion/exclusion criteria</p> <p><u>Design</u> Empirical intervention studies, including experimental, quasi-experimental and longitudinal designs.</p> <p><u>Participants</u> Adult cancer patients. Excluded studies where the unit of analysis was couples, families and health care providers.</p> <p><u>Interventions</u> Treatment methods used by social workers in psychosocial oncology. Excluded interventions which would not be carried out by social workers (e.g. administering and evaluating compliance to drugs)</p> <p><u>Outcomes</u> Outcomes measured included assessments of coping, psychological function and distress, symptoms, physiological indicators of anxiety or immune function, knowledge, quality of life and survival.</p> <p><u>Other</u> Studies had to report include at least the minimum number of cases for basic descriptive statistical analyses, and be published after 1970.</p> <p><u>Study selection procedure</u> Unclear</p>	
<p>Methods</p> <p><u>Validity assessment tool</u> Studies were graded on validity according to commonly used criteria (e.g. Winsor & Orleans. Health Educ Quarterly 1986; 13: 131-61): (1) low-quality non-random (non-random allocation to treatment and controls, small numbers of cases, incomplete pre- or post-test measures), (2) acceptable quasi-experimental (matching on demographics, non-random allocation to experimental and control groups, retrospective follow-up, including pre- and post-test measures, adequate number of cases), and (3) high quality RCT (randomised controlled trials, pre-test, post-test assessments of outcome measures, adequate number of cases).</p> <p><u>Validity assessment procedure</u> Each study was read and independently rated by two authors.</p> <p><u>Data extracted from primary studies</u> Data extracted from primary studies included: reference, validity rating, number of participants in each group, participant characteristics (sex and type of cancer), intervention format (individual, group, both), intervention type (cognitive/behavioural, information/education, non-behavioural counseling, social support, other), role of social worker, outcome rating and vote score.</p> <p>For the vote-count review, outcomes for each study were rated on a four-point scale: 0 - no treatment effect observed 1 - positive results on only a few of the outcome measures, less than half, or some positive and null results. 2 - positive results on half or more of the outcome measures or mostly positive mixed with a few negative or null results. 3 - strongly positive on outcome measures or almost all significant results.</p> <p>For the meta-analysis, study results were coded according to four categories of outcomes: psychological state (e.g. depression, mood states, anxiety, denial, fear, and psychological distress), functional indicators (family/work function, coping, sexual functioning and social functioning), physical symptoms (pain, discomfort, nausea, vomiting, need for medication), and medical/survival measures (survival in months/years, time to recurrence, measures of cortisol, leukocytes, or natural killer cell counts).</p> <p><u>Data extraction procedure</u> Each study was read and independently rated by two authors.</p> <p><u>How were studies combined in the review?</u> Vote count review and effect-size meta-analysis (Glass. 1976).</p> <p><u>How were studies weighted in the synthesis?</u> Vote count review:</p>	

For each study, the outcome rating (0-3) was multiplied by the research design rating (1-3), to give an overall vote-count score which could range from 0-9. Longitudinal studies were analysed separately from experimental and quasi experimental studies.

Meta-analysis:

g values greater than 2.0 were viewed as outliers probably not indicative of the true population-ES value. Values greater than 2.0 were "winsorized" to 2.0. Studies reporting nonsignificant effects were coded to have an ED of zero.

How was publication bias assessed?

Only published research was included. Publication bias was assessed in the meta-analysis using Rosenthal's "fail-safe N".

How was heterogeneity assessed?

Vote count review:

Intervention studies were divided into those evaluating interventions delivered (1) immediately after diagnosis, (2) treatment stage, and (3) late stage (metastatic and terminal stages).

Meta-analysis: The effect of moderator variables does not appear to have been investigated.

Results

Number of studies included in the review

42 publications reporting 40 different studies. (11 newly diagnosed cancer intervention studies, 24 treatment studies, 5 late stage cancer studies)

Number of participants

3597 (1343 newly diagnosed, 1998 treatment phase, 256 late stage)

Results of validity assessment

Designs of included studies:

22 RCTs, 12 quasixperimental, 3 pretest-posttest, 2 retrospective, 1 multiple time series.

Newly diagnosed cancer:

Five of the 11 included studies received a research design rating of 2, and the six remaining studies received a rating of 3.

Treatment phase cancer:

Three out of 24 studies received a rating of 1, seven received a rating of 2, and 14 received a rating of 3.

Late stage cancer:

Two studies received a rating of 1, one study a rating of 2, and two studies a rating of 3.

Main outcome

Vote count review. Each study was discussed, with a summary at the end of each section:

Newly diagnosed cancer - The mean vote-count score of the 11 included studies was 4.18. Three studies showed null results, with the modal average representing positive results on about half of the outcome measures. Only 2 studies had strongly positive results. Common to some of the studies was the finding that respondents improved over time, regardless of intervention.

Treatment phase - The mean vote-count score for the 24 included studies was 5.79, with nine studies achieving the maximum score of 9. Most studies were recents and had high-quality research designs. Quite a few compared different treatment programmes (e.g. coping skills vs support group, relaxation with guided imagery vs coping skills, CBT versus support group).

Late stage cancer: The mean vote-count score for the five included studies was 3.0. Three of the five studies were small (n<25), and only one of the larger studies received a maximum vote-count score. Several studies reported difficulties in recruitment of subjects, participation, and attrition, due to mortality over the course of treatment. Four of the studies evaluated the effect of psychosocial interventions on the survival time of participants. Two showed strongly positive effects and two were unable to demonstrate an effect.

Using only vote-count scores, greater effects were shown in treatment phase studies than those in the early and late stages (though the differences between phases are not significant).

Similar scores were obtained for individual and group treatment formats.

There was a slightly greater (nonsignificant) efficacy found for studies that included mixed diagnoses, compared to gynaecologic or breast cancer.

There was no significant effect of the gender of the participants.

Vote-count scores were significantly greater for studies that included cognitive behavioural therapy than those that didn't (p<0.001).

Studies showed significantly greater effects when social workers were not involved in the intervention than when they were.

Secondary outcome

Meta-analysis:

All outcomes (75 effect sizes): Mean effect size (r) = 0.23 (95% CI: 0.17, 0.29); standardised mean difference (g) = 0.48, z=15.73, Fail-safe N=273.***

Psychological outcomes (40 effect sizes): Mean effect size (r) = 0.29 (95% CI: 0.22, 0.37); standardised mean difference (g) = 0.62, z=12.58, Fail-safe N=196.****

Functional measures (19 effect sizes): Mean effect size (r) = 0.19 (95% CI: 0.06, 0.31); standardised mean difference (g) = 0.38, z=7.23, Fail-safe N=53.****

Symptoms: (10 effect sizes): Mean effect size (r) = 0.16 (95% CI: 0.018, 0.30); standardised mean difference (g) = 0.33, z=4, Fail-safe N=22.***

Medical measures/survival (6 effect sizes): Mean effect size (r) = 0.09 (95% CI: -0.08, 0.25); standardised mean difference (g) = 0.17, z=1.77, Fail-safe N=5.*

Newly diagnosed cancer (16 effect sizes): Mean effect size (r) = 0.15 (95% CI: 0.05, 0.24); standardised mean difference (g) = 0.39, z=4.55, Fail-safe N=32.****

Treatment phase (52 effect sizes): Mean effect size (r) = 0.25 (95% CI: 0.18, 0.32); standardised mean difference (g) = 0.51, z=15.23, Fail-safe N=204.****

Late stage cancer (7 effect sizes): Mean effect size (r) = 0.28 (95% CI: 0.01, 0.56); standardised mean difference (g) = 0.59, z=0.96, Fail-safe N=33.

Cognitive treatments (16 effect sizes): Mean effect size (r) = 0.38 (95% CI: 0.24, 0.50); standardised mean difference (g) = 0.81, z=10.99, Fail-safe N=104.****

Non-cognitive treatments (24 effect sizes): Mean effect size (r) = 0.24 (95% CI: 0.16, 0.32); standardised mean difference (g) = 0.49, z=7.76, Fail-safe N=92.****

Social work involvement (20 effect sizes): Mean effect size (r) = 0.29 (95% CI: 0.19, 0.39); standardised mean difference (g) = 0.61, z=9.39, Fail-safe N=96.****

Other professions (no social work involvement) (20 effect sizes): Mean effect size (r) = 0.29 (95% CI: 0.19, 0.40); standardised mean difference (g) = 0.63, z=12.73, Fail-safe N=105.****

Results presented for type of treatment (cognitive/non-cognitive) and social worker involvement are for psychological outcomes only.

*p<0.05, ***p<0.001, ****P<0.000.

Studies were categorised as consisting primarily of, or including cognitive behavioural strategies (18 studies), social support interventions (8 studies), or other types of counseling (14 studies). t tests indicated cognitive behavioural packages had greater average g scores than other types of counseling on psychological outcomes (p<0.05), but not on all outcomes together. Cognitive behavioural packages had larger g scores than social support interventions for both psychological and all outcomes, though these differences were not significant. No significant differences in average g scores were found between social support and other counseling interventions.

Other outcomes

Correlations between meta-analysis and vote count results:

Phase of intervention was significantly associated with vote count score (-0.32, p<0.01) and research results rating (-0.42, p<0.01), but not with research design rating.

Research results score and the total vote count score were strongly related to the g values from the meta-analysis. However, the study design rating alone was not significantly related to the meta-analysis results.

Publication bias

See Fail-safe N statistics in results.

Heterogeneity

Conclusions/interpretation

Authors interpretation

See conclusions.

Conclusion

The results here suggest that interventions in psychosocial oncology are largely effective in improving psychological status, functional status, and physical symptoms, but their ability to positively affect medical outcomes has still not been shown conclusively.

Implications for research

Both the efficacy of targeting high distress subgroups and the question as to whether psychosocial interventions can have a positive effect on survival time remain inconclusive, suggesting that this is an area where more intervention research is needed.

Implications for practice

The review suggests that intervention research is more easily and effectively conducted during the treatment phase of illness. Furthermore, cognitive-behavioural techniques appear to have an efficacy advantage.

Quality assessment

Is there a defined search strategy? Partly.

Is there a well defined question? Partly

Are inclusion/exclusion criteria stated? Yes.

Are study designs and number of studies clearly stated? Partly.

Have the primary studies been quality assessed? Yes (in vote count review only)

Have the studies been appropriately synthesised? Unclear.

Has more than one author been involved at each stage of the review process? Unclear, but appears so.

Reviewer's comment

Three databases were searched, with follow up of references from identified studies and reviews. However, very little description of the search was given and only published studies were sought. The review question was framed by broad inclusion criteria relating to participants and interventions. Some summary data on the included interventions was presented in tables, and more detailed descriptions of populations and interventions involved in these studies were given in the text of the vote count review. Studies were given a 'research design rating' in the vote count review, though this only gave a very broad indication of validity based on study design, and may not have been an appropriate measure for weighting study results in the vote-count synthesis. The vote-count approach also meant that outcomes ranging from psychological distress to survival were all combined into a non-specific 'vote-count score'. The effect size meta-analysis was appeared to conform to the usual standards commonly used in this approach. However, general criticisms of the approach still apply: subjective decisions can be made about how to appropriately group outcomes, how to categorise interventions, which moderator variables to investigated, and how to interpret summary effect sizes. In the meta-analysis presented here, moderator variables also do not appear to have been adequately investigated. Two authors independently coded studies in the vote count review, though it is unclear how many reviewers were involved at the other stages.

Reference Plante ²⁶ 2001 USA	Title Review of group interventions for pediatric chronic conditions Objective/review question To identify treatment studies on group interventions for paediatric conditions and to review their efficacy using standard criteria.
Literature search PsychLit and Medline computerised databases were searched from 1970-2000. Reference lists of retrieved primary studies and reviews were searched for other relevant publications.	
Inclusion/exclusion criteria <u>Design</u> None stated (the methodological rigour of the studies was not a criterion for inclusion or exclusion). <u>Participants</u> Children or adolescents (birth to age 18 years) with an identified medical problem. <u>Interventions</u> Psychological intervention in a group format with the goal of improving psychological adjustment to the illness or reducing physical symptoms. Interventions that included a collateral parent- or family-group component were also included, but parent groups existing in the absence of direct treatment for patients were excluded. <u>Outcomes</u> None stated. <u>Other</u> Articles had to be published in English in a peer reviewed journal. <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> The validity of individual studies was not addressed. Each type of group intervention was considered 'well-established', 'probably efficacious' or 'promising' according to a modified form of the Chambless criteria (the Society for Pediatric Psychology modifications to the criteria for empirically supported treatments outlined by the Task Force on Promotion and Dissemination of Psychological Procedures (1995; Chambless et al., 1996)). <u>Validity assessment procedure</u> Not stated. <u>Data extracted from primary studies</u> Not stated. <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Group interventions were classified into four main types, distinguished by their primary goals and intended outcomes: emotional support, psychoeducation, adaptation/skill development, and symptom reduction. A fifth type of group, summer camps, contained elements of the four categories, but were considered separately. <u>How were studies weighted in the synthesis?</u> None. <u>How was publication bias assessed?</u> Not assessed. <u>How was heterogeneity assessed?</u> Not assessed.	
Results <u>Number of studies included in the review</u> 125 in total. 17 in cancer (9 emotional support, 7 summer camp, 1 adaptation/skill development) <u>Number of participants</u> Unclear. <u>Results of validity assessment</u> Not stated. <u>Main outcome</u> Emotional support groups: Nine studies included cancer patients. One study found that group participants in active treatment reported pre-post increases in psychological symptoms whereas groups participants no longer in active treatment reported pre-post decreases in psychological symptoms. No other results from cancer studies were reported. Overall, emotional support groups do not meet minimal Chambless criteria for empirical validation. <u>Secondary outcome</u> Adaptation/skill development groups: One study included cancer patients found (at 6 months follow-up) that combination of a multifamily format with a cognitive-behavioural approach decreased anxiety and posttraumatic stress disorder (PTSD) symptoms in all family members and improved family functioning in several domains. <u>Other outcomes</u> Summer camps: Seven studies included patients with cancer. Pre-post evaluations without control groups for children with cancer found increased knowledge of cancer, equivocal findings regarding self-concept, and improvement in campers' social and physical activity after camp. Because controlled comparisons were rarely reported, summer camp interventions do not meet minimum Chambless	

criteria for empirical evaluation.

Publication bias

None stated.

Heterogeneity

None stated.

Conclusions/interpretation

Authors interpretation

See conclusions.

Conclusion

Although well-established group interventions do exist, much work is required to establish the efficacy of most group treatments for children and adolescents with chronic illness.

Implications for research

Studies evaluating group interventions need to:

- be randomised, with waiting list controls and use standardised measures.
- increased correspondence between treatment objectives and outcome measurement.
- include a range of patients that reflect those seen in typical clinical conditions.
- investigate how efficacy might differ across population by age/developmental level, gender, race, ethnicity, and family and psychosocial factors.
- consider cost effectiveness relative to individual therapy.
- use multi-centre designs to increase sample size.

Implications for practice

None stated.

Quality assessment

Is there a defined search strategy? Yes.

Is there a well defined question? Partly.

Are inclusion/exclusion criteria stated? Yes.

Are study designs and number of studies clearly stated? No.

Have the primary studies been quality assessed? Not individually. The overall methodological quality of all included studies in each section determined the strength of recommendation.

Have the studies been appropriately synthesised? No.

Has more than one author been involved at each stage of the review process? Unclear.

Reviewer's comment

A reasonable search of the literature was undertaken and selection criteria were developed in terms of populations and interventions of interest. However, it is unclear how many reviewers were involved, no validity assessment of individual studies was carried out, and no information was available on the majority of included studies (with no clear indication of type of included study designs presented in the review). The review is very broad in scope (covering all pediatric chronic conditions) and presents insufficient data to determine the effects of group interventions in paediatric cancer patients.

Reference Sheard ²⁶ 1999 UK	Title The effect of psychological interventions on anxiety and depression in cancer patients: results of two meta-analyses <hr/> Objective/review question To undertake meta-analyses of trials of interventions which sought to treat or prevent anxiety and/or depression in cancer patients.
Literature search Medline, PsychLit and BIDS social sciences computerised databases were searched. Citations in identified papers and reviews, Aslib. Index to theses, and Comprehensive Dissertation Abstracts: Psychology were manually searched.	
Inclusion/exclusion criteria <u>Design</u> Studies were included if they had a control condition. <u>Participants</u> Oncology patients. <u>Interventions</u> Psychosocial or psychiatric interventions aimed specifically at alleviating psychological distress (e.g. education and counselling to relaxation and imagery). Studies were excluded if the main focus was reduction of physical symptoms, prolongation of survival, impact on immune parameters, or reduction of prei-surgical distress. <u>Outcomes</u> Anxiety and/or depression. <u>Other</u> Only English language studies were included. <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> A system for scoring aspects of study methodology was devised based on Cook and Campbell's (1979) four categories of threats to internal validity. Studies which used more reliable methods were identified using three factors: (i) use of randomisation, (ii) falling into the top 75% on overall quality score, and (iii) sample size greater than 40. <u>Validity assessment procedure</u> Not stated. <u>Data extracted from primary studies</u> For included studies, data were presented on: type of therapy, dose of therapy, participant prognosis, setting variables, experimental method, anxiety and depression, and quality of reporting. <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Meta-analysis. Using the methods described by Hedges and Olkin (1985), the effect size 'g' was estimated as a standardised mean difference from each study. A random effects model was used in the main meta-analyses. The results of fixed and random effects analysis were compared in the sensitivity analysis. <u>How were studies weighted in the synthesis?</u> Effect size 'g' was corrected into the unbiased estimator 'd' which compensates for small sample bias and confidence intervals were calculated. <u>How was publication bias assessed?</u> Three methods were used: The summary effect sizes for published and unpublished studies were compared, funnel plots of sample size against effect size were constructed, and Rosenthal's (1979) 'fail safe n' was used to estimate the number of unpublished results with effect size zero required to reduce the mean effect size to a specific level. <u>How was heterogeneity assessed?</u> Heterogeneity was assessed using the Q statistic and associated p values.	
Results <u>Number of studies included in the review</u> Trials identified: 26 anxiety, 30 depression. Included in meta-analyses: 19 anxiety (15 randomised), 20 depression (14 randomised). <u>Number of participants</u> Anxiety, n=1023. Depression, n=1101 <u>Results of validity assessment</u> Not stated. <u>Main outcome</u> Anxiety: Mean effect size 0.42 (95% CI: 0.08, 0.74) Sensitivity analysis mean effect sizes: Published (14 studies) = 0.51 Unpublished (5 studies) = 0.16 More reliable design (8 studies) = 0.63 Less reliable design (11 studies) = 0.24 Two extreme positive outliers removed (17 studies) = 0.27 Fixed effects analysis (19 studies) = 0.36 Random effects analysis (19 studies) = 0.42 More reliable studies with one positive outlier removed = 0.36 (95% CI: 0.095-0.63) <u>Secondary outcome</u>	

Depression:

Mean effect size 0.36 (95% CI: 0.06, 0.66)

Sensitivity analysis mean effect sizes:

Published (14 studies) = 0.34

Unpublished (5 studies) = 0.27

More reliable design (8 studies) = 0.21

Less reliable design (12 studies) = 0.50

Two extreme positive outliers removed (17 studies) = 0.19

Fixed effects analysis (20 studies) = 0.25

Random effects analysis (20 studies) = 0.36

Other outcomes

Publication bias

Anxiety: The difference in mean effect sizes between published studies (0.51) and unpublished theses (0.16) suggests publication bias. However, inclusion of the unpublished theses in funnel plot resulted in a fairly symmetrical distribution. Rosenthal's 'fail safe n' indicated that 20 undetected studies of effect size zero would be required to reduce the overall effect size to 0.2.

Depression: There does not appear to be publication bias amongst the sample. Published and unpublished studies had very similar mean effect sizes (0.34 vs 0.27) and a funnel plot did not show a skewed distribution. Sixteen unpublished studies with an effect size of zero would be needed to reduce the mean effect size to 0.20.

Heterogeneity

Anxiety:

The full dataset (19 studies) was strongly heterogeneous ($Q=69.22, p<0.00000$). Interventions delivered in an individual format had an effect size similar to relaxation alone and only approximately 50% that of interventions in a group format ($p=0.0076$). This difference was almost entirely accounted for by the inclusion of three group therapy trials with very large effects (two of which were positive outliers). The data suggest a dose-response effect ($p=0.0017$). The use of more experienced therapists is associated with larger effect but this falls just below the 5% level ($p=0.054$). Effects were preserved in the small number ($n=4$) of studies that looked at post-intervention follow-up.

Depression: There was considerable heterogeneity in the main dataset of 20 trials ($Q=40.65, p<0.0027$). Individual interventions had a smaller effect than group interventions, but this difference was not significant. A larger effect size was associated with higher therapist level of training and experience in oncology ($p=0.0375$). Effect size was greater for those with advanced disease ($p=0.0327$). Mean effect was at least sustained at follow up from the three trials which examined this.

Conclusions/interpretation

Authors interpretation

See authors' conclusions.

Conclusion

The findings suggest that preventative psychological interventions in cancer patients may have a moderate clinical effect upon anxiety but not depression. There are indications that interventions targeted at those at risk of suffering significant psychological distress have strong clinical effects. Evidence on the effectiveness of such targeted interventions and of the feasibility and effects of group therapy in a European context is required.

Implications for research

Routine use of randomisation and samples large enough to provide to provide adequate statistical power will improve the reliability of future trial data. The analyses suggest current priorities as being to establish:

- (a) the effectiveness of interventions targeted at those at risk of, or suffering significant distress.
- (b) the viability and effectiveness of group therapy in European oncology settings.
- (c) whether the large effects associated with group psycho-educational courses can be replicated.
- (d) whether positive effects are maintained at long-term follow-up.

Implications for practice

Clinically strong and cost-effective outcomes are likely to result from interventions targeted at those suffering from or at risk of significant psychological distress. However, more data are needed to confirm this suggestion. Group interventions, particularly psycho-educational courses, are at least as effective as individual. If this finding can be replicated in Europe, then group interventions should prove considerably more cost-effective than individual.

Quality assessment

Is there a defined search strategy? Yes.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Yes.

Are study designs and number of studies clearly stated? Partly.

Have the primary studies been quality assessed? Yes.

Have the studies been appropriately synthesised? Yes?

Has more than one author been involved at each stage of the review process? Unclear.

Reviewer's comment

An attempt was made to identify both published and unpublished studies of relevance. The inclusion criteria were appropriate to the review question. The authors investigated sources of heterogeneity amongst the included studies through sensitivity analysis and examined the influence of publication bias using sensitivity analysis, funnel plots and Rosenthal's fail-safe n. However, little information from the included studies was presented in the review and although aspects of study validity were assessed, these were simply used in the synthesis to dichotomize studies into being of either 'more reliable' or 'less reliable' design. Nevertheless, the authors' conclusions were appropriately cautious where necessary and appear to follow from the evidence presented.

Reference Ross ³² 2002 Denmark	Title Mind and cancer: does psychological intervention improve survival and psychological well-being? Objective/review question To evaluate the scientific evidence for an effect of psychosocial intervention on survival from cancer and well-being and in particular on anxiety and depression.
Literature search Medline (1966-June 2001) and PsychLit (1974-June 2001) were searched. Citations were also sought manually in the papers and reviews identified.	
Inclusion/exclusion criteria <u>Design</u> Randomised studies which included an untreated control group. Studies that were randomised by time period were excluded. <u>Participants</u> Cancer patients aged 18 years or more. <u>Interventions</u> Psychosocial interventions. Studies on interventions aimed exclusively at reducing the side-effects of treatment were excluded. Interventions evaluated in primary studies included: individual, group and family counselling, supportive group therapy alone and with self-hypnosis, psycho-educational group therapy, education on coping pain management and communication, supportive group sessions with and without leadership, group and individual cognitive behavioural therapy, individual psychotherapy, home visits and telephone calls from specialised nurses after surgery or during radiation therapy, preoperative information, relaxation training, meditation training, physical training, biofeedback, support from volunteers, emotional expression. Some interventions combined two or more of these approaches. <u>Outcomes</u> Studies which reported effects of treatment on prognosis and/or well-being. Outcomes reported in included studies were: survival, anxiety, depression, emotional adjustment, mood, quality of life, pain. <u>Other</u> <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> Validity was not formally assessed. Aspects of the included studies such as randomisation, blinding, handling of missing data, and length of follow-up were discussed in the narrative summary. <u>Validity assessment procedure</u> Not stated. <u>Data extracted from primary studies</u> Author, year, study location, cancer site, number of patients, intervention, duration of follow-up on survival, statistical significance of outcomes (survival, anxiety, depression, other). <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Narrative summary. Survival and 'well-being' outcomes were presented separately. <u>How were studies weighted in the synthesis?</u> Studies do not appear to have been weighted. <u>How was publication bias assessed?</u> Publication bias does not appear to have been assessed. <u>How was heterogeneity assessed?</u> No formal test of heterogeneity was undertaken, but differences between studies in terms of populations, interventions and outcomes were discussed.	
Results <u>Number of studies included in the review</u> 43 randomised studies. <u>Number of participants</u> Eight studies measuring survival, n=1246; 35 studies measuring well-being, n=3054 <u>Results of validity assessment</u> No results of formal validity assessment are reported, but the authors mention various methodological limitations of the included studies. Limitations of 'survival' studies included: small sample sizes, inadequate handling of dropouts, length of follow-up, and inadequate reporting of patient characteristics. Limitations of 'well being' studies, included: inadequate description of randomisation procedure and characteristics of non-responders, failure to follow and report intention-to-treat results, failure to report whether outcomes were assessed by persons involved in the intervention, and lack of long-term follow-up. <u>Main outcome</u> Effect of psychosocial intervention on length of survival: Of eight included randomised studies, four found the intervention to be positively correlated with survival from cancer, and four failed to find this association. Significant improvements in survival for intervention over control were found for: One year of group therapy plus instruction in self hypnosis to control physical pain (intervention group lived 18 months longer than control at 10 year follow-up, p<0.0001. Spiegel et al); Six weekly psycho-educational group therapy sessions (significant reduction in mortality in intervention group at 6-year follow-up, p=0.0066. Fawzy et al); individual psychotherapy during hospital stay (significant difference between intervention and control groups after 2 years of follow-up, p<0.002. Kuchler et al); Three home visits and five telephone calls from specialised nurses over four weeks postsurgery (significant positive effect on survival after 44 months of follow-up, p=0.001. McCorkle et al).	

No significant differences in survival between intervention and control groups were found for: One year of individual counselling (Linn et al); Six months of group therapy with or without professional leadership (Illyckyj et al); 35 weekly 2-hour sessions of supportive and cognitive behaviour therapy and an intensive weekend coping skills course (Cunningham et al); Eight weeks of cognitive-behavioural therapy (no difference between intervention and control groups at 5 year follow-up. Edelman et al). Mechanisms for effects in survival were not uncovered.

Secondary outcome

Effect of psychosocial intervention on well-being: Of the 38 studies which assessed well-being within 1 month of termination of the intervention, 13 found interventions to significantly improve anxiety and 11 studies reported improvements in depression. Improved mood, emotional adjustment and quality of life were each reported in four studies, and significant improvements in pain were reported in three.

Anxiety and/or depression were measured in five studies of breast cancer patients. The results were inconsistent, the more recent studies tending to show no effect.

All five studies that included only patients who were found on screening to be suffering from psychological distress found a significant effect on anxiety and/or depression.

Other outcomes

Intervention strategies: No clear pattern emerged regarding the relative effectiveness of different intervention strategies in relation to well-being. In terms of reducing anxiety/depression, eight of the studies which used psychological education showed a positive effect and four showed no effect. Long-term (>6 months) psycho therapeutic intervention has a positive effect on well-being in two studies and no effect in two others. Short-term psychotherapeutic intervention had a positive effect in two studies and no effect in two others. Short-term provision of information only had a beneficial effect in three studies and no effect in one other.

Publication bias

Not assessed.

Heterogeneity

The populations studied were heterogeneous with respect to sex, cancer type, stage of disease and other treatment. Breast cancer was the only site that was examined in more than three studies.

Conclusions/interpretation

Authors interpretation

See authors' conclusions.

Conclusion

The results of a large number of studies fail to demonstrate a conclusive effect of psychosocial intervention on survival and psychological well-being. First, different intervention strategies were used in different studies, and perhaps only some of them affect prognosis and/or well-being and in only certain patient groups. Secondly, the effect may be weak, accounting for the inconsistent results found for the generally small study populations. Thirdly, the effect of the interventions may have been diluted by the inclusion of unselected patient groups rather than being restricted to selected groups of patients in need of psychosocial support. The issue of possible beneficial effects of psychosocial intervention for cancer patients remains unresolved.

Implications for research

Large scale studies are needed that allow evaluation of a possibly small effect. Identifying patients in need of psychosocial intervention by screening for psychological distress or available social support could enhance any effect on well-being. Sound methods regarding the randomisation procedure and assessment of outcomes should be used, and international collaboration might be considered in order to increase the study size and the comparability of the findings. Future studies on survival should address the possible mechanisms underlying an improved prognosis.

Implications for practice

None stated.

Quality assessment

Is there a defined search strategy? Yes. Two electronic databases plus examining bibliographies of retrieved papers.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Yes. Limited to randomised trials of psychosocial interventions in adults with cancer. 'Psychosocial interventions' was not explicitly defined.

Are study designs and number of studies clearly stated? Unclear. Some studies may not have been presented in tables.

Have the primary studies been quality assessed? No. Aspects of validity were discussed throughout, but quality was not systematically assessed.

Have the studies been appropriately synthesised? Yes. Narrative summary was appropriate given the considerable heterogeneity between studies.

Has more than one author been involved at each stage of the review process? Unclear. Not stated.

Reviewer's comment

This was a reasonably well conducted and reported review of the literature, though considering all included studies were RCTs, formal assessment of the validity of included studies could have been undertaken. Publication bias was mentioned but not formally assessed. Nevertheless, the authors' conclusions appear to appropriately follow from the evidence presented.

Reference Bottomley ³⁴ 1998 Belgium	Title Psychotherapy groups and cancer patient survival: chasing fools gold? Objective/review question To review the literature of randomised controlled trials (RCTs) reported to examine survival rates among cancer patients involved in group interventions.
Literature search The following electronic databases were searched: MEDLINE (1976-1996), PsycLit (1976-1996) and the Cumulative Index to Nursing & Allied Health Literature (1982-1996), the Cochrane Library, the National Health Service Research Registry, and Dissertation Abstracts International. Textbooks and bibliographies of all primary articles were searched manually. Personal contacts and personal files were also used to identify relevant literature. When reviewing articles, references were checked; and then the references cited by these references. A third check of references was undertaken, and grey literature was examined. Authors of identified studies were contacted to determine if they had knowledge of any ongoing studies.	
Inclusion/exclusion criteria <u>Design</u> Randomised controlled trials (RCTs). <u>Participants</u> No specific inclusion criteria other than 'cancer patients'. <u>Interventions</u> No specific inclusion criteria other than 'group interventions'. Specific interventions were: Spiegel et al - Intervention consisted of 90-min weekly supportive expressive psychotherapy meetings over 12 months. Patients were encouraged to share feelings with one another, and talk about physical and treatment problems. Self-hypnosis was also taught to control pain. Groups were facilitated by a psychiatrist or social worker who suffered from breast cancer in remission. Fawzy et al - Patients randomised immediately following standard surgical removal of malignant melanoma. Intervention consisted of a structured 6-week psychoeducational approach lasting 90 min per session. These were conducted by a psychiatric nurse and a mental health nurse who focused on education, stress management, problem-solving and psychological support (I.e. encouraging open discussion and encouraging hope). Illnckey et al - Intervention consisted of weekly 90 min social support sessions over 6 weeks. Interventions varied in context, but all aimed to offer the patient a chance to express emotions, discuss feelings and views, and gain support from one another. There were two group facilitators, either social workers, psychiatrists, or both. <u>Outcomes</u> No specific inclusion criteria other than 'survival'. <u>Other</u> <u>Study selection procedure</u> None stated.	
Methods <u>Validity assessment tool</u> Not stated. <u>Validity assessment procedure</u> Data were presented on whether included studies had reported possible key prognostic variables and research procedures that might influence survival outcomes, including: Histological grade, immunological response, timing of surgery, stage of disease, type of disease, clinical workload of staff, co-morbidity, race, demographics other than race, life events and other stresses, sessions attended, use of psychotropic medication, medical compliance, follow-up procedure, follow-up treatments, follow-up of other non-medical factors, specifics of death, site of original tumour, and site of metastasis. Aspects covered by the included articles were discussed in the narrative summary of the review. <u>Data extracted from primary studies</u> See validity assessment. <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Narrative summary <u>How were studies weighted in the synthesis?</u> Studies do not appear to have been weighted. <u>How was publication bias assessed?</u> Publication bias was not assessed. <u>How was heterogeneity assessed?</u> Though differences between studies were discussed in the text of the article, no formal assessment of heterogeneity was undertaken.	
Results <u>Number of studies included in the review</u> Three RCTs. <u>Number of participants</u> 278 cancer patients. <u>Results of validity assessment</u> Of 19 listed prognostic variables and research procedures, seven were reported by Spiegel and Fawzy, and three were	

reported by Illnckey.

Main outcome

Spiegel et al: At 10 year follow-up from randomisation, survival time was 36.6 months (intervention group) and 18.9 months (control group).

Fawzy et al: At 5-6 year follow-up 3/34 patients from the intervention group had died compared with 10/34 in the control group (p=0.03).

Illnckey et al: Results of survival analysis at 10 years showed no significant difference between intervention and control groups.

Secondary outcome

Other outcomes

Publication bias

Not stated.

Heterogeneity

Conclusions/interpretation

Authors interpretation

Generally, those RCTs that have been reported may have been well designed and implemented, but there are numerous variables clinically relevant to the course of disease which were not taken into full consideration when the results of these studies were presented.

Conclusion

Caution is needed regarding the possible survival benefits conferred by group interventions.

Implications for research

Key issues researchers need to consider when designing group interventions with survival as one endpoint:

1. The careful grouping of disease sites in any analysis and examination of all known prognostic variables in the analysis is essential.
2. Complete recording and longitudinal monitoring of changes in patients' medical status over the entire period until death is also important.
3. While it is obvious that the need for larger samples is valid, smaller studies, if conducted in a robust manner – ideally multi-centred, following a standard protocol, and using homogeneous populations may be most valuable in future systematic reviews.

Implications for practice

None stated.

Quality assessment

Is there a defined search strategy? Yes. Electronic database searches were supplemented by handsearching of textbooks and bibliographies, searching of grey literature, and contacting authors.

Is there a well defined question? Yes. Though no specific inclusion criteria were stated, the review question was reasonably clear and the included evidence was relevant to this question.

Are inclusion/exclusion criteria stated? No.

Are study designs and number of studies clearly stated? Yes.

Have the primary studies been quality assessed? No. Though aspects of study validity were examined, no formal validity assessment was undertaken.

Have the studies been appropriately synthesised? Yes. Narrative synthesis was appropriate given the apparent heterogeneity between interventions and study samples.

Has more than one author been involved at each stage of the review process? Unclear. Appears not - the review article is by a single author.

Reviewer's comment

The search for relevant literature was reasonably comprehensive. No specific inclusion criteria were reported, and study selection appears to have been undertaken a single reviewer. However, the selected studies appear to be relevant to the review question. The author identified several important prognostic variables which need to be measured and reported in this area of research, and discussed these appropriately in the narrative summary.

Reference Bottomley ³⁵ 1997 UK	Title Where are we now? Evaluating two decades of group interventions with adults cancer patients. Objective/review question To provide the mental health worker with a comprehensive understanding of the key issues in both conducting and evaluating cancer group interventions.
Literature search Computerised databases: MEDLINE (1976-96), PsycLit (1976-1996) and Cumulative Index to Nursing and Allied Health Literature (1976-1996). A computerised search of Dissertation Abstracts International was also completed to identify unpublished studies.	
Inclusion/exclusion criteria <u>Design</u> No inclusion criteria were specified in relation to design. <u>Participants</u> Adult cancer patients. Studies that reported work with children were excluded. <u>Interventions</u> Group interventions that examined the effects of professionally conducted intervention groups (rather than those of a self-help nature or facilitated by non-professional leaders). Studies were broadly categorised into supportive or psychoeducational interventions). <u>Outcomes</u> No inclusion criteria were specified in relation to outcomes. Outcomes examined in included studies were: Depression, anxiety, coping, self esteem, information, locus of control, general health status, quality of life, qualitative and various ad hoc measures. <u>Other</u> <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> Not stated. <u>Validity assessment procedure</u> Not stated. <u>Data extracted from primary studies</u> Study details presented in tables included: Author(s), year, category of intervention (e.g. supportive vs structured psychoeducation approaches), number of patients in each group, cancer type, intervention duration, type of intervention (e.g. coping skills training, problem solving, relaxation, social support, information etc), randomisation (yes or no), length of follow-up, key outcomes measured. Details of one RCT discussed in the text of the review (Cain et al 1986) were not presented. <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Narrative summary. Each included study was summarised, and specific design aspects which may have influenced study validity were discussed. Included studies were broadly classified as either 'supportive' or 'structured psychoeducational' approaches. <u>How were studies weighted in the synthesis?</u> None. <u>How was publication bias assessed?</u> Not assessed. <u>How was heterogeneity assessed?</u> Not assessed.	
Results <u>Number of studies included in the review</u> 27 studies in total. Fifteen of the included studies included a control group and 11 of these were randomised. <u>Number of participants</u> n=2064. <u>Results of validity assessment</u> Several limitations in the design of the included studies were noted by the authors, particularly relating to sampling methods and sample size, description of the sample, randomisation and use of controls, length of follow-up, description of the intervention and therapists, and use of appropriate outcome measures. (See 'Recommendations for research'). <u>Main outcome</u> Fourteen of the 27 included studies evaluated a 'supportive' approach and 11 evaluated a 'psychoeducational' approach. Most studies reported some benefit of intervention, with only one study finding a negative effect (newly diagnosed breast cancer patients receiving supportive therapy were significantly more depressed and had less vigour than a control group at first post-intervention assessment). Two studies evaluated both supportive and more structured interventions against control. One study randomised a mixed-sex and diagnosis group of cancer patients to supportive discussion groups, structured coping skills training, or a control group. Significant improvements in anxiety and depression were seen for both intervention groups, but these improvements were significantly greater in the coping skills group than in the supportive discussion group. The second study allocated (sequentially) newly diagnosed, clinically distressed patients to supportive group therapy or cognitive behavioural therapy (CBT), or a refusal non-intervention group. Post-intervention, significant improvements in both affective functioning and coping were observed in the CBT group. At 3-months post intervention, both intervention groups had significantly better psychological functioning (anxiety and depression) and coping styles than the refusal non-	

intervention group.

Methodological limitations which may have influenced outcomes were discussed for all of the included studies.

Secondary outcome

Other outcomes

Publication bias

Not assessed.

Heterogeneity

Not assessed.

Conclusions/interpretation

Authors interpretation

The evidence suggests that both structured problem-focused interventions (e.g. with problem solving, education and behavioural methods) and supportive therapy both have benefits over no treatment. Only one study has reported a negative effect caused by the intervention and this was limited in duration.

More structured interventions were often better designed, for example, detailing specific aims and methods and generally using more robust methodologies.

Some evidence suggests that structured interventions may offer more benefit than those of a purely supportive nature. This may be caused by the therapy providing patients with the skills needed to cope with their situation when the group ends. Structured interventions (e.g. CBT, education and information model) may also offer the greatest potential of benefit to any newly diagnosed cancer patients.

Supportive-based interventions can also be valuable for patients. These may be more appropriate for those patients who prefer a less structured approach or those who are at a more advanced stage of disease. More research is required on the use of supportive interventions.

Conclusion

Overall, the reviewed evidence suggests that group interventions offer mental health benefits for cancer patients.

Nevertheless, if we are to establish the value of such interventions for use in mainstream cancer care, the many design issues noted in this review need to be addressed.

Implications for research

The author makes several recommendations for future research, including:

- Providing adequate descriptions of sampling procedures, and undertaking multicentred group trials with large samples where possible.
- Provide adequate sample characteristics (included concurrent treatments).
- Appropriate use of randomisation and control groups.
- Long-term follow-up of patients.
- Greater description of the interventions and procedures used. Better description of therapists delivering interventions in terms of training, experience, qualifications and therapeutic orientation.
- The use of appropriate standardised outcome measures.
- The use of robust qualitative methodologies alongside quantitative strategies.
- Greater consideration of potential confounding variables, such as concurrent stressors and medication, pain, energy levels, concern regarding appearance and uncertainty over treatments, length of hospitalisation, religious background and beliefs, satisfaction with care, premature voluntary termination of chemotherapy, leisure activities, sexual satisfaction, works satisfaction, unemployment, infertility and family income and family cohesion.

Implications for practice

None stated.

Quality assessment

Is there a defined search strategy? Yes.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Yes. Exclusion criteria mentioned, though not explicitly, in relation to patients and interventions.

Are study designs and number of studies clearly stated? Yes.

Have the primary studies been quality assessed? No.

Have the studies been appropriately synthesised? Unclear. Narrative summary was appropriate, but could have been clearer.

Has more than one author been involved at each stage of the review process? Unclear. Probably not (only one review author).

Reviewer's comment

Electronic databases were searched to find published and unpublished research over a 20 year period. The review question was broad, with fairly poorly described selection criteria. Despite the breadth of the review question, the total number of included studies was not particularly large (27 studies). It is unclear whether there were language restrictions. The validity of included studies was not assessed systematically. However, methodological limitations of each study were discussed and formed the basis for appropriate recommendations for future research. Included studies were presented in reasonable detail, though little information on study outcomes other than their direction and significance were reported. Narrative summary seemed appropriate, though a more organised summary (perhaps by type of intervention) may have been simpler to interpret than the chronological discussion of studies presented here.

Reference Barsevick ³⁸ 2002 USA	Title A systematic qualitative analysis of psychoeducational interventions for depression in patients with cancer Objective/review question To determine whether research-based recommendations can be made about the clinical management of depression in patients with cancer.
Literature search Electronic searches of CINAHL, MEDLINE, PsychLit, and CancerLit (1980-2000). Reference lists of relevant studies and reviews were examined to identify additional relevant articles.	
Inclusion/exclusion criteria <u>Design</u> Scientific studies, qualitative or quantitative systematic reviews of scientific studies, and practice guidelines based on research. Controlled studies had to use a usual care or attentional control group. <u>Participants</u> No specific inclusion criteria. Studies of children with cancer and spouses of patients with cancer were excluded. <u>Interventions</u> 'Psychoeducational interventions', defined as "therapeutic approaches that involve information giving and receiving, discussion of concerns, problem solving, coping skills training, expression of emotion, and social support". Controlled studies were only included if a usual care or attentional control group was used. Categories (adapted from Meyer and Mark 1995) were: counseling/psychotherapy, behaviour therapy, education/information, social support, other. The most frequently used single intervention was behaviour therapy (N=17 studies), including one or more of the following: relaxation training, biofeedback, or cognitive coping strategies. Nondirective counseling (N=10) was also used as a single intervention. Seven studies tested education interventions. Fourteen studies tested a combination of two or more interventions. Twelve studies combined counselling or behavioural intervention with cancer education. <u>Outcomes</u> Depressive symptoms. Seventeen different measures of depression were used in the included studies. The most common were the Profile of Mood States (12 studies) and the Hospital Anxiety and Depression Scale (10 studies). <u>Other</u> Systematic reviews were also eligible for inclusion and had to examine specific hypotheses, describe the search strategy, and state conclusions explicitly. <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> All articles were rated according to the level of evidence criteria developed for the PRISM (Priority Symptom Management) review. Quality criteria were based on study design characteristics, including sample size, allocation of participants to treatment groups, eligibility criteria, exposure to the experimental intervention, outcome evaluation, and consideration of potential confounding factors. For studies which reported nonsignificant results, an rating of NS was given rather than a level of evidence rating. <u>Validity assessment procedure</u> Not stated. <u>Data extracted from primary studies</u> Data presented in tables were: author, number of participants, cancer diagnosis, type of intervention in each group, number of sessions, type of control group (attentional or usual care), format (group or individual), and level of evidence. <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Narrative summary. <u>How were studies weighted in the synthesis?</u> Not stated. <u>How was publication bias assessed?</u> Not assessed. <u>How was heterogeneity assessed?</u> Not assessed.	
Results <u>Number of studies included in the review</u> 55 articles (6 systematic reviews, 36 RCTs, 7 quasi-experimental studies, 5 descriptive studies, 1 treatment guideline) <u>Number of participants</u> RCTs n>1465, quasi-experimental studies n=869, descriptive studies n=730. <u>Results of validity assessment</u> According to the PRISM criteria, 11 studies provided level I evidence, 19 studies contributed level II evidence, and 18 studies did not receive an evidence level as they reported non-significant results. <u>Main outcome</u> Thirty of 48 individual studies provided evidence in support of the benefit of psychoeducational intervention for depression in patients with cancer. Eleven of 17 behavioural intervention studies (65%) and 7 of 10 counselling intervention studies (70%) had positive results. Four of seven education interventions (57%) were beneficial in relieving depression, and 7 of 12 combination interventions that included education (58%) had beneficial results. The three qualitative reviews concluded that psychoeducational interventions benefit depression. Two of the three	

quantitative meta-analyses found psychoeducational interventions to benefit depression, and one found no such benefit. Clinical treatment guidelines published by the National Cancer Center Network (Holand, 1997) were evidence-based and included recommendations for counseling psychotherapy in combination with pharmacologic treatment for patients with cancer with major depression.

Publication bias

None

Heterogeneity

None

Conclusions/interpretation

Authors interpretation

Overall the evidence supports the benefit of psychoeducational interventions in reducing depressive symptoms in patients with cancer.

Conclusion

The evidence supports the conclusion that psychoeducational interventions reduce depressive symptoms in patients with cancer and that behaviour therapy or counselling alone or in combination with cancer education is beneficial.

Implications for research

The authors state that studies should be sufficiently powered and should control physical symptoms and medical treatment variables which might account for beneficial effects. They also state that:

-RCTs need to include patients who have depression at baseline to investigate the management rather than prevention of depression.

-RCTs directly comparing behaviour therapy with counselling psychotherapy are needed.

-RCTs looking at the effects of intervention intensity/longevity are needed.

-RCTs need to compare therapeutic interventions with inert alternative interventions that control for time and attention from health care providers.

Implications for practice

Nurses can select from a variety of educational, behavioural, and counselling techniques to prevent or manage depression in their patients.

Quality assessment

Is there a defined search strategy? Yes.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Yes.

Are study designs and number of studies clearly stated? Partly.

Have the primary studies been quality assessed? Partly.

Have the studies been appropriately synthesised? Unclear.

Has more than one author been involved at each stage of the review process? Unclear.

Reviewer's comment

A reasonable search of the literature was undertaken, with searching of four databases and following up references from retrieved papers. Inclusion and exclusion criteria were stated, though some (e.g. study design) were quite vague. The selected primary studies and reviews were graded according to the level of evidence they provided, using criteria developed for a previous review. However, included studies which did not report statistically significant results in favour of psychoeducational interventions did not receive an evidence grade, but were simply classed as "NS" (non-significant). Therefore, there was no indication of the validity of these 'nonsignificant' studies in relation to those studies which supported the authors' hypothesis. Data on the characteristics of the included studies were presented in tables, but no information was presented on the size of observed effects from each study. Narrative synthesis appeared to be an appropriate approach to take with a group of studies which varied in terms of participants, interventions, and study designs. However, the approach of essentially ignoring the 18 studies which reported nonsignificant results in the synthesis was inappropriate, and the authors' conclusions should duly be treated with some caution. Nevertheless, the authors' make sensible recommendations for future research in this area.

Reference Bauman ³⁹ 1997 USA	Title A Review of Psychosocial Interventions for Children with Chronic Health Conditions
	Objective/review question To identify psychosocial interventions whose efficacy has been objectively evaluated, to describe these programmes and the theoretical models on which they are based, to summarise the findings and to recommend future directions for research and practice.
Literature search The reviewers searched Index Medicus and Psychological Abstracts with a variety of keywords including specific conditions (a list of the keywords is available on request from the authors). References of retrieved articles were also examined and experts contacted to identify other research. Search dates were not given.	
Inclusion/exclusion criteria <u>Design</u> The study needed to meet two methodologic criteria: a minimum of 15 participants in the experimental group and to have a comparison group. A random control group, a matched comparison group or a convenience comparison group were acceptable but comparison to published norms was not. <u>Participants</u> The intervention needed to target children with a chronic health condition or their family members. <u>Interventions</u> The study needed to evaluate a planned psychosocial intervention. Naturally occurring family resources (e.g. maternal support systems) were excluded as being unplanned. Medical interventions, physical therapy, medications and treatment regimens were all excluded as they were designed to improve health, not psychosocial, outcomes. <u>Outcomes</u> Studies needed to examine psychologic or social outcomes. They could include medical or functional outcomes but results are not reported for these outcomes. <u>Other</u> Articles needed to have been published in a peer reviewed journal between 1979 and 1993. Articles needed to be published in English. <u>Study selection procedure</u> Two reviewers screened titles and abstracts and eligibility was determined by consensus. Each eligible article was then reviewed independently by two authors. Rating forms were completed for intervention, theory and methods and all rating discrepancies were reconciled by consensus.	
Methods <u>Validity assessment tool</u> Designed by the reviewers. The methodology of each study was described as follows: whether the comparison group was randomised, matched or convenience; sample size; the sample's representativeness; sociodemographic characteristics of the sample; types of chronic illnesses included; whether losses to follow-up were accounted for; whether this was a replication of another programme; the outcomes considered; whether findings were statistically significant in the expected direction and whether the magnitude of any significant change was clinically important. <u>Validity assessment procedure</u> Rating forms were completed for the methods and all rating discrepancies were reconciled by consensus. <u>Data extracted from primary studies</u> Data was extracted for the intervention, the theory and the methodology as described in the validity assessment. For the intervention each paper was coded for type(s) of intervention, the target group, the intensity of the intervention, how integrated the programme was with the child's medical care and level of training of the intervener. Details were also extracted on consistency of intervention and monitoring of consistency and quality assurance. Data was also extracted on the contribution of a theoretical model to the development and rationale of the programme. The role of theory in the selection of outcome measures, timing of measurement and power calculations was also assessed. <u>Data extraction procedure</u> Rating forms were completed and all rating discrepancies were reconciled by consensus. <u>How were studies combined in the review?</u> Narrative summary. <u>How were studies weighted in the synthesis?</u> None. <u>How was publication bias assessed?</u> Not investigated. <u>How was heterogeneity assessed?</u> Due to clinical heterogeneity (nature of programmes evaluated, research designs used and populations targeted) the reviewers decided against formal meta-analysis.	
Results <u>Number of studies included in the review</u> 15 included studies of which 10 used experimental designs(randomised), one was partially randomised. The other four studies used convenience samples for comparison. Seven studies focused on children with asthma, three on children with cancer, two on children with epilepsy and three included children with various diagnostic conditions. <u>Number of participants</u> 2391 <u>Results of validity assessment</u> Not stated. <u>Main outcome</u> All three cancer trials demonstrated some positive outcomes. Child Depression Inventory (CDI) (2 studies 0), Child Behaviour Checklist (CBCL) (2 studies +), Self Competence Scale (SCS) (1 study +, 1 study 0), Adjustment to school (1 study +), Family functioning (1 study 0), Interaction (1 study +), Depressed mood (1 study 0), General feelings (1 study + for anger, 0 for depressed and 0 for upset / tense), Social Support Scale for Children (1 study +), Stait-Trait Anxiety Scale	

for children (STAIC) (1 study 0), Social competence (1 study +).

Secondary outcome

Publication bias

Not applicable.

Heterogeneity

Not applicable.

Conclusions/interpretation

Authors interpretation

Studies often lacked detail on implementation, interventions varied in their intensity and duration (from 3 weeks to 15 months (4 did not specify)). Five studies clearly specified a theory but in the 10 others theory was either not clear or not explicit. Only six made reference to theory to justify the type of intervention, the remainder using the results of prior research as a rationale. Many of the studies examined other outcomes than psychosocial ones and some found significant effects (not reported here).

Conclusion

The evidence is clear that there are some interventions that can help children and families cope with the psychologic and social consequences of chronic health conditions.

Implications for research

Future work must include acceptable and methodologically sound evaluations. They must provide strong and convincing evidence to justify the costs of psychosocial interventions for children with chronic illnesses and disabilities. One priority for future research is to replicate successful programmes with broader populations, different sites and longer time periods. Sample sizes should be larger and based on a power analysis, a comparison group should be used, measurement tools should be sufficiently sensitive to the outcome and have adequate reliability and validity, interventions should be piloted / tested and if several outcome measures are used investigators should state a priori which ones must improve in order for the programme to be deemed a success. Details of interventions should be made available, researchers need to pay more attention to their clinical findings, programmes should be guided by theory, researchers need to examine effects for subgroups of patients and should, where feasible, include multidisciplinary teams.

Implications for practice

Not stated.

Quality assessment

Is there a defined search strategy? Yes, but limited to two databases and reference checking and English language publications.

Is there a well defined question? Yes, although broad in scope.

Are inclusion/exclusion criteria stated? Yes, for all categories.

Are study designs and number of studies clearly stated? Yes.

Have the primary studies been quality assessed? Yes, although not with validated or published criteria.

Have the studies been appropriately synthesised? Unsure if this approach really is appropriate.

Has more than one author been involved at each stage of the review process? Yes for selection, data extraction and validity checking.

Reviewer's comment

The review had a broad scope but had defined inclusion criteria for study design, participants, interventions and outcomes. The search strategy was defined but limited and only included English language publications. A validity assessment was performed and interventions were also evaluated as to their theory base. More than one reviewer was involved in the review process, thus helping to minimise bias. Due to clinical heterogeneity the reviewers summarised results narratively. They discussed together studies with varying patient groups, study designs, interventions and outcomes. No separate conclusions could be drawn on the effects of a given intervention for different clinical conditions. Studies were not weighted on quality or study design and randomised and nonrandomised studies were presented together in the results. Although the evidence points to the usefulness of psychosocial interventions no further conclusions can reliably be drawn until further studies are performed using methods highlighted by the reviewers.

Reference Devine ⁴⁰ 1995 USA	Title The effects of Psychoeducational care provided to adults with cancer: Meta-analysis of 116 studies Objective/review question To determine how educational and psychosocial care provided to adults with cancer affects seven outcomes - anxiety, depression, mood, nausea, vomiting, pain, and knowledge.
Literature search CINAHL (1983-1992), MEDLINE (1966-1993), Dissertation Abstracts International (1861-1992), and PsycLit (1974-1993). Lists of thesis and dissertations obtained from graduate nursing programs and lists of all dissertations completed by nurses obtained from University Microfilms International were examined. The reference lists of relevant studies and reviews were examined using the ancestry method.	
Inclusion/exclusion criteria <u>Design</u> Studies had to use an experimental, quasiexperimental, or pre-post single group study design. Studies with fewer than five participants in each treatment group were excluded. Studies were excluded if all the treatment groups were not selected from the same setting(s). Eighty-seven percent of included studies involved a control group; participants were randomly assigned in 68%. <u>Participants</u> Adults with cancer. The age of included patients ranged from 27 to 69 years. Most studies (55%) involved people with various types of cancer, though 32% included only women with breast cancer. <u>Interventions</u> Studies had to examine the effectiveness of psychoeducational care. Studies in other areas (e.g. the effect of psychoeducational care versus that of pharmacotherapy in reducing nausea) were excluded. Included interventions were organised into the following categories of psychoeducational care: education, nonbehavioural/noncognitive counseling, and behavioural/cognitive counseling. <u>Outcomes</u> Measures of physical well-being, psychological well-being, or knowledge about one's health condition from which the direction of treatment effect was discernible. These included: anxiety, depression, mood, nausea, vomiting, pain and knowledge. <u>Other</u> Certain outcomes were not assessed if they were measured in less than five primary studies (e.g. leukocyte count, hope). Measures were also excluded if either high or low was not commonly accepted as the desired clinical outcome (e.g. locus of control). <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> Not stated. <u>Validity assessment procedure</u> Univariate and multivariate weighted regression procedures (Hedges and Olkin, 1983) were used to estimate the relationship between threats to validity and size of effect. Aspects of validity considered were; whether studies were published, whether subjects were randomly assigned to treatment condition and whether a placebo control group was included. <u>Data extracted from primary studies</u> Data were extracted on characteristics of the: study (publication form and date, professional preparation of first author, manner of assignment of participants to treatment group, type of control group); sample (age, gender, ethnicity, type of cancer, time since diagnosis); treatment (content, timing, duration, frequency, and mode of delivery of experimental intervention); setting (country and site where intervention occurred); and outcomes (measures of physical and psychological well-being and patient knowledge that were prevalent in the included studies and are relevant for nurses). <u>Data extraction procedure</u> Studies were coded by nurses with doctoral preparation and doctoral students in nursing. Inter-rater reliability, based on percent agreement, was 87%. <u>How were studies combined in the review?</u> Meta-analysis. For each study outcome, an effect size statistic g was calculated. If a study used multiple measures of a single construct, effect sizes values were averaged to provide a single measure of effect. This was multiplied by coefficient that includes information on the sample sizes of both experimental and control groups to yield the unbiased effect-size statistic d . Effect-sizes were then averaged across studies. Also, all studies measuring the outcomes examined in the meta-analysis were included in a test of treatment effectiveness based on the direction of treatment effect using a Z-test for difference in sample proportions. This analysis allows the inclusion of articles providing insufficient data for effect-size calculation. <u>How were studies weighted in the synthesis?</u> Each effect size value was weighted by the inverse of its variance before averaging the effect size values across studies. <u>How was publication bias assessed?</u> Publication bias was assessed using regression procedures and by calculating fail-safe N values. The fail-safe N statistic estimates the number of additional studies in support of the null hypothesis that would need to be found before the conclusions of the review would be reversed. <u>How was heterogeneity assessed?</u> Studies with very large effect sizes (i.e. >2) were not included in the analysis. Heterogeneity between studies was tested using the Q statistic.	
Results	

Number of studies included in the review

In total 116 studies met the inclusion criteria. Eighteen only provided the direction of the treatment effect. Sample size and at least one effect size value could be determined in 98 studies (involving 116 experimental treatment groups).

Number of participants

5,326 (in 98 studies).

Results of validity assessment

Sixty-eight percent of studies involved randomised allocation to treatment groups and 26% included a placebo-type group. Neither of these aspects of study validity appeared to explain the observed effect sizes for any outcome.

Main outcome

Physical well-being.

(+ve = total percentage of studies with positive outcomes. ES = number of effect sizes combined)

Nausea (+ve=93%, 21 ES): 0.69 (95% CI: 0.45, 0.92). Heterogeneous (Q=38).

Vomiting (+ve=81%, 12 ES): 0.34 (95% CI: 0.09, 0.69). Homogeneous (Q=15).

Pain (+ve=92%, 11 ES): 0.43 (95% CI: 0.16, 0.69). Heterogeneous (Q=20).

Secondary outcome

Psychological well-being.

Anxiety (+ve=95%, 55 ES): 0.56 (95% CI: 0.42, 0.70). Heterogeneous (Q=113).

The effects of treatments studied in four or fewer studies were excluded from the meta-analysis but were reported for descriptive purposes: Statistically significant and homogeneous effects on anxiety were found for nonbehavioural therapy/noncognitive counseling (3 studies; d=0.95), other combinations of education and behavioural or nonbehavioural treatments (4 studies; d=0.56). The effect of systematic desensitisation (4 studies; d=0.98) on anxiety was significant but heterogeneous. A homogenous effect-size value indicated no significant beneficial effect of problem solving/crisis intervention (2 studies; d=0.01).

Depression (+ve=92%, 40 ES): 0.54 (95% CI: 0.43, 0.65). Homogeneous (Q=39).

Prevalent treatments included in the overall meta-analysis included education alone (4 studies; d=0.50), nonbehavioural/noncognitive counseling alone (5 studies; d=0.66), muscle relaxation or muscle relaxation with guided imagery only (12 studies; d=0.40), and combination-type treatments with educational, behavioural or non-behavioural counseling (12 studies; d=0.52). All of these effect size values were statistically significant and homogeneous.

Mood (+ve=87%, 25 ES): 0.45 (95% CI: 0.32, 0.58). Heterogeneous (Q=44).

Other outcomes

Knowledge (+ve=95%, 18 ES): 0.90 (95% CI: 0.61, 1.20). Heterogeneous (Q=46).

Publication bias

Forty-seven percent of studies were published in a journal/book, the rest were primarily doctoral dissertations (45%) or theses (6%) that were published in a journal. Fail-safe N values were 70 for vomiting, 84 for pain, and were 200 or larger for anxiety, depression, mood, nausea, and knowledge. Publication status did not appear to explain the observed effect sizes for any outcome.

Heterogeneity

Further analyses were conducted where heterogeneity between effect sizes was detected.

Nausea:

In some studies, very low ratings for nausea were present in both treatment and control groups, suggesting a possible floor effect. When analysis was restricted to 11 studies which selected only patients with documented nausea, vomiting or high anxiety prior to treatment, the effect on nausea was larger and homogeneous (1.04 (95% CI: 0.69, 1.39), Q=17). Among these 11 studies were statistically significant and homogeneous effect-size values for systematic desensitisation (d=0.91; 4 studies) and muscle relaxation with guided imagery or meditation (d=1.35; 6 studies).

The effects of psychoeducational treatment on nausea at different points in time was also investigated. In the nine studies where nausea was measured at both points in time, treatment effects on nausea were larger before chemotherapy (d=0.81) than during chemotherapy (d=0.36). Six studies indicated that treatment effects on nausea were larger after chemotherapy (d=0.99) than during chemotherapy (d=0.31). Results of five studies indicated the effect on nausea was small at the first chemotherapy cycle measured (d=0.13) and much larger at the last cycle measured (d=0.93). Four studies indicated that the effect of nausea was medium to large at the first cycle measured (d=0.78) and very large at the last cycle measured (d=1.61).

Pain:

Relaxation interventions (e.g. muscle relaxation alone or with guided imagery; music therapy) were most the commonly investigated type of treatment in studies measuring pain (5 studies). The effect of relaxation on pain was large and homogeneous (d=0.91 (95% CI: 0.35, 1.47), Q=7). Small homogeneous non-significant effects on pain were found for education only (2 studies; d=0.36) and multiple behavioural strategies with or without education (4 studies; d=0.19).

Anxiety:

As heterogeneity was found for the effect on anxiety, subgroup analyses by type of psychoeducational care were carried out. Significant and homogeneous effects were found for: education only (7 studies; 0.74 (95% CI: 0.24, 1.23), Q=12), relaxation/distraction alone (excluding muscle relaxation alone) (7 studies; 0.66 (95% CI: 0.21, 1.10), Q=9), multiple behavioural interventions with relaxation (8 studies; 0.59 (95% CI: 0.27, 0.91), Q=8), education and relaxation and nonrelaxation behaviour (7 studies; 0.46 (95% CI: 0.24, 0.68), Q=10). Significant but heterogeneous effects on anxiety were found for muscle relaxation alone (7 studies; 0.60 (95% CI: 0.28, 0.92), Q=18) and muscle relaxation with guided

imagery (11 studies; 0.62 (95% CI: 0.24, 1.00), $Q=38$). Moderator variables within these latter two treatment groups could not be determined. When large effect sizes in these two groups were winsorized (i.e. made smaller) until results were homogeneous, the effect remained significant.

Mood:

Given a lack of independence with earlier analyses and the small number of studies within individual types of treatments, further analyses involving mood were not undertaken.

Knowledge:

The association between effect size values and the treatment characteristic (i.e. presence of printed material) was tested using the analogue of multiple regression (Hedges, 1994). The hypothesis that this treatment characteristic was unrelated to magnitude of effect size values was rejected ($Q(\text{change})=20.4$, $df=1$; $p<0.01$). Treatment effect on knowledge was significantly larger in treatments that included written content.

Conclusions/interpretation

Authors interpretation

Many types of psychoeducational care have been shown to have beneficial effects on both anxiety and depression. With other outcomes, however, less variability existed in the types of psychoeducational care tested. Nonetheless, behavioural strategies (e.g. relaxation, relaxation with guided imagery, systematic desensitisation) were well tested and shown to be effective for nausea, relaxation-type interventions were shown to be effective for pain and teaching interventions were shown to be effective for increasing knowledge.

Conclusion

Across all types of psychoeducational care, statistically significant benefits were found for all seven outcomes examined (anxiety, depression, mood, nausea, vomiting, pain and knowledge). For none of those outcomes were effects threatened by alternate explanations based on publication bias, low internal validity, or a Hawthorne effect. Differentiating amongst the effectiveness of various types of psychoeducational care was problematic.

Implications for research

Researchers must look more closely and deliberately at whether some types of care are better than others. More complete reports of characteristics of participants and interventions are needed. Future research clearly needs to include multiple experimental treatments in the same study so that the relative effectiveness of different types of psychoeducational care can be assessed.

Implications for practice

Nurses and other clinicians should continue to explore where and how to incorporate psychoeducational interventions into their practice.

Quality assessment

Is there a defined search strategy? Yes.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Yes.

Are study designs and number of studies clearly stated? Partly. Numbers in each comparison given.

Have the primary studies been quality assessed? Partially.

Have the studies been appropriately synthesised? Yes.

Has more than one author been involved at each stage of the review process? Unclear. Not stated by authors.

Reviewer's comment

This review identified a large number of studies from a broad search of the published and unpublished literature. Inclusion criteria were broad but reasonably well described. The methods and results were clearly reported, though little information was available on primary studies included in each analysis. Attempts were made to assess the influence of publication bias on the results of the meta-analysis. The influences of randomisation and inclusion of a placebo control group on the observed summary effect sizes were assessed, though other aspects of study validity were not examined.

Reference Newell ⁴¹ 2002 Australia	Title Systematic review of psychological therapies for cancer patients: Overview and recommendations for future research. Objective/review question To conduct a critical review of the literature to identify areas where consistent evidence exists regarding the effectiveness of psychological therapies at reducing cancer patients' morbidity and mortality, as well as areas in which further research is required.
Literature search MEDLINE Psychlit, Healthplan, and Allied and Complementary Medicine databases (up to December 1998). Also searched were the bibliographies of all located relevant papers for further potentially relevant references. This process was performed iteratively, until no new potentially relevant references were identified. The review authors also contacted relevant research groups within the Cochrane Collaboration and other key authors known or suggested by others to locate relevant but currently unpublished studies.	
Inclusion/exclusion criteria <u>Design</u> No inclusion criteria regarding study design were applied during the literature review stage. To be included in the effectiveness review, papers had to report the results of randomised controlled trials (RCTs) of fair or good methodological quality. <u>Participants</u> Patients with cancer. Participants in these studies varied in age, cancer site, disease stage and concurrent treatment(s). <u>Interventions</u> For inclusion in the literature review, papers had to discuss any psychological therapy in relation to cancer patients. For inclusion in the effectiveness stage of the review, papers had to evaluate the effectiveness of a psychological intervention. <u>Outcomes</u> The authors do not state any inclusion criteria specifically relating to outcomes. The included studies evaluated a variety of psychological therapies which targeted: anxiety, depression, general or overall affect, hostility, stress or distress, overall functional ability of quality of life, coping or control skills, vocational or domestic adjustment, interpersonal or social relationships, sexual or marital relationships, nausea, vomiting, pain, fatigue, overall physical symptoms, conditioned nausea, conditioned vomiting, survival, and immune outcomes. <u>Other</u> Only English language studies were included in the review. <u>Study selection procedure</u> Two individuals were trained in applying all eligibility and classification systems. The first 350 papers considered eligible for inclusion were rated by both coders and agreement was assessed by the kappa statistic.	
Methods <u>Validity assessment tool</u> Each RCT was rated against 10 indicators of internal validity, following Cochrane guidelines. These were: concealment of allocation, randomisation, blinding of patients, blinding of care-providers, balancing of groups, monitoring of care-provider adherence, details on loss to follow-up, percentage of patients not in analyses, intention to treat analyses, and blinded measurement of outcomes. A trial received a score of 3 points for each indicator entirely fulfilled, 2 point for each mostly fulfilled, 1 point for each mostly not fulfilled, and 0 points for each indicator not at all fulfilled or with insufficient information for assessment. Consequently, each trial could achieve a maximum total score of 30 points. The quality of a trial was considered to be good if it had a total score greater than 20 points, fair if it score 11-20 points, and poor if it scored less than 11 points. <u>Validity assessment procedure</u> Around 10% of the papers that discussed intervention studies were randomly selected for double coding of their study characteristics and, where relevant, methodological quality. Agreement between coders was assessed using the kappa statistic. <u>Data extracted from primary studies</u> Data were only presented for trials which received 'fair' or 'good' scores on the validity assessment scale. Data were extracted on: author, year, country, quality score, patient characteristics, length of follow-up and number of subjects at each follow-up, and statistically significant outcomes. <u>Data extraction procedure</u> Data were extracted by two reviewers. <u>How were studies combined in the review?</u> Narrative summary, categorised by outcome. Recommendations were based on the number of trials with statistically significant results for each intervention in each outcome category. <u>How were studies weighted in the synthesis?</u> None. <u>How was publication bias assessed?</u> Not stated. <u>How was heterogeneity assessed?</u> The authors did not carry out a formal assessment of heterogeneity, though differences between the included studies in terms of design and outcomes were discussed in the narrative summary.	
Results <u>Number of studies included in the review</u> Literature review: 627 papers eligible for inclusion were identified. These included four measure studies, 47 descriptive studies, 271 intervention studies involving 329 separate trials, 293 commentaries, and 12 reviews. Effectiveness review: 155 RCTs were identified. Of these, a total of 82 provided sufficient data and were of sufficient methodological quality for inclusion in the review of effectiveness. Thirty-four RCTs reported psychosocial outcomes, 28 RCTs reported physical side effects, 10 reported conditioned side effects, and 10 reported survival or immune outcomes.	

Number of participants

Psychosocial outcomes, n>1655; physical and conditioned side-effect outcomes, n>1444; survival or immune outcomes, n=558.

Results of validity assessment

The median methodologic quality score for the 155 randomised trials was 9 points (range = 0-21 points). Only 60 (39% trials) had scores of 10 or more points (of a maximum of 30) and only nine (6%) trials had scores of 15 or more points. Only five trials could be assessed on all 10 methodologic indicators, whereas 52 (34%) trials provided insufficient information for assessment on five or more indicators. Two coders were in 95% agreement (kappa statistic = 0.87) about the eligibility and classification of the references that were double coded.

Number and percentage of 'trials' excluded on methodological quality for each outcome (i.e. 'poor' quality studies scoring less than 11 points):

Psychosocial outcomes - 87/129 (67%)
Physical side-effect outcomes - 57/93 (61%)
Conditioned side-effect outcomes - 9/19 (47%)
Survival/immune outcomes - 6/16 (38%)

Main outcome

Psychosocial outcomes.

Strong recommendations for or against an intervention strategy were made only when at least three trials, including at least one of good methodologic quality, had investigated the strategy and found consistent results (at least 75% of trials with statistically significant results). Tentative recommendations for or against an intervention strategy were made when consistent evidence (at least 75% of trials with statistically significant results) from fair-quality trials was obtained. Inconsistent evidence produced no recommendation for or against an intervention strategy.

Recommendations: F=tentatively for, ?=neither for nor against, A=tentatively against, (no. of statistically significant 'trials'/total no. of 'trials').

Anxiety: Group therapy A(1/4), Individual therapy ?(9/34), nontherapist delivered A(0/2), therapist delivered ?(9/33), audiotape delivered A(1/4), significant-other involvement ?(1/3), information and education A(3/14), unstructured counselling A(1/7), structured counselling A(1/5), relaxation training A(7/28), cognitive behavioural therapy ?(3/11), communication/expression training ?(2/7), guided imagery/visualisation ?(4/14), self-practice ?(2/7), improving self-esteem/self image A(0/1), music therapy F(1/1).

Depression: Group therapy ?(2/6), Individual therapy A(2/18), therapist delivered A(4/24), significant-other involvement A(1/5), information and education ?(4/13), unstructured counselling A(1/5), structured counselling ?(2/5), relaxation training A(3/15), cognitive behavioural therapy ?(3/10), communication/expression training ?(2/7), guided imagery/visualisation A(0/3), self-practice A(1/6), improving self-esteem/self image ?(1/3).

General affect: Group therapy ?(3/6), Individual therapy A(6/27), nontherapist delivered A(0/2), therapist delivered ?(8/26), audiotape delivered A(1/5), significant-other involvement A(1/5), information and education ?(5/14), unstructured counselling F(2/2), structured counselling ?(1/2), relaxation training A(5/25), cognitive behavioural therapy ?(5/10), communication/expression training ?(4/8), guided imagery/visualisation A(0/8), self-practice A(1/9), improving self-esteem/self image A(0/3), hypnosis A(0/1) music therapy F(1/1).

Hostility: Group therapy A(0/4), Individual therapy A(0/10), therapist delivered A(0/14), information and education A(0/4), unstructured counselling A(0/3), structured counselling A(0/2), relaxation training A(0/11), cognitive behavioural therapy A(0/4), communication/expression training A(0/2), guided imagery/visualisation A(0/4), self-practice A(0/5), improving self-esteem/self image A(0/2).

Stress/distress: Group therapy A(1/4), Individual therapy A(2/11), nontherapist delivered F(1/1), therapist delivered A(3/15), significant-other involvement ?(2/5), information and education A(1/6), structured counselling F(1/1), relaxation training A(2/10), cognitive behavioural therapy ?(3/7), communication/expression training ?(2/6), guided imagery/visualisation A(0/2), self-practice A(0/2), improving self-esteem/self image ?(1/3), hypnosis A(0/1).

Quality of life/functioning: Group therapy A(1/4), Individual therapy ?(5/7), therapist delivered ?(6/11), significant-other involvement ?(1/2), information and education ?(2/4), unstructured counselling F(2/2), structured counselling F(1/1), relaxation training ?(4/8), cognitive behavioural therapy ?(4/7), communication/expression training ?(2/6), guided imagery/visualisation F(1/1), self-practice A(0/1), improving self-esteem/self image A(0/2).

Coping/control: Group therapy F(3/4), Individual therapy A(1/13), therapist delivered A(4/17), significant-other involvement A(1/5), information and education A(2/10), structured counselling A(0/1), relaxation training ?(4/12), cognitive behavioural therapy ?(3/6), communication/expression training ?(2/5), self-practice A(0/7), improving self-esteem/self image A(0/2).

Vocational/domestic adjustment: Group therapy A(0/2), Individual therapy A(0/7), therapist delivered A(0/9), significant-other involvement A(0/4), information and education A(0/7), unstructured counselling A(0/1), structured counselling A(0/1), relaxation training A(0/4), cognitive behavioural therapy A(0/4), communication/expression training A(0/4).

Social relationships: Group therapy A(0/4), Individual therapy A(3/10), therapist delivered A(3/14), significant-other involvement A(0/4), information and education A(2/9), unstructured counselling F(2/2), structured counselling F(2/2), relaxation training A(0/8), cognitive behavioural therapy A(1/6), communication/expression training A(0/6), self-practice

A(0/3), improving self-esteem/self image A(0/2).

Marital relationships: Group therapy A(0/2), Individual therapy ?(3/9), therapist delivered ?(3/11), significant-other involvement A(0/5), information and education ?(3/9), unstructured counselling ?(1/2), structured counselling ?(1/3), relaxation training A(0/5), cognitive behavioural therapy A(0/5), communication/expression training A(0/5), self-practice A(0/1), improving self-esteem/self image A(0/1).

Secondary outcome

Physical side-effect outcomes.

Nausea: Individual therapy ?(6/22), nontherapist delivered A(0/2), therapist delivered ?(6/18), audiotope delivered A(0/2), information and education A(0/1), unstructured counselling ?(3/9), structured counselling A(0/2), relaxation training ?(6/18), cognitive behavioural therapy A(0/2), guided imagery/visualisation A(2/10), self-practice ?(4/11).

Vomiting: Individual therapy A(0/16), nontherapist delivered A(0/2), therapist delivered A(0/12), audiotope delivered A(0/2), unstructured counselling A(0/8), structured counselling A(0/2), relaxation training A(0/14), guided imagery/visualisation A(0/8), self-practice A(0/8).

Pain: Individual therapy ?(3/9), therapist delivered A(2/8), audiotope delivered ?(1/3), information and education A(0/3), unstructured counselling A(0/1), structured counselling A(0/1), relaxation training ?(3/7), cognitive behavioural therapy ?(1/3), guided imagery/visualisation A(1/4), self-practice ?(3/5), hypnosis A(0/1) music therapy A(0/1).

Fatigue: Group therapy A(1/4), Individual therapy A(0/7), therapist delivered A(1/11), information and education A(1/4), relaxation training A(1/11), cognitive behavioural therapy A(1/4), communication/expression training A(0/2), guided imagery/visualisation A(0/2), self-practice A(0/6), improving self-esteem/self image A(0/2).

Overall side effects: Individual therapy A(2/13), nontherapist delivered A(0/2), therapist delivered A(2/8), audiotope delivered A(0/3), significant-other involvement A(0/4), information and education A(0/4), relaxation training A(2/8), cognitive behavioural therapy A(0/3), communication/expression training A(0/2), guided imagery/visualisation ?(2/6), music therapy A(0/1).

Other outcomes

Conditioned side-effect outcomes.

Conditioned nausea: Individual therapy ?(4/10), nontherapist delivered A(0/1), therapist delivered ?(4/8), audiotope delivered A(0/1), unstructured counselling ?(1/3), relaxation training ?(3/7), guided imagery/visualisation ?(3/6), self-practice F(1/1), hypnosis F(1/1).

Conditioned vomiting: Individual therapy ?(2/7), nontherapist delivered A(0/1), therapist delivered ?(2/5), audiotope delivered A(0/1), unstructured counselling A(0/2), relaxation training ?(2/5), guided imagery/visualisation ?(2/5), self-practice F(1/1), hypnosis F(1/1).

Survival/immune outcomes.

Survival length: Group therapy ?(1/3), Individual therapy A(0/1), therapist delivered A(1/4), information and education ?(1/2), unstructured counselling A(0/2), structured counselling A(0/2), relaxation training ?(1/3), cognitive behavioural therapy A(1/4), communication/expression training A(0/1), guided imagery/visualisation A(0/1), self-practice A(0/1).

Immune system: Group therapy A(1/4), Individual therapy ?(2/5), therapist delivered ?(3/9), information and education ?(2/4), relaxation training ?(3/9), cognitive behavioural therapy ?(2/5), communication/expression training A(1/4), guided imagery/visualisation ?(1/2), self-practice A(1/4), improving self-esteem/self image A(0/2), electromyography feedback ?(1/2).

Publication bias

None.

Heterogeneity

Included studies differed in terms of patient characteristics (age and sex, cancer site, disease stage, concurrent treatments), and intervention characteristics.

Conclusions/interpretation

Authors interpretation

The authors state: "Group therapy education, structured and unstructured counseling, and cognitive behavioural therapy offered the most promise for their medium- and long-term benefits for many of the psychosocial outcomes explored". The authors consider that this finding, and the comparative lack of immediate- and short-term findings may be because psychosocial interventions work in the longer term, or may simply be an artifact of the smaller number of trials that assessed long-term effects, whereby one statistically significant trial carries more weight in the review synthesis.

Several strategies could be tentatively recommended for reducing patients' conditioned side effects. However, though a greater number of trials looked at reducing physical side-effects, only relaxation training and guided imagery appeared to provide benefits for most of the side effects explored.

No intervention strategies could be recommended for improving patients' length of survival, though all the strategies which measured immune outcomes appeared to have some medium- or long-term benefits.

Conclusion

The major finding of the effectiveness review stage of this review was that, despite a body of literature that spans more than 40 years and includes more than 150 randomised controlled trials, we could make no strong recommendations and

relatively few tentative recommendations about the effectiveness of psychological intervention strategies at improving cancer patients' outcomes.

Implications for research

The authors make extensive recommendations to maximise the internal validity and reporting of RCTS in this area. The recommendations related to the ten validity criteria applied in the review (concealment of allocation, randomisation, blinding of patients, blinding of care-providers, balancing of groups, monitoring of care-provider adherence, details on loss to follow-up, percentage of patients not in analyses, intention to treat analyses, and blinded measurement of outcomes).

Implications for practice

The authors state: "Although this is one of the most extensive and rigorous literature reviews conducted in this area of research, we can offer only tentative recommendations for or against most intervention strategies overall or within the different follow-up periods"... "Thus, these recommendations should be considered with appropriate caution and should not be seen as supporting the current wide-scale adoption of these strategies".

Quality assessment

Is there a defined search strategy? Yes.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Partially.

Are study designs and number of studies clearly stated? Partially.

Have the primary studies been quality assessed? Yes.

Have the studies been appropriately synthesised? Unclear. 'Vote count' approach undertaken.

Has more than one author been involved at each stage of the review process? Yes.

Reviewer's comment

An adequate search for evidence was undertaken and inclusion criteria, though broad, were appropriate to the stated review question. Validity was assessed using published criteria recommended by the Cochrane Collaboration. Agreement between reviewers on inclusion and quality assessment was assessed using the kappa statistic with a sample of papers, and characteristics of the selected studies were provided in reasonable detail. However, only English language studies were included in the review and the potential influence of publication bias was not assessed.

Studies were combined in the review according to category of intervention. Though the categories specified in the review may have been appropriate no rationale for, or description of, the classification system used was provided. Therefore it is not clear why, for example, 'relaxation training' and 'guided imagery/visualisation' were separate categories in this review, but have been combined in a single group elsewhere.

The authors' recommendations were based on the number of trials reporting statistically significant for each intervention group and outcome. Several recommendations were based upon significant results being reported for only one or two small, 'fair' quality trials. In many cases, the inclusion of just a single small trial reporting a null result would negate the authors' recommendation. This is acknowledged by the authors and they make recommendations with appropriate caution.

Reference Sellick ⁴³ 1999 Canada	Title Depression and cancer: an appraisal of the literature for prevalence, detection, and practice guideline development for psychological interventions. <hr/> Objective/review question To review the literature concerning the prevalence and incidence of depression in cancer, review studies of therapeutic interventions in this area, and make suggestions for practice guidelines for the identification and treatment of depression in cancer patients and survivors.
Literature search The following databases were searched: Medline (1976-1996), CINAHL (1982-1996), HealthSTAR (1985-1996), PsychINFO (1990-1996). Reference lists from journals were scanned for additional relevant articles.	
Inclusion/exclusion criteria <u>Design</u> RCTs. <u>Participants</u> Patients with cancer. <u>Interventions</u> Psychological counselling interventions for depression in cancer. Included interventions that were individually tailored to the individual patient situation of existential concerns; cognitive behavioural structured sessions focusing on skill development in coping or problem solving; or behavioural interventions including relaxation or guided imagery. Studies were excluded if the intervention was limited to information exchange. <u>Outcomes</u> Included studies focused on depression. <u>Other</u> None stated. <u>Study selection procedure</u> Abstracts were reviewed by the authors and studies meeting the criteria were selected for inclusion (no further details given).	
Methods <u>Validity assessment tool</u> Guyatt et al. JAMA 1993; 270: 2598-2601. Evaluated studies on: randomisation, description of randomisation, bias in treatment assignments, sample size calculation, whether all patients accounted for, completeness of follow-up (80%), whether patients were analysed in randomised groups, criteria for measuring outcomes, criteria are objective, blinded outcome assessment, inclusion/exclusion criteria, therapeutic regimen described for each group, statistical analysis-test p value, appropriateness of analysis, size of treatment effect, if study was negative were CI and power calculated? <u>Validity assessment procedure</u> Not stated. <u>Data extracted from primary studies</u> Author, year, country, design, intervention, timing of intervention, sample, expected outcome for depression, instruments measuring depression, timing of measures, counselling practitioner and qualifications, results, suggestions for practice guidelines, limitations. <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Narrative summary. <u>How were studies weighted in the synthesis?</u> None <u>How was publication bias assessed?</u> Not assessed. <u>How was heterogeneity assessed?</u> Not assessed.	
Results <u>Number of studies included in the review</u> 10 RCTs <u>Number of participants</u> >1403 (n in one study unclear) <u>Results of validity assessment</u> Included studies fulfilled between 8 and 11 of the 16 validity criteria. All were randomised, stated criteria for measuring outcomes, and conducted appropriate statistical analysis reporting p values. All but one RCT used objective criteria for measuring outcome. None of the studies undertook a sample size calculation. <u>Main outcome</u> Of the ten included RCTs measuring depression, five reported a large treatment effect, two reported medium-sized effect, two reported a small effect, and one reported no effect (though no definition was given for what constituted a 'large', 'medium' or 'small' effect) In nine of the ten studies, counselling decreased the degree of depression for a varying period of time with effects lasting up to 12 months. Significant positive changes in depression scores from baseline measurements occurred in all treatment groups. Patients reported positive outcomes resulting from the use of new skills and knowledge gained during the counselling intervention. Negative outcomes were not directly addressed, although some patients found relaxation techniques did not work for them and others were too ill to attend sessions. Generally group interventions achieved similar results to individual interventions in the degree of change in depression scores and in sustaining improved mood.	

<p><u>Secondary outcome</u> <u>Other outcomes</u></p> <p><u>Publication bias</u> Not assessed.</p> <p><u>Heterogeneity</u> Important differences between the reviewed studies included: type of intervention evaluated (tailored, structured cognitive behavioural, behavioural), timing and duration of counselling intervention, length of follow-up, practitioner delivering intervention, study sample, and instruments used to measure depression.</p>
<p>Conclusions/interpretation</p> <p><u>Authors interpretation</u> See conclusions.</p> <p><u>Conclusion</u> There is sufficient evidence to credit a counselling intervention with a positive effect on depression for both statistical and clinical significance.</p> <p><u>Implications for research</u> None stated.</p> <p><u>Implications for practice</u> The authors make several recommendations regarding the screening of cancer patients for depression, referral of distressed/high risk patients, consideration of both pharmacological and counselling interventions, training professionals delivering interventions to understand cancer, continuity of care and follow-up.</p>
<p>Quality assessment</p> <p>Is there a defined search strategy? Yes. Is there a well defined question? Partly. Are inclusion/exclusion criteria stated? Yes. Are study designs and number of studies clearly stated? Yes. Have the primary studies been quality assessed? Yes. Have the studies been appropriately synthesised? Unclear. Has more than one author been involved at each stage of the review process? Unclear.</p> <p><u>Reviewer's comment</u> Four electronic databases were searched for relevant evidence, with following up of references from journal articles. The authors do not indicate any other method for identifying relevant studies and it is unclear why the different databases were searched for different time periods. The inclusion criteria were broad but appeared appropriate to the review question. It is not clear whether only English language articles were included in the review and it is unclear how many reviewers were involved at any stage of the review. Aspects of study validity were assessed using a previously published checklist and relevant study details were presented in tables. However, specific information on the size of effects was not given. The approach used to synthesize these studies makes it difficult for any firm conclusions to be drawn regarding the effectiveness of counselling interventions for depression in cancer.</p>

Reference Luebbert ⁴⁴ 2001 Germany	Title The effectiveness of relaxation training in reducing treatment-related symptoms and improving emotional adjustment in acute non-surgical cancer treatment: A meta-analytical review Objective/review question To examine the effectiveness of relaxation training in helping cancer patients undergoing acute medical treatment.
Literature search MEDLINE, PsychINFO, PSYINDEX and CANCERLIT databases (1980-December 1995). Reference sections of located studies, review articles and informal sources were also screened for relevant studies. Information on further relevant studies was obtained by interviewing expert professionals.	
Inclusion/exclusion criteria <u>Design</u> The abstract stated that randomised controlled studies were included in the review. Studies were excluded from the review if they were missing a control group, if dependent studies used the same patients as other studies, if the study was stopped, or it didn't report information needed to calculate effect sizes. <u>Participants</u> Included adult (aged 16 years and older) cancer patients undergoing different medical cancer treatments. Studies were included if patients were undergoing acute medical treatment (e.g. chemotherapy, radiotherapy, bone marrow transplantation). Studies of patients undergoing surgery were excluded. Amongst the studies which gave participant details, the mean age of patients was 50 years (range 32.7-61 years). The mean percentage of participants who were women was 64.4% (range 42.22-100%). <u>Interventions</u> The definition of relaxation training was kept broad, including induction techniques which 'aim to reduce a relaxed physical and mental state' in the patient: PMR with or without guided imagery, hypnosis and autogenic training. Excluded from the review were: intervention packages/programmes, psychological intervention combined with different pharmacological treatments, general psychotherapy, relaxation as part of systematic desensitisation and biofeedback without relaxation training. PMR was used in 87.5% of interventions and PMR was combined with relaxation in 73% of included interventions. In 81.82% of studies, guided imagery was tailored to individual patients' needs. In two intervention groups, PMR was combined with autogenic training. In 86.6% of studies, patients were told to practice at home. The mean number of sessions was 3.6 (range 1-7), with a mean session duration of 40 mins (range 15-90 mins). The mean intervention intensity (overall duration) was 149.1 mins (range 15-360 mins). <u>Outcomes</u> No specific inclusion criteria were specified regarding outcomes. To be included in the meta-analysis, a variable had to be measured in at least two studies. <u>Other</u> It appears studies were excluded if they could not be obtained within a certain timeframe. <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> Not stated. <u>Validity assessment procedure</u> Not stated. <u>Data extracted from primary studies</u> Data were extracted on dependent variables and moderator variables. These variables were organised into categories: Dependent variables - (1) Treatment-related symptoms (including subcategories: nausea, vomiting/emetis, pain, pulse rate, blood pressure), (2) Emotional adjustment (including subcategories: anxiety, depression, hostility, tension, mood, fatigue, confusion, and vigour). Moderator variables - (1) Intervention intensity: high or low intensity (more or less than 120 mins spent with the health professional). (2) Intervention schedule - psychological intervention was administered in conjunction with, or independent of, medical procedures. (3) Intervention focus (chemotherapy, radiotherapy, bone marrow transplantation, and hyperthermia). <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Meta-analysis. Effect sizes (ES) were calculated using the method proposed by Hedges and Olkin (1985) which involves calculating the unit-free effect size g. One average effects size per variable per study was included. <u>How were studies weighted in the synthesis?</u> The effect size g was multiplied by a small sample size correction factor to obtain an unbiased value of d. A weighted mean D(w) was calculated following the single effect sizes depending on variance. <u>How was publication bias assessed?</u> Fail-safe N values were calculated to determine the number of null studies which would be needed to invalidate the summary effects derived from studies in the meta-analysis. <u>How was heterogeneity assessed?</u> Heterogeneity was tested for in the analyses using the Q statistic.	
Results <u>Number of studies included in the review</u> Fifteen studies were included in the review. A total of 56 independent effect sizes were included in the final calculations of the meta-analysis.	

Number of participants

742

Results of validity assessment

Not stated.

Main outcome

Treatment-related symptoms -

Blood pressure (5 studies, 23 ES, n=144): 0.5518 (95% CI: 0.21, 0.89, p<0.05)

Pulse rate (4 studies, 26 ES, n=103): 0.5382 (95% CI: 0.14, 0.94, p<0.05)

Nausea (10 studies, 56 ES, n=399): 0.4545 (95% CI: 0.25, 0.65, p<0.05)

Pain (3 studies, 8 ES, n=96): 0.4383 (95% CI: 0.03, 0.84, p<0.05)

Vomiting (heterogeneous): 0.5451 (95% CI: 0.12, 0.97)

Secondary outcome

Emotional Adjustment -

Depression (6 studies, 24 ES, n=274): 0.5422 (95% CI: 0.30, 0.78, p<0.05)

Tension (2 studies, 5 ES, n=150): 0.5156 (95% CI: 0.19, 0.84, p<0.05)

Anxiety (Heterogeneous. 8 studies, 61 ES, n=351): 0.4511 (95% CI: 0.23, 0.67, p<0.05)

Mood (2 studies, 5 ES, n=151): 0.4421 (95% CI: 0.12, 0.77, p<0.05)

Hostility (6 studies, 27 ES, n=284): 0.3438 (95% CI: 0.11, 0.58, p<0.05)

Fatigue (2 studies, 5 ES, n=150): 0.2366 (95% CI: -0.09, 0.56)

Confusion (2 studies, 5 ES, n=150): 0.2266 (95% CI: -0.10, 0.55)

Vigour (3 studies, 7 ES, n=214): 0.0849 (95% CI: -0.18, 0.35)

Other outcomes

Publication bias

Heterogeneity

All summary effect sizes for treatment-related symptoms were reported to be homogenous, with the exception of vomiting which was not interpreted or further analysed.

The summary effect sizes for all emotional-adjustment measures were homogenous, with the exception of anxiety. Neither the removal of an outlier nor the splitting of the variables into subgroups could resolve this heterogeneity.

Investigation of moderator variables showed a highly significant difference between relaxation training offered independently and that offered in conjunction with medical treatment on anxiety (favouring independent treatment, p=0.0079). There was a tendency towards significant differences favouring low intensity (<2hr) versus high intervention intensity for anxiety (p=0.05). The impact of 'intervention focus' on anxiety could not be assessed since all studies measuring anxiety focused on chemotherapy.

Conclusions/interpretation

Authors interpretation

The magnitudes of effect sizes were interpreted in terms of the Cohen index, i.e. D(w), 0.20 small effect, 0.50 medium effect, 0.80 large effect. The relaxation intervention proved to have a small but significant effect on the treatment-related symptoms of the medical treatment of cancer: nausea and pain. Relaxation training also significantly reduced pulse rate and blood pressure in these patients (medium effect).

Concerning emotional adjustment, relaxation training has a significant (medium) effect on depression and a significant (small) effect in the reduction of anxiety and hostility. The analysis of two studies only indicated a reduction of tension and amelioration of the overall mood state. Apparently relaxation has no effect on patients' levels of vigour, fatigue, or confusion.

The effect of relaxation on the anxiety level of patients depends on two intervention features. First, if relaxation techniques have been learned prior to the acute medical treatment, they reduce anxiety significantly better. Second, relaxation interventions below 2 hours overall intensity (time spent with the professional) have a tendency towards a higher effect on the reduction of anxiety.

Some caution is necessary in assuming that the results apply equally to different populations. The average population represented by this meta-analysis consists of mainly female patients, around the age of 50 with breast, haematological, lymphomas and lung cancer. These patients were treated in an outpatient setting receiving highly emetogenic chemotherapy. They were trained in PMR with individually tailored guided imagery consisting of three sessions at 40 min each, the mean overall duration being 2.5 hours. Most patients were given a relaxation audiocassette or written instructions to practise relaxation at home.

Conclusion

Overall, it can be assumed that relaxation during the courses of cancer treatment makes the experience less stressful in effectively reducing side effects.

Implications for research

Extending the results of meta-analysis by analysing the variance of effectiveness depending on individual factors is a worthwhile target for future research.

Implications for practice

According to these results relaxation training should be implemented into clinical routine for cancer patients in acute medical treatment.

Quality assessment

Is there a defined search strategy? Yes. Four electronic databases, reference lists, contacting authors.

Is there a well defined question? Yes. Specified relaxation therapies in cancer patients receiving acute medical treatment.

Are inclusion/exclusion criteria stated? Yes, but not for outcomes.

Are study designs and number of studies clearly stated? Partly. Numbers are given, but very little information on individual studies is available.

Have the primary studies been quality assessed? No.

Have the studies been appropriately synthesised? Unclear.

Has more than one author been involved at each stage of the review process? Unclear. Not stated by the authors.

Reviewer's comment

The search for relevant studies appeared adequate, with the authors presenting information on search sources, dates and terms. Relevant inclusion criteria regarding the interventions and participants were given, though criteria relating to design and outcomes were unclear. It is not clear how many reviewers were involved at any stage of the review process. No information of individual included studies was presented in the review, making it impossible for the reader to examine aspects of study validity or evaluate the possible presence of clinical heterogeneity between combined studies. Studies appear to have been weighted by sample size in the analysis and statistical heterogeneity was investigated. However, the validity of the primary studies was not systematically assessed or taken into account during the synthesis.

Reference Redd ⁴⁵ 2001 USA	Title Behavioural intervention for cancer treatment side effects Objective/review question To examine the effectiveness of behavioural intervention methods in the control of aversive side effects of cancer treatments.
Literature search Computer search of the PubMed database, including MEDLINE, PreMEDLINE and other related databases (1979-January 2000) in English. The search was also run in PsychLIT, and reference list from previous reviews were examined.	
Inclusion/exclusion criteria <u>Design</u> Randomised controlled studies, within-subject studies, and case reports. <u>Participants</u> A cancer patient population undergoing or having undergone traditional cancer treatment (e.g. chemotherapy, surgery and radiation therapy). <u>Interventions</u> Studies had to include a behavioural intervention. Behavioural components in the selected studies included: relaxation, cognitive/attentional distraction, hypnosis, desensitisation, rehearsal modelling, contingency management, emotive imagery, cognitive restructuring. <u>Outcomes</u> Studies had to include outcome data on the effects of the behavioural intervention on treatment-related side effects. Outcomes measured in the included studies were: anxiety and distress, nausea/vomiting, physiologic arousal and pain. <u>Other</u> <u>Study selection procedure</u> Studies were screened independently by each of the three review authors to ensure that they met the inclusion criteria.	
Methods <u>Validity assessment tool</u> None stated. <u>Validity assessment procedure</u> Not stated. <u>Data extracted from primary studies</u> Data were extracted on: author, number of participants, male/female ratio, diagnosis, control group intervention, experimental group intervention, study design, intervention format (e.g. individual/group), no. and length of sessions, behavioural components and outcomes. <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Narrative summary, categorised by outcome. <u>How were studies weighted in the synthesis?</u> None. <u>How was publication bias assessed?</u> Not assessed. <u>How was heterogeneity assessed?</u> Not assessed.	
Results <u>Number of studies included in the review</u> 54 <u>Number of participants</u> n=1902 <u>Results of validity assessment</u> N/A <u>Main outcome</u> Nausea and vomiting: A series of individual analyses of relaxation and hypnosis to control persistent anticipatory vomiting in chemotherapy patients were included. In that series, the clinician first trained patients to go into a state of deep relaxation and then guided them through relaxation exercises immediately before and during chemotherapy infusions. The intervention was used or withheld during alternative infusions. During those chemotherapy treatments where behavioural methods were implemented, no anticipatory vomiting occurred; however, during those chemotherapy treatments when the behavioural methods were not implemented, anticipatory vomiting occurred. Twelve of 13 randomised controlled trials that compared behavioural interventions with no treatment/attention control conditions also supported the effectiveness of behavioural intervention to control anticipatory nausea and vomiting. In the four identified studies that reported the impact of behavioural intervention on post-chemotherapy infusion side effects, the results were modest. In those studies, behavioural intervention reduced the intensity of post-chemotherapy side-effects, but it did not block their occurrence. <u>Secondary outcome</u> Anxiety and distress: A total of 19 published studies investigated the efficacy of behavioural intervention to reduce acute anxiety and distress associated with diagnostic and treatment procedures. Four out of 5 randomised studies comparing behavioural intervention with no treatment/attention control demonstrated a clear beneficial effect. The remaining 14 used a variety of study designs, including within-subject approaches and case reports. Thirteen of these 14 reported a beneficial effect of behavioural intervention.	

The majority of studies including children incorporated multiple behaviour methods (e.g. distraction, modeling, relaxation, contingency management, and cognitive restructuring) within a behavioural intervention package. Results support the efficacy of such multimodal packages to control anxiety and distress associated with invasive medical procedures. One study found that the children's age predicted which specific behavioural method was most helpful: imaginal involvement through hypnotic procedures appeared to be the critical component of the intervention in younger children.

Similar positive results were reported for adult cancer patients (one study reported that behavioural intervention reduced distress, anxiety and somatic preoccupations in patients receiving radiation therapy). Some included studies reported behavioural intervention to be as effective as pharmacologic interventions in reducing anxiety and depression.

Other outcomes

Pain:

Of the 12 studies investigating the impact of behavioural intervention on cancer treatment-related pain, five were randomised controlled trials with either no treatment or attention control conditions. Four of these five supported the efficacy of behavioural intervention. The seven remaining studies, employing a variety of designs, found a reduction in pain following behavioural intervention. All studies were limited to the control of acute pain.

Publication bias

N/A

Heterogeneity

N/A

Conclusions/interpretation

Authors interpretation

(1) Behavioural intervention can effectively control anticipatory nausea and vomiting in adult and paediatric cancer patients undergoing chemotherapy; however, the evidence for the efficacy of behavioural intervention to control post-chemotherapy nausea and vomiting is less clear. (2) Multimodal behavioural intervention can ameliorate anxiety and distress associated with invasive medical treatments. (3) Although a variety of behavioural methods have been shown to reduce treatment-related pain, increasing evidence demonstrates that these methods are not equally effective. Hypnotic-like methods, involving relaxation, suggestions for reduced pain, and distracting imagery, hold the greatest promise for benefit to the patient.

Conclusion

The results from this review provide strong support for the integration of behavioural intervention into standard care of cancer patients.

Implications for research

The authors state that "identification of the active components of effective behavioural intervention will help to determine how to streamline clinical applications and make them more effective" and that "research on behavioural intervention to control prolonged pain associated with cancer treatment is scant, and this issue demands further study". They also recommend further scrutiny of the cost-effectiveness of behavioural interventions, their positive side benefits for patients and investigation of "less traditional" behavioural methods such as those generated by patients from other cultures.

Implications for practice

The authors state that the results of their review provide strong support for the integration of behavioural intervention into standard care of cancer patients.

Quality assessment

Is there a defined search strategy? Yes, but limited to only published material.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Yes.

Are study designs and number of studies clearly stated? Yes.

Have the primary studies been quality assessed? No.

Have the studies been appropriately synthesised? Unclear.

Has more than one author been involved at each stage of the review process? Partly.

Reviewer's comment

This review provided a useful introduction to behavioural interventions for cancer treatment side effects, but provided only a broad indication of the potential effectiveness of these methods.

Reasonable attempts were made to identify (English-language only) literature through databases and scanning of reference lists. Studies were independently selected by three authors according to selection criteria which were broad, but appropriate to the review question. No validity assessment was undertaken, and though occasional emphasis was placed on the results of RCTs, the potential for confounding and bias inherent in different included study designs and procedures was not generally considered. Study details were presented in tables, though useful detailed information on outcomes was lacking. Three broad outcome categories were used in the review, with no information on the outcome measures used in the included studies presented.

Each study was extracted as showing either a "statistically significant improvement" in favour of the behavioural intervention or a "statistically non-significant improvement". No data was extracted to give an indication of the actual size of reported effects, and consequently it is impossible to assess the relative effectiveness of different interventions.

The narrative summary of the heterogeneous group of included studies according to outcome reported seemed sensible, though differences between interventions were largely ignored, meaning that the authors applied their conclusions to the very broadly defined "behavioural intervention".

Reference Edelman ⁴⁶ 2000 Australia	Title Can psychotherapy increase the survival time of cancer patients? Objective/review question To review the evidence regarding the possibility of a relationship between psychological intervention and survival time of cancer patients or to evaluate the effects of psychological intervention and survival time of cancer patients.
Literature search Medline, PsychInfo, Health Star, CINAHL and Current Contents were searched. Dates were not given.	
Inclusion/exclusion criteria <u>Design</u> Studies that have used "scientifically acceptable methodology". All but one of the included studies were RCTs. <u>Participants</u> Cancer patients. <u>Interventions</u> Psychological intervention (ranged from brief education to CBT). <u>Outcomes</u> Survival time. <u>Other</u> <u>Study selection procedure</u> Not stated	
Methods <u>Validity assessment tool</u> None stated. Aspects of methodological quality were discussed for some individual studies. <u>Validity assessment procedure</u> Not applicable. <u>Data extracted from primary studies</u> Data were extracted on: study details, design, patient group (type of cancer), type of intervention, number of sessions, number of participants in each group, survival outcome (significant or no significant improvement in survival time), other relevant factors. <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Narrative summary. Studies were categorised as those which found a relationship between psychotherapy and survival time, and those who failed to find evidence for such a relationship. <u>How were studies weighted in the synthesis?</u> Not applicable. <u>How was publication bias assessed?</u> Not assessed. <u>How was heterogeneity assessed?</u> Not assessed.	
Results <u>Number of studies included in the review</u> Eight (7 RCTs, 1 matched control study) <u>Number of participants</u> 816 (439 in treatment groups, 377 controls) <u>Results of validity assessment</u> Not applicable. <u>Main outcome</u> Three studies reported a significant increase in survival time for cancer patients receiving psychological intervention. Five studies found no difference in survival between those patients who received psychological intervention and those who did not. <u>Publication bias</u> Not assessed. <u>Heterogeneity</u> Studies differed in terms of the types of cancer patients included, type of intervention, number of sessions, and length of follow-up.	
Conclusions/interpretation <u>Authors interpretation</u> While it is clear that psychological intervention does not necessarily affect patients' survival time, the question of whether it can, under some circumstances do so has not been conclusively demonstrated. <u>Conclusion</u> To date, a direct relationship between psychological intervention and patient survival time has not been conclusively demonstrated. Large-scale replication studies which are currently under way will provide more conclusive evidence on this question within the next few years. <u>Implications for research</u> None stated. <u>Implications for practice</u> None stated.	
Quality assessment Is there a defined search strategy? Yes. Is there a well defined question? Yes.	

Are inclusion/exclusion criteria stated? Only implied in the stated objective.
Are study designs and number of studies clearly stated? Yes.
Have the primary studies been quality assessed? No.
Have the studies been appropriately synthesised? Unclear.
Has more than one author been involved at each stage of the review process? Unclear.

Reviewer's comment

A search of five databases was undertaken, though search dates or other search sources were not mentioned. Inclusion criteria were not stated explicitly but were implied in the review question, though it is unclear what exactly constituted the criterion of "scientifically acceptable methodology". Neither is it clear how many reviewers were involved at any stage of the review. Relevant details of the included studies were presented in the text and tables of the review, though more detail on study outcomes would have been desirable. No formal validity assessment was undertaken, but relevant aspects of methodology were discussed in relation to individual studies. The narrative summary approach seemed reasonable given the small number of heterogeneous studies included in the review. Though some relevant research may have been missed, the authors' conclusions seem relevant given the evidence presented.

Reference Fredheim ⁵⁰ 2001 Norway	Title Kan psykologisk behandling hjelpe kreftpasienter? (Could cancer patients benefit from psychological interventions?) Objective/review question To consider whether psychological interventions are effective as an adjunct treatment for cancer patients by examining recent controlled studies from a methodological perspective.
Literature search MEDLINE, EMBASE, PsychInfo were searched from 1992-2000.	
Inclusion/exclusion criteria <u>Design</u> Controlled studies were eligible for inclusion. All studies found were randomised. Most of the studies compared psychological treatment to normal medical care. Four studies compared different types of psychological intervention. <u>Participants</u> Adult cancer patients only were included. Mean age of patients was 50 and there were various cancer locations. Several (unspecified) studies included patients who were at low risk of suicide and who had low levels of anxiety and depression. Two studies specifically excluded patients with diagnosed psychic illness. In half of the studies the patients in the intervention group had higher levels of depression and anxiety than in the control group(unclear if this was significant). <u>Interventions</u> No specific inclusion criteria were specified. Four main groups of intervention were identified: cognitive therapy, psychoeducational interventions, supportive psychotherapy, relaxation exercises and there were also combinations of treatments. Sessions were between 30 and 90 minutes. Five studies used group and five individual therapy. <u>Outcomes</u> Studies were excluded if they focused solely on extending patient life. Psychological outcomes included: depression, anxiety, self-esteem, psychological stress, locus of control, social support, health beliefs, psychosocial adjustment and difficulties, general symptoms. Medical outcomes included: quality of life, pain, affective disorders. All studies evaluated pain outcomes. <u>Other</u> <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> Not stated. Various aspects of quality were discussed in the text. The reviewers commented that many studies used modified scales which may not have been fully validated. <u>Validity assessment procedure</u> N/A <u>Data extracted from primary studies</u> Author, cancer location, numbers in intervention and control groups, pre-test and posttest details, outcome measures, outcomes, intervention type, duration and delivery and results. <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Narrative summary <u>How were studies weighted in the synthesis?</u> N/A <u>How was publication bias assessed?</u> Not investigated. <u>How was heterogeneity assessed?</u> Not investigated although differences between the studies are highlighted in the text.	
Results <u>Number of studies included in the review</u> 10 controlled studies <u>Number of participants</u> 881 participants <u>Results of validity assessment</u> N/A <u>Main outcome</u> Seven of ten studies showed a reduction in levels of anxiety and depression, increases in quality of life scores, mastery of emotions and fighting spirit, reduced feeling of helplessness, reduced hostility and fewer episodes of somatic pain. Three studies showed insignificant effects or no effect of the psychological intervention. <u>Secondary outcome</u> <u>Other outcomes</u> <u>Publication bias</u> N/A <u>Heterogeneity</u> N/A	
Conclusions/interpretation <u>Authors interpretation</u> <u>Conclusion</u> All of the four main categories of treatment were found to be effective in this review. Changes were consistent at follow up 6-12 months after therapy. It is not clear which components of the interventions work best. Results are unclear as to whether group or individual therapy is superior but a combination of treatments appears to work best.	

Implications for research

Future research needs to address issues of cost-effectiveness, targeting patients who might benefit the most and issues of delivery of the intervention. Better randomisation procedures, more homogeneous selection of cancer types, stages of illness, psychological illness, sex and age in addition to specifying the aim of the intervention. Does better quality of life and reduced psychological illness improve prognosis and survival with different types of cancer?

Implications for practice

Not stated.

Quality assessment

Is there a defined search strategy? Yes, but restricted years asfollowing on from other reviewers' meta-analyses. Only published material.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Unclear.

Are study designs and number of studies clearly stated? Unclear. It appears that all controlled studies were acceptable yet all those found are RCTs.

Have the primary studies been quality assessed? Not formally, comments made in the report.

Have the studies been appropriately synthesised? Yes.

Has more than one author been involved at each stage of the review process? Unclear.

Reviewer's comment

Not sure restriction to 1992-2000 is justified. Search limited to published material. Some lack of clarity on inclusion criteria. Lacking detail on participants. Unclear if review process carried out by more than one reviewer. No formal quality assessment. Some useful pointers for future research.

Reference Trijsburg ⁵¹ 1992 Netherlands	Title Effects of psychological treatment on cancer patients: a critical review. Objective/review question To review empirical evidence on the psychological treatment of cancer patients.
Literature search Studies from an earlier review by Watson (Psychol Med 1983; 13(2): 839-46) were identified. Psychlit and Medline were searched (1976-1990) for further studies.	
Inclusion/exclusion criteria <u>Design</u> Studies that compared one or more experimental condition with at least one control group. <u>Participants</u> Cancer patients. <u>Interventions</u> "Psychological interventions" (included group therapy, individual therapy and counselling, self-help counselling, problem solving, stress and activity management). Studies on the effects of educational programmes or information per se, or self-help groups were excluded. <u>Outcomes</u> Not stated. <u>Other</u> <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> Included studies were assessed in terms of design (experimental conditions, comparability with respect to crucial variables, use of pretesting and post-testing), instrumentation (psychometric measures used), and selection of patients (type of cancer, time since diagnosis, type and timing of medical treatment etc). <u>Validity assessment procedure</u> Not stated. <u>Data extracted from primary studies</u> Data were extracted on: Cancer site, time since diagnosis, type and timing of medical treatment, number of patients in experimental and control groups, inclusion/exclusion criteria, method of group assignment (randomisation, stratification), baseline comparability (medical, demographic and psychological factors), measurement instruments used, refusals and drop-outs, description of intervention, intervention details (duration, frequency, setting, background of counselor/therapist), description of main outcome, outcomes (statistical significance). <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Narrative summary and 'vote-count' of the number of studies reporting a significant effect in favour of each type of intervention. Studies were grouped under "tailored counseling interventions", "structured counseling interventions" and "behavioural interventions and hypnosis". <u>How were studies weighted in the synthesis?</u> None. <u>How was publication bias assessed?</u> Not assessed. <u>How was heterogeneity assessed?</u> Not formally assessed. Differences between included studies were discussed in the text of the review.	
Results <u>Number of studies included in the review</u> 22 (14 RCTs, 8 non-RCTs) <u>Number of participants</u> Unclear (>1379) <u>Results of validity assessment</u> The authors discussed various aspects of validity of the included studies in terms of design, instrumentation and patient selection. For example, 14 of the 22 included studies randomised patients to groups. Eleven studies contained a normal care group. Other control conditions included non-specific attention and different forms of psychological intervention. Twenty-one of the studies measured outcomes that were known to be valid and reliable or could be validated. The basis for patient selection was variable across the studies. The most commonly chosen aspects were: type of cancer, time elapsed since diagnosis, drop-out rate and refusals, and seriousness of the psychological problems. <u>Main outcome</u> Psychological effects: Tailored counseling interventions were effective with respect to distress (six of nine studies reporting positive results), self-concept (4/5 studies positive), and (health) locus of control (2/3 studies). These interventions were the least effective with respect to anxiety (2/8 studies positive), depression (2/9 studies), anger, hostility or confusion (2/5 studies). Overall, 46% of the variables measure showed positive results, whereas 54% were negative. Structured counseling interventions were found to be effective in three studies. Positive effects were shown for depression and distress (2/3 studies each), anxiety (1/3 studies), and self-concept (1/2 studies). Overall, structured types of intervention yielded positive results in 50% of the variables measured.	

Behavioural interventions and hypnosis were effective with respect to anxiety (4/5 studies), depression (1/2 studies), anger, hostility, or confusion (one study) and distress (one study). Overall, positive effects were found in seven out of 10 variables measured.

Secondary outcome

Somatic and other effects:

Tailored counseling was found to have positive effects in 10 out of 19 studies (53%). The effects concerned fatigue (3/6 studies), nausea/vomiting (1/2), weight loss (1/2), activity level (1 study), sexual relations (3/3) and survival (1/2).

Of the six variables measured for structured counseling interventions, four yielded positive effects. These were for leisure activities (1/2 studies), work (1 study), sexual relations (2/2) and activity level (1 positive nonsignificant result).

Positive effects were reported for the three somatic variables measured for behavioural interventions/hypnosis. These were nausea/vomiting (3/3 studies), pain (3/3 studies), and pulse rate/blood pressure (3/3 studies).

Other outcomes

Publication bias

Not assessed.

Heterogeneity

The authors noted that there were "rather great differences" between studies in terms of design, instruments, patient selection, psychological interventions and outcome variables, making it difficult to draw general conclusions regarding the effects of psychological interventions in cancer patients.

Conclusions/interpretation

Authors interpretation

Nineteen of the 22 studies report positive effects of psychological interventions in at least some aspects of the psychological and somatic functioning of patients. Since all studies described used at least one control group, the conclusion is warranted that psychological treatment of cancer patients is beneficial to at least some extent. With the exception of studies using survival analysis, positive effects were found up to about 1 year after the intervention.

Conclusion

Tailored counseling has been shown to be most effective with respect to distress, self-concept, (health) locus of control, fatigue and sexual problems. Studies applying structured counseling have shown positive effects mainly with respect to depression and distress. When behavioural interventions or hypnosis were applied, positive effects were found with respect to specific symptoms such as anxiety, pain, nausea and vomiting. The studies did not control for nonspecific attention (except for some behavioural and hypnosis studies), nor for personality characteristics or social support. The variables measured and patient selection were rather variable across the studies. The replication of studies could be difficult at times due to vague descriptions of the psychological intervention.

Implications for research

The authors recommend that future studies should:

- use precise designs and more restrictive criteria in the selection of patients, treatment targets, psychological interventions and outcome measures.
- control for levels of attention and social support.
- investigate the effects of counseling aimed at strengthening the social support system and assertiveness during contact with the medical profession.
- control for psychological variables (e.g. trait anxiety, neuroticism, level of premorbid functioning).
- study the differential effects of (spaced-out) long-term counseling and short-term interventions. Longer follow-up periods, extending over several years, could yield important findings concerning adaptation and survival.
- study the effects of psychological interventions on patients at risk of psychological distress.
- compare the effects of educational programmes/information with those of psychological interventions.
- compare the effects of self-help groups with psychological interventions.

Implications for practice

None stated.

Quality assessment

Is there a defined search strategy? Yes.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Yes.

Are study designs and number of studies clearly stated? Yes.

Have the primary studies been quality assessed? Partly.

Have the studies been appropriately synthesised? Yes.

Has more than one author been involved at each stage of the review process? Unclear.

Reviewer's comment

Primary research studies were identified from a previous review of the literature with supplemental searching of two electronic databases. No other search sources were mentioned and it is possible that some relevant studies could have been missed. It is unclear whether any language restrictions were imposed, nor is it clear how many reviewers were involved at the selection (or any other) stage of the review. Inclusion criteria were appropriate to the review question and relevant characteristics of the included studies were presented in several tables. However, as with many studies in this area, the term "psychological interventions" was not clearly defined and no statistical details of the study outcomes were presented. The authors acknowledged the considerable heterogeneity between included studies and employed a narrative summary approach which appeared to be appropriate. Aspects of study validity were discussed and formed the basis of sensible recommendations for any subsequent research.

Reference Chow ⁵² 2004 Canada	Title Does psychosocial intervention improve survival in cancer? A meta-analysis. Objective/review question To determine whether psychosocial intervention prolonged survival in cancer patients. The secondary objective was to examine this outcome specifically in patients with metastatic breast cancer.
Literature search The authors searched MEDLINE, EMBASE, CancerLit, CINAHL, and The Cochrane Library databases from inception to June 2002. The citation list of all retrieved articles were examined to identify other potentially relevant articles. Search terms were reported in the paper. Inclusion of papers was not restricted by language.	
Inclusion/exclusion criteria <u>Design</u> Randomised controlled trials (RCTs). Patients in both arms had to receive the same medical care. <u>Participants</u> Patients aged 18 years or older, with cancer of any histology. <u>Interventions</u> 'Psychosocial intervention'. <u>Outcomes</u> Survival data/curves reported. <u>Other</u> Trials had to be published in a peer-reviewed journal. <u>Study selection procedure</u> The selected citations were reviewed independently by two of the investigators.	
Methods <u>Validity assessment tool</u> Jadad AR, Moore RA, Carroll D, et al. Assessing the quality of reports of randomised clinical trials: is blinding necessary? Control Clin Trials 1996; 17: 1-12. The item on double blinding was not applicable to studies of psychosocial intervention. <u>Validity assessment procedure</u> Not stated. <u>Data extracted from primary studies</u> Data were extracted on: authors, year of publication, study location, number of patients randomised to the intervention or control, types of cancer, types of intervention, duration of follow-up on survival and survival rates at one and four years. <u>Data extraction procedure</u> Data were extracted independently by two of the investigators. Any disagreement in abstracted data was resolved by consensus with reference to the published article. <u>How were studies combined in the review?</u> The absolute number of survivors in each group was calculated and the results were pooled using meta-analysis. Revman 4.1 was used to conduct the analysis. Relative risk (RRs) with 95% confidence intervals using the fixed effects model was used. All analyses were conducted on an intention to treat basis. <u>How were studies weighted in the synthesis?</u> Studies appear to be weighted using the inverse-variance method. <u>How was publication bias assessed?</u> Not investigated. <u>How was heterogeneity assessed?</u> Heterogeneity was investigated using the chi-squared statistic. Where significant heterogeneity was found, the random effects model was used to combine the results.	
Results <u>Number of studies included in the review</u> Eight RCTs (including four limited to patients with metastatic breast cancer). <u>Number of participants</u> 1062 (n=511 with metastatic breast cancer). <u>Results of validity assessment</u> Four trials received a score of 2 on the Jadad criteria, and four received a score of 3. The trials that scored 3 provided adequate description of the randomisation procedure and the handling of withdrawals and dropouts. None of the trials were blinded due to the nature of the intervention. <u>Main outcome</u> There was no statistically significant difference in overall survival at one year (p=0.6; RR 0.94 (95% CI: 0.72, 1.22)) nor was there any difference at 4 years (p=0.5; RR 0.93 (95% CI: 0.77, 1.13)). <u>Secondary outcome</u> For the four breast cancer trials, again there was no statistically significant difference in overall survival at one year (p=0.3; RR 0.87 (95% CI: 0.67, 1.14)) and at four years (p=0.3; RR 0.91 (95% CI: 0.76, 1.10)). <u>Publication bias</u> Not investigated <u>Heterogeneity</u>	
Conclusions/interpretation <u>Authors interpretation</u> Due to a small number of randomised studies, one cannot conclude whether psychosocial intervention might work better in a short-term versus long-term program, or in early stage versus late stage of illness in terms of survival. <u>Conclusion</u> Psychosocial intervention does not prolong survival in cancer. This meta-analysis cannot rule out small effect sizes	

because of the small number of trials and trial sizes.

Implications for research

Future studies on survival should also explore the possible mechanisms underlying an improved prognosis.

Implications for practice

None stated.

Quality assessment

Is there a defined search strategy? Yes. Search dates and terms were listed.

Is there a well defined question? Yes. The question was clear in terms of the population of interest, study design, outcome. The intervention of interest was only vaguely defined.

Are inclusion/exclusion criteria stated? Yes. The inclusion criteria are stated explicitly.

Are study designs and number of studies clearly stated? Yes.

Have the primary studies been quality assessed? Yes. The criteria developed by Jadad et al was used.

Have the studies been appropriately synthesised? Yes. The methods used were appropriate to this type of meta-analysis.

Has more than one author been involved at each stage of the review process? Yes.

Reviewer's comment

This was a well conducted meta-analysis, though the authors' conclusions were cautious because of the review's methods (failure to search for unpublished trials, the use of estimated data from survival curves, use of aggregate rather than individual patient data) and problems with the identified literature (only a small number of trials were identified, with only short periods of follow-up, and interventions were not consistent across trials).

APPENDIX 11: DATA EXTRACTION – HEART DISEASE REVIEWS

<p>Reference Dusseldorp²⁷ 1999 Netherlands</p>	<p>Title A Meta-Analysis of Psychoeducational Programs for Coronary Heart Disease Patients</p> <hr/> <p>Objective/review question To assess quantitatively the effects of psychoeducational programmes for CHD patients on cardiac and physical health outcomes. To test the hypothesis that success on proximal targets contributes to a reduction of cardiac mortality and cardiac recurrences. To explore the moderating effects of key study features.</p>
<p>Literature search The reviewers performed a Psychlit and MEDLINE search (1974 - 1998). Reference lists from empirical and review studies found in the search were used to locate further articles. Key words were given.</p>	
<p>Inclusion/exclusion criteria</p> <p><u>Design</u> Controlled studies of a randomised or quasi-experimental design. Quasi-experiments were included only when samples were stratified or matched pairwise or when a certain time period was used as an assignment rule for patients from the same hospital. For risk factors, related behaviours and psychological variables a pretest measurement was required. For studies with multiple comparisons one comparison was selected. Given random assignment the chosen comparison was the one between the most extensive psychosocial treatment versus a standard care condition.</p> <p><u>Participants</u> Patients who had experienced a cardiac event within the 6 months prior to the start of the treatment. A cardiac event was defined as MI, CABG, PTCA or some combination of these. 31 trials had MI patients, 4 had CA and 2 had a mix.</p> <p><u>Interventions</u> Psychoeducational programmes including: 9 health education, stress management and exercise training; 14 health education and stress management; 3 health education and exercise training, 3 health education alone and 8 stress management alone. Both stress management and health education had to include at least one face-to-face session. Information provision not organised systematically was considered standard care. Programmes varied substantially in duration and number of sessions. The average duration was 28 weeks and the average number of sessions was 18 (range 1-234 weeks).</p> <p><u>Outcomes</u> Cardiac outcomes (cardiac mortality, recurrence of MI, CABG, incidence of angina pectoris) and physical health outcomes (blood pressure, cholesterol, weight, and smoking) were included. Studies reporting effects on emotional distress were included only if effects on risk factors, related behaviours, morbidity or cardiac mortality were also reported.</p> <p><u>Other</u> <u>Study selection procedure</u> Two reviewers coded the studies but it is unclear if both were involved in the selection of the studies.</p>	
<p>Methods</p> <p><u>Validity assessment tool</u> Not stated.</p> <p><u>Validity assessment procedure</u> Not applicable.</p> <p><u>Data extracted from primary studies</u> Data was extracted on intervention type, year of publication, use of random assignment and matching, country, type of patient, mean age and gender of patients, exclusion criteria in selection of patients, setting, measurement point of pretest, length of the programme, profession of programme providers, participation of partners, target of the treatment (individual, group or both) and data concerning the quality of the study. Data were coded on computation of effect size, measurement point of each posttest, description and units of measurement, exact results or if not available p values. Details of proximal and distal outcomes were extracted and where a study did not formulate the proximal targets explicitly the following procedure applied: For studies categorised as evaluating stress management measures of emotional distress were considered proximal targets. For health education risk factors and related behaviours were considered proximal targets.</p> <p><u>Data extraction procedure</u> Two independent raters (one methodologist and one health psychologist) coded the study features and effect size data. In the case of a divergence of opinion a third rater (a second health psychologist) chose the most plausible coding.</p> <p><u>How were studies combined in the review?</u> Meta-analysis using Mantel-Haenzel random effects model for OR. WAES combined using Fisher's r-to-z transformation.</p> <p><u>How were studies weighted in the synthesis?</u> Weighted Average Effect Size (WAES) for other outcomes calculated by multiplying study effect size estimates within one measurement period by corresponding sample sizes</p> <p><u>How was publication bias assessed?</u> Not stated.</p> <p><u>How was heterogeneity assessed?</u> Homogeneity was assumed if percentage of observed variance accounted for by sampling error was at least 75% and the chi-square test was not significant. In cases of heterogeneity (with >5 studies) study features were sought that might account for systematic variation in the effect sizes. Success on proximal targets was investigated as a moderating factor. A study feature was considered to be a moderator if its categories (or combinations of categories) identified distinct homogenous sets of study effect sizes.</p>	
<p>Results <u>Number of studies included in the review</u></p>	

37 controlled trials of which 9 were non randomised (quasi experimental - 2 using matching by pairs, four stratified sampling and remaining 3 a certain time period as rule for assigning patients to conditions)

Number of participants

Total: 8988; 7839 (RCT), 1149 (CCT)

Results of validity assessment

Not applicable.

Main outcome

Cardiac Mortality

Estimate of population effect size was significant for the long term (OR = 1.52) and for the part success cluster (OR = 1.44). Effect sizes for the total measurement period were not homogeneous. Success on proximal targets was found to be a moderator (31% versus 14% for studies with no success).

Secondary outcome

MI recurrence

for the total term, medium term and long term periods ORs reflect 20%, 26% and 29% reduction in recurrence of MI. Effect sizes were not homogeneous and success on proximal targets was again found to be a moderator (at 1-10 years follow up 36% versus 2% in studies without success or with only partial success).

CABG and angina

All sets of study effect sizes were homogeneous but the estimated population effect size was significant only for the short term for angina pectoris. (OR = 1.22).

Other outcomes

Risk Factors and Psychological Variables

Population effect size estimates for the risk factors are in general higher than those for mortality and cardiac recurrences.

Systolic BP

Total period: WAES $r = 0.121$ (95% CI, 0.061, 0.180, $p < 0.025$, one tailed)

Total Serum Cholesterol

Significant at all terms but sets of effect sizes not homogeneous.

Total period: WAES $r = 0.249$ (95% CI, 0.100, 0.211, $p < 0.025$, one tailed)

Weight

WAES r significant at all terms and study effect sizes homogeneous.

Total period: WAES $r = 0.088$ (95% CI, 0.027, 0.149, $p < 0.025$, one tailed)

Smoking behaviour

WAES r significant for the total measurement period and for the medium term. At each measurement term population effect size estimates suggested heterogeneity.

Total period: WAES $r = 0.064$ (95% CI, 0.033, 0.095, $p < 0.025$, one tailed)

Medium period (exact studies): WAES $r = 0.233$ (95% CI, 0.171, 0.294, $p < 0.025$, one tailed)

Physical exercise data was based on low quality measurement and no single indicator could be determined. Moderator variables were not found and heterogeneity was a problem. The same problems were found with healthy eating data. For anxiety and depression all sets of study effects were homogeneous but the WAES r was not significant for any of the measurement terms.

Cohen's kappa for study classification was 0.85.

Publication bias

Not applicable.

Heterogeneity

Not stated.

Conclusions/interpretation

Authors interpretation

Psychoeducational programmes show promising effects but several methodological limitations of the review should be noted. The quality of measurement of risk factors and related behaviours is low and in the case of smoking is based on self report. Only published material has been included in this review which may have led to overestimates of treatment effect.

Conclusion

Psychoeducational programmes can reduce cardiac mortality and recurrence of MI and have positive effects on risk factors and related behaviours. Cardiac rehabilitation programmes which are successful on proximal targets (known risk factors and related behaviours) are more effective on distal targets (cardiac mortality, recurrence of MI) than programmes without success on proximal targets. The lack of effects on anxiety and depression may have been due to the inclusion of two recent trials which showed null findings. However an effect on anxiety and depression cannot be dismissed.

Implications for research

Not stated.

Implications for practice

Psychoeducational programmes in cardiac rehabilitation should be developed. Risk factor modification and reduction of emotional distress should be targeted in CHD patients to decrease their chances of a fatal or nonfatal recurrence of MI. The development of these programmes should be based on theory-driven research focusing on the relationship between specific components of the intervention and changes in proximal and distal targets related directly to the needs of the individual patient.

Quality assessment

Is there a defined search strategy? Yes, although based on 2 databases and reference checking.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Yes for all categories.

Are study designs and number of studies clearly stated? Yes.

Have the primary studies been quality assessed? No.

Have the studies been appropriately synthesised? Yes, with a variety of subgroup analyses.

Has more than one author been involved at each stage of the review process? Yes for data extraction but unclear for selection.

Reviewer's comment

The review addresses clear questions with defined inclusion criteria for study design, participants, interventions and outcomes. The search was appropriate but limited to 2 databases and reference checking. Only published material was included and no checks were made for publication bias. No validity assessments were performed. Data extraction was performed by 2 reviewers and appears to be thorough. The reviewers tested for heterogeneity and noted where results were based on heterogeneous studies. Random effects models were used in meta-analysis. Subgroup analysis was carried out to clarify effects over the short, medium and total time periods. Studies were appropriately synthesised and the authors provided reasons for combining randomised and nonrandomised studies in meta-analyses. The reviewers' conclusions appear to be robust but where based on heterogeneous data should be interpreted with caution.

Reference Linden ²⁹ 1996 Canada	Title Psychosocial Interventions for Patients with Coronary Artery Disease
Objective/review question To discover whether the addition of psychosocial interventions improves the outcome of standard rehabilitation programmes for patients with coronary artery disease.	
Literature search The reviewers searched MEDLINE, checked reviews for references and checked the reference lists of articles they had found. No search dates or key words were given.	
Inclusion/exclusion criteria <u>Design</u> Randomised controlled trials <u>Participants</u> Participants needed to have documented coronary artery disease at the time of treatment assignment. Eighteen of the 23 studies used only patients who had suffered an MI, one study included patients after the occurrence of MI who underwent coronary artery bypasses and the remainder included all patients with documented CAD. <u>Interventions</u> At least one treatment condition in which patients were offered psychosocial treatment in addition to usual care, control conditions. In 13 of the 23 studies patients were explicitly identified as being pharmacologically treated in line with current practice and in the other studies this was assumed although it was not explicitly stated. In six studies the usual care included an exercise programme in addition to medication. <u>Outcomes</u> No specific inclusion or exclusion criteria for outcomes are given. However outcomes studied were: anxiety, depression, biological risk factors, mortality and recurrence of cardiac events. <u>Other</u> The reviewers wished to include the Recurrent Coronary Prevention Project (RCPP). However in the RCPP patients were randomised into the two active psychosocial treatment conditions but the control group had not been randomised largely because of ethical reasons. The reviewers therefore analysed the data both with and without the RCPP study. <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> Not stated. <u>Validity assessment procedure</u> Not stated. <u>Data extracted from primary studies</u> Data were extracted on: type of intervention, sample size, therapists performing the intervention and available clinical end points. Anxiety and depression were combined as a single measure of psychological distress. <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Meta-analysis using one effect size per category per study. Log-adjusted, cross-product ORs were calculated and the Mantel-Haenzel statistic was calculated. <u>How were studies weighted in the synthesis?</u> Studies were weighted by degrees of freedom using Rosenthal's formula Weight= N-3 <u>How was publication bias assessed?</u> Not stated. <u>How was heterogeneity assessed?</u> Clinical - No exploration of differences in interventions. Follow up data were clustered into follow up of 2 years or less and more than 2 years. Statistical - tested but no name given.	
Results <u>Number of studies included in the review</u> 23 including RCPP trial <u>Number of participants</u> 3180 (RCTs and RCPP trial (number not given)) <u>Results of validity assessment</u> Not applicable. <u>Main outcome</u> Psychological distress In 14 of 15 studies a benefit of psychosocial intervention was shown. E: -0.30 (0.37), C: -0.04 (0.16) (p< 0.001) <u>Secondary outcome</u> Biological risk factors Systolic BP (4 studies): E: -0.14 (0.22), C: -0.10 (0.05) (p<0.05) Diastolic BP(4 studies): E: -0.07 (0.09), C: -0.04 (0.17) (p=0.12) HR (5 studies): E: -0.30 (0.17), C: -0.08 (0.17) (p<0.01) Cholesterol level (4 studies but huge difference between number in treatment group vs. control group E: 934, C: 59): E: -0.59 (0.62), C: -0.95 (0.15) (p<0.01) <u>Other outcomes</u> Morbidity RCTs only <2 years (8 studies)	

Log OR 1.84 (95% CI: 1.12, 2.99, p=0.02)
> 2 years (3 studies)
Log OR 1.64 (95% CI: 1.06, 2.54, p=0.02)

Controlled trials including RCPP
< 2 years (10 studies)
Log OR 2.29 (95% CI: 1.56, 3.58, p<0.001)
> 2 years (5 studies)
Log OR 1.28 (95% CI: 0.91, 1.80, p=0.16)

Mortality
RCTs only
<2 years (10 studies)
Log OR 1.70 (95% CI: 1.09, 2.64, p=0.02)
> 2 years (3 studies)
Log OR 1.35 (95% CI: 0.83, 1.53, p=0.13)

Controlled trials including RCPP
< 2 years (12 studies)
Log OR 1.76 (95% CI: 1.16, 2.69, p=0.001)
> 2 years (5 studies)
Log OR 1.39 (95% CI: 1.03, 1.88, p=0.04)

Publication bias

Not applicable.

Heterogeneity

Not stated.

Conclusions/interpretation

Authors interpretation

The number of studies contributing to the long term effects on morbidity and mortality was low which may not be a true reflection of weak effects but of lack of power to determine larger effects.

Conclusion

The addition of psychosocial treatments to standard cardiac rehabilitation programmes reduces mortality and morbidity, psychological distress and some biological risk factors. The benefits were clear during the first two years but then became weaker. Much of the observed benefit is attributable to shared nonspecific therapy factors such as emotional support, establishment of hope and a sense of control. More lengthy interventions that are spread over a long time especially when individually tailored will lead to the greatest benefits. Although a formal cost-benefit evaluation was not performed costs were found to be small even for lengthy treatments.

Implications for research

There is an urgent need to identify the most effective types of psychosocial interventions via controlled research. They should also identify which patient is likely to benefit the most from which treatment. Trials should include measures of biological risk as outcomes.

Implications for practice

The reviewers recommend the inclusion of psychosocial treatments in cardiac rehabilitation.

Quality assessment

Is there a defined search strategy? Yes, but it is just MEDLINE and reference checking.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Yes, except for outcome inclusion and exclusion criteria.

Are study designs and number of studies clearly stated? Yes, but it is not possible to ascertain the numbers in the control group of the RCPP trial.

Have the primary studies been quality assessed? No.

Have the studies been appropriately synthesised? Unclear, interventions are diverse so perhaps should not have been combined even when outcome data is the same.

Has more than one author been involved at each stage of the review process? Unclear for all stages.

Reviewer's comment

This review had a clear question with defined inclusion and exclusion criteria for participants and interventions. Outcome criteria were not pre-specified and study design criteria were relaxed to allow inclusion of the RCPP trial. Data were, however, analysed with and without this large trial. The search strategy was limited to one database and reference checking and therefore may have missed relevant studies. No assessment of publication bias was performed, nor was there an assessment of study quality. It is unclear how many reviewers were involved at each stage of the review. Meta-analysis was appropriate in terms of sufficient numbers of studies having similar outcomes. However interventions were diverse and this meta-analysis does not highlight which were more effective.

Reference Sebregts ³⁰ 2000 Netherlands	Title Risk factor modification through nonpharmacological interventions in patients with coronary heart disease Objective/review question To ascertain whether nonpharmacological interventions help modify risk factors in patients with CHD and if so whether this leads to a reduction in mortality and morbidity or to improvements of atherosclerotic stenosis.
Literature search The reviewers searched MEDLINE and PSYCHLIT and checked the reference list of articles found. No search dates are given. Key words are listed.	
Inclusion/exclusion criteria <u>Design</u> Studies needed to have one or more control conditions and random assignment to conditions. <u>Participants</u> Patients with established CHD (angiographically documented coronary artery disease) or patients who had undergone percutaneous transluminal coronary angioplasty (PTCA), AMI or coronary artery bypass grafting (CABG) <u>Interventions</u> Nonpharmacological interventions aimed at CHD risk factor modification. Interventions included counselling/advice, cognitive-behavioural approaches and those aimed at direct risk factor reduction such as exercise training or lipid lowering diets. <u>Outcomes</u> Modification of one of the risk factors (smoking, serum cholesterol, physical exercise, type A behaviour, hypertension or body weight), reduction in mortality and morbidity or improvements of atherosclerotic stenosis. Studies focusing on multiple risk factor modification were included only if one of the risk factors was the main object of change. <u>Other</u> <u>Study selection procedure</u> Details of numbers of reviewers and methods of selection are not given.	
Methods <u>Validity assessment tool</u> No validity assessment appears to have been performed. <u>Validity assessment procedure</u> <u>Data extracted from primary studies</u> Type of intervention, number of patients, length of follow up and main results. <u>Data extraction procedure</u> No details of the data extraction procedure are given. <u>How were studies combined in the review?</u> Narrative summary. <u>How were studies weighted in the synthesis?</u> Studies do not appear to have been weighted. <u>How was publication bias assessed?</u> Publication bias was not assessed <u>How was heterogeneity assessed?</u> Heterogeneity was not assessed. Results are presented according to risk factor.	
Results <u>Number of studies included in the review</u> 23 RCTs (of which 7 are psychological interventions) <u>Number of participants</u> 1699 in psychological intervention RCTs(527 smoking cessation and 1172 modification of type A behaviour) <u>Results of validity assessment</u> Not applicable. <u>Main outcome</u> Smoking cessation Two of the three psychological interventions for smoking cessation (one advice and telephone contact, the other multicomponent behavioural intervention) showed significant results with larger numbers of smokers quitting in the experimental groups than the control groups. For one of the studies results were only statistically significant when severity of disease was taken into account. A third study of a cognitive behavioural intervention showed no significant differences between groups at 1 and 5.5 years. <u>Secondary outcome</u> Modification of Type A behaviour All three trials (two of cardiac counselling with Type A behavioural counselling, one a behavioural intervention aimed at reduction of Type A behaviour and psychosocial risk factors) had significant results for reduction of Type A behaviour. <u>Other outcomes</u> Results of interventions aimed at reduction of serum cholesterol and increase of exercise are not described here as they relate to non-psychological interventions. <u>Publication bias</u> Not applicable. <u>Heterogeneity</u> Not applicable.	
Conclusions/interpretation <u>Authors interpretation</u> Behaviourally oriented interventions showed positive results in smoking cessation in AMI patients but less favourable	

results were found for CABG patients. Modification of Type A behaviour can be achieved through interventions based on multiple cognitive-behavioural techniques. Reduction in type A behaviour may lead to reduced morbidity in AMI and CABG patients. The lack of significant reductions in cardiovascular mortality or morbidity in some trials may be explained partially by their sample size being too small to detect any clinically significant differences. There are issues of motivation in that there may be selective dropout of those less motivated to make long term lifestyle changes.

Conclusion

Conclusions are based on all nonpharmacological interventions. Behavioural modification of each separate risk factor may add considerably to usual care in coronary patients. However programmes which focus on the modification of all important risk factors may be more effective. Additionally, patients should be selected for a particular programme that is most appropriate for their individual needs.

Implications for research

There is a need for well-designed studies focusing on smoking cessation in coronary patients. Hypertension and obesity studies aimed at secondary prevention are lacking.

Implications for practice

Considerable attention should be paid to all important risk factors as programmes focused on modification of multiple risk factors may be more effective.

Quality assessment

Is there a defined search strategy? Yes, but no dates are given and only two databases and reference checking are used. It is unclear if unpublished material or non-English language material was acceptable.

Is there a well defined question? Yes, but the review is not just based on psychological interventions, it also includes other nonpharmacological interventions.

Are inclusion/exclusion criteria stated? Yes, for all categories

Are study designs and number of studies clearly stated? No. The authors refer to studies not included in the review.

Tables provide some detail but do not give methods of randomisation.

Have the primary studies been quality assessed? No.

Have the studies been appropriately synthesised? Yes although no weighting or heterogeneity testing.

Has more than one author been involved at each stage of the review process? Unclear at all stages.

Reviewer's comment

This review has a defined question and inclusion criteria for study design, participants, intervention and outcomes. It includes other nonpharmacological interventions in addition to psychological ones. The search is limited with just two databases and reference checking. There may be publication bias as the inclusion of unpublished or non-English language material was not discussed. No validity assessment was performed although all studies appeared to be RCTs suggesting better quality evidence was used. Larger studies were not given extra weight in the narrative discussion. It is unclear if more than one author was involved in each stage of the review process. Some of the conclusions of this review are based on a small number of trials and therefore should be interpreted with caution.

Reference Moore ³³ 1997 USA	Title Effects of Interventions to Promote Recovery in Coronary Artery Bypass Surgical Patients Objective/review question To critically review the available research on the effectiveness of interventions that aim to promote recovery after coronary artery bypass surgery and to identify limitations and gaps which future research should address.
Literature search The following sources were searched: MEDLINE Express, CINAHL and Psychlit Journal Articles (all from 1980 to 1996). The search only encompassed published material.	
Inclusion/exclusion criteria <u>Design</u> The review included only experimental studies with control or comparison groups. However related review summaries and meta-analyses were also analysed. <u>Participants</u> The review focused on adults recovering from CABG surgery. <u>Interventions</u> The review excluded studies of the effectiveness of cardiac rehabilitation programmes and studies of the effectiveness of hemodynamic monitoring techniques and endotracheal suctioning. Theoretical frameworks were used to formulate the interventions in nine studies. <u>Outcomes</u> No specific inclusion criteria are given for outcomes. A range of outcomes both medical and psychological are included. <u>Other</u> Studies were restricted to those published in the English language including one published dissertation. <u>Study selection procedure</u> Details of the selection procedure are not given but it appears that one reviewer selected studies for inclusion in the review.	
Methods <u>Validity assessment tool</u> The reviewer does not appear to have performed a validity assessment. <u>Validity assessment procedure</u> <u>Data extracted from primary studies</u> Data are available on the nature of the intervention, assignment to groups (I.e if randomised), study design, sample size, outcomes studied, when outcome measures were taken and effectiveness of the intervention (coded as + for effective, P for partially effective and 0 for not effective). <u>Data extraction procedure</u> One reviewer performed the data extraction. <u>How were studies combined in the review?</u> Narrative summary. <u>How were studies weighted in the synthesis?</u> Studies do not appear to have been weighted. <u>How was publication bias assessed?</u> Publication bias was not assessed. <u>How was heterogeneity assessed?</u> Heterogeneity was not assessed but interventions were grouped into those for in-hospital recovery, discharge / home care for home recovery and information and behavioural interventions for risk factor modification.	
Results <u>Number of studies included in the review</u> 19 (14 RCTs, 5 CCTs) all of which used convenience samples. <u>Number of participants</u> 1348 (RCTs - 956 (2 trials no numbers given), CCTs - 392) <u>Results of validity assessment</u> Not applicable <u>Main outcome</u> Mood states Preoperative preparatory information + Pre-admission education + Pre-admission self instruction 0 Music, visual imaging, scheduled rest Day 2 0, Day 3 + for pre-post Teaching and counselling with telephone follow up 0 Slide presentation and telephone coaching 0 at 1,4,8,12 and 24 weeks Audiotaped discharge information 0 Role supplementation programme + for psychological adaptation. <u>Secondary outcome</u> Physical Functioning Preadmission self instruction - physical activity 0 Audiotaped discharge information + at 1 month post-op Psychoeducational programme including telephone counselling + for activity such as lifting and walking, P for self efficacy Slide / tape teaching and counselling programme with telephone follow up P for self efficacy and 0 for activity <u>Other outcomes</u> Other Medical Outcomes Post-surgical physical measures Pre-operative preparatory information 0 for recovery at 7th post-op day, + for BP at 12 hr post-op	

Pre-admission preoperative education + for recovery at 4 to 6 days post-surgery
Music, visual imaging and scheduled rest 0 for BP and HR
Inpatient cardiac education + for post-op recovery at 7th day
Post-operative analgesic use
Pre-operative preparatory information 0
Pre-operative and postoperative counselling Days 1-2 0, Days 3-4 +
Pre-admission self instruction 0

Length of hospital stay
Pre-operative preparatory information 0
Pre-operative and postoperative psychological counselling +
Complications
Preoperative and postoperative psychological counselling + for medical complications and 0 for psychological complications
Angina
Structured teaching programme on self care after surgery +
Quality of life
Psychoeducational programme including telephone counselling 0

Other Psychological Outcomes

Knowledge of CAD and expected home recovery experience
Inpatient cardiac education programme + at 7th post-op day
Supportive / educative programme with telephone follow up +
Structured teaching programme +
Structured teaching programme on self care after surgery 0
Inpatient teaching post-discharge with telephone follow up 0

Risk factor modification

Nurse directed education and behavioural intervention 0 for cigarettes and body composition and physical activity, P for dietary intake 1 year post-operatively
Structured teaching programme + at 6 weeks postoperatively
Role supplemental programme P for regimen compliance
Slide / sound teaching programme 0 at 1 and 3 months postoperatively
Structured programme on self care P

anxiety

Preadmission preparatory programme 0
Music, visual imaging and scheduled rest 0
Supportive education with telephone follow up + at 6 weeks postoperatively
Slide / sound teaching programme 0
Postcardiotomy psychosis or delirium
Structured family involvement P
Preoperative preparatory information +

Family functioning

Role supplemental programme 0 for marital adjustment at 10 weeks and 6 months postoperatively
Slide / tape teaching and counselling with telephone follow up 0 for family functioning at 3 and 6 months
Return to work
Structured programme on self care after surgery 0 at 1 year postoperatively
Satisfaction with teaching
Inpatient teaching with postdischarge telephone follow up and post-discharge group teaching 0

Publication bias

Not applicable.

Heterogeneity

Not applicable.

Conclusions/interpretation

Authors interpretation

Preparatory information effectively increased knowledge and enhanced resumption of activities during recovery. Its effect on mood states remains unclear. Interventions seeking to increase knowledge about coronary artery disease and expected recovery experiences were effective. Education to enhance compliance with medical regimens and risk factor modifications was found to be effective for some behavioural changes but no for others.

Conclusion

There is a need for further research as described in the implications.

Implications for research

Secondary prevention of cardiac risk factors should be investigated, in particular ascertaining the social and psychological variables which influence long-term behaviour change for risk reduction. The reviewer points out that women, elders and minority races were underrepresented in the included studies. Future research should ensure that control groups are carefully monitored. Future interventions should include variables which might explain the mechanisms by which interventions work. A broad measure of comorbidity should be used to control this variable in CABG recovery studies. Multiple measurement points would also provide information about effectiveness over time. More information is needed on the effectiveness of preparatory information so that clinicians could tailor information to specific clinical groups. Future interventions should test the effectiveness of interventions for shorter LOS patients, those with multiple intervention

procedures in addition to CABG and those having minimal surgical techniques.

Generally, there is a need to build knowledge that is highly generalisable.

Implications for practice

the addition of a behavioural component to educational / counselling interventions may be appropriate for behaviour modification interventions.

Quality assessment

Is there a defined search strategy? Yes, but only published material and English language.

Is there a well defined question? Yes, but it is a very broad question

Are inclusion/exclusion criteria stated? Partially - study design and participants are clearly stated but intervention is less clear and outcomes not defined.

Are study designs and number of studies clearly stated? Yes

Have the primary studies been quality assessed? No

Have the studies been appropriately synthesised? Unclear. A narrative summary was appropriate but not all data was described in the text.

Has more than one author been involved at each stage of the review process? No

Reviewer's comment

There are a number of problems with this review. The review question was very broad with a variety of interventions and outcomes. Searching was restricted to published material which may have introduced publication bias. Only English language material was considered, which may have missed relevant studies. No quality assessment was performed and equal weight was given to studies irrespective of sample size and study design. Studies were appropriately synthesised narratively as they were heterogeneous in terms of interventions and outcomes. This broad-based review raises several implications for future research.

Reference Nunes ³⁶ 1987 USA	Title Psychologic treatment for the Type A behavior pattern and for Coronary Heart Disease: A Meta-Analysis of the Literature <hr/> Objective/review question To discover whether psychological interventions reduce Type A behaviour pattern and if so which treatments might be the most powerful. To consider whether psychological interventions improve the prognosis for CHD morbidity and mortality if so which treatments work best.I
Literature search The reviewers searched MEDLINE and examined the bibliographies of located articles. No dates are reported. No further details are given.	
Inclusion/exclusion criteria <u>Design</u> Controlled studies <u>Participants</u> No inclusion criteria are given but all studies deal with patients with TABP and / or those at risk of CHD morbidity and mortality. <u>Interventions</u> No specific inclusion criteria are listed but the review included: education about CHD (EC), Education about TABP (ET), Relaxation Training (RT), Cognitive therapy (CT), Imaging (IM), Behaviour Modification (BM), Emotional support (ES) and Psychodynamic interpretation (PD). <u>Outcomes</u> No specific inclusion criteria for outcomes are given but all studies tested the hypothesis that psychological interventions reduce TABP and / or CHD morbidity and mortality. <u>Other</u> Published studies. <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> The reviewers do not appear to have performed a validity assessment. <u>Validity assessment procedure</u> Not applicable. <u>Data extracted from primary studies</u> The reviewers calculated mean effect sizes (ES) for TABP scores (averaging diverse measures where appropriate), CHD morbidity and mortality (at 1 year and at 3 years after treatment) and angina pectoris frequency. <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Meta-analysis <u>How were studies weighted in the synthesis?</u> In instances of serious methodological flaws the reviewers adjusted the ESs where possible or excluded the flawed studies and then recalculated a 'corrected' mean ES or combined probability. <u>How was publication bias assessed?</u> Publication bias was assessed using the 'Fail-Safe N' method. <u>How was heterogeneity assessed?</u> Clinical heterogeneity is noted and discussed by the reviewers.	
Results <u>Number of studies included in the review</u> 18 controlled studies <u>Number of participants</u> 1977 in 17 studies, 1 study N unknown. <u>Results of validity assessment</u> Not applicable. <u>Main outcome</u> TABP Mean effect size (based on 10 studies): 0.61(95% CI: 0.41, 0.81, p <0.001) No single treatment modality correlates significantly with TABP ES but treatments with more modalities correlate significantly with TABP ES (r = 0.48, t = 2.14, p <0.05). Corrected Mean Effect Size (correcting RCPP and omitting four methodologically flawed studies) 0.57 (95% CI: 0.21, 0.93, p<0.001) <u>Secondary outcome</u> CHD Morbidity and Mortality (based on 9 studies) Deaths 1-year Mean Effect size 0.44 (95% CI: 0.26, 0.62) Corrected Mean Effect Size (based on 5 studies) 0.34(95% CI: -0.07,0.75) Combined Significance Probability 0.15 MIs 1-Year Mean Effect size 0.32 (95% CI: -0.03, 0.67) Corrected Mean Effect Size 0.45(95% CI: -0.14, 1.04) Combined Significance Probability 0.05	

Death + MI 1 Year

Mean Effect size 0.51(95% CI: 0.04, 0.98)

Corrected Mean Effect Size 0.57(95% CI: -0.85, 1.29)

Combined Significance Probability 0.05

Death + MI 3 Year

Corrected Mean Effect Size 0.97(95% CI: -0.04, 2.34)

Combined Significance Probability 0.0001

Other outcomes

Angina

(based on 6 studies)

Mean Effect size 0.43 (95% CI: -0.95, 0.91)

Combined Significance Probability 0.004

Publication bias

35 null studies would be needed to bring the mean effect size close to zero for TABP when all 10 studies were pooled.

Based on the corrected estimate the 'fail-safe N' is 5. For CHD morbidity and mortality 3 null studies can be added before the significance level approaches the Bonferroni criterion ($p = 0.001$) and 18 null studies can be added before approaching the standard criterion ($p = 0.05$).

Heterogeneity

Not applicable.

Conclusions/interpretation

Authors interpretation

Many of the included studies used self report measures which may be more prone to bias. Another problem was that they did not necessarily use TABP measures that are validated predictors of CHD. Most of the study participants were well motivated, male, middle-aged volunteers which limits the generalisability of the results. The finding that after 3 years the combined reduction in mortality and myocardial infarction was reduced by 50% should be interpreted with caution as it is based only on 2 studies.

A combination of treatment techniques is most effective in reducing TABP and CHD recurrences.

Conclusion

Psychological interventions reduce TABP and may improve the clinical outcome of CHD but this merits further study. A comprehensive approach addressing a number of different facets of the TABP is most effective. However the largest TABP effect sizes were for treatments educating participants on TABP or cognitive therapy. Treatment of TABP may be more evident for effect on CHD at 3 years which suggest a need for longer follow up. Psychological interventions may be effective for reduction of angina pectoris.

Implications for research

Further study is needed on the impact of psychological interventions on TABP and CHD. Future studies should avoid self reported measures and should use validated predictors of CHD. The studies should be of sufficient duration (follow up of at least 3 years) to determine whether improvements in TABP are sustained over time. They should follow a variety of clinical outcome measures and the full complement of CHD risk factors. A more diverse range of participants should be investigated including women and the elderly. Primary prevention of CHD through interventions for TABP should be investigated.

Implications for practice

Clinicians should seriously consider the inclusion of psychological treatments in the routine care of post-MI and other CHD patients.

Quality assessment

Is there a defined search strategy? Yes, but it is limited to MEDLINE and reference searching.

Is there a well defined question? Yes

Are inclusion/exclusion criteria stated? Only for study design, unclear on other variables.

Are study designs and number of studies clearly stated? Not always clear how many studies each analysis is based on.

Have the primary studies been quality assessed? No.

Have the studies been appropriately synthesised? Unclear. The studies do not appear to have been weighted for sample size.

Has more than one author been involved at each stage of the review process? Unclear

Reviewer's comment

Inclusion criteria are not well defined. The search is limited to MEDLINE and reference checking which may have missed studies. No formal validity assessment appears to have been performed but methodologically flawed studies are omitted from certain analyses to obtain a more reliable effect size. It is unclear how many reviewers were involved in the review process at each stage. Studies were appropriately combined in meta-analysis although no subgroup analysis by intervention was performed. Studies do not appear to have been weighted despite their differences in sample size. Heterogeneity was not formally assessed. Publication bias was assessed which lends some credence to the results.

Some results are based on a small number of studies and should therefore be interpreted with caution.

Reference Mullen ³⁷ 1992 USA	Title A Meta-analysis of Controlled Trials of Cardiac Patient Education
	Objective/review question To answer 4 questions: What methods of education have been the subject of controlled trials? What is the overall effect of patient education on adherence to therapeutic regimen and morbidity and mortality for coronary artery disease? What are the relative effects of various methods of education? What are the major gaps and innovations in the design of patient education for CHD?
Literature search MEDLINE (1971-1990), Health Planning and Administration File (1979-1990), Sociological Abstracts (1971-1990), Books in Print (1971-1990), Dissertation Abstracts (1971-1990) and Booksinfo (1971-1990). A range of keywords was used. The bibliographies of retrieved studies and the databases of the National Heart, Lung and Blood Institute and the Veterans Administration Health Services Research and Development Section were also searched.	
Inclusion/exclusion criteria <u>Design</u> Overall sample size needed to be at least 10 in each experimental group at the end of the follow up period. Randomised, quasi-experimental comparison group design or a one group pre-test posttest design. <u>Participants</u> Adult patients diagnosed with coronary artery disease, including MI, CABG surgery and angina. 15 of the 28 controlled studies were with patients aged 65 years or over, 12 were with younger adults and 1 was with a mixed population. <u>Interventions</u> Psychosocial or educational interventions were included. <u>Outcomes</u> No inclusion criteria for outcomes is stated. <u>Other</u> Foreign language publications not included as no resources to translate them. The review included both published and unpublished studies. <u>Study selection procedure</u> The reviewers do not state how the papers were selected for review or how many reviewers performed the selection.	
Methods <u>Validity assessment tool</u> No assessment of study quality was performed. <u>Validity assessment procedure</u> Not applicable. <u>Data extracted from primary studies</u> The following intervention characteristics were coded: contact frequency and total length of contact, channel of learning, use of specific educational techniques, educational emphasis and rating according to five principles of education (relevance, individualisation, feedback, reinforcement and facilitation). Data provided in the paper includes: intervention description, participant details, design, follow up, education rating and clinical and behavioural effect size estimates. <u>Data extraction procedure</u> A coding scheme was developed (based on Sackett and Haynes 1976) and three raters worked in rotating pairs to code the studies. <u>How were studies combined in the review?</u> Meta-analysis. For the four studies with multiple intervention groups and a single control group, the intervention with the highest education rating was selected. One group of pretest-posttest studies were subsequently excluded due to their significantly larger effect sizes. <u>How were studies weighted in the synthesis?</u> WAES was calculated based on sample size and variance of individual study size. <u>How was publication bias assessed?</u> Not assessed. <u>How was heterogeneity assessed?</u> A chi squared test of heterogeneity was performed. Where groups were found to be heterogeneous (p greater than or equal to 0.05) interventions with outlier effect sizes were removed from the WAES. Because such outlier values might have resulted from unusually strong or innovative interventions, they were carefully considered. Test of differences between or among subgroupings of studies were conducted using an ANOVA analogue based on homogeneity testing.	
Results <u>Number of studies included in the review</u> 38 studies (47 interventions): 28 controlled studies (of which 15 randomised, 7 matched comparison and 6 non-matched comparison) and 10 single group pre-test posttest. <u>Number of participants</u> 4967(4500 in controlled studies, 467 in single group pre-test posttest). <u>Results of validity assessment</u> Not applicable. <u>Main outcome</u> Clinical Outcomes Blood Pressure (all 5 studies homogeneous) WAES = 0.51 (95% CI: 0.24, 0.77) Drug adherence (all 3 studies homogeneous) WAES = -0.09 (95% CI: -0.39, 0.22) Mortality (7 studies, one outlier study removed to achieve statistical homogeneity - Maelund 1987) 0.24 (95% CI: 0.14, 0.33) Morbidity (combining rehospitalisation and repeat MI, 9 studies, one study with large ES deleted - Rahe 1979)	

WAES = 0.05 (95% CI: -0.04, 0.13)

Secondary outcome

Psychological outcomes

Stress (could not be made into a homogeneous group)

No WAES available.

Other outcomes

Social Outcomes

Return to work (6 studies, one outlier deleted - Waites 1983)

WAES = 0.08 (95% CI: -0.11, 0.27)

Exercise (12 studies, one outlier deleted with postcardiac surgery patients, Marshall 1986)

WAES = 0.18 (95% CI: 0.07, 0.29)

Diet (9 studies, 3 outliers removed - Linde 1979, Mayou 1983 and Arntzenous 1986)

WAES = 0.19 (95% CI: 0.05, 0.34)

Smoking (two outliers removed both had large and positive Ess - Burt 1974 and Salonen 1985)

WAES = 0.07 (95% CI: -0.08, 0.22)

Mean education rating based on the five principles of education for the 28 intervention studies was 15.7 (3.3), range 6-23. Median duration of contact was 7.5 hours and the median number of contacts was 10.5. Median follow up was 25 days (range 0-1460 days). Higher education ratings (>17) were associated with significantly larger WAESs for diet: WAES = 0.05 (95% CI: -0.15, 0.24) versus 0.36 (95% CI: 0.15-0.56) but not for exercise. No differences were found for contact frequency, total contact hours, channel of intervention and length of follow up.

Publication bias

Not applicable.

Heterogeneity

Not stated.

Conclusions/interpretation

Authors interpretation

The reviewer highlighted some limitations in the review: the number of studies was relatively small when the one group studies were removed, nonindependent experimental groups from a single study could not be included, the variety of outcomes in included studies led to a small number of studies within each outcome, no unpublished studies met the inclusion criteria which may have led to an overestimation of effects although some included studies did report negative outcomes. More exploration of less intensive programmes than those included may be necessary. Several principles of education were rarely applied and many interventions were designed without explicit reference to a theoretical or educational model

Conclusion

Cardiac patient education programmes have shown a measurable impact on clinical and behavioural outcomes. These include blood pressure, mortality, exercise and diet. Other outcomes were positively affected although less consistently. Type of communication channel did not influence outcome but adherence to educational principles (relevance, individualisation, feedback, reinforcement and facilitation of behaviour change) did.

Implications for research

Not stated.

Implications for practice

Cardiac patient education programmes should: reinforce positive behaviour; offer feedback on progress; individualise the programme to the learner's needs; facilitate behaviour change and assure relevance of content and educational methods.

Quality assessment

Is there a defined search strategy? Yes, thorough but no foreign language material.

Is there a well defined question? Yes, 4 well defined questions.

Are inclusion/exclusion criteria stated? Yes for participants and interventions. Single group studies were originally included but deleted when their effect sizes differed to a large extent. Outcome criteria are not stated.

Are study designs and number of studies clearly stated? Yes, although unclear which are randomised and which are not.

Have the primary studies been quality assessed? No.

Have the studies been appropriately synthesised? Yes. However exclusion of certain outliers could be questioned.

Has more than one author been involved at each stage of the review process? Yes for data extraction but unclear for the rest of the process.

Reviewer's comment

The reviewers had a clearly defined question and defined inclusion criteria for study design, participants and interventions. Outcome criteria are not stated. The search was thorough and the reviewers attempted to find unpublished material.

Foreign language papers were not eligible which may have led to some selection bias. Although educational quality was assessed, a formal assessment of the quality of the study was not performed. Data extraction was carried out by more than one reviewer but it is unclear if other stages of the process involved more than one reviewer. Data were appropriately synthesised and reasons given for the exclusion of outliers from the meta-analyses.

Reference Godin ⁴² 1989 Canada	Title The Effectiveness of Interventions in Modifying Behavioral Risk Factors of Individuals with Coronary Heart Disease Objective/review question To evaluate the effectiveness of interventions to modify dieting, exercising and smoking behaviours of individuals with CHD. To provide guidelines for the development of more effective interventions.
Literature search Index Medicus and Psychological Abstracts from 1970 to date. References mentioned in retrieved articles were also examined.	
Inclusion/exclusion criteria <u>Design</u> Not stated. 14 of the 24 studies were D, E, or F on Green's scale (quasi-experimental, controlled experiment, factorial design) and were classified as 'rigorous' (Green LW: how to evaluate health promotion. Hospitals 1979; October: 106-108). <u>Participants</u> Individuals with coronary heart disease. Studies of those who were at risk of CHD were excluded. 12 of the 24 trials were with male participants only, 8 had both male and female participants and 4 were unclear. Women represented less than 10% of the samples. <u>Interventions</u> Interventions reporting effects on risk factors other than behavioural were excluded. Interventions where reports of modification of risk factors were not the main focus were included. Interventions were as follows: 2 for diet, 6 for exercise, 7 for smoking and 9 for a combination of 2 or 3 of the behavioural risk factors. Educational lectures with or without printed material and advice from health professionals was the main approach used to modify diet and smoking habits. Most of the interventions were offered at the hospital, at specialised rehabilitation centres or at both locations. Half of the interventions provided follow up clinics for the patients but only one provided home visits by community nurses. The duration of the interventions varied between a few weeks and a few years and the follow up period ranged from 6 months to 5 years with no obvious pattern. <u>Outcomes</u> Change in behavioural risk factor: smoking, diet and exercise. <u>Other</u> <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> None. <u>Validity assessment procedure</u> Not applicable. <u>Data extracted from primary studies</u> Data were extracted on objectives of the study, population, study design, intervention, duration of the study, measurement criteria and the major findings. Study designs were classified based on a framework proposed by Green. Designs were graded A (historical record keeping) to F (RCT of factorial design permitting multiple group comparisons of multiple treatments). <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Narrative summary <u>How were studies weighted in the synthesis?</u> Studies are evaluated with reference to their classification according to Green. Data is presented separately for the less rigorous studies (A, B and C on Green) and rigorous (D, E and F on Green). <u>How was publication bias assessed?</u> Not assessed. <u>How was heterogeneity assessed?</u> Not assessed formally.	
Results <u>Number of studies included in the review</u> 24: 1 RCT of multifactorial design, 9 RCTs, 4 Controlled Trials, 2 Comparative study, 6 Pre-post single group, 2 Historical Record keeping (Chart Review) <u>Number of participants</u> 3760 (1 study n unknown) 194 in RCT of multifactorial design, 1546 in RCTs, 264 in Controlled Trials, 91 in Comparative study, 972 (1 n unknown) Pre-post single group, 693 in Historical Record keeping (Chart Review) <u>Results of validity assessment</u> Not applicable. <u>Main outcome</u> Combination of risk factors (nine interventions) Diet and Exercise(one study) The study (less rigorous) reported success on both. The programme was intensive with individualised counselling. Diet and Smoking (one study) The study (of rigorous design) was unsuccessful but content was not specific to diet and smoking. Exercise and Smoking (four studies) Three interventions were successful for exercise (two rigorous, one not), one was not (less rigorous). Three were able to reduce smoking (one rigorous, two less rigorous). The two studies which included individualised counselling on the two	

target behaviours were successful in modifying both health habits.

All Three Behavioural Risk Factors (three studies)

All three had partial success. One educational intervention was positive for exercise only, one exercise programme succeeded in changing diet and exercise but not smoking habits and one educational intervention conducted in a hospital setting enhanced patients' knowledge of CHD and motivation to comply a new regimen.

Secondary outcome

Diet only (two interventions)

Both were based on educational approaches supplemented by counselling.

Both were successful in modification of diet although both were based on dietary history interview. The larger study with the more rigorous design found statistically significant differences in changes in intake for half of the foods and nutrients examined whereas the smaller, less rigorous design found significant alteration in the total energy and nutrient intakes over the follow up year but patients did not fully achieve the recommended nutrient intakes.

Other outcomes

Exercise only (six interventions)

Designs were superior in the unsuccessful studies.

Three interventions resulted in positive outcomes and three others failed to achieve significant modifications in exercise habits. All successful interventions were based on treadmill exercise testing supplemented with counselling. Unsuccessful interventions were fairly similar to successful ones so the it is not clear which aspects of the interventions were associated with success.

Smoking only (seven interventions)

Designs were superior in the unsuccessful studies.

Four were successful and three did not report significant results. All successful studies had interventions that focused exclusively on smoking.

Publication bias

Not applicable.

Heterogeneity

Not applicable.

Conclusions/interpretation

Authors interpretation

There is a trend towards positive findings when the study design is less rigorous. More rigorous studies present an equal proportion of positive and negative outcomes.

Conclusion

When a general form of intervention is used to modify specific behaviours (e.g. group therapy) there is less success than when the intervention is content-specific with regard to the targeted behavioural risk factors. However the actual effectiveness of interventions to modify behavioural risk factors is controversial and improved studies are needed to establish their benefits.

Implications for research

Improved studies are needed to clearly establish the benefits of risk factor modification programmes in secondary prevention. There is a need to identify whether educational interventions focusing on a certain Health Belief Model (HBM) are appropriate. There is a need to identify the variables that influence behaviour (and their underlying behavioural models) and to investigate ways of directing educational programmes at such behaviour. Any influence of age on behaviour change should be investigated within this context. Reliable and valid outcome measures should be developed which are suited to CHD patients. Multiple measures should be used where feasible for the study of multidimensional behaviours. More appropriate study designs should be used. These should not only be able to measure behaviour but also assess changes in cognitive structure (beliefs, attitudes, perceived social norms, perceived barriers to a behaviour, intentions).

Implications for practice

Not stated.

Quality assessment

Is there a defined search strategy? Yes, but limited to 2 databases and reference checking.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Yes, except for study design.

Are study designs and number of studies clearly stated? Yes.

Have the primary studies been quality assessed? No.

Have the studies been appropriately synthesised? Yes.

Has more than one author been involved at each stage of the review process? Unclear.

Reviewer's comment

This review had a clear question and inclusion criteria for participants, intervention and outcomes. The search was limited to two databases and reference checking and no attempts were made to check for publication bias so studies may have been missed. It is not clear whether foreign language papers were eligible for inclusion. Quality assessment was not performed but evidence from better quality studies was identified. Sufficient study details were provided to ascertain that the reviewer's conclusions appear to be based on the evidence. It is unclear if a further reviewer took part in any of the stages of the review process. If not, bias could have been introduced at various points in the review process. The reviewer makes recommendations for future research.

Reference Lip ⁴⁷ 2002 UK	Title Psychological interventions for depression in congenital heart disease (Protocol)
	Objective/review question To review the efficacy of psychological interventions (CBT, psychotherapy, talking / counselling therapy) to reduce levels of depression in patients with congenital heart disease and to determine which type of psychosocial intervention is most effective in reducing depression. In addition to assess the safety and tolerability of these psychological interventions to reduce depression.
Literature search Cochrane Review Group Specialised registers, Cochrane controlled Trial Register (CTTR), the Cochrane library CENTRAL Register, MEDLINE, EMBASE, Psychlit, Database of Abstracts of Review of Effectiveness (DARE), Biological abstracts, CINAHL. All relevant foreign language papers will be translated. Reference lists of retrieved articles will be checked, contact will be made with lead authors of reported studies, investigators in the field and conference abstracts will be scrutinised. The Cochrane Heart Group will be contacted and Dissertation abstracts will be searched.	
Inclusion/exclusion criteria <u>Design</u> Randomised controlled trials. <u>Participants</u> Adolescents (aged 15-17 years) and adults (aged 18 years and older) with congenital abnormalities of the heart or great vessels defined by clinical diagnosis and / or echocardiography / angiography / other diagnostic procedures will be eligible for inclusion. All adolescents and adults with congenital heart disease with or without depression. Depression defined as either major depression (APACNS 1994) or depressive symptomatology (above or below a predefined cut-off on the questionnaires employed in this study). <u>Interventions</u> CBT as defined by Jones (Jones 2001). Interventions for CBT classified as 'well defined' or 'less well -defined' and to be analysed separately. Psychotherapy representing any psychological intervention described as non-cognitive therapy. Talking / counselling therapy defined as other psychosocial interventions such as non-directive counselling and supportive therapy and other 'talking therapies', 'attention' placebo - interventions where participants are involved in education or relaxation etc. Standard care is understood to be the care a person would normally receive if they were not entered into the trial. This may include participants receiving anti-depressant medication. No intervention represents an untreated control group. <u>Outcomes</u> The primary outcome measure is reduction in depression defined as the number of participants whose depression score is below the pre-defined cut-off for depression following the intervention. Secondary outcome measures: acceptability of treatment, quality of life, hospital re-admission related to their congenital heart disease abnormality, non-fatal cardiovascular events, cardiac behavioural risk factors reduction, health economics and death (cardiovascular and all-cause mortality). Outcomes will be grouped into short-term (within 12 weeks of the start of therapy), medium-term (between 13 to 24 weeks after beginning of therapy) and long-term (more than 24 weeks after the start of therapy). <u>Other</u> <u>Study selection procedure</u> Two reviewers will independently select articles for inclusion in the review. Disagreements will be resolved by consensus with the help of a third reviewer. Selection will be blinded to authors' names, institutions and journal title. 10% of the citations and articles will be checked by a third reviewer.	
Methods <u>Validity assessment tool</u> Guidelines from the Cochrane Handbook to include assessment of the method and adequacy of randomisation, assessment of the degree of blinding (of outcome assessors), losses to follow-up <u>Validity assessment procedure</u> Quality will be scored independently by two reviewers. <u>Data extracted from primary studies</u> Data will be extracted on: patient characteristics - number of participants, age, sex, ethnicity, marital status, type of congenital heart disease; type of depression (major, minor, depressive symptomatology); depression assessment tool; cut-off on depression scale; type of intervention; type of outcomes; timing of follow-up and assessment of methodological quality. <u>Data extraction procedure</u> This will be conducted independently by two reviewers. <u>How were studies combined in the review?</u> Meta-analysis where appropriate. <u>How were studies weighted in the synthesis?</u> Not stated. <u>How was publication bias assessed?</u> Data from all identified and selected trials will be entered into a funnel plot to attempt to detect the possibility of publication bias. <u>How was heterogeneity assessed?</u> Data will be inspected graphically and differences between the results of each included trial will be checked using a test of heterogeneity fixed at the more conservative 0.10 cut-off point. If there is statistically significant heterogeneity the data will be presented separately rather than pooled. Results will be analysed using both the fixed and random effects models. However where there is significant heterogeneity a random effects model will be used and the reviewers will attempt to explore the reasons for this in post-hoc analyses. Sensitivity analyses will be conducted on studies which define depression differently from an operational point of view, differences between 'well-defined' and 'less well-defined' interventions and differences between analyses involving all studies and excluding trials of low methodological quality.	

<p>Results</p> <p><u>Number of studies included in the review</u> Not yet known.</p> <p><u>Number of participants</u> Not yet known.</p> <p><u>Results of validity assessment</u> Not yet known.</p> <p><u>Main outcome</u> Not yet known.</p> <p><u>Secondary outcome</u></p> <p><u>Other outcomes</u></p> <p><u>Publication bias</u> Not yet known.</p> <p><u>Heterogeneity</u> Not yet known.</p>
<p>Conclusions/interpretation</p> <p><u>Authors interpretation</u> Not yet known.</p> <p><u>Conclusion</u> Not yet known.</p> <p><u>Implications for research</u> Not yet known.</p> <p><u>Implications for practice</u> Not yet known.</p>
<p>Quality assessment</p> <p>Is there a defined search strategy? Yes, very well defined and thorough.</p> <p>Is there a well defined question? Yes, very well defined.</p> <p>Are inclusion/exclusion criteria stated? Yes, in great detail.</p> <p>Are study designs and number of studies clearly stated? RCTs only - number not yet known</p> <p>Have the primary studies been quality assessed? They will be.</p> <p>Have the studies been appropriately synthesised? Not yet known</p> <p>Has more than one author been involved at each stage of the review process? They will be.</p> <p><u>Reviewer's comment</u> Just a protocol but likely to produce a very useful review.</p>

Reference Rees ⁴⁹ 2003 UK	Title Objective/review question To determine the effectiveness of psychological interventions and in particular stress management training in patients with CHD.
Literature search The Cochrane Controlled Trials Register (CTR) was searched to December 2001. This was updated with a search of MEDLINE (1999 to end 2001), EMBASE (1998 to end 2001), PsychINFO and CINAHL were also searched from the earliest date available to December 2001. Searches of reference lists were also undertaken along with contact with experts.	
Inclusion/exclusion criteria <u>Design</u> RCTs with parallel group design <u>Participants</u> Adults of all ages with CHD including those who had suffered MI, a revascularisation procedure (CABG or PTCA), those with angina or angiographically defined CHD. <u>Interventions</u> All non-pharmacological psychological interventions delivered by health care workers with specific training in such techniques were eligible. Particular emphasis was placed on Stress Management interventions (defined as the use of specific cognitive behavioural strategies to help the patient reduce or manage their stress). Stress management techniques included learning relaxation, the use of cognitive techniques such as self-instruction training and cognitive challenge and / or consideration of specific coping strategies to be used at times of stress. Less specific approaches such as counselling, psychodynamic or educational interventions were excluded from this definition as were self-management techniques used to change risk factors such as smoking and low levels of exercise that were not specifically targeted at stress reduction. The cognitive behavioural treatment of aversive mood states including anger and depression was also excluded. The comparison group had to be usual care (which could include other components of cardiac rehabilitation) or no intervention. <u>Outcomes</u> Physical (all-cause and CHD-related mortality, MI, CABG, PTCA, modifiable cardiac risk factors – BP, cholesterol, smoking), Psychological (anxiety, depression, measures of stress and type A behaviour / hostility) and Quality of life. <u>Other</u> Follow up needed to be 6 months or more following the start of the intervention. <u>Study selection procedure</u> Two reviewers examined potentially relevant references and independently selected trials to be included in the review using a 7-question inclusion / exclusion form. If disagreements about study inclusion could not be resolved by consensus a third reviewer was consulted.	
Methods <u>Validity assessment tool</u> Trials were assessed for concealment of allocation, losses to follow up and blind assessment of outcomes. <u>Validity assessment procedure</u> Quality of trials was assessed independently by the reviewers. <u>Data extracted from primary studies</u> Data were collected on patient characteristics: age, sex, type of CHD, identified levels of psychopathology as selection criteria and details of intervention and follow up. The reviewers intended to analyse the data using meta-regression techniques. Dichotomous outcomes for each study were expressed as odds ratios. Continuous variables were expressed as the mean change from baseline to follow up with standard deviations for each comparison group. Where standard deviations were not reported allowance was made for patient correlation from baseline to follow up measurements by using the correlation coefficient between the two. A weighted mean difference (WMD) or standardised mean difference (SMD) was calculated for each study. <u>Data extraction procedure</u> Data were abstracted independently by two reviewers and chief investigators were contacted where necessary to provide additional information. Trials included in the review were then divided into those reporting a stress management intervention determined from the reported methods section and other psychological interventions. Agreement was sought between reviewers on what constituted a stress management intervention. <u>How were studies combined in the review?</u> Meta-analysis using a fixed effects model or a random effects model where substantial heterogeneity existed. For outcomes where there was insufficient data or where it was inappropriate to combine studies statistically a qualitative overview was presented. <u>How were studies weighted in the synthesis?</u> Not stated. <u>How was publication bias assessed?</u> Not stated. <u>How was heterogeneity assessed?</u> Sensitivity analyses were carried out excluding studies of low methodological quality. Heterogeneity was tested using the Z statistic.	
Results <u>Number of studies included in the review</u> 36 trials met the inclusion criteria. 18 were SM trials. <u>Number of participants</u> The review included 12,841 patients (5242 were in SM trials).	

Results of validity assessment

Quality of many trials was poor with most not reporting adequate concealment of allocation. Only 6/36 studies report that outcome assessors were blind to group allocation.

Main outcome

Mortality

There was no strong evidence of effect on total mortality (based on 22 trials, 10634 patients). (OR = 0.93 (95% CI: 0.81, 1.06)). There was no evidence of an effect of the intervention on total mortality in the 10 stress management trials (3425 patients) reporting this outcome (OR = 0.88 (95% CI: 0.67, 1.15)).

Cardiac mortality was reported in 11 trials (7544 patients) with no strong evidence of a reduction in the intervention group. (OR = 0.86 (95% CI: 0.72, 1.03)). In the 4 SM trials reporting this outcome there was weak evidence of a reduction in the number of deaths in the intervention group (OR = 0.62 (95% CI: 0.38, 0.99)).

Reinfarction

Based on 18 trials (10200 patients) there was a reduction in the number of non-fatal re-infarctions in the intervention group (OR=0.78 (95% CI: 0.67, 0.90)) but the two largest trials with 4809 patients were null for this outcome. In the 8 SM trials reporting this outcome (3990 patients) the OR was 0.69 (95% CI: 0.52, 0.92).

Revascularisation

The pooled estimate for this combined outcome of CABG and PTCA for 15 trials (8368 patients) was 0.87 (95% CI: 0.67, 1.13)). For the 7 SM trials (3025 patients) the OR was 0.82 (95% CI: 0.42, 1.62).

Anxiety and Depression

Both all of the trials and the SM subgroup of trials showed small reductions for anxiety and depression. Based on 9 trials of 2756 patients SMD was -0.08 (95% CI: -0.16, -0.01). For the 7 SM trials (2651 patients) there was weak evidence of a small decrease in anxiety with the intervention (SMD = -0.07 (95% CI: -0.15, 0.01)). Depression was measured in 11 trials of 4535 patients with significant heterogeneity. There was a significant reduction in depression (SMD = -0.3 (-0.48, -0.13)). For 8 SM trials (2642 patients) there was evidence of a reduction in depression scores in the intervention group (SMD = -0.32 (95% CI: -0.56, -0.08)). Results were dominated by one large trial which showed a null effect. Based on 5 trials of 347 patients reporting composite measures for anxiety, depression and mental health there was a significant beneficial reduction (SMD = -0.22(95% CI: -0.44, -0.01)). Other psychological outcomes included stress and Type A behaviour. Perceived stress was measured in 2 trials, one of which showed no effect whilst the other showed a significant reduction in stress. One of several measures in one trial of Type A attitudes showed an effect of a SM intervention whilst the other showed significant reductions in type A behaviour.

The evidence was dominated by two large trials both of which produced null findings for all clinical outcomes.

Secondary outcome

Modifiable cardiac risk factors

A statistically significant reduction in total cholesterol was found (WMD = -0.27 (95% CI: -0.55, 0) based on 9 trials with 1525 patients. In the 4 SM trials (634 patients) no effect of the intervention was seen. No significant effects were noted for LDL or HDL cholesterol or triglycerides. Blood pressure was reported in 5 trials with 805 patients and psychological interventions showed favourable effects in 3 trials and harmful effects in 2 trials. In the 2 SM trials reporting this outcome no overall effect of the intervention was seen. Heterogeneity was observed between trials reporting smoking as an outcome (8 trials of 3690 patients) with the largest trial containing over 60% of the weight in the meta-analysis showing a null effect. The 3 SM trials (2472 patients) showed no evidence of any benefit of intervention (OR = 1.03 (95% CI: 0.85, 1.24)).

Health related quality of life

5 SM trials reported this outcome, 2 of which found beneficial effects of the intervention.

Other outcomes

-

Publication bias

There was evidence of significant publication bias for non-fatal re-infarction (-0.98, p =0.03) but not for total mortality (-0.3, p=0.37).

Heterogeneity

Statistical heterogeneity was assessed and results reported where appropriate. Meta-regression techniques to explore clinical and quality differences between trials could not be used due to limited information on trial quality and the relatively small number of trials.

Conclusions/interpretation

Authors interpretation

The effectiveness of the SM component per se is difficult to separate from the effectiveness of other rehabilitation interventions.. It may be inferred that both SM and more general psychological interventions aiming to reduce depression and anxiety would be helpful in reducing recurrent cardiovascular events.

Conclusion

Overall, psychological interventions showed no evidence of effect on total or cardiac mortality but did show small reductions in anxiety and depression in patients with CHD. Similar results were seen for SM interventions when considered separately. The overall finding of an effect of psychological interventions on reduction in non-fatal heart attacks is insecure due to the poor quality of trials, heterogeneity between trials and evidence of publication bias.

Implications for research

Negative trials that have not been published should be presented to allow further research synthesis. Future trials should be better designed and should evaluate whether the focus should be placed on those patients with psychological distress and on sufficiently intensive interventions. If promising interventions are found it may then be worth testing them in larger trials for effects on recurrent clinical events.

Implications for practice

Combined psychological interventions appear more likely to result in appropriate behavioural change. Due to the small number of included trials, it is not clear if SM interventions might be more effective in patients with evidence of high distress.

Quality assessment

Is there a defined search strategy? Yes

Is there a well defined question? Yes

Are inclusion/exclusion criteria stated? Yes

Are study designs and number of studies clearly stated? Yes

Have the primary studies been quality assessed? Yes

Have the studies been appropriately synthesised? Yes

Has more than one author been involved at each stage of the review process? Yes

Reviewer's comment

Attempted to avoid selection bias by considering all trials of psychosocial interventions then selecting SM ones.

Differences between this review and previous ones could be explained by trial inclusion criteria, quality of search, later publication date and inclusion of the recently completed ENRICHD trial.

Reference Lip ⁴⁸ 2003 UK	Title Psychological interventions for depression in heart failure (protocol)
Objective/review question To review the efficacy of psychological interventions (CBT, psychotherapy, talking / counselling therapy) to reduce levels of depression in patients with heart failure and to determine which type of psychosocial intervention is most effective in reducing depression.	
Literature search Cochrane Review Group Specialised registers, Cochrane controlled Trial Register (CTTR), the Cochrane library CENTRAL Register, MEDLINE, EMBASE, Psychlit, Database of Abstracts of Review of Effectiveness (DARE), Biological abstracts, CINAHL. All relevant foreign language papers will be translated. Reference lists of retrieved articles will be checked, contact will be made with lead authors of reported studies, investigators in the field and conference abstracts will be scrutinised and their authors contacted. The Cochrane Heart Group will be contacted and Dissertation abstracts will be searched.	
Inclusion/exclusion criteria <u>Design</u> Randomised controlled trials <u>Participants</u> Patients aged 18 years or older with heart failure defined as New York Heart Association (NYHA 1964) grade I to IV at rest or during exercise with or without objective evidence of left ventricular dysfunction (I.e. echocardiography or radionuclide ventriculography) at rest (Cleland 1995). <u>Interventions</u> CBT as defined by Jones (Jones 2001). Interventions for CBT classified as 'well defined' or 'less well -defined' and to be analysed separately. Psychotherapy representing any psychological intervention described as non-cognitive therapy. Talking / counselling therapy defined as other psychosocial interventions such as non-directive counselling and supportive therapy and other 'talking therapies', 'attention' placebo - interventions where participants are involved in education or relaxation etc. Standard care is understood to be the care a person would normally receive if they were not entered into the trail. This may include participants receiving anti-depressant medication. No intervention represents an untreated control group. <u>Outcomes</u> The primary outcome measure is significant reduction in depression as defined in the individual studies following the intervention. Secondary outcome measures: acceptability of treatment, quality of life, hospital re-admission for heart failure, non-fatal cardiovascular events, cardiac behavioural risk factors reduction, health economics and death (cardiovascular and all-cause mortality). Outcomes will be grouped into short-term (within 12 weeks of the start of therapy), medium-term (between 13 to 24 weeks after beginning of therapy) and long-term (more than 24 weeks after the start of therapy). <u>Other</u> <u>Study selection procedure</u> Two reviewers will select suitable studies for inclusion in the review(blinded to authors' names, institutions and journal title) and disagreements resolved by consensus or by contacting the author.	
Methods <u>Validity assessment tool</u> Guidelines from the Cochrane Handbook to include assessment of the method and adequacy of randomisation, assessment of the degree of blinding (of outcome assessors), losses to follow-up. <u>Validity assessment procedure</u> Validity will be assessed independently by two reviewers. <u>Data extracted from primary studies</u> Data will be extracted on: patient characteristics - number of participants, age, sex, ethnicity, marital status, type of heart failure; type of depression (major, minor, depressive symptomatology); depression assessment tool; cut-off on depression scale; type of intervention; type of outcomes; timing of follow-up and assessment of methodological quality. <u>Data extraction procedure</u> This will be completed independently by two reviewers. <u>How were studies combined in the review?</u> Meta-analysis where appropriate. <u>How were studies weighted in the synthesis?</u> Not stated. <u>How was publication bias assessed?</u> Data from all identified and selected trials will be entered into a funnel plot to attempt to detect the possibility of publication bias. <u>How was heterogeneity assessed?</u> Data will be inspected graphically and differences between the results of each included trial will be checked using a test of heterogeneity fixed at the more conservative 0.10 cut-off point. If there is statistically significant heterogeneity the data will be presented separately rather than pooled. Results will be analysed using both the fixed and random effects models. However where there is significant heterogeneity a random effects model will be used and the reviewers will attempt to explore the reasons for this in post-hoc analyses. Sensitivity analyses will be conducted on studies which define depression differently from an operational point of view, differences between 'well-defined' and 'less well-defined' interventions and differences between analyses involving all studies and excluding trials of low methodological quality.	
Results <u>Number of studies included in the review</u> Not yet known. <u>Number of participants</u> Not yet known.	

Results of validity assessment

Not yet known.

Main outcome

Not yet known.

Secondary outcome

Other outcomes

Publication bias

Not yet known.

Heterogeneity

Not yet known.

Conclusions/interpretation

Authors interpretation

Not yet known.

Conclusion

Not yet known.

Implications for research

Not yet known.

Implications for practice

Not yet known.

Quality assessment

Is there a defined search strategy? Yes, well defined and thorough.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Yes, in detail.

Are study designs and number of studies clearly stated? Not yet known.

Have the primary studies been quality assessed? They will be.

Have the studies been appropriately synthesised? Not yet known.

Has more than one author been involved at each stage of the review process? Yes.

Reviewer's comment

Just a protocol but likely to produce a useful review.

APPENDIX 12: DATA EXTRACTION – REVIEWS INCLUDING BOTH CANCER AND HEART DISEASE

Reference Stetter ²⁵ 2002 Germany	Title Autogenic Training: A Meta-Analysis of Clinical Outcome Studies
	Objective/review question To evaluate the clinical effectiveness of autogenic training following on from Linden (1994).
Literature search MEDLINE and bibliographies of relevant reviews and monographs. No search dates given.	
Inclusion/exclusion criteria <u>Design</u> At least one control group or control phase had to be included in the studies. These were either psychologically nontreated groups ('real control groups': participants were in waiting status or on medical basic therapy or received a placebo therapy) or treatment groups receiving another (psychological) therapy. At least 5 participants had to be in each treatment or control group. <u>Participants</u> Clinically defined groups of patients suffering from a specific disorder or a syndrome or clinically significant symptom (e.g. anxiety). <u>Interventions</u> AT had to be applied for therapeutic purposes in at least one group. AT had to be the only or the main treatment method in one group or had to be added as a therapeutic component to one group only. Studies were excluded if AT played an inferior or not clearly discernible role within the treatment plan. AT needed to be administered giving participants chance to practise without therapeutic guidance. Studies were included even if not all six standard exercises of AT were included. However at least the heaviness and warmth concentration and the rest presentation had to be administered. <u>Outcomes</u> At least one outcome criterion relating to the disorder or syndrome had to be evaluated (physiological and behavioural or psychological). <u>Other</u> Study was published in journals or books 1932-1999. Unpublished dissertations of AT were not included in the review. <u>Study selection procedure</u> Two reviewers discussed the studies and disputes were resolved by consensus.	
Methods <u>Validity assessment tool</u> Not applicable <u>Validity assessment procedure</u> Not assessed formally but issues discussed within the report. <u>Data extracted from primary studies</u> Author, year, number of groups, description of different treatment conditions, methodological details, variables to be included in meta-analyses, total sample size and group sizes and descriptive assessment of main symptoms. <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Meta-analysis <u>How were studies weighted in the synthesis?</u> If only one study with one ES was available the Hedges-corrected estimator of population ES was used ('d'). If more ES were available either the ES weighted by its own variance (if data homogeneous) or the ES weighted by the sample size (if heterogeneous) <u>How was publication bias assessed?</u> The fail-safe N was calculated. <u>How was heterogeneity assessed?</u> A test of heterogeneity was performed.	
Results <u>Number of studies included in the review</u> Heart Disease: 6 (1 RCT, 5 CCT). Cancer: 1RCT <u>Number of participants</u> Heart Disease (441), Cancer (74) <u>Results of validity assessment</u> Not applicable <u>Main outcome</u> Effect sizes are labelled 'small' if 0.2-0.49, 'medium' if 0.50-0.79 and 'large' if greater than or equal to 0.8. In CHD 1 RCT gave ES of 0.56 (NS), 2 CCTs gave ES of 0.87 (p < 0.001). Overall ES 0.80 (p < 0.001). <u>Secondary outcome</u> Quality of life in cancer patients was not positively influenced by AT (0.13, NS) (1 study). <u>Publication bias</u> Not given for above outcomes. <u>Heterogeneity</u> Not given for above outcomes.	

Conclusions/interpretationAuthors interpretation

AT proved to be an effective relaxation method being about as effective as other relaxation methods. Perhaps all relaxation methods should not be seen as stand-alone therapies. In the psychosomatic area relaxation should be seen as an 'add-on' to medical treatment.

Conclusion

General - not just HD and cancer.

AT results in medium to large clinical main effects that are stable at follow-up and that exceed placebo effects (control conditions). Compared to other psychological treatments AT seems to be nearly equal or a little less effective.

Comparisons with medical treatments are rare and should be treated with caution. AT results in mostly medium to large ES concerning unspecific therapeutic effects.

Implications for research

Crossover trials may answer questions about AT's role as a 'preparation therapy' or an 'add-on therapy'.

Implications for practice

Not stated.

Quality assessment

Is there a defined search strategy? Yes, but limited to MEDLINE and reference checking.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Yes.

Are study designs and number of studies clearly stated? Yes, but a little unclear which were included in meta-analysis.

Have the primary studies been quality assessed? Not formally.

Have the studies been appropriately synthesised? Yes, reasons are given for excluding some studies from the meta-analysis.

Has more than one author been involved at each stage of the review process? For relevance checking yes, but unclear for other stages.

Reviewer's comment

Question and inclusion criteria defined, limited search strategy, no validity checking. Unclear if more than one reviewer involved in all stages of the review process. ES of cancer based on one study.

Reference Hill ¹⁶ 1992 USA	Title Psychosocial Interventions in Adult Patients with Coronary Heart Disease and Cancer Objective/review question To review the mental health impact of psychosocial interventions with patients diagnosed with heart disease or cancer.
Literature search MEDLINE and Psychological Abstracts databases. Searches of individual issues of relevant journals in the areas of psychiatry, nursing, psychology and social work for the past 5 years. Citations from experts, reviews and government documents were also examined.	
Inclusion/exclusion criteria <u>Design</u> Studies had to incorporate a control or comparison group. <u>Participants</u> Studies were of adult patients. Patients with diseases other than heart disease and cancer were excluded. One study included the female spouses of MI patients and two included spouses of cancer patients. <u>Interventions</u> Studies had to use a replicable global psychosocial intervention. Psychosocial interventions were defined as any of the following techniques: education, counselling, therapy (either group or individual), stress management and cognitive behaviour therapy methods. Interventions to address Type A behaviour in cardiac patients were excluded. Interventions incorporating hypnosis techniques were excluded as were studies on pharmacological interventions. <u>Outcomes</u> Studies had to include a standardised mental health outcome. Mental health outcomes were broadly defined to include any of the following: standardised psychiatric interviews that yielded psychiatric diagnoses or a score on psychological functioning or emotional symptoms as well as reliable and valid self-report questionnaires on mood or emotional symptoms. Other outcomes such as physical functioning, health services utilisation, morbidity and mortality were not included. <u>Other</u> <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> Not stated. <u>Validity assessment procedure</u> None. <u>Data extracted from primary studies</u> Sample size and description, intervention type and number, mental health outcome and results presented as (a) generally effective in relieving psychological distress across various psychological measures and across time, (b) mixed results and (c) results showing no benefit on psychological distress. <u>Data extraction procedure</u> Not stated. <u>How were studies combined in the review?</u> Narrative summary <u>How were studies weighted in the synthesis?</u> None. <u>How was publication bias assessed?</u> Not stated. <u>How was heterogeneity assessed?</u> Not stated.	
Results <u>Number of studies included in the review</u> 29 controlled studies: 12 Heart disease and 17 Cancer <u>Number of participants</u> HD: 1171 + 1 n unknown; Cancer: 1672 (excluding spouses) + 1 n unknown <u>Results of validity assessment</u> N/A <u>Main outcome</u> Of 12 studies that targeted post-MI and CABG patients 10 reported some beneficial effects of psychosocial interventions. Results suggest that interventions including patient education, counselling and behavioural techniques may help alleviate psychological distress as defined primarily by self-report measures of anxiety and depression in adults. <u>Secondary outcome</u> Postmyocardial infarction patients or their spouses. 6 of 7 studies suggest that psychosocial interventions reduce distress as defined by self-reporting of anxiety, depression and stress. The one which showed no difference appeared to contain more optimistic patients and study authors conclude that such intervention programmes may be better targeted at those patients who have more than usual anxiety and depression. CABG Patients Four of five studies showed that interventions reduce distress. Focus is mainly on management of distress as it impacts on immediate recovery from CABG surgery. Of the four positive studies three defined stress primarily as self-reported anxiety. The one negative study still beneficially impacted on length of hospital stay and post-operative complications. <u>Other outcomes</u> Cancer Patients	

Of the 17 studies 15 provide evidence that psychosocial interventions reduce psychological distress. Most of the studies conducted follow-ups several months after the intervention programme that attest to the longevity of the effects. The studies used a variety of interventions.

Publication bias

N/A

Heterogeneity

N/A

Conclusions/interpretation

Authors interpretation

It is important to assess other outcomes than psychological distress, such as health care utilisation, costs, days in hospital, other disabilities associate with psychological and psychiatric difficulties, work days lost, productivity and physical measures such as morbidity and mortality.

Conclusion

Psychosocial interventions are effective in relieving self-reported psychological distress in heart disease and cancer. The efficacy is strongest for short-term outcomes in most cases. There is some suggestion that interventions targeting patients at higher risk of psychological distress are probably more useful than those aimed at the general population of patients with heart disease or cancer.

Implications for research

Future research should address the issues of sampling (sampling frame, recruitment procedures with response and attrition rates and the ultimate sample used); broadening study populations to include more women, ethnic minorities and children and provide more details of the study participants; more use of randomisation to study groups and provide more details of the interventions used to allow for investigation of successful components. Studies involving family members especially spouses should be further investigated. More research is needed on whether interventions should target those with elevated psychological distress rather than all patients. Researchers should check that their intervention actually communicated what it intended to. There is a need to investigate the impact of pharmacological interventions on mental health as well as data on combination treatments of medication and psychosocial interventions. The timing of interventions should be investigated so that interventions are introduced at an appropriate time point during illness or recovery period. Both short and long-term effects should be ascertained. Researchers should ensure appropriate use of statistical techniques and control for confounding variables. Standardised measurements are needed to test the efficacy of a treatment. Outcomes should ideally not rely on self report measures. Future research should aim to understand which of the multiple strategies of an intervention are actually responsible for improvement in a patient.

Implications for practice

Not stated.

Quality assessment

Is there a defined search strategy? Yes.

Is there a well defined question? Yes.

Are inclusion/exclusion criteria stated? Yes.

Are study designs and number of studies clearly stated? Unclear, randomisation where used untabled.

Have the primary studies been quality assessed? No.

Have the studies been appropriately synthesised? Yes, separated into CABG and post-MI and by intervention type for HD.

For cancer discussed by intervention type

Has more than one author been involved at each stage of the review process? Unclear.

Reviewer's comment

Clearly defined inclusion criteria and reasonable search but no validity checking. Unclear how many reviewers were involved in each stage of the review process. Appropriately synthesised and many useful pointers to further research.

Reference Kibby ³¹ 1998 USA	Title Effectiveness of Psychological Intervention for Children and Adolescents with chronic medical illness: a meta-analysis Objective/review question To evaluate the efficacy of psychological interventions among chronically ill children and adolescents from studies published between 1990 and 1995.
Literature search The databases MEDLINE, CINAHL and Psychlit were searched for studies published between 1990 and 1995. Volumes of the journals 'Journal of Pediatric Psychology' and 'Health Psychology' were handsearched. Citations from identified studies and reviews were also checked.	
Inclusion/exclusion criteria <u>Design</u> Studies using between-group and within-subject designs were included. Studies using within-subject designs were included only if three or more patients participated in each condition. <u>Participants</u> Children or adolescents 18 years of age or younger with a specific chronic medical illness or a sample of children or adolescents with various chronic illnesses that had been pooled for data analysis were included. Studies that focused on the parent or siblings but did not include the paediatric patient were excluded. The mean age of participants was 10.34 (3.36). No studies actually included children under 3 years of age. Most studies included patients with mild or moderate disease severity ratings (based on 11 of 42 studies). Eleven studies included participants with cancer and just one study included participants with heart disease. <u>Interventions</u> Psychological interventions including those performed by paraprofessionals as well as those conducted by psychologists were eligible. Studies were classified on the basis of problems targeted for intervention: disease management and control studies, emotional / behavioural studies, health promotion / Health-related behaviours and Prevention of illness or injury. Interventions were classified as behavioural, non-behavioural or didactic. <u>Outcomes</u> No inclusion criteria for outcome measures are stated. Outcome measures were categorised into five types: psychophysiological, medical services, procedure-related distress, disease-related knowledge or psychosocial problems. <u>Other</u> Studies needed to have been published from 1990 to 1995. <u>Study selection procedure</u> Not stated.	
Methods <u>Validity assessment tool</u> Not stated. <u>Validity assessment procedure</u> N/A <u>Data extracted from primary studies</u> For between-group designs effect sizes were calculated based on a comparison of the treatment group to a control group. For within-subject designs the effect size was derived by comparing posttreatment data to pretreatment data. Standardised measures of effect size were computed according to Cohen. When effect sizes could not be calculated in this way due to lack of data and raw data was unavailable effect sizes were estimated from other statistical techniques described elsewhere. Where a study reported that an intervention was nonsignificant without providing other data the estimated effect size was given a default value of zero. For studies with multiple outcomes a single effect size was calculated by averaging effect sizes from multiple outcome measures. Severity of disease was coded on a scale of mild, moderate or severe when this information was included in the study. <u>Data extraction procedure</u> It is unclear how many reviewers were involved in the data extraction process. <u>How were studies combined in the review?</u> Meta-analysis. The mean overall effect size was calculated. <u>How were studies weighted in the synthesis?</u> Studies were not weighted. <u>How was publication bias assessed?</u> Not assessed. <u>How was heterogeneity assessed?</u> Not assessed.	
Results <u>Number of studies included in the review</u> 42 (numbers in each study design not given) <u>Number of participants</u> Not stated. <u>Results of validity assessment</u> N/A <u>Main outcome</u> The mean overall effect size was 1.12 ($p < 0.001$) showing that children receiving psychological interventions gained significantly greater benefit than those not receiving an intervention. The overall effect size across intervention categories for between-subject studies did not differ significantly from those employing within-subject designs (0.87 (1.0) vs. 1.4 (0.94), $t(41) = 1.8$, $p = 0.08$). Separate outcomes for heart disease and cancer are not available. <u>Secondary outcome</u> <u>Other outcomes</u>	

Publication bias

N/A

Heterogeneity

N/A

Conclusions/interpretation

Authors interpretation

Psychological interventions for children with chronic medical conditions are effective and effectiveness is maintained for at least 1 year following the end of the intervention. Psychological interventions directed at disease-related or emotional/behavioural problems were found to be effective but too few studies of health promotion or disease prevention were available for analysis. Behavioural interventions, which were most heavily represented, demonstrated similar positive effects for disease management and emotional/behavioural problems. Although disease type, severity and duration did not affect the effectiveness of interventions there were some influences of patient age and gender. Effect sizes may overestimate actual effects of therapies with chronically ill paediatric patients due to publication bias and the large number of behavioural studies that match the problems targeted in treatment.

Conclusion

The present study provides only initial validation of the general effectiveness of psychological interventions for children with chronic medical conditions. Continued research is needed to extend the scope of the conclusions.

Implications for research

Studies need to have a longer follow up as there is evidence of effectiveness up to 12 months posttreatment. There needs to be greater uniformity of assessment intervals across studies to evaluate long-term treatment effects. Continued investigation is needed to improve on the rigour of study design for example larger sample sizes, including representatives of all population, random assignment to treatment groups, improving attrition rates, concealment of allocation and greater information on disease parameters.

Implications for practice

Not stated.

Quality assessment

Is there a defined search strategy? Yes, although restricted years.

Is there a well defined question? Yes, although it is extremely broad.

Are inclusion/exclusion criteria stated? Yes but not for outcomes.

Are study designs and number of studies clearly stated? Number of studies clear but study designs unclear.

Have the primary studies been quality assessed? No

Have the studies been appropriately synthesised? Debateable. No details of individual studies provided, no weighting and studies have been combined across study designs, types of illness, interventions and outcomes although differences have been subsequently explored.

Has more than one author been involved at each stage of the review process? Unclear.

Reviewer's comment

This is a very broad review answering a wide question. Broad inclusion criteria are defined for study design, participants and interventions. Outcome criteria are not defined. The search covered a range of databases and information sources but was restricted to a 5 year period (1990-1995) and to published material. No validity assessment was performed and it is unclear if more than one reviewer was involved in the selection and data extraction of included studies. Details of individual studies were not provided so it is not possible to verify the conclusions of the reviewers. The number of included studies was fairly small and sample sizes small so the overall number of participants on which conclusions are based is small. Studies have not been weighted before being pooled and have been combined across different study designs, types of illness, interventions and outcomes. Combining within-subject designs and between-group designs may exaggerate the treatment effect. Differential effects of therapy for types of illness are not explored. Treatment effects for different interventions and outcomes have been explored but need confirmation from further research before conclusions can be drawn. This review helps to confirm the validity of psychological interventions for children with chronic medical conditions but does not allow detailed conclusions on selected illnesses to be drawn.