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Interventions for supporting informal caregivers of patients in the terminal phase of a disease (Review)

Candy B, Jones L, Drake R, Leurent B, King M

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[Intervention Review]

Interventions for supporting informal caregivers of patients in the terminal phase of a disease

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ABSTRACT

Background

Patients in the terminal phase of a disease may have complex needs. It is often family and friends who play a central role in providing support, despite health professional input and regardless of whether the patient is at home or elsewhere. Such informal caring may involve considerable physical, psychological, and economic stresses. A range of supportive programmes for caregivers is being developed including psychological support and practical assistance.

Objectives

To assess the effects of supportive interventions that aim to improve the psychological and physical health of informal caregivers of patients in the terminal phase of their illness.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library*, Issue 2 2010); MEDLINE (1950 to May 2010); EMBASE (1980 to May 2010); PsycINFO (1872 to May 2010); CINAHL (1937 to May 2010); National Health Service Research Register (2000 to November 2008) and Dissertation Abstracts (1716 to May 2010). We searched the reference lists of relevant studies; contacted experts; and handsearched journals.

Selection criteria

Randomised controlled trials (RCTs) of interventions to support adults who were caring for a friend or relative with a disease in the terminal phase. Interventions could include practical and emotional support and/or the facilitation of coping skills. Interventions could support caregivers indirectly via patient care.

Data collection and analysis

Two authors independently screened citations against the selection criteria. Data were extracted by one author and checked by another. This included extraction of any adverse effects. Risk of bias assessment was undertaken by two authors. We contacted trial authors to obtain missing information. Trial data were combined, where appropriate, on the review's primary outcomes.

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Main results

We included eleven RCTs involving 1836 caregiver participants. Nine interventions were delivered directly to the caregiver. Seven of these provided support in the caring role, another involved a family life review, and one grief therapy. None provided practical support. The other two interventions aimed to support caregivers indirectly via patient care. Overall the risk of bias is unclear, as all trials under-reported methods.

There is low quality evidence that interventions directly supporting the caregiver significantly reduce psychological distress in the short term (8 trials: standardised mean difference (SMD) -0.15; 95% confidence interval (CI) -0.28 to -0.02). There is also low quality evidence that these interventions in the short term may marginally improve coping skills and quality of life, but neither results were statistically significant (7 trials: SMD -0.05; 95% CI -0.24 to 0.14; 6 trials: SMD 0.08; 95% CI -0.11 to 0.26, respectively). One study assessed physical outcomes, specifically sleep improvement, and found no difference (median effect 0.00). No study measured health service use or adverse outcomes. In one study, however, a subgroup of intervention participants had higher levels of family conflict.

Evidence was less clear on the indirect interventions. While both trials in this category found that supporting the patient may reduce psychological distress, none of the four assessments were statistically significant. There were no evaluations of coping with the caring role, quality of life, service use or adverse outcomes. In one trial there was no difference between trial arms in the proportion of caregivers reporting good physical health.

Authors' conclusions

There is evidence that supportive interventions may help reduce caregivers' psychological distress. These findings suggest that practitioners should enquire about the concerns of caregivers and should consider that they may benefit from additional support. There is, however, a need for further research to explore the benefits identified, and to assess the interventions' effects on physical health, and potential harms. Trials need to report their methods fully.

PLAIN LANGUAGE SUMMARY

Interventions for supporting family and friends of patients at the end of life

Family and friends are often central to the care of patients at the end of life. While providing such informal care can generate strong positive emotions, caring can be extremely stressful both mentally and physically. Support strategies are being developed. These can involve, for example, advice on caring and practical support. However, it is unclear if these strategies are beneficial.

We conducted our review through searches for studies that were randomised controlled trials and that evaluated an intervention to support family and/or friends of patients at the end of life.

We found 11 trials involving 1836 caregiver participants in total. The trials commonly evaluated an intervention that provided emotional support and advice on coping. Two studies aimed to help support the family and friends indirectly by addressing the needs of the patient. Apart from one trial providing patient care, none provided practical support. Trials compared those who received the intervention with those who did not, to see if the intervention helped the family, family member or friend cope with their caring role. Trials commonly evaluated the intervention by measuring whether it improved the caregiver's general wellbeing.

The review found that interventions that directly support the family and/or friends help them to cope emotionally, and may help them to cope with their role in caring and improve their quality of life. There were few assessments of the impact of the interventions on physical health; one study found overall no difference in sleep improvement. No study looked at whether the interventions increased or decreased the carers' health service use or looked for potential harms, although higher levels of family conflict was identified in some participants in one trial. Interventions that aimed to help support the family and/or friends indirectly via patient care, may also help them cope emotionally. There were no assessments on whether the indirect interventions helped them cope with their role in caring, improved quality of life, increased or decreased their health service use, or had potential harms. In one of these trials there was no difference in caregiver physical health between those whose friend or relative had received the additional patient care, and those who had not. The findings of some studies included in this review may be at risk of bias, because they under-report key design features and may have been conducted poorly.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Population: informal caregivers of patients in the terminal phase of a disease					
Outcomes	Illustrative comparative risks* (95% CI)		No of participants	Quality of the evidence	Comment
	Assumed risk	Corresponding risk			
	Control	Direct intervention			
Psychological distress	The mean score for psychological distress ranged across control groups from 0.4 to 12	The mean psychological distress in the intervention groups was 0.15 standard deviations lower (0.28 to 0.02 lower)	936 (8 studies)	⊕⊕○○ low ^{1,2}	
Coping with the caring role	The mean score for coping with the caring role ranged across control groups from -139 to 71	The mean coping with the caring role in the intervention groups was 0.05 standard deviations lower ³ (0.24 lower to 0.14 higher).	738 (7 studies)	⊕⊕○○ low ^{1,2}	
Quality of life	The mean score for quality of life ranged across control groups from -48 to 65	The mean quality of life in the intervention groups was 0.08 standard deviations higher (0.11 lower to 0.26 higher)	631 (6 studies)	⊕⊕○○ low ^{1,2}	
Physical health: sleep quality	See comment	See comment	30 (1 study)	⊕⊕○○ low ^{1,2}	The median effect size of the eight evaluations undertaken in the study was 0.00
Health service use	See comment	See comment			None of the 9 studies measured health service use
Adverse events	See comment	See comment			None of the 9 studies set out to measure adverse events but in one study a subgroup of intervention participants had higher levels of family conflict
CI: Confidence interval					

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

1. Not all studies provided/study did not provide full methodological details.
2. It is difficult to exclude the risk of publication bias.
3. Outcome expressed as the lower the better in coping with the caring role.

BACKGROUND

The terminal phase of a disease is defined as the stage when a person's disease is not amenable to cure, their health is progressively deteriorating and the health professionals involved in their care do not expect them to survive longer than days, weeks or months. At this time, the aim of treatment is supportive or palliative, in order to ensure maximum comfort for patients and ease of coping for those close to them. In this final phase of life a person may have complex care and support needs, and many concerns. Needs may include: symptom management; emotional and spiritual support; assistance with personal and instrumental care; transportation; and the monitoring and assessment of, and help with, communication with health professionals about disease progression and palliative treatment.

It is often family members and friends who play a central role in providing care, despite health professional input and regardless of whether the patient is at home or in a formal healthcare setting. Although such informal caregivers (for clarity hereafter expressed as caregivers) often undertake the role and derive personal rewards, such as greater meaning, purpose and commitment from care giving (Horowitz 1985; Hudson 2005; Nijboer 2001), being a caregiver may also involve considerable physical, psychological, economic and domestic challenges. These can take their toll on a caregiver, who also needs to deal with their own sorrow and sense of impending loss. Such challenges and stresses, sometimes called caregiver burden, can affect aspects of caregivers' wellbeing; they may feel isolated and lack time to reflect on their own needs and regain energy. It may also affect their own health, resulting in fatigue, sleeping problems, weight loss, depression, anxiety and an increased risk of death (see, for instance: Low 1999; Pinguart 2007; Schulz 1999; Schulz 2004; Thomas 2002). Family and friends often have their own emotional and physical distress, experience financial strain, have to cope with medical decisions and may have other dependants. These issues may impact on the patient, affecting the quality and duration of their home care (Gomes 2006; Higginson 2008; Holicky 1996). The public health implications of caregiving include use of health care by the caregivers themselves in addition to patients. As populations age, the impact of such effects increases; palliative care is shifting into patients' homes with longer survival time in the terminal phase. These effects are compounded by more potential caregivers working away from home and by increased social mobility, with the result that fewer family members are available to commit to regular caregiving than was the case a generation ago.

Healthcare policies in a number of countries recognise that caregivers of patients in the terminal phase may require a wide range of support, including information about the disease process and personal support. Resources are also needed for emotional distress, for spiritual wellbeing, and for physical needs such as adequate sleep, in addition to domestic help and financial support (see for instance, the WHO National Cancer Control Programmes (WHO

2002), the UK NHS Cancer Reform strategy 2007 (DH Strategy 2007), the US National Family Caregiver Support Program (US DHHS 2003) and the Australian National Palliative Care Programme (DHA 2008)). Whilst support for caregivers is a core tenet of palliative care philosophy, and in some countries charitable organisations offer caregiver support, it is not uncommon that caregivers' needs are unmet (see for instance Osse 2006 and Soothill 2003). Caregivers may have considerably more unmet psychosocial needs than the patients themselves (Soothill 2003). In their review of the literature on palliative caregiver support services Harding et al (Harding 2003) conclude that since the main focus of specialist palliative care services is the patient, it is not surprising that caregivers' needs remain unmet. It is also likely that healthcare providers do not always know how or when to provide support to caregivers, and may feel it is beyond their skills and resources to do so. Addressing caregivers' needs is not straightforward. Their needs may be broad ranging and may change during the period of caregiving, as well as in the bereavement phase. This complexity may explain why support for caregivers is less developed than other aspects of palliative care services. Caregivers may also not recognise or, in an attempt to avoid redirecting resources away from the patient, may be reluctant to seek support for their own needs. They may feel a need to preserve self-reliance, independence, dignity and familiar aspects of life (Grande 1997; Soothill 2003). By revealing their own needs, caregivers may worry that health professionals might conclude that they are not able to care appropriately for their loved one.

A wide range of healthcare programmes and strategies are being developed and implemented that aim to support caregivers. This support has a number of general aims:

- to reduce the amount of care provided by a caregiver, for example by offering respite services;
- to improve coping skills, for example by providing programmes that facilitate problem solving;
- to improve wellbeing, for example by providing psychological programmes such as counselling, relaxation and psychotherapy;
- to deliver such interventions at an appropriate time ('window of opportunity').

The importance of evaluating these strategies for caregivers in general, and for those involved in terminal care specifically, is recognised by several organisations, for example, the International Palliative Care Family-Carer Research Collaboration 2007 (<http://www.ipcfrc.unimelb.edu.au/>) and National Institute for Clinical Excellence (NICE 2004).

There is some evidence on the impact of such interventions in related topics. In a narrative review of evaluations of interventions

for caregivers of older patients with a chronic, severe and progressive disease, or a physical disability, Sørensen and colleagues identified 78 studies (Sørensen 2002). Although they noted a lack of random assignment to treatment and control groups in many of these studies, they concluded that interventions which provided psychological support, were educational (such as providing information about the care recipients' disease process), aimed to enhance caregivers' coping skills, or provided a combination of such interventions, appeared effective in the short term in ameliorating caregiver burden and depression as well as increasing caregiver satisfaction, ability and knowledge. The interventions also seemed to reduce symptoms in the patient who was the focus of care. Since the publication of this review, interventions intended specifically to support caregivers of patients in the terminal phase have been evaluated in controlled comparison studies. These commonly assess interventions aimed to improve 'wellbeing' such as quality of life and emotional health. Wellbeing is perhaps more consistently measured in studies compared to other outcomes, such as health service use. However, the context of caring for a dying relative can be extremely stressful and it is likely that any intervention to improve support will have a limited impact on improving the distressing outcome of that experience.

The evidence base on trialled interventions to support family and friends caring for patients in the terminal phase of disease has not been reviewed systematically and it remains unclear:

- which type(s), elements or combinations of interventions or services have been evaluated;
- which interventions provide greater potential benefit to caregivers and are more acceptable;
- how interventions are best delivered - as part of care services for the patient or as a separate programme of support; and
- which caregivers (such as those at higher risk) might benefit most.

OBJECTIVES

To assess the effects of supportive interventions that aim to improve the psychological and physical health of informal caregivers of patients in the terminal phase of their illness.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs). We anticipated that there would be few, if any, RCTs in this area and intended to include a range of study types, specifically RCTs, quasi RCTs, controlled before-and-after studies and interrupted time series studies. However, as our search identified 11 RCTs, we chose to limit the review to RCTs, as they provide a higher level of evidence of effectiveness.

Types of participants

We included adults (at least 18 years of age) who were caring informally for a friend or relative with a disease in the terminal phase. We defined a caregiver as an unpaid person providing physical, practical and/or emotional care and support to a relative or friend. We planned to include evaluations where caregivers were in receipt of financial or other benefits in recognition of their caregiving role and to take account of this additional support in our interpretation of the results. We did not exclude, however, trials that did not provide an indication of caregiving. This was based on the assumption that such close persons (i.e. family and/or friends) would be involved to some extent in the supportive care of the patient by the nature of their relationship, and also because the patient had reached the terminal phase. We recorded, where reported, the extent of caregiving and planned to explore this factor in subgroup analysis.

We included studies in which the care recipient (the patient) had a terminal disease and met one or more of the following criteria: (1) disease stage described as 'at an advanced stage', 'terminal stage', 'end-stage', 'end-of-life', 'dying', (2) a prognosis of less than a year, (3) health was progressively deteriorating or (4) was receiving palliative care. Care recipients with diseases in the terminal phase may have included, but were not restricted to, people with cancer, chronic obstructive pulmonary disease (COPD), heart failure or AIDS. Care recipients could have been living at home, in the community, or any healthcare setting such as a hospital or a hospice.

Types of interventions

Studies were included if they evaluated an intervention that aimed to provide support to the caregiver in addition to usual care. These interventions could have provided support directly and involved one or more of the following (1) practical support such as domestic or respite services; (2) aim to increase coping skills, for example by providing programmes that develop problem solving; or (3) aim to enhance wellbeing, for example by providing counselling, relaxation or psychotherapy. Interventions could also have provided support indirectly by providing, for example, support for patients such as a palliative care intervention. Health professionals, other professionals or lay persons could have delivered the intervention. To reduce the risk of reporting bias, trials were only included if they stated that a main aim of the evaluation was to assess the impact of the intervention on the caregiver, as opposed, for example, to a secondary analysis on trial data that was collected to answer a

different research question, such as the impact of the intervention on the patient only.

Specific comparisons included usual patient care and other forms of the intervention, or input from palliative care services. Usual care (which may be specialist or generalist for patients in the terminal phase) was likely to include varying levels of caregiver support offered either directly or indirectly, and may not have been itemised or defined. However, in the true spirit of randomised trial methodology, these known and unknown differences were assumed to be accounted for in the randomisation.

Types of outcome measures

Primary outcomes

1. Psychological health outcomes included measures of psychological distress such as symptoms of depression, anxiety or feelings of hopelessness, measures of quality of life (QOL) or wellbeing, and ability to cope with the stresses of caring for a terminally ill family member such as caregiver strain or experiencing a negative appraisal of their caregiving role.
2. Physical health outcomes such as fatigue, tiredness and sleeping difficulties.
3. Service delivery outcomes including health service use.
4. Adverse outcomes.

Secondary outcomes

1. Acceptability to the caregiver.
2. The caregiver's knowledge of the patient's disease process, and of resources and services available to support them in providing care.
3. The perceived impact on the care received by the patient, such as the duration of and satisfaction with care, and place of death.
4. The impact on caregiver bereavement.
5. Cost evaluation.

Search methods for identification of studies

Electronic searches

We searched the following electronic databases:

- The Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library, Issue 2 2010*);
- MEDLINE (OVID) (1950 to May 2010);
- EMBASE(OVID) (1980 to May 2010);
- PsycINFO (OVID) (1872 to May 2010);
- CINAHL (EBSCO) (1937 to May 2010);
- National Health Service Research Register (2000 to November 2008);

- Dissertation Abstracts (INDEX TO THESES) (1716 to May 2010);

Search terms

The search terms we used reflected components of our research question: A) Intervention, B) Caregiver, and C) Terminal phase. We tailored search strategies to databases. There were no language or date restrictions. The strategies for CENTRAL, MEDLINE, EMBASE, PsycINFO, and CINAHL are provided in [Appendix 1](#); [Appendix 2](#); [Appendix 3](#); [Appendix 4](#); [Appendix 5](#).

Searching other resources

We searched reference lists and undertook forward citation checks of all included trials and relevant reviews identified. We contacted experts in the field for advice as to other potentially relevant studies (See [Acknowledgements](#)). We handsearched the following peer-reviewed journals from January 2005 to May 2010: *Palliative Medicine*, *Journal of Pain and Symptom Management*, and the *British Journal of Psychiatry*.

Data collection and analysis

Selection of studies

Two review authors (BC; LJ) independently screened all citations against the selection criteria. Following screening, the same two review authors assessed the full text of potentially eligible citations for inclusion. If differences of opinion had arisen we planned to discuss this with the other review authors (RD, BL, MK and AT) and if resolution had been difficult, we planned to attempt to contact the study authors for clarification. We documented studies excluded after full text assessment, giving reasons (see [Characteristics of excluded studies](#)).

Data extraction and management

Two review authors (BC and LJ) independently extracted data from the included studies. A data extraction form was designed for this review. Where possible, the following information was extracted for each trial:

- Type of intervention and terms used to describe the disease stage.
- The number of caregivers eligible, the number randomised, and reasons why any caregivers were not included in the trial.
- The number of caregivers evaluated at follow-up(s), reasons for loss to follow-up, and how the trials, if stated, handled deviations from randomised allocation and missing response.
 - Caregiver characteristics, namely the relationship to the patient (such as spouse or adult child), age, gender, health, physical function, whether caregiver and patient were living in

the same household, and whether the caregiver received any financial or other benefit for their role.

- Patient characteristics including the type of setting in which the patient was being cared for, as well as their age, gender, terminal disease, physical functionality and co-morbidities.
- The number of hours provided in caregiving and the level and nature of care, including duration of caregiving.
- Study design features including masking [MP: Is this the same as blinding? If so, please call it blinding], and features of randomisation.
- Content of the intervention including the aim, who delivered it, duration and number of sessions and the mode of delivery (including whether it was conducted with individuals or in a group setting). We also reported whether the content of the intervention was standardised by the use of a manual.
- Comparison intervention including content, duration and mode of delivery.
- Outcome quantitative data at the end of treatment and at the end of follow-up, including how it was measured.
- We also planned to extract any qualitative evidence in included studies, such as analysis of participants' views on the value of the intervention.

Where information was lacking, we attempted to contact the trial authors or trial sponsors. We successfully contacted the authors of six trials (see [Acknowledgements](#)).

One author (BC) entered the extracted data in Revman and data were checked by a second author; specifically LJ checked entries on trial description and RD/BL checked entries on trial findings. If there had been any discrepancies, the other review authors (MK and AT) would have been consulted and discrepancy resolved by consensus.

Meta-analytical framework: selection of outcomes

We developed a meta-analytical framework after the search to manage the diversity of outcomes found. Ideally, trials included in a meta-analysis will use the same outcome measures at the same time points, however the trials we identified posed several challenges. The framework we developed recognises differences between the trial evaluations, and has a broad remit on what trial data can be combined to provide a pooled effect estimate while preventing the loss of potentially relevant information. It follows an approach used by the Cochrane Effective Practice and Organisation of Care (EPOC) Review Group ([Grimshaw 2003](#)).

The framework addresses four specific issues:

- different interventions that aimed to facilitate change in a similar manner;
- different outcomes that could be considered broadly similar;
- no primary outcome and more than one assessment to measure similar outcomes, such as those relating to coping with the caring role; and

- different follow-up times, for example a few days after trial treatment phase to several months after patient's death.

These issues were addressed in the following way:

Similar but different interventions

We initially grouped trial data based on similarity in terms of how an intervention aimed to facilitate change. Specifically, we considered whether the intervention was provided directly to the caregiver or provided indirectly to the caregiver, such as giving support to the patient.

Similar but different outcomes

We grouped outcomes which were different but which could be considered broadly similar into three main areas: psychological health; physical health; and service delivery.

a. Psychological health, which included three outcome subcategories:

- Psychological distress, which included outcomes such as symptoms of depression or anxiety.
- Coping with the caring role, which included outcomes such as caregiver burden or stress or appraisal of caring role.
- Quality of life and wellbeing.

b. Physical health.

c. Service delivery outcomes including health service use.

Multiple outcomes per category

Some trials used multiple measures to assess similar categories of outcomes, such as coping with the caring role measured by perceived role preparedness, or competency in role, or level of caregiver burden. We extracted all outcomes within a category for each trial, standardised the direction of effect by multiplying by -1 if scales were in opposite directions, and ranked the effect estimates or the standardised mean effect which we generated for ordinal outcomes. We report the median effect estimate for each outcome, or, where there were an even number of outcomes, the most conservative of the two central median effect estimates. For all trials reporting multiple outcomes, we used the median outcome.

Different follow-up times

To manage differences in the follow-up times we selected outcomes at two follow-up time-points only:

- The first follow-up after the end of the intervention programme. The choice of this time-point was to reduce the risk of attrition bias which was likely to be high in these study populations because of declining health or death. Some trials included a booster or refresher phase, but to avoid dilution of treatment effect we extracted data immediately after the bulk of the intervention had been delivered.

- The final follow-up. The choice of this time-point was to capture longer term effects. However, as this time-point differed across trials and had increased risk of attrition, we anticipated that we would not be able to pool these data.

The Additional tables detail the effect estimates selected for the trials included in the review.

Qualitative evidence

We planned that if any qualitative data were reported in the included trials, we would extract this in consultation with the Cochrane Qualitative Methods Group. Such qualitative data could have captured caregivers' views on the value of the intervention.

Assessment of risk of bias in included studies

We assessed and reported on the risk of bias of included RCTs in accordance with the guidelines of the Cochrane Consumers and Communication Review Group ([Template 2008](#)), which recommends the explicit reporting of the following elements for RCTs: sequence generation; allocation concealment; blinding; completeness of outcome data; and selective outcome reporting. For blinding we only considered blinding of outcome assessors, i.e. data collectors, as it would have been difficult because of the nature of the intervention to blind the treatment provider or the recipient of the intervention. For each domain we assessed whether there was a low risk of bias (if the study matched the criteria), a high risk (if the study did not match the criteria) or unclear risk of bias (for example, because of under reporting), and reported this in Risk of Bias tables (see [Characteristics of included studies](#)). We defined trials as having an overall low risk of bias if they scored a low risk of bias on four of the five domains in the risk of bias table. We labelled a trial as having an unclear risk of bias if the trial provided too few details to make a judgement of 'high' or 'low' risk. We also assessed the intervention, in terms of whether there was a manual used to guide the interventionist in how to deliver the intervention, and whether there was sufficient information available for the intervention to be replicated elsewhere.

Two review authors (BC and RD/BL) assessed the risk of bias of included studies, with disagreements resolved by discussion and consensus. Where possible we contacted study authors for additional information (See [Acknowledgements](#)). We incorporated the results of the risk of bias assessment into the review through systematic narrative description and commentary about each item, leading to an overall assessment of the risk of bias of included studies and a judgement about the internal validity of the review's results.

Measures of treatment effect

Treatment effects were measured using dichotomous data, or ordinal rating scales.

Dichotomous data

Where dichotomous data were reported, we extracted or generated odds ratios (ORs) and their 95% confidence intervals (CIs).

Continuous data

Where continuous data were reported, we extracted or generated the mean difference (MD) from the means and standard deviations. Effect measures for ordinal data were assessed as continuous data.

Unit of analysis issues

For identified cluster randomised controlled trials we checked for unit of analysis errors, and planned, if analysis errors were found and sufficient data were available, to recalculate the results using the appropriate unit of analysis ([Higgins 2008](#)).

Dealing with missing data

Missing studies can result from an inadequate search for data or from publication bias in that papers with negative findings are less likely to be published. How we dealt with this is detailed in [Search methods for identification of studies](#) and in [Assessment of reporting biases](#).

We anticipated finding a significant amount of loss to follow-up in this review, due either to the patient's declining health and the caregiver's need for more time with their loved one, or because of the death of the patient. We report attrition rates, per trial, in the Risk of Bias tables (see [Characteristics of included studies](#)). This included, if available, per trial arm reasons for attrition, and whether the trial stated any re-inclusions performed in analyses. We did not undertake any imputation for missing participant data. A common item missing in outcome data is the standard deviation (SD) for continuous outcomes. Where data were not reported, but might be available we attempted to contact the study authors. If contact with the author was not possible, we planned to calculate or impute it using relevant data, only if a minority of the trials (to be combined in a meta-analysis) had a missing SD ([Higgins 2008](#)). If we had undertaken such imputation we would have performed sensitivity analyses to assess its impact on combined analysis.

We did not exclude trials on the basis of missing data. In the [Discussion](#) section we address the potential impact of missing data on the findings of the review.

Assessment of heterogeneity

Where meta-analysis was possible, we assessed statistical heterogeneity between trials using the Chi² statistic and I² statistic (a Chi² P value of less than 0.05 or an I² value equal to or more than 50% was considered to indicate substantial heterogeneity). If substantial heterogeneity was identified, we planned to undertake subgroup analyses to investigate its possible sources.

Assessment of reporting biases

Publication bias

We explored publication bias visually using funnel plots.

Data synthesis

As the interventions and patient populations were quite variable, we employed random-effects meta-analyses. We planned to compute an absolute risk reduction from the results of any meta-analysis of odds ratios (ORs). For outcomes where meta-analysis was not appropriate, including for all secondary outcomes and all outcomes at the end of follow-up, we provide information on the consistency of effects across all trials using the median effect estimate, the number of comparisons showing a positive direction of effect of the intervention and the number of comparisons that showed a statistically significant effect.

Summary of Findings table

We use a summary of findings table to present the main findings of the review, specifically on the quality of the evidence, the sum of available data on the main outcome and the magnitude of effect of the interventions.

Subgroup analysis and investigation of heterogeneity

Subgroup analysis explores whether the overall effect varied with different trial populations, and with the nature and content of the interventions. Specifically, within the broad subgroups of direct and indirect interventions, we planned to explore (1) whether the intervention was composed of more than one distinct component, and (2) what the intervention primarily aimed to improve, such as coping by facilitating problem solving skills, or wellbeing by providing relaxation therapies.

We also aimed to explore the modification effect of caregiver characteristics by performing the following subgroup analyses:

1. Caregiver at higher risk of a negative outcome ([Stroebe 2007](#))
2. Intensity of care giving ([Abernethy 2008](#))

Sensitivity analysis

We planned to perform sensitivity analyses in order to explore (by excluding trials) the influence of the following factors:

1. Unpublished trials
2. Trials that did not use a validated scale to measure psychological wellbeing
3. Trials of high or unclear risk of bias.

Consumer participation

We developed a consumer advisory group that was consulted when drafting the full review and will continue to be involved whenever a significant amendment of the published review is considered. Members of the group assisted the review authors to interpret the outcomes, highlighted evidence gaps and ensured the review was readable and understandable from a consumer perspective. Specifically, this was undertaken by one consumer commenting on the protocol, and review authors presenting to the group for their feedback on drafts of our findings and inviting them to comment on a written draft before submission to the Cochrane Consumers and Communication Review Group. The consumer advisory group involved members of the North London Cancer Partnership Network. The majority of active members of this group are lay persons including people with terminal cancer, survivors of cancer, as well as caregivers of patients with a terminal illness.

Consumers were also involved in the standard peer review process of the Cochrane Consumers and Communication Review Group, providing feedback at protocol and review stages.

RESULTS

Description of studies

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

Results of the search

Electronic searches generated a total of 8269 citations. Screening of titles and abstracts identified 45 studies that were potentially relevant. On full text, we excluded 34 of these studies, primarily because they were not RCTs and/or they did not include caregiver outcomes (see [Characteristics of excluded studies](#)). Following completion of the searches, we identified a relevant new trial through attending a palliative care conference, however its results are not yet available ([O'Hara 2010](#)).

Included studies

Eleven relevant RCTs were identified ([Addington-Hall 1992](#); [Allen 2008](#); [Carter 2006](#); [Hudson 2005](#); [Kane 1984](#); [Keefe 2005](#); [Kissane 2006](#); [McMillan 2005](#); [Northouse 2005](#); [Northouse 2007](#); [Walsh 2007](#)). Seven trials were conducted in America ([Allen 2008](#); [Carter 2006](#); [Kane 1984](#); [Keefe 2005](#); [McMillan 2007](#); [Northouse 2005](#); [Northouse 2007](#)), two in Australia ([Hudson 2005](#); [Kissane 2006](#)), and two in the UK ([Addington-Hall 1992](#); [Walsh 2007](#)). Eight of the eleven trials included more than 100 participants ([Addington-Hall 1992](#); [Hudson 2005](#); [Kane 1984](#); [Kissane 2006](#); [McMillan 2005](#); [Northouse 2005](#); [Northouse 2007](#); [Walsh 2007](#)).

In total the eleven trials analysed outcomes for 1836 caregivers of patients in the terminal phase of disease.

Informal caregivers

Caregiver participants in the trials were, where reported, middle-aged spouses or an adult child of the patient. In ten trials the mean age of the caregivers was between 50 and 65 years, in the other trial details on age were limited (Addington-Hall 1992).

Trials provided limited details on the level of caregiving. Four trials provided details on the amount of caregiving provided by the trial participant to the patient (Allen 2008; Carter 2006; Hudson 2005; Walsh 2007). These were measured quite differently. One study reported the mean length of care provision, which was 16 weeks (Hudson 2005), while another trial reported that the average amount caregiving per day was 17 hours (Carter 2006). Two other studies had specific caregiving requirements for participant inclusion. To be eligible in one the caregiver had to provide support to the patient for at least one activity of daily living per week (Allen 2008), whereas in the other study the caregiver had to be the main person providing unpaid practical and emotional support to the patient on a regular basis (Walsh 2007).

Three trials looked at caregivers with greater risk of a poor outcome (Carter 2006; Kissane 2006; Walsh 2007). In these trials, eligibility criteria for the caregivers were: those who reported having difficulty with initiating or maintaining sleep, or had non-restorative sleep for at least one month (Carter 2006); families at risk of poor psychosocial outcome based on the Family Relationships Index (Kissane 2006); and those with measurable emotional distress using the General Health Questionnaire (Walsh 2007).

Care recipients

Care recipients were, as per our review's inclusion criteria, patients in the terminal phase of a disease. Apart from one trial (Allen 2008) all care recipients had a type of cancer. In eight trials patients resided at home (Allen 2008; Carter 2006; Hudson 2005; Keefe 2005; Kissane 2006; Northouse 2005; Northouse 2007; Walsh 2007). No details were provided in the trials on the patients' care needs.

Patients were described as: not expected to live longer than six months (Kane 1984; Keefe 2005; McMillan 2005; Walsh 2007) or a year (Addington-Hall 1992); as being at an advanced disease stage (Allen 2008; Carter 2006; Keefe 2005); as having functional decline (Allen 2008); and/or as receiving palliative care (Hudson 2005; Kissane 2006; McMillan 2005; Walsh 2007). In the Northouse 2007 trial prostate cancer patients were recruited either at diagnosis, on biochemical recurrence or at an advanced stage of the disease. This trial was included as randomisation was stratified by phase of disease, and in their analysis the authors found that effectiveness of the intervention was not moderated by disease phase. In Northouse 2005, patients were eligible if, after a disease free interval, they had had within the previous month or

so a diagnosis of breast cancer recurrence. We included this trial as the majority (84%) of patients had reached the stage where their cancer was likely to be at an advanced stage, i.e. had metastasised. The mean age of patients was reported in seven trials and ranged from 54 to 71 years (Kane 1984; Keefe 2005; Kissane 2006; McMillan 2005; Northouse 2005; Northouse 2007; Walsh 2007). In ten trials all patients were diagnosed with a cancer (Addington-Hall 1992; Carter 2006; Hudson 2005; Kane 1984; Keefe 2005; Kissane 2006; McMillan 2005; Northouse 2005; Northouse 2007; Walsh 2007). In two of these trials patients had a particular type of cancer; in the Northouse 2005 trial all patient participants were women with breast cancer, while in the trial by Northouse 2007 all were men with prostate cancer. In the eleventh trial the patients were mixed in diagnoses, including having general disability, a variety of multiple chronic illnesses, heart disease or cancer (Allen 2008).

In eight trials patients resided in their own home (Allen 2008; Carter 2006; Hudson 2005; Keefe 2005; Kissane 2006; Northouse 2005; Northouse 2007; Walsh 2007). In another trial the patients were receiving community-based hospice care, which suggested - although it is not specifically reported - that these patients were also residing at home (McMillan 2005). In one trial patients were enrolled in a hospice program that involved inpatient and home care (Kane 1984). In another, at recruitment the patients were a mix of inpatients and outpatients (Addington-Hall 1992). None of the trials reported the patient's care needs.

Interventions

Nine studies trialled interventions aimed at supporting the caregiver directly (Allen 2008; Carter 2006; Hudson 2005; Keefe 2005; Kissane 2006; McMillan 2005; Northouse 2005; Northouse 2007; Walsh 2007) and the other two trials were of interventions aiming to support the caregiver indirectly via patient support (Addington-Hall 1992; Kane 1984). Nine interventions involved a nurse (Addington-Hall 1992; Carter 2006; Kane 1984; Keefe 2005; McMillan 2005; Hudson 2005; Northouse 2005; Northouse 2007; Walsh 2007). The intensity of the intervention, where reported, varied from two (Carter 2006) to nine (Kissane 2006) contact sessions. Apart from a hospice care intervention (Kane 1984) none of the interventions provided any type of practical support.

Direct interventions

In nine trials the interventions aimed to directly support the caregiver (Allen 2008; Carter 2006; Hudson 2005; Keefe 2005; Kissane 2006; McMillan 2005; Northouse 2005; Northouse 2007; Walsh 2007). In five of these trials the intervention was also directed at the patient (Allen 2008; Keefe 2005; Kissane 2006; Northouse 2005; Northouse 2007). The interventions aimed to facilitate coping skills in seven trials (Allen 2008; Hudson 2005; Kissane 2006; McMillan 2005; Northouse 2005; Northouse 2007;

Walsh 2007) and enhance wellbeing in two trials (Carter 2006; Keefe 2005). None of the direct interventions in these nine trials provided practical support.

Across the trials the interventions aimed primarily to target a range of outcomes: to decrease caregiving stress and increase communication (Allen 2008); to reduce emotional distress (Carter 2006), or anxiety (Hudson 2005); to increase quality of life (Keefe 2005; McMillan 2005), levels of preparedness, mastery, self-efficacy, competence, rewards (Hudson 2005) or coping (McMillan 2005); to facilitate support and communication (Northouse 2005; Northouse 2007); and to reduce the morbid effects of grief (Kissane 2006). All interventions were distinct from care or service provision to the patient and their family.

Seven trials involved a nurse in delivery of the intervention (Carter 2006; Keefe 2005; McMillan 2005; Hudson 2005; Northouse 2005; Northouse 2007; Walsh 2007), although in two of these the intervention was delivered either by a nurse or by a social worker (Carter 2006; Walsh 2007). One trial was a grief therapy intervention delivered by social workers who were qualified family therapists (Kissane 2006). One trial did not report who delivered the intervention (Allen 2008). The interventions ranged from two (Carter 2006) to nine (Kissane 2006) contact sessions. One intervention continued to be provided after the death of the patient (Kissane 2006).

Five trials provided types of advice and support including facilitating problem-solving skills, emotional support, financial advice, future planning and/or patient care education (Hudson 2005; McMillan 2005; Northouse 2005; Northouse 2007; Walsh 2007). One trial with three trial arms included a control group given usual hospice care, one arm that acted as an attention-control group where participants received supportive visits during which nurses discussed the caregiver's feelings and fears, and an intervention arm in which the nurse spent the same amount of time with each participant as in the supportive care arm, providing problem-solving training and giving support to assist caregivers with their caring and management of the patient's symptoms (McMillan 2005). We only included the intervention arm and the usual control group from this trial. We did not include the active treatment control as the comparison arm as it was not relevant to our research question. Both trials by Northouse (Northouse 2005; Northouse 2007) eval-

uated the same intervention, the FOCUS programme, in different populations. As well as aiming to improve coping strategies, this intervention aimed to improve communication between the patient and his or her family.

Two trials delivered the intervention to all the family (Allen 2008; Kissane 2006). In one the intervention aimed to reduce stress and increase family communication by undertaking a life review by constructing a personal legacy, commonly involving the production of a scrapbook of their life together (Allen 2008). The other trial evaluated a family focused grief therapy intervention (Kissane 2006). The therapy aimed to prevent complications of bereavement in families at risk of psychological morbidity by enhancing family functioning and handling of conflict. An eighth trial aimed to improve sleep quality by providing an intervention involving stimulus control, relaxation, cognitive therapy and practical advice on sleep environment (Carter 2006). The ninth trial provided pain management education and training to the patient and their partner (Keefe 2005).

Indirect interventions

Two trials aimed to improve caregiver outcomes indirectly via patient support (Addington-Hall 1992; Kane 1984). Both aimed to enhance the wellbeing of patients and their families. One intervention was provided by a nurse (Addington-Hall 1992); the other by a multidisciplinary hospice team of nurses, physicians, a chaplain, social workers and volunteers (Kane 1984). Neither reported contact time between those who provided the intervention, and the patients and their families.

The evaluated interventions formed part of care services for the patient. One trial involved the impact of inpatient hospice care (Kane 1984). The other evaluated care coordinators who acted as 'brokers' of services. The coordinators' role was to assess the need for advice on how to obtain services and to contact the agencies themselves if necessary; and to ensure that services were provided and were well coordinated (Addington-Hall 1992).

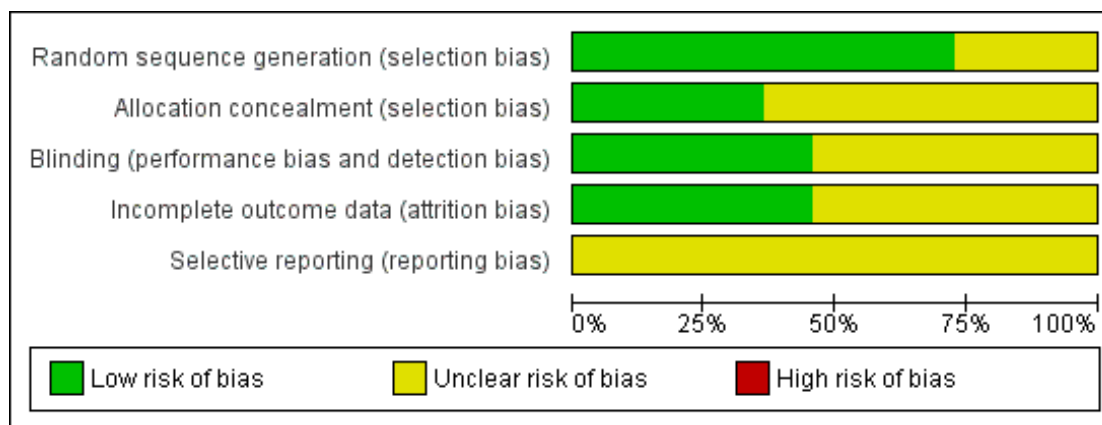
Risk of bias in included studies

See Figure 1 and Figure 2.

Figure 1. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)
Addington-Hall 1992	?	?	+	?	?
Allen 2008	+	?	?	?	?
Carter 2006	?	?	?	?	?
Hudson 2005	+	+	?	?	?
Kane 1984	?	?	?	?	?
Keefe 2005	+	?	+	+	?
Kissane 2006	+	+	?	+	?
McMillan 2005	+	+	+	+	?
Northouse 2005	+	?	+	+	?
Northouse 2007	+	?	+	+	?
Walsh 2007	+	+	?	?	?

Figure 2. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.



Because of under-reporting of some methodological design features, overall the included trials had an unclear risk of bias. Only one trial met our criteria for a low risk of bias (McMillan 2005).

Allocation

Sequence generation: Five of the eleven trials reported adequately how they generated the random allocation sequence (Hudson 2005; Keefe 2005; Kissane 2006; McMillan 2005; Walsh 2007). Allocation concealment: Four trials reported adequate methods to conceal random allocation (Keefe 2005; Kissane 2006; McMillan 2005; Walsh 2007).

Blinding

Six trials provided details on blinding of the outcome assessor (Addington-Hall 1992; Keefe 2005; Kissane 2006; McMillan 2005; Northouse 2005; Northouse 2007).

Incomplete outcome data

In five trials it is unclear if the authors adequately addressed incomplete outcome data (Addington-Hall 1992; Allen 2008; Hudson 2005; Kane 1984; Walsh 2007).

Selective reporting

In all trials there was insufficient information to permit judgement of selective reporting.

Other potential sources of bias

Two trials were cluster randomised trials (Addington-Hall 1992; Kissane 2006). Studies using this design are at increased risk of bias (in terms of allocation concealment) if individuals are recruited after the clusters had been randomised. They are also at an increased risk of bias if clusters are missing from the analysis, and if the statistical methods used do not account for the clustering. Neither trial reported whether individuals were recruited to the trial after clusters were randomised; neither reported that any clusters were missing from analysis. Only in the trial by Kissane 2006 were methods for allocation concealment reported and statistical methods used to account for clustering.

In our assessment of the standardisation of the intervention, seven trials report standardising the implementation of the intervention by use of a manual outlining the intervention delivery (Addington-Hall 1992; Allen 2008; Keefe 2005; Kissane 2006; McMillan 2005; Northouse 2005; Northouse 2007). Two trials provided limited details on the interventions (Addington-Hall 1992; Kane 1984).

Effects of interventions

See: [Summary of findings for the main comparison](#) Direct interventions: primary outcomes on psychological health at end of treatment phase

Outcomes evaluated

All trials measured outcomes using validated psychometric scales. Common outcomes were psychological distress, which was measured in ten trials (Addington-Hall 1992; Allen 2008; Carter 2006; Hudson 2005; Kane 1984; Keefe 2005; Kissane 2006; Northouse 2005; Northouse 2007; Walsh 2007), coping with the caring role which was measured in seven trials (Allen 2008; Hudson 2005; Keefe 2005; McMillan 2005; Northouse 2005; Northouse 2007; Walsh 2007) and quality of life which was measured in five trials (Allen 2008; Carter 2006; McMillan 2005; Northouse 2005; Northouse 2007).

Trials measured outcomes using a variety of scales including:

- for psychological distress, the Hospital Anxiety and Depression Scale (HADS) (Zigmond 1983), and the Centre for Epidemiological Studies Depression Scale (CES-D) (Weissman 1977)
- for quality of life, the Caregiver Quality-of-Life Cancer Scale (Weitzner 1999)
- for coping with the caring role, the Caregiver Burden Interview (Montgomery 1989), and the Carer Strain Index (Robinson 1983).

Trials varied in the length of follow-up, from one week after the completion of the treatment phase (Allen 2008; Keefe 2005) to 13 months (Kissane 2006). In four trials evaluations were undertaken into the bereavement phase (Addington-Hall 1992; Hudson 2005; Kissane 2006; Walsh 2007); in one trial outcomes were measured only in bereavement (Kissane 2006).

Qualitative data

None of the trials undertook a qualitative analysis of any data collected.

Interventions and outcomes not evaluated

None of the trials evaluated health service use, costs, caregiver fatigue, caregiver's knowledge of the patient's disease process, or their knowledge of resources and services available to support them. None of the included trials provided practical domestic support. We identified no trials evaluating supporting caregivers of paediatric patients.

Interventions directed at the caregiver

Nine trials evaluated an intervention that aimed to support the caregiver directly (Allen 2008; Carter 2006; Hudson 2005; Keefe 2005; Kissane 2006; McMillan 2005; Northouse 2005; Northouse 2007; Walsh 2007). Eight of these trials evaluated psychological distress (Allen 2008; Carter 2006; Hudson 2005; Keefe 2005; Kissane 2006; Northouse 2005; Northouse 2007; Walsh 2007), seven evaluated coping with the caring role (Allen 2008; Hudson 2005; Keefe 2005; McMillan 2005; Northouse 2005; Northouse 2007; Walsh 2007), and six quality of life (Allen 2008; Carter 2006; McMillan 2005; Northouse 2005; Northouse 2007; Walsh 2007). Combined analysis of these outcomes suggested these interventions are of benefit, but results were statistically significant only for psychological distress. Apart from one trial evaluating sleeping difficulties (Carter 2006), none of the trials evaluated caregiver physical health.

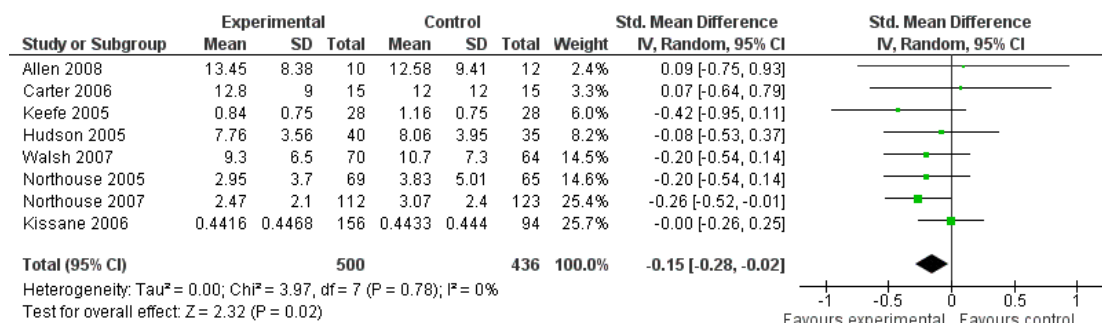
Primary outcomes

Psychological distress

At the end of treatment

See [Summary of findings for the main comparison, Analysis 1.1, Figure 3.](#)

Figure 3. Forest plot of comparison: I Direct Interventions: Primary outcome at end of intervention - Psychological health, outcome: I.I Psychological distress.



Seven of the eight trials measured psychological distress at the end of treatment using one measure (Allen 2008; Carter 2006; Hudson 2005; Keefe 2005; Northouse 2005; Northouse 2007; Walsh 2007). The eighth trial used two assessments of psychological distress: psychological morbidity and symptoms of depression (Kissane 2006). Four of the eight trials measured symptoms of depression (Allen 2008; Carter 2006; Kissane 2006; Walsh 2007), one measured anxiety (Hudson 2005), two studies measured hopelessness (Northouse 2005; Northouse 2007) and one study measured mood (Keefe 2005). In the trial that reported two outcomes, as per the meta-analytical framework we report the most conservative effect, namely psychological morbidity (Kissane 2006). There was a total of 934 participants across these eight trials. The interventions reduced psychological distress (Standardised Mean Difference (SMD) -0.15; 95% CI -0.28 to -0.02). The I^2 at 0% indicates that heterogeneity between trials may not be important. These findings are detailed in the [Summary of findings for the main comparison](#), where we conclude that the quality of the evidence is low as not all trials provided full methodological details and it is difficult to exclude the risk of publication bias. Table 1 provides details on selection of measures used in combined analysis.

Only one subgroup analysis and none of the planned sensitivity

analyses were possible. In a subgroup analysis exploring whether the intervention effect varied in caregivers at a higher risk of poor outcome, those in the intervention continued to have lower psychological distress than the comparison group, but this was no longer statistically significant (two trials: SMD -0.15; 95% CI -0.46 to 0.16) (Carter 2006; Walsh 2007).

At the end of trial follow-up

See Table 2.

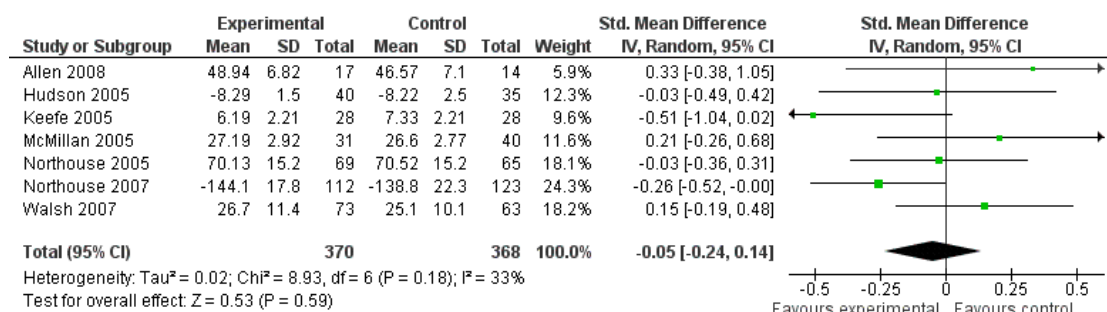
Five trials evaluated psychological distress at the end of the trial follow-up (Carter 2006; Hudson 2005; Keefe 2005; Northouse 2007; Walsh 2007). The median effect size across trials was 0.05; five of the seven evaluations showed a positive benefit in reducing psychological distress, none were significant.

Coping with the caring role

At the end of treatment

See [Summary of findings for the main comparison, Analysis 1.2, Figure 4](#).

Figure 4. Forest plot of comparison: 1 Direct Interventions: Primary outcome at end of intervention - Psychological health, outcome: 1.2 Coping with the caring role.



Two trials measured coping with the caring role at the end of treatment using one measure (Allen 2008; Walsh 2007), the five other trials used multiple assessments (Hudson 2005; Keefe 2005; McMillan 2005; Northouse 2005; Northouse 2007). In combined analysis (selecting the median effect where there were multiple outcomes) we included outcomes on rewarding interaction (Hudson 2005), general mastery of task (McMillan 2005), uncer-

tainty (Northouse 2005), self efficacy (Northouse 2007), and caregiver strain (Keefe 2005; Walsh 2007). When combined, these trials involved 738 patients and showed that the intervention compared to the control marginally improved coping with the caring role, but this was not statistically significant (SMD -0.05; 95% CI -0.24 to 0.14). The I^2 at 33% indicated some heterogeneity between trials. These findings are detailed in the [Summary of findings](#)

for the main comparison, where we conclude that the quality of the evidence is low as not all trials provided full methodological details and it is difficult to exclude the risk of publication bias. Table 3 provides details on selection of measures used in combined analysis.

There were insufficient differences between trials to undertake any of the planned subgroup or sensitivity analyses.

At the end of trial follow-up

See Table 4.

Four trials evaluated coping with the caring role at the end of trial follow-up (Hudson 2005; Northouse 2005; Northouse 2007;

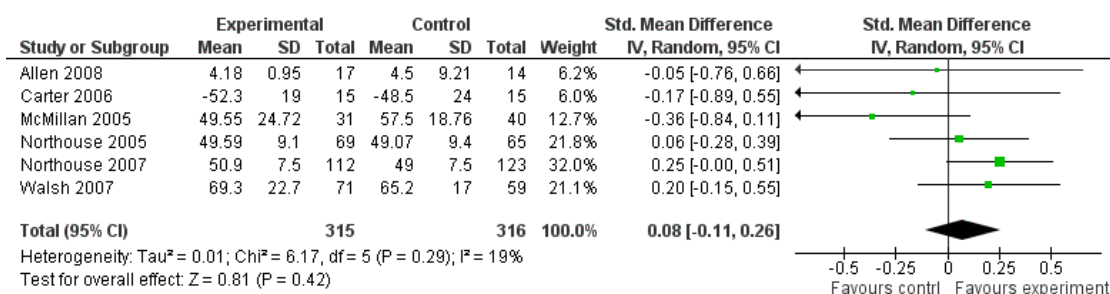
Walsh 2007); the median effect size across trials was -0.05. Twelve of the thirteen evaluations showed a positive impact on coping; the evaluation of active coping and self efficacy showed a significant effect.

Quality of life

At the end of treatment

See Summary of findings for the main comparison, Analysis 1.3, Figure 5.

Figure 5. Forest plot of comparison: I Direct Interventions: Primary outcome at end of intervention - Psychological health, outcome: 1.3 Quality of life.



Four trials measured quality of life at the end of treatment using one measure (Allen 2008; Carter 2006; McMillan 2005; Walsh 2007); two other trials used multiple assessments (Northouse 2005; Northouse 2007). The quality of life assessments included an overall measure of quality of life (Carter 2006; McMillan 2005; Walsh 2007), physical quality of life (Northouse 2005), mental quality of life (Northouse 2007), and subjective wellbeing (Allen 2008). Combining results from these trials (Allen 2008; Carter 2006; McMillan 2005; Northouse 2005; Northouse 2007; Walsh 2007) resulted in a total of 631 patients and a small but not statistically significant improvement favouring the intervention in quality of life (SMD 0.08; 95% CI -0.11 to 0.26). The I² at 19% indicated some heterogeneity between trials. These findings are detailed in the Summary of findings for the main comparison, where we conclude that the quality of the evidence is low as not all trials provided full methodological details and it is difficult to exclude the risk of publication bias. Table 5 provides details on selection of measures used in combined analysis.

There were insufficient differences in trials to undertake any planned subgroup or sensitivity analyses.

At the end of trial follow-up

See Table 6.

Four trials evaluated quality of life at the end of trial follow-up (Carter 2006; Northouse 2005; Northouse 2007; Walsh 2007). Across these trials five of seven comparisons showed a beneficial improvement in quality of life, of which only one (the evaluation of physical quality of life) was significant. The median effect size across the trials was 0.13.

Funnel plots for the meta-analyses on psychological distress, coping with the caring role and quality of life at the end of treatment

See Figure 6, Figure 7, Figure 8.

Figure 6. Funnel plot of comparison: I Direct Interventions: Primary outcome at end of intervention - Psychological health, outcome: I.I Psychological distress.

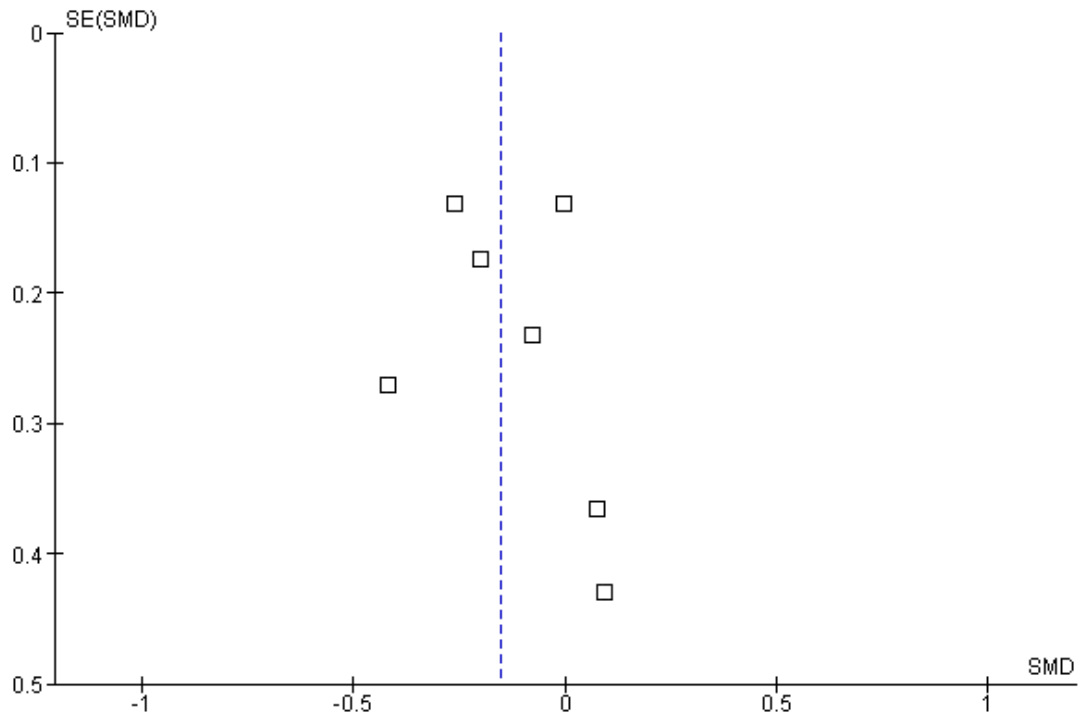


Figure 7. Funnel plot of comparison: I Direct Interventions: Primary outcome at end of intervention - Psychological health, outcome: 1.2 Coping with the caring role.

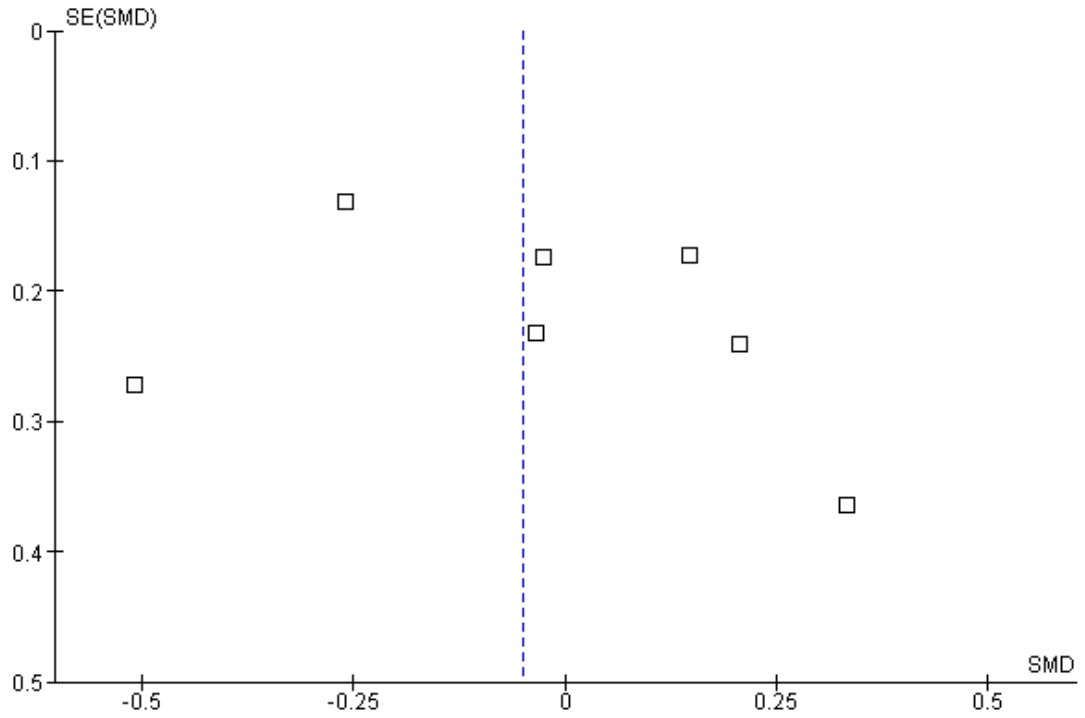
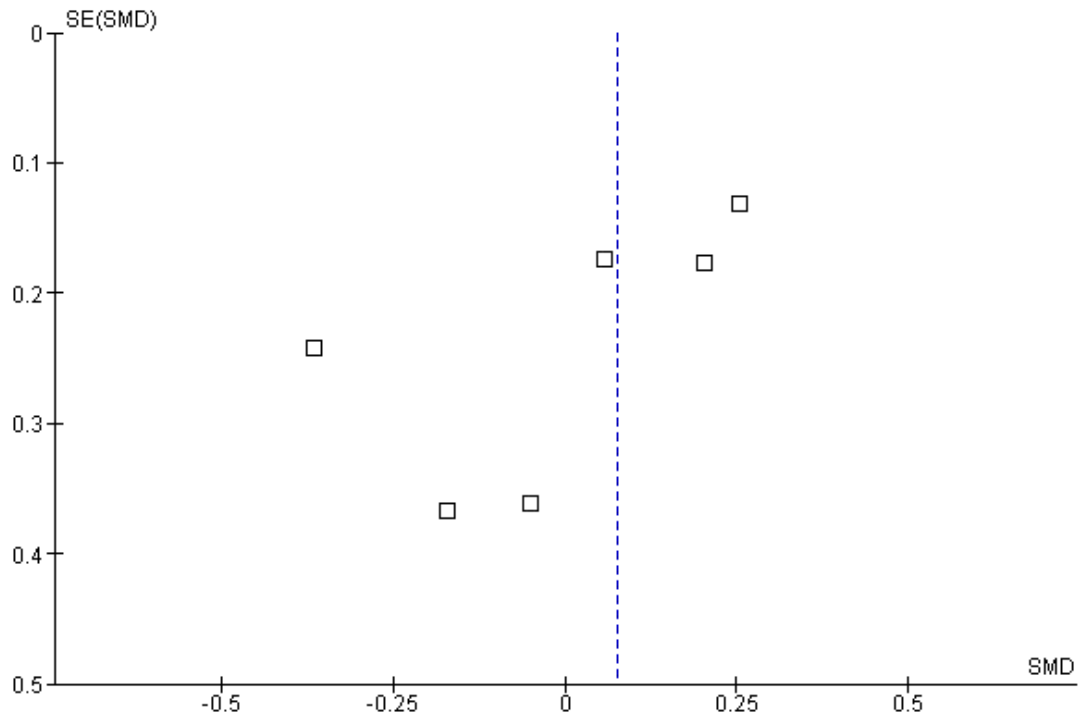


Figure 8. Funnel plot of comparison: I Direct Interventions: Primary outcome at end of intervention - Psychological health, outcome: I.3 Quality of life.



The funnel plots for combined analyses on psychological distress, coping with the caring role and quality of life were all asymmetrical, but the direction of the asymmetry does not indicate publication bias. As there were few trials and as this test typically has relatively low power, publication bias cannot be excluded.

Physical health

At the end of treatment

See [Table 7](#).

One trial assessed a physical outcome at the end of treatment in caregivers, specifically sleep quality ([Carter 2006](#)). The median effect size of the eight evaluations undertaken in the trial was 0.00. Six of the eight evaluations showed greater sleep quality in the intervention group compared with the control group, of which only one was a significant improvement.

At the end of trial follow-up

See [Table 8](#).

At the end of trial follow-up in same trial the median effect of evaluations of sleep quality was 0.49, with most of the assessments, 6/7, showing that the intervention improved sleep compared with the control ([Carter 2006](#)). Two of the results were statistically significant.

Service delivery

None of the trials assessed outcomes relating to caregivers' health service use.

Adverse outcomes

None of the trials set out to identify adverse outcomes. The authors of one trial note that there were no negative outcomes of the intervention ([Hudson 2005](#)). In the trial on family-focused grief therapy, a subgroup of families in the intervention group fared worse than similar families in the control group; these were those classed as hostile in that they tended to reject help, had high family conflict levels, poor cohesion, and poor expressiveness ([Kissane 2006](#)). Specifically, in this small group of participants (n = 19) the trial researchers found that those in the intervention group

had significantly more family conflicts at the end of follow-up (13 months after the treatment phase) than those in the control group.

Secondary outcomes

Bereavement grief

See Table 9.

Two trials assessed outcomes relating to caregiver bereavement grief (Kissane 2006; Walsh 2007). In one trial they found no difference between groups in those experiencing more morbid forms of distress and depression (Kissane 2006); in the other trial they found groups were similar in the intensity of bereavement grief experienced (Walsh 2007).

Acceptability of the intervention to the caregiver

See Table 10

One trial between the trial arms compared caregiver satisfaction with care provision; it found no significant difference (Walsh 2007).

Three trials explored participants' experience of the intervention (Allen 2008; Carter 2006; Walsh 2007). In the Walsh 2007 trial, caregivers in the intervention group were asked what they valued most, and reported that it was the additional emotional support. In the trial by Allen 2008, intervention families reported that the process of undertaking the life review intervention did not evoke feelings of discomfort. This trial also found that 81% (n = 14) of the families were very satisfied with the intervention. In the third trial, participants stated that the sleep intervention guidelines were easy to understand and follow (Carter 2006).

Other secondary outcomes

The included trials did not measure any other of the secondary outcomes including caregiver knowledge, perceived impact on patient care, or cost evaluation.

Other outcomes

At the end of treatment

See Table 11, Table 12, Table 13, Table 14.

Other outcomes at the end of treatment, including communication and social adjustment, were reported in five trials (Allen 2008; Keefe 2005; Kissane 2006; Northouse 2005; Northouse 2007). We did not combine these in meta-analysis because the outcome

was not an outcome of interest identified a priori. A higher proportion of these assessments, 32/49, favoured the intervention, although only three were statistically significant.

Three trials assessed caregiver outcomes (Allen 2008; Kissane 2006; Northouse 2007): namely communication between the caregiver and patient (Northouse 2007); spirituality (Allen 2008); social adjustment and family functioning (Kissane 2006). Four of these assessments found the intervention improved outcomes, of which one was significant (communication with patient (Northouse 2007)).

Four trials evaluated psychological outcomes in patients (Allen 2008; Keefe 2005; Northouse 2005; Northouse 2007). The median effect size across trials was 0.03; 17 of the 26 evaluations found the intervention improved psychological health, although only one was significant (caregiver reporting patient is more talkative). Three trials evaluated patient physical outcomes (Allen 2008; Keefe 2005; Northouse 2007), five of the ten evaluations across the trials showed a non-significant positive improvement favouring the intervention. One trial assessed existential concerns, its two assessments showed a non significant effect (Allen 2008).

Indirect interventions

Two trials aimed to improve caregiver outcomes indirectly via patient support (Addington-Hall 1992; Kane 1984). In one trial the aim was to ensure that patients received appropriate and coordinated healthcare services, that were tailored to the individual patient's needs (Addington-Hall 1992). In the other they evaluated the effectiveness of hospice care (Kane 1984). The caregiver outcomes assessed were limited to psychological distress and physical health. One trial provided data in a format that was inappropriate for meta-analysis (Kane 1984). As this trial was published over 25 years ago, no attempt was made to contact authors to request data on estimates for differences between trial arms. Overall across the two trials, whilst many positive outcomes were found, only one was significant.

Primary outcomes

Psychological distress

Both trials of indirect (patient-support) interventions evaluated psychological distress (Addington-Hall 1992; Kane 1984). One trial provided full details of the analyses (Addington-Hall 1992).

At the end of treatment

See Table 15.

In the Addington-Hall 1992 trial both outcomes showed a positive benefit of the intervention in reducing psychological distress, although neither was significant.

At the end of follow-up.

See [Table 16](#)

One trial assessed psychological distress at the end of follow-up ([Addington-Hall 1992](#)). All three assessments found that those in the intervention group had less psychological distress than those in the control group, but none of the differences were significant. In the other trial the researchers report overall, during the follow-up, significant differences favouring the intervention group in reduction of symptoms of anxiety, but not for symptoms of depression ([Kane 1984](#)).

Coping with the caring role, quality of life, adverse outcomes and service delivery

Neither trial assessed coping with the caring role, quality of life, adverse events or service delivery.

Physical health

See [Table 17](#).

One trial assessed physical health at the end of follow-up ([Addington-Hall 1992](#)). There were no differences found between the two trial arms in physical health.

Secondary outcomes

Acceptability of the intervention

See [Table 18](#).

Both trials explored acceptability of the intervention ([Addington-Hall 1992](#); [Kane 1984](#)). In one they report no significant difference in care satisfaction between caregivers and patients in either trial arm ([Addington-Hall 1992](#)). In the other trial they report that whilst patients randomised to the hospice intervention were overall more satisfied compared to the control group, this was not replicated in their caregivers ([Kane 1984](#)).

Impact of the care received by the patient

See [Table 19](#).

Both trials evaluated patient health and social service use ([Addington-Hall 1992](#); [Kane 1984](#)). In the [Addington-Hall 1992](#), trial four of the twelve comparisons showed a positive direction of effect favouring those in the intervention group in increasing access to support services, such as occupational therapy and physiotherapy, but none of the effects were significant. The other trial reports no significant difference in general hospital use ([Kane 1984](#)).

Other secondary outcomes

None of trials measured other secondary outcomes, including caregiver knowledge, impact on caregiver bereavement, or cost evaluation.

Other outcomes

See [Table 20](#), [Table 21](#).

Both trials evaluated patient psychological distress ([Addington-Hall 1992](#); [Kane 1984](#)). Across the trials in three of the four outcomes it is reported that those in the intervention group had less distress than those in the control group, although none of the effects were significant. Both trials evaluated patient physical outcomes. One reported no significant differences in physical outcomes between the trial arms ([Kane 1984](#)). In the other, for ten of the twelve assessments those in the intervention group had fewer physical symptoms than those in the control group, although none of the differences were significant ([Addington-Hall 1992](#)).

DISCUSSION

Summary of main results

This review evaluates the effects of interventions designed to support informal caregivers of patients in the terminal phase of a disease. The evidence reported represents all of the meaningful data from the included trials on the review's primary outcomes at the end of treatment and follow-up. Some of the review's primary outcomes received only limited assessment, notably caregiver physical health, or were not assessed, as in the case of caregiver health service use. Eleven RCTs involving 1836 caregiver participants met the review's inclusion criteria. The evaluated interventions varied. Nine were delivered directly to the caregiver. These aimed to support the caregiver in various ways, although commonly they involved psychological support and advice on caring. The other two trials evaluated interventions that aimed to provide support indirectly, by addressing patient care needs. None of the studies provided the carer with practical domestic support.

In combined analysis of eight trials totaling 934 participants, it was found that interventions directed at the caregiver helped in the short-term to buffer against psychological distress ([Analysis 1.1](#)). However, the estimated effect size was small: SMD -0.15. In the other combined analyses it was found that, in the short-term, caregivers who received the intervention compared to those in the control group had a marginally better quality of life and a marginally increased ability to cope with the caring role. However these findings were not statistically significant ([Analysis 1.2](#); [Analysis 1.3](#)). In the [Summary of findings for the main comparison](#) we conclude that the quality of this evidence is low.

None of the trials set out to identify adverse outcomes. However, one trial on family-focused grief therapy reported increased family

conflicts in a subgroup of participants who received the intervention (Kissane 2006).

The review is limited in providing a summary of the main results for the two indirect (patient care) interventions as the outcomes across the trials were variable. Evidence suggests, however, that they may help buffer against psychological distress.

Overall completeness and applicability of evidence

The body of evidence we identified allows a conclusion on the objectives of the review. There was evidence of effectiveness on interventions directed at the caregiver. However, because of the limited amount of trial data, and the variability in the types of interventions and in how they were evaluated, the review was limited in its capacity to answer other questions; specifically which interventions provide greater potential benefit and are more acceptable, how they are best delivered and which caregivers might benefit most.

The external validity of some of the evidence presented in this review is affected by the risk of recruitment bias. In two of the trials included, up to 50% of those invited to participate chose not to (Hudson 2005; Kissane 2006). This is perhaps not unexpected in this study population, but it suggests that these interventions may not be appropriate to all caregivers. The generalisability of the review findings is also limited as many of the trials had small sample sizes, suggesting they were under-powered to find a true effect. Caregivers were also predominantly caring for patients with an end-stage cancer. Therefore findings may not be entirely relevant to caregivers of patients with other diseases. Also not all potential types of interventions, such as those that involve financial support or practical support through respite care, and not all outcomes, for example costs, have been evaluated.

How the results of this review fit into the context of current practice differs as current provision of formal support for family and friends who are caring for a loved one in the terminal phase of a disease varies internationally. Many countries provide no such services.

Agreements and disagreements with other studies or reviews

Our findings are in accordance with other reviews on caregiving in the terminal phase, in that the available evidence is based on a wide variety of interventions, making comparison and pooling of results difficult (Harding 2003; Ingleton 2003; Hudson 2004; Grande 2009; Stajduhar 2010). One related systematic review undertook meta-analyses on interventions for family caregivers of cancer patients (Northouse 2010). It included 29 trials, of which only four were included in our review because of differences in inclusion criteria. The Northouse review accords with our findings in that it found the interventions improved psychological wellbeing in the

short-term, although in only four of the authors' nine combined assessments was this significant.

AUTHORS' CONCLUSIONS

Implications for practice

The review findings suggest that, at the very least, healthcare practitioners should enquire about the concerns of family and friends involved in caring for a loved one and should consider that they may benefit from additional support to help them cope with caring. Although it is unclear from this review which types of support may be of more benefit, emotional support and information on managing the care of their loved one were common features of the interventions that were found to help buffer against psychological distress.

Implications for research

The interventions evaluated should be repeated in sufficiently powered rigorous trials in other populations. These trials should include, as appropriate, outcome measures where analysis suggests the interventions may benefit caregivers, such as for psychological health, as well as outcomes under-, or not yet, evaluated, including health service use. Studies should also set out to report any adverse effects, such as for instance an intervention causing greater emotional distress. There is also the need to evaluate interventions that involve practical support. Future trials should fully report key methodological design features.

Although going beyond the evidence generated in this review, there is the need for more theoretical and conceptual work to inform intervention design (Grande 2009). This includes further research on identifying those at in greater need of support (Hudson 2005; Kissane 2006).

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- * Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Addington-Hall 1992

Methods	Randomised parallel controlled trial: cluster randomisation by general practice, stratified by number of partners and postal district	
Participants	<p>Caregivers: 118 caregivers were interviewed at least once. 84% of caregivers lived with patient, 65% were married to patient and 30% were male. Does not provide details on the level of caregiving</p> <p>Patients: 203 UK terminally ill cancer patients (common cancers were breast, lung and colon); male and female (n = 109). Patients were expected to live less than a year. Over 50% were 75 years or older</p>	
Interventions	<p>Directed at the patient.</p> <p>Aim: To evaluate the effects on patients and their families of coordinating care services</p> <p>Interventionist: Two community qualified nurses.</p> <p>Duration: No details.</p> <p>Content: The nurses' role was to ensure that patients received appropriate and coordinated healthcare services, that were tailored to the individual patient's needs and circumstances. The nurses offered advice to the family on how to obtain services and, if necessary, contacted the services themselves. Services were within the NHS, local authority and voluntary sector. The nurses kept in regular contact with patients and their families to assess their changing needs. They encouraged patients to contact them if they needed help or advice. The intervention did not provide any practical support or counselling</p> <p>Standardisation: The intervention was not manualised.</p> <p>Comparison group: Patients continued to receive routinely available services</p>	
Outcomes	<p>Caregiver: Satisfaction with care, impact of caring on day-to-day life, and physical health. Psychological health was assessed using the Leeds Depression and Anxiety Scale. Outcomes were assessed up to 8 weeks following the patient's death</p> <p>Patient: The presence and severity of physical symptoms, psychiatric morbidity, use of treatments, quality of life using the Spitzer Quality-of-Life Index, use of care services, access to benefit entitlement, satisfaction with care and place of death</p>	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information provided.
Allocation concealment (selection bias)	Unclear risk	No information provided.

Addington-Hall 1992 (Continued)

Blinding (performance bias and detection bias) Outcome assessor	Low risk	Outcome assessor: 'Independent interviewers, who were not informed which group the patients were in, interviewed patients at home'
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	118 caregivers were interviewed at least once, 94 were interviewed around 8 weeks following the patient's death. 281/554 patients who entered the study completed baseline interview, of which 203 completed at least one follow-up interview (most common reason for loss to follow up was death (n = 194)). The authors do not state any re-inclusions in analyses performed
Selective reporting (reporting bias)	Unclear risk	No information provided.

Allen 2008

Methods	Randomised parallel controlled trial pilot study.
Participants	<p>Caregivers: American family members who had at least weekly face-to-face contact with the patient to provide assistance with activities of daily living (ADL), and were cognitively intact as measured by a score of 24 or greater on the Mini Mental State Examination (MMSE)</p> <p>Mean age was 55 years (SD 15.23) in the intervention group and 58 years (SD 10.42) in the control group. Most caregivers were female (79% in control and 88% in intervention). 71% in intervention and 65% in control were African American. Mean years in education were 15 years (SD 3.14) in the intervention group and 14 years (SD 2.49) in the control. Does not provide details on level of caregiving (but all patients required assistance with activities of daily living (ADL))</p> <p>Patients: 31 male and female (n = 23) patients. Eligibility included living in the community, aged 60 or older, having a life-limiting (does not define this any further) illness or combination of chronic illnesses, approaching the end of life, has functional decline, and receiving assistance in ADL. The diagnoses of patients varied: around half were classified as either general debility or multiple chronic illnesses, 7/31 had heart disease and 3/31 had cancer</p>
Interventions	<p>Directed at the family.</p> <p>Aim: To evaluate an intervention designed to decrease caregiving stress and increase family communication</p> <p>Interventionist: No details provided.</p> <p>Duration: The intervention involved 3 home visits. The first session averaged in length 82 minutes, the second 66 minutes and the third 70 minutes. Between sessions the family was given homework</p> <p>Content: Intervention involved legacy activities. The researchers defined these as activities that aimed to initiate the process of life review, that can be enjoyed by the family and friends before and after the patient's death. The intervention activities involved generating</p>

	<p>a scrapbook of photographs or an audiotape of stories</p> <p>In the first session a problem solving approach was used to help patients and their families identify a legacy project, it involved coaching family members in generating and sharing positive memories. They were then guided into focusing on a time period in the patient's life that could be adequately represented in a project. They were given a specially designed notebook to help construct their legacy project. It was planned that at the third session the family would share its legacy project with the interventionist. The family was encouraged to construct other legacy projects</p> <p>Standardisation: manual based.</p> <p>Comparison group received 3 supportive phone calls. At the end of the intervention period those in the comparison group received the specially designed legacy participant notebook and guidance in how to construct a legacy</p>	
<p>Outcomes</p>	<p>Caregiver and patient outcomes: Wellbeing (three questions developed specifically for the study. They were designed to capture perception of life satisfaction), and depression using the Center for Epidemiological Studies Depression scale (CES-D)</p> <p>Caregiver stress assessed using the Caregiver Stressors Scale. This measured caregiving competency, strain, role overload, role captivity and emotional control</p> <p>Patients: Symptoms of pain, tiredness, nausea, drowsiness, appetite, and shortness of breath measured using the Edmonton Symptom Assessment Scale. This was completed by patients and caregivers. Patient and caregivers independently completed visual analogue scales in reference to patient on talkativeness, weight loss and agitation. Indices from the Brief Mulidimensional Measure of Religion and Spirituality to assess daily spiritual experience</p> <p>Assessed at 9 to10 weeks from baseline (one week after intervention finished)</p>	
<p>Notes</p>		
<p>Risk of bias</p>		
<p>Bias</p>	<p>Authors' judgement</p>	<p>Support for judgement</p>
<p>Random sequence generation (selection bias)</p>	<p>Low risk</p>	<p>Sequence generated using a random number generator. Block randomisation stratified by race</p>
<p>Allocation concealment (selection bias)</p>	<p>Unclear risk</p>	<p>No information provided.</p>
<p>Blinding (performance bias and detection bias) Outcome assessor</p>	<p>Unclear risk</p>	<p>Outcome assessor: No information provided.</p>
<p>Incomplete outcome data (attrition bias) All outcomes</p>	<p>Unclear risk</p>	<p>42/47 completed baseline assessment, reasons for 5 dyads discontinuing were: patient too cognitively impaired to consent (n = 2), patient changed his/her mind (n = 3). 31/47 families completed the trial, does not provide reasons for the 11 dyads who discontinued the trial later but states</p>

		that they were not significantly different to those who completed in age, education, and mental or health status. CES-D was missing at baseline for 9 couples. Two of the 31 patients and caregiver dyads were assessed at first follow-up only completed the first intervention session. The authors state they were included in the analysis using an intention-to-treat design but do not state how the analysis was performed
Selective reporting (reporting bias)	Unclear risk	No information provided.

Carter 2006

Methods	Randomised parallel controlled trial.
Participants	<p>Caregivers: 30 American male and female (n = 19) caregivers. Participants identified themselves as family caregivers living with patient and reported difficulty with initiating or maintaining sleep or having non-restorative sleep for at least one month. Mean age in intervention group 52 years (SD 16) and in control group 55 (SD 18). Seventeen were spouse/partners (10 of these were in the intervention group), 9 were adult children</p> <p>Mean years in education in the intervention group was 16 (SD 3) and 15 (SD 4) in the control group. 87% in the intervention group and 73% in the control were Caucasian, 20% in the control group were African American, no African Americans were in the intervention group. Mean hours caregiving per day in the intervention group were 17 (SD 6) and in the control group 17 (SD 8). Caregivers were excluded if they reported being diagnosed with a major depressive disorder and/or a preexisting sleep disorder other than insomnia</p> <p>Patients: advanced cancer and rated one symptom as severe or daily, at least two symptoms as moderate or at least three symptoms as mild. Additionally, patient were expected (the study does not report from whose point of view this is) to live no longer than six months</p>
Interventions	<p>Directed at the caregiver.</p> <p>Aim: To evaluate whether behavioural interventions that support caregivers' restful sleep may delay the onset of, or decrease, emotional distress</p> <p>Interventionists: nurses.</p> <p>Duration: Two hour sessions.</p> <p>Content: The Brief Behavioural Sleep Intervention was developed specifically for the study. It incorporated aspects on stimulus control i.e. how the environment affects sleep, relaxation therapies, cognitive therapy, and also sleep hygiene i.e. planning of a good night's sleep. The first session involved guiding participants in self-assessment of maladaptive habits affecting their sleep, and assisting them to develop personal sleep and relaxation goals. The second session reviewed attainment goals</p> <p>Standardisation: The intervention was detailed in a protocol</p> <p>Comparison group received two sessions on information and training about body mechanics such as back health</p>

Carter 2006 (Continued)

Outcomes	Caregiver: Pittsburgh Sleep Quality Index, the Actigraph Sleep Watch, depression measured using the CES-D, and the Caregiver Quality-of-Life Index-Cancer. Outcomes evaluated at 3 and 5 weeks, and at 2 (first after intervention) and 4 months	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information provided.
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding (performance bias and detection bias) Outcome assessor	Unclear risk	Outcome assessor: No information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	5 participants were lost to follow-up (4 as patient died and 1 because of patient's declining health) the authors do not state what group they were enrolled in. The authors do not state any re-inclusions in analyses performed
Selective reporting (reporting bias)	Unclear risk	No information provided.

Hudson 2005

Methods	Randomised parallel controlled two centre trial.	
Participants	<p>Caregivers: 106 Australian family caregivers (primary family caregivers were identified by the patients) aged over 18 years residing with the care recipient. 54 caregivers received the intervention, 52 received standard care</p> <p>Mean age of caregivers who completed study was 60.78 years (SD 13.98). 34.9% were male; 66.7% spouse, 16% adult child, 7.6% parent. 72% of caregivers rated their health as 'good' or 'very good'. 32% of caregivers had a professional or university degree. The mean number of weeks caregivers had been caregiving was 16.3 weeks (SD 5.0)</p> <p>Patients: Advanced cancer (does not define 'advanced' any further) admitted to a community home-based palliative care service. The patient needed to be capable of minimal self care, and up and about more than 50% of waking hours. 54% of patients were female, 48% were rated as having limited self care and confined to a bed or a chair more than 50% of the time, 11% were considered to be completely disabled and confined to a bed or chair all of the time. 43% had at least three friends/family members assisting them to provide care</p>	

Interventions	<p>Directed at caregiver. Aim: To evaluate the effectiveness of the intervention in enhancing the support and guidance offered to caregivers Interventionist: Nurse. Duration: The intervention involved two home visits and one follow-up phone call between the visits. It was supported by a caregiver guidebook and audiotape Content: (1) provision of an opportunity to access information to enhance their understanding of issues and provide a basis for skill acquisition, (2) reinforcement of the role of the palliative care service and other services, and providing strategies to involve family and friends, (3) helping the caregiver make a sense of/find meaning by normalising emotional reactions to the situation and encouraging caregivers to see the positive aspects of experience and offering access to spiritual guidance, (4) promoting caregivers to enhance their own physical and mental health by taking regular time out, having a healthy diet, taking exercise and providing advice on relaxation strategies and (5) providing advice on their rights Standardisation: No details provided. Comparison group: The patients in the comparison group and intervention received standard care from the community home based palliative care service. This included 24 hour phone advice with, if needed, emergency visits from a nurse, in addition to pre-scheduled home visits from nurses, social workers, medical consultants, pastoral care workers, volunteers and bereavement counsellors</p>	
Outcomes	<p>Caregiver: Coping resources</p> <ol style="list-style-type: none"> 1. Preparedness for Care-giving Scale 8 item scale that assessed how ready caregivers perceive they are for their role. 2. Caregiver Competence Scale 4 item scale, this assessed perceived adequacy as a caregiver. 3. 11 items from the Rewards of Care-giving Scale, this assessed perceived potential benefits or positive aspects associated with being a caregiver. 4. Mastery, using one scale from the caregiving appraisal instrument (6 of the 12 items in scale used), which they defined as how much control a person perceives they have over an event. <p>Psychological distress using the Hospital Anxiety and Depression Scale (14 item scale) Appraisal of role using Self Efficacy Instrument by Zeiss: this relates to people's belief that they can initiate courses of action to change. It has 2 sub-scales: 1) caregiver self-care efficacy, on behaviours caregivers could initiate or participate in, intended to reduce stress and heighten wellbeing (e.g., social activities, hobbies, and rest), and 2) problem-solving self-care behaviours</p> <p>Data were collected at baseline, five weeks later (after the intervention) and eight weeks after the patient's death. All outcomes were assessed by self-reported questionnaire</p>	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Hudson 2005 (Continued)

Random sequence generation (selection bias)	Low risk	Generated via computer software.
Allocation concealment (selection bias)	Low risk	'the principal investigator provided a participant identification number to an independent person to facilitate random allocation'
Blinding (performance bias and detection bias) Outcome assessor	Unclear risk	Outcome assessor: No information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	20/54 in intervention group and 25/52 in control completed final follow-up, of which 15 control and 12 intervention participants completed assessments at all three time points. The authors do not provide reasons for loss of participants or state any re-inclusions in analyses performed
Selective reporting (reporting bias)	Unclear risk	No information provided.

Kane 1984

Methods	Randomised parallel controlled trial. The allocation to groups was weighted in favour of hospice care
Participants	Caregiver: When patients agreed to participate they were asked to identify a significant other (SO) who was then invited to participate. The SO was commonly a relative, around half were spouses. Over 80% were female. Does not provided detail on SO's involvement in care of patient Patient: 246/263 terminally ill American veteran patients with a cancer and having a terminal prognosis of 2 weeks to 6 months. The most common cancer was lung cancer (34%). Other cancers were colorectal, prostate, ear, nose and throat, brain, bladder and stomach. The mean age of hospice patients was 63.3 years and in the control group 64 years. More than 97% of patients were men. 59% in the hospice group were white and 64% in the control group were white
Interventions	Directed at the patient. Aim: to evaluate the effectiveness of hospice care. Interventionists: Multidisciplinary team. Duration: No details provided. Content: Hospital-based hospice care included: (1) a 11 bed inpatient unit staffed by two physicians, 19 nurses, a social worker, a chaplain and approximately 30 volunteers; (2) a home-based program which served approximately 25 patients and (3) a consultation service for hospice eligible patients in other hospital services. The hospital unit had a higher staffing ratio than the rest of the general hospital wards Standardisation: The intervention was not manualised.

Kane 1984 (Continued)

	Comparison group: Patients received the standard treatment plan developed before study entry
Outcomes	<p>Patient and caregiver outcomes:</p> <ol style="list-style-type: none"> 1. Satisfaction with care assessed by Interpersonal Care Satisfaction Scale adapted from the Ware Satisfaction Scale, Physical Environment Scale Satisfaction Scale adapted from McCaffree and Harkins Satisfaction with Nursing Home Scale and questions on the degree of satisfaction with involvement in care adapted from the National Cancer Institute's Hospice Study. 2. Depression measured using 16 of the 20 items from the National Institute of Mental Health's Center for Epidemiologic Studies Depression Scale. 3. Anxiety measured using a 5-item sub-scale from the Ware General Well-Being Measure. <p>Patient only: Absence of pain and the intensity of pain using symptom scale adapted from the California Pain Assessment Profile</p> <p>Measured to 22 weeks from baseline (until patient's death or until a pre-established number of interviews had been conducted)</p>

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information provided.
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding (performance bias and detection bias) Outcome assessor	Unclear risk	Outcome assessor: No information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	10/246 patients dropped out during the course, 6% of caregivers dropped out. The authors do not provide reasons for loss of participants or state any re-inclusions in analyses performed
Selective reporting (reporting bias)	Unclear risk	No information provided.

Keefe 2005

Methods	Randomised parallel controlled trial.
Participants	Caregiver: American, n = 78, 76% spouse and 14% daughters, mean age 58.5 years, 62% female, 79% white, 20% African American. Does not provide details on level of caregiving

	<p>Patient: From hospices and medical clinics, advanced (defined as metastatic or disseminated disease) cancer patients with disease-related pain. Life expectancy of less than six months, and had no change in planned treatment. Most frequent diagnoses were lung, breast and prostate cancer. Mean age 60.5 years, 44% female, 78% white and 21% African American</p>	
Interventions	<p>Directed at spouse/partner. Aim: To test the feasibility of intervention in managing pain, effect on quality of life and wellbeing Interventionist: nurse. Duration: Three face-to-face home sessions of 45 to 60 minutes over one to two weeks Content: Partner-guided cancer pain management. Nurse educator conducted the sessions with the patient and partner on coping with pain, including types of pain, treatment including relaxation training and imagery and activity pacing method, and communication with health providers. The intervention was supported by a videotape and book Standardisation: The treatment was manualised and, for the purpose of supervision sessions, was audio-taped Comparison group: Patients received usual care through their medical outpatient or hospice programme</p>	
Outcomes	<p>Caregiver: Patients' self-efficacy in pain management using a caregiver version of the Chronic Pain Self-Efficacy Scale (5 items). Caregiver strain using the caregiver strain index (13 items). Positive and negative mood measured using the condensed version of the Profile of Mood States-B Patient: Pain measures to assess usual and worse pain using the Brief Pain Inventory. Quality of life assessed using the Functional Assessment of Cancer Therapy-General version 4, two sub-scales used on physical wellbeing and social/family wellbeing None declared a primary outcome.</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'generated by an individual who was not involved in the study using a random number table'
Allocation concealment (selection bias)	Unclear risk	'concealed in envelopes that were not opened until the patient/partner was randomised'
Blinding (performance bias and detection bias) Outcome assessor	Low risk	Outcome assessor: 'the research assistant collecting evaluation data was kept blind with regard to patient treatment group assignment'

Keefe 2005 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	22/78 randomised did not complete study. These were 13 in intervention group (of whom 8 died, 2 were too ill and 3 were lost to follow-up) and 9 in control group (of whom 4 died, 2 were too ill and 1 dropped out)
Selective reporting (reporting bias)	Unclear risk	No information provided.

Kissane 2006

Methods	Multi-centre cluster randomised parallel controlled trial. Five research sites: two sites were clinics in palliative care centres within Melbourne University, and three were hospice home services. Randomisation by family
Participants	<p>Caregiver: from the Australian population. 53 families (n = 233) were randomised to grief therapy and 28 (n = 130) to control; giving a total number of 363 individuals randomised. Only families at risk of poor psychosocial outcome were eligible. This was assessed using the Family Relationship Index. In the final study cohort, 51% of families were classified as having family intermediate functioning, 26% were designated as sullen and 23% as hostile. Hostile families were defined as tending to reject help and are distinguished by high family conflict levels, poor cohesion and poor expressiveness. Sullen families were defined as moderately impaired across three domains that define hostile families. Intermediate functioning families were those that exhibited moderate cohesiveness but are prone to psychosocial morbidity. The study provided no detail on family caregiving of patient. The mean age of the patient's spouse was 56 years (SD 9) and for their offspring it was 29 years (SD 9). There were slightly more female caregivers than male (96/180). Most participants were either of professional or clerical occupational group (123/189)</p> <p>Patient: Cancer patients given a prognosis of six months by treating physician, had a living partner and one or more children more than 12 years old. The most common cancer was breast (25%) and lung (20%). The mean age was 57 years (SD 8)</p>
Interventions	<p>Directed at the family.</p> <p>Aim: To evaluate whether grief therapy reduced the morbid effects of grief among families at risk of poor outcomes</p> <p>Interventionist: Social workers who were qualified family therapists</p> <p>Duration: Started during palliative care and continued into bereavement. It comprised of 4 to 8 sessions of 90 minutes duration, across 9 to 18 months</p> <p>Content: The family focused grief therapy intervention aimed to enhance the functioning of the family to prevent complications of bereavement. It was operationalised through exploring family cohesion, communication of thoughts and feelings, and handling of conflict. In the process it was envisaged that the personal story of the illness and related grief would be shared. There were three intervention phases: ascertainment which involved identifying concerns relevant to the specific family, devising and acting on a plan to deal with concerns and, at the end of the therapy, consolidation of what was gains and was confronted during the therapy</p> <p>The therapy was conducted either in the hospital or, more commonly, at home</p> <p>Standardisation: Documented in a manual. This was published in a book as a series of</p>

	<p>guidelines. The social workers received training to conduct the intervention. Fidelity to the intervention was assessed independently</p> <p>Comparison group: Families received standard home care palliative care; counselling was included where needed</p>	
Outcomes	<p>Caregiver: The primary outcome was psychosocial functioning in bereaved family members, particularly levels of distress, depression and social adjustment</p> <p>Family function was measured using two scales. These were items from the 40-item Family Environment Scale and from the 60-item Family Assessment Device</p> <p>Psychological morbidity was measured using two scales: the Brief Symptom Inventory and the cognitive items from the Beck Depression Inventory. To differentiate normal grief expressions from more morbid forms of distress and depression, the 22-item Bereavement Phenomenology Questionnaire was used</p> <p>The Social Adjustment Scale was used to measure social functioning including housework, work, social and leisure activities, relationships with children and extended family and overall functioning</p> <p>Outcomes were evaluated at 6 and 13 months after the patient's death</p>	
Notes	<p>The study was adjusted for clustered data analysis.</p>	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was performed independently using a computer generated table of random numbers, to make the allocation in the 2:1 ratio, stratifying by recruitment site
Allocation concealment (selection bias)	Low risk	Randomisation was performed independently.
Blinding (performance bias and detection bias) Outcome assessor	Unclear risk	Outcome assessor: No information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	<p>64/81 families that consented to take part received the treatment they were allocated to receive and completed the trial. Two families that dropped out early did so as they were dissatisfied with intervention, does not provide reasons for other families not completing, or information on trial arm allocation</p> <p>The effect of missing data was assessed by examining differences at baseline between those with missing outcome data and complete outcome data, then the authors com-</p>

		pared whether these differences were the same for the treatment and control groups. Participants with missing data had significantly poorer family functioning according to baseline score on the family assessment scales, however these did not differ significantly between the treatment groups Analysis was on an intention-to-treat basis; the authors analysed patients according to which treatment group they were randomised to, irrespective of whether or not they received that treatment
Selective reporting (reporting bias)	Unclear risk	No information provided.

McMillan 2005

Methods	Randomised parallel controlled trial. Three armed trial.
Participants	Caregivers: 329 American family caregivers providing care for adult patients with cancer. All were recruited from an organisation providing hospice care in the community. Does not state cancer stage of patients In the COPE intervention group caregiver mean age was 63 years (SD 13.58), 77% were female and mean years in education was 13.06 (SD 2.98). In the group that had supportive visits the mean age was 61 years (SD 15.47), 99% were female and mean years in education was 12.70 (SD 2.40). In the standard care group the mean age was 60 years (SD 15.27), 81% were female and mean years in education was 12.86 (SD 2.25). The mean age of patients was 70 years (SD 12.58), 44% were female and mean years in education was 12.49 (SD 2.80). No details were provided on the extent of caregiving Patient: In the intervention group the mean age was 71 years (SD 10.99) and 37% were female. Mean years in education was 11.84 (SD 3.41). In the supportive group mean age was 71 years (SD 12.12), 38% were female and mean years in was education 12.28 (SD 3.21)
Interventions	Intervention directed at caregiver. Aim: To determine whether hospice plus a coping skills training intervention improved quality of life and coping Interventionist: nurse. Duration: Three supportive visits. Content: Standard hospice care plus coping skills intervention was delivered by nurses, it involved 1:1 teaching of problem-solving methods that aimed to assist caregivers with assessing and managing patient symptoms. It was composed of 4 components: <ol style="list-style-type: none"> 1. creativity, defined as viewing problems from a different perspective and developing new strategies for solving caregiving problems; 2. optimism, defined as having a positive but realistic attitude toward problem solving; 3. planning, which involved setting reasonable caregiving goals and the steps necessary to reach these goals; and

	<p>4. the provision of lay information about the nature of the problem.</p> <p>Standardisation: Documented in a manual and audiotapes of interventions were reviewed. The nurses were provided with training to delivered the intervention. The fidelity of the intervention was monitored</p> <p>Comparison groups:</p> <p>Comparison 1: Standard hospice care plus a coping skills intervention (n = 111); arm 2: standard hospice care plus 3 supportive visits (n = 109) from intervention nurse; arm 3: standard hospice care (n = 109)</p> <p>Comparison 2: Attention control of standard hospice care plus supportive visits involved the nurse discussing with the caregiver their feelings, fears and relationships with their loved one dying from cancer. The nurse did not give advice to caregivers about managing problems and did not teach any structural problem-solving skills</p> <p>Delivery of attention control and intervention took the same time</p> <p>Description of standard hospice care not provided.</p>	
Outcomes	<p>Caregiver.</p> <p><i>Primary outcome measures</i></p> <p>Quality of life using the 35-item Quality-of-Life Index-Cancer (CQOL-C)</p> <p>General caregiver mastery using a 6-item validated scale.</p> <p>Burden and mastery specific to care giving tasks was measured used the 46-item Caregiver Demands Scale</p> <p>Burden of cancer symptoms was assessed using the 24-item Memorial Symptoms Assessment Scale</p> <p><i>Secondary outcomes</i></p> <p>Coping responses to intervention was measured using the 28-item Brief COPE scale</p> <p>Outcomes assessed at 16 (one week post intervention) and 30 days</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Computerised randomisation procedure by telephone'.
Allocation concealment (selection bias)	Low risk	'Computerised randomisation procedure by telephone'.
Blinding (performance bias and detection bias) Outcome assessor	Low risk	The data collectors were blind to subjects' group assignment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Number of participants that dropped out before the study finished was 63% in control group and 71% in support group, and 72% in coping group. Most commonly attrition was due to patient decline in health, or death, or caregiver feeling overwhelmed.

		More younger caregivers dropped out. The authors do not state any re-inclusions in analyses performed. All individuals who contributed any data were included in the random effects model (main analysis) . Those who completed follow-up were compared to those who did not on a wide range of outcomes
Selective reporting (reporting bias)	Unclear risk	No information provided.

Northouse 2005

Methods	Randomised parallel controlled trial. Groups were stratified by treatment
Participants	<p>182 American families. 88 families assigned to comparison group</p> <p>Caregiver: Primary caregiver, either a family member or a significant other who was identified by the patient as her primary source of emotional and physical support during the recurrent phase of breast cancer and confirmed by the designated individual. Both patient and caregivers were eligible only if aged 21 years or older. Mean age 52 years (SD 14), 62% of family members were husbands, the remaining were siblings (9%), adult daughters (13%), adult sons (3%) or other relatives or friends (13%). Does not provide details on extent of caregiving</p> <p>Patient: Recurrent breast cancer defined as cancer that had progressed within previous month confirmed by clinical tests and that this necessitated change in treatment although life expectancy was at least 6 months. Patients with stage 3 (cancer spread beyond the breast such as lymph nodes or chest wall) and stage 4 (cancer spread to other organs) breast cancer were included in analysis only (n = 182). Mean age 54 years (SD 11)</p> <p>Despite randomisation, group differences emerged the control group patients at baseline had significantly less negative appraisal of illness and less hopelessness than intervention patients; these aspects were controlled for in subsequent analysis</p>
Interventions	<p>Intervention directed at the family.</p> <p>Aim: To explore whether the intervention facilitate support and their communication</p> <p>Interventionist: nurse.</p> <p>Duration: Three monthly home visits with the patient and her family. Visits were around 1.5 hours long. During the booster phase the nurse made two prearranged follow-up phone calls, these were around 30 minutes each</p> <p>Content: The FOCUS program provided patients and their family information and support. It involved 5 contacts, and had 5 main components; specifically, promoting a cohesive family, encouraging an optimistic attitude, helping them to cope effectively, provision of information to help reduce uncertainty and to assist them in symptom management</p> <p>94 patients were assigned to intervention group. Components of the intervention were based on a literature review</p> <p>Standardisation: A protocol manual outlined the interventions for each home visit and phone calls, although some flexibility of the intervention was permitted based on individual needs</p>

	Comparison group: No details provided on what usual care group received	
Outcomes	<p>Caregiver and patient.</p> <p>Quality of life was measured using two scales: the FACT scale version three and the SF-36 Health Survey</p> <p>Coping was measured using the 24-item Brief COPE. The scale assesses 12 coping strategies: self-distraction, active coping, denial, alcohol/drug use, emotional support, behavioral disengagement, venting, positive re framing, planning, use of humor, acceptance, and religion</p> <p>Hopelessness was measured using the 20-item Beck Hopelessness Scale; uncertainty was measured by the 28-item community version for patients and the 29-item family version for caregivers of the Mishel Uncertainty in Illness Scale</p> <p>Patients' appraisal of illness was measured with the 27-item Appraisal of Illness Scale and caregivers' with the 27-item Appraisal of Caregiving scale</p> <p>All outcomes were assessed for both caregivers and patients. Follow-up was at 3 months (after home visit phase) and 6 months (after booster phone calls)</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Used lists generated by random numbers.
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding (performance bias and detection bias) Outcome assessor	Low risk	The data collectors were blind to subjects' group assignment
Incomplete outcome data (attrition bias) All outcomes	Low risk	134/182 completed follow-up assessments (these were 69 in intervention and 65 in control group), of those lost to follow-up 38/48 died, 5 refused to continue, 2 were too ill, 2 caregiver and patient relationship ended and 1 was unable to be contacted. Patients lost to follow-up had significantly shorter disease free intervals, more uncertainty about the illness and more symptoms. There was no difference in loss, or reasons for loss, to follow-up between intervention and control groups (intervention lost n = 25, control lost n = 25). The authors do not state any re-inclusions in analyses performed

Northouse 2005 (Continued)

Selective reporting (reporting bias)	Unclear risk	No information provided.
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Northouse 2007

Methods	Randomised parallel controlled trial.
Participants	<p>263 American patient-spouse couples. 84% of couples were Caucasian, 14% were African American. Patient and spouses reported averages of 16 and 15 years of formal education, respectively</p> <p>Caregiver: Spouse/partners were eligible if they were aged over 21 years and were identified by patients as their primary caregiver. Mean age 59 years (SD 9.7 years). 25% had health problems, such as arthritis or back pain. No information provided on the extent of caregiving</p> <p>Patient: In one of three phases of prostate cancer (i.e. newly diagnosed, biochemical recurrence or advanced). Patient were aged over 30 years, with a life expectancy of more than 12 months, with a spouse or live-in partner. Mean age 63 years (SD 9.1), 21% were in the advanced phase of prostate cancer</p>
Interventions	<p>Intervention directed at patient-spouse couples.</p> <p>Aim: The hypothesis was that couples that received the intervention would report fewer negative outcomes on appraisal variables, more positive outcomes on coping and have a higher quality of life</p> <p>Interventionist: Nurse.</p> <p>Duration: The four month programme consisted of three 90 minute home visits and two 30 minute telephone sessions which were 2 weeks apart</p> <p>Content: Received standard clinic care plus the FOCUS program. This was a modified intervention tested initially on breast cancer patients and their family caregivers (See Northouse 2005). The content involved encouraging couples to work as a team, promoting an optimistic attitude to maintain hope which involved focusing on achievable short term goals, coping strategies that aimed to reduce stress, reducing uncertainty by providing information and ways to live with uncertainty, and support with symptom management</p> <p>Standardisation: Interventionist had a training video and a protocol checklist outlining the intervention, although the intervention allowed tailoring of topics to the needs of the individual couple</p> <p>Comparison group: Patients received standard clinic care at their cancer treatment centre. The clinic addressed primarily diagnosis and treatment of patients' disease; there were no specific psychosocial resources targeted at the couples</p>
Outcomes	<p>Caregiver and patient.</p> <p>Quality of life of patient and spouse assessed using the Medical Outcomes Study 12-item short form and a cancer specific measure, the general Functional Assessment of Cancer Treatment (FACT-G) 27-item. In addition patients completed FACT-P a prostate-specific QOL scale</p> <p>Illness and caregiving appraisals were assessed with the 27-item Appraisal of Illness or Appraisal of Care-giving Scales. This measures patients' level of threat associated with the illness as well as the spouse's perception of caregiving. Uncertainty was measured using the 28-item Mishel Uncertainty in Illness Scale, and hopelessness using the 20-item Beck Hopelessness Scale</p>

	<p>Coping strategies were assessed using the 28-item Brief Coping Orientations to Problems Experienced scale, self-efficacy using the 17-item Lewis Cancer Self-Efficacy Scale (measures confidence in managing stress and changes associated with cancer or treatments) and communication using the 32-item Lewis Mutuality and Interpersonal Sensitivity Scale</p> <p>Symptom distress using the 16-item Symptom Scale of the Omega Screening Questionnaire of which both the patient and spouses rated how much they were experiencing symptoms such as fatigue and sleeping problems. The 50-item Expanded Prostate Cancer Index Composite (EPIC) measured specific prostate symptoms. Spouses completed the 4-item spousal version of the EPIC, this assess the extent to which husbands' prostate specific symptoms created problems for the spouses</p> <p>The risk of developing future emotional distress was measured at baseline only, using the 77-item Omega Clinical Screening Interview</p> <p>None declared primary outcome.</p> <p>Outcomes assessed at 4 (end of intervention), 8 and 12 months</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Used lists generated by random numbers.
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding (performance bias and detection bias) Outcome assessor	Low risk	Data collection nurses were blinded to group assignment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	218/263 couples completed all 3 follow-up assessments. Among the 45 couples that did not complete the study, reasons included patient death (n = 15), 9 declined intervention, and 6 were too busy. There was no significant differences between groups in terms of the number of follow-up visits, number of lost to follow-up, number completing all assessments or numbers lost for other reasons. The authors do not state any re-inclusions in analyses performed
Selective reporting (reporting bias)	Unclear risk	No information provided.

Methods	Randomised parallel controlled trial.
Participants	<p>Caregiver: 271 British male and female (n = 215) primary caregivers who scored over 5/6 on the 28-item General Health Questionnaire (GHQ-28)</p> <p>Intervention group n = 137, male and female (n = 108) caregivers, mean age 56.4 years (SD 14.6), spouse/partner 92/137, adult child 29/137, received tertiary education 38/137, white ethnic group 114/137, socioeconomic groups 1,2 n = 92/137 (using the 3 socio-economic class system for the UK office of National statistics. Group 1 = managerial and professional occupations, group 2 = intermediate occupations, and group 3 = routine and manual occupations)</p> <p>Comparison group n = 134, male and female (n = 107) caregivers, mean age 56.1 years (SD 13.2), adult child 38/134, spouse/partner 80/134, received tertiary education 45/134, white ethnic group 118/134, Socio-economic groups 1,2 n = 93/134</p> <p>Does not report details on caregiving, but reports caregiver strain using the Caregiver Strain Index</p> <p>Patient: In intervention group, diagnosis was lung cancer n = 32, gastrointestinal cancer n = 23, genitourinary cancer n = 27, head and neck cancer n = 15, breast cancer n = 6, and other cancers n = 34. Time since diagnosis was a median 8 months (range 2 to 75.6 months). The time to death in weeks was a median of 13 (range 2 to 41.1 weeks). In comparison group, diagnosis was lung cancer n = 47, gastrointestinal cancer n = 32, genitourinary cancer n = 13, head and neck cancer n = 9, breast cancer n = 12, and other cancers n = 21. Time since diagnosis was a median 4 months (range 1 to 89.5 months). The time to death in weeks was a median of 11 (range 1 to 39.6 weeks)</p>
Interventions	<p>Intervention directed at the caregiver.</p> <p>Aim: evaluation of the effectiveness of increased support for distressed, informal caregivers of patients receiving palliative care</p> <p>Interventionist: trained advisors, one experienced in community nursing and one experienced in social work</p> <p>Duration: Six weekly sessions.</p> <p>Content: The advisors aimed to meet the caregiver alone, although sometimes they were replaced with telephone calls. A needs assessment was conducted, and information and emotional support provided. Topics covered at each session were patient care, caregiver physical health needs, need for time away from the patient in the short-term and longer term, need to plan for the future, psychological health, relationships and social networks, contact with health and social services providers and their personal finances</p> <p>Standardisation: No information provided.</p> <p>Comparison group: Involved specialist palliative care provided by a team of clinical nurse specialists who had specialist medical support. It also sometimes involved social work support. Patients were assisted with control of pain and other physical symptoms as well as with social, psychological, emotional and spiritual issues</p>
Outcomes	<p>Caregiver outcome.</p> <p>The primary outcome measure was caregiver's psychological distress using the GHQ-28, with the proportion of patients scoring over 5/6. [MP: Unclear]</p> <p>Secondary outcomes were GHQ-28 score, caregiver strain (the Carer Strain Index), and quality of life (Caregiver Quality-of-Life-Index)</p> <p>Outcomes were assessed via self report using a postal questionnaire</p> <p>All outcomes were assessed at 4, 9 (first follow-up after intervention) and 12 weeks and</p>

	there was a follow-up 4 months after the patient's death Satisfaction with care and scores on the Core Bereavement Items were assessed at 4 months after the patient's death. A brief, semi-structured interview at the final follow-up was undertaken to assess acceptability and helpfulness of the support provided by the intervention	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation sequence using computer generated table. Block randomisation (block size 12) and stratified according to study teams
Allocation concealment (selection bias)	Low risk	'took place at the trial centre under the supervision of the trial statistician'
Blinding (performance bias and detection bias) Outcome assessor	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	134 were randomised to control group; of these 62 patients died, 54/72 remaining responded to final follow-up at 12 weeks 137 were randomised to intervention group; of these 47 patients died, 69/90 remaining responded to final follow-up The authors do not state any re-inclusions in analyses performed
Selective reporting (reporting bias)	Unclear risk	No information provided.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Belasco 2000	Review on interventions in supportive care
Black 1991	Intervention delivered in bereavement only
Brodsky 1991	Not advanced disease and no caregiver outcomes
Buick 2000	No caregiver outcomes

(Continued)

Chan 2004	No caregiver outcomes
Christakis 2003	Not an experimental study
Clark 2006	Patients not in the terminal phase of a disease
Clayton 2007	No caregiver outcomes
Collinge 2007	Does not state patients are in the terminal phase of a disease
Demiris 2005	Not an evaluative study
Dobrof 2006	Not a controlled evaluation
Gaugler 2003	Does not state patients are in the terminal phase of a disease
Gavrilova 2008	Patients not in the terminal phase of a disease
Goelitz 2003	Not a controlled evaluation
Grand 2004	Secondary analysis of trial data
Haggmark 1987	Inappropriate control
Harding 2004	Inappropriate control
Hays 2006	Not an evaluative study
Henrich 1985	Patients unlikely to be in end stage
Hudson 2008	Not a controlled evaluation
Jepson 1999	Patient not in the terminal phase of a disease
Kirk 2006	No caregiver outcomes
Kissane 2004	No caregiver outcomes
Kurtz 2005	Patients not in the terminal phase of a disease
Low 2008	Not a primary evaluation
Mason 2007	Systematic review of evidence
McCorkle 1998	Study was a secondary analysis of an RCT
McDonald 2006	Not a controlled evaluation

(Continued)

McMillan 2007	No caregiver outcomes
McMillian 1994	Not an experimental study
Murray 2004	Not an evaluative study
Nurock 2007	No caregiver outcomes
Smeenk 1998	Quasi-experimental design
Toseland 1995	Does not state patients are in the terminal phase of a disease

Characteristics of ongoing studies [ordered by study ID]

Fegg 2009

Trial name or title	Supportive group psychotherapy for relatives of palliative care patients: a randomised controlled prevention study
Methods	Randomised controlled trial
Participants	Relatives of palliative care patients in Germany
Interventions	Supportive group psychotherapy
Outcomes	
Starting date	
Contact information	Dr Martin Fegg praxis@psychotherapeut-muenchen.de
Notes	Plan to finish October 2010

O'Hara 2010

Trial name or title	Randomised controlled trial of ENABLE
Methods	Randomised controlled trial. Two trial arms intervention
Participants	322 American male and female (n = 135) patients with advanced cancer from a single rural cancer centre. A proportion of the patients identified someone close to them that was involved in their care Intervention group n = 161 male and female (n = 70) patients, mean age 64.7 years (SD 10.8), received tertiary education 17/161, white ethnic group 143/161. Patient diagnosis was lung cancer n = 59, gastrointestinal cancer n = 64, genitourinary cancer n = 19, breast cancer n = 17. No details on caregivers Control group n = 161 male and female (n = 65) patients, mean age 65.4 years (SD 11.6), received tertiary education 20/161, white ethnic group 132/161. Patient diagnosis was lung cancer n = 58, gastrointestinal

O'Hara 2010 (Continued)

	cancer n = 67, genitourinary cancer n = 20, breast cancer n = 16. No details on caregivers Does not report details on caregiving.
Interventions	Intervention, ENABLE, provided to patient that aim to provide education, emotional support and advice. This was a manualised telephone intervention. One of two advanced practice nurses with palliative care training held 4 education and problem solving sessions. This was followed by telephone sessions at least monthly Comparison group: Involved use of all oncology, supportive services and palliative care service The intervention was reported in a manual.
Outcomes	Caregivers self reported burden using the Montgomery-Borgatta Caregiver Burden Scale measured at one month and every three months until the patients death Patient outcomes: self reported quality of life, symptom intensity and resource use
Starting date	Trial completed, write up of evidence on caregiver outcomes underway
Contact information	Marie.A.Bakitas@hitchcock.org
Notes	

DATA AND ANALYSES

Comparison 1. Direct Interventions: Primary outcome at end of intervention - Psychological health

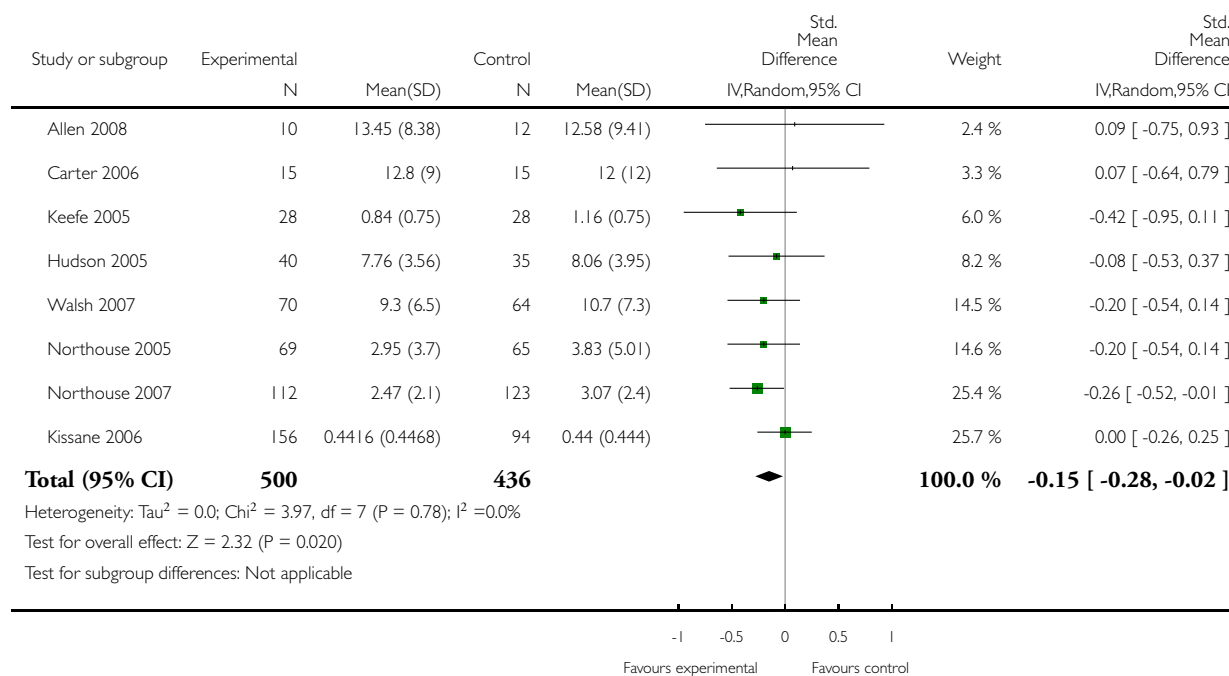
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Psychological distress	8	936	Std. Mean Difference (IV, Random, 95% CI)	-0.15 [-0.28, -0.02]
2 Coping with the caring role	7	738	Std. Mean Difference (IV, Random, 95% CI)	-0.05 [-0.24, 0.14]
3 Quality of life	6	631	Std. Mean Difference (IV, Random, 95% CI)	0.08 [-0.11, 0.26]

Analysis 1.1. Comparison 1 Direct Interventions: Primary outcome at end of intervention - Psychological health, Outcome 1 Psychological distress.

Review: Interventions for supporting informal caregivers of patients in the terminal phase of a disease

Comparison: 1 Direct Interventions: Primary outcome at end of intervention - Psychological health

Outcome: 1 Psychological distress

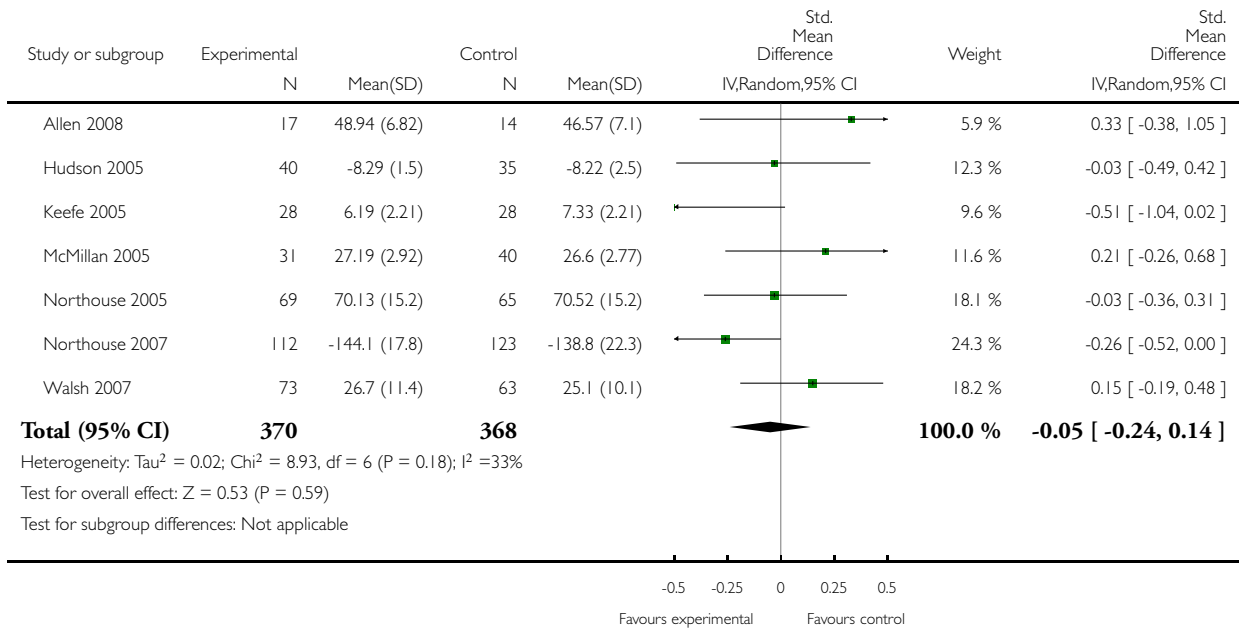


Analysis 1.2. Comparison 1 Direct Interventions: Primary outcome at end of intervention - Psychological health, Outcome 2 Coping with the caring role.

Review: Interventions for supporting informal caregivers of patients in the terminal phase of a disease

Comparison: 1 Direct Interventions: Primary outcome at end of intervention - Psychological health

Outcome: 2 Coping with the caring role

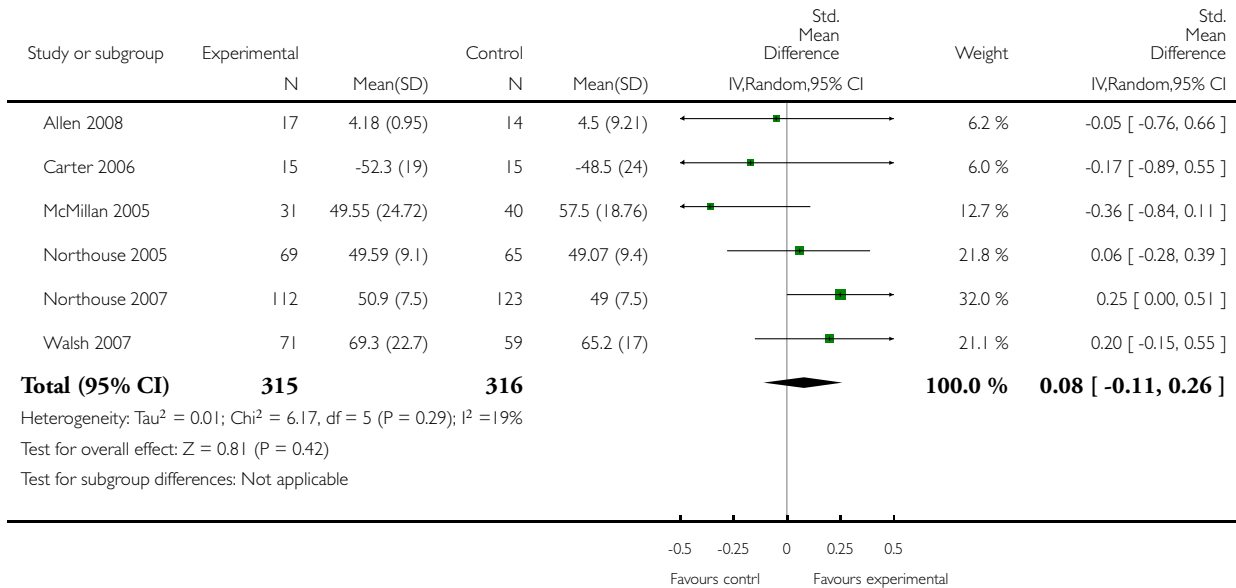


Analysis 1.3. Comparison 1 Direct Interventions: Primary outcome at end of intervention - Psychological health, Outcome 3 Quality of life.

Review: Interventions for supporting informal caregivers of patients in the terminal phase of a disease

Comparison: 1 Direct Interventions: Primary outcome at end of intervention - Psychological health

Outcome: 3 Quality of life



ADDITIONAL TABLES

Table 1. Direct intervention: Psychological distress at the end of treatment

Trial, time since baseline and end-of-treatment	Outcomes displayed, unless indicated otherwise, as: Intervention mean, standard deviation (SD), n versus (v) control mean, SD, n.
Allen 2008 One week	Depression 12.58 (9.41) n = 10 v 9.17 (6.98) n = 12
Carter 2006 2 months	Depression 12.8 (9) n = 15 v 12 (12) n = 15
Hudson 2005 4 weeks	Anxiety 7.76 (3.56) n = 40 v 8.06 (3.95) n = 35
Keefe 2005 Mean 6 days, (range 0 to 31 days)	Mood negative 0.84 (0.75) n=28 v 1.16 (0.75) n=28 (Analysis adjusted for participants' pre treatment score)

Table 1. Direct intervention: Psychological distress at the end of treatment (Continued)

Kissane 2006* 6 months	Psychological morbidity 0.4416 (0.4468) n = 156 v 0.4433 (0.444) n = 94 Depression 3.60 (3.74) n = 154 v 4.21 (4.92) n = 94
Northouse 2005 3 months	Hopelessness 2.95 (3.7) n = 69 v 3.83 (5.01) n = 65
Northouse 2007 4 months	Hopelessness 2.47 (2.1) n = 112 v 3.07 (2.4) n = 123
Walsh 2007 9 weeks	Depression 9.3 (6.5) n = 72 v 10.7 (7.3) n = 64

Scores expressed as the lower the better the outcome. See Analysis 1.1, for overall effect size. (In trials with multiple outcomes the median effect was used in combined trial analysis).

* Most conservative estimate was used in combined analysis.

Table 2. Direct interventions: Psychological distress at the end of follow-up

Trial, time since end of treatment phase	Displayed unless stated otherwise as: Intervention mean (SD), n versus (v) control mean (SD), n. Standardised mean difference (MD) and [confidence interval]
Carter 2006 2.5 months	Depression 8.5 (7) n = 15 v 8 (8.5) n = 15 MD 0.06 [95% CI -0.65 to 0.78]
Hudson 2008 At least 8 weeks after patient's death	Anxiety 6.96 (4.02) n = 20 v 6.76 (3.72) n = 25 MD 0.05 [95% CI -0.54 to 0.64]
Kissane 2006 13 months	Depression* -0.36 (4.61) n = 148 v -0.10 (4.26) n = 83 MD -0.06 [95% CI -0.33 to 0.21] Psychological morbidity* -0.12 (0.48) n = 147 v -0.01 (0.38) n = 83 MD -0.25 [95% CI -0.52 to 0.02]
Northouse 2005 3 months	Hopelessness 2.62 (3.3) n = 69 v 3.89 (4.6) n = 65 MD -0.32 [95% CI -0.66 to 0.02]
Northouse 2007 8 months	Hopelessness 2.71 (2.2) n = 104 v 3.06 (2.5) n = 114 MD -0.15 [95% CI -0.41 to 0.12]
Walsh 2007 6 weeks	Depression 11.3 (7.3) n = 69 v 11.7 (7.8) n = 54 MD 0.05 [95% CI -0.41 to 0.30]
Median effect size* 0.05 Number of comparisons showing a positive direction of effect of intervention 5/7 Number of comparisons showing a statistically significant effect 0/7	

Scores expressed as the lower the better the outcome.

*Change in mean scores baseline to 13 months

Table 3. Direct intervention: Coping with the caring role at the end of treatment

Trial, time since baseline	Outcomes displayed, unless stated otherwise, as: Intervention mean, standard deviation (SD), n versus (v) control mean (SD) n. Summary statistics provided if trial is not included in review analysis
Allen 2008 One week	Caregiver stress 48.94 (6.82) n = 17 v 46.57 (7.10) n = 14
Hudson 2005 4 weeks	Rewarding interaction 8.29 (1.5) v 8.22 (2.5)* Rewards 3.09 (0.82) v 2.82. (0.99)* Preparedness 2.76 (0.81) v 2.67 (0.81)* Problem solving 7.37 (1.92) v 8.14 (1.35)* Competence 2.37, 0.63 v 2.4 (0.54)* Respite 6.79 (2.16) v 6.23, 2.67* All n = 40 v n = 35
Keefe 2005 Mean 6 days, (range 0 to 31 days)	Caregiver strain 6.19 (2.21) v 7.33 (2.21) Caregiver self-efficacy For pain 57.90 (17.97) v 43.68 (17.92)* For other symptoms 66.93 (18.21) v 54.03 (18.20)* For physical activities 57.20 (23.04) v 63.06 (22.98)* All n = 28 v n = 28
McMillan 2005 One month	Symptom burden 19.52 (14.84) n = 31 v 22.75 (11.80) n = 40 Care giving task burden 1.95 (.99) n = 31 v 2.49 (.77) n = 40 General Mastery 27.19 (2.92) n = 31 v 26.60 (2.77) n = 40* Caregiver task mastery 4.31 (.85) n = 31 v 4.11 (.77) n = 40* Problem focused coping 11.73 (4.56) n = 30 v 11.34 (3.16) n = 38* Emotion focused coping 16.60 (5.32) n = 30 v 16.84 (4.70) n = 38*
Northouse 2005 3 months	Active coping 5.66 (1.2) v 5.17 (1.3)* Avoidant coping 3.28 (0.96) v 3.29 (1.0) Negative appraisal of care-giving 2.50 (0.55) v 2.62 (0.70) Uncertainty 70.13 (15.2) v 70.52 (15.2) All n = 69 v n = 65
Northouse 2007 4 months	Active coping 29.9 (5.7) v 29 (5.5)* Avoidant coping 14.4 (3.1) v 15 (2.9) Self efficacy 144.1 (17.8) v 138.8 (22.3)* Negative appraisal of care-giving 2.29 (0.49) v 2.44 (0.46) Uncertainty 59.5 (12.2) v 63.1 (13.9) Symptom distress 5.10 (3.4) v 6.28 (3.6) All n = 112 v n = 123
Walsh 2007 9 weeks	Caregiver strain 26.7 (11.4) n = 73 v 25.1 (10.1) n = 63

Scores expressed as the lower the better the outcome.

*Effect measure reversed as scale in the opposite direction. See Analysis 1.2 for overall effect size. (In trials with multiple outcomes the median effect was used in combined trial analysis).

Table 4. Direct interventions: Coping with the caring role at the end of follow-up

Trial, time since end of treatment phase	Displayed as: Intervention mean (SD) n versus (v) control mean (SD) n, standardised mean difference (MD) and [confidence interval]
<p>Hudson 2005 At least 8 weeks after patient's death</p>	<p>Rewards 3.5 (0.7) n =20 v 3.04 (0.82) n = 25 MD -0.59 [95% CI -1.19 to 0.01]* Preparedness 2.83 (0.79), n = 20 v 2.59 (0.88) n = 25 MD -0.28 [95% CI -0.87 to 0.31]* Competence 2.53 (0.51) n = 20 v 2.47 (0.48) n = 25 MD -0.12 [95% CI -0.71 to 0.47]*</p>
<p>Northouse 2005 3 months</p>	<p>Active coping 5.41(1.2) v 5.19 (1.3) MD -0.18 [95% CI -0.51 to 0.16]* Avoidant coping 3.25 (0.9) v 3.30 (1.0). MD -0.05 [95% CI -0.39 to 0.29] Negative appraisal of care-giving 2.53 (0.57) v 2.56 (0.68), MD -0.05 [95% CI -0.39 to 0.29] Uncertainty 76.19 (12.9) v 78.43 (13.4) MD -0.17 [95% CI -0.51 to 0.17] All n = 69 v n = 65</p>
<p>Northouse 2007 8 months</p>	<p>Active coping 30.5 (5.5) v 28.9 (6) MD -0.28 [95% CI -0.54 to -0.01]* Avoidant coping 14.9 (3.1) v 14.9 (2.9) MD 0.00 [95% CI -0.27 to 0.27] Self-efficacy 143.8 (17.9) v 137.8 (22.6) MD -0.29 [95% CI -0.56 to -0.02]* Negative appraisal 2.35 (0.51) v 2.39 (0.49) MD -0.08 [95% CI -0.35 to 0.19] Uncertainty 60.3 (12.5) v 61.1 (13.9) MD -0.06 [95% CI -0.33 to 0.21] All n = 104 v n = 114</p>
<p>Walsh 2007 6 weeks</p>	<p>Caregiver strain 27.2 (11.7) n = 69 v 27.3 (10.2) n = 54 MD -0.01 [95% CI -0.37 to 0.35]</p>
<p>Median effect size -0.05 Number of comparisons showing a positive direction of effect of intervention 12/13 Number of comparisons showing a significant effect 2/13 (both favour the intervention)</p>	

Scores expressed as the lower the better the outcome *Effect outcome reversed as scale in the opposite direction

Table 5. Direct interventions: Quality of life at the end of treatment

Trial, time since baseline	Outcomes displayed unless stated otherwise as: Intervention mean, standard deviation (SD), n versus (v) control mean (SD) n. Summary statistics provided if trial is not included in review analysis.
<p>Allen 2008 One week</p>	<p>Subjective wellbeing 4.08 (0.95) n = 17 v 4.50 (0.92) n = 14</p>
<p>Carter 2006 2 months</p>	<p>Quality of life (QOL) 52.3 (19) n =15 v 48.5 (24) n = 15*</p>
<p>McMillan 2005 One month</p>	<p>QOL 49.55 (24.72) n = 31 v 57.50 (18.76) n = 40</p>

Table 5. Direct interventions: Quality of life at the end of treatment (Continued)

Northouse 2005 3 months	Mental QOL 50.46 (9.7) v 49.47 (10.4) Physical QOL 49.59 (9.1) v 49.07 (9.4) Both n = 69 v n = 65.
Northouse 2007 4 months	Physical QOL 50 (7.8) v 50.3 (7.2) Mental QOL 50.9 (7.5) v 49 (7.5) Cancer specific QOL 86.5 (11.3) v 83.5 (11.4) All n = 112, n = 123
Walsh 2007 9 weeks	QOL 69.3 (22.7) n = 71 v 65.2 (17) n = 59

Scores expressed as the higher the better.

*Effect measure reversed as scale, as reported by author, was in the opposite direction. See Analysis 1.3, for overall effect size. (In trials with multiple outcomes the median effect was selected for combined trial analysis).

Table 6. Direct interventions: Quality of life at the end of follow up

Trial, time since end of treatment phase	Displayed as: Intervention mean (SD) n versus (v) control mean (SD) n, standardised mean difference (MD) and [confidence interval]
Carter 2006 2.5 months	QOL 44 (17) n = 15 v 39 (19) n = 15 MD -0.27 [95% CI -0.99 to 0.45]*
Northouse 2005 3 months	Mental QOL 50.81 (12.3) v 49.21 (12.0) MD 0.13 [95% CI -0.21 to 0.47] Physical QOL 50.54 (9.7) v 48.93 (10.2) MD 0.16 [95% CI -0.18 to 0.50] Both n = 69, n = 65.
Northouse 2007 8 months	Mental QOL 51.5 (7.6) v 52 (7.6) MD -0.07 [95% CI -0.33 to 0.20] Physical QOL 44.6 (7.2) v 42.3 (7.2) MD 0.32 [95% CI 0.05 to 0.59] Cancer specific QOL 85.2 (11.6) v 83.6 (11.9) MD 0.14 [95% CI -0.13 to 0.40] All n = 104, n = 114.
Walsh 2007 6 weeks	QOL 65.2 (21.3) n = 64 v 62.2 (19.8) n = 52 MD -0.14 [95% CI -0.51 to 0.22]
Median effect size 0.13 Number of comparisons showing a positive direction of effect of intervention 5/7 Number of comparisons showing a statistically significant effect 1/7 (favouring the intervention)	

Scores expressed as the higher the better the outcome

*Effect outcome reversed as scale in the opposite direction

Table 7. Direct interventions: Physical health, sleep improvement at the end of treatment

Trial, time since baseline	Outcomes displayed as: Intervention mean standard deviation (SD) n versus (v) control mean (SD) n, standardised mean difference (MD) and confidence interval []
<p>Carter 2006 2 months</p>	<p>Waking after sleep onset 50 (46) v 50 (45) MD 0.00 [95% CI -0.72 to 0.72]* Sleep latency (time to fall asleep upon going to bed) - Actigraph 7 (6) v 15 (13) MD -0.77 [95% CI -1.51 to -0.02]* - Self-report 12 (7) v 14 (10) MD -0.23 [95% CI -0.94 to 0.49]* Sleep efficiency - Actigraph 87 (9) v 83 (11) MD 0.39 [95% CI -0.34 to 1.11] - Self-report 85.4 (10) v 78 (18) MD 0.49 [95% CI -0.23 to 1.22] Pittsburgh Quality of Sleep Scale 6 (3) v 8.4 (5.5) MD -0.53 [95% CI -1.26 to 0.20]* Sleep duration - Actigraph 6.3 (1.3) v 5.2 (2.2) MD 0.59 [95% CI -0.14 to 1.33] - Self-report 6.6 (1.5) v 5.8 (2) MD 0.44 [95% CI -0.29 to 1.17] All n = 15 v n = 15</p>
<p>Median effect size 0.00 Number of comparisons showing a positive direction of effect of intervention = 6/8 Number of comparisons showing a statistically significant effect = 1/8 (favouring the intervention)</p>	

Scores expressed as the higher the better the outcome.

*Effect outcome reversed as scale in the opposite direction.

Table 8. Direct interventions: Physical health, sleep improvement at the end of follow up

Trial, time since end of treatment phase	Displayed as: Intervention mean (SD) n versus (v) control mean (SD) n, standardised mean difference (MD) and [confidence interval]
<p>Carter 2006 2.5 months</p>	<p>Waking after sleep onset 32 (28) v 40 (39) MD 0.23 [95% CI -0.49 to 0.95]* Sleep latency (time to fall asleep upon going to bed) - Actigraph 10 (11) v 14 (21) MD 0.23 [95% CI -0.49 to 0.95]* - Self-report 19 (25) v 26 (30) MD 0.25 [95% CI -0.47 to 0.97]* Sleep efficiency - Actigraph 91 (6) v 84 (13) MD 0.67 [95% CI -0.07 to 1.41] Pittsburgh Quality of Sleep Scale 5.4 (3) v 10.3 (6) MD 1.01 [95% CI 0.24 to 1.77]* Sleep duration - Actigraph 7.5 (1.2) v 5.6 (2.0) MD 1.12 [95% CI 0.34 to 1.90] - Self-report 7 (2) v 6 (2) MD 0.49 [95% CI -0.24 to 1.21] All n = 15 v n = 15</p>
<p>Median effect size 0.49 Number of comparisons showing a positive direction of effect of intervention 6/7 Number of comparisons showing a statistically significant effect 2/7 (both favouring the intervention)</p>	

Scores expressed as the higher the score the better the outcome.

*Effect outcome reversed as scale in the opposite direction.

Table 9. Direct interventions: Caregiver bereavement grief at the end of follow up

Trial, time since baseline	Outcome unless stated otherwise displayed as: Intervention mean (SD) n v control mean SD n, standardised mean difference (MD) and [confidence interval]
Kissane 2006 13 months	Abnormal grief expression n = 19 families, mean change score from 6 to 13 months follow-up 11.73 v 14.19, difference in mean scores -2.46 P value 0.05
Walsh 2007 4 months after death	Intensity of grief using Core Bereavement Items 47.1 (11.2), n = 82 v 45.6 (11.6) n = 96. MD 0.13 [95% CI -0.16 to 0.43]

Table 10. Direct interventions: Caregiver acceptability of intervention

Trial, time since baseline	Outcome displayed as: Intervention n versus (v) control n, Odds ratio (OR)[confidence interval]
Walsh 2007 4 months after death	Considered care poor 16/83 v 21/95 OR 0.84 [95% CI 0.41 to 1.75]

Table 11. Direct interventions: Other outcomes at the end of treatment

Trial, time since baseline	Outcomes displayed as: Intervention mean standard deviation (SD) n versus (v) control mean (SD) n, standardised mean difference (MD) and [confidence interval]
Allen 2008 One week	Daily spiritual experience 30.71 (3.5) n = 17 v 31.29 (3.73) n = 14 MD -0.16 [95% -0.87 to 0.55] Meaning 7.06 (0.75) n = 17 v 7.0 (0.78) n = 14 MD 0.08 [95% CI -0.63 to 0.78]
Kissane 2006 6 months	Social Adjustment Scale 0.06 v 0.05, difference in mean scores since baseline 0.01 [95% CI -0.74 to 0.09] Family Assessment Devise: General Functioning Scale 0.04 v 0.01, difference in mean scores since baseline 0.06 [95% CI 0.05 to 0.17]
Northouse 2007 4 months	Communication with care receiver mean 3.74 (0.53) n = 112 v 3.57 (0.56) n = 123 MD = 0.31 [95% CI -0.05 to 0.57]

Number of comparisons showing a positive direction of effect of intervention 4/5

Number of comparisons showing a significant effect 1/5 (favouring the intervention)

**These outcomes are a measure of caregiver's wellbeing but did not form part of the review's primary outcome. A median effect was not reported because of heterogeneity in type of outcomes. Meaning, daily spiritual experience and communication are reported as the higher the score the more the participant is experiencing the outcome being measured. Social Adjustment Scale and the Family Assessment Devise Scale are reported as the lower the better the outcome.*

Table 12. Direct interventions: Patient psychological outcomes at the end of treatment

Trial, time since baseline	Displayed as: Intervention mean (SD) n versus (v) control mean (SD) n, standardised mean difference (MD) and [confidence interval]
<p>Allen 2008 One week</p>	<p>Patient self-report Subjective wellbeing 4.47 (1.73) n = 17 v 4.93 (1.07) n = 14 MD -0.30 [95% CI -1.02 to 0.41] Depression 15.3 (11.54) n =10 v 14.58 (9.55) n = 12 MD 0.07 [95% CI -0.91 to 0.77]* Talkativeness 4.47 (3.34) v 2.71 (2.27) MD 0.59 [95% CI -0.14 to 1.31] Agitation 3.43 (2.62) v 2.21 (2.58) MD -0.46 [95% CI -1.17 to 0.26]* Caregiver report Talkativeness 4.94 (2.77) v 2.64 (1.69) MD 0.95 [95% CI 0.20 to 1.71] Agitation 4.35 (2.89) v 4.64 (2.76) MD 0.10 [95% CI -0.61 to 0.81]* Talkativeness and agitation outcomes all n = 17, n = 14.</p>
<p>Keefe 2005 Mean 6 days, (range 0 to 31 days)</p>	<p>Physical wellbeing 2.02 (0.77) v 2.08 (0.77) MD -0.08 [-0.60, 0.45] Social/family wellbeing 3.55 (0.52) v 3.33 (0.52) MD 0.42 [95% CI -0.11 to 0.95] Both n = 28 v n = 28</p>
<p>Northouse 2005 3 months</p>	<p>Negative appraisal of illness 3.03 (0.74) v 3.00 (0.82) MD -0.04 [95% CI -0.38 to 0.30]* Uncertainty 70.13 (15.2) v 70.52 (15.2) MD 0.03 [95% CI -0.31 to 0.36]* Hopelessness 3.56 (4.3) v 3.96 (4.1) MD 0.09 [95% CI -0.24 to 0.43]* Active coping 6.25 (1.1) v 6.29 (1.1) MD -0.04 [95% CI -0.37 to 0.30] Avoidant coping 4.05 (0.90) v 3.91(0.77) MD -0.17 [95% CI -0.51 to 0.17]* Mental QOL 51.34 (9.5) v 49.13(9.9) MD 0.23 [95% CI -0.11 to 0.57] Physical QOL 50.80 (9.3) v 49.9 0 (9.8) MD 0.09 [95% CI -0.25 to 0.43] All n = 69 v n = 65</p>
<p>Northouse 2007 4 months</p>	<p>Negative appraisal of illness 2.16 (0.74) v 2.23 (0.71) MD 0.10 [95% CI -0.16 to 0.35]* Uncertainty 56.9 (14.2) v 60 (13.5) MD 0.22 [95% CI -0.03 to 0.48]* Hopelessness 2.23 (2.4) v 2.69 (3.1) MD 0.16 [95% CI -0.09 to 0.42]* Active coping 31.3 (5.7) v 31 (6) MD 0.05 [95% CI -0.20 to 0.31] Avoidant coping 14.4 (2.8) v 14.2 (2.7) MD -0.07 [95% CI -0.33 to 0.18]* Physical QOL 48.6 (6.7) v 48.7 (6.5) MD -0.02 [95% CI -0.27 to 0.24] Mental QOL 52.4 (6.5) v 51.9 (6.6) MD 0.08 [95% CI -0.18 to 0.33] Cancer specific QOL 87.2 (10.6) v 85.5 (10.3) MD 0.16 [95% CI -0.09 to 0.42] Self-efficacy 146.1 (19) v 146 (20.2) MD 0.01 [95% CI -0.25 to 0.26] Communication 3.80 (0.46) v 3.69 (0.52) MD 0.22 [95% CI -0.03 to 0.48] All n = 112 v n = 123</p>
<p>Median effect 0.03 Number of comparisons showing a positive direction of effect of intervention 17/26 Number of comparisons showing a statistically significant effect 1/26 (favouring the intervention)</p>	

*Scores expressed as the higher the better the outcome *Effect measure reversed as scale in the opposite direction*

Table 13. Direct interventions: Patient physical outcomes at the end of treatment

Trial, time since baseline	Displayed as: Intervention mean (SD) n versus (v) control mean (SD) n standardised mean difference (MD) and [confidence interval]
<p>Allen 2008 One week</p>	<p>Patient self-report: Symptom score 14.27 (9.19) v 15.35 (10.29) MD -0.11 [95% CI -0.82 to 0.60] Additional symptom: Weight loss 3.93 (3.06) v 3.93 (3.61) MD 0.00 [95% CI -0.71 to 0.71] Caregiver assessment of patient: Overall symptom score 24.53 (15.07) v 21.71 (9.54) MD 0.21 [95% CI -0.50 to 0.92] Additional symptom: Weight loss 3.59 (3.32) v 1.57 (1.10) MD 0.76 [95% CI 0.03 to 1.50] All n = 17, n = 14.</p>
<p>Keefe 2005 Mean 6 days, (range 0 to 31 days)</p>	<p>Patient pain intensity Worse 6.46 (2.15) v 6.93 (2.15) MD -0.22 [95% CI -0.75 to 0.30] Both n = 28 v n = 28</p>
<p>Northouse 2007 4 months</p>	<p>Self report: Symptom distress 5.99 (3.6) v 6.19 (3.6) MD -0.06 [95% CI -0.31 to 0.20] Urinary symptoms 86.9 (12.7) v 81.6 (13.8) MD 0.40 [95% CI 0.14 to 0.66] Bowel symptoms 89.5 (7) v 90.3 (8.4) MD -0.10 [95% CI -0.36 to 0.15] Sexual symptoms 28.5 (21.4) v 29.3 (20.9) MD -0.04 [95% CI -0.29 to 0.22] Hormone symptoms 83.7 (9.9) v 83.8 (10.4) MD -0.01 [95% CI -0.27 to 0.25] All n = 112 v n = 123</p>
<p>Median effect -0.04 Number of comparisons showing a positive direction of effect of intervention 5/10 Number of comparisons showing a statistically significant effect 2/10 (favouring the comparison group)</p>	

Scores expressed as the lower the better the outcome

Table 14. Direct interventions: Other patient outcomes at the end of treatment

Trial, time since baseline	Outcome displayed as: Intervention mean (SD) n v control mean (SD) n, Standardised mean difference (MD) and [confidence interval]
<p>Allen 2008 One week</p>	<p>Daily spiritual experience 28.86 (4.19) v 31.36, (2.76) MD -0.67 [95% CI -1.40 to 0.06] Meaning 7.21 (0.8) v 6.43 (1.28) MD 0.73 [95% CI -0.01 to 1.46] For both n = 17 v n = 14</p>

Table 15. Indirect interventions: Psychological distress at end of treatment

Trial, time since baseline	Outcome* unless states otherwise displayed as: Intervention proportion with distress v control proportion with distress, Odds ratio (OR) [confidence interval]
Addington-Hall 1992 follow-up before death of patient	Depression* 21/56 v 25/62 OR 0.89 [95% CI 0.42 to 1.86] Anxiety* 22/56 v 32/62 OR 0.61 [95% CI 0.29 to 1.26]
Number of comparisons showing a positive direction of effect 2/2 Number of comparisons showing a statistically significant effect 0/2	

*Number of caregivers with scores above cut off for psychological morbidity on the Leeds Anxiety and Depression Scale

Table 16. Indirect interventions: Psychological distress at the end of follow up

Trial, time since end of treatment phase	Outcome displayed as either: Intervention OR (odds ratio) or mean (SD) n versus (v) control, standardised mean difference (MD) [confidence interval]
Addington-Hall 1992 Unclear but in bereavement	Depression* 20/51 v 19/40 OR 0.71 [95% CI 0.31 to 1.65] Anxiety* 10/51 v 13/40 OR 0.51 [95% CI 0.19 to 1.32] Felt angry when they thought about the patient's death 8/51 v 15/40 OR 0.31 [95% CI 0.12 to 0.83]
Kane 1984 Assessments were taken as overall during the follow-up	Depression states 'no significant differences'. Anxiety using 5 cohorts per trial arm (cohort groupings are by number of sessions attended); 3/5 cohorts they report there was a significant difference ($P < 0.01$) between the trial arms that favoured the intervention group
Number of comparisons showing a positive direction of effect** 3/3 Number of comparisons with significant outcomes** 0/3	

*Number of caregivers with scores above cut off for psychological morbidity on the Leeds Anxiety and Depression Scale.

**Only one trial provided full data

Table 17. Indirect interventions: Physical health

Trial, time since baseline	Outcome displayed unless stated otherwise as Intervention mean (SD) n versus (v) control mean (SD) n, standardised mean difference (MD) and [confidence interval]
Addington-Hall 1992 follow-up before and after patient's death	Physical health: There were no differences in the proportions of caregivers of each group reporting excellent or good physical health, in the proportion feeling physically ill in some way, or in the proportion reporting that their health was at least as good as

Table 17. Indirect interventions: Physical health (Continued)

	it was before the patient's death
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Table 18. Acceptability of intervention by patient and caregiver

Trial, time since baseline	Outcomes
Addington-Hall 1992*	Caregiver and patient satisfaction with care services did not differ significantly between groups, nor did caregiver satisfaction with place of death
Kane 1984*	Overall, hospice patients were more satisfied than control patients. Specifically, consistent significant difference between control and intervention groups in interpersonal care, and in four of the five cohorts on involvement with care. There was no difference in satisfaction in physical care environment between the two comparative groups. For family caregivers there was overall no consistent difference in satisfaction with care in interaction with professional, and involvement with care

*Does not provide summary information on time since baseline

Table 19. Indirect interventions: Patient treatment and service utilisation

Trial, time since baseline	Outcomes. Numerical findings displayed intervention v control, odds ratio (OR)[confidence interval]
Addington-Hall 1992*	<p>Home helps 41 v 43 OR 0.86 [95% CI 0.49 to 1.51] Meals on wheels 15 v 18 OR 0.77 [95% CI 0.36 to 1.62] Social worker 7 v 12 OR 0.53 [95% CI 0.20 to 1.40] Physiotherapist 3 v 2 OR 1.46 [95% CI 0.24 to 8.90] Occupational therapist 6 v 3 OR 1.98 [95% CI 0.48 to 8.14] Chiropodist 7 v 1 OR 7.15 [95% CI 0.86 to 59.18] Special laundry services 2 v 3 OR 0.63 [95% 0.10 to 3.88] District nurses 38 v 39 OR 0.90 [95% CI 0.51 to 1.59] Oncology sister 14 v 13 OR 1.04 [95% CI 0.46 to 2.34] Hospice or MacMillan sister 7 v 11 OR 0.58 [95% CI 0.22 to 1.57] GP home visit 23 v 23 OR 0.95 [95% CI 0.49 to 1.83] GP surgery consultation 13 v 18 OR 0.65 [95% CI 0.30 to 1.41] N = 103 v n = 99</p> <p>There were no group difference in the type of analgesics taken, nor in the proportions of patients taking anti-emetics, laxatives, antidepressant drugs, sedatives or anxiolytics, or in the proportion having unmet needs or who had aids and appliances for use in their home</p>
Kane 1984*	<p>There were no statistically significant differences in the total number of days spent in the hospital by hospice and controls patients. Hospice patients spent fewer days in general medical wards (13.2 v 20.7) and in nursing homes (1 v 11.4) than controls, and spent more days at home 44.8 v 37.9 Had major surgical procedures 0.09 v 0.01, minor surgical procedure 0.42 v 0.30, radiation treatment 7.4 v 7.7, or chemotherapy 1.3 v 0.49 Place of death did not differ significantly between the groups</p>

Table 19. Indirect interventions: Patient treatment and service utilisation (Continued)

Median effect 0.86 **
Number of comparisons showing a positive direction of effect in increasing services 4/12 **
Number of comparisons with significant outcomes 0/12 **

**Does not provide summary information on time since baseline*
*** Summary outcomes only for fully reported data*

Table 20. Indirect interventions: Patient psychological outcomes at the end of treatment

Trial, time since baseline	Outcomes. Numerical findings displayed as: Intervention versus (v) control, summary measure odds ratio (OR)[confidence interval]/standardised mean difference (MD) [confidence interval]
Addington-Hall 1992 Time since baseline not stated	Depression* 17/85 v 28/77, OR 0.44 [95% CI 0.22 to 0.89] Anxiety* 12/85 v 20/77, OR 0.47 [95% CI 0.21 to 1.04]
Kane 1984**	No significant difference reported in for depression or anxiety scores. Although patients in the intervention group had consistently lower scores for depression than those in the control

Number of comparisons showing a positive direction of effect 2/2
 Number of comparisons with significant outcomes 1/2

**Number of caregivers with scores above cut off for psychological morbidity on the Leeds Anxiety and Depression Scale*
***Does not provide complete data*

Table 21. Indirect interventions: Patient physical outcomes at the end of treatment

Trial, time since baseline	Outcomes. Numerical findings displayed as: Intervention versus (v) control, summary measure odds ratio (OR)[confidence interval]
Addington-Hall 1992* Caregiver report last week of life	Pain 55 v 56 OR 0.86 [95% CI 0.50 to 1.50] Loss of appetite 54 v 49 OR 1.10 [95% CI 0.64 to 1.91] Difficulty swallowing 9 v 14 OR 0.58 [95% CI 0.24 to 1.40] Vomiting 4 v 11 OR 0.32 [95% CI 0.10 to 1.04] Nausea 20 v 19 OR 1.00 [95% CI 0.50 to 2.02] Breathlessness 61 v 61 OR 0.88 [95% CI 0.50 to 1.55] Cough 36 v 37 OR 0.89 [95% CI 0.50 to 1.57] Itchy skin 27 v 30 OR 0.81 [95% CI 0.44 to 1.49] Constipation 31 v 36 OR 0.74 [95% CI 0.41 to 1.34] Diarrhoea 10 v 6 OR 1.65 [95% CI 0.58 to 4.72] Incontinence or retention 15 v 21 OR 0.63 [95% CI 0.30 to 1.30] Sleeplessness 35 v 37 OR 0.85 [95% CI 0.48 to 1.51] All n = 104, n = 99

Table 21. Indirect interventions: Patient physical outcomes at the end of treatment (Continued)

	'there were few statistically significant differences in severity of symptoms, concern about symptoms and effectiveness of treatment'
Kane 1984**	'The survival curves for hospice and control groups were essentially the same' No significant difference reported in symptom score or activities of daily living scores
Median effect 0.85 Number of comparisons showing a positive direction of effect 10/12*** Number of comparisons with significant outcomes 0/12***	

*Authors report ORs that are adjusted for baseline scores and change in randomisation, these do not differ in direction or significant to these report in this table

** Does not provide complete data

*** Only reported for outcomes where full data is provided

APPENDICES

Appendix I. Search strategy for Cochrane Central

1. terminal* or palliative or dying or hospice or "end of life" or endstage or ((advanced or late or last or end or final) next (stage or phase))
2. "advanced cancer":kw
3. (#1 OR #2)
4. (family or families or parent or friend or relative or spouse or partner or husband or wife or wives or child or children or (close next person) or (significant next other)) and (care* or caring)
5. (family or families or parent or friend or relative or spouse or partner or husband or wife or wives or child or children or (close next person) or (significant next other)) near/10 (support* or information or help* or assist* or service or improv* or enhanc* or benefit or train* or educat* or teach* or advis* or advice or counsel* or intervention or therap* or program* or need* or burden or quality or outcome or satisfaction or "well being" or well being or psycho* or social or pastoral or spiritual or religio* or (future next plan*) or coping or "problem solving" or relaxation or respite or retreat or sleep or massage or yoga or meditation or reflexology or acupuncture or listen* or advocate or "day care" or daycare)
6. MeSH descriptor Professional-Family Relations, this term only
7. "human relation":kw
8. "social support":kw
9. "family health":kw
10. family next (centered or centred or focused or focussed)
11. MeSH descriptor Psychotherapy explode all trees
12. psychotherap*
13. "pastoral care":kw
14. counseling:kw
15. education:kw
16. "health education":kw
17. teaching:kw

18. MeSH descriptor Complementary Therapies explode all trees
19. "alternative medicine":kw
20. MeSH descriptor Religion explode all trees
21. religion:kw
22. (#5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21)
23. (#4 AND #22)
24. carer* or caregiv* or (care next giv*)
25. MeSH descriptor Home Nursing explode all trees
26. "family nursing":kw
27. "family therapy":kw
28. "home care":kw
29. "respite care":kw
30. parent:kw
31. spouse:kw
32. (#23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31)
33. (#3 AND #32)
34. (#33) in Clinical Trials
35. sr-commun in Clinical Trials
36. (#34 AND #35) in Clinical Trials

Appendix 2. Search strategy for Medline

1. (terminal* or palliative or dying or hospice* or end of life or endstage or ((advanced or late or last or end or final) adj (stage* or phase*))).tw.
2. terminally ill/
3. terminal care/
4. palliative care/
5. hospice care/
6. hospices/
7. or/1-6
8. (family or families or parent? or friend? or relative? or spouse? or partner? or husband? or wife or wives or child or children or close person? or significant other?).tw. and (care* or caring).mp.
9. ((family or families or parent? or friend? or relative? or spouse? or partner? or husband? or wife or wives or child or children or close person? or significant other?) adj10 (support* or information* or help* or assist* or service* or improv* or enhanc* or benefit* or train* or educat* or teach* or advis* or advice* or counsel* or intervention* or therap* or program* or need* or burden or quality or outcome* or satisfaction or well being or well being or psycho* or social or pastoral or spiritual or religio* or future plan* or coping or problem solving or relaxation or respite or retreat or sleep or massage or yoga or meditation or reflexology or acupuncture or listen* or advocate* or day care or daycare)).tw.
10. professional family relations/
11. social support/
12. family health/
13. (family adj (cent?red or focus?ed)).tw.
14. exp psychotherapy/
15. exp counseling/
16. education/
17. health education/
18. teaching/
19. exp complementary therapies/
20. exp religion/
21. or/9-20
22. 8 and 21

23. (carer* or caregiv* or care giv*).tw.
24. caregivers/
25. exp home nursing/
26. family nursing/
27. family therapy/
28. spouses/
29. parents/
30. or/22-29
31. 7 and 30
32. randomized controlled trial.pt.
33. controlled clinical trial.pt.
34. random*.tw.
35. placebo*.tw.
36. drug therapy.fs.
37. trial.tw.
38. groups.tw.
39. clinical trial.pt.
40. evaluation studies.pt.
41. research design/
42. follow up studies/
43. prospective studies/
44. (control* or prospectiv* or volunteer*).tw.
45. cross over studies/
46. comparative study.pt.
47. experiment*.tw.
48. time series.tw.
49. (pre test or pretest or post test or posttest).tw.
50. (pre intervention or preintervention or post intervention or postintervention).tw.
51. (impact* or intervention* or chang*).tw.
52. effect?.tw.
53. or/32-52
54. humans.sh.
55. 53 and 54
56. 31 and 55

Appendix 3. Search strategy for EMBASE

1. (terminal* or palliative or dying or hospice* or end of life or endstage or ((advanced or late or last or end or final) adj (stage* or phase*))).tw.
2. exp terminally ill patient/
3. terminal disease/
4. advanced cancer/
5. terminal care/
6. exp palliative therapy/
7. palliative nursing/
8. hospice care/
9. hospice/
10. hospice nursing/
11. or/1-10
12. (family or families or parent? or friend? or relative? or spouse? or partner? or husband? or wife or wives or child or children or close person? or significant other?).tw. and (care* or caring).mp.

13. ((family or families or parent? or friend? or relative? or spouse? or partner? or husband? or wife or wives or child or children or close person? or significant other?) adj10 (support* or information or help* or assist* or service* or improv* or enhanc* or benefit* or train* or educat* or teach* or advis* or advice* or counsel* or intervention* or therap* or program* or need* or burden or quality or outcome* or satisfaction or well being or well being or psycho* or social or pastoral or spiritual or religio* or future plan* or coping or problem solving or relaxation or respite or retreat or sleep or massage or yoga or meditation or reflexology or acupuncture or listen* or advocate* or day care or daycare)).tw.
14. human relation/
15. social support/
16. family health/
17. (family adj (cent?red or focus?ed)).tw.
18. exp psychotherapy/
19. counseling/
20. bereavement counseling/
21. family counseling/
22. education/
23. health education/
24. teaching/
25. alternative medicine/
26. religion/
27. or/13-26
28. 12 and 27
29. (carer* or caregiv* or care giv*).tw.
30. caregiver/
31. exp home care/
32. family nursing/
33. family therapy/
34. spouse/
35. parent/
36. or/28-35
37. 11 and 36
38. Randomized Controlled Trial/
39. random*.tw.
40. experiment*.tw.
41. time series.tw.
42. (pre test or pretest or post test or posttest).tw.
43. impact.tw.
44. intervention*.tw.
45. chang*.tw.
46. evaluat*.tw.
47. effect?.tw.
48. compar*.tw.
49. control*.tw.
50. or/38-49
51. nonhuman/
52. 50 not 51
53. 37 and 52

Appendix 4. Search strategy for PsycINFO

1. (terminal* or palliative or dying or hospice* or end of life or endstage or ((advanced or late or last or end or final) adj (stage* or phase*))).tw.
2. terminally ill patients/
3. terminal cancer/
4. palliative care/
5. hospice/
6. or/1-5
7. (family or families or parent? or friend? or relative? or spouse? or partner? or husband? or wife or wives or child or children or close person? or significant other?).tw. and (care* or caring).mp.
8. ((family or families or parent? or friend? or relative? or spouse? or partner? or husband? or wife or wives or child or children or close person? or significant other?) adj10 (support* or information or help* or assist* or service* or improv* or enhanc* or benefit* or train* or educat* or teach* or advis* or advice* or counsel* or intervention* or therap* or program* or need* or burden or quality or outcome* or satisfaction or well being or well being or psycho* or social or pastoral or spiritual or religio* or future plan* or coping or problem solving or relaxation or respite or retreat or sleep or massage or yoga or meditation or reflexology or acupuncture or listen* or advocate* or day care or daycare)).tw.
9. social support/
10. exp psychotherapy/
11. counseling/
12. pastoral counseling/
13. (family adj (cent?red or focus?ed)).tw.
14. education/
15. health education/
16. client education/
17. teaching/
18. exp alternative medicine/
19. exp religious practices/
20. spirituality/
21. or/8-20
22. 7 and 21
23. (carer* or caregiv* or care giv*).tw.
24. caregivers/
25. caregiver burden/
26. respite care/
27. home care/
28. elder care/
29. family therapy/
30. spouses/
31. parents/
32. or/22-31
33. 6 and 32
34. random*.tw.
35. experiment*.tw.
36. trial.tw.
37. placebo.ab.
38. groups.ab.
39. ((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)).tw.
40. time series.tw.
41. time series/
42. (pre test or pretest or post test or posttest).tw.
43. (pre intervention or preintervention or post intervention or postintervention).tw.
44. (cross over or crossover).tw.

45. latin square.tw.
46. (prospective* or volunteer*).tw.
47. impact.tw.
48. intervention*.tw.
49. chang*.tw.
50. evaluat*.tw.
51. effect?.tw.
52. compar*.tw.
53. control*.tw.
54. treatment effectiveness evaluation/
55. mental health program evaluation/
56. exp experimental design/
57. or/34-56
58. limit 57 to human
59. 33 and 58

Appendix 5. Search strategy for CINAHL

1. terminal* or palliative or dying or hospice* or “end of life” or endstage
2. advanced stage* or advanced phase* or late stage* or late phase* or last stage* or last phase* or end stage or end phase or final stage* or final phase*
3. 1 or 2
4. (family or families or parent* or friend* or relative* or spouse* or partner* or husband* or wife or wives or child or children or close person* or significant other*) and (care* or caring)
5. (family or families or parent* or friend* or relative* or spouse* or partner* or husband* or wife or wives or child or children or close person* or significant other*) and (support* or information or help* or assist* or service* or improv* or enhanc* or benefit* or train* or educat* or teach* or advis* or advice* or counsel* or intervention* or therap* or program* or need* or burden or quality or outcome* or satisfaction or well being or well being or psycho* or social or pastoral or spiritual or religio* or future plan* or coping or problem solving or relaxation or respite or retreat or sleep or massage or yoga or meditation or reflexology or acupuncture or listen* or advocate* or day care or daycare)
6. MH professional-family relations
7. MH family health
8. family cent*red or family focus*ed
9. MH home health care 10. MH psychotherapy+
11. MH counseling
12. MH education
13. MH health education
14. MH alternative therapies+
15. spiritual*
16. MH “religion and religions+”
17. 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18. 4 and 17
19. carer* or caregiv* or care giv*
20. MH home nursing
21. MH family nursing
22. MH family therapy
23. MH respite care
24. MH spouses
25. MH parents
26. 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
27. 3 and 26

28. randomized controlled trial*
 29. MH Experimental Studies+
 30. MH Random Assignment
 31. MH Comparative Studies
 32. MH Crossover Design
 33. MH Placebos
 34. MH Quantitative Studies
 35. MH Quasi-Experimental Studies+
 36. PT Clinical Trial
 37. 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36
 38. AB (random* or trial or groups or placebo* or experiment* or control* or compar* or intervention* or chang* or evaluat* or impact* or effect?) or TI (random* or trial or groups or placebo* or experiment* or control* or compar* or intervention* or chang* or evaluat* or impact* or effect?)
 39. AB ((singl* or doubl* or tripl* or trebl*) and (blind* or mask*)) or TI ((singl* or doubl* or tripl* or trebl*) and (blind* or mask*))
 40. AB time series or TI time series
 41. AB (pre test or pretest or post test or posttest or pre intervention or preintervention or post intervention or postintervention) or TI (pre test or pretest or post test or posttest or pre intervention or preintervention or post intervention or postintervention)
 42. 38 or 39 or 40 or 41
 43. 37 or 42
 44. 27 and 43
 45. 44 Limiters - Exclude MEDLINE records
- Search modes - Boolean/Phrase
 * All Search modes - Boolean/Phrase except

Appendix 6. Details on analysis categories and outcomes per trial

Primary outcome categories where data per trial was available:

Psychological distress

The review's outcome category of psychological distress included per trial:

[Allen 2008](#)

- Symptoms of depression using the CES-D (Radloff 1977).

[Carter 2006](#)

- Symptoms of depression using the CES-D (Radloff 1977)

[Hudson 2005](#)

- Symptoms of anxiety using the Hospital Anxiety and Depression Scale ([Zigmond 1983](#))

[Northouse 2005](#), [Northouse 2007](#)

- Feelings of hopelessness using the Beck Hopelessness Scale (Beck 1974)

[Keefe 2005](#)

- Negative and positive mood using the Profile of Mood States-B (Lorr 1982)

[Kissane 2006](#)

- Psychological morbidity using the Brief Symptom Inventory (Derogatis 1982)
- Symptoms of depression using the Beck Depression Inventory (Beck 1972)

[Walsh 2007](#)

- Symptoms of depression using the General Health Questionnaire-28 (Goldberg 1970)

Coping with the caring role

The review's outcome category of coping with the caring role included per trial:

[Allen 2008](#)

- Caregiving competency, strain, role overload, role capacity and emotional control measured using The Caregiver Stressors Scale (Zarit 1998)

Hudson 2005

- Perceived readiness for their role using the Preparedness for Caregiving Scale (Archbold 1996)
- Perceived adequacy using the Caregiver Competence Scale (Pearlin 1990)
- Perceived potential positive aspects associated with being a caregiver using the Rewards of Caregiving (Archbold 1996)
- Perceived control over caring role using the Caregiving Appraisal Scale subscale on mastery (Lawton 1989)
- The belief they can initiate or participate in courses of action that are intended to reduce stress and heighten wellbeing and that they can use problem-solving self-care behaviours measured using the Self Efficacy Instrument (Zeiss 1999)

Keefe 2005

- To assess the level of strain experienced using the Caregiver Strain Index (Robinson 1983)
- To assess confidence in the ability to help the patient manage pain using the caregiver version of the Chronic Pain Self-Efficacy Scale (Anderson 1995)

McMillan 2005

- To assess the ability to adapt to problems (burden of patient's cancer symptoms) using an adaptation of the Memorial Symptom Assessment Scale (Portenoy 1994)
- Mastery in care-giving using a six-item scale (Moody 1990)
- To assess burden and mastery in caregiver role measured using the Caregiver Demands Scale (Stetz 1987)
- Problem focused and emotion focused coping using the Brief COPE Scale (Carver 1997)

Northouse 2005 and 2007

- Coping strategies of self-distraction, active coping, denial, alcohol/drug use, emotional support, behavioural disengagement, venting, positive reframing, planning, use of humour, acceptance, and religion using the Brief COPE Scale (Carver 1997)
- Negative appraisal of caregiving using the Appraisal of Care-giving Scale (Oberst 1991)
- Feelings of uncertainty using the Mischel Uncertainty in Illness Scale (Mischel 1983)

Northouse 2007

- The extent to which husbands prostate-specific symptoms created problems for their spouses using the spousal version of the Prostate Cancer Index (Northouse 2007b)
- Confidence in managing stress and changes associated with cancer or treatment using the Self-efficacy Scale (Lewis 1996)

Walsh 2007

- Strain relating to providing care using the Carer Strain Index (Robinson 1983)

Quality of life

The review category included outcomes on wellbeing as well as quality of life in this category. Per trial these were measured using the following scales:

Allen 2008

- Psychological wellbeing (Tran 1991)

Carter 2006

- Caregiver Quality of Life Index (Cancer) (Weitzner 1999)

McMillan 2006

- Caregiver Quality of Life Index (Cancer) (Weitzner 1999)

Northouse 2005

- The General Functional Assessment of Cancer Treatment (Cella 1993)
- SF-36 Health Survey (Ware 1993)

Northouse 2007

- Medical Outcomes Study (Ware 1996)
- The General Functional Assessment of Cancer Treatment (Cella 1993)

Walsh 2007

- Caregiver Quality of Life Index (Cancer) (Weitzner 1999)

WHAT'S NEW

Last assessed as up-to-date: 30 April 2010.

Date	Event	Description
16 May 2011	Amended	Declaration of interest updated to include declaration by Michael King

HISTORY

Protocol first published: Issue 1, 2009

Review first published: Issue 6, 2011

CONTRIBUTIONS OF AUTHORS

LJ and BC conceived the idea for the review. RD and BL provided statistical advice. BC drafted the review on which LJ, MK, RD, BL and AT provided constructive comment. BC is guarantor of the review.

DECLARATIONS OF INTEREST

LJ and MK were co-authors of the included study [Walsh 2007](#). Neither LJ nor MK was involved in extracting data from this study. Data extraction for all trials was reviewed critically and checked repeatedly by BL.

SOURCES OF SUPPORT

Internal sources

- Marie Curie Palliative Care Research Unit, UK.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The Methods section has been revised. We no longer include non randomised trials in light of identifying more RCTs than we expected. We have also provided more detail on our inclusion criteria for participants and the intervention. In order to improve the clarity of the findings, we used new methodological approaches for combining trial evidence, as described in the section on meta-analytical framework. We have also extended our search by handsearching key journals.

INDEX TERMS

Medical Subject Headings (MeSH)

*Social Support; Adaptation, Psychological; Caregivers [*psychology]; Family [psychology]; Friends [psychology]; Randomized Controlled Trials as Topic; Stress, Psychological [*prevention & control]; Terminal Care [*psychology]

MeSH check words

Adult; Humans